scienceINDUSTRIES
SWITZERLAND

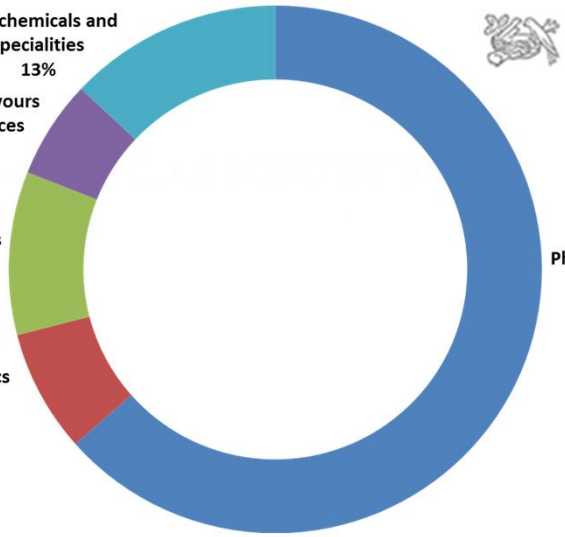
Pharma Self-regulation in Switzerland

scienceindustries
Business Association Chemistry Pharma Biotech

Basel, 16 April 2018

Jürg Granwehr

Broad Membership



Only one Pharma Self-regulation

- To guarantee a lean implementation of the self-regulation, scienceindustries is the **only responsible organisation** for the self-regulation of the Pharma industry in Switzerland
- Founded in 1882, scienceindustries has the **broadest membership** among all pharma associations in Switzerland
- Therefore, the Swiss Pharma self-regulation covers companies from **different sub-industries**:
  - Innovative Pharmaceuticals
  - Biopharmaceuticals
  - Generics
  - OTCs
- **Medical devices** are not covered by the Pharma Self-regulation

Pharma Self-regulation

- Based on the IFPMA Code of Practice and the three EFPIA Codes, scienceindustries transposed the Pharma self-regulation by adopting:
  - Code of Conduct (PC) -> integrity rules
  - Disclosure Code (PCC) -> cooperation and disclosure
- Companies can sign off only one or both codes
  => around **130 signed off the PC**
  => around **60 companies signed off the PCC**
- Meanwhile, coverage with regard to the PC is estimated to excede 95% of pharma turnover in CH, whereas coverage of the PCC is estimated to excede 85% of said turnover

Self-regulation

- Self-regulation is a **privat agreement**, to which a defined group of addressees **volunteer**
- By **signing off** the signatory companies **accept to be bound** by the rules of the self-regulation
- According to the Swiss law, self-regulation is permitted within the **limits of competition law**
- **Enforcement** is not carried out by state institutions, but by a **private secretariat**
- **Swissmedic acknowledges** the self-regulation and does not interfere as long as a procedure is pending in the Code Secretariat (except if there is a critical danger to public health)

Self-regulation vs. Legislation

- There are **legal provisions** on federal level, which is **mandatory law** (e.g. Therapeutic Product Act/Act on Research involving Human Beings etc.)
- **Self-regulation** goes in many aspects **beyond the legal standards**: by singing off the signatory companies declare to be bound by this additional rules and to accept the competence of the Code Secretariat in enforcing them
- **Purpose** of the **legal provisions** is to guarantee the **security of the public health** (=> protection against danger and deception)
- **Purpose** of the **self-regulation** is to guarantee a **fair competition** (=> avoiding offenses against good morals in competition and guarantee high ethical standards)

Content of the Swiss Self-regulation

- There are two Codes in Switzerland
- **Pharma Code (PC)** => addressing **integrity rules** in general and framing the conduct of companies in the field of professional promotion and events
- **Pharma Cooperation Code (PCC)** => addressing additional rules in the cooperation between the industry and stakeholders of the health care system as well as the **disclosure of the transfers of value** resulting from this cooperation

Content of the Swiss Self-regulation

- PC contains rules addressing:
  - **General provisions** and obligations of the companies
  - **Principles of integrity** and **ban on gifts**
  - **Professional promotion** of medicinal products
  - Organisation and support of **events/congresses**
  - Sponsoring of **clinical trials**
- PCC contains rules addressing:
  - **Cooperation rules** with healthcare professionals (HCP), healthcare organisations (HCO) as well as patient organisations (PO)
  - **Disclosure** of pecuniary benefits to such recipients

Enforcement Procedure

- There is a **Code Secretary** (physician), who is employed by scienceindustries to guarantee his independence from the companies
- **He is responsible for** the implementation of the Codes and deals with the complaints
- **Procedure** is enshrined in the Codes: simple ruling with **short timelines** (Ø = 8 working days) - Secretary decides finally
- **Sanction** consists in **immediate compliance** with the self-regulation, which has to be confirmed in writing
- An **interdisciplinary Code Committee** is responsible for the Code revisions, guidance as well as recommendations

Tasks of the Code Secretariat

- It **supervises** the companies and **raises complaints** in cases, where he suspects a misconduct
- It **treats complaints** from signatory companies and third parties
- Secretary is **bound by the procedure** set out in the codes but he **decides finally** after hearing the involved parties
- Secretary **informs** on a regular base about the interpretation of the codes by editing anonymous **case reports**
- Secretary **publishes the annual reports** and informs the Code Committee as well as the EFPIA-Board

Statistics of the Code Secretariat 2017

- Number of cases concerning the PC: **121** (2016: 119)
- Number of complaints filed against competitors: **54** (2016: 39)
- No cases were classified as potentially hazardous to health (2016: 1), and to the best of the Secretariat's knowledge, no cases were escalated to Swissmedic (2016: 3)
- 64 pharma companies submitted **4'657 sample copies** of their promotional material and information; 3'625 sample copies (77.8%) were sent to the Secretariat electronically
- **More than 200 enquiries**, mostly from member companies, but also from professional associations, congress organisers, law offices etc.

Statistics of the Code Secretariat 2017

- Average duration of proceedings was **8.7 days**
- In 2017, **90 proceedings** were **concluded** (74% of all the cases dealt with as against 69% in the previous year)
- After the contested advertising had either been **corrected or removed**
- Secretariat rejected 8 (7%) of the complaints because there had been no breach of the Code
- In 3 cases (2%) the concluding letter to the company responsible imposed a condition requiring an amendment to comply with the Code
- In no cases (previous year: 2) an **immediate correction** of the advertising was required; in 2 cases (previous year: 1), the immediate and complete withdrawal of the disputed advertising was required
- In only 1 case the Code Secretariat carried out a **mediation procedure**

Disclosure 2017 - Consolidated Data

- **Total**: **153,3 Mio.** vs. 138,6 Mio. in 2016 (+ 14,7 Mio.)
- Transfers of Value (ToV) to **HCP**: **14 Mio.** (9%)
- ToV to **HCO**: **90 Mio.** (59%)
- ToV in **R&D**: **49 Mio.** (32%)

- Average **consent rate*** for **HCP** at about **75%**
- Average a **consent rate*** for **HCO** at about **84%**

*Consent rate indicates the number of recipients of ToV which agreed being individually mentioned when publishing data in comparison to the total of recipients of ToV (incl. those, who rejected individual publishing)

Thank you for the invitation
and
your attention!