

Country Code Update Austria

PHARMIG

Verband der pharmazeutischen
Industrie Österreichs

DISCLAIMER

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Agenda

- Facts about PHARMIG
- PHARMIG Code of Conduct
 - Basics
 - Events
 - Benefits
- Questions & Answers

PHARMIG – Organisation and Mission

- Founded in 1954
- Approx. 120 member companies
- Members cover approx. 95% of pharmaceutical market
- Politically independent
- Financed by membership fees
- 20 staff (incl. Pharmig Academy)
- Ensure the value of pharmaceutical products are an integrative part of the society
- Active player in health care system
- Service oriented – inside & outside the industry



Interest Representation

- Representation of the Austrian Pharmaceutical Industry on the national, European and global level
- External representation → state and regional level, Social Security Funds



Communication

- Voice of the Austrian Pharmaceutical Industry
- Clear and active communication both internal and external

Service

- Committees: dynamically adopted and tailored towards the needs and functional areas of our member companies
- Competent point of contact, training & networking



PHARMIG-Member Companies in Austria

150

pharmaceutical companies are committed to your health and wellbeing.

[Source - Pharmig survey 2016: Austrian pharma sector]

18.000

employees work for your health on a daily basis. With 63,000 people employed indirectly, the sector even accounts for 1.7 percent of total employment.

[Source: Haber, G. (2016): Life Sciences und Pharma: Ökonomische Impact Analyse]

9,6

billion euros is the added value contributed by the pharma industry, equalling a 2.8% share in gross domestic product (GDP).

1 euro invested thus generates 1.94 euros.

[Source: Haber, G. (2016): Life Sciences und Pharma: Ökonomische Impact Analyse]

448

studies and trials including 5,644 patients were conducted in 2016 to ensure the safety, potency and tolerance of therapies and drugs.

[Source: Pharmig survey „Clinical research in Austria 2016“]

294

million euros were invested in research and development by pharmaceutical companies in 2015 in order to be able to offer you state-of-the-art and better healthcare.

[Source: Statistik Austria 2015]

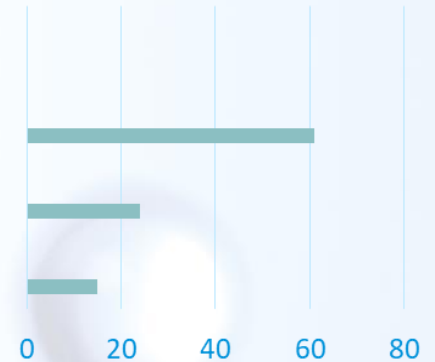
178

new products were launched on the Austrian market between 2011 and 2016. Plenty of innovations are in the pipeline for years to come, providing for optimal patient care.

[Source: IMS DPMO 2016]

company structure

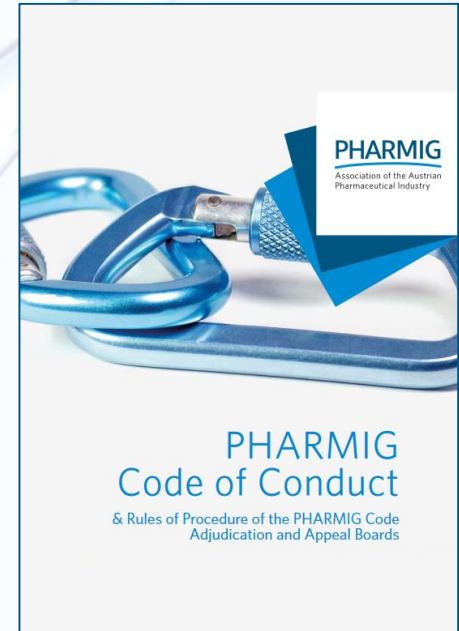
small enterprises
(0-50 employees)
medium enterprises
(51-200 employees)
large enterprises
(>200 employees)



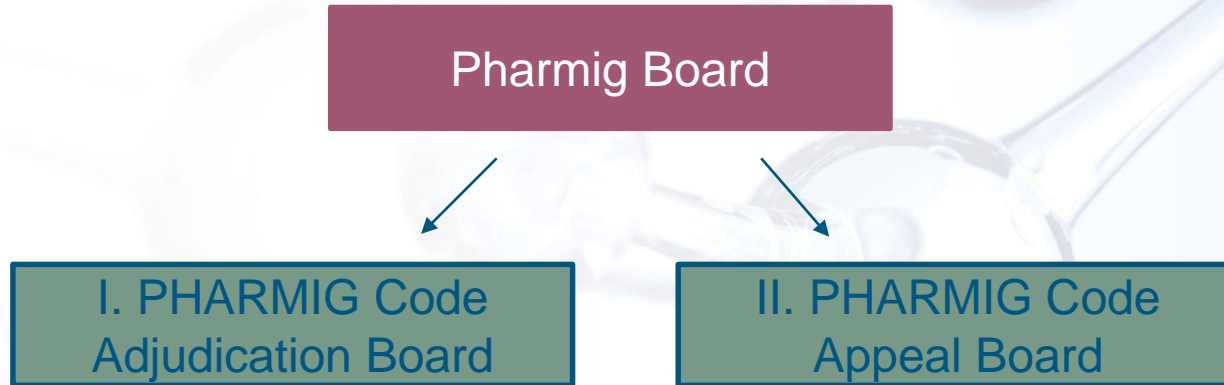


PHARMIG Code of Conduct

- Visible signpost for the industry's culture
- Self Regulation – Pharmaceutical Industry demonstrates high level of responsibility
- Providing legal certainty – since 1970
 - Code of Conduct – reliable framework for fair and cooperative interactions
 - Complaint Procedure – ensures fair competition
 - Recent amendment 05/2020



PHARMIG Code of Conduct Code authority



- Rules of Procedure including Flowchart see PHARMIG Code

Publication of Decisions



Suchregister der VHC-Entscheidungssammlung

Die Entscheidungen können durch das direkte Anklicken der Geschäftszahl aufgerufen werden. Des Weiteren besteht die Möglichkeit, Entscheidungen mit der Filterfunktion nach einzelnen VHC-Artikelnummern (z.B.: 7.2) zu suchen. Als Suchergebnis werden dann jene Entscheidungen angezeigt, die sich mit dem ausgewählten VHC-Artikel inhaltlich befassen.

GZ	Beschwerdegegenständliche Verstoße gegen VHC Artikel:	Festgestellte Verstöße gegen VHC Artikel:
Pharmig VHC - FA I / 18-05	Artikel 7.4 VHC	Streitbeilegung
Pharmig VHC - FA I / 18-04	Artikel 4, 5 VHC, § 50a Abs 3 AMG	Streitbeilegung
Pharmig VHC - FA I / 18-03	-	kein Verfahren eingeleitet
Pharmig VHC - FA I / 18-02	Art. 4.2 iVm Art. 5.9 VHC; Art. 4.4 iVm Art. 5.9 VHC; Art. 4.5 iVm Art. 5.9 VHC; Art. 4.6 iVm Art. 5.9 VHC; Art. 4.9 iVm Art. 5.9 VHC; Art. 5.7 c) VHC; Art. 5.8 VHC; § 6 AMG iVm Art. 15 VHC; sowie § 54 AMG iVm Art. 15 VHC	Art. 4.2 iVm Art. 5.9 VHC; Art. 4.4 iVm Art. 5.9 VHC; Art. 4.5 iVm Art. 5.9 VHC; Art. 4.6 iVm Art. 5.9 VHC; Art. 4.9 iVm Art. 5.9 VHC; Art. 5.7 c) VHC; Art. 5.8 VHC; § 6 AMG iVm Art. 15 VHC; sowie § 54 AMG iVm Art. 15 VHC

Artikel 4.6 iVm Artikel 5.9 VHC, Artikel 5.7 c) VHC, Artikel 5.7 f) VHC, § 6 (2) AMG iVm Artikel 15 VHC sowie § 50a (3) Z 3 AMG iVm Artikel 15 VHC Artikel 4.6 iVm

Artikel 4.6 iVm Artikel 5.9 VHC, Artikel 5.7 c) VHC, Artikel 5.7 f) VHC, § 6 (2) AMG

PHARMIG Code of Conduct

Code of Conduct

- Article 1 – Introduction
- Article 2 – Scope & Definitions
- Article 3 – General principles
- Article 4 – Medicinal product information
- Article 5 – Promotion of medicinal products
- Article 6 – Information online and online promotion
- Article 7 – Events for healthcare professionals
- Article 8 – Interactions with HCP & HCO
- Article 9 – Transparency
- Article 10 – Interactions with Patient Organizations
- Article 11 – Benefits
- Article 12 – Games of chance
- Article 13 – Employees of pharmaceutical companies
- Article 14 – Clinical trials
- Article 15 – AMG violations
- Article 16 – PHARMIG Code guidance

Guidances of the PHARMIG Board

Guidance 1/2010 regarding Article 8
(Non-interventional studies)

Guidance 1/2014 regarding Article 7
& 8 (Caps: meals, hospitality)

Guidance 2/2014 regarding Article 9
(Transparency)

Guidance 1/2015 regarding Article 7
(Events)

Groups of Interaction

■ Healthcare Professionals (HCPs)

- Means any natural person(s) authorized to administer, to dispense and to prescribe medicinal products (...) provided, that such medicinal products are necessary for the discharge of their duties.

■ Healthcare Organizations (HCOs)

- Means any legal person(s), association or organization predominantly comprised of HCPs such as hospitals, clinics, foundations(..).

■ Patient Organizations (PO)

- Means voluntary, non-profit entities mainly composed of patient and/or caregivers (....) whose sole purpose is to represent the interests of patients and/or caregivers and which exist or were founded to serve those interests.



Interaction Areas

WHAT?	WHO?
Interactions (<i>Art 8, 10</i>)	HCP, HCO, PO
Donations & Grants (<i>Art 8.5, 10</i>)	HCO, PO
Events (<i>Art 7, 10, Guidances!</i>)	HCP, HCO, PO
Benefits (<i>Art 11, Art 8.7, Art 10.8</i>)	HCP, HCO, PO
Transparency (<i>Art 9, Art 10, Guidance!</i>)	HCP, HCO, PO

Events for Healthcare Professionals

Article 7

“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.”

Article 7

Events for Healthcare Professionals

Scope of application

- Events organized and / or supported by a pharm. company
- Events organized and / or supported by third parties and supported by a pharm. company
- Events to which the pharm. company invites HCPs
- Events when costs for the HCPs are assumed by the pharm. company

Article 7

Events for Healthcare Professionals

- The **purpose** of events must be, **exclusively**, to provide **scientific and/or educational information** related to continuing education efforts (Art. 7.1)
- **Assumption of costs must be appropriate and restricted to travel, meals, accomodation** and genuine **registration fees** (Art. 7.2)
- **Assumption of costs must not include** the sponsoring or organisation of **leisure activities and / or entertainment** (such as theater, concert, sporting events) (Art 7.2)
- **Assumption of costs for guests accompanying HCPs is prohibited** (Art 7.2)
- **Event 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.** (Art 7.4)
- International Events: costs may be assumed if (Art. 7.5)
 - Significant proportion of attendees are from abroad
 - Necessary resources or expertise are available at the location (logistical reasons)

Guidance 1/2015 regarding Article 7 Events

- Events must be considered in their **entirety** by giving due consideration to **all the elements involved** in each event
- **No** - even seemingly - **improper influence** in connection with any HCP is revealed
- **Purpose** of events must be **restricted only to scientific information** and / or **continuing educational efforts** (Art. 1 Guidance 01/2015)
- In case of support of events by pharm. companies they must ensure that the support provided by them is used only for the legitimate purposes (applicable law, PHARMIG Code)
 - Organizer must confirm that any support is in compliance with applicable law and the PHARMIG Code (Exhibit .1 to Guidance 1/2015 – Confirmation Form for Pharmaceutical Company Support – *not obligatory*)

Guidance 1/2015 regarding Article 7 Events

- Any **leisure activity and / or entertainment program** which takes place in **close chronological connection** with any event stands in contradiction to this purpose (**24 hours**) – independent whether this takes place as part of a scientific program and/or prior to or after a scientific program (Art. 2.2 Guidance 01/2015)
 - Every kind of program which is not conducive to providing 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,...)

Examples

- Code Decision 13/10



- Code Decision 18/05



- Code Decision 11/01



Guidance 1/2014 regarding Article 7 & 8 Caps: meals, hospitality

- Assuming costs for meals during events 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)

Prohibition of benefits – Article 11

- 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. (*Art 11.1*)
- Pharmaceutical companies and their employees must never offer, promise, or grant HCPs any bonuses or in cash or in-kind benefits. (*Art 11.2*)
- **The foregoing is without prejudice to any benefits permitted by the PHARMIG Code and applicable law. (Art 11.3)**

Prohibition of benefits – Article 8

- 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. (*Art 8.1*)
- 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. (*Art 8.2 d*)
- Donations & grants to HCPs are prohibited (*Art 8.5 d*)
- *Prohibition of undue benefits for representatives of HCOs – Art. 8.7*

Permitted benefits

→ ***only if they meet code requirements!***

- **Representation expenses**, appropriate costs restricted to travel, meals, accomodation and genuine registration fees connected with events (*Art 7.2*)
- **Hospitality** – only as a part of events or business meals whose purpose consist of exchanging information → reasonable and moderate (local standards) (*Art 8.2 f*)
- **Donations & grants** (*Art 8.5*)
- **Informational or educational materials** → inexpensive and have direct bearing on the HCPs practice and directly enhance patient care (*Art 4.1 i*)
- **Items of medical utility** – aimed directly at HCPs education & patient care → inexpensive, do not offset routine business practices (*Art 4.1 j*)

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