April 2014

Conference Report

ALTERNATIVES TO CLASSIFIED PHTHALATES IN PVC MEDICAL DEVICES

Copenhagen, 27 March 2014

Collaboration and shared interests between industry and environmental and health authorities is the key to finding innovative solutions for quality healthcare. This is one of the conclusions from the conference held in Copenhagen on 27 March 2014 on the occasion of the publication of a new report about the substitution of classified phthalates in medical devices.

In partnership with the Danish Environmental Protection Agency (DEPA) and the Danish Health and Medicines Authority (DHMA), the PVCMed Alliance invited stakeholders from around the world to participate in the publication of the results of a unique report. The Danish health and environmental authorities have analysed the available alternative plasticisers to classified phthalates in medical devices. The PVCMed member companies provided data for this report which is an encouraging example of efficient collaboration between industry, authorities and healthcare professionals.

The conference featured speakers from many different organisations, ranging from regulatory authorities (who prepared the report), environmental NGOs, companies having phased out of DEHP for some of their products, industry associations expressing their willingness to cooperate and organisations dealing with PVC waste management.

Patient safety prevails

The report was produced to respond to medical device manufacturers' need for clarification on the safety of alternatives to classified phthalates used as plasticisers in medical devices. It was designed as a support tool for these companies.

The report analysed ten alternative plasticisers, which are already in use in some medical devices, for their health and environmental profiles. While numerous alternatives showed better toxicological profiles to DEHP, the presentations and discussions also showed how substitution is a complicated matter.

All parties agreed on the need to phase out of classified phthalates as much as possible. The question marks in the discussions focused on the appropriate speed and way to proceed. NGOs, authorities and industry associations alike emphasised the complex nature of substituting classified phthalates along with the importance of never compromising patient safety. Possibilities of substituting previously used plasticisers by new ones must be determined case by case for each medical device. It is feasible but manufacturers should not underestimate the length and cost uncured. This is why cooperation between industry and authorities was identified as a key element in this process.

The debate also revealed conflicting interest between the various stakeholders: the industry argues for innovation and continued cooperation between all involved parties, whereas the Danish NGO, The Ecological Council, wanted to push for even stricter regulation and stronger requirements for procurement policies. MEP Christel Schaldemose expressed optimism for upcoming legislative measures based on the precautionary principle, as she believes a united European Parliament can support stricter regulation. Nevertheless, the debate came down to the conclusion that there can never be a 100% safe list. Consequently all agreed that, particularly in the healthcare sector, a "risk benefit" approach is a necessity.

Perspective and optimism for future collaboration

The conference ended with other examples of the industry's willingness to cooperate and innovate. Brigitte Dero from the PVCMed Alliance shared industry development on PVC recycling through the Vinyl Plus project. In recent years, the industry has revolutionised the management of PVC waste through close collaboration with outside parties, such as medical professionals, NGOs and national and international regulatory institutions. Similarly, Sophie Macmillan, Chief Executive Officer of the Australian Vinyl Council shared the Council's experience in setting up recycling and waste management systems for PVC medical device in hospitals.

Ultimately, the conference outlined the general societal agreement to phase out classified substances from medical devices, but at a controlled pace, where patient safety is never compromised. As the DEPA and DHMA concluded upon rounding up the day: industry, NGOs and authorities are working together to reach the same goal. In this respect the two regulatory authorities felt positive that we were on the way to reaching that goal.