

***NB: Please note that that up to the best of our knowledge, there is no official translation of this decree, this text is for orientation only.***

**Decree no. 20/2005. (VI.10.) of the Ministry of Health, on human pharmaceutical waste, its packaging and its management**

According to the authorization conform to point *ba*) of paragraph (3) of §59<sup>th</sup> of law XLIII. of year 2000 on waste management (henceforth: Wm), I decree the following:

§ 1.

(1) The decree applies to:

- a*) all individuals, legal entities, organisations without legal personality which own human pharmaceutical (henceforth: pharmaceutical) waste,
- b*) those waste managers who accept pharmaceutical waste in their scope of business from their owner for handling purposes
- c*) to pharmaceutical manufacturers and dealers,
- d*) the pharmaceutical waste created at the waste owner described in point *a*), except for those enclosed in (2).

(2) The decree does not extend to individuals, legal entities, organisations without legal personality under the scope of decree no.1/2002. (I.11.) of the Ministry of Health concerning the handling of waste created in health institutions, to pharmaceutical waste created in those institutions and to the handling of pharmaceutical waste produced during pharmaceutical manufacturing and pharmaceutical wholesale activities. This does not concern pharmacies and branch pharmacies.

§ 2.

In the present decree the expressions hereunder shall have the following meaning:

- a*) *medication*: preparations defined by points *a*)-*c*) of 4. § of law XXV of year 1998 on medicines (henceforth: MI);
- b*) *pharmaceutical waste*: human medication accumulated at the population, or the medication expired in pharmacies or otherwise unfit for usage;
- c*) *pharmaceutical manufacturer (henceforth: manufacturer)*: the entity entitled to product distribution, regardless of the fact that the preparation is self-manufactured, or imported;
- d*) *pharmaceutical dealers (henceforth: dealer)*: the entity in charge of the medication's wholesale;
- e*) *pharmacies*: health institutions defined by points *a*)-*b*) of law no. LIV of year 1994 on

pharmacy establishing and running;

*f) consumer packaging:* packaging defined in point *a)* of paragraph (2) of the statutory order no. 94/2002. (V.5) (henceforth: O) on packaging and packaging waste detailed regulations.

### § 3.

(1) According to paragraph (3) of § 5. and paragraph (1) of § 12. of the Wm, pharmaceutical waste should be collected in a closed system and disposed of thermically, separated from solid domestic waste.

(2) According to paragraph (2) of § 6. of the O and to paragraph (1) of § 10. and paragraph (1) of § 8. of the Wm, it is the manufacturer's duty to establish and to operate a system fit for waste reception and disposal. The manufacturer's duty includes the reception and disposal of pharmaceutical waste handed in at the country's any pharmacy.

(3) The manufacturer fulfills his duty defined in paragraph (2), or, according to paragraph (4) of § 8. of the Wm, he can transfer his duty to the dealer or an entitled coordinating organisation. The common coordinating organisation established according to § 11. of the Wm plans, completes the reception and disposal of pharmaceutical waste, or has it made by other party.

(4) The legal consequences for the manufacturer to fail to his duties defined in paragraph (2) are defined in § 49 of the Wm.

### § 4.

(1) All pharmacies and branch pharmacies (henceforth together: pharmacies) take part in the population pharmaceutical waste collecting during their opening hours. The collecting should be planned in a way that does not hinder the usual activity of the pharmacy.

(2) A closed, one-way and disposable waste collecting container should be used during the collecting, which secures that the pharmaceutical waste cannot get out of the handling system during the transport from the collecting point to the disposal's location and that the already disposed (thrown in) waste cannot be accessed.

(3) The waste collecting containers should be placed inside the pharmacy's building, either:

*a)* in the area which is open to the public (the officina), in a way that people do not need the pharmacy's staff's help to place its pharmaceutical waste, or

*b)* in an area closed to the public. In this case, the pharmaceutical waste is placed into the waste collecting container by the pharmacy's staff.

(4) According to paragraphs (2)-(3) of § 3. the pharmacy operator is obliged to sign a contract concerning the collecting and transport of pharmaceutical waste. The waste collecting container's disposal and transport fees are to be borne by the company determined in paragraphs (2)-(3) of § 3. of present decree.

### § 5.

(1) The placing of the pharmaceutical waste collecting containers in the pharmacies, their scheduled or extraordinary transport on demand of the pharmacy's director is the task of the company regulated by paragraphs (2)-(3) of § 3. Only containers accredited by a quality controller company can be placed in pharmacies. Another legislative provision regulates the order of documentation for transportations, the registration and the data supply obligation of the organisation responsible for the container's collecting.

(2) Special legislative provision regulates the handling of narcotics.

(3) The placing of pharmaceutical waste collecting containers in pharmacies and the observation of present decree is also checked by the National Public Health and Medical Officer Service's (henceforth: ÁNTSZ) regional chief pharmacy officer.

(4) Until the coming into force of present decree, the manufacturer is obliged to inform the ÁNTSZ's National Chief Medical Officer Office on the mode of fulfilment of his duties defined in present decree.

#### § 6.

(1) Present decree, except for paragraph (2) comes into force on the first day of the sixth month following its declaration

(2) The (4) paragraph of § 5. of present decree comes into force on the fifth day following its declaration.

*Dr. Jenő Rácz*  
Minister of Health