Congenius

Congenius Whitepaper

EU Green Deal | What does it mean for the medical device industry?

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What is the EU Green Deal?

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The European Green Deal is a **set of policy initiatives on climate action** laid out by the EU Commission that aim to **make Europe the first climate-neutral continent by 2050**. Proposed in 2019, and approved in 2020, the deal aims to transform the EU to become a more modern, resource-efficient, and competitive circular economy - increasing its resilience, and decreasing its carbon footprint.

In July 2021, the European Commission adopted a series of legislative proposals on how to achieve climate neutrality which include a revision of EU climate legislation and concrete ways to reach the EU climate targets.

Most recently in March 2023, three proposals from the Green Deal Industrial Plan, which supports the transition to climate neutrality by enhancing the competitiveness of Europe's net-zero industry, were presented: the European Critical Raw Materials Act, the Net-Zero Industry Act and the reform of the electricity market design. These proposals will support the Plan by helping create a simpler and more predictable regulatory environment for clean technologies to either find or secure their home in the EU.

What is the EU Green Deal?

Centred on climate action, the EU Green Deal has three main goals:

- To achieve zero net emissions of greenhouse gases by 2050 (with a reduction of 55% compared with 1990 levels by 2030)
- To decouple economic growth from resource use
- To not leave any person or place behind

The measures seek to preserve the natural environment in Europe, with the health and well-being of current and future EU generations set to benefit considerably from the deal which works towards:

- Fresh air, clean water, healthy soil, & biodiversity
- Healthy & affordable food
- Reduced inequality and energy poverty
- Renovated energy-efficient buildings
- More public transport
- Cleaner energy & cutting-edge clean technological innovation
- Longer lasting products that can be repaired, recycled & re-used
- Future-proofed jobs
- A globally competitive and resilient industry

How does the EU Green Deal impact the medical devices industry?

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Reducing the environmental impact of the Healthcare Sector

According to Health Care without Harm's 2019 report the global healthcare sector is responsible for 4.4% of global greenhouse gas emissions, with emissions from the EU, US and China amounting to more than half of the world's healthcare climate footprint.

The main drivers of greenhouse gas emissions in the healthcare sector according to the report are carbon-intensive supply chains - through manufacturing, transport, and disposal of goods, including medical devices.

With the prevalence of single-use products and devices, the healthcare sector is a large producer of waste. A part of this waste is considered harmful and its incorrect disposal can have serious environmental impact, causing air pollution or water contamination. Other aspects such as sterilization methods, wasteful design, and device packaging also have a negative impact.

To counter the current environmental impact of the healthcare sector, the EU Green Deal intends to foster sustainability in manufacturing, use, and disposal of products. Its goal is to decarbonise all sectors of industry and to transform the linear economy (extract resources, use them, dispose of them) into a circular economy, which is carbon neutral and minimises resource waste and loss by focusing design on longer lasting products, maintenance, repair, reuse, and recycling.

On the following pages, this whitepaper delves deeper into:

- The existing environmental requirements regarding medical devices
- Regulations and legislative initiatives connected to the EU Green Deal concerning medical devices
- How the EU Green Deal will improve sustainability in the medical devices sector

What are the existing environmental requirements regarding medical devices?

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There are already several European environmental regulations applicable for medical devices:

The REACH Regulation | Registration, Evaluation, Authorisation and Restriction of Chemicals

REACH is a European Union regulation, adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry. The regulation also promotes alternative methods for the hazard assessment of substances to reduce animal testing.

The RoHS Directive | Restriction of Hazardous Substances

Electrical and electronic equipment (EEE) is now one of the fastest growing waste streams in the EU. The RoHS Directive aims to prevent the risks posed to human health and the environment related to the management of electronic and electrical waste by restricting the use of certain hazardous substances in EEE that can be substituted by safer alternatives.

The Directive currently restricts the use of ten substances including: lead, cadmium, mercury, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE), bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP).

What are the existing environmental requirements regarding medical devices?

WEEE Directive | Waste from Electrical and Electronic Equipment

The WEEE Directive aims to contribute to sustainable production and consumption by preventing the creation of WEEE, contributing to the efficient use of resources and the retrieval of secondary raw materials through re-use, recycling, and other forms of recovery, and by improving the environmental performance of everyone involved in the life cycle of EEE.

The Directive requires the separate collection and proper treatment of WEEE and sets targets for its collection, recovery, and recycling. It also helps European countries fight illegal waste exports more effectively by making it harder for exporters to disguise illegal shipments of WEEE.

The PPWD | Packaging and Packaging Waste Directive

The EU Packaging and Packaging Waste Directive (PPWD) is considered the centrepiece of EU legislation on packaging and packaging waste. The Directive sets out recycling targets for used packaging, as well as the Essential Requirements for packaging that stipulate design requirements for a wide range of packaging materials and packaged goods, and aim to reduce packaging waste. Packaging that meets these requirements is guaranteed free circulation in the EU.

There are also environmental requirements contained in the EU MDR and IVDR, for example regarding harmful substances, reprocessing, and disposal of devices.

Which medical device regulations and initiatives are connected to the Green Deal?

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Industry has a key role to play in reaching the goals of the Green Deal. The expectation is a reduction in carbon footprint, updating of infrastructure, and the development of clean technology solutions and sustainable business models.

To reach these goals, the European Commission is creating new policies, new standards and technical regulations, and the EU is also expected to increase participation in international standardization bodies.

The Circular Economy Action Plan

The new Circular Economy Action Plan by the EU Commission announces a sustainable product policy legislative initiative, to ensure the reduction of waste, and to make all products placed on the EU market sustainable and resource-efficient.

One of the legislative instruments will be a **widening of the existing Ecodesign Directive** to make it applicable to the broadest possible range of products. The EU Commission is also considering creating **sustainability principles**, some of which may impact medical devices:

- Product durability, reusability, reparability, resource and energy efficiency
- Reduced presence of hazardous chemicals
- The use of recycled content
- Remanufacturing and high-quality recycling
- Reduction of carbon and environmental footprints
- Restriction of single-use products and premature obsolescence
- Rewards based on sustainability performance

The Commission expects that these product sustainability principles will guide future policy and legislative developments, and therefore potentially new regulations in the medical device space.

New requirements may be linked to environmental and social aspects along the value chain, from manufacturing and use through to end of life.

The Commission plans to **cooperate with national authorities** more closely within the Union regarding the enforcement of sustainability requirements for products placed on the EU market and expects to increase concerted inspections and market surveillance actions.

Which medical device regulations and initiatives are connected to the Green Deal?

Here are some of the legislative initiatives included in the EU Green Deal that may most closely impact healthcare and the medical device industry:

The Chemicals Strategy for Sustainability

Adopted in 2020, this strategy is part of the EU's zero pollution goal and centres on protecting humans and the environment from harmful chemicals. The Chemical Strategy for Sustainability will cover issues such as endocrine disruptors, hazardous chemicals in products, combination effects of different chemicals, and highly persistent chemicals.

The EU will continue to support manufacturers of vital chemicals, including those vital for healthcare, such as for medical devices, pharmaceuticals, or disinfectants. The Union will also encourage the development and production of these products using safer and sustainable alternatives, leading to less toxic healthcare solutions.

In turn, the information requirements in REACH will be amended and expanded, for example with the extension of registration for certain substances such as polymers.

Regulation (EU) 1013 / 2006 | Shipments of waste

There is a proposal for the complete revision of Regulation (EU) 1013 / 2006 regarding the shipments of waste, which will see stricter regulations for the export of waste, as well as prosecution and more severe punishment for those who illegally dispose of waste. The revised regulation sets out digitised and harmonised procedures for waste disposal, with the responsibility for waste sitting with its creators and owners.

Which medical device regulations and initiatives are connected to the Green Deal?

Marketing using "Green Claims"

When companies make unreliable environmental claims about the impacts or benefits of their products, consumers can be misled by the false impression portrayed. To avoid this "greenwashing", the EU has started an initiative that requires companies to provide substantiation for such environmental claims – in an attempt to find a harmonised approach for making "green claims" more comparable and reliable.

In March 2022 the EU Commission proposed to update EU consumer law to ensure that consumers are protected and to empower them to contribute actively to the green transition. The proposal provides more specific rules and complements the proposed changes to the Unfair Commercial Practices Directive.

In regulatory terms, the EU Commission is now in a position where there are different options to update requirements around green claims to help achieve the Green Deal objectives:

Option 1 | Update the existing Directive 2013 / 179 / EU on the use of common methods to measure and communicate the lifecycle environmental performance of products and organisations.

Option 2 | Create a non-mandatory EU regulatory framework to allow companies to make claims that align with "environmental footprint methods" in addition to existing methods.

Option 3 | Create an EU regulatory framework that requires companies to declare which impacts are considered by specific environmental footprint methods. These environmental footprint rules would facilitate the substantiation of green claims, allowing concrete calculations of the footprint to be made.

How will the EU Green Deal improve sustainability in the medical devices sector?

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Reprocessing

Single-use medical devices produce costly medical waste, dominating a significant amount of the operating room supply budget. The reprocessing or re-manufacturing of single-use medical devices can be an effective way to reduce waste and cost, with several medical device manufacturers already reprocessing medical devices successfully.

EU MDR Article 17 contains requirements for reprocessing single-use devices, but only allows it under the condition that national law in Member States allows reprocessing. To date, only a minority of EU member states (Belgium, Croatia, Germany, Ireland, the Netherlands, and Sweden) allow reprocessing, while the remaining Member States do not allow it within their territory.

As such, there's currently a missed opportunity for EU countries to take advantage of the possibilities that remanufacturing of single-use medical devices has brought to other parts of the world such as the US or Canada.

How will the EU Green Deal improve sustainability in the medical devices sector?

Procurement

The biggest contributor to climate footprint in the healthcare sector is carbon emission. Sustainable procurement could therefore have a significantly positive impact. The Circular Economy Action Plan (CEAP) is a non-binding policy initiative within the Green Deal that promotes sustainable growth within planetary boundaries.

If health care providers are encouraged to leverage their purchasing power towards more sustainable products and services, medical device development could be influenced accordingly, leading to increased product sustainability through improved durability, reusability, upgradability, and repairability.

The EU Public Procurement Directive provides an existing legal framework to prioritise procurement of services with a lower environmental impact, and it's likely that countries in the EU will start to require sustainable procurement for medical devices, comparable to the pharmaceutical industry. Sweden, Norway, and France have already implemented sustainability criteria for pharmaceutical procurement. And in recent years, pharma companies have started to address sustainability issues, with many creating sustainability departments to focus on the environmental and social impact of their products.

How will the EU Green Deal improve sustainability in the medical devices sector?

Alliances and Initiatives

The new Industrial Strategy as part of the Green Deal encourages the development of new industrial alliances and initiatives to help make the EU economy more resilient. Some of them may be of particular interest for the medical device industry, such as:

The European Raw Materials Alliance

Many raw materials currently used by industry in the EU are produced outside of the EU, making the industry within the Union vulnerable to potential supply chain disruptions. The European Raw Materials Alliance was created to diversify supply chain, and to foster innovative material recycling.

The Battery Alliance

Batteries are considered a key technology in the transition to climate neutrality and a more circular economy. The European Battery Alliance aims to secure access to raw materials for batteries, sustainable battery manufacturing within the Union and accelerated research and innovation for more sustainable battery technology. The new Batteries Regulation will contain requirements regarding the sustainability and durability of batteries, aiming to reduce their environmental impact.

How will the EU Green Deal improve sustainability in the medical devices sector?

Alliances and Initiatives (continued)

The Circular Plastics Alliance

The Circular Plastics Alliance endorses recycling in plastics, the reduction of plastic pollution, and the increased use of recycled plastics. One of its goals is to increase the recyclability and the intentional design of plastics with recycling in mind, as well as the increased collection of plastic waste.

Challenge for Climate Smart Healthcare

There are initiatives to reduce the climate impact of healthcare, such as the European Health Climate Council and Health Care Climate Challenge, which challenges health care providers across Europe to make ambitious decarbonisation commitments. The goal of the challenge is to educate on the connection between climate and health, and to promote advocacy for change.

Conclusion

In conclusion…

The EU Green Deal will surely present varied challenges for the medical device industry. Many of the approximately 80 initiatives as part of the deal will impact products, services, and processes at numerous stages of the lifecycle from design development to production, to use and end of life. The journey to climate neutrality will demand upskilling in ecological design for medical devices for example, as well as resource-efficient manufacturing processes.

Medical device manufacturers will need to balance meeting the new EU requirements on sustainability with continuously meeting user needs regarding device safety and functionality, as well as all other applicable regulations. Those organisations that already assess their products regarding ecological performance and publish sustainability reports will have a head start, with the Green Deal set to increase this practice.

There's no doubt that the EU Green Deal presents ambitious targets that require a considerable combined effort from the industry. Yet the policies, strategies and regulations within the Deal also offer opportunities for the medical device industry in the EU to reach its sustainability goals. The pressure to utilise less resource will arguably lead to more economical device design, and the EU's plan to financially incentivise manufacturers for successful efforts in sustainability will inevitably encourage the positive change needed to secure the health and well-being of our future generations.

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For more information on the EU Green Deal and how it relates to medical device compliance, feel free to get in touch with our Regulatory team.

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