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EDQM launches public consultation on first pilot monographs for European Paediatric Formulary

The EDQM has launched a public consultation on the first two pilot monographs and on two general texts for its European Paediatric Formulary. Pharmacists and paediatricians across Europe are called to provide their feedback on the draft monographs on Hydrochlorothiazide oral solution and on Sotalol oral solution.

The European Paediatric Formulary collects together on a European level monographs on formulations for extemporaneous preparations currently either described in national formularies, or those which are well-established in European countries, and make them freely available. Pharmacists and clinicians will be provided with specific formulations of appropriate quality to allow preparation when no licensed alternative is available on the market. The project has been launched jointly by the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH) and the European Pharmacopoeia Commission.

Monographs to be included in the European Paediatric Formulary are selected on the basis of criteria for inclusion and evaluation adopted by the CD-P-PH end of 2015. These include quality criteria, for example that the preparation process is prescribed in a way to ensure reproducibility, and criteria for therapeutic relevance and clinical justification of the preparation, for example following the therapeutic needs identified by the European Medicines Agency. The verification also includes the excipients to ensure they comply with Ph. Eur. requirements, are not harmful and suitable for their intended use.

The European Paediatric Formulary is elaborated by a dedicated working party which comprises 17 experts from hospital pharmacies, academia and national authorities from 14 countries.

The work programme of the European Paediatric Formulary already includes 8 additional monographs: Furosemide oral solution, Azathioprine oral suspension, Isoniazide oral solution, Oxybutynin hydrochloride intravesical solution, Ranitidine oral solution, a monograph on an oral vehicle without active substance, Omeprazole oral suspension and Chloral hydrate oral solution. Several further monographs will soon be added to the work programme.

The final European Paediatric Formulary will be an easily accessible, science-based online tool with a collection of child-appropriate formulations that supports its users by promoting the health of children in all countries where no licensed alternative is available.

Consultation

The public consultation will be run on a new dedicated platform on the EDQM website, which will specifically cover the European Paediatric Formulary: <https://paedform.edqm.eu>. Explanatory texts with general principles are issued along the first two pilot monographs on Hydrochlorothiazide 0.5 mg/mL oral solution and Sotalol 20 mg/mL oral solution, which will remain open for comments until 31 January 2019. The EDQM calls on pharmacists and doctors worldwide to provide feedback, test the application of the draft monograph and submit their comments.

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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, paediatric formulary and consumer health issues.

¹There 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.*

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