

**COC**

# **CODE OF CONDUCT**

**PHARMIG CODE OF CONDUCT**

**AND**

**CODE OF PROCEDURE OF THE  
COC COMMITTEES OF EXPERTS OF THE  
1<sup>ST</sup> AND 2<sup>ND</sup> INSTANCE**

07/2009

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COC COMMITTEES OF EXPERTS OF  
THE 1<sup>ST</sup> AND 2<sup>ND</sup> INSTANCE**

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### GENDER NEUTRALITY

All terms referring to individuals are generic and refer to both genders.

# FOREWORD

Ladies and Gentlemen,

Medicinal products are precious, technologically well developed products, which provide an essential part for the public health care of a society.

Efficient medicinal therapies guarantee the efficient use of resources within the public health care system. Medicinal products help to save costs in the public health care system. A successful research into medicinal products is not conceivable without the cooperation between pharmaceutical enterprises and specialist circles. Therefore it is essential to define the basic rules of this cooperation in a transparent and fair manner.

In addition to research and marketing of medicinal products, it is of high importance for the pharmaceutical industry, to provide support for a highly developed public health care system on supplying appropriate and balanced information. To highlight the value and potential risks of medicinal products is an indispensable and necessary duty of the pharmaceutical companies. It is the pharmaceutical industry's social obligation, even its social responsibility to communicate relevant information on medicinal products to patients as well as to specialist circles of the public health care system. Therefore it is of general importance to consider the principles of exactitude, objectivity and fairness, in order to guarantee a safe use of medicinal products for physicians and for patients.

In addition to the scientific information on medicinal products, advertising is an essential element of market economy and expression of intensive competition. Therefore not only the principles of the Pharmig Code of Conduct have to be met, but also the competition regulations have to be followed.

The voluntary restraint of the Pharmig Code of Conduct bears witness to a strong sense of responsibility and to the declared intention of our members, to represent the ethic standards of the pharmaceutical branch. The pharmaceutical industry gives actively a clear sign to support the reasonable and responsible use of medicinal products.

Thus: Our aim remains to provide all patients in Austria with the appropriate medicinal products to bear our responsibility within the Austrian public health care system to the best of our knowledge.

The current version of the Pharmig Code of Conduct and the Code of Procedure of the CoC Committees of the 1st and 2nd instance came into force on 01/07/2007 and has been amended on 01/07/2009.



Jan Oliver Huber  
Secretary General of  
Pharmig

# Page

# TABLE OF CONTENTS

9	<b>1. Pharmig Code of Conduct</b>
9	Article 1 – Introduction
9	Article 2 – Scope
10	Article 3 – General principles
10	Article 4 – Information on medicinal products
12	Article 5 – Advertising medicinal products
14	Article 6 – Information and advertisement via the Internet
15	Article 7 – Events
17	Article 8 – Cooperation with specialist circles or third parties
20	Article 8a – Cooperation with patients' organisations
22	Article 9 – Gifts
22	Article 10 – Raffles
22	Article 11 – Company employees
23	Article 12 – Clinical trials
23	Article 13 – Violation of the MPA
23	Article 14 – CoC ordinance
24	<b>2. Code of Procedure of the CoC Committees of Experts of the 1st and 2nd Instance</b>
24	Article 1 – Tasks and responsibilities of the Committees of Experts 1st and 2nd Instance
24	Article 2 – Language of correspondence / Language of proceedings
25	Article 3 – Venue for proceedings
25	Article 4 – Rights of defence
25	Article 5 – Complainant
26	Article 6 – Object and admissibility of the complaint
26	Article 7 – Content and form of the complaint
27	Article 8 – Rights and liabilities of the complainant
27	Article 9 – CoC Committee of Experts of the 1st Instance
28	Article 10 – Simplified proceedings before the CoC Committee of Experts of the 1st Instance

Article 11 – Continuation of the proceedings before the CoC Committee of Experts of the 1st Instance	29
Article 12 – Oral proceedings	29
Article 13 – Representation of the company concerned	30
Article 14 – Decision of the CoC Committee of Experts of the 1st Instance	30
Article 15 – Sanctions of the CoC Committee of Experts of the 1st Instance	32
Article 16 – Appeal	33
Article 17 – CoC Committee of Experts of the 2nd Instance	34
Article 18 – Decision of the CoC Committee of Experts of the 2nd Instance	35
Article 19 – Non-appealability of the decision of the CoC Committee of Experts of the 2nd Instance	35
Article 20 – Partiality	35
Article 21 – Deadlines, deliveries and notifications	36
Article 22 – Pharmig Office	36
Article 23 – Secrecy	37
Article 24 – Members of the CoC Committee of Experts of the 1st Instance	37
Article 25 – Members of the CoC Committee of Experts of the 2nd Instance	37
Article 26 – Common regulations for the appointment of members to the CoC Committees of Experts of the 1st and 2nd Instance	38
Article 27 – Costs of the CoC Committees of Experts of the 1st and 2nd Instance	39
Article 28 – Cost of the simplified proceedings before the CoC Committee of Experts of the 1st Instance	39
Article 29 – Cost of continuation of the proceedings before the CoC Committee of Experts of the 1st Instance	39
Article 30 – Costs of the proceedings before the CoC Committee of Experts of the 2nd Instance	40
Article 31 – Necessary expenses	41
Article 32 – Due date of costs and necessary expenses / Value-added tax	41
Article 33 – Publication of decisions	41
Article 34 – Use of gender nouns	41
Article 35 – Other regulations	42
Article 36 – Coming into force / Transitional provisions	42



# PHARMIG CODE OF CONDUCT

# 1

## INTRODUCTION

## ARTICLE 1

The purpose of the Pharmig Code of Conduct is to enable the pharmaceutical industry to meet its responsibility in health care in a professional manner while maintaining the high ethical standards of the pharmaceutical industry. The imperative balance between the various interests of patients, persons in health care professions and the general public in consideration of legal, political and social environment of the pharmaceutical industry and its partners must be guaranteed.

Apart from the General Principles, the Code of Conduct of Pharmig, the Association of the Austrian Pharmaceutical Industry (hereinafter referred to as the "Pharmig Code of Conduct") contains rules for information regarding medicinal products, advertisement for medicinal products, information and advertising via the Internet, events, cooperation with specialist circles or third parties, cooperation with patients' organisations, gifts, raffles, company employees, clinical trials and infringements of the Medicinal Products Act (MPA).

## SCOPE

## ARTICLE 2

The Pharmig Code of Conduct applies to all information, advertising and marketing activities for medicinal products, including advertising in print and electronic media, mailings and events, implemented by a pharmaceutical company itself or in its commission. Furthermore it applies to employees of pharmaceutical companies, medical sales representatives, for the use of audiovisual systems, telecommunications or the Internet, films, videos and data carriers, for cooperation with specialist circles or third parties, for cooperation with patients' organisations, for the presentation of gifts and give-aways as well as for all other regulated areas. The Pharmig Code of Conduct does not restrict the exchange of medical and scientific information during the development of a product before its authorisation in Austria.

## ARTICLE 3

## GENERAL PRINCIPLES

The comprehensive and regular information regarding medicinal products and their research results is an essential component of the services provided by pharmaceutical companies to wholesale, physicians, pharmacists, patients and the general public.

This information serves to ensure medicinal product safety and is indispensable for the proper administration of medicinal products. It is therefore essential that users as defined by § 2 (1) MPA (physicians, dentists, veterinary surgeons, denturists, midwives, members of the nursing profession, medical laboratory services and paramedic services as well as the legal entities of hospitals without an in-house hospital pharmacy and any other medical facilities, provided they require medicinal products to fulfil their tasks), pharmacists and, if applicable, persons as defined by § 59 (3 and 4) MPA be immediately, comprehensively and reliably informed about the existence and properties of medicinal products that they may prescribe, use or dispense.

- 3.1 In applying the Pharmig Code of Conduct, not only the terms of the individual provisions, but also their spirit and intent as well as the applicable law, in particular the regulations of the Austrian Medicinal Products Act (MPA), the Unfair Competition Act and the Austrian Criminal Code, are to be taken into account and observed.
- 3.2 The behaviour of pharmaceutical companies must always abide by the highest of ethical standards. In particular, their behaviour shall in no way cause discredit to the pharmaceutical industry, impair the trust given it or be in any way objectionable. Furthermore, the special nature of medicinal products, the well-being of the patients and the professional identity of the specialist circles addressed must be taken into consideration.

## ARTICLE 4

## INFORMATION ON MEDICINAL PRODUCTS

A key task of pharmaceutical companies is to communicate the knowledge required for the proper selection and application of medicinal products by means of issue-related and objective scientific information on medicinal products. Therefore, all the necessary and appropriate information on the significance and properties of medicinal products must be communicated.

- 4.1 The following is deemed to be non-promotional information:
  - 4.1.1 correspondence and documents of a non-promotional nature needed to answer a specific question on a particular medicinal product;

- 4.1.2 sales catalogues and price lists, provided they include no product information,
  - 4.1.3 issue-related information relating to diseases or human health, provided no reference is made - also no indirect reference - to a medicinal product;
  - 4.1.4 information as part of the pharmacovigilance activities in coordination with the authorities;
  - 4.1.5 company-related information, e.g. to investors or current or future employees, including financial data, reports on research and development programmes as well as information on regulatory developments concerning the company and its products;
  - 4.1.6 information on non-authorised medicinal products in response to a documented request from specialist circles;
  - 4.1.7 correspondence with the authorities, as in the course of marketing authorisation, pharmacovigilance or inspections;
  - 4.1.8 texts approved by the authorities, e.g. summary of product characteristics or the patient information leaflet.
- 4.2 Scientific and expert information on medicinal products must be based on state-of-the-art scientific findings. The information must be accurate, balanced, fair, objective, verifiable and complete in order to give the recipient the possibility of forming his own personal opinion of the properties and the therapeutic value of the product in question.
- 4.3 All statements concerning medicinal products must correspond with the summary of product characteristics and be limited to the medical indications for which they have been authorised. This, however, should not impede the provision of purely scientific information on research results that extend beyond the approved medical indications and effects.
- 4.4 Scientific articles must be quoted conscientiously and objectively with reference made to their source. Reference must be given to the source of data and statements relating to scientific studies or publications. Quotations, tables, graphics or other depictions must be faithfully reproduced and the precise sources must be indicated.
- 4.5 Statements on scientific studies, publications, quotations, tables, graphics or other depiction must render the content correctly and may not be misleading.
- 4.6 In particular, information and the data on medicinal products must be truthful and must not be misleading through distortion, inappropriate emphasis, omission or in any other way, neither directly nor indirectly.
- 4.7 Each pharmaceutical company must ensure that qualified, scientific information is made available for its products. This information must meet the requirements of the recipient and must not offend against normal expectations in terms of integrity and dignity.

- 4.8 Information on medicinal products must be provided upon the request of specialist circles. Documentary evidence to support the authorised indications is not required.
- 4.9 Written documentation for specialist circles shall contain at least the requirements of the short summary of product characteristics acc. to § 54 MPA in conjunction with § 15 MPA in a clearly legible font size, form and colour.
- 4.10 Written documentation for specialist circles on authorised or registered medicinal products for which no summary of product characteristics is required must contain at least the analogous text sections of the published patient information leaflet.
- 4.11 Written documentation on medicinal products available on prescription which are provided by the physician to the patient and serve to improve patient compliance and as special concomitant therapeutic measure must not contain any business-to-layman advertisement relating to preparations. The indication of the trade name of the preparation is permitted.
- 4.12 The determination or treatment of diseases is reserved for physicians. Upon requests relating to individual therapy situations, the company shall advise the person placing the request to consult a physician.

## ARTICLE 5

## ADVERTISING MEDICINAL PRODUCTS

Advertising is an essential aspect of the market economy and an expression of the intensive competition between pharmaceutical companies.

- 5.1 All measures taken by pharmaceutical companies as part of their advertising activities must be appropriate and within the constraints of applicable law.
- 5.2 No medicinal product may be advertised before it has been authorised by the authorities for sale or dispensation. This shall not apply to business-to-business advertising as defined in § 54 Medicinal Products Act in connection with scientific events, if the participants predominantly come from abroad.
- 5.3 Advertisement must meet the professional requirements of the recipient and must not offend against normal expectations in terms of integrity and dignity.
- 5.4 Advertising material may not be designed in such a way as to conceal the true intent. In advertisement, medicinal products are to be depicted in an objective fashion without exaggerating their properties to enable

the recipient to form his or her own opinion of the therapeutic value of the medicinal product.

- 5.5 Advertising may not be concealed and must be transparent. For example, advertising paid for or published by a pharmaceutical company must be designed such that it cannot be mistaken for independent editorial publications.
- 5.6 In publications by third parties entirely or partly financed by a pharmaceutical company on medicinal products and their applications, it must be ensured that these publications contain a clear reference to the financing by the company.
- 5.7 Pharmaceutical companies are not permitted:
  - 5.7.1 to make reference to brands of competitors in their documentation or in their advertisement, unless permission has been granted to do so or this reference is admissible according to the provisions of the Unfair Competition Act
  - 5.7.2 to imitate typical advertising features of competitors, the presentation, packaging or labelling of competitor products
  - 5.7.3 to publish misleading or causing damage to reputation advertisement;
  - 5.7.4 to behave themselves in a blatant manner (as through exaggerated emphasis);
  - 5.7.5 to assert in their statements that a product has no undesirable effects, side effects or toxic effects and/or addictive or habit-forming effects;
  - 5.7.6 to use the terms "safe" and "safety" without clearly defining them;
  - 5.7.7 to use the word "new" without any specification and/or definition so that it is not clear from the information provided to what the word "new" is actually referring;
  - 5.7.8 to use the word "new" after one year has passed since the medicinal product, the respective indication, the respective pharmaceutical form, the respective application, the respective dosage or the respective package size was first put into circulation.
- 5.8 In keeping with § 54 sec. 1 MPA, business-to-business advertising must contain the essential information on the medicinal product in agreement with the summary of product characteristics (short summary of product characteristics). Business-to-business advertisements for authorised or registered medicinal products for which no summary of product characteristics is required shall contain at least the analogous text sections of the patient information leaflet.
- 5.9 Advertisement (business-to-business and business-to-layman advertisement) shall also be subject to the respective provisions of

Article 4 of the Pharmig Code of Conduct (Information on Medicinal Products) and the provisions of part V of the Medicinal Products Act (Advertising Restrictions).

## ARTICLE 6

### INFORMATION AND ADVERTISEMENT VIA THE INTERNET

#### 6.1 General requirements

- 6.1.1 For information and advertisement on medicinal products made accessible by pharmaceutical companies, in their commission or with their approval in the Internet, Article 4 (Information on Medicinal Products) and Article 5 (Advertising Medicinal Products) apply analogously.
- 6.1.2 The presentation on the Internet must clearly specify the pharmaceutical company that operating the website or directly or indirectly supporting it and which information on the website is addressed to specialist circles and/or to the general public.
- 6.1.3 Information on the website must be updated on a regular basis and checked for its accuracy and should provide updated information.

#### 6.2 Information on the company

- 6.2.1 Websites may contain information of interest to investors, the media and general public.
- 6.2.2 Websites may contain financial data, descriptions of research and development programmes, information regarding regulatory matters which concern pharmaceutical companies and their products, information for future employees, etc.

#### 6.3 Information for patients and the general public

- 6.3.1 Information addressed to the layman and containing advertisement must comply with the applicable provisions of part V of the Medicinal Products Act and the according provisions of Article 5 (Advertising Medicinal Products) of the Pharmig Code of Conduct.
- 6.3.2 Websites may contain non-promotional information on the medicinal products sold by the company for patients and the general public (incl. information regarding indication, side effects, interactions with other substances, application, reports on clinical research, etc.).
- 6.3.3 Conditionally, this information must be balanced, accurate and in harmony with the authorised summary of product characteristics (SPC).

- 6.3.4 The website may contain a link to the complete, unmodified evaluation report as published by the CHMP (Committee for Human Medicinal Products) or a competent national authority.
  - 6.3.5 The website may contain links to other websites containing reliable information on medicinal products (websites of authorities, medical research institutions, patient organisations, etc.).
  - 6.3.6 Apart from the brand name, the international non-proprietary name (INN) must also be mentioned.
  - 6.3.7 The website must always contain a reference to a physician or pharmacist for further information.
- 6.4 Information for specialist circles
- 6.4.1 Information addressed to the specialist circles and containing advertisement must comply with the applicable provisions of part V of the Medicinal Products Act and the respective provisions of Article 5 (Advertising Medicinal Products) of the Pharmig Code of Conduct.
  - 6.4.2 Information for specialist circles must be clearly indicated as such. It must be ensured that the access to this information is reserved exclusively to specialist circles.

## EVENTS

## ARTICLE 7

Symposia, scientific congresses, workshops, lectures and the like, also small-scale events, are recognised vehicles for the dissemination of knowledge and experience on medicinal products and therapies as well as recognised means of training and continuing education. The organisation, implementation and/or support or assumption of costs for participants in these events is only admissible if the event complies with the conditions set forth in Article 7.

- 7.1 These events must exclusively serve to provide scientific information and/or further specialisation.
- 7.2 The assumption of costs for these events shall be restricted to travel costs, room and board as well as the original admission fee and shall be appropriate. Leisure-time activities and/or social programmes (e.g. theatre, concerts, sports events) for participants may not be financed or organised. The invitation of any accompanying persons is not permitted. Therefore, pharmaceutical companies are not permitted to take care of the organisation nor assume the costs for travel, room and board or expenditures for recreational activities.
- 7.3 The attendance of the participants, the programme and the scientific and/or technical content of the event implemented must be documented.

- 7.4 The venue must be appropriate for the purpose of the event, located in the home country and be chosen based on objective factors. The recreational value of a conference venue is no selection criterion.
- 7.5 International events are events at which the company organising and implementing the event or supporting the event or its participants has its registered office outside of the country in which the event venue is located.
- 7.5.1 The organisation, implementation and/or support of international events or the assumption of costs for participation in these events is not admissible if
- i) the majority of participants come from a different country than the country in which the member company is based , or
  - ii) the necessary resources or specialised knowledge are available at the event venue, and in view of this there are appropriate logistical reasons for choosing a venue in a different country (in the case of recognised specialised congresses with international speakers or visits to the company's own scientific or production facilities abroad).
- 7.5.2 Both the code of the country in which the company organising, implementing or supporting the international event is based and the code of the country in which the international event is taking place apply to the organisation, implementation and/or support of the international event and to the invitation to, and support of the participation of, specialists in this event. In this respect, code is the Pharmig Code of Conduct as well as the code applicable at the event venue by virtue of which the EFPIA\* Code of Practice on the Promotion of Medicines is implemented. In any case, the more stringent of these is applicable. The company must announce in advance activities subject to line. 1 to an associated company with registered office in the country where the event is taking place, if decided, or consult this company for advice on the proper implementation of activities.
- 7.6 The invitation of persons as participants or speakers to events may not be made dependent on the recommendation, prescription or distribution of specific medicinal products.
- 7.7 The speakers must inform the event organiser of any conflicts of interest and appropriately disclose their presentation to the participants of the event prior to the start of the event. The speaker's fee must be adequate to the service rendered. In addition, their expenses, including travel costs, incurred through the participation in the event may be reimbursed appropriately.
- 7.8 If companies distributes speeches or discussion contributions held at an event, or reports on these, they must ensure that this information correctly express what was communicated at the event. The same

\* EFPIA = European Federation of Pharmaceutical Industries and Associations

applies if they commission other persons, media or companies to do this.

- 7.9 According to Article 14, the board of Pharmig is authorised to adopt a CoC ordinance for Articles 7.1 through 7.4 concerning the type, scope and appropriateness of the events and their documentation.

## COOPERATION WITH SPECIALIST CIRCLES OR THIRD PARTIES

## ARTICLE 8

In order to research and further develop effective medicinal products, close cooperation with physicians, pharmacists and other members of specialist circles (persons authorised to prescribe, dispense or use) is necessary.

- 8.1 It is not permitted to grant, offer or promise a premium, financial or non-financial benefits to members of specialised circles for prescribing, dispensing or using a medicinal product or recommending a medicinal product to a patient.
- 8.2 Cooperation with physicians
- 8.2.1 In the cooperation with physicians, the generally recognized principles of the medical profession and the principles of the representation of interests of the pharmaceutical industry which go beyond these shall be observed.
- 8.2.2 The company is also responsible for the cooperation with physicians when it commissions others (e.g. advertising agencies – especially event marketing, market research companies or other service-providing companies) to organise or implement events as defined in Article 7.
- 8.2.3 Any service rendered by a physician for a pharmaceutical company of any kind (e.g. lectures, consulting, clinical trials, non-interventional studies) must be based on a written contract clearly indicating the service to be provided and the consideration received.
- 8.2.4 Such contractual service to be provided by a physician must be a scientific or technical activity performed for a company, this also includes educational purposes (prohibition of “sham contracts”).
- 8.2.5 Non-interventional studies as well as all other studies or data surveys may not be misused for the purpose of influencing therapy or procurement decisions or for mere advertising purposes.
- 8.2.6 Considerations may only consist of money and must be proportionate to the service provided. Among other options, the fee schedule for physicians can be used to assess the proportionality of a consideration. Appropriate hourly fees may also be agreed to compensate for the time spent in providing the service.

8.2.7 A physician or a third party shall not be granted, offered or promised any remuneration or benefit in kind to ensure that the physician agrees to receive a medical sales representative or accept information from members of other companies.

8.2.8 Visits to physicians and hospitals should not seem importunate with regard to frequency and the manner in which they are conducted. Employees who work as medical sales representatives must be obliged by their companies to observe the standard practices in the trade.

### 8.3 Non-interventional studies

8.3.1 Non-interventional studies are systematic studies of medicinal products with patients in accordance with the definition in sec. 1a (3) AMG which serve to obtain knowledge of the application of medicinal products and their efficacy and tolerance in practice.

8.3.2 A non-interventional study must be set up, verified and authorised under the supervision of a medical department of the pharmaceutical company or, if not available, under the supervision of an appropriately medically qualified person.

8.3.3 For the required documentation in the course of the non-interventional study, a financial consideration that meets the local standard and appears appropriate for the service provided may be paid. Among other options, the fee schedule for physicians can be used to assess the appropriateness of a consideration. In any case, the payment of a consideration for the services provided in the course of a non-interventional study may not represent an incentive for the prescription of a medicinal product.

### 8.4 Medical samples

The whole purpose of dispensing medical samples is to familiarise the physician and patient with the use and efficacy of the medicinal product and thereby improve treatment compliance.

8.4.1 In accordance to § 58 MPA pharmaceutical companies are permitted to provide medical samples to physicians, dentists, veterinary surgeons and denturists.

8.4.2 Pharmaceutical companies must have an adequate system for the control and documentation of the samples supplied. Appropriate records must be kept for all medical samples supplied. Medical samples may be supplied only free of charge and in a package that is no larger than the smallest presentation on the market with a clearly legible and irremovable notice attached with the wording 'Unverkäufliches Ärztemuster' (free medical sample - not for sale) as shown in the following table:

#### 8.4.3 Free medical samples may be supplied to recipients:

1. within a period of one year after initial distribution of the proprietary medicinal product within the scope of § 57 MPA in a quantity sufficient to evaluate the treatment success of a maximum of 10 patients, but no more than a total of 30 medical samples of one proprietary medicinal product per recipient, and
2. after the period stated in item 1 in the amount of a max. of 2 samples per request; per recipient, however, no more than five samples of a medicinal product per year.

#### 8.4.4 No medical samples containing psychotropic or narcotic substances may be supplied.

### 8.5 Hospitality

8.5.1 Hospitality is only admissible in the course of events and business dinners for the purpose of an information exchange with members of specialist circles and only to a reasonable degree, not lavish, and to the extent that is considered socially appropriate. The occasion for extending hospitality is to be documented. Granting hospitality to accompanying persons the members of specialist circles is not permitted.

### 8.6 Give-aways

8.6.1 The provisions set forth by Article 8.1 and Article 9 (gifts) do not prevent the provisions of give-aways by pharmaceutical companies, provided they have only a small value commensurate with the occasion they are used for and have causal and direct connection to the addressee's customary activity and serve the activity's purpose.

8.6.2 Give-aways may not contain any further reference or advertising messages than the company name, company logo or the company mark and/or the name of the medicinal product or the product logo of the medicinal product or the designation of the active agent it contains.

8.7 According to Article 14, the board of Pharmig is authorised to adopt a CoC ordinance for Articles 8.3 through 8.6 concerning the type, scope and appropriateness of the non-interventional studies and their documentation, the supply of medical samples and its documentation, hospitality and its documentation as well as give-aways.

## ARTICLE 8a

### COOPERATION WITH PATIENTS' ORGANISATIONS

Patients' organisations are non-profit organisations which solely represent the interests of patients and/or their families and exist or were founded out of their interests.

Cooperation between patients' organisations and pharmaceutical companies is based on common interests and has to take place in an ethical and transparent way.

The self-determination of patients' organisations and hence their independence shall apply as a principle of the cooperation.

Support is deemed to be any direct and/or indirect financial or non-financial contribution to patients' organisations. The following clauses shall not apply where the support in an individual case is of small value.

8a.1 Any support of patients' organisations shall serve solely the interests of the patients and/or their families.

8a.2 Any support of patients' organisations may only be provided on the basis of a written agreement. This agreement shall in any event contain information about the nature and scope as well as a description of the support involved and the consent of the patients' organisation to disclosure by the pharmaceutical company in accordance with Article 8a.4.1.

8a.3 Pharmaceutical companies must not influence the editorial work of the publications of patients' organisations supported by them without a justifiable factual reason (such as a correction of inaccuracies of content or correction from scientific aspects).

8a.4 Transparency

8a.4.1 Pharmaceutical companies shall detail on their publicly accessible homepage on the internet all the patients' organisations they support. This publication shall contain information about the nature and scope as well as a description of the support involved and shall be updated at least once a year (not later than 31.3. for the preceding calendar year).

8a.4.2 Pharmaceutical companies shall ensure contractually in the written agreement in accordance with 8a.2 that patients' organisations disclose to the public the relevant support provided by pharmaceutical companies transparently at all times and clearly from the outset.

8a.5 The exclusive support of patients' organisations and/or their programmes must not be required by pharmaceutical companies and/or granted by patients' organisations.

## 8a.6 Events/Patients' organisations

8a.6.1 Events are symposia, congresses, workshops, lectures and the like, also small-scale events/meetings between patients' organisations, their members, patients and/or their families as well as other invited participants, which are vehicles for information delivery, exchange of information, the dissemination of knowledge and experience concerning medicinal products and therapies and/or a means of training and continuing education.

8a.6.2 The assumption of costs for members of patients' organisations, patients and/or their families as well as other invited participants in the course of these events shall be restricted to travel costs, room and board as well as the original admission fee and shall be appropriate.

Activities which have no factual and/or technical connection with the actual aim and purpose of the event must not be supported or organised by the pharmaceutical company.

Provided the participants are members of the specialist circles, the provisions of Article 7 shall be observed.

8a.6.3 The organisation, implementation and/or support as well as the assumption of costs for members of patients' organisations, patients and/or their families as well as other invited participants at events taking place outside the country in which the pharmaceutical company is based are only admissible provided

- i) the majority of the participants come from a different country from that in which the member company is based, or
- ii) necessary resources or specialised knowledge are available at the event venue and, in view of this, there are appropriate logistical reasons for choosing a venue in a different country.

8a.6.4 For events organised, implemented and/or supported by a pharmaceutical company or on the company's instruction, the provisions of Articles 7.3, 7.4, 7.6, 7.7 and 7.8 shall additionally apply.

8a.7 According to Article 14, the board of Pharmig is authorised to adopt a CoC ordinance for Articles 8a (concerning the small value of the support), 8a.2 (concerning the type and scope of the relevant support) and 8a.6.2 (concerning the appropriateness of events and their documentation).

## ARTICLE 9

## GIFTS

- 9.1 In their business, pharmaceutical companies and their employees shall not request or accept a promise for or accept any gift, whether in money or in kind.
- 9.2 In their business, pharmaceutical companies and their employees shall not influence the buying, selling, prescription or distribution behaviour by granting, offering or promising any gifts, whether in money or in kind.

## ARTICLE 10

## RAFFLES

- 10.1 Pharmaceutical companies are prohibited from advertising through raffles in which the prize is exclusively subject to a random draw.
- 10.2 Prize competitions, in which participation is subject to scientific and technical performance and in which the prize awarded to the winner is a give-away as defined in Article 8.6, are permitted. The provision of medicinal products in the course of prize competitions is not permitted.
- 10.3 According to Article 14, the board of Pharmig is authorised to adopt a CoC ordinance for Article 10.2 concerning the type, scope and appropriateness of the prizes awarded to the winner.

## ARTICLE 11

## COMPANY EMPLOYEES

- 11.1 The pharmaceutical companies must ensure and document that all employees and all persons active in their name and under their commission are adequately qualified. In addition, persons in qualified positions must be appropriately informed about the general legal conditions, the internal conduct guidelines and the Pharmig Code of Conduct in order to provide accurate and complete information on the products.
- 11.2 The pharmaceutical companies must warrant that medical sales representatives fulfil the requirements of §§ 72–74 MPA and possess the necessary specialist knowledge about the medicinal products they discuss in order to be able to inform the physicians, pharmacists and persons according to § 2 (1) and § 59 (3 and 4) MPA without limitation. Medical sales representatives must perform their duties

responsibly, in accordance with the requirements of the Pharmig Code of Conduct and ethical principles.

- 11.3 Persons who design information and advertising material must be completely familiar with the requirements of the Pharmig Code of Conduct. Information and advertising documents must be approved by a physician, pharmacist or the person designated responsible for information before they are published.

## CLINICAL TRIALS

- 12.1 Clinical trials must be conducted in accordance with the currently applicable provisions (MPA, GCP, data protection, etc.). Their only goal is the collection of new scientific findings and the scientific confirmation of available knowledge.
- 12.2 Information provided about a clinical trial and its results must satisfy the scientific requirements of the clinical trial and provide necessary protection of personal data.

## VIOLATION OF THE MPA

A violation of the regulations in part V (advertising restrictions) of the Medicinal Products Act (MPA) also represents a violation of this Code of Conduct.

## COC ORDINANCE

The board of Pharmig is authorised to adopt more detailed provisions (CoC ordinance) for the individual CoC articles. The CoC ordinance must refer to the relevant articles indicated in the CoC and be covered by the respective articles.

## ARTICLE 12

## ARTICLE 13

## ARTICLE 14

# 2

## CODE OF PROCEDURE

### ARTICLE 1

#### TASKS AND RESPONSIBILITIES OF THE CoC COMMITTEES OF EXPERTS 1<sup>ST</sup> AND 2<sup>ND</sup> INSTANCE

- 1.1 The CoC Committees of Experts 1st and 2nd Instance are in charge of negotiating and deciding in the case of disputes relating to the violation of the Pharmig Code of Conduct vis-à-vis Pharmig members. Non-members of Pharmig are subject to the code of procedure only if they have concluded a written agreement with Pharmig regarding the application of the code of procedure of the CoC Committees of Experts of the 1st and 2nd Instance (hereinafter referred to as "CoC Agreement") and committed to complying with the Pharmig Code of Conduct. The above companies which have concluded a CoC Agreement with Pharmig shall hereinafter be referred to as "Pharmig Members".
- 1.2 The CoC Committees of Experts of the 1st and 2nd Instance shall act in accordance with the Code of Procedure and shall conduct procedures in the case of violations of the Pharmig Code of Conduct by Pharmig Members subject to the Code of Procedure.
- 1.3 The CoC Committees of Experts of the 1st and 2nd Instance shall be responsible for all admissible complaints.
- 1.4 The CoC Committee of Experts of the 2nd Instance shall rule on all objections made to decisions made by the CoC Committee of Experts of the 1st Instance as well as on all decisions regarding request for the transfer of jurisdiction due to the inaction of the CoC Committee of Experts of the 1st Instance and, if considered legitimate, the CoC Committee of Experts of the 2nd Instance shall rule on admissible complaints.

### ARTICLE 2

#### LANGUAGE OF CORRESPONDENCE / LANGUAGE OF PROCEEDINGS

- 2.1 Correspondence with the CoC Committee of Experts of the 1st and 2nd Instance, the Secretary General and the Pharmig Office shall be

in German only. The chairman of the responsible decision panel is entitled to request translation of all documents presented which are not written in German (also court-certified translation).

- 2.2 Oral and written agreements shall be made in German.

## VENUE FOR PROCEEDINGS

- 3.1 Any proceedings of the CoC Committee of Experts of the 1st and 2nd Instance shall be conducted at the registered office of Pharmig in Vienna. Proceedings may also take place outside of the registered office of Pharmig if this is expedient and the chairman of the competent decision panel decides this.

## RIGHTS OF DEFENCE

- 4.1 Proceedings are based on the principle of equal treatment with observance of the rights of defence.

## COMPLAINANT

- 5.1 Anybody is entitled to file a complaint against a Pharmig Member. If the complaint is made by a Pharmig Member, the complaint must be signed by the general management of the complainant. If a complaint is brought against a Pharmig Member by a non-member of Pharmig, the non-member must conclude a written CoC Agreement with Pharmig on the relevant proceedings before the complaint may be brought before the competent CoC Committee of Experts. To this end, the Pharmig Office transfers the relevant CoC Agreement to the complainant for signing and return, while setting a deadline for the return of the document. If the document is not returned on time, the proceedings shall not commence and the complaint will be deemed withdrawn.
- 5.2 Complaints against non-members of Pharmig who have not concluded a CoC Agreement shall be forwarded to the Association of the Austrian Chemical Industry, a division of the Austrian Federal Economic Chamber by Pharmig.

## ARTICLE 3

## ARTICLE 4

## ARTICLE 5

- 5.3 Complaints shall be made in writing to the Secretary General of Pharmig and with the allegation that a Pharmig Member has violated the provisions of the Pharmig Code of Conduct.
- 5.4 Complaints regarding alleged violations of Articles 7 (Events) and 9 (Gifts) of the Pharmig Code of Conduct may also be made anonymously, as long as the regulations on the complaints procedure are observed.
- 5.5 The Secretary General shall forward anonymous complaints to the Board of Directors of Pharmig. The latter shall make a final decision by simple majority of the votes cast on whether or not proceedings will be initiated, if there is reasonable suspicion. Depending on the decision on the initiation of the proceedings, the complaint shall be forwarded to the Secretary General for further processing.

## ARTICLE 6

### OBJECT AND ADMISSIBILITY OF THE COMPLAINT

- 6.1 Only alleged violations of the provisions of the Pharmig Code of Conduct may be the object of a complaint.
- 6.2 The complaint is inadmissible if at the time of filing the complaint:
  - a) the company in question has already made a cease-and-desist declaration,
  - b) the complainant has already obtained a court ruling on the object of the complaint,
  - c) the object of the complaint is pending court proceedings which have not been completed,
  - d) the facts of the case lie more than six months in the past and no longer persist.
- 6.3 However, an earlier declaration to cease and desist made to third parties does not discharge the company concerned of its obligation to make a declaration to cease and desist in accordance with these rules of procedure.

## ARTICLE 7

### CONTENT AND FORM OF THE COMPLAINT

- 7.1 Seven copies of the written complaint and its enclosures as well as all further written opinions in the proceedings shall be sent to the Secretary General of Pharmig and addressed to Pharmig, the Association of the Austrian Pharmaceutical Society. The proceedings shall be pending as of the date of receipt of the complaint.

- 7.2 The complaint shall contain precise information on the facts of the matter of the complaint, which article(s) of the Pharmig Code of Conduct have been violated by the facts of the matter of the complaint and the reason for which the complainant makes the complaint or feels he has been harmed in his interests.
- 7.3 If the complaint does not satisfy Article 7.1 and Article 7.2, or if the copies or enclosures are missing, the Secretary General shall ask the complainant to remedy, complete, or further substantiate his complaint, and set a deadline. If any defects are not remedied before passing of the deadline, the complaint shall be deemed withdrawn.

## **RIGHTS AND LIABILITIES OF THE COMPLAINANT**

## **ARTICLE 8**

- 8.1 The complainant has the following obligations to inform, verify and collaborate:
- a) the complainant shall be notified of the result of the proceedings by being sent the decision and a statement of the main grounds for the decision.
  - b) the complainant undertakes to collaborate in the clarification of the facts and in the proceedings if asked to do so by the relevant competent decision panel as per Article 10.2 and Article 10.3.
  - c) the complainant shall have the right,
    - i) to appeal against the decisions of the competent decision panel of the CoC Committee of Experts of the 1st Instance if his complaint is rejected as unfounded;
    - ii) to have recourse to the CoC Committee of Experts of the 2nd Instance if the competent decision panel of the CoC Committee of Experts of the 1st Instance fails to act, if the competent decision panel of the CoC Committee of Experts of the 1st Instance has not reached a decision within 6 months of receipt of the complaint by the Secretary General of Pharmig, and if within this period of time the company concerned has not made a declaration to cease and desist from the violation of the Pharmig Code of Conduct that forms the object of the complaint.

## **COC COMMITTEE OF EXPERTS OF THE 1ST INSTANCE**

## **ARTICLE 9**

- 9.1 The competent decision panel of the CoC Committee of Experts of the 1st Instance shall investigate the received complaint and prepare the proceedings by engaging in fact-finding activities; in the course of

these fact-finding activities, the competent decision panel of the CoC Committee of Experts of the 1st Instance may examine the facts which have come to its attention in any direction.

## ARTICLE 10

### SIMPLIFIED PROCEEDINGS BEFORE THE COC COMMITTEE OF EXPERTS OF THE 1ST INSTANCE

- 10.1 The Secretary General shall forward the admissible complaint and enclosures to the company concerned for the purpose of preparing its defence and set a deadline. The complaint and the enclosures shall also be sent to the members of the competent decision panel of the CoC Committee of Experts of the 1st Instance.
- 10.2 For the purpose of fact-finding, the competent decision panel of the CoC Committee of Experts of the 1st Instance may:
  - a) request further statements, while setting deadlines,
  - b) request further documents, while setting deadlines,
  - c) question witnesses or experts.
- 10.3 If the company concerned or the complainant fail to act on a request for collaboration by the competent decision panel of the CoC Committee of Experts of the 1st Instance in a timely fashion, the complaint shall be evaluated in accordance with the available documents and on the basis of the submitted evidence.
- 10.4 If the competent decision panel of the CoC Committee of Experts of the 1st Instance decides that the complaint is justified, it shall give warning to the company concerned and call upon the company to make a written declaration to cease and desist within a period of two weeks. The obligation to make a declaration to cease and desist may, if the violation of the Pharmig Code of Conduct is of a serious nature, be combined with an obligation to pay a penalty in accordance with Article 15. In this case, the cease-and-desist declaration shall also contain the agreement of the company concerned with the fixed penalty and the obligation of its immediate payment.
- 10.5 The timely written declaration to cease and desist of the company concerned shall conclude the simplified proceedings.
- 10.6 If the written declaration to cease and desist is not made on time or is incomplete, the proceedings shall be extended, unless the competent decision panel of the CoC Committee of Experts of the 1st Instance accepts as sufficient a declaration to cease and desist that deviates from the demanded declaration to cease and desist. A declaration to cease and desist that is not made on time or is incomplete shall not conclude the proceedings, but will be taken into account in the formulation of any additional sanctions.

## CONTINUATION OF THE PROCEEDINGS BEFORE THE CoC COMMITTEE OF EXPERTS OF THE 1ST INSTANCE

## ARTICLE 11

- 11.1 If a complaint is not settled or not fully settled in the simplified procedure, the procedure shall be continued before the CoC Committee of Experts of the 1st Instance. The chairman of the competent decision panel of the CoC Committee of Experts of the 1st Instance shall order the written procedure or set a date for the oral proceedings.
- 11.2 If oral proceedings are ordered, they shall take place within eight weeks of passing of the two-week deadline for making a declaration to cease and desist. For material reasons, this deadline may be extended by the chairman of the competent decision panel.
- 11.3 In principle, the decision panel of the CoC Committee of Experts of the 1st Instance meets at the registered office of Pharmig in Vienna.
- 11.4 The chairman shall, if necessary, order further measures to guide the proceedings and prepare sessions (obtaining further statements, etc.). Article 10.2 and Article 10.3 shall apply correspondingly.
- 11.5 The general management of the company concerned, witnesses if any, experts and other respondents shall be summoned to the oral proceedings. The oral proceedings shall not be open to the public.
- 11.6 The summons shall contain at least the following information:
  - a) object of the proceedings,
  - b) time and date of the oral proceedings,
  - c) the members of the relevant competent decision panel,
  - d) a notice that members of the decision panels may be rejected on the grounds of partiality,
  - e) a notice that the proceedings may take place and a decision may be reached even if the company concerned, its representative or other summoned persons are absent without excuse,
  - f) a notice to the company concerned that it may seek representation by a suitably empowered employee and/or a solicitor at any stage of the proceedings.
- 11.7 Insofar as the proceedings are written, the chairman of the relevant decision panel shall make the necessary procedural arrangements.

## ORAL PROCEEDINGS

## ARTICLE 12

- 12.1 The chairman shall open, preside over, and conclude the oral proceedings. He shall grant the right to speak and may direct

the speaker to discontinue his speech if he does not follow his instructions; he questions the persons who shall answer for the purpose of giving evidence and explains the other pieces of evidence. Under special circumstances, witnesses may also be questioned in a written procedure or prior to the proceedings by the chairman or his appointed representative. The result of such questioning shall be recited by the chairman during the oral proceedings. Questioning by telephone during the proceedings is admissible.

- 12.2 If the general management, representative of the company concerned or other summoned persons remain absent from the oral proceedings without excuse despite a proper summons, the competent decision panel shall decide in accordance with the existing documentation and on the basis of the submitted evidence.
- 12.3 Minutes of the oral proceedings shall be taken, recording the main contents of the proceedings. Any motions by those involved in the proceedings and decisions by the competent decision panel shall be recorded word for word as much as possible, or enclosed with the minutes.
- 12.4 The minutes shall be signed by the chairman and sent to the company concerned.

## ARTICLE 13

### REPRESENTATION OF THE COMPANY CONCERNED

- 13.1 The company concerned may seek representation by a suitably empowered employee and/or a solicitor at any stage of the proceedings.
- 13.2 The company shall bear the costs of its own representation or counsel out of its own resources, irrespective of the final decision reached in the proceedings.
- 13.3 Those empowered by the company concerned shall present their power of attorney if requested to do so by the competent decision panel.

## ARTICLE 14

### DECISION OF THE COC COMMITTEE OF EXPERTS OF THE 1ST INSTANCE

- 14.1 If a complaint is not settled or not fully settled in the simplified proceedings, the relevant competent decision panel of the CoC Committee of Experts of the 1st Instance shall decide.

- 14.2 The decision of the decision panel of the CoC Committee of Experts of the 1st Instance shall be reached by simple majority of the votes cast. If the event of a parity of votes, the complaint shall be rejected as unfounded.
- 14.3 Decisions are made in written form. They shall be explained where the complainant and the company concerned have not waived the explanation either in the written proceedings or in the oral proceedings.
- 14.4 Written decisions shall be signed by the members of the relevant competent decision panel of the CoC Committee of Experts of the 1st Instance. Copies of written decisions shall be signed by the chairman of the competent decision panel. The signature of the majority of the members of the relevant competent decision panel – including the chairman – shall suffice, if it is noted in the decision that a member of the competent decision panel refuses his signature or that this member is impeded from signing by an obstacle that cannot be surmounted suitably quickly. If the decision is reached by a majority vote, this must be noted in the decision if requested by the outvoted member of the competent decision panel of the CoC Committee of Experts of the 1st Instance.
- 14.5 The seal of the competent decision panel shall be affixed on all copies of the decision. This is to confirm that the document is a decision by the competent decision panel of Pharmig, and that it has been decreed and signed by the members of the relevant competent decision panel appointed in accordance with these rules of procedure.
- 14.6 The decision shall, in addition, contain the following information:
- a) the exact name of the company concerned participating in the proceedings,
  - b) date and place,
  - c) object, type, extent and time of the obligation to cease and desist and/or other sanctions.
- 14.7 The Pharmig Office shall send the decision to the company concerned. The decision becomes effective for the company as of receipt of the copy. One copy of the decision shall be kept on file in the Pharmig Office.
- 14.8 A decision that establishes a violation against the Pharmig Code of Conduct has taken place must be accompanied by an admonition and the obligation of the company concerned to desist from the behaviour that formed the object of the complaint.
- 14.9 The complainant shall be notified in writing of the result of the proceedings by being sent the decision and a statement of the main grounds for the decision. Business secrets and/or company secrets,

if any, shall be stricken; the names of employees of the company concerned or other involved persons or companies, organisations, etc., shall also be anonymised.

- 14.10 Every decision by the CoC Committee of Experts of the 1st Instance shall include instructions about legal remedies. The instructions about legal remedies shall include the remedy of appeal, the period within which an appeal can be sought and the instance to be appealed to.

## ARTICLE 15

### SANCTIONS OF THE COC COMMITTEE OF EXPERTS OF THE 1ST INSTANCE

- 15.1 If such is deemed necessary and appropriate by the competent decision panel of the CoC Committee of Experts of the 1st Instance, it is entitled to impose the following sanctions in addition to the admonition and the cease-and-desist order, if it is established that the Pharmig Code of Conduct has been violated
- a) in the case of a serious violation, a penalty of not less than EUR 5,000.00 up to a maximum of EUR 100,000.00. A violation is deemed serious if the company concerned repeats the violation within 24 months or sets it against the Pharmig Code of Conduct for the same reason, and these violations have each been established by final decision in accordance with these rules of procedure. A violation of the provisions of Article 7 or Article 9 of the Pharmig Code of Conduct always constitutes a serious violation, even if it has been committed for the first time.
  - b) the penalty range is increased to EUR 200,000.00 if the company concerned has committed 3 violations of Article 7 or Article 9 of the Pharmig Code of Conduct within 24 months and these violations have each been established by a non-appealable decision in accordance with these rules of procedure.
  - c) the violation may be publicly announced and the company concerned named in a Pharmig publication;
  - d) the parent company of the company concerned will be notified accordingly.
  - e) the Secretary General of EFPIA will be notified accordingly.
  - f) exclusion from Pharmig or termination of the CoC Agreement, whereas these sanctions do not release the excluded or resigning company or the company affected by the termination of the CoC Agreement from existing payment obligations or other imposed sanctions.

- 15.2 The imposed penalties become payable as of non-appealability of the decision within the meaning of these rules of procedure. The penalties shall be paid to Pharmig and must be used by Pharmig for charitable purposes within 3 months of reception.
- 15.3 A combination of the above sanctions is possible.
- 15.4 When elaborating the sanctions, their ramifications for the company affected by the sanctions shall be taken into account. It shall also be taken into account whether and to what extent the company concerned has put in place organisational measures to remedy the violation of the Pharmig Code of Conduct, or whether the object of the complaint is merely a one-time mistake. In addition, it shall be taken into account which internal sanctions and organisational measures the company concerned has taken and implemented or promised to implement as a reaction to the object of the complaint in general and in each specific case.

## APPEAL

## ARTICLE 16

- 16.1 The company concerned may appeal against a decision within a period of two weeks after notification of the decision. The company concerned may limit its appeal to the sanctions imposed or the scope of the sanctions imposed.
- 16.2 The complainant may appeal against decisions within a period of two weeks, insofar as his complaint is rejected as unfounded. An appeal by the complainant for sanctions not imposed or the scope of the sanctions imposed is not admissible.
- 16.3 The appeal must be substantiated and received in writing by the chairman of the competent decision panel of the CoC Committee of Experts of the 1st Instance within two weeks of notification of the decision. The chairman of the competent decision panel of the VHC Committee of Experts of the 1st Instance shall forward the appeal without delay to the competent decision panel of the VHC Committee of Experts of the 2nd Instance.
- 16.4 If no appeal is lodged within two weeks of reception of the notification of the decision, the decision of the decision panel of the CoC Committee of Experts of the 1st Instance shall become non-appealable as per these rules of procedure. Restitution is not admissible.
- 16.5 A separate appeal by the company concerned or by the complainant against procedural measures and decisions is not admissible. The competent decision panel of the CoC Committee of Experts of the 2nd Instance shall only review the decision insofar as it has been appealed against.

- 16.6 In the event of an appeal, the review of the decision by the competent decision panel of the CoC Committee of Experts of the 2nd Instance shall require a prior payment of an advance on costs equal to the cost of the proceedings in accordance with Article 30.

## ARTICLE 17

### COC COMMITTEE OF EXPERTS OF THE 2ND INSTANCE

- 17.1 The competent decision panel of the CoC Committee of Experts of the 2nd Instance shall investigate the received appeals and make preparations for the proceedings.
- 17.2 If an appeal is not rejected on the grounds that it is inadmissible or late, the proceedings shall continue before the CoC Committee of Experts of the 2nd Instance. The chairman of the competent decision panel of the CoC Committee of Experts of the 2nd Instance shall order the written procedure or set a date for the oral proceedings.
- 17.3 If oral proceedings are ordered, they shall take place within eight weeks of the date on which the appeal was lodged. For material reasons, this deadline may be extended by the chairman of the competent decision panel.
- 17.4 In principle, the decision panel of the CoC Committee of Experts of the 2nd Instance meets at the registered office of Pharmig in Vienna.
- 17.5 The chairman shall, if necessary, order further measures to guide the proceedings and prepare meetings (obtaining further statements, etc.). Article 10.2 and Article 10.3 shall apply correspondingly.
- 17.6 The chairman of the competent decision panel of the CoC Committee of Experts of the 1st Instance shall be summoned as a respondent to the oral appeal proceedings of the competent decision panel of the CoC Committee of Experts of the 2nd Instance. The oral proceedings shall not be open to the public.
- 17.7 Insofar as the proceedings are conducted in writing, the chairman of the relevant decision panel shall make the necessary procedural arrangements.
- 17.8 In all other respects, the provisions applicable to procedures before the CoC Committee of Experts of the 1st Instance shall apply correspondingly.
- 17.9 A request for the transfer of jurisdiction shall be made to the competent decision panel of the CoC Committee of Experts of the 1st Instance within two weeks of expiry of the 6-month period. The latter shall forward the request for the transfer of jurisdiction without delay to the competent decision panel of the CoC Committee of Experts of the 2nd Instance for decision.

## **DECISION OF THE CoC COMMITTEE OF EXPERTS OF THE 2ND INSTANCE**

### **ARTICLE 18**

- 18.1 The CoC Committee of Experts of the 2nd Instance adjudicates the case on the basis of an appeal. It shall, if needed, supplement the proceedings of the CoC Committee of Experts of the 1st Instance. The decision may also merely be changed with respect to the sanctions imposed. The decisions of the decision panels of the CoC Committee of Experts of the 2nd Instance shall be reached by simple majority of the votes cast. If the event of a parity of votes, the complaint shall be rejected as unfounded.
- 18.2 The competent decision panel of the CoC Committee of Experts of the 2nd Instance shall decide on a request for the transfer of jurisdiction by analogous application of the regulations governing the decision of the CoC Committee of Experts of the 1st Instance.
- 18.3 Decisions by the CoC Committee of Experts of the 2nd Instance shall be executed and notified in accordance with Articles 14.3 through 14.9.

## **NON-APPEALABILITY OF THE DECISION OF THE CoC COMMITTEE OF EXPERTS OF THE 2ND INSTANCE**

### **ARTICLE 19**

- 19.1 The decisions of the CoC Committee of Experts of the 2nd Instance shall be non-appealable within the meaning of these rules of procedure and shall include a notice to this effect.

## **PARTIALITY**

### **ARTICLE 20**

- 20.1 Members of the relevant competent decision panel of a CoC Committee of Experts may only be rejected in the presence of circumstances that give rise to justified doubt as to their impartiality or independence. They shall declare themselves partial if they are in the employ of the company concerned or of the complainant, or if they themselves were or are involved in the matter of the complaint.
- 20.2 If the complainant or the company concerned rejects a member of the relevant competent decision panel of a CoC Committee of Experts on the grounds of partiality, they shall immediately inform the Pharmig Office thereof, giving notice as to the reason for partiality. The latter shall forward the request of rejection to the relevant decision panel.

The member of the decision panel concerned shall make a statement on the rejection within one week of reception of the request of rejection and submit the statement to the Pharmig Office.

- 20.3 If a member of the relevant competent decision panel of a CoC Committee of Experts who has been declared partial does not resign, the Board of Directors of Pharmig shall decide about the rejection on the basis of the information in the request of rejection, the enclosed evidence and the statement of the rejected member.
- 20.4 A rejected member of the relevant competent decision panel of a CoC Committee of Experts may continue participating in the proceedings until a decision is taken by the Board of Directors of Pharmig.

## ARTICLE 21

### DEADLINES, DELIVERIES AND NOTIFICATIONS

- 21.1 A deadline is met, if the document is sent off on the last day of the period in the manner provided for in Article 21.2.
- 21.2 Deliveries shall be deemed properly made if they have been made by recorded letter, courier service or fax to the last address communicated in writing, as the delivery address, to the competent decision panel by the addressee of the document, or if the document to be delivered has been handed over to the addressee. If documents are sent by fax, seven corresponding duplicates thereof shall be submitted in writing immediately thereafter.
- 21.3 As soon as one party has instated a representative, deliveries to the last known address of this representative are deemed made to the represented party.
- 21.4 Except as otherwise provided in these rules of procedure, the company concerned may be granted reinstatement in the status quo ante upon request if it was prevented from keeping to the deadline due to no fault of its own by an unforeseeable and unavoidable event. The request must be made in writing to the chairman of the relevant competent decision panel within one week of the removal of the impediment. The missed procedural step shall be carried out at the time of making the request for reinstatement in the status quo ante.

## ARTICLE 22

### PHARMIG OFFICE

- 22.1 The Pharmig Office shall act as the Office of the CoC Committees of Experts of the 1st and 2nd Instance. The Pharmig Office shall administrate and manage the files of the CoC Committees of Experts of

the 1st and 2nd Instance. The Pharmig Office shall be obliged to keep secrecy of all information obtained through the exercise of its duties.

## **SECRECY**

- 23.1 All those involved in the proceedings, the members of the decision panels, the managing board, the Board of Directors and all employees of Pharmig are obliged to keep secrecy about their activities, the information gained through these activities and about all processes that by their very nature require secrecy or are expressly declared as being subject to secrecy.

## **ARTICLE 23**

## **MEMBERS OF THE CoC COMMITTEE OF EXPERTS OF THE 1ST INSTANCE**

- 24.1 The members of the CoC Committee of Experts of the 1st Instance are elected according to §14 of the Pharmig statutes by the managing board of Pharmig by simple majority of the votes cast.
- 24.2 The CoC Committee of Experts of the 1st Instance consists of nine members who are entitled to vote. Eight of the members of the CoC Committee of Experts of the 1st Instance are representatives of the Pharmig members. The Secretary General of Pharmig is a permanent member with voting rights of the CoC Committee of Experts of the 1st Instance and at the same time the chairman of the decision panels of the Committee of Experts of the 1st Instance.
- 24.3 The CoC Committee of Experts of the 1st Instance shall make its decisions through decision panels. A decision panel is composed of the Secretary General of Pharmig and 4 other members of the CoC Committee of Experts of the 1st Instance.
- 24.4 The chairman of each decision panel of the CoC Committee of Experts of the 1st Instance shall inform Pharmig of all non-appealable decisions as per these rules of procedure.

## **ARTICLE 24**

## **MEMBERS OF THE CoC COMMITTEE OF EXPERTS OF THE 2ND INSTANCE**

- 25.1 The members of the CoC Committee of Experts of the 2nd Instance

## **ARTICLE 25**

are elected according to §14 of the Pharmig statutes by the managing board of Pharmig by simple majority of the votes cast.

- 25.2 The CoC Committee of Experts of the 2nd Instance consists of 10 members who are entitled to vote. The CoC Committee of Experts of the 2nd Instance shall be composed of six representatives of Pharmig members – two of which are members of the Board of Directors of Pharmig –, two emeritus judges and two practising physicians.
- 25.3 The CoC Committee of Experts of the 2nd Instance shall make its decisions through decision panels. A decision panel is composed of 5 members of the CoC Committee of Experts of the 2nd Instance. Each decision panel of the CoC Committee of Experts of the 2nd Instance shall be composed of three representatives of Pharmig members – of which one is a member of the Board of Directors of Pharmig –, one emeritus judge and one practising physician. The emeritus judges each take the chair of the decision panel and have voting rights.
- 25.4 The chairman of the decision panel of the CoC Committee of Experts of the 2nd Instance may not work for a member of Pharmig or any other pharmaceutical company (neutrality).
- 25.5 The chairman of the relevant decision panel of the CoC Committee of Experts of the 2nd Instance shall inform Pharmig of all non-appealable decisions as per these rules of procedure.

## ARTICLE 26

### COMMON REGULATIONS FOR THE APPOINTMENT OF MEMBERS TO THE COC COMMITTEES OF EXPERTS OF THE 1ST AND 2ND INSTANCE

- 26.1 The instatement of the members of the CoC Committees of Experts of the 1st and 2nd Instance shall be valid throughout the duration of the instatement of the managing board of Pharmig. Re-elections are admissible.
- 26.2 The managing board of Pharmig shall formulate the Articles of Association and a schedule of responsibilities, which shall govern the competence of the various decision panels of the CoC Committees of Experts of the 1st and 2nd Instance and the responsibilities of the representatives of each decision panel of the CoC Committees of Experts of the 1st and 2nd Instance in the event of members' partiality or inability to attend. The work rules and the schedule of responsibilities are each decided by the managing board of Pharmig by single majority of the votes cast at the same time as the members of the decision panels are instated.
- 26.3 If members of the decision panels of the CoC Committees of Experts of the 1st or 2nd Instance are partial or prevented from attending

sessions, the managing board of Pharmig may instate one or more substitutes for each member. The substitutes must be instated from among the members of the decision panel of the same instance who are not partial or prevented from attending.

- 26.4 The members of the CoC Committees of Experts of the 1st and 2nd Instance shall be independent and not bound by instructions in their activities.
- 26.5 Members of the CoC Committee of Experts of the 1st Instance may not, at the same time, act as members of the CoC Committee of Experts of the 2nd Instance, and vice versa.
- 26.6 The chairmen of the CoC Committees of Experts of the 1st and 2nd Instance are authorised to assign tasks to technically qualified persons in the course of their activity in the relevant proceedings.

## **COSTS OF THE COC COMMITTEES OF EXPERTS OF THE 1ST AND 2ND INSTANCE**

- 27.1 Pharmig shall provide the administration of the CoC Committees of Experts of the 1st and 2nd Instance and bear their financial expenses, inasmuch as they are not covered by the costs to be borne by the parties to the proceedings.

## **COST OF THE SIMPLIFIED PROCEEDINGS BEFORE THE COC COMMITTEE OF EXPERTS OF THE 1ST INSTANCE**

- 28.1 If the company concerned makes a cease-and-desist declaration before the competent decision panel of the CoC Committee of Experts of the 1st Instance under the simplified procedure, the company concerned shall pay Pharmig EUR 3,000.00 for the cost of the proceedings.

## **COST OF CONTINUATION OF THE PROCEEDINGS BEFORE THE COC COMMITTEE OF EXPERTS OF THE 1ST INSTANCE**

- 29.1 If the competent decision panel of the CoC Committee of Experts of the 1st Instance, in its decision during the continued proceedings, takes the view that the company concerned has violated the Pharmig Code of Conduct, the cost of the proceedings to be paid to Pharmig

## **ARTICLE 27**

## **ARTICLE 28**

## **ARTICLE 29**

shall be EUR 6,000.00. The cost for the continuation of proceedings of 1st Instance shall not be payable by the company concerned, if upon appeal by the company concerned the original decision is repealed by the competent decision panel of the CoC Committee of Experts of the 2nd Instance on the grounds of being unfounded.

## ARTICLE 30

### COSTS OF THE PROCEEDINGS BEFORE THE COC COMMITTEE OF EXPERTS OF THE 2ND INSTANCE

- 30.1 An advance on costs of EUR 10,000.00 must be paid by the appellant/complainant before the proceedings before the CoC Committee of Experts of the 2nd Instance may commence. This amount shall be paid to the Pharmig Office within 14 days of reception of the relevant payment request from the Pharmig Office. If this advance on costs is not credited to a Pharmig account before the deadline lapses, the proceedings before the CoC Committee of Experts of the 2nd Instance shall not be held.
- 30.2 In the event that the competent decision panel of the CoC Committee of Experts of the 2nd Instance makes the non-appealable decision, in accordance with these rules of procedure, that the company concerned has violated the Pharmig Code of Conduct, any advance on costs paid by the company concerned shall accrue to Pharmig. If, in the above case, the advance on costs has been paid by the complainant, the Pharmig Office shall refund the advance on costs to the complainant and send a payment request to the company concerned, payable within 14 days, for the reimbursement of costs.
- 30.3 If the competent decision panel of the CoC Committee of Experts of the 2nd Instance rejects an appeal by the company concerned or an appeal by the complainant against a decision of the competent decision panel of the CoC Committee of Experts of the 1st Instance, the advance on costs shall accrue to Pharmig. In all other events, in which no violation by the company concerned has been established in a non-appealable decision in accordance with these rules of procedure, the advance on costs paid by the company concerned shall be refunded to the same.
- 30.4 Article 30.1 shall not apply if proceedings before the CoC Committee of Experts of the 2nd Instance are opened on the basis of a request for the transfer of jurisdiction. In this event, the regulations on costs for proceedings before the CoC Committee of Experts of the 1st Instance shall apply correspondingly.

## NECESSARY EXPENSES

## ARTICLE 31

- 31.1 If the various CoC Committees of Experts establish in their non-appealable decisions in accordance with these rules of procedure that the company has violated the Pharmig Code of Conduct, the company concerned shall bear the costs of the proceedings as well as appropriate expenses for travel and accommodation of any witnesses, respondents or experts summoned. The same shall apply for a suitable remuneration of experts' work.

## DUE DATE OF COSTS AND NECESSARY EXPENSES / VALUE-ADDED TAX

## ARTICLE 32

- 32.1 The costs of the proceedings and necessary expenses shall be determined by the Pharmig Office and become payable, including any VAT charged on these costs, when the decision in accordance with these rules of procedure become non-appealable. This does not apply to the costs of the proceedings before the CoC Committee of Experts of the 2nd Instance, which are payable prior to the commencement of proceedings.

## PUBLICATION OF DECISIONS

## ARTICLE 33

- 33.1 The Secretary General may publish non-appealable decisions in accordance with these rules of procedure in anonymised form. The type of publication may be regulated in the Articles of Association.

## USE OF GENDER NOUNS

## ARTICLE 34

- 34.1 Inasmuch as these rules of procedure include references to persons in the masculine, they shall apply equally to women and men. If used to refer to specific persons, the gender-specific form of address shall be used.

**ARTICLE 35****OTHER REGULATIONS**

- 35.1 In proceedings for violation of the Pharmig Code of Conduct, members of Pharmig shall recognise the rules of procedure of the CoC Committees of Experts and the sanctions regulated therein. Pharmig Members undertake to comply with decisions of the CoC Committees of Experts, to pay any imposed penalties and to recognise these decisions as enforceable titles. Throughout the duration of such Pharmig proceedings, the members of Pharmig shall not, at the same time, bring the same matter before a court of law.
- 35.2 Any liability by Pharmig, its executive bodies and agents for decisions of the CoC Committees of Experts is excluded to the extent admissible by law. The above regulation does not apply to liability for intent.

**ARTICLE 36****COMING INTO FORCE / TRANSITIONAL PROVISIONS**

- 36.1 Pharmig Code of Conduct shall come into force on 01/07/2007. The amended rules of procedure shall apply to all proceedings of which the complaint has been received after 30/06/2007 and the facts of the case have arisen after this date.
- 36.2 Articles 7, 7.2, 7.9, 8.6.2, 8.7, 10.2, 10.3 and 14 of the Pharmig Code of Conduct and articles 5.2, 7.1, 9.1, 10.6, 11.2, 14.4, 17.3, 17.9 and 21.2 of the Code of Procedure of the CoC Committees of Experts of the 1st and 2nd Instance in the "Amended CoC 01/2008" version enter into force on 01/05/2008. The version of the Code of Procedure (Amended CoC 01/2008) applies to all proceedings of which the complaint has been received after 30/04/2008 and the facts of the case have arisen after this date.
- 36.3 Articles 1, 2, 5.5, 7.2, 7.3, 8, 8.1, 8.2.3, 8.2.5, 8.3, 8.4, 8.4.1, 8.7, 8a, 11.1 and 11.3 of the Pharmig Code of Conduct and Articles 8.1, 10.5, 11.1, 11.2, 11.6, 12.2, 14.1, 17.3, 17.9, 26.6, 28.1 and 29.1 of the Code of Procedure of the CoC Committees of Experts of the 1st and 2nd Instance in the "Amended CoC 01/2009" version come into force on 01/07/2009. The version of the Code of Procedure (Amended CoC 01/2009) applies to all proceedings of which the complaint has been received after 30/06/2009 and the facts of the case have arisen after this date.

**Flowchart**  
**Procedure of the CoC Committees of Experts of the 1st and 2nd Instance**



