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A EUROPEAN FORMULARY FOR PAEDIATRIC MEDICINES: RULES AND CRITERIA APPROVED

The European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH) adopted, at its last session in November 2015, the detailed framework of a project for a European Paediatric Formulary. This is a recent initiative launched by the CD-P-PH and the European Pharmacopoeia Commission. The EDQM provides the scientific secretariat for the project.

The future online publication will give hospital and retail pharmacies across Europe easy access to a formulary for the preparation of unlicensed formulations of paediatric medicines. Although there have been significant efforts to increase the number of available licensed medicines for children, there is still a shortfall – especially of those containing well-known active substances.

Today, national or regional formularies on pharmacy preparations for the treatment of children still play an important role in paediatrics. Although some individual countries have good approaches, these are not shared across all countries. This leads to the fact that currently, poorly-developed or even inadequate medicines are sometimes used.

The European Paediatric Formulary is intended to provide clinicians and pharmacists with a compilation of appropriate formulations, easily and freely accessible all over Europe, in case no appropriate licensed product is available. It is neither intended to be mandatory nor to replace, nor hinder the market entry of, licensed products. Medicines which have been authorised for use in the paediatric population by a regulatory authority and which are manufactured at an industrial scale are the preferred option and the ultimate goal.

The CD-P-PH has now approved criteria for selection and evaluation of formulations from already existing national or regional formularies. The committee has also approved criteria for the maintenance of the European Paediatric Formulary as well as a procedure for how to elaborate it. The procedure includes for example a public consultation period before final inclusion.

A working party under the auspices of the European Pharmacopoeia Commission will start in 2016 to evaluate existing formulas and to initiate the elaboration of first monographs for the European Paediatric Formulary. Draft monographs will in future be published for public consultation in EDQM's online forum [Pharmeuropa](#) before final adoption by the two committees. A poster with a more detailed overview of the project and of the criteria can be accessed [here](#).

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Note for the Editor: Further information is available on the internet site 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 world-wide. 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.

¹There are thirty-eight 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, 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.