

Criteria for Scientific Material in Support of Clinical Indications in Homeopathy

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The German Medicines Act (AMG) in section 25 sub-section 7, governing decision taking in the renewal of marketing authorisations pursuant to section 105 AMG, provides that the Federal Institute for Drugs and Medical Devices (BfArM) involves Commission D in the decision taking process in cases of total refusal or questions of fundamental relevance.

In the review phase from 1978 to 1994, Commission D was responsible for the assessment of the scientific material available in homeopathy. This work resulted in the publication of monographs. These monographs in combination with other documents may be presented as "anderes wissenschaftliches Erkenntnismaterial" (other scientific documents ¹) for the assessment of homeopathic medicinal products, pursuant to section 22 sub-section 3 AMG. However, from today's perspective the Commission D monographs do no longer suffice as the only scientific documents supporting the evidence of efficacy and safety. The following documents are required to be considered as well: the AMG, the guidelines for the testing of medicinal products, according to section 26 AMG, as amended (*Arzneimittelprüfrichtlinien*), as well as Directive 2001/83/EC.

In the first version of the Commission D "Assessment Criteria for Fixed Combinations of Homeopathic Preparations" (January 1989), it was pointed out that "indication claims for severe diseases can only be accepted on the basis of scientifically evaluable findings for the specific fixed combination."

Since many of the Commission D monographs do no longer reflect the state of the art and as a consequence of the experience gained in the assessment of homeopathic preparations in the review of the old market, both Commission D and BfArM have come to the conclusion that it is necessary to present once more, in all clearness, the assessment criteria for '*homöopathisches Erkenntnismaterial*' (scientific documents). With their review experience, Commission D see their opinion corroborated that due to the self-concept of homeopathy it is generally difficult or impossible to transfer statements from homeopathic *materiae medicae* into clinical indications. Especially in severe diseases a transfer of symptoms into clinical indications is problematic. To ensure drug safety and safe use under the conditions of self-medication indications in homeopathy have been graded. Following the recommendations of evidence-based medicine, the below presented paper has been developed to provide criteria for the scientific material in support of clinical indications in homeopathy and a scoring system for the level of homeopathic evidence. The indication assessment scheme is structured according to disease severity grades. Commission D and BfArM believe that the paper will markedly improve the transparency of assessment.

The paper has been adopted by Commission D and is attached here.

¹ Documents on empirical medical findings prepared in accordance with scientific methods shall also be deemed to be documents on scientific findings. (Section 26 sub-section 2 sentence 2 AMG)

Criteria for Scientific Material in Support of Clinical Indications in Homeopathy

Grade of severity of disease (claimed indication)	Therapeutic aim	Kind of scientific material	Evidence level	Required scores	Formulation of indications
I *) Mild disease	Improvement of symptoms (without naming a specific disease/disorder/state), or mild diseases	Updated scientific documents including Commission D monographs; justification of fixed combinations of homeopathic preparations where applicable	IV	2-6	Indication/s without “accompanying therapy“ + information about differential diagnosis *****)
II **) Moderately severe disease a)	Support of treatment of a specific disease/disorder/state	see I additionally: Reproducibly evaluated literature survey of the use of the specific homeopathic product in the claimed indication or Systematic, scientifically evaluable, prospective or retrospective studies (exclusive of clinical trials)	III	4-6	Indication/s with “accompanying therapy“ + information about differential diagnosis
b)	Reduction of frequency of occasionally occurring disorders or Improvement of symptoms of a specific disease/disorder/state or Treatment of a specific disease / disorder/state	see I additionally: Reproducibly evaluated literature survey of the use of the specific homeopathic product in the claimed indication and Systematic, scientifically evaluable, prospective or retrospective studies (exclusive of clinical trials),	III	7	Indication/s without “accompanying therapy“ + information about differential diagnosis

Grade of severity of disease (claimed indication)	Therapeutic aim	Kind of scientific material	Evidence level	Required scores	Formulation of indications
III ***) Severe disease a)	Support of treatment of a specific disease/disorder/state /	see IIa	III	4-6	Indication/s with “accompanying therapy“ + information about differential diagnosis
b)	Improvement of symptoms of a specific disease/disorder/state or Treatment of a specific disease/disorder/state	see I additionally: Reproducibly evaluated literature survey of the use of the specific homeopathic product in the claimed indication, + at least 1 clinical trial of good quality	II	9	Indication/s without “accompanying therapy“ + information about differential diagnosis
IV ****) Life threatening disease a)	Palliative therapy	see IIa	III	4-6	Indication/s with “accompanying therapy“ + information about differential diagnosis
b)	Treatment of accompanying symptoms, improvement of symptoms of a specific disease/disorder/state or treatment of a specific disease/disorder/state	see I additionally: Reproducibly evaluated literature survey of uses of the product in the indication + at least 2 reproducible clinical trials of good quality	I	11	Indication/s without “accompanying therapy“ + information about differential diagnosis

- *) Easy to recognise, known to non-professionals, no immediate medical aid needed for diagnosis and therapy, self-limiting, patients insignificantly affected
- **) Functional ailments, reversible involvement of organ/s, temporary self-medication, uncomplicated courses of disease, medical intervention rarely needed for diagnosis and therapy
- ***) Irreversible changes to organ/s, involvement of organ/s, danger in case of delayed treatment, severe complications possible, medical intervention usually needed for diagnosis and therapy, disease not self-limiting
- ****) High rate of complications, mortality
- *****) Information about differential diagnosis is provided to patients to protect them from health hazards due to misjudgement of a disease in the context of self-medication. The symptoms presented in this information require medical consultation.

Assessment criteria for homeopathic evidence

Assessment Score

Kind of scientific material	Score	Maximum score
Randomised placebo-controlled double blind study	8	8
Metaanalysis	8	8
Randomised controlled study	6	6
Observational study, cohort study, comparative epidemiological study	4	4
controlled study	4	4
Case histories	2	2
Proving of a homeopathic substance	2	2
Expert opinions (consensus conference)	1	1
Evaluated literature survey of the specific homeopathic medicinal product	1	1
Monographs	1	1
Long-time use (at least since 1978)	1	1

Note: Scores should also reflect the quality of the scientific material in planning and execution