GUIDANCE ON THE INFORMATION SUPPLIED IN

# MODULE 5 OF HOMEOPATHIC MEDICINAL PRODUCT MARKETING AUTHORISATION APPLICATIONS ACCORDING TO RD OF 14/12/06 CONCERNING MEDICINAL PRODUCTS FOR HUMAN AND VETERINARY USE, ART 41 OR 176

**(Directive 2001/83/EC art. 16 / directive 2001/82/ec art. 19) "complete procedure" :**

## INTRODUCTION

The content of this module is applicable for homeopathic drug products containing 1 or more homeopathic drug substances.
Module 5 consists of a well developed rationale* that justifies the homeopathic use/nature of the homeopathic drug substance(s) and the therapeutic indication, symptomatology or field of application of the homeopathic drug product, based on the documentation that has to be supplied separately in the following sections:
*option: module 2 except for section 5.R.
The introduction should include the proprietary name of the homeopathic drug product, its composition, dosage form, route of administration, proposed indication and posology in accordance with the data submitted in module 1.

## 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 another pharmacopoeia monograph(s), 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 or double-blind experimentations in healthy subjects) as well as the value of those provings in the context of the symptoms linked to the substance under evaluation for the proposed indication.

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 | Value* |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | |

* *Value* should be understood as the relevance of the data presented in the cited document in relation to the proposed therapeutic indication, symptomatology or field of application of the homeopathic drug product
Detailed texts for each proving mentioned in the table should be included in annex 5.R.S.3 (for each reference, symptoms linked must be highlighted).

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

If available, the information related to the therapeutic indication, symptomatology or field of application of the homeopathic drug product should be provided in this section in tabulated format as follows:

| Name of the Materia Medica | Author | Relevant extracts in the claimed indication |
|---|---|---|
| | | |

Detailed texts for each entry mentioned in the table should be included in annex 5.R.S.4 (for each reference, symptoms linked must be highlighted).

### 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 therapeutic indication, symptomatology or field of application of the homeopathic drug product need to be given.

The bibliographical data could, for example, consist of relevant classical homeopathic texts and documented homeopathic traditions, other literature references, recent publications (including laboratory research when available), published clinical cases or other clinical results (e.g. non

interventional study results, controlled clinical trial results), 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<br>**L**: other literature references<br>**R**: recent publications (including laboratory research when available)<br>**P**: published clinical cases<br>**N**: non interventional study results<br>**C**: controlled clinical trial results (if available)<br>**O**: other clinical results<br>**T**: toxicological data related to the stock and or the raw material<br>**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)

### 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 target population + 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 for the claimed therapeutic indication, symptomatology or field of application with bibliographical data.

Detailed texts for each reference mentioned should be included in annex 5.R.P.2. unless already provided in section 5.R.S (for each reference, symptoms linked must be highlighted).

### 5.P.3. Justification of the level(s) of dilution(s) in the homeopathic drug product for the claimed therapeutic indication, symptomatology or field of application 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. (for each reference, symptoms linked must be highlighted).

### 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. Other bibliographical data established with the homeopathic drug product.

In absence of relevant and conclusive justification/argumentation of the claimed therapeutic indication, symptomatology or field of application of the homeopathic drug product in the previous sections, further bibliographical data need to be provided.

The bibliographical data could consist e.g. of relevant laboratory research results, published clinical cases, or other clinical results (e.g. non interventional study results, controlled clinical trial results), 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 |
|---|---|---|---|
| **R**: recent publications (including laboratory research)<br>**P**: published clinical cases<br>**N**: non interventional study results<br>**C**: controlled clinical trial results (if available)<br>**O**: other clinical results | | | |

Detailed texts for each reference mentioned should be included in annex 5.R.P.6.

### 5.P.7. Summary of product characteristics (SmPC)

Any deviation from the QRD template due to the specific nature of homeopathic medicinal products needs to be justified in this section.

## 5.R. Detailed references

The bibliographical references should be provided hereafter in the following order:

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 for the claimed therapeutic indication, symptomatology or field of application with bibliographical data.
5.R.P.3 Justification of the level(s) of dilution(s) in the homeopathic drug product for the claimed therapeutic indication, symptomatology or field of application 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 Other bibliographical data established with the homeopathic drug product.
5.R.P.7 Summary of product characteristics (SmPC).