Decree no. 11/2017. (VI. 12.) EMMI

On waste management activities regarding waste pharmaceuticals produced in community medical product supply

On the basis of my empowerment vested on me by 88. § (3) *a) aa)* of Act CLXXXV of 2012 on waste; acting under my obligation determined by 48. § point 3 of Decree no. 152/2014. (VI. 6.) Korm. on the functions and responsibilities of Members of the Hungarian Government and in agreement with the Minister of Agriculture acting in accordance with 65. § , point 8 of Decree no. 152/2014. (VI. 6.) Korm. on the functions and responsibilities of Members of the Hungarian Government -,

regarding 18. §, on the basis of the empowerment of Section 32(1) a) of Act XCV of 2005 On medicinal products for human use and on the basis of other acts as amended regulating the market of medicinal products and acting under my obligation determined by 48. § point 3 of Decree no. 152/2014. (VI. 6.) Korm. on the functions and responsibilities of Members of the Hungarian Government,

I decree the following:

1. General provisions

1. § (1) Except for the contents of paragraphs (2) an (3), the scope of this Decree shall cover

a) all natural persons, legal persons and entities without legal personality, who produce waste pharmaceuticals during their operations or who possess waste pharmaceuticals (hereinafter all will be called: Possessors of Waste), and

b) waste pharmaceuticals generated at the place of the Possessors of Waste.

(2) This Decree shall not cover

a) waste management activities affecting waste pharmaceuticals produced by health service providers during their health care operations, as provided for by Ministerial Decree on waste management produced at health service providers, and

b) treatment of waste pharmaceuticals produced through the operations of medicine producers and pharmaceutical wholesalers.

(3) This Decree shall not cover the collection of waste from medicinal products qualified as screened preparations as defined by the Ministerial Decree on the use,

record keeping and storing of medicines marketed for prescriptions in pharmacies and used by health service providers.

2. § (1) For the purpose of this Decree –

1. "*Pharmaceuticals" shall mean* Any material named by Section 1 point 1 of Act XCV of 2005 On medicinal products for human use and on the amendment of acts regulating the market of medicinal products (hereinafter: the "Drug Act");
2. "*medical product supplier*" shall mean an economic entity engaged in an activity settled in Section 11(1) of the Drug Act;
3. "*Manufacturer of medicinal product" shall mean:* a marketing authorization holder – independently of the fact whether the preparation was produced by himself or was imported by him;
4. "*Waste Pharmaceuticals" shall mean:*
   a) waste from medicines held by households or pharmacies or premises of units marketing pharmaceutical products, which are out of date or pharmaceutical products that cannot be used, and their waste packaging materials, and
   b) hypodermic needles becoming waste, injection syringes, injection syringes fitted with needle or infusion sets;
5. "*Pharmacy" shall mean:* any unit open to the public of marketing authorization holder medical product suppliers and branch pharmacies and parts of hospital pharmacies fulfilling tasks directly in their community medical product supply;
6. "*other units marketing pharmaceutical products" shall mean:* any store engaged in the marketing of pharmaceutical products under a permit issued by the State health administration;
7. "*Special collecting point" shall mean:* separated collecting places that receive communal waste pharmaceuticals under Government Decree on the regulation of developing and operating of certain waste management facilities in consideration to public health interests.

(2) Beyond those settled in paragraph (1) hereto, for the purpose of this Decree, the Definitions of

a) Act CLXXXV of 2012 on waste management (hereinafter: "Waste Management Act"),

b) the Drug Act,

c) Act On the General Rules of a Safe and Economic Supply and Distribution of Medicines and Medical Devices,

d) the Health Care Act, and

e) Government Decree on packaging and waste management activities regarding packaging waste

must be applied.

2. Liabilities of manufacturers of medicinal product and health care providers – inpatient and outpatient institutions – regarding waste pharmaceuticals handling

3. § (1) Each medicinal product manufacturer shall operate a system for receiving, collecting, conveying and managing waste pharmaceuticals as defined by 2. § (1)4a) from Medical Product Suppliers and to other units marketing such products open to the public.

(2) In order to fulfil the tasks mentioned in paragraph (1) above, manufacturers of medicinal products shall ensure the installation of receptacles applicable for the collection of waste pharmaceutical defined by 2. § (1)4a) hereto in the special premises of pharmacies open to the public or of other units marketing pharmaceutical products, open to Customers during normal business hours.

(3) it is forbidden to put waste pharmaceutical per 2. § (1) 4b) hereto Into receptacles installed in the special collecting points of premises of pharmacies or of other units marketing pharmaceutical products

(4) Manufacturers of medicinal products shall fulfil their obligation to take over, collect, remove and handle waste pharmaceutical per 2. § (1)4*a)* hereto at special collecting places

a) independently, or

b) under a contract – made in accordance with 26. § and 29 of the Waste Management Act – through the medical product supplier or

an agent.

(5) If the manufacturers of medicinal products fulfil their obligations to take over, collect, remove and handle waste pharmaceutical defined in 2. § (1) 4*a)* hereto in line with the provisions of paragraph (4) *b)*, the rules governing the activities of this manufacturer of medicinal products shall be applied together with the relevant variations worded in this Decree.

(6) In case referred to in paragraph (4) *b)*, the agreement made by and between the signatories shall contain at least the following provisions:

a) name, physical address, seat and number in the Trade Register of the medical product supplier and/or the agent;

b) indication of the obligations assumed;

c) the method of fulfilling the obligation;

d) type, kind and nature of the waste foreseen by the contract; and

e) a detailed description of activities to be done in the frame of the obligation assigned.

4. § (1) Beyond information to be given in the Summaries of product Characteristics (SmPC) per 1. §, point 17 of the Drug Act and in the Patient Information Leaflet per 1. §, point 18 of the same, and beyond information to be given in the Label per 1. §, point *a)* of Decree no. 30/2005. (VIII. 2.) EüM On the contents of labels and information of medicinal products for human use, the Manufacturer of Medicinal Products is also obliged to make available a notice about liabilities to collect and manage waste pharmaceutical as provided for in 2. § (1)4*a)* hereto and about liabilities to be borne by the citizens and about the methods of satisfying these prescriptions in the premises of pharmacies open to the public and in premises of units marketing such products open to customers, at places within such premises easily noticeable for customers, in Hungarian language and in an understandable manner.

(2) The Manufacturer of Medicinal Products shall satisfy his obligation to give information per paragraph (1)

a) independently,

b) collectively - in cooperation with other manufacturers of medicinal products – , or

c) through an agent

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5. § (1) Health care providers – inpatient and outpatient institutions – shall satisfy their obligations regarding takeover, collection, conveying and managing waste pharmaceuticals produced by the population per 2. § (1)4*b)* hereto in accordance with Ministerial Decree on waste management activities affecting waste pharmaceuticals produced by health service providers and in accordance with this Decree.

(2) Health care providers – inpatient and outpatient institutions – shall ensure the installation of receptacles applicable for the collection of waste pharmaceuticals – as provided for 2. § (1)4*b)* hereto in special premises open before patients during normal business hours.

3. Rules governing the separated collection and removal of waste pharmaceuticals

6. § (1) The possessor of waste shall collect waste pharmaceuticals separated from mixed and other types of waste materials by type or nature.

(2) The possessor of waste is liable to remove waste pharmaceuticals to special collection premises and place it into special waste receptacles installed at such special collecting facilities.

7. § (1) At special collecting places in the premises of pharmacies or at units marketing pharmaceutical product per 2. § (1) 4*a)*, exclusively disposable hard-wall receptacles fitted with liners resistant to physical, biological and micro-biological impacts shall be placed that are closed in a way that prevents taking out of the waste and that are certified by an accredited conformity assessment body as defined by the Act on the Activities of Conformity Assessment Bodies.

(2) waste pharmaceuticals per 2. § (1) 4*a)*

a) shall be placed by the possessor of waste into receptacles installed in special collecting points located in the premises of pharmacies or of other units marketing pharmaceutical products, or

b) the possessor of waste gives the waste to the support staff, if no receptacle is installed at a place per point *a).*

(3) In cases mentioned in paragraph (2) *b)*, the support staff shall, immediately after receiving the waste pharmaceuticals, see to the disposal of the waste pharmaceuticals in a way that ensures that waste pharmaceuticals collection will not impose detrimental impacts to the environment or the human health until removal.

(4) The Hungarian National Institute of Pharmacy (Országos Gyógyszerészeti Intézet, hereinafter: “OGYI”) oversees the placement of the receptacles in pharmacies and in other units marketing pharmaceutical products, and also oversees the compliance with other provisions of this Decree.

8. § (1) Medicinal Product Manufacturers, Medical Product Suppliers and Agents shall fulfil their obligations to take over, collect and remove waste pharmaceuticals per 2. § (1)4*a)* from pharmacies and other units marketing pharmaceutical products under contracts signed with the operators of the pharmacies and other units marketing pharmaceutical products.

(2) Costs of installation and removal of receptacles placed at special collecting points in premises of pharmacies and other units marketing pharmaceutical products and the cost of handling of waste pharmaceuticals as per 2. § (1)4a) shall be borne by the Manufacturer of Medicinal Products or by the Medical Product Supplier or by the Agent, under the contract. In the absence of a binding contract, the subject to this obligation is the Manufacturer of Medicinal Products.

(3) The receptacles installed at special collecting points shall be removed from pharmacies, at least in every six months, from other units marketing pharmaceutical products, at least once a year, or – depending on the degree of fill up – out of turn, upon a notice per paragraph (4) sent by the manager of the pharmacy or the unit marketing pharmaceutical products.

(4) The operator of the pharmacy or of any other unit marketing pharmaceutical products shall send notice to the Manufacturer of Medicinal Products – or, if the contract per paragraph (1) above states otherwise, to the Medical Product Supplier or to the Agent – about the need to replace the receptacle in time to ensure the continual availability of receptacles ready to receive waste pharmaceuticals.

9. § (1) At health care providers for inpatients and outpatients, closed receptacles (from where waste cannot be taken out) for collecting special medical hazardous waste produced by these health care providers for inpatients and outpatients – provided for in the Decree on waste management activities of health care providers for inpatients and outpatients – can be installed at separated special collecting places for waste pharmaceuticals per 2. § (1) 4*b)*.

(2) The receptacles at special collecting points shall be installed in a way and at a place whereby the possessor of waste can place the waste pharmaceuticals per 2. § (1)4*b)* hereto without the involvement of the support staff of the health care provider inpatient or outpatient institution.

(3) Storage and removal of pharmaceutical waste per 2. § (1) 4*b)* at and from health care providers for inpatients and outpatients shall be performed in accordance with the Decree on waste management activities of health care providers for inpatients

and outpatients in line with the rules pertaining to the collection of special medical hazardous waste.

(4) Health care providers – inpatient and outpatient institutions – shall ensure the installation of receptacles applicable for the collection of waste pharmaceuticals per 2. § (1) 4*b)* hereto, which shall be continually available in the special collecting places.

(5) The installation of the receptacles at health care providers for inpatients and outpatients and the compliance with other provisions of this Decree shall be inspected by Budapest Metropolitan Government Office and by the County Government Offices through their Regional (or in case of Budapest, its District) Government Offices acting as competent public health authorities.

10. § (1) As their sites, pharmacies and other units marketing pharmaceutical products and institutions providing health care services for inpatients, at the same time shall operate special collecting points.

(2) The collection of pharmaceutical waste shall be organized in a way that doesn't hinder the normal activities of pharmacies or other units marketing pharmaceutical products or of institutions providing health care services for inpatients and outpatients.

(3) The economic entity engaged in the takeover and transfer of pharmaceutical waste shall ensure that during transfer, the pharmaceutical waste taken over will not become available for unauthorized individuals.

4. Obligation of the Medicinal Product Manufacturer to Announce

11. § (1) The Medicinal Product Manufacturer shall submit an announcement to the National Office for the Environment – with contents delineated in Annex 1 hereto – on the ways and methods he satisfies his obligations to take over, collect, remove and manage the pharmaceutical waste per 2. § (1) 4*a)* and also shall describe in this announcement the way he gives information. This announcement must be submitted before the commencement of the first marketing action, the latest, of the medicinal products authorised by OGYI to be marketed.

(2) If the Manufacturer of Medicinal Products transfers his liability per this Decree under 3. § (6) *b)* to the Medical Product Supplier or to the Agent, the medicinal

product manufacturer shall send for approval the relative agreement signed with the medical product supplier or the Agent within 15 days to the National Office for the Environment as an attachment to the announcement.

(3) The National Office for the Environment will approve the agreement or its amendments, if its contents comply with the requirement provided for in 3. § (6).

(4) The termination of the agreement must be announced to the National Office for the Environment within 15 days.

(5) The approval of the agreement must be rejected if within 3 years from the date of the agreement, an effective administrative decision or judicial decision was made against the medical product supplier (or the agent) stating that they endangered the environment or caused damage to the natural environment.

(6) The term of the agreement shall be 5 years

(7) If the medical product supplier (or the Agent) endangers the natural environment or causes damage to the environment under an effective administrative decision or judicial decision during the term of the agreement, the approval of a newer agreement shall be rejected.

(8) If the manufacturer of medicinal products terminates his activities foreseen in this Decree, this fact must be announced to the National Office for the Environment within 15 days from the termination.

5. Registration of the Agent

12. § (1) The agent shall be registered in accordance with the relative provisions of the Waste Management Act and of Decree no. 439/2012. (XII. 29.) Korm. On the registration of waste management activities and on the issue of waste management activity permits by public authorities.

(2) Those registered non-profit economic entities can be registered as agents,

a) whose services are available for anyone who satisfy the criteria listed in non-profit economic entity's Articles of Association; and

b) who possesses a registered capital necessary for the continuation of its core activity – at least HUF 30 million.

6. Obligation of the Medicinal Product Manufacturer to Provide Security

13. § (1) The medicinal product manufacturer shall provide financial security for warranting the acceptance, collection and management of pharmaceutical waste – except for the case mentioned in paragraph (2) hereunder.

(2) Financial security shall be warranted by the organization of the supplier of the agent, if the medicinal product manufacturer renders his takeover, collection, removal and management services through the supplier or the agent under a finalized agreement.

(3) The size of the financial security shall be HUF1 million or an amount, which is the product of the quantity of the supplied drug expressed in the number of boxes and the amount of security per unit mass. The amount of security per unit mass shall be HUF 0.5 per boxes.

(4) If the medicinal product manufacturer was engaged in the activity provided for in this Decree on 31th December of the year before the year in under consideration, he shall build financial security until the 20th day of February of the year under considerations. The medicinal product manufacturer shall send a written certificate to the National Office for the Environment on depositing the financial security within 8 days from the date of deposition.

(5) The medicinal product manufacturer - if he commences his activity in the year under consideration, shall build a financial security until the end of the same year in proportion to the planned quantity of the trading of goods. The medicinal product manufacturer shall send a written certificate to the National Office for the Environment on depositing the financial security within 8 days from the date of deposition.

(6) Thee security may take the form of:

a) guarantee issued by a credit institute or an insurance company or an equivalent bank covenant,

b) a promissory note assuming a collateral security, issued by an Insurer on the basis on an insurance contract,

c) an amount deposited with a credit institute managed set aside and blocked, or

d) an insurance contract.

(7) The approval for the disposition over the financial security built up for the year under consideration may be initiated by the medicinal product manufacturer at the National Office for the Environment concurrently with the submission of the security certificate. If the medicinal product manufacturer is not engaged anymore in activities governed by this Decree, after terminating this activity, he may initiate the approval of his disposition over the financial security.

(8) The application for the approval of disposition over the security deposited for the year under consideration will be approved until the 1st day of September of the year following the one under consideration, if in the year under consideration, the obligations

a) to take over, collect and dispose of, and

b) toprovide security

were carried out.

(9) After the National Office for the Environment gives their approval, the manufacturer of medicinal products can dispose freely of the security of the year under consideration.

7. Closing Stipulations

14. § This Decree shall take effect on the 60th day after adjournment.

15. § (1) Those medicinal manufacturers who are operating on the date this Decree becomes effective shall satisfy their obligations to make the announcement per 11. § at the first time within 60 days from the effective date.

(2) An agent engaged in activities subject to this Decree, shall meet the provisions of 12. § (2) for the first time by the first day of the ninth month from the date this Decree becomes effective.

(3) The manufacturer of medicinal products shall give evidence of his compliance with the requirement to build financial security per 13. § within 6 months from the date this Decree becomes effective.

(4) Health care providers – inpatient and outpatient institutions – shall satisfy their obligations to build out their system for the takeover, collection, conveying and managing waste pharmaceuticals per 2. § (1)4*b)* within 18 months from the date this Decree becomes effective.

16. § (1) In accordance with Articles 5-7 of Directive (EU) no. 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services, the draft Decree has been announced in advance.

(2) The preliminary announcement of the draft of 12. § (2) of this Decree was effected in accordance with Article 15(7) of Directive no. 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market.

(3) This Decree serves the compliance with Directive no. 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market.

17. § The text in 43. § (4) of Decree no. 52/2005. (XI. 18.) EüM On the marketing of medicinal products for human use – "4-5 § of Decree no. 20/2005. (VI. 10.) EüM on the handling of waste packaging materials of human medicinal products" is replaced by this text: "in 3-4 §, 7-8 § , and 10 § Decree no. 11/2017. (VI. 12.) EMMI on the handling of waste packaging materials of human medicinal products".

18. § The Decree no. 20/2005. (VI. 10.) EüM on the handling of waste packaging materials of human medicinal products is repealed.

Zoltán Balog,A.S.,
Minister of Human Resources

Annex 1 of Decree no. 11/2017. (VI. 12.) EMMI

Information about the Manufacturer of Medicinal Products and on the takeover, collection, removal and handling of waste pharmaceuticals as per

2. § (1)4a) by this Manufacturer of Medicinal Products

1. Information on the Manufacturer of Medicinal Products:

1.1. Information identifying the Manufacturer of Medicinal Products:

1.1.1. Environmental Client Code (hereinafter: "KÜJ" – *abbreviation of the expression in Hungarian*);

1.1.2. Statistical ID number (registered with the Central Statistical Office of Hungary or KSH);

1.1.3. name;

1.1.4. Physical address (post code, settlement, name of the public area (*i.e. of the street, square, etc*.), type of the public area (*i.e. street, square, etc*.), number);

1.1.5. Name of the person representing the organization;

1.1.6. Physical address (post code, Settlement, house number, e-mail address, post office box) of the person representing the organization;

1.1.7. National tax identification number o EU VAT number;

1.1.8. Number in the Trade Register.

1.2. Information on the obligations of the Manufacturer of Medicinal Products to take over, collect, remove and handle waste pharmaceuticals:

1.2.1. Independent provision of services;

1.2.2. Provision of services by the medical product supplier;

1.2.2. Provision of services by an agent;

1.3. Information on the obligation of the Manufacturer of Medicinal Products to inform:

1.3.1. Independent provision of services;

1.3.2. Collective provision of services;

1.3.3. Provision of services by an agent;

1.4. Title of notification:

1.4.1. new notification;

1.4.2. Amendment of data;

1.4.3. cessation.

2. Information identifying the Agent:

2.1. KÜJ /*Environmental Client Code*/;

2.2. Statistical ID number (registered with the Central Statistical Office of Hungary or KSH);

2.3. name;

2.4. Physical address (post code, settlement, name of the public area (*i.e. of the street, square, etc*.), type of the public area (*i.e. street, square, etc*.), number);

3. Information on the individual in charge for making the announcement

3.1. name;

3.2. position;

3.3. phone and fax number;

3.4. e-mail.