

PHARMACOPOEIAL STANDARDS FOR HERBAL MEDICINAL PRODUCTS IN EUROPE

Dr. Agnès Artiges
Director, European Pharmacopoeia Commission,
European Department for the Quality of Medicines, Council of Europe

Medicinal plants and products made thereof have a long history and tradition in Europe and were described in many national pharmacopoeias ; despite the predominance of synthetic substances, natural products, especially from plants, play an important role in modern medicine. This can also be seen from market evaluations showing clearly that phytomedicines are not to be considered any longer as “domestic medicines” but as internationally applied and recognised medicines.

Since its creation in 1964, the European Pharmacopoeia has devoted part of its work to the establishment of monographs on vegetable drugs which are used either in their natural state after dessiccation or concentration or for the isolation of natural active ingredients.

The European Pharmacopoeia is one of many components of the regulatory framework (such as the registration dossier prepared by industry, GMP, inspection and OMCL) which ensure the quality of medicines as well as the tripartite relationship between the Pharmacopoeia – Licensing authorities – Industries, is defined in the appropriate Directives.

The European Pharmacopoeia is replacing increasingly the national pharmacopoeias is implemented in 26 European countries including the EU countries [1] and may be referred to by the Observer countries [2].

The European Pharmacopoeia has a dual function:

- It has to provide recognised common standards for use by health care professionals and others concerned with the quality of medicines. Such standards must be of appropriate quality as a basis for the safe use of medicines by patients and consumers;
- Such standards must be appropriate to the needs of
 - regulatory authorities,
 - those engaged in the control of the quality (Official Medicines Control Laboratories - OMCL),
 - manufacturers of medicinal products and
 - community pharmacists.

There are now about 90 monographs which have

1 15 members of E.U. + Switzerland, Iceland, Norway, Cyprus, Croatia, Slovenia, Former Yugoslav Republic of Macedonia, Bosnia, Turkey, Slovak Republic, Czech Republic.

2 Eastern and Central Europe: Hungary, Poland, Albania, Bulgaria, Lithuania, Romania, Estonia, Ukraine, Latvia, Canada, Australia, China, Syria, Tunisia, Malaysia, Morocco.

either already been published in the Pharmacopoeia or have been adopted by the European Pharmacopoeia Commission for publication, 82 monographs are at present under study and recently 56 new monographs have been authorised by the Commission for elaboration.

Many general methods of analysis are also described including tests for pesticides or for microbial contamination.

The European Pharmacopoeia has decided to increase its activity in this field as shown by the numbers of monographs published for enquiry in Pharmeuropa (8 monographs in 1996, 5 monographs in 1997, more than 30 in 1998)

The drafting of appropriate quality specifications in the form of a monograph, is composed of the following chapters:

- Definition
- Characters
- Identification
- Assay
- Storage

In conclusion, a collaboration and a dialogue among everyone concerned with Quality is important, but we have to bear in mind that requirements should be based on what can scientifically be demonstrated, taking into account the need to protect the consumers.

Contact address: Dr A. Artiges, 226 Avenue de Colmar, B.P. 907 - F67029 Strasbourg Cedex 1.
email: Agnes.Artiges@mail.pheur.org