# IPCAA Webinar Country Code Update\_Switzerland

Daniel Simeon; MD, MHA, Head Pharma Code Secretariat

Jürg Granwehr, Attorney at Law, Department Head Pharma & Law

02.09.2020

Wirtschaftsverband
Chemie Pharma Life Sciences



# Agenda

- Pharma Code in Switzerland Short Overview
  - Signature companies of Pharma Code
  - Legal requirements
  - Pharma Code Practice
- Events
  - Financial contributions by participants
  - Conduct of Companies as sponsor of Events
  - Locations & Venues
  - Satellite events
  - Information about new, not (yet) authorised medicinal products
- Implementation

### Pharma Code

- 1. General provisions
- 2. Professional promotion of and information about medicinal products
- 3. Events for the professional promotion of and dissemination of information about medicinal products as well as postgraduate medical training and continuing medical education for healthcare professionals
- 4. Cooperation with healthcare professionals, healthcare organisations and patient organisations
- 5. Sponsoring of clinical trials with medicinal products and execution of non-interventional studies
- 6. Obligations of pharmaceutical companies when implementing the Pharma Code
- 7. **Supervision** of compliance with the Pharma Code
- **8. Consultative activity** of the Code Secretariat
- 9. Code Committee
- 10. Final provisions

## Signature companies of Pharma Code

### 126 Companies (as of 31.07.2020)

- AbbVie. Baar
- Acino Pharma AG, Liesberg
- Alfasigma Schweiz AG, Zofingen
- Alk-Abelló AG, Volketswil
- Allergan AG, Zürich
- AllergyCare AG, Kilchberg
- Almirall AG. Wallisellen
- Amgen Switzerland AG, Rotkreuz
- APS Arzneimittel Parallelimport Service AG, Cham
- Astellas Pharma AG. Wallisellen
- AstraZeneca AG, Zug
- Bausch & Lomb Swiss AG, Steinhausen ZG
- Baxter AG, Glattpark (Opfikon)
- Baver (Schweiz) AG. Zürich
- Bial SA, Nyon
- Bioforce AG, Roggwil TG
- Biogen Switzerland AG, Baar
- Biomed AG, Dübendorf
- Bio-Strath AG, Zürich
- Biotest (Schweiz) AG, Rupperswil
- Boehringer Ingelheim (Schweiz) GmbH, Basel
- Boots Healthcare (Switzerland) AG, Zug
- Bracco Suisse S.A., Manno
- Bristol-Myers Squibb GmbH, Cham
- Celgene GmbH, Zürich
- Chiesi SA, Villars-sur-Glâne
- Clinipace AG, Volketswil
- CSL Behring AG, Bern
- Daiichi Sankyo (Schweiz) AG, Thalwil
- Debiopharm Group, Lausanne
- Doetsch Grether AG, Basel

- Dr. H. Welti AG, Gebenstorf
- Eisai Pharma AG, Zürich
- Eli Lilly (Suisse) SA, Vernier
- ESBATech AG, Schlieren
- Ferring AG, Baar
- Forest Laboratories GmbH Switzerland, Zürich
- Fresenius Kabi (Schweiz) AG. Oberdorf
- Future Health Pharma GmbH, Wetzikon
- Galderma SA, Cham
- GE Healthcare AG, Opfikon-Glattbrugg
- Geistlich Pharma AG. Wolhusen
- GILEAD Sciences Switzerland Sàrl, Zug
- Ginsana Products Lugano SA, Lugano
- GlaxoSmithKline AG. Münchenbuchsee
- GSK Consumer Healthcare AG. Rotkreuz
- Grünenthal Pharma AG, Mitlödi
- Guerbet AG, Zürich
- Hänseler AG, Herisau
- Helvepharm AG, Frauenfeld
- HRA-Pharma Switzerland Sàrl, Nyon
- IBSA Institut Biochimique SA, Pambio-Noranco
- Incyte Biosciences International Sàrl, Epalinges
- Indivior Schweiz AG. Baar
- Indivior Scriwerz AG, Baar
- Interdelta Spécialités Pharmaceutiques, Givisiez
- iQone Healthcare Switzerland Sàrl, Eysins
- Janssen-Cilag AG, Zug
- Leo Pharmaceutical Products Sarath Ltd., Zürich
- Lundbeck (Schweiz) AG, Glattbrugg
- 3M (Schweiz) AG, Rüschlikon
- MEDA Pharma GmbH. Wangen-Brüttisellen
- Medinova AG, Zürich
- Melisana AG, Zürich

- A. Menarini AG. Zürich
- Mepha Pharma AG. Aesch BL
- Merck (Schweiz) AG, Zug
- MSD Merck Sharp & Dohme AG, Luzern
- Merz Pharma (Schweiz) AG, Allschwil
- Midro AG. Riehen
- Milupa SA, Domdidier
- Mitsubhishi Tanabe Pharma GmbH, Zürich
- Mundipharma Medical Company, Basel
- Mylan Pharma GmbH, Steinhausen
- Neurim Pharmaceuticals AG, Zug
- Nordic Pharma GmbH, Zürich
- Norgine AG, Muttenz
- Novartis Consumer Health Schweiz AG, Rotkreuz
- Novartis Pharma Schweiz AG, Rotkreuz
- Novo Nordisk Pharma AG, Zürich
- Octapharma AG, Lachen
- Omida AG, Küssnacht am Rigi
- Opopharma AG, Glattbrugg
  - Orion Pharma AG. Zug
- Pharmaceutical (Switzerland) GmbH. Glattbrugg
  - Parsenn-Produkte AG, Küblis
- Pfizer AG, Zürich
- Pfizer AG. Consumer Healthcare Schweiz
  - Pfizer PFE Switzerland GmbH. Zürich
  - PharmaMar AG, Basel
- Pharmaton SA, Bioggio
- Pierre Fabre Pharma AG. Allschwil
- Pierre Fabre (Suisse) SA. Allschwil
- Pierrel Research Switzerland AG. Thalwil.
- Piniol AG, Küssnacht am Rigi

- Portola Schweiz GmbH, 5001 Aarau
- Reckitt Benckiser (Switzerland) AG
- Recordati AG, Baar
- Roche Pharma (Schweiz) AG, Reinach BL
- Salmon Pharma GmbH, Basel
- Sandoz AG, Rotkreuz
- Sanofi-aventis (Suisse) SA. Vernier
- Schwabe Pharma AG, Küssnacht am Rigi
- Servier (Suisse) SA, Satigny
- SFL Pharma GmbH. Basel
- Shire Switzerland GmbH. Zug
- Similasan AG, Jonen
- Spirig Healthcare AG, Egerkingen
- Stallergenes AG, Dietlikon
- Streuli Pharma AG, Uznach
- Takeda Pharma AG, Pfäffikon
- Tentan AG, Itingen
- Teva Pharma AG. Aesch
- Theramex Switzerland GmbH. Zürich
- UCB-Pharma AG, Bulle
- F. Uhlmann-Eyraud SA, Meyrin
- VERFORA SA. Villars-sur-Glâne
- Vertex Pharmaceuticals (CH) GmbH, Zug
- Vifor Pharma, Villars-sur-Glâne
- ViiV Healthcare GmbH, Münchenbuchsee
- WALA Schweiz GmbH. Bern
- Weleda AG, Arlesheim
- Louis Widmer AG, Schlieren
- Dr. Wild & Co. AG, Muttenz
- Zambon Schweiz AG, Cadempino
- Zeller Medical AG, Romanshorn
- Max Zeller Söhne AG, Romanshorn

IPCAA Webinar Country Update Switzerland

# Legal Requirements

812.21

English is not an official language of the Swiss Confederation. This translation is provided for information purposes only and has no legal force.

#### Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA)

of 15 December 2000 (Status as of 1 August 2020)



https://www.admin.ch/opc/en/classified-compilation/20002716/202008010000/812.21.pdf

810.30

English is not an official language of the Swiss Confederation. This translation is provided for information purposes only and has no legal force.

#### Federal Act on Research involving Human Beings (Human Research Act, HRA)

of 30 September 2011 (Status as of 1 January 2020)

https://www.admin.ch/opc/en/classified-compilation/20061313/202001010000/810.30.pdf

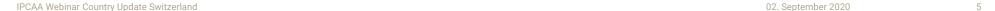
nung 812.212.5

Verordnung über die Arzneimittelwerbung (Arzneimittel-Werbeverordnung, AWV)

vom 17. Oktober 2001 (Stand am 1. Januar 2020)

Verordnung über die Integrität und Transparenz im Heilmittelbereich (VITH)

vom 10. April 2019 (Stand am 1. Januar 2020)



### Pharma Code Practice

- There are 6 Recommendations to the Pharma Code in the public domaine of the website of scienceindustries
   www.scienceindustries.ch/en/article/13931/pharma-code-practice
- No 5 is of specific interest in the field of events
  - -> Conduct of companies on the occasion of congresses, symposia and similar events which are held for health care professionals in Switzerland under the responsibility of professional organisations.
- Further information is available over the membernet (esp. the Q&A),
   which is only accessible for member companies

# Organisation - Code Secretariat

- HCP with experience in the pharmaceutical industry => 0.4 FTE
- Supervision of the work and activities subject to this Code.
- Suspected breach of the Code
  - Identified by Code Secretariat on its own initiative
  - Receiving notification from third parties
  - Inform the company concerned in writing
  - Stating reason(s)
  - If notified to the Code Secretariat, copy of notification forwarded to the company concerned
  - Company concerned is asked to state a written opinion within a reasonable time
  - About 110 to 120 suspected breach of the Code annually
  - Solved within short period of time (mean 7.7 days / median 9.0 days)



Dr. Demel Simeo

scienceindustries Wirtschaftsverband Chemie Pharma Life Sciences

Nordstrasse 15 Poetfach, CH-8021 Zürich

T +41 44 368 17 38 damiel simecon Escience industries of

Frau

25. August 2020

#### Vermuteter Verstoss gegen den Pharmakodex

#### Sehr geehrte

Die nachstehend erwähnte Aktivität<sup>1</sup> Ihres Unternehmens verletzt mutmasslich den Pharmakodex (PK). Eine Koole der Anzeige und der beanstandeten Werbeunterlagen liegt bei.

Ich ersuche Sie als Unternehmen, das diese Aktivität organisiert, der nachstehenden Aufforderung in die sem Brief innerhalb der genannten Fristen Folge zu leisten.

Sollten Sie den vermuteten Verstoss bestreiten, so ersuche ich Sie um schriftliche Begründung dafür

Betroffene(s) Arzneimittel: x
Medium\* / Zusammenhang\*: x
Datum der Aktivität: aktue
Vermuteter Verstoss: x
Betroffene PK-Ziffer(n): x
Vorläufige Einschätzung:

Die Werbung muss so rasch als möglich angepasst werden. / muss so-

rt gestoppt werden.

Vorgeschlagene Massnahme: Stopp, Anpassen der Werbung und Stellungnahme.

Massnahme starten: so rasch als möglich / sofort
Stellungnahme an das
Kodex-Sekretariat bis: 02.06.2020

Abschliessend verweise ich Sie auf die Ziffer 6 des Pharmakodexes (Aufsicht und Verfahrensregeln).

Freundliche Grüss

M. Junial Simon

Ur, med. Daniel Simeon Konie ner Emell:

### Events

Support of events in the field of medical education is allowed

### Financial contributions by participants are compulsory:

- HCP one third of the direct cost
- HCP in post-graduate medical training 20%
- A financial contribution may be waived if:
  - event held in Switzerland and
  - last for half a working day at most and
  - does not require to stay overnight

# Conduct of Companies as sponsor of Events (1/2)

- No sponsoring or support of any events whose programme includes leisure,
   cultural, sport or other entertainment opportunities.
- The offers made by companies on their information stands or otherwise on the congress site which extend beyond professional information and promotion (catering, distribution of information- and training materials or of writing implements and pads) must be of modest value and compliant with the customary practice.
- The company must not pay participants to attend their information stand.

# Conduct of Companies as sponsor of Events (2/2)

- Alcohol is not to be served on the information stands.
- Personnel of the company must adopt appropriate conduct and dress on the information stand and in the further framework of the congress, consistent with its professional and scientific environment.
- Personnel of the company should behave fairly and properly in relation to the other companies which are taking part in an event as sponsors

IPCAA Webinar Country Update Switzerland 02. September 2020 10

### Locations & Venues

- Locations which are famous for their entertainment facilities or regarded as extravagant should be avoided
- The events should take place at appropriate venues conducive to the main purpose of the event
- Their choice should be **guided primarily by the space and infrastructure availability**, with a view to the appropriate performance of the main purpose.

### Satellite events

- Satellite events and similar meetings must be part of the official programme of an event.
- Satellite events should be **led by a HCP who is independent** of the company (e.g. a representative of the organising professional society).
- Companies must **not arrange competing events held in parallel** with the congress programme.
- The title, programme and description of the satellite events must contain no promotion for medicinal products.
- The companies will obtain **approval from the appropriate entity** (e.g. management) for the title, programme and description of satellite events.
- Information activities at satellite events must be **separated physically** from promotional activities at these events.
- In order to highlight the informational nature of the event, **no promotion for medicinal products is permitted** on the satellite event.
- Marketing and sales personnel may attend satellite events but will not take part in the discussion.

# Information about new, not (yet) authorised medicinal products

- The companies may provide information at these events about new medicinal products which are not (yet) authorised in Switzerland; however, no promotion for these medicinal products is allowed
- With such information, it must always be clearly stated that this medicinal product, or the new indication, possible application, dosage, pharmaceutical form or packaging for the medicinal product has not yet received marketing authorization from Swiss health authority
- At events with international participation such information materials must be accompanied by the following declarations:
  - Reference to the countries where the medicinal products concerned are authorised, and to the
    fact that the medicinal products concerned are not authorised in Switzerland or are subject to
    different conditions in Switzerland;
  - **Reference to the possible differences** in registration requirements and the governmentapproved professional information (indications, warnings, etc.) in the country or countries where the medicinal products concerned are authorised

### Implementation

- Code Secretariat has not enough resources to follow up on all events taking place in Switzerland
- However
  - Signature Companies approached Code
     Secretariat in advance whether participation is possible / informed about critical events (location / venue)
  - Code Secretariat contacted Organizers / PCOs
  - Multiple organizers / PCOs contacted Code Secretariat to learn how to organize events according to Pharma Code













scienceindustries Nordstrasse 15, Postfach 8021 Zurich Switzerland

info@scienceindustries.ch scienceindustries.ch

Telefon: +41 44 368 17 11 Telefax: +41 44 368 17 70 Wirtschaftsverband Chemie Pharma Life Sciences

science**industries** 

SWIT7FRIANT