



Code of conduct as an efficient tool – the Swedish experience

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The self-regulatory system in Sweden

- Part of a strategy to build trust
 - Partnership
 - Transparency
 - Based on facts
 - Code of conduct
 - Fass.se
 - Database on cooperation with NGOs and Professional organisations
 - Environment classification
 - Etc.



Access to information on medicines



Accessibility

- Compliance
- Text to voice
- Braille

- Product information
 - SPC, PIL
 - Links to company websites
 - Product e-mail
- Clinical trials
- “All about medicines”
- Future Medicines
- Access to Clinical Studies

- Virtual Health Center
 - Links to extended disease information

- Patient Forum
 - Patient Organizations

- Medicines University
 - Elderly people and medicines
 - Number of students 200.000+



Access, transparency and patient safety

- My Fass
- "Rapid Alert" information on changes of product characteristics



Self regulation system

- System agreed with the MPA (regulatory agency)
- First rules governing Drug Information in 1969
- Quality certification system for websites
- IGM (ex-post review of all marketing)
- Approx 100 cases / year (of which 1/3 is regarding information to patients)



Sanctions

- Publicity
- Fines (max 500.000 SEK, approx 50 000 EURO)
- Suspension



IGM and NBL

IGM

IGM shall be a registered medical practitioner with scientific competence, significant and comprehensive clinical experience and a good general overview of medical and pharmaceutical research.

NBL

NBL consists of a chairman and 10 members.

- The chairman: an experienced lawyer. Not engaged in the pharmaceutical industry.
- Six members shall hold executive positions in the pharmaceutical industry
- Two members shall represent medical expertise
- Two members shall represent public interests, especially consumer interests.



Experiences (in general)

The needs of patients;

- Information with good quality, updated and in their own language
- Information should be available on the Internet. There is also a need for non-electronic channels
- Information which all citizens can use irrespective of individual abilities and disabilities

The role of different stakeholders:

- Information from multiple sources is needed, including from the pharmaceutical industry
- Public Private Partnerships is essential
- "In all systems: The same updated information at the same time"



Swedish experiences: concluded

- The self-regulatory system is only one part of a long-term comprehensive strategy to build trust
- Trust is built on partnership through transparency and by providing high-quality and unbiased information/facts
- "There's times to compete and times to cooperate" (companies' alignment and active support)
- The self-regulatory system works well, but only in combination (and in cooperation) with a regulatory agency
 - MPA: "The Self-regulatory system is well functioning and consistent with the role and mandate of the MPA"

