

National Medicines Institute  
00-725 Warsaw, Chełmska 30/34  
e-mail: a.ziolko@nil.gov.pl

## MEDICAL WASTE – LEGAL AND ORGANIZATIONAL CHALLENGES FOR MEDICAL ENTITIES

### ODPADY MEDYCZNE – PRAWNE I ORGANIZACYJNE WYZWANIE DLA PODMIOTÓW MEDYCZNYCH

**Summary:** The article tries to answer the question of what legal and organizational challenges are faced by producers of medical waste today. Defining medical waste in the over 100-year history of waste management in Poland was not always clear and simple. Over the years, Polish law has not only failed to define medical waste, but also the waste itself. And even when the law specified the rules of handling waste, these provisions were not always precise.

**Keywords:** medical waste, environmental protection, medical entities, legal and organizational challenges

**Streszczenie:** Artykuł stara się odpowiedzieć na pytanie przed jakimi wyzwaniami prawnymi i organizacyjnymi stoją dziś wytwórcy odpadów medycznych. Zdefiniowanie odpadów medycznych w całej, przeszło stuletniej historii gospodarki odpadami w Polsce, nie zawsze było jednoznaczne i proste. Na przestrzeni wielu lat prawo polskie nie tylko nie definiowało odpadów medycznych, ale także samych odpadów. A nawet, gdy przepisy prawa określały zasady postępowania z odpadami, to zapisy te nie zawsze były precyzyjne.

**Słowa kluczowe:** odpady medyczne, ochrona środowiska, podmioty medyczne, prawne i organizacyjne wyzwania

#### Introduction

According to the current binding regulations in Poland (Act on waste, Official Journal of Laws 2022, item 699, consolidated text), **medical waste** mean the waste, generated in connection with **rendering the health benefits and running the scientific tests and experiments in the field of medicine** and, as such, in accordance with the regulation of the Minister of Climate *on the matter of waste catalogue* (Official Journal of Laws 2020, item 10), they are classified as:

- group: **18**
- subgroup: **1801**
- type: from **180101 to 180182\***

It has not been, however, always univocal; throughout many years, Polish law has defined neither medical waste nor the waste themselves. Even in the case when the legal regulations specified the principles of proceeding with the waste, the mentioned provisions were not always precise. Therefore, in the present publication, we will try to answer the question: what are the legal and organizational challenges faced to-day by the producers of medical waste.

#### Historical aspect of defining the waste, including medical waste

Definition of medical waste in the total, over a hundred year's old history of waste management in Poland, has not been always simple. When considering the way of defining the waste, we may distinguish three periods when:

- the waste were defined as impurities (1919–1980);
- there was a general binding definition of the waste from among which municipal waste and hazardous waste were distinguished (1980–2001); and
- the definition of medical waste was introduced (since 2001 until now).

The rules concerning the principles of proceeding with the waste in Poland date back to the interwar period. The first time the duty of "... care of the purity of air, soil and water and appropriate removal of impurities" was introduced by Principal Health Law of 19 July, 1919 (Official Journal of Laws 1919, No 63, item 371). The detailed principles of proceeding were specified in the Regulation of the President of the Republic of Poland of 16 march 1928 on disposal of impurities and rain water (Official J. of Laws 1928, No 32, item 311) which, as defining **the impurities** as "... human and animal excretions, sewage, garbage and **municipal waste**..." included also waste management. The mentioned

regulation imposed, *inter alia*, the duty of collecting, storage and disposal of the impurities by the communes. The Regulation had a binding force for 31 years.

During the post-war period, the problem of waste management was regulated by the Law of 22 April 1959 on maintenance of cleanness and order in the cities and settlements (Official Journal of Laws 1959, No 27, item 167); the mentioned act extended the definition of impurities, defining them as "... *domestic waste, street sweepers, human and animal excretions and urban sewage and rainwater on the streets, squares and other places, intended for public use...*". The mentioned Act was obligatory for the next 21 years.

The successive legal act, the Law of 31 January 1980 on protection and shaping of environment (Official J. of Laws, 1980, No 3, item 6) introduced, first time in Polish legislation, the **definition** of the waste, describing them as: "...*used products and solid substances, also liquid substances, being not sewage, resulting in the connection with living of man or economic activity, unsuitable at the site or time at which they were generated and being strenuous for the environment*".... One year later, the Act of 13 September 1996 on maintenance of cleanness and order in the communities (Official J. of Laws 1996, No 132, item 622) introduced the conception of **municipal waste**, defined as "... *solid and liquid waste, generated in households, objects of public utility and public service (...) excluding hazardous waste coming from health care entities...*".

Year 1997 in respect of waste management in Poland is considered as the breakthrough year as since that date, the first Polish act on the waste became to be binding. Apart from the defined earlier municipal waste, the Law on the waste of 27 June 1997 (Official J. of Laws, No 96, item 592) distinguished a new group of the **hazardous waste**, describing them as "... *the waste which due to their origin, chemical and biological origin and other properties constitute a hazard to life of health of humans and for the environment...*".

The successive milestone in the respect of the rules, regulating the waste management in Poland was passing of a new Act on the waste (27, April, 2001) (Official J. of Laws 2001, No 62, item 628). The mentioned Law has changed not only the so-far existing definition of municipal and hazardous waste but first of all, it made a general definition of **the waste** more precise, specifying them as "... *each substance of object, belonging to one of the categories, listed in Annex 1 to the Act, which the holder disposes of, intends to dispose of, or is obliged to dispose of them...*" Besides it, the discussed Law has considerably extended the so-far existing catalogue of the waste, introducing the new definitions of: **neutral waste, biodegradable waste, biological waste, green waste, veterinary waste and the waste coming from accidents**. First of all, however, the mentioned law introduced currently valid definition of medical waste, understood since that moment as "... *the waste generated in connection with rendering health benefits and running scientific tests and experiments in the field of medicine...*".

As it can be seen, **medical waste** in Polish legislation has officially functioned only for 21 years; perhaps it causes that

we are constantly encountered with the problems with their appropriate classification. Three most important (in the opinion of the author of the present paper) problems which constitute the serious challenges for the producers of medical waste, have been discussed in the present publication.

## Challenge No 1.

### Who produces medical waste in practice and who does not definitely produce them?

In spite of the binding definition in Polish legislation, the answer to the above question still causes many emotions. Especially it is the case when it concerns production of the waste which is generated during the treatments, infringing the continuity of human tissue.

According to the obligatory definition, medical waste is produced by:

- medical entities and the persons, rendering health benefits, including, *inter alia*:
  - hospitals, clinics and sanatoria,
  - basic and specialist ambulatories and advisory centres,
  - physicians and nurses within the frames of individual care,
- medical diagnostic laboratories,
- research institutes performing the scientific research activities in the field of medicine.

At the same time, the separate regulations (in spite of apparently the same group of sick patients as it is found in the hospitals) are referred to the sick persons, staying at home of the inhabitants of social aid houses (DPS) which do not enter the composition of medical entity. The waste generated during the care of the mentioned above group of the sick people are classified as:

- medical waste – only when it is generated during rendering the health benefits at the site of stay of a sick person (*inter alia*, at home, DPS) (e.g. performance of injections) by medical employee (*inter alia*, physician, nurse, medical rescuer). Such waste is then taken away by the mentioned employee, transported according to the adopted procedure and transmitted to be neutralized at the site, specified by a separate agreement;
- municipal waste – when it is generated at the site of stay of a sick person (*inter alia*, at home, DPS) by the sick person himself or by the person who is not a medical employee and who takes care of the mentioned patient (e.g. performs injections). The discussed waste is disposed then as:
  - mixed municipal waste;
  - on the grounds of art. 3 par. 2 point 6 of the Act on maintenance of cleanness and order in the communities (Official J. of Laws 2021, item 888) they may be transmitted to the points of selective collection of the municipal waste, as indicated by the competent authorities.

Besides it, according to the currently binding law, we should remember that medical waste **DOES NOT** include the waste, generated during performing of cosmetic service, inter alia, during the treatments like manicure, pedicure, tattoo, piercing or needle mesotherapy. In spite of the fact that the mentioned cosmetic procedures infringe the continuity of human tissue, they are not classified as health benefit; it causes that the waste produced during their performance **IS NOT** medical waste. Consideration of the waste, generated in cosmetology as medical waste is not consistent with the current binding law in Poland.

## Challenge No 2.

### How should be the disposable diapers and diaper pants classified? (Which waste group?)

It is the next problem which causes great emotions. Until 2014, on the grounds of the binding regulations in Poland, the disposable (single-use) diapers and diaper pants produced in the sphere of medicine – unless they were contaminated with biological material, containing living pathogens – were disposed as mixed municipal waste (200301).

The regulation of the Minister of Environment dated December 9, 2014 on the matter of waste catalogue extended the qualifications of the waste group having code 180104. The mentioned code group instead of the so-far existing provision sounding: "...other waste than that one listed in 180103\*..." received the following text: "... other waste than in 180103\* (e.g. material and plaster dressings, bedclothes, single-use clothes, diapers)...". Owing to it, all used disposable clothes (including also aprons, masks and gloves) and the disposable diapers and diaper pants must be considered as medical waste. And, although they will be placed in different bags/containers as follows:

- those contaminated with infectious material (single-use diapers, diaper pants coming, *inter alia*, from the patients with the contagious diarrhoea or infection of urinary system, disposable bedclothes and single-use clothes, contaminated with human biological material – to red bags/containers marked with code 180103\*;
- the remaining disposable diapers or diaper pants (coming, *inter alia*, from healthy newborn infants or patients of long-term care at whom the diarrhoea symptoms or infections of urinary system were not recognized) or single-use bedclothes and disposable clothes, being not contaminated with biological material – to bags/containers in colour different than red or yellow, marked with code 180104;
- in connection with the lack of an access to alternative methods of neutralization of medical waste, not possessing infectious properties, they shall be neutralized by thermal treatment in hazardous waste incineration plants. As the mentioned plants dictate the price, neutralization of all disposable diapers, diaper pants, bedclothes and clothes may be a great challenge for the medical entities due to the increase of costs. In turn, the increase of the costs may cause the restrictions in the application of single-use bedclothes and other clothes and disposable diapers and diaper pants in the hospitals what

may result in the increased risk of transmission of biological pathogens in the hospital environment and by this, spreading of infections and infectious diseases; such situation remains in the contradiction with the provisions of Art. 11 and 14 of the *Law on prevention and control of infections and infectious diseases in humans* (Official Journal of Laws 2008.234,1570 with later amendments).

The described procedures cause that the disposable diapers and diaper pants, employed in the sphere of medicine, irrespectively of the epidemiological status of the patient from whom they derive, are always treated as medical waste. Differentiation of code (180103\* or 180104) has not greater meaning because due to the limited availability of methods D9 and D5, they will be neutralized by thermal transformation (D10), in the process which causes emission of harmful gases (inter alia, SO<sub>2</sub>, HCl, SO<sub>3</sub>) and heavy metals and dusts

## Challenge No 3.

### What are the methods of neutralizing the disposable diapers and diaper pants if they have been classified into group 180104?

At present, in conformity with the provisions of art.2 par.1 of the Regulation on the matter of requirements and methods for neutralization of medical and veterinary waste, binding since 22 November 2016, the following methods of neutralizing medical waste are admitted:

- thermal transformation on land (D10) is referred to:
  - ALL medical infectious waste (180102\*, 180103\*, 180180\* and 180182\*)
  - THE SELECTED medical waste, not possessing infectious properties (180101, 180104, 180106\*, 180107, 180108\* and 180109);
- physico-chemical treatment excluding autoclaving, thermal disinfection, microwave impact if the technology, employed in the discussed treatment ensures the neutralization of the waste (D9) which is safe to environment and human health and life . It concerns:
  - EXCLUSIVELY THE SELECTED medical waste, not possessing infectious properties (180104, 180106\*, 180107, 180110 and 180181);
- landfill storage of the waste different than dangerous and neutral (D5) is referred to:
  - EXCLUSIVELY THE SELECTED medical waste, not possessing infectious properties (180104, 180181).

The provisions of art. 95 par. 2 of the Law on waste, in the case of neutralizing infectious medical waste, **demand** the thermal transformation in the incineration plants for hazardous waste, and at the same time, **it is forbidden** to neutralize infectious medical waste in the waste co-incineration plants (art. 95 par. 3).

The above mentioned legal provisions, due to a limited availability of the physico-chemical treatment methods (D9) and of the possibilities of landfill storage of waste different than dangerous and neutral (D5) in practice:

- restrict the methods of neutralization of infectious medical waste exclusively to thermal transformation of the waste on land (D10);
- univocally **repeal** the so-far existing possibility of neutralizing the infectious medical waste by the **autoclaving method, thermal disinfection or microwave action**.

Meanwhile, other European countries (*inter alia*, the Czech Republic, Germany, Italy, Hungary, Spain, Portugal, Sweden, Lithuania, Latvia) – in respect of infectious medical waste – admit the application of modern technologies of autoclaving and microwave operations as the methods equivalent to thermal transformation of the waste.

We should remember that any of the European directives has not introduced the demand of transforming the infectious medical waste exclusively with the application of thermal transformation in the waste incineration plants (D10). Other neutralization processes, including process D9 (e.g. application of microwaves or autoclaving) are considered as equivalent always when they guarantee environment and human life protection. Polish regulations relating to the methods of neutralization of infectious medical waste belong to the most restrictive in Europe.

## Summing up

The principles of disposal of medical waste in the sites of their origin cause still many practical problems in spite of the fact that they have functioned in the provisions of Polish law for many years. We should also remember that the provisions of law introduce the minimum requirements and in the cases where the safety aspects speak for tightening up of the regime of proceeding with the waste, in comparison to that one dictated by the regulations, we should be guided by the experience and opinion of experts.

## Literature

- [1] Ustawa o odpadach z dnia 29 marca 2022 (Dz. U. 2022, poz. 699 tekst jednolity);
- [2] Rozporządzenie Ministra Klimatu z dnia 2 stycznia 2020 r. w sprawie katalogu odpadów (Dz. U. 2020, poz. 10);
- [3] Obwieszczenie Marszałka Sejmu Rzeczypospolitej Polskiej z dnia 15 kwietnia 2021 r. w sprawie ogłoszenia jednolitego tekstu ustawy o utrzymaniu czystości i porządku w gminach (Dz. U. 2021, poz. 888)
- [4] Rozporządzenie Ministra Zdrowia z dnia 5 października 2017 r. w sprawie szczegółowego sposobu postępowania z odpadami medycznymi (Dz. U. 2017, poz. 1975).

Article reviewed

Received: 02.06.2022 r./Accepted: 08.06.2022 r.

**WYDAWNICTWO SIGMA-NOT**

ponad **70** LAT NA RYNKU  
**34** TYTUŁY  
**129 000** PUBLIKACJI

WYGODNY DOSTĘP  
 DO ARTYKUŁÓW FACHOWYCH

**Nowy**  
 PORTAL INFORMACJI TECHNICZNEJ  
[www.sigma-not.pl](http://www.sigma-not.pl)

**Zmieniamy się dla Ciebie**

Instagram and Facebook icons are visible in the bottom left corner.