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Raw material

Question 1

Could a raw material be used as a dried herbal substance instead of the fresh plant as defined in its individual Ph. Eur. monograph for homeopathic preparation?

Should the same requirements be applied?

Answer

The scope of Ph. Eur. monographs is given in the definition section. Requirements for preparations prepared with dried herbal raw materials are not transposable to preparations prepared with fresh herbal raw materials, and vice versa.

When no individual Ph. Eur. monograph exists, general Ph. Eur. texts apply (General Notices, General Chapters, General monographs).

Question 2

Are suppliers of raw materials reported within the CTD dossier of HMP? Under which section?

Answer

Yes, according to the HMPWG guidance on Module 3 of HMP dossier, all suppliers of raw material have to be listed at the date of submission.

Therefore, all information on suppliers should be clearly indicated:

- in Module 1 under the section 2.5.5 "source/manufacturer of the raw material"
- in Module 3 under the section 3.2.S.2 Manufacture / 3.2.S.2.1 Manufacturers

Question 3

Do variation procedures apply to the suppliers of raw material?

Answer

Yes, changes affecting suppliers should be notified through variation procedures. For any modification regarding a supplier, the applicant should apply for a variation application, by analogy with variations procedures pursuant to Commission Regulation (EC) 1234/2008 as amended, as:

- A.4. "Change in the name and/or address of a manufacturer". in case a change in the name/address of the supplier occurs;
- B.I.a.1.z. "Change in a manufacturer of a starting material ...". The presentation as "unforeseen variation (z)" is needed since the category of this variation could be a *type IB* or *type II* on a case-by-case basis (e.g. depending on the nature of the raw material or in case of consequent substantial changes in the manufacturing process).