

Recommendations no. 3 to the Pharma Code¹

Advertising for medicinal products: documents, references and comparisons

Background:

Sections 251 and 261 to 266 of the Pharma Code (PC - references and comparisons) often give rise to the same questions in practice:

- What is a “recognised scientific medium”?
- What kinds of publication are permitted as references?
- When has a document been “published”?
- How are references correctly cited?

Recommendations

Recognised scientific media (section 262 PC)

Scientific journals for medical professionals are recognised scientific media in which manuscripts (including reports on clinical trials) are published. The editors of such scientific journals check these manuscripts for compliance with international requirements (in technical jargon: “peer reviewed”). These requirements are formulated by the following international organisations:

- *International Committee of Medical Journal Editors (ICMJE)*²: “Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication”³;
- *World Association of Medical Editors (WAME)*⁴: “Recommendations on Publication Ethics Policies for Medical Journals”⁵.

All journals captured in the MEDLINE database that can be searched on MEDLINE via PubMed are deemed to be scientifically recognised media⁶. Plausible arguments for scientific recognition have to be submitted for other scientific journals. Here, the main criterion is that the manuscript has been subjected to a peer review process.

Scientific books are also recognised scientific media. Although books are seldom up to date, certain documents published in book form (e.g. therapeutic guidelines issued by medical associations) can serve as valid references over a longer period of time. As a rule, several authors are responsible for the contents of a scientific book.

Websites can also be recognised scientific media. Data and information that can be important for the advertising of medicinal products are published on the websites of scientific associations, other organisations and institutions that are active in the areas relevant to the PC. Examples include national and international therapeutic guidelines. Such guidelines published on a website can be updated very quickly. Similar to the peer review process for scientific publications, these documents have to be written by a group of recognised experts identified by name.

¹ <https://www.scienceindustries.ch/pharmakodex-praxis>

² <http://www.icmje.org/>

³ http://www.icmje.org/recommendations/archives/2008_urm.pdf

⁴ <http://www.wame.org/>

⁵ <http://www.wame.org/about/recommendations-on-publication-ethics-policie>

⁶ <https://www.ncbi.nlm.nih.gov/pubmed/>

* PC: Pharma Code; PCC: Pharma Cooperation Code

Kinds of publications that are permitted as references (sections 251, 261 and 266 PC)

All kinds of **scientific articles** published in a scientifically recognised medium are permitted as references, provided that they **successfully passed a peer review process**. This ensures that the referenced data and information are generally recognised.

If these refer to **clinical trials**, these must have been carried out in accordance with the Good Clinical Practice (GCP) guidelines that were valid at the time of the trials. The cited clinical trial reports must reflect the current state of scientific knowledge.

An **editorial** - even one published in a scientifically recognised medium - usually does not pass through a peer review process and may therefore **not be used as a reference**. It is possible, however, for statements published in an editorial to be used to supplement a referenced publication (but section 265 must be observed).

Abstracts are abridged forms of scientific investigations that can be submitted during scientific conferences and events. Although abstracts go through a peer review process, this process is not very strict. As a general rule, reference should always be made to the accepted abstract. It is acceptable to use additional data that can only be found in the supporting poster or oral presentation, provided that these additional data are mentioned comprehensibly in the reference and the referenced data are made available immediately on request to all market players by the relevant pharma company. The principle applies that the data derived from posters/oral presentations may not contradict the data in the abstract, but must be plausibly derived from these data.

The data provided in the abstracts are often “work in progress”. Such results should be seen as preliminary findings which have to be revised during the rest of the process. This means that abstracts that are older than 24 months are no longer considered to be up to date and may not be used as references. The determining factor is the date on which the abstract was presented at the relevant scientific congress. The month and year of presentation of the abstract and the name of the scientific congress should be cited as the reference. Abstracts should essentially only be used until the final study is published. For more complex studies, the process of publication can often take more than a year. Abstracts, supporting posters and oral presentations can be published in printed, electronic or other forms.

Market data provide important information that is often used in advertising for medicinal products. According to section 251 PC, statements made in professional promotion must be proven. However, as market data are seldom found in classic scientific publications, the **Code Secretariat accepts** a reference to market research data, for example, if the name of the company and the month/year in which the data were collected are cited.

Publication of documents as a condition for references

A document cited as reference for specific statements in professional promotion is deemed to have been **published** (i.e. made available to the public) if an **informed and authorised person** (e.g. a documentalist) can procure the document as a printed work **in a scientific library**. A document is also considered to have been published if it can be obtained **in a database accessible via the internet**, if necessary with the usual access rights (password protected access for subscribers to a scientific journal, etc.). It is not important from a scientific point of view whether the reference has been published in print or on the internet.

A document is considered to be an **unpublished** document if the reader of the professional promotion can only access the document with the help of the company responsible for this professional promotion. Section 264 PC applies to data in professional promotion that have *not yet* been published.

Market data are often not available to the public. The referenced data must therefore be provided immediately on request to all market players by the relevant pharma company.

Correct citation of references (section 263 PC)

References to scientific journals must be cited with the name and initials of the author (if there are several authors, only the name of the first author can be provided, followed by "et. al."). The full title and name or abbreviation of the scientific journal in which it was published must also be provided. The year or volume and page numbers are usually available for most scientific journals. For abstracts, the month and year of publication must be cited. Early publication in electronic format is by now a common practice. Here, the year, month and day, usually followed by a DOI number and [Epub ahead of print] in brackets are cited. This type of reference is permitted, but should be changed to the usual manner of citation once the details are available. This can be changed when the advertising materials are reprinted, for example. If a scientific journal is only published electronically, an e-number is provided instead of a page number (e.g. PloS One. 2017 Jul 20;12(7):e0181256), followed by a DOI number, if available. If there are any questions, it is a good idea to contact the [PubMed website](#). This website also lists the generally accepted abbreviations for scientific journals.

References to scientific books must be cited with the name and initials of the author of the book or chapter (if there are several authors, only the name of the first author can be provided, followed by "et. al."), the full title of the book or chapter, the name of the publishing house, the edition and the ISBN number.

If **websites are used as references** it is very important to provide a clear link to the website as well as the date (month/year) on which the website was visited. The contents of websites (e.g. updates of guidelines) can change. The pharma company is responsible for ensuring that the data used as reference are still available at a later date.

Excerpt from the PC rules that are relevant in this context

25 Requirements concerning the content of professional promotion

251 The statements made in professional promotion must be proven.

26 References and comparisons

261 Should promotion to healthcare professionals refer to clinical trials, these trials must have been carried out in accordance with the Good Clinical Practice (GCP) guidelines that were valid at the time of the trials. The cited clinical trial reports must reflect the current state of scientific knowledge.

262 Should promotion to healthcare professionals refer to clinical trials, the corresponding clinical trial reports must have been published in a recognised scientific medium.

263 The clinical trial reports must be cited with the full title, authors' names, date and the scientific medium in which they were published; in addition, for scientific journals, the year or volume as well as the page number must be indicated.

264 Under the following conditions, promotion to healthcare professionals may refer to clinical trial reports which have not yet been published:

264.1 They must have been submitted to, and accepted by, a recognised scientific medium for publication;

264.2 These reports must be cited in the promotion to healthcare professionals with the full title, authors' names and date; the corresponding scientific medium must also be indicated;

264.3 In the promotion to healthcare professionals, mention must be made of the fact that a copy of the full clinical trial report may be requested from the pharmaceutical company by the healthcare professionals.

265 Citations from professional medical literature or from lectures by experts at scientific events may not distort or otherwise alter the results of the clinical trials or the opinion of the author.

266 Should promotion refer to investigations such as meta-analyses, pharmaco-economic studies or field reports from practice, these must have been published in a recognised scientific medium. The requirements for the

citation should correspond to Sections 261 to 265.

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Code Secretariat