

HAZARDOUS MEDICAL WASTE AS A SUBJECT-MATTER OF A PUBLIC CONTRACT

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Summary. The present article provides an analysis considering the definition of medical waste, waste management system, classification, transport and waste disposal on the basis of Public Procurement Law. The authors outlined the fact that awarding entities are obliged to demonstrate their certain requirements based on a formalized system of procurement. The object of the present article is to display the grounds of certain requirements in a logical and consistent manner and also to depict that such requirements could constitute an impediment for some of the economic operators to even compete for the award of the contract in a certain market sector.

Key words: hazardous medical waste, public contracts, awarding entity, economic operator, subject-matter of the contract, contract award procedure

The definition of hazardous medical waste indicates the waste, including biological infectious agents with an ability to cause disease symptoms and microbes or their products, human internal and external parasites or their products, non-cellular infectious agents with an ability to replicate or transfer genetic material including genetically modified cell cultures or their products¹. This outlines the distinctive point of view on the component included in medical waste and their characteristics with an ability to spread and its destructive potential. Therefore, the outcome of it is especially harmful for both health and life of a human being.

Coming into existence of hazardous medical waste is an effect of both medical treatment and medical research and experiments. The vast majority of medical waste are created as a result of medical treatment, including such activities as diagnosis, therapy and preventive healthcare². Looking at the characteristics of hazardous medical waste, it should be noted that these are i. a.: human tissues and organs; post-autopsy and post-operative waste; spent blood containers; bodily fluids used in laboratory research and diagnostics; microbiological and laboratory cultures; biological preparations; attenuated vaccines; blood and its prod-

¹ See Article 2 point 2 Prevention and Eradication of Communicable Diseases Act 5th of December 2008 (Journal of Laws from 2013 item 947 including latter revisions).

² Regulation of Minister of Environment 9 of December 2014 – Waste Catalogue (Journal of Laws from 2014 item 1923).

ucts containing plasma and serum; used bandages, tampons contaminated with infectious material, patients bodily fluids, secretions and excretions; waste from patients suffering from infectious diseases; materials, disposable equipment, medical components created in contact with an infected patient or his secretions; spent biologically active baths contaminated with products of infectious diseases; immunomodulatory and anti-cancer drugs; fillings containing mercury amalgam³. In the context of the aforementioned classification of hazardous medical waste there exists a distinct risk factor, which directly results from the pathogens as content of medical waste. This is especially related to the content of the organic tissue and biological infectious agents like bacteria, viruses, fungi and hazardous chemicals from the expired cytotoxic or cytostatic drugs. Therefore, hazardous medical waste have infectious properties caused by the inclusion of substances and preparations containing viable microorganisms or their toxins which are known or for which there are reasonable grounds to adopt the view they are a cause of a disease in a human or other living organisms⁴.

Therefore, according to the aforementioned, the waste management system is of particular importance, which is the cause why it is regulated by numerous acts of international law, EU law and national law⁵. This regulations rigorously oblige to separate the process of collection, transport and storage of hazardous medical waste from other waste; proper labeling of hazardous medical waste; registration and identification of hazardous medical waste; disposal or recovery of hazardous medical waste⁶. Those entities whose activity is associated with the potential of creating hazardous medical waste are obliged to respect and comply with the principles of proper waste management. Hazardous medical waste management is a process which consists of the following successive stages: collection, storage, labeling, transportation to the internal warehouse, temporary storage, transportation to the place of disposal. In general, the transportation of hazardous medical waste is conducted on the basis of the law regulating the transportation of dangerous goods. Aforesaid compliance with the principles of waste transportation includes i.a.: owning a transport permit; appropriate protection and labelling of the load; particular regulations concerning the type of vehicles

³ See K. Brońska, *Klasyfikacja odpadów medycznych*, in: *Teczka procedur zapobiegających zakażeniom w placówkach medycznych. Od dezynfekcji po postępowanie z odpadami medycznymi*, ed. M. Błaszczak, FORUM, Poznan 2011.

⁴ Waste Management Act 14th of December 2012 Appendix No. 3 – Hazardous waste characteristics (Journal of Laws from 2013 item 21 including latter revisions).

⁵ See M. Furtak-Niczyporuk, *Proces gospodarowania niebezpiecznymi odpadami medycznymi*, in: *Prawo w ochronie zdrowia. Doświadczenia i perspektywy rozwoju*, red. M. Szewczak, B. Drop, R. Śmiech, KUL, Lublin 2013, p. 75–99.

⁶ See B. Wierzbowski, B. Rakoczy, *Podstawy prawa ochrony środowiska*, LexisNexis, Warsaw 2004, p. 61.

used to transport the load⁷. Hazardous medical waste is transported to the entity whose area of activity involves the disposal of the waste. The disposal process consists of subjecting the waste to the process of biological, physical and chemical modification in order to establish a state in which the waste does not pose as a threat to the life and health of human beings or to the environment. The objective of processing hazardous medical waste is to eliminate the infectious properties with the application of suitable methods. This means that the entity authorized to undertake the process of disposal of hazardous medical waste is bound to have the facilities or equipment necessary and adequate to conduct the process. Therefore, both transport and disposal of hazardous medical waste, requires the entity to meet a number of specific conditions. That is the reason that the manufacturer of hazardous medical waste can outsource transport and disposal of this waste to other entities. If the entity responsible of creating waste is a public finance sector unit, the matter of transport and disposal of the waste is conducted on the basis of the regulation of Public Procurement Law.

The rules for awarding public contracts settled on the basis of Polish law are defined in the Act of 29th of January 2004 Public Procurement Law⁸, hereinafter referred to as the Act. The system of public procurement specifies the rules and procedures for awarding public contracts. The most vital purpose being the base of the system of public procurement is to ensure a rational, effective and optimal expenditure of public funds⁹. The very aim of the public procurement is the realization of the certain requirements of the awarding entity. These requirements and realization thereof should be established in as actual, proportionate and justified on the basis of existing circumstances and conditions. Each and every proceedings are considered as separate with the design to meet the existing requirements of the awarding entity and in which this entity can and should take current technical capabilities of the branch of industry and its own experience into consideration. Article 29 paragraph 1 of the Act states that the subject-matter of the contract should be described in an unequivocal and exhaustive manner by means of sufficiently precise and comprehensive wording, taking into consideration all requirements and circumstances which could influence the preparation of a tender. The very essence of this provision is to oblige the awarding entity to determine its requirements of the contract in such a detailed and precise manner that each economic operator would have the possibility to identify the requirements set by the awarding entity. Establishment of the subject-matter of the contract reflects the certain requirements of the awarding entity, allows the economic operator to calculate the price of the tender in ac-

⁷ See M. Furtak-Niczyporuk, *Warunki transportu niebezpiecznych odpadów medycznych*, „Białostockie Studia Prawnicze”, Wydział Prawa Uniwersytetu w Białymstoku, Białystok 2015, Book 18, p. 99–111.

⁸ Journal of Laws from 2010 No. 113 item 759.

⁹ J. Żuk, *Budowanie systemu zamówień publicznych w Polsce*, Warsaw 1995, p. 5.

cordance with the principle of equal treatment of economic operators and ensures that the establishment of the subject-matter of the contract is unambiguously intelligible by all economic operators¹⁰. The awarding entity, when establishing the subject-matter of the contract, provides its certain requirements and specifies (within the Specification of Essential Terms of the Contract) the instruments with the use of which the compatibility of the tender with its requirements shall be examined. The awarding entity, when considering the essence of the proceedings and the subject-matter of the contract in a certain case, may demand the submission of certain documentation issued for a certain kind of an economic operator i.e., COC, declaration of conformity, etc. It is also important that the awarding entity is obliged to take all possible measures to eliminate the element of uncertainty by establishing the parameters of the contract in a comprehensive and unambiguous manner. If the awarding entity does not possess the necessary knowledge needed to prepare the establishment of the subject-matter of the contract it should do so with the use of a qualified professionals in order to avoid any unnecessary conflict in the process of the performance and the execution of the contract. The principles defined in the Act, including the principle of fair competition, are not only the “backbone” of each of the contract award procedures but also of the whole system of public procurement. Awarding entities shall be obliged to include all the necessary information in the open tendering documentation and make it accessible to all economic operators in order to allow them the preparation of a suitable tender and the necessity of compliance with the principles set in articles 7 and 29 of the Act means the removal of all terms which could indicate certain economic operators or those that would lead to the rejection of certain economic operators in a manner which would exclude them from the possibility to submit the tender or would lead to a situation in which one of the economic operators would be favored over the other competing for the contract¹¹. The subject-matter of the contract should be described in the most comprehensive and specific manner and the economic operator should be aware of all the duties, and their scope, which they shall be obliged to perform in the execution of the contract in order to take them into account and price them when preparing a tender¹². It should be noted that almost

¹⁰ Judgment of the National Appeals Chamber in case KIO 1786/14.

¹¹ Judgment of the National Appeals Chamber 24th of March 2015 in case KIO 469/15.

¹² See also Judgment of the National Appeals Chamber 22th of July 2013 in case KIO 1589/13
”The awarding entity is obliged to establish the so-called. “neutral” establishment of the subject-matter of the contract in an exhaustive and transparent manner. Establishment of the subject-matter of the contract should enable equal access to the contract for all economic operators and cannot create unjustified obstacles for the availability of public contracts and the competition. Violation of the principle of fair competition set out in Public Procurement Law due to the incorrect establishment of the subject-matter of the contract arises from i. a. when the awarding entity provides an unjustified over-detailed establishment of the subject-matter of the contract leading to an indication of a certain product. This breach takes place, including when the awarding entity describes

every establishment of the subject-matter of the contract entails the limitation of competition in a way that it favors certain economic operators against the other¹³. However, this does not imply that it leads to a violation the principle settled in article 7 paragraph 1 of the Act. It is also important that the awarding entity, when establishing the subject-matter of the contract, shall apply to the regulations provided in other acts of universally binding law. The specificity of the subject-matter of the contract must consider the conditions of the relevant market of certain services, in particular the rules regulating this market. Hence, the proper establishment of the subject-matter of the contract determines the correct conduct of the contract award procedures also created by the appropriate choice of tender evaluation criteria. According to the article 91 paragraph 1 of the Act the awarding entity chooses the most advantageous tender¹⁴ based on the evaluation criteria as set in the specification of essential terms of the contract. Preferably, tender evaluation should be based on measurable criteria. Even if the criteria cannot be described in a precisely measurable manner the sub-criteria should be established and a diversified way of scoring as a part of the tender evaluation based on the given criterion should apply. Economic operators shall act to ensure that the measurable criteria should be established at the stage of providing the specification of essential terms of the contract¹⁵. It should be noted that the principles of establishment of the contract award criteria were the object of Judgment of the Court of Justice of The European Union 17th December 2002 in case C-513/99 which outlined that they are linked to the subject-matter of the contract, do not confer an unrestricted freedom of choice on the authority and are expressly mentioned in the contract documents or the tender notice. Provisions of the Act also require the awarding entity to precisely determine the documents that economic operator is obliged to submit within the tender, in order to exhibit the compliance with the conditions of participation, as well as to precisely determine the conditions of participation. The awarding entity is bound by the set requirements which means that it is entitled to demand only previously listed documents. Consequently, the awarding entity does not have an unrestricted freedom in the decision making process as to which economic operator shall be awarded the contract, which economic operator excluded or its tender rejected, and is bound by applicable mandatory provisions of the Public Procurement Law and performing each of such activities must arise from these regulations.

The awarding entity, when conducting contract award procedures for transport and disposal of hazardous medical waste, in undoubtedly obliged to establish re-

the subject of the order by the over-specification of the subject-matter of the contract causing, without justification, an indication of a specific product. This violation includes determination of the subject-matter of a contract in a manner that is not justified neither by technical nor the functional regulation of the certain requirements of the awarding entity”.

¹³ See J. Pieróg, *Prawo zamówień publicznych. Komentarz*, 13th edition, Warsaw 2004, p. 99.

¹⁴ P. Granecki, *Prawo zamówień publicznych. Komentarz*, Warsaw 2009, p. 15 and following.

¹⁵ Judgment of the National Appeals Chamber 14th of April 2015 in case KIO 645/15.

quirements – for economic operators applying for the contract – arising from the Waste Management Act 14th of December 2012¹⁶ which proscribes the disposal of hazardous medical waste outside the area of a voivodeship in which they were created. It should be noted that the disposal of hazardous medical waste is permitted within the area of a voivodeship other than the voivodeship they were created only if there is no spare disposal capacity or there is no sufficient facility in the voivodeship within the area of which hazardous medical waste were created. Economic operator participating in contract award procedures is obliged to own an authorization in a form of a permit to perform waste management (transport, collection and disposal of waste) issued by the competent authority. This condition arises not only from the aforementioned Waste Management Act, but also Environmental Protection Law, 27th of April 2001¹⁷ along with regulations issued on the basis of these acts. Such a service must be performed in accordance with the Regulation of the Minister of the Environment, 12th of December 2014 – Model documents of waste registration, Regulation of the Minister of Environment, 9th of December 2014 – Waste Catalogue¹⁸, Environmental Protection Law¹⁹, 27th of April 2001, Transportation of Dangerous Goods Act²⁰, 19th of August 2011. The purpose of the conditions prescribed in the contract award procedure is to determine the economic operator who ensures the due performance of the contract. Therefore, a certain condition serves as a guarantee of the due performance of a contract. The essence of establishing a condition is to reassure that the contract will be duly performed²¹. It should be noted that the conditions of participation in the contract award procedure, as well as other elements of the documentation, should be presented in a comprehensive and precise manner and the awarding entity which shall not comply with these constraints cannot exercise any negative consequences arising from the Specification of Essential Terms of the Contract for participating economic operators²². Providing the definition of the conditions of participation in the contract award procedure lies within the competence of the awarding entity who acts as a host of the procedure. The essence of these conditions should therefore be seen as providing the ability of the choice of an economic operator who gives a guarantee of the due performance of the contract. These conditions also constitute a constraint against unlimited access to the contract for all of the entities operating in a certain branch of industry. In conclusion, it

¹⁶ Journal of Laws from 2013 item 21.

¹⁷ Journal of Laws from 2008 No. 25 item 150 including latter revisions.

¹⁸ Journal of Laws item 1923.

¹⁹ Journal of Laws from 2013 item 1232 including latter revisions.

²⁰ Journal of Laws from 2011 No. 227 item 1367, No. 244 item 1454.

²¹ J. Sadowy, *Warunki udziału w postępowaniu, opis sposobu spełnienia warunków oraz dokumenty potwierdzające ich spełnienie*, „Informator Urzędu Zamówień Publicznych” 2010, No. 1, p. 15.

²² Judgment of the National Appeals Chamber 28th of September 2015 in case KIO 2014/15.

should be noted that the awarding entity must be able to demonstrate its certain requirements, each time the award contract procedure is conducted because what is the essence of his activity is to exhibit the very foundation of establishing certain requirements in a credible, logical and comprehensive manner.

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NIEBEZPIECZNE ODPADY MEDYCZNE W ZAMÓWIENIACH PUBLICZNYCH

Streszczenie. Przedmiotowy artykuł zawiera analizę dotyczącą samego znaczenia odpadów medycznych, gospodarowania nimi oraz ich klasyfikacji, a także transportu i unieszkodliwiania w kontekście stosowania przepisów Prawa zamówień publicznych. Autorzy zwrócili uwagę na fakt, iż zamawiający musi potrafić każdorazowo wykazać swoje uzasadnione potrzeby, realizując zadania oparte na sformalizowanym systemie zamówień. Istotą jest bowiem przedstawienie w sposób logiczny i spójny, jaka była podstawa takich a nie innych jego żądań, co niejako stanowi zaporę przed nieograniczonym dostępem do zlecenia wszystkich podmiotów funkcjonujących w danym sektorze rynku.

Słowa kluczowe: niebezpieczne odpady medyczne, zamówienia publiczne, zamawiający, wykonawca, przedmiot zamówienia, postępowanie o zamówienie publiczne