PHARMIG

Association of the Austrian Pharmaceutical Industry

PHARMIG Code of Conduct

& Rules of Procedure of the PHARMIG Code Adjudication and Appeal Boards

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Where only masculine personal identifiers are used for the sake of easier readability, they refer to both men and women in equal measure.

Our Ethos

Upholding a culture of trust

Trust, Care, Fairness, Respect, Honesty

PHARMIG, the Verband der pharmazeutischen Industrie Österreichs or, in English, the Association of the Austrian Pharmaceutical Industry, and its member companies are committed to providing the best possible pharmaceutical care within the healthcare community and to assuring societal and medicinal advancement through quality and innovation. Therefore, member companies not only hold themselves to high standards of accountability, but also comply with applicable legal requirements and adhere to high ethical standards.

Staying true to this commitment, they supply the Austrian healthcare community with information regarding the science of medicinal products in order to advance understanding of patient treatment options and to bolster high-quality patient care.

By voluntarily adopting the PHARMIG Code, member companies attest to their strong sense of accountability and to their clear intention to live a common industry culture dedicated to high standards. Accordingly, the pharmaceutical industry's stance is clear: we actively encourage the appropriate and rational use of medicinal products. In keeping with that fundamental stance, we adopted the standard set by the International Federation of Pharmaceutical Manufacturers & Associations and, by extension, are committed to a culture based on trust, care, fairness, respect, and honesty. This ethos forms the foundation upon which the pharmaceutical industry maintains trust and confidence in the face of society's ever-changing expectations.

Care

Protect the safety of those who use our products – from the conduct of clinical trials and throughout the product lifecycle.

Innovation

Improve global health through innovative products and services, upholding the highest ethical, scientific, and medical standards.

Quality

Commit to providing high-quality products that have proven clinical efficacy and have a reliable safety profile.

Fairness

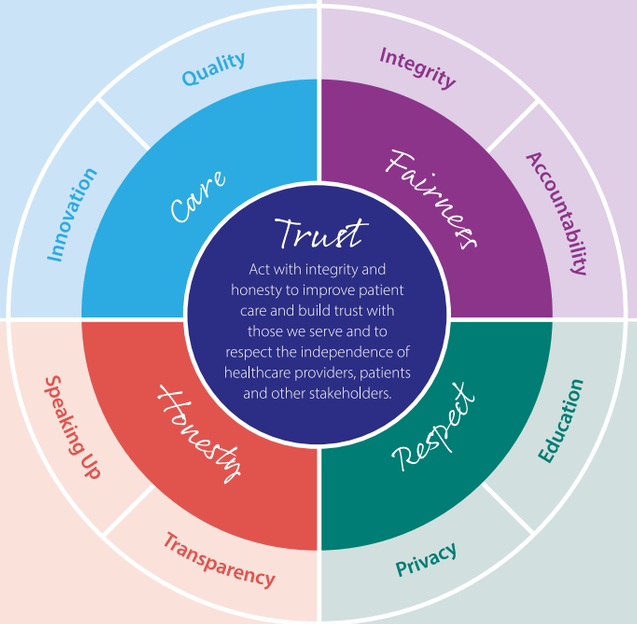
Support and respect fair trade practices and open competition.

Integrity

Act responsibly, ethically and professionally. Do not offer, promise, provide, or accept anything of value in order to inappropriately influence a decision, gain an unfair advantage.

Accountability

Be accountable for our actions and decisions, including the appropriate oversight of external third parties that act on our behalf.



IFPMA

Honesty

Ensure truthful and balanced communication with governmental authorities, healthcare professionals, patients and other stakeholders.

Speaking Up

Foster a culture in our respective organisations where concerns are shared openly and honestly so that we learn from mistakes and continuously improve.

Transparency

Advance science and patient care by sharing industry-sponsored clinical trial data in a responsible, accurate and appropriate manner.

Respect

Respect all people and embrace a culture of diversity and inclusion. Protect the environment. Treat animals under our care responsibly.

Privacy

Respect privacy rights and appropriately manage and protect personal information.

Education

Support the advancement of the scientific and medical education for the ultimate benefit of patients.

Foreword

Health is the greatest wealth. And the pharmaceutical industry is a vital partner: medicinal products contribute to our well-being, cure disease, increase our quality of life when we're ill, and make for a life worth living despite illnesses we might have.

The pharmaceutical industry is held to high standards when it comes to researching, developing, producing, and distributing medicinal products. The complexity of the processes involved and the increasing specialized or person-centered therapies make cooperation between pharmaceutical companies and professionals from our healthcare communities and patient organizations more important and more valuable than ever. Part and parcel of this cooperation is a steady stream of information to doctors, pharmacists, patients, and the public, which helps to ensure that medicinal products are used both properly and safely. But what is more, by sharing our experiences with one another, we ensure that key information can be incorporated into our efforts to advance therapeutic concepts.

All this requires a rationale for interactions within the healthcare industry embodied in industry-wide compliance rules and regulations. The rules set forth in the PHARMIG Code of Conduct (PHARMIG Code) have ensured, since 1970, compliance with statutory requirements and the absence of undue influence not only on healthcare community professionals' procurement and therapeutic freedoms, but on their freedom of choice as well. The rules governing transparency, firmly anchored in the PHARMIG Code since 2015, have been critical in building public trust in these interactions.

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For the first time ever, ethical principles stand clearly at the fore of the PHARMIG Code. The new ethos is based not on lifeless rules, but instead on a culture of principles. At the heart of this culture is trust, and this forms the foundation of our interactions, regardless of kind or form. In keeping with our core values of care, fairness, respect, and honesty, our ethos forms the basis upon which the pharmaceutical industry maintains trust and confidence in the face of society's ever-changing expectations.

The PHARMIG Code, now in its 50th year, was revisited and revised in 2020 and received a more modern look and a more user-friendly structure. By continuously enhancing our voluntary self-regulation efforts, we are creating, over and above the provisions prescribed by law, a reliable framework within which fair and cooperative interactions can take place. As such, we are sending a clear and vital signal to the public and living, to the best of our knowledge and belief, our responsibility to the Austrian healthcare community in the interest of the patients within that community.

The present version of the PHARMIG Code of Conduct and the Rules of Procedure of the Adjudication and Appeal Boards has been in force since 1 July 2007, with the most recent amendment effective as of 1 July 2020.

Alexander Herzog
PHARMIG Secretary General

Contents

Abbreviations

HCP	Healthcare Professional(s)
AMG	Arzneimittelgesetz (Medicinal Products Act)
CHMP	Committee for Human Medicinal Products
EFPIA	European Federation of Pharmaceutical Industries and Associations
GCP	Good Clinical Practice
HCO	Healthcare Organization(s)
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
INN	International Nonproprietary Name (a designation used by the World Health Organization to identify pharmaceutical substances or active pharmaceutical ingredients)
NIS	Non-Interventional Study
PHARMIG	PHARMIG – Verband der pharmazeutischen Industrie Österreichs
PO	Patient Organization(s)
SPC	Summary of Product Characteristics
StGB	Strafgesetzbuch (Criminal Code)
UWG	Gesetz gegen den unlauteren Wettbewerb (Act against Unfair Competition)
PHARMIG Code	Code of Conduct of PHARMIG – Verband der pharmazeutischen Industrie Österreichs

PHARMIG Code of Conduct

Article 1

Introduction

The guiding precept of the PHARMIG Code is that the pharmaceutical industry can be held accountable within the healthcare community and, at the same time, maintain its high ethical standards. The PHARMIG Code aims not only to strike the requisite balance between the competing interests of patients, healthcare workers, and the general public, but also to guarantee that balance by giving due consideration to the legal, political, and social environments to which the pharmaceutical industry and its stakeholders belong.

Article 2

Scope & Definitions

2.1 Scope

The PHARMIG Code applies to all promotional, advertising, and marketing efforts relating to medicinal products, including, but not limited to, advertising in print and electronic media, broadcasts, and events, as those efforts may be made by a pharmaceutical company or, directly or indirectly, caused to be made through any third party acting on behalf of a pharmaceutical company. The PHARMIG Code also applies to the employees of pharmaceutical companies; medical sales representatives; the use of audiovisual systems, telecommunications and the internet, films, video recordings, and data storage devices; interactions with HCPs and HCOs; transparency; interactions with patient organizations; the granting of benefits; and all other areas covered. The PHARMIG Code is not intended to impose restraints on the exchange of medical or scientific information during the product development process prior to marketing authorization in Austria.

2.2 Definitions

Healthcare professional(s) *(HCP)* means any natural person(s) authorized to administer, to dispense, and to prescribe medicinal products such as doctors, pharmacists, dental practitioners, veterinarians, dentists, midwives, nursing professionals, medical technicians, medical service professionals, and other medical services organizations, provided that such medicinal products are necessary for the discharge of their duties.

Public officials are persons within the meaning of § 74(1) item 4a StGB, as it may be amended from time to time, including, but not limited to;

- persons engaged on behalf of the federal, state, or municipal governments or municipal associations; on behalf of other public entities (such as universities or social insurance carriers, except for churches and religious communities); on behalf of countries and international organizations as their governing bodies or civil servants within any legislative or executive branch (that is, administration and jurisdiction); also such as EU officials or persons who have been entrusted with and discharge public duties in connection with the management or decision-making process relating to the financial interests of the European Union in Member States or third countries;
- persons who are otherwise authorized to execute laws in an official capacity; and
- all persons in the employ of any company as part of its governing body or a service relationship, where (1) a foreign or domestic corporate entity holds, directly or indirectly, a minimum of 50% of the registered capital, capital stock, or equity of that company or (2) that company is controlled, in point of fact, by any corporate entity in the form of financial or other pecuniary or organizational measures or (3) that company is subject to audits by the court of audit, any entity of any country similar in nature to the court of audit or any comparable international or foreign auditing entity.

Medicinal product means any substance or combination of substances which

1. may be administered for application in or on the body or for treating, relieving, or preventing disease or pathological issues or
2. can be applied or administered in or on the body with a view either
   a. to restoring, correcting, or modifying any physiological function through any pharmacological, immunological, or metabolic effect or
   b. to serving as the basis of a medical diagnosis.

Third party means any natural or legal person, association, or organization who acts, directly or indirectly, on behalf of a pharmaceutical company: such as advertising agencies, market research companies, organizers, or other service-provider enterprises.

Transfer(s) of value means direct/indirect service or any direct/indirect in cash or in-kind performances, or any direct/indirect performances of any other nature that are provided directly or indirectly to any recipient (for instance, HCP/HCO).

Healthcare organization *(HCO)* means any legal person, association, or organization predominantly comprised of healthcare professionals such as hospitals, clinics, foundations, universities, or teaching institutions which render medical services or perform medical research, irrespective of their legal or organizational form, with the exception of patient organizations as set forth in Article 10 below.

Clinical trial(s) means any systematic study of any medicinal product administered to a subject, the objective of which is (1) to discover or to demonstrate the effects of investigational medicinal products, (2) to identify adverse reactions of investigational medicinal products, or (3) to investigate the absorption, distribution, metabolism, and excretion of investigational medicinal products.
This definition includes clinical trials conducted at one or more study sites in one or more of the countries within the European Economic Area.

Non-interventional study or studies means any systematic study, as defined in § 2a(3) AMG, in which medicinal products are administered to patients with the aim of advancing knowledge regarding the use of a medicinal product as well as its effectiveness and tolerance in practice.
Non-interventional studies are not clinical trials.

Patient organization(s) (including their umbrella organizations) means voluntary, non-profit entities mainly composed of patients and/or caregivers and/or other patient organizations whose sole purpose is to represent the interests of patients and/or caregivers and which exist or were founded to serve those interests.

Pharmaceutical company means any company headquartered in Austria (or the EEA) that researches, places in the stream of commerce, or manufactures medicinal products or active substances or that distributes by wholesale medicinal products or active substances.

Medical sales representative(s) means any person(s) who interact(s) with doctors, dental practitioners, veterinarians, dentists, midwives, pharmacists, or other professionals specified in § 59(3), (4), and (8) AMG in connection with the promotion of medicinal products

undue benefits means bonuses, financial or in-kind benefits, transfers of value, or sponsorships, the acceptance or the grant of which serve to influence improperly the conduct of the recipient and/or to benefit the recipient personally.

Support (Article 10) means any financial support, any indirect support, or any non-financial support provided to a PO.

PHARMIG Code Rules of Procedure Rules of Procedure of the PHARMIG Code Adjudication and Appeal Boards.

Article 3

General principles

A vital part of the services pharmaceutical companies provide to wholesalers, doctors, pharmacists, patients, and the general public consists of providing, as a matter of routine, comprehensive information regarding medicinal products and the findings of any research relating to those products. That information is intended to advise on safetyrelated issues regarding, and is indispensable for the proper use of, medicinal products. For these reasons, it is imperative that HCPs and persons subject to § 59(3) and § 59(4) AMG receive direct, sufficiently complete, and reliable information regarding the existence and the characteristics of any medicinal products they are licensed to prescribe, to administer, and to dispense.

In applying the PHARMIG Code, one must consider and comply with not only the black-letter, but also the spirit and purpose of the individual provisions contained herein as well as with all applicable laws including, but not limited to, those set forth in the AMG, the UWG, and the StGB.

Pharmaceutical companies must, at all times, maintain high ethical standards. In particular, their conduct must never bring discredit upon or reduce confidence in the pharmaceutical industry, and must never be likely to cause offense. They must also give due consideration to the special nature of medicinal products, the wellbeing of patients, and the professional standing of the HCPs addressed.

Pharmaceutical companies must comply with the obligations set forth in the PHARMIG Code even if third parties act on their behalf, be it directly or indirectly.

Article 4

Medicinal product information

Pharmaceutical companies have a key responsibility to communicate all appropriate and objective scientific evidence needed to select and to use medicinal products properly. For this reason, all relevant information must be communicated so as to reflect adequately the significance and the characteristics of medicinal products.

4.1 However, communication efforts may include the following, as they are considered to be of a non-promotional nature:

a. correspondence and documents which are non-promotional and necessary for responding to a specific inquiry regarding a determinate medicinal product;
b. sales catalogs and price lists, provided they do not contain medicinal product information;
c. issue-related information regarding diseases or human health, provided such information does not include any (indirect) reference to any medicinal product;
d. information forming part of pharmacovigilance efforts as coordinated with the proper authorities;
e. company-related information such as for investors or present or future employees, including financial data, research and development program reports and information regarding regulatory developments concerning the company and its products;
f. information about non-authorized medicinal products in response to a documented inquiry made by a HCP;
g. correspondence with authorities such as during the marketing authorization process, as part of pharmacovigilance efforts, or regarding inspections;
h. texts approved by authorities such as SPCs or patient leaflets;
i. informational or educational materials, provided these materials are inexpensive, have direct bearing on the HCP's business practice, and directly enhance patient care;
j. items of medical utility that are aimed directly at the education of HCPs and patient care, provided they are inexpensive and do not offset routine business practices.

Informational or educational materials (i above) and items of medical utility (j above) can include the pharmaceutical company's name, but must not include the name of any prescription-only medicinal product, unless that name is essential for the correct use of those items by the patient. Where names of companies or products may be specified, as described above, they must always be specified in a manner that complies with the applicable promotion and advertising requirements as prescribed by Section V. AMG (Promotion and advertising requirements).

4.2 Scientific and product information relating to medicinal products must be based on state-of-the-art science. It must be accurate, balanced, fair, objective, capable of substantiation, and sufficiently complete to enable the recipient to form an opinion of his or her own regarding the characteristics and the therapeutic value of the product concerned.

4.3 All medicinal product information must be consistent with the label, patient leaflet, and SPC and must be restricted to approved indications. However, this requirement is not intended to impose restraints on purely scientific information regarding outcomes of research which goes beyond approved indications and effects.

4.4 Scientific articles must identify, objectively and conscientiously, any sources used. The source(s) of any data and statements excerpted from scientific studies or publications must be identified. Quotes, tables, and other artwork must indicate the source and be reproduced faithfully.

4.5 Statements excerpted from scientific studies, publications, quotes, tables, graphs, or other artwork must be reproduced faithfully and must not be misleading.

4.6 In particular, due care must be exercised to ensure that any information regarding and any statements about medicinal products is truthful and does not mislead, directly or indirectly, by distortion, undue emphasis, omission, or in any other way.

4.7 Pharmaceutical companies must ensure that they provide substantiated scientific data. That data must recognize the professional standing of the recipients and must not be likely to cause offense.

4.8 Medicinal product information must be provided whenever requested by HCPs. Evidence substantiating approved indications is not required.

4.9 To comply with § 54 AMG in conjunction with § 15 AMG, documents written for HCPs must, at minimum, meet the requirements for SPCs and be in a typeface of sufficient size, design, and color so as to be clearly legible.

4.10 Documents written for HCPs about approved or registered proprietary medicinal products, for which no SPC is required, must contain, at minimum, the relevant sections of text published in the patient leaflet.

4.11 Product-related, direct-to-consumer advertising must never be included in any documents written about prescription-only medicinal products, where those documents will be provided by doctors to patients; are intended to enhance patient compliance and to be used as a complimentary therapeutic measure; and are not informational and training materials (Article 4.1(i)) or items of medical utility/informational or educational items (Article 4.1(j)). Medicinal products can be named.

4.12 Diseases must be identified and treated by doctors only. In response to inquiries concerning individual therapies, the company must advise the person who made the inquiry that he must consult a doctor.

Article 5

Promotion of medicinal products

Promotion is a vital part of the market economy and an expression of intense competition among pharmaceutical companies.

5.1 All promotional efforts undertaken by pharmaceutical companies must be appropriate and consistent with applicable law.

5.2 Medicinal products must never be promoted prior to the grant of the marketing authorization by or registration with the proper authority allowing their sale or supply. The foregoing rule does not apply to the promotion of prescription-only medicinal products within the meaning of § 54 AMG, where that promotion is effectuated at scientific events with a significant proportion of speakers and attendees from other countries.

5.3 Promotion must recognize the professional standing of the recipients and must not be likely to cause offense.

5.4 The true intention of promotional efforts must be evident in their design. So as to enable the recipient to form his or her own opinion of the therapeutic value of the medicinal product, promotion of medicinal products must be objective and must not mislead by exaggeration.

5.5 Promotion must not be disguised and must be transparent. For example: where a pharmaceutical company pays for or otherwise publishes promotional material, that material must not resemble independent editorial matter.

5.6 Third-party publications which treat of medicinal products and their uses and which have been sponsored, in whole or in part, by a pharmaceutical company must indicate clearly that such publications have been so sponsored by that pharmaceutical company.

5.7 Pharmaceutical companies must never:

a. make reference, in their writings or promotional materials, to brands of competitors, unless they have received permission to do so or the reference involves one contemplated by the provisions of the UWG;
b. imitate distinctive features of any promotional element of any competitor, the presentation, the packaging, or the labelling of competitor products;
c. engage in misleading or disparaging promotional efforts;
d. engage in puffery (such as by undue emphasis);
e. claim that a product has no adverse effects, side-effects, toxic hazards, and/or risks of addiction or dependency;
f. use the words "safe" and "safely" without proper qualification;
g. use the word "new" in a non-specific and/or unqualified manner, such that it is unclear to what the word "new" refers;
h. use the word "new" for any medicinal product, indication, pharmaceutical form, application option, dosage, or packaging size, where that medicinal product has been in the stream of commerce for more than one year;
i. make claims about effects not sufficiently reflective of relevant and available scientific evidence.

5.8 To comply with § 54(1) AMG, advertising of medicinal products to persons qualified to prescribe or supply them must include the key information relating to those medicinal products as required by the SPC. Promotion of prescription-only proprietary medicinal products, for which no SPC is required, must contain, at minimum, the relevant sections of text published in the patient leaflet.

5.9 In addition, advertising (be it advertising of medicinal products to persons qualified to prescribe or supply them or direct-to-consumer advertising) must comply with the relevant provisions of this Article 4 (Medicinal product information), the provisions of Section V. AMG (Promotion and advertising requirements), and the relevant provisions of the UWG.

Article 6

Information online and online promotion

6.1 General requirements

a. Article 4 (Medicinal product information) and Article 5 (Promotion of medicinal products) apply, with the relevant modifications, to any informational and promotional material that is made accessible on the internet by pharmaceutical companies, on their behalf, or with their consent.
b. Company websites must clearly specify which pharmaceutical Company operates or, directly or indirectly, sponsors the website and which information on that website is intended for HCPs and/or the general public.
c. Information provided on websites and in emailing lists must be updated regularly and reviewed for accuracy and should include the date of and any relevant information regarding the most recent update. Requests to be removed from emailing lists must be honored.

6.2 Company information

a. Websites may include information of possible interest to investors, the media, and the general public.
b. Websites may include financial data, descriptions of research and development programs, regulatory information pertaining to pharmaceutical companies and their products, information for future employees, and the like.

6.3 Information for patients and the general public

a. Direct-to-customer information that includes any form of promotion must comply with the relevant provisions of Section V. AMG (Promotion and advertising requirements) and the relevant provisions of this Article 5 (Promotion of medicinal products).
b. Websites may include patient and general information of a non-promotional nature regarding the medicinal products distributed by the company (including information about indications, side-effects, interactions with other substances, use, clinical research reports, and the like).
c. Such information must be balanced, accurate, and commensurate with the SPC.
d. Websites can include a link to the complete, unmodified evaluation report published by CHMP or any competent national authority.

e. Websites can include links to other websites, provided the latter contains reliable information regarding medicinal products (websites of authorities, medicinal research institutions, POs, and the like).
f. INNs should be given alongside brand names.
g. Websites must always include the advisory notice to consult a doctor or a pharmacist for more information.

6.4 Information for HCPs

a. Information intended for HCPs that includes any form of promotion must comply with the relevant provisions of Section V. AMG (Promotion and advertising requirements) and the relevant provisions of this Article 5 (Promotion of medicinal products).
b. Information intended for HCPs must be clearly identified as such. There must exist safeguards to ensure that only HCPs receive access to such information.

Article 7

Events for healthcare professionals

Symposia, scientific congresses, workshops, lectures, and similar – small-scale – events are recognized avenues not only of continuing medical education, but also of sharing knowledge and experience relevant to medicinal products and therapies. Events may be organized, undertaken, or sponsored; invitations provided; and costs assumed for participants only if those events are in compliance with the provisions of this Article 7.

7.1 The purpose of events must be, exclusively, to provide scientific and/or educational information related to continuing education efforts.

7.2 Where costs are assumed with these events they must be appropriate and restricted to travel, meals, accommodation, and genuine registration fees. Cost assumption must not include the sponsoring or organizing of leisure activities and/or entertainment (such as theater, concerts, sporting events). It is prohibited to invite and to have participate in events any person accompanying any participant; for this reason, pharmaceutical companies must neither organize nor assume the costs for travel, meals, accommodation, or expenses in connection with leisure activities.

7.3 The attendees, the program, and the scientific and/or subject-matter specific nature of the event must be documented.

7.4 The location must be conducive to the purpose of the event, inside the country, and selected based on objective criteria. The leisure activities available at a location do not constitute a selection criterion.

7.5 International events are events where the registered office of the company that organizes, undertakes, or sponsors the event or its participants is in a country other than the one in which the venue is located.

a. Events may be organized, undertaken, or sponsored and costs may be assumed for participants only if
   1) a significant proportion of attendees are from countries other than the country in which the member company's registered office is located; or
   2) necessary resources or expertise are available at the location and, in view of those resources and expertise, it makes greater logistical sense to select a location outside the country (for instance, professional congresses with international speakers or a tour of the company's own science or manufacturing facilities located outside the country).
b. Organizing, undertaking, and sponsoring international events; providing invitations to international events, and the assumption of costs for their participants are governed by two codes: the national code of the country in which the registered office of the pharmaceutical company is located that organizes, undertakes, or sponsors the international event or that invites or assumes the costs; and the national code of the country in which the international event is located. Here, the term 'code' means the PHARMIG Code and the code applicable at the location with which the EFPIA Code of Practice and/or the IFPMA Code of Practice has or have been implemented. In all cases, the more stringent arrangement applies. The company must give advance notice of activities within the meaning of sentence 1 to an affiliate, if it has one, whose registered office is in the country in which the venue is located or the company must seek relevant advice on how those activities can be carried out appropriately in that country.

7.6 Organizing, undertaking, or sponsoring events; providing invitations; or assuming the costs for their participants must not constitute an inducement to prescribe, to dispense or to recommend any particular medicinal product.

7.7 Where a HCP offers services during an event, pharmaceutical companies must ensure that, prior to the start of the event, all potential conflicts of interest are duly disclosed to the organizer and the participants.

7.8 Where pharmaceutical companies disseminate information regarding the subject matter covered at an event, they must ensure that such information is accurate.

7.9 Under Article 16, PHARMIG's Board has the authority to issue PHARMIG Code Guidance regarding Articles 7.1 through 7.4 (governing the nature, scope, and appropriateness of event locations and venues and their documentation).

Article 8

Interactions with healthcare professionals and healthcare organizations

Researching and enhancing effective medicinal products requires close, professional interactions with HCPs.

8.1 Prescriptions and recommendations

HCPs must not be granted, offered, or promised bonuses or benefits, be they in cash or in-kind, in exchange for prescribing, dispensing or administering any medicinal product or for recommending any medicinal product to patients.

8.2 Interactions with healthcare professionals

a. HCP services provided on behalf of pharmaceutical companies (such as speaking or consulting engagements, clinical trials, NIS) must be conducive to training, continuing education, research, or healthcare system support efforts and must be provided as part of scientific or subject-matter specific activities. A written contract or agreement must be entered into, which clearly specifies not only the compensation for, but also the nature, scope, and purpose of the services to be provided.

b. Compensation must consist of money only and be reasonable and reflect the proportionate value of the service provided. Hourly rates can be agreed to account for time expended. The compensation arrangement can include the reimbursement of reasonable cash outlays, including travel expenses. To determine how to compensate doctors appropriately for their services, one can consult, among other things, the *Gebührenordnung für Ärzte* (the Doctor's Fee Schedule).

c. Engaging HCPs to provide services must not be an inducement to recommend, to prescribe,dispense or to administer any particular medicinal product.

d. HCPs must not be granted, offered, or promised bonuses or benefits, be they in cash or in-kind, to induce them to receive medical sales representatives or to accept information from other people who belong to the company.

e. Visits to HCPs and hospitals should not be obtrusive either with respect to their frequency or to the manner in which they are made. Pharmaceutical companies must require their medical sales representatives to respect fair trade practices.

f. Hospitality may be extended to HCPs only as part of events or business meals whose purpose consist of exchanging information and must be reasonable and moderate as judged by local standards. The occasion must be documented. Hospitality must not be extended to any persons accompanying any HCP.

8.3 Interactions with healthcare professionals who are public officials

In addition to being governed by the PHARMIG Code, interactions with HCPs who are public officials are also governed by the StGB and any and all applicable professional and organizational rules and regulations.

8.4 Interactions with healthcare organizations

a. HCO services provided for pharmaceutical companies must be conducive to training, continuing education, research, or healthcare system support efforts and must be provided as part of scientific or subject-matter specific activities. A written contract or agreement must be entered into, which clearly specifies not only the compensation for, but also the nature, scope, and purpose of the services to be provided.

b. Engaging HCOs to provide services must not constitute an inducement to recommend, to prescribe, to dispense or to administer any particular medicinal product.

c. Pharmaceutical companies must never agree to and HCOs must never grant any exclusive support of any HCO and/or their programs.

8.5 Donations and grants

a. Pharmaceutical companies may make donations and grants, be they in cash or in-kind, to HCOs only if they are made for the purpose of supporting healthcare, research, or educational efforts or are provided as part of scientific or subject-matter specific activities.
b. Whenever pharmaceutical companies make donations or grants, they must keep back-up material showing the donation or grant including the nature, scope, and purpose of that donation or grant; the recipient of the donation or grant; and the recipient's consent to the disclosure of that donation or grant by the pharmaceutical company. Donations and grants must be disclosed to the public online in accordance with Article 9.
c. Donations and grants by pharmaceutical companies must never constitute an inducement to recommend, to prescribe, or to dispense any particular medicinal product.
d. Donations and grants to individuals who are HCPs are prohibited.
e. The foregoing is without prejudice to support permitted by the PHARMIG Code.

8.6 Non-interventional studies

a. A NIS must be designed, verified, and authorized under the direction of the scientific service of the pharmaceutical company or, if no such service exists, under the direction of a person with the requisite scientific qualifications.
b. Any financial compensation provided for the requisite NIS documentation must be reasonable and moderate as judged by local standards. To determine how to compensate doctors appropriately for their services, one can consult, among other things, the *Gebührenordnung für Ärzte* (the Doctor's Fee Schedule).
In any event, the compensation for any service provided as part of any NIS must not constitute an inducement to prescribe, to dispense or to administer any particular medicinal product.
c. The conduct of a NIS in Austria must comply with the AMG and the *Verordnung des Bundesministers für Gesundheit über die Meldepflicht von Nicht-Interventionellen Studien* (Regulation of the Federal Minister of Health governing non-interventional studies and reporting requirements), published in the BGBl (Federal Law Gazette). II Nr. 180/2010, as these may be amended from time to time.

8.7 Undue benefits for representatives of healthcare organizations

Pharmaceutical companies must not offer or give undue benefits, be it directly or indirectly, to any representatives of any HCO.
The foregoing is without prejudice to any benefits permitted by the PHARMIG Code and applicable law.

8.8 Medical samples

Medical samples are provided to doctors and patients so that they may acquire experience in the use and effectiveness of the medicinal product and, by extension, to enhance medication adherence.
a. Under § 58 AMG, pharmaceutical companies may provide medical samples to doctors, dental practitioners, veterinarians, and dentists.
b. Pharmaceutical companies must have adequate systems of control and accountability for medical samples provided by them. Relevant back-up material must be kept showing all medical samples provided.
Medical samples must be provided, exclusively, free of charge and only after they have been marked, in a manner that is clearly legible and nonremovable, 'free medical sample – not for sale,' and such samples must be in packaging that is no larger than the smallest retail package of the particular medicinal product.
c. Under § 58 AMG, free medical samples may be provided to recipients:
   - within a time period of one year after initial distribution of the proprietary medicinal product within the meaning of § 57 AMG in a quantity sufficient to evaluate the therapeutic response for a maximum of ten patients, but for a total not to exceed 30 medical samples of any proprietary medicinal product per recipient; and
   - after the time period specified in item 1 has lapsed, a total not to exceed 2 medical samples per request, for any one recipient, but for a total not to exceed five medical samples of any proprietary medicinal product per year.
d. There exists a ban on medical sampling of medicinal products containing psychotropic or narcotic substances.

8.9 Contribution for promotional material/use of logos or proprietary information

All HCO-supported advertising and any use of logos or copyright-protected proprietary material by pharmaceutical companies or by HCOs is subject to the requirements governing promotion as set forth in the PHARMIG Code and requires written permission.

8.10 Authority to issue guidance

Under Article 16, PHARMIG's Board has the authority to issue PHARMIG Code Guidance regarding Articles 8.2 (documenting interactions, compensation), 8.5 (governing donations and grants), 8.6 (governing the nature, scope, and appropriateness of NIS and their documentation), 8.8 (governing the provision of doctor samples and their documentation), and 8.2(f) (governing hospitality).

Article 9

Transparency

Interactions between pharmaceutical companies, on the one hand, and HCOs and HCPs, on the other, are vital to the maintenance and advancement of the best possible pharmaceutical care. Transparency is an important means of building and maintaining trust and confidence in these interactions. And the greatest transparency is afforded by disclosing specific information relating to every transfer of value engendered by these interactions on an individual basis. For this reason, all parties involved in such transfers must work, amicably, toward the individual disclosure of transfers of value.

9.1 Scope

Article 9 covers the disclosure of interactions between pharmaceutical companies, on the one hand, and HCOs and HCPs, on the other, and applies to the documentation and disclosure of transfers of value by pharmaceutical companies in connection with prescription-only medicinal products.
The purchase and sale of medicinal products is not covered by this Article 9.

9.2 Documentation and disclosure requirement

Pharmaceutical companies must document and disclose any and all transfers of value to HCOs and HCPs.

9.3 Categories of transfers of value

The disclosure requirement applies only to transfers of value in connection with

a. research and development;
b. donations and grants;
c. events;
d. fees for services and consultancy, including all outlays.

9.4 Form of disclosure

Disclosures must contain information, on an individual basis, for each clearly identifiable HCO and HCP, and the amount attributable to transfers of value during the reporting period, unless they constitute support of the kind specified in Article 9.3(b), 9.3(c), or 9.3(d).

Disclosures must be itemized as follows:

a. Transfers of value to individual HCPs:
   1) Transfers of value in connection with events:
      (i) genuine registration and attendance fees;
      (ii) travel and accommodation expenses.
   2) Fees for services and consultancy, broken down by fee payments and the reimbursement of outlays.
b. Transfers of value to individual HCOs:
   1) In cash or in-kind donations and grants;
   2) Transfers of value in connection with events:
      (i) genuine registration and attendance fees;
      (ii) sponsorship of HCOs or third parties retained by HCOs to undertake the event;
      (iii) travel and accommodation expenses.
   3) Fees for services and consultancy, broken down by fee payments and the reimbursement of outlays.

Where transfers of value covered by Article 9.4(a) are made indirectly to a HCP via a HCO, disclosure should be made only once.

9.5 Aggregated (summarized) disclosure

Research and development transfers of value must be disclosed on an aggregate basis and not on an individual HCP or individual HCO named basis. Such includes the reimbursement of outlays for the participation in events connected with research and development activities.
Beyond the foregoing, transfers of value must be disclosed on an aggregate basis, where names of HCOs or HCPs cannot be disclosed for legal reasons. In these cases, transfers of value must be broken down by category and disclosed on an aggregate basis, stating not only the number of recipients on an absolute basis and as a percentage of all recipients of transfers of value per category, but also the aggregate amount attributable to each category.

9.6 Reporting period, disclosure date, methodology

The reporting period is the calendar year. The initial reporting period is the 2015 calendar year. Disclosures must be made once per year and by no later than 6 months after the reporting period has ended.

9.7 Location and duration of disclosures

The information disclosed must remain on a public, pharmaceutical-company-controlled website and be in the English or German language. The information disclosed must remain in the public domain for at least 3 years from the date of initial disclosure, unless a shorter time period is mandated by law.

9.8 Transfers of value to foreign HCOs and HCPs

Where transfers of value are made by pharmaceutical companies to any HCO or HCP, who primarily practice their profession or have their registered office in a European country other than Austria, these transfers must be disclosed by the affiliate which operates in the country in which the relevant recipient of any such transfer of value has its registered office. The information and documents subject to disclosure must be forwarded, in due time, by the pharmaceutical company to the affiliate for purposes of disclosure. Where no affiliate exists that can disclose the transfer of value, the pharmaceutical company that made the transfer must make the disclosure.

Where transfers of value are made to HCOs or HCPs, who primarily practice their profession or whose registered office is in Austria, by companies whose registered office is outside Austria, these transfers must be disclosed by the affiliate pharmaceutical company in Austria, to the extent that the information and documents subject to disclosure are provided by the affiliate.

In addition to the foregoing, transfers of value to any foreign country shall be subject to the applicable national code of that country.

9.9 Authority to issue guidance

Under Article 16, PHARMIG's Board has the authority to issue PHARMIG Code Guidance regarding Articles 9.4 through 9.8 (governing individual disclosures, aggregate disclosures, the reporting period, the date of disclosure, the methodology, location and duration of disclosure, and foreign transfers of value); and standard documentation and disclosure forms.

Article 10

Interactions with patient organizations

Interactions between pharmaceutical companies and POs are based on common interests and must occur in an ethical and transparent manner.

Interactions shall be guided by the principle of PO self-determination and, by extension, PO independence.

10.1 Promotion and advertising requirements

All PO-sponsored advertising and any use of logos or copyright-protected proprietary material by pharmaceutical companies or by POs is subject to the requirements governing promotion as set forth in the PHARMIG Code and requires written permission as set forth in Article 10.3.

10.2 Support

a. Support means any financial support, any indirect support, or any non-financial support provided to a PO and its members. This Article 10 applies neither to indirect support nor to non-financial support, provided that support is of minimal value.
b. Support of POs and their members must serve only the interest of patients and/or their families.
c. Pharmaceutical companies must never agree to and POs must never grant the exclusive support of POs and/or their programs.

10.3 Written permission

a. Support requires written permission.
b. Such permission must contain sufficiently complete information pertaining to the nature, scope, and purpose of the sponsorship, a description of the relevant sponsorship, and the consent of the PO to disclosure by the pharmaceutical company as set forth in Article 10.6. In each case, written permissions must include the amount provided for the sponsorship.
c. Furthermore, pharmaceutical companies must ensure that their support to POs is always clearly acknowledged and apparent from the outset.

10.4 Service agreements

a. PO services for pharmaceutical companies are allowed only if they are conducive to continuing education, research, or healthcare system support efforts and are provided as part of scientific or subject-matter specific activities.

b. Service agreements must be entered into in writing; specify not only the compensation for, but also the nature, scope, and purpose of the services to be provided; and contain the consent of the PO to disclosure by the pharmaceutical company as set forth in Article 10.6. The compensation must consist of money only and be reasonable and reflect the appropriate balance of the service provided.

c. Service agreements must require POs to make sufficiently complete disclosures of their activities whenever they write or speak in public about a matter that is subject of or contained in the agreement or any other matter relating to the pharmaceutical company generally.

d. Entering into service agreements must never constitute an inducement to recommend any particular medicinal product.

e. Pharmaceutical-company service agreements for POs, provided they are of minimal value, must be entered into in writing.

10.5 Transparency

Interactions between pharmaceutical companies and POs must be transparent. Accordingly, pharmaceutical companies must maintain clear back-up material showing the PO sponsored by the pharmaceutical company as well as the nature, scope, and purpose of that sponsorship.

10.6 Publication requirements

a. Pharmaceutical companies must make publicly available on their websites a list of all POs which have been sponsored by or – as contemplated under Article 10.4 – have entered into agreements with the pharmaceutical company. The publication must include the nature, scope, and purpose of the sponsorship or the nature, scope, and purpose of the service. This publication requirement applies neither to indirect support nor to non-financial support nor to agreements pursuant to Article 10.4, provided such support is of minimal value.

b. Publications must include, for each calendar year and for each PO, the sum of the financial support or non-financial support provided and the sum of the fees for services provided. Where indirect support or non-financial support cannot be assigned a meaningful monetary value, the benefits provided to the PO must be described in a clear and sufficiently complete manner.

c. All information published must be updated at least once per year (but by no later than as of 30 June for the previous calendar year).

10.7 Events/patient organizations

a. Events are symposia, congresses, workshops, lectures, and similar – small-scale-events/meetings between POs, their members, patients, and other invited participants conducted with the purpose of sharing information, exchanging information, sharing knowledge and experience relevant to medicinal products and therapies, and/or continuing medical education.
Events may be organized, undertaken, or sponsored; invitations provided; and costs may be assumed only if those events are in compliance with the provisions of this Article 7.

b. The assumption of costs for POs, patients, and other invited participants in connection with these events must be appropriate and restricted to travel, meals, accommodation, and genuine registration fees. Where illness or disability requires assistance by another person, costs may be assumed to cover the costs incurred. It is prohibited to invite or to arrange for the participation of any person accompanying any participant as well as to assume their costs.

c. Activities bearing no factual and/or professional connection to the actual objective and purpose of the event must never be sponsored, financed, or organized by pharmaceutical companies; in particular, the foregoing applies to leisure activities and/or entertainment (such as theater, concerts, sporting events).

d. Where the participants are HCPs, the provisions of Article 7 must be observed.

e. Events outside the country in which the pharmaceutical company has its registered office may be organized, undertaken, or sponsored; invitations provided; and costs may be assumed for members of POs, patients, and other invited participants only if
   1) a significant proportion of attendees are from countries other than the country in which the member company's registered office is located; or
   2) necessary resources or expertise are available at the location and, in view of those resources and expertise, it makes greater logistical sense to select a location outside the country.

f. In addition, Articles 7.3, 7.4, 7.6, 7.7, and 7.8 apply to events organized, undertaken, and/or sponsored by or on behalf of any pharmaceutical company.

10.8 Undue benefits for patient organization representatives

Pharmaceutical companies must not offer or give undue benefits, be it directly or indirectly, to any representatives of any PO.
The foregoing is without prejudice to any benefits permitted by the PHARMIG Code and applicable law.

10.9 **Editorial work**

Pharmaceutical companies must never influence the editorial work of any PO publication sponsored by them absent a legitimate factual reason to do so (such as correcting factual inaccuracies or correcting points of science). Commercial interests do not constitute such a legitimate factual reason.

10.10 **Authority to issue Guidance**

Under Article 16, PHARMIG's Board has the authority to issue PHARMIG Code Guidance regarding Articles 10.2 (governing support of minimal value and governing the nature and scope of any sponsorship), Article 10.4 (governing service agreements and the documentation of interactions and compensation), Article 10.5 (transparency), Article 10.6 (publication requirement), and 10.7(b) (governing the appropriateness and documentation of events).

Article 11

Benefits

11.1 Pharmaceutical companies and their employees must never accept any bonuses or in cash or in-kind benefits from HCPs or allow them to promise such, unless they are of minimal value. There exists an across-the-board ban on demanding bonuses and in cash and in-kind benefits.

11.2 Pharmaceutical companies and their employees must never offer, promise, or grant HCPs any bonuses or in cash or in-kind benefits.

11.3 The foregoing is without prejudice to any benefits permitted by the PHARMIG Code and applicable law.

Article 12

Games of chance

12.1 Pharmaceutical companies are prohibited from engaging in any promotional efforts involving games of chance, the winning or losing of which depends on chance alone.

12.2 Contests are permitted, where participation in those contests depends on the participant's scientific or professional achievement and where the prize for those contests constitutes a benefit within the meaning of Article 11. It is prohibited to dispense medicinal products as part of contests.

12.3 Under Article 16, PHARMIG's Board has the authority to issue PHARMIG Code Guidance regarding Article 12.2 (governing the nature, scope, and appropriateness of prizes offered).

Article 13

Employees of pharmaceutical companies

13.1 Pharmaceutical companies must ensure and document that all staff and all third parties have appropriate qualifications. Moreover, persons in qualified positions must be fully conversant with applicable legal requirements, internal policies, and the PHARMIG Code to ensure their ability to provide complete and accurate product information. Every company must designate one contact person who shall be responsible for questions in connection with the PHARMIG Code.

13.2 Pharmaceutical companies must ensure that medical sales representatives engaged on their behalf satisfy the requirements set forth in § 72 through § 74 AMG and have the requisite scientific knowledge of the medicinal products they promote to ensure their ability to provide precise and complete information to doctors, pharmacist, and the persons contemplated by § 2(1), § 59(3), and § 59(4) AMG. Medical sales representatives must discharge their duties not only responsibly and ethically, but also in accordance with applicable law and the PHARMIG Code.

13.3 Persons who design informational and promotional materials must be fully conversant with the requirements imposed by the PHARMIG Code. Informational and promotional materials must be approved prior to publication by a doctor, pharmacist, or information officer.

Article 14

Clinical trials

14.1 Clinical trials must conform to any and all applicable laws, rules, and regulations (AMG, GCP, data protection etc.). Their sole purpose is to advance scientific knowledge and to verify scientifically what is already known; as such, no other purposes are allowed to be pursued.

14.2 The details provided in connection with ongoing clinical trials and the results of completed clinical trials must be consistent not only with applicable data protection law, rules, and regulations, but also with the scientific mission of such trials.

Article 15

AMG violations

Violations of Section V. AMG (Promotion and advertising requirements) are breaches of the PHARMIG Code.

Article 16

PHARMIG Code guidance

PHARMIG's Board has the authority to issue specific guidance regarding individual articles of the PHARMIG Code (PHARMIG Code Guidance). PHARMIG Code Guidance must refer to each specified article of the PHARMIG Code and fall within the purview of such article.

Guidances of the PHARMIG Board

Guidance 1/2010
of the PHARMIG Board regarding Article 8 of the PHARMIG Code of Conduct (Non-interventional studies)

Non-interventional studies are systematic studies of medicinal products involving the collection of patient data in connection with the use, the effectiveness, and the tolerance of medicinal products in practice.

A NIS must be designed, verified, and approved under the direction of the scientific service of the pharmaceutical company or, if no such service exists, under the direction of a person with the requisite scientific qualifications.

Under Article 16 of the PHARMIG Code, the PHARMIG Board issues, in connection with Article 8.6 of the PHARMIG Code and Article 8.10 of the PHARMIG Code, the following

Guidance regarding article 8 of the PHARMIG Code

Article 1

Scope

1.1 In addition to the provisions both of the AMG, with its implementing regulations, and of the PHARMIG Code, the guidance set forth herein applies to NIS, as defined in § 2a(3) AMG.

1.2 In particular, the term "NIS" denotes post-market surveillance, case-control studies, cross-sectional studies, correlation studies involving aggregated data, registry analyses, and spontaneous reporting systems.

1.3 This guidance applies to any pharmaceutical companies who design, review, approve, and/or finance any NIS or on whose behalf any NIS is designed and/or reviewed.

Article 2

Definitions

2.1 For purposes of this guidance, the following terms shall have the following meanings:

- **a.** "design" is defined to mean, but shall not be limited to, the planning of NIS; the developing of the study plan; the drafting of the requisite contracts/agreements; the selecting of suitable research tools (such as questionnaires, hemograms, peak flows, x-rays, ECGs); the implementing of NIS (such as selecting and approaching physicians/medical institutions/pharmacies); the preparing of the appropriate documentation; the conducting of the NIS, including assisting in the NIS during the run time; the analyzing of the study results; the preparing of the summary report;
- **b.** "review" is defined to mean, but shall not be limited to, all quality assurance measures whose objective is to assure that data are complete and valid and to remedy any shortcomings;
- **c.** "approval" is defined to mean, but shall not be limited to, companies' internal approval process.

Article 3

Purpose of NIS

3.1 NIS are studies designed to collect data as well as to broaden and to advance knowledge concerning the use, the effectiveness, and the tolerance of medicinal products, when prescribed in the usual manner in accordance with the terms of their marketing authorization. In particular, this means:

- **a.** collecting data in connection with SPC and patient leaflet adherence, acceptance and compliance, practicability, adherence to marketing authorization requirements;
- **b.** collecting data in connection with previously unknown, especially rare, adverse, medicinal effects and interactions;
- **c.** collecting data in connection with special populations within the parameters of authorized indications;

d. broadening knowledge of known adverse effects of any medicinal product when prescribed in the usual manner (for instance, severity assessment, frequency estimates, interactions);
e. advancing knowledge within the parameters of approved indications of any medicinal product when prescribed in the usual manner.

3.2 NIS do not constitute evidence of efficacy in terms of phase II through phase IV clinical trials.

3.3 NIS must not be abused to induce therapy or supply decisions or for purely promotional purposes. The decision to prescribe a medicinal product must be separated from the decision to include the patient in a NIS.

Article 4

NIS are not clinical trials

4.1 NIS differ from clinical trials, in that they are non-interventional. For purposes of NIS, the term "non-interventional" means that
a. the attending physician is given no information whether or not medicinal products should be included in any therapeutic strategy and which facts and circumstances must hold to discontinue or to modify any given strategy and
b. any treatment involving the medicinal products adheres to the terms of their marketing authorization (such also includes all information specified in the marketing authorization regarding contraindications, dosages, and dosage schedules, ancillary medicines, patient populations, combination therapies, and the like); and
c. the physician provides treatment, including diagnosis and monitoring, as he or she would routinely provide treatment in keeping with local practice; and
d. no additional diagnostic and/or therapeutic procedures are applied to and no additional burdens placed upon any patient.

Article 5

Designing a NIS

5.1 A NIS must be designed under the direction of the scientific service of the pharmaceutical company or, if no such service exists, under the direction of a person with the requisite scientific qualifications, which person must not be subordinated to a marketing/sales department. Where employees from other departments are involved in the design of a NIS, those employees must receive appropriate training, and that training must be documented.

5.2 The choice of a suitable research tool shall be determined by the scientific objective pursued with the NIS. Obtaining this objective necessitates that the research tool chosen be methodically sound, meaningful, and efficient (for instance, as regards the number of patients).

5.3 Study plan

5.3.1 The study plan must follow routine practice/treatment, though specifications set forth in the study plan should render possible systematic observation and reinforce the objective of observational equality.

5.3.2 Study plans must contain, at least, the following information:
a. formulation of a (or several) detailed question(s), complete with the justification for why the NIS constitutes a proper method to answer the question(s) posed;
b. determination of the surveyable features, a description of their relevance, and the role they play in answering the question(s) posed (command, influencing, and disturbance variables);
c. observation schedule (procedure and survey periods);
d. description of the survey tools required for observation, including the reason why the data so collected can answer the question(s) posed;
e. description of the selection procedure for identifying candidate physicians/medical institutes/pharmacies;
f. description of the nature and scope of the documentation for physicians/medical institutes/pharmacies;
g. justification of the number of patients to be included;
h. stipulation of the reporting channels for adverse effects;
i. description of quality assurance procedures;
j. description of the statistical analysis method to be used, though the data must be analyzed with biometric methods befitting the issues addressed and the proposed procedure must be memorialized in the study plan at the outset;

k. stipulation of the roles (such as sponsor, project manager, head biometrician), though the pharmacovigilance officer must be involved in order to ensure compliance with applicable reporting requirements, as set forth in the *Pharmakovigilanz-Verordnung* (Pharmacovigilance Regulation);
l. stipulations governing not only reporting modalities, including biometric and medicinal evaluation, but also proposed publication efforts;
m. justification whether the manner in which patient data will be handled necessitates the provision of additional information; where applicable, description regarding how patient consent shall be obtained.

5.3.3 In addition to the foregoing, study plans must, where applicable, contain the following information:
a. description of patient selection procedure, though measures must be taken, not only which are specific to the question(s) posed, but also which guarantee the greatest possible representativeness of the patients included in the NIS (such as through the inclusion, where possible, of all patients of each physician; through a logbook of available patients);
b. description of the methods used to guarantee representativeness (for physicians/medical institutes/pharmacies and/or patients);
c. discussion of possible disturbance variables and description of neutralization procedures;
d. documentation template and patient consent form template.

5.4 Summary report

5.4.1 The summary report must contain, at least, the following information:
a. all information required by Article 5.3.2 and, where applicable, by Article 5.3.3, as engendered by the study plan;
b. a biometric analysis of the data collected;
c. where applicable, an assessment of the effects, including, but not limited to, adverse effects, from a medicinal standpoint;
d. all adverse effects reported during the NIS, which are required to be reported under § 75b(1) AMG;
e. a list of all participating physicians/medical institutes/pharmacies.

5.4.2 The summary report must be finalized by no later than twelve (12) months after the NIS has concluded (based on the last observation of the last patient who participated in the NIS) and must be archived for a minimum time period of fifteen (15) years.

5.5 The NIS results must be presented, properly, in periodic safety update reports. Where necessary, the medicinal product's benefits-versus-risk profile must be updated and, where one exists, the risk management plan revised.

Article 6

Reviewing a NIS

6.1 A NIS must be reviewed under the direction of the scientific service of the pharmaceutical company or, if no such service exists, under the direction of a person with the requisite scientific qualifications, which person must not be subordinated to a marketing/sales department. Where employees from other departments are involved in the design of a NIS, those employees must receive appropriate training, and that training must be documented.

6.2 Quality assurance must involve systems which assure that the data collected are valid and representative. For instance: where no data controls exist on site, as is customarily the case, greater care must be given to plausibility and completeness controls.

6.3 Data must be reviewed, coordinated, and analyzed with the aid of a sufficiently qualified person.

Article 7

Approving a NIS

7.1 A NIS must be approved under the direction of the scientific service of the pharmaceutical company or, if no such service exists, under the direction of a person with the requisite scientific qualifications, which person must not be subordinated to a marketing/sales department. Where employees from other departments are involved in the design of a NIS, those employees must receive appropriate training, and that training must be documented.

Article 8

Entry into force and transitional provisions

8.1 This guidance enters into force on 1 March 2010.

8.2 NIS for which the initial patient is documented after 30 June 2010 must comply with the specifics of this guidance.

8.3 The amendments set forth in the preamble to this guidance enter into force on 1 July 2014.

Guidance 1/2014 of the PHARMIG Board regarding Article 7 and Article 8 of the PHARMIG Code of Conduct (Caps: meals, hospitality)

Events for healthcare professionals such as symposia, scientific congresses, workshops, lectures, and similar – small-scale – events are recognized avenues not only of continuing medical education, but also of sharing knowledge and experience relevant to medicinal products and therapies. Events must serve the exclusive purpose of providing scientific information and/or continuing medical education.

Where events are organized, undertaken, or supported; where invitations to events are made; or where participants' costs are assumed, the *Arzneimittelgesetz* (Medicinal Products Act, the "AMG"); the PHARMIG Code of Conduct (the "PHARMIG Code") including, but not limited to, Article 7 of the PHARMIG Code; and the provisions of any laws as may be applicable in any specific case must be complied with as a matter of necessity.

Under Article 7.2 of the PHARMIG Code, the assumption of costs during such events must be appropriate and restricted to travel, accommodation, and genuine registration fees; leisure activities and/or entertainment programs must be never be financed or organized.

Extending hospitality to healthcare professionals under Article 8.2f) of the PHARMIG Code as part of business meals is for the purpose of exchanging information and must be reasonable and moderate as judged by local standards.

Under Article 16 of the PHARMIG Code, the PHARMIG Board issues, in connection with Article 7.2 of the PHARMIG Code and Article 8.2f) of the PHARMIG Code, as reserved under Articles 7.9 the PHARMIG Code and Article 8.10 of the PHARMIG Code, the following

Guidance regarding Article 7 and Article 8 of the PHARMIG Code

Assuming costs for meals during events within the meaning of Article 7 of the PHARMIG Code and/or as part of business meals for the purpose of exchanging information within the meaning of Article 8.2f) of the PHARMIG Code shall, in any case, be regarded as appropriate if the amount does not exceed **EUR 75.00 per person per meal** (including taxes and/or duties and tips).

Where costs for meals during an event are assumed within the meaning of Article 7 of the PHARMIG Code and/or as part of business meals for the purpose of exchanging information within the meaning of Article 8.2f) of the PHARMIG Code, the code of the country applies in which the meal has been provided. Where no dispositive rules and regulations exist in that country, the PHARMIG Code shall apply.

This guidance enters into force on 1 July 2014.

1st amendment to Guidance 1/2014 of the PHARMIG Board regarding Article 7 and Article 8 of the PHARMIG Code of Conduct:

The amount of Euro 75.00 mentioned in the CoC-Guidance 1/2014 is replaced by **Euro 85.00 per person per meal.**
The rest of the text remains unchanged.

The amended version of the guidance enters into force on 1 January 2022.

Guidance 2/2014 of the PHARMIG Board regarding Article 9 of the PHARMIG Code of Conduct (Transparency)

Interactions between pharmaceutical companies, on the one hand, and HCOs and HCPs, on the other, are vital to the maintenance and advancement of the best possible pharmaceutical care. Transparency is an important means of building and maintaining trust and confidence in these interactions. And the greatest transparency is afforded by disclosing specific information relating to every transfer of value engendered by these interactions on an individual basis. For this reason, all parties involved in such transfers must work, amicably, toward the individual disclosure of transfers of value.

Under Article 16 of the PHARMIG Code, the PHARMIG Board issues, in connection with Articles 9.4 and 9.5 of the PHARMIG Code, the following

Guidance regarding Article 9 of the PHARMIG Code

1. In order to ensure that the data disclosable under Article 9 of the PHARMIG Code can be duly documented, the PHARMIG Board issues, in the form set forth in **Exhibit ./1 of this PHARMIG Code Article 9 Guidance, as appended hereto, a "Standardized disclosure template."**
   The objective of **Exhibit ./1** is to render it possible that the data of the persons concerned can be documented in a unified manner.
   Use of **Exhibit ./1** is not obligatory; however, where pharmaceutical companies refrain from using **Exhibit ./1,** those companies must ensure that the scope and the content of the methodology they use to document data comports in full with the methodology which is contained in **Exhibit ./1,** prescribing which data must be disclosed in what form.
   To facilitate use, PHARMIG shall make available **Exhibit ./1,** as an electronic Excel file, on its website – www.pharmig.at – under the "Code of Conduct" section.

2. The following methods must be used to document disclosable data:
   - The accepted accounting principles used by the respective pharmaceutical company must be applied to disclosures as concerns questions of accrual, valuation, and/or other matters.
   - The accepted accounting principles must be used and applied especially as concerns the accrual of performances such as in cases involving contractual relationships extending over several years or services being rendered recurrently through more than one reporting period.
   - Documented transfer-of-value disclosures must be given as net amounts (less payable taxes and/or duties).
   - Documented transfer-of-value disclosures must be given in EURO. Where disclosable transfers of value have been rendered in a foreign currency, such must be converted into EURO; the conversion must be effectuated in keeping with accepted accounting principles.

This guidance enters into force on 1 July 2014.

Exhibit ./1 to Guidance 2/2014
Standardized disclosure template

Disclosure template – Article 9 CoC (Transparency)							Reporting period (calendar year):			Date of publication:		
	Full Name	**Practice or business address**			Where available: physician number, commercial register number, association register number	**Donations and Grants to HCOs**	**Contribution to costs of events** (cf. Article 9.4a 1) (i), (ii) CoC and/or Article 9.4b 2) (i), (ii), (iii) CoC)			**Fees for services and consultancy** (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 agreements with HCOs / third partiesappointed by HCOs to mange an event	Registration fees	Travel & Accomodation	Fees	Outlays	
HCPs	**Individual named disclosure for healthcare professionals**											[one line per HCP, all transfers of value during a reporting period for an individual HCP will be 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
HCOs	**Individual named disclosure for healthcare organizations**											[one line per HCO, all transfers of value during a reporting period for an individual HCO will be summed up]
	HCO 1					Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Optional
	HCO 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 organizations											
	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 HCO recipients by subtype					%	%	%	%	%	%	N/A
R & D	**Aggregate disclosure for research & development**											
	Transfers of value re 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 2.2 CoC
HCO = healthcare establishments, organizations or institutions within the meaning of Article 2.2 CoC
R&D = research and development
The reporting period is the calendar year

Guidance 1/2015
of the PHARMIG Board regarding Article 7of the PHARMIG Code of Conduct (Events)

Events for Healthcare Professionals such as symposia, scientific congresses, workshops, lectures, and similar – small-scale – events are recognized avenues not only of continuing medical education, but also of sharing knowledge and experience relevant to medicinal prod-ucts and therapies.

Where events are organized, undertaken, or supported; where invitations to events are made; or where participants' costs are assumed, the *Arzneimittelgesetz* (Medicinal Products Act, the "AMG"); the PHARMIG Code of Conduct (the "PHARMIG Code") including, but not limited to, Article 7 of the PHARMIG Code; and the provisions of any laws as may be applicable in any specific case must be complied with as a matter of necessity.

Under Article 16 of the PHARMIG Code, the PHARMIG Board issues, in connection with Articles 7.1 through 7.4, as reserved under Article 7.9 of the PHARMIG Code, the following

Guidance regarding Article 7 of the PHARMIG Code:

At the threshold, it should be noted that, in evaluating events within the meaning of Article 7 of the PHARMIG Code, events must be considered in their entirety by giving due consideration to all the elements involved in each event; in particular, it is imperative that, in considering the event in its entirety, no – even seemingly – improper influence in connection with any healthcare professional is revealed.

1. In keeping with Article 7.1 of the PHARMIG Code, the purpose of events must be restricted only to scientific information and/or continuing educational efforts. Any leisure activity and/or entertainment program which takes place in close chronological connection with any event stands in contradiction to this purpose. A close chronological connection exists whenever leisure activities or entertainment programs take place during or within twenty-four (24) hours prior to or after the end of an event. This applies independent of whether the leisure activity and/or the entertainment program is organized, undertaken, or supported by any pharmaceutical company.

2. Under Article 7.2 of the PHARMIG Code, the assumption of costs in connection with these events must be appropriate and restricted to travel, meals, accommodation, and genuine registration fees. Exactly how and which costs are assumed will be determined by the agreement reached between the pharmaceutical company and the respective attendees.

2.1 Where pharmaceutical companies support an event, they must ensure that the support provided by them is used only for the purpose of providing scientific information and/or continued medical education or is conducive to said purpose; the organizer must confirm that any support provided by any pharmaceutical company is in compliance with applicable law and the PHARMIG Code.
In this connection, the PHARMIG Board issues, in the form set forth in Exhibit ./1 of this PHARMIG Code Article 7 Guidance, as appended hereto, a "Legal and PHARMIG Code Compliance Confirmation Form for Pharmaceutical Company Support."
Use of Exhibit ./1 is not obligatory; however, where pharmaceutical companies refrain from using Exhibit ./1, those companies must ensure that the scope of the confirmation they use comports in full with Exhibit ./1.

2.2 In keeping with Article 7.2 of the PHARMIG Code, leisure activities and/or entertainment programs must never be organized and/or supported for event attendees. Such applies independent of whether the leisure activity and/or entertainment program is organized and/or supported by the organizer himself; HCPs; HCOs; or a third party.
Every kind of program which is not conducive to providing scientific information and/or continuing medical education and which creates the impression of a private and experience-oriented character (such as musical renditions, cultural outings, sporting events, and the like) must be regarded as prohibited leisure activities and entertainment programs. Such applies independent of whether the leisure activity and/or entertainment program takes place as part of a scientific program and/or prior to or after a scientific program.

2.3 Reasonable travel expenses within the meaning of Article 7.2 of the PHARMIG Code are as follows: for individual travel by car, the official kilometrage allowance; for travel by train, first class train tickets; for air travel within Europe (continental flights), economy tickets; and for air travel outside Europe (intercontinental flights), business class tickets.

2.4 Meals during events must be reasonable; here, one must take due care that the meal itself or the choice and/or kind of meal does not take on the character of an experience.
Reference is made to the Guidance of the PHARMIG Board regarding Article 7 and Article 8 of the PHARMIG Code of Conduct (Caps: meals, hospitality) for when it is reasonable for meal costs to be assumed (food and beverages).

2.5 Accommodation within the meaning of Article 7.2 of the PHARMIG Code will not cease to be reasonable if the hotel or conference center has suitable infrastructure and/or the technical facilities/equipment and the space required for holding the event and if that center does not maintain above-standard recreational or entertainment facilities and/or does not offer recreational or entertainment services and if that center is not particularly luxurious and/or extravagant (for instance, congress hotels, conference hotels, educational facilities).
In determining whether a hotel or conference center is reasonable, it is imperative that, by assuming accommodation costs for that hotel or conference center, the invitation extended to attendees does not create an impression that improper influence is being exerted upon any healthcare professional and that such invitation is not likely to influence how he or she prescribes and administers what products.

3. The location within the meaning of Article 7.4 of the PHARMIG Code must be selected based on objective criteria alone. Objective criteria include, for instance, the geographical location, giving due consideration to the participants' country of origin, the subject matter of the event, and the accessibility of that location for the participants. The objective criteria must never involve the leisure activities available at a location.

This guidance enters into force on 1 September 2015.

Exhibit ./1 to Guidance 1/2015 Legal and PHARMIG Code Compliance Confirmation Form for Pharmaceutical Company Support

Confirmation

Organizer's identifying information:

_____

(the "organizer")

Pharmaceutical company's identifying information

_____

(the "pharmaceutical company")

Description of the event

_____

(the "event")

Description of the pharmaceutical company's support or assumption of costs

_____

(the "support")

The *organizer* hereby confirms that the *event* organized and/or undertaken by it shall serve the exclusive purpose of providing scientific information and/or continuing medical education and that no leisure activities and/or entertainment programs shall take place in connection with the *event*. The *pharmaceutical company's* support pertains, exclusively, to one, several, or all of the following purposes:

- registration fees for one/several attendee(s) and/or expenses for undertaking and organizing the scientific event
- travel expenses for one/several attendee(s)
- meals for one/several attendee(s)
- accommodation for one/several attendee(s)

Article 7 of the PHARMIG Code of Conduct and the Guidance issued regarding that article are agreed and accepted, and it is hereby confirmed that the *event*, in its entirety, shall comply with the foregoing article and guidance and that the *pharmaceutical company's* support shall be used in accordance with the PHARMIG Code.

Should the event be held in a manner that breaches applicable law or the PHARMIG Code and/or should the support not be used by the *organizer*, as that use has been stipulated, then the *pharmaceutical company* shall have the right to withdraw from that agreement and to rescind the support in its entirety. The *organizer* shall be required to render return payment of the support in its entirety within seven (7) days of the *pharmaceutical company's* withdrawal.

Date, (company) signature of the organizer

_____

Guidance 1/2025 of the PHARMIG Board regarding Article 9 of the PHARMIG Code of Conduct (Transparency)

Interactions between pharmaceutical companies, on the one hand, and healthcare professionals (HCP) and healthcare organizations (HCO), on the other, are vital to the development, maintenance and advancement of the best possible supply of medicinal products. Transparency is an important means of increasing public trust in these interactions.

Under Article 9 of the PHARMIG Code, pharmaceutical companies are obligated to disclose transfers of value in connection with prescription-only medicinal products made to healthcare professionals and healthcare organizations. To improve the coherence of disclosure by PHARMIG members, its format and methodology should be further harmonized and adjusted to the European standards.

Under Article 16 of the PHARMIG Code, the PHARMIG Board issues, in connection with Articles 9.6 and 9.7 of the PHARMIG Code the following

Guidance regarding Article 9 of the PHARMIG Code:

1. The disclosure of transfers of value must be done in a searchable and machine-readable format. The minimum standard for this format is a searchable pfd.
   This applies both to the standardized disclosure template according to Exhibit ./1 to Guidance 2/2014 of the PHARMIG Board regarding Article 9 of the PHARMIG Code of Conduct, and to any other used format identical in terms of content and scope.
   The annual disclosure report must be made available online in a downloadable format on a publicly accessible website under the control of a pharmaceutical company.

2. The system used for the disclosure of transfers of value must be described by a respective pharmaceutical company in a methodological note, which is to be published together with the disclosed amounts of value transferred.
To ensure consistency and thereby enhance transparency, the methodological note should follow the structure outlined in Exhibit ./1.
If the methodological note specifically refers to Austria, this should be clearly indicated.
In addition to the German version of the methodological note, it is recommended to also publish an English translation.

3. This Guidance is applicable to the 2027 disclosure of 2026 transfers of value at the latest.

This Guidance enters into force on 1 July 2025.

Exhibit ./1 to Guidance 1/2025: Standardized Template of the methodological note structure for the disclosure of transfer of values under Article 9 PHARMIG Code

Definitions

- Type of Recipients
  (If needed, include the definition of "Healthcare Professional" at national level. Clarification on treatment of retired and deceased Healthcare Professionals)
- Kind of transfers of value
  (donations and grants; contribution to costs of events; fees for services and consultancy; R&D; others)

Applicability and scope of the disclosure

- Medicines concerned
  (type of products included in the disclosure report, for instance prescription-only medicines)
- Company concerned
  (affiliate, merger, or company rebrand, as applicable)
- Transfers of value excluded from disclosure
- Date of the transfer of value
- Direct transfers of value
- Indirect transfers of value
- Non-monetary transfers of value
- Transfers of value in case of partial attendance or cancellation and refund
- Cross-border activities
- Research & Development
- Voluntary disclosure
  (description in case anything is disclosed beyond the national code)

Specific considerations (as applicable)

- Country unique identifier
  (if needed, specify which identifier is used and for which purpose)
- Self-incorporated Healthcare Professionals
  (depending on the local legislation, qualified as individual or company)
- Multi-year agreements
- Country specialties
- Quality Checks
  (optional for pre-disclosure)

Data protection legal basis

- Consent collection
  (including consent withdrawal possibility for individuals)
  - Partial consent
- Legitimate interest
  (including balancing test, right to object)

Form of Disclosure

- Date of publication
- Disclosure platform
- Disclosure language

Disclosure of financial data

- Currency
  (local or if not, specify the exchange rate)
- VAT included or excluded
- Calculation rules
  (e.g., for in-kind transfers of value)

Additional Information

Rules of Procedure of the PHARMIG Code Adjudication and Appeal Boards

Article 1

Duties and responsibility of the PHARMIG Code Adjudication and Appeal Boards

1.1 The PHARMIG Code Adjudication and Appeal Boards are responsible for hearing and adjudicating all disputes among PHARMIG members in connection with breaches of the PHARMIG Code. Nonmembers of PHARMIG are subject to these Rules of Procedure only in cases where they have entered into a written agreement with PHARMIG governing the application of the Rules of Procedure of the PHARMIG Code Adjudication and Appeal Boards ("PHARMIG Code Agreement") and agree to comply with the PHARMIG Code. For purposes of the following, the companies mentioned above which have signed a PHARMIG Code Agreement with PHARMIG are subsumed under the term "PHARMIG members."

1.2 PHARMIG Code Adjudication and Appeal Boards are bound by these Rules of Procedure and shall conduct procedures for any PHARMIG members in breach of the PHARMIG Code in accordance with these Rules of Procedure.

1.3 The PHARMIG Code Adjudication Board is responsible for all admissible complaints.

1.4 The PHARMIG Code Appeal Board is responsible for all decisions regarding appeals made against decisions rendered by the PHARMIG Code Adjudication Board, for decisions regarding transfer of competence request compelled by inaction on the part of the PHARMIG Code Adjudication Board, and for – in cases where such transfer of competence requests are admissible – decisions regarding admissible complaints.

Article 2

Language of Correspondence/ Language of Procedure

2.1 Correspondence with the PHARMIG Code Adjudication and Appeal Boards, with the secretary general, with the PHARMIG Code Decision Panels' administrative counsel, and with the procedural advisor must be conducted in German. The chairperson of the competent Decision Panel can require that a (even certified) translation be submitted for any and all documents not composed in German.

2.2 Written and oral procedures shall be conducted in German.

Article 3

Venue

3.1 Procedures of the PHARMIG Code Adjudication and Appeal Boards shall be conducted in Vienna at the registered office of the PHARMIG Code Decision Panels' administrative counsel. Hearings can also be conducted outside the registered office of the PHARMIG Code Decision Panels' administrative counsel, provided such is expedient to the case and the chairperson of the competent Decision Panel rules accordingly.

3.2 Any simplified procedure pursuant to Article 10 can be conducted either by means of remote written communication without the need to hold a prior meeting or by means of a video or simple telephone conference.

Article 4

Due process

4.1 Procedures shall be governed by the principle of equitable treatment, and participants shall have a right to due process.

Article 5

Complainant

5.1 Everyone shall have the right to make a complaint against any PHARMIG member. Should a PHARMIG Member make a complaint, then that complaint must be signed by the complainant's management board. Should a nonmember of PHARMIG make a complaint against a PHARMIG member, then the nonmember must enter into a written PHARMIG Code Agreement with PHARMIG, which shall govern the respective procedure at issue, before the complaint can be processed by the PHARMIG Code Adjudication or Appeal Board, as the case may be. For this purpose, the PHARMIG Code Decision Panels' administrative counsel shall transmit to the complainant, and set a deadline for, the requisite PHARMIG Code Agreement to be signed and returned. Where said agreement is not returned by the deadline set, the procedure shall not be instituted and the complaint shall be deemed to have been withdrawn.

5.2 Complaints against nonmembers of PHARMIG who have not entered into a PHARMIG Code Agreement shall be forwarded by PHARMIG to the *Fachverband der chemischen Industrie der Wirtschaftskammer Österreich* (Association of the Chemical Industry of the Austrian Economic Chambers).

5.3 Complaints shall be filed in writing with PHARMIG – Verband der pharmazeutischen Industrie Österreichs, addressed to the PHARMIG Code Decision Panels' administrative counsel, and allege that a PHARMIG member has breached the PHARMIG Code.

5.4 Complaints regarding alleged breaches of Article 7 (Events) and Article 11 (Benefits) of the PHARMIG Code can also be made anonymously, provided the rules governing complaints have been duly followed.

5.5 Anonymous complaints shall be forwarded by the PHARMIG Code Decision Panels' administrative counsel to PHARMIG's Executive Committee. Where reasonable cause exists, this committee shall render a final decision, with a simple majority of votes cast, to institute a procedure. After the Executive Committee has rendered its decision regarding how to proceed with the complaint, that decision shall be transmitted to the PHARMIG Code Decision Panels' administrative counsel for further processing.

Article 6

Subject matter and admissibility of complaints

6.1 Only alleged breaches of the PHARMIG Code shall be permissible subject matter of a complaint.

6.2 A complaint shall be inadmissible if, as of the date the complaint was made,

- **a.** the company concerned has already provided to the complainant a cease-and-desist undertaking;
- **b.** the complainant has already effectuated a decision by a court of law regarding the subject matter of the complaint;
- **c.** a court proceeding is pending regarding the subject matter of the complaint and that proceeding has yet to be terminated with finality;
- **d.** that facts incorporated into the complaint are older than six months and have ceased to exist.

6.3 However: the fact that, at some earlier point in time, a third party has been provided with a cease-and-desist undertaking shall not release the company concerned of its obligation to provide a cease-and-desist undertaking under these Rules of Procedure attesting to the cessation of the conduct in question.

Article 7

Content and form of the complaint

7.1 The complaint, together with all supporting evidence, and all further written opinions concerning the procedure shall be reduced to writing and served in septuplicate to PHARMIG – Verband der pharmazeutischen Industrie Österreichs, and addressed to the PHARMIG Code Decision Panels' administrative counsel. Once the complaint is served, the procedure shall be pending.

7.2 The complaint shall contain precise details regarding which facts are incorporated into the complaint, which article(s) of the PHARMIG Code are breached by the facts incorporated into the complaint, and the grounds on which the complainant believes himself, herself, or itself to be aggrieved or injured.

7.3 Furthermore, the complaint can contain details whether a dispute resolution procedure under Article 10a should be instituted; the absence of those details shall be deemed a refusal to participate in such a procedure.

7.4 Where the complaint does not comply with Article 7.1 and Article 7.2 or where there exists an insufficient number of copies or where supporting evidence is lacking, the procedural advisor shall set a deadline requiring the complainant to render the complaint compliant, to provide a sufficient number of copies, to supplement the supporting evidence, and/or to show cause for the noncompliance. Where the noncompliance is not remedied by the deadline set, the complaint shall be deemed to have been withdrawn.

7.5 All complaints received shall be forwarded by the PHARMIG Code Decision Panels' administrative counsel to, and for the information of, the PHARMIG secretary general.

Article 8

Complainant's rights and duties

8.1 The complainant shall have the following rights to information and validation, on the one hand, and the following duties to assist, on the other:

- **a.** the complainant shall be notified of the outcome of the procedure, with the ruling and the material grounds of that ruling being sent to the complainant.
- **b.** under Article 10.2 and Article 10.3, the complainant shall be required, upon request of the respective competent Decision Panel to assist in the clarification of the facts and to participate in the procedure.
- **c.** The complainant shall have the right
  - **i)** to appeal decisions rendered by the competent Decision Panel of the PHARMIG Code Adjudication Board to the extent that his complaint was dismissed as unfounded;
  - **ii)** to call on the competent Decision Panel of the PHARMIG Code Appeal Board in the event of inaction by the competent Decision Panel of the PHARMIG Code Adjudication Board, provided the competent Decision Panel of the PHARMIG Code Adjudication Board has failed to render a decision within six (6) months of receipt of the complaint by PHARMIG and, within said time period, no cease-and-desist undertaking has been submitted by the company concerned.

Article 9

PHARMIG Code Adjudication Board

9.1 The competent Decision Panel of the PHARMIG Code Adjudication Board shall review the complaint received and shall prepare the procedure through its own clarification of the facts; in the course of its clarification of the facts, the competent Decision Panel of the PHARMIG Code Adjudication Board can review, in any direction, the facts of which it has learned.

9.2 The chairperson of the competent Decision Panel of the PHARMIG Code Adjudication Board can cause to be discharged by the procedural advisor the duties incumbent upon the chairperson and avail himself or herself of the support of the PHARMIG Code Decision Panels' administrative counsel.

Article 10

Simplified procedure before the PHARMIG Code Adjudication Board

10.1 The procedural advisor shall forward the admissible complaint, together with all supporting evidence, to the company concerned and set a deadline for its response; where a dispute resolution procedure as contemplated by Article 10 has been proposed in the complaint, the procedural advisor shall request that the company concerned advise whether it consents to such dispute resolution procedure. The admissible complaint, together with all supporting evidence, shall also be forwarded to the members of the competent Decision Panel of the PHARMIG Code Adjudication Board.

10.2 For purposes of clarifying the facts, the procedural advisor can

- **a.** request, and set a deadline for, further response to the complaint;
- **b.** request, and set a deadline for, the production of further documents;
- **c.** conduct witness or expert depositions.

10.3 Should the company concerned or the complainant fail to meet the deadline to assist as requested by the procedural advisor, the complaint shall be adjudicated by the competent Decision Panel of the PHARMIG Code Adjudication Board based on the record and on the evidentiary material submitted.

10.4 Should the competent Decision Panel of the PHARMIG Code Adjudication Board hold that the complaint is founded, then it shall censure the company concerned and require, and set a deadline of two weeks for, that company to undertake in writing that it will immediately cease and desist from the breach in question. In cases involving a severe breach of the PHARMIG Code, the requirement to so undertake can be tethered to the requirement that a fine be paid in accordance with Article 15. In such cases, the cease-and-desist undertaking must also contain a statement in which the company concerned agrees to the fine assessed and to the requirement that it be paid immediately.

10.5 The simplified procedure shall terminate where and once the written cease-and-desist undertaking of the company concerned has been submitted by the deadline set.

10.6 Where the written cease-and-desist undertaking of the company concerned is not submitted by the deadline set or is submitted lacking in completeness, the procedure shall continue, unless the competent Decision Panel of the PHARMIG Code Adjudication Board recognizes as sufficient a written cease-and-desist undertaking which deviates from the undertaking requested. Where a cease-and-desist undertaking is not submitted by the deadline set or is submitted lacking in completeness, such shall not terminate the procedure, but rather be taken into consideration regarding the assessment of any additional sanctions imposed.

Article 10a

Dispute resolution procedure

10a.1 The dispute resolution procedure presents the parties with the opportunity to conduct, amicably and voluntarily, talks moderated by the neutral procedural advisor and to possibly resolve the complaint even prior to the institution of the procedure before the PHARMIG Code Adjudication Board. The objectives and guiding precepts informing the dispute resolution procedure consist of presenting with sufficient completeness, expounding, and clarifying the issue at hand whether and under what conditions the conflicting positions and interests can be settled.

10a.2 Where the complainant, in his complaint, and the company concerned, in its response, affirm their wish to commence a dispute resolution procedure, the procedural advisor shall not only schedule, by mutual agreement with the parties, a conference (and potential subsequent conferences), but also set the agenda for the talks; for scheduling purposes, the procedural advisor shall provide for sufficient time to ensure that all parties can prepare for the talks. At any point during the talks, any party can advise in writing that the talks have foundered. A requirement for instituting a dispute resolution procedure is that the parties reach an agreement in advance regarding who shall bear which costs.

10a.3 Based on the talks, the procedural advisor shall draft an agreement which

- **a.** describes the solution reached between the parties and which contains language forgoing the institution of the procedure before the PHARMIG Code Adjudication Board; or
- **b.** provides that the parties shall forgo the institution of the procedure before the PHARMIG Code Adjudication Board; or
- **c.** memorializes that the talks have foundered.

Said agreement must be signed by the parties. Any refusal to sign the agreement shall be deemed an admission that the dispute resolution procedure has foundered.

10a.4 Where a dispute resolution procedure has foundered, the procedural advisor shall report such to the PHARMIG Code Adjudication Board, which shall require that the procedure move forward as provided for under Article 10.

10a.5 The running of the deadline to conduct the procedure before the competent Decision Panel of the PHARMIG Code Adjudication Board shall be tolled for the time period that commences on the date on which the dispute resolution procedure begins and that ends on the date on which the procedural advisor makes his or her report under Article 10a.4.

Article 11

Continuation of the procedure before the PHARMIG Code Adjudication Board

11.1 Where a complaint is not settled or not settled in its entirety during a simplified procedure, the procedure before the PHARMIG Code Adjudication Board must be continued. The procedural advisor shall order that the procedure be conducted in writing or shall schedule a date and time for the oral hearing.

11.2 Where an oral hearing has been scheduled, that hearing must be held within eight (8) weeks of the date on which the two-week deadline has lapsed for the submission of a cease-and-desist undertaking. The procedural advisor can extend this deadline for cause.

11.3 In general, the Decision Panel of the PHARMIG Code Adjudication Board shall meet in Vienna at the registered office of the PHARMIG Code Decision Panels' administrative counsel.

11.4 Where necessary, the procedural advisor must cause to be taken further measures conducive to managing the procedure and to preparing any meetings (obtaining supplementary information, and the like). Article 10.2 and Article 10.3 apply with the relevant modifications.

11.5 The following persons shall be given summons to appear at the oral hearing: the management board of the company concerned; witnesses, where necessary; experts; and other persons able to produce responsive information. The oral hearing shall not be a public hearing.

11.6 The summons shall include at least the following information:

- **a.** purpose of the hearing;
- **b.** place, date, and time of the oral hearing;
- **c.** the composition of the competent Decision Panel;
- **d.** the advisory notice that the Decision Panel members can be disqualified where their impartiality can be reasonably questioned;
- **e.** the advisory notice that the hearing can take place and that a decision can be rendered during that hearing even if the company concerned, its representative, or any other person summoned fails to appear absent cause;
- **f.** the advisory notice addressed to the company concerned that, at any juncture of the procedure, it can be represented by any employee holding the relevant proxy and/or by its legal counsel.

11.7 Where the procedure is conducted in writing, the procedural advisor shall take any measures required for managing the procedure.

Article 12

Oral hearing

12.1 The chairperson shall convene, conduct, and adjourn the oral hearing. He can give the floor to any person and compel any person to yield the floor if he does not follow the chairperson's instructions; the chairperson shall hear the persons required to give testimony for evidentiary purposes; and the chairperson shall specify and explain any other evidentiary material. Where special circumstances exist, witnesses can also be deposed in writing or in advance by the chairperson or any representative acting on behalf of the chairperson. The outcome of these depositions must be submitted by the chairperson during the oral hearing. Deposition by telephone during the hearing is allowed.

12.2 Where the management board, representative of the company concerned, or any other person summoned fails to appear at the oral hearing absent cause, despite their having been duly summoned to that hearing, the competent Decision Panel shall render a decision based on the record and the evidentiary material submitted.

12.3 A transcript shall be made of the oral hearing and reflect the material parts of the hearing. Any requests made by the parties to the procedure and orders made by the competent Decision Panel shall be reduced to writing and appended to the transcript as exhibits.

12.4 The transcript shall be signed by the chairperson and sent to the company concerned.

Article 13

Representation of the company concerned

13.1 At any juncture of the procedure, the company concerned can be represented by any employee holding the relevant proxy and/or by its legal counsel.

13.2 Irrespective of the outcome of the procedure, the company concerned shall itself bear the costs of its own representation and counsel.

13.3 Upon request, attorneys-in-fact of the company concerned must produce their power of attorney to the competent Decision Panel.

Article 14

Decision by the PHARMIG Code Adjudication Board

14.1 Where a complaint is not settled or not settled in its entirety during a simplified procedure, the competent Decision Panel of the PHARMIG Code Adjudication Board shall render a decision in the form of an order.

14.2 The order of the Decision Panel of the PHARMIG Code Adjudication Board shall be passed with a simple majority of votes cast. Where there is a tie in the votes cast, the complaint shall be dismissed as unfounded.

14.3 Decisions shall be rendered in writing. Where the complainant and the company concerned have not waived the substantiation of the decision either during the written procedure or during the oral hearing, decisions must be substantiated.

14.4 Written decisions shall be signed by the members of the competent Decision Panel of the PHARMIG Code Adjudication Board. Authenticated copies of the decisions shall be signed by the chairperson of the competent Decision Panel. Where the majority of the members of the competent Decision Panel – with the chairperson among them – has signed a written decision, that majority shall suffice, provided it has been noted in the decision that a member of the competent Decision Panel has refused to sign or that such member is prevented from signing by some hinderance which is unable to be overcome within a reasonable period of time. Where the decision rendered is a majority decision, such must be specified in the decision, if any member of the competent Decision Panel of the PHARMIG Code Adjudication Board in the minority should so request.

14.5 All authenticated copies of decisions shall bear the stamp of the competent Decision Panel. Said stamp serves to confirm that the decision is one rendered by the competent PHARMIG Decision Panel and that this decision has been rendered and signed by members of the competent Decision Panel as prescribed by these Rules of Procedure.

14.6 In addition, the decision shall include the following information:

- **a.** exact name of the company concerned which is party to the procedure;
- **b.** date and place; and
- **c.** purpose, nature, scope, and time of the injunctive relief owed and/or other sanctions.

14.7 The decision shall be served on the company concerned by the Decision Panels' administrative counsel. The decision shall take effect for that company once the authenticated copy has been served. An authenticated copy of the decision shall be retained on file with the administrative counsel.

14.8 Any decision with which a breach of the PHARMIG Code has been determined must be tethered to a censure and the requirement that the company concerned cease the conduct at issue immediately.

14.9 The complainant shall be notified of the outcome of the procedure in writing, with the ruling and the material grounds of that ruling being sent to the complainant. Business and/or trade secrets, if any, must be redacted; the names of employees of the company concerned or of other persons involved, or enterprises, organizations, and the like, if any, must be anonymized.

14.10 Every decision rendered by the PHARMIG Code Adjudication Board shall include a remedies notice. That notice shall include the remedy of appeal, the notice of appeal filing deadline, and the name and address of the body with which the notice of appeal can be filed.

Article 15

Sanctions imposed by the PHARMIG Code Adjudication Board

15.1 Where, in view of the conduct at issue, the competent Decision Panel of the PHARMIG Code Adjudication Board deems it necessary and appropriate – in addition to a censure and an order compelling injunctive relief – that Decision Panel shall be authorized, where it determines a breach of the PHARMIG Code, to impose on the company concerned the following sanctions in its decision:

- **a.** in the event of a severe breach, the imposition of a fine in an amount equal to no less than Euro 5,000.00, but not to exceed Euro 100,000.00. A severe breach shall exist in cases in which the company concerned repeats a breach

within twenty-four (24) months or has contravened the PHARMIG Code on the same grounds and each of these breaches has been determined by an unappealable decision rendered in accordance with these Rules of Procedure. All breaches, including first-time breaches, of Article 7 or Article 11 of the PHARMIG Code shall be deemed severe breaches.

b. the fine imposition guidelines shall increase to EUR 200,000.00, provided the company concerned has breached Article 7 or Article 11 of the PHARMIG Code three times within twenty-four (24) months and each of these breaches has been determined by an unappealable decision rendered in accordance with these Rules of Procedure.

c. announcement of the breach in a PHARMIG publication, naming the company concerned.

d. formal notice to the parent company of the company concerned of the sanctions imposed.

e. formal notice to the EFPIA secretary general regarding the sanctions imposed.

f. expulsion from PHARMIG or termination of the PHARMIG Code Agreement entered into; yet, such sanctions shall not release the expelled or separating member company or the company affected by the termination of the PHARMIG Code Agreement from any existing payment obligations or other sanctions imposed.

15.2 The fines imposed shall be due and payable to PHARMIG once the respective decision becomes unappealable within the meaning of these Rules of Procedure and shall be used for charitable purposes by the PHARMIG Board within three (3) months of receipt of payment.

15.3 A combination of the sanctions set forth above is possible.

15.4 In determining sanctions, due consideration shall be given to the ramifications for the company affected by the sanctions. In particular, due consideration shall also be given to whether and to what extent the company concerned works to prevent breaches of the PHARMIG Code through organizational measures or the conduct at issue solely involves a single instance of misconduct. Moreover, due consideration shall be given to which internal sanctions and organizational measures the company concerned has resolved and implemented and/or proposed in reaction to the misconduct at issue, both in general and in particular.

Article 16

Appeal

16.1 The company concerned can file a notice of appeal against any decision within two (2) weeks of the decision being served. The company concerned can limit its appeal to the sanctions imposed or to the amount of the sanctions imposed.

16.2 The complainant can file a notice of appeal against any decision within two (2) weeks to the extent that his complaint has been dismissed as unfounded. A notice of appeal by the complainant on the grounds that sanctions were not imposed or the amount of the sanctions imposed shall be inadmissible.

16.3 The notice of appeal shall be reduced to writing, substantiated, and filed with the PHARMIG Code Decision Panels' administrative counsel within two (2) weeks of the decision being served. The procedural advisor shall forward the notice of appeal without undue delay to the members of the competent Decision Panel of the PHARMIG Code Appeal Board.

16.4 Where no notice of appeal has been filed within two (2) weeks of the decision being served, the decision of the Decision Panel of the PHARMIG Code Adjudication Board shall become unappealable within the meaning of these Rules of Procedure. Status quo ante reinstatement shall not be allowed.

16.5 Separate notices of appeal by the company concerned or the complainant directed against measures and decisions relating to the management of the procedure shall be inadmissible. The competent Decision Panel of the PHARMIG Code Appeal Board shall review the decision only to the extent that it has been appealed.

16.6 Where a notice of appeal has been filed, the decision shall be reviewed by the competent Decision Panel of the PHARMIG Code Appeal Board only if the advance – in an amount equal to the procedural costs as contemplated by Article 30 – has been deposited beforehand.

Article 17

PHARMIG Code Appeal Board

17.1 The competent Decision Panel of the PHARMIG Code Appeal Board shall review all notices of appeal received and shall set in motion procedural preparation efforts.

17.2 Where the notice of appeal has not been dismissed either because it is inadmissible or because it has been filed too late, the procedure shall proceed before the PHARMIG Code Appeal Board. The chairperson of the competent Decision Panel of the PHARMIG Code Appeal Board shall either order that the procedure be conducted in writing or schedule a date and time for the oral hearing.

17.3 Where an oral hearing has been scheduled, that hearing shall be held within eight (8) weeks of the date on which the notice of appeal was filed. The competent Decision Panel can extend this deadline for cause.

17.4 In general, the Decision Panel of the PHARMIG Code Appeal Board shall meet in Vienna at the registered office of the PHARMIG Code Decision Panels' administrative counsel.

17.5 Where necessary, the chairperson must cause to be taken further measures conducive to managing the procedure and to preparing any meetings (obtaining supplementary information, and the like). Article 10.2 and Article 10.3 apply with the relevant modifications.

17.6 Because he can produce responsive information, the chairperson of the competent Decision Panel of the PHARMIG Code Adjudication Board shall be among the persons summoned to the oral hearing, as caused by a notice of appeal and conducted by the competent Decision Panel of the PHARMIG Code Appeal Board. The oral hearing shall not be a public hearing.

17.7 Where the procedure is conducted in writing, the Decision Panel's chairperson shall take any measures required for managing the procedure.

17.8 Apart from the foregoing, the provisions governing procedures before the PHARMIG Code Adjudication Board apply with the relevant modifications.

17.9 Transfer of competence requests shall be filed with the PHARMIG Code Decision Panels' administrative counsel within two (2) weeks of the date on which the six-month deadline lapses. That administrative counsel shall forward the change of forum request without undue delay to the members of the competent Decision Panel of the PHARMIG Code Appeal Board, which shall render a decision.

17.10 The chairperson of the competent Decision Panel of the PHARMIG Code Appeal Board can cause to be discharged by the procedural advisor the duties incumbent upon the chairperson and avail himself or herself of the support of the PHARMIG Code Decision Panels' administrative counsel.

Article 18

Decision by the PHARMIG Code Appeal Board

18.1 The PHARMIG Code Appeal Board shall rule on the matter based on the notice of appeal. Where necessary, that board shall supplement the procedure conducted by the PHARMIG Code Adjudication Board. The decision can also be modified solely with regard to the sanctions imposed.

18.2 The order of the Decision Panel of the PHARMIG Code Appeal Board shall be passed with a simple majority of votes cast. Where there is a tie in the votes cast, the appeal shall be dismissed as unfounded.

18.3 The competent Decision Panel of the PHARMIG Code Appeal Board shall decide on a transfer of competence request by applying the provisions applicable to decisions rendered by the PHARMIG Code Adjudication Board, but with the relevant modifications.

18.4 Decisions rendered by the PHARMIG Code Appeal Board shall be authenticated and served in accordance with Articles 14.3 through Article 14.9.

Article 19

Unappealability of the PHARMIG Code Appeal Board's decision

19.1 Decisions rendered by the PHARMIG Code Appeal Board shall be unappealable within the meaning of these Rules of Procedure and shall include an advisory notice stating such.

Article 20

Disqualification

20.1 Members of any competent Decision Panel of any PHARMIG Code Board can be disqualified only if facts and circumstances exist that give rise to reasonable doubts regarding their impartiality or independence. They shall recuse themselves if they are in the employ of the company concerned or of the complainant or if they are or were involved in the matter at issue.

20.2 Where the complainant or the company concerned wishes to disqualify a member of the competent Decision Panel of the PHARMIG Code Boards, they shall advise the PHARMIG Code Decision Panels' administrative counsel of such without undue delay and show cause for disqualification. That administrative counsel shall forward the request to disqualify to the members of the appropriate Decision Panel. The Decision Panel member concerned shall respond within one (1) week of receipt of the request to disqualify and transmit his or her response to the PHARMIG Code Decision Panels' administrative counsel.

20.3 Where the member of the competent Decision Panel of the PHARMIG Code Board, against whom a request to disqualify has been made, does not recuse himself or herself, PHARMIG's Executive Committee shall decide whether to disqualify that member based on the details provided in the request to disqualify, on the evidentiary material appended to that request, and on the response of the member concerned.

20.4 A member of the competent Decision Panel of the PHARMIG Code Board, against whom a request to disqualify has been made, can continue to participate in the procedure until such time as PHARMIG's Board has rendered its decision.

Article 21

Deadlines, service of process, and notices

21.1 A deadline shall be preserved, if the filing is sent on the last day of the deadline in any manner prescribed in Article 21.2.

21.2 Service of process shall be considered to have been duly effectuated if it is effectuated by means of registered mail, courier, or telefax to the address which the addressee of the filing most recently provided – as the address for service of process – in writing to the PHRAMIG Code Decision Panels, or if the filing to be served has been handed to the addressee. Where filings are served via telefax, the relevant authenticated copies in septuplicate must be submitted in hardcopy without delay.

21.3 As soon as a party has appointed a representative, service of process shall be effectuated to the address most recently provided for that representative and deemed effectuated as regards the party represented.

21.4 Unless otherwise prescribed in these Rules of Procedure: where a deadline has been missed, the company concerned can, upon request, be placed in the position it would have occupied, if due to no fault of its own, it had not been prevented from preserving the deadline on the grounds of an unforeseeable or unavoidable event. The request shall be filed in writing with the PHARMIG Code Decision Panels' administrative counsel within one (1) week of the date on which the cause that prevented preservation of the deadline ceases to exist. Where a procedural matter has been neglected, that matter shall be effectuated at the same time as the status quo ante reinstatement request.

Article 22

PHARMIG Code Decision Panels' Administrative Counsel and Procedural Advisor

22.1 The administrative counsel of the PHARMIG Code Adjudication and Appeal Boards (PHARMIG Code Decision Panels) is Liebenwein Rechtsanwälte GmbH, Hohenstaufengasse 7, 1010 Vienna, Austria.

22.2 The PHARMIG Code Decision Panels' administrative counsel is responsible for administrative matters, maintains and manages the files of the PHARMIG Code Adjudication and Appeal Boards, and appoints the procedural advisor.

22.3 The procedural adviser shall discharge his or her duties not only by preserving the objectives and the values memorialized in the PHARMIG Code, but also in accordance with the provisions prescribed by the PHARMIG Code Rules of Procedure.

Article 23

Nondisclosure

23.1 All parties to all procedures, the Decision Panel members, the chairperson, the Executive Committee, all PHARMIG employees, all employees of the PHARMIG Code Decision Panels' administrative counsel, and the procedural advisor shall be required to hold in confidence any and everything pertaining to their roles, any information obtained while acting in that role, and all matters that are either inherently confidential or expressly identified as confidential.

Article 24

Composition of the PHARMIG Code Adjudication Board

24.1 As prescribed by § 13 of the PHARMIG-Statutes, the members of the PHARMIG Code Adjudication Board shall be selected by PHARMIG's Board with a simple majority of votes cast.

24.2 The PHARMIG Code Adjudication Board shall be comprised of nine (9) voting members. Of the members of the PHARMIG Code Adjudication Board, eight (8) persons shall be representatives of PHARMIG members. The PHARMIG secretary general is a standing voting member of the PHARMIG Code Adjudication Board and, at the same time, chairperson of the Decision Panel of the PHARMIG Code Adjudication Board.

24.3 The PHARMIG Code Adjudication Board shall render decisions in the form of decision panels. Each decision panel shall be comprised of the PHARMIG secretary general and four (4) other members of the PHARMIG Code Adjudication Board.

24.4 The chairperson of each Decision Panel of the PHARMIG Code Adjudication Board shall advise the PHARMIG Board of the unappealable decisions rendered in accordance with these Rules of Procedure.

Article 25

Composition of the PHARMIG Code Appeal Board

25.1 As prescribed by § 13 of the PHARMIG-Statutes, the members of the PHARMIG Code Appeal Board shall be selected by PHARMIG's Board with a simple majority of votes cast.

25.2 The PHARMIG Code Appeal Board shall be comprised of ten (10) voting members. Of the members of the PHARMIG Code Adjudication Board, six (6) persons shall be representatives of PHARMIG members – of those, two (2) persons shall be members of the PHARMIG Executive Committee – two (2) persons emeritus judges and two (2) persons practicing doctors.

25.3 The PHARMIG Code Appeal Board shall render decisions in the form of decision panels. Each decision panel shall be comprised of five (5) members of the PHARMIG Code Appeal Board. Each Decision Panel of the PHARMIG Code Appeal Board shall be comprised of three (3) representatives of PHARMIG members – of which one (1) shall be a member of the PHARMIG Executive Committee – one (1) an emeritus judge and one (1) a practicing doctor. Each of the emeritus judges shall be the chairperson of their Decision Panels and shall have powers to vote.

25.4 The chairperson of the Decision Panel of the PHARMIG Code Appeal Board shall not be engaged for any PHARMIG member or any other company of the pharmaceutical industry (neutrality).

25.5 The chairperson of each Decision Panel of the PHARMIG Code Appeal Board shall advise the PHARMIG Board of the unappealable decisions rendered in accordance with these Rules of Procedure.

Article 26

Joint provisions governing the composition of the PHARMIG Code Adjudication and Appeal Boards

26.1 Members of the PHARMIG Code Appeal Board shall be appointed for a term equal to the respective term of PHARMIG's Board. Reelections are allowed.

26.2 PHARMIG's Board shall establish bylaws and a business allocation plan, the latter of which shall govern the jurisdiction of the individual Decision Panels of the PHARMIG Code Adjudication and Appeal Boards and the jurisdiction of the representatives of the individual Decision Panels of the PHARMIG Code Adjudication and Appeal Boards where a member has been prevented or disqualified from discharging his or her duties. The bylaws and the business allocation plan shall each be voted on and passed with a simple majority of votes cast whenever the members of the decision panels are appointed by the PHARMIG Board.

26.3 Where members of the individual Decision Panels of the PHARMIG Code Adjudication and Appeal Boards are prevented or disqualified from discharging their duties, the PHARMIG Board can appoint one or more proxies for each member. The proxies shall be appointed not only from among the members of the same board on which the prevented or disqualified member sits, but also from the decision panel which has not been affected by the prevention or disqualification.

26.4 With regard to their duties on the PHARMIG Code Boards, the members of the PHARMIG Code Adjudication and Appeal Boards shall be independent and not subject to instructions.

26.5 Members of the PHARMIG Code Adjudication Board shall not be allowed to be members of the PHARMIG Code Appeal Board at one and the same time, and vice versa.

26.6 The chairpersons of the PHARMIG Code Adjudication and Appeal Boards shall have the right, within the purview of their duties in the respective procedure, to transfer tasks and responsibilities to any person possessing the requisite professional qualifications.

Article 27

Costs of the PHARMIG Code Adjudication and Appeal Boards

27.1 PHARMIG shall assume the management of the PHARMIG Code Adjudication and Appeal Boards and shall bear their financial expenses, provided such are not the costs to be borne by the parties to the procedure.

Article 28

Costs of the simple procedure before the PHARMIG Code Adjudication Board

28.1 Where, in any simple procedure, the company concerned submits to the competent Decision Panel of the PHARMIG Code Adjudication Board a cease-and-desist undertaking, procedural costs in the amount of EUR 3,500.00 shall be paid to PHARMIG by the company concerned. Where the facts are complex and contain several issues of complaint, the procedural costs to be paid to PHARMIG shall increase to EUR 5,000.00.

Article 29

Costs in the event a procedure is continued before the PHARMIG Code Adjudication Board

29.1 Where a procedure is continued and the competent Decision Panel of the PHARMIG Code Adjudication Board determines, in its decision, that the company concerned has breached the PHARMIG Code, the procedural costs to be paid to PHARMIG by the company concerned shall be:

- **a.** EUR 7,000.00.
- **b.** Where an oral hearing is conducted in accordance with Article 12, the procedural costs to be paid to PHARMIG shall increase by EUR 2,000.00 for each oral hearing conducted.
- **c.** Where the facts are complex and contain several issues of complaint, the procedural costs to be paid to PHARMIG shall increase by EUR 2,000.00.

29.2. The procedural costs for the continuation of any adjudication board procedure shall not be paid by the company concerned, if based on an appeal by the company concerned the decision is vacated as unfounded by the competent Decision Panel of the PHARMIG Code Appeal Board.

Article 30

Costs of the procedure before the PHARMIG Code Appeal Board

30.1 A procedure shall be conducted before the PHARMIG Code Appeal Board only if the advance in the amount of EUR 10,000.00 has been deposited by the appellee/complainant, which must be deposited within fourteen (14) days of receipt of the relevant request for payment as made by the PHARMIG Code Decision Panels' administrative counsel. Where this advance is not credited to a PHARMIG account within said time period, the procedure before the PHARMIG Code Appeal Board shall not be conducted. Furthermore, the following amounts in additional procedural costs shall be paid to PHARMIG by the appellee/complainant:

a. EUR 5,000.00 in the event an oral hearing is conducted

b. EUR 2,000.00 for each additional oral hearing conducted.

Where additional procedural costs are incurred, the PHARMIG Code Decision Panels' administrative counsel shall assess those costs with due consideration for the outcome of the procedure.

30.2 Where the competent Decision Panel of the PHARMIG Code Appeal Board determines, and that determination is unappealable, under these Rules of Procedure that the company concerned has breached the PHARMIG Code, the advance shall be forfeited for the benefit of PHARMIG, insofar as it has been paid by the company concerned. Where, in the aforementioned event, the advance has been covered by the complainant, the advance shall be returned to the complainant and the company concerned shall be requested by the PHARMIG Code Decision Panels' administrative counsel to reimburse those costs within fourteen (14) days of receipt of the request to render said payment.

30.3 Where the competent Decision Panel of the PHARMIG Code Appeal Board dismisses the appeal by the company concerned or the appeal by the complainant and confirms a decision rendered by the competent Decision Panel of the PHARMIG Code Adjudication Board, the advance shall be forfeited for the benefit of PHARMIG. In all other cases in which it has been determined, and that determination is unappealable, that the company concerned has not breached the PHARMIG Code, the advance rendered by the company concerned shall be returned to said company.

30.4 Where a procedure is conducted before the PHARMIG Code Appeal Board due to a transfer of competence request, Article 30.1 shall not apply. In this case, the provisions governing costs for procedures before the PHARMIG Code Adjudication Board shall apply with the relevant modifications.

Article 31

Necessary outlays

31.1 Where the respective PHARMIG Code Board determines, and that determination is unappealable, under these Rules of Procedure that the company concerned has breached the PHARMIG Code, the company concerned shall pay not only the procedural costs, but also any reasonable travel and accommodation expenses of any witnesses summoned, of any persons able to produce responsive information, and of any experts. The same applies to any reasonable fees for services rendered by experts.

Article 32

Maturity of costs and necessary outlays/sales tax

32.1 The procedural costs and any necessary outlays shall be assessed by the PHARMIG Code Decision Panels' administrative counsel and shall become due and payable, together with any and all sales tax (Umsatzsteuer) prescribed by law, once the decision rendered has become unappealable under these Rules of Procedure.

Article 33

Publication of decisions

33.1 PHARMIG can publish, in anonymized form, unappealable decisions rendered in accordance with these Rules of Procedure. The nature of the publication can be specified in the bylaws.

Article 34

Gender specific-language

34.1 Where only masculine personal identifiers are used in these Rules of Procedure, they refer to both men and women in equal measure. In their application to specific persons, the correct gender-specific form must be used.

Article 35

Miscellaneous

35.1 PHARMIG members shall recognize the Rules of Procedure of the PHARMIG Code Boards and the sanctions set forth in those rules as concerns any procedures conducted in connection with a breach of the PHARMIG Code. PHARMIG members shall be required to comply with the decisions rendered and to pay any fines imposed by the PHARMIG Code Boards as well as to recognize those decisions as enforceable writs. In principle, PHARMIG members shall forgo filing any matter with any ordinary court of law for as long as a PHARMIG procedure is being conducted regarding that matter.

35.2 To the extent permitted by law, PHARMIG, its governing bodies, the members of its governing bodies, the PHARMIG Code Decision Panels' administrative counsel, and the procedural advisor disclaim all liability for any decisions rendered by the PHARMIG Code Boards. The foregoing disclaimer is without prejudice to any liability based on wrongful conduct.

Article 36

Entry into force/transitional provisions

36.1 The PHARMIG Code enters into force on 1 July 2007. This version of the Rules of Procedure applies to all procedures in which the complaint was filed after 30 June 2007 and the facts, as incorporated into the complaint, existed after said date.

36.2 Articles 7, 7.2, 7.9, 8.6.2, 8.7, 10.2, 10.3, and 14 of the PHARMIG Code and Articles 5.2, 7.1, 9.1, 10.6, 11.2, 14.4, 17.3, 17.9, and 21.2 of the Rules of Procedure for the PHARMIG Code Adjudication and Appeal Boards, as memorialized in the "VHC-Novelle 1/2008," enter into force on 1 May 2008. This version of the Rules of Procedure (VHC-Novelle 1/2008) applies to all procedures in which the complaint was filed after 30 April 2008 and the facts, as incorporated into the complaint, existed after said 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 PHARMIC Code 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 Rules of Procedure for the PHARMIG Code Adjudication and Appeal Boards, as memorialized in the "VHC-Novelle 1/2009," enter into force on 1 July 2009. This version of the Rules of Procedure (VHC-Novelle 1/2009) applies to all procedures in which the complaint was filed after 30 June 2009 and the facts, as incorporated into the complaint, existed after said date..

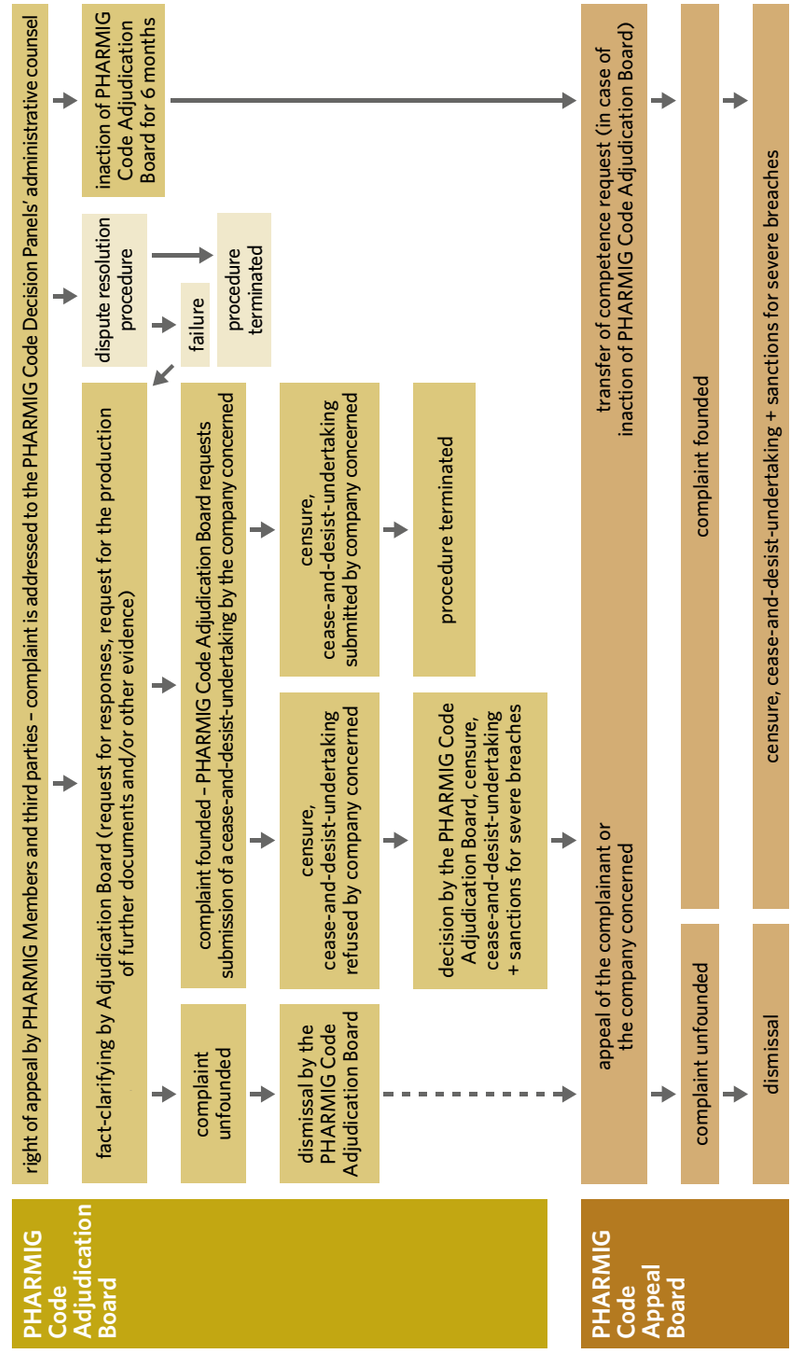
36.4 Amendments to Articles 1, 2, 3, 4, 5, 6, 7, 8.1, 8.2, 8.3, 8.4, 8.5 (limited) 8.6, 8.7, 8.8, 8.9, 9, 10, 11, 12, 13, 14, and 15 of the PHARMIG Code, as memorialized in the "VHC-Novelle 1/2013," enter into force on 1 July 2013. This version of the PHARMIG Code and of the Rules of Procedure (VHC-Novelle 1/2013) applies to all procedures in which the complaint was filed after 30 June 2013 and the facts incorporated into the complaint existed after said date. The rules concerning the publication of donations and grants set forth in Article 8.5 enter into force on 1 January 2016 in connection with any donations and grants rendered and continuously rendered as of 1 January 2015.

36.5 Amendments to Articles 1, 2, 4, 7, 8, 9, 10, 11, 12, 13, 14, 15, and 16 of the PHARMIG Code, as memorialized in the "VHC-Novelle 1/2014," enter into force on 1 July 2014. This version of the PHARMIG Code and of the Rules of Procedure (VHC-Novelle 1/2014) applies to all procedures in which the complaint was filed after 30 June 2014 and the facts, as incorporated into the complaint, existed after said date. The rules concerning transparency as set forth in Article 9 must be applied, for the first time, in connection with the reporting period for the 2015calendar year. Disclosures for the initial reporting period of the 2015 calendar year must be made by no later than 30 June 2016.

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 Rules of Procedure of the PHARMIG Code Adjudication and Appeal Boards, as memorialized in "VHC-Novelle 01/2015," enter into force on 1 July 2015. This version of the Rules of Procedure (VHC-Novelle 01/2015) applies to all procedures in which the complaint was filed after 30 June 2015 and the facts, as incorporated into the complaint, existed after said date.

36.7 Amendments to Articles 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, and 16 of the PHARMIG Code, as memorialized in the "VHC-Novelle 05/2020," enter into force on 1 July 2020. This version of the PHARMIG Code and the PHARMIG Code Rules of Procedure (VHC-Novelle 05/2020) applies to all procedures in which the complaint was filed after 30 June 2020 and the facts, as incorporated into the complaint, existed after said date.

Flowchart – Procedure of the PHARMIG Code Adjudication and Appeal Boards



PHARMIG Code of Conduct

& Rules of Procedure of the PHARMIG Code Adjudication and Appeal Boards

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