The European Paediatric Formulary: a reinforced approach for improved monographs

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ABOUT THE EUROPEAN PAEDIATRIC FORMULARY (PaedForm)

- Freely available collection of formulations for age-appropriate extemporaneous preparations
- Gives pharmacists access to paediatric formulations of appropriate quality, allowing preparation of a medicinal product when no licensed alternative is available
- **Initially a bibliographic-only exercise:** collection and publication of formulations, including preparation methods and analytical QC methods, based on those available in existing formularies

WHAT?

An **experimental verification** step has been **implemented** to better evaluate candidate formulations:

- Evaluation of the **feasibility of the formulation** (preparation of samples)
- Evaluation of the **quality of the formulation** and of the **Quality Control** methods
- When necessary, include **supplemental tests** such as microbial challenge test (Ph. Eur. *5.1.3*) or assessment of critical impurities

WHY?

Several cases in the initial bibliographical exercise were incomplete or incorrect data sets were observed:

- Errors in dilution factors
- Missing data (e.g. osmolality)
- Inappropriate composition (e.g. conservative content)

⇨An experimental verification step is imperative **to ensure feasibility, reliability & appropriate quality of formulations described in PaedForm.**


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HOW?

Experts from the Paedf Working Party support the need for practical verification and perform, whenever possible:

- An evaluation of the preparation of samples
- An evaluation of the described quality and QC methods

The EDQM supports this work by:

- Sourcing active substances and consumables
- Organising analytical testing for techniques not available to the experts

PAEDFORM MONOGRAPHS

- Chloral hydrate 100 mg/mL oral solution
- Clonidine hydrochloride 10 µg/mL oral solution
- Furosemide 2 mg/mL oral solution
- Hydrochlorothiazide 0.5 mg/mL oral solution
- Phosphate 60 mg/mL oral solution
- Simple syrup (preservative-free)
- Sotalol hydrochloride 20 mg/mL oral solution


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ACHIEVEMENTS

Case study: **Enhancement of a furosemide oral paediatric formulation**

- In source material: methyl parahydroxybenzoate (MP) content 0.1 % (m/m) reported insufficient for adequate microbial preservation.
- Challenge test as per Ph. Eur. General chapter *5.1.3* showed 0.15 % minimal efficient content for MP.
- Formulation corrected with updated composition & published in the Formulary.

Evaluation of sample preparation and sample quality is now included in the elaboration process (see Fig.1)

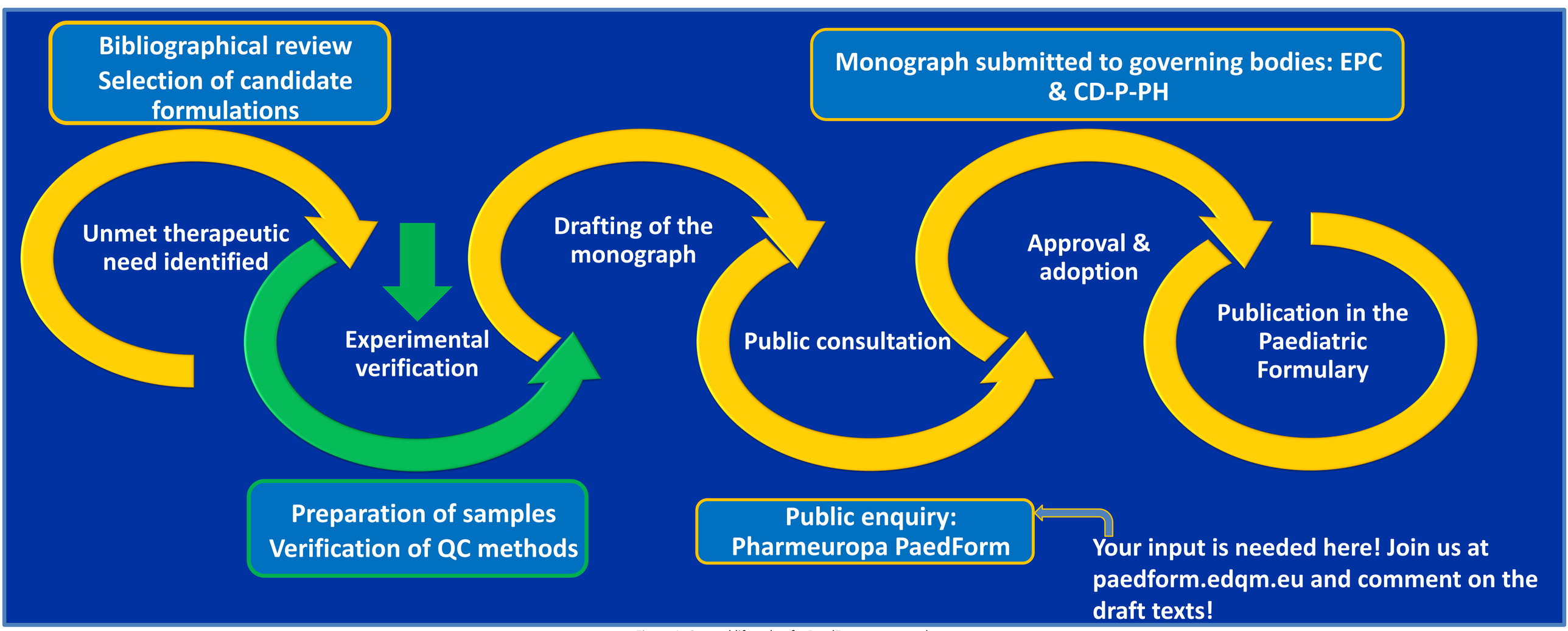

Figure 1: General lifecycle of a PaedForm monograph

NEXT STEPS?

The working party will continue to expand the European Paediatric Formulary beyond the current 7 monographs by elaborating new monographs covering needs not currently met by licensed medicinal products. Users are invited to contribute to this process by commenting on draft texts published in the PaedForm Pharmeuropa public consultation platform.

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