Review of the RoHS Directive

POSITION PAPER

MedTech Europe
from diagnosis to cure

Contents

Review of the RoHS Directive

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Executive Summary

Medical technologies include more than 500,000 types of medical devices and *in vitro* diagnostic medical devices that aim to improve, extend, and transform people's lives. Medical technologies which fulfil the definition of 'electrical and electronic equipment' (EEE) are covered by Category 8 (medical devices & *in vitro* diagnostic medical devices) of the Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (hereafter 'RoHS'). Examples of medical technologies that are EEE are complex devices, such as total body scanners, ultrasounds, life-supporting machines, implantable devices, neurostimulators and patient monitoring devices, and intensive care unit equipment.

MedTech Europe supports the objectives of RoHS to protect human health and the environment. RoHS has been a successful tool in reducing the presence of hazardous substances in EEE. This success is observed by the fact that RoHS has been mirrored in over 50 jurisdictions outside the EEA.[1] At the same time, our sector faces certain challenges, such as:

(1) disproportionate requirements, given medical technologies account for only 1%[2] of the overall EEE, and
(2) uncertainty in the availability of products regulated under RoHS due to the delays in decision-making and increasing complexity of exemptions.

MedTech Europe recommends that RoHS be maintained, but simplified to resolve the challenges the sector has faced, by:

1. **Exempting existing medical equipment from future RoHS changes (substance restrictions and exemption requests)**
2. **Granting category 8 medical devices and *in vitro* diagnostic medical devices longer transition and validity periods**
3. **Establishing a default exemption for recovered parts**
4. **Improving predictability and efficiency of substance restrictions and exemption reviews**
5. **Considering the global dimension of RoHS when making changes**
6. **Ensuring all relevant stakeholders are consulted throughout the decision-making process**
7. **Updating the definition of Active Implantable Medical Devices, RoHS Article 2(4)(h)**
8. **Transforming RoHS into a Regulation**
9. **Keeping RoHS & REACH Separate**

[1] DIGITALEUROPE, https://www.digitaleurope.org/resources/digitaleuropes-initial-views-on-the-revision-of-directive-2011-65-eu-on-the-restriction-of-the-use-of-certain-hazardous-substances-in-electrical-electronic-equipment-rohs/

[2] RINA Ltd 2020 report, commissioned by MedTech Europe and submitted by MedTech Europe with the Call for Evidence consultation of 11 March 2022. In 2015, the volume of medical devices (including *in vitro* diagnostic medical devices) placed on the EU market amounted to 104,961 tonnes, which represents ca. 1 % of the total volume of EEE placed on the market in that year: 9,822,496 tonnes.

MedTech Europe recommendations for the RoHS review

1. Exempting existing/legacy medical equipment from future RoHS changes (substance restrictions and exemption requests)

When a new substance is restricted, existing medical technology designs can become obsolete and, in the absence of an exemption, must be redesigned to be lawfully placed on the EU market. New RoHS restrictions should not cause additional risk for shortages for healthcare systems that rely on the continual supply of existing medical technology designs. It must be considered that substitution of substances in existing designs (legacy products) can create high compliance cost that may not be covered by future sales, and thereby can force manufacturers to cease marketing medical technologies that exist to meet critical healthcare needs. For more details, please refer to Annex I.

As outlined in the RINA cost-benefit analysis[3] submitted with the 2022 Call for Evidence, medical technology companies invest a disproportionate level of product engineering resources to continuously assess new and existing designs, to account for dozens of amendments to RoHS Annex III & IV, with a limited reduction in RoHS substances and associated emissions at end of life. Accordingly, critical product design and engineering resources are diverted from working on new technologies and product development (including ensuring new products are designed to the latest RoHS compliance standards), and instead are deployed to work on legacy products that will be phased out as new designs are launched on the market.

A way forward that could potentially address the above challenges is by following the approach taken by the European Commission in the draft Delegated Act for exemption 27 of Annex IV,[4] as well as the Oeko April 2022 "Study to assess requests for renewal of 16 exemptions to Annex IV of Directive 2011/65/EU" [5] by referring to the date the Declaration of Conformity was issued for the first time.

2. Granting category 8 medical devices and *in vitro* diagnostic medical devices longer transition and validity periods

One of the main differences between medical technologies and consumer products, is that it may take three up to seven years to bring a new medical device to market, and may take up to 10 years or more for an IVD. Our sector is a downstream user of electronics and often relies on EEE/electrical components provided by external suppliers who are the value chain partner responsible for RoHS compliance and for making their products available to many industries. These suppliers work to substitute substances restricted under RoHS; however, once alternatives are available, it then falls to us as downstream medical technology manufacturers to validate the alternatives/changed component in the medical setup. Medical technologies are strictly regulated under the sectoral Regulations 2017/745 (MDR) and 2017/746 (IVDR)[6]. Under these regulations, a change in material that could impact the safety, effectiveness or reliability of the device may trigger: (re-) validation, bench and/or clinical testing, risk management, relabelling, as well as updates to both product technical documentation and to existing certifications granted by designated Notified Bodies (as applicable).

[3] See footnote 2.
[4] Draft delegated act available at the link here: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12880-Hazardous-substances-exemption-for-use-of-lead-in-non-magnetic-components-for-specific-medical-devices_en
[5] Oeko April 2022 Study, available at the link here: https://op.europa.eu/en/publication-detail/-/publication/65558f0a-b61f-11ec-b6f4-01aa75ed71a1/language-en
[6] Medical Devices Regulation (EU) 2017/745 and the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746

These stringent requirements exist to ensure the safety and performance of medical technologies for patients and users, ensuring continued compliance, therefore, requires considerable time and resources.

Data on the reliability of new substances is critical before a new medical technology can be developed, CE-marked and placed on the market. This is essential in preventing unexpected failures of medical technologies and in meeting the strict safety and performance requirements of our sectoral legislation.

To allow medical device and IVD manufacturers to complete the necessary steps under sectoral legislation and ensure product safety and availability, we recommend the following changes to category 8 for medical technologies:

- Transition periods that are minimum three years later compared to other EEE (for denied exemptions) (in response to question 26)
- New substance restrictions that foresee a transition period of at least seven years (in response to question 28, six-eight years proposed)
- Validity periods for exemptions (renewals) of 10 years (in response to question 25)

3. Establishing a Default Exemption for Recovered Parts

RoHS allows the reuse of parts recovered from medical devices placed on the EU market after 21 July 2014 or *in vitro* diagnostics medical devices after 21 July 2016. This allowance does not extend to parts recovered from equipment sold outside of the EU. A temporary exemption 31(a) has been granted to allow the use of non-EU spare parts but this exemption requires constant renewal, both in time as well as to cover new substance restrictions. In the spirit of fostering innovation and enabling a more circular economy, RoHS should always make allowances for reused parts in medical technologies in scope. This would extend the useful life of a component and avoid pulling the device from the market when it is still serviceable.

MedTech Europe calls for a default exemption (instead of the temporary exemption 31(a) for parts recovered from medical technologies.

4. Improving predictability and efficiency of substance restrictions and exemption reviews

The industry has experienced uncertainty in the availability of products regulated under RoHS due to the increasing complexity, number of exemptions, and increasingly narrow wording of exemptions. Delays in the exemption review process have led to a lack of foreseeability on when exemptions will be published. This prevents the industry from having a clear timeframe to communicate changes within its complex supply chain and implement them. This also stifles innovation, as delays in granting new exemptions prevent new technologies from being placed on the market and made available to patients, hospitals, and other users etc. One way to improve the efficiency and predictability of the processes is to have clear timelines published from the offset by the European Commission and consultants, as well as any updates on those timelines, for the various 'Packs' and draft delegated acts (similarly to the Commission '*Exemptions list – validity and rolling plan*'[7]).

[7] European Commission excel available at the link here: https://ec.europa.eu/environment/document/download/683f0651-ffbd-4f2b-a070-c67311203c79_en?filename=Exemptions%20list%20-%20validity%20and%20rolling%20plan_July2021_V2.xlsx

5. Considering the global dimension of RoHS when making changes

EU RoHS-like legislation has been introduced in over 50 jurisdictions outside the EEA.[8] This illustrates the value of this piece of legislation, but also that any changes made in the EU are likely to have rippling effects in other jurisdictions. This is an element that needs to be considered when the European Commission introduces any changes in RoHS either with exemption and/or substance restrictions and more generally as part of the review of RoHS.

6. Ensuring all relevant stakeholders are consulted throughout the decision-making process

The European Commission and its consultants ought to have discussions with the impacted industries. The medical technologies industry is regulated under category 8 and any changes, decisions or evaluations related to this category need to be communicated to the sector. As manufacturers of products in the scope of RoHS, we can share our expertise to support a well-rounded decision. MedTech Europe remains available for any future consultations.

7. Update the definition of Active Implantable Medical Devices in RoHS

The definition of the term 'Active Implantable Medical Device' (hereinafter AIMD) in the context of RoHS needs to be clarified. The reason being that the Directive 90/385/EEC on Active Implantable Medical Devices (the 'AIMDD') was repealed on 26 May 2021 and replaced by the Regulation (EU) 2017/745 on Medical Devices (the 'MDR') which does not clearly define AIMD.

MedTech Europe proposes the following amendment that we believe would achieve more consistency[9]:

(23) 'active implantable medical device' means any active implantable medical device ***or system*** *within the meaning of point (c) of Article 1(2) of Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices* ***or any medical device within the meaning of both Article 2(4) and Article 2(5) of 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****;*

8. Transforming RoHS into a Regulation

MedTech Europe finds that Regulations are in general a preferred legislative tool over Directives, as they prevent fragmentation and divergence in Member State implementation and practices.

9. Keeping RoHS & REACH Separate

As part of the revision of RoHS, the Commission's 2022 Call for Evidence and the Open Public Consultation asked stakeholders to express their views on the further alignment of RoHS with the Restriction, Evaluation, Authorization and Restriction of Chemicals (REACH) Regulation (i.e. involving ECHA in RoHS substance and exemption evaluations or repealing the RoHS Directive and incorporating its provisions into REACH).

RoHS has already established processes that are applied by stakeholders globally, as non-EU companies are subject to RoHS requirements prior to placing EEE on the EU market. The process for the addition of substances to Annex II, as well as the revision of exemption (renewal) requests, allows for multiple

[8] See footnote 1.
[9] For more details, please refer to the letter MedTech Europe sent to DG Environment on 8 July 2021.

opportunities for stakeholders to engage by virtue of public consultations, targeted consultations, and interviews organized by the Commission's consultants.

Additionally, the REACH Regulation is currently being revised in parallel to the RoHS Directive. Whilst this is an opportunity to ensure consistency between the two pieces of legislation, until it is known how the REACH Regulation will be amended, it is not certain what the consequences would be of moving/outsourcing parts of RoHS to ECHA/REACH.

Whilst RoHS and REACH are kept separate, it is important that they do not lead to contradictory decisions. For instance, Phthalates are regulated under both and consistency should be ensured in the decision-making process.

MedTech Europe believes that whilst there are challenges that the medical technologies sector has faced with RoHS, it is nevertheless a legislative tool that has been successful in eliminating hazardous substances. It should therefore be maintained as its own legislative tool. Additionally, the substance restrictions and exemption review processes should continue to be led by the Commission and its consultants as the current practice stands.

Conclusion

MedTech Europe supports the objectives of the RoHS Directive to protect human health and safety and the environment. The success of RoHS has led to many jurisdictions outside the EEA introducing RoHS-like legislation.

As a sector with its own sectoral legislation, we have encountered certain challenges that we have proposed solutions to with the revision of RoHS. They would acknowledge the specificities of the medical technologies sector, and improve the efficiency of the Commission and industry, whilst supporting health and environmental protection.

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

For more information, visit www.medtecheurope.org.

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Annex I - Specificities of the medical technology sector

As part of the RoHS review, there is a need to review individual sectors. This approach is not new to RoHS, and the existing categories support this consideration. The medical technologies sector faces challenges beyond the electronics industry, such as complex supply chains, many components in a single product, its global approach to compliance and stringent requirements under sectoral legislation. Also, the efforts to keep existing medical technologies in compliance with the moving target of RoHS amendments (new substances and expiring exemptions) can detract product design teams' focus from innovation in healthcare.

A. Quantities of RoHS substances

The reported decrease in RoHS substance uses due to the inclusion of medical technologies in the scope of the RoHS Directive, is limited. The COCIR Report[10] estimated that the entire category 8 and 9 reduction was 27 tonnes or 2.4% of the pre-RoHS total usage of restricted materials. The 2020 study performed by RINA Consulting Ltd.[11], estimated that <80 tonnes out of 1300 tonnes of lead or 6.2% was used by the non-imaging medical technologies sector pre-RoHS. Thus, the reduction of lead from the medical technologies sector due to RoHS was 16 tonnes, or 0.15% of the pre-RoHS total usage of lead. Also, only **0.16% of the pre-RoHS EU total usage** of restricted materials were avoided due to RoHS restrictions on medical technology equipment. In terms of cost **€137,800 - €551,400 per gram** of substance emission was avoided in one year.

B. R&D and innovation

The medical technology industry is characterised by a constant flow of innovation, which is the result of a high level of research and development and allows for better and earlier diagnosis, more effective treatment as well as completely new designs.[12] All of these are crucial to protect and improve the health of EU citizens. Products (that are being newly designed) are expected to comply with RoHS. Finding alternatives to RoHS restricted substances may either not be possible or take considerable resources to assure the required levels of safety and performance. Where there are alternatives, these substances may not yet have been assessed for use in medical technologies and the reliability of such devices could be largely unknown.

C. Product lifetime

EEE medical technologies can have long lives since they are designed with high reliability as a prerequisite. While in service, they must be maintained/serviced using components produced according to the original specifications, necessitating an uninterrupted supply of spare parts. The MDR states, *"an item that is intended specifically to replace a part or component of a device and that significantly changes the performance or safety characteristics or the intended purpose of the device shall be considered to be a device."*[13] If spare parts need to be changed to comply with RoHS, products, which are still serviceable, may be taken off the market instead of going through the lengthy process of re-validation and re-registration under sectoral legislation. This might impact patients if RoHS updates cause products to be obsolete or not be maintained/serviced.

[10] RoHS Directive and Medical Imaging Devices (2006-2021) - Lessons Learned and a Closer Look on Benefits and Impacts (link)
[11] Impact of the RoHS Directive, Report No. 2019-0921 Rev. 0 – December 2019, Project No. REG02864-001
[12] It is amongst the top sectors that file patent applications. European Patent Office, Infographic for the Patent Index 2021 showing the main trends in applications at the European Patent Office in 2021, available at https://www.epo.org/news-events/press/photos-infographics.html
[13] Article 23, Medical Devices Regulation (EU) 2017/745