# GUIDELINES

for the procurement of safer

## medical devices

## BACKGROUND

Medical devices are a broad spectrum of instruments, materials, or other products intended for medical purposes; they range from simple, disposable products (such as gloves and syringes) to more complex devices (such as defibrillators and surgical robots) used in healthcare practices.[1] Whilst medical devices play an essential role in healthcare delivery, they may contain hazardous substances that pose risks to patient health and staff safety through their use and disposal.[2]

Harmful substances contained in medical devices include carcinogenic, mutagenic and reprotoxic substances (CMRs) and endocrine disrupting chemicals (EDCs), particularly phthalates.[3] Initiatives aimed at phasing out medical devices containing such substances and replacing them with safer alternatives should be a key component of sustainable procurement strategies within healthcare facilities.

Sustainable procurement in healthcare draws on the principles and practices of traditional public procurement, but also considers additional factors such as:

- Social – e.g. fair working conditions, developing local communities
- Environmental – e.g. carbon footprint reduction
- Economic factors – e.g. evaluating lifecycle costs

Sustainable procurement not only benefits the procurer, it also benefits local communities and the wider society.[4]

This publication gives an overview of the European regulatory framework surrounding procurement of medical devices and provides some guiding principles for the implementation of sustainable procurement initiatives in healthcare settings.

## THE REGULATORY FRAMEWORK

There are two main pieces of EU legislation applicable to the procurement of medical devices.

The **Public Procurement Directive (PPD) - Directive 2014/24/EU**[5] was adopted in February 2014 and came into force in April 2016. It establishes rules for procurement procedures of public contracts over given thresholds (as per article 4 of the Directive). Importantly, the PPD also ensures that greater consideration is given to environmental protection and the promotion of sustainable development, as well as the "best value for money" approach to public purchases.

This Directive gives public authorities the power to outline environmental and social criteria when procuring products and services for the healthcare sector through simplified procedures, respecting principles of transparency and competition between providers. The PPD identifies that contracts should be awarded to suppliers providing the "most economically advantageous tender" (art. 67.1). Although these tenders should be identified by cost and price, a cost-effectiveness approach can also be used that includes a best price-quality ratio – including life-cycle costing based on environmental and/or social criteria (art. 67.2).

Additionally, through testing, reports, certifications, and labelling, public authorities are now better placed to verify compliance with sustainability criteria outlined in the tendering process - particularly relevant to procuring medical devices and their safer alternatives. This legislation allows procurers to move away from solely concentrating on disease management, and to take a more holistic approach to patient care.

**The Medical Devices Regulation (MDR) - Regulation 2017/745/EU**[6] was adopted in March 2017 and will apply from May 2020, this regulation provides a promising foundation for the substitution of harmful chemicals contained in medical devices when safer alternatives are available and technically feasible.

According to the MDR, medical devices should only contain hazardous substances (such as EDCs or CMRs) in a concentration below an established concentration limit - 0.1% weight by weight (w/w). Medical devices will only be permitted to contain levels of certain hazardous chemicals above this limit if adequate justification is provided to a Notified Body - which is overseen by the national Competent Authority.[7] Such justifications must be based on several elements, including the latest relevant scientific committee's benefit-risk assessment of such substances. Furthermore, hazardous substances in medical devices must be indicated on labelling, and the risks for vulnerable populations (such as children and pregnant or breastfeeding women) outlined in the instructions for use.

One key aspect of implementing the regulation is the establishment of a European database on medical devices (EUDAMED) that should integrate different electronic systems to collate information regarding medical devices on the market. This database (which is due to be fully operational by 26 May 2020) will also include information about conformity assessments for certifications and labelling. With the objective of enhancing transparency, the database will allow for a better understanding of what medical devices are placed on the EU market, including their risks to patient safety.

# RECOMMENDATIONS

To initiate more sustainable procurement practices at your facility, whilst working within these regulations, HCWH Europe recommends the following steps:

## 1. CONDUCT A BASELINE ASSESSMENT

Having an accurate picture of the full procurement process (including the purchasing and use of medical devices) is a crucial step in identifying how environmental and health considerations can best be integrated. Collecting data will support prioritisation and provide compelling arguments to inform the decision-making process. Such data can include lists of procured devices and their manufacturers, overviews of purchasing and maintenance costs, information on the usage of procured devices, and staff satisfaction. This data can be used to raise awareness amongst staff and other stakeholders about the risk of hazardous chemicals in medical devices and the industry's manufacturing practices. A baseline assessment is an important first step, reviewing your organisation's current procurement practices will help you to develop a clear and coherent procurement and substitution strategy and carefully design your action plan.[8]

## 2. PRIORITISE PRODUCTS

Spending and usage data gathered in the baseline assessment can be cross-referenced with information available on the safety data sheet of individual products (data that may become publicly available via EUDAMED) as well as socially responsible manufacturing requirements, allowing for a product matrix to be developed. With this information, particularly problematic products can be identified for potential substitution based on environmental and social criteria.

Devices can be prioritised according to the MDR, which states that devices shall be designed and manufactured to reduce (as far as possible) the risks posed by substances or particles that may be released from the device.

Devices containing parts or materials that:

1. Are invasive and come into direct contact with the human body
2. (Re)administer medicines, body liquids, or other substances
3. Transport or store such medicines, body fluids, or substances

can only contain hazardous substances in a concentration that is above 0.1% weight by weight (w/w) with appropriate justification.

Since it will not be possible phase out all hazardous chemicals immediately, one useful approach is to identify potentially vulnerable patient groups (e.g. neonates), or specific procedures where substitution will have the greatest impact. Another useful approach is to begin with products that are more easily substituted, and scale up substitution product by product.

## 3. IDENTIFY ALTERNATIVES

Once a specific set of products has been identified for potential substitution, the next step it to identify safer and more sustainable alternatives. Although this can be challenging, there are some tools/platforms exist that can assist in this process:

- HCWH Europe's **Safer medical device database** - an open-access database intended to help procurers make informed decisions and purchase medical devices free from phthalates and PVC.[9] The database contains over 150 products that are PVC-free or where phthalates have not been intentionally added. The database is also useful for regulatory bodies when dealing with the pre-market authorisation process of medical devices and for manufacturers to promote their safer products in the European market. **www.safermedicaldevices.org**
- The **Global Green & Healthy Hospitals (GGHH) network** - a community of over 1,000 members in 54 countries representing more than 32,100 hospitals and health centres. A project of HCWH, the GGHH sustainability agenda has ten overarching goals, including purchasing. Members of the network have exclusive access to GGHH Connect - an innovative online platform that connects the community with leading hospitals, health systems, and experts from around the globe.[10] Via this platform, members can access tools and resources, share best practice and case studies, post their questions, and receive advice from other members and experts near and far. **www.greenhospitals.net**

## 4. RAISING AWARENESS INTERNALLY AND GETTING BUY-IN

Implementing any sustainable procurement strategy/policy or substitution plan requires leadership support, as well as the engagement and commitment of management, colleagues from different departments, and external stakeholders.

A key group of people to engage in driving a shift towards more sustainable medical devices are the clinicians that ultimately use the product. However, they are often not actually aware of the wider implications beyond functionality and cost. Clinicians need to be engaged as early as possible in the procurement process, along with other stakeholders who can introduce sustainability principles into the decision-making process (see box [right] for a list of suggested stakeholders).

HCWH Europe recommends the following steps in raising awareness and getting buy-in:

A. **Stakeholder mapping** - Work with colleagues across different departments and at different levels to identify who should be consulted, to what level, and what their stake in the process should be.

B. **Asses stakeholder knowledge** - Their understanding of the medical device supply chain (and the potential for substitution with safer alternatives) should be assessed. This can be done through an online survey or face-to-face interviews, depending on time and resources.

C. **Design an awareness-raising plan** - Communications strategies should be developed with different stakeholder groups in mind, tailoring them to specific audiences for maximum effect. For some, the business case (i.e. that a particular product is cheaper or will reduce lifecycle costs) may be a more convincing argument than patient and staff health and safety or environmental concerns. Highlighting the incurred risks of inaction is equally important when providing positive incentives to change stakeholders' behaviour.

The ultimate goal of this awareness-raising is to create a culture in which sustainability is prioritised. This culture can be instilled in staff from the beginning when sustainability are incorporated into the induction of new employees. Performance indicators can also be linked to sustainability initiatives and also embedded into the continued professional development of staff.

**SUGGESTED LIST OF STAKEHOLDERS (NOT EXHAUSTIVE) THAT SHOULD BE INVOLVED:**

- Initiators (this could be users such as health professionals, who flag the need for a product).
- Procurers, lawyers, and contract managers (ensuring that procurers are informed about the more sustainable alternatives (see Step 5)).
- Patients and patient groups (as the final users of the product, who aren't necessarily aware of the potential hazards of certain medical devices).
- The wider community (they may be affected, for example, by the disposal of medical device waste).
- Senior management/leadership (whose buy-in is essential and who should endorse any sustainable substitution plan).
- Suppliers and manufacturers (continued open dialogue with suppliers is crucial to implementing sustainable procurement practices).
- Health professionals (as users of medical devices and patient safety advocates) and medical professional associations (to scale-up initiatives through a 'bottom-up' approach).
- Policy-makers (who should be made aware of legislative barriers to substituting medical devices with safer alternatives and can facilitate this process at regional, national, and international levels).

Within these categories, identify "champions" – leaders who can positively influence their peers and contribute to the successful implementation of your plan.

## 5. TENDER PREPARATION AND CONTRACT MONITORING

An effective and participatory substitution plan, paired with a meaningful stakeholder engagement process, should also underpin each step of your procurement process and contribute to its success. When implementing a substitution plan across the entire procurement process, consider the following recommendations:

### A. Pre-tender phase

- Develop a list of hazardous substances to avoid, that initiators and procurers can easily consult.[11] Having a comparative list of certifications and labels is equally essential. Health systems should be ambitious in their scope; implement the precautionary principle and go beyond currently restricted substances.
- When performing market research and market consultation, careful documentation should be kept (as required by law) to avoid any conflict of interest and/or unfair competition.
- Engage with manufacturers to better understand the feasibility and availability of products to meet newly defined environmental and social criteria.
- Ensure that each bidder is fully informed about the weighting given to the different criteria (e.g. price, technical characteristics, and environmental and social aspects).

### B. Tender publication

The tender should be simple, clear, and specify:

- Buyers' needs (e.g. need for safer alternatives and associated employee training).
- Suppliers' eligibility and evaluation criteria (i.e. "value for money", life cycle assessment, environmental footprint, occupational health and safety, and social considerations).
- Contract provisions (i.e. timeframe, monitoring, penalties for breach, etc.).
- Provisions regarding the possibility to test the products for compatibility and maintenance (e.g. compatibility with disinfectants already purchased or in use).

### C. Selection of suppliers

- If none of the bids meet your criteria, engage with the closest competing suppliers to understand their challenges and find a consensus on the criteria, engaging an innovation procurement approach if needed.[12]

### D. Implementation and monitoring

- Train staff to ensure the appropriate use and disposal of new devices.
- Compare the performance of alternatives with the expected outcomes through audits and site visits throughout the duration of the contract. Maintain a constant dialogue with suppliers to ensure the quality and correct implementation of the framework agreements.
- To reduce costs, consider partnering with other organisations using the same supplier, this can avoid duplication of work and time-consuming exercises. Collaborate with other organisations in administering a survey to common suppliers to identify any risks. Share your results and provide feedback, or introduce corrective actions.
- Engage with environmental and human rights NGOs working on the ground, particularly in low and middle-income countries where production takes place. Also regularly check local news outlets for information regarding environmental risks and working conditions.
- In the case of a breach of contract, depending on their gravity, there are corrective actions that can be taken to improve the situation before terminating the contract. When following up with suppliers, provide feedback and suggest areas for improvement, allowing them the appropriate amount of time to implement such recommendations and meet expectations.

## CONCLUSIONS:

Implementing sustainable procurement practices in healthcare not only provides environmental and financial benefits for the procuring organisation, but can also contribute to greater patient and employee safety, and social well-being.

To take full advantage of an improved procurement process in line with the recommendations provided above, healthcare procurers need to be aware of the great purchasing power of the sector.

Accounting for an average 7.1% of GDP of EU countries,[13] and with over 15,000 hospitals in the region,[14] the healthcare sector has the ability to influence the medical device market and lead the transition to safer, more sustainable products.

Hospitals and health systems have the moral responsibility and social obligation to make responsible decisions that guarantee both human and environmental health, as well as social justice throughout their entire supply chain. There is a great opportunity for the healthcare sector to substitute medical devices with safer alternatives through procurement practices and build a European healthcare sector that truly does no harm.



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Health Care Without Harm (HCWH) Europe is the

European arm of a global not-for-profit NGO whose mission is to transform healthcare worldwide so that it reduces its environmental footprint, becomes a community anchor for sustainability, and a leader in the global movement for environmental health and justice. HCWH's vision is that healthcare mobilises its ethical, economical, and political influence to create an ecologically sustainable, equitable, and healthy world.

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