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Ph. Eur. seeks feedback on alternatives to DEHP for blood bags

The European Pharmacopoeia (Ph. Eur.) Commission has launched a public consultation on its proposal to include in its texts 4 plasticisers that can be added to PVC (poly(vinyl chloride)) for manufacturing blood containers and sets for blood transfusions. The proposal, which concerns the revision of 6 general chapters of the European Pharmacopeia, is published in the *Pharmeuropa* issue 29.2 of April-June 2017[1] and will be open for comments from the public until June 2017.

Plastic is used in all aspects of daily life. Packaging for medicinal products and medical devices is no exception: in the field of blood transfusion, plastic has been favoured over glass for the production of blood containers since the 1940s for its safer and easier handling. However, PVC is a rather stiff and brittle material which requires compounding with additives called plasticisers in order to make it softer. Within the family of plasticisers used in PVC items, DEHP [di-(2-ethylhexyl) phthalate] is a well-established chemical and one of the most frequently used for manufacturing containers and tubing sets for the transfusion of blood and blood components.

In 2008 the European Chemicals Agency (ECHA) included DEHP as a substance of very high concern (SvHC)[2] on the grounds that it can damage fertility, and in accordance with the criteria set in the REACH regulation.[3] Consequently, there is a strong need to promote alternative materials that could replace DEHP in these products.

In line with its mission of contributing to the basic human right of access to good quality medicines and healthcare, the EDQM strives to ensure that blood transfusion in Europe is of high quality and that blood containers and transfusion sets are fit for their intended uses. In this context, the European Pharmacopoeia is proposing 4 additional plasticisers for inclusion in its texts, so as to provide manufacturers and users with alternatives which are free from DEHP, whenever possible:

- cyclohexane 1,2-dicarboxylic acid, diisononyl ester;
- butyryl tri-n-hexyl citrate;
- tris(2-ethylhexyl) trimellitate;
- bis(2-ethylhexyl) terephthalate.

The revision concerns the following 6 general chapters:

- 3.1.1.1/90001. *Materials based on plasticised poly(vinyl chloride) for containers for human blood and blood components*;
- 3.1.1.2/90002. *Materials based on plasticised poly(vinyl chloride) for tubing used in sets for the transfusion of blood and blood components*;
- 3.1.13. *Plastic additives*;
- 3.1.14. *Materials based on plasticised poly(vinyl chloride) for containers for aqueous solutions for intravenous infusion*;
- 3.2.4. *Empty sterile containers of plasticised poly(vinyl chloride) for human blood and blood components*;
- 3.2.5. *Sterile containers of plasticised poly(vinyl chloride) for human blood containing anticoagulant solution*.

1 Pharmeuropa 29.2 of April 2017. Pharmeuropa Online: http://pharmeuropa.edqm.eu/home/
2 More information on the classification made by ECHA can be found here: https://echa.europa.eu/substance-information/-/substanceinfo/100.003.829
3 Article 57 of regulation (EC) 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), the regulation of the European Union that controls chemicals.

Interested parties are invited to provide their comments through the procedure for commenting on *Pharmeuropa* drafts[4].

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Note for the Editor

The EDQM is an organisation that leads the protection of public health by enabling development, supporting implementation, and monitoring the application of quality standards for safe medicines and their safe use. Our standards are recognised as a scientific benchmark world-wide. The European Pharmacopeia is legally binding in member states. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues. Further information is available on the web site **www.edqm.eu**

There are thirty-nine members of the European Pharmacopoeia Commission: *Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Republic of Moldova, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, "the Former Yugoslav Republic of Macedonia", Turkey, Ukraine, United Kingdom and the European Union.*

A political organisation set up in 1949, the Council of Europe works to promote democracy and human rights continent-wide. It also develops common responses to social, cultural and legal challenges in its 47 member states.

[4] More information on public enquiries is published in *Pharmeuropa Online* under "Useful information".