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Synopsis

The Current Environmental Law on Medical Waste and its Impact as Hazardous Pollutant – A Short Review

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Abstract. In order to guarantee the society a safe living environment, each state regulates rules and normative procedures for their implementation, in accordance with the established international ecological standards. In essence, their subject content covers a wide range of human activities, the secondary result of which is the generation of household, medical and industrial waste. In view of this review, we will examine the applicable national and European acts governing the storage, transport, disposal and incineration of medical waste. Such a regulatory analysis would make a positive contribution to the modernization of the national legal framework, in line with existing good environmental practices within the European Union.

Key words: environmental law, medical waste, environmental pollution.

Introduction

In order for a specific normative act to be fully applicable, it should be approved or transposed in accordance with the procedure provided by law and should regulate as much as possible an aspect of the procedural activity for which it has been approved. When we talk about medical waste, the starting point for regulating the activity should be the content of hazardous substances that pose a serious threat to the environment and human health. In this sense, the pandemic of Coronavirus disease 2019 (COVID-19) also contributed to the discussion and raised a number of issues concerning the direct and immediate consequences for the environment, as a result of the introduced requirements for the use of personal protective equipment worldwide. Disposable masks and gloves used by the public should be treated in accordance with international standards, as medical waste. This raises the question of the extent to which the member states of the European Union, including the Republic of Bulgaria, have managed to create conditions for limiting environmental pollution from the increased amounts of medical waste generated daily by medical and healthcare institutions and society. In order to adequately assess the risk to the environment and biodiversity, in the event of unregulated/unauthorized disposal and storage of medical and biomedical waste as a residual product of medical activity, attention should be paid to the basic European and national legal framework of developed countries, for comparison and formulation of relevant proposals for optimization of the national regulation. Such

an overview would have its practical usefulness in terms of optimizing our national legislation, given the reported gaps and weaknesses in the regulations of these countries.

Common regulatory framework for the management and legal regulation of medical waste within the European Union

The European regulatory framework is a key foundation for the harmonization of procedures and rules in the Member States on medical waste. From a legal point of view, there are a number of council regulations and directives that change with the development of science and technology to meet the needs of modern societies. In the light of this review and timeliness, the most relevant acts transposed into the legislation of most of the Member States will be considered.

- *Council DIRECTIVE 90/385/EEC on Active Implantable Medical Devices (AIMDD) (1990).* The directive regulates all issues concerning implantable medical devices. The basic concepts have been defined, procedures have been outlined regarding their use, storage and destruction. The texts are also in line with the technological progress of the member states in the field of this type of medical devices. Basic concepts are defined in the context of the diversity of this type of medical devices.

- *Council DIRECTIVE 93/42/EEC on Medical Devices (MDD) (1993).* It regulates the use of medical devices and in particular *in vitro* diagnostic medical devices, including reagent, reactive product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of samples, including donations of blood and tissues obtained from the human body, solely or principally for the purpose of providing information:

- regarding a physiological or pathological condition;

- regarding a congenital anomaly;

- to determine safety and compatibility with potential recipients, or to monitor therapeutic measures.

- *DIRECTIVE 98/79/EC of the European Parliament and of the Council on in vitro Diagnostic Medical Devices (IVDMD) (1998).* It complements the content of Directive 93/42/EEC on Medical Devices concerning the part for self - testing devices. Requirements have been introduced regarding the obligation of Member States to monitor the safety and quality of these devices, as well as to specify the method of disposing of used disposable tests. This Regulation sets high standards of quality and safety for *in vitro* diagnostic medical devices in order to meet the general safety expectations for such products.

- *DIRECTIVE 2000/532 / EC: Commission Decision of 3 May 2000 replacing Decision 94/3 / EC establishing a list of wastes pursuant to Article 1 (a) of Council Directive 75/442 / EEC on waste and Council Decision 94/904 / EC establishing a list of hazardous waste pursuant to Article 1 (4) of Council Directive 91/689 / EEC on hazardous waste (notified under document number C (2000) 1147).* The directive regulates the laws, regulations and administrative provisions related to the classification, packaging and labeling of dangerous substancesA list of wastes in accordance with Article 1 (a) of DIRECTIVE 75/442 / EEC on waste and Article 1 (4) of DIRECTIVE 91/689 / EEC on hazardous waste is also annexed to the Directive. The list is harmonized according to the national laws of the member states and is applied in full by each of them.

- *Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.* This regulation aims to ensure the smooth functioning of the internal market for medical devices, based on a high level of protection of the health of patients and consumers. It sets high standards for the

quality and safety of medical devices in order to meet the general safety requirements for such products. This Regulation harmonizes the rules for the placing on the market and commissioning into service of medical devices and their accessories on the Union market, thus enabling them to benefit from the principle of free movement of goods. As regards Article 168 (4) (c) of The Treaty on the functioning of The European Union(TFEU), this Regulation lays down high standards of quality and safety for medical devices, as well as ways to safely recycle or dispose of them, in order to ensure a safe and healthy environment.

- *Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.* This Regulation establishes high standards of quality and safety for *in vitro* diagnostic medical devices in order to meet the general safety expectations for such products. The Regulation provides guidelines developed for *in vitro* diagnostic medical devices at international level, in particular in the context of the Global Working Group on Harmonization and the Follow-up Initiative, the International Forum of Medical Device Regulators, to promote global regulatory convergence, which contributes to for a high level of global safety protection and for trade facilitation, in particular in the provisions on the unique identification of the device, general safety and performance requirements, technical documentation, classification rules, conformity assessment procedures and clinical evidence.

- *DIRECTIVE (EU) 2018/851 of the European Parliament and of the Council of 30 May 2018 amending Directive 2008/98/EC on waste.* Improving resource efficiency and ensuring that waste is valued as a resource can help reduce the Union's dependence on imports of raw materials and facilitate the transition to more sustainable materials management and a circular economy model. This transition must contribute to the goals of smart, sustainable and inclusive growth set out in the Europe 2020 strategy and create important opportunities for local economies and stakeholders, while helping to increase the synergies between the circular economy and policies in the field. energy, climate, agriculture, industry and research, as well as bring environmental benefits in terms of greenhouse gas savings and the economy. Consistency is envisaged between Directive 2008/98/EC and related Union legislation such as Directive 2009/28/EC of the European Parliament and of the Council (5) and Regulation (EC) № 1907/2006 of the European Parliament and of the Council. The directive also states that many Member States have not yet fully developed the necessary waste management infrastructure. It is therefore essential to set clear long-term policy objectives in order to target measures and investments, in particular by preventing the creation of structural overcapacity for residual waste treatment and blockages of recyclable materials at lower levels of the hierarchy of waste. The directive also states that waste management requires a very complex system, including an efficient collection scheme, an effective system for sorting and properly tracing waste streams, active participation of citizens and businesses, infrastructure adapted to the specific composition of waste, and a complex financing system.

- *DIRECTIVE 2000/532/EC: Commission Decision of 3 May 2000 replacing Decision 94/3/EC establishing a list of wastes pursuant to Article 1 (a) of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant to Article 1 (4) of Council Directive 91/689/EEC on hazardous waste (notified under document number C (2000) 1147).* The directive stipulates that all waste included in the list of hazardous waste must be included in the European waste catalog defined in Commission Decision 94/3/EC. In order to increase the transparency of the enumeration

system and to simplify the existing provisions, a Unified European Community list should be established, including the list of waste set out in Decision 94/3/EC and that of hazardous waste set out in Decision 94/904/EC requires full harmonization of the general categorization of hazardous waste within the EU. Article 2 of the Directive states that Member States may decide, in exceptional cases, on the basis of documentary evidence duly provided by the holder, that specific wastes listed as hazardous do not show any of the properties listed in Annex III to Directive 91/689/EEC. Without prejudice to the second indent of Article 1 (4) of Directive 91/689/EEC, Member States may decide, in exceptional cases, that the wastes listed as non-hazardous show one or more of the properties listed in Annex III to Directive 91/689/EEC. All such decisions taken by the Member States shall be announced annually at sessions of the Commission(EC). It shall compare these decisions and examine whether the Community list of wastes and hazardous wastes should be amended or supplemented.

- *DIRECTIVE 2000/76/EC of the European Parliament and of the Council of 4 December 2000 on the incineration of waste (OJ L 332, 28.12.2000, p. 91*). Points out that the Protocol on Persistent Organic Pollutants, signed by the Community in the framework of the United Nations Economic Commission for Europe (UN/ECE) Convention on Long-range Transboundary Air Pollution, sets legally binding limit values for dioxins and furans emissions of 0,1 ng/m^2; TE (toxic equivalents) for installations incinerating more than 3 tonnes per hour of municipal solid waste, 0.5 ng/m; TE for installations burning more than 1 tonne per hour of medical waste and 0.2 ng/m; TE for installations burning more than 1 tonne per hour of hazardous waste. The Protocol on Heavy Metals, signed by the Community in the framework of the UNECE Convention on Long-range Transboundary Air Pollution, sets legally binding limit values for particulate emissions of 10 mg/m^3 for the incineration of hazardous and medical wastes and for emissions of 0.05 mg/m^3 mercury for hazardous waste incineration and 0.08 mg/m^3 mercury for municipal waste incineration. The International Agency for Research on Cancer and the World Health Organization indicate that some polycyclic aromatic hydrocarbons (PAHs) are carcinogenic. Therefore, Member States may set emission limit values for PAHs among other pollutants. Furthermore, Article 174 of this Directive provides that Community policy on the environment is to contribute to protecting human health. Paragraph 16 of the Directive clarifies that „The distinction between hazardous and non-hazardous waste is based mainly on the characteristics of the waste before incineration or co-incineration and not on the differences between emissions. The incineration or co-incineration of hazardous and safe waste should be subject to the same emission limit values, but it is appropriate to maintain different incineration techniques or conditions or different co-incineration and different measures to verify the acceptance of different wastes".

Comparative analysis of the legal acts regulating the procedures for medical waste management in the Republic of Germany, the Hellenic Republic, the Republic of Hungary and the Republic of Bulgaria

Germany. In Germany, the management of medical waste is regulated by a number of regulations that aim to cover relatively in detail the procedures for the storage and disposal of medical waste**.** In essence, these acts represent a fundamental plane on the basis of which the management activity is regulated, as well as the subsequent administrative control is exercised in view of regulatory requirements. The Basic Law is the Closed Cycle Waste Management Act, which regulates the prevention, recycling, reuse and disposal of waste (Kreislaufwirtschaftsgesetz vom 24. Februar 2012 (BGBl. I S. 212), das durch § 44 Absatz 4

des Gesetzes vom 22. Mai 2013 (BGBl. I S. 1324) geändert worden ist.). There are also a number of bylaws - regulations and instructions related to the regulation of control over the spread of infections and safety in medical and health care facilities. (Hansen et al., 2014). Procedures are also provided, in the German Dangerous Goods Regulation and the Federal Pollution Control Act, for the transport of medical waste from hospitals to landfills for storage and disposal and destruction. (BImSchG 2013: Bundes – Immissionsschutzgesetz in der Fassung der Bekanntmachung vom 17. Mai 2013 (BGBl. I S. 1274), das durch Artikel 1 des Gesetzes vom 2. Juli 2013 (BGBl. I S. 1943) geändert worden ist, 2013). Germany, as well as a number of other European countries, including Bulgaria, have adopted the standards of division according to the European Waste Catalog, in view of which the lists of hazardous and non-hazardous medical waste are separated in bylaws according to the domestic legislation of each country. (2000/532/EC: Commission Decision of 3 May 2000 replacing Decision 94/3/EC establishing a list of wastes pursuant to Article 1(a) of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive 91/689/EEC on hazardous waste (notified under document number C (2000) 1147). Based on the brief regulatory review of the applicable legislation in the field of medical waste management in the Republic of Germany, it can be concluded that the frequency of audits of waste storage areas should be increased, as well as strict compliance with the adopted rules in the by-laws, according to the safety requirements of the persons working with medical waste (Hansen et al., 2014).

Greece. Unlike a number of European countries, significant progress has been made in the legislation of the Hellenic Republic on medical waste management. With the issuance of the first ministerial decree on medical waste management in 2003, the modernization of the legislation in this field began. The European Directive 2008/2009 „Crimes in the field of the environment" has also been transposed, which marks the beginning of the criminalization of certain types of crimes committed by officials responsible for the management of medical waste in the units entrusted to them. n 2012 Law N4042/2012 – „Framework for waste from production and management" was adopted. The Law contains the Annex with the European Wastes Catalogue (EWC) which isa hierarchical list of waste description established by Commission Decision 2000/532/EC. With its adoption, the Ordinance on Hospital Waste Management (KYA 146163/2012 (ΦΕΚ1537/B/2012)) was approved, in which the following classification for effective management was adopted:

1.Prevention of creation;
2.Preparation for reuse;
3.Recycle;
4.Recovery of raw materials or energy;
5.Disposal.

Explicit prohibitions have also been introduced with the ordinance for storage or disposal of medical waste without supervision (Halazonitis, 2015). At present and in view of the brief overview of the applicable regulations in the Hellenic Republic on medical waste, the following conclusions can be drawn:

- Despite the adapted domestic legislation of Greece in accordance with the European management requirements, the country encounters difficulties in auditing and controlling the management of medical waste generated in the medical establishments located on Its islands.

- The territorial remoteness of these medical and health units increases the cost of transporting medical waste and creates preconditions for the formation of illegal practices that would lead in certain cases to environmental disasters. In this sense, it would be reasonable to strengthen the administrative and control function of local

authorities with regard to the audit of medical waste storage and management procedures.

Hungary. In Hungary, the main piece of legislation governing hazardous waste management is Act CLXXXV of 2012 on waste. The Act covers all wastes, all preventive activities, waste management and waste management facilities. A basic decree in the field of hazardous waste management, and in particular medical waste Decree No. 225 of 2015 (VIII.7)- regulates all activities related to the carriage, distribution, storage and classification of HW. Government decree No. 439 of 2012 (XII.29.) (on the registration and authorization of waste management activities) points out, that waste can only be handed over to authorized intermediates and traders. Formal requirements on the request for permission on related activities can be found in this Decree as well. The competent authority for general permissions is the National Inspectorate for Environment and Nature. Decree No. 1 of 2002 (I. 11.) of the Ministry of Health on waste management in medical institutes regulates the storage of such waste and the quality requirements of the appropriate packings. Infectious medical waste can be stored no longer than 48 hours without cooling, no longer than 30 days in case of storage in dedicated refrigerator, between 0-5 °C. Annex 4 rules the quality requirements on tools used for related activities. Strict regulations regarding the transport of radioactive materials as a residual product have also been adopted. The regime for carrying out activity is mandatory licensing. The main transport mode is road. In most of the cases, the industrial companies arrange their own deliveries, medical institutes mainly contract with a professional forwarder.

Compared to the legal regulation of Greece and Germany in the field of medical waste management, Hungary is significantly less adapted in view of the adopted European standards supplementing by transposing the procedures of domestic legislation. Impressive is the limited range of normative documents that regulate the main issues of the activity of medical waste management. An update in this sense was made in the field of pharmaceutical waste in 2017.

From the review of the regulations relevant to the issues under consideration, it can be concluded that for the most part the procedures related to the regulation of medical waste in Hungary overlap with the adopted general rules for handling hazardous waste. From the current regulatory review, it is to be noted that, unlike Bulgaria, Hungary has not fully adopted the transposition of the European Waste Catalog, which to some extent creates differences regarding the components and categorization of medical waste.

When we talk about state environmental policy, we should keep in mind that in essence these are a set of goals, principles and practical approaches to solving environmental problems of modern society, which are regulated in regulations and programming documents adopted by the state (Penchev, 2017).

Bulgaria. In view of the subject of this review, we will consider in detail the regulatory framework of the Republic of Bulgaria adopted in the field of medical waste. Among the main normative acts is the Environmental Protection Act (EPA). Article 5 specifies the factors that pollute or damage the environment, and can be: natural and anthropogenic substances and processes; different types of waste and their locations; risky energy sources - noise, vibration, radiation, as well as some genetically modified organisms. Chapter Three - „Protection and Use of Environmental Components and Waste Management" of EPA and in particular Article 44 set out requirements regarding the owners and operators of landfills, including tailings, ash dumps and others, as well as of facilities for storage of waste and / or hazardous chemicals, preparations and products and how to organize and operate them in a way

that excludes pollution and damage to soil and other components of the environment. In section seven - „Waste management" of the said law are set out in three provisions the basic requirements that should be met in waste management processes. In essence, the Environmental Protection Act sets a general regulatory framework covering the scope of waste as a residual product of human activity, without being formalized in a specific area of waste.

Next comes The Waste Management Act (WMA) - according to Article 1, paragraph 3 „waste management is carried out in order to prevent, reduce or limit their harmful effects on human health and the environment. "Chapter three of the law regulates the procedures for treatment and transportation of waste. Permits for carrying out activities for recovery and/or disposal of waste, including pre-treatment before recovery or disposal, shall be issued by the director of the regional inspectorate for environment and water on whose territory the activities are carried out or by the Minister of Environment and Water, when the activities are carried out on the territory of more than one regional inspectorate for environment and water. Section five provides that shipments of waste within the European Community with or without transit through third countries, imports into the Community from third countries, exports from the Community to third countries and transits through the Community to and from third countries of waste shall be carried out under the conditions and by the order of Regulation 1013/2006. Regulation 1013/2006 regulates the requirements for notifications for transportation of waste from, to and through the territory of the Republic of Bulgaria, for import or export from or to countries that are not members of the European Union. Chapter Six, Section Two also provides for the forms of administrative violations, as well as the penalties provided for them.

Last but not least in the field of waste management, and in particular medical waste, is the Law on Ratification of the Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (the Basel Convention) - Article 2, paragraph 1, of the Basel Convention states that „Waste" means substances or objects which are disposed of or are intended to be disposed of, or must be disposed of in accordance with the provisions of national law. Definitions of „environmentally sound management of hazardous or other wastes" have also been introduced, which includes taking all practical action to ensure that management of hazardous or other wastes is such as to protect human health and the environment against the harmful effects of such wastes. The Convention introduces a six-month period for each of the ratifying parties and parties to it to harmonize their categories and definitions in domestic legislation with those provided for in Annex 1 and Annex 2, which are an integral part of the Basel Convention. In this sense, the Republic of Bulgaria has unified all required definitions according to the cited annexes, upon ratification of the Convention.

By-laws, the content of which deals in detail with all relevant regulations related to medical waste management.

Ordinance 1/2015 on the requirements for the activities for collection and treatment of waste on the territory of medical and health establishments, determines in general the circle of the subjects generating medical waste - medical and health establishments. Of course, the division is not exhaustive and in a more detailed analysis can be distinguished subcategories of these two main groups, namely - doctors' offices, dental offices, veterinary facilities, medical laboratories, research centers, etc. According to their nature of work, these entities generate in their daily activities different types of medical waste, which according to the regulations can be classified as hazardous and non-hazardous waste. Experience has shown that if the legal requirements for the management of

hazardous medical waste are met, they do not pose a greater danger to health than non-hazardous waste, and vice versa - their improper management can lead to a significant increase in health risk for the people and the environment (Chartier et al., 2014).

Medical waste from medical and/or healthcare facilities that does not have hazardous properties can be classified into subgroups in general as follows:

- ''Household"/ urban waste;
- Paper, cardboard, plastic, including wrappings;
- Glass and plastic cans of saline, not used in patient transfusion or other infusion systems;
- Ampoules and vials other than those of used vaccines and cytotoxic and cytostatic medicinal products;
- Metal packagings, other than those containing residues of dangerous substances/mixtures or contaminated with dangerous substances/mixtures;
- Bandages, plaster casts, bed linen, clothing and disposable linen, not contaminated with biological fluids, and diapers, excluding waste generated by the operation of isolators in infectious wards/clinics and laboratories for particularly dangerous infections;
- Food waste, excluding food waste from infectious hospitals and clinics/wards.

It should be noted here that the non-hazardous waste, separated from the medical and health establishments, as a waste product of their activity, is managed as household waste and is deposited onto the landfills for non-hazardous waste, after separation of the materials suitable for reuse and recycling – Waste processing is in fact a process in which waste is recycled to produce a raw material that can be used to produce new products. It is an indisputable fact that waste has been a major environmental problem for decades or more precisely since the beginning of the industrial revolution. he recycling process contributes to saving raw materials, on the one hand, and reducing waste and environmental pollution, on the other hand, and therefore recycling technologies are a priority in the policies of public and private companies in environmental terms.

Hazardous waste from medical and/or healthcare facilities are:

- Biomedical:

• Biological medical waste - body parts and organs and other anatomical waste, including blood, biological fluids and pathological waste, which may be distinguished as such by citizens or medical staff and for which, for ethical reasons, a specially treated.

• Laboratory waste - crops and strains containing viable biological agents formed in health establishments operating in the field of hygiene, microbiology and virology, as well as in medical establishments where the multiplication of pathogenic microorganisms may occur, as well as vessels and utensils used for the transport, inoculation and mixing of cultures of infectious agents and infected animals from laboratories.

• Waste contaminated with blood and biological fluids - medical devices and equipment contaminated with blood, blood products, secretions and excreta, whether or not previously tested and categorized as infectious waste that are reasonably believed to carry a potential risk of transmission of infectious agents (bandages, tampons, syringes without needle, infusion sets without needle, bandages, contaminated sheets, underwear, gloves and disposable aprons, etc.).

- Sharp waste - all medical waste with sharp or pointed and/or cutting parts that can cause injury, trauma or cutting/breaking the integrity of the skin of the human body (such as used needles, drainage tubes, syringes with a needle, broken glassware, ampoules, pipettes, scalpel blades, lancets, etc.).

- Waste containing dangerous chemical substances/mixtures - waste from diagnostics, experimental work, cleaning and disinfection activities:

- residues of chemicals/mixtures, fixing solutions, solvents, biocides (disinfectants) and cleaning agents, organic and inorganic chemicals/mixtures;
- unusable batteries containing heavy metals (such as mercury, cadmium, etc.);
- diagnostic instruments and consumables containing heavy metals (such as mercury, cadmium, etc.);
- wastes from dental amalgam, including amalgam residues, particles and fillings, including those contained in used water, as well as teeth or parts thereof contaminated with dental amalgam.

With regard to hazardous medical waste, according to „Ordinance No. 2/2014 on waste classification", potentially infectious waste is classified with code 18 01 03 * - waste, the collection and disposal of which is subject to special requirements in order to prevent infections. Waste Management Act formulates the property H9 - infectivity the property H9 - infectivity. Wastes with this property contain „vital micro-organisms or their toxins which are known or reasonably believed to cause disease in humans or other living organisms". Undoubtedly, such data are of potential interest for periodic monitoring by the competent state authorities, as well as by the World Health Organization (WHO). A safe and healthy environment is one of the fundamental factors for the stability of any society and any ecosystem worldwide. Medical waste is classified as hazardous on the basis of one or a combination of several of the following properties: content of infectious microorganisms; content of toxic chemicals having oxidizing, irritating, flammable properties, etc.; radioactivity, content of sharp objects, etc. The need for safe management of biomedical and medical waste arises from the presumed or actual risk of potential transmission of infectious diseases through accidental injury or contact with infected biological fluids. Disposal of sharp objects (needles, scalpels, etc.) attracts special interest due to the small number of cases of infection of medical workers with hepatitis and human immunodeficiency virus (HIV) due to injuries with sharp objects. Therefore, reducing the risk of injury is a „good practice" in waste management.

For the difference between hazardous and non-hazardous medical waste and the consequences for human health in their improper management and their impact as a pollutant on the environment.

Based on officially released data from the WHO, Safe Management of Wastes from Health-care Activities - Second Edition, by 2019, the most common infectious diseases that occur as a result of improper management of medical waste are presented in Table 1 (Practical guide for safe waste management from medical and healthcare facilities, et, al. 2017). The infections described in Table 1 illustrate the possible negative consequences that can occur directly on human health, if stored improperly, in accordance with the requirements of the regulations on body fluids that can infect waste.

Different concepts and approaches are used in the definition and classification of biomedical and medical waste in the world, especially with regard to infectious waste. The World Health Organization (WHO) follows the concept of „universal precautions", which describes a set of measures formulated to prevent the transmission of contagious diseases. Definitions and criteria for the identification of infectious substances are an area in which international harmonization is important and cooperation with the WHO and the UN Commission of Experts on the Transport of Dangerous Goods plays an important role. (Peiry, 2000). In this regard, the WHO proposed in 2002. the so-called „Universal precautions to prevent the transmission of HIV and other blood-borne infections". These measures eliminated the need for the isolation category - „Precautions in case of contact with blood and biological fluids„. However, the application of universal precautions does not eliminate the need for other isolation precautions, such as measures to protect against airborne infections in the case of influenza, air isolation in cases of pulmonary tuberculosis or contact isolation in methicillin-resistant strains of *Staphylococcus aureus*.

Table 1. Consequences for human health, due to improper management of medical waste.

Type of infection	Examples of causes	Body fluid infecting the waste
1. Respiratory	*Mycobacterium tuberculosis*, *Streptococcus pneumoniae* and other *bacteria*; viruses causing Severe acute respiratory syndrome (SARS).	Secretions from the respiratory tract, saliva.
2. Meningitis	*Neisseria meningitidis*	Cerebrospinal fluid (CSF)
3. Acquired Immunodeficiency Syndrome (AIDS)	Human immunodeficiency virus (HIV)	Blood and other body fluids
4. Viral hepatitis B and C	Hepatitis B and C viruses	Blood and other body fluids
5. Genitourinary	*Neisseria-gonorrhoeae, Herpesvirus*	Urinary secretions and urine

Table 2 presents the pollutants that are released in the form of chemical elements in the air, water and soil during the decomposition and incineration of medical waste as a residual product. The basic data are taken from the special report of the European Court of Auditors „Air pollution - our health is still not sufficiently protected". The report has been drawn up in conjunction with the second subparagraph of Article 287 (4) TFEU. Based on the synthesized analysis presented in the table below, it can be concluded that even in compliance with the normatively defined rules for disposal and destruction there are risks of environmental pollution. Undoubtedly, they are minimized and evaluated by experts as relatively safe for human health. But in the event of unauthorized disposal, the consequences would lead to a serious environmental catastrophe and permanent damage to human health. Regarding the purity and quality of the air in the Republic of Bulgaria, of interest is Case C-488/1 of the European Court in Luxembourg (2017), by whose decision our country was sentenced to pay the financial sanctions related to the systematic and constant non-compliance from 2007 to 2014. including both annual and daily limit values applicable to PM10 concentrations in the following zones and agglomerations: BG0001 Sofia agglomeration, BG0002 Plovdiv agglomeration, BG0004 North, BG0005 Southwest and BG0006 South East.

Methodology for collection, deposit and dissolution of medical waste

The wide variety of types of medical waste classified in these groups, in essence, imply a different methodology for collection, storage, deposit and dissolution. Such a requirement has its logical character, in view of the content and the final residue of the product after its dissolution, incineration or recycling. A basic principle in medical waste management is to preventing generation and searching for opportunities to reduce the amount of waste generated. This principle is accepted for all types of waste in the member states of the European Union. Prior to the final disposal of the waste, the possibilities for reuse and recycling must be used by pre-separating the non-hazardous (household) from the hazardous medical waste (Rushbrook, 2000; Rushbrook & Zghondi, 2004).

Separate waste collection and in-hospital transport - the safe separation of medical waste is the responsibility of the staff of the medical institution. Regarding the color coding of waste containers, Ordinance 1/2015 on the requirements for the activities for collection and treatment of waste on the territory of medical and health establishments regulates the following requirements:

Table 2. Environmental consequences in case of regulated destruction of medical waste and residual elements that are released during the disposal and incineration of waste.

	Atmospheric pollution from incineration of medical waste	**Soil contamination due to improper storage of medical waste**	**Water pollution from improper storage of medical waste**
1.	The pollution is anthropogenic. According to the origin of the pollution: Primary - disposed of directly from identifiable sources. This group includes CO, SO_2, H_2S, NO, NH_3, a small amount of NO_2, hydro-carbons, dust, smoke, soot and others.	Contamination is most often caused by improper disposal and burial of waste. The sites are divided into three categories: landfills for hazardous waste, landfills for safe waste and landfills for inert materials.	The pollution can be physical, chemical or biological.
2.	The main pollutants are carbon monoxide (CO), sulfur compounds (SO_2, H_2S, CS_2), nitrogen compounds (NO_x, NH_3), hydrocarbons (CH), ozone (O_3), photochemical smog and finely divided substances (dust).	The main soil pollutants are metals, a number of organic molecules, pathogens, biologically active mate-rials.	Contaminants are mainly microorganisms, including highly pathogenic microorganisms such as *E. coli, Salmonella sp*. and others. In industrial wastewater, harmful impu-rities in them are very diverse - from abiotic to microbial pollution.
3.	The consequences for the atmosphere during the incineration of waste are expressed in dust and gaseous pollutants. Gaseous pollutants can be divided into organic and inorganic (Guide for pre-treatment before waste disposal in the Republic of Bulgaria, 2014)	The consequences for the soil and groundwater would be irreparable in certain cases of contamination with radioactive medical waste.	The main sources of surface water pollution can be summarized as follows: by physical state are divided into: insoluble, colloidal and dissolved impurities. By their nature they are divided into: mineral, organic, bacterial and biological (Ivanov, 2015).

- non-hazardous waste is collected in transparent polyethylene bags/sacks, placed in containers with lids and pedals, marked with the inscription „Non-hazardous waste".

- hazardous waste is collected separately.

- biomedical waste, with the exception of biological waste, is collected in yellow plastic bags/sacks placed in containers with lids and pedals and marked with the international hazardous waste symbol.

- biological medical waste is collected separately in red plastic bags/sacks/bags.

All used needles are collected together, whether contaminated with biological fluids or not. They are classified as hazardous waste. Containers for collection of used needles must be yellow with the international symbol for hazardous waste, be impenetrable (usually made of high-density plastic) and covered with a lid. These containers must be tight and impermeable so

as to retain not only the needles but also the liquids left in the syringes. In cases where disposable syringes are used, the uncontaminated packaging should be disposed of in the non-hazardous waste container and the used syringe itself in the sharps container (Practical guide for safe waste management in medical and healthcare facilities).

Regarding the methodology for safe storage, collection and disposal of biomedical waste, the legislation of the Republic of Bulgaria provides for the following requirements:

- non-hazardous waste, are collected in collected in transparent plastic bags/sacks, placed in containers with lids and pedals, marked with the inscription «Non-hazardous waste»;

- *hazardous waste* is always collected separately. Biomedical waste, with the exception of biological waste, is collected in yellow plastic bags/sacks placed in containers with lids and pedals and marked with the international symbol for hazardous waste. Biological medical waste is collected separately in red plastic bags/sacks/bags.

- small amounts of chemical or pharmaceutical waste may be collected together with infectious waste using yellow containers. Waste with a high content of heavy metals (eg cadmium or mercury) must be collected separately.

- pharmaceutical products that will not be used or have expired should be collected by the medical establishment until they are returned to the supplier, importer or manufacturer for further disposal.

Containers and bags for waste should be located in each structural unit of the medical institution, and they should be accompanied by written instructions for separation and identification of medical waste in the two groups „hazardous“ and „non-hazardous“.

In order to limit the possibility of environmental pollution, normative rules have been introduced for the transportation of hazardous medical waste on the public road network. This type of waste should be transported in closed secondary packaging in accordance with the method of waste treatment. Secondary packaging (stationary and/or transportable vessels/containers) should be made of rigid impermeable material that does not allow puncture/breakage and meet the requirements of "Ordinance № 40 of 2004 on the terms and conditions for road transport of hazardous goods" and should be marked with the international hazardous waste symbol (Rushbrook, 2000; Rushbrook & Zghondi, 2004).

Treatment and disposal of hazardous medical waste

In view of the entities involved in the waste management process - waste generators; transport and disposal operators; control authorities, good collaboration should be in place to minimize the potential for unregulated pollution or environmental catastrophe. The quantities of non-hazardous medical waste represent 80-85% of the total quantities of all medical waste. Hazardous fractions occupy between 10-15% of the medical waste. The treatment of non-hazardous waste is done by landfilling the designated landfills and they are recycled or incinerated in the facilities for non-hazardous waste. In the case of hazardous waste, the treatment and disposal aims at (WHO, 2018):

- destruction of pathogenic microorganisms;

- destruction/transformation of residual pharmaceuticals and drugs into safe components;

- destruction of sharp and cutting tools and other technical means that can cause physical injuries;

- final disposal/destruction of biological medical waste and other organic materials.

The most common practices in the destruction of hazardous fractions are landfilling, incineration, autoclaving, microwave irradiation, chemical disinfection.

Conclusions

Based on the analysis made in relation to the impact of pollution of medical waste on the environment and the regulations governing the procedures, the following conclusions were drawn:

1. Hazardous medical waste, due to its content of vital microorganisms or their toxins, which can be considered to cause diseases in humans and other living organisms, is the most serious threat to the environment and biodiversity. With the development of European practices in this direction, the national rules and requirements that regulate and control its destruction should be updated. At present, they do not fully comply with established European practices, which creates preconditions for unregulated practices in order to save financial resources.

2. It would also be relevant to review the control powers of the bodies exercising supervision and control over the operators exercising the activity of disposal and destruction of medical and biomedical waste.

3. Checks carried out by the competent authorities should increase their frequency and not be carried out solely on a signal from the institutions or the citizens concerned. Such a practice would impose better control to the behavior and actions of operators treating and disposing of waste, medical institutions and all entities involved in the process.

4. It would be relevant to reconsider the size of the sanctions when we talk about imposing an administrative penalty on violators. The minimum thresholds of restriction create a precondition for neglect of the rules and good practices by the violators.

5. The commissions for ecology and communal activity on the ground, as well as the National Center for Public Health should exercise more actively their powers by regions, in order to prevent preconditions for the formation of pollutants by waste agents. It would be reasonable to establish a register of operators engaged in the disposal of medical waste, in order to exercise more effective control over their activities.

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