

## **Act XCVIII of 2006**

### **on the General Provisions Relating to the Reliable and Economically Feasible Supply of Medicinal Products and Medical Aids and on the Distribution of Medicinal Products<sup>1</sup>**

Having taken into consideration the unique role that medicinal products and medical aids have in the preservation of health, in the identification and prevention of disease and its cure, and in the improvement of the quality of life,

having regard for the fact that achieving success in the endeavor of preventing disease does not eliminate individual inequalities stemming from diseases and poor health in general, and that in the interest of reducing these disparities state regulations for the realization of impartiality, justice and efficacy are necessary,

recognizing that the economic and effective appropriation of funds from the social security system and individual outlays for medicinal products and medical aids is an important societal value,

in the conviction that a modern health-care system cannot be realized without the transformation of Pharmacology and that for this transformation to happen, national traditions, international standards and practices must be relied upon,

recognizing that the industrialization of the production and marketing of medicinal products, the latest trends in consumer habits and demands, furthermore, the development of information technology has brought about significant changes in the retail distribution of medicinal products,

taking into consideration that the State must adopt regulations guaranteeing that an adequate range of medicinal products are safely placed at the disposal of patients, in the appropriate places and on time,

acknowledging that medicinal products are purchased by persons who feel vulnerable due to their sickness and that they do not possess any expertise in connection with medicinal products, and that in the interest of protecting consumers of medicinal products it is essential that the distribution of medicinal products be enforced by stricter regulations than those which generally apply to commercial practices,

and keeping in mind that in light of the characteristics of the retail supply of medicinal products regulated competition is favorable to consumers, improving their access to medicinal products and the quality of care,

Parliament has adopted the following Act:

#### ***General Provisions***

##### ***Section 1<sup>2</sup>***

This Act contains provisions relating to the distribution - including the related commercial practices -, and public financing of medicinal products for human use and medical aids, to the measures intended to provide access to the financing of medicinal products and medical aids and the safe and reliable supply of medicinal products and medical aids to the general public, and laying down the basic principles for the retail supply of medicinal products and the activities of suppliers of medicinal products.

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<sup>1</sup> Promulgated on 29 November 2006.

<sup>2</sup> Amended: by paragraph (6) Section 73 of Act CVI of 2008. In force: as of 01. 01. 2009.

## Section 2

(1) The purpose of this Act is to guarantee the transparency of the definition of provisions available within the compulsory social security system, to offer foresight and safety to the relevant operators, to improve the feasibility and the equitable and more effective use of the financial means available to the compulsory social security system, and to lay down the basic requirements for the activities of direct suppliers of medicinal products to the general public.

(2)<sup>1</sup> Unless otherwise prescribed by law, medicinal products may be dispensed to patients, the general public, doctors and veterinarians by pharmacies.

(3)<sup>2</sup> Pharmacy means a medical facility that provides healthcare services. Pharmacies may operate in the form of a public pharmacy, institutional pharmacy, branch pharmacy or dispensing pharmacy.

(4)<sup>3</sup> The responsibility of pharmacies within the entire healthcare system is to dispense medicinal products, dietary supplements and medical aids, and other products that may be sold in pharmacies to the general public, with the necessary and usual instructions for proper use, and to provide information and advice in connection with these products with a view to the prevention of diseases within the framework of cooperation with patients, the enhancement and follow-up of the efficacy of proper therapeutic medical treatments, and participating in prophylaxis and public health programs.

## Section 3

For the purposes of this Act:

1. <sup>4</sup> 'medicinal products' shall mean any substance as defined in Point 1 of Section 1 of Act XCV of 2005 on Medicinal Products for Human Use and on the Amendment of Other Regulations Related to Medicinal Products (hereinafter referred to as "MPH");

2. <sup>5</sup> 'medicinal products with public financing' shall mean those medicinal products and dietary supplements for special nutritional needs, whose prices are subsidized under specific other legislation from the central budget or by the Health Insurance Fund (hereinafter referred to as "H. Fund") to those eligible;

3. <sup>6</sup> 'medicinal products with special funding' shall mean medicinal products for which subsidies are provided under a public contract between the health insurance administration agency and the manufacturer/distributor/supplier in accordance with specific other legislation;

4. <sup>7</sup> 'marketing authorization' shall mean an official decision issued by the authority of competence and jurisdiction authorizing a certain medicinal product for human use;

5. <sup>8</sup> 'marketing authorization holder' shall mean a natural or legal person or business association lacking the legal status of a legal person, to whom the authority vested with competence and jurisdiction has granted authorization for the marketing of a specific medicinal product;

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1 Established: by Section 57 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.

2 Established: by Section 90 of Act CCXII of 2012. In force: as of 1. 01. 2013.

3 Established: by Section 57 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.

4 Numbering amended: by paragraph (1) Section 82 of Act CLIV of 2009. In force: as of 1. 01. 2010.

5 Numbering amended: by paragraph (1) Section 82 of Act CLIV of 2009. In force: as of 1. 01. 2010.

6 Numbering amended: by paragraph (1) Section 82 of Act CLIV of 2009. In force: as of 1. 01. 2010.

7 Amended: by Section 360 of Act LVI of 2009. In force: as of 1. 10. 2009. Numbering amended: by paragraph (1) Section 82 of Act CLIV of 2009. In force: as of 1. 01. 2010.

8 Amended: by Section 360 of Act LVI of 2009. In force: as of 1. 10. 2009. Numbering amended: by paragraph (1) Section 82 of Act CLIV of 2009. In force: as of 1. 01. 2010.

6. <sup>1</sup> 'medical aid' shall mean any medical device made available for personal use to patients suffering in a temporary or persistent health impairment or disability (including in vitro diagnostic medical devices for self-testing purposes), and other technical devices for nursing and caring purposes, which are not treated as medical devices, designed for use without the continued presence of a healthcare professional. Personal use shall mean where the medical aid is worn, applied or administered in body cavities with exterior opening, whether natural or artificial, or on the body, including the use of in vitro diagnostic medical devices for self-testing purposes on specimens derived from the human body, and the use of equipment for supporting or moving the body for diagnostics purposes or for the purpose of therapy, rehabilitation or nursing;

7. <sup>2</sup> 'therapeutic preparations which are not classified as medicinal products' shall mean a substance or compound which is not treated as a pharmaceutical product, but which has been registered by the authority of competence and jurisdiction with authorization granted for marketing designated as a therapeutic preparation which is not classified as a medicinal product;

8. <sup>3</sup> 'inexpensive gift' shall mean any benefit provided in kind whose value including value added tax, or failing this, its purchase price or production cost including value added tax is less than 5 per cent of the prevailing monthly minimum wage;

9. <sup>4</sup> 'reasonable support' shall mean any support where the costs of the event per person does not exceed the amount specified in Point 8;

10. <sup>5</sup> 'commercial practice' shall mean professional, scientific information or any act, omission, course of conduct or representation, commercial communication including marketing, directly connected with or capable of the promotion, prescription, procurement, sale or supply of a medicinal product, dietary supplement or medical aid. In the case of public pharmacies, units of institutional pharmacies engaged in supplying medicinal products directly to the general public, and branch pharmacies, the concept of commercial practice shall not cover the medical services relating to the information to be provided when dispensing medicinal products or medical aids, and also in connection with medicinal products as prescribed by law, furthermore, it shall not include consultation by pharmacists;

11. <sup>6</sup> 'advertising' shall mean the commercial advertising defined in Paragraph *d*) of Section 3 of Act XLVIII of 2008 on the Basic Requirements and Certain Restrictions of Commercial Advertising Activities, excluding the following:

*a*) <sup>7</sup> the labels and package leaflets of medicinal products described in specific other legislation, and the user's manual of medical aids,

*b*) <sup>8</sup> the factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general drug precautions relating to medicinal products or medical aids, furthermore

*c*) <sup>9</sup> trade catalogues and price lists, provided they include no product claims concerning the efficacy of medicinal products or the application of medical aids;

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1 Established: by paragraph (1) Section 102 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.

2 Amended: by Section 360 of Act LVI of 2009. In force: as of 1. 10. 2009. Numbering amended: by paragraph (1) Section 82 of Act CLIV of 2009. In force: as of 1. 01. 2010.

3 Numbering amended: by paragraph (1) Section 82 of Act CLIV of 2009. In force: as of 1. 01. 2010.

4 Numbering amended: by paragraph (1) Section 82 of Act CLIV of 2009. In force: as of 1. 01. 2010. Amended: by subparagraph a) Section 82 of Act LXXXI of 2011. In force: as of 1. 07. 2011.

5 Established by Subsection (1) of Section 58 of Act CLXXIII of 2010. Amended by Paragraph a) of Section 130 of Act CI of 2021.

6 Established: by paragraph (2) Section 24 of Act CVI of 2008. In force: as of 01. 01. 2009.

Numbering amended: by paragraph (1) Section 82 of Act CLIV of 2009. In force: as of 1. 01. 2010.

7 Amended: by subparagraph a) paragraph (10) Section 127 of Act CLIV of 2009. In force: as of 1. 01. 2010.

8 Amended: by subparagraph a) paragraph (10) Section 127 of Act CLIV of 2009. In force: as of 1. 01. 2010.

9 Amended: by subparagraph a) paragraph (10) Section 127 of Act CLIV of 2009. In force: as of 1. 01. 2010.

12.<sup>1</sup> 'persons qualified to prescribe or supply medicinal products and medical aids' shall mean physicians, pharmacists, and manufacturers and traders of medicinal products and medical aids holding the appropriate authorization and engaged in their commercial distribution;

13.<sup>2</sup> 'ATC-group' shall mean the system of classification of medicinal products according to anatomical, therapeutic and chemical actions;

14.<sup>3</sup> 'reference medicinal product' shall mean the medicinal products in a specific (fixed) subsidy group, for which subsidy is provided at a specific percentage fixed for the ATC-group in question based on its gross retail price as defined in specific other legislation and its market share;

15.<sup>4</sup> 'reference medical aid' shall mean the medical aids in a specific (fixed) subsidy group, for which subsidy is provided at a specific percentage fixed for the subsidy group in question based on its price as defined in specific other legislation serving the basis for public financing, its rental fee and market share;

16.<sup>5</sup> 'public pharmacy' shall mean a full-service medical facility supplying medicinal products directly to the public;

17.<sup>6</sup> 'branch pharmacy' shall mean a medical facility that functions as the satellite of a public pharmacy at another location, or operated as a mobile unit or as a temporary facility, and engaged in supplying medicinal products directly to the public;

18.<sup>7</sup> 'institutional pharmacy' shall mean a full-service health-care facility supplying medicinal products as part of an institution providing inpatient care to that institution, or comprising a part of integrated institutional pharmaceutical services, that may also engage in supplying medicinal products directly to the general public as a specialized activity;

19.<sup>8</sup> 'dispensing pharmacy' shall mean a method of supply of specific medicinal products by general practitioners and general pediatricians (hereinafter referred to as "general practitioner");

20.<sup>9</sup> 'independent pharmacy operation right' shall mean an authorization granted to an experienced pharmacist to manage and operate a public pharmacy (hereinafter referred to as "independent right");

21.<sup>10</sup> 'direct supply of medicinal products to the public' shall mean the sequence of activities in the healthcare services sector conducted by pharmacies covering preparation of medicinal products, the procurement, stocking and the supply of medicinal products directly or indirectly, or by way of home delivery to the public, including the instructions for application, and including the dispensing of medicinal products ordered online;

22.<sup>11</sup> 'home delivery of medicinal products' shall mean the transport of medicinal products to the address the buyer has indicated within the framework of the direct supply of medicinal products to the public;

23.<sup>12</sup> 'new pharmacy' shall mean a pharmacy that did not have an operating permit before the time of this Act entering into force;

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1 Numbering amended: by paragraph (1) Section 82 of Act CLIV of 2009. In force: as of 1. 01. 2010.

2 Numbering amended: by paragraph (1) Section 82 of Act CLIV of 2009. In force: as of 1. 01. 2010.

3 Numbering amended: by paragraph (1) Section 82 of Act CLIV of 2009. In force: as of 1. 01. 2010.

4 Established: by paragraph (1) Section 91 of Act CCXII of 2012. In force: as of 1. 01. 2013.

5 Established by Subsection (1) of Section 49 of Act CCXXIV of 2015, effective as of 1 January 2016.

6 Established by Section 46 of Act XXXIV of 2016, effective as of 6 May 2016.

7 Established by Subsection (1) of Section 52 of Act LIII of 2023, effective as of 7 July 2023.

8 Numbering amended: by paragraph (1) Section 82 of Act CLIV of 2009. In force: as of 1. 01. 2010.

9 Established: by paragraph (3) Section 58 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.

10 Established by Subsection (2) of Section 49 of Act CCXXIV of 2015, effective as of 1 January 2016.

11 Established by Section 62 of Act CCXLIV of 2013. Amended by Paragraph a) of Section 19 of Act CXXIX of 2021.

12 Numbering amended: by paragraph (1) Section 82 of Act CLIV of 2009. In force: as of 1. 01. 2010.

24.<sup>1</sup> 'subsidy volume agreement' shall mean the agreement defined in Section 30/A of Act LXXXIII of 1997 on the Services of the Compulsory Health Insurance System (hereinafter referred to as "HIS");

25.<sup>2</sup> 'neighborhood' shall mean a particular area of a community that constitutes a separate entity from other neighborhoods of the community based on geographical (topographical), spatial and architectural features;

26.<sup>3</sup> 'consultation by pharmacist' shall mean an activity performed - and documented - by pharmacists on a voluntary and prudential basis, aiming to improve - in collaboration with the doctors affected - the efficiency, reliability and cost-effectiveness of treatment using medicinal products, and to promote the education of patients for better health awareness, to provide technical assistance for the administration of medicinal products, for improving their disposition to cooperate and to improve their quality of life, in a controlled environment.

27.<sup>4</sup> 'official manager' shall mean a pharmacist appointed by a regulatory decision for the temporary operation of a public pharmacy;

28.<sup>5</sup> 'subsidy group' shall mean a group of products which are subsidized at a specific (fixed) sum determined based on the percentage rate fixed for the price of the group's reference medical aid;

29.<sup>6</sup> 'distributor of medical aids' shall mean the manufacturer of medical aids if manufactured in Hungary, or the importer of medical aids manufactured outside of Hungary, operating as a private entrepreneur or in the form of a business association and authorized by the manufacturer of the medical aids in question;

30.<sup>7</sup> 'qualified distributor' shall mean a distributor admitted to the approved list of suppliers of the health insurance administration;

31.<sup>8</sup> 'durable medical aid' shall mean any medical aid with an approved period of use of over six months;

32.<sup>9</sup> 'simplified list of subsidized products (ETJ)' shall mean a list described in specific other legislation containing subsidized function groups where the doctor enters the description or the ISO code of the function group on the prescription, and the health insurance administration sets the same amount of subsidy for each and every product within a specific function group;

33.<sup>10</sup> 'medical aid store' shall mean a retail establishment whose function is to supply medical aids directly to the general public;

34.<sup>11</sup> 'supplier of medical aids' shall mean a natural or legal person engaged in the sale of medical aids to end users, including the rental and repair of medical aids, excluding those manufacturers of custom-made medical aids, other than healthcare service providers, who do not themselves dispense the medical aids to the insured person;

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1 Numbering amended: by paragraph (1) Section 82 of Act CLIV of 2009. In force: as of 1. 01. 2010.  
2 Established by Section 60 of Act LXXVII of 2015. Amended by Section 56 of Act XXXIV of 2016.  
3 Enacted: by paragraph (3) Section 24 of Act CVI of 2008. In force: as of 01. 01. 2009. Numbering amended: by paragraph (1) Section 82 of Act CLIV of 2009. In force: as of 1. 01. 2010.  
4 Numbering amended: by paragraph (1) Section 82 of Act CLIV of 2009. In force: as of 1. 01. 2010.  
5 Enacted: by paragraph (4) Section 82 of Act CLIV of 2009. In force: as of 1. 01. 2010.  
6 Established: by paragraph (4) Section 58 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.  
7 Enacted: by paragraph (4) Section 82 of Act CLIV of 2009. In force: as of 1. 01. 2010.  
8 Enacted: by paragraph (4) Section 82 of Act CLIV of 2009. In force: as of 1. 01. 2010.  
9 Enacted: by paragraph (4) Section 82 of Act CLIV of 2009. In force: as of 1. 01. 2010.  
10 Enacted: by paragraph (5) Section 58 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.  
11 Established by paragraph (3) Section 102 of Act CLXXVI of 2011. Amended by Subsection (3) of Section 12 of Act CCLII of 2013.

35.<sup>1</sup> 'preferred reference price range medicinal product' shall mean, from among the medicinal products determined by the fixation procedure decreed by the minister in charge of the health insurance system, in the case of fixed amount subsidies based on the active ingredient, the medicinal product whose daily cost based on therapeutic efficacy exceeds that of the reference medicinal products by not more than 20 per cent, or it is lower than the daily cost of the reference product, moreover, in the case of fixed support based on therapeutic efficacy, in normative subsidy categories, medicinal product whose daily cost based on therapeutic efficacy exceeds that of the reference medicinal products by not more than 15 per cent, or it is lower than the daily cost of the reference product;

36.<sup>2</sup> 'private individual' shall mean any person having a residence within the administrative jurisdiction of a community as registered according to Section 26 of Act LXVI of 1992 on Records of the Personal Data and Addresses of Citizens;

37.<sup>3</sup> 'discount' shall mean a price reduction made available to the general public without any discrimination, indicating also the period to which it applies;

38.<sup>4</sup> 'patient cooperation' shall mean when the patient is acting in concert with the instructions of healthcare professionals in connection with medication, diet and life style;

39.<sup>5</sup> 'preferred biological medicinal product' shall mean, from among the medicinal products determined by the procedure decreed by the minister in charge of the health insurance system relating to biological medicinal products, the medicinal product that features the best daily cost based on therapeutic efficacy, or that exceeds such cost by not more than 10 per cent;

40.<sup>6</sup>

41.<sup>7</sup> 'employment-related relationship' shall mean an employment relationship defined in the Labor Code, including the activities of members of business associations and civil law companies where personal participation is required;

42.<sup>8</sup> 'home delivery of medical aids' shall mean the transport of medical aids to the address the buyer has indicated after the medical aid is ordered or purchased, as part of the sales service;

43.<sup>9</sup> 'order of service' shall mean the duration when the pharmacy performs the supply of medicinal products directly to the public, covering regular business hours and after-hours and stand-by duty;

44.<sup>10</sup> 'pharmacy after-hours duty' shall mean a service the pharmacy provides past regular opening hours for the supply of medicinal products to the public with a pharmacist present, including weekly rest days and public holidays;

45.<sup>11</sup> 'pharmacy stand-by duty' shall mean a service the pharmacy provides with a view to supplying medicinal products to the public past regular opening hours, including weekly rest days and public holidays, where the pharmacist on duty begins the process of dispensing medicine within thirty minutes after receiving the call;

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1 Established by Section 66 of Act LXXIX of 2012. Amended by Paragraph a) of Section 80 of Act CCXLIV of 2013, Paragraph b) of Section 130 of Act CI of 2021.  
2 Enacted: by Section 51 of Act LXXXI of 2011. In force: as of 1. 07. 2011.  
3 Enacted: by Section 51 of Act LXXXI of 2011. In force: as of 1. 07. 2011.  
4 Enacted: by paragraph (4) Section 102 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.  
5 Enacted: by paragraph (4) Section 102 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.  
6 Repealed by Paragraph a) of Section 27 of Act CLXXXVIII of 2017, effective as of 1 January 2018.  
7 Enacted: by paragraph (4) Section 102 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.  
Amended: by subparagraph a) Section 82 of Act LXXIX of 2012. In force: as of 1. 07. 2012. The change does not effect the English version.  
8 Enacted: by paragraph (4) Section 102 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.  
9 Enacted by Subsection (3) of Section 49 of Act CCXXIV of 2015, effective as of 1 January 2016.  
10 Enacted by Subsection (3) of Section 49 of Act CCXXIV of 2015, effective as of 1 January 2016.  
11 Enacted by Subsection (3) of Section 49 of Act CCXXIV of 2015, effective as of 1 January 2016.

46.<sup>1</sup> 'medicinal products containing active substances subject to itemized accounting requirements' shall mean a medicinal product provided with special subsidy by a health insurance agency through public procurement procedure in kind or within a financial framework;

47.<sup>2</sup> 'integrated institutional pharmaceutical services' shall mean the provision of institutional pharmaceutical services to State-maintained institutions providing inpatient care under an integrated system of uniform quality requirements throughout the territory of Hungary (including procurement, ancillary purchasing services, coordination and logistics services);

48.<sup>3</sup> 'individual drug delivery system' shall mean a patient-specific medication method where medicinal products prescribed by institutional pharmacies for inpatients are dispensed in customized doses.

## **PART I**

### ***Reliable and Economically Feasible Supply of Medicinal Products and Medical Aids***

#### Chapter I

#### **BASIC PRINCIPLES FOR THE COST-EFFECTIVE PRESCRIPTION AND DISTRIBUTION OF MEDICINAL PRODUCTS AND MEDICAL AIDS**

##### *Section 4*

(1) The rate of social security subsidy claimed for the price of medicinal products containing the same active ingredients or of the same therapeutic efficacy may not exceed the rate of subsidy established for the reference medicinal products.

(2)<sup>4</sup> Subject to the exception set out in specific other legislation, the rate of social security subsidy claimed for the price of medical aids within the same group in terms of function may not exceed the rate of subsidy established for the reference medical aid.

##### *Section 5*

In the process of admission into the sphere of subsidized products by the simplified procedure, the preparations containing the same active ingredients and having the same therapeutic effect as medicinal products already approved for subsidies will be granted preferential treatment if their price is lower than that of the said subsidized medicinal products, as well as the medical aids within the same group in terms of function with those already approved for subsidies, if their price is lower and if they possess the same or better value in terms of use.

##### *Section 6*

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1 Enacted by Section 111 of Act CI of 2021, effective as of 29 June 2021.

2 Established by Subsection (2) of Section 52 of Act LIII of 2023, effective as of 7 July 2023.

3 Enacted by Subsection (3) of Section 52 of Act LIII of 2023, effective as of 7 July 2023.

4 Amended: by paragraph (9) Section 127 of Act CLIV of 2009. In force: as of 1. 01. 2010.

Outside the provisions of this Act, it is prohibited to engage in any activity for the promotion or sponsorship of any medicinal products or medical aids which may be prescribed at a price with a social security subsidy.

#### *Section 7*

Marketing authorization holders are required to pay a contribution in the amount specified in this Act in connection with the medicinal products they supply with a social security subsidy, consistent with the volume of turnover of such medicinal products, to enhance the cost-effectiveness of the supply of medicinal products which are available in exchange for the contributions paid on behalf of the persons insured under the social security system.

#### *Section 8*

The doctors prescribing medicinal products and medical aids shall inform their patients concerning the availability of another lower priced medicinal product having the same active ingredient or therapeutic efficacy, or another lower priced medical aid of the same function, and shall disclose the price of the product in question, the amount of social security subsidy available and the difference between that and the price the patient is required to pay.

#### *Section 9<sup>1</sup>*

Any dispenser of medicinal products and medical aids shall inform their patients, properly documented and in a manner that is accessible and understandable to disabled persons as well, concerning any lower priced medicinal products having the same active substance or therapeutic efficacy, which are subsidized by the health insurance administration agency, as well as any lower priced medical aid of the same function, and shall disclose the price of the product in question, the amount of social security subsidy available and the difference between that and the price the patient is required to pay.

#### *Section 10*

The health insurance administration agency has powers to determine the conditions - within the framework of this Act - for the procedures of the prescription of medicinal products and medical aids for doctors engaged under contract in terms of financing or subsidization, and shall have powers to inspect and supervise the conduct of doctors in terms of prescription of medicinal products and medical aids, and to take action in accordance with the provisions of specific other legislation in the event of any infringement or breach of contract.

#### *Section 10/A<sup>2</sup>*

The parameters checked for the purposes of patient cooperation shall include the patient's lifestyle and history of administration of medicinal products.

#### *Section 10/B<sup>3</sup>*

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<sup>1</sup> Established: by Section 103 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.

<sup>2</sup> Enacted: by Section 104 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.

<sup>3</sup> Enacted: by Section 104 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.



If there is only one medicinal product that may be applied as a preferred biological medicinal product, the medicinal product that features the next best daily cost based on therapeutic efficacy shall be treated as a preferred biological medicinal product.

### *Section 11<sup>1</sup>*

(1) A financing contract or an agreement granting entitlement for the prescription of subsidized medicinal products and medical aids may be concluded with the medical service providers who satisfy the requirements set out in this Act concerning the cost-effectiveness of medicinal products and medical aids, as well as the conditions prescribed by the health insurance administration agency, such as the use of an approved computer program designed to enhance cost-efficiency in the prescription of medicinal products.

(2)<sup>2</sup> Subject to the exceptions set out in Subsections (3)-(4), the supply, rental and repair of medical aids may be conducted if authorized by the government body in charge of the healthcare system, and may be performed under the conditions set out by the relevant legislation.

(2a)<sup>3</sup> The home delivery of medical aids may be carried out - under the conditions set out in the ministerial decree on technical requirements concerning the distribution, repair and rental of medical aids - by distributors (vendors specializing in medical aids or pharmacies) holding an operating permit, if they are able to meet the requirements decreed by the minister in charge of the healthcare system, with the proviso that no auxiliary agent may be engaged for the home delivery of medical aids prescribed with social security subsidies, subject to the exceptions provided for by the decree on the admission of medical aids for subsidies within the social security system, and on their prescription, distribution, repair and rental with social security subsidies.

(3)<sup>4</sup> Where a pharmacy employs a medical aid sales specialist, the authorization referred to in Subsection (2) is not required. If the pharmacy has no medical aid sales specialist, without the authorization referred to in Subsection (2) only mass produced medical aids may be supplied, and no repair and rental services may be offered. The prohibition of repair and rental activities shall not apply to the enforcement of guarantee and warranty obligations whether specified in specific other legislation or fixed under contract between the parties.

(3a)<sup>5</sup> With the exception of custom-made medical aid, services for the repair of medical aids may be provided without an operating permit for the provision of healthcare services, if the repair service provider is able to satisfy the personnel and infrastructure requirements set out in the ministerial decree on technical requirements concerning the distribution, repair and rental of medical aids for repair services performed away from business premises.

(4) Any service provider with the right to exercise the freedom to provide services according to the Act on the General Provisions Relating to the Taking Up and Pursuit of the Business of Service Activities shall notify the government body in charge of the healthcare system of his intention to engage in the supply, rental and repair of medical aids in the form of cross-border services. The health insurance administration specified in specific other legislation may also conclude the contracts referred to in Subsection (2) of Section 30 of Act LXXXIII of 1997 on the Services of the Compulsory Health Insurance System with a service provider with the right to exercise the freedom to provide services.

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1 Established: by paragraph (1) Section 359 of Act LVI of 2009. In force: as of 1. 10. 2009. Shall apply to proceedings opened subsequently and to reopened cases.

2 Established: by Section 52 of Act LXXXI of 2011. In force: as of 1. 07. 2011.

3 Established by Section 63 of Act CCXLIV of 2013, effective as of 1 January 2014.

4 Amended by Paragraph a) of Section 114 of Act CXI of 2014.

5 Enacted: by Section 92 of Act CCXII of 2012. In force: as of 1. 01. 2013.

(5) The government body in charge of the healthcare system shall maintain a register of the persons authorized according to Subsection (2), and of the service providers with entitlement to engage in the supply, rental and repair of medical aid, notified according to Subsection (4). Information may be disclosed from the register solely for the verification of authorization for the said activity.

(6)<sup>1</sup> The data contained in the register shall be made available free of charge to the Központi Statisztikai Hivatal (*Central Statistics Office*) in accordance with Section 28 of Act CLV of 2016 on Official Statistics (hereinafter referred to as "Statistics Act") for statistical purposes to the extent necessary, in a form enabling individual identification, provided that the statistical objective is verified in advance. The data thus received may be used by the Központi Statisztikai Hivatal for statistical purposes. The type of data to be disclosed and the detailed rules of disclosure shall be laid down in a cooperation agreement provided for in Section 28 of the Statistics Act.

## Chapter II

### PROVISIONS RELATING TO THE PROMOTION OF MEDICINAL PRODUCTS AND MEDICAL AIDS AND TO BUSINESS-TO-CONSUMER COMMERCIAL PRACTICES RELATING TO MEDICINAL PRODUCTS AND MEDICAL AIDS <sup>2</sup>

#### General Provisions <sup>3</sup>

##### Section 11/A <sup>4</sup>

All forms of commercial practices relating to any medicinal product which does not have a valid marketing authorization shall be prohibited.

##### Section 11/B <sup>5</sup>

(1) Commercial practices relating to medicinal products and medical aids shall encourage the rational use of the medicinal product or medical aid, by presenting it objectively and without exaggerating the properties of the medicinal product or medical aid.

(2) The information conveyed in a commercial communication relating to a medicinal product or medical aid shall be in conformity with the information contained in the label and package leaflet of the medicinal product as approved in the authorization for placing the medicinal product on the market, or with the information contained in the user's manual of the medical aid.

(3)<sup>6</sup> In the commercial communication of a mono-component homeopathic medicinal product, and/or a homeopathic medicinal product without indication apart from the label information no other information may be communicated.

(4) The detailed regulations relating to the contents of information contained in commercial communication for medicinal products or medical aids are laid down in specific other legislation.

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1 Enacted by Subsection (1) of Section 37 of Act XLIV of 2017, effective as of 2 June 2017.

2 Established: by paragraph (1) Section 25 of Act CVI of 2008. In force: as of 01. 01. 2009.

3 Enacted: by paragraph (2) Section 25 of Act CVI of 2008. In force: as of 01. 01. 2009.

4 Enacted: by paragraph (2) Section 25 of Act CVI of 2008. In force: as of 01. 01. 2009.

5 Enacted: by paragraph (2) Section 25 of Act CVI of 2008. In force: as of 01. 01. 2009.

6 Established by Section 112 of Act CI of 2021, effective as of 29 June 2021.

## Promotion of Medicinal Products, Medical Aids and Dietary Supplements <sup>1</sup>

### Section 12

(1)<sup>2</sup> The promotion of medicinal products, mother's milk substitutes with public financing, mother's milk supplements with public financing and dietary supplements for special medicinal purposes with public financing (in the application of this Chapter hereinafter referred to as "dietary supplement"), as well as medical aids (hereinafter referred to as "promotion") shall mean commercial practices pertaining to medicinal products, dietary supplements and medical aids applied for or against healthcare professionals with proper entitlement for the prescription and distribution of medicinal products, dietary supplements and medical aids, including instructions as to the use thereof and information provided in connection with the composition and efficacy of the medicinal products and dietary supplements and for the application of medicinal products, medical aids and dietary supplements.

(2)<sup>3</sup> The provisions of this Chapter relating to the promotion of medical aids shall also apply to dietary supplements.

(3)<sup>4</sup> Where

*a)* the holder of the marketing authorization of a medicinal product, the authorized distributor of a medicinal product, or the manufacturer or distributor of medical aid, or

*b)* another economic operator on behalf of the persons referred to in Paragraph *a)*, (the persons referred to in Paragraphs *a)* and *b)* hereinafter referred to collectively as "promoter of medicinal products") wishes to engage in promotional activities, they shall notify the government body for pharmaceuticals thereof.<sup>5</sup>

(4)<sup>6</sup> In addition to the data specified in the Act on the General Provisions Relating to the Taking Up and Pursuit of the Business of Service Activities, the notification referred to in Subsection (3) shall contain:

*a)*<sup>7</sup> the name, home address or registered office, and the registered number of the medical sales representative or promoter of medicinal products, including the duration of promotional activities if the medical sales representative wishes to engage in such activities for a fixed period;

*b)* in connection with medicinal products, the name of the holder of the marketing authorization or the authorized distributor of the medicinal product or products proposed to be represented, or their authorized agent; as regards medical aids the authorization shall contain the name of the manufacturer, distributor of the medical aid or aids proposed to be represented, or their authorized representative;

*c)*<sup>8</sup> the natural identification data and home address of the person or persons referred to in Section 13, engaged in promotional activities acting in the name and on behalf of the medical sales representative, including the duration of promotional activities if the medical sales representative wishes to engage in such activities for a fixed period;

1 Established by Subsection (1) of Section 47 of Act XXXIV of 2016, effective as of 1 July 2016.

2 Established by Section 113 of Act CI of 2021, effective as of 29 June 2021.

3 Established by Subsection (3) of Section 47 of Act XXXIV of 2016, effective as of 1 July 2016.

4 Established: by paragraph (2) Section 359 of Act LVI of 2009. In force: as of 1. 10. 2009. Shall apply to proceedings opened subsequently and to reopened cases.

5 Amended: by Section 1 of Act LXXXIX of 2010. In force: as of 16. 09. 2010. Amended: by subparagraph *a)* Section 88 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.

6 Established: by paragraph (2) Section 359 of Act LVI of 2009. In force: as of 1. 10. 2009. Shall apply to proceedings opened subsequently and to reopened cases.

7 Established: by paragraph (1) Section 53 of Act LXXXI of 2011. In force: as of 1. 07. 2011.

8 Established: by paragraph (2) Section 53 of Act LXXXI of 2011. In force: as of 1. 07. 2011.

d) a statement from the medical sales representative referred to in Section 13 that he is not exposed to any conflict of interest as prescribed in Subsection (3) of Section 13;

e)<sup>1</sup> the copy of the diploma of the medical sales representative referred to in Section 13, and his registration number, if available.

(4a)<sup>2</sup> The notification referred to in Subsection (3) shall have enclosed a picture of the medical sales representative made not more than a year ago (facial picture).

(5)<sup>3</sup> The promoter of medicinal products referred to in Subsection (3) shall forthwith notify any change in the particulars contained in the notification to the government body for pharmaceuticals.

(6)<sup>4</sup> The provisions of this Act shall also apply to activities for the promotion of medicinal products and medical aids by a service provider with the right to exercise the freedom to provide services according to the Act on the General Provisions Relating to the Taking Up and Pursuit of the Business of Service Activities in the form of cross-border services.

(7)-(8)<sup>5</sup>

(9)<sup>6</sup> Upon the notification of promotional activities as prescribed in Subsection (3), and upon the notification of any changes in the particulars notified, the notifier shall be liable to pay an administrative service fee.

### *Section 13*

(1)<sup>7</sup> Promoters of medicinal products must have a natural person holding a certificate issued to medical sales representatives engaged under contract of employment or some other form of employment relationship, who satisfies the requirements decreed by the minister in charge of the healthcare system in terms of training and qualifications (hereinafter referred to as "medical sales representative").

(2)<sup>8</sup> A medical sales representative engaged under contract for the provision of healthcare services, or for participating in such activities shall not be allowed to be involved in the activity specified in Point 10 of Section 3 of promoters of medicinal products, except for scientific activities and/or activities under copyright protection independent of the activity specified in Point 10 of Section 3.

(3)<sup>9</sup> With the exception set out in Subsection (4), a conflict of interest shall exist where a medical sales representative is engaged in activities for the promotion of medicinal products - exclusive of scientific activities under copyright protection - in a medical institution with which the representative is engaged under contract for the provision of healthcare services, or for participating in such activities.

(4) The conflict of interest referred to in Subsection (3) shall not apply to the persons engaged in the network of medical sales representatives of the government body for pharmaceuticals.

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1 Established: by paragraph (3) Section 53 of Act LXXXI of 2011. In force: as of 1. 07. 2011.

2 Enacted: by paragraph (4) Section 53 of Act LXXXI of 2011. In force: as of 1. 07. 2011.

3 Established: by paragraph (2) Section 359 of Act LVI of 2009. In force: as of 1. 10. 2009. Shall apply to proceedings opened subsequently and to reopened cases. Amended: by Section 1 of Act LXXXIX of 2010. In force: as of 16. 09. 2010. Amended: by subparagraph a) Section 88 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.

4 Established: by paragraph (2) Section 359 of Act LVI of 2009. In force: as of 1. 10. 2009. Shall apply to proceedings opened subsequently and to reopened cases.

5 Repealed: by Section 361 of Act LVI of 2009. No longer in force: as of 1. 10. 2009.

6 Amended: by Section 360 of Act LVI of 2009. In force: as of 1. 10. 2009.

7 Established by paragraph (1) Section 54 of Act LXXXI of 2011. Amended by Paragraph b) of Section 27 of Act CLXXXVIII of 2017.

8 Established by Section 114 of Act CI of 2021, effective as of 29 June 2021.

9 Amended: by Section 360 of Act LVI of 2009. In force: as of 1. 10. 2009.

(5)<sup>1</sup> Pursuant to the Act on the General Provisions Relating to the Taking Up and Pursuit of the Business of Service Activities, when a medical sales representative is removed from the register the medical sales certificate shall be surrendered to the government body for pharmaceuticals within eight days upon gaining knowledge of the removal.

### *Section 13/A*<sup>2</sup>

(1)<sup>3</sup> The government body for pharmaceuticals shall maintain a register of promoters of medicinal products and medical sales representatives relying on the notifications made under Section 12. The register shall contain the data specified in Subsection (4) of Section 12. Registration shall remain in effect for the duration indicated in the notification or, failing this, for an unfixed period. Data from the register shall be deleted following the time period referred to in Subsection (4) of Section 12 or, failing this, upon notification of changes in the data.

(1a)<sup>4</sup> The register referred to in Subsection (1) shall be construed as an official public register, containing the number of medical sales certificates and the duration of promotional activities, as public information.

(2)<sup>5</sup>

(3) The provisions of the Act on the General Provisions Relating to the Taking Up and Pursuit of the Business of Service Activities pertaining to notifications, to the monitoring of activities subject to notification and to the registration of service providers engaged in activities subject to notification shall also apply to the notification procedures described in Section 12 and to the registers of promoters of medicinal products and medical sales representatives, subject to the exceptions set out in this Act, regardless of whether the activities of promoters of medicinal products are recognized as service activities.

### *Section 14*

(1)<sup>6</sup> Gifts, pecuniary advantages or other material benefits may not be provided, offered or promised by promoters of medicinal products, directly or indirectly to persons authorized to prescribe or supply medicinal products or medical aids, including instructions as to the use thereof, except if carried out within the framework of the activity specified in Point 10 of Section 3, and if they are of small value and related to the healthcare activity in which the person with entitlement for the prescription and distribution of medicinal products is engaged, and if the aggregate value thereof does not exceed 60 per cent of the prevailing monthly minimum wage on a yearly basis. Monetary benefits or financial advantage may not be provided, offered or promised by promoters of medicinal products to healthcare professionals with proper entitlement for the prescription and distribution of medicinal products, dietary supplements and medical aids, including instructions for their use.

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1 Enacted: by paragraph (2) Section 54 of Act LXXXI of 2011. In force: as of 1. 07. 2011.

2 Enacted: by paragraph (4) Section 359 of Act LVI of 2009. In force: as of 1. 10. 2009. Shall apply to proceedings opened subsequently and to reopened cases.

3 Established: by paragraph (1) Section 55 of Act LXXXI of 2011. In force: as of 1. 07. 2011.

4 Enacted: by Section 112 of Act CXXXVII of 2013. In force: as of 6. 07. 2013.

5 Repealed by Point 1 of Subsection (1) of Section 186 of Act LXVII of 2016, effective as of 1 January 2017.

6 Established by Subsection (1) of Section 115 of Act CI of 2021, effective as of 29 June 2021.

(2)<sup>1</sup> Entertainment and hospitality functions may be arranged by promoters of medicinal products for healthcare professionals with proper entitlement for the prescription and distribution of medicinal products, dietary supplements and medical aids, including instructions for their use, solely for professional, scientific or educational reasons. The costs of such entertainment and hospitality functions by promoters of medicinal products and medical sales representatives per day and per person may not exceed the limit specified in Point 8 of Section 3 and shall remain subordinate to the main objective of the event. Only healthcare professionals and persons engaged in the supply and distribution of medicinal products and/or medical aids may be invited to such trade and promotional events.

(3)<sup>2</sup> Any support provided - whether directly or indirectly - for events and programs for purely professional and scientific purposes shall always be reasonable in scope and remain subordinate to the main scientific objective of the meeting. Only healthcare professionals and persons engaged in the supply and distribution of medicinal products and/or medical aids may be invited to such trade and scientific events. Representation of medicinal products may be carried out during events and programs held for purely professional and scientific purposes, if the promotional activity (a lecture concerning the application of a specific product, demonstration of a specific product, leasing of exhibition space) - whether performed directly or indirectly - is clearly distinguished from the trade and scientific programs.

(4)<sup>3</sup> Support may be provided in kind to persons engaged in healthcare or scientific activities for participating in trade events and training courses. This type of in-kind support may be provided to cover only the expenses (such as, in particular, travel expenses, accommodations, entry fees) arising directly out of or in connection with attending the above-specified events.

(5)<sup>4</sup> An event held at a specific location may be sponsored or arranged, or support for participating in an event connected to a specific location may be provided only if the resources required for the subject-matter of the event or the necessary expertise is available at that location only, or if the costs of staging such event at a location closer to the work places of the participants would be disproportionately higher.

(6)<sup>5</sup> At a place where a trade and scientific event is held for participants authorized to prescribe medicinal products and/or medical aids with social security subsidies, support may be provided for any facultative trade or scientific program connected to the event, or for participating in such events, and such programs may be arranged only if it is held during the same time as the main trade and scientific event.

(7)<sup>6</sup> The prohibitions and restrictions specified in Subsections (1)-(4) shall not concern the conditions laid down in specific other legislation regarding the prices, markup, discounts and any other commercial allowances of medicinal products and medical aids for operators active in the commercial supply of medicinal products.

(8) Persons qualified to prescribe or supply medicinal products and medical aids shall not solicit or accept any inducement prohibited under Subsection (1) or contrary to Subsections (2)-(4) of this Section.

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1 Established by Subsection (1) of Section 115 of Act CI of 2021, effective as of 29 June 2021.

2 Amended: by subparagraph c) paragraph (4) Section 73 of Act CVI of 2008. In force: as of 01. 01. 2009. Amended: by Section 360 of Act LVI of 2009. In force: as of 1. 10. 2009.

3 Amended: by paragraph (6) Section 73 of Act CVI of 2008. In force: as of 01. 01. 2009.

4 Established: by paragraph (3) Section 56 of Act LXXXI of 2011. In force: as of 1. 07. 2011. Amended: by point 1 Section 137 of Act CXXVII of 2013. In force: as of 6. 07. 2013.

5 Established: by paragraph (3) Section 56 of Act LXXXI of 2011. In force: as of 1. 07. 2011. Amended: by point 2 Section 137 of Act CXXVII of 2013. In force: as of 6. 07. 2013.

6 Amended: by paragraph (6) Section 73 of Act CVI of 2008. In force: as of 01. 01. 2009.

(9)<sup>1</sup> Promoters of medicinal products referred to in Subsection (3) of Section 12, shall furnish a certificate to persons qualified to prescribe or supply medicinal products and/or medical aids to enable them to satisfy their tax payment obligation; such certificate must be in compliance with the tax regulations in force, where the conditions therefor exist.

(10)<sup>2</sup> Promoters of medicinal products are required to notify - by way of electronic means - the government body for pharmaceuticals concerning the particulars referred to in Subsection (11) in connection with trade and scientific events and training courses which they support or which they have arranged under Subsections (2)-(6), fifteen days before the time of the opening of such trade and scientific events and training courses.

(11)<sup>3</sup> The notification shall contain:

- a) the name, location and date of the proposed event, including its program;
- b) the name of the person to whom the support is provided;
- c)<sup>4</sup> the amount of support, the costs of organization;
- d)<sup>5</sup> the reasons for using that particular location or if held online;
- e) description of the additional, facultative program referred to in Subsection (6), including the place and time where and when it is held, and a brief description.

(12)<sup>6</sup> Contracts concluded in connection with seminars and performances at events organized by the promoter of medicinal products shall be enclosed with the notification. Furthermore, when so requested by the government body for pharmaceuticals the following shall be enclosed as well:

- a) a copy of the document in proof of payment of the entry fee, or a copy of the document evidencing prior registration;
- b) copies of other contracts concluded in connection with staging the event;
- c) copies of documents in proof of the amount of support provided for or the costs of organization of the event.

(13)<sup>7</sup> In addition to what is contained in Subsections (10) and (11), the promoter of medicinal products shall notify to the government body for pharmaceuticals the name, location and date of all trade events, training courses, including their program, sponsored from funds the promoter has arranged or provided, including the name and address of the organizer, fifteen days before the time of the opening of such trade event or training course.

(14)<sup>8</sup> The person authorized to prescribe medicinal products and/or medical aid shall - before the promotional activities - ascertain relying on the data made available according to Subsection (2) of Section 16 the authorization of the medical sales representative for engaging in the pursuit of the activities.

### *Section 15<sup>9</sup>*

Further provisions concerning promotional activities, including the regulations pertaining to free product samples and donations that may be provided to persons qualified to prescribe or supply medicinal products or medical aids are contained in specific other legislation.

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1 Amended: by paragraph (6) Section 73 of Act CVI of 2008. In force: as of 01. 01. 2009. Amended: by Section 360 of Act LVI of 2009. In force: as of 1. 10. 2009.

2 Established by Subsection (4) of Section 56 of Act LXXXI of 2011. Amended by Paragraph b) of Section 82 of Act LXXIX of 2012, Point 3 of Section 137 of Act CXXVII of 2013, Paragraph a) of Section 58 of Act CCXXIV of 2015, Paragraph b) of Section 45 of Act CLXXII of 2016, Paragraphs c), d), e) of Section 130 of Act CI of 2021.

3 Enacted: by paragraph (4) Section 56 of Act LXXXI of 2011. In force: as of 1. 07. 2011.

4 Amended: by point 4 Section 137 of Act CXXVII of 2013. In force: as of 6. 07. 2013.

5 Amended by Paragraph f) of Section 130 of Act CI of 2021.

6 Established by Section 34 of Act CLXXII of 2016, effective as of 1 January 2017.

7 Established by Subsection (2) of Section 115 of Act CI of 2021, effective as of 29 June 2021.

8 Enacted: by paragraph (4) Section 56 of Act LXXXI of 2011. In force: as of 1. 07. 2011.

9 Established: by Section 27 of Act CVI of 2008. In force: as of 01. 01. 2009.

*Section 16<sup>1</sup>*

(1) The register specified in Section 13/A serves the purpose of regulatory supervision of the activities of medical sales representatives and for providing information to the persons to whom promotional services are provided.

(2)<sup>2</sup> The government body for pharmaceuticals shall make available to the general public the data indicated below, updated on a daily basis, on its website from the register it maintains according to Section 13/A and relying on the information notified according to Subsection (11) of Section 14, free of charge, in the interest of providing information to persons visited by medical sales representatives, and for the purpose of verification of payment of the fee payable to the tax authority as specified in Subsections (4)-(4a) of Section 36:<sup>3</sup>

a) the names of promoters of medicinal products;

b)

ba) in connection with medicinal products, the name of the holder of the marketing authorization or the authorized distributor of the medicinal product or products proposed to be represented, or their authorized agent,

bb) as regards medical aids, the name of the manufacturer, distributor of the medical aid or aids proposed to be represented, or their authorized representative;

c) the names and registration numbers of medical sales representatives;

d) the names of promoters of medicinal products and medical sales representatives that/who have been banned from the pursuit of promotional activities by definitive decision;

e)<sup>4</sup> the name, location and date of the proposed event, including its program, from the date when notified until the event is concluded, and the name of the sponsor of the event;

f)<sup>5</sup> the name of the event for a period of one year after the event, the amount of support received in connection with the event, and the name of the sponsor of the event.

(3)<sup>6</sup> The government body for pharmaceuticals shall proclaim its definitive resolutions under Paragraph d) of Subsection (2) and Subsection (2a) of Section 19 - not including the resolutions on fines for one million forints or less - containing the information specified under Subsection (5).

(4)<sup>7</sup> The government body for pharmaceuticals shall proclaim its definitive resolutions under Paragraphs b) and c), as well as under Paragraph d) of Subsection (2) of Section 19 on fines for one million forints or less, in the case of repeat infringement, containing the information specified under Subsection (5).

(5)<sup>8</sup> The documents proclaimed as specified above shall indicate:

a) the date of proclamation;

b) the name of the competent authority;

c) the case number and the subject matter;

d) the name and registration number of the infringer;

e)<sup>9</sup> a summary statement of the relevant facts of the case;

f) the statutory provisions infringed upon;

g) the operative part of the decision; and

h) an indication if the decision has been appealed.

1 Established: by Section 57 of Act LXXXI of 2011. In force: as of 1. 07. 2011.

2 Amended by Point 1 of Section 283 of Act L of 2017.

3 Amended: by subparagraph c) Section 82 of Act LXXIX of 2012. In force: as of 1. 07. 2012.

4 Established: by paragraph (1) Section 68 of Act LXXIX of 2012. In force: as of 1. 07. 2012.

5 Enacted: by paragraph (2) Section 68 of Act LXXIX of 2012. In force: as of 1. 07. 2012.

6 Amended by Point 2 of Section 283 of Act L of 2017.

7 Amended by Point 2 of Section 283 of Act L of 2017.

8 Amended by Points 3, 5 of Section 283 of Section 283 of Act L of 2017.

9 Established: by Section 113 of Act CXXVII of 2013. In force: as of 6. 07. 2013.



(6)<sup>1</sup> Upon being apprised of a decision of an authority or a court ruling delivered and proclaimed for altering a decision, the government body for pharmaceuticals shall proclaim, using the same means as used for the proclamation of the resolution or ruling of the first instance:

- a) the information under Subsection (5) relating to the decision to which the remedy pertains;
- b) the decision of an authority or a court ruling adopted in the remedy proceedings, including a brief explanation; and
- c) the date of proclamation.

### **Provisions Relating to Unfair Business-to-Consumer Commercial Practices in Connection with Medicinal Products and Medical Aids<sup>2</sup>**

#### *Section 17*

(1) Medicinal products for human use may be advertised to the general public if they may be dispensed from a pharmacy without a prescription, for which no social security subsidies are available, or if no subsidies are available as regards medical aids if:<sup>3</sup>

- a) the product in the advertisement is clearly identified as a medicinal product or as a medical aid;
- b) the advertisement includes the name of the medicinal product, as well as the internationally used common name if the medicinal product contains only one active substance, or the name of the medical aid;
- c) the advertisement contains the information necessary for correct use of the medicinal product or medical aid;
- d) the advertisement demonstrates the medicinal product and the medical aid based on the summary of the product characteristics or the user's manual, respectively;
- e) the advertisement contains the information leaflet and warning specified in specific other legislation as necessary for the correct use of the medicinal product or medical aid;
- f) the advertisement contains an express, legible invitation to read carefully the instructions for the application of the medicinal product or the user's manual of the medical aid.

(2) The advertisement referred to in Subsection (1) shall not contain any reference or expression which:

- a) claims or gives the impression that a medical consultation or surgical operation is unnecessary or redundant;
- b) suggests that the effects of taking the medicinal product are guaranteed, or are unaccompanied by adverse reactions;
- c) suggests that the medicinal product is a foodstuff or cosmetic product;
- d) suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural;
- e) could, by a description or detailed representation of a case history, lead to erroneous self-diagnosis;
- f) uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product or a medical aid on the human body or parts thereof;
- g) refers to a recommendation by scientists, health professionals or celebrities;

1 Amended by Points 4-6 of Section 283 of Act L of 2017. Amended by Point 6 of Section 283 of Act L of 2017.

2 Established: by paragraph (1) Section 28 of Act CVI of 2008. In force: as of 01. 01. 2009.

3 Amended: by subparagraph c) Section 88 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.

*h)* suggests that the health of the subject could be affected by not taking the medicinal product or by not using the medical aid.

(3) Subsection (1) of this Section shall not apply to the advertising of any non-prescription medicinal products or medical aids for which no social security subsidies are available, if it contains only the registered name of the medicinal products or medical aids in question, the name or trademark of its manufacturer (flash-back advertising). Such flash-back advertising may be published through radio or television, only as part of the same advertising package, and following the display of a commercial message which satisfies the requirements laid down in Subsections (1)-(2).

(4)<sup>1</sup> Medicinal products and dietary supplements may not be advertised to the general public if they can be dispensed from the pharmacy solely with a prescription or which are approved for social security subsidies, as well as medical aids subsidized under the social security system.

(4a)<sup>2</sup> The restriction set out in Subsection (4) shall not apply to brochures made available in stores specializing in medical aids and in pharmacies, and on the websites of manufacturers, distributors and vendors for the purpose of providing objective information to patients, featuring the information contained in the catalogue specified in Section 21/A.

(5)<sup>3</sup> The prohibition set out in Subsection (4) above shall not apply to public service information conveyed in connection with campaigns for the promotion of vaccination programs which are authorized by the government body in charge of the healthcare system, and to information on the medicinal products connected to these campaigns.

(6) Advertising may not be published if:

*a)* it concerns a medicinal product or medical aid that is not authorized to be marketed or used in Hungary;

*b)* it concerns a medicinal product that contains narcotics or psychotropic materials, as defined in specific other legislation;

*c)*<sup>4</sup> it concerns an investigational medicinal product;

*d)*<sup>5</sup> is directed at children, including advertising in children's programs and children's publications;

*e)* it concerns a non-prescription medicinal product that bears the same name as a prescription medicinal product that is in circulation;

*f)* it concerns a non-prescription medicinal product, whose price is subsidized according to specific other legislation by the central budget or by the H. Fund to those eligible;

*g)* it concerns a medical aid that bears the same name as a medical aid for social security subsidies that are available, that differs only in designation or number.

(7)<sup>6</sup>

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1 Established: by paragraph (1) Section 59 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.

2 Established: by paragraph (1) Section 93 of Act CCXII of 2012. In force: as of 1. 01. 2013.

3 Established: by paragraph (1) Section 59 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.

4 Amended by Paragraph g) of Section 130 of Act CI of 2021.

5 Established by Subsection (1) of Section 116 of Act CI of 2021, effective as of 29 June 2021.

6 Repealed: by subparagraph c) paragraph (4) Section 73 of Act CVI of 2008. No longer in force: as of 01. 01. 2009.

(8)<sup>1</sup> Apart from the product samples defined in the decree of the minister in charge of the healthcare system, it is prohibited to provide or offer any gifts, product samples or gift certificates (coupons), winnings to patients and customers directly, or by way of doctors or dispensers of medicinal products and medical aids, that is intended to sponsor or promote the use of medicinal products or the products of a specific marketing authorization holder, or a specific medical aid that is subsidized by the social security system, if such use is made a precondition. Furthermore, any reduction, refund or reimbursement of the price the patient is required to pay for medicinal products, dietary supplements and medical aids which are subsidized by the social security system is also prohibited in any direct or indirect way or form (gift, sample, gift certificate, coupon, frequent buyer programs, offers made for filling prescriptions in specific pharmacies, offering any pecuniary or other advantage in connection with the number of prescriptions filled, and other similar promotional campaign, or offering any benefits or advantages in connection therewith). Any privilege or allowance provided in connection with dispensing any medicinal products which are not subsidized by the social security system - other than cash discounts - may be used solely for consultation by pharmacist in the pharmacy. The dispensing of medicinal products, dietary supplements and medical aids in pharmacies, including other products that may be sold in pharmacies, and discounts and other advantages connected to consultation by pharmacists under this Act may be granted exclusively in pharmacies through the dispensing staff. The dispensing of medicinal products, dietary supplements and medical aids in pharmacies, including other products that may be sold in pharmacies, and consultation by pharmacists may not serve any basis for discounts and other advantages made available by any other establishment of the economic operator that operates the pharmacy or from any other economic operator.

(8a)<sup>2</sup> The collection, processing of data on illness or medication patterns in a manner allowing for the identification of the data subjects in the framework of patient support programs or other programs, and encouraging or rewarding the disclosure of such data is prohibited.

(9)<sup>3</sup> With respect to commercial practices, any business association that operates a pharmacy shall not be allowed to make donations to civil society organizations, health, social and children's institutions (for the purposes of this Section hereinafter referred to as "institution"), that may be tied to purchases of medicinal products for the institution or its members, or for the patients treated in the institution.

(10)<sup>4</sup> With the exception of books, publications and brochures, printed or electronic, offering health-related information, guides to health awareness, promoting healthy living and a health-conscious lifestyle, prevention, and featuring treatments and pharmaceutical care, it is prohibited to give away products sold in pharmacies to consumers free of charge.

(11)<sup>5</sup> Advertisements of pharmacies and of the services of pharmacies may contain the pharmacy's name and contact information, the opening hours and the services the pharmacy provides, including the use of electronic devices. Comparison with other pharmacies and dissemination of information for raising awareness is prohibited.

### **Vested Responsibilities<sup>6</sup>**

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1 Established by Subsection (2) of Section 93 of Act CCXII of 2012. Amended by Paragraphs h), i) of Section 130 of Act CI of 2021.

2 Enacted by Subsection (2) of Section 116 of Act CI of 2021, effective as of 29 June 2021.

3 Enacted: by paragraph (3) Section 107 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.  
Amended: by subparagraph d) Section 82 of Act LXXIX of 2012. In force: as of 1. 07. 2012.

4 Enacted by Section 69 of Act LXXIX of 2012. Amended by Paragraph a) of Section 71 of Act XIX of 2023.

5 Enacted: by Section 69 of Act LXXIX of 2012. In force: as of 1. 07. 2012.

6 Established: by Section 29 of Act CVI of 2008. In force: as of 01. 01. 2009.

### *Section 18<sup>1</sup>*

(1) Subject to the exceptions set out in Subsections (3) and (4), liability for any infringement of the regulations laid down in this Act and in the decree adopted by authorization conferred under Paragraph j) of Subsection (2) of Section 77 of this Act (for the purposes of Sections 18-19 hereinafter referred to as "Decree") on commercial practices relating to medicinal products and medical aids shall lie with the person who, in commercial practices, is acting for purposes relating to his trade or business and who is directly connected with the promotion, sale or supply of medicinal products or medical aids to which the commercial practice in question pertains.

(2) The person referred to in Subsection (1) shall be held liable also if the commercial practice is carried out under contract by another person acting on behalf of or for the said person referred to in Subsection (1).

(3)<sup>2</sup> Liability for any infringement of the regulations pertaining to promoters of medicinal products shall lie with the promoter of medicinal products; whereas for the infringement of regulations pertaining to medical sales representatives, liability shall lie with the medical sales representative affected.

(4) Liability for any infringement arising in connection with the representation of commercial communication shall also lie with the person who uses means suitable for the publication of commercial communication to disseminate commercial communication, and with the person professionally involved in producing or creating commercial communication in the context of his economic activities, or in providing other related services, with the exception if the infringement originates from the carrying out of the instructions of the person referred to in Subsection (1).

(5) The aforesaid persons shall bear joint and several liability with the persons referred to in Subsection (1) for damages resulting from the unlawful commercial practices mentioned in Subsection (4).

### **Rules of Procedure<sup>3</sup>**

#### *Section 18/A<sup>4</sup>*

(1)<sup>5</sup> Subject to the exceptions set out in Subsection (2), the authority specified in the Act on the Prohibition of Unfair Business-to-Consumer Commercial Practices shall have jurisdiction in connection with any infringement of the provisions relating to business-to-consumer commercial practices set out in this Act and in the Decree in connection with medicinal products and medical aids. The competent authority shall proceed in accordance with the relevant provisions of the Act on the Prohibition of Unfair Business-to-Consumer Commercial Practices.

(2)<sup>6</sup> In connection with any infringement of the provisions of Subsections (4) and (6) of Section 17 the consumer protection authority shall have jurisdiction according to the provisions set out in the Act on Consumer Protection.

(3)<sup>7</sup> The civil society organizations active in the field of protection of patients' rights shall be treated as a party as well in the proceedings referred to in Subsections (1) and (2).

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1 Established: by Section 29 of Act CVI of 2008. In force: as of 01. 01. 2009.

2 Amended: by Section 360 of Act LVI of 2009. In force: as of 1. 10. 2009.

3 Enacted: by Section 30 of Act CVI of 2008. In force: as of 01. 01. 2009.

4 Enacted: by Section 30 of Act CVI of 2008. In force: as of 01. 01. 2009. Shall apply to proceedings opened after entry into force of these provisions.

5 Amended: by Section 360 of Act LVI of 2009. In force: as of 1. 10. 2009.

6 Amended: by Section 360 of Act LVI of 2009. In force: as of 1. 10. 2009.

7 Amended: by Section 360 of Act LVI of 2009. In force: as of 1. 10. 2009. Amended: by Section 170 of Act CLXXV of 2011. In force: as of 22. 12. 2011.

(4)<sup>1</sup> The following authorities shall also have jurisdiction to enforce the provisions relating to business-to-consumer commercial practices set out in this Act and in the Decree:

a) in connection with medicinal products, therapeutic preparations which are not classified as medicinal products and medical aids, the government body for pharmaceuticals;

b) in connection with dietary supplements, the government body in charge of the healthcare system.

(4a)<sup>2</sup> Having regard to the provisions relating to business-to-consumer commercial practices set out in this Act and in the Decree, where pharmacies are concerned the government body in charge of the healthcare system shall also have jurisdiction to enforce such regulations.

(5)<sup>3</sup> The provisions relating to business-to-consumer commercial practices set out in this Act and in the Decree in connection with medicinal products and medical aids are treated as consumer protection regulations in the application of the Act on Consumer Protection.

(6)<sup>4</sup>

### *Section 18/B<sup>5</sup>*

(1)<sup>6</sup> The implementation of Regulation (EU) 2017/2394 of the European Parliament and of the Council of 12 December 2017 on cooperation between national authorities responsible for the enforcement of consumer protection laws and repealing Regulation (EC) No. 2006/2004 (hereinafter referred to as "Regulation 2017/2394/EU") shall be conferred upon:

a)<sup>7</sup> the consumer protection authority and the Hungarian Competition Authority in the cases referred to in Subsection (1) of Section 18/A, in line with the distribution of powers and competencies laid down in the Act on the Prohibition of Unfair Business-to-Consumer Commercial Practices,

b) the consumer protection authority in the cases referred to in Subsection (2) of Section 18/A,

with a view to any intra-Community infringements of national laws on the transposition of Articles 86-100 of Directive 2001/83/EC of the European Parliament and of the Council, as amended by Directive 2004/27/EC of the European Parliament and of the Council.

(2) In connection with mutual assistance, the authorities mentioned in Subsection (1) shall proceed in accordance with Commission Decision 2007/76/EC, as amended by Commission Decision 2008/282/EC.

(3) For information purposes, the minister in charge of the judicial system shall publish on the official website of his Ministry the list of legislation on the transposition of Articles 86-100 of Directive 2001/83/EC of the European Parliament and of the Council, as amended by Directive 2004/27/EC of the European Parliament and of the Council.

### *Section 19*

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1 Established by Section 68 of Act CIV of 2016, effective as of 1 January 2017.

2 Enacted: by paragraph (2) Section 59 of Act LXXXI of 2011. In force: as of 1. 07. 2011.

3 Amended: by Section 360 of Act LVI of 2009. In force: as of 1. 10. 2009.

4 Repealed: by point 42 Section 84 of Act CLXVI of 2011. No longer in force: as of 1. 01. 2012.

5 Enacted: by Section 30 of Act CVI of 2008. In force: as of 01. 01. 2009.

6 Amended by Section 112 of Act LXVII of 2019.

7 Amended: by Section 360 of Act LVI of 2009. In force: as of 1. 10. 2009.

(1)<sup>1</sup> The proceedings in connection with any infringement of the provisions laid down in this Act and in the Decree pertaining to the promotion of medicinal products and medical aids shall be conducted by the government body for pharmaceuticals.

(2)<sup>2</sup> If the promoter of medicinal products, a medical sales representative, the holder of the marketing authorization of a medicinal product, a manufacturer of medical aids, a person qualified to prescribe or supply medicinal products and/or medical aids or the authorized representative of any of these persons has infringed upon the provisions of this Act or the Decree pertaining to the promotion of medicinal products or medical aids, the government body for pharmaceuticals:

a) may contact the competent trade association requesting ethics proceedings, where applicable;

b)<sup>3</sup> in its decision with warning, may order the infringer to eliminate the discrepancies within the prescribed deadline and may suspend his authorization until the said discrepancies are eliminated;

c) shall declare the fact of infringement, may order the state of infringement to be terminated and prohibit continuation of the illegal conduct;

d) may impose a fine in the amount of:

da) between five hundred thousand and twenty-five million forints in the case of authorized distributors,

db) between five hundred thousand and five hundred million forints in the case of promoters of medicinal products, holders of marketing authorizations and manufacturers,

dc) between five hundred thousand and five million forints in the case of medical sales representatives.

(2a)<sup>4</sup> If the promoter of medicinal products, a medical sales representative, the holder of the marketing authorization of a medicinal product, a manufacturer of medical aids, a person qualified to prescribe or supply medicinal products and/or medical aids or the authorized representative of any of these persons has repeatedly or seriously infringed upon the provisions of this Act or the Decree pertaining to the promotion of medicinal products or medical aids, the government body for pharmaceuticals:

a) shall ban the promoter of medicinal products governed under Subsection (3) of Section 12, that is held accountable for the infringement, from engaging in promotional activities for a period of between six months and three years;

b) shall contact the health insurance administration agency and request:

ba) the suspension - in accordance with the HIS - of the contract of the infringer service provider authorized under contract for dispensing operations within the social security system,

bb) the suspension of the right of prescription of doctors with entitlement for the prescription of subsidized medicinal products for up to one month.

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1 Amended: by Section 2 of Act LXXXIX of 2010. In force: as of 16. 09. 2010. Amended: by subparagraph a) Section 88 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.

2 Established: by Section 60 of Act LXXXI of 2011. In force: as of 1. 07. 2011.

3 Amended by Section 87 of Act CLXVIII of 2020.

4 Enacted: by Section 60 of Act LXXXI of 2011. In force: as of 1. 07. 2011.

(3)<sup>1</sup> The amount of the fine and the applied sanction shall be determined with regard to all applicable circumstances of the case, in particular, the circumstances provided for in Subsection (1) of Section 10 of Act CXXV of 2017 on Penalizing Administrative Infractions (hereinafter referred to as "Sanctions Act"), and the scope and gravity of the injury caused to persons authorized to order and supply medicinal products or medical aids, and/or to patient care interests. In the case of repeat violations the amount of the fines imposed may be cumulative. The circumstance referred to in Paragraph *g*) of Subsection (1) of Section 10 of the Sanctions Act shall apply in the application of this Act in the benefit of the infringer solely in the case where the infringement committed had no impact on patient safety or patient care interests.

(4)<sup>2</sup> In administrative proceedings opened ex officio for any breach of the provisions of this Chapter and the Decree, there shall be no recourse to warning if the government body for pharmaceuticals decides to impose another sanction under Subsections (2) and (2a) of Section 19.

(5)<sup>3</sup> In the application of Subsection (3):<sup>4</sup>

*a*)<sup>5</sup> repeat infringement means if the infringer or his authorized representative in this capacity, or the principal had been found guilty of any infringement of the provisions of this Act or the Decree by definitive decision within the last two years;

*b*)<sup>6</sup> grave infringement means where the unlawful commercial practices relating to medicinal products or medical aids represent twenty-five million forints or more at fair market value.

(6)<sup>7</sup> In the proceedings the provisions of Section 12/A of Act XXXIV of 2004 on Small and Medium-sized Enterprises and the Support Provided to Such Enterprises shall not apply.

(7)<sup>8</sup>

### *Section 19/A*<sup>9</sup>

Decisions adopted in proceedings under Section 19 may not be appealed.

### *Section 20*

(1)<sup>10</sup> The government body for pharmaceuticals shall monitor compliance with the provisions of Sections 14-15.

(2)<sup>11</sup> With a view to ascertaining the relevant facts of the case, the government body for pharmaceuticals shall have authority:

*a*) to conduct a site inspection anywhere it deems appropriate, and

*b*) to make a hard mirror image of the data medium held by any person, and to inspect the contents through this image,

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1 Established by Section 83 of Act CLXVIII of 2020, effective as of 1 January 2021.

2 Established by Section 117 of Act CI of 2021, effective as of 29 June 2021.

3 Amended by Point 1 of Section 284 of Act L of 2017.

4 Amended: by paragraph (6) Section 73 of Act CVI of 2008. In force: as of 01. 01. 2009.

5 Amended by Point 1 of Section 283 of Act L of 2017.

6 Amended: by paragraph (6) Section 73 of Act CVI of 2008. In force: as of 01. 01. 2009.

7 Enacted by Section 64 of Act CCXLIV of 2013, effective as of 1 January 2014.

8 Repealed by Point 2 of Section 284 of Act L of 2017, effective as of 1 January 2018.

9 Established: by Section 4 of Act LXXXIX of 2010. In force: as of 17. 08. 2010.

10 Amended: by Section 361 of Act LVI of 2009. In force: as of 1. 10. 2009. Amended: by Section 2 of Act LXXXIX of 2010. In force: as of 16. 09. 2010. Amended: by subparagraph a) Section 88 of Act CLXXIII of 2010. In force: as of 1. 01. 2011. Amended: by subparagraph e) Section 82 of Act LXXIX of 2012. In force: as of 1. 07. 2012.

11 Established by Subsection (1) of Section 65 of Act CCXLIV of 2013, effective as of 1 January 2014.

if there is reason to believe that the site inspection is likely to reveal information concerning the infringement of the provisions of Sections 14-15. The client and the parties concerned need not be notified of the impending site inspection if this is likely to compromise the outcome thereof. Any person and organization contacted shall be liable to make available data from their records and copies of documents in their possession with facilities for reading and copying to the government body for pharmaceuticals.

(3)<sup>1</sup> The government body for pharmaceuticals shall be entitled to inspect and process - in connection with monitoring compliance with the provisions of Sections 14-15 - the personal data of the party to the case and other persons who may be tied to the party. Where a means of evidence contains personal data that does not pertain to the investigation, and if this data cannot be detached without compromising the probative value of the evidence, the government body for pharmaceuticals shall be entitled to process all personal data affected, however, the entitlement to inspect the personal data that does not pertain to the investigation is valid only to the extent required to ascertain that the data is not connected to the infringement investigated.

(4)<sup>2</sup> With a view to ascertaining the relevant facts of the case, the government body for pharmaceuticals shall have authority:

a) to inspect the contract between a holder of the marketing authorization of a medicinal product, or the manufacturer or distributor of medical aids and promoter of medicinal products contracted,

b) to inspect the contract between a promoter of medicinal products and the person qualified to prescribe and supply medicinal products and medical aids, being the other party to the contract,

c) to inspect the contract between a subcontractor of a promoter of medicinal products and a person qualified to prescribe and supply medicinal products and/or medical aids and to make inquiries relating to activities which are in fact carried out from the perspective of ensuring and demonstrating the principle of value for money, and for compliance with rules of promotional activities set out in Sections 13-15.

(4a)<sup>3</sup> For the inspection referred to in Subsection (4), the parties to the contract and to the activity shall make available all evidence to show that the activities which are in fact carried out have been effectively implemented in conformity with the relevant contracts, and that they are not considered unlawful commercial practices, and no monetary benefits or financial advantage is provided unlawfully as described in Subsection (1) of Section 14 within the framework of such legal relationship. A contractual relationship between the promoter of medicinal products and the person qualified to prescribe and supply medicinal products and/or medical aids, including instructions for their use and marketing, shall not culminate in the creation of means of information, activity, communication and presentation intended to promote the sales, prescription and distribution of the products of the promoter of medicinal products.

(5)<sup>4</sup> Any data, or document recording such data, created during or for the purpose of communications between the party and his defense attorney may not be admissible as evidence in the proceedings of the government body for pharmaceuticals, they may not be examined or seized, and the holder of such documents may not be compelled to produce them for the purpose of inspection.

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1 Amended: by Section 361 of Act LVI of 2009. In force: as of 1. 10. 2009. Amended: by Sections 2 and 3 of Act LXXXIX of 2010. In force: as of 16. 09. 2010. Amended: by subparagraphs a) and b) Section 88 of Act CLXXIII of 2010. In force: as of 1. 01. 2011. Amended: by subparagraph g) Section 82 of Act LXXIX of 2012. In force: as of 1. 07. 2012.

2 Established by Subsection (1) of Section 118 of Act CI of 2021, effective as of 29 June 2021.

3 Established by Subsection (1) of Section 118 of Act CI of 2021, effective as of 29 June 2021.

4 Amended: by Section 2 of Act LXXXIX of 2010. In force: as of 16. 09. 2010. Amended: by subparagraph a) Section 88 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.



(6)<sup>1</sup> Any dispute as to whether a document should enjoy the protection under Subsection (5) shall be decided, upon the request of the government body for pharmaceuticals, by the Fővárosi Bíróság (*Budapest Metropolitan Court*) in non-contentious civil proceedings - upon hearing the client - within eight days from the date of submission of the request. If the court rules that the protection under Subsection (5) not applies to the document, it shall be released to the government body for pharmaceuticals; henceforward the general provisions applicable to documents shall apply to the released document. If the court's decision is in the client's favor the document shall released to the client.

(7)<sup>2</sup> In the course of enforcement of the provisions of Sections 14-15, the government body for pharmaceuticals shall be empowered to search any premises, to enter such premises under probable cause under his own authority, without the consent of the owner (tenant) or any other person in the premises, and to open any sealed-off area or building for this purpose. In the process of the search the acting officer shall have powers to demand information, written or oral, from the client, the client's representative (former representative) or employee (former employee), and may gather intelligence in any other way. An on-site inspection may be carried out in the private domain, including vehicles and other premises, if it is in the use of any former or current executive officer of the party, employee or representative, or any other person who effectively exercises control or who used to exercise control.

(8)<sup>3</sup> The investigative measures specified under Subsection (7) shall be carried out subject to the public prosecutor's prior consent. The prosecuting authority shall authorize the above-specified investigative measure if the government body for pharmaceuticals is able to substantiate probable cause that any other investigative measure is unlikely to produce the required results, and if there is reason to believe that the source of information - relating to the illegal activity investigated - indicated is in the location for which the court order is requested and it is presumed that this information will not be surrendered voluntarily or that it would be destroyed. If the investigative measure is only partially accepted, the prosecuting authority shall specify the type of procedure and the person who is the subject of such procedure. On the basis of having in possession the prosecuting authority's consent the investigative measure may be carried out within a period of ninety days from the date of issue.

(9)<sup>4</sup> Regarding the investigative measure carried out under Subsection (8) the persons affected shall be informed verbally at the time the investigative measure commences, and it shall be carried out if possible in the presence of these persons. Before the investigative measure is carried out the court order shall be presented and the purpose of the investigative measure shall be communicated.

(10)<sup>5</sup> Upon hearing a witness, the government body for pharmaceuticals may order to keep the witness's data confidential if deemed necessary with a view to ascertaining the relevant facts of a case.

(11)<sup>6</sup> The administrative time limit for administrative proceedings opened ex officio for any infringement of the provisions of the decree on the detailed provisions regarding the promotion of medicinal products for human use and medical aids, the registration of persons pursuing promotional activities and business-to-consumer commercial practices relating to the medicinal products and medical aids shall be one hundred and ten days.

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1 Established by Section 60 of Act CLXXIII of 2010. Amended by Section 64 of Act CXXX of 2017.

2 Amended: by Section 360 of Act LVI of 2009. In force: as of 1. 10. 2009. Amended: by Section 3 of Act LXXXIX of 2010. In force: as of 16. 09. 2010. Amended: by subparagraph b) Section 88 of Act CLXXIII of 2010. In force: as of 1. 01. 2011. Amended: by subparagraph g) Section 82 of Act LXXIX of 2012. In force: as of 1. 07. 2012.

3 Established: by Section 114 of Act CXXVII of 2013. In force: as of 6. 07. 2013.

4 Amended: by Section 361 of Act LVI of 2009. In force: as of 1. 10. 2009.

5 Enacted: by Section 70 of Act LXXIX of 2012. In force: as of 1. 07. 2012.

6 Established by Section 62 of Act XIX of 2023, effective as of 1 June 2023.

## Chapter III

### SUPPLY GUARANTEES FOR MEDICINAL PRODUCTS AND MEDICAL AIDS

#### Section 21

(1)<sup>1</sup> In the process of the admission of certain medicinal products, dietary supplements and medical aids into the social security subsidy system the health insurance administration agency may render such admission contingent upon a commitment for keeping such products on the market within the subsidized system for a fixed period of minimum three years, or - in cases under specific other legislation - upon a commitment for keeping a specific quantity of such products on stock.

(1a)<sup>2</sup> The marketing authorization holder shall ensure the continuous supply of medicinal products having preferential status justified with a view to ensure the safe supply of the general public (hereinafter referred to as "medicinal product with preferential status") during the period of preferential status.

(1b)<sup>3</sup> If the marketing authorization holder wishes to terminate the preferential status of a medicinal product before the end of the five-year period provided for in Subsection (3) of Section 31/C, the health insurance administration agency shall be notified thereof at least six months before the proposed date of termination.

(1c)<sup>4</sup> The marketing authorization holder, if failing to honor the supply commitment for reasons within his control, shall be liable to reimburse the benefits and allowances granted in connection with preferential status and to cover the extra costs stemming from the purchase made under Subsection (4).

(2)<sup>5</sup> The holder of the marketing authorization of a medicinal product, the distributor of dietary supplements or the manufacturer of the medical aid, or its authorized representative, for which social security subsidies are granted under Subsection (1), if failing to discharge the supply or stocking commitment for reasons within its control, shall be liable to bear the extra costs stemming from the purchase made under Subsection (4).

(3) The holder of the marketing authorization of a medicinal product or the manufacturer of the medical aid, or its authorized representative, that has been admitted into the social security subsidy system shall notify the health insurance administration agency at least half a year in advance if it plans to terminate the distribution of subsidized preparations or products in Hungary.

(4) Where the holder of the marketing authorization of a medicinal product that is in commercial circulation in Hungary with public financing intends to discontinue or is unable to continue the marketing of such product that is already in circulation, temporarily or for any extended duration, in the territory of Hungary, however:

a) if being deprived of the medicinal product in question is likely to result in severe or persistent disability for the patients treated with such products; and

b) there is no other medicinal product of similar active ingredients, pharmaceutical form and strength available in the territory of Hungary,

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1 Established: by paragraph (1) Section 84 of Act CLIV of 2009. In force: as of 1. 01. 2010.

2 Enacted by Section 66 of Act CCXLIV of 2013. Amended by Paragraph a) of Section 26 of Act CLXXXVIII of 2017.

3 Enacted by Section 66 of Act CCXLIV of 2013, effective as of 1 January 2014.

4 Enacted by Section 66 of Act CCXLIV of 2013, effective as of 1 January 2014.

5 Established: by paragraph (1) Section 84 of Act CLIV of 2009. In force: as of 1. 01. 2010.

the administrator of state healthcare, emergency and safety reserves shall have powers to purchase the medicinal products in question from any legal person or business association lacking the legal status of a legal person as laid down in specific other legislation that is authorized in a State other than Hungary to engage in the wholesale distribution and/or retail supply of medicinal products.

(5) Business associations authorized for the wholesale distribution of medicinal products shall be required to procure and supply the medicinal products to which their authorization for wholesale distribution pertains. To this end they are required to maintain a purchase and inventory management system with facilities to ensure the transparency and controllability of the distribution and supply.

(6) Business associations authorized for the wholesale distribution of medicinal products, apart from the obligation referred to in Subsection (5), shall be required to cooperate with the administrator of state healthcare, emergency and safety reserves, and shall partake - as prescribed in specific other legislation - in ensuring the availability of the Central Healthcare Reserve and continuous replacement in order to maintain quality.

(7) The detailed regulations for maintaining a wholesale stock of medicinal products and specifying the products which are to be kept in compulsory reserve, and for their distribution shall be laid down in specific other legislation.

(8)<sup>1</sup> Wholesale distributors and retail suppliers of medicinal products are required to carry preferred reference price range medicinal products, preferred biological medicinal products and reference medicinal products in connection with all specific (fixed) subsidy groups and all other subsidy groups set up specifically for biological medicinal products.

(9)<sup>2</sup> In connection with mass produced medical aids which are subsidized by the social security system, distributors are required to carry reference products for the function group of the device in question, or a device of the same price.

(9a)<sup>3</sup> A medical aid may be prescribed with social security subsidies only if the distributor procured the medical aid from the holder of marketing authorization listed in the register provided for in Subsections (6) and (7) of Section 33, or from an economic operator provided for in Point 10 of Section 3 of Act CXLI of 2015 on Public Procurement (hereinafter referred to as "Procurement Act") who is able to evidence - by means of a document verifying receipt of the goods - that the medical aid in question originates from the holder of marketing authorization shown in the register provided for in Subsections (6) and (7) of Section 33.

(9b)<sup>4</sup> If the distributor of the medical aid and the holder of marketing authorization is one and the same, Subsection (9a) shall not apply.

(10)<sup>5</sup> The government body in charge of the healthcare system shall withdraw the operating permit of a wholesale distributor or retail supplier of medical aids if it finds that the wholesale distributor or retail supplier has repeatedly and seriously infringed upon the relevant provisions concerning the distribution of medical aids.

(11)<sup>6</sup> The health insurance administration agency may prescribe rules for the distribution of medicinal products, dietary supplements and medical aids subsidized under the social security system with a view to ensure the continuous and safe supply of the general public.

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1 Established: by Section 108 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.

2 Established: by Section 115 of Act CXXVII of 2013. In force: as of 6. 07. 2013.

3 Enacted by Section 51 of Act CCXXIV of 2015. Amended by Point 1 of Section 56 of Act LIII of 2023.

4 Enacted by Section 51 of Act CCXXIV of 2015, effective as of 1 April 2016.

5 Enacted: by paragraph (3) Section 84 of Act CLIV of 2009. In force: as of 1. 01. 2010.

6 Enacted: by paragraph (3) Section 84 of Act CLIV of 2009. In force: as of 1. 01. 2010.

(12)<sup>1</sup> Business associations authorized for the wholesale distribution of medicinal products shall be required to keep frequently updated records - as decreed by the minister in charge of the healthcare system - on the liabilities of pharmacies towards business associations authorized for the wholesale distribution of medicinal products, and shall regularly inform the pharmacies affected concerning their existing financial obligations.

#### *Section 21/A*<sup>2</sup>

(1) The health insurance administration agency shall operate a web-based medical aid catalogue containing information on subsidized medical aids - as decreed by the minister in charge of the healthcare system - on its website with a view to lend assistance to doctors wishing to prescribe medical aids, as well as to patients for enabling them to make an informed decision.

(2)<sup>3</sup> The distributor of medical aids shall make available by way of electronic means, as decreed by the minister in charge of the healthcare system, to the health insurance administration agency the documents and information prescribed by the minister in charge of the healthcare system with a view to gaining admission to the catalogue mentioned in Subsection (1) hereof.

(3) If the distributor of medical aids fails to comply with the requirement referred to in Subsection (2) hereof upon receipt of notice from the health insurance administration agency, the health insurance administration agency shall impose a financial penalty upon the distributor in the amount specified in the relevant government decree, with the proviso that such penalty shall not exonerate the distributor from discharging the obligation referred to in Subsection (2).

(4) If the distributor - other than the distributors of custom-made medical aids and their authorized representatives - remains to discount the obligation referred to in Subsection (2) within fifteen days from the date of the penalty imposed under Subsection (3), the health insurance administration agency shall exclude the medical aid in question from social security subsidies and shall remove the distributor from the list of suppliers referred to in Subsection (1) of Section 32/B, if applicable.

### Chapter IV

## GENERAL RULES FOR THE ADMISSION OF MEDICINAL PRODUCTS AND MEDICAL AIDS INTO THE SOCIAL SECURITY SUBSIDY SYSTEM

#### *Section 22*<sup>4</sup>

Unless otherwise prescribed by law, social security subsidies may be granted to medicinal products and medical aids if:

a)<sup>5</sup> the holder of the marketing authorization of a medicinal product, the distributor of dietary supplement or the manufacturer of medical aid, or its authorized representative, applies for subsidies within the compulsory health insurance system for the product in question;

b) in connection with medicinal products, the authority vested with powers under specific other legislation has recognized the safety and efficacy of the product, and authorized the release of the product into free circulation;

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1 Enacted: by Section 61 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.

2 Established: by Section 109 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.

3 Established: by Section 116 of Act CXXVII of 2013. In force: as of 6. 07. 2013.

4 Established: by Section 32 of Act CVI of 2008. In force: as of 01. 01. 2009.

5 Amended: by Section 360 of Act LVI of 2009. In force: as of 1. 10. 2009.

- c) the cost-effectiveness of the medicinal product, dietary supplement or medical aid in question has been verified;
- d) the medicinal product, dietary supplement or medical aid in question is effectively available for therapeutic use;
- e)<sup>1</sup> the person applying for subsidies undertakes - by way of the means and for the duration prescribed in Section 26 and also by specific other legislation - to comply with the regulations pertaining to insurance costs;
- f) the funds required are or can be made available within the social security system;
- g) the holder of the marketing authorization of a medicinal product, the distributor of the dietary supplement or the manufacturer of medical aids, or its authorized representative undertakes the commitment for the distribution and stocking of the subsidized product.

#### Section 22/A<sup>2</sup>

(1) In the case provided for in Subsection (2) of Section 16 of the MPH, if the government body for pharmaceuticals authorized the procurement pursuant to the decree of the minister in charge of the healthcare system, the health insurance agency may ex officio approve the given medicinal product for social security subsidies.

(2) In the case under Subsection (1), the amount of subsidy shall be the same as the price serving as the basis for public financing of preparations approved for social security subsidies by the health insurance agency, of which there is a shortage.

#### Section 23

(1)<sup>3</sup> Proceedings concerning the admission of medicinal products and dietary supplements for subsidies under the social security system are opened upon request, notification or *ex officio* where:

a)<sup>4</sup> if opened upon request, the application may pertain to the admission of medicinal products and dietary supplements - which have already been authorized for marketing - into the social security subsidy system, for the review of the subsidy category, the type and rate of subsidy, and for any subsequent modification of these, including the award of preferential status;

b) if opened upon notification, the application may pertain to the notification of changes in the particulars referred to in Subsection (4) of Section 29;

c)<sup>5</sup> if opened ex officio, the proceedings of the health insurance administration agency may pertain to the total and partial review of the list of subsidized medicinal products and dietary supplements in accordance with Subsections (7)-(8) hereof, or for their approval for social security subsidies under Section 22/A.

(2)<sup>6</sup>

(3)<sup>7</sup> The health insurance administration agency shall adopt a decision concerning the admission of medicinal products and dietary supplements - which have already been authorized for marketing - into the social security subsidy system, including the subsidy category, the type and rate of support, and the first day from which the social security subsidy can be claimed (hereinafter referred to as "initial day of sponsorship"), furthermore, concerning exclusion from social security subsidies and any change in the particulars referred to in Subsection (4) of Section 29, within ninety days.

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1 Established: by Section 86 of Act CLIV of 2009. In force: as of 1. 01. 2010.

2 Enacted by Section 35 of Act CLXXII of 2016, effective as of 1 January 2017.

3 Established: by paragraph (1) Section 87 of Act CLIV of 2009. In force: as of 1. 01. 2010.

4 Amended by Paragraph b) of Section 80 of Act CCXLIV of 2013.

5 Established by Subsection (1) of Section 36 of Act CLXXII of 2016, effective as of 1 January 2017.

6 Repealed by Point 3 of Section 284 of Act L of 2017, effective as of 1 January 2018.

7 Established by paragraph (1) Section 87 of Act CLIV of 2009. Amended by Point 4 of Section 284 of Act L of 2017.

➡(4)<sup>1</sup> In the decisions the initial day of sponsorship provided for in Subsection (3) shall be established for a point in time inside a five year period following the definitive date of the decision.

(5)<sup>2</sup> The applicant shall be charged an administrative service fee in the amount provided for in the relevant ministerial decree for the proceedings referred to in Subsections (3)-(4). The administrative service fee need not be paid in the case of proceedings related to medicinal products with preferential status.

(5a)<sup>3</sup> If upon submission of the application provided for in Subsection (1) of Section 31/B the health insurance administration agency grants the preferential status requested, it shall refund to the marketing authorization holder the administrative service fee such holder has paid.

(6)<sup>4</sup> The health insurance administration agency shall - based on criteria set out in Subsection (7) - routinely review the scope of subsidized medicinal products.

(7)<sup>5</sup> Covered by the review referred to in Subsection (6), the health insurance administration agency shall *ex officio* open proceedings:

a) in the event of any doubt arising in terms of cost-efficiency with respect to products already approved for subsidies;

b) where any product that has already been approved for subsidies imposes an unreasonable burden upon the budget of the Health Fund relative to the advantage it offers in terms of therapeutic efficacy;

c) where so justified by any changes in the relevant legislation;

d) where *ex officio* proceedings are prescribed by the relevant legislation;

e) where the extension of the commitment defined in Section 21 for the distribution of products within the subsidized system or for keeping them on stock is justified with a view to ensure the continuous and safe supply of the general public.

f)<sup>6</sup> where a preparation fails to comply with the requirements set out for areas of indication for special subsidies or premium subsidies.

(8)<sup>7</sup> In the cases described in Subsection (7) above, the health insurance administration agency shall adopt its decision within ninety days concerning the exclusion of subsidized medicinal products or for modifying the rate of subsidy, for making any changes in the subsidy category or the type of subsidy, for the termination of preferential status, or for the extension or prescribing of the commitment defined in Section 21 for the distribution of products within the subsidized system or for keeping them on stock.

(8a)<sup>8</sup>

(9)<sup>9</sup> The health insurance administration agency shall conduct the proceedings referred to in Paragraph a) of Subsection (1) using the regular or simplified technique.

(10)<sup>10</sup> In all re-examination procedures opened *ex officio* which are concluded without the exclusion of the medicinal product examined, the health insurance administration agency shall adopt a resolution according to Subsection (11) in connection with the medicinal product examined, and shall proclaim it on its website. The health insurance administration agency shall notify the clients concerned regarding the resolution and access to the proclaimed notice by means of electronic mail.

1 Established by Section 36 of Act XCI of 2023, effective as of 1 January 2024.

2 Established by Subsection (2) of Section 67 of Act CCXLIV of 2013, effective as of 1 January 2014.

3 Enacted by Section 99 of Act CXI of 2014, effective as of 1 January 2015.

4 Established: by paragraph (2) Section 87 of Act CLIV of 2009. In force: as of 1. 01. 2010.

5 Enacted: by paragraph (2) Section 87 of Act CLIV of 2009. In force: as of 1. 01. 2010.

6 Enacted: by Section 62 of Act LXXXI of 2011. In force: as of 1. 07. 2011.

7 Enacted by paragraph (2) Section 87 of Act CLIV of 2009. Amended by Paragraph c) of Section 80 of Act CCXLIV of 2013.

8 Repealed by Point 6 of Section 284 of Act L of 2017, effective as of 1 January 2018.

9 Enacted: by paragraph (2) Section 87 of Act CLIV of 2009. In force: as of 1. 01. 2010.

10 Enacted by paragraph (2) Section 110 of Act CLXXVI of 2011. Amended by Point 7 of Section 283 of Act L of 2017.

(11)<sup>1</sup> The resolution referred to in Subsection (10) shall contain:

- a) the name of the competent authority, the case number and the name of the officer in charge;
- b) description of the subject matter of the case;
- c) in the operative part:
  - ca)<sup>2</sup> the authority's decision, and information on the form of remedy available,
  - cb)<sup>3</sup> the decision ordering payment of the duties and fees charged for the proceedings to the client;
- d) in the statement of reasons:
  - da) the calculations used during the proceedings,
  - db) the statutes upon which the authority has adopted the resolution,
  - dc) reference to the relevant legislation conferring the authority's powers and competencies;
- e) the venue and the time where and when the decision was adopted, the name and title of the competent officer, and the name and title of the issuer, if other than the competent officer;
- f) the signature of the issuer of the decision and the stamp of the authority;
- g) in the annex to the resolution the full spectrum of the medicinal products admitted for subsidies in conclusion of the proceedings.

#### *Section 24*

(1) The health insurance administration agency shall determine the rate of subsidy under Subsections (2)-(4) of Section 23 as a percentage (percentage base and rate) or as a specific (fixed) sum. Subsidy may be set as a fixed amount for medicinal products containing the same active ingredients, or for a group of medicinal products formulated to treat the same disease.

(2)<sup>4</sup> Groups of medicinal products for fixed subsidies are set up on a regular basis, where the producer prices quoted cannot be withdrawn. The detailed regulations for making proposals, for publicity, for determining the amount of subsidies whether at a percentage rate or in a fixed amount, for setting up groups and for the admission procedures shall be decreed by the minister in charge of health insurance. The health insurance administration agency shall communicate its decisions concerning the setting up of fixed-subsidy groups electronically.

(2a)<sup>5</sup> Groups of biological medicinal products are set up on a regular basis. The detailed regulations for making proposals, for publicity, for determining the amount of subsidies and for setting up groups shall be decreed by the minister in charge of health insurance.

(3)<sup>6</sup> The resolutions containing the decisions referred to in Subsections (3)-(4) and (6) of Section 23 as prescribed in specific other legislation shall contain explanations based on the objective and verifiable criteria.

(4)<sup>7</sup> The health insurance administration agency - relying on the final and enforceable resolutions and in consideration of what is contained in Subsection (6) - shall publish on its official website the complete list of subsidized medicinal products by the 20th of each calendar month for information purposes.

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1 Enacted: by paragraph (2) Section 110 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.

2 Amended by Point 7 of Section 284 of Act L of 2017.

3 Amended by Point 8 of Section 284 of Act L of 2017.

4 Established: by paragraph (1) Section 111 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.

5 Enacted by paragraph (2) Section 111 of Act CLXXVI of 2011. Amended by Point 8 of Section 283 of Act L of 2017.

6 Amended: by subparagraph c) paragraph (4) Section 73 of Act CVI of 2008. In force: as of 01. 01. 2009.

7 Established: by paragraph (5) Section 359 of Act LVI of 2009. In force: as of 1. 10. 2009. Shall apply to proceedings opened subsequently and to reopened cases.

(5)<sup>1</sup> The health insurance administration agency shall send the notice referred to in Subsection (4) to the European Commission.

(6)<sup>2</sup> The notice referred to in Subsection (4) shall indicate the registration number of the medicinal products, including its name, packaging, producer price, gross retail price, the amount of subsidy, the retail price with the amount of subsidy deducted (retail price as charged), designation of preferential status, and the initial day of sponsorship under the social security system.


(6a)<sup>3</sup> The health insurance administration agency shall maintain an official public register:

a) on all subsidized medicinal products, and

b) on the rate and the amount of subsidies.

(7)<sup>4</sup> The decisions of the health insurance administration agency adopted under Subsections (3), (4) and (6)-(8a) of Section 23 may not be overturned by the court.

### Section 25

 (1)<sup>5</sup> If the marketing authorization holder wishes to change the price, or the initial day of sponsorship indicated in the decision, of a medicinal product approved for subsidies and for marketing after the date when the resolution the health insurance administration agency has adopted according to Section 23 becomes definitive, a new application shall be submitted for authorization for subsidies.

(2)<sup>6</sup> In the case where the health insurance administration agency has adopted a decision following the proceedings referred to in Subsection (6) of Section 23:

a)<sup>7</sup> for the termination of subsidies for a certain medicinal product or dietary supplement, the date of termination of subsidies, or the day of cutting back the subsidies to zero per cent may not be set inside a ninety-day period, or a one hundred and eighty-day period for biological medicinal products, following the date of the resolution,

b) for reducing the rate or amount of subsidies for a certain medicinal product or dietary supplement, the initial day of sponsorship at the new rate shall be set for the first day of the quarter following the date of the resolution.

(3)<sup>8</sup>

(4)<sup>9</sup>

(5)<sup>10</sup> The health insurance administration agency, with a view to ensuring publicity relating to its proceedings under Sections 23-25 shall publish or proclaim on its website by way of electronic means:<sup>11</sup>

a) in connection with applications submitted in due compliance with formal requirements, within eight days following the date of receipt:

aa) the subject matter of the case,

ab) the case number,

ac) the date of the opening of proceedings,

ad) the administrative time limit applicable to the case in question,

ae) the time periods which are not included in the administrative time limit,

af) information concerning access to the documents and for making statements,

1 Amended: by subparagraph ea) paragraph (1) Section 25 of Act LXXXIX of 2010. In force: as of 17. 08. 2010.

2 Amended by Paragraph d) of Section 80 of Act CCXLIV of 2013.

3 Enacted: by Section 117 of Act CXXVII of 2013. In force: as of 6. 07. 2013.

4 Established by Subsection (1) of Section 282 of Act L of 2017, effective as of 1 January 2018.

5 Amended by Point 9 of Section 283 of Act L of 2017, Paragraph a) of Section 40 of Act XCI of 2023.

6 Established: by Section 34 of Act CVI of 2008. In force: as of 01. 01. 2009.

7 Established: by paragraph (1) Section 112 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.

8 Repealed by Point 9 of Section 284 of Act L of 2017, effective as of 1 January 2018.

9 Repealed: by subparagraph eb) paragraph (1) Section 25 of Act LXXXIX of 2010. No longer in force: as of 17. 08. 2010.

10 Established: by paragraph (2) Section 112 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.

11 Amended by Point 10 of Section 283 of Act L of 2017.



- ag*) the name of the applicant; and
- b*)<sup>1</sup> the abridged version of the definitive resolution adopted in the case, in addition to having it delivered to the applicant, for information purposes by the fifth day of the month following the date of the resolution, containing:
  - ba*)<sup>2</sup> the date of proclamation,
  - bb*) the name of the competent authority,
  - bc*) the case number and the object of the proceedings,
  - bd*) the authority's decision,
  - be*) the statutes upon which the authority has adopted the resolution,
  - bf*)<sup>3</sup> information on the form of remedy available,
  - bg*) the date and place when and where the decision was adopted,
  - bh*) the name and title of the competent officer, and
  - bi*) the name and title of the issuer, if other than the competent officer.

## Section 26

👉(1)<sup>4</sup> Medicinal products are approved for social security subsidies in different categories. In the various subsidy categories all sponsorship methods specified according to Section 28 may be applied. The amounts of subsidies as per the various sponsorship methods shall be calculated based on the percentage rates indicated in the tables containing the ATC-groups specified in the health insurance agency's public statement in due observation of the current health-care policy objectives. The maximum percentage rates available in the various subsidy categories, and the classification of the ATC-groups in the percentage subsidy categories are contained in the health insurance agency's public statement.

(2)<sup>5</sup> The health insurance administration agency, with a view to enforcing the relevant budgetary limits, may enter into a subsidy volume agreement under Subsection (5) with respect to medicinal products which are already or recently have been approved for subsidies, including their subsidy categories and indications, for funding molecular diagnostic tests required for the use of the medicinal product, and medicinal products subsidized under special consideration.

(3)<sup>6</sup> Subject to the exception specified in Subsection (3c), a preparation may be subsidized solely under a subsidy volume agreement if:

- a*) it contains an active ingredient which has not yet been approved for subsidies,
- b*) the applicant is requesting admission for subsidies based on an indication which has not yet been approved for special subsidies or premium subsidies, where it is contingent upon indication for maximum percentage rates available under specific other legislation,
- c*)<sup>7</sup> the applicant requests the approval of medicinal products containing active substances subject to itemized accounting requirements based on an indication which has not yet been approved.

(3a)<sup>8</sup> The following medicinal products may be subsidized under efficacy-based subsidy volume agreements:

- a*) medicinal products newly approved for subsidies, and for which efficacy-based parameters can be established and which satisfy the parameters decreed by the minister in charge of the healthcare system for the patient number and daily cost based on therapeutic efficacy;
- b*) orphan medicinal products;
- c*) medicinal products subsidized under special consideration;

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1 Amended by Point 11 of Section 283 of Act L of 2017.

2 Amended by Point 12 of Section 283 of Act L of 2017.

3 Amended by Point 7 of Section 284 of Act L of 2017.

4 Amended by Paragraph b) of Section 40 of Act XCI of 2023.

5 Established by Subsection (1) of Section 119 of Act CI of 2021, effective as of 29 June 2021.

6 Established by Subsection (2) of Section 52 of Act CCXXIV of 2015, effective as of 1 January 2016.

7 Enacted by Subsection (2) of Section 119 of Act CI of 2021, effective as of 29 June 2021.

8 Established by Subsection (3) of Section 52 of Act CCXXIV of 2015, effective as of 1 January 2016.

d) medicinal products subject to itemized accounting; and

e) medicinal products used for treating the conditions specified by the minister in charge of the healthcare system by way of a decree, up to the patient number and daily cost based on therapeutic efficacy defined therein.

(3b)<sup>1</sup> With respect to efficacy-based subsidy volume agreements, the health insurance administration agency shall review annually the medicinal products subsidized under the social security system relying on the criteria decreed by the minister in charge of the healthcare system.

(3c)<sup>2</sup> If the preparation contains an active ingredient which has not yet been approved for subsidies, however, at the time of admission the conditions for setting up a group for fixed subsidies are satisfied, the health insurance agency may enter into a subsidy volume agreement.

(3d)<sup>3</sup> Preparations containing a new active substance or a new indication of a preparation already approved for subsidies shall be approved only within the framework of efficacy-based subsidy volume agreements containing the limits referred to in Paragraph b) of Subsection (5), where, relying on the approval process, the average subsidy foreseen for the next three years, projected for a twelve-month period, is likely to exceed 0.3 per cent of the sum appropriated as shown under the Medicinal Product Subsidies account of the Health Fund on the first day of January of the year in question.

(4)<sup>4</sup> Except for the case defined in Subsection (2) of Section 31/C, a subsidy volume agreement may be concluded for a maximum term of four calendar years.

(5)<sup>5</sup> The payment obligation stipulated in the subsidy volume agreements may be determined:

a) in proportion to the price subsidies provided for any batch sold with price subsidies;

b) on the basis of the difference between the full amount of price subsidies provided during the life of the agreement for one or more product and the limit value fixed in the agreement;

c) based on the estimated costs arising upon the lack of expected efficacy and the lack of therapeutic efficacy relative to the efficacy result fixed in the agreement;

d)<sup>6</sup> in the event of lack of compliance with the criteria fixed in the agreement relating to the activities intended to enhance patient cooperation in connection with specific treatments;

e)<sup>7</sup> by way of derogation from the administration, applied dosage fixed in the agreement and considered relevant for reasons of cost-effectiveness, according to the summary of product characteristics of the medicinal product in question.

(6)<sup>8</sup> In respect of any one preparation the provisions contained in Subsection (5) may be applied concurrently.

(7)<sup>9</sup> In connection with subsidy volume agreements, the health insurance administration agency may prescribe prepayment obligations.

(8)<sup>10</sup> The mandatory layout for subsidy volume agreements, the conditions for contracting and for the application of certain types of agreements, and the rules concerning the disclosure obligation of the health insurance administration agency shall be laid down in specific other legislation.

1 Enacted: by paragraph (2) Section 113 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.

2 Enacted by Subsection (4) of Section 52 of Act CCXXIV of 2015, effective as of 1 January 2016.

3 Enacted by Subsection (3) of Section 119 of Act CI of 2021, effective as of 29 June 2021.

4 Established by Section 68 of Act CCXLIV of 2013, effective as of 1 January 2014.

5 Enacted: by paragraph (2) Section 89 of Act CLIV of 2009. In force: as of 1. 01. 2010.

6 Amended: by subparagraph a) Section 137 of Act CLXXVI of 2011. In force: as of 1. 01. 2012. The change does not effect the English version.

7 Enacted by Section 100 of Act CXI of 2014, effective as of 1 January 2015.

8 Enacted: by paragraph (2) Section 89 of Act CLIV of 2009. Amended by Paragraph a) of Section 74 of Act LXXVII of 2015.

9 Established by Subsection (4) of Section 119 of Act CI of 2021, effective as of 29 June 2021.

10 Enacted: by paragraph (2) Section 89 of Act CLIV of 2009. In force: as of 1. 01. 2010.

Section 27

➡(1)<sup>1</sup> The admission of new products of the same group of efficacy into a subsidy category upon the request of the holder of the marketing authorization of a medicinal product that contains a new active ingredient shall be decreed by the health insurance agency, with the approval of the minister in charge of the healthcare system, in a public statement after receiving the opinion of local and international experts of medicine and pharmacology with effect from the first day of each calendar quarter.

➡(2)<sup>2</sup>

(2a)<sup>3</sup> If the health insurance administration agency receives a request for subsidies for a medicinal product that contains a new active substance:

a) the approval of which is pending amendment of the decree of the minister in charge of health insurance - made in agreement with the minister in charge of public finances - on the financing of specialized healthcare services under the social security system; or

b) the approval of which is pending amendment of the financing mechanism decreed by the minister in charge of health insurance;

the health insurance administration agency shall suspend the proceedings for the approval of the medicinal product in question until the date of the amendments entering into force, in any case up to ninety days following the date of submission of the request, or from the time of remedying deficiencies, and shall notify the party affected accordingly.

➡(3)<sup>4</sup> If the legal regulation referred to in Subsection (2a) is not amended, the health insurance administration agency shall adopt a decision after the 90-day time limit on the basis of the legal provisions in force at that time.

(4) The special subsidies or premium subsidies which are contingent upon indication are subject to indication and entitlement for prescription. The subsidy approved for a specific medicinal product may differ according to the types of diseases it is intended to treat and the function of the health service provider that prescribed the medicinal product in question, and depending on the recommendation of a specialist required for the approval of the medicinal product. The name of the group of diseases and the areas of indication for special subsidies or premium subsidies and entitlements for prescription of these subsidized products shall be decreed by the minister in charge of the healthcare system in agreement with the minister in charge of public finances.

➡(5)<sup>5</sup> Where the health insurance administration agency receives a request for subsidies for a medicinal product in connection with which a new group of diseases and areas of indication for special subsidies or premium subsidies has to be defined in a ministerial decree, such new group of diseases and the areas of indication for special subsidies or premium subsidies and entitlements for prescription of these subsidized products shall be decreed - based on the recommendation of the health insurance administration agency - by the minister in charge of the healthcare system in agreement with the minister in charge of public finances. Pending such decision, the health insurance administration agency shall suspend the proceedings for the approval of the medicinal product in question until the decree of the minister in charge of health insurance - made in agreement with the minister in charge of public finances - enters into force, in any case up to ninety days following the date of submission of the request, or from the time of remedying deficiencies.

1 Established by Subsection (1) of Section 37 of Act XCI of 2023, effective as of 1 January 2024.

2 Repealed by Paragraph a) of Section 41 of Act XCI of 2023, effective as of 1 January 2024.

3 Enacted: by paragraph (2) Section 114 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.

4 Amended by Paragraph h) of Section 82 of Act LXXIX of 2012, Paragraph c) of Section 40 of Act XCI of 2023.

5 Established by Subsection (2) of Section 37 of Act XCI of 2023, effective as of 1 January 2024.

➡(5a)<sup>1</sup> For the purposes of Subsection (5), a new indication shall mean only an ICD code other than the ICD code or codes stipulated as acceptable in the indication point specified in the decree of the minister in charge of the health insurance system.

(6) The social security subsidies provided for medicinal products with special funding may be claimed based on a special agreement between the medical institutions - a list of which is published by the health insurance administration agency each year - where the medicinal products in question are dispensed, and the health insurance administration agency. The terms and conditions and the mandatory layout of these agreements are contained in specific other legislation.

(7) The list of medicinal products with special funding shall be decreed by the minister in charge of the healthcare system -in agreement with the minister in charge of public finances - indicating the active ingredients of the medicinal products and the group of diseases.

➡(8)<sup>2</sup> In connection with any request for subsidies for a medicinal product that contains an active ingredient that is not listed in the legal provision referred to in Subsection (7), the proceedings under Subsection (5) shall be applied as appropriate.

### Section 28

(1) The health insurance administration agency shall use the following sponsorship methods in connection with the medicinal products approved for social security subsidies:

- a) percentage-based subsidy;
- b) fixed amount subsidy:
  - ba) fixed amount based on the active ingredient,
  - bb) fixed support based on therapeutic efficacy;
- c) subsidy volume agreement;
- d) special subsidies for medicinal products purchased by public procurement;
- e)<sup>3</sup> subsidies granted up to a limited amount, reduced by a specific amount or percentage;
- f)<sup>4</sup> variable percentage subsidies or subsidies granted up to a limited amount, depending on patient cooperation;
- g)<sup>5</sup> subsidies granted on the basis of the maximum amount charged to patients as specified by the minister in charge of health insurance in a decree.

(2) The detailed regulations concerning sponsorship methods are laid down in specific other legislation.

### Section 29

(1)<sup>6</sup>

(2)<sup>7</sup>

(3) The health insurance administration agency shall adopt its decisions concerning the approval of medicinal products within the time limit specified in Subsection (3) of Section 23 if the request pertains:

- a) to a new pharmaceutical form and a new method of administration;
- ➡b)<sup>8</sup> to a novel indication, or a change in indication notwithstanding a new ICD code;

1 Enacted by Subsection (3) of Section 37 of Act XCI of 2023, effective as of 1 January 2024.

2 Amended by Paragraph d) of Section 40 of Act XCI of 2023.

3 Established: by paragraph (1) Section 115 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.

4 Enacted: by paragraph (2) Section 115 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.

5 Enacted: by paragraph (2) Section 115 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.

6 Repealed: by Section 361 of Act LVI of 2009. No longer in force: as of 1. 10. 2009.

7 Repealed: by subparagraph b) Section 137 of Act CLXXVI of 2011. No longer in force: as of 1. 01. 2012.

8 Established by Section 38 of Act XCI of 2023, effective as of 1 January 2024.

- c) to a novel active ingredient;
  - d) to a novel combination, if any active ingredient it contains is not approved for subsidies;
  - e)<sup>1</sup> to increasing its price serving as the basis for public financing, with the exception set out in Paragraph c) of Subsection (4) of Section 23;
  - f) to any change in the subsidy category;
  - g) to cases of a combination specified in specific other legislation;
  - h)<sup>2</sup> with the exception set out in Subsection (4) of Section 23, to a novel medicinal product that contains an approved active ingredient;
  - i) to a medicine offering significant therapeutic advantages, approval at a higher price and to the granting of subsidies;
  - j) to a medicinal product that contains an active ingredient which is or has been subsidized if:
    - ja) offered in a new packaging,
    - jb) it features higher potency,
    - jc) offered in a novel pharmaceutical form with the same method of administration,
    - jd) offered in a novel combination.
- (4) In the proceedings conducted under Subsection (4) of Section 23 and Subsection (3) hereof, the marketing authorization holder - or the distributor submitting a request for subsidies in connection with a dietary supplement - shall notify:<sup>3</sup>
- a) in connection with its medicinal product that contains an active ingredient which is or has been subsidized, or dietary supplement:
    - aa) any changes in terms of dispensing,
    - ab) any changes in its name,
    - ac) any changes in its registration number,
    - ad) if removed from the register,
    - ae) any price reduction;
  - b) any revision intended in the subsidy category of its subsidized medicinal product that results in the transfer of the preparation in question to preparations which are not included in the social security subsidy system;
  - c) if its product that has been authorized for marketing in Hungary with social security subsidies has been authorized for marketing by the European Commission in a central registration procedure;
  - d) any change in the person of the holder of authorization listed in the register of medicinal products.
- (5) Discharging the obligation of notification under Subsection (4) shall be exempt from any administrative service fee.
- (6) The health insurance administration agency shall publish the notices under Subsection (4) on the first day of the month following notification.
- (7)<sup>4</sup> If the health insurance administration agency refuses the request for admission of a medicinal product for subsidies within the social security system citing the lack of funding as the sole reason, the holder of the medicinal product's marketing authorization may re-submit the application for approval for subsidies without making any changes, inside a period of two years following the definitive date of the decision to refuse admission, without having to pay the administrative service fee again.

### *Section 30*

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1 Amended: by paragraph (6) Section 73 of Act CVI of 2008. In force: as of 01. 01. 2009. Amended: by point 7 Section 137 of Act CXXVII of 2013. In force: as of 6. 07. 2013.

2 Amended: by point 8 Section 137 of Act CXXVII of 2013. In force: as of 6. 07. 2013.

3 Amended: by Section 360 of Act LVI of 2009. In force: as of 1. 10. 2009. Amended: by subparagraph a) Section 136 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.

4 Enacted by Section 71 of Act LXXIX of 2012. Amended by Point 13 of Section 283 of Act L of 2017.

(1)<sup>1</sup> Based on the applications submitted under Paragraphs *a)-f)* and *i)* of Subsection (3) of Section 29, a preparation may be approved for social security subsidies only if the producer price that the holder of the marketing authorization of a medicinal product has indicated in the request is not higher than the mathematical average of the price of a medicinal product indicated in other legislation that contains the same or similar active ingredient that has the three lowest prices among the products actually in circulation with social security subsidies in any Member State of European Union or in any State that is a party to the Agreement on the European Economic Area.

(1a)<sup>2</sup> The preparations referred to in Subsection (1) may be supplied with social security subsidies even if the three lowest producer prices required under Subsection (1) are not available for establishing the mathematical average defined in Subsection (1). In that case the mathematical average shall be established based on the lowest producer prices available and existing in the States referred to in Subsection (1).

(1b)<sup>3</sup> Subsection (1) shall not apply if no medicinal product that contains the same or a similar active ingredient is actually in circulation in the States referred to in Subsection (1).

(2)<sup>4</sup> The health insurance administration agency shall carry out an audit at least once a year - based on the mechanism and criteria set out in specific other legislation - for the purpose of comparison of the prices of medicinal products approved for social security subsidies within seven digit ATC-groups, recognized to consume substantial subsidies in accordance with specific other legislation, with the prices of medicinal products actually in circulation in any Member State of European Union or in any State that is a party to the Agreement on the European Economic Area in accordance with specific other legislation, that contain the same or a similar active ingredient. Relying on the findings of such *ex officio* proceedings, the health insurance administration agency shall adopt a decision concerning the medicinal product in question, in terms of granting subsidies, for modifying the rate of subsidy or for the withdrawal of subsidies.

(3)<sup>5</sup> The health insurance administration shall - for the purposes of the audit referred to in Subsection (2) - apply the producer prices of medicinal products of the same active ingredients, pharmaceutical form and strength as the medicinal products available in Hungary, which are manufactured by the same manufacturer as the medicinal products available in Hungary.

### Section 31

(1) The health insurance administration agency shall withdraw the social security subsidy from any medicinal product:

*a)*<sup>6</sup> that does not have a valid marketing authorization, except for the case under Section 22/A;

*b)* in the event of justified doubts in terms of cost-efficiency;

*c)* that imposes an unreasonable burden upon the budget of the H. Fund relative to the advantage it offers in terms of therapeutic efficacy;

*d)*<sup>7</sup>

*e)* whose cost-effectiveness cannot be verified;

*f)*<sup>8</sup> that is not available on the market for over six months, or one month in the case of reference preparations;

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1 Established by Section 63 of Act XIX of 2023, effective as of 1 June 2023.

2 Enacted by Section 63 of Act XIX of 2023, effective as of 1 June 2023.

3 Enacted by Section 63 of Act XIX of 2023, effective as of 1 June 2023.

4 Enacted: by Section 90 of Act CLIV of 2009. In force: as of 1. 01. 2010.

5 Enacted: by paragraph (2) Section 63 of Act LXXXI of 2011. In force: as of 1. 07. 2011.

6 Established by Section 37 of Act CLXXII of 2016, effective as of 1 January 2017.

7 Repealed: by subparagraph a) paragraph (1) Section 83 of Act LXXXI of 2011. No longer in force: as of 1. 07. 2011.

8 Amended: by subparagraph b) Section 136 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.

- g) whose marketing authorization had been withdrawn;
- h)<sup>1</sup> in the case of medicinal products approved for fixed amount subsidies based on the active ingredient, the cost of the medicinal product if used for a daily therapy, or its unit price if according to its active ingredient it exceeds at least by 100 per cent the daily cost of the reference preparations;
- i)<sup>2</sup> in the case of medicinal products approved for fixed support based on therapeutic efficacy, if the cost of the medicinal product when used for a daily therapy exceeds at least by 100 per cent the mathematical average of the daily costs of the medicinal products comprised in the group;
- j)<sup>3</sup> if - based on the findings of the international price comparison conducted - the producer price of the medicinal product in question is at least 20 per cent higher than the mathematical average of the prices of three medicinal products that have the lowest price applied in any Member State of European Union or in any State that is a party to the Agreement on the European Economic Area;
- k)<sup>4</sup> if the daily cost based on therapeutic efficacy of a biological medicinal product exceeds the daily cost of the preferred biological medicinal product that has the lowest daily cost based on therapeutic efficacy by at least 10 per cent, except if the holder of the biological medicinal product's marketing authorization covers the difference between the retail price and the maximum amount charged to the patient, or the difference from the amount that is 10 per cent higher than the retail price of the preferred biological medicinal product that has the lowest daily cost based on therapeutic efficacy;
- l)<sup>5</sup> if the daily cost based on therapeutic efficacy of a biological medicinal product exceeds the daily cost of the preferred biological medicinal product that has the lowest daily cost based on therapeutic efficacy by at least 50 per cent;
- m)<sup>6</sup> whose preferential status had been withdrawn.
- (1a)<sup>7</sup> If the holder of the marketing authorization or his authorized agent was found guilty of any infringement of the provisions of this Act and the decree pertaining to the advertisement and promotion of medicinal products and medical aids by definitive decision of the authority vested with powers and jurisdiction under advertising control proceedings on two occasions within one year in connection with subsidized medicinal products, and if fined for a total of at least five million forints for the same infringements, the health insurance administration agency shall withdraw the social security subsidy from the medicinal product affected, if there is another medicinal product available in the same indication priced not more than 50 per cent above the medicinal product that was excluded from the social security system.
- (2) The health insurance administration agency shall withdraw the subsidy from any medicinal product that is cancelled from the register of medicinal products effective as of the first day of the fourth month following the date of cancellation.
- (3)<sup>8</sup> The health insurance administration agency shall have authority to exclude any medicinal product from the social security subsidy system if the marketing authorization holder fails to satisfy the obligation of marketing and for keeping a specific quantity of such products on stock under Subsection (8) of Section 21.

1 Established by paragraph (1) Section 72 of Act LXXIX of 2012. Amended by Paragraph e) of Section 80 of Act CCXLIV of 2013.

2 Established by Section 35 of Act CVI of 2008. Amended by Paragraph f) of Section 80 of Act CCXLIV of 2013.

3 Established: by paragraph (1) Section 64 of Act LXXXI of 2011. In force: as of 1. 07. 2011.

4 Enacted: by paragraph (1) Section 116 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.

5 Enacted by paragraph (1) Section 116 of Act CLXXVI of 2011. Amended by Paragraph g) of Section 80 of Act CCXLIV of 2013.

6 Enacted by Section 69 of Act CCXLIV of 2013, effective as of 1 January 2014.

7 Enacted by paragraph (2) Section 64 of Act LXXXI of 2011. Amended by Point 1 of Section 283 of Act L of 2017.

8 Enacted: by paragraph (2) Section 91 of Act CLIV of 2009. In force: as of 1. 01. 2010.



(4)<sup>1</sup> Where a medicinal product has been excluded from the social security system under Subsection (1), (1a) or (3), such medicinal product shall not be approved for social security subsidies within nine months from the date when the decision on exclusion became definitive.

(5)<sup>2</sup> If a medicinal product that has been excluded from the social security subsidy system under Paragraph *b*) of Subsection (4) of Section 29 is readmitted within six months, it will be subsidized at a reduced rate established in accordance with the decree of the minister in charge of health insurance, as prescribed for medicinal products falling outside the preferred reference price range.

#### *Section 31/A*<sup>3</sup>

The health insurance administration agency may provide aid for the deposit fee charged to the patient for the use of an oxygen supply system, including cylinder and auxiliary equipment, in the patient's home, as decreed by the minister in charge of the health insurance system.

#### *Section 31/B*<sup>4</sup>

(1) The holder of the marketing authorization of a medicinal product may request in the application for admission of a medicinal product into the social security subsidy system the health insurance administration agency to grant preferential status for the medicinal product in question.

(2) An application for preferential status may be submitted by the holder of marketing authorization for a medicinal product:

*a*) that have been authorized for marketing in Hungary, including if the marketing authorization was ordered ex officio under Section 6 of the MPH, and

*b*) that is considered essential based on its therapeutic function, where treatment of a patient with another authorized medicinal product is not possible or unsuccessful according to the summary of product characteristics, or access to a medicinal product with marketing authorization for a specific indication is inhibited to an extent where it would likely to delay the treatment prescribed for the patient, hence causing disproportionately great risk of irreversible health impairment.

#### *Section 31/C*<sup>5</sup>

(1)<sup>6</sup> The decision for granting preferential status under Section 31/B lies with the health insurance administration agency subject to approval by the minister in charge of the healthcare system.

(2)<sup>7</sup> The health insurance administration agency may admit a medicinal product into the social security subsidy system with preferential status if the medicinal product in question meets the requirements set out in Subsection (2) of Section 31/B, and if the holder of the marketing authorization of the medicinal product provides a statement enclosed with the application undertaking to enter into a subsidy volume agreement - with an annual limit value of one hundred million forints at producer prices - for a period of five years with the health insurance administration agency under Paragraph *b*) of Subsection (5) of Section 26, covering medicinal product(s) used for a specific indication.

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1 Established by paragraph (2) Section 72 of Act LXXIX of 2012. Amended by Point 13 of Section 283 of Act L of 2017.

2 Enacted: by paragraph (2) Section 116 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.

3 Established: by Section 62 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.

4 Enacted by Section 70 of Act CCXLIV of 2013, effective as of 1 January 2014.

5 Enacted by Section 70 of Act CCXLIV of 2013, effective as of 1 January 2014.

6 Established by Section 121 of Act CI of 2021, effective as of 29 June 2021.

7 Established by Section 121 of Act CI of 2021, effective as of 29 June 2021.



(2a)<sup>1</sup> By way of derogation from Subsection (2), the health insurance administration agency may admit a medicinal product into the subsidy category with no value limit under preferential status, if the medicinal product meets the requirements set out in Subsection (2) of Section 31/B, and if the medicinal product's annual turnover is not expected to exceed 30 million forints at producer prices.

(2b)<sup>2</sup> The health insurance administration agency shall review the turnover data relating to the subsidized medicinal products provided for in Subsection (2a) each year, and if the medicinal product's turnover exceeds the limit specified in Subsection (2a), the health insurance administration agency may decide to abolish the preferential status before the expiry of the five-year period provided for in Subsection (3).

(3) Preferential status may be granted for a period of five years, and it may be renewed at the marketing authorization holder's request submitted within six months prior to the expiry of the five-year period. If no application is submitted within the said deadline, the health insurance administration agency shall ex officio adopt a decision following the review provided for in Subsection (5) for the withdrawal of preferential status and to exclude the medicinal product from the social security subsidy system.

(4) If a medicinal product has been granted preferential status, no other medicinal product having the same active substance, the same method of administration, or used in the same areas of indication may be granted preferential status.

(5) Before the renewal of preferential status as under Subsection (3), the health insurance administration agency shall review to determine as to whether an application had been submitted since the effective date of the preferential status by the holder of marketing authorization of another medicinal product used in the same areas of indication as the medicinal product with preferential status, for the admission of such medicinal product into the social security subsidy system.

(6) If during the review referred to in Subsection (5) the health insurance administration agency finds that an application had been submitted by the holder of marketing authorization of another medicinal product used in the same areas of indication as the medicinal product with preferential status for the admission of such medicinal product into the social security subsidy system, and it meets the requirements set out in this Act and in the relevant ministerial decree for admission into the social security subsidy system, and

a) did not request preferential status, the health insurance administration agency shall decide on the admission of such medicinal product and, at the same time, on the termination of the previous preferential status and on the exclusion of such medicinal product from the social security subsidy system, or

b) requested preferential status, the health insurance administration agency shall decide along cost-effective criteria as to which medicinal product to choose for preferential status.

(7) The health insurance administration agency shall inform the government body for pharmaceuticals of the actions taken under Subsection (3) hereof and under Subsection (1b) of Section 21.

### Section 32<sup>3</sup>

(1)<sup>4</sup> Proceedings concerning subsidies available for medical aids under the social security system are opened upon request or notification, or *ex officio*.

(2)<sup>5</sup> The application or notification can relate:

a) to medical aids for which no social security subsidies are available,

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1 Enacted by Section 101 of Act CXI of 2014, effective as of 1 January 2015.

2 Enacted by Section 101 of Act CXI of 2014, effective as of 1 January 2015.

3 Established: by Section 93 of Act CLIV of 2009. In force: as of 1. 03. 2010.

4 Established: by paragraph (1) Section 63 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.

5 Established: by paragraph (2) Section 63 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.

*aa)* requesting subsidies,  
*ab)* requesting the award of daily rental fees for products which are made available only by way of rental;  
*b)* to medical aids which have already been approved for subsidies,  
*ba)* requesting the award of higher daily rental fees for products which are made available only by way of rental,  
*bb)* requesting the reduction of daily rental fees for products which are made available only by way of rental,  
*bc)* requesting transfer to another function group (sub-group),  
*bd)* requesting to have the name of the medical aid changed,  
*be)* requesting to have its price serving as the basis for public financing reduced,  
*bf)* requesting to have its price serving as the basis for public financing increased,  
*bg)* requesting its removal from the subsidy system,  
*bh)* requesting to have its size changed or the award of subsidies for the new version.

(3)<sup>1</sup> The application referred to in Subsection (2) above - except for the collective applications under Subsection (11) - may be submitted to the health insurance administration agency only by a qualified distributor shown in the list of suppliers referred to in Section 32/B of the health insurance administration. The notification referred to in Subparagraphs *bb)*, *be)* and *bg)* of Paragraph *b)* may be submitted by the distributor of medical aids only.

(4) The health insurance administration agency:

*a)*<sup>2</sup> shall adopt a decision concerning the requests referred to in Paragraphs *aa)*, *ab)*, *ba)*, *bc)* and *bf)* of Subsection (2), subject to the requirements set out in specific other legislation, within ninety days of receiving the complete application under the normal procedure;

*b)*<sup>3</sup> shall - by way of derogation from Paragraph *a)* - adopt a decision concerning the requests referred to in Paragraphs *aa)*, *ab)* and *bc)* of Subsection (2), subject to the requirements set out in specific other legislation, within sixty days of receiving the complete application under the accelerated procedure where the distributor of medical aids

*ba)* indicates in the application a price serving as the basis for the lowest public financing in respect of his product that is below the price of a product that has already been admitted into a function group (sub-group) by 10 per cent or more, or

*bb)* produces the findings of a clinical trial conducted in Hungary involving at least one hundred patients.

(5)<sup>4</sup> The health insurance administration agency shall adopt a resolution concerning the requests referred to in Paragraphs *bd)* and *bh)* of Subsection (2), subject to the requirements set out in specific other legislation, by the simplified procedure within thirty days from the day following the date of receipt of the complete application.

(6) The distributor of subsidized medical aids shall be subject to the obligation of notification in the cases of Subparagraphs *bb)*, *be)* and *bg)*. The health insurance administration agency shall publish these notifications under the conditions set out in specific other legislation within fifteen days of the time of submission.

(7) The resolutions adopted under Subsections (4)-(5) - except for resolutions of refusal - shall indicate in due consideration of the provisions laid down in specific other legislation relating to the award of subsidies:

*a)* the name and description of the medical aid, its function group (sub-group) and ISO code;

*b)* the presentation of the medical aid;

1 Established: by paragraph (3) Section 63 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.

2 Amended by Point 14 of Section 283 of Act L of 2017.

3 Amended by Point 15 of Section 283 of Act L of 2017.

4 Amended by subparagraph e) Section 88 of Act CLXXIII of 2010, Point 16 of Section 283 of Act L of 2017.

- c) in connection with any equipment
  - ca) that can be made available by ways other than rental, the price serving as the basis for public financing,
  - cb) which are made available only by way of rental, the daily rental fee serving as the basis for public financing;
  - d) the rate of the subsidy and the means by which it is provided;
  - e) the net amount of the subsidy;
  - f) the approved period of use and the maximum quantity that can be prescribed for the approved period;
  - g) the actual conditions for prescription (indication, qualification requirements and other medical specifications);
  - h) the initial day of support, whether for new products or for products already included in the list of subsidized products, and approved for continued support under modified conditions;
  - i) as to whether the medical aid in question can be supplied under the fully subsidized public healthcare system;
  - j) in connection with medical aids where title of ownership may be transferred to the patient upon expiry of the rental period, the rental fee index number assigned to the equipment's function group (sub-group) in accordance with specific other legislation;
  - k) in connection with durable medical aids, the flat-rate repair charges applicable to the given function group (sub-group);
  - l) the price the patient is required to pay for the medical aid.
- (8) The distributor shall be charged an administrative service fee in accordance with the provisions of specific other legislation for the proceedings referred to in Subsections (4)-(5).
- (9)<sup>1</sup>
- (10)<sup>2</sup> The health insurance administration agency, with a view to ensuring publicity shall publish or proclaim on its website:<sup>3</sup>
- a) in connection with applications submitted in due compliance with formal requirements, within twenty-one days following the date of receipt of the application, or from the time of remedying deficiencies,
    - aa) the subject matter of the case,
    - ab) the case number,
    - ac) the date of the opening of proceedings,
    - ad) the administrative time limit applicable to the case in question,
    - ae) the time periods which are not included in the administrative time limit,
    - af) information concerning access to the documents and for making statements,
    - ag) the name of the applicant; and
  - b)<sup>4</sup> the abridged version of the definitive resolution adopted in the case, within fifteen days of the time of conclusion of the case, containing:
    - ba)<sup>5</sup> the date of proclamation,
    - bb) the name of the competent authority,
    - bc) the case number and the object of the proceedings,
    - bd) the authority's decision,
    - be) the statutes upon which the authority has adopted the resolution,
    - bf)<sup>6</sup> information on the form of remedy available,
    - bg) the date and place when and where the decision was adopted,
    - bh) the name and title of the competent officer, and
    - bi) the name and title of the issuer, if other than the competent officer.

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1 Repealed by Point 11 of Section 284 of Act L of 2017, effective as of 1 January 2018.  
2 Established: by Section 117 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.  
3 Amended by Point 10 of Section 283 of Act L of 2017.  
4 Amended by Point 18 of Section 283 of Act L of 2017.  
5 Amended by Point 12 of Section 283 of Act L of 2017.  
6 Amended by Point 7 of Section 284 of Act L of 2017.

(11)<sup>1</sup> In connection with custom-made medical aids, all distributors of such medical aids engaged under contract with the health insurance administration agency for entitlement to social security subsidies, or the authorized representatives of such distributors shall be required to submit applications collectively relating to the type of the device. At least half of the distributors engaged under contract for entitlement to social security subsidies, or the authorized representatives of such distributors shall participate in the collective application or notification. The decision rendered upon a collective application shall apply to all distributors engaged under contract for entitlement to social security subsidies relating to medical aids to which the application or notification pertains.

(12) The application referred to in Subsection (11) above may be submitted to the health insurance administration agency solely with respect to Subparagraphs *aa*), *be*), *bf*) and *bg*) of Subsection (2).

(13)<sup>2</sup>

### Section 32/A<sup>3</sup>

(1) The health insurance administration agency shall routinely carry out full or partial review of subsidized medical aids along the criteria set out in Subsection (2).

(2) As part of the review procedure referred to in Subsection (1) above, the health insurance administration agency shall initiate proceedings *ex officio*:

*a*) if the subsidized medical aid imposes an unreasonable burden upon the budget of the Health Fund relative to the advantage it offers in terms of therapeutic efficacy;

*b*) where justified by changes in the relevant legislation;

*c*) where *ex officio* proceedings are prescribed by the relevant legislation;

*d*) where there is any doubt as to the quality and/or conformity of a medical aid.

(3) In the process of carrying out the review procedure under Subsection (1), the health insurance administration agency shall have powers - conferred under specific other legislation - for excluding a subsidized medical aid from the subsidy system, for changing the rate of subsidy, for clarifying the name of a medical aid shown in the subsidy list, for changing the approved period of use or the quantity that can be prescribed for the approved period and the actual conditions for prescription, and for transferring it to another function group (sub-group).

(3a)<sup>4</sup> The health insurance administration agency shall render its decision in proceedings under this Section within ninety days.

(4a)<sup>5</sup> If the health insurance administration agency has decided to open *ex officio* proceedings pursuant to Subsection (4) hereof on account of a new function group having been opened by ways other than the procedure under Subsection (2) of Section 34 and, in addition to the changes made under Subsection (3) hereof, and the price approved as the basis for public financing of a product transferred to a new group has to be changed as well, it shall be decided by the health insurance administration agency in accordance with the decree of the minister in charge of the healthcare system.

(5) The health insurance administration agency shall *ex officio* conduct the fixation procedure prescribed in specific other legislation semi-annually with a view to re-establishing the subsidy groups of medical aids.

1 Established: by paragraph (4) Section 63 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.

2 Repealed: by subparagraph *ee*) paragraph (1) Section 25 of Act LXXXIX of 2010. No longer in force: as of 17. 08. 2010.

3 Enacted: by Section 94 of Act CLIV of 2009. In force: as of 1. 03. 2010.

4 Enacted by Section 127 of Act CLXXXVI of 2015, effective as of 1 January 2016.

5 Established: by paragraph (1) Section 118 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.

(6)<sup>1</sup> In the proceedings under Subsection (5) - in the cases defined by specific other legislation - the price quoted to serve as the basis for public financing cannot be withdrawn. The detailed regulations for making proposals, for publicity, for determining the amount of subsidies whether at a percentage rate or in a fixed amount and for setting up groups shall be laid down in specific other legislation.

(7)<sup>2</sup> In all re-examination procedures opened *ex officio* which are concluded without the exclusion of the medical aid examined, the health insurance administration agency shall adopt a resolution according to Subsection (8) in connection with the medical aid examined, and shall proclaim it on its website. The health insurance administration agency shall notify the clients concerned regarding the resolution and access to the proclaimed notice by means of electronic mail.

(8)<sup>3</sup> The resolution referred to in Subsection (7) shall contain:

a) the name of the competent authority, the case number and the name of the officer in charge;

b) description of the subject matter of the case;

c) in the operative part:

ca)<sup>4</sup> the authority's decision, and information on the form of remedy available,

cb)<sup>5</sup> the decision ordering payment of the duties and fees charged for the proceedings to the client;

d) in the statement of reasons:

da) the calculations used during the proceedings,

db) the statutes upon which the authority has adopted the resolution,

dc) reference to the relevant legislation conferring the authority's powers and competencies;

e) the venue and the time where and when the decision was adopted, the name and title of the competent officer, and the name and title of the issuer, if other than the competent officer;

f) the signature of the issuer of the decision and the stamp of the authority;

g)<sup>6</sup> in the annex to the resolution the full spectrum of the medical aids affected by the proceedings.

### Section 32/B<sup>7</sup>

(1) The health insurance administration agency, shall rate distributors of medical aids, and shall admit the ones who satisfy the conditions set out in specific other legislation into the list of suppliers described in specific other legislation.

(1a)<sup>8</sup> The list of suppliers referred to in Subsection (1) shall be construed as an official public register as regards the following information:

a) the distributor's qualified distributor status;

b) an indication if the qualified distributor's status is to be cancelled according to the decree of the minister in charge of the healthcare system;

c) the type of distribution activity pursued by the qualified distributor.

(2) The rating of suppliers shall be subject to the payment of an administrative service fee prescribed in specific other legislation.

### Section 33<sup>9</sup>

1 Enacted: by paragraph (2) Section 118 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.

2 Enacted by paragraph (2) Section 118 of Act CLXXVI of 2011. Amended by Point 7 of Section 283 of Act L of 2017.

3 Enacted: by paragraph (2) Section 118 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.

4 Amended by Point 7 of Section 284 of Act L of 2017.

5 Amended by Point 8 of Section 284 of Act L of 2017.

6 Established: by Section 119 of Act CXXVII of 2013. In force: as of 6. 07. 2013.

7 Enacted: by Section 95 of Act CLIV of 2009. In force: as of 1. 03. 2010.

8 Enacted: by Section 120 of Act CXXVII of 2013. In force: as of 6. 07. 2013.

9 Established: by Section 96 of Act CLIV of 2009. In force: as of 1. 03. 2010.

(1) The resolutions containing the decisions referred to in Subsections (4)-(5) of Section 32 and Subsection (1) of Section 32/A shall contain explanations which are based on objective and verifiable criteria.

(2) Subject to the exceptions set out in Subsections (3)-(4), the resolutions shall set the initial day of assistance, whether under the previous or modified conditions:

a)<sup>1</sup> inside a 180-day period following the operative date of the resolution,

→ b)<sup>2</sup>

(3) In the case where the health insurance administration agency has adopted a decision following the proceedings referred to in Subsection (1) of Section 32/A for the exclusion of a certain medical aid from the subsidy system, for changing the rate or amount of subsidies, or for transferring it to another function group (sub-group), the date of termination of subsidies, the initial day of change in the rate of subsidies, or the initial day of transfer to another function group (sub-group) may not be set before the first day of the quarter directly following the date of the resolution, or after the first day of the second quarter following the date of the resolution.

(4) In the case where the health insurance administration agency has adopted a decision following the proceedings referred to in Subsection (1) of Section 32/A, that was opened pursuant to Paragraph b) of Subsection (2) of Section 32/A, for the exclusion of a certain medical aid from the subsidy system, for changing the rate or amount of subsidies, for transferring it to another function group (sub-group), for clarifying the name of a medical aid, for changing the approved period of use or the quantity that can be prescribed for the approved period and the actual conditions for prescription, the date of termination of subsidies, the initial day of change in the rate of subsidies, the initial day of assistance in another function group (sub-group), under the modified period of use or with a modified quantity that can be prescribed for the approved period, or under a different name shall be the effective date of the legislation upon which the underlying procedure was initiated.

(5)<sup>3</sup>

(6)<sup>4</sup> The health insurance administration agency shall maintain a register on subsidized medical aids relying on definitive resolutions, and such register shall be construed as an official public register as regards the data defined in Subsection (7). The health insurance administration agency shall publish on its official website the particulars decreed by the minister in charge of the healthcare system of the register maintained relying on definitive resolutions, which are considered public information regarding the complete list of subsidized medicinal products, by the 20th of each calendar month for information purposes.

(7)<sup>5</sup> The register referred to in Subsection (6) shall authentically contain the following information on subsidized medical aids:

a) name and description of the medical aid, its function group (sub-group) and ISO code;

b) the price serving as the basis for public financing, or - in the case of devices that can be leased or rented with social security subsidies - the daily or monthly rental fee;

c) the rate of the subsidy and the means by which it is provided;

d) the net amount of the subsidy;

e) an indication if it can be prescribed under the fully subsidized public healthcare system;

1 Amended: by subparagraph g) Section 88 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.

2 Repealed by Paragraph b) of Section 41 of Act XCI of 2023, effective as of 1 January 2024.

3 Repealed by Point 12 of Section 284 of Act L of 2017, effective as of 1 January 2018.

4 Established by Section 121 of Act CXXVII of 2013. Amended by Point 17 of Section 283 of Act L of 2017.

5 Enacted: by Section 121 of Act CXXVII of 2013. In force: as of 6. 07. 2013.

f) where applicable, improved guarantee conditions the manufacturer or distributor has voluntarily undertaken over the ones laid down in the decree on the statutory guarantee of durable consumer goods, if it was taken into consideration in the process of admission of the medical aids into the social security subsidy system;

g)<sup>1</sup> name of the distributor;

h)<sup>2</sup> an indication if a subsidy volume agreement exists in connection with a specific medical aid.

(8)<sup>3</sup> In addition to what is contained in Subsection (7), the register referred to in Subsection (6) shall also contain:

a) the medical aid's packaging;

b) the approved period of use and the maximum quantity that can be prescribed for the approved period; and

c) the conditions for prescription (indication, qualification and work requirements, supplementary conditions and notes pertaining to the indication).

(9)<sup>4</sup> The decisions of the health insurance administration agency adopted under Subsections (4) and (5) of Section 32 and Subsections (1)-(3) of Section 32/A may not be overturned by the court.

### *Section 34*

(1)<sup>5</sup> If the manufacturer of the medical aid or its authorized representative wishes to change the price or rental fee of a medical aid approved for subsidies and for marketing, and that can be leased or rented with social security subsidies, after the date when the resolution the health insurance administration agency has adopted according to Section 32 becomes definitive, an application provided for in Subparagraph *ba*) or *bf*) of Paragraph *b*) of Subsection (2) of Section 32 or a notification provided for in Subparagraph *bb*) or *be*) of Paragraph *b*) of Subsection (2) of Section 32 shall be submitted.

(2)<sup>6</sup> If the health insurance administration agency receives a request for subsidies for a novel medical aid, whose function group (sub-group), or the rate subsidy for that specific function group (sub-group) is not contained in specific other legislation, the health insurance administration agency shall suspend the proceedings for the approval of medical aid for subsidies until the amendment of the specific other legislation enters into force, or for a maximum period of two hundred and ten days following the date of receipt of the request, or from the time of remedying deficiencies.

(3)<sup>7</sup> If the legal regulation referred to in Subsection (2) is not amended, the health insurance administration agency shall adopt a decision after two hundred ten days on the basis of the legal provisions in force at that time.

(4)<sup>8</sup> The health insurance administration agency shall recommend to the minister in charge of the healthcare system the opening of a new function group if support under special consideration is granted - under Paragraph *c*) of Subsection (1) of Section 26 of the HIS - on the basis of more than fifty patient requests submitted within twelve consecutive months for medical aids which are not subsidized by the social security system, and the function group of the device is not yet included in the decree of the minister in charge of the healthcare system.

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1 Enacted by Section 62 of Act LXXVII of 2015, effective as of 1 October 2015.

2 Enacted by Section 53 of Act CCXXIV of 2015, effective as of 23 January 2016.

3 Enacted: by Section 121 of Act CXXVII of 2013. In force: as of 6. 07. 2013.

4 Enacted by Subsection (2) of Section 282 of Act L of 2017, effective as of 1 January 2018.

5 Established by Subsection (1) of Section 102 of Act CXI of 2014. Amended by Point 9 of Section 283 of Act L of 2017.

6 Established by paragraph (1) Section 97 of Act CLIV of 2009. Amended by subparagraph *c*) Section 136 of Act CLXXVI of 2011, Point 19 of Section 283 of Act L of 2017.

7 Amended by subparagraph *b*) paragraph (10) Section 127 of Act CLIV of 2009, Point 20 of Section 283 of Act L of 2017.

8 Established by Subsection (2) of Section 102 of Act CXI of 2014, effective as of 1 January 2015.

(5)<sup>1</sup> Persons employed by the institutions which are involved in the proceedings referred to in Subsections (4)-(5) of Section 32 under contract of employment or other similar relationship and the persons directly involved in the administration of the proceedings shall file a statement declaring their independence from the distributor who filed the underlying request in terms of any business or other similar interest, and the distributor of another device that belongs to the same function group.

(6)<sup>2</sup>

(7)<sup>3</sup> Subsidized dressings and bandages may be dispensed by pharmacies and vendors specializing in medical aids.

(8)<sup>4</sup> The health insurance administration agency, with a view to enforce the relevant budgetary limits, may enter into a subsidy volume agreement with respect to medical aids which are already or recently have been approved for subsidies.

(8a)<sup>5</sup> A medical aid may be admitted to a new function group opened under Subsections (2) and (4) only if it is subsidized within the framework of a subsidy volume agreement.

(9)<sup>6</sup> The provisions for making payments are laid down in the subsidy volume agreement concluded between the manufacturer or its authorized representative and the health insurance administration agency.

### Section 35


(1)<sup>7</sup> Distributors of medicinal products, in the process of dispensing:

a) may not exceed the maximum retail price approved by the health insurance administration agency in proceedings for the approval for subsidies,

b) may not deviate - either directly or indirectly - from the amount of subsidy and the amount of compensation established by the health insurance administration agency in proceedings for the approval for subsidies.

(2)<sup>8</sup> Distributors of medical aids, in the process of dispensing subsidized by the social security system:

a) may not market the given device at a price lower than the price approved by the health insurance administration agency as the basis for public financing in proceedings for the approval for subsidies and, apart from the exception set out in Paragraph b), may not exceed that price,

 b)<sup>9</sup> may exceed the price approved by the health insurance administration agency as the basis for public financing in proceedings for the approval for subsidies by the rate decreed by the Minister with respect to the types of devices decreed by the Minister,

c) may not deviate - either directly or indirectly - from the amount of subsidy established by the health insurance administration agency in proceedings for the approval for subsidies,

d) may deviate - in accordance with Paragraph b) - from the amount of compensation established by the health insurance administration agency in proceedings for the approval for subsidies.

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1 Established: by paragraph (2) Section 97 of Act CLIV of 2009. In force: as of 1. 03. 2010.

2 Repealed: by subparagraph c) Section 137 of Act CLXXVI of 2011. No longer in force: as of 1. 01. 2012.

3 Enacted: by paragraph (3) Section 97 of Act CLIV of 2009. In force: as of 1. 03. 2010.

4 Numbering amended: by paragraph (3) Section 97 of Act CLIV of 2009. In force: as of 1. 03. 2010.

5 Enacted by Section 54 of Act CCXXIV of 2015, effective as of 1 January 2016.

6 Numbering amended: by paragraph (3) Section 97 of Act CLIV of 2009. In force: as of 1. 03. 2010.

7 Established: by paragraph (1) Section 64 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.

8 Established: by Section 123 of Act CXXVII of 2013. In force: as of 6. 07. 2013.

9 Established by Subsection (1) of Section 39 of Act XCI of 2023, effective as of 1 January 2024.



(2a)<sup>1</sup> As regards the derogation specified in Paragraph *b*) of Subsection (2), distributors of medical aids shall notify patients concerning the percentage of increase together with the information conveyed according to Section 9, using the same means defined therein.

(3)<sup>2</sup> The detailed regulations for the admission of medicinal products, dietary supplement and medical aids into the social security subsidy system is contained in specific other legislation.

(4)<sup>3</sup> Electronic communication shall be carried out via the IT systems of the health insurance administration in connection with proceedings for the admission of medicinal products and medical aids for subsidies within the social security system.

(5)<sup>4</sup> Changes in the particulars referred to in Subsection (4) of Section 29 shall be notified on the official website of the health insurance administration agency.

(6)<sup>5</sup> A medical aid may be prescribed under the fully subsidized public healthcare system only if not admitted to the function group mentioned in Subsection (7), and

*a*) if - within the group - it is either a reference product, or a product sold at a price (or rented at a daily rental fee) serving as the basis for public financing that is the same or lower than the price of the reference product, or

*b*) if it is a product sold at a price serving as the basis for the lowest public financing for which subsidy is provided at a specific percentage.

(6a)<sup>6</sup> Medical aids prescribed under the fully subsidized public healthcare system to eligible persons shall be repaired free of charge, if the device in question can be repaired with subsidies.

👉(6b)<sup>7</sup> As regards the repair of medical aids prescribed under the fully subsidized public healthcare system to eligible persons no fee of any kind may be requested from the patient on any grounds.

(7)<sup>8</sup> The function groups that cannot be dispensed under the fully subsidized public healthcare system are contained in specific other legislation.

👉(8)<sup>9</sup> A medicinal product may be prescribed under the fully subsidized public healthcare system if defined by the health insurance agency and published on its website accompanied by the public statement referred to in Subsection (4) of Section 24 based on the guidelines published by the Országos Gyógyszerterápiás Tanács (*National Council for Therapeutic Medicine*) (hereinafter referred to as "OGYTT") according to the criteria specified by decree of the minister in charge of the healthcare system. OGYTT shall inter alia take into account in respect of the public healthcare system the aspects specified in Act III of 1993 on Social Administration and Social Welfare Benefits and the Government Decree on the Detailed Provisions for Requesting, Establishing and Disbursement of Social Benefits in Cash and in Kind, adopted for the implementation thereof.

(9)<sup>10</sup> If a medicinal product is available for prescription in more than one subsidy category, it may be prescribed in all subsidy categories available for the medicinal product in question in the fully subsidized public healthcare system as well.

## Chapter V

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1 Enacted: by paragraph (3) Section 72 of Act LXXIX of 2012. In force: as of 1. 07. 2012.  
2 Established: by Section 37 of Act CVI of 2008. In force: as of 01. 01. 2009.  
3 Enacted by paragraph (2) Section 98 of Act CLIV of 2009. Amended by Section 51 of Act CXXI of 2016.  
4 Enacted: by paragraph (2) Section 98 of Act CLIV of 2009. In force: as of 1. 01. 2010.  
5 Established: by paragraph (2) Section 64 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.  
6 Enacted by Section 103 of Act CXI of 2014, effective as of 1 January 2015.  
7 Enacted by Subsection (2) of Section 39 of Act XCI of 2023, effective as of 1 January 2024.  
8 Enacted: by paragraph (2) Section 98 of Act CLIV of 2009. In force: as of 1. 01. 2010.  
9 Established by Subsection (3) of Section 39 of Act XCI of 2023, effective as of 1 January 2024.  
10 Established by Section 16 of Act CXXIX of 2021, effective as of 1 May 2022.

PROVISIONS INTENDED TO ENSURE THE CONTINUOUS SUPPLY OF MEDICINAL  
PRODUCTS AND THE ENFORCEMENT OF THE APPROPRIATION OF MEDICINAL  
PRODUCT SUBSIDIES

*Section 36*

(1)<sup>1</sup> Holders of the marketing authorization of medicinal products, or - if they are not engaged in any distribution activities in Hungary as fixed in an agreement with a distributor subject to the approval of the state tax authority - the distributor, furthermore, the person submitting a request for subsidies in connection with a dietary supplement if other than the distributor of the dietary supplement in question (for the purposes of this Chapter hereinafter referred to collectively as "holder of the marketing authorization of a medicinal product"), shall be required to pay 20 per cent on the social security subsidies commensurate (producer price/import price) with the producer price or import price (hereinafter referred to collectively as "producer price") of all its medicinal products and dietary supplements (for the purposes of this Chapter hereinafter referred to collectively as "medicinal product") sold in pharmacies with public financing - other than the medicinal products specified in Subsection (1) of Section 38 and the dietary supplements provided for in the Decree on Mother's Milk Substitutes and Supplements - based on and consistent with (producer price/retail price) the amount of social security subsidies shown under the volume of sales under prescription for the month. Holders of the marketing authorization of medicinal products shall be required to pay 10 per cent on the producer price of dietary supplements sold in pharmacies with public financing provided for in the Decree on Mother's Milk Substitutes and Supplements based on and consistent with (producer price/retail price) the amount of social security subsidies shown under the volume of sales under prescription for the month. The amount payable shall be calculated separately for each product and subsidy type. Social security subsidy shall be understood as a subsidy comprising value added tax (gross), retail price shall mean the gross retail price, and producer price shall be applied exclusive of value added tax (net).

(1a)<sup>2</sup> The register maintained by the state tax authority on the approval of agreements between holders of the marketing authorization of medicinal products and distributor shall be construed as an official public register with the exception of data comprising a part of another official public register pursuant to the relevant legislation.

(2)<sup>3</sup> Business associations authorized for the wholesale distribution of medicinal products, and business association authorized for the wholesale distribution of dietary supplements (hereinafter referred to collectively as "authorized wholesale distributor of medicinal products") shall be required to pay two-and-a-half per cent of the wholesale price margin on all their medicinal products sold during the month in public pharmacies and in institutional pharmacies engaged in supplying medicinal products to the general public with public financing, based on the amount of social security subsidies.

(3)<sup>4</sup>

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1 Established by Section 71 of Act CCXLIV of 2013, effective as of 1 January 2014.

2 Enacted: by Section 61 of Act LXXXIV of 2013. In force: as of 1. 07. 2013.

3 Established: by paragraph (1) Section 363 of Act CXXVI of 2007. In force: as of 01. 01. 2008.

4 Repealed: by Section 47 of Act LXIX of 2012. No longer in force: as of 1. 01. 2013.

(4)<sup>1</sup> Subject to the exception set out in Subsection (4a), the promoter of medicinal products referred to in Subsection (3) of Section 12 shall be required to pay eight hundred and thirty-two thousand forints a month for all medical sales representatives - registered according to Subsection (1) of Section 13/A - they employ under contract in connection with medicinal products, and eighty-three thousand forints in connection with medical aids. Where - upon notification - the medical sales representative is admitted to or removed from the register during the month, the payment liability shall apply with the above-specified amount prorated for the duration of employment expressed in days as commensurate for the calendar days of the month.

(4a)<sup>2</sup> Any small and medium-sized enterprise covered by Act XXXIV of 2004 on Small and Medium-sized Enterprises and the Support Provided to Such Enterprises, that is engaged in the activities of promoters of medicinal products specified in Subsection (3) of Section 12 and that employs twelve medical sales representatives maximum under contract and that is authorized to manufacture medicinal products in Hungary, furthermore, the medical sales representative offers exclusively those products for which the promoter of medicinal products, operating in the form of a small or medium-sized enterprise, holds the marketing authorization, and the authorization for the manufacture of medicinal products is not limited to packaging or batch release exclusively, the promoter of medicinal products shall be required to pay eighty-three thousand forints a month in connection with the activities of the medical sales representatives - registered according to Subsection (1) of Section 13/A - it employs under contract.

(5)<sup>3</sup> The payment obligations specified under Subsections (1)-(4) of this Section and in Section 42 shall be subject to the provisions of the Code of Tax Administration Procedure and the Act on the Rules of Taxation, with the exceptions set out in this Act.

(6)<sup>4</sup> The state tax authority, if granting approval for the agreement between the holder of the marketing authorization of a medicinal product and the distributor, shall notify the health insurance administration agency thereof within eight days of the date of approval.

(7)-(9)<sup>5</sup>

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1 Established: by paragraph (2) Section 66 of Act LXXXI of 2011. In force: as of 1. 07. 2011.  
Amended: by subparagraph d) Section 136 of Act CLXXVI of 2011. In force: as of 1. 01. 2012. The change does not effect the English version.

2 Enacted: by paragraph (3) Section 66 of Act LXXXI of 2011. In force: as of 1. 07. 2011. Amended: by subparagraph b) Section 83 of Act LXXIX of 2012. In force: as of 1. 07. 2012.

3 Amended by Point 1 of Section 123 of Act CLIX of 2017.

4 Enacted: by paragraph (2) Section 363 of Act CXXVI of 2007. In force: as of 01. 01. 2008.

5 Repealed: by paragraph (2) Section 83 of Act LXXXI of 2011. No longer in force: as of 1. 01. 2012.

(10)<sup>1</sup> A person who is the holder of a marketing authorization for a medicinal product shall be eligible for a reduction from the payment obligations described in Subsections (1) and (4), (4a) of Section 36, in Subsection (1) of Section 40/A (for the purposes of this Act hereinafter referred to as "payment obligations") in respect of the costs of research and development carried out affecting the healthcare services sector in accordance with the provisions contained in Point 32 of Section 4 of Act LXXXI of 1996 on Corporate Tax and Dividend Tax (hereinafter referred to as "CorpTx. Act"), if shown in this person's own annual account prepared according to Act C of 2000 on Accounting (hereinafter referred to as "Accounting Act") for the financial year beginning in the previous year or in the annual account prepared by its consolidated subsidiary for the financial year beginning in the previous year, taking also into consideration of what is contained in Subsection (12), provided that these expenditures (for the purposes of this Subsection hereinafter referred to as "expenditures") exceed 15 per cent of the social security subsidy paid for the subsidized medicinal products supplied by the marketing authorization holder relative to output prices (import prices) (for the purposes of this Subsection hereinafter referred to as "output price-based subsidy"), and if the staff costs shown under operating charges exceed 3 per cent of the output price-based subsidy, and if having satisfied all payment obligations described in this Act. The investments made by the said holder of a marketing authorization in research and development - as laid down in the relevant legislation - and those of any consolidated subsidiary according to the Accounting Act shall be taken into account on the aggregate, with facilities to ensure that the same expense item is claimed only once when applying for the allowance. The costs of research and development incurred in connection with the exchange of services between consolidated subsidiaries relating to research and development activities may be claimed as an allowance only by one of the parties involved. The reduction shall be calculated based on the beneficiary's payment obligation pertaining to the previous year:<sup>2</sup>

a) up to 90 per cent, if the expenditures are above 25 per cent of the output price-based subsidy;

b) up to 60 per cent, if the expenditures are between 20 per cent and 25 per cent of the output price-based subsidy;

c) up to 20 per cent, if the expenditures are between 15 per cent and 20 per cent of the output price-based subsidy.

(11)<sup>3</sup> The costs of research and development claimed in the process of determining the amount of the allowance shall be reduced:

a)<sup>4</sup> by the costs of phase IV clinical trials, and the costs of non-interventional studies under Point 4 of Article 2(2) of Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC;

b) by the sums of support requested for research and development purposes before the balance sheet date from the tax authority or from any subsystem of the central budget or from the various financial funds of the European Union, or by any non-repayable aid and grant received during the tax year and recognized as income;

c) by the amount of tax allowance of the wages and salaries charged during the tax year to the direct costs of basic research, applied research and experimental development under the provisions of Subsection (9) of Section 22 of the CorpTx. Act in effect on 31 December 2011;

d) by the costs of research and development incurred (claimed) by foreign branches under the CorpTx. Act if:

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1 Enacted: by paragraph (3) Section 119 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.

2 Amended: by subparagraph a) Section 26 of Act CLIV of 2012. In force: as of 26. 10. 2012.  
Amended: by subparagraph b) Section 102 and subparagraph b) Section 103 of Act CCXII of 2012.  
In force: as of 1. 01. 2013.

3 Enacted: by paragraph (3) Section 119 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.

4 Established by Section 122 of Act CI of 2021, effective as of 31 January 2022.

*da)* the branch is situated in a State that is not a member of the European Union, nor the Organization for Economic Cooperation and Development (hereinafter referred to as "OECD"), or that is not a party to the Agreement on the European Economic Area, or with which Hungary did not enter into an international agreement on double taxation, or

*db)* the branch is situated in a Member State of the European Union, or in a State that is a member of the OECD, or that is a party to the Agreement on the European Economic Area, or with which Hungary did enter into an international agreement on double taxation, and the marketing authorization holder is subject to payment obligation according to the national laws of the State where the branch is located relating to medicinal products and dietary supplements with public financing in an amount determined as commensurate on the basis of social security subsidies, or on the basis of the number of medical sales representatives, and these costs of research and development have already been claimed in the State where the branch is located as deductions from liabilities, or such research and development expenditure have already been claimed in the given State in respect of any type of tax for the purpose of allowance, or has been enforced in an other form of tax credit.

(12)<sup>1</sup> The allowance shall not concern the State's obligation conferred under Subsection (2) of Section 2 of Act CXXII of 2019 on Entitlements to Social Security Benefits and on Funding These Services.

### *Section 37*

(1)<sup>2</sup> The health insurance administration agency vested with authority to manage the Health Insurance Fund shall communicate to the person affected the information concerning subsidies and turnover for compliance with the payment obligations specified in Subsections (1)-(2) of Section 36 by the tenth day of the second month that follows the current month, and shall post them on its official website as well.

(2)<sup>3</sup> Holders of the marketing authorization of medicinal products and business associations authorized for the wholesale distribution of medicinal products shall be required to file a declaration on the payment obligations specified in Subsections (1)-(2) of Section 36 by the twentieth day of the third calendar month following the current month, using the standard form prescribed by the state tax authority, and shall pay the sum required to the account of the state tax authority opened at the treasury for this particular purpose.

(3)<sup>4</sup>

(4)<sup>5</sup> The persons engaged in promotional activities in accordance with Subsection (3) of Section 12 shall be required to file a declaration on the payment obligations specified in Subsections (4)-(4a) of Section 36 by the twentieth day of the third calendar month following the current month, and shall pay the sum required to the account of the state tax authority opened at the treasury for this particular purpose.

(5)<sup>6</sup>

(6) The health insurance administration agency vested with authority to manage the Health Insurance Fund shall disclose the data required for the audit of the operators subject to payment obligations, concurrently with supplying the data referred to in Subsection (1), to the state tax authority by way of electronic means.

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1 Enacted by Subsection (3) of Section 119 of Act CLXXVI of 2011. Amended by Section 150 of Act CXXII of 2019.

2 Established: by Section 364 of Act CXXVI of 2007. In force: as of 01. 01. 2008. Amended: by subparagraph b) Section 138 of Act CXXVII of 2013. In force: as of 6. 07. 2013.

3 Established: by Section 364 of Act CXXVI of 2007. In force: as of 01. 01. 2008.

4 Repealed: by Section 47 of Act LXIX of 2012. No longer in force: as of 1. 01. 2013.

5 Established: by Section 364 of Act CXXVI of 2007. In force: as of 01. 01. 2008. Amended: by Section 360 of Act LVI of 2009. In force: as of 1. 10. 2009. Amended: by subparagraph i) Section 82 of Act LXXIX of 2012. In force: as of 1. 07. 2012.

6 Repealed: by Section 467 of Act CXXVI of 2007. No longer in force: as of 01. 01. 2008.

(7)<sup>1</sup> The government body for pharmaceuticals shall forthwith notify the state tax authority by way of electronic means concerning the notification specified in Subsection (3) of Section 12, the notification of the termination of activities and on the prohibition of promotional activities.

### *Section 38*

(1)<sup>2</sup> Holders of the marketing authorization of medicinal products shall be exempt from the payment obligation prescribed in Subsection (1) of Section 36:

*a)* as regards the amount of subsidy paid on medicinal products with special funding; and

*b)* as regards the amount of social security subsidy determined by the health insurance administration agency provided for medicinal products supported under special consideration, with the exception of the medicinal products placed on the market by authorization of the government body for pharmaceuticals or the European Commission;

*c)*<sup>3</sup> as regards the sum of social security subsidies paid for medicinal products with preferential status;

*d)*<sup>4</sup> having regard to the subsidy paid for a medicinal product approved for social security subsidies pursuant to Section 22/A.

(2)<sup>5</sup> Holders of the marketing authorization of medicinal products may be granted an allowance up to the full amount of their payment obligation broken down according to medicinal products, calculated separately for each product and the types of subsidies, if they undertake to reduce the producer price - with a view to reducing the reference price - of the medicinal products they supply with social security subsidies under Subsection (1) of Section 36 within the framework of the fixation procedure decreed by the minister in charge of health insurance by the twentieth day of the second month preceding the first day of the calendar quarter. In this case, the payment obligation prescribed in Subsection (1) of Section 36 pertaining to the products affected by the price reduction:

*a)* shall be reduced consistent with the applicable rate of reduction, if the rate of price reduction remains below 50 per cent,

*b)* shall be reduced fully, if the rate of price reduction exceeds 50 per cent, for the period to which the price reduction pertains, in any case for a period of up to one year from the effective date of the price reduction.

(3)<sup>6</sup>

(4)<sup>7</sup> Holders of the marketing authorization of medicinal products shall deduct the amount paid, exclusive of value added tax, under the subsidy volume agreement pertaining to the subject period from the amount of the payment obligation defined in Subsection (1) of Section 36 and in Subsection (1) of Section 40/A.

### *Section 38/A*<sup>8</sup>

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1 Amended: by Section 360 of Act LVI of 2009. In force: as of 1. 10. 2009. Amended: by Section 3 of Act LXXXIX of 2010. In force: as of 16. 09. 2010. Amended: by subparagraph b) Section 88 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.

2 Established: by paragraph (1) Section 120 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.

3 Enacted by Section 72 of Act CCXLIV of 2013, effective as of 1 January 2014.

4 Enacted by Section 38 of Act CLXXII of 2016, effective as of 1 January 2017.

5 Established: by paragraph (2) Section 120 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.

6 Repealed: by Section 467 of Act CXXVI of 2007. No longer in force: as of 01. 01. 2008.

7 Established by Subsection (3) of Section 365 of Act CXXVI of 2007. Amended by Paragraph b) of Section 26 of Act CLIV of 2012, Section 47 of Act XXIV of 2022.

8 Enacted: by Section 39 of Act CVI of 2008. In force: as of 15. 02. 2009.

The promoter of medicinal products referred to in Subsection (3) of Section 12 shall be exempt from the payment obligation specified in Subsections (4)-(4a) of Section 36 in respect of the medical sales representatives they employ under contract to whom either of the provisions contained under Paragraphs *a)-g)* apply: <sup>1</sup>

*a)* <sup>2</sup> who is drawing sick-pay, benefits for accident-related injuries, infant care benefits, adoption allowance or child-care benefits, for the duration of drawing such benefits;

*b)* <sup>3</sup> who is drawing child-care assistance benefits, for the duration of drawing such benefits, except if the beneficiary is working during that period;

*c)* who is unable to work due to incapacity;

*d)* who is on leave of absence without pay;

*e)* <sup>4</sup> who is drawing child home care benefits or nursing allowance, for the duration of drawing such benefits, except if the beneficiary is working during that period;

*f)* who is drawing child-rearing allowance, for the duration of drawing such benefits, except if the beneficiary is working during that period;

*g)* who has been detained, for the duration of detention.

### *Section 39* <sup>5</sup>

### *Section 40*

The state tax authority shall forthwith transfer:

*a)* <sup>6</sup> the sums collected under Subsections (1)-(2) and (4)-(4a) of Section 36 to the account of the H. Fund opened at the treasury according to specific other legislation;

*b)* <sup>7</sup>

### *Section 40/A* <sup>8</sup>

(1) <sup>9</sup> Holders of the marketing authorization of medicinal product, or - if they are not engaged in any distribution activities in Hungary as fixed in an agreement with a distributor subject to the approval of the state tax authority - the distributor (for the purposes of this Section hereinafter referred to collectively as "holder of the marketing authorization of a medicinal product") shall be required to pay - in addition to the payment prescribed in Subsection (1) of Section 36 - 10 per cent on the producer price or import price (hereinafter referred to collectively as "producer price") of all its medicinal products sold in pharmacies with public financing for at least six years for over 1000 forints as the price approved as the basis for public financing, based on and consistent with the producer price or import purchase price (producer price/retail price) the amount of social security subsidies shown under the volume of sales under prescription for the month, if there is no other medicinal product with public financing available of the same active substance and pharmaceutical form, which are manufactured under a different brand name, and distributed by another holder of the marketing authorization. The amount payable shall be calculated separately for each medicinal product and subsidy type.

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1 Amended: by Section 360 of Act LVI of 2009. In force: as of 1. 10. 2009. Amended: by subparagraph j) Section 82 of Act LXXIX of 2012. In force: as of 1. 07. 2012.

2 Amended by Paragraph b) of Section 114 of Act CXI of 2014, Subsection (2) of Section 85 of Act CXVII of 2018.

3 Amended by Subsection (2) of Section 74 of Act CCXXIII of 2015.

4 Amended by Subsection (1) of Section 85 of Act CXVII of 2018.

5 Repealed: by Section 47 of Act LXIX of 2012. No longer in force: as of 1. 01. 2013.

6 Amended: by subparagraph k) Section 82 of Act LXXIX of 2012. In force: as of 1. 07. 2012.

7 Repealed: by Section 47 of Act LXIX of 2012. No longer in force: as of 1. 01. 2013.

8 Enacted: by Section 73 of Act LXXIX of 2012. In force: as of 1. 08. 2012.

9 Amended: by subparagraph c) Section 26 of Act CLIV of 2012. In force: as of 26. 10. 2012.

(1a)<sup>1</sup> In the application of Subsection (1), the pharmaceutical forms of different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance and the same pharmaceutical form, if their level 5, 7-digit ATC code is one and the same.

(1b)<sup>2</sup> In the application of Subsection (1), a biological medicinal product shall be considered to be the same active substance and the same pharmaceutical form, if showing bio-equivalence with the reference biological medicinal product as verified during the marketing authorization procedure.

(2) In the application of Subsection (1), social security subsidy shall be understood as a subsidy comprising value added tax (gross), retail price shall mean the gross retail price, and producer price shall be applied exclusive of value added tax.

(2a)<sup>3</sup> In determining the payment obligation under Subsection (1) hereof, the specified strength, packaging and the final presentation of medicinal products of specific pharmaceutical form with public financing, as shown in the marketing authorization and any amendment thereof, shall be taken into consideration on the aggregate, if at least one specified strength, packaging and final presentation of a medicinal product of a specific pharmaceutical form is or has been sold with public financing for at least six years.

(3) Holders of the marketing authorization of medicinal products shall be exempt from the payment obligation prescribed in Subsection (1) as regards the amount of social security subsidy determined by the health insurance administration agency provided for medicinal products supported under special consideration, with the exception of the medicinal products placed on the market by authorization of the government body for pharmaceuticals or the European Commission.

(3a)<sup>4</sup> The holder of the marketing authorization of a medicinal product shall be exempt from the payment obligation referred to in Subsection (1) hereof from the effective date of price reduction with respect to any medicinal product whose producer price the marketing authorization holder has reduced by 10 per cent or more relative to the producer price in effect at the time of commencement of said payment obligation.

(3b)<sup>5</sup> Holders of the marketing authorization of medicinal products shall be exempt from the payment obligation defined in Subsection (1) as regards preparations where the holder of the marketing authorization of a medicinal product enters into a limit-value subsidy volume agreement with the health insurance administration agency under Paragraph *b*) of Subsection (5) of Section 26.

(4)<sup>6</sup> The payment obligation specified in Subsection (1) hereof shall be governed by the relevant provisions of the Code of Tax Administration Procedure and the Act on the Rules of Taxation, subject to the exceptions set out in this Act.

(5) The state tax authority, if granting approval for the agreement referred to in Subsection (1) between the holder of the marketing authorization of a medicinal product and the distributor, shall notify the health insurance administration agency thereof within eight days of the date of approval.

(6) The health insurance administration agency vested with authority to manage the Health Insurance Fund shall communicate to the person affected the information concerning subsidies and turnover for compliance with the payment obligation specified in Subsection (1) by the tenth day of the second month that follows the month to which the information pertains.

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1 Enacted: by paragraph (1) Section 25 of Act CLIV of 2012. In force: as of 26. 10. 2012.

2 Enacted: by paragraph (1) Section 25 of Act CLIV of 2012. In force: as of 26. 10. 2012.

3 Enacted: by paragraph (2) Section 25 of Act CLIV of 2012. In force: as of 26. 10. 2012. Amended: by point 9 Section 137 of Act CXXVII of 2013. In force: as of 6. 07. 2013.

4 Enacted: by paragraph (3) Section 25 of Act CLIV of 2012. In force: as of 26. 10. 2012.

5 Enacted: by Section 94 of Act CCXII of 2012. In force: as of 1. 01. 2013.

6 Amended by Point 2 of Section 123 of Act CLIX of 2017.



(7) Holders of the marketing authorization of medicinal products shall be required to file a declaration on the payment obligation specified in Subsection (1) by the twentieth day of the third calendar month following the month in question, using the standard form prescribed by the state tax authority, and shall pay the sum required to the account of the state tax authority opened at the treasury for this particular purpose.

(8) The health insurance administration agency vested with authority to manage the Health Insurance Fund shall disclose the data required for the audit of the operators subject to payment obligations, concurrently with supplying the data prescribed in Subsection (6), to the state tax authority by way of electronic means.

(9) The state tax authority shall forthwith transfer the sums collected according to Subsection (1) to the account of the Health Fund opened at the treasury - as prescribed by specific other legislation - for this particular purpose.

#### *Section 41<sup>1</sup>*

(1)<sup>2</sup> Any business association that operates or has an implementation permit to open a public pharmacy (pharmacies) in a community where the supply of medicinal products for the entire community is ensured or planned to be ensured by only one public pharmacy and - as regards an existing public pharmacy - the aggregated price margin from the sale of subsidized medicinal products over a specific period fails to reach the limit specified by the government decree on the accounting and payment of subsidies made available for medicinal products, medical aids and thermal bath treatments prescribed to outpatients (hereinafter referred to as "government decree") in spite of prudent and effective management - on account of the population to be supplied or due to the pharmacy's geographical location -, shall be entitled to financial support in a calendar quarter to cover its operating expenses from the appropriation chapter of the Ministry of the minister in charge of the healthcare system according to the annual budget act. The Ministry shall publish the names of the companies to whom such financial support was provided on its official website, including the amount of support.

(2)<sup>3</sup> The official certificate to verify compliance with the conditions for entitlement, that is to be enclosed with the application for the financial support referred to in Subsection (1) shall be made out for the authorized operator of a public pharmacy by the government body in charge of the healthcare system.

(3)<sup>4</sup> The government body in charge of the healthcare system shall make out the official certificate referred to in Subsection (2) in ex officio proceedings, covering the period beginning on the twenty-first day of the third month following the given quarter and ending on the thirtieth day of the third month following the given quarter.

(4) The government body in charge of the healthcare system shall make out the official certificate referred to in Subsection (3) within ten days.

(5) The authorized operator of a public pharmacy may claim the financial support referred to in Subsection (1) above from the first day of the fourth month following the given quarter from the competent state tax authority of the first instance.

(6)<sup>5</sup> The financial support referred to in Subsection (1) shall be treated as budgetary subsidies by definition of the Code of Tax Administration Procedure and the Act on the Rules of Taxation. The provisions of the RTA shall apply concerning the requests for and the payment of such subsidies. The conditions for entitlement are laid down in specific other legislation.

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1 Established: by Section 7 of Act LXXXIX of 2010. In force: as of 17. 08. 2010.

2 Amended by point 10 Section 137 of Act CXXVII of 2013, Paragraph c) of Section 114 of Act CXI of 2014.

3 Established by Section 64 of Act XIX of 2023, effective as of 1 June 2023.

4 Established by Section 64 of Act XIX of 2023, effective as of 1 June 2023.

5 Amended by Point 3 of Section 123 of Act CLIX of 2017.

(7)<sup>1</sup> The authorized operator of a public pharmacy may apply for the financial support for operating expenses under Subsection (1) for such part of the six-month period provided for in Subsection (2) of Section 57, following the waiver of independent right, where it is under obligation - by decision of the government body in charge of the healthcare system - to operate a public pharmacy following the waiver of independent right.

#### *Section 42*

(1)<sup>2</sup> If the amount of social security subsidies paid out for approved medicinal products based on their volume of sales for the year - exclusive of the sums available for medicinal products provided for in Subsection (1) of Section 38 - exceeds the sum appropriated as shown under the Medicinal Product Subsidies account of the Health Fund on the first day of January of the year in question, the surplus shall be financed - according to the provisions of Subsections (2)-(3) - by the operator of the Health Fund and by the holders of marketing authorizations.

(2)<sup>3</sup> In determining the amount overdrawn, the sums received under the payment obligation specified in Subsections (1)-(2) and (4)-(4a) of Section 36 and in Subsection (1) of Section 40/A, and the sums paid for the given year under subsidy volume agreements shall be deducted from the social security subsidies paid out based on the volume of sales calculated for the year according to Subsection (1) hereof.

(3)<sup>4</sup> The amount of overdraft referred to in Subsection (2) shall be covered collectively by the operator of the Health Fund and the marketing authorization holders according to Subsections (4)-(5). The part of overdraft to be covered by the marketing authorization holders shall be distributed in proportion of the difference between the amount of social security subsidies actually paid out and the given appropriation, that shall be paid back by the marketing authorization holders in accordance with Subsections (4) and (4a).

(4)<sup>5</sup> The payment obligation referred to in Subsection (1) shall be shared by the marketing authorization holders - in due observation of what is contained in Subsection (2) - based on the same percentage as the amount of social security subsidies paid for the medicinal products of each marketing authorization holder relying on the prescription sales records of pharmacies during the given year, less any payments made under the subsidy volume agreements, having regard to Subsections (4a) and (5).

(4a)<sup>6</sup> In cases of exceptional circumstances, if the sum provided for in the annual Budget Act for subsidizing medicinal products is exceeded, the amount of excess calculated from the overdraft referred to in Subsection (3) shall be divided in proportion of the support granted on an ad hoc basis under special consideration - minus the payments made under subsidy volume agreements - among the holders of the marketing authorizations of the medicinal products affected.

(5)<sup>7</sup> The payment obligation prescribed for reference products approved for fixed amount subsidies based on the active ingredient, for medicinal products whose daily cost based on therapeutic efficacy is the same or lower than the daily cost of the reference product, and for medicinal products approved for fixed support based on therapeutic efficacy, whose daily cost based on therapeutic efficacy is the same or lower than the reference price shall not be charged to the distributors of such products. Such overdraft shall be covered by the operator of the Health Fund.

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1 Enacted by Section 2 of Act CXI of 2019, effective as of 1 January 2020.

2 Established by Subsection (1) of Section 39 of Act CLXXII of 2016, effective as of 19 January 2017.

3 Established: by paragraph (1) Section 122 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.  
Amended: by subparagraph d) Section 26 of Act CLIV of 2012. In force: as of 26. 10. 2012.

4 Established by Subsection (2) of Section 39 of Act CLXXII of 2016, effective as of 19 January 2017.

5 Established by paragraph (2) Section 122 of Act CLXXVI of 2011. Amended by Paragraph d) of Section 45 of Act CLXXII of 2016.

6 Enacted by Subsection (3) of Section 39 of Act CLXXII of 2016, effective as of 19 January 2017.

7 Established: by paragraph (2) Section 65 of Act CLXXIII of 2010. In force: as of 1. 03. 2011.

(6)<sup>1</sup> If the total amount of social security subsidies paid out based on the volume of sales of the subsidized medicinal products during the year, for the first nine months - in the application of Subsections (1)-(2) - exceeds three-quarters of the sum appropriated as shown under the Medicinal Product Subsidies account of the Health Fund on the first day of January of the year in question, the marketing authorization holder - based on the information supplied by the health insurance administration agency vested with authority to manage the Health Fund concerning subsidies in accordance with Subsections (2)-(5) hereof by 10 November, shall be required to declare to the state tax authority and pay an advance by 20 December of the same year, using the standard form prescribed by the state tax authority, to the account of the state tax authority opened at the treasury for this particular purpose.

(7)<sup>2</sup> The health insurance administration agency vested with authority to manage the Health Insurance Fund shall communicate to the marketing authorization holders the information concerning subsidies for compliance with the payment obligations specified in Subsection (1) by 15 February of the year following the year to which it pertains.

(8)<sup>3</sup> Marketing authorization holders shall declare the payment obligation specified in Subsection (1) by the twenty-fifth day of the month following the time referred to in Subsection (7), using the standard form prescribed by the state tax authority, to the state tax authority, and shall pay the sum that remains taking into account the advance paid under Subsection (6) to the account of the state tax authority opened at the treasury for this particular purpose.

(9)<sup>4</sup> The state tax authority shall forthwith transfer the sums collected from the payment obligations specified in Subsection (1) to the account of the H. Fund opened at the treasury - as prescribed by specific other legislation - for this particular purpose.

(10)<sup>5</sup> The health insurance administration agency vested with authority to manage the Health Fund shall disclose the data for three-quarters of the year by 10 November as required for the audit of the operators subject to the payment obligations pursuant to Subsection (1), and the data from the current year by 15 February of the calendar year following the current year, to the state tax authority by way of electronic means.

(11)<sup>6</sup> In the application of this Section, of the payments made under subsidy volume agreements the ones made on annual accounts shall be taken into consideration proportionately for the period under review, whereas payments made on monthly accounts shall be taken into account according to the payment dates.

(12)<sup>7</sup> The operator of the Health Fund shall publish the turnover data for calculating the payment referred to in Subsection (1) on its official website separately for each month, broken down according to the titles indicated in the budget of the Health Fund.

### *Section 43*

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- 1 Established: by paragraph (3) Section 122 of Act CLXXVI of 2011. In force: as of 1. 01. 2012. Amended: by subparagraph l) Section 82 of Act LXXIX of 2012. In force: as of 1. 07. 2012.
  - 2 Established: by paragraph (2) Section 368 of Act CXXVI of 2007. In force: as of 01. 01. 2008. Amended: by subparagraph h) Section 88 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.
  - 3 Established: by paragraph (2) Section 368 of Act CXXVI of 2007. In force: as of 01. 01. 2008. Amended: by subparagraph h) Section 88 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.
  - 4 Amended: by subparagraph h) Section 88 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.
  - 5 Established: by paragraph (4) Section 122 of Act CLXXVI of 2011. In force: as of 1. 01. 2012. Amended: by subparagraph c) Section 83 of Act LXXIX of 2012. In force: as of 1. 07. 2012.
  - 6 Established: by paragraph (5) Section 122 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.
  - 7 Enacted: by paragraph (5) Section 122 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.

(1)<sup>1</sup> With a view to prevent and check any disturbance in the market in medicinal products and to maintain equilibrium of the market of medicinal products, the Government shall have powers to prohibit by decree any increase in the prices shown at the time of promulgation of the decree adopted under this Subsection in the agreement between the manufacturer and the distributor for medicinal products for human use and dietary supplements for special nutritional needs - including the price determined by law in accordance with the Civil Code - for a maximum period of two years, and that the manufacturers and distributors may not make any contract offer to one another for a higher price for a maximum period of two years from the time of promulgation of the said decree.

(2) If the measure specified in Subsection (1) had been ordered, an inquiry shall be conducted at least once a year to determine as to whether it should be continued without changes with a view to maintain equilibrium of the market of medicinal products. Within ninety days following the time of opening the inquiry, the competent authority shall make an announcement concerning any price increases or reductions, if applicable.

(3) The price may be increased relative to the one specified in Subsection (1) only upon the prior consent of the health insurance administration agency granted if requested. The consent may be granted if:<sup>2</sup>

*a)* the medicinal product in question is the only product available for the primary treatment of a specific disease (first selection); and

*b)* the manufacturer or the distributor is able to verify that the cost to produce the medicinal product in question is higher than the highest price that can be charged under Subsection (1).

(4)<sup>3</sup> A decision concerning the request referred to in Subsection (3) shall be adopted within ninety days. The health insurance administration agency shall proclaim a notice without delay concerning its consent granted according to Subsection (3).

(5)<sup>4</sup> During the period referred to in Subsection (1), a price above the highest price specified or approved by the Government may not be charged in commercial circles.

(6) If the price is not expressly fixed in the contract, the price specified under the aforesaid measure shall be applied for the product in question. This price shall also apply if the companies involved stipulated a different price unlawfully.

(7) If the price specified in Subsection (1) is abolished between the time when the contract is signed and discharged, the contract shall be discharged at the price stipulated, unless otherwise prescribed by law.

## Chapter VI

### PROVISIONS CONCERNING THE PRESCRIPTION OF MEDICINAL PRODUCTS AND MEDICAL AIDS WHICH ARE EFFICIENT AND OF GOOD QUALITY

#### *Section 44*

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1 Amended by Paragraph a) of Subsection (2) of Section 12 of Act CCLII of 2013.

2 Amended: by Section 8 of Act LXXXIX of 2010. In force: as of 16. 09. 2010.

3 Amended by Sections 360-361 of Act LVI of 2009, Section 8 of Act LXXXIX of 2010, Paragraph b) of Section 129 of Act CLXXXVI of 2015, Point 22 of Section 283 of Act L of 2017.

4 Amended: by Section 360 of Act LVI of 2009. In force: as of 1. 10. 2009.

(1)<sup>1</sup> In the process of prescription of medicinal products and medical aids - including where medicinal products and medical aids are prescribed for treatment in inpatient medical institutions - the doctor shall inform the patient, in a manner that is accessible and understandable to handicapped persons as well and in due compliance with the relevant professional standards and legal provisions on medical treatment, concerning any alternative for the medicinal products and medical aids prescribed for treatment, the difference between the estimated costs to the patient of medicinal products having the same active ingredient and those of the same fixed subsidy group, and medical aids within the same function group, and on any potential substitutes available according to specific other legislation.

➡(2)<sup>2</sup> The person dispensing medicinal products - if the doctor did not preclude substitution on the prescription - shall inform the patient as provided by law, properly documented and according to the potential substitution available under the relevant legislation that a substitute reference medicinal product, or a preferred reference price range medicinal product is available at a lower price instead of the medicinal products prescribed.

➡(3)<sup>3</sup> The person dispensing medicinal products shall, as provided by law, replace the medicinal product prescribed, subject to the patient's consent, with a reference medicinal product, or a preferred reference price range medicinal product specified in Subsection (2) whose price that is payable by the patient is the lowest.

(4) The patient is required to verify receipt of the information referred to in Subsection (1) in the doctor's records, and shall concurrently sign the statement he has made according to the HIS in accordance with specific other legislation.

(5)<sup>4</sup> As regards biological medicinal products, the minister in charge of health insurance shall specify by way of a decree the mandatory minimum ratio of preferred biological medicinal product to be prescribed.

#### *Section 44/A<sup>5</sup>*

Any authorized operator of a public pharmacy and any institutional pharmacy engaged in supplying medicinal products to the general public shall be eligible for reward according to the relevant government decree - funded from the special appropriation earmarked for this purpose in the annual budget of the Health Fund - if:

a) dispensing a preferred reference price range medicinal product, or failing this, the reference medicinal product, or a medicinal product whose daily cost based on therapeutic efficacy is the same or lower than the daily cost of the reference product, or

b) the group of products approved for fixed subsidies is not yet set up, dispensing a medicinal product whose daily cost based on therapeutic efficacy is lower, and that is declared as an equivalent substitute by the government body for pharmaceuticals.

#### *Section 44/B<sup>6</sup>*

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1 Established: by Section 99 of Act CLIV of 2009. In force: as of 1. 01. 2010. Amended: by subparagraph d) Section 83 of Act LXXIX of 2012. In force: as of 1. 07. 2012.

2 Established by Paragraph (1) of Section 123 of Act CLXXVI of 2011. Amended by Paragraph e) of Section 40 of Act XCI of 2023.

3 Established by Subsection (1) of Section 123 of Act CLXXVI of 2011. Amended by Paragraph f) of Section 40 of Act XCI of 2023.

4 Enacted: by paragraph (2) Section 123 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.

5 Established: by Section 124 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.

6 Enacted: by Section 11 of Act CXCVI of 2012. In force: as of 1. 01. 2013.

Any authorized operator of a public pharmacy and any institutional pharmacy engaged in supplying medicinal products to the general public directly shall be eligible for reward in the form of service fee according to the relevant government decree - funded from the special appropriation earmarked for this purpose in the annual budget of the Health Fund - for services provided with a view to promoting patient safety and the safety of medicines.

#### *Section 45*

(1)<sup>1</sup> The service providers and doctors prescribing medicinal products and medical aids with social security subsidy shall perform these activities using an approved computer program with facilities to make recommendations - in accordance with specific other legislation and taking into consideration the provisions contained in Subsection (2) - concerning any alternative for the medicinal products and medical aids prescribed for treatment, to provide information concerning the difference between the estimated costs to the patient and the Health Fund of medicinal products having the same active ingredient and those of the same fixed subsidy group, and medical aids within the same function group, and to make recommendations for medicinal products, medical aids, reference medicinal products, preferred reference price range medicinal products, preferred biological medicinal products and reference medical aids which constitute the least amount of financial burden upon the patients.

(1a)<sup>2</sup> In addition to what is contained in Subsection (1), medicinal products subject to itemized accounting and high-priced medicinal products defined by the relevant legislation may be prescribed by service providers and doctors only if using an approved special computer program featuring a content layout defined by the relevant legislation.

(2) The doctor may prescribe a treatment using medicinal products or medical aids other than those referred to in Subsection (1) in consideration of what is required for the individual patient and for the sickness in question, and in light of the venue where the treatment is provided, after providing the information specified in Subsection (1) of Section 44. The aforesaid substitution shall be recorded in the patient file with a detailed explanation attached.

(3) Any recommendation for medication requiring outpatient treatment, and also the hospital's final report shall indicate the active ingredient, as well as the strength and the pharmaceutical form of the medicinal product, if necessary.

#### *Section 46<sup>3</sup>*

(1) The health insurance administration agency shall assess the performance of healthcare service providers in terms of their practice for the prescription of medicinal products to determine as to whether the products they prescribe are the best in terms of therapeutic efficacy decreed, from the standpoint of the patient and the Health Fund alike, in accordance with the conditions laid down in the relevant decree. The health insurance administration agency may reward the healthcare service providers practicing the prescription of medicinal products according to the conditions and criteria above specified, funded from the special appropriation earmarked for this purpose in the annual budget of the Health Fund.

(2) The health insurance administration agency shall publish on its official website the key data relating to the practice of the healthcare service providers evaluated according to Subsection (1) in terms of their prescription of medicinal products, together with the assessment in a manner enabling analysis.

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1 Established: by paragraph (1) Section 125 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.  
Amended: by subparagraph d) Section 83 of Act LXXIX of 2012. In force: as of 1. 07. 2012.  
2 Enacted: by paragraph (2) Section 125 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.  
3 Established: by Section 67 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.

(3) The detailed regulations concerning the assessment and evaluation criteria, as well as the incentives, rewards and the relevant conditions shall be decreed by the Government.

#### *Section 47*

(1) The health insurance administration agency shall monitor compliance with the professional standards pertaining to the prescription of medicinal products and medical aids when processing prescriptions, and also through the doctors of its supervisory network.

(2) Where a doctor is found engaged in the prescription of medicinal products and/or medical aid without proper eligibility or unlawfully, the health insurance administration agency shall forthwith notify the doctor affected and the health service provider concerning the said discrepancies, and shall proceed according to Section 37 of the HIS.

### **PART II**

## **GENERAL PROVISIONS FOR THE SUPPLY OF MEDICINAL PRODUCTS**

### Chapter I

#### implementation and operation of pharmacies

#### *Section 48<sup>1</sup>*

(1)<sup>2</sup> A new pharmacy - other than temporary branch pharmacies - may be opened and operated in possession of an implementation and an operating permit issued by the government healthcare administration body. The authority shall communicate its definitive decision for authorization of the opening of the new pharmacy to the municipal government of the community where the pharmacy is located, and shall communicate its decisions for authorization of the opening and operation of a pharmacy to the Magyar Gyógyszerészi Kamara (*Hungarian Association of Pharmacists*) as well.

(2)<sup>3</sup> In the proceedings specified in this Act concerning the authorization and control of the establishment, operation, relocation and suspension of the operation of a pharmacy, and the authorization of the right to operate an independent pharmacy the proceedings may be suspended where the decision concerning the incidental question lies with another body, or if the case cannot be reliably resolved without a decision in another proceeding under the competence of the same authority that relates to the case on hand.

(3)<sup>4</sup>

(4)<sup>5</sup>

#### *Section 49<sup>6</sup>*

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1 Established: by Section 68 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.

2 Established by Section 65 of Act XIX of 2023, effective as of 1 June 2023.

3 Established by Section 123 of Act CI of 2021, effective as of 29 June 2021.

4 Repealed by Point 13 of Section 284 of Act L of 2017, effective as of 1 January 2018.

5 Repealed by Point 13 of Section 284 of Act L of 2017, effective as of 1 January 2018.

6 Established: by Section 68 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.

(1) The opening of new public pharmacies shall be authorized - subject to the conditions set out in Subsections (1)-(2) of Section 49/A - by the government body in charge of the healthcare system following a national tender.

(2)<sup>1</sup> The government body in charge of the healthcare system shall publish a tender notice for the implementation of a new pharmacy:

a) upon request by the council of the local government of the community where the registered office of the pharmacy is located, and

aa) if there is no public pharmacy in the community in question, or

ab) the conditions set out in Subsection (2) of Section 49/A are satisfied; or

b) on its own motion, if deemed necessary upon reviewing the requirements set out in Subsections (1)-(2) of Section 49/A; such reviews shall be conducted semi-annually in a calendar year.

(2a)<sup>2</sup> Where it is possible to establish more than one public pharmacy in a municipality based on the population, a tender may be published for the establishment of another public pharmacy in the municipality if the implementation permit and operating license issued upon the previous tender has become final. If considered necessary from the point of view of the supply of medicinal products to the public, at the request of the council of representatives of the municipal government a new tender may be published before the operating license becomes final, indicating the previous implementation address.

(3)<sup>3</sup> The government body in charge of the healthcare system shall publish a nation-wide tender notice, and the content requirements for the tender within sixty days from the time when the tender is requested in the case of Paragraph a) of Subsection (2), or from the date of closure of the review in the case of Paragraph b) of Subsection (2) in the official journal of the ministry governed by the minister in charge of the healthcare system and on its own website. The government body in charge of the healthcare system shall send the tender to the minister in charge of the healthcare system for approval in advance.

(4) The government body in charge of the healthcare system shall evaluate tenders within sixty days from the deadline prescribed in the tender notice for submission of tenders, and shall publish the results in the journal referred to in Subsection (3) and also on its official website. The time limit for the receipt of tenders shall in all cases be at least thirty days from the date of publication.

(5) If the tender notice did not elicit sufficient response within the prescribed time limit, a new tender notice may be published within one month from the original deadline.

(6) The government body in charge of the healthcare system shall authorize the opening of the public pharmacy by way of a resolution addressed to the successful tenderer.

(7)-(11)<sup>4</sup>

(12)<sup>5</sup> The government body in charge of the healthcare system shall withdraw the resolution referred to in Subsection (6) if the pharmacy is not opened by the deadline specified in the resolution.

(13)<sup>6</sup> A tender submitted shall be deemed inadmissible if:

a) the tenderer had no entitlement to submit a tender;

b) the tender submitted is incomplete;

c) the tender does not comply with the requirements set out in the tender notice; or

d) the tender was submitted past the deadline.

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1 Established: by Section 69 of Act LXXXI of 2011. In force: as of 1. 07. 2011.

2 Enacted by Section 124 of Act CI of 2021, effective as of 29 June 2021.

3 Amended: by subparagraph b) paragraph (1) Section 83 of Act LXXXI of 2011. In force: as of 1. 07. 2011.

4 Repealed by Point 3 of Subsection (1) of Section 186 of Act LXVII of 2016, effective as of 1 January 2017.

5 Enacted: by paragraph (2) Section 125 of Act CXXVII of 2013. In force: as of 6. 07. 2013.

6 Enacted by Section 50 of Act XXXIV of 2016, effective as of 1 July 2016.



(14)<sup>1</sup> The tenderers whose tender was rejected may not participate in the tender procedure, or in further stages of the procedure.

(15)<sup>2</sup> A tender procedure shall be declared inconclusive if:

- a) no tenders had been submitted, or
- b) no admissible tenders had been submitted.

#### *Section 49/A*<sup>3</sup>

(1)<sup>4</sup> In any community without a public pharmacy or a branch pharmacy, the government body in charge of the healthcare system shall publish a tender notice for the implementation of a new public pharmacy if the community has a population of at least 4,500.

(2)<sup>5</sup> In any community that already has a public pharmacy, the government body in charge of the healthcare system may publish a tender for the opening of a new public pharmacy if each of the public pharmacies, including the new pharmacy, serve on average at least four thousand residents in a community of an average population of at least fifty thousand and in a Budapest district of an average population of at least fifty thousand, or four thousand and five hundred residents in other communities and other Budapest districts.

(2a)<sup>6</sup> In any community that already has a public pharmacy, the opening of a new public pharmacy may be permitted if the tenderer demonstrates that the existing public pharmacies and the new public pharmacy are at least 250 meters apart, from customer entrance to customer entrance, in a community of a population of at least fifty thousand and in a Budapest district of an average population of at least fifty thousand, or 300 meters apart elsewhere.

(3) The minimum distance between an existing and a new public pharmacy shall be understood as the shortest way by road connection or over public domain.

#### *Section 49/B*<sup>7</sup>

(1) Where a municipality or neighborhood has a branch pharmacy, the government body in charge of the healthcare system shall ask the entity operating a public pharmacy that operates the branch pharmacy - before publishing a tender notice for the opening of a new public pharmacy - to state within thirty days whether it intends to open a public pharmacy in the municipality or neighborhood in question.

(2) If in response to the request made by the government body in charge of the healthcare system under Subsection (1) the entity operating the public pharmacy that operates the branch pharmacy declares:

a) that it intends to operate a public pharmacy in the municipality or neighborhood in question, it shall - at the same time as making a statement - submit an application to the government body in charge of the healthcare system for the opening of a public pharmacy, with the proviso that the provision set out in Subsection (2a) of Section 62 shall apply to both public pharmacies,

b) that it does not intend to operate a public pharmacy in the municipality or neighborhood in question, or fails to respond to the request within thirty days, the government body in charge of the healthcare system shall publish a tender notice for the opening of a new public pharmacy.

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1 Enacted by Section 50 of Act XXXIV of 2016, effective as of 1 July 2016.

2 Enacted by Section 50 of Act XXXIV of 2016, effective as of 1 July 2016.

3 Enacted: by Section 69 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.

4 Established: by Section 70 of Act LXXXI of 2011. In force: as of 1. 07. 2011.

5 Established by Subsection (1) of Section 125 of Act CI of 2021, effective as of 29 June 2021.

6 Enacted by Subsection (2) of Section 125 of Act CI of 2021. Amended by Section 48 of Act XXIV of 2022.

7 Enacted by Section 23 of Act CLXXXVIII of 2017, effective as of 1 July 2018.

(3) Paragraph *b*) of Subsection (2) notwithstanding, the government body in charge of the healthcare system shall publish the tender notice for the opening of a new public pharmacy also if the applicant mentioned in Paragraph *a*) of Subsection (2) fails to comply with the requirements for setting up a new public pharmacy.

(4) The detailed regulations for the proceedings under Subsections (1)-(3) shall be decreed by the Government.

#### *Section 49/C*<sup>1</sup>

(1) The entity operating the public pharmacy shall provide the extra services it has undertaken for a period of at least five years after the opening of the new public pharmacy. The duration of extra services undertaken may not be reduced inside the period specified in the implementation permit, except if the operator is unable to provide such extra services due to unavoidable external reasons (force majeure) relating to its operation. When the force majeure no longer applies, the operator shall perform the extra services undertaken.

(2) The operator shall without delay notify the government body in charge of the healthcare system of the force majeure underlying the reduction under Subsection (1) of extra services undertaken, at the latest within twelve hours after the occurrence of the force majeure.

#### *Section 49/D*<sup>2</sup>

New public pharmacy may not be opened in the premises of State-maintained inpatient care institutions.

### **Implementation of Branch Pharmacies**

#### *Section 50*<sup>3</sup>

(1)<sup>4</sup> In any community or neighborhood of a community that has its own self-government (self-government subdivision) without a public pharmacy or a branch pharmacy, the government body in charge of the healthcare system shall authorize - upon request - the opening and operation of a branch pharmacy, if the applicant is able to satisfy the conditions set out in this Act. A branch pharmacy may be opened in a building, or may be operated as a mobile unit. The operation of the branch pharmacy may be authorized upon the client's request - if the conditions set out in this Act and in the legislation adopted by authorization of this Act are satisfied - for a specific period (season), which has to be so indicated in the resolution authorizing its operation.

(2)<sup>5</sup> With the exception set out in Paragraph *a*) of Subsection (10) of Section 49, the operation of a branch pharmacy shall be authorized, first and foremost, to the operator of the public pharmacy nearest to the entrance of the property at the address indicated by the requesting applicant or the entrance shown on the design of the building planned to be constructed, depending on accessibility by road. If

*a*) the applicant is unable to satisfy the conditions set out in this Act and in the decree adopted by the competent minister by authorization of this Act,

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1 Enacted by Section 3 of Act CXI of 2019, effective as of 1 January 2020.

2 Enacted by Section 53 of Act LIII of 2023, effective as of 7 July 2023.

3 Established: by Section 70 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.

4 Amended by Paragraph *b*) of Section 74 of Act LXXVII of 2015, Paragraph *b*) of Section 55 of Act XXXIV of 2016, Point 1 of Subsection (2) of Section 186 of Act LXVII of 2016.

5 Established by Subsection (1) of Section 65 of Act LXXVII of 2015. Amended by Point 13 of Section 283 of Act L of 2017, Paragraph *b*) of Section 71 of Act XIX of 2023.

b) the operator of the nearest public pharmacy does not wish to open a branch pharmacy in the given community or neighborhood, or

c) the nearest public pharmacy fails to respond within fifteen days to the request made by the government body in charge of the healthcare system for the opening of a branch pharmacy in due consideration of accessibility by road, the government body in charge of the healthcare system may grant authorization to the operator of another public pharmacy - that is considered the nearest in consideration of accessibility by road if there are more than one tenderers involved - for the opening of a branch pharmacy. The operator of a public pharmacy may not be authorized to operate more than three branch pharmacies. Out of three branch pharmacies, one may be operated as a mobile unit. Where the operating permit of the branch pharmacy of a public pharmacy operator has been withdrawn under Subparagraph *ab*) of Paragraph *a*) of Subsection (2) of Section 54 on at least two occasions, such operator may not apply for authorization for the opening and operation of a branch pharmacy for a period of three years calculated from the date when the resolution on the second withdrawal became definitive.

(2a)<sup>1</sup> If, at the request of the government body in charge of the healthcare system, the operator of the public pharmacy - that is considered the nearest depending on accessibility by road - declares his intention to open a branch pharmacy in the community, he shall - at the same time - submit to the government body in charge of the healthcare system an application for the opening of a branch pharmacy.

(2b)<sup>2</sup> Authorization for opening a branch pharmacy in a neighborhood of a community shall be granted if:

a) approved by the local council of the self-government (self-government subdivision) of the neighborhood, and

b)<sup>3</sup> the proposed branch pharmacy and other public pharmacies already existing are at least 1000 meters apart, from customer entrance to customer entrance, measured on public roads.

(3) A branch pharmacy shall function as the satellite of the public pharmacy for which it was authorized. In the case of mobile branch pharmacies, the government body in charge of the healthcare system shall specify in the authorization the communities which are geographically located the closest to the public pharmacy which applied for the operation of the mobile unit, and which may be served by such mobile unit. The population served by a mobile branch pharmacy may not exceed 4,500 on the aggregate covering all communities indicated in the authorization.

#### *Section 50/A*<sup>4</sup>

At the request of the operator of a public pharmacy the government body in charge of the healthcare system shall authorize the relocation of a branch pharmacy. Relocation may only take place inside the limits of the given municipality, within six months from the date when the resolution of authorization of relocation became definitive.

#### *Section 50/B*<sup>5</sup>

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1 Enacted: by Section 126 of Act CXXVII of 2013. In force: as of 6. 07. 2013.

2 Enacted by Subsection (2) of Section 65 of Act LXXVII of 2015, effective as of 1 July 2015.

3 Amended by Paragraph a) of Section 9 of Act CXI of 2019.

4 Established by Section 106 of Act CXI of 2014. Amended by Point 9 of Section 283 of Act L of 2017.

5 Enacted by Section 51 of Act XXXIV of 2016, effective as of 6 May 2016.

(1) In non-stop outdoor events running for at least three consecutive days without interruption, hosting an estimated 20,000 people at any given time and where there is no public or branch pharmacy, the government body in charge of the healthcare system shall authorize - upon request - a temporary branch pharmacy to be installed for the duration of the event, at the venue of the event, if the applicant is able to comply with the conditions set out in this Act and in the ministerial decree adopted by authorization of this Act.

(2)<sup>1</sup> The operation of a temporary branch pharmacy shall be authorized, first and foremost, to the operator of one of three public pharmacies nearest to the main entrance of the event ranked by distance, depending on accessibility by road. If:

a) the applicant is unable to satisfy the conditions set out in this Act and in the decree adopted by the competent minister by authorization of this Act,

b) neither of the three nearest public pharmacies wish to open a temporary branch pharmacy in the given event, or

c) the three public pharmacies which are considered the nearest for reasons of accessibility by road fail to respond within five days to the request made by the government body in charge of the healthcare system for the opening of a temporary branch pharmacy,

the government body in charge of the healthcare system may grant authorization to the operator of another public pharmacy - upon request - for the opening of a temporary branch pharmacy.

(3) The applicant shall be charged an administrative service fee in the amount provided for in the relevant ministerial decree for the proceedings referred to in Subsection (1).

(4)<sup>2</sup>

## **Institutional Pharmacies**

### *Section 51*<sup>3</sup>

(1)<sup>4</sup> Institutional pharmacies may be operated by institutions providing inpatient care subject to authorization by the government body in charge of the healthcare system upon request by the institution providing inpatient care, if the applicant is able to satisfy the conditions set out in this Act and in the Decree on the Operation, the Order of Service and Records System of Public Pharmacies, Branch Pharmacies, Dispensing Pharmacies and Institutional Pharmacies. Institutional pharmacies may dispense medicinal products for use in the institution providing inpatient care and as a direct supply of medicinal products to the public.

(2) Institutional pharmacies are required to provide the necessary facilities separately for institutional supply and for the direct supply of medicinal products to the public. The professional standards for the operation of institutional pharmacies, personnel and infrastructure requirements, mandatory business hours, and the necessary facilities for institutional supply and for the direct supply of medicinal products to the public are laid down in other legislation.

### *Section 51/A*<sup>5</sup>

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1 Amended by Paragraph c) of Section 71 of Act XIX of 2023.

2 Repealed by Point 14 of Section 284 of Act L of 2017, effective as of 1 January 2018.

3 Established: by Section 74 of Act LXXIX of 2012. In force: as of 1. 07. 2012.

4 Amended: by subparagraph c) Section 102 of Act CCXII of 2012, Paragraph a) of Section 75 of Act LXXVII of 2015.

5 Established by Section 54 of Act LIII of 2023, effective as of 7 July 2023.

(1) The State shall provide integrated institutional pharmaceutical services to State-maintained inpatient care institutions also by way of a procedure opened with prior publication of a notice in accordance with the Procurement Act, by signing a contract with the successful tenderer.

(2) The minister delegated by the relevant government decree shall be given authority to carry out the procedure defined in the Procurement Act, to award the contract under the Procurement Act to the successful tenderer, and to amend or terminate such contract with respect to certain procurement procedures.

(3) The successful tenderer of the procedure defined in the Procurement Act shall be liable to establish a special purpose company for the provision of integrated institutional pharmaceutical services.

(4) The special purpose company defined in Subsection (3) shall be liable to obtain the permits related to the provision of integrated institutional pharmaceutical services within one calendar year from the date of conclusion of the contract provided for in the Procurement Act; failure to do so shall result in the termination of the contract provided for in the Procurement Act one calendar year after its conclusion, on the next day.

(5) The detailed provisions for the provision, authorization, performance and regulatory control of the integrated institutional pharmaceutical services shall be decreed by the Government.

(6) In providing integrated institutional pharmaceutical services, the special purpose company referred to in Subsection (3) shall take measures to ensure the quality of service and the level of supply defined in the contract provided for in the Procurement Act and the relevant legislation (hereinafter referred to as "security of supply"). Where the security of supply is compromised for any reason, the successful tenderer of the procedure defined in the Procurement Act and the special purpose company shall provide the State with means of immediate and full-scale intervention, including direct access to the IT and procurement system, during the term of the contract provided for in the Procurement Act on a regular basis.

(7) After the end of the term of the contract provided for in the Procurement Act, the successful tenderer of the procedure defined in the Procurement Act shall surrender the individual drug delivery system free of charge to the State-maintained inpatient care institution in the framework of a take back procedure.

(8) The contract provided for in the Procurement Act may contain a clause stipulating that where performance of the contract provided for in the Procurement Act after changes in the provisions of this Act and in sectoral regulations introduced following conclusion of the contract provided for in the Procurement Act under the same terms and conditions is likely to result in economic disadvantages or harm to the successful tenderer of the procedure defined in the Procurement Act, and such potential changes in the provisions of this Act and in sectoral regulations could not have been anticipated by the successful tenderer of the procedure defined in the Procurement Act at the time of conclusion of the contract provided for in the Procurement Act, the successful tenderer of the procedure defined in the Procurement Act shall have the option to either

a) withdraw from contract provided for in the Procurement Act subject to a notice period of at least three months,

b) request a proportionate reduction of the fee payable by the provider of integrated institutional pharmaceutical services for the provision of integrated institutional pharmaceutical services subject to amendment of the contract provided for in the Procurement Act by court order,

c) request financial compensation of an amount in proportion to the economic disadvantage or harm suffered in a lump sum or in installments.

(9) For the purposes of Subsection (8), sectoral regulation shall include any legislation and legal regulation adopted by the State and the European Union, such as in particular legal provisions relating to public dues applicable to integrated institutional pharmaceutical services, professional and other standards, regulations and internal rules containing binding decisions, as well as any international treaty and agreement pertaining to integrated institutional pharmaceutical services.

(10) In providing integrated institutional pharmaceutical services, the special purpose company referred to in Subsection (3) shall cooperate with the State-maintained institutions providing inpatient care as regards the use of binding IT and document management provisions, standards, software and procedural rules laid down in the contract provided for in the Procurement Act for the healthcare sector (hereinafter referred to as "binding health informatics provisions"). The special purpose company referred to in Subsection (3) shall take measures to ensure the continuous and complete compliance with binding health informatics provisions of the tangible assets, equipment, software it uses, as well as the work processes and procedures it controls or supervises for the provision of integrated institutional pharmaceutical services.

(11) The institutional pharmacy of any non-State-maintained inpatient care institution may sign up voluntarily, in a contractual way for the contract concluded for the provision of integrated institutional pharmaceutical services in accordance with the Procurement Act and Subsections (1)-(9) hereof under the detailed provisions defined by decree of the Government.

## Dispensing Pharmacies

### Section 52

(1)<sup>1</sup> In any community without a public pharmacy or a branch pharmacy, upon the request of a general practitioner the operation of a dispensing pharmacy may be authorized if the conditions set out in this Act and in the legislation adopted by authorization of this Act are satisfied. Such authorization is valid for the applicant only.

(2) A dispensing pharmacy may be authorized for a geographical area where the general practitioner has a practice, provided that there is no public pharmacy or branch pharmacy in the community in a specific calendar period of the year.

(3) If a public pharmacy or branch pharmacy is authorized for a community where a dispensing pharmacy functions as authorized, the authorization for the dispensing pharmacy shall be amended or withdrawn effective as of the day of the opening of such pharmacies.

(4)<sup>2</sup> The medicinal products that may be stocked in a dispensing pharmacy must be purchased in a public pharmacy. Supplies for a dispensing pharmacy shall be obtained - under agreement - primarily from the public pharmacy that is the nearest to the establishment indicated in the general practitioner's operating permit. A public pharmacy may agree to supply not more than four dispensing pharmacies.

(4a)<sup>3</sup> If no agreement is reached with the nearest public pharmacy, an agreement for the supply of medicinal products may be concluded with another public pharmacy that is considered the nearest for reasons of accessibility by road, located no further than thirty kilometers from the proposed dispensing pharmacy.

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1 Established: by paragraph (1) Section 72 of Act CLXXIII of 2010. Amended by Paragraph b) of Section 75 of Act LXXVII of 2015.

2 Established: by Section 75 of Act LXXIX of 2012. In force: as of 1. 07. 2012. Amended: by point 12 Section 137 of Act CXXVII of 2013. In force: as of 6. 07. 2013.

3 Enacted by Section 52 of Act XXXIV of 2016, effective as of 1 July 2016.

(5) The general practitioner may dispense medicinal products from the dispensing pharmacy to his own patients and only based on his own prescription, with the exception of cases of emergency.

(6) In a contract specified in specific other legislation for entitlement to prescribe medicinal products with social security subsidies the health insurance administration agency may define the list of subsidized medicinal products which the general practitioner may dispense from his dispensing pharmacy consistent with professional standards and the principle of cost-efficiency.

### **Authorization of Pharmacies**

#### *Section 53<sup>1</sup>*

(1) A pharmacy may operate:<sup>2</sup>

a) in possession of an implementation permit issued by the government body in charge of the healthcare system;

b) if it has a pharmacist vested with independent right, if a public pharmacy;

c) in possession of an operating permit issued by the government body in charge of the healthcare system;

d) in the case of public pharmacies, if the operator has sufficient liability insurance coverage for damages that the pharmacy may cause; and

e) if the pharmacy is able to meet the conditions decreed by the competent minister regarding architectural requirements, equipment and furniture, and personnel requirements.

(1a)<sup>3</sup> A temporary branch pharmacy may operate in possession of an operating permit issued by the government body in charge of the healthcare system.

(2)<sup>4</sup> A copy of the insurance policy referred to in Paragraph d) of Subsection (1) shall be provided to the government body in charge of the healthcare system before commencing operations, and the opening of the pharmacy shall be notified.

(3) The government body in charge of the healthcare system shall verify compliance with the provisions of Section 75 in the course of the proceedings for the authorization of public pharmacies.

(4)<sup>5</sup> An application for the operating permit shall be submitted to the government body in charge of the healthcare system at least thirty days before the proposed date of opening.

(5)-(6)<sup>6</sup>

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1 Established: by Section 73 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.

2 Amended: by point 13 Section 137 of Act CXXVII of 2013. In force: as of 6. 07. 2013.

3 Enacted by Subsection (1) of Section 53 of Act XXXIV of 2016, effective as of 6 May 2016.

4 Established: by paragraph (1) Section 127 of Act CXXVII of 2013. In force: as of 6. 07. 2013.

5 Amended: by point 14 Section 137 of Act CXXVII of 2013. In force: as of 6. 07. 2013.

6 Repealed by Point 4 of Subsection (1) of Section 186 of Act LXVII of 2016, effective as of 1 January 2017.

(6a)<sup>1</sup> The order of service of a public or branch pharmacy shall be determined - taking into account the prevailing conditions of establishment - by the government body in charge of the healthcare system on a recommendation by the operator of the pharmacy and the manager vested with independent right, fixed in the pharmacy's operating permit. In determining the opening hours the government body in charge of the healthcare system shall take into consideration the order of service of healthcare service providers in the given municipality or neighborhood. All authorized public pharmacies and institutional pharmacies supplying medicinal products to the public as well may be obligated to perform after-hours duty and stand-by duty. In establishing pharmacy after-hours duty and pharmacy stand-by duty the government body in charge of the healthcare system shall take into consideration the accessibility of healthcare service providers in the given municipality or neighborhood, the place and time of medical on-call services, the number of people to be served, and the pharmacy's price margin from the sale of medicinal products with public financing. In order to ensure the uninterrupted supply of medicinal products to the public the process to establish the after-hours and stand-by duty of a pharmacy may be initiated ex officio as well.

(6b)<sup>2</sup> The entity operating the public pharmacy shall be allowed to dispense throughout the opening hours specified in the operating license medicinal products and other products that may be sold in pharmacies exclusively in the customer area. During opening hours medicinal products and other products that may be sold in pharmacies may not be dispensed through a serving window.

(7)<sup>3</sup> The government body in charge of the healthcare system shall send its definitive decision relating to the operation of the pharmacy to the health insurance administration agency, and also to the notary of the competent municipal government.

(8)<sup>4</sup> The right conferred in the authorization for setting up and operating a pharmacy is non-tradable.

#### *Section 53/A<sup>5</sup>*

(1)<sup>6</sup> Operators of pharmacies are to notify any proposed changes affecting the conditions for the issue of the operating permit, or in the particulars shown in the operating permit in advance, in writing to the government body in charge of the healthcare system. Unforeseeable events shall be notified within five working days from the time when detected. If any change concerns the mandatory information to be contained in the operating permit, the amendment of the operating permit shall be requested simultaneously with the notification, with the exception of what is contained in Subsection (4a) and excluding the events occurring owing to unforeseeable, unavoidable external reasons beyond the obligor's control.

(1a)<sup>7</sup> In the case of branch pharmacies and dispensing pharmacies, if the name or address of the supplier public pharmacy is changed, the government body in charge of the healthcare system shall ex officio modify the pharmacy's operating permit.

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1 Enacted by Section 55 of Act CCXXIV of 2015. Amended by Point 16 of Section 284 of Act L of 2017.

2 Enacted by Section 4 of Act CXI of 2019, effective as of 1 January 2020.

3 Enacted by paragraph (2) Section 127 of Act CXXVII of 2013. Amended by Point 18 of Section 283 of Act L of 2017.

4 Enacted by Subsection (3) of Section 53 of Act XXXIV of 2016, effective as of 6 May 2016.

5 Enacted: by Section 74 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.

6 Established by Subsection (1) of Section 74 of Act CCXLIV of 2013, effective as of 1 January 2014.

7 Enacted by Section 108 of Act CXI of 2014, effective as of 1 January 2015.



(2)<sup>1</sup> Upon receipt of the notice referred to in Subsection (1) hereof, the government body in charge of the healthcare system shall amend the operating permit after having carried out an on-site inspection, or without one if the nature of the notification so requires.

(2a)<sup>2</sup> The government body in charge of the healthcare system shall withdraw the implementation permit and the operating permit, if the change in the person of the holder of the independent right has occurred for reasons other than those under Sections 60/B-60/D, or under Paragraph b) of Section 65.

(3)<sup>3</sup> The operator of the pharmacy shall have the right to suspend operations for a maximum period of twenty-one day in a given calendar year. The suspension shall be notified to the government body in charge of the healthcare system at least one month in advance. Unforeseeable suspension shall be notified without delay upon gaining knowledge of the reason substantiating the suspension, in any case on the next day at the latest. The first day of any unplanned suspension may be the day immediately preceding the notification, with retroactive effect, at the earliest.

(4)<sup>4</sup> The written notice referred to in Subsections (3) and (4a) shall indicate the reason for the suspension or change, and the first and - estimated - last day of suspension or change. Re-opening the pharmacy shall be notified to the government body in charge of the healthcare system, if other than the date indicated in the advance notice.

(4a)<sup>5</sup> Where a public pharmacy is the sole supplier of medicinal products in a given municipality, and in connection with changes prescribed by law to accommodate public holidays, the operator of any pharmacy may change the opening hours on not more than ten days in a given calendar year. Any deviation from the order of service as provided for in this Subsection shall be notified to the government body in charge of the healthcare system at least two working days in advance, or if the change cannot be foreseen, immediately upon learning of the reasons thereof, at the latest on the next working day of the order of service.

(5)<sup>6</sup> The government body in charge of the healthcare system, if it finds during the inspection of the pharmacy that certain personnel or infrastructure conditions are temporarily lacking, may call upon the operator of the pharmacy to remedy such deficiencies in its decision with warning.

(5a)<sup>7</sup> If there can be no recourse to the provisions under Subsection (5), in particular if the deficit of personnel or infrastructure conditions has a direct impact on or endangers patient safety and/or patient care interests, the government body in charge of the healthcare system acting in healthcare and pharmaceutical supervisory capacity shall suspend the operation of the pharmacy up to the time limit prescribed for remedying deficiencies.

(5b)<sup>8</sup> If the operator of the pharmacy fails to remedy the discrepancies within the prescribed time limit, the government body in charge of the healthcare system acting in healthcare and pharmaceutical supervisory capacity shall withdraw the operating permit simultaneously with the implementation permit.

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1 Established: by paragraph (1) Section 127 of Act CLXXVI of 2011. Amended by Point 2 of Subsection (2) of Section 186 of Act LXVII of 2016.

2 Enacted: by paragraph (2) Section 127 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.

3 Established by Section 126 of Act CI of 2021, effective as of 29 June 2021.

4 Amended: by point 15 Section 137 of Act CXXVII of 2013. In force: as of 6. 07. 2013.

5 Established by Subsection (2) of Section 74 of Act CCXLIV of 2013, effective as of 1 January 2014.

6 Established by Subsection (1) of Section 84 of Act CLXVIII of 2020, effective as of 1 January 2021.

7 Enacted by Subsection (2) of Section 84 of Act CLXVIII of 2020, effective as of 1 January 2021.

8 Enacted by Subsection (2) of Section 84 of Act CLXVIII of 2020, effective as of 1 January 2021.

(6)<sup>1</sup> If a pharmacy is forced out of business temporarily in the process of being relocated or remodeled, or in a force majeure event, at the operator's written request the government body in charge of the healthcare system shall authorize the suspension of the pharmacy's operation for a period not exceeding one year. The government body in charge of the healthcare system shall establish the first day of suspension upon request, with retroactive effect, as of the day of notification at the earliest. The pharmacy's operating permit shall be withdrawn simultaneously with the implementation permit, if the operator fails to reopen the pharmacy within the one-year period indicated in the decision of suspension.

*Section 53/B<sup>2</sup>*

(1) At the request of the operator of a public pharmacy the government body in charge of the healthcare system shall authorize to have the public pharmacy relocated by amending the operating license.

(2)<sup>3</sup> Relocation according to Subsection (1) hereof shall be permitted only within the same community or locale or district, if the existing public pharmacies and the relocated public pharmacy are at least two hundred fifty meters apart, from customer entrance to customer entrance, in a community or Budapest district of a population of at least fifty thousand, or at least three hundred meters apart in other communities or Budapest districts. The minimum distance between an existing and a relocated public pharmacy shall be understood as the shortest way by road connection or over public domain.

*Section 53/C<sup>4</sup>*

A public pharmacy may be operated only if available to serve the general public at least thirty hours a week, including the opening hours of its branch pharmacy as well.

*Section 53/D<sup>5</sup>*

(1)<sup>6</sup> The government body in charge of the healthcare system shall monitor the ownership structure and lawful representation, and the provisions contained in the memorandum of association or charter document of the business association that operates a pharmacy, or the provisions of other agreements, legal statements having an effect on the provisions described in Subsection (2), for the purposes of control provided for in Subsection (2) and within the framework thereof.

(2) The government body in charge of the healthcare system shall monitor the operations of business associations which operate pharmacies, including pharmacists vested with independent right, for compliance with Section 73, Subsections (3), (5) and (6) of Section 74, Section 75, and Subsections (3), (7) and (8) of Section 83/A.

(3) With a view to ascertaining the relevant facts of the case, the government body in charge of the healthcare system shall have authority:

- a) to conduct a site inspection anywhere it deems appropriate, and
- b) to make a hard mirror image of the data medium held by any person, and to inspect the contents through this image,

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1 Established by Subsection (3) of Section 84 of Act CLXVIII of 2020, effective as of 1 January 2021.  
2 Established by Section 127 of Act CI of 2021, effective as of 29 June 2021.  
3 Established by Section 67 of Act XIX of 2023, effective as of 1 June 2023.  
4 Enacted by Section 67 of Act LXXVII of 2015, effective as of 1 July 2015.  
5 Enacted by Section 40 of Act CLXXII of 2016, effective as of 1 January 2017.  
6 Amended by Paragraph c) of Section 9 of Act CXI of 2019.

if there is reason to believe that the site inspection is likely to reveal information concerning the infringement of the provisions of Section 73, Subsections (3), (5) and (6) of Section 74, Section 75, and Subsection (3) of Section 83/A. The client and the parties concerned need not be notified in advance of the impending site inspection if this is likely to compromise the outcome thereof. Any person and organization contacted shall be liable to make available data from their records and copies of documents in their possession with facilities for reading and copying to the government body in charge of the healthcare system.

(4) The government body in charge of the healthcare system shall be entitled to inspect and process - in connection with monitoring compliance with the provisions of Section 73, Subsections (3), (5) and (6) of Section 74, Section 75, and Subsection (3) of Section 83/A - the personal data of the party to the case and other persons who may be tied to the party. Where a means of evidence contains personal data that does not pertain to the investigation, and if this data cannot be detached without compromising the evidentiary effect of the means of evidence, the government body in charge of the healthcare system shall be entitled to process all personal data affected, however, the entitlement to inspect the personal data that does not pertain to the investigation is valid only to the extent required to ascertain that the data is not connected to the infringement investigated.

(5) With a view to ascertaining the relevant facts of the case, the government body in charge of the healthcare system shall have authority to examine the legal relationship:

a)<sup>1</sup> between the business association that operates the pharmacy and persons engaged under contractual employment relationship,

b) between the business association that operates the pharmacy and any person or organization engaged under contract for the purpose of operating the pharmacy,

c) between a person or organization engaged under contract with the business association that operates the pharmacy for acting on its behalf, and any person or organization engaged in connection with operating the pharmacy, and to make inquiries relating to activities which are in fact carried out.

(6) For the purposes of the inspection referred to in Subsection (5), the parties to the contract, and to the activity shall make available all evidence to show that the activities which are in fact carried out have been effectively implemented in conformity with the relevant contracts.

(7) In the course of enforcement of the provisions of Section 73, Subsections (3), (5) and (6) of Section 74, Section 75, and Subsection (3) of Section 83/A, the government body in charge of the healthcare system shall be empowered to search any premises, to enter such premises under probable cause under his own authority, without the consent of the owner (tenant) or any other person in the premises, and to open any sealed-off area or building for this purpose. In the process of the search the acting officer shall be entitled to demand information, written or oral, from the client, the client's representative (former representative) or employee (former employee), and may gather intelligence in any other way. An on-site inspection may be carried out in the private domain, including vehicles and other premises, if it is in the use of any former or current executive officer of the client, employee or representative, or any other person who effectively exercises control or who exercised control previously.

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1 Amended by Paragraph b) of Section 26 of Act CLXXXVIII of 2017.

(8) The investigative measures specified under Subsection (7) shall be carried out subject to the public prosecutor's prior consent. The prosecuting authority shall authorize the above-specified investigative measure if the government body in charge of the healthcare system is able to show probable cause that any other investigative measure is unlikely to produce the required results, and if there is reason to believe that the source of information - relating to the illegal activity investigated - indicated is in the location for which the court order is requested and it is presumed that this information will not be surrendered voluntarily or that it would be destroyed. If the investigative measure is only partially approved, the prosecuting authority shall specify the type of procedure and the person who is the subject of such procedure. On the basis of having in possession the prosecuting authority's consent the investigative measure may be carried out within a period of ninety days from the date of issue.

(9) Regarding the investigative measure carried out under Subsection (7) the persons affected shall be informed verbally at the time the investigative measure commences, and it shall be carried out, if possible, in the presence of these persons. Before the investigative measure is carried out the purpose of the investigative measure shall be communicated.

(10) Upon hearing a witness, the government body in charge of the healthcare system may order to keep the witness's data confidential if deemed necessary with a view to ascertaining the relevant facts of a case.

(11) If the government body in charge of the healthcare system finds that the business association that operates the pharmacy or the pharmacist vested with independent right infringed either of the provisions of Section 73, Subsections (3), (5) and (6) of Section 74, and Subsection (3) of Section 83/A, it shall suspend the license of the public pharmacy involved and shall simultaneously set a deadline for terminating the infringement. If the business association that operates the pharmacy fails to terminate the infringement in due time, the government body in charge of the healthcare system shall revoke the implementation and operating permit of the public pharmacy within fifteen days after the expiry of the deadline.

(12) If the government body in charge of the healthcare system finds that the business association that operates the pharmacy infringed the provisions of Section 75, it shall suspend the license of four of the public pharmacies involved in the concentration and shall simultaneously set a deadline for terminating the infringement. If the business association that operates the pharmacy fails to terminate the infringement in due time, the government body in charge of the healthcare system shall revoke the implementation and operating permit of the public pharmacy affected within fifteen days after the expiry of the deadline.

(13) Any data, or document recording such data, created during or for the purpose of communications between the party and his lawyer may not be admissible as evidence in the proceedings of the government body in charge of the healthcare system, they may not be examined or seized, and the holder of such documents may not be compelled to produce them for the purpose of inspection.

(14) Any dispute as to whether a document should enjoy the protection under Subsection (13) shall be decided, upon the request of the government body in charge of the healthcare system, by the Fővárosi Törvényszék (*Budapest Metropolitan Court*) in non-contentious proceedings - upon hearing the client - within eight days from the date of submission of the request. If the court rules that the protection under Subsection (13) does not apply to the document, it shall be released to the government body in charge of the healthcare system; henceforward the general provisions applicable to documents shall apply to the released document. If the court's decision is in the client's favor the document shall be released to the client.

(1) The operation of pharmacies is supervised by the government body in charge of the healthcare system. The authority shall withdraw the operating permit, together with the implementation permit, if it finds that the operator of the pharmacy has repeatedly and seriously infringed upon the relevant professional standards concerning:<sup>1</sup>

- a) the stocking of medicinal products;
  - b) the order of service;
  - c) the dispensing of medicinal products, including the prices of medicinal products;
- and

d) the pharmacy's furniture, equipment and products authorized for marketing.

(2)<sup>2</sup> In addition to what is contained in Subsection (1), the operating permit shall be withdrawn - with the exception set out in Subsection (3) of this Section and in Subsection (2) of Section 58 - simultaneously with the implementation permit, within fifteen days upon gaining knowledge of the grounds for withdrawal if:

a)<sup>3</sup> in the case of a branch pharmacy:

aa)<sup>4</sup> a public pharmacy is opened in the community or neighborhood indicated in the operating permit of the branch pharmacy;

ab) it fails to commence operations within six months from the operative date of the implementation permit;

b) in connection with a dispensing pharmacy:

ba) a public or branch pharmacy is opened in the community indicated in the operating permit of the dispensing pharmacy,

bb) the person authorized to operate it no longer satisfies the requirements for authorization;

c)<sup>5</sup> the bodies vested with authority to oversee the operation of pharmacies find any discrepancies, on account of which the pharmacy had to be suspended once again - under the direction of the same business association or pharmacist vested with independent right - within a period of two years;

d)<sup>6</sup> the institution providing inpatient care where the institutional pharmacy is located is terminated;

e)<sup>7</sup> the independent right is withdrawn pursuant to Section 58, or if the independent right is terminated, except where Section 60/B, Section 60/C, Section 60/D and Paragraph b) of Section 65 apply;

f) in the case of mobile branch pharmacies, the operating permit of the branch pharmacy with respect to the community where a non-mobile branch pharmacy or a public pharmacy is opened;

g)<sup>8</sup> so requested by the operator of the pharmacy;

h)<sup>9</sup> the operator of the pharmacy is terminated without succession;

i)<sup>10</sup> the pharmacy did not open for business by the deadline prescribed in the tender notice for reasons attributable to the successful tenderer;

j)<sup>11</sup> the successful tenderer fails to perform the extra services offered in the tender;

k)<sup>12</sup> the business association operating a public pharmacy fails to comply with the requirements set out in Subsection (1) of Section 74;

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1 Amended: by Section 361 of Act LVI of 2009. In force: as of 1. 10. 2009. Amended: by subparagraph e) Section 136 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.

2 Established: by paragraph (1) Section 75 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.

3 Established by Subsection (1) of Section 109 of Act CXI of 2014, effective as of 1 January 2015.

4 Amended by Paragraph c) of Section 26 of Act CLXXXVIII of 2017.

5 Amended by Paragraph h) of Section 80 of Act CCXLIV of 2013.

6 Amended: by subparagraph d) Section 102 of Act CCXII of 2012. In force: as of 1. 01. 2013.

7 Established: by Section 128 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.

8 Enacted: by Section 129 of Act CXXVII of 2013. In force: as of 6. 07. 2013.

9 Enacted: by Section 129 of Act CXXVII of 2013. In force: as of 6. 07. 2013.

10 Enacted by Section 129 of Act CXXVII of 2013. Amended by Paragraph i) of Section 80 of Act CCXLIV of 2013.

11 Enacted by Subsection (2) of Section 109 of Act CXI of 2014, effective as of 1 January 2015.

12 Enacted by Subsection (1) of Section 41 of Act CLXXII of 2016, effective as of 20 December 2016.

l)<sup>1</sup> the pharmacy's contract with the health insurance administration agency for price subsidies ceases to exist;

m)<sup>2</sup> the entity operating the public pharmacy claimed force majeure pursuant to Section 49/C without reason.

(3) The operating permit shall be withdrawn:

a)<sup>3</sup>

b)<sup>4</sup> in the case referred to in Paragraphs a), b) and k) of Subsection (2), on the day when the change occurs;

c) in the case referred to in Paragraph c) of Subsection (2), on the day of gaining knowledge.

## Guarantees for the Supply of Medicinal Products

### Section 55

(1)<sup>5</sup> The activities of public pharmacies may cover the supply of medicinal products to retail stores of daily consumer goods located in small communities with less than 2,000 permanent residents, if licensed to supply medicinal products as non-pharmacy retail establishments, and if providing such service with State subsidies.

(2)<sup>6</sup> Pharmacies - other than dispensing pharmacies, and other than branch pharmacies with opening hours of thirty hours or less - shall operate an information center in their customer area or on their website, if available, or to afford access to an existing electronic information center free of charge. The information center shall have facilities to compare the prices of medicinal products which are interchangeable, or in connection with medical aids, the prices of products within the same group in terms of function, which are available in the pharmacy, and to offer information to customers, patients concerning the administration of non-prescription medicinal products before making a decision whether to buy the medicinal products in question. The person dispensing medicinal products to persons with disabilities and to persons in need of help shall provide assistance for obtaining information concerning the administration and use of the product.

(3)<sup>7</sup>

(4) Pharmacies shall keep stock of the medicinal products specified in specific other legislation, in the quantities defined therein. In connection with pharmacies under contract for the marketing of medicinal products with public financing, the health insurance administration agency may stipulate additional contractual conditions in terms of their service obligation, including the range of medicinal products, dispensing unavailable medicinal products at a later time, the price at which they are dispensed, and the detailed rules for the settlement of subsidies.

(5) Medicinal products may not be dispensed to persons under fourteen years of age. The dispenser of medicinal products - upon providing proof of his own entitlement upon request - may request the person wishing to purchase medicinal products to produce proof of his/her age. In the absence of adequate proof of age the medicinal products may not be dispensed.

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1 Enacted by Subsection (1) of Section 41 of Act CLXXII of 2016, effective as of 20 December 2016.

2 Enacted by Section 6 of Act CXI of 2019, effective as of 1 January 2020.

3 Repealed: by subparagraph e) Section 89 of Act CLXXIII of 2010. No longer in force: as of 1. 01. 2011.

4 Established by Subsection (2) of Section 41 of Act CLXXII of 2016, effective as of 20 December 2016.

5 Established by Section 242 of Act XCIX of 2021, effective as of 1 December 2021.

6 Established: by Section 97 of Act CCXII of 2012. In force: as of 1. 01. 2013.

7 Repealed: by subparagraph b) paragraph (2) Section 126 of Act CLIV of 2009. No longer in force: as of 1. 01. 2010.

(6) With the exception of institutional pharmacies, publicly subsidized medicinal products may not be provided, supplied or offered to pharmacies without any valuable consideration.

(7)<sup>1</sup> The personnel and infrastructure conditions for the operation of pharmacies, including the floor plan, type and quantity of furniture and equipment required, and the requirements for information technology and records systems are contained in specific other legislation.

## **Independent Pharmacy Operation Right**

### *Section 56*

(1)<sup>2</sup> Public pharmacies shall be authorized to function only under the guidance of a pharmacist vested with independent right by authorization of the government body in charge of the healthcare system, covering the entitlements referred to in Section 73 as well. The authorization of independent right may be requested by a pharmacist who is able to satisfy the requirements set out by law. The independent right is granted by the government body in charge of the healthcare system, constituting entitlement for the management and operation of a specific public pharmacy.

(2)<sup>3</sup> Independent right may be authorized for a pharmacist:

a) who, after receiving a diploma in pharmacology, has obtained at least five years of experience (hereinafter referred to as "practical experience") in a public, branch or institutional pharmacy in any Member State of the European Economic Area (hereinafter referred to as "EEA"), or any State enjoying equal treatment with EEA Member States by virtue of an agreement with the European Communities or with the EEA (hereinafter referred to collectively as "EEA Member State"), and

b) within a period of three years since the termination of this activity.

For the purposes of authorization of independent right, the practical experience obtained outside the territory of EEA Member States may also be taken into consideration.

(3)<sup>4</sup> Up to three years of practical experience may be included in the period provided for in Subsection (2) for a pharmacist who was engaged in practicing pharmacy:

a) in connection with pharmacology:

aa) in scientific,

ab) educational, or

ac) in administrative activities;

b) in connection with the manufacturer and supply of medicinal products; or

c) in a pharmacy in a country other than any Member State of the European Union or a State that is a party to the Agreement on the European Economic Area, within a period of three years since the termination of this activity [Paragraphs a)-c) hereinafter referred to collectively as "professional experience"].

(4)<sup>5</sup>

(5) The three-year period referred to in Subsections (3) and (4) shall mean the period between the termination of the activity and the date of filing the application.

### *Section 57*

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1 Established: by paragraph (2) Section 76 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.

2 Established: by Section 77 of Act CLXXIII of 2010. In force: as of 1. 01. 2011. Amended: by subparagraph e) Section 102 of Act CCXII of 2012. In force: as of 1. 01. 2013. Amended: by subparagraph c) Section 138 of Act CXXVII of 2013. In force: as of 6. 07. 2013.

3 Established by Section 75 of Act CCXLIV of 2013, effective as of 1 January 2014.

4 Established by Section 75 of Act CCXLIV of 2013, effective as of 1 January 2014.

5 Repealed by Section 81 of Act CCXLIV of 2013, effective as of 1 January 2014.

- (1) Independent right shall not be authorized to a pharmacist:  
a) whose independent right was withdrawn, for a period of five years from the operative date of the resolution ordering the withdrawal;  
b)<sup>1</sup> who has a prior criminal record or has been restrained by court order from exercising the profession of pharmacist.  
(2)<sup>2</sup> Independent right may be surrendered in writing submitted to the government body in charge of the healthcare system. The operation of a public pharmacy that was operated under independent right may not be terminated within six months from the time of notice, unless another public pharmacy is already operating or one is opened in the same community.

### Section 58<sup>3</sup>

- (1) The authorization for independent right shall be withdrawn if:  
a) the holder of the independent right acted in bad faith during the proceedings for the authorization of the independent right;  
b) the holder of the independent right manages a public pharmacy and:  
ba) the government body in charge of the healthcare system has appointed an official manager for the same public pharmacy within the last three years at least on two occasions for reasons attributable to the holder of the independent right, or  
bb) fails to manage the public pharmacy in person in spite of repeated warning by the government body in charge of the healthcare system;  
c)<sup>4</sup> the holder of the independent right has been convicted of professional malpractice [Section 165 of Act C of 2012 on the Criminal Code (hereinafter referred to as "Criminal Code"), or Section 171 of Act IV of 1978 on the Criminal Code in force until 30 June 2013 (hereinafter referred to as "Act IV/1978")] or for any crime under Chapters XXXVIII-XLIII of the Criminal Code or under Chapter XVII of Act IV/1978 in force until 30 June 2013 by final court verdict, or the holder of the independent right has been sentenced to imprisonment without parole or has been restrained by court order from exercising the profession of pharmacist;  
d)<sup>5</sup> the pharmacist vested with independent right, or any other person working in the pharmacy repeatedly violated the provisions of Subsections (8)-(11) of Section 17 or Subsection (1) of Section 35;  
e)<sup>6</sup> the pharmacist vested with independent right is convicted for fraudulent bankruptcy (Section 404 of the Criminal Code or Section 290 of Act IV/1978 in force until 30 June 2013) by final court verdict;  
f)<sup>7</sup> the implementation and operating permit is withdrawn in case of repeated and grave infringement of regulations relating to the marketing, stocking and dispensing of medicinal products.  
(2) In the cases defined in Subsection (1), after the authorization for independent right is withdrawn, the pharmacy's implementation and operating permit must be withdrawn as well, if the company operating the pharmacy fails to provide a replacement pharmacist vested with independent right within six months, save where Subsection (3) applies.  
(3) In the case referred to in Paragraph e) of Subsection (1), the implementation and operating permit of the business association operating the pharmacy shall be invalidated on the day when the court verdict becomes final. The court shall send the final verdict to the government body in charge of the healthcare system without delay.

1 Established: by Section 102 of Act CLIV of 2009. In force: as of 1. 01. 2010.

2 Established: by Section 78 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.

3 Established: by Section 79 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.

4 Established: by paragraph (1) Section 298 of Act CCXXIII of 2012. In force: as of 1. 07. 2013.

5 Established: by Section 76 of Act LXXIX of 2012. In force: as of 1. 07. 2012. Amended: by subparagraph f) Section 102 of Act CCXII of 2012. In force: as of 1. 01. 2013.

6 Established: by paragraph (2) Section 298 of Act CCXXIII of 2012. In force: as of 1. 07. 2013.

7 Enacted by Section 110 of Act CXI of 2014, effective as of 1 January 2015.



(4) A permit for the implementation and operation of a pharmacy to a business association whose members include a person with independent right had been withdrawn pursuant to Paragraph *e*) of Subsection (1), or if such person held the right of control of the capital or assets - or any part thereof - of a business association operating a pharmacy as referred to in Subsection (3), may not be granted until the time of exoneration from the detrimental consequences attached to prior convictions, or for a period of five years from the date when the court verdict mentioned in Subsection (3) became final.

#### *Section 59<sup>1</sup>*

(1)<sup>2</sup> The independent right shall terminate:

*a*) if the holder of the independent right:

*aa*) has surrendered it, on the day when communicated to the government body in charge of the healthcare system,

*ab*) has died, on the date of death,

*ac*) transfers the independent right pursuant to Section 60/B, on the definitive date of the resolution authorizing the transfer;

*b*) if the independent right is withdrawn, on the day when the resolution has become final;

*c*)<sup>3</sup> if the operating and implementation permit of the public pharmacy managed and operated by a holder of independent right is withdrawn, on the definitive date of the decision on withdrawal.

(2) The decision for the withdrawal of independent right lies with the government body in charge of the healthcare system.

#### *Section 60<sup>4</sup>*

The government body in charge of the healthcare system shall maintain a register that shall be construed as an official public register as regards the data defined in Subparagraph *aa*) of Paragraph *a*), Subparagraph *ca*) of Paragraph *c*) and Paragraph *e*) hereof:<sup>5</sup>

*a*) on pharmacies, broken down according to type, for a period of five years after the termination of the pharmacy, containing:

*aa*)<sup>6</sup> the pharmacy's name and address, electronic mail address and website address, telephone number, any extra services, scope of distribution, the individual identifier received from the government body for pharmaceuticals during the authorization process, order of service and the range of municipalities supplied,

*ab*) the number of the resolution authorizing implementation and operation,

*ac*) the name of the operator, and the ownership structure if a business association,

*ad*) the name of the pharmacist vested with independent right, if a public pharmacy,

*ae*) the name of the general practitioner, if a dispensing pharmacy;

*b*) on the pharmacists holding independent rights, for a period of five years after the termination of the independent right, indicating the independent right holder's:

*ba*) name,

*bb*) place and date of birth,

*bc*) pharmacist registration number,

*bd*) the number of the resolution for authorizing the independent right;

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1 Amended by Point 23 of Section 283 of Act L of 2017.

2 Established: by Section 130 of Act CXXVII of 2013. In force: as of 6. 07. 2013.

3 Established by Section 68 of Act LXXVII of 2015. Amended by Section 46 of Act CLXXII of 2016.

4 Established: by paragraph (1) Section 80 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.

5 Amended: by point 16 Section 137 of Act CXXVII of 2013, Paragraph *c*) of Section 74 of Act LXXVII of 2015.

6 Established by Subsection (1) of Section 128 of Act CI of 2021, effective as of 29 June 2021.

c) on commercial establishments engaged in the retail supply of medicinal products, for a period of five years after the termination of the retail supply of medicinal products, containing:

ca) the name and address of the commercial establishment, and the name of the operator,

cb) the number of the resolution authorizing operation; and

d)<sup>1</sup> on official, sitting and caretaker managers;

e)<sup>2</sup> on pharmacies dispensing medicinal products ordered online;

f)<sup>3</sup> on the particulars of healthcare workers performing healthcare activities in the name of operators of pharmacies and under their responsibility, relating to carrying out such healthcare activities.

#### *Section 60/A<sup>4</sup>*

The government body in charge of the healthcare system shall check in the course of a regulatory inspection relating to the authorization and exercise of independent right and during the period of operation of the public pharmacy as to whether the grounds for exclusion provided for in Paragraph b) of Subsection (1) of Section 57 apply with respect to the pharmacist vested with independent right, or the person referred to in Subsection (4) of Section 58. To that end the government body in charge of the healthcare system shall request information from the penal register.

#### *Section 60/B<sup>5</sup>*

(1) An independent right may be transferred - subject to authorization by the government body in charge of the healthcare system and to approval by the business association operating the pharmacy - to another person with eligibility for independent right under this Act, in which case the operating permit has to be amended.

(2)<sup>6</sup> If transfer is requested, the pharmacist vested with independent right shall be responsible to provide for the management of the pharmacy insofar as the decision for the amendment of the operating license becomes definitive with respect to the transfer of the independent right.

(3)<sup>7</sup> The operator, upon giving consent for the transfer, shall proceed in accordance with Subsection (1) of Section 53/A for the amendment of the operating permit.

#### *Section 60/C<sup>8</sup>*

(1)<sup>9</sup> Where an independent right terminates due to the reason under Subparagraph ab) of Paragraph a) of Subsection (1) of Section 59, it shall be assigned - upon request - to the spouse, or relative in the direct line, or adopted, step and foster child of the holder of the previous independent right, if able to meet the conditions set out in Section 56.

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1 Established by Subsection (2) of Section 128 of Act CI of 2021, effective as of 29 June 2021.

2 Enacted by Section 69 of Act LXXVII of 2015, effective as of 1 July 2015.

3 Enacted by Section 68 of Act XIX of 2023, effective as of 1 June 2023.

4 Established by Subsection (3) of Section 282 of Act L of 2017, effective as of 1 January 2018.

5 Established: by Section 131 of Act CXXVII of 2013. In force: as of 6. 07. 2013.

6 Amended by Point 24 of Section 283 of Act L of 2017.

7 Enacted by Section 54 of Act XXXIV of 2016, effective as of 1 July 2016.

8 Enacted: by paragraph (3) Section 80 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.

9 Amended by subparagraph d) Section 82 of Act LXXXI of 2011, Paragraph j) of Section 80 of Act CCXLIV of 2013.

(2)<sup>1</sup> If there is more than one person who can claim entitlement to the independent right pursuant to Subsection (1) above, who is able to meet the conditions set out in Section 56 as well, such persons shall have forty-five days from the time of death of the previous independent right holder to submit an agreement to the government body in charge of the healthcare system, in which to indicate the person to whom the independent right is transferred.

(3)<sup>2</sup> If the spouse or relative in the direct line of the holder of the previous independent right referred to in Subsection (1) is unable to meet the conditions set out in Section 56, however, one of them is a student of pharmacology or has a diploma in pharmacology, the pharmacy may continue to operate - upon request by the business association operating the pharmacy - under an interim manager until the conditions set out in Section 56 for obtaining the independent right are satisfied.

### *Section 60/D*<sup>3</sup>

(1)<sup>4</sup> Where independent right terminates under Subparagraph *ab*) of Paragraph *a*) of Subsection (1) of Section 59 of this Act, if unanimously requested within six months from the time of death by the spouse or or relative in the direct line, or adopted, step and foster child of the holder of the previous independent right and the supreme body of the business association operating the pharmacy, the government body in charge of the healthcare system may authorize a qualified person who is not currently engaged in the management of the public pharmacy, to manage the pharmacy indicated in the request temporarily.

(1a)<sup>5</sup> An interim manager may be a pharmacist who is able to satisfy the requirements set out in Subsections (2)-(4) of Section 61.

(2) The manager mentioned in Subsection (1) shall be allowed to manage the pharmacy - for which he shall be held fully accountable for medical considerations - for a period of ninety days following the operative date of the grant of probate.

(3) The pharmacist unanimously designated by the heir specified in the grant of probate and the supreme body of the business association operating the pharmacy for authorization concerning the independent right may apply for authorization of the independent right within forty-five days following the operative date of the grant of probate submitted to the government body in charge of the healthcare system. In this case, the government body in charge of the healthcare system shall decide concerning the authorization of the independent right in priority proceedings.

(4) If there are several heirs, the heirs shall decide - in accordance with Subsection (3) - by simple majority in designating a pharmacist vested with independent right.

## **Management of Pharmacies**

### *Section 61*

(1) With the exception of dispensing pharmacies, pharmacies may be managed only by authorized pharmacists.

(2)<sup>6</sup> A public or institutional pharmacy may be managed by a pharmacist who:

*a*) obtained a diploma in pharmacology in a Hungarian university, or whose diploma in pharmacology received in a foreign university had been adopted or provided with a certificate of equivalence, or is recognized;

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1 Amended: by subparagraph d) Section 138 of Act CXXVII of 2013. In force: as of 6. 07. 2013.

2 Amended by point 17 Section 137 of Act CXXVII of 2013, Paragraph k) of Section 80 of Act CCXLIV of 2013, Paragraph h) of Section 114 of Act CXI of 2014.

3 Enacted: by Section 72 of Act LXXXI of 2011. In force: as of 1. 07. 2011.

4 Amended by Paragraph j) of Section 80 of Act CCXLIV of 2013.

5 Enacted by Section 111 of Act CXI of 2014, effective as of 1 January 2015.

6 Established by Section 70 of Act LXXVII of 2015, effective as of 1 July 2015.

b) is authorized to pursue activities independently according to the register of active pharmacists; and

c) has a pharmacist professional qualification for the activity provided for in the decree adopted by the minister in charge of the healthcare system.

(3)<sup>1</sup> In addition to what is contained in Subsection (2), pharmacists who are foreign nationals shall provide proof of their command of the Hungarian language in accordance with specific other legislation. If the professional qualification referred to in Paragraph c) of Subsection (2) is obtained abroad, it shall be recognized according to Article 45(3) of Directive 2005/36/EC on the recognition of professional qualifications.

(4) The following persons may not be authorized to manage a pharmacy:

a)<sup>2</sup> any person whose legal capacity has been partially limited in specific matters or who is under guardianship invoking fully limited legal competency;

b) any person who was banned from practicing pharmacy by final court decision, during the period of the ban.

### *Section 62*

(1) Unless otherwise prescribed in this Act, public pharmacies may be managed only by pharmacists vested with independent right. Holders of independent right may not assign management of the public pharmacy to others, with the exception of another pharmacist with independent right, interim manager or official manager.

(2)<sup>3</sup> Managers of pharmacies which are open more than forty-eight hours a week may not enter into an employment or other similar relationship, and may not maintain such relationship, with the exception of:<sup>4</sup>

a) scientific, educational, lecturing and intellectual activities subject to copyright protection, or

b)<sup>5</sup> substitution up to sixty days per year on the basis of an agreement between public pharmacists with independent rights, relating to public pharmacies operating with a single pharmacist in communities where no other pharmacy is available, or

c)<sup>6</sup> pharmacist activities performed in a public pharmacy or a branch pharmacy of any other public pharmacy, provided that the pharmacist controls a share in the given business association that operates the pharmacy reserved for pharmacists and his or her worktime does not exceed sixty hours a week on the aggregate.

(2a)<sup>7</sup> Managers of pharmacies may manage only one pharmacy, not including the branch pharmacy of the public pharmacy they manage.

(3) Pharmacy managers shall supervise the work performed in the pharmacy, including the branch pharmacy of the public pharmacy. Pharmacy managers have the authority to oversee the work of the pharmacy's staff and to provide professional guidance and give instructions to them.

### *Section 63*

(1)<sup>8</sup> Where the holder of independent right is unable to attend to his/her duties in person relating to the management of the pharmacy for a specific period of time, an interim manager must be appointed in his/her stead to manage the pharmacy.

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1 Established by Section 70 of Act LXXVII of 2015, effective as of 1 July 2015.

2 Established by Subsection (1) of Section 12 of Act CCLII of 2013, effective as of 15 March 2014.

3 Established: by paragraph (1) Section 98 of Act CCXII of 2012. In force: as of 1. 01. 2013.

4 Amended: by point 18 Section 137 of Act CXXVII of 2013. In force: as of 6. 07. 2013.

5 Amended by Paragraph d) of Section 9 of Act CXI of 2019.

6 Enacted by Section 7 of Act CXI of 2019, effective as of 1 January 2020.

7 Enacted: by paragraph (2) Section 98 of Act CCXII of 2012. In force: as of 1. 01. 2013.

8 Established: by paragraph (1) Section 82 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.

(1a)<sup>1</sup> Where the holder of independent right is unable to attend to his duties in person relating to the management of the pharmacy through no fault of his own, and is unable to appoint an interim manager through no fault of his own, the government body in charge of the healthcare system shall permit, if requested by the operator of the pharmacy, the employment of an interim manager for a period of twelve months.

(2)<sup>2</sup> An interim manager may be a pharmacist who is able to satisfy the requirements set out in Subsections (2)-(4) of Section 61. If an interim manager has to be installed for an estimated period of more than sixty days, the person employed must satisfy the requirements laid down in Section 56 for pharmacists vested with independent right.

(3) If an interim manager has to be installed for a period of less than sixty days, the appointment of the interim manager shall be notified to the government body in charge of the healthcare system.

(3a)<sup>3</sup> Irrespective of the person of the interim manager, within a twelve-month period another mandate may be given - at the time of notification - on one occasion, for a maximum duration of thirty days, if the interim manager's mandate was for less than sixty days.

(4) If an interim manager has to be installed for an estimated period of more than sixty days, the appointment of the interim manager is subject to the consent of the government body in charge of the healthcare system.

(5) The authorization for the appointment of an interim manager shall be withdrawn if:

a) independent right is terminated, on the day of termination of the independent right;

b)<sup>4</sup> the interim manager is vested with independent right, on the date when the resolution authorizing independent right becomes definitive;

c) the interim manager is unable to manage the pharmacy for reasons within his control, or if an official manager has to be appointed for the pharmacy in question.

(6)<sup>5</sup> Any person who does not have a diploma in pharmacology may assist in the preparation of medicinal products only under the guidance and supervision of a pharmacist. As regards the home delivery of medicinal products, the manager of the pharmacy shall be held liable for the medicine dispensed. Home delivery of medicinal products may be carried out only by a specialist employee - authorized by law to engage in such activity - of a company holding an authorization for the direct supply of medicinal products to the public. Medicinal products may not be dispensed via mail order houses. In pharmacies medicinal products may be dispensed only by pharmacists or qualified pharmacy staff, with the exceptions specified by decree of the minister in charge of the healthcare system. Conditions for entitlements to dispense medicinal products and for the training of employees who participate in the operation of pharmacies without a diploma in pharmacology are laid down in a decree of the relevant minister.

(6a)<sup>6</sup>

## Government Control of Pharmacies

### Section 64

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1 Enacted by Section 71 of Act LXXVII of 2015, effective as of 1 July 2015.

2 Established by Section 105 of Act CLIV of 2009. Amended by Paragraph i) of Section 114 of Act CXI of 2014.

3 Enacted: by paragraph (1) Section 133 of Act CXXVII of 2013. In force: as of 6. 07. 2013.

4 Amended by Point 25 of Section 283 of Act L of 2017.

5 Established by Section 132 of Act CLXXVI of 2011. Amended by Paragraph l) of Section 80 of Act CCXLIV of 2013, Paragraph b) of Section 19 of Act CXXIX of 2021.

6 Repealed by Paragraph c) of Section 19 of Act CXXIX of 2021, effective as of 1 January 2022.

(1)<sup>1</sup> Responsibility for supervising the operation of pharmacies lies with the State. The government body in charge of the healthcare system is vested with supervisory powers for controlling pharmacies in connection with the distribution of medicinal products, medical aids, dietary supplements and other products that may be sold in pharmacies. In terms of other products sold in pharmacies supervisory powers shall be conferred upon the consumer protection authority for the enforcement of regulations laid down in specific other legislation pertaining to the marketing of such products, and shall take action as specified in the Act on Consumer Protection in the event of any infringement of these provisions.

(2)<sup>2</sup> The government body in charge of the healthcare system shall inform the health insurance administration agency concerning the measures adopted under its supervisory powers.

(3)<sup>3</sup> In accordance with the Act on the General Rules for Trust Services for Electronic Transactions, the government body in charge of the healthcare system shall maintain communication electronically with natural person clients, and/or with the natural persons who are parties to the proceedings in its administrative proceedings related to the establishment and operation of pharmacies.

(4)<sup>4</sup> By way of derogation from Subsection (3), at the request of a natural person client or a natural person who is a party to the proceedings the government body in charge of the healthcare system shall maintain communication in its administrative proceedings related to the establishment and operation of pharmacies on paper.

### Section 65

The government body in charge of the healthcare system may appoint an official manager for a public pharmacy if it is the only public pharmacy in the community for supplying medicinal products and:

a)<sup>5</sup> the independent right was terminated and no application for authorization under Subsection (1) of Section 60/D had been submitted within six months; or

b) following notification of the surrender of independent right in writing, the operator did not notify the replacement pharmacist vested with independent right within six months from the date of the said notification; or

c) the holder of independent right or the interim manager ceased management of the public pharmacy without notice, for reasons within his control; or

d) the holder of independent right has seriously violated the relevant professional standards, in particular the provisions relating to the stocking of medicinal products and the order of service.

### Section 66

(1)<sup>6</sup> A pharmacist with entitlement to manage a pharmacy, and who is not currently engaged in the management of a public pharmacy, may be appointed - in accordance with Subsections (2)-(4) of Section 61 - as an official manager.

(2) The official manager shall be required to take all measures necessary to maintain the operation of the public pharmacy.

(3) The remuneration of the official manager shall be covered by the pharmacy for which he was appointed.

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1 Established: by Section 73 of Act LXXXI of 2011. In force: as of 1. 07. 2011.

2 Amended: by subparagraph ef) paragraph (1) Section 25 of Act LXXXIX of 2010. In force: as of 17. 08. 2010. Amended: by subparagraph e) Section 138 of Act CXXVII of 2013. In force: as of 6. 07. 2013.

3 Enacted by Section 129 of Act CI of 2021, effective as of 29 June 2021.

4 Enacted by Section 129 of Act CI of 2021, effective as of 29 June 2021.

5 Established: by Section 74 of Act LXXXI of 2011. In force: as of 1. 07. 2011.

6 Amended by Paragraph j) of Section 114 of Act CXI of 2014.

(4) The appointment of the official manager shall be withdrawn before the original term of appointment if the official manager has breached his obligations specified in Subsection (2) repeatedly in spite of warning.

## Chapter II

### MARKETING MEDICINAL PRODUCTS BY ENTITIES OTHER THAN PHARMACIES

#### *Section 67*

(1) Companies which are not authorized to operate pharmacies may engage in the retail supply of medicinal products subject to compliance with the requirements set out in other legislation governing trade and commercial activities and in this Act, and also other legal regulations adopted under authorization conferred by this Act.

(2) Medicinal products may be supplied by entities other than pharmacies if:

- a)* they may be dispensed in pharmacies without a prescription; and
- b)* before applied, self-diagnosis can be clearly obtained, and any error is unlikely or it is not presumed to result in grave consequences; and
- c)* the risk factor it carries (side-effect, interaction) is insignificant even in the event of a massive overdose.

#### **Requirements for Authorization**

#### *Section 68*

(1)<sup>1</sup> Commercial establishments authorized to pursue commercial activity under the Trade Act may engage in the supply of medicinal products if so authorized by the government body in charge of the healthcare system. The government body in charge of the healthcare system shall inter alia communicate its decision authorizing the retail supply of medicinal products to the authority that has registered the commercial establishment in question. The government body in charge of the healthcare system shall authorize the supply of medicinal products if the commercial establishment is able to comply with the requirements set out in this Act and in the ministerial decree on the marketing of medicinal products for human use. The authorization, however, shall not cover the offering of medicinal products for sale to the public within the framework of distance contracts.

(2) The commercial establishment referred to in Subsection (1) may engage in the retail supply of medicinal products if:

- a)* it has facilities for the proper storage of medicinal products, safely isolated from all other products, in compliance with the instructions contained in the marketing authorization of the medicinal products; and
- b)* it has an approved information center that is available during the business hours of the commercial establishment, or is able to afford access to an existing electronic information center free of charge for providing information to consumers for the safe use of medicinal products;
- c)* notifies to the government body in charge of the healthcare system the person placed in charge in the commercial establishment to enforce the legal regulations pertaining to medicinal products.

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<sup>1</sup> Established by Subsection (1) of Section 243 of Act XCIX of 2021, effective as of 1 December 2021.

(3)<sup>1</sup> Except as provided in Subsection (3a), a commercial establishment authorized for the retail supply of medicinal products may purchase medicinal products only from authorized wholesale distributors of medicinal products, and may sell them only to the final consumers.

(3a)<sup>2</sup> Retail stores of daily consumer goods located in small communities with less than 2,000 permanent residents, licensed to supply medicinal products as non-pharmacy retail establishments with State subsidies shall on general principle conclude an agreement with the public pharmacy that is located the closest for the procurement of medicinal products. If no agreement is reached with the closest public pharmacy, an agreement for the supply of medicinal products may be concluded with another public pharmacy that is considered the closest for reasons of accessibility by road, located no further than thirty kilometers.

(4)<sup>3</sup> The operator of a non-pharmacy retail establishment licensed to supply medicinal products shall submit a notification if planning to terminate such activity, or planning to close the authorized commercial establishment or if it was terminated. Upon receipt of such notification the government body in charge of the healthcare system shall withdraw the authorization for the marketing of medicinal products.

### Section 69

(1)<sup>4</sup> With the exception of herbal medicinal products of tea form or traditional herbal medicinal products of tea form, medicinal products may not be displayed in the commercial establishment in places which are directly accessible to consumers; they must be kept in locked cabinets.

(2) The quantity of medicinal products or a certain specific group of medicinal products that may be dispensed at any one time may be limited under specific other legislation.

(3) Medicinal products may not be dispensed to persons under fourteen years of age.

(4) In order to enforce the age limit specified in Subsection (3), the person acting on behalf of the retail supplier of medicinal products - upon providing proof of his own entitlement upon request - may request the person wishing to purchase medicinal products to produce proof of his/her age. In the absence of adequate proof of age the medicinal products may not be dispensed.

## Information Obligations

### Section 70

(1) In addition to what is contained in Paragraph *b*) of Subsection (2) of Section 68, commercial establishments engaged in the retail supply of medicinal products are required to display in their customer area all information material provided to patients in connection with the medicinal products supplied - as specified in the marketing authorization - in printed format to enable the customers to access the information relating to the administration of the product in question before making a decision as to whether to buy the medicinal products in question.

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1 Established by Subsection (2) of Section 243 of Act XCIX of 2021, effective as of 1 December 2021.

2 Enacted by Subsection (3) of Section 243 of Act XCIX of 2021, effective as of 1 December 2021.

3 Enacted by Section 76 of Act CCXLIV of 2013, effective as of 1 January 2014.

4 Established: by Section 75 of Act LXXXI of 2011. In force: as of 1. 07. 2011.



(2)<sup>1</sup> Commercial establishments shall - in their Standard Operating Procedures - designate a person appointed to provide assistance to handicapped persons and to persons in need of help in obtaining the information concerning the administration and use of medicinal products as specified in Paragraph *b*) of Subsection (2) of Section 68 and in Subsection (1) of this Section.

### *Section 71*

(1)<sup>2</sup> The provisions relating to discounts provided directly to consumers shall also apply to the retail supply of medicinal products by entities other than pharmacies.

(2) The list of medicinal products that may be supplied by entities other than pharmacies and professional standards for their selection, and the detailed regulations for marketing shall be laid down in specific other legislation.

(3)<sup>3</sup> The provisions of Subsections (2)-(3) of Section 73 of this Act shall also apply in connection with the retail supply of medicinal products by entities other than pharmacies.

## **Control of the Retail Supply of Medicinal Products by Entities Other Than Pharmacies**

### *Section 72*

(1) The government body in charge of the healthcare system is vested with authority to supervise the retail supply of medicinal products by entities other than pharmacies in terms of the requirements set out in this Act and in other legislation adopted by authorization conferred under this Act.

(2) In the control proceedings the government body in charge of the healthcare system shall establish the facts, and shall take the measures consistent with the nature and severity of any discrepancies and irregularities, and shall monitor their implementation.

(3) Where the government body in charge of the healthcare system finds that a retail supplier of medicinal products is in non-compliance with the requirements set out in this Act or any other legislation adopted by authorization of this Act, or is in breach of the obligations conferred upon it, the government body in charge of the healthcare system shall:<sup>4</sup>

- a*) order the state of infringement to be terminated;
- b*) prohibit continuation of the illegal conduct;
- c*) order the medicinal product or the production batch that is deemed harmful to life, health or physical safety to be removed from the market;
- d*) order the infringer to eliminate the discrepancies within the prescribed deadline and may suspend the further supply of medicinal products until the said discrepancies are eliminated;
- e*)<sup>5</sup> withdraw the authorization of repeat offenders for the supply of medicinal products in the commercial establishment.

(4) If the infringement is committed by a retail supplier of medicinal products that is part of store chain, the decisions specified in Paragraphs *c*)-*e*) of Subsection (3) may be applied with respect to all commercial establishments in that chain.

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1 Amended by Paragraph *k*) of Section 114 of Act CXI of 2014.

2 Amended: by subparagraph *c*) paragraph (4) Section 73 of Act CVI of 2008. In force: as of 01. 01. 2009.

3 Amended: by subparagraph *f*) Section 138 of Act CXXVII of 2013. In force: as of 6. 07. 2013.

4 Amended: by Section 361 of Act LVI of 2009. In force: as of 1. 10. 2009.

5 Amended: by point 20 Section 137 of Act CXXVII of 2013. In force: as of 6. 07. 2013. The change does not effect the English version.

(5)<sup>1</sup> The government body in charge of the healthcare system shall have powers to impose penalties upon the person having committed the infringement. In the case of multiple violations the amount of fines imposed may be cumulative.

(6)<sup>2</sup> The fine shall be minimum one hundred thousand forints, or maximum 1 per cent of the infringing business entity's net domestic sales of the product in question in the previous calendar year.

(7)<sup>3</sup> The period of suspension under Paragraph *d*) of Subsection (3) may not exceed ninety days.

## Miscellaneous Provisions

### Section 73

(1)<sup>4</sup> The business association that operates a pharmacy may not give instructions to the pharmacy's managerial staff nor to persons providing specialized services in the pharmacy regarding technical matters relating to the supply of medicinal products, such as the dispensation and storage of medicinal products, and information provided to patients in connection with medicinal products, including the related commercial practices. The decisions of the supreme body of a business association that operates a pharmacy (meeting of members, members' meeting, general meeting) relating to the management of the pharmacy and to the technical and professional aspects of public financing must have the affirmative vote of the pharmacist vested with independent right, who manages the pharmacy, such as defining the order of service and the scope of products the pharmacy wishes to supply, activities relating to purchases and to maintaining a stock of medicinal products, the dispensation and storage of medicinal products, and to providing information to patients in connection with medicinal products, including the related commercial practices, to the employment of persons providing specialized services in the pharmacy, and to the conclusion and amendment of contracts for public financing. Any arrangement, statement made, or contract or agreement concluded to the contrary or in circumvention thereof shall be null and void.

(2) Operators of pharmacies may not enter into any agreement and shall not accept any inducement that may jeopardize or compromise the safe and reliable supply of medicinal products to consumers. Members of the technical staff of pharmacies may not undertake any contractual obligation and shall not accept any inducement that may restrict or compromise their independence, in particular that could affect their impartiality or objectivity toward patients.

(3) The prohibition of accepting any inducement shall not apply - with the exception contained in Subsection (6) of Section 55 - to the use of discounts based on generally accepted prices and other contractual terms, nor the fulfillment of contractual obligations applied by the health insurance administration agency in connection with medicinal products with public financing.

(4)<sup>5</sup> Monitoring compliance with the provisions contained in Subsections (1) and (2) shall fall within the competence of the government body in charge of the healthcare system.

### Section 74

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1 Amended: by Section 361 of Act LVI of 2009. In force: as of 1. 10. 2009.

2 Established by Subsection (1) of Section 85 of Act CLXVIII of 2020, effective as of 1 January 2021.

3 Enacted by Subsection (2) of Section 85 of Act CLXVIII of 2020, effective as of 1 January 2021.

4 Established by Section 56 of Act CCXXIV of 2015. Amended by Paragraph e) of Section 9 of Act CXI of 2019.

5 Established: by Section 9 of Act LXXXIX of 2010. In force: as of 16. 09. 2010.

(1)<sup>1</sup> A business association may operate a public pharmacy if:

a) the ownership share of the pharmacist vested with independent right, who manages the pharmacy, or

b)<sup>2</sup> the ownership share of the pharmacist vested with independent right together with other pharmacists employed in the pharmacy under some other form of employment relationship, combined with the ownership share of pharmacists holding an ownership share in the business association that operates a pharmacy, including also the share acquired by way of inheritance of a university student attending - as verified - a college of pharmacy, exceed 50 per cent.

(1a)<sup>3</sup> The ownership share of the pharmacist vested with independent right, the share of any other pharmacist employed in the pharmacy under some other form of employment relationship, and the ownership share of pharmacists holding an ownership share in the business association that operates a pharmacy may be taken into account with respect to not more than four public pharmacies indicated by the pharmacist in question.

(2)<sup>4</sup> A copy of the articles of association shall be provided to the government body in charge of the healthcare system when the company is established, and any subsequent amendment shall be notified within thirty days of their effective date with a copy of the amended articles of association enclosed.

(3)<sup>5</sup> An authorized manufacturer of medicinal products or a business association authorized for the wholesale distribution of medicinal products may not acquire any share - either directly or indirectly - in a business association that operates a pharmacy contracted to dispense medicinal products with public financing, nor any natural person, company or company group that has a share - either directly or indirectly - in a company that operates at least four pharmacies, or any business association that is established in a State in which it is not involved in the pursuit of economic activities and where national tax laws do not impose any tax liability in the nature of corporate tax, or if the quotient of the tax amount payable for the tax year - that is the equivalent to corporate tax - and the amount construed as the pre-tax profit is less than two-thirds of the percentage rate defined in Section 19 of Act LXXXI of 1996 on Corporate Tax and Dividend Tax.

(4)<sup>6</sup> In pharmacies already existing on 1 January 2011, and in any pharmacy established after the time of this Act entering into force, in which a doctor with entitlement for the prescription of subsidized medicinal products has an ownership share, the government body in charge of the healthcare system shall check as to whether any agreement exist among pharmacies marketing medicinal products with public financing under contract, manufacturers and distributors of medicinal products, and doctors with entitlement for the prescription of subsidized medicinal products, that may jeopardize or compromise the safe and reliable supply of medicinal products to patients. Where this is considered to jeopardize or compromise the safe and reliable supply of medicinal products to patients, the government body in charge of the healthcare system shall approach the health insurance administration agency to terminate the contract in which the right for supplying subsidized products is granted.

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1 Established: by paragraph (1) Section 100 of Act CCXII of 2012. In force: as of 1. 01. 2013.

2 Amended by Paragraph m) of Section 80 of Act CCXLIV of 2013.

3 Enacted: by paragraph (2) Section 100 of Act CCXII of 2012. In force: as of 1. 01. 2013.

4 Established: by paragraph (1) Section 134 of Act CXXVII of 2013. In force: as of 6. 07. 2013.

5 Established by Subsection (2) of Section 84 of Act CLXXIII of 2010. Amended by Paragraph d) of Section 71 of Act XIX of 2023.

6 Established: by paragraph (2) Section 84 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.

(5)<sup>1</sup> The management and representation of a business association operating a public pharmacy shall be carried out, in the case defined under Subsection (1) of Section 73, independently by a pharmacist vested with independent right in respect of the given pharmacy.

(6)<sup>2</sup> The business association that operates a public pharmacy shall ensure that the pharmacist holding an ownership share is able to exercise members' rights in the percentage of his holding, as fixed in the articles of association. Any arrangement to the contrary is null and void.

(7)<sup>3</sup> In the event of the death of a pharmacist holding an ownership share in the business association that operates a pharmacy, the requirements set out in Paragraph *b*) of Subsection (1) shall be satisfied within forty-five days after the grant of probate becomes final.

(8)<sup>4</sup> If dissolution without succession of the business association operating a public pharmacy takes place on the grounds that only one partner remains, and the partnership does not apply for the registration of a new member at the registration authority within a preclusive period of six months from that time, the pharmacist with independent right for operating the public pharmacy, who remained in the business association as a sole member, shall be entitled to continue to operate the pharmacy as a private entrepreneur following modification of the operating license.

#### *Section 74/A*<sup>5</sup>

Acting for and on behalf of a private individual, home delivery of medicinal products is not permitted within the framework of the business of shopping and home delivery service.

#### *Section 74/B*<sup>6</sup>

#### *Section 75*<sup>7</sup>

Concentration shall not be authorized if it would give - direct or indirect - control to a given business association or company group, or the same natural person over more than four public pharmacies, moreover, concentration shall not be authorized if it would give - direct or indirect - control to a given business association or company group, or the same natural person over three or more pharmacies in a community with a population of less than twenty thousand.

#### *Section 76*

(1)<sup>8</sup> The pharmacist who operates a public pharmacy under independent right - not including the case when the holder of independent right is a member of a business association - shall be treated as a private entrepreneur as regards the application of social security and financial regulations, furthermore, a public pharmacy may be set up as a sole proprietorship as well.

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1 Enacted: by paragraph (3) Section 84 of Act CLXXIII of 2010. In force: as of 1. 01. 2011. Amended: by point 22 Section 137 of Act CXXVII of 2013. In force: as of 6. 07. 2013.

2 Enacted: by paragraph (2) Section 134 of Act CXXVII of 2013. In force: as of 1. 01. 2014.

3 Enacted by Section 30 of Act LIX of 2017, effective as of 9 June 2017.

4 Enacted by Section 8 of Act CXI of 2019, effective as of 1 January 2020.

5 Established by Section 17 of Act CXXIX of 2021, effective as of 1 January 2022.

6 Repealed by Point 6 of Subsection (1) of Section 186 of Act LXVII of 2016, effective as of 1 January 2017.

7 Established by Section 77 of Act LXXIX of 2012. Amended by Point 2 of Section 56 of Act LIII of 2023.

8 Established: by Section 76 of Act LXXXI of 2011. In force: as of 1. 07. 2011.

(2)-(5)<sup>1</sup>

*Section 77*

(1) The Government is hereby authorized to decree:

a)<sup>2</sup> the detailed regulations concerning the evaluation of healthcare service providers in terms of their practice for the prescription of medicinal products, the criteria for such evaluation, the incentives, grants, and the relevant conditions;

b) the conditions for providing financial support to cover the operating expenses of pharmacies;

c)<sup>3</sup> the regulations for the fines to be imposed in connection with any infringement of the provisions governing the promotion of medicinal products and medical aids, including the conditions for their payment;

d)<sup>4</sup> the regulations concerning the conditions of eligibility for the benefits referred to in Section 44/A, as well as for the rate, amount and payment of such benefits;

e)<sup>5</sup> the detailed regulations concerning the allowances available in respect of the costs of research and development;

f)<sup>6</sup> the detailed regulations relating to subsidy volume agreements;

g)<sup>7</sup> the amount of the financial penalty relating to the web-based medical aid catalogue of the health insurance administration agency, and the rules for the payment of such penalties;

h)<sup>8</sup> the detailed regulations relating to the payment and the amount of the service fee to be provided to pharmacies;

i)<sup>9</sup> the detailed regulations relating to setting up a pharmacy, to the authorization procedures, to publishing a tender notice for the opening of a new public pharmacy and for the evaluation of tenders, and the detailed regulations for the proceedings under Subsections (1)-(3) of Section 49/B;

j)<sup>10</sup> the procedural rules for the approval of the computer program for the prescription of medicinal products and medical aids;

k)<sup>11</sup> the detailed regulations concerning the list of medical aid suppliers and the rating of such suppliers;

l)<sup>12</sup> the rules relating to the procedures for providing subsidies for custom-made medical aids;

m)<sup>13</sup> the detailed provisions for the provision, authorization, performance and regulatory control of the integrated institutional pharmaceutical services;

n)<sup>14</sup> the body delegated for the authorization and regulatory control of the provision of integrated institutional pharmaceutical services;

o)<sup>15</sup> the appointment of the minister referred to in Subsection (2) of Section 51/A;

1 Repealed: by subparagraph c) paragraph (2) Section 126 of Act CLIV of 2009. No longer in force: as of 1. 01. 2010.

2 Established: by paragraph (1) Section 86 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.

3 Established: by paragraph (3) Section 23 of Act CLXVI of 2011. In force: as of 1. 01. 2012.

4 Enacted: by paragraph (2) Section 145 of Act I of 2008. In force: as of 19. 02. 2008.

5 Established: by Section 77 of Act LXXXI of 2011. In force: as of 1. 07. 2011.

6 Enacted: by paragraph (1) Section 106 of Act CLIV of 2009. In force: as of 1. 01. 2010.

7 Enacted: by paragraph (1) Section 134 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.

8 Enacted: by Section 12 of Act CXCVI of 2012. In force: as of 1. 01. 2013.

9 Established by Subsection (1) of Section 25 of Act CLXXXVIII of 2017, effective as of 1 July 2018.

10 Enacted by Subsection (4) of Section 282 of Act L of 2017, effective as of 1 January 2018.

11 Enacted by Subsection (4) of Section 282 of Act L of 2017, effective as of 1 January 2018.

12 Enacted by Subsection (4) of Section 282 of Act L of 2017, effective as of 1 January 2018.

13 Established by Subsection (1) of Section 55 of Act LIII of 2023, effective as of 7 July 2023.

14 Enacted by Subsection (2) of Section 55 of Act LIII of 2023, effective as of 7 July 2023.

15 Enacted by Subsection (2) of Section 55 of Act LIII of 2023, effective as of 7 July 2023.

p)<sup>1</sup> the detailed provisions for non-State-maintained inpatient care institutions for signing up voluntarily for the contract concluded for the provision of integrated institutional pharmaceutical services in accordance with the Procurement Act and Subsections (1)-(9) of Section 51/A.

(2) The minister in charge of the healthcare system is hereby authorized to decree:

a) professional standards for the operation of institutional pharmacies, personnel and material conditions, mandatory business hours, and the necessary facilities for institutional supply and for the direct supply of medicinal products to the public;

b) the medicinal products and other products that may be sold in pharmacies, and the detailed regulations for dispensing them;

c) the list of medicinal products and therapeutic preparations which are not classified as medicinal products that may be supplied by entities other than pharmacies and the professional standards for their selection, the personnel and material conditions for supplying them, and the rules for maintaining a stock of them;

d) the order of service of pharmacies;

e) the list of medicinal products to be kept in compulsory reserve in pharmacies;

f)<sup>2</sup> the personnel requirements required for pharmacies, and other requirements concerning the floor plan, type and quantity of furniture and equipment of pharmacies;

g) the records and administration procedures of pharmacies;

h) the provisions for maintaining the register of pharmacist;

i)<sup>3</sup>

j)<sup>4</sup> the detailed regulations pertaining to the promotion of medicinal products, medical aids and dietary supplements and the detailed conditions for the pursuit of such promotional activities, the detailed procedural rules for the notification of promotional activities and for maintaining the register of promoters of medicinal products and medical sales representatives, for the issue and any subsequent amendment of the certificates of medical sales representatives and the contents of such certificates other than personal data, furthermore, the sanctions for any infringement of the provisions of the relevant legislation or of the resolutions adopted by the competent authorities pertaining to the promotion of medicinal products, medical aids and dietary supplements, and the provisions relating to business-to-consumer commercial practices in connection with therapeutic preparations which are not classified as medicinal products and dietary supplements, and the data and information to be reported in connection with any event or training course arranged by promoters of medicinal products;

k)<sup>5</sup> the ATC-groups for the assessment of procedures of healthcare service providers for the prescription of medicinal products, the active ingredients to be assessed, the preferred ratio of apportionment, target parameters, and the conditions relating to the quantity or volume of prescribed medicinal products, under which the procedures for the prescription of medicinal products will not be evaluated;

l)<sup>6</sup> the information to be disclosed in the notice published under Subsection (4) of Section 24 and Subsection (6) of Section 33 concerning the medicinal products, dietary supplements and medical aids which are subsidized under the social security system;

m)<sup>7</sup>

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1 Enacted by Subsection (2) of Section 55 of Act LIII of 2023, effective as of 7 July 2023.

2 Established: by paragraph (2) Section 86 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.


3 Repealed by Point 17 of Section 284 of Act L of 2017, effective as of 1 January 2018.

4 Established by Subsection (2) of Section 185 of Act LXVII of 2016, effective as of 1 January 2017.

5 Established: by paragraph (3) Section 86 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.

6 Enacted: by paragraph (7) Section 359 of Act LVI of 2009. In force: as of 1. 10. 2009. Shall apply to proceedings opened subsequently and to reopened cases. Amended: by subparagraph c) paragraph (10) Section 127 of Act CLIV of 2009. In force: as of 1. 03. 2010.

7 Repealed by Point 17 of Section 284 of Act L of 2017, effective as of 1 January 2018.

- n)<sup>1</sup> the detailed regulations concerning the online medical aid catalogue of the health insurance administration agency;
- o)<sup>2</sup> the criteria for the prescription of medicinal products under the fully subsidized public healthcare system;
- p)<sup>3</sup> the conditions for the approval of the computer program for the prescription of medicinal products and medical aids;
- q)<sup>4</sup> the detailed regulations concerning the mandatory layout of records the business associations authorized for the wholesale distribution of medicinal products are required to keep on the liabilities of pharmacies towards business associations authorized for the wholesale distribution of medicinal products, including the provision of information;
- r)<sup>5</sup> the procedures connected to dispensing medicinal products within the framework of the direct supply of medicinal products to the public and to patient cooperation;
- s)<sup>6</sup> the parameters relating to the patient number and daily cost based on therapeutic efficacy referred to in Paragraph a) of Subsection (3a) of Section 26;
- t)<sup>7</sup> the conditions referred to in Paragraph e) of Subsection (3a) of Section 26;
- u)<sup>8</sup> the criteria for the re-examination of medicinal products affected by the conclusion of efficacy-based subsidy volume agreements;
- v)<sup>9</sup> the mandatory minimum ratio of preferred biological medicinal product to be prescribed;
- w)<sup>10</sup> the conditions of and the rules for the home delivery of medical aids;
-  x)<sup>11</sup> the type of medical aids, in the case of which the distributor of such medical aids is allowed to derogate in the process of dispensing from the price approved as the basis for public financing and from the amount the patient is required to pay as determined by the health insurance administration agency in proceedings for the approval for subsidies, including the amount of change;
- y)<sup>12</sup> the list of medical aids prescribed with social security subsidies, which are eligible for home delivery with the involvement of auxiliary agents.
- (3) The minister in charge of supervising the food supply chain is hereby authorized to decree:<sup>13</sup>
- a) the regulations concerning institutional pharmacies operating in veterinary institutions, and for the stocking of medicinal products in the dispensing pharmacies of veterinarians;
- b) the conditions for the supply of packaged products used solely for veterinary purposes.
- (4)<sup>14</sup> The minister in charge of the healthcare system is hereby authorized to decree, in agreement with the minister in charge of taxation, the types of administrative service fees, including their amounts and other regulations relating to payment terms and conditions:
- a)<sup>15</sup> according to Subsection (9) of Section 12;

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1 Enacted: by paragraph (2) Section 106 of Act CLIV of 2009. In force: as of 1. 03. 2010.

2 Established by Section 18 of Act CXXIX of 2021, effective as of 1 May 2022.

3 Established by Subsection (2) of Section 25 of Act CLXXXVIII of 2017, effective as of 1 January 2018.

4 Enacted: by paragraph (4) Section 86 of Act CLXXXIII of 2010. In force: as of 1. 01. 2011.

5 Enacted: by paragraph (2) Section 134 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.

6 Enacted: by paragraph (2) Section 134 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.

7 Enacted: by paragraph (2) Section 134 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.

8 Enacted: by paragraph (2) Section 134 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.

9 Enacted: by paragraph (2) Section 134 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.

10 Enacted: by paragraph (2) Section 134 of Act CLXXVI of 2011. In force: as of 1. 01. 2012.

11 Enacted by Section 78 of Act LXXIX of 2012. Amended by Paragraph g) of Section 40 of Act XCI of 2023.

12 Enacted by Section 77 of Act CCXLIV of 2013, effective as of 1 January 2014.

13 Amended: by subparagraph s) Section 85 of Act XLVI of 2008. In force: as of 01. 09. 2008.

14 Enacted: by paragraph (3) Section 44 of Act CVI of 2008. In force: as of 01. 01. 2009.

15 Amended: by Sections 360-361 of Act LVI of 2009. In force: as of 1. 10. 2009.

b) for all proceedings opened upon request for the admission of medicinal products, dietary supplements for special nutritional needs and medical aids into the social security subsidy system, for proceedings relating to determining the amount of subsidies to be provided for the rental costs of medical aids, for changing their approved period of use or indication, for increasing its price serving as the basis for public financing, for changing its name or size, and for the related remedy procedures;

c) for the certification procedure relating to the manufacture and supply of custom-made medical aids;

d)<sup>1</sup>

e) for the approval of the computer program for the prescription of medicinal products and medical aids;

f) for the certification procedure relating to the electronic information center designed to enhance the supply of medicinal products by entities other than pharmacies.

g)<sup>2</sup> for the rating of suppliers.

(5)<sup>3</sup> The minister in charge of the healthcare system is hereby authorized to decree, in agreement with the minister in charge of social policies, the function groups that cannot be dispensed under the fully subsidized public healthcare system.

(6)<sup>4</sup> The minister in charge of the healthcare system is hereby authorized to decree, in agreement with the minister in charge of public finances, the regulations concerning the aid that may be provided for the deposit fee charged to the patient for the use of an oxygen supply system, including cylinder and auxiliary equipment, in the patient's home.

#### *Section 78<sup>5</sup>*

(1) The business association operating a public pharmacy and holding a valid operating license on 1 January 2017 shall submit to the government body in charge of the healthcare system by 31 January 2017 a copy of the consolidated version of the memorandum of association referred to in Subsection (2) of Section 74 subject to content requirements set out in the relevant government decree, as effective at the time of submission, signed by the executive officers.

(2) If the public pharmacy's memorandum of association in effect on 1 January 2017 fails to comply with the requirements set out in Subsection (1) of Section 74, the government body in charge of the healthcare system shall revoke the implementation and operating permit of the public pharmacy within fifteen days from the time of gaining knowledge thereof, with effect from 1 January 2017.

#### *Section 79<sup>6</sup>*

In the authorization and control procedures provided for in this Act and/or other legislation adopted by authorization under this Act the client's statement shall not be admissible as a substitute for any unavailable evidence.

#### *Section 80<sup>7</sup>*

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1 Repealed: by subparagraph eg) paragraph (1) Section 25 of Act LXXXIX of 2010. No longer in force: as of 17. 08. 2010.

2 Enacted: by paragraph (3) Section 106 of Act CLIV of 2009. In force: as of 1. 03. 2010.

3 Enacted: by paragraph (4) Section 106 of Act CLIV of 2009. In force: as of 1. 01. 2010.

4 Enacted: by paragraph (5) Section 86 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.

5 Established by Section 42 of Act CLXXII of 2016, effective as of 20 December 2016.

6 Established by Subsection (5) of Section 282 of Act L of 2017. Amended by Paragraph j) of Section 130 of Act CI of 2021.

7 Established by Section 86 of Act CLXVIII of 2020, effective as of 1 January 2021. Amended by Paragraph k) of Section 130 of Act CI of 2021.



Within the competence of the government body for pharmaceuticals and the government body in charge of the healthcare system in accordance with this Act and/or other legislation implemented by authorization of this Act no administrative sanction may be imposed:

- a) after two years following the time of the authority of jurisdiction for levying the penalty gaining knowledge of the infringement, or
- b) after five years from the time the infringement was committed.

### *Sections 81-82<sup>1</sup>*

### *Section 83*

(1) This Act - subject to the exceptions set out in Subsection (2) - shall enter into force on 29 December 2006.

(2) The following provisions of this Act shall enter into force as follows:

- a) Sections 4-35 and 43-47 - with the exception set out in Paragraph c) - on 1 January 2007,
  - b) Sections 36-42 on 15 January 2007,
  - c) Subsection (2) of Section 25 and Subsection (3) of Section 34 on 1 April 2007.
- (3)-(6)<sup>2</sup>  
(7)<sup>3</sup>  
(8)<sup>4</sup>

### *Section 83/A<sup>5</sup>*

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1 Repealed by point 931 Section 2 of Act LXXXII of 2007. No longer in force as of 1. 07. 2007.

2 Repealed: by point 931 Section 2 of Act LXXXII of 2007. No longer in force: as of 1. 07. 2007.

3 Repealed: by subparagraph d) paragraph (2) Section 126 of Act CLIV of 2009. No longer in force: as of 31. 12. 2009.

4 Repealed by Point 7 of Subsection (1) of Section 186 of Act LXVII of 2016, effective as of 1 January 2017.

5 Enacted: by Section 87 of Act CLXXIII of 2010. In force: as of 1. 01. 2011.

(1)<sup>1</sup> The public pharmacies existing on 1 January 2013 are required to satisfy the conditions set out in Subsection (1) of Section 74 - also in accordance with Subsection (1a) of Section 74 -, as established by Section 100 of Act CCXII of 2012 on the Amendment of Health Regulations, by 1 January 2017, with the exception that the ownership share of the pharmacist vested with independent right together with other pharmacists employed in the pharmacy under some other form of employment relationship, combined with the ownership share of pharmacists holding an ownership share in the business association that operates a pharmacy contracted to dispense medicinal products with public financing must exceed 25 per cent by 1 January 2014, and with the proviso that in the event of any change - subject to the exception set out in Subsection (2) - that may take place after 1 January 2013 in the - direct or indirect - ownership structure of the business association that operates the pharmacy actions must be taken to ensure that the combined ownership share of the pharmacist vested with independent right together with other pharmacists employed in the pharmacy under some other form of employment relationship, including the ownership share of pharmacists holding an ownership share in the business association reaches 25 per cent, and after 1 January 2014 in the event of any change - subject to the exception set out in Subsection (2) - in the - direct or indirect - ownership structure of the business association that operates the pharmacy actions must be taken to ensure that the pharmacist vested with independent right, together with other pharmacists employed in the pharmacy under some other form of employment relationship and with the pharmacists holding an ownership share in the business association have majority ownership.

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1 Established: by paragraph (1) Section 101 of Act CCXII of 2012. In force: as of 1. 01. 2013.

(2)<sup>1</sup> In the event of any change in the person of the pharmacist vested with independent right in a public pharmacy existing on 1 January 2013, that may take place before 1 January 2014 due to death, or to having surrendered or transferred the independent right, or on the grounds listed under Subsections (1) and (2) of Section 58, or if the change takes place in the person of any pharmacist with an ownership share in the given pharmacy, the combined ownership share of the pharmacist vested with independent right together with other pharmacists employed in the pharmacy under some other form of employment relationship, including the ownership share of pharmacists holding an ownership share in the business association must reach the percentage existing on 1 January 2013 within one hundred and eighty days from the effective date of the change, and thereafter the combined ownership share of the pharmacist vested with independent right together with other pharmacists employed in the pharmacy under some other form of employment relationship, including the ownership share of pharmacists holding an ownership share in the business association may not be allowed to drop below the level registered on 1 January 2013 by 1 January 2014. In the event of any change in the person of the pharmacist vested with independent right in a public pharmacy existing on 1 January 2013, that may take place between 1 January 2014 and 1 January 2017 due to death, or to having surrendered or transferred the independent right, or on the grounds listed under Subsections (1) and (2) of Section 58, or if the change takes place in the person of any pharmacist with an ownership share in the given pharmacy, the combined ownership share of the pharmacist vested with independent right together with other pharmacists employed in the pharmacy under some other form of employment relationship, including the ownership share of pharmacists holding an ownership share in the business association must reach the percentage existing on 1 January 2014, or the percentage provided for in Subsection (1) of Section 74 if the combined ownership share of pharmacists holding an ownership share exceeds 50 per cent within one hundred and eighty days from the effective date of the change, and thereafter the combined ownership share of the pharmacist vested with independent right together with other pharmacists employed in the pharmacy under some other form of employment relationship, including the ownership share of pharmacists holding an ownership share in the business association may not be allowed to drop below the level registered on 1 January 2014, or below the percentage provided for in Subsection (1) of Section 74 if the combined ownership share of pharmacists holding an ownership share exceeds 50 per cent, by 1 January 2017.

(3) After 31 May 2011 a business association that is established in a State in which it is not involved in the pursuit of economic activities and where national tax laws do not impose any tax liability in the nature of corporate tax, or if the quotient of the tax amount payable for the tax year - that is the equivalent to corporate tax - and the amount construed as the pre-tax profit is less than two-thirds of the percentage rate defined in Section 19 of Act LXXXI of 1996 on Corporate Tax and Dividend Tax may not acquire any share - either directly or indirectly - in a business association that operates a public pharmacy existing on 1 January 2011.

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<sup>1</sup> Established by paragraph (1) Section 101 of Act CCXII of 2012. Amended by Paragraphs n)-o) of Section 80 of Act CCXLIV of 2013.

(4)<sup>1</sup> If the ownership share of the pharmacist vested with independent right together with other pharmacists employed in a public pharmacy existing on 1 January 2013 under some other form of employment relationship, combined with the ownership share of pharmacists holding an ownership share in the business association exceeds the limit set out in Subsection (1) of Section 74, as established by Section 100 of Act CCXII of 2012 on the Amendment of Health Regulations, in the ownership structure of the business association that operates the pharmacy no change shall be allowed that would result in dropping the combined ownership share of the pharmacist vested with independent right together with other pharmacists employed under some other form of employment relationship, including the ownership share of pharmacists holding an ownership share in the business association below 50 per cent. Any arrangement to the contrary is null and void.

(5) On 1 January 2011, the independent right of pharmacist vested with such right, involved in the management of public pharmacies on the basis of independent right shall be converted into authorizations for the management and operation of the same pharmacies. If a pharmacist vested with independent right is not currently engaged in managing a public pharmacy, his independent right shall be valid if there is intent for the management and operation of a pharmacy, and no further application has to be submitted to the government body in charge of the healthcare system.

(6)<sup>2</sup> The pharmacist's ownership share referred to in Subsection (1) of Section 74 and in Subsection (1) hereof shall include the ownership share acquired in the business association operating a public pharmacy by the Private Equity Fund managed by the capital fund manager delegated by the Government (hereinafter referred to as "capital fund manager"), if the pharmacist is given the opportunity to exercise a buy option within seven years from the time of acquisition of ownership by the Private Equity Fund managed by the capital fund manager. The acquisition of ownership by the Private Equity Fund managed by the capital fund manager under this Subsection shall be construed as a development investment for the purpose of equity finance provided to small and medium-sized enterprises established in Hungary. As regards the acquisition of ownership by the Private Equity Fund managed by the capital fund manager the provisions of Subsection (7) hereof, Subsection (3) of Section 74 and Section 75 shall not apply. As regards the sale of the share of the Private Equity Fund managed by the capital fund manager acquired under this Subsection to the holder of the buy option referred to in this Subsection, Subsection (7) of this Section shall not apply.

(7)<sup>3</sup> With the exception of transactions between close relatives, as regards the transfer of any ownership share of a business association operating a public pharmacy, any pharmacist holding an ownership share in the business association in question, any pharmacist employed by the business association in question under contractual employment relationship, or any other pharmacist listed in the register of active healthcare professionals, and the State - in that order - shall have the right of preemption, preceding any other right of preemption based on other legislation. The body exercising the State's right of preemption, or ownership rights on the State's behalf shall be delegated by the Government in a decree. As regards the acquisition of ownership by the State under this Subsection the provisions of Subsection (3) of Section 74 and Section 75 shall not apply. If the holder of the right of preemption fails to make his position known within thirty days after the conditions for the sales offer, including the price, are communicated, he shall be considered to have forfeited his preemption right. The ownership share acquired by the State by exercising its right of preemption shall be taken into account for the purposes of compliance with the requirements set out in Subsection (1) of this Section and in Subsection (1) of Section 74.

1 Established: by paragraph (2) Section 101 of Act CCXII of 2012. In force: as of 1. 01. 2013.

2 Established by Section 20 of Act CXVIII of 2018, effective as of 1 January 2019.

3 Established by Subsection (1) of Section 78 of Act CCXLIV of 2013. Amended by Paragraph d) of Section 26 of Act CLXXXVIII of 2017.

(8)<sup>1</sup> If the ownership share of a business association operating a public pharmacy is transferred to a holder of preemption right under Subsection (7), the right of preemption may be exercised only by those right-holders ranked before the buyer.

(9)<sup>2</sup> In order to ensure the participation of a pharmacist holding an ownership share, the State shall open a tender procedure for alienating its ownership share acquired under Subsection (7) within three years from the date of acquisition, however, if a pharmacist holding an ownership share in the business association in question, or a pharmacist employed by the business association in question under contractual employment relationship in the public pharmacy in question indicates his intention to buy, the tender notice shall be published immediately.

(10)<sup>3</sup> In connection with the sale - by way of tender - of the State's ownership share acquired under Subsection (7), the right of preemption referred to in Subsection (7), and any right of preemption stipulated by specific other legislation or under contract shall not apply.

(11)<sup>4</sup> The Government is hereby authorized:

a) to decree the detailed rules relating to the exercise of the preemption rights under Subsection (7), and to the tender procedure referred to in Subsection (9) covering the publication of the tender notice and the conduct of the procedure;

b) to delegate by way of a decree the body exercising the State's right of preemption under Subsection (7), or the State's ownership rights.

(12)<sup>5</sup> In communities with a population of more than 2,000, which have only one public pharmacy on the day of entry into force of Act CXXVII of 2013 on the Amendment of Regulations Relating to the Health Insurance and Healthcare Systems, and the ownership share of the business association operating a public pharmacy is acquired by the State by means other than exercising the right of preemption, this ownership share shall also be included in the pharmacist's ownership share referred to in Subsection (1) of Section 74 and in Subsection (1) hereof. As regards the acquisition of ownership by the State under this Subsection the provisions of Subsection (3) of Section 74 and Section 75 shall not apply.

(13)<sup>6</sup> Where a pharmacist's ownership share pledged as collateral for a low-interest credit or loan available within the Patika Credit Program is acquired by the lender financial institution through the enforcement of the collateral, such ownership share shall be included in the pharmacist's ownership share provided for in Subsection (1) of Section 74 and in Subsection (1) hereof for a period of up to one year from the time of acquisition. Subsection (7) shall not apply if the ownership share acquired by the lender financial institution under this Subsection is transferred - within one year from the time of acquisition of the collateral - to the pharmacist who provided the collateral." As regards the acquisition of ownership by the lender financial institution the provisions of Subsection (3) of Section 74 and Section 75 shall not apply.

(14) For the purposes of this Act, the ownership share acquired by way of inheritance of a university student attending - as verified - a college of pharmacy shall be construed the same as the testator's ownership share.

### *Section 83/B<sup>7</sup>*

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1 Enacted: by Section 136 of Act CXXVII of 2013. In force: as of 6. 07. 2013.

2 Enacted by Section 136 of Act CXXVII of 2013. Amended by Paragraph d) of Section 26 of Act CLXXXVIII of 2017.

3 Established by Subsection (2) of Section 78 of Act CCXLIV of 2013, effective as of 1 January 2014.

4 Enacted: by Section 136 of Act CXXVII of 2013. In force: as of 6. 07. 2013.

5 Enacted: by Section 136 of Act CXXVII of 2013. In force: as of 6. 07. 2013.

6 Enacted by Subsection (3) of Section 78 of Act CCXLIV of 2013, effective as of 1 January 2014.

7 Enacted: by Section 87 of Act CLXXXIII of 2010. In force: as of 1. 01. 2011.

The provisions contained in Paragraph *e*) of Subsection (1) of Section 58 and Subsections (3)-(4) of Section 58, as established by Section 79 of Act CLXXIII of 2010 on the Amendment of Health Regulations shall apply in connection with the final court verdicts rendered after the time of Act CLXXIII of 2010 on the Amendment of Health Regulations entering into force.

*Section 83/C*<sup>1</sup>

*Section 84*<sup>2</sup>

*Section 85*<sup>3</sup>

*Section 86*

(1)<sup>4</sup>

(2)<sup>5</sup> The provisions of Paragraphs *h*)-*i*) and *l*) of Subsection (1) of Section 31, as established by Act CCXLIV of 2013 on the Amendment of Regulations Relating to the Health Insurance and the Healthcare System, shall apply to cases opened after the time of Act CCXLIV of 2013 on the Amendment of Regulations Relating to the Health Insurance and the Healthcare System entering into force.

(3)<sup>6</sup>

(4)<sup>7</sup>

(5) The persons having a relative independent right at the time of this Act entering into force shall be authorized to operate a public pharmacy - in accordance with the provisions of the PhA in effect on the day immediately preceding the operative date of this Act, governing the operation of public pharmacies under relative independent rights - until the period of eligibility shown in the register of persons with relative independent right.

(6)-(7)<sup>8</sup>

*Section 86/A*<sup>9</sup>

Subsection (1) of Section 48, Subsection (2) of Section 50, Subsection (2) of Section 50/B, Subsection (2) of Section 53/B and Subsection (3) of Section 74 of this Act, as established by Act XIX of 2023 on the Amendment of Certain Acts Relating to Healthcare, Health Insurance and Pharmaceuticals (hereinafter referred to as "Act/2023") shall also apply to cases in progress on 1 June 2023.



*Section 86/B*<sup>10</sup>

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- 1 Repealed by Point 8 of Subsection (1) of Section 186 of Act LXVII of 2016, effective as of 1 January 2017.
  - 2 Repealed by Point 9 of Subsection (1) of Section 186 of Act LXVII of 2016, effective as of 1 January 2017.
  - 3 Repealed by Point 10 of Subsection (1) of Section 186 of Act LXVII of 2016, effective as of 1 January 2017.
  - 4 Repealed by Point 11 of Subsection (1) of Section 186 of Act LXVII of 2016, effective as of 1 January 2017.
  - 5 Established by Section 79 of Act CCXLIV of 2013, effective as of 1 January 2014.
  - 6 Repealed by Point 11 of Subsection (1) of Section 186 of Act LXVII of 2016, effective as of 1 January 2017.
  - 7 Repealed: by Section 361 of Act LVI of 2009. No longer in force: as of 1. 10. 2009.
  - 8 Repealed: by Section 361 of Act LVI of 2009. No longer in force: as of 1. 10. 2009.
  - 9 Established by Section 70 of Act XIX of 2023, effective as of 1 June 2023.
  - 10 Repealed by Section 72 of Act XIX of 2023, effective as of 1 January 2024.

### *Section 87*

(1) The provisions of Sections 22-35 of this Act shall apply to the proceedings opened after the operative date of this Act.

(2)<sup>1</sup> The minister in charge of the healthcare system is hereby authorized to decree the detailed conditions for the procedures relating to the authorization and notification of activities for the supply, repair and rental of medical aids, the contents of the register other than personal data, and the detailed procedural rules for operating the register, furthermore, the sanctions for any infringement of the provisions of the relevant legislation or of the resolutions adopted by the competent authorities pertaining to the supply, repair and rental of medical aids.

(3)-(4)<sup>2</sup>

(5) The minister in charge of the healthcare system is hereby authorized to decree the time from which medicinal products with social security subsidies will be dispensed and medical aids and medical treatment will be provided only if the prescription is made out using the computer program specified in Subsection (1) of Section 45.

(6)<sup>3</sup> The provisions of Chapter II and of the decree adopted by authorization conferred under Paragraph *j*) of Subsection (2) of Section 77 shall apply in connection with business-to-consumer commercial practices relating to therapeutic preparations which are not classified as medicinal products. Therapeutic preparations which are not classified as medicinal products may be sold by commercial establishments holding an operating permit and authorized to supply medicinal products in due compliance with the provisions of specific other legislation.

### *Sections 87/A-87/D<sup>4</sup>*

### *Section 87/E<sup>5</sup>*

(1) Subsection (4) of Section 52, as established by Act LXXIX of 2012 on the Amendment of Health Regulations, shall apply to the agreements concluded after 1 July 2012.

(2) Section 75, as established by Act LXXIX of 2012 on the Amendment of Health Regulations, shall apply to concentrations executed after 1 July 2012.

### *Section 87/F<sup>6</sup>*

### *Section 87/G<sup>7</sup>*

### *Section 87/H<sup>8</sup>*

- 
- 1 Established: by paragraph (8) Section 359 of Act LVI of 2009. In force: as of 1. 10. 2009. Shall apply to proceedings opened subsequently and to reopened cases.
  - 2 Repealed: by Section 361 of Act LVI of 2009. No longer in force: as of 1. 10. 2009.
  - 3 Established: by Section 81 of Act LXXXI of 2011. In force: as of 1. 07. 2011.
  - 4 Repealed by Point 14 of Subsection (1) of Section 186 of Act LXVII of 2016, effective as of 1 January 2017.
  - 5 Enacted: by Section 81 of Act LXXIX of 2012. In force: as of 1. 07. 2012.
  - 6 Repealed by Point 15 of Subsection (1) of Section 186 of Act LXVII of 2016, effective as of 1 January 2017.
  - 7 Repealed by Point 16 of Subsection (1) of Section 186 of Act LXVII of 2016, effective as of 1 January 2017.
  - 8 Enacted by Section 113 of Act CXI of 2014, effective as of 1 January 2015.

Any reference made in this Act to infant care benefits shall be construed as pregnancy-maternity benefits if entitlement to such benefits opened before 1 January 2015.

*Section 87/I<sup>1</sup>*

(1) Existing pharmacies shall comply with the provisions of Section 53/C, as established by Act LXXVII of 2015 on the Amendment of Regulations Relating to the Health Insurance and the Healthcare System, effective as from 1 January 2016.

(2) Paragraph c) of Subsection (2) and Subsection (3) of Section 61, as established by Act LXXVII of 2015 on the Amendment of Regulations Relating to the Health Insurance and the Healthcare System, shall apply after 1 January 2025.

(3) Paragraph c) of Subsection (2) of Section 61, as established by Act LXXVII of 2015 on the Amendment of Regulations Relating to the Health Insurance and the Healthcare System, shall not apply to pharmacists who reached the age of fifty before 1 January 2025.

(4)<sup>2</sup> Paragraph c) of Subsection (2) of Section 61, as established by Act LXXVII of 2015 on the Amendment of Regulations Relating to the Health Insurance and the Healthcare System, shall not apply to pharmacists qualified as certified specialized pharmacists, and who started specific training for qualification as a certified specialized pharmacist before 15 July 2015.

*Section 87/J<sup>3</sup>*

Subsections (9a) and (9b) of Section 21, as established by Act CCXXIV of 2015 on the Amendment of Regulations Relating to the Health Insurance and the Healthcare System, shall not apply to medical aids acquired before 1 April 2016.

*Section 87/L<sup>4</sup>*

Any reference made in this Act to child-care assistance benefits shall be construed as child-care allowance if entitlement to such benefits opened before 1 January 2016.

*Section 87/M<sup>5</sup>*

The payment obligation provided for in Subsection (1) of Section 42, as established by Act CXXV of 2016 on the Amendment of Tax Laws and Other Related Acts, shall apply to payments made for 2016.

*Section 87/N<sup>6</sup>*

The payment obligation provided for in Subsections (1), (3) and (4a) of Section 42, as established by Act CLXXII of 2016 on the Amendment of Certain Acts Relating to the Health Insurance and the Healthcare System, shall apply for the first time to the payment obligation for 2017 after the date of entry into force of Subsections (1), (3) and (4a) of Section 42.

*Section 87/O<sup>7</sup>*

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1 Enacted by Section 72 of Act LXXVII of 2015, effective as of 1 July 2015.  
2 Enacted by Section 43 of Act CLXXII of 2016, effective as of 1 January 2017.  
3 Enacted by Section 57 of Act CCXXIV of 2015, effective as of 1 April 2016.  
4 Enacted by Subsection (1) of Section 74 of Act CCXXIII of 2015, effective as of 1 January 2016.  
5 Enacted by Section 45 of Act CXXV of 2016, effective as of 26 November 2016.  
6 Enacted by Section 44 of Act CLXXII of 2016, effective as of 19 January 2017.  
7 Enacted by Subsection (6) of Section 282 of Act L of 2017, effective as of 1 January 2018.



The provisions of this Act established by Act L of 2017 on Amendments Relating to the Implementation of the Act on General Public Administration Procedures and the Act on the Code of Administrative Procedure (hereinafter referred to as "Administrative Amendments Act") shall apply to proceedings opened after the date of entry into force of the Administrative Amendments Act and to reopened cases.

### *Section 88*

(1) This Act - in conjunction with the regulations adopted for its implementation - serves the purpose of conformity with the following legislation of the Communities:

a) Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use, as amended by Directives 2002/98/EC, 2004/24/EC and 2004/27/EC of the European Parliament and of the Council,

b) Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems,

c) Council Directive 85/433/EEC of 16 September 1985 concerning the mutual recognition of diplomas, certificates and other evidence of formal qualifications in pharmacy, including measures to facilitate the effective exercise of the right of establishment relating to certain activities in the field of pharmacy, as amended by Council Directives 85/484/EEC and 90/658/EEC, and Directive 2001/19/EC of the European Parliament and of the Council, having regard to the Act of Accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded,

d) Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorization of the manufacturing or importation of such products.

(2)<sup>1</sup> This Act contains provisions for the implementation of the following legislation of the Communities in connection with the duties and proceedings of the consumer protection authority and the Hungarian Competition Authority:

a)<sup>2</sup> Article 5(1) of Regulation 2017/2394/EU;

b)<sup>3</sup>

c)<sup>4</sup>

(3)<sup>5</sup> This Act contains provisions for the implementation of Regulation (EC) No. 223/2009 of the European Parliament and of the Council of 11 March 2009 on European statistics and repealing Regulation (EC, Euratom) No. 1101/2008 of the European Parliament and of the Council on the transmission of data subject to statistical confidentiality to the Statistical Office of the European Communities, Council Regulation (EC) No. 322/97 on Community Statistics, and Council Decision 89/382/EEC, Euratom establishing a Committee on the Statistical Programs of the European Communities.

### *Section 89<sup>6</sup>*

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<sup>1</sup> Established: by Section 46 of Act CVI of 2008. In force: as of 01. 01. 2009.

<sup>2</sup> Established by Section 111 of Act LXVII of 2019, effective as of 17 January 2020.

<sup>3</sup> Repealed by Section 113 of Act LXVII of 2019, effective as of 17 January 2020.

<sup>4</sup> Repealed by Section 113 of Act LXVII of 2019, effective as of 17 January 2020.

<sup>5</sup> Enacted by Subsection (2) of Section 37 of Act XLIV of 2017, effective as of 2 June 2017.

<sup>6</sup> Repealed: by Section 361 of Act LVI of 2009. No longer in force: as of 1. 10. 2009.

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