

Scientific relevance of the Vademecum of Anthroposophic Medicines

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This article is translated and adapted from an article in German:

Hamre HJ. Bedeutung des Vademecum-Projekts. *Der Merkurstab* 2017;70(6):482–486.

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■ Abstract

The Vademecum of Anthroposophic Medicines (Anthroposophic Medicinal Products, AMPs), 4th edition, covers 627 AMP groups with 1,778 indications, recommendations for use and other core information. The Vademecum is based on a systematic survey and analysis of physicians' clinical experiences with the respective AMPs. While originally developed as a practical tool for physicians, the Vademecum can also be used for scientific purposes.

AMP treatment involves more than 1,000 products, used in different ways. Accordingly, there are thousands of therapy options that cannot be evaluated in clinical studies or high-quality case reports. Therefore, for most indications of AMPs, physician reports of their clinical experience with the AMP remain the best available evidence for efficacy/effectiveness. In order to secure the continued existence of the body of AMPs in the future, such evidence is needed. And here the Vademecum can have a purpose.

Compared to many other experiential reports of AMP therapy, the Vademecum has a number of strengths: Participation of 274 anthroposophic physicians of different specialties from 19 countries; systematic detailed survey; critical assessment of all experiential reports by an independent, interdisciplinary panel; explicit use also of experiences of lack of efficacy; enhancement by a comprehensive, representative literature database; independence of industry.

An important limitation, compared to clinical studies, stems from the design (retrospective overall assessment of the AMP therapy option instead of prospective documentation of consecutive patients). In the domain of physicians' experiential treatment reports, the Vademecum has set standards which other experiential reports will have to be judged by.

■ Keywords

Anthroposophic Medicinal Products

Experiential reports

Indications

Vademecum

The story of the Vademecum of Anthroposophic Medicines

The Vademecum (from Latin: vade mecum – 'walk with me') of Anthroposophic Medicines is essentially a series of mini-reviews of Anthroposophic Medicinal Products (AMPs), including indications, recommendations for use, therapeutic rationale, and literature references. A defining feature of the Vademecum lies in its structure, with the recommendations and information grouped according to AMPs or AMP groups, although an index of indications is also provided. In this respect, the Vademecum is distinct from textbooks of Anthroposophic Medicine (AM), in which the information is grouped according to organ systems, diseases groups, medical specialties and similar (1–9).

The idea of such a Vademecum of AMPs was formulated in the early 1920s by Rudolf Steiner, the inaugurator of AM. This Vademecum (which did not materialize) was to have a strong focus on the AM rationale, and was to be written by one physician (10).

Since then, many 'Vademecum-like' collections of AMP reviews have been published, written by single authors (2, 11–23) or working groups (24–26). Largely based on physicians' therapy experiences, they are often presented as aggregated experiential reports or statements, without any reference to individual cases, case series or clinical studies. These works differ substantially regarding the number of AMPs described, overall structure, length as well as their overall scope or focus, which may be

- AMP therapy rationale as formulated by Rudolf Steiner (11–13),
- portraits of AMPs or substances therein, of metal and mineral (2, 15, 22, 23), herbal (12, 16–18) or zoological (19) origin,
- or therapy recommendations for a large number of AMPs and indications (14, 20–22, 25).

A special case are the 'Commission C Monographs', a large collection of AMP Monographs written and published for specific regulatory purposes in Germany (24).

In 1999 a Vademecum book of 186 pages was published, which had an explicit orientation towards the original Vademecum conception, except being the work of a group: 36 authors from 10 different countries de-

scribed 44 AMPs or AMP substances (27). The second, expanded edition from 2002 (28) (English transl. (25)) had 285 pages; the number of AMPs/substances had increased to 56.

Six years later, in 2008 another working group presented a new *Vademecum* (29) (1st English edition (30)), which has now appeared in its fourth, expanded edition (31). Compared to the *Vademecum* book from 1999 (28), this *Vademecum* from 2017 (31) – a moon node later – is of a much bigger scale: involving 274 physicians from 19 different countries, and covering 627 AMPs or AMP groups over altogether 2,175 pages.

Another important difference between these two *Vademecum* projects lies in the documentation procedure and structure: While the AMP descriptions of the earlier *Vademecum* (25, 27, 28) had each been written by a single author and, with varying text structure and length, the corresponding AMP entries in the *Vademecum* of the new work group (2008–2017) (31) adhere to a largely pre-defined structure. Moreover, each of the AMP descriptions of the current *Vademecum* (henceforth in this paper, the term ‘*Vademecum*’ refers to the work of the second working group described above, unless otherwise stated) are based on one or several pre-structured experiential reports. These reports were submitted by the participating physicians and subsequently peer reviewed by an interdisciplinary editorial board of experienced physicians, enhanced by therapy experiences of the board members, and summarized in a consensual process.

In repeated encounters with the members of the *Vademecum* Editorial Board, their ongoing enthusiasm for this project was apparent. The translations (so far altogether 10 editions in four languages: FR, EN, ES, IT) and the international participation, without financial compensation for any of the involved physicians, testify to the high standing of the *Vademecum* in the AM medical community.

New possibilities for use of the *Vademecum*

The primary target group of the *Vademecum* are physicians who, for their training or patient care, need a quickly accessible, brief description of a specific AMP or AMP group, either directly or via an index of indications.

In recent years, two other possibilities for use of the *Vademecum* have emerged:

- The transfer of contents from the *Vademecum* into the Anthromedics Project (a web-based AM portal, structured as a textbook with the same target group as the *Vademecum*: <https://www.anthromedics.org/>).
- The use of the *Vademecum* as a validated source of physicians’ clinical experience with AMP therapy for scientific purposes.

This second use of the *Vademecum* will be discussed in the following sections.

Use of the *Vademecum* for scientific purposes

The idea of using the *Vademecum* for scientific purposes arose from the need for an adequate framework for registration and marketing authorisation of the AMPs in Europe and worldwide. With regard to this

need, the European Scientific Cooperative on Anthroposophic Medicinal Products (ESCAMP – <http://www.escamp.org/>) was founded. One of the tasks of ESCAMP is to compile and publish a research synthesis of the available scientific documentation on the pharmaceutical quality, safety, and efficacy/effectiveness of the AMPs.

For scientific evidence of drug effects, clinical studies for the respective indications are usually required. Notably, AMP treatment involves well over 1,000 products (in 2015 a total of 1,519 different AMPs were on the German market; when identical AMPs in different potencies are counted separately, the number was 3,299). These AMPs are often used in different combinations for individualised therapy. Accordingly, for AMP therapy, which is used in virtually all medical fields (32), there are many thousand therapy options. It would not be feasible to conduct clinical studies, regardless of design or other features, for such an amount of therapy options. Similarly, the compilation of thousands of case reports of AMP therapy according to current standards (33, 34) would not be feasible. Furthermore, it seems questionable whether such a hypothetical, immensely large number of studies or case reports, which would have to be assessed and summarized, would be meaningful and of practical use.

In this situation, for the large majority of AMP therapy options, validated physician reports of their therapy experience remain the best available evidence for efficacy/effectiveness. And here the *Vademecum* can have a purpose.

Strengths of the *Vademecum* with regard to its use for scientific purposes

Physicians’ experiential reports are available as publications on several AMPs (‘*Vademecum*-type’ and text books as described above) or on single AMPs (35) as well as in unpublished reports. Together, this amounts to a large body of literature of AMP therapy, of different formats and structure. However, compared to the *Vademecum*, most other experiential reports have obvious limitations: They are usually based on the experience of one single physician. Often there are only sparse data on how these experiences came about (e. g. setting, number of patients treated, time period) and how they were aggregated and assessed. Altogether, a systematic and transparent approach is often lacking.

In contrast, the *Vademecum* has a number of strengths (36) (*Fig. 1*):

1. Broad, international participation of AM physicians of different specialties.
2. Participation is principally open to all qualified AM physicians.
3. Systematic, transparent documentation by the participating physicians.
4. Participants are explicitly asked also to document experiences of lack of efficacy.
5. Critical assessment of all experiential reports by an independent panel with currently 10 members of different specialties, working in different settings.

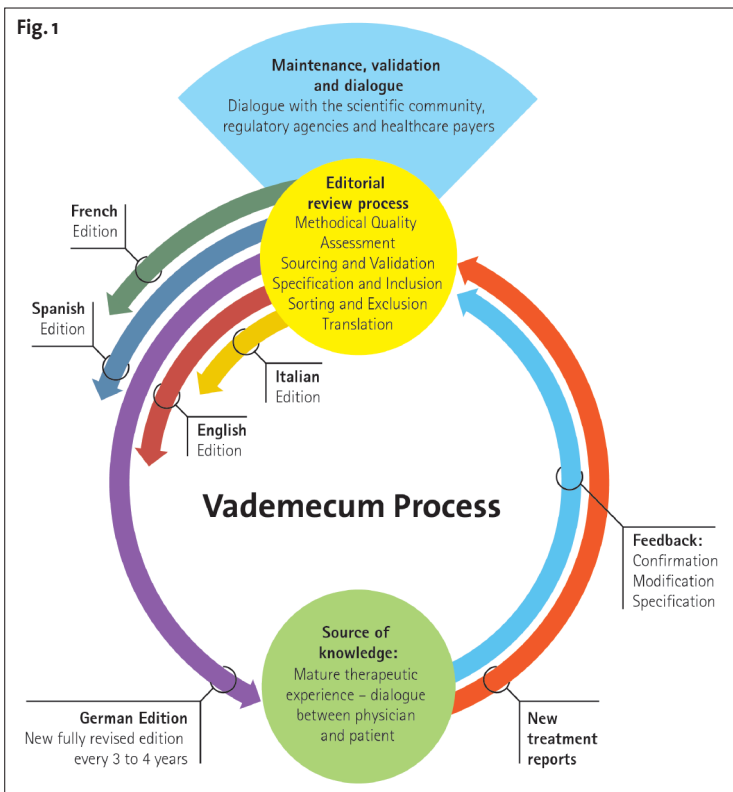


Fig. 1 Vademecum Process. From: *Vademecum of Anthroposophic Medicines, 4th edition [in German], 2017.*

6. Enhancement by a comprehensive, representative literature database.
 7. Independence of industry.
- Out of these seven features, only a few (No. 3, 7, possibly also 6) will to some extent be found in other experiential reports.

The questionnaires in the Vademecum project are largely semi-structured. The current version of the questionnaire 'New contribution to a medicinal product or an indication' (31) includes 17 items on the AMP in question, thereof

- 16 items that are documented in free text, covering the following topics: name, manufacturer, country of manufacture, indication, typical symptoms and findings, constitution type and other relevant modalities, dosage (general, for adults and for children), time until the effect can be expected, first symptoms to improve, average treatment duration, side effects, adjunctive and alternative therapies, approximate number of cases successfully treated in this way;
- 1 item with pre-structured response categories: 'How sure are you that this medication was key to the successful outcome?' – 'Effectiveness certain or reliable' / 'Effective' / 'Effective in some cases' / 'Effective in some cases, only a few observations'.

In this respect the Vademecum seems to have a good balance between pre-structuring and flexibility, at least with regard to its original aim as a practical tool written by physicians for physicians.

Limitations and room for improvement of the Vademecum project

Like most scientific projects, the Vademecum has various limitations:

One limitation is inherent to the *design*: The Vademecum is not a prospective treatment study. A retrospectively compiled experiential report will usually be more prone to error than a prospective documentation of consecutive patients. The physicians' recollection of previous therapy cases can be selective and influenced, e. g. by the intentionality of the physician. Dropout of patients that were treated (perhaps unsuccessfully) with the AMP in question may be underestimated or completely disregarded.

Another limitation comes from the *secondary use of the Vademecum*, that is, the use of data that were originally collected for one specific purpose (collection of mini-reviews of AMPs, for practical use by physicians), for other purposes (scientific analyses) that were not taken into consideration when planning the original project. As an example, in the Vademecum certain descriptive items (e. g. manufacturer or dosage form) are included for some AMPs and absent for others. This may be relatively unimportant, as long as the missing information can be deduced unequivocally from the context, which however is not always the case. For the purpose of scientific analyses, all these missing items should be added.

A third type are *accidentally occurring limitations*. For example, the addition of certain data would – at least from the point of view of ESCAMP – be welcome and perhaps feasible within the scope of the existing documentation system:

- Information on the participating physicians: age, number of years of clinical experience, medical specialty, work setting.
- Number of participating AM physicians vs. number of AM-qualified physicians, grouped by country and medical specialty.
- Number of experiential reports excluded because of incomplete or implausible data.
- Estimated number of treatment cases which the indication is based on (sum of the numbers in the respective experiential reports and among the involved members of the editorial panel).
- Editorial process: Is there a reporter in the editorial board for each AMP (or indication) that can be named? To what extent is the literature listed for each AMP used in the editorial process?

Any additional information on the physicians could be presented anonymously or, if desirable and if consent is given, with disclosure of names.

In order to overcome or ameliorate such limitations, different precautions can be made. In this respect, the Vademecum also in its current form has a number of helpful features:

- *Compensation*: One-sidedness in the reporting by individual physicians can be compensated by the detailed structure of the questionnaires as well as by the acquisition of reports from several physicians in different settings. Similarly, any one-sidedness in the assessment by an individual editorial board member can be balanced by other members in the broad, interdisciplinary panel.

- *Transparent, detailed information*: The inclusion of the number (even the names) of reporting physicians for each indication brings transparency for the Vademecum users. Likewise, the categorisation of ‘Evidence of medicinal effectiveness’ – *Well-established, standard AMP therapy / ‘normal’ indications / indications requiring further experience and review* – is a helpful measure of the strength of therapy recommendation for the respective indication.

As a first step in the secondary use of the Vademecum for scientific purposes by ESCAMP, we have checked all the AMPs and AMP groups listed in the Vademecum with the corresponding AMPs in the ESCAMP Database of AMPs. Thereby, a number of technical shortcomings (inconsistent and unclear entries for AMPs or indications) were identified and resolved in collaboration with the Vademecum team. This regularisation was necessary in order to prepare a quantitative analysis of the Vademecum dataset (Hamre HJ et al., publication in preparation); but the regularised entries should also become incorporated into future editions of the Vademecum.

This data check illustrates the well-known phenomenon that project limitations are often easier to spot by people not directly involved in the project. It could be useful to have an external peer-review of the Vademecum project or to establish an advisory board, in order to assess and improve the quality of this large and valuable project.

Summary and conclusions

The Vademecum of Anthroposophic Medicines is an important and valuable tool, based on a structured collection and critical assessment of physicians’ aggregated experience with AMP therapy. A product of overall high quality, the Vademecum can also be used for scientific purposes. The Vademecum is of course not the only acceptable scientific source of physicians’ experiences with AMP therapy. Nonetheless, in the domain of physicians’ experiential treatment reports, the Vademecum has set standards which other experiential reports will have to be judged by.

Abbreviations

AM: Anthroposophic Medicine

AMPs: Anthroposophic Medicinal Products

Conflict of interest statement

The author is scientific director of the European Scientific Cooperative on Anthroposophic Medicinal Products (ESAMP), which has in the past 3 years received research grants from WALA GmbH and Weleda AG, manufacturers of AMPs. The sponsors had no influence on the preparation of this manuscript, nor on the decision to submit it for publication.

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