

# 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

Holger Diener, FSA Managing Director



## 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**



## II. Implementation of EFPIA's Disclosure Code

### 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)

**ÄrzteZeitung**

**Transparenz contra Korruption**

**Sanktionskontrolle: So funktioniert die Überwachung und Sanktionierung**

**USA: Der Physician Payment Sunshine Act**

**Ärztetag: Klares Votum für Transparenz**

**Kooperation und klare Verhältnisse**

### III. Position of relevant Stakeholders

#### Position of a regional Doctor's Association

##### Lower Saxonia:



[http://www.haeverlag.de/nae/0114\\_heft.pdf](http://www.haeverlag.de/nae/0114_heft.pdf)

### Conclusion

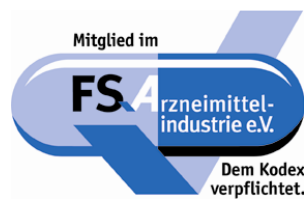
- Transparency is the consequent next step
- Reactions in Germany so far are overall positive
- A lot of work is already done, however there is still a lot to do

*Transparency creates confidence and dispels distrust.*



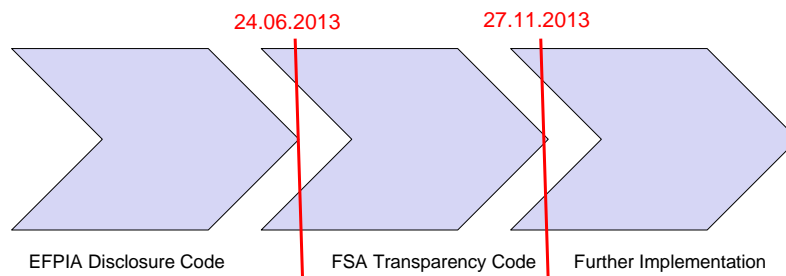
for more information:  
[www.pharma-transparency.com](http://www.pharma-transparency.com)

# Questions?



# Backup

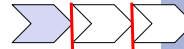
## Adopting the new Disclosure rules



## The EFPIA Disclosure Code

- **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

FS4  
Arzneimittel-  
Industrie e.V.

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

13

## The EFPIA Disclosure Code

FS4  
Arzneimittel-  
Industrie e.V.

- **Communication re EFPIA Process (2)**

**Gesamtzahl:**  
ca. 200 Medienberichte

**dpa** Deutsche Presse-Agentur  
**dapd** Nachrichtenagentur

**SPIEGEL ONLINE** **FOCUS** **stern** **Frankfurter Allgemeine**  
**ZEITUNG ONLINE** **WAZ** **DIE WELT** **Hamburger Abendblatt**  
**ÄRZTE ZEITUNG** **apotheken adhoc** **Süddeutsche Zeitung**  
**HEUTE** **pharma** **Pharmabranche**  
**Transparenz gegen Ärztekorrumpion**

**Das Ende zäher Klischees**  
ZÄHLUNGEN AN FELDGEHILFEN  
Pharma-Industrie will sich zu Transparenz verpflichten

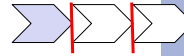
Neue Regeln gegen zuviel Pharma-Einfluss auf Ärzte  
Zusammenhang der Pharmaindustrie offenlegen  
Regierung und Industrie wollen Pharma-Einfluss auf Ärzte eindämmen

Pharmabranche gelobt mehr Transparenz



14

## The EFPIA Disclosure Code



### Communication support re EFPIA Process

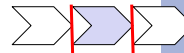
- **FSA Communication Toolkit for the Members of FSA and vfa (Juni 2013)**
  - Draft EFPIA Disclosure Code (with a German working translation)
  - Draft EFPIA HCP Code (with a German working translation)
  - Factsheet re the upcoming changes for the compliance departments of the companies
  - Factsheet 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



**Over 26.000 (!)  
Copies delivered**

15

## 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)

16



## The FSA Disclosure Code

FSA Arzneimittel-  
industrie e.V.

### •Communication support re FSA Process

#### •FSA Communication Toolkit for the Members of FSA and vfa (November 2013)

- oDraft FSA Transparency Code
- oDraft FSA HCP Code
- oFactsheet re the upcoming changes for the compliance departments of the companies
- oFactsheet re the FSA Transparency Code for the communication departments of the companies
- oQ&As (company communication) as a reactive tool for questions coming from the press
- oShort model Flyer as a reactive communication tool for the sales representatives of the member companies => uniform communication towards the doctors
- oModel presentation re the upcoming changes



Over 48.500 (!)  
Copies delivered

17

## The FSA Disclosure Code

vfa. Die forschenden  
Pharma-Unternehmen

FSA Arzneimittel-  
industrie e.V.

### •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“)

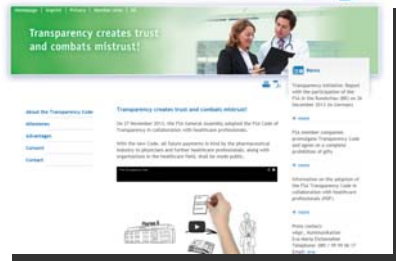
18

# The FSA Disclosure Code

vfa. Die forschenden Pharma-Unternehmen

FS4 Arzneimittel-industrie e.V.

## Dedicated Website for the Transparency Project



[www.pharma-transparenz.de](http://www.pharma-transparenz.de)



[www.pharma-transparency.de](http://www.pharma-transparency.de)  
[www.pharma-transparency.com](http://www.pharma-transparency.com)  
[www.pharma-transparency.eu](http://www.pharma-transparency.eu)

19

# The FSA Disclosure Code

vfa. Die forschenden Pharma-Unternehmen

FS4 Arzneimittel-industrie e.V.

## Flyer re the ban on gifts

**Section 21: Gifts**

(1) It is prohibited to promise, offer or grant gifts to healthcare professionals. This applies irrespective to product-related or non-product-related advertising.

(2) The prohibition of paragraph 1 does not apply if the benefits are allowed under this Code or an exclusion under § 7 para. 1 sent. 1 no. 2-5. BfArG is applicable.

**Section 15a: Scientific Information**

(1) In consideration of § 6 para. 1 no. 2 of this Code, and § 7 German Advertising Code, Companies may only provide healthcare professionals with:

1. informational and educational materials. Such materials must be inseparable from the professional activity of the healthcare professional and be genuinely linked to the medical profession.
2. items of medical utility and complex, aimed directly at the education of the recipient, which support diagnostic analysis and the treatment and indication of the member company.

(2) The board of management of the association is issuing binding guidelines in accordance with the meaning of this clause.

**Please note:** The prohibition can be based on the validity of the FSA as of the date for each regulation to become valid the approval of the Federal Cartel Office the first quarter of 2016.

For additional information, please contact: T1 Kommunikation & S. (FSA) / Self-Regulation for the Pharmaceutical Industry, Dr. Ralph Binner - info@fsa-pharma.de Phone: +49 (0)30 6 67 26-00 / E-mail: [kommunikation@fsa-pharma.de](mailto:kommunikation@fsa-pharma.de)

**Information for the Revision of the Prohibition on Gifts in the FSA Code of Conduct Healthcare Professionals**

Patient trust in the individual prescription decision of the physician is the FSA's highest guiding principle. Consistent with this philosophy, FSA members at the General Assembly on 27 November 2013 decided on a comprehensive prohibition on all gifts to members of the healthcare profession. This rule, subject to prior approval by the Federal Cartel Office, shall go into effect on 1 July 2014.

**What is changing?**

Permissible	Impermissible
It is still allowed to distribute the below "scientific information":	Starting on 1 July 2014, the following benefits in kind are prohibited:
<ul style="list-style-type: none"> <li>Product- or indication-specific informational material</li> <li>scientific (educational) brochures, treatment schemes, special gifts, product monographs, training materials</li> <li>medical instruction and demonstration items (for training the application of medications, for example)</li> </ul>	<ul style="list-style-type: none"> <li>promotional items (such as pens, notepads, etc.), independent of their actual value</li> <li>General practice supplies such as cannula disposal boxes, gloves, alcohol swabs, syringes, injection needles, ECG modules, sensors, disinfectants, etc.</li> <li>Reference books, medical periodicals or magazine subscriptions</li> </ul>

Please refer to the separate page for new concrete rules on the prohibition of gifts and on scientific information.

Over 63.750 (!)  
Copies delivered

20

## The FSA Disclosure Code

vfa. Die forschenden  
Pharma-Unternehmen

FS.4  
rzneimittel-  
industrie e.V.

### Online Training Tool for the Transparency Code



=> Will be ready in April 2014