

**CODE OF CONDUCT FOR PHARMACEUTICAL ADVERTISING (subdivided into the following chapters):**

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**FINAL PROVISION**

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Below there follows the full text of the Dutch Code of Conduct for Pharmaceutical Advertising:

**I SCOPE OF APPLICATION**

This Code of Conduct governs advertising for medicinal products in the broadest sense of the term, i.e. oral; written; via audiovisual methods; via exhibitions, conferences and symposia; and in any other way.

The Code of Conduct also lays down standards for a number of activities that are more concerned with encouraging sensible behaviour in the relations between marketing authorisation holders and practitioners, such as the provision of general information about medicinal products, the offering of hospitality to practitioners, the offering/requesting of special offers or benefits in cash or in kind to/from practitioners, the supplying of samples of medicinal products, and research involving registered medicinal products.

The Code of Conduct does not cover the following:

- labelling and package leaflets ('package inserts') of medicinal products;
- letters, where appropriate accompanied by documentation, that do not have any advertising purpose and that are sent in response to a specific request for information about a specific medicinal product;
- factual information and the related documentation, e.g. about changes in packaging, warnings about adverse drug reactions within the framework of post-marketing surveillance, and information about sales lists and price lists, as long as these do not contain any information about the medicinal product, and
- information relating to public health or human disease, as long as this does not contain any reference (not even an indirect one) to a medicinal product.

**II SUPERVISION**

The task of supervising compliance with this Code of Conduct is entrusted to the Codecommissie (Code of Conduct Committee) and Commissie van Beroep (Appeals Committee) established by the Stichting Code Geneesmiddelenreclame, in accordance with the provisions laid down for that purpose.

### III DEFINITIONS

For the purpose of the application of this Code of Conduct the following terms shall be understood as follows:

- *medicinal products*: medicinal products falling within the scope of the Wet op de Geneesmiddelenvoorziening (Medicines Act), i.e. including serums, vaccines, allergen extracts and toxins for application to or in man, as well as blood products falling within the scope of the Wet inzake Bloedvoorziening (Blood Supply Act).

- *advertising*: any promotion of medicinal products and the services or concepts associated therewith, including the offering or requesting of goods or services in the framework of the relationship between marketing authorisation holders and practitioners.

- *public advertising*: any advertising aimed at or intended for the customer, consumer or end user.

- *the Act*: the Wet op de Geneesmiddelenvoorziening (Medicines Act) and/or the Wet inzake Bloedvoorziening (Blood Supply Act).

- *practitioners*: practitioners of professions as described in article 1, sub d, of the Medicinal Products Advertising Decree (Bulletin of Acts and Decrees 1994, 787, most recently modified in Bulletin of Acts and Decrees 1999,37). (*see the explanation below*)

- *marketing authorisation holders*: holders of a marketing authorisation ('vergunning') as referred to in section 2, first paragraph, under d of the Medicines Act, as well as holders of a marketing authorisation as referred to in section 15 of the Wet inzake Bloedvoorziening (Blood Supply Act).

- *medical representatives*: persons whose principal task – acting on the instructions of a marketing authorisation holder and in personal contact with practitioners – is to provide medicopharmaceutical information and consult with practitioners on the use of medicinal products for the purpose of diagnosis and/or treatment of patients.

- *sales representatives*: persons whose principal task – acting on the instructions of a marketing authorisation holder – is to visit practitioners primarily for purposes other than the provision of medicopharmaceutical information.

### IV GENERAL RULES OF CONDUCT

1. Notwithstanding the legal provisions applicable in this field as well as that stipulated elsewhere in this Code of Conduct, marketing authorisation holders and practitioners must display a concern for sensible and responsible behaviour in their mutual relations. This involves, more specifically, an obligation to ensure that their behaviour is always in the best interests of the end user as well as of public health in general, including an appreciation of the fact that a significant part of the costs of medicinal products is covered by funds realised through collective provision.

2. In their mutual relations, marketing authorisation holders and practitioners should avoid acting in any way in conflict with their professional oath or any other obligations incumbent upon them in the exercise of their profession or the conduct of their business or in such a way that they feel improperly obligated to each other.

### V ADVERTISING

## **General**

3. Notwithstanding the stipulations relating to this matter in or by virtue of the Act as well as other effective legal provisions, pharmaceutical advertising in the Netherlands shall be conducted in accordance with this Code of Conduct.

4. In pharmaceutical advertising, whether this be performed orally, in writing, via audio and/or visual methods or in any other way, the following must be taken into consideration:

4.1. the advertising must not in any way conflict with the officially approved summary of product characteristics (SPC) for the medicinal product, as prescribed in or by virtue of the Act.

4.2. the advertising must be performed in such a way that the rational use of the medicinal product is encouraged from a pharmacotherapeutic perspective and so that the person to whom the recommendation is made is not misled in any way.

4.3. the advertising must be in such a form that the promotional nature thereof can be recognised by the person at whom the advertising is aimed.

4.4. the advertising must otherwise be in compliance with the Act and must, both as regards text and as regards presentation, meet the prevailing standards of good taste and conduct, for which due regard must be shown with respect both to the person at whom the advertising is aimed and one's colleagues in the sector.

5. In evaluating whether advertising complies with the rules of conduct stated above, the following criteria must be used as a guide:

5.1. a degree of dignity and prudence appropriate to the nature of the product must have been displayed.

5.2. to encourage rational use of the medicinal product, an effort must have been made to avoid the use of vague terms or superlatives or any other form of exaggeration of the characteristics of the medicinal product in question.

5.3. the advertising statement, when considered in relationship with the advertising for the medicinal product as a whole, must be accurate, up to date and truthful, and correct and verifiable in its constituent parts.

5.4. the totality of the advertising material aimed at practitioners must provide as complete and accurate a picture as possible of the effect of the medicinal product. In evaluating this criterion, the indication and the clinical effectiveness according to the registration details as well as the undesirable effects and contra-indications (see, in this context, also article 8.1) must in every case be taken into account.

5.5. no harm must be done to the reputation of the pharmaceutical industry or its products or to the reputation of practitioners.

5.6. in the use of unpublished research, the researcher concerned must have given his or her prior permission, notwithstanding the provisions of the Code Publieksreclame (Code for the Advertising of Medicinal Products for the Public).

5.7. all citations of publications must be accurate and must mention their sources; a check must have been performed to ensure that the use of these citations is not in conflict with the tenor of the publication. The cited publications must be a fair reflection of the current status of science and technology.

5.8. if a comparison is made with another substance or another medicinal product in which a competitor or a medicinal product offered by a competitor is expressly or implicitly named, then due care must be taken to ensure that, notwithstanding the provisions of the Code Publieksreclame:

- the comparison is not misleading; the drugs that are being compared meet the same need or are intended for the same purpose; the comparison relates objectively to one or more essential, relevant, verifiable and representative characteristics of the medicinal products, e.g. the (clinical) effect;
- the comparison does not harm the value of these other substances or medicinal products;
- the marketing authorisation holder for these other substances or preparations, his tradename and/or brandnames of these other substances or medicinal products are not brought into discredit;
- the comparison does not give rise to any confusion between the substances or medicinal products being compared with one another and their brandnames and/or between the marketing authorisation holders involved and/or their tradenames;
- the comparison does not present medicinal products as an imitation or copy of medicinal products with a protected trademark or protected tradename;
- the comparison does not create any unfair advantage as a result of the reputation of a mark, tradename or other distinguishing characteristics of a competitor;
- the accuracy of the comparison can be scientifically demonstrated and the comparison is in accordance with the latest state of scientific knowledge;
- the comparison is complete with regard to the effect, undesirable effects, indications, contra-indications and other relevant details of the substances or medicinal products being compared and, in general, due regard has been shown both to one's colleagues in the sector and to those at whom the advertising is aimed.

6. Marketing authorisation holders must ensure that their advertising complies with this Code of Conduct and must provide adequate facilities for monitoring that compliance.

To that end:

6.1. marketing authorisation holders must maintain accurate records of all their advertising statements, which must at least include one copy of every advertising message and a note of the recipient, the method of distribution and the date of first distribution. The records must remain available for a period of at least five (5) years to anyone who is entrusted with the task of supervising pharmaceutical advertising;

6.2. marketing authorisation holders must ensure that all their advertising is tested against the requirements of this Code of Conduct by the scientific department referred to in article 14;

6.3. marketing authorisation holders must furnish to those entrusted with the task of supervising pharmaceutical advertising the information and assistance necessary to exercise this supervision, and

6.4. marketing authorisation holders must ensure that the decisions that are made by these supervisory authorities or bodies are immediately and fully taken into account.

#### **Specific provisions for oral advertising**

7.

7.1. Medical representatives must have a suitable education/training and sufficient scientific knowledge to be able to provide accurate and complete information about the drugs that they are advertising.

7.2. Medical representatives must be such effective discussion partners for practitioners that they enable adequate communications to be established with the marketing authorisation holder that they represent.

7.3. Medical representatives must observe the above rules of conduct in all their advertising activities.

7.4. Medical representatives shall make available at each visit they make to a practitioner, for each medicinal product for which they are advertising, the officially approved summary of product characteristics (SPC) for the medicinal product as prescribed in or by virtue of the Act.

That means that the medical representative must have with them at all times the relevant texts in their most recent versions to be able to show them at the visit. The medical representative can also refer to the

Repertorium (Pharmacopoeia) for this purpose if this contains the most recent version of this summary of product characteristics.

When recommending new drugs the relevant summary of product characteristics must always be handed over.

7.5. Medical representatives must not offer any inducements and must not resort to any false pretexts to make an appointment with a practitioner.

7.6. Medical representatives must respect the wishes of the practitioner or the rules of a hospital and must ensure that the frequency, timing and length of their visits to practitioners or hospitals, as well as the way in which these visits are made, do not cause any nuisance.

7.7. Medical representatives must take the necessary measures with regard to the safety and security of the medicinal products that they have in their possession, such as measures against theft and loss and measures relating to proper storage in order to maintain their quality.

7.8. Oral advertising via the telephone is not permitted except by prior arrangement with the practitioner concerned.

7.9. Medical representatives must report to the marketing authorisation holder whom they represent every visit that they have made to a practitioner, stating the medicinal product(s) for which they have been advertising, the date of the visit, and the written information presented during the visit. Marketing authorisation holders must retain these reports for five (5) years for inspection by the authorities and bodies that are entrusted with the supervision of pharmaceutical advertising, as part of the records referred to in article 6.1. In addition, marketing authorisation holders must ensure that these records are organised in conformity with the Wet Persoonsregistraties (Data Protection Act) and that the reports in question are made available to the relevant practitioner in accordance with that stipulated in the Data Protection Act.

7.10. If a practitioner gives a medical representative information regarding the use, effect and (in particular) the undesirable effects of the medicinal products for which the medical representative is advertising, the medical representative must immediately pass on this information to the scientific department of the marketing authorisation holder whom the medical representatives represents.

7.11. Marketing authorisation holders are responsible for ensuring that the medical representatives who represent them act in accordance with the present rules of conduct. Marketing authorisation holders must take the necessary measures to guarantee that the medical representatives who represent them satisfy the conditions laid down in this Code of Conduct as regards education, knowledge and skills.

7.12. Marketing authorisation holders must ensure that the medical representatives who represent them are listed in the register of medical representatives as maintained by the Stichting FarmEduca (Postbus 3140, 3502 GC) in Utrecht.

7.13. That stipulated in articles 7.5, 7.6 and 7.7 is applicable by analogy to sales representatives.

### **Specific provisions for written advertising aimed at practitioners**

8.

8.1. Every written advertisement aimed at practitioners must comply with the instructions laid down in this Code of Conduct and must in every case state:

- the name of the medicinal product;
- the name and address of the marketing authorisation holder,
- the qualitative and quantitative composition of the active ingredients;
- the pharmacotherapeutic group, if relevant;

- the pharmaceutical form;
- the major therapeutic indications;
- the most important undesirable effects (showing frequency and severity);
- the most important warnings (precautionary measures for use);
- all contra-indications; and
- the classification of the drug (POM or OTC) with regard to dispensing channels,
- at a place and in a typeface that does justice to the importance of this information. If, in the case of written advertising, the information referred to here is of such an extent that the text cannot in all reasonableness be accommodated within a standard-sized document, then a cross-reference can be made to the place where this information can be found elsewhere in the relevant medium.

8.2. The criteria referred to in article 8.1 are not applicable if the written advertising aimed at practitioners is exclusively intended as

- a. a reminder of the name of the medicinal product and if it contains no data other than:
  - the composition of the medicinal product;
  - the name of the pharmacotherapeutic group;
  - the name and address of the marketing authorisation holder, or
- b. practical information for the identification of the medicinal product to be supplied, without this involving any pharmacotherapeutic claims.

8.3. Each written advertisement must, before distribution, be tested against the regulations of this Code of Conduct by the scientific department as referred to in article 14.

#### **Specific provisions for advertising via exhibitions and via audio and/or visual or other methods**

9. Advertising at exhibitions and trade fairs or via audio and/or visual or other methods must, making due allowance for the specific character of the methods referred to, be in agreement with and be in the spirit of the rules of conduct as stated above for oral and written advertising.

#### **Specific provisions for public advertising**

10. Notwithstanding that stipulated in this Code of Conduct in general and that stipulated in article 6.2 in particular, in public advertising the Code voor de Publieksreclame voor Geneesmiddelen (Code for the Advertising of Medicinal Products for the Public) must be taken into consideration. This Code – which is reproduced in the appendix to this document – forms an integral part of this Code of Conduct and is also referred to as the Code Publieksreclame.

11. Holders of marketing authorisations must refrain from sponsoring activities by third parties if the reward for these third parties consists wholly or partially of public advertising for medicinal products that are specified in or by virtue of the Act as medicinal products that are dispensed only on prescription (POM).

#### **Specific provisions for conferences, symposia and other gatherings**

12. Marketing authorisation holders must ensure, when offering hospitality to practitioners in the context of conferences, symposia or other gatherings, including the gatherings referred to in section 14, second paragraph, and section 15 of the Medicinal Products Advertising Act – irrespective of whether these are organised by the marketing authorisation holder himself or by a third party acting on his instructions or in consultation with the marketing authorisation holder – that this hospitality remains within reasonable bounds and is subordinate to the objective of the gathering.

13. With regard to gatherings as referred to in the previous article, a scheme of preventive supervision applies. This scheme is further elaborated in article 13 of the Regulations of the Codecommissie and the Commissie van Beroep van de Stichting Code Geneesmiddelenreclame.

### **Scientific department**

14. Marketing authorisation holders must ensure the availability of a scientific department entrusted with the task of explaining the medicinal products that are being marketed by the authorisation holder as well as with the internal testing of the content of the advertising for these medicinal products against the stipulations of this Code of Conduct.

The activities of the relevant scientific department are performed within their own professional responsibility by duly qualified personnel. These activities shall, whether or not in the context of a formal contract of employment, be performed on the instructions of the marketing authorisation holder.

## **VI OTHER SUBJECTS**

### **The supplying of samples**

15. Notwithstanding that stipulated in this regard in or by virtue of the Act, marketing authorisation holders must maintain adequate records of the samples of medicinal products provided by them and of the prescribing practitioners to whom they have furnished the samples, as well as the quantities involved. These records must be retained for five (5) years.

### **Research involving registered medicinal products**

16. This Code also applies to research with medicinal products unless the research falls within the scope of the Wet medisch-wetenschappelijk onderzoek met mensen (Medical Research Involving Human Subjects Act – the WMO) and unless, under section 3 of the WMO, it has been, will be or must be evaluated and approved by a recognised medical ethics committee or by the Centrale Commissie Mensgebonden Onderzoek (CCMO).

### **Special offers, gifts and other benefits**

17. The provisions of articles 18 to 22 inclusive must be understood against the background of the general rules of conduct contained in this Code.

18. Marketing authorisation holders must refrain from the following activities involving practitioners:

- offering or promising gifts in any form whatsoever,
- offering or promising discharge for the payment of invoices other than in return for full payment, notwithstanding section 6:127 of the Dutch Civil Code (regarding the set-off of reciprocal debts and receivables),
- making the price of medicinal products dependent on purchasing other medicinal products or other products,
- making or promising other special offers or benefits in cash or kind,
- any other act of omission or commission through which dispensers and prescribers might feel improperly obligated to companies.

19. Holders of marketing authorisations must refrain, when supplying medicinal products, from offering or providing practitioners with discounts in the form of gifts (including bonus deliveries of other medicinal products or products alien to the sector). This provision does not apply to discounts made in connection with the supply of medicinal products provided that, in the case of discounts in kind, in the form of bonus deliveries of the same drug or in the case of discounts in cash, these are made expressly in writing (specifically on an invoice or credit notes).

20. Holders of marketing authorisations must ensure that the rewarding of practitioners – irrespective of whether that is done in cash or in kind – for advisory work or services rendered is in reasonable proportion to the work done by the practitioners, and that the advisory work or the services rendered does not give rise to any connection between the marketing authorisation holders and the practitioners other than the holding of a direct relationship with the advisory work or services rendered.

21. Exempted from that stipulated in article 18 are gifts or benefits in cash or in kind that are of meagre value and that are also of significance for the exercise of medicine or pharmacy. The concept of ‘meagre value’ suggests something modest in size. The value must also be viewed in relationship to the frequency with which the gifts or benefits are offered. It is not the intention that gifts of meagre value be offered so often or in such a volume that the value of them as a totality becomes substantial.

22. Notwithstanding that stipulated in article 21, practitioners must refrain from asking for or accepting special offers or benefits in cash or in kind as mentioned in article 18.

### **FINAL PROVISION**

23. Holders of marketing authorisations must organise their activities with regard to medicinal products in such a way that a correct compliance with this Code of Conduct as well as an adequate monitoring of that compliance is guaranteed, and they must refrain from any act of omission or commission that, although not expressly provided for in this Code of Conduct, is in conflict with the spirit or tenor thereof.

24. The marketing authorisation holder is obliged to extend to the supervisory body referred to in chapter II of this Code of Conduct all cooperation that it reasonably requires for the performance of its task.

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**Explanation of the definition of practitioners**

In article 2d of the Medicinal Products Advertising Decree the following are regarded as professional:

- pharmacists
- doctors also maintaining a pharmacy
- pharmacist's assistants within the meaning of the Act on Provision of Medicines
- persons to whom article 2f, first paragraph of the Act on Provision of Medicines (WOG) applies
- doctors
- dentists
- obstetricians

Article 2f, first paragraph of the Act includes a list of a number of categories of persons who (providing they possess a valid licence) are allowed to sell medicines to private users other than on prescription. It concerns for example chemists and food companies.

With the adapted definition of professionals, assistants of family doctors and nurses and any other persons who on account of their profession or position are involved in prescribing, supplying or administering medicines are not regarded anymore as professional within the meaning of the Medicinal Products Advertising Conduct Code. They are therefore regarded as public.

Laid down during the board meeting on 29 June 2004.

Effectuation: 1 January 2005