CODE OF CONDUCT

PHARMIG CODE OF CONDUCT AND CODE OF PROCEDURE OF THE COC COMMITTEES OF EXPERTS OF THE 1ST AND 2ND INSTANCE

PHARMIG

Verband der pharmazeutischen Industrie Österreichs

CODE OF CONDUCT

PHARMIG CODE OF CONDUCT

AND

CODE OF PROCEDURE OF THE COC COMMITTEES OF EXPERTS OF THE 1ST AND 2ND INSTANCE

Coming into force on 01/07/2007
Last amendment at the General Assembly on 24/04/2015
coming into force on 01/07/2015

PHARMIG
Verband der pharmazeutischen Industrie Österreichs

IMPRINT

OWNER AND PUBLISHER

Pharmig – Association of the Austrian Pharmaceutical Industry

Garnisongasse 4/1/6, 1090 Vienna, Austria

Phone. +43/1/40 60 290

Fax +43/1/40 60 290-9

E-mail: office@pharmig.at

Web: www.pharmig.at

This edition can also be downloaded from our homepage.

In any case the German version prevails.

PRODUCED BY

Grasl FairPrint

Druckhausstraße 1, 2540 Bad Vöslau, Austria

GENDER NEUTRALITY

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

LADIES AND GENTLEMEN,

Photo: © sticklerfotografie.at

Medicinal products are precious, technologically well developed products, which provide an essential part for the public healthcare of our society. Effective medicinal therapies guarantee the efficient use of recourses within the public health care system. Medicinal products help to save costs in the public healthcare system. A successful research into medicinal products is not conceivable without the cooperation between pharmaceutical enterprises and healthcare professionals. Therefore it is essential to define the basic rules of this cooperation in a transparent and fair manner.

The trust in this cooperation is strengthened and continually enhanced by common shared transparency. A separate provision requires the pharmaceutical companies to disclose the transfers of value made to healthcare professionals or institutions. Transparency is a strength and self-regulation ensures the right balance.

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 healthcare 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, fairness and transparency, 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 with the last amendment as by 01/07/2015.

Jan Oliver Huber
Secretary General of Pharmig

PHARMIG CODE OF CONDUCT

Article 1 – Introduction 7
Article 2 – Scope 7
Article 3 – General principles 8
Article 4 – Information on medicinal products 8
Article 5 – Advertising medicinal products 11
Article 6 – Information and advertisement via the Internet 12
Article 7 – Events for healthcare professionals 14
Article 8 – Cooperation with healthcare professionals and institutions 15
Article 9 – Transparency 18
Article 10 – Cooperation with patients' organisations 21
Article 11 – Benefits 24
Article 12 – Raffles 25
Article 13 – Pharmaceutical company employees 25
Article 14 – Clinical trials 26
Article 15 – Violation of the MPA 26
Article 16 – CoC ordinance 26

ORDINANCE 1/2010 OF THE PHARMIG BOARD REGARDING NON-INTERVENTIONAL STUDIES (VO-NIS 1/2010)

Artikel 1 – Scope of Application 27
Artikel 2 – Definitions 28
Artikel 3 – Purpose of NIS 28
Artikel 4 – Distinction from Clinical Studies 29
Artikel 5 – Designing a NIS 29
Artikel 6 – Reviewing a NIS 31
Artikel 7 – Approving a NIS 32
Artikel 8 – Commencement and Transitional Provisions 32

ORDINANCE 1/2014 ADOPTED BY THE BOARD OF PHARMIG ON ARTICLES 7 AND 8 OF THE PHARMIG CODE OF CONDUCT (VALUE LIMITS FOR BOARDS AND HOSPITALITY)

33

Ordinance on Articles 7 and 8 CoC 33

ORDINANCE 2/2014 ADOPTED BY THE BOARD OF PHARMIG ON ARTICLE 9 OF THE PHARMIG CODE OF CONDUCT (TRANSPARENCY)

35

Ordinancy on Article 9 CoC 35
COC – Ordinance on Article 9 – Standardized template for the documentation of data to be disclosed 37

ORDINANCE 1/2015 ADOPTED BY THE BOARD OF PHARMIG ON ARTICLE 7 OF THE PHARMIG CODE OF CONDUCT (EVENTS) 39

Ordinance on Article 7 CoC 39
Sample confirmation on the holding of an event and the use of support provided by pharmaceutical companies in conformity with the law and the CoC 42

CODE OF PROCEDURE OF THE COC COMMITTEES OF EXPERTS OF THE 1ST AND 2ND INSTANCE

Article 1 – Tasks and responsibilities of the Committees of Experts 1st and 2nd Instance 43
Article 2 – Language of correspondence / Language of proceedings 44
Article 3 – Venue for proceedings 44
Article 4 – Rights of defence 44
Article 5 – Complainant 44
Article 6 – Object and admissibility of the complaint 45
Article 7 – Content and form of the complaint Article 8 46
Article 8 – Rights and liabilities of the complainant 46
Article 9 – CoC Committee of Experts of the 1st Instance 47
Article 10 – Simplified proceedings before the CoC Committee of Experts of the 1st Instance 47
Article 10a – Alternative dispute resolution proceedings 48
Article 11 – Continuation of the proceedings before the CoC Committee of Experts of the 1st Instance 50
Article 12 – Oral proceedings 51
Article 13 – Representation of the company concerned 51
Article 14 – Decision of the CoC Committee of Experts of the 1st Instance 52
Article 15 – Sanctions of the CoC Committee of Experts of the 1st Instance 53
Article 16 – Appeal 54
Article 17 – CoC Committee of Experts of the 2nd Instance 55
Article 18 – Decision of the CoC Committee of Experts of the 2nd Instance 56
Article 19 – Non-appealability of the decision of the CoC Committee of Experts of the 2nd Instance 57
Article 20 – Partiality 57
Article 21 – Deadlines, deliveries and notifications 58
Article 22 – Office of the CoC decision panels and attorney of record 58
Article 23 – Secrecy 59
Article 24 – Members of the CoC Committee of Experts of the 1st Instance 59
Article 25 – Members of the CoC Committee of Experts of the 2nd Instance 59
Article 26 – Common regulations for the appointment of members to the CoC Committees of Experts of the 1st and 2nd Instance 60
Article 27 – Costs of the CoC Committees of Experts of the 1st and 2nd Instance 61
Article 28 – Cost of the simplified proceedings before the CoC Committee of Experts of the 1st Instance 61
Article 29 – Cost of continuation of the proceedings before the CoC Committee of Experts of the 1st Instance 62
Article 30 – Costs of the proceedings before the CoC Committee of Experts of the 2nd Instance 62
Article 31 – Necessary expenses 63
Article 32 – Due date of costs and necessary expenses / Value-added tax 63
Article 33 – Publication of decisions 64
Article 34 – Use of gender nouns 64
Article 35 – Other regulations 64
Article 36 – Coming into force / Transitional provisions 64

Flowchart 67

PHARMIG CODE OF CONDUCT

ARTICLE 1

INTRODUCTION

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 the 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 for healthcare professionals, co-operation with healthcare professionals and institutions, transparency, cooperation with patients' organisations, benefits, raffles, company employees, clinical trials and infringements of the Medicinal Products Act (MPA).

ARTICLE 2

SCOPE

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 on its behalf. Furthermore it applies to employees of pharmaceutical companies, medical sales representatives, for the use of audio- visual systems, telecommunications or the Internet, films, videos and data carriers, for cooperation with healthcare professionals and institutions, for transparency, for cooperation with patients' organisations, for the granting of benefits 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 wholesalers, 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 healthcare professionals and any persons as defined by § 59 (3) and (4) MPA be directly, comprehensively and reliably informed about the existence and properties of medicinal products that they may prescribe, use or dispense.

Healthcare professionals are persons authorised to apply, administer or prescribe such as physicians, dentists, veterinary surgeons, dental practioners, midwives, members of the nursing profession, medical laboratory services and paramedic and any other medical facilities, provided they require medicinal products to fulfil their tasks.

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 provisions of the Austrian Medicinal Products Act (MPA), the Unfair Competition Act and the Austrian Criminal Code, are to be taken into account and observed.

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 wellbeing of the patients and the professional identity of the healthcare professionals addressed must be taken into consideration.

The pharmaceutical companies are also responsible for complying with the obligations of the Pharmig Code of Conduct if third parties are acting directly or indirectly on their behalf (e.g. advertising agencies, market research companies, other service providers).

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 admissible and non-promotional information:

a) correspondence and documents of a non-promotional nature needed to answer a specific question on a particular medicinal product;
b) sales catalogues and price lists, provided they include no product information;
c) issue-related information relating to diseases or human health, provided no reference is made – also no indirect reference – to a medicinal product;
d) information as part of the pharmacovigilance activities in coordination with the authorities;
e) 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;
f) information on non-authorised medicinal products in response to a documented request from healthcare professionals;
g) correspondence with the authorities, as in the course of marketing authorisation, pharmacovigilance or inspections;
h) texts approved by the authorities, e.g. summary of product characteristics or the patient information leaflet;
i) informational or educational materials provided it is inexpensive, directly relevant to the practice of medicine or pharmacy; and directly beneficial to the care of patients;
j) Items of medical utility aimed directly at the education of healthcare professionals and patient care if they are inexpensive and do not offset routine business practices of the recipient.

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 or her own personal opinion of the properties and the therapeutic value of the product in question.

4.3 All statements concerning medicinal products must comply with the labelling, patient information leaflet and summary of product characteristics (SmPC) 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 depictions must render the content correctly and must 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 healthcare professionals. Documentary evidence to support the authorised indications is not required.

4.9 Written documentation for healthcare professionals 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 healthcare professionals 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 shall 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 shall 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:

a) 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;
b) to imitate typical advertising features of competitors, the presentation, packaging or labelling of competitor products;
c) to publish advertisement that is misleading or damaging to someone's reputation;

d) to resort to exaggerated marketing claims (as through excessive emphasis);
e) to assert in their statements that a product has no undesirable effects, side effects or toxic effects and/or addictive or habitforming effects;
f) to use the terms "safe" and "safety" without clearly defining them;
g) 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;
h) 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 (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 (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
a) For information and advertisement on medicinal products made accessible on the Internet by pharmaceutical companies, on their behalf or with their approval, Article 4 (Information on Medicinal Products) and Article 5 (Advertising Medicinal Products) apply analogously.
b) The presentation on the Internet must clearly specify the pharmaceutical company operating the website or directly or indirectly supporting it and which information on the website is addressed to healthcare professionals and/or to the general public.
c) Websites must be updated on a regular basis and checked for accuracy and should provide up-to-date information.

6.2 Information on the company

a) Websites may contain information of interest to investors, the media and general public.
b) 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

a) Information addressed to the layman and containing advertisement must comply with the applicable provisions of part V of the Medicinal Products Act (Advertising Restrictions) and the respective provisions of Article 5 (Advertising Medicinal Products).
b) 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.).
c) This information must be balanced, accurate and in harmony with the authorised summary of product characteristics (SPC).
d) The website may contain a link to the complete, unmodified evaluation report as published by the CHMP (Committee for Human Medicinal Products) or by a competent national authority.
e) The website may contain links to other websites containing reliable information on medicinal products (websites of authorities, medical research institutions, patient organisations, etc.).
f) Apart from the brand name, the international non-proprietary name (INN) must also be mentioned.
g) The website must always contain a reference to a physician or pharmacist for further information.

6.4 Information for healthcare professionals

a) Information addressed to healthcare professionals 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).
b) Information for healthcare professionals must be clearly indicated as such. It must be ensured that the access to this information is reserved exclusively for healthcare professionals.

ARTICLE 7

EVENTS FOR HEALTHCARE PROFESSIONALS

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 or support of events, invitation to events or the 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 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. Leisuretime activities and/or social programmes (e.g. theatre, concerts, sports events) 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.

a) The organisation, implementation and/or support of international events or the assumption of costs for participation in these events is only admissible if
   1. the majority of participants come from a different country than the country in which the member company is based, or
   2. 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).

b) Two codes apply to the organisation, implementation or support of international events, the invitation to international events or the

assumption of costs for their participants: The code of the country in which the pharmaceutical company which organises, implements, supports or assumes the costs of the international event is based, as well as the code of the country in which the international event takes place. In this respect, these codes are 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 the two codes is applicable. The company must inform in advance an affiliated company with a registered office in the country where the event is taking place about any activities subject to line 1, if applicable, or seek advice on the proper implementation of the activities.

7.6 The organisation, implementation or support of events, the invitation to events or the assumption of costs for their participants may not be made dependent on the recommendation, prescription or distribution of specific medicinal products.

7.7 In the case of services being provided by healthcare professionals within the framework of events, pharmaceutical companies must ensure that all potential conflicts of interest are disclosed in writing to the organiser and the participants in a suitable manner prior to the event starting.

7.8 If pharmaceutical companies distribute information regarding the contents of an event they must ensure that it is accurate.

7.9 According to Article 16, 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).

ARTICLE 8

COOPERATION WITH HEALTHCARE PROFESSIONALS AND INSTITUTIONS

In order to research and further develop effective medicinal products, close co-operation with the healthcare professionals is necessary.

8.1 Prescriptions and recommendations
It is not permitted to grant, offer or promise premiums, financial or material benefits to healthcare professionals for prescribing, dispensing or using a medicinal product or recommending a medicinal product to a patient.

8.2 Cooperation with healthcare professionals
a) Any service rendered by healthcare professionals for pharmaceutical companies (e.g. for lectures, consulting, clinical trials, non-interventional

studies) must serve the purpose of training/ education, research, support of the healthcare system or be provided within the framework of scientific and specialist activities. A written contract must be concluded, clearly indicating the service and remuneration to be provided, as well as the scope, type and purpose of the service.

b) Remuneration may only consist of money and must be proportionate to the service provided. Hourly fees may be agreed to compensate for the time spent in providing the service. Any expenses incurred, including travel costs, may be additionally reimbursed to an appropriate degree. Among other options, the fee schedule for physicians can be used to assess the proportionality of remuneration.

c) The provision of services by healthcare professionals must not be linked with conditions relating to the recommendation, prescription or the administering of medicinal products.

d) Healthcare professionals shall not be granted, offered or promised any premiums, financial or material benefits to ensure that they agree to receive a medical sales representative or accept information from other staff members.

e) Visits to healthcare professionals 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 pharmaceutical companies to observe the standard practices in the trade.

f) Hospitality to healthcare professionals is only admissible in the course of events and business dinners for the purpose of exchanging information and only to a reasonable degree, not lavish, and to the extent that is considered socially appropriate. The occasion is to be documented. Hospitality to persons accompanying healthcare professionals is not permitted.

8.3 Cooperation with healthcare professionals as public officials

Within the framework of cooperation with healthcare professionals as public officials, in supplement to the conditions of the Pharmig Code of Conduct the provisions of the penal code (StGB) as well as any professional and organisational regulations must be observed.

8.4 Cooperation with institutions

a) Services for pharmaceutical companies supplied by institutions, organisations or establishments which predominantly comprise healthcare professionals must exclusively serve the purpose of training/ education, research or support of the healthcare system, or must be provided within the framework of scientific or specialist activities. A written contract must be concluded, clearly indicating the service itself, the remuneration, as well as the scope, type and purpose of the service.

b) The provision of services by pharmaceutical companies must not be linked with conditions relating to the recommendation, prescription or the administering of medicinal products.

8.5 Donations and subsidies

a) Pharmaceutical companies are only permitted to make financial or material donations or provide subsidies to institutions, organisations or establishments which predominantly comprise healthcare professionals for the purpose of training/education, research or support of the healthcare system or within the framework of scientific or specialist activities.
b) When making financial donations or providing subsidies, pharmaceutical companies are obligated to keep records which clearly list the donations or subsidies – and in particular the scope, type and purpose of the same – the recipient of the donation or subsidy as well as the permission of the same to disclose the donation or subsidy provided by the pharmaceutical company. Donations and subsidies must be made accessible to the public on the internet as defined in Article 9.
c) The provision of donations and subsidies by pharmaceutical companies must not be linked with conditions relating to the recommendation, prescription or the administering of medicinal products.
d) Donations and subsidies to individual healthcare professionals are not permitted.
e) Permissible support benefits according to the conditions of the Pharmig Code of Conduct remain unaffected.

8.6 Non-interventional studies

a) Non-interventional studies are systematic studies of medicinal products with patients in accordance with the definition in § 1a (3) AMG which serve to obtain knowledge of the application of medicinal products and their efficacy and tolerance in practice.
b) A non-interventional study must be set up, verified and authorised under the supervision of a medical department of the pharmaceutical company or, in its absence, under the supervision of an appropriately medically qualified person.
c) For the required documentation in the course of the non-interventional study in accordance with § 2a (3) MPA, 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 for the services provided in the course of a non- interventional study may not represent an incentive for the prescription of a medicinal product.

8.7 Medical samples

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

a) In accordance to § 58 MPA pharmaceutical companies are permitted to provide medical samples to physicians, dentists, veterinary surgeons and denturists.
b) 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):
c) Free medical samples may be supplied to recipients in accordance with § 58 MPA:
   - 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
   - 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.
d) No medical samples containing psychotropic or narcotic substances may be supplied.

8.8 Authorisation to adopt ordinances

According to Article 16, the board of Pharmig is authorised to adopt a CoC ordinance relating to Articles 8.5 b) (concerning the publication of donations and subsidies), 8.6 (concerning the type, scope and appropriateness of the non-interventional studies and their documentation), 8.7 (concerning the supply of medical samples and its documentation), and 8.2f) (concerning hospitality and its documentation).

ARTICLE 9

TRANSPARENCY

The interactions between pharmaceutical companies and healthcare professionals and institutions are essential in order to develop and maintain the best possible supply of medicinal products. A practicable way to increase public trust in these interactions is transparency. The highest degree of transparency

is the disclosure, at the individual level, of transfers of value arising from this cooperation. All parties involved should therefore strive for the disclosure of transfers of value at the individual level.

9.1 Scope
Article 9 regulates the disclosure of the cooperation of the pharmaceutical companies with healthcare professionals and institutions and governs the documentation and disclosure of transfers of value (ToV) by the pharmaceutical companies in connection with medicinal products which are subject to prescription. Article 9 does not apply to the purchase and sale of medicinal products.

9.2 Duty to document and disclose
Pharmaceutical companies have to document and disclose any and all transfers of value granted to healthcare professionals and/or institutions.

9.3 Type of Transfers of Value (ToV)
The duty to disclose relates exclusively to transfers of value in connection with
a) research and development;
b) donations and subsidies;
c) events;
d) services rendered and consulting provided including expenses incurred.

9.4 Disclosure at individual level
Disclosure at individual level shall comprise specific information on each healthcare professional and/or each institution which allows for such expert or institution to be unambiguously identified, as well as on the total of the transfers of value granted throughout the reporting period, to the extent that such contributions fall under the types set out in Article 9.3 b), c) or d).

The information to be disclosed is to be broken down as follows:
a) Transfers of value granted to individual healthcare professionals:
   1) Transfers of value granted in connection with events:
      (i) admission and attendance fees
      (ii) travel costs and costs for overnight accomodation.
   2) Fees for services rendered and consulting provided, a distinction being made between the payment of fees and reimbursement of expenses
b) Transfers of value granted to individual institutions:
   1) financial or material donations as well as subsidies;
   2) transfers of value granted in connection with events:
      (i) admission and attendance fees;
      (ii) support of institutions or third parties appointed by such institutions for implementing the event;

(ii) travel costs and costs for overnight accomodation.

3) Fees for services rendered and consulting provided, a distinction being made between the payment of fees and reimbursement of expenses.

If transfers of value under Article 9.4 a) have been allocated indirectly to healthcare professionals via an institution, only one disclosure shall be made.

9.5 Aggregate (summarised) disclosure

Disclosure shall be made in aggregate form without stating the names of the individual healthcare professionals and/or institutions if the relevant ToV relate to research and development. This includes also the reimbursement of expenses for attendance at events in connection with research and development activities.

Furthermore, those transfers of value are to be disclosed in aggregate form where legal reasons do not permit the names of individual healthcare professionals and/or institutions to be disclosed. In such cases, transfers of value have to be allocated to the relevant types and disclosed in aggregate form. Detailed information has to be provided on the total number of recipients as well as their percentage as compared to all recipients of transfers of value of this type and the aggregate amount attributable to the relevant category.

9.6 Reporting period, time of disclosure, methodology

The reporting period shall be the calendar year. The first reporting period comprises the 2015 calendar year. The information shall be disclosed once a year. The information must be disclosed at the latest 6 months after the end of the reporting period.

9.7 Location and duration of the disclosure

The information shall be disclosed in German or English on a publicly accessible website for which the pharmaceutical companies are responsible. The information shall be disclosed for a duration of at least 3 years starting from the date when it was first disclosed, unless a shorter duration is mandatory for legal reasons.

9.8 Transfers of value granted to healthcare professionals and institutions abroad

Transfers of value provided by pharmaceutical companies to healthcare professionals and institutions that mainly practice their profession or have their registered office in a European country other than Austria are to be disclosed by the affiliated company active in the country where the relevant recipient of transfers of value is based. The information and documents required for the disclosure shall be handed over by the pharmaceutical company to the affiliated company in due time for disclosure. If there is

no affiliated company disclosing the transfer of value, the pharmaceutical company granting the transfer of value has to disclose it.

Transfers of value granted to individual healthcare professionals and institutions that mainly practice their profession or have their registered office in Austria by companies that have their registered office outside of Austria have to be disclosed by the pharmaceutical company affiliated in Austria to the extent that the information and documents required for disclosure are provided by the affiliated company.

In addition to the above, transfers of value involving a foreign country are always subject to the applicable provisions of the relevant national code.

9.9 Authorisation to adopt ordinances
According to Article 16, the board of Pharmig is authorised to adopt a CoC ordinance for Articles 9.4 through 9.8 (concerning disclosure at individual level, aggregate disclosure, reporting period, time of disclosure, methodology, location and duration of the disclosure, transfers of value granted to healthcare professionals and institutions abroad) as well as standardised forms for the proper documentation of any data to be disclosed.

ARTICLE 10

COOPERATION WITH PATIENTS' ORGANISATIONS

Patients' organisations, including their umbrella organisations, are voluntary, non-profit orientated associations which predominantly comprise patients and/or their families and/or patient 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.

10.1 Advertising restrictions
Any advertising with support of patients' organisations as well as any use of logos or copyright protected materials by pharmaceutical companies or the patients' organisation is subject to advertising restrictions per the Pharmig Code of Conduct and must be exercised exclusively on the basis of a written agreement per Article 10.3.

10.2 Support
a) Support is deemed to be any financial contribution as well as any indirect contribution or any non-financial contribution to patients' organisations.

The provisions of Article 10 do not apply to indirect contributions or non-financial contributions provided that they are inexpensive.

b) Any support of patients' organisations shall serve solely the interests of the patients and/or their families.

c) The exclusive support of patients' organisations and/or their programs must not be agreed by pharmaceutical companies and/or granted by patients' organisations.

10.3 Written agreement

a) Any support may only be provided on the basis of a written agreement.

b) This agreement shall contain comprehensive information about the type, scope and purpose, 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 10.6. The value of the support must also be detailed.

c) Furthermore, pharmaceutical companies shall ensure by contract that patients' organisations disclose to the public the relevant support provided by pharmaceutical companies transparently at all times and clearly from the outset.

10.4 Agreements regarding the provision of services

a) Services provided by patient organisations to pharmaceutical companies must only be provided for the purpose of training/education, research or support of the healthcare system or be supplied within the framework of scientific or specialist activities.

b) Service agreements must be concluded in writing and they must detail scope, type and purpose of the service, remuneration for the service and contain the consent of the patient organisation to disclosure by the pharmaceutical company per Article 10.6. The remuneration must be appropriate and must constitute fair market value.

c) Service agreements must obligate the patient organisation to disclose their activity in full, where verbal or written public notifications of the patient organisation refer to the subject or contents of the service agreement or, in general, to the pharmaceutical company.

d) Conclusion of an agreement regarding the provision of services must not be linked to the recommendation of certain medicinal products.

e) Agreements regarding the provision of services by the pharmaceutical company to the patient organisation must be concluded in writing – unless they are inexpensive.

10.5 Transparency

The cooperation between pharmaceutical company and patient organisation must be transparent in nature. Pharmaceutical companies must therefore

maintain comprehensive records regarding this co-operation, which clearly indicate which patient organisations are supported by the pharmaceutical company, as well as the type, scope and purpose of this support.

10.6 Publication duties

a) Pharmaceutical companies must publish on their website on the internet, all patient organisations that receive support from the pharmaceutical company or that have concluded agreements with the pharmaceutical company per Article 10.4. The publication must include the type, scope and purpose of the support or the type, scope and purpose of the service. The publication duties do not apply to indirect contributions or non-financial contributions, as well as agreements per Article 10.4, provided that they are inexpensive.

b) This publication must include the total value of the financial contributions or non-financial contributions, as well as the total of the service charges per calendar year and per patient organisation. If no precise monetary value can be determined in the case of indirect contributions or non-financial contributions then the advantage gained by the patient organisation must be described comprehensively and in verifiable form.

c) All published details must be updated at least once a year (no later than by the 30th June for the respective preceding calendar year).

10.7 Events/Patients' organisations

a) Events are symposia, congresses, workshops, lectures and the like, also small-scale events/meetings between patients' organisations, their members, patients, 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. The organisation, implementation or support of the events, the invitation to events as well as the assumption of costs are only admissible provided that the event meets with the conditions of Article 7.

b) The assumption of costs for members of patients' organisations, patients, 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. If, as a result of illness or disability, it is necessary for a carer to accompany a patient then the assumption of costs for this person is permissible. Not permissible is the organisation of participation, the invitation to participate or the assumption of costs for any other accompanying individual.

c) Activities which have no factual and/or technical connection with the actual aim and purpose of the event must not be supported, financed or organised by the pharmaceutical company; this applies in particular to leisure time and/or entertainment programmes (e.g. theatre, concert, sports events).

d) Provided the participants are healthcare professionals, the provisions of Article 7 shall be observed.
e) The organisation, implementation or support of events, invitations to events, as well as the assumption of costs for members of patients' organisations, patients, as well as other invited participants outside the country in which the pharmaceutical company is based are only admissible provided
   1) the majority of participants come from a different country than the country in which the member company is based , or
   2) 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.
f) 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.

10.8 Editorial work
Pharmaceutical companies are not permitted to influence the editorial work of publications of patient organisations supported by them without legitimate factual reason (for example, in order to correct inaccuracies in content or scientific aspects). Financial interests do not constitute a legitimate factual reason.

10.9 Authorisation to adopt ordinances
According to Article 16, the board of Pharmig is authorised to adopt a CoC ordinance for Articles 10.2 (concerning inexpensive support and the type and scope of the relevant support), 10.4 (regarding inexpensive service agreements) and 10.7 b) (concerning the appropriateness of events and their documentation).

ARTICLE 11

BENEFITS

11.1 Pharmaceutical companies and their employees shall not accept any premiums or financial or material benefits from healthcare professionals or accept the promise of any premiums or financial or material benefits, unless they are inexpensive. In all cases, requesting any premiums or financial or material benefits is not permitted.

11.2 Pharmaceutical companies and their employees shall not grant, offer or promise neither any premiums nor any financial or material benefits to healthcare professionals.

11.3 Benefits that are admissible according to the provisions of the Pharmig Code of Conduct or the applicable statutory provisions remain unaffected.

ARTICLE 12

RAFFLES

12.1 Pharmaceutical companies are prohibited from advertising through raffles in which the prize is exclusively subject to a random draw.

12.2 Prize competitions in which participation is subject to scientific and specialist performance and in which the prize awarded to the winner is an admissible benefit as defined in Article 11, are permitted. The provision of medicinal products in the course of prize competitions is not permitted.

12.3 According to Article 16, the board of Pharmig is authorised to adopt a CoC ordinance for Article 12.2 (concerning the type, scope and appropriateness of the prizes awarded to the winner).

ARTICLE 13

PHARMACEUTICAL COMPANY EMPLOYEES

13.1 The pharmaceutical companies must ensure and document that all employees and all persons active in their name and on their behalf 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.

13.2 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.

13.3 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.

ARTICLE 14

CLINICAL TRIALS

14.1 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.

14.2 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.

ARTICLE 15

VIOLATION OF THE MPA

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

ARTICLE 16

COC ORDINANCE

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

ORDINANCE 1/2010 ADOPTED BY THE BOARD OF PHARMIG ON ARTICLE 8 OF THE PHARMIG CODE OF CONDUCT (NON-INTERVENTIONAL STUDIES)

Non-interventional studies (NIS) are systematic studies of medicinial products with patients in order to obtain knowledge of the application of medicinal products and their efficacy and tolerance in practice.

A non-interventional study must be designed, reviewed and approved under the supervision of a medical department of the pharmaceutical company or, in its absence, under the supervision of a person with relevant medical qualifications.

According to Article 16 of the Pharmig Code of Conduct (CoC) and in accordance with Article 8.8 CoC the Board of Pharmig adopts, relating to Article 8.6 CoC, the following

ORDINANCE ON ARTICLE 8 COC

ARTICLE 1

SCOPE OF APPLICATION

1.1 In addition to the provisions of the Austrian Medicinal Products Act (AMG) and its implementing ordinances as well as the Code of Conduct, the provisions of the present Ordinance shall apply to NIS in accordance with § 2a (3) AMG.

1.2 The term NIS includes, in particular, post-marketing surveillances, case control studies, cross-sectional studies, correlation studies with aggregated data, analyses of registers and spontaneous reporting systems.

1.3 The provisions of the present Ordinance shall apply to pharmaceutical companies, which directly design, review, approve and/or finance a NIS or on whose behalf a NIS is designed and/or reviewed.

ARTICLE 2

DEFINITIONS

2.1 For the purposes of the present Ordinance, the following definitions shall apply:

a) "Design", in particular the planning of NIS, the development of the study plan, the drafting of the necessary agreements, the selection of suitable survey instruments (such as questionnaires, blood count, peak flow, X-ray, ECG), implementation (such as selecting and approaching physicians/hospitals /pharmacies), the preparation of adequate documentation, the realisation and support throughout the run time, the analysis of study results, the drafting of the final report;

b) "Review", in particular any and all quality assurance measures in order to secure the completeness and validity of data and remedying shortcomings;

c) "Approval", in particular the internal approval process.

ARTICLE 3

PURPOSE OF NIS

3.1 NIS are used to obtain, further develop and expand knowledge in the use of a medicinal product as well as its effectiveness and tolerance after marketing authorisation according to the daily use practice. In particular, the above shall include the following:

a) Gaining knowledge in the consideration of the summaries of product characteristics and patient information leaflets, acceptance and compliance, practicability, consideration of marketing authorisation requirements;

b) Gaining knowledge of hitherto unknown, particularly rare adverse drug reactions to the medicinal product and interactions;

c) Gaining knowledge of special populations within the approved indications;

d) Further developing knowledge of known adverse drug reactions in daily use practice(e.g. assessment of severity, incidence and interactions);

e) Expanding knowledge of approved indications under conditions of daily use practice.

3.2 NIS are not suitable as evidence of efficacy in the sense of phase II to IV in a clinical trial.

3.3 NIS may not be misused for the purpose of influencing therapy or procurement decisions or for pure marketing purposes. Any decision on the

prescription of a medicinal product shall be made independently from the decision of including a patient in a NIS.

ARTICLE 4

DISTINCTION FROM CLINICAL STUDIES

4.1 The distinction between NIS and clinical trials lies in the observance of non-intervention. Non-intervention in the context of NIS means:

a) the attending physician shall not be given any instructions on whether there should be any treatment at all or which medicinal product should be administered and under what circumstances a therapy should be discontinued or modified and

b) treatment with medicinal products complies with the information regarding their application specified in their marketing authorisation (this also includes all marketing authorisation information regarding contraindications, dosage and dosage schedules, concomitant medication, patient populations, combination therapies, etc.) and

c) the physician performs the treatment, including diagnosis and monitoring, in accordance with customary local medical therapeutic practice and

d) no additional diagnostic and/or therapeutic measures will be made necessary for the patient or no additional burdens will result for the patient.

ARTICLE 5

DESIGNING A NIS

5.1 A NIS shall be designed under the direction of the pharmaceutical company's medical department or, in its absence, under the direction of a person with relevant medical qualifications who does not belong to the marketing/sales division. If staff from other divisions are involved in preparing a NIS, they shall be trained accordingly and such training shall be documented.

5.2 The selection of an adequate survey instrument shall be determined in accordance with the scientific objective of the NIS. The selected survey instrument must be methodologically adequate, conclusive, and efficient (with regard to the number of patients, for instance) so as to attain the scientific objective.

5.3 Study plan

5.3.1 The study plan shall be based on daily use practice/treatment; to this end, requirements set forth in the study plan should allow for systematic observation and should support the objective of consistency in the observations.

5.3.2 Study plans shall include at least the following information:

a) Formulating one (or several) detailed question(s), including a justification to explain why the NIS is an adequate instrument for answering them;
b) Determining the characteristics to be surveyed, a description of their relevance as well as their significance for answering the questions (target variable, influencing variable, confounding variable);
c) Observation schedule (procedure and survey periods);
d) Description of the survey instruments required for observation, including a justification that the data collected in this manner are suitable for answering the formulated question;
e) Description of the approach used in selecting suitable physicians/ hospitals/pharmacies;
f) Description of type and scope of documentation for physicians/ hospitals/pharmacies;
g) Justification of the number of patients to be included;
h) Reporting regulation for adverse drug reactions to the medicinal product;
i) Description of quality assurance measures;
j) Description of statistic analysis; data analysis shall use biostatistical methods that do justice to the problem issues at hand and the planned approach shall be determined in advance in the study plan;
k) Definition of responsibilities (sponsor, project manager, responsible biostatistician, for instance); the person responsible for pharmacovigilance must always be involved so as to ensure compliance with the applicable reporting provisions of the Pharmacovigilance Ordinance;
l) Regulations regarding the reporting modalities - including biostatistical and medical assessment - and planned publication;
m) Justification, whether there is additional need for information in view of the handling of patient data; as the case may be, description of how patient consent is obtained.

5.3.3 In addition, study plans shall include the following information if applicable:

a) Description of patient selection. With a view to the question(s), measures shall be taken to guarantee the best possible representativeness of the patients included in the NIS (if possible,

by including all suitable patients for each physician, by using a log for available patients);
b) Description of measures to achieve representativeness (for physicians/hospitals/pharmacies and/or patients);
c) Discussion of possible confounding variables and description of measures to control these;
d) Documentation templates and patient consent form templates.

5.4 Final report
5.4.1 The final report shall include at least the following information:
a) All information in accordance with Article 5.3.2 and, if applicable, in accordance with Article 5.3.3 of the study plan;
b) A biostatistical analysis of the collected data;
c) If applicable, an assessment of effectiveness from a medical point of view, particularly of adverse reactions;
d) All adverse reactions reported as part of the NIS, which need to be reported to comply with § 75b (1) AMG;
e) A list of all involved physicians/hospitals/pharmacies.
5.4.2 The final report shall be completed 12 months after completion of the NIS at the latest (after final observation of the last NIS patient) and shall be archived for no less than 15 years.

5.5 The NIS results shall be presented in a suitable manner in the periodic safety update reports. If necessary, the risk-benefit profile of the medicinal product shall be updated and, if available, the risk management plan shall be revised.

ARTICLE 6

REVIEWING A NIS

6.1 A NIS shall be reviewed under the direction of the pharmaceutical company's medical department or, in its absence, under the direction of a person with relevant medical qualifications who does not belong to the marketing/sales division. If staff from other divisions are involved in reviewing a NIS, they shall be trained accordingly and such training shall be documented.

6.2 Quality assurance systems shall be used that ensure the validity and representativeness of the collected data. For example, greater attention must be paid to checking the data sets for plausibility and completeness when no data control is ensured on site, as customarily is the case.

6.3 Data validation, data coordination and data analysis shall be performed by involving an adequately qualified person.

ARTICLE 7

APPROVING A NIS

7.1 A NIS shall be approved under the direction of the pharmaceutical company's medical department or, in its absence, under the direction of a person with relevant medical qualifications who does not belong to the marketing/sales division. If staff from other divisions are involved in approving a NIS, they shall be trained accordingly and such training shall be documented.

ARTICLE 8

COMMENCEMENT AND TRANSITIONAL PROVISIONS

8.1 The present Ordinance shall come into force on 01/03/2010.

8.2 NIS, in which the first patient is documented after 30/06/2010, must be in compliance with the provisions of this Ordinance.

8.3 The amendments to the preamble of the present Ordinance shall come into force on 01/07/2014.

ORDINANCE 1/2014 ADOPTED BY THE BOARD OF PHARMIG ON ARTICLES 7 AND 8 OF THE PHARMIG CODE OF CONDUCT (VALUE LIMITS FOR BOARD AND HOSPITALITY)

Events for healthcare professionals, such as 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. Events must exclusively serve to provide scientific information and/or further specialisation.

As regards the organisation, implementation or support of events, invitation to events or the assumption of costs for participants in these events, it is mandatory to comply with the provisions of the Medicinal Products Act (Arzneimittelgesetz or AMG), the provisions of the Pharmig Code of Conduct (CoC), in particular the provisions set forth in Article 7 CoC, and the provisions of any other laws as may be applicable.

The assumption of costs for these events shall, according to Article 7.2 CoC, be restricted to travel costs, room and board as well as the original admission fee and shall be appropriate; leisuretime activities and/or social programmes may not be financed or organised.

According to Article 8.2 f) CoC, hospitality to healthcare professionals is only admissible in the course of business dinners for the purpose of exchanging information and only to a reasonable degree, not lavish, and to the extent that is considered socially appropriate.

According to Article 16 CoC and in accordance with Articles 7.9 and 8.8 CoC, the board of Pharmig adopts, relating to Articles 7.2 and 8.2 f) CoC, the following

ORDINANCE ON ARTICLES 7 AND 8 COC:

The assumption of costs for board at events within the meaning of Article 7 CoC and/or at business dinners for the purpose of exchanging information within the meaning of Article 8.2 f) CoC shall be deemed appropriate in any case if the cost

is lower than EUR 75.00 per person and meal (including taxes and/or charges and tips).

Any assumption of costs for board at events within the meaning of Article 7 CoC and/or at business dinners for the purpose of exchanging information within the meaning of Article 8.2 f) CoC held abroad, the code of the country where board is supplied is applicable. In the absence of pertinent provisions abroad, the relevant provision of the CoC shall apply.

This ordinance shall come into force on 01/07/2014.

ORDINANCE 2/2014 ADOPTED BY THE BOARD OF PHARMIG ON ARTICLE 9 OF THE PHARMIG CODE OF CONDUCT (TRANSPARENCY)

The interactions between pharmaceutical companies and healthcare professionals and institutions are essential in order to develop and maintain the best possible supply of medicinal products. A practicable way to increase public trust in these interactions is transparency. The highest degree of transparency is the disclosure, at the individual level, of transfers of value arising from this cooperation. All parties involved should therefore strive for the disclosure of transfers of value at the individual level.

According to Article 16 CoC and in accordance with Article 9.9 CoC, the board of Pharmig adopts, relating to Articles 9.4 and 9.5 CoC, the following

ORDINANCE ON ARTICLE 9 COC:

1. In order to ensure that the data to be disclosed under Article 9 CoC are properly documented, the board of Pharmig adopts the "STANDARDIZED TEMPLATE FOR THE DOCUMENTATION OF DATA TO BE DISCLOSED", which is annexed to this document as SCHEDULE ./1 FOR COC ORDINANCE ARTICLE 9.

   The purpose of SCHEDULE ./1 is to enable uniform data documentation for all parties included.

   Use of SCHEDULE ./1 is not mandatory; however, if a pharmaceutical company does not use SCHEDULE ./1, it has to ensure that the method of data documentation it uses fully maps the classification in terms of content and representation of the data to be disclosed as shown in SCHEDULE ./1.

   For ease of use, Pharmig will also make SCHEDULE ./1 available electronically in the form of an Excel file on its website www.pharmig.at under Code of Conduct.

2. The following methodologies have to be adhered to when documenting the data to be disclosed:

- As to accrual accounting, measurement and/or other issues, the pharmaceutical company shall, with respect to the amounts to be disclosed, rely on the accounting principles it applies.
  The Standard Accounting Principles shall be relied on and applied in particular when it comes to accrual accounting for services, for instance in the case of contractual relationships spanning several years or services rendered recurrently for more than one reporting period.
- The recorded amounts of transfers of value shall be shown as net amounts (less any taxes and/or charges as applicable).
- The recorded amounts of transfers of value shall be shown in EURO. Where the recorded amounts of transfers of value are amounts denominated in foreign currency, such amounts shall be converted into EURO amounts; conversion shall be based on the Standard Accounting Principles.

This ordinance shall come into force on 01/07/2014.

COC - ORDINANCE ON ARTICLE 9 - STANDARDIZED TEMPLATE FOR THE DOCUMENTATION OF DATA TO BE DISCLOSED

DATA DOCUMENTATION - ARTICLE 9 COC (TRANSPARENCY)

Reporting period (calendar year): .....

Date of publication: .....

	Name	Practice or business address			Where available: physician number commercial register number, association register number	Financial or material donations as well as subsidies	Transfers of value granted in connection with events *(cf. Article 9.4a 1) (i), (ii) CoC and/or Article 9.4b 2) (i), (ii), (iii) CoC)*			Fees for services rendered and consulting provided *(cf. Article 9.4a 2) CoC and/or Article 9.4b 3) CoC)*			TOTAL *Optional*
	(cf. Article 9.4 CoC)	*(cf. Article 9.4 CoC)*	*(cf. Article 9.4 CoC)*	*(cf. Article 9.4 CoC)*	*(cf. Article 9.4 CoC)*	*(cf. Article 9.4b 1) CoC)*	Support of institutions or third parties appointed by such organizations for implementing the event	Admission and attendance fees	Travel costs and costs for overnight accommodation	Fees	Expenses		
HCPs	***INDIVIDUAL NAMED DISCLOSURE FOR HEALTHCARE PROFESSIONALS*** *[one row per HCP, with all transfers of value for the reporting period summed up]*												
	HCP 1					N/A	N/A	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*		*Optional*
	HCP 2					N/A	N/A	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*		*Optional*
	etc.					N/A	N/A	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*		*Optional*
	AGGREGATE DISCLOSURE FOR HEALTHCARE PROFESSIONALS												
	Total amount					N/A	N/A	*Aggregate amount*	*Aggregate amount*	*Aggregate amount*	*Aggregate amount*		*Optional*
	Total number of recipients of transfers of value by subtype					N/A	N/A	*Number*	*Number*	*Number*	*Number*		*Optional*
	% of total transfers of value to all HCP recipients by subtype					N/A	N/A	%	%	%	%		N/A
HCIs	***INDIVIDUAL NAMED DISCLOSURE FOR HEALTHCARE INSTITUTIONS*** *[one row per HCI, with all transfers of value for the reporting period summed up]*												
	HCI 1					*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*		*Optional*
	HCI 2					*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*		*Optional*
	etc.					*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*		*Optional*
	AGGREGATE DISCLOSURE FOR HEALTHCARE INSTITUTIONS												
	Total amount					*Aggregate amount*	*Aggregate amount*	*Aggregate amount*	*Aggregate amount*	*Aggregate amount*	*Aggregate amount*		*Optional*
	Total number of recipients of transfers of value by subtype					*Number*	*Number*	*Number*	*Number*	*Number*	*Number*		*Optional*
	% of total transfers of value to all HCI recipients by subtype					%	%	%	%	%	%		N/A
R & D	***AGGREGATE DISCLOSURE FOR RESEARCH & DEVELOPMENT***												
	Transfers of value granted in connection with research & development, cf. Article 9.3a CoC												*Total*

The rules referred to are those set out in the Pharmig Code of Conduct (CoC)

HCP = healthcare professional within the meaning of Article 3 CoC

HCI = healthcare establishments, organizations or institutions within the meaning of Article 8.4 CoC

R&D = research and development

The reporting period is the calendar year

ORDINANCE 1/2015 ADOPTED BY THE BOARD OF PHARMIG ON ARTICLE 7 OF THE PHARMIG CODE OF CONDUCT (EVENTS)

Events for healthcare professionals, such as symposia, scientific congresses, workshops, lectures and the like, also smaller-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.

As regards the organisation, implementation or support of events, invitations to events or the assumption of participants' costs for these events, it is mandatory to comply with the provisions of the Medicinal Products Act (AMG), the provisions of the Pharmig Code of Conduct (CoC), in particular the provisions set forth in Article 7 CoC, and the provisions of any other laws as may be applicable.

Pursuant to Article 16 CoC, the board of Pharmig adopts, in respect of Article 7.1 through 7.4 CoC and in conformity with Article 7.9 CoC, the following

ORDINANCE ON ARTICLE 7 COC:

Firstly, it should be noted that the assessment of an event in accordance with Article 7 CoC has to consider all elements characterising the event. It is particularly important that the overall picture of the event does not give the impression that undue influence is being exerted over healthcare professionals.

1. The purpose of an event is exclusively to provide scientific information and/or further specialisation in accordance with Article 7.1 CoC. Leisure and/or social programmes taking place in a close timely correlation to the event run counter to this purpose. Close timely correlation is defined as leisure and/or social programmes taking place during the event or within 24 hours before or after the event. This is independent of whether the leisure and/or social progamme is organised, held or supported by the pharmaceutical company.

2. The assumption of costs for these events shall, pursuant to Article 7.2 CoC, be restricted to travel costs, room and board as well as the original admission fee and shall be appropriate. What costs are actually reimbursed depends on the agreement between the pharmaceutical company and the respective participant.

   2.1 If pharmaceutical companies support an event, they have to ensure that the support provided serves exclusively to provide scientific information and/or further specialisation or that they are used for this purpose. The organiser has to confirm that the support provided by pharmaceutical companies is used in conformity with the law and the CoC.

   In this context, the board of Pharmig adopts the "Sample confirmation on the use of support provided by pharmaceutical companies in conformity with the law and the CoC", which is annexed to this document as Schedule ./1 CoC Ordinance Article 7 (Events).

   Use of SCHEDULE ./1 is not mandatory; however, if a pharmaceutical company does not use SCHEDULE ./1, it has to ensure that the confirmation it uses fully maps the content as shown in SCHEDULE ./1.

   2.2 In accordance with Article 7.2 CoC, organising or supporting leisure and/or social programmes for the participants of the event in any way is not permitted. This is independent of whether the leisure and/or social programme has been organised and/or is being held by the organiser, HCI, HCP or a third party.

   Inadmissible leisure and/or social programmes are any kind of programmes which do not serve the purpose of providing scientific information and/or further specialisation and give the impression that the event is of a private and entertaining nature (e.g. musical performances, cultural excursions, sports events or similar activities). This is independent of whether the leisure and/or social programme takes place during, before or after the scientific programme.

   2.3 Appropriate travel costs in accordance with Article 7.2 CoC are the costs in the amount of the official kilometre allowance for individual travel by car, the costs for a first class train ticket for travel by train, the costs for an economy ticket for flights within Europe (continental flights) and the costs for a business class ticket for flights outside Europe (intercontinental flights) for travel by air.

2.4 Board in connection with an event has to be adequate. Care must be taken that the board itself or the selection and/or arrangement thereof is not of any entertaining nature whatsoever.

Concerning adequate cost reimbursement for board (meals and beverages), we refer to the ORDINANCE ADOPTED BY THE BOARD OF PHARMIG ON ARTICLE 7 AND ARTICLE 8 OF THE PHARMIG CODE OF CONDUCT ARTICLE ON VALUE LIMITS FOR BOARD AND HOSPITALITY.

2.5 Overnight accommodation or lodging within the meaning of Article 7.2 CoC is considered appropriate if the hotel or the conference centre features adequate infrastructure and the necessary technical equipment and rooms for holding the event and does not have leisure and entertainment areas and/or does not offer leisure or entertainment activities which exceed standard facilities and/or offers and if the venue as such is not particularly luxurious and/or extravagant (e.g. conference hotels, seminar hotels, training facilities).

In terms of assessing a hotel or seminar centre, it is important that inviting the participants to assume the cost for their overnight accommodation or lodging does not give the impression that undue influence is being exerted over healthcare professionals and is not likely to influence how they issue prescriptions and/or distribute medical products.

3. As specified in Article 7.4 CoC, the conference venue has to be chosen solely based on objective factors. Objective factors are, for example, the geographical location in consideration of the participants' place of departure and the contents of the event as well as its accessibility for participants. The recreational value of a conference venue is not to be considered as an objective factor.

This ordinance shall come into force on 01/09/2015.

SAMPLE CONFIRMATION ON THE HOLDING OF AN EVENT AND THE USE OF SUPPORT PROVIDED BY PHARMACEUTICAL COMPANIES IN CONFORMITY WITH THE LAW AND THE COC

CONFIRMATION

Details of the organiser:

(hereinafter referred to as *"Organiser"*)

Details of the pharmaceutical company:

(hereinafter referred to as *"Pharmaceutical Company"*)

Details of the event:

(hereinafter referred to as *"Event"*)

Description of the support or reimbursement provided by the Pharmaceutical Company:

(hereinafter referred to as *"Support Provided"*)

The *Organiser* hereby confirms that the *Event* organised or to be held by them exclusively serves to provide scientific information and/or further specialisation and that no leisure and/or social programmes take place in connection with the *Event*. *Support Provided* by the *Pharmaceutical Company* exclusively serves one, several or all of the following purposes:

- Admission fees for one/several participants and/or costs for holding and organising the scientific event
- Travel costs for one/several participants
- Board for one/several participants
- Room for one/several participants

The provisions of the Pharmig Code of Conduct in respect of Article 7 and the related Ordinance (Schedule 1) are hereby acknowledged and agreed to and it is hereby confirmed that the *Event* meets the conditions mentioned above and that the *Support Provided* by the *Pharmaceutical Company* is used in accordance with the provisions of the CoC.

If the *Event* is not held in conformity with the law and the CoC and/or if the *Support Provided* is used by the *Organiser* in breach of this agreement, the *Pharmaceutical Company* is expressly entitled to withdraw from this agreement and to have any *Support Provided* refunded to it in full. The *Organiser* undertakes to pay back to the *Pharmaceutical Company* any *Support Provided* within 7 days following the declaration of withdrawal.

Date, (company) signature of the *Organiser*

CODE OF PROCEDURE OF THE COC COMMITTEES OF EXPERTS 1ST AND 2ND INSTANCE

ARTICLE 1

TASKS AND RESPONSIBILITIES OF THE COC COMMITTEES OF EXPERTS 1ST AND 2ND 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, the office of the CoC decision panels and the attorney of record 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 courtcertified translation).

2.2 Oral and written proceedings shall be conducted in German.

ARTICLE 3

VENUE FOR PROCEEDINGS

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

3.2 Simplified proceedings as set out in Article 10 may be conducted in writing by circulation of documents without any prior meeting or by means of video or phone conferences.

ARTICLE 4

RIGHTS OF DEFENCE

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

ARTICLE 5

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 office of the CoC decision panels 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.

5.3 Complaints shall be made to Pharmig – the Association of the Austrian Pharmaceutical Industry c/o the office of the CoC decision panels – in writing 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 11 (Benefits) 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 office of the CoC decision panels 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. Following a decision to initiate proceedings, the Board's decision that the complaint will be addressed shall be forwarded to the office of the CoC decision panels 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 to the complainant,
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 Pharmig, the Association of the Austrian Pharmaceutical Industry c/o the office of the CoC decision panels. 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 they have been harmed in their interests.

7.3 In addition, the complaint may indicate whether alternative dispute resolution proceedings as set out in Article 10a are to be initiated; if no such indication is provided, this shall be deemed a rejection of such proceedings.

7.4 If the complaint does not satisfy Article 7.1 and Article 7.2, or if the copies or enclosures are missing, the attorney of record shall ask the complainant to remedy, complete, or further substantiate his complaint, and set a deadline. If any defects are not remedied before the passing of the deadline, the complaint shall be deemed withdrawn.

7.5 The office of the CoC decision panels shall forward any and all complaints it receives to the Secretary General of Pharmig for his/her information.

ARTICLE 8

RIGHTS AND LIABILITIES OF THE COMPLAINANT

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 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.

ARTICLE 9

COC COMMITTEE OF EXPERTS OF THE 1ST INSTANCE

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.

9.2 The chairman of the competent decision panel of the CoC Committee of Experts of the 1st Instance may delegate the tasks incumbent upon him to the attorney of record and enlist the help and support of the office of the CoC decision panels.

ARTICLE 10

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

10.1 The attorney of record shall forward the admissible complaint and enclosures to the company concerned for the purpose of providing a statement within a set deadline and shall request a statement by the company on whether or not it consents to alternative dispute resolution proceedings as set out in Article 10a, provided such proceedings were

proposed in the complaint. The complaint and the enclosures shall also be forwarded 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 attorney of record 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 attorney of record in a timely fashion, the complaint shall be evaluated by the competent decision panel of the CoC Committee of Experts of the 1st Instance 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.

ARTICLE 10a

ALTERNATIVE DISPUTE RESOLUTION PROCEEDINGS

10a.1 The alternative dispute resolution proceedings enable the parties to conduct – voluntarily and by mutual consent and subject to neutral

moderation by the attorney of record – negotiations on an agreement to potentially settle the complaint even before the initiation of proceedings before the CoC Committee of Experts of the 1st Instance. The aims and principles of alternative dispute resolution proceedings are to present the problem at hand in a manner that all parties can understand, to discuss it and to clarify whether, and if so, under which terms and conditions, the positions and interests of the parties may be balanced and settled.

10a.2 Provided that the complainant (in the complaint) and the relevant company (in its statement) propose the initiation of alternative dispute resolution proceedings, the attorney of record shall, in consultation with the parties, set a date (and subsequent dates, where necessary) and prepare an agenda for the conciliation talks, with due consideration of giving all parties sufficient time to prepare for such tasks. Each party may, at any time during the conciliation talks, declare in writing that it deems such talks to have failed. For alternative dispute resolution proceedings to be initiated, it is necessary for the parties to have agreed on who is to bear which costs beforehand.

10a.3 Based on the conciliation talks, the attorney of record shall draw up a written agreement which

a) describes the contents of the solution arrived at by the parties and contains a provision waiving the initiation of the proceedings before the CoC Committee of Experts of the 1st Instance; or
b) sets out that the parties have agreed to waive the initiation of the proceedings before the CoC Committee of Experts of the 1st Instance; or
c) sets out that the conciliation talks have failed.

Such agreement shall be signed by the parties. Refusal to sign the agreement shall be deemed a form-free declaration that the alternative dispute resolution proceedings have failed.

10a.4 Where the alternative dispute resolution proceedings fail, the attorney of record shall notify the CoC Committee of Experts of the 1st Instance of this fact, upon which the steps set out in Article 10 shall be taken.

10a.5 The deadlines for conducting the proceedings before the competent CoC Committee of Experts of the 1st Instance shall be suspended for as long as during the time while the alternative dispute resolution proceedings are being conducted, until such time when the attorney of record makes the notification as set out in Article 10a.4.

ARTICLE 11

CONTINUATION OF THE PROCEEDINGS BEFORE THE COC COMMITTEE OF EXPERTS OF THE 1ST INSTANCE

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 attorney of record 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 the passing of the two-week deadline for making a declaration to cease and desist. For material reasons, this deadline may be extended by the attorney of record.

11.3 In principle, the decision panel of the CoC Committee of Experts of the 1st Instance meets at the office of the CoC decision panels in Vienna.

11.4 The attorney of record 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 conducted in writing, the attorney of record shall make the necessary procedural arrangements.

ARTICLE 12

ORAL PROCEEDINGS

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. In 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/her 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 office of the CoC decision panels 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 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 non-appealable decision in accordance with these rules of procedure. A violation of the provisions of Article 7 or Article 11 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 11 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.

ARTICLE 16

APPEAL

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 office of the CoC decision panels within two weeks of notification of the decision. The attorney of record shall forward the appeal without delay to the members of the competent decision panel of the CoC 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 an advance payment of 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 competent decision panel of the CoC Committee of Experts of the 2nd Instance meets at the registered address of the office of the CoC decision panels 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 office of the CoC decision panels 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 members of the competent decision panel of the CoC Committee of Experts of the 2nd Instance for decision.

17.10 The chairman of the competent CoC Committee of Experts of the 2nd Instance may delegate the tasks incumbent upon him to the attorney of record and enlist the help and support of the office of the CoC decision panels.

ARTICLE 18

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

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.

18.2 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. In the event of a parity of votes, the complaint shall be rejected as unfounded.

18.3 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.

18.4 Decisions by the CoC Committee of Experts of the 2nd Instance shall be drawn up and forwarded in accordance with Articles 14.3 through 14.9.

ARTICLE 19

NON-APPEALABILITY OF THE DECISION OF THE COC COMMITTEE OF EXPERTS OF THE 2ND INSTANCE

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.

ARTICLE 20

PARTIALITY

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 office of the CoC decision panels thereof, giving notice as to the reason for partiality. The latter shall forward the request of rejection to the members of 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 office of the CoC decision panels.

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 set 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 office of the CoC decision panels 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 office of the CoC decision panels 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

OFFICE OF THE COC DECISION PANELS AND ATTORNEY OF RECORD

22.1 The office of the CoC Committees of Experts of the 1st and 2nd Instance (CoC decision panels) shall be provided by Liebenwein Rechtsanwälte GmbH, 1010 Vienna, Hohenstaufengasse 7.

22.2 The office of the CoC decision panels shall handle administrative matters and shall administrate and manage the files of the CoC Committees of Experts of the 1st and 2nd Instance and appoint the attorney of record.

22.3 The attorney of record for the proceedings shall carry out his tasks in compliance with the aims and values set out in the Pharmig Code of Conduct and in conformity with the provisions of the CoC Code of Procedure.

ARTICLE 23

SECRECY

23.1 All those involved in the proceedings, the members of the decision panels, the managing board, the Board of Directors, all employees of Pharmig, all employees of the office of the CoC decision panels and the attorney of record 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 24

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 25

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 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. Reelections are admissible.

26.2 The managing board of Pharmig shall formulate the Articles of Association and a schedule of responsibilities, which shall govern the competences 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 Articles of Association 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.

ARTICLE 27

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.

ARTICLE 28

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 3,500.00 for the cost of the proceedings. Where matters are complex and a complaint involves several issues, the cost of the proceedings payable to Pharmig shall increase to EUR 5,000.00

ARTICLE 29

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 shall be
a) EUR 7,000.00.
b) In the event of oral proceedings as set out in Article 12, the cost of the proceedings payable to Pharmig shall increase by EUR 2,000.00 in each case of oral proceedings to be held.
c) Where matters are complex and a complaint involves several issues, the cost of the proceedings payable to Pharmig shall increase by EUR 2,000.00.

29.2 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 within 14 days of reception of the relevant payment request from the office of the CoC decision panels. 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. Furthermore, the appellant/complainant shall pay additional costs of the proceedings to Pharmig as follows:
a) in the event of oral proceedings, EUR 5,000.00;
b) for any further oral proceedings, EUR 2,000.00 in each case.

Where additional costs of proceedings become payable, the office of the CoC decision panels shall request payment of such costs separately, with due consideration of the outcome of the proceedings.

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 office of the CoC decision panels 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.

ARTICLE 31

NECESSARY EXPENSES

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.

ARTICLE 32

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

32.1 The costs of the proceedings and necessary expenses shall be determined by the office of the CoC decision panels and become payable, including any VAT charged on these costs, when the decision in accordance with these rules of procedure becomes non-appealable.

ARTICLE 33

PUBLICATION OF DECISIONS

33.1 Pharmig 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.

ARTICLE 34

USE OF GENDER NOUNS

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 concerning a 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 and the office of the CoC decision panels and the attorney of record 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 The 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.

36.4 The amendments to Articles 1, 2, 3, 4, 5, 6, 7, 8.1, 8.2, 8.3, 8.4, 8.5 (restricted), 8.6, 8.7, 8.9, 9, 10, 11, 12, 13, 14 and 15 of the Pharmig Code of Conduct in the version "Amended Version of the CoC 01/2013" come into effect on 01/07/2013. The version of the CoC Code of Conduct and the CoC Code of Procedure (Amended version of the CoC 01/2013) apply to all procedures whereby complaints have been lodged after 30/06/2013 and where the subject of the complatint occurred as of this date. The regulations governing the publication of donations and subsidies per Article 8.5, which have been provided from the 01/01/2015 and thereafter, come into effect on 01/01/2016.

36.5 The amendments to Articles 1, 2, 4, 7, 8, 9, 10, 11, 12, 13, 14, 15 and 16 of the Pharmig Code of Conduct in the version "Amended version of the CoC 01/2014" come into effect on 01/07/2014. The version of the CoC Code of Conduct and the CoC Code of Procedure (Amended version of the CoC 01/2014) apply to all procedures where complaints have been lodged after 30/06/2014 and where the subject of the complaint occurred as of this date. The regulations concerning transparency per Article 9 apply for the first time in the reporting period calendar year 2015. Disclosure for the first reporting period (calendar year 2015) shall take place by 30/06/2016 at the latest.

36.6 Articles 2.1, 3., 5.1, 5.3, 5.5, 7.1, 7.3, 7.4, 7.5, 8.1 a) ii), 9.2, 10.1, 10.2, 10.3, 10a, 11.1, 11.2, 11.3, 11.4, 11.7, 14.7, 16.3, 17.4, 17.9, 17.10, 20.2, 21.2, 21.4, 22, 23, 28, 29, 30.1, 30.2, 32, 33, and 35.2 of the Code of Procedure of the CoC

Committees of Experts of the 1st and 2nd Instance (Amended version of the CoC 01/2015) come into effect on 01/07/2015. The version of the CoC Code of Procedure (Amended version of the CoC 01/2015) applies to all procedures where complaints have been lodged after 30/06/2015 and where the subject of the complaint occurred after this date.

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