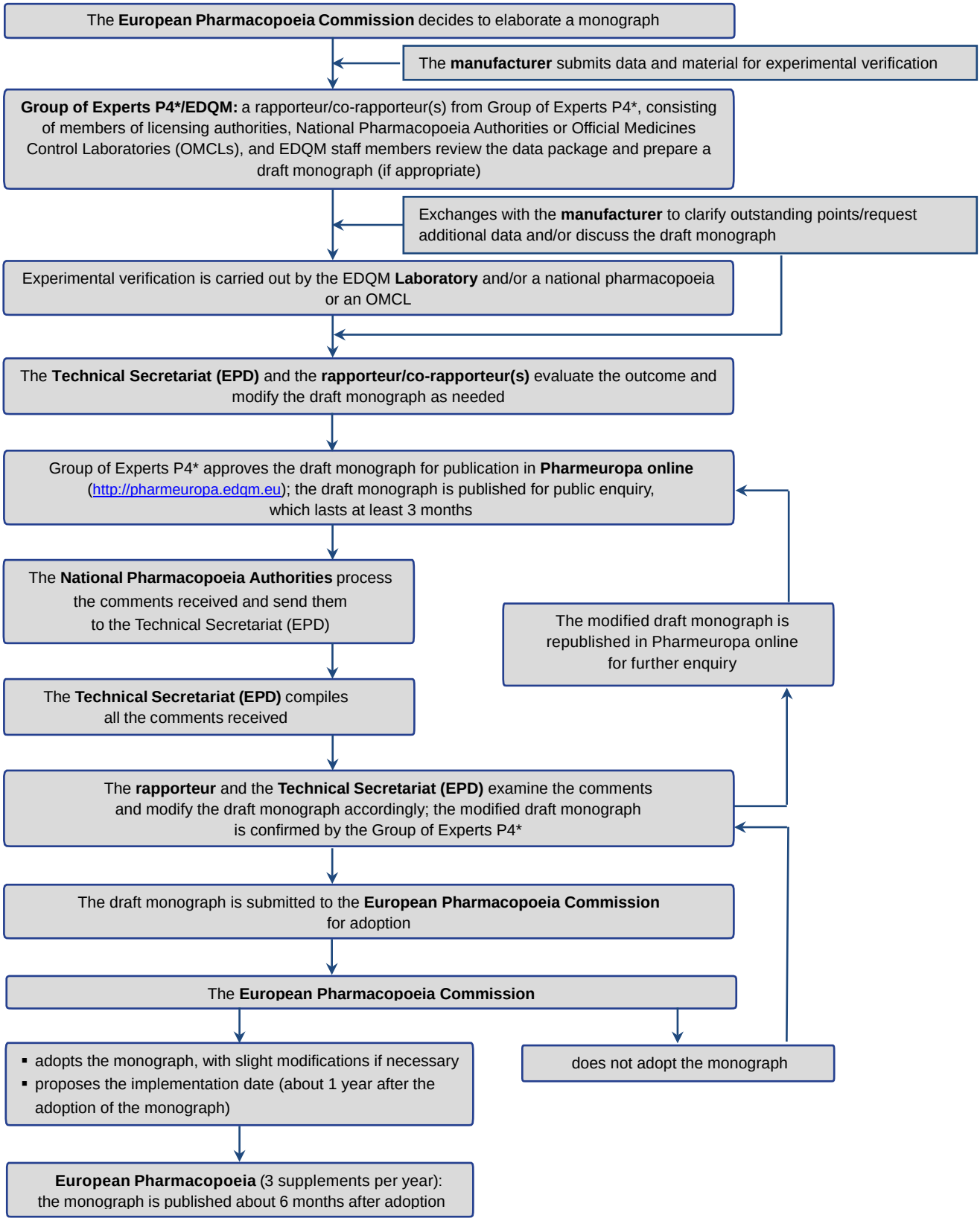
ELABORATE A MONOGRAPH

Procedure 4

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



*'Group of Experts P4' means both the Group of Experts P4 and the P4Bio Working Party