Transparency of payments to the healthcare sector
- Introduction -

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Session overview

• The speakers

  Samantha Regenthal, Head Legal Services, SFL, Basel
  Richard Bergström, Director General, EFPIA
  Patricia Lanssiers, Senior Director, Ethics and Compliance Officer. Eli Lilly Benelux N.V

• Aim of this session
  – Overview of the new EFPIA Disclosure Code, its background and purpose
  – Insights on the impact on companies and elements of successful implementation
  – Q&A
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Transparency in the wider context

**Industry & regulatory authority transparency:**
- Authority decision making processes
  - MAA dossiers
  - Interactions industry/authorities
- Clinical / non-clinical data
- Interactions with healthcare professionals / institutions

**Healthcare Professionals (HCPs) / Researchers / Academia:**
- Facilitating own research
- Second assessments

**Industry:**
- Increased clarity on authority decision making
  - Access to competitor data
  - Increased internal overview

**Patients:**
- Access to info to understand / influence decisions on own health / treatment

**Media / Public:**
- Scrutiny of industry behaviour
  - Scrutiny of authority behaviour
  - Democratic process

**Patients:**
- Access to info to understand / influence decisions on own health / treatment
Transparency in the wider context

HCPs / HCOs may re-think collaborations with and support from industry and may change prescription behaviour

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Patients: - Access to info to understand / influence decisions on own health / treatment

Professionals (HCPs) / Researchers / Academia: - Facilitating own research - Second assessments

Industry: - Increased clarity on authority decision making - Access to competitor data - Increased internal overview

Industry may re-think collaborations with and support to HCPs / HCOs

Media / Public: - Scrutiny of industry behaviour - Scrutiny of authority behaviour - Democratic process

Media may perform own assessments of data and form public opinion

Patients may question treatment decisions and consider change of healthcare provider
Transparency in HCP interactions

• HCP / industry knowledge exchange is essential for the quality of patient treatment and future research
• Integrity as basis; interactions between industry and HCPs can create the potential for conflicts of interest
• Ethics and transparency in the sector gain increased priority for the EU Commission
  – Commissioner Tajani process on corporate responsibility in the field of pharmaceuticals (2010)
    • Platform on Ethics & Transparency
    • Guiding Principles Promoting Good Governance in the Pharmaceutical Sector (signed off in 2013)
Regulator and industry initiatives

- Recent developments involving data collection 2011 - 2015
  - US Sunshine Act (law)
  - Portugal (law)
  - France (law)
  - Netherlands (self-regulation)
  - Slovakia (law)
  - UK (self-regulation)
  - Denmark (law)
  - Japan (self-regulation)
  - EFPIA Patient Organisation Code (self-regulation patient org. payments)
  - EFPIA HCP/HCO Disclosure Code
EFPIA HCP/HCO Disclosure Code*

- Adoption of EFPIA HCP/HCO Disclosure Code in 2013
  - National implementation (33 countries)
  - Compliance is condition for EFPIA membership
  - Member companies to disclose direct and indirect transfers of value
  - First disclosure in 2016 (of 2015 figures)

*EFPIA Code on disclosure of transfers of value from pharmaceutical companies to healthcare professionals and healthcare organisations
Implementation challenges

- Successful implementation requires substantial company efforts and resources
  - Self-regulation encouraging a consistent approach to data disclosure in Europe
  - …but still challenges meeting multi-jurisdictional requirements
  - Complex data collection and validation requiring substantial resources
- Transparency alone does not eliminate conflict of interest issues
  - Need to further explain value and importance of HCP interactions
  - Higher expectations on compliance systems and processes
Q&A Session

- Is increased transparency really an improvement in itself? Is it fit for the purpose of securing trust?
  - Data overload / missing context of data
  - Extensive need for information about value of interactions

- What about legal issues (privacy, competition law etc) – all clear?
- Are the efforts for implementation of measures to comply with these new rules justified by the expected benefits?
- Have there been any indications that HCPs would be increasingly reluctant to work with industry due to the new EFPIA disclosure requirements (see US)?
- What about transparency initiatives in the medical devices industry?
Backup slides
Outlook - US Sunshine Act

- Data to be centrally available in September 2014
  - Lacking awareness about data availability
  - Even when aware, patients tend to choose healthcare providers based on other factors
  - Patients may have difficulties evaluating the undesirable and beneficial aspects of various types of payments
  - Implementation costs vs. benefits considered unbalanced
  - Potential unintended consequences on research, education, and other scientific activities due to reduced interactions HCPs/industry

## Disclosure template

### Schedule 2 - TEMPLATE

<table>
<thead>
<tr>
<th>Article 2 - Section 3E8</th>
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<tbody>
<tr>
<td><strong>Full Name</strong></td>
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<tr>
<td><strong>HCPI: City of Principal Practice</strong></td>
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<tr>
<td><strong>Country of Principal Practice</strong></td>
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<td><strong>Donations and Grants to HCOs (Art. 301.1.a)</strong></td>
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<tr>
<td><strong>Contribution to costs of Events (Art. 301.1.b &amp; 301.2.a)</strong></td>
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<tr>
<td><strong>Sponsorship agreements with HCOs / third parties appointed by HCOs to manage an Event</strong></td>
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<td><strong>Registration Fees</strong></td>
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<tr>
<td><strong>Travel &amp; Accommodation</strong></td>
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<tr>
<td><strong>Fee for service and consultancy (Art. 301.1.c &amp; 301.2.a)</strong></td>
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<tr>
<td><strong>Transfers of Value to Research &amp; Development as defined (Art. 304)</strong></td>
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<tr>
<td><strong>TOTAL</strong></td>
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#### INDIVIDUAL NAMED DISCLOSURE - one line per HCP (i.e. all transfers of value during a year for an individual HCP will be summed up. Information should be available for the individual Recipient or public authorities' consultation only, if appropriate)

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<tr>
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#### OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons

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<th>Aggregate amount attributable to transfers of value to such Recipients - Art. 302</th>
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<td>HCO 2</td>
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#### INDIVIDUAL NAMED DISCLOSURE - one line per HCO (i.e. all transfers of value during a year for an individual HCO will be summed up. Information should be available for the individual Recipient or public authorities' consultation only, if appropriate)

<table>
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</tr>
</thead>
<tbody>
<tr>
<td>Number of Recipients (named list, where appropriate) - Art. 303</td>
</tr>
<tr>
<td>Number of Recipients (named list, where appropriate) - Art. 304</td>
</tr>
</tbody>
</table>

#### Aggregate Disclosure:

| N/A |

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References