

## *Recommendations No. 1 to the Pharma Code*

### **Professional promotion for medicinal products: distinction between editorial texts and advertising in professional medical media**

#### **Background**

*What points must be borne in mind when distinguishing between professional promotion (advertisements) for medicinal products and editorial articles in the professional media (Section 23.6 Pharma Code [PC])?*

*Problem 1:* Articles and reports in the editorial part of medical journals which have an essentially commercial slant repeatedly give rise to controversy. A commercial slant means that they are not (in the professional jargon) "peer reviewed". If certain medicinal products are mentioned in such articles and reports, it may be supposed that they were published at the initiative of the particular pharmaceutical company. A pointer in that direction is that such publications often fail to mention whether their author has relevant interests. In a "peer reviewed" article, that would be one of several conditions for publication according to the rules applicable to such professional media.

*Problem 2:* Furthermore, advertisements in professional journals and enclosures with those journals whose graphic design gives rise to confusion with the appearance of the journal itself but for whose content the editorial board is not responsible, are another source of controversy.

#### **Recommendations**

##### **Purpose of the rules in the Pharma Code and in the AWV**

The principle of integrity is one of the *fundamental rules of fair competition*. On that basis, the PC stipulates that the pharmaceutical companies must *not mislead* the readers of a professional medium with their information and advertising materials (Section 24.2). Section 23.6 of the PC prohibits veiled advertising for medicinal products in articles and reports contained in the editorial part of a professional medium.

In other words, the reader should be readily aware whether the material that he reads in a professional media is scientific or commercially motivated information.

##### **Scientific and non-scientific professional media**

Professional media which are edited and drafted with a scientific purpose in mind (in the professional jargon "peer reviewed") are guided by the criteria laid down by their global organisations:

- *International Committee of Medical Journal Editors (ICMJE):* "Recommendations for the Conduct, Editing, and Publication of Scholarly in Medical Journals"<sup>1</sup>;
- *World Association of Medical Editors (WAME):* "Policies for Medical Journal Editors, prepared by the WAME Ethics and Policy Committee"<sup>2</sup>.

Reports and information (about clinical studies etc.), which are published in such professional media are deemed not to be influenced by commercial interests. The editors of such professional media call attention, according to the requirements cited in footnote 3 and the Federal Act against

<sup>1</sup> [www.icmje.org/icmje-recommendations.pdf](http://www.icmje.org/icmje-recommendations.pdf)

<sup>2</sup> [www.wame.org/policies](http://www.wame.org/policies)

\*PC: Pharma Code; PCC: Pharma Cooperation Code

Unfair Competition (Bundesgesetz gegen den unlauteren Wettbewerb - UWG), to the consistent distinction which must be made between editorial information and advertising, if indeed the media concerned allow any advertising.

For practical reasons, all journals that are listed in the MEDLINE database<sup>3</sup> are considered scientifically recognized. For all other journals, scientific recognition should be made plausible.

The duty of diligence imposed upon pharmaceutical companies by Section 23.6 of the PC therefore applies in the first instance to professional media which are not affiliated to the ICMJE or WAME and are therefore not bound by the rules of those bodies. Reports and information about medicinal products contained in the editorial part of such professional media (including PR texts, promotional reports and so forth) which are directly or indirectly placed by pharmaceutical companies, e.g. through advertisements in the same medium, must be clearly *recognisable* as such.

In addition, such commercially motivated information (as the second sentence of Section 23.6 of the PC points out) must be "clearly distinguishable from the contributions for which the editors of the professional medium are responsible".

Professional journals which are not "peer reviewed" are at liberty to design their editorial and commercial pages as they think fit and to determine how they make a distinction between the editorial content and advertising. They are not required to comply with the PC nor with the ICMJE and WAME rules referred to above. The reader therefore has no guarantee that articles and reports in their editorial section are independent from commercial interests and dedicated to purely scientific purposes.

### **Editorial and journalistic freedom of professional media versus obligations of the Pharma Code signatories**

The freedoms of the professional journals which are not "peer reviewed" apply only to their editors and publishers. They do *not* apply to the pharmaceutical companies which have undertaken to comply with the PC. The pharmaceutical companies must comply at all times with the PC and in particular with its Section 23.6.

According to that provision, they may neither directly nor indirectly arrange for commercial, i.e. not scientifically motivated articles and reports, which may be regarded as veiled professional advertising within the meaning of the first sentence of Section 23.6 of the PC, to appear in the editorial part of non-peer reviewed professional journals. In this context, the words "indirectly arrange" likewise mean that such articles must not be deemed to be published as a support for advertisements placed in the same professional medium.

The prohibition of veiled advertising likewise implies that advertisements and PR texts in the professional media must be clearly separated from the contributions for which the editors of the professional medium are responsible. "Clearly separated" applies both to the presentation (advertisements must be recognisable as such at first glance by their appearance and separated from the editorial texts) as also to the content of texts in the professional medium: these must not create the appearance of editorial contributions, i.e. resemble editorial contributions in their presentation and so disguise their true intention.

### **Notifications in headings such as "Pharma-News", "Pharma-Info" etc.**

Various medical and pharmaceutical professional media regularly publish special pages under headings such as those quoted above. "Congress News" and so forth must be seen in the same light. Such headings have in common the fact that they contain reports about particular medicinal products and their characteristics. Generally, the pharmaceutical companies concerned send out communications of that kind. Such communications are governed both by the requirements of the above-mentioned Section 23.6 of the PC and also more generally by those which apply to all forms of professional promotion (Section 23 PC). In such communications, the "succinct statement"

<sup>3</sup> <http://www.ncbi.nlm.nih.gov/nlmcatalog/journals>

(Section 24.5 PC) must always be included. This statement however should be available at least once in the bound edition of a journal.

The publishers and editorial boards of the non-peer reviewed professional journals are at liberty to decide on the graphic design of such headings. That freedom does *not* apply to the pharmaceutical companies which have undertaken to comply with the PC. If they publish communications about medicinal products in these headings, they must respect the aforementioned Section 23.6 of the PC, even from the design angle. If there is any risk of confusion with editorial texts, the pharmaceutical companies may only publish communications about medicinal products in such headings if they are identified by the qualification as an "advertisement" or by some similar reference.