MedTech Europe Response to the Public Consultation on the EU POPs Regulation Implementation of UV-328
19 August 2024

FINAL

General Comments

MedTech Europe welcomes the opportunity to share its views on the European Commission's proposal for a delegated act implementing the Stockholm Convention UV-328 nomination into the EU POPs Regulation[1]. UV-328 is used in a range of medical technology applications (medical devices, IVDs, device part of a drug-device combination product, medical packaging etc.).

We note that certain derogations have already been provided for applications that are important to the medical technology sector (e.g. for mechanical separators in blood collection tubes, LCD replacement parts and triacetyl cellulose film in polarisers). There are however certain applications not yet covered by derogations and in the absence of such, MedTech Europe calls on the Commission **to extend the application date of the UV-328 requirements for the medical technology applications listed in the table below,** to allow sufficient time for the medical technology industry to transition to alternatives that are feasible from both a material and patient safety perspective.

Uses of UV-328

MedTech Europe's submission to the 2023 ECHA call for evidence, which ran until 18 August 2023, elaborated numerous identified uses of UV-328 in medical technologies, such as in:

1. Soft-touch, thermoplastic polyurethane grips of various devices used to cut, seal and staple tissues during surgical procedures;
2. Flexible tubing and wiring, thin polymer sheets, and coating applications specifically where there is prolonged exposure to UV light);
3. Soft-touch of various component parts of integral drug-device combination (iDDC) and drug-device combination (DDC);

[1] Available at the link here: Persistent organic pollutants - UV-328 (europa.eu)

4. Invasive medical devices, but also in parts and components of medical technologies, including penetrable septum in blood collection tubes, or electrical and electronic components;
5. UV-328 is used in liquid crystal displays:
   - In liquid crystal displays in medical and *in vitro* diagnostic devices (such as monitoring screens, ultrasound diagnostic devices, flexible endoscopes, immunoassay analysers, clinical chemistry analysers and blood coagulation analysers). LCD monitoring screen is the primary user interface between the medical device and the healthcare practitioner, displaying critical clinical information. Changes to the polarizer layer may impact the viewing angle and as such the readability of the display which may have a safety impact on the end user.
   - Liquid crystal displays in instruments for analysis, measurements, control, monitoring, testing, production and inspection (such as recorders, infrared radiation thermometers, digital storage oscilloscopes and radiographic testing instruments);
6. Cables of medical devices;
7. Thermoplastic polyurethane packaging materials.

MedTech Europe Recommendations

In the absence of derogations for the declared uses of UV-328 in medical technologies, **the sector requires sufficient transitional periods** to identify, source, test and validate potential alternatives that meet chemical, but also patient safety requirements, under the sectoral legislation.[2] Modifications to the chemical composition of existing medical technologies can constitute "significant design changes." Implementation of significant design changes triggers stringent requirements under the MDR/IVDR[3], notably: validation, bench and/or clinical testing, risk management, relabelling, and updates to both product technical documentation and to existing certifications granted by designated Notified Bodies. These stringent requirements exist to ensure the safety and performance of medical technologies for patients and users, and compliance with them requires considerable time and resources. These processes therefore necessitate longer transitional periods to bring those medical technologies into compliance with both sectoral legislation and the new UV-328 requirements stemming from the Stockholm Convention on Persistent Organic Pollutants.

[2] Medical Device Regulation EU/2017/745 and *In Vitro* Diagnostic Medical Devices Regulation EU/2017/746.
[3] Ibid

The appropriate timelines for the uses of UV-328 in medical technologies, based on the regulatory approval processes for the specified use cases, can be found below:

Use	Transitional period needed
1. Medical devices using UV-328, other than the use cases listed below	up to 5 years
2. Invasive medical devices using UV-328	up to 5 years
3. Parts of integral Drug Device Combination (iDCC) and Drug Combination (DDC) devices using UV-328	up to 10 years
4. Penetrable septum in blood collection tubes using UV-328	up to 5 years
5. Electrical and electronic components in medical devices (like LCDs monitoring or cables) using UV-328	up to 7 years
6. Uses of UV-328 in thermoplastic polyurethane packaging materials	up to 5 years
7. Specific cutting instruments for ophthalmic surgery using UV-328	up to 5 years

It should also be noted that many of the substances potentially recommended as substitutes are in the benzotriazoles group. This group of 35 chemicals was the subject of an Assessment of Regulatory Needs with a final recommendation of the need for regulatory risk management action at EU level. UV-326, for instance, is classified as vPvB as of December 2023 and included on the REACH Candidate list. Thus, there is an increasing risk of regrettable substitution of this family of substances.

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. www.medtecheurope.org.

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