SUSTAINABLE TENDERS
FOR MEDICAL AND IVD DEVICES

A SHORT GUIDE TO APPLYING
ESG AND DNSH PRINCIPLES
IN HOSPITAL PROCUREMENT

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ESG, CSRD, sustainable development... What does each of these terms mean for hospitals?

'ESG', which stands for environmental, social and governance criteria, is a new, comprehensive approach to conducting business that can affect the planet and people. This approach applies to practically all human activities involving natural and human resources (not only business activities), including in particular healthcare activities.

The ESG philosophy is focused on sustainable development and activities, where special attention is paid to the impact on the climate and the environment (including air, soil, water) and promoting the development of an economy founded on the recycling of raw materials, with the lowest possible carbon footprint, as well as the protection of ecosystems and biodiversity.

The ESG objectives are implemented in a rather complicated way:

- new legal regulations frequently include obligations directly related to compliance with specific requirements for sustainable business (e.g. regulations on industrial emissions or planned changes in regulations on municipal wastewater treatment)

- some entities must prepare complex reports on their activities based on the principle of double materiality – these entities also include some hospitals (see below)

- entities benefitting from certain EU funds (e.g. National Recovery Plan) must meet the so-called **DNSH** requirements (see below)

- Compliance with DNSH requirements already plays a role in obtaining public and private funding and in the public perception of a particular activity and will play an increasingly important role in the future.

The above list is not exhaustive. From the perspective of hospitals, the most important obligations are those arising from CSRD regulations and the possibility of complying with requirements that are relevant to obtaining funding.

CSRD reporting - what is it all about?

In keeping with EU regulations and the Act of 6 December 2024 amending the Accounting Act, the Act on Statutory Auditors, Audit Firms and Public Oversight, and certain other acts, **starting from 2025**, some entities will have to submit extensive, multi-layered reports on their activities in terms of sustainability principles.

This obligation will apply to 'large' hospitals, i.e. any hospital run as **a corporation** (limited liability company, joint-stock company), if it meets two of the following three conditions:

- its total assets on the balance sheet at the end of the financial year are at least PLN 110,000,000,
- its net revenues from the sale of services amount to at least PLN 220,000,000,
- it employs at least 250 people on an annual average, calculated as full-time equivalents.

Hospitals subject to the above obligation will have to **prepare a report** developed according to the ESRS (*European Sustainability Reporting Standards*) and **have it audited**, taking into account the so-called taxonomy regulation. This is a very difficult project, which requires expertise and knowledge on the part of the persons preparing the report.

The CSRD report does not have to prove anything; its purpose is to make proven and verified information about the impact of a given entity on the environment and society public.

These obligations are completely independent of any other obligations that hospitals may have. The fact that the organisation complies with current environmental legislation does not determine the content of the report, nor does it determine whether the organisation is operating in a sustainable manner.

Meeting the requirements for EU support (including as part of the so-called National Recovery Plan)

Acting in accordance with the DNSH principle or conducting business in a sustainable manner (and proving this with documents) is extremely important in the context of certain public and private sources of funding, including, above all, the finances available under the EU's Just Transition Fund and the Recovery and Resilience Facility, which in Poland is most commonly referred to as the NRP (National Recovery Plan).

The regulations on the NRP and many other funds require that funding should be consistent with the Sustainable Development Objectives, as well as the Paris Agreement and the DNSH principle. **The 'do no significant harm' (DNSH) principle** is assessed against the following six environmental objectives:

- climate change mitigation;
- adaptation to climate change;
- proper use and protection of water and marine resources;
- circular economy, including waste prevention and recycling;
- prevention and control of air, water or land pollution;
- protection and restoration of biodiversity and ecosystems.

This means that when applying for NRP grants or loans, the hospital shall be obliged to analyse whether the investment violates any of the DNSH principles.

In most cases, this analysis requires the vetting of suppliers of goods and services: this follows directly from the requirements of the EU methodology. And this, in turn, means that hospitals will be interested in obtaining information, commitments and documents from suppliers (or their subcontractors) of goods and services in the public procurement mechanism.

In the case of the National Recovery Plan, compliance with DNSH is examined for each specific investment financed. This should not be confused with a sustainable investment or activity. **An activity or investment is 'sustainable' if the entity:**

- makes a significant contribution to the fulfilment of at least one of the six environmental objectives set out above,
- does not violate the DNSH rule,
- is conducted in accordance with procedures that ensure compliance with the OECD Guidelines for Multinational Enterprises and the UN Guiding Principles on Business and Human Rights, including the principles and rights set out in the eight fundamental conventions identified in the International Labour Organization's Declaration on Fundamental Principles and Rights at Work and the principles and rights set out in the International Bill of Human Rights; and
- meets the technical qualification criteria established by the Commission in separate regulations.

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ESG and public procurement of medical devices by hospitals

Sustainable activities do not only focus on processes within the medical facility. It also requires the vetting and appropriate selection of external goods and services (e.g. CSRD reporting includes information on ESG aspects on the supplier side). In many cases, the selection of goods and services is part of the adopted ESG policy and allows for proof of compliance with specific DNSH requirements (for example, only the inspection of purchased materials can determine whether the hospital implements the principles of a circular economy due to the use of recycled goods).

The public procurement process in hospitals is a significant place for implementing the hospital's ESG policy. Purchasing goods and services that meet specific sustainability requirements means that the hospital can prove that its activities meet the requirements necessary to obtain funding (e.g. from EU sources).

In a properly conducted procurement process, the hospital can be provided by contractors with the documents necessary to conduct its own ESG analyses and justify that the facility meets certain requirements (e.g. related to the aforementioned external financing).

The principles described above also apply to medical devices. However, the products are specific because they are used to save human health and life. For this reason, not all methods aimed at implementing the DNSH principles will be fully applicable (an example is the use of regenerated products, which is prohibited by Polish law and can be dangerous for patients).

<u>Appendix 1 to this document contains basic information and recommendations on sustainable public procurement of medical devices.</u>

<u>Appendix 2 of this document contains sample tender criteria for medical devices that can be useful for implementing the ESG policy adopted by the hospital, as well as negative examples for educational purposes.</u>

Appendix 1
Basic information and recommendations on sustainable public procurement in hospitals

GUIDANCE
When preparing a tender for medical devices:

- remember that **the law has always allowed** and allows for the evaluation and rewarding of ESG (environmental, social and good governance) aspects of supplies and services; in most cases, it is optimal to use so-called weighted criteria for this purpose
- select criteria that promote ESG aspects **in accordance with the hospital's sustainable development policy**
- **do not use random criteria** that do not contribute to the fulfilment of ESG objectives (e.g. do not require unknown certificates of limited significance)
- if you request certificates confirming the fulfilment of specific ESG requirements, **rely on reputable certification systems**, e.g. those compliant with ISO 14001; such certificates ensure that their issuers are audited and supervised by specialised state bodies, such as the Polish Centre for Accreditation
- remember that according to EU regulation no. 66/2010, **the 'Eco-label' designation does not apply to medical devices** and cannot be requested or be the subject of an evaluation of the offer by the hospital
- build non-price criteria based on **objective, purposeful and adequate requirements**, which in fact serve to ensure the implementation of DNSH rules in accordance with the hospital's ESG policy
- ESG requirements if structured correctly in a tender **can give certain suppliers of modern technologies an advantage over their competitors in a tender** (e.g. due to the weighted criteria used) – this is legal and serves the interests of the hospital and the environment
- require contractors **to train your staff in how to use the equipment in a way that benefits the hospital and the environment** (e.g. how to save energy and water, reduce waste, etc.) as part of their contractual obligations
- make it clear that **your requirements apply to the main supply item** – consider whether far-reaching requirements for services accompanying the delivery of the main item (e.g. correspondence, installation tools, small technical accessories, etc.) will make any sense

CAUTIONS

Be cautious:

- **give priority to quality requirements that are important from the perspective of the health and life of patients:** medical devices are intended to diagnose and provide treatment
- **do not forget about minimum parameters and non-price quality criteria relating to the safety and effectiveness of medical technology:** prevent a situation where the tender can be won by a contractor offering a product that is not optimal for patients, i.e. with relatively worse safety and effectiveness parameters
- **there are no 'magic' all-purpose certificates or documents** that, when obtained in a tender, guarantee that a hospital complies with DNSH requirements; on the contrary, a tender for any type of medical device requires a separate analysis of what may be required and whether such a requirement is related to the sustainability policy adopted by the hospital.
- **the use of inadequate and unreasonable tender requirements, even if they nominally refer to environmental protectio**n, can be challenged in legal proceedings
- do not require anything from supplier-distributors that should be required from the manufacturer of the device (e.g. statements regarding environmental management systems at the stage of medical device production – distributors are not responsible for the production stage and often do not have access to such reports and information)
- do not require anything from manufacturers of the device that should be required from the supplier-distributor (e.g. statements by the manufacturer, not being a supplier, on compliance with requirements for transport and distribution logistics the manufacturer is not responsible for)
- **passing on the obligation to dispose of packaging and used equipment to contractors does not serve the ESG objectives.** On the contrary, in many cases, this can disrupt the logistics of disposal, which is under the control of the hospital, and increase the social financial and environmental costs of the disposal process; it is irrelevant to the planet who carries out the disposal, what matters is how the process is carried out;
- medical devices and in vitro diagnostic medical devices are very diverse product groups (from simple dressings to very complex hospital machines and implants) – remember to properly match the tender criteria related to ESG policy to the products being ordered; for example, note that not all medical devices (due to physical parameters) are suitable for transport by ecological means (e.g. electric cars);
- when designing requirements, take into account that some ESG-related tender criteria may have a significant impact on the tender process - e.g. the use of low-emission transport can in some cases be associated with a significant increase in delivery time (e.g. switching from fast but high-emission air transport to transport by water or train).

Appendix 2

Good and bad examples of tender criteria related to ESG policy for the procurement of medical devices

Sample good practices:

Sample criterion content	Criterion type	Criterion justification	Document
The contractor shall provide the contracting authority's personnel with [...] hours of training, at a time agreed by the parties, within [...] months of signing the agreement, which shall cover the principles of handling goods in a way that minimises the consumption of electricity and water and the generation of waste	Mandatory requirement or highly rated weighted criterion (>20%)	These training courses support the environmental (E) aspect of the ESG principles by educating staff in the efficient use of resources, which will reduce energy and water consumption and waste. These practices are not only beneficial for the environment, but can also result in savings for the hospital, which is an important element of responsible management. Implementing DNSH training contributes to avoiding negative impacts on environmental objectives such as the conservation of natural resources and the reduction of environmental impacts. Raising environmental awareness among staff helps to create a more sustainable and responsible approach to daily activities, which is in line with broader environmental objectives.	Contractor's obligation stipulated in the agreement
The contractor shall supply goods from a manufacturer who has implemented the PN-EN ISO 14001 environmental management standard and obtained a certificate thereof	Weighted criterion – e.g. 5%	This criterion supports manufacturers who operate in accordance with environmental management principles, meaning that their production model takes into account all environmentally relevant factors. This criterion can, of course, also be applied to contractor-distributors, but this is less important because the key risks to sustainability are located in the manufacturing process	Certificate of implementation of the standard by the device manufacturer
User manual (if the device has any) and individual packaging of the device are X% recyclable	Weighted criterion - e.g. 1%	The criterion fulfils the objectives of the DNSH principle - promoting the circular economy and reducing the environmental costs of goods production. + EXPLANATION OF WHERE 50% COMES FROM (TAXONOMY) + EXPLANATION OF THE	Statement by the manufacturer or authorised representative

		WEIGHTING OF THE CRITERION	
The contractor shall present a written commitment from the manufacturer of the goods regarding the availability of service, spare parts and software in the coming years.	Weighted criterion: >10 years - 20% 8-9 years - 15% 5-7 years - 5% <5 years - 0	This criterion is extremely important to ensure a long product life cycle and the possibility of repairing it. Thus, this criterion fulfils the objectives of the DNSH principle - promoting the circular economy and reducing the environmental costs of replacing medical devices.	Commitment of the manufacturer or authorised representative

Sample negative practices:

Content of the incorrect criterion	**Criterion type**	**Document**	**Why is the example negative?**
The contractor claims to have a sustainable business	Weighted criterion of 60%	Contractor's statement and ESG report	Vague claims of sustainable business are worthless. Sustainable business activities are a legally defined term, as stipulated in Article 3 of EU Regulation 2020/852 on the establishment of a framework to facilitate sustainable investment (the so-called Taxonomy Regulation). Furthermore, when requiring evidence of sustainable investments or activities, preference should be given to evidence from third parties, auditors, etc. What's more, it is not advisable to set a weighted criterion of 60%, as this makes it difficult to set quality requirements related to the safety and effectiveness of treatment and significantly limits price competition for companies that take an honest and comprehensive approach to ESG issues.
The device does not have a negative impact on the environment.	Weighted criterion of 50%	Contractor's statement	Much like above, generalised statements about environmental protection are a form of greenwashing and can be considered an act of unfair competition. The contractor should define very precisely which part of his business or manufacturing process is beneficial or neutral for the environment. The contractor's statement alone has little evidential value. In addition, the

			criterion, which is weighted at 50%, makes it difficult for competitors to compete and may lead to the selection of equipment with better quality parameters.
The manufacturer implements a significant beneficial impact on air quality protection	Cut-off criterion	'Bright Green Forest Animal Friend' certificate issued by the Bright Green Forest Animal Friends Association	Much like above – general environmental protection claims are a manifestation of greenwashing. The requirement for third-party certification should always be carefully analysed, i.e. the criteria should be based on the equivalence of certificates with a specific legal character (e.g. type I according to ISO 14024), audit methodology and documented circumstances. The prioritisation of certification systems that are unusual or not widely available to market players should be avoided, as they can provide an unnatural market advantage that does not translate into value for the hospital, society or the environment.
The contractor disposes of the generated waste at his own expense.	Weighted criterion	The contracting authority receives a written confirmation from the contractor that the disposal has been carried out.	The criterion presented defies the ESG idea and shifts the responsibility for waste disposal to the supplier of a specific device. The contradiction to the ESG idea lies in this solution creating extra-systemic, additional environmental costs of waste handling outside of hospital logistics. It is also beyond the hospital's control, and it is not known whether the disposal is carried out in an environmentally friendly and lawful manner. From an environmental perspective, it is not important who disposes of the waste, but how the process is carried out.