18 December 2019, Strasbourg, France

European Paediatric Formulary goes live on 11 December 2019

The EDQM is pleased to announce that the European Paediatric Formulary is now available free of charge on a dedicated online platform. This is a major achievement for the PaedForm Working Party and all the stakeholders involved, since it not only embodies several years’ work and dedication to the project, but feeds into the fundamental human right of equal access to quality healthcare.

Launched by the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH) and the European Pharmacopoeia Commission, the European Paediatric Formulary project is carried out by experts of a dedicated working party. The aim is to bring together, for the first time, formulations of appropriate quality from all around Europe to allow pharmacists and clinicians to prepare paediatric treatments when no licensed alternative is available.

Two general texts introducing the formulary and stating its general principles, and two monographs, Hydrochlorothiazide 0.5 mg/mL oral solution and Sotalol hydrochloride 20 mg/mL oral solution, can now be accessed through the platform. All four texts were approved by the European Pharmacopoeia Commission and adopted by the CD-P-PH.

Commenting on the release of the new formulary, Susanne Keitel, Director of EDQM, wished to thank all the experts who contributed to the elaboration of these first texts and added: “their continued support will have a real impact for the benefit of young patients’ health”.

These two initial monographs, the first of many, are the result of an exhaustive and inclusive consultation process. Numerous formulations described in national formularies, as well as other well-established formulations, were collected from organisations in the pharmaceutical sector throughout Europe. Information on the selected formulations was reviewed and transferred into a common monograph format, providing full details of quantitative composition, extemporaneous preparation instructions, validated test methods for quality control and storage conditions.

Monographs for development are prioritised based on patients’ needs and further texts are already on the work programme. These include monographs on azathioprine oral suspension, chloral hydrate oral solution, furosemide oral solution, isoniazid oral solution, omeprazole oral suspension and phosphate oral solution, as well as a monograph on an oral vehicle. Additional items will be added as work progresses. Draft monographs for public consultation and final texts will subsequently be made available on the European Paediatric Formulary platform to ensure that pharmacists throughout Europe receive dedicated support in their work.

The formulary can be accessed free of charge by creating an account.

Interested parties wishing to propose an item for inclusion or to become involved in the work on the formulary are invited to contact the EDQM HelpDesk.

More information on the European Paediatric Formulary.
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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 states. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

1. There are 39 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, North Macedonia, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, 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.