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Modification of the structure of Section 3. *Materials and containers* for the 10th Edition of the Ph. Eur.

The European Pharmacopoeia (Ph. Eur.) includes a Section 3. on materials for containers (Subsection 3.1) and containers (Subsection 3.2). For historical reasons, the general chapters of this Section 3. include texts on primary packaging, as well as on medical devices. To clarify the interpretation of the legal status of these two types of containers, the Ph. Eur. Commission decided at its 162nd session to modify the structure of Section 3. of the Ph. Eur. This change will involve the creation of a new Subsection: 3.3. *Containers for human blood and blood components, and materials used in their manufacture; transfusion sets and materials used in their manufacture; syringes*. This decision is based on the results of an EDQM survey launched in 2017 to collect feedback from some of its stakeholders and on subsequent discussions.

Up to now, the Ph. Eur. Section 3. *Materials and containers* has consisted of two subsections: 3.1. *Materials used for the manufacture of containers* and 3.2. *Containers*, which represent a total of 26 general texts. Eighteen of these texts cover quality requirements for primary packaging while eight texts define quality requirements for items that are classified as medical devices according to EU (European Union) legislation (i.e. containers for blood and blood components, sets for transfusion and syringes) and are not used for primary packaging of pharmaceutical preparations.

The creation of the new Subsection 3.3. simplifies the distinction between primary packaging and medical devices and consequently clarifies the legal status of the texts in the different sections. As defined in the Ph. Eur. General Notices, unlike monographs that are mandatory per se, general texts are provided for information and only become mandatory when applying the monograph in which they are cross-referenced. For example, the dosage form monographs refer to these general texts, therefore making them mandatory, whereas the texts on medical devices, until now included in Subsections 3.1. and 3.2., are not systematically associated with monographs and, as a consequence, are not systematically mandatory. The plan now is to move the eight texts concerned to Subsection 3.3. and change their numbering, while leaving the numbering of the other 18 general texts unchanged.

Parties concerned by this project are invited to send their feedback to EDQM by 15 February 2019. The new structure of Section 3. (as shown below) will be published in the 10th Edition of the Ph. Eur. which will enter into force on 1 January 2020.

Section 3. *Materials and containers*

Subsection 3.1. *Materials used for the manufacture of containers*

3.1.3. Polyolefins

3.1.4. Polyethylene without additives for containers for parenteral preparations and for ophthalmic preparations

3.1.5. Polyethylene with additives for containers for parenteral preparations and for ophthalmic preparations

3.1.6. Polypropylene for containers and closures for parenteral preparations and ophthalmic preparations

3.1.7. Poly(ethylene-vinyl acetate) for containers and tubing for total parenteral nutrition preparations

3.1.8. Silicone oil used as a lubricant

3.1.9. Silicone elastomer for closures and tubing



3.1.13. Plastic additives

3.1.14. Materials based on plasticised poly(vinyl chloride) for containers for aqueous solutions for intravenous infusion

3.1.15. Polyethylene terephthalate for containers for preparations not for parenteral use

Subsection 3.2. Containers

3.2.1. Glass containers for pharmaceutical use

3.2.2. Plastic containers and closures for pharmaceutical use

3.2.2.1. Plastic containers for aqueous solutions for infusion

3.2.9. Rubber closures for containers for aqueous parenteral preparations, for powders and for freeze-dried powders.

Subsection 3.3. Containers for human blood and blood components, and materials used in their manufacture; transfusion sets and materials used in their manufacture; syringes

3.3.1. Materials for containers for human blood and blood components

3.3.2. Materials based on plasticised poly(vinyl chloride) for containers for human blood and blood components

3.3.3. Materials based on plasticised poly(vinyl chloride) for tubing used in sets for the transfusion of blood and blood components

3.3.4. Sterile plastic containers for human blood and blood components

3.3.5. Empty sterile containers of plasticised poly(vinyl chloride) for human blood and blood components

3.3.6. Sterile containers of plasticised poly(vinyl chloride) for human blood containing anticoagulant solution

3.3.7. Sets for the transfusion of blood and blood components

3.3.8. Sterile single-use plastic syringes

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Note for the Editor: Further information is available on the internet site <https://www.edqm.eu/>

The EDQM is a leading organisation that protects 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 worldwide. The European Pharmacopoeia is legally binding in member states¹. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

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.

¹ 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.