Association of Voluntary Self-Regulation for the Pharmaceutical Industry ("FSA")

Germany
Global Transparency Regulatory Update
Roundtable

International Pharma Congress Day I: Opening
Plenary Session, New Business Models Driving new Ethics and
Compliance Challenges

Pharmaceutical Compliance Congress and Best Practices
Forum
5 May 2014, Dubai

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I. Current (legal) situation in Germany

- **Fully self-regulatory approach**
  - No co-regulation schemes in place
  - No transparency law in place or planned so far

- **Strong data privacy requirements**

Is (written) consent needed?
Can the consent be revoked and what will be the consequence?
Can companies process personal data without consent for aggregate disclosure?

=> A solvable dilemma?
II. Implementation of EFPIA’s Disclosure Code

• FSA General Assembly approved the „FSA-Transparenzkodex“ at its yearly meeting on 27 November 2013

• 100% transposition of EFPIA’s requirements
  ▪ Code applies to HCPs and HCOs
  ▪ Categories are:
    – Donations and Grants
    – Contributions to costs related to Events
    – Fees for Services and Consultancy
    – Research and Development

• First Disclosure in 2016 based on 2015 data

Possible Pitfalls and Challenges

e.g.
• Convince doctors and all other concerned HCPs about the individual positive benefit of the transparency initiative (role model Code on Patient Organisations?)
• Support member companies with their implementation efforts (flyer, Q&As, model clauses for contracts, training etc.)
• Raise awareness and gain support by the general public and press
• etc.
III. Position of relevant Stakeholders

Position of the German Medical association (1)

Decision of the 16th German Medical Assembly in June 2013

I – 50: Physicians Payment Sunshine Act

• Representatives are in favor of transparency based on the US Physicians Payment Sunshine Act
• The Board of the German Medical Association shall strive for a law applicable to all players in the healthcare sector
• Position towards the self-regulatory approach of the industry?

III. Position of relevant Stakeholders

Position of the German Doctor’s Association (2)
III. Position of relevant Stakeholders

Position of a regional Doctor’s Association

Lower Saxonia:

http://www.haeverlag.de/nae/0114_heft.pdf

Conclusion

• Transparency is the consequent next step
• Reactions in Germany so far are overall positive
• A lot of work is already done, however there is still a lot to do

Transparency creates confidence and dispels distrust.

for more information:
www.pharma-transparency.com
Questions?

Backup
Adopting the new Disclosure rules

- Active Support to EFPIA Process
  - October 2012: Establishment of a Working Group with FSA und vfa member companies (Bayer, Boehringer, Grünenthal, GSK, Janssen-Cilag, Lilly, Pfizer, Roche)
    - Discussion of EFPIA Drafts; Input to EFPIA process
    - In parallel, preparation for national support
  - First Workshop for the vfa/FSA members on 11 April 2013 (approx. 70 participants)
  - Update and discussion in relevant vfa/FSA committees
  - Briefing of the German representatives in EFPIA’s bodies
  - Consultation among members on EFPIA drafts (April 2013)
  - Communication to the member companies’ managements
  - Ongoing information about the process to the vfa/FSA members

The EFPIA Disclosure Code
The EFPIA Disclosure Code

- Communication re EFPIA Process (1)
  - Media coverage I August 2012 (first announcement by EFPIA):
    o Press releases of the FSA
  - Media coverage II January 2013 (“Criminal Code loophole for corrupt physicians in private practice”):
    o Press releases of the vfa and FSA
    o NDR Info Redezeit (Radio Discussion with the president of the German Doctor’s Association)
  - Media coverage III February 2013:
    o Press releases of the vfa and FSA
  - Media coverage IV: Approval of the EFPIA Disclosure Code on 24 June 2013:
    o Press releases of the vfa and FSA
    o Two wired reports of the dpa
    o FSA Newsletter (over 600 recipients)
The EFPIA Disclosure Code

Communication support re EFPIA Process

- FSA Communication Toolkit for the Members of FSA and vfa (Juni 2013)
  - Draft EFPIA Disclosure Code (with a German working translation)
  - Factsheet re the upcoming changes for the compliance departments of the companies
  - Factsheet re the EFPIA Disclosure Code for the communication departments of the companies
  - Q&As (company communication) as a reactive tool for questions coming from the press
  - Short model Flyer as a reactive communication tool for the sales representatives of the member companies => uniform communication towards the doctors
  - Model presentation re the upcoming changes
  - Best practice sharing with examples from Boehringer Ingelheim, Grünenthal and Lilly

The FSA Disclosure Code

Work on the adoption of the FSA Disclosure Code

- vfa/FSA Working Group: Discussion of the transposition of the disclosure requirements into an FSA Code of Practice
- Second Workshop for the vfa/FSA membership on 23 July 2013 (approx. 100 participants)
- Consultation among member companies on draft FSA Disclosure Code (until end of August 2013)
  - Feedback from 10 member companies (mainly on the „ban of gifts“)
  - Analysis and incorporation into the final draft of the FSA Disclosure Code
- Update and discussion in relevant vfa/FSA committees
- Third Workshop for the vfa/FSA membership on 28 January 2014 (over 90 participants)
- Support documents on data privacy (model consent declaration for HCPs, model contract clause for HCOs, Q&As)
The FSA Disclosure Code

• Communication support re FSA Process

• FSA Communication Toolkit for the Members of FSA and vfa (November 2013)
  - Draft FSA Transparency Code
  - Draft FSA HCP Code
  - Factsheet re the upcoming changes for the compliance departments of the companies
  - Factsheet re the FSA Transparency Code for the communication departments of the companies
  - Q&As (company communication) as a reactive tool for questions coming from the press
  - Short model flyer as a reactive communication tool for the sales representatives of the member companies => uniform communication towards the doctors
  - Model presentation re the upcoming changes

Over 48,500 (!) Copies delivered

The FSA Disclosure Code

• Communication support re FSA Process

• Press releases of vfa and FSA re the approval of the new Transparency Code

• Start of the approval process at the Federal Cartel Office („Bundeskartellamt“)
The FSA Disclosure Code

Dedicated Website for the Transparency Project

www.pharma-transparenz.de

1. Website Flyer re the ban on gifts

Over 63,750 (!) Copies delivered
The FSA Disclosure Code

Online Training Tool for the Transparency Code

=> Will be ready in April 2014