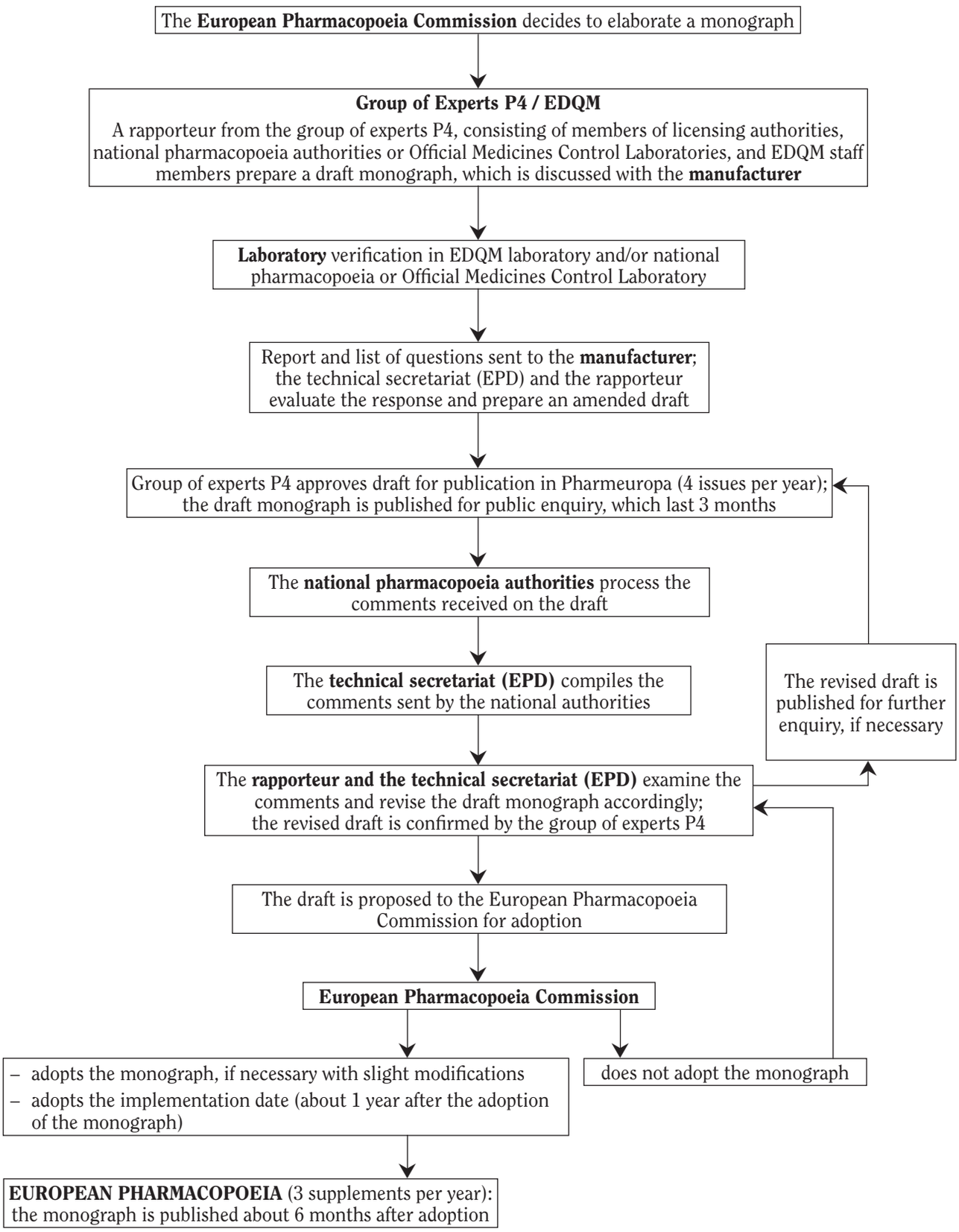
Elaboration of a Monograph (Procedure 4)

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 monograph draft 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.