MedTech Europe views on the ‘One Substance, One Assessment’ European Commission package of legislative proposals

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POSITION PAPER

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from diagnosis to cure

Contents

Executive Summary

MedTech Europe Key Findings and Recommendations

MedTech Europe, the European industry association representing manufacturers of medical technologies (medical devices and *in vitro* diagnostic medical devices- IVDs), takes the opportunity to share its views on the 'One Substance, One Assessment' (OSOA) package of legislative proposals published on 7 December 2023[1]. The concept behind the OSOA package to streamline the assessment of chemicals across EU legislation is welcomed as a means to bring efficiency and a harmonized approach to chemical assessments and processes. Some potential benefits include reduced animal testing and the prevention of duplicate testing and regulatory activities. For instance, Bisphenols have been undergoing parallel regulatory activities under the European Chemical Agency (ECHA)- REACH Restriction process, as well as the European Food Safety Authority (EFSA); RoHS-restricted substances such as lead, mercury and cadmium are evaluated and regulated under RoHS and REACH under different methodologies. Furthermore, ECHA's involvement in RoHS could lead to more transparency, predictability, and legal certainty in the exemption process for businesses. The medical technology industry finds it important to have opportunities in the long-term to continue shaping the OSOA approach and the three legislative proposals that implement it. Given this, we consider that several clarifications are needed to optimize the legislative proposals in the OSOA package, namely:

- ✓ Ensuring ECHA has the **necessary expertise at hand** to handle the new responsibilities envisaged in the targeted amendments to RoHS and the Medical Devices Regulation (MDR)[2], i.e. in specific technologies (electronics, medical devices and IVDs) and their respective legislation (medical devices and IVDs in the scope of RoHS are regulated by sectoral legislation MDR and IVDR).
- ✓ Ensuring that a formal **Impact Assessment** is carried out, considering the additional resources and budget needed for ECHA to deliver on its new tasks[3].
- ✓ Providing **ECHA with the necessary funding** via the ECHA Founding Regulation, to ensure it is empowered to complete its (new) tasks. The reallocation of tasks to an already overburdened ECHA and its Committees raises concerns about resource efficiency, effectiveness and accuracy of evaluation outcomes. For instance, due to the new RoHS tasks, SEAC will have 33 additional opinions to prepare per year[4].
- ✓ Using the OSOA package and specifically the common data platform as an opportunity to **streamline existing databases and regulatory requirements for business operators** and remove any such duplication of existing information requirements.
- ✓ Clarifying **the interface between REACH and RoHS**, considering the new role of ECHA (e.g. preventing regulatory overlaps: lead is currently subject to RoHS exemptions, whereas under REACH, there is a potential REACH Authorisation Annex XIV inclusion pending for decision by the Commission).
- ✓ A **common data platform** seems to be an improvement in principle; however, more details need to be provided as to what information will be made available in the public domain and how confidential business information will be protected.

[1] Available at the link (here)
[2] The Medical Device Regulation 2017/745 (MDR)
[3] Page 19 of the Staff Working Documents states that '**no formal impact assessment was carried out'**. (link)
[4] Page 23 of the Staff Working Document (link)

Recommendations per OSOA legislative proposal

Proposal for a Regulation establishing a common data platform, 2023/0453 (COD)

MedTech Europe welcomes the endeavour to streamline the information and databases on chemicals in one place. We believe there are several particularities that need to be considered in the development of the 'one common data platform' on chemicals. We therefore call on the Commission, ECHA, and other agencies tasked with developing, managing and populating the common platform, to:

1. Ensure confidentiality of company-specific data is upheld

The industry is concerned by the potential risk of business confidential information being made publicly available to potentially competitive business operators. There needs to be a clarification by the Commission and respective agencies as to how:

1) The Commission and respective agencies will ensure that when migrating information from other databases, confidential information will not be released and that the provisions on the confidentiality of information under sectoral legislation, such as REACH and the MDR, remain applicable.
2) The possible confidential information notified by business operators under Article 22 will be protected.

While we appreciate the inclusion of provisions on the protection of confidential information, we also note that these provisions do not seem sufficient to ensure that information that is marked as 'confidential' under the sector-specific legislation, e.g. REACH and the MDR, will be maintained confidential when included in the common data platform.

We recommend strengthening the confidentiality provisions to ensure consistency with the sectoral regulatory framework, and that the protection afforded by the (sectoral) legislation is not undermined by this proposal. In case of a potential conflict on the application of confidentiality provisions, the provisions set out in the sectoral legislation should apply.

With respect to the obligation to notify studies under Article 22, we note that there needs to be a precise overview of what information the industry will be required to submit and how confidentiality will be ensured.

We consider it important for there to be an opportunity for businesses to request certain information to be maintained confidential, as concerns exist regarding the confidentiality of studies notified by business operators and laboratories. Article 22(7) stipulates that '*ECHA shall lay down the practical arrangements for implementing the provisions of this Article*'. We would welcome the opportunity to share our views and participate in any discussions (e.g. workshops, consultations, etc.) on the practical arrangements for the notification of studies to ECHA.

2. Avoid duplication and deviations from existing information/databases

The Annexes to the Proposal for the Regulation contain long lists of existing legislation that contain chemical requirements and/or databases. Whilst we welcome the approach to streamline all chemical information in one place, there needs to be clarity on how the Commission and respective Agencies will avoid any duplication of information, but also potential deviations from the contents of the various existing databases. Duplicating information found in multiple databases would defy the purpose of the 'one common platform'. We would therefore like to understand what would happen and what would be the further relevance of existing databases that contain chemical information, e.g. the SCIP database under the EU Waste Framework Directive, and ensure that if more than one database is maintained, there is a strict policy upheld with regard to which database takes legal precedence.

The medical technology sector is particularly impacted by this, as our sectoral legislation MDR established a database 'EUDAMED' in which companies must disclose chemical information pursuant to Annex I Section 10.4. The MDR is listed in the Annex of the Proposal for a Regulation establishing the common data platform as one of those sources of information on chemicals that will be pooled into the common platform and we would require details as to what information will be migrated – i.e. from EUDAMED, as well as how consistency between the two platforms will be ensured.

3. **Provide clarity on what *existing* information will be pooled and what *additional* information will be required from business operators**

The Proposal for the Regulation lists clearly that the duty-holders to establish, manage and populate the common data platform are for the most part the Commission, ECHA and other Agencies.

Article 22 appears to be the only exception where business operators must themselves notify information to the database. Irrespective of this, the Regulation does not specify the precise information, format and frequency of data that will be pooled.

We therefore call on the Commission and Agencies to clarify what information will be made available in the common data platform. As far as Article 22 is concerned, the industry needs clarity regarding the specific scope and contents of the studies that will have to be notified to ECHA.

4. **Ensure the robustness of data**

When making available information on the common platform, it should be the responsibility of the relevant actors, namely the Commission, ECHA and other agencies, to ensure that the data is comprehensible, standardized, but also high quality, for it to be understood and comparable.

Proposal for a Regulation amending Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals 2023/0455 (COD)

1. Amendment to the Medical Devices Regulation 2017/745 (MDR)

The targeted amendment to the MDR is twofold, on the one hand, it adds justification requirements for substances that will be identified as per the new CLP hazard class for Endocrine Disruptors to Human Health Category 1, and on the other hand, ECHA will replace the role of SCHEER in issuing guidelines on how to perform the benefit-risk assessment on the presence of CMR or endocrine-disrupting substances in medical devices.

On the proposed amendment to involve ECHA in the assessment of chemicals (i.e. phthalates and Endocrine Disruptors) in medical devices and issuing guidelines, we call on the Commission to clarify how ECHA will be funded for carrying out these new activities, their timelines and processes for doing so, but also how it will be ensured that ECHA will be equipped with the necessary expertise on medical devices to carry out its newly assigned tasks in a timely manner. Today, the experience of the medical technology industry already demonstrates that the MDR is costly, highly complex, and takes a significant amount of time from product design to regulatory approval and placing on the market. Mandating another external agency in the medical technology field should result in a reduction of administrative complexity, not an increase. Furthermore, it should ensure that not only the necessary technical and medical expertise and experience is included, but also profound know-how in healthcare. We therefore ask that the industry and/or other actors such as SCHEER, Notified Bodies, etc. have the right to contribute to these processes to ensure that the technical knowledge on medical technologies is available (e.g. knowledge revolving around clinical trials, and the risk-benefit assessment under MDR, which is different to the risk-assessment that is performed under REACH, etc.).

On the second change proposed to the MDR, namely in Annex I Section 10.4.1(b) to identify Endocrine Disruptors for Human Health (Category 1), per the new hazard classes introduced in CLP in 2022, we underline that this hazard class is currently only applicable to the EU market, as it is not adopted at the UN GHS level.

2. Amendment to the Persistent Organic Pollutants (POPs) Regulation (EU) 2019/1021

In response to the proposed amendment on the POP concentration limits in waste, we underscore the significant impact these changes could have on the medical devices industry. While we understand that the industry is not required to collect and submit data, we strongly encourage participation in the consultation process. The lowering of POP concentration limits could severely affect the recycling of POP-containing waste, leading to a shortage of recycled materials vital for manufacturing and packaging of medical devices.

This scenario necessitates a re-evaluation of material sourcing and may increase costs and generate challenges on healthcare systems, particularly if:

a) Dependence on recycled materials for device manufacturing is compromised
b) Packaging options are limited due to the restricted use of recycled POP materials.

MedTech Europe is committed to a proactive approach, engaging in dialogues to ensure these regulations are sustainable and practical for the industry.

Proposal for a Directive amending Directive 2011/65/EU (RoHS), 2023/0454 (COD)

MedTech Europe acknowledges that the substance and especially exemption review processes are lengthy and complicated, involving many actors, from regulators, consultants, industry, etc. Key challenges that the medical technology sector has faced with RoHS are the delays and lack of predictability around exemption request decisions.

The clear processes and timelines introduced in the targeted amendment to RoHS have the potential to address these challenges and provide to industry with the legal certainty and transparency needed. We do however, ask a clarification as to how it will be ensured that ECHA will be properly funded to carry out its newly assigned tasks and be equipped with the relevant expertise on EEE/product-level assessments in all relevant Committees, e.g. by involving RoHS exemption evaluation consortia. Throughout ECHA's process, we recommend that stakeholders with experience in medical technologies have the opportunity to support ECHA in its given tasks (e.g. Notified Bodies, SCHEER, and from previous RoHS exemption evaluation consortia etc.) . Proper stakeholder consultations throughout the process, including the affected industry, will be essential for providing sector-specific expertise and technical know-how for making well-informed policy decisions on any exemption request or possible amendment of the list of restricted substances of Annex II.

Furthermore, we note that the Report[5] accompanying this targeted amendment states that "*at this stage this general review of the RoHS Directive, as required by Article 24(2), will not be accompanied by a revision of the Directive but by a targeted amendment as regards the re-attribution of scientific and technical tasks to ECHA*"[6]. Whilst we welcome the endeavour to improve the efficiency and transparency of the substance restriction and exemption request procedures, there are several additional revisions that MedTech Europe recommends in the future revision of RoHS, which have not been addressed in the OSOA targeted amendment, namely:

- ✓ Exempting existing medical equipment from future RoHS changes (substance restrictions and exemption requests)
- ✓ Granting category 8 medical devices and in vitro diagnostic medical devices longer transition and validity periods
- ✓ Establishing a default exemption for recovered parts

[5] Available at the link here: COM_2023_760_1_EN_ACT_part1_v4.pdf (europa.eu)
[6] Ibid, page 12.

- ✓ Considering the global proliferation of RoHS when making changes
- ✓ Ensuring all relevant stakeholders are consulted throughout the decision-making process
- ✓ Updating the definition of "Active Implantable Medical Devices", RoHS Article 2(4)(h)
- ✓ Transforming RoHS into a Regulation
- ✓ Keeping RoHS & REACH separate[7]

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. We therefore believe that RoHS should continue to exist as an independent piece of legislation, whilst being revised taking into account the open points above to improve its workability for businesses.

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.
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[7] For more information on these points, please consult MedTech Europe's 2022 Position Paper on the RoHS General Revision, available at the link here.