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Translation of information purposes / No legal value

Code of Conduct of members of VDGH (Verband der Diagnostica-Industrie e. V. - German Diagnostics Association) who manufacture self-application IVD according to § 3 no. 5* of the German Medical Devices Act (Gesetz über Medizinprodukte/MPG) ("Self-Application IVD Code")

dated
(announced in the Federal Gazette of)

* A self-application IVD is an IVD that can be used, according to the intended use as defined by the manufacturer, by non-experts in their own homes. (In-vitro Diagnostikum zur Eigenanwendung ist ein In-vitro Diagnostikum, das nach der vom Hersteller festgelegten Zweckbestimmung von Laien in der häuslichen Umgebung angewendet werden kann.)

Adaptation of the version of the "Code of Conduct of the Members of the Association "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e. V." (FSA), with changes for VDGH members who manufacture self-application IVD (§ 3 no. 5 MPG).
The FSA Code of Conduct of 16.02.2004 was first promulgated in the German federal gazette/Bundesanzeiger of 22.04.2004, BAnz. no. 76, p. 8732. The amended version on 02.12.2005 was promulgated in the German federal gazette/Bundesanzeiger of 29.03.2006, BAnz. no. 62, p. 2220.

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Introduction

Health is our most valuable possession. Self-application IVD make key contributions to human health and well-being. Requirements are high for manufacturers in the research, development, manufacture and distribution of self-application IVD. The patients are at the centre of efforts to prevent or cure diseases or to relieve their consequences with effective self-application IVD.

The members of ~~the~~ this ~~association Verband der Diagnostica-Industrie e. V. (VDGH) who manufacture self-application IVD according to § 3 no. 5 MPG~~Code of Conduct~~,~~ are committed to communicating the knowledge needed for an appropriate selection and use of self-application IVD by disseminating accurate and objective scientific information. Self-application IVD are technically sophisticated and complex goods requiring comprehensive explanations. Therefore, it is an essential task of any self-application IVD company to provide healthcare professionals with all necessary and suitable information regarding the significance and characteristics of self-application IVD, describing not only possible uses and benefits of self-application IVD but also the limits and risks of their use and taking into account the latest findings of medical sciences. Furthermore, the research and development of self-application IVD of good diagnostic value would not be possible without close expert cooperation between physicians, pharmacists and other healthcare professionals and service providers. They all ensure adequate advice in the supply of self-application IVD prescribed by the physician in charge.

Advertising is a key element of market economy and an expression of intense competition within the self-application IVD industry. This Code of Conduct is not intended to restrain fair competition. Rather, for ~~the~~ its members ~~of VDGH who manufacture self-application IVD according to § 3 no. 5 MPG,~~ the principle applies that self-application IVD are to be adequately advertised, avoiding unfair practices and conflicts with healthcare professionals in relation to professional ethics. All measures in advertising and collaborating with physicians and other healthcare professionals must remain within certain appropriate bounds and in accordance with the law. In this respect, the principles of separation, transparency, documentation and, for mutual services, the principle of equivalence as stipulated in the "Common Position" of the associations (Common Position of the Associations for assessing the Collaboration between Industry, Medical Facilities and their Employees in Reference to German Criminal Law) for the clinical sector also outline valuable reference points for the collaboration of the self-application IVD industry with office-based physicians and other healthcare professionals.

With the objective of promoting professional conduct in accordance with these principles, fostering an environment where the general public can be confident that choices regarding their self-application IVD are being made on the basis of the merits

of each product and the healthcare needs of patients and ensuring fair competition in advertising as well as in the collaboration with physicians and other healthcare professionals, ~~the following members:~~

~~Abbott GmbH & Co. KG, Bayer Vital GmbH, A. MENARINI DIAGNOSTICS DEUTSCHLAND, eine Division der Berlin-Chemie AG, LIFESCAN, Geschäftsbereich der Ortho-Clinical Diagnostics GmbH, Roche Diagnostics GmbH, TERUMO DEUTSCHLAND GMBH~~

~~of VDGH~~ the members of VDGH who manufacture self-application IVD according to § 3 no. 5 MPG have passed the following:

Code of Conduct of members of VDGH who manufacture self-application IVD in accordance with § 3 no. 5 MPG

Section 1: Scope of application

§ 1
Scope of application

(1) This Code of Conduct is applicable to the ~~above mentioned companies~~members of VDGH who manufacture self-application IVD in accordance with § 3 no. 5 MPG as well as to any companies affiliated with such member companies, if these affiliated companies have acknowledged the binding nature of the Code of Conduct in a separate written agreement ("member companies" or "companies").

(2) Self-application IVD in the meaning of this Code of Conduct are in vitro diagnostics also intended for self-application (§ 3 no. 5 MPG – in the version of 07.02.2002, last amended on 25.11.2003).

This Code is applicable

1. to product-related promotion and advertising for self-application IVDs in the meaning of § 2 MPG, as regulated in §§ 7–13 of this Code, if promotional and advertising measures are addressed to healthcare professionals in the meaning of § 2 of this Code

   and

2. the collaboration of the companies with healthcare professionals in the fields of research, development, manufacture and distribution of self-application IVD, as regulated in §§ 14 et seq. of this Code.

(3) The Code of Conduct is not applicable to non-promotional information, including, within the meaning of this Code of Conduct, in particular:

1. the labeling and instructions for use of self-application IVD;

2. correspondence and documents of a non-promotional nature, needed to answer a specific question about a particular self-application IVD;

3. factual information such as announcements relating to pack changes, adverse-reaction warnings as well as reference materials (e.g. trade catalogues and price lists, provided they include no product claims);

4. factual information relating to diseases or human health;

5. information about companies, e.g. information directed to investors or to current or prospective employees, including financial data, descriptions of research and development programs as well as information about regulatory developments affecting the company or its products.

§ 2
Definitions

"Healthcare professionals" are physicians and pharmacists as well as any member of the medical, dental, pharmacy or other nursing professions or any other person who in the course of his or her professional activities may prescribe or apply or lawfully trade in self-application IVD.

§ 3
Responsibility for the conduct of third parties

The company shall comply with the obligations imposed by this Code of Conduct also if the company commissions others (e.g. advertising agencies or market research companies) to design or implement the activities covered by this Code of Conduct.

Section 2: Principles of interpretation

§ 4
General principles of interpretation

(1) When applying this Code of Conduct, not only the letter of the individual provisions but also their spirit and intention as well as all applicable laws must be observed, especially the regulations of the German Drugs Act (Arzneimittelgesetz/AMG), the German Advertising in the Health Care System Act (Heilmittelwerbegesetz/HWG), the German Fair Trade Practices Act (Gesetz gegen den unlauteren Wettbewerb/UWB) and the German Penal Code (Strafgesetzbuch/StGB), and the generally recognized legal principles applicable to healthcare professionals and the conduct recommendations of the participating association(s) of the self-application IVD industry, which are based on these principles by considering their wording as well as their meaning and purpose.

(2) The companies must maintain high ethical standards at all times. In particular, their conduct must never be such as to bring discredit upon, or reduce confidence in, the self-application IVD industry or to cause offence. Additional regard must be paid to the special nature of self-application IVD and the professional standing of the healthcare professionals addressed.

§ 5
Promotion

When applying Section 3 of this Code of Conduct, particular attention is to be paid to the following principles of interpretation:

1. Promotion must enable the healthcare professionals addressed to form their own opinion of the diagnostic value of a self-application IVD. It must, therefore, be accurate, balanced, fair, objective and sufficiently complete to give a correct overall impression. It should be based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly.

2. Promotion must encourage the rational use of self-application IVD by presenting them objectively and without exaggerating their properties.

3. Sales representatives for self-application IVD must approach their duties responsibly and ethically correct.

§ 6
Collaboration

(1) When applying Section 4 of this Code of Conduct, particular attention is to be paid to the following principles of interpretation:

1. Healthcare professionals must not be unfairly influenced in their decisions regarding prescriptions or procurement. Therefore, it is unlawful to offer, promise or grant them or any third party any unfair advantages. Especially the forms of collaboration described in Section 4 below must not be used in any unfair manner to influence the decision-making freedom of healthcare professionals regarding diagnosis, prescriptions or procurement.

2. Considered unfair are in particular those advantages that are granted in violation of the provisions of the German Advertising in the Health Care System Act (HWG), the German Fair Trade Practices Act (UWG), the German Penal Code (StGB), or the generally recognized legal principles applicable to healthcare professionals.

(2) ~~The Board of VDGH may issue guidelines for the interpretation of this Code of Conduct, in particular of the terms "reasonable" (angemessen), "socially acceptable" (sozialadäquat) and "inexpensive" (geringwertig) within the meaning of Section 4 of this Code, that need to be acknowledged by the German Federal Cartel Office (Bundeskartellamt). VDGH will publish such guidelines on the internet (http://www.vdgh.de/).~~DELETED, as pharma-specific

Section 3: Promotion

§ 7
Prohibition of misleading practices

(1) Misleading promotion is inadmissible, irrespective of whether it is misleading by distortion, exaggeration, undue emphasis, omission or in any other way.

(2) A misleading practice is in particular found to exist if

1. self-application IVD are attributed with a diagnostic efficiency, effects or a use they do not possess,

2. untrue or misleading information is given concerning the characteristics of self-application IVD.

(3) When evaluating the question of whether the non-disclosure of a fact is misleading, special regard is to be paid to the potential influence such a non-disclosure may have on the decision of the healthcare professionals addressed regarding prescriptions.

(4) Promotion must be based upon sufficient scientific evidence and must be consistent with the product information ~~addressed to healthcare professionals.~~. This rule applies in particular to advertising claims referring to specific benefits, qualities or properties of a self-application IVD. Claims that are already included in the marketing authorization of the self-application IVD do not require further scientific evidence. If so requested by healthcare professionals, the relevant scientific evidence must be directly made available to an appropriate extent.

(5) The word "safe" must never be used to describe a self-application IVD without proper scientific evidence (see Annex I IVDD).

(6) DELETED

(7) The word "new" may be used for self-application IVD only in the first year after the first placing on the market, unless rules to the contrary are provided in the MPG (see § 3 no. 6 MPG).

§ 8
Prohibition of disguised promotion / Requirement of transparency

(1) The commercial character of promotional measures must not be disguised.

(2) Advertisements that are paid for or inserted by companies must be designed in such a way that they cannot be confused with independent editorial matter.

(3) In the case of any publications made by third parties about self-application IVD and their use which are either wholly or partly sponsored by a company, particular care must be taken to ensure that such publications clearly indicate that they have been sponsored by that company.

§ 9
Prohibition of promotion of non-authorized medicinal products and non-authorized indications

DELETED, as pharma-specific

§ 10

Compulsory information

DELETED, as pharma-specific

§ 11
Reference to publications

A promotion shall be inadmissible when

1. referring to scientific, expert or other publications without indicating whether the publication concerns the self-application IVD, the method, the treatment, the object or any other means being advertised and without mentioning the name of the author, the date of publication and the source reference,

2. quotations, tables, copies, other representations or expert remarks of third persons taken from scientific publications have not been faithfully reproduced, except where the modification can be based upon an objectively justified reason, in which case it must be clearly stated which modification has been made.

§ 12
Comparative advertising

(1) Any advertising which explicitly or by implication identifies the self-application IVD of a competitor shall be deemed to be comparative advertising.

(2) Any comparative advertising that fails to objectively refer to one or more essential relevant, verifiable and typical properties or to product prices or services ~~of the compared self-application IVD~~ is inadmissible.

(3) Comparative advertising must not be misleading or disparaging with regard to a competitor's self-application IVD.

§ 13
Unreasonably molesting advertising

(1) Healthcare professionals shall not be unreasonably molested by advertising. An unreasonable molestation is found to exist where advertising action can be recognized by the advertising person as not being desired by the recipient.

(2) The use of faxes, automated calling systems or e-mails for promotion is prohibited except with the prior permission of the recipient.

When using e-mail, a putative permission can be assumed to have been given if the company has received the e-mail address from the recipient and the recipient is clearly informed in any e-mail that he may object to the use of e-mail at any time.

(3) The permission to be given by the addressee of the advertising action must not be obtained by using any inducement or subterfuge, in particular by misleading the addressee as to the identity of the sales representative for self-application IVD or the company represented by him.

(4) Mailing lists may be used for promotion only if the data included therein are kept up-to-date. Requests by healthcare professionals to be removed from promotional mailing lists must be complied with.

§ 14
The "Red Hand" symbol

DELETED, as pharma-specific

§ 15
Tests of self-application IVD

(1) Entrepreneurs of the self-application IVD industry may make available self-application IVD free-of-charge to healthcare professionals who wish to test the product or to have it tested, within the bounds of what is permissible under competition law.

(2) Self-application IVD may be made available only at request and without any payment for the test or the accompanying counseling. Companies must operate an adequate system for the control and proof of requests or products made available.

§ 16
Prohibition of distant treatment / Response to individual enquiries

The diagnosis or treatment of diseases is reserved for physicians. In case of enquiries referring to individual diagnosis situations, the company is to advise enquirers to consult a physician.

Section 4: Collaboration with healthcare professionals

§ 17
Prescriptions and recommendations

It is unlawful to offer, grant or promise healthcare professionals or any third party a fee or monetary advantage for prescribing, applying or recommending a self-

application IVD. Sales representatives are not third parties, but in all other respects they are subject to the provisions of this Code.

§ 18
Contractual collaboration with healthcare professionals, clinics and other service providers

(1) Services rendered by physicians for companies (e.g. lectures, consulting, clinical trials, post-marketing application surveys) and services of clinics and other service providers (e.g. for clinical trials, post-marketing application surveys) must be based on written agreements that clearly state both the nature of the service and the remuneration.

(2) The contractually stipulated service to be rendered to the company must be scientific or medical in nature, including educational purposes (prohibition of "fictitious contracts"). Commercial services in connection with the exercise of the medical profession are excluded, unless they are necessary part of the medical therapy because of their specific character. Clinical trials and post-marketing application surveys as well as any other studies or data collections must not be misused with a view to influencing, in disguised form, diagnostics or procurement decisions or for mere promotional purposes.

(3) The remuneration must be exclusively monetary and must be proportionate to the service rendered. When judging the appropriateness of the intended remuneration, the physician's fee schedule may serve as a reference guide. To take into account the physician's time expended, appropriate hourly rates may also be arranged.

(4) In addition, the physicians, clinics and other service providers may be reimbursed for their out-of-pocket and travel expenses while rendering the contractual services.

(5) Physicians, clinics and other service providers or third parties must not be granted any payment for their willingness to meet with self-application IVD representatives or to receive information from other members of the self-application IVD company.

(6) Physicians and employees of clinics or other medical service providers in the public sector must disclose the working relationship to their administration and obtain a confirmation in writing from their administration.

§ 19
Post-marketing application surveys

(1) Post-marketing application surveys are studies conducted with authorized self-application IVD, in order to gather new knowledge about the use in practice of self-application IVD.

(2) With regard to diagnostic measures, the principle of non-intervention applies to post-marketing application surveys.

(3) The planning, designing and implementing of post-marketing application surveys must be laid down in writing beforehand, completed questionnaires must be evaluated with adequate expertise, and the implementing of post-marketing application surveys must undergo appropriate quality control.

(4) In addition, the company must justify and document the planned number of patients and the amount remunerated for each survey questionnaire in the project file. After completion, really conducted questionings and remunerations must be documented.

(5) With regard to the amount remunerated for the implementation of a post-marketing application survey, § 18 (3) applies subject to the provision that said remuneration should be set in such a manner that it does not create an incentive to prescribe the self-application IVD in question. The prerequisite for payment of remuneration is that the company has received the completed survey questionnaires.

§ 20
Invitations to job-related, science-oriented training events

(1) The member companies may invite healthcare professionals to their own, job-related training events, who are particularly concerned with said companies' research areas, self-application IVD and their ~~therapeutic indications~~field of application (in-house training events).

(2) The company may only pay reasonable travel and accommodation costs for the invited healthcare professionals, if the career-related, scientific character of the in-house training event clearly takes centre stage. During such training events, reasonable hospitality arrangements for the participants are also possible. However, the company must neither finance nor organize any entertainment programs of the participants (e.g. theatre, concert or sports events). The actual participation of the invited persons and the event program must be documented.

(3) Accommodation and hospitality must not exceed reasonable limits and must be of minor importance in relation to the job-related, science-oriented purpose of the in-house event. The selection of the conference location and conference venue for in-house training events as well as the invitation of healthcare professionals must be made exclusively based on factual criteria. For instance, the leisure offerings of the conference venue do not qualify as such a reason.

(4) The invitation of healthcare professionals to job-related training events of any third party (external training events) may only include reasonable travel expenses, necessary accommodations and participation fees charged by said third party, if the scientific character of these events clearly takes centre stage and if the company has a relevant factual interest in such a participation. The company may only assume the costs, if the event provides a link to the member company's field of activities as well as a link to the expertise of the event participant.

(5) Within appropriate limits, financial support for the organizers of external training events is permissible. However, entertainment programs must neither be supported financially or in the form of donations, nor must they be organized. Member companies supporting external training events must request that the financial support be officially disclosed by the organizer when the event is announced and when it takes place.

(6) If the organizer is a member of the medical profession, the nature, content and presentation of the training event must be determined solely by said medical organizer.

(7) The invitation and assumption of the costs for in-house and external training events must not include accompanying persons. This also applies to any hospitality offered.

(8) No member company may organize, hold and/or sponsor international events or pay for the costs of the participants unless

1. the majority of the participants are from outside its home country where the member company is domiciled, or

2. the relevant resource or expertise are available at the venue (e.g. for recognized medical congresses with international lecturers),

and, in view of these factors, it makes greater logistical sense to hold the event in another country. International events are in-house or external training events in which the company organizing, holding or supporting the event or supporting its participants is not domiciled in the country where the relevant event takes place.

(9) The organization, holding and/or sponsoring of international events as well as the invitation of healthcare professionals to, and the support of their participation in, such events are subject to both the code of the country in which the company organizing, holding or supporting the international event is domiciled and the code of the country in which the international event takes place. Code within the meaning of this provision shall mean ~~the~~ this ~~VDGH~~ Code as well as ~~the~~ an applicable code at the place of the event. In the event of a conflict, the more restrictive rule shall apply. The company must notify any activities within the meaning of sentence 1 in advance to its affiliated company, if any, domiciled in

the country where the event takes place or obtain, from there, appropriate advice for the due and proper implementation of such activities.

(10) If healthcare professionals are commissioned by member companies to hold lectures at in-house or external training events or provide other services, § 18 shall apply.

§ 21
Gifts

(1) For advertising gifts offered within the scope of a product-related promotion, the limits stated in § 7 of the German Advertising in the Health Care System Act (HWG) must be observed. ~~Advertising gifts must not contain any indications or advertising claims other than the company name, the company logo or the trademark of the company or the name of the self-application IVD or the designation of its active substance~~Unless otherwise provided for by section 7 of the German Advertising in the Health Care System Act, such gifts must be "inexpensive"..

(2) In addition, gifts offered within the scope of a non-product-related promotion may be made only for special occasions (e.g. for practice openings or anniversaries), as long as their value is within socially acceptable limits. ~~and they are intended for use in the professional practice.~~

§ 22
Hospitality

Hospitality for healthcare professionals is only permissible during in-house training events and work lunches/dinners to a reasonable and socially acceptable extent. The occasion for such a work lunch/dinner must be documented. Sales conversations are no work lunches/dinners. Hospitality for accompanying persons is not permissible.

§ 23
Sweepstakes for healthcare professionals

(1) Sweepstakes, in which winning is solely due to chance, may not be advertised to healthcare professionals.

(2) Sweepstakes, in which the entry depends on a scientific or expert service of the participating healthcare professionals and for which the promised prize is appropriate proportionate to the scientific or expert service rendered by the entrants, are permissible.

§ 24
Collaboration with healthcare professionals in their function as civil servants and/or employees of medical institutions

When collaborating with healthcare professionals who are civil servants and/or employees of medical institutions, the information and recommendations of the "Common Position" of the associations must be observed as well.

Section 5: Commitment and training of employees and third-party contractors

§ 25
Qualification and duties of employees

(1) The companies shall ensure that their sales representatives for self-application IVD, including personnel retained by way of contract with third parties, and any other company representatives who call on healthcare professionals, hospitals or other healthcare facilities in relation to the advertising of self-application IVD, are adequately trained and have sufficient expert knowledge to be able to provide precise and sufficiently complete information about the self-application IVD they promote.

(2) Sales representatives for self-application IVD must be familiar with the companies' obligations under this Code and with all applicable laws and regulations. Companies are responsible for ensuring that their sales representatives for self-application IVD comply with these requirements.

(3) All other company staff, and any personnel retained by way of contract with third parties who are concerned with the preparation or approval of promotional materials or activities must also be fully conversant with the requirements of the applicable codes and relevant laws and regulations.

(4) DELETED, as pharma-specific

(5) Sales representatives for self-application IVD must submit to the scientific service of their companies any information they receive in relation to the use of their company's self-application IVD, particularly reports of adverse reactions.

(6) Sales representatives for self-application IVD must ensure that the frequency and duration of their visits to healthcare professionals, together with the manner in which they are made, do not cause unacceptable inconvenience to the practice operation.

§ 26
Commitment and training of employees and third-party contractors

(1) Member companies must commit their employees and third-party contractors being concerned with the advertising of self-application IVD or collaborating with healthcare professionals to adhere to this Code of Conduct and ensure compliance through suitable organizational measures, including the establishment and definition of the function of a "compliance officer" by appointing one or several employees.

(2) In addition, the employees must be informed of the most important principles of the professional regulations and obligations of the healthcare professions. Furthermore, they must be trained with regard to the content of this Code of Conduct ~~of members of VDGH who manufacture self-application IVD according to § 3 no. 5 MPG~~.

Section 6: Entry into force

§ 27
Entry into force

~~The~~ This Code of Conduct ~~of members of VDGH who manufacture self-application IVD according to § 3 no. 5 MPG, agreed on by Abbott GmbH & Co. KG, Bayer Vital GmbH, A. MENARINI DIAGNOSTICS DEUTSCHLAND, eine Division der Berlin-Chemie AG, LIFESCAN, Geschäftsbereich der Ortho-Clinical Diagnostics GmbH, Roche Diagnostics GmbH, TERUMO DEUTSCHLAND GMBH on May 4, 2007 and August 13, 2007~~
will enter into force as soon as it has been acknowledged as competitive regulations by the Federal Cartel Office (Bundeskartellamt) pursuant to § 24 (3) of the German Restraints of Competition Act (Gesetz gegen Wettbewerbsbeschränkungen/ GWB).

[The Federal Cartel Office acknowledged the Code of Conduct in the present version as competitive regulations by decision of ???, received on ???]

Frankfurt am Main, ~~19~~13. ~~Juli~~August 2007