GUIDANCE ON THE INFORMATION SUPPLIED IN

MODULE 5 OF HOMEOPATHIC MEDICINAL PRODUCT REGISTRATION APPLICATIONS ACCORDING TO RD OF 14/12/06 CONCERNING MEDICINAL PRODUCTS FOR HUMAN AND VETERINARY USE, ART 38 OR 173

(Directive 2001/83/EC art. 14 / directive 2001/82/ec art. 17) "simplified procedure" :

Module 5 consists of a well developed rationale* that justifies the homeopathic use/nature of the stock(s), based on the documentation that has to be supplied separately in the following sections:

* Option: module 2 except for section 5.R .

5.S. DRUG SUBSTANCE (NAME)

For a drug product containing more than one drug substance, the information requested for part "S" should be provided in its entirety for each drug substance.

5.S.1. Nomenclature (name):

When homeopathic synonyms are used in accordance with the scientific name, these synonyms should be justified by literature, presented in section 5.R.S.1.

5.S.2. Reference monograph for stock or homeopathic preparation (name):

If the homeopathic stock is described in the European Pharmacopoeia or in absence thereof in a pharmacopoeia officially used in a Member state, or in another pharmacopoeia monograph, the reference to the pharmacopoeia should be stated and the monograph provided in section 5.R.S.2.

5.S.3. Homeopathic proving(s) (name):

Information should be provided, if available, according to the type of method used for the proving (experimentations in healthy subjects, double-blind experimentations in healthy subjects).

The information should be presented in tabulated format as follows:

Author	Date of publication	Number of provers	Symptoms	Administered dilution	Frequency and number of administration	Duration	Method

Detailed texts for each proving mentioned in the table should be included in annex 5.R.S.3.

5.S.4. Materia Medica (name):

If available, the information should be provided in this section in tabulated format as follows:

Name of the Materia Medica	Author

Detailed texts for each entry mentioned in the table should be included in annex 5.R.S.4.

5.S.5. Other bibliographical data (name):

In addition to (if available) and certainly in absence of relevant and conclusive information in the previous sections, further bibliographical data related to the homeopathic use/ nature of the stock need to be given.
The relevant bibliographical data could, for example, consist of classical homeopathic texts and documented homeopathic traditions, other literature references, recent publications (including laboratory research when available), toxicological data related to the stock and/or the raw material, physiological or pathological data, etc.

The relevant information (with the reference of the source of data and search engine used) should be presented in tabulated format as follows:

Category of references	Search engine used (if applicable)	Author	Reference
H: Classical homeopathic texts and documented homeopathic traditions **L**: other literature references **R**: recent publications (including laboratory research when available) **T**: toxicological data related to the stock and or the raw material **F**: physiological or pathological data			

Detailed texts (in which the relevant data are highlighted).for each entry in the table should be included in section 5.R.S.5

5. P. HOMEOPATHIC DRUG PRODUCT (NAME)

Part P is needed if the homeopathic drug product contains more than one drug substance

5.P.1. History of the formula.

Unless justified, the history should be documented based on **e.g**. the following criteria (non-exhaustive)

- Date of first manufacture
- Original formula (composition, including excipients, dilutions and dosage) + subsequent changes thereof
- Original posology + subsequent changes thereof
- Exposure data based on units sold
- …

Detailed texts for each reference mentioned should be included in annex 5.R.P.1.

5.P.2. Justification of the choice of the association of drug substances in the homeopathic drug product

Detailed texts for each reference mentioned should be included in annex 5.R.P.2. unless already provided in section 5.R.S

5.P.3. Justification of the level(s) of dilution(s) in the homeopathic drug product for example with bibliographical data.

Detailed texts for each reference mentioned should be included in annex 5.R.P.3. unless already provided in section 5.R.S.

5.P.4. Justification of the pharmaceutical form and the route of administration if different from oral route.

Detailed texts for each reference mentioned should be included in annex 5.R.P.4.

5.P.5. Provings established with the finished homeopathic medicinal product, if available.

This information should be provided in function of the type of method used for the proving (e.g. experimentations in healthy subjects, double-blind experimentations in healthy subjects)

The information should be presented in tabulated format as follows:

Author	Date of publication	Number of provers	Frequency and number of administration	Duration	Method

Detailed texts for each proving mentioned in the table should be included in annex 5.R.P.

5.P.6 Package leaflet

Any deviation from the QRD template due to the specific nature of homeopathic medicinal products and taking into account art 60 or 173 needs to be justified in this section.

5.R. Detailed references

5.R.S. Detailed references of each drug substance

5.R.S.1 Nomenclature
5.R.S.2 Reference monograph for stock or homeopathic preparation
5.R.S.3 Homeopathic provings
5.R.S.4 Materia Medica
5.R.S.5 Other bibliographical data

5.R.P. Detailed references of the homeopathic drug product (cross-references to section 5.R.S. are acceptable)
5.R.P.1 History of the formula.
5.R.P.2 Justification of the choice of association of drug substances in the homeopathic drug product with bibliographical data.
5.R.P.3 Justification of the level(s) of dilution(s) in the homeopathic drug product for example with bibliographical data.
5.R.P.4 Justification of the pharmaceutical form and the route of administration if different from oral route.
5.R.P.5 Provings established with the finished homeopathic medicinal product, if available.
5.R.P.6 Package leaflet