MINISTRY OF HEALTH

DIRECTION no. 6.226
of 4 April 2024 on management of unused and/or expired medicinal product waste from the population

Published in: the Official Gazette of Romania no. 331 of 10 April 2024

On seeing approval report of the General Directorate for Public Health and Health Programs of the Ministry of Health no. A.R./6.227 of 5.04.2024 and notice of the National Institute for Public Health no. 380 of 5.03.2024,

taking into account the provisions of Art. 2 (6), Art. 5 j) and Art. 244 (6) of Law 95/2006 on healthcare reform, republished, as further amended and supplemented,

in line with Art. 7 (4) of Government Decision no. 144/2010 on the organisation and operation of the Ministry of Health, as further amended and supplemented,

the minister of health hereby issues the following Direction:

Art. 1 – This Direction establishes the manner of managing unused and/or expired medicinal product waste from the population.

Art. 2 - Medicinal product waste from the population is represented by medicinal products with expired shelf life, medicinal products which are no longer used, medicinal product residues, medicinal products with damaged containers, medicinal products withdrawn from the market, etc.

Art. 3 - (1) Medicinal product waste is deposited by citizens at public or private hospitals, according to the schedule established and posted by the respective units. Public or private hospitals may establish a schedule for collecting medicinal product waste from the population, on certain days of the week and during a certain timeframe.

(2)The containers for collecting medicinal product waste are placed in the hospital courtyard, in a specially designated area, as provided for in paragraph (3).

(3) When determining the space intended for the location of containers for collecting medicinal product waste from the population, the following aspects shall be taken into account:

a) easy access for citizens;

b) covered area;

c) monitored area, by security personnel or through video surveillance systems;

d) ensuring appropriate hygienic and sanitary conditions.

(4) Medicinal product waste is collected separately from the waste resulting from the hospital's medical activity, considering the following categories:

a)Cytotoxic and cytostatic medicinal product waste is collected in cardboard or

plastic containers, provided with a polyethylene bag inside, which does not allow liquid leakage. The containers are equipped with an anti-return system, to prevent waste recovery;

b) medicinal product waste, other than cytotoxic and cytostatic ones are collected in cardboard or plastic containers, provided with a polyethylene bag inside, which does not allow liquid leakage. The containers are equipped with an anti-return system, to prevent waste recovery;

c) Liquid medicinal product waste contained in a stinging-cutting container (containing glass ampoules, pre-filled syringes with leftover medicinal product residue) is collected in containers specific to stinging-cutting medicinal product waste, equipped with a temporary and permanent closure system;

c) Medicinal product waste in pressurised containers are collected separately from other categories, without being disposed of by incineration. These follow the recyclable waste cycle.

(5) The containers are labelled with the name of the medicinal product waste (category) to be collected, the source of generation: population, specific hazard marking, container capacity (l or kg), the maximum filling level marking line, the date of the container's first use, the healthcare unit, the person responsible for handling it, the date of final filling.

(6) The containers are sealed after filling, in order to prevent possible accidents which may occur during the collection and transport period until they are to be incinerated. The containers are marked in accordance with the regulations of the Agreement concerning the International Carriage of Dangerous Goods by Road.

(7) In the area for collection of medicinal product waste from the population, posters describing the categories of waste collected with examples are displayed in a visible place, together with warning messages for the population regarding the risks arising from uncontrolled disposal of this waste into the environment.

Art. 4 - (1) The medicinal product waste collected from the population in the respective containers enters the transport and disposal circuit of waste resulting from medical activity generated by hospital, being handed over to economic operators authorised for this activity, in line with Order of the Minister of Health No. 2829/2022 on approval of the Methodology for the evaluation of vehicles used for the transport of waste resulting from medical activity.

(2) The medicinal product waste is disposed of only by incineration, only in authorised units, with the exception of medicinal product waste in pressurised containers, which are recommended to be recycled after complete depressurisation.

Art. 5 - In order to monitor the activity of taking over medicinal product waste from the population, the hospital nominates a person responsible for this activity, within the hospital.

Art. 6 - (1) The generation of medicinal product waste from the population is monitored by the nominated person and the quantities resulting from weighing are recorded in the internal waste management record of the respective hospital.

(2) The data represented by the quantities of medicinal product waste from the population are reported to the public health departments and the Bucharest municipality, separately from the quantity of medicinal product waste generated by hospitals, based on electronic reporting templates, under codes 180108* -

waste of cytotoxic and cytostatic medicinal products and 180109 - waste of medicinal products, other than those specified in 180108*, class 18, subclass 1801, according to Decision 2014/955/EU amending Decision 2000/532/EC on the list of waste pursuant to Directive 2008/98/EC of the European Parliament and of the Council and Government Decision no. 856/2002 on waste management and approval of the list of waste, including hazardous waste, as further supplemented.

(3) The models are approved by the methodology for monitoring the system of management of the waste resulting from medical activity, developed on a yearly basis by the National Institute of Public Health (INSP), and are posted on the institution's website.

Art. 7 - County and Bucharest municipality public health departments and public or private hospitals carry out the provisions of this Direction.

Art. 8 - This Direction is published in the Official Gazette of Romania, Part I.

On behalf of the Minister of Health,
Adriana Pistol,
Secretary of State