How can I submit a draft monograph for inclusion in the European Pharmacopoeia?

Answer:

You should normally submit draft monographs to your national pharmacopoeia authority. In some instances (e.g. industry associations or other associations, manufacturers and other interested parties from states that are not signatories to the Ph. Eur. Convention, and multinational interested parties) it is possible to submit proposals to the EDQM directly. For your submission to qualify for consideration, an active substance or excipient must be used in a medicinal product approved in at least one country that is a signatory to the Ph. Eur. Convention (Ph. Eur. member state).

When submitting a monograph, you should:

- indicate the country/ies in which a medicinal product containing the substance is approved;
- state your willingness to provide data and samples (you should be prepared to co-operate with the EDQM by providing data and samples).

Further information is available upon request. Where requested, data is treated in a confidential manner. Data is always treated confidentially for P4 procedures (products still under patent protection).

The final decision on whether the monograph will be added to the Ph. Eur. work programme will be taken by the Ph. Eur. Commission.