



**Re: Draft Commission Regulation(EU) amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), as regards carcinogenic, mutagenic or reproductive toxicant (CMR) substances, devices covered by Regulation (EU) 2017/745 of the European Parliament and of the Council, persistent organic pollutants, certain liquid substances or mixtures, nonylphenol and testing methods for azocolourants.**

To: Members of the REACH Committee

Brussels, 8 May 2020

Dear members of the REACH Committee,

We are writing to you regarding the REACH Committee meeting that will take place on 13 May. At this meeting, a discussion is planned on the Draft Commission Regulation(EU) amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), as regards carcinogenic, mutagenic or reproductive toxicant (CMR) substances, devices covered by Regulation (EU) 2017/745 of the European Parliament and of the Council, persistent organic pollutants, certain liquid substances or mixtures, nonylphenol and testing methods for azocolourants.

The undersigned NGOs would like to comment on the proposed exemption to devices within the scope of Regulation (EU) 2017/745 [Medical Device Regulation (MDR)] from the restrictions laid down in entries 28-30 of Annex XVII to Regulation (EC) No 1907/2006 as regards the use of CMRs in medical devices for supply to the general public.

We would like to comment on the two following issues:

**1) Conflict in EU legislation with respect to use of CMRs in Medical Devices and general exemption for products under the scope of the Regulation (EU) 2017/745 on medical devices (the MDR)**

The Commission has [proposed](#) that *“devices within the scope of Regulation (EU) 2017/745 should be exempted from the restrictions laid down in entries 28-30 of Annex XVII to Regulation (EC) No 1907/2006”*.

It is worth emphasising that Regulation (EU) 2017/745 covers medical devices defined as products, services or solutions that prevent, diagnose, monitor, treat and care for human beings by physical means. Due to the large variety of products, the level of control before placing them in the market depends on the level of impact on the human body that their use might imply.

Medical devices can be everyday objects such as sticking plasters, syringes, latex gloves, dental filling and contact lenses, as well as advanced technologies like implantable devices such as heart valves and pacemakers, and replacement joints for knees and hips.

The MDR obligations related to CMRs substance are not a full ban in all medical devices, they create some restrictions on the use of CMRs in some medical devices. Indeed, they **only cover patient contact materials, which are invasive, (re)administer, transport or store medicines, body liquids or other substances, including gases, to/from the body.** They require substitution **only** when replacement is technically possible and benefits of substitution outweigh risk. And only CMR 1A and B are concerned.

**The MDR Annex I section 10.4** requires substitution of carcinogens, reproductive toxins and mutagens (CMR) of category 1A and 1B unless the manufacturer can show that the use of the substance is justified from a benefit-risk analysis.

There are currently more than 500,000 medical devices available in hospitals, community-care settings and at home ([The European Medical Technology Industry in figures 2019](#)). Therefore, any general derogation from the REACH CMR Restrictions (i.e. for all CMRs substances and for all products under the scope of the MDR) has a potential to exempt a high number of medical devices which safety will not be ensured under Annex I Section 10.4 of the MDR once it enters into force.

A minima the entry into force of the exemption should match the entry into force of the new MDR (May 2021). In other terms, were the exemption of Medical Device from Annex XVII entries 28-30 to be adopted and to enter into force soon, there would be several months of an unacceptable gap in the protection of people from CMRs via Medical Devices.

To conclude, to avoid a reduction of the level of health protection currently ensured, the derogation should be formulated as ***“devices within the scope of Annex I section 10.4 of Regulation (EU) 2017/745 should be exempted from the restrictions laid down in entries 28-30 of Annex XVII to Regulation (EC) No 1907/2006”.***

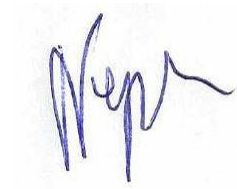
In any case, as rightly affirmed by Belgium, it is indispensable to assess the number and type of Medical Devices that are today covered by the CMR ban and that the exemption would impact. The exemption cannot be adopted with a blind spot on its effects on health protection. It is also necessary to assess the exact scope of the overlap: some medical devices available to the general public might not be covered by the CMR provisions under the MDR, and a protection against CMR might necessary nevertheless.

## 2) Procedural problems

We would like to express our disappointment with this process. The [legislative proposal](#) that is going to be discussed next week (on 13 May) at the REACH Committee meeting has not been previously shared or even discussed with CARACAL (at least on the open session). We would like to ask for clarification by

the European Commission on why CARACAL members and observers are invited to provide written comments to an industry stakeholder's position paper (CARACAL document CA/18/2020: Euromcontact AESGP MedTechEurope position paper) and not to the draft regulation presented to the REACH Committee. We also ask the Commission to follow the adequate channels foreseen in order to ensure transparency and public participation in the EU decision making process.

Yours faithfully,

A handwritten signature in blue ink, appearing to read 'D. Napierska', is centered on the page.

Dorota Napierska, PhD, ERT

Chemicals Policy and Projects Officer, HCWH

On behalf of:

ClientEarth

European Environmental Bureau (EEB)

Health Care Without Harm (HCWH) Europe