MedTech Europe
from diagnosis to cure

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MedTech Europe response to stakeholder consultation on RoHS Pack 17 (Request for renewal of Annex IV exemption 31a submitted by COCIR)

Dear Ms Baron,

This is MedTech Europe's response to specific question 2:

COCIR requests the exemption for all medical devices, including in vitro diagnostic medical devices, and their accessories, but mainly provides supporting data for medical imaging devices. Please provide information and data to support the request for other than medical imaging devices falling under Cat. 8 of RoHS Directive Annex I.

MedTech Europe is of the opinion that the rationale applied for the exemption of reused spare parts containing the six RoHS 2 substances should be extended to spare parts containing phthalates. The extended exemption should cover all medical devices, including *in vitro* diagnostic medical devices (IVDs).

Medical devices in scope of the RoHS Directive can have extremely long lives since they are designed with high reliability as a prerequisite. Keeping these systems operational requires an uninterrupted stream of spare parts, which were designed with the systems. Changing the spare parts to be compliant with new regulations such as RoHS would be the same as redesigning the entire system from a regulatory perspective, so the replacement parts must remain unchanged to keep the systems in service. Some components of robust medical electrical equipment can also be reused in refurbished systems, rather than being scrapped, which has benefit for the circular economy. Extending Annex IV exemption 31a to phthalates will therefore ensure that medical device service lives can be extended to the maximum and that components do not need to be scrapped when they are still serviceable.

These considerations apply to all medical devices which are electrical and electronic equipment, also those other than medical imaging devices. Each medical device will need to comply with the new Medical Device Regulation (EU) 2017/745; each *in vitro* diagnostic medical device (IVD) with the In Vitro Diagnostic Medical Device Regulation (EU) 2017/746. It takes 3 up to 7 years to bring a new medical device to market; for an IVD this may be even 10 years or longer. On average, a product stays on the market for over 10 years, during which it may be refurbished using components produced according to the original specifications. Any change in material (including for spare parts) that could impact the reliability of the device will trigger its evaluation as

a new device. This requires time for testing and re-validation as well as for re-registration (to get approval from a Notified Body when a medical device dossier is submitted or re-submitted for change) of affected products on an individual basis, both in Europe and in any other regulated regions in the world.

In vitro diagnostic medical devices:

The nature and long lifespan (up to 20 years and more) of IVD instrument systems (including immunoassay, clinical chemistry, haematology and blood screening assay systems) mean that IVD companies must carry out periodic refurbishment for normal repair and maintenance activities. It is likely that at least a part of the IVD instruments installed at customer sites across Europe (compliant at the time of installation) contain phthalates. It is often difficult and sometimes impossible to replace an original part that contains phthalates (or other newly added restricted substances) with a different, phthalate-free spare part. As product reuse, refurbishment and extension of lifetime are both environmentally and economically beneficial, spare parts need to be sufficiently available.

IVD systems require extensive validation to ensure that they perform appropriately. The equipment performing the transfer can be placed within laboratory environments for periods typically up to 10-15 years. The performance of the equipment and associated reagents relies in part on the critical transfer and contact properties of guide tubes and contact surfaces that need to transfer precise amounts of fluids for the assay to work within stated analytical performance criteria. During the normal working lifetime of the equipment, replacement of phthalate-containing parts may be required. Replacement with any other parts would require extensive validation of the performance of the assay to ensure a “like for like” approach. There is still a risk even then that the device may not perform exactly as originally specified as all states cannot necessarily be replicated during testing. The extra testing may also cause or create delays in the availability of equipment with the associated impact to patients. Extending exemption 31a to phthalates in reused spare parts would allow for cover of existing equipment and would also allow transfer to new plasticisers for new equipment coming through.

The following numbers have been provided by a MedTech Europe member company that places spare parts on the market for analysers, flow cytometers and sample preparation devices:

Year	Weight of spare parts placed on the EU market (tonnes)
2014	0.115
2015	0.355
2016	3.625
2017	20.821
2018	31.105
Q1 2019	6.974
TOTAL	**62.996**

While these volumes may be much lower than those for spare parts placed on the market for big imaging equipment, they are equally significant. The numbers also show that the amount of spare parts placed on the market has been steadily growing each year.

Another MedTech Europe company reported that with the repair of service-parts (instead of manufacturing new ones), they avoid 40 tonnes of EEE waste per year in their IVD business. This figure is increasing at an estimated rate of 10-20% year, as the company is about to leverage the potential of circular economy.

Medical devices (other than IVDs and other than medical imaging equipment):

Laser treatment system for prostate enlargement: Information from one MedTech Europe member company shows that approximately 2 resonators are replaced per month in the EU across an installed base of nearly 600 units. These resonators are refurbished and sent back out in an exchange pool; they are almost never scrapped. The refurbishment cost is approximately 12,000 USD. Building new RoHS resonators costs approximately 32,000 USD each. The difference is 20,000 USD each. This means that without access to non-RoHS compliant spare parts, it would cost the company approximately 40,000 USD a month (almost 500,000 USD a year). Additionally, 3 laser systems were never converted to RoHS. The company continues to support an aging installed base of these units in the EU and would be forced to stop if they could not supply non-RoHS components. Approximately 250 units across the 3 product lines are still active in Europe (the range is 150-400 units). The users of these systems would need to purchase new systems at a cost of approximately 80,000-100,000 USD each, or somewhere around 22.5 million USD (13.5 million-36 million USD).

Other medical devices that may need the exemption are neurosurgery kits and planning stations, electrosurgical products, as well as catheters and stylets operating on radiofrequency energy. This list is not exhaustive.

Best regards,

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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.