The European Pharmacopoeia Commission decides to elaborate a monograph

Group of Experts P4/EDQM: a rapporteur from the Group of Experts P4, consisting of members of licensing authorities, National Pharmacopoeia Authorities or Official Medicines Control Laboratories, and EDQM staff members prepare a draft monograph, which is discussed with the manufacturer

The draft monograph is verified experimentally in EDQM laboratory and/or national pharmacopoeia or Official Medicines Control Laboratory

Report and list of questions are sent to the manufacturer; the Technical Secretariat (EPD) and the rapporteur evaluate the response and modify the draft monograph

Group of Experts P4 approves draft monograph for publication in Pharmeuropa online (http://pharmeuropa.edqm.eu); the draft monograph is published for public enquiry, which last at least 3 months

The National Pharmacopoeia Authorities process the comments received and send them to the Technical Secretariat (EPD)

The Technical Secretariat (EPD) compiles all the comments received

The rapporteur and the Technical Secretariat (EPD) examine the comments and modify the draft monograph accordingly; the modified draft monograph is confirmed by the Group of Experts P4

The draft monograph is proposed to the European Pharmacopoeia Commission for adoption

The European Pharmacopoeia Commission

- adopts the monograph, with slight modifications if necessary
- proposes the implementation date (about 1 year after the adoption of the monograph)

The modified draft monograph is republished in Pharmeuropa online for further enquiry

European Pharmacopoeia (3 supplements per year): the monograph is published about 6 months after adoption

Elaborate a Monograph

Procedure 4

The procedure applies to substances for which a single interested party amongst manufacturers has been identified. It is usually applied to substances still under patent protection where there is potential for future production of generics. The draft monograph will be based on substances which are used in medicinal products that have been authorised by the competent authorities of Parties to the European Pharmacopoeia convention.