EFPIA Data Demonstrates the Challenges Confronting Companies

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Brian P. Sharkey
Pharmaceutical companies commence open disclosure of payments to Healthcare Organisations and Professionals

Pharmaceutical companies commence open disclosure of payments to Healthcare Organisations and Professionals
Voluntary transparency initiative by industry sees details of ‘transfers of value’ in Ireland in 2015 published

Thursday 30th June 2016

04.07.2016 - International Pharmaceutical Industry Discloses Information on Transfers of Value to Healthcare Professionals and Organizations

By July 1, 2016, in accordance with the requirements of the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the Code of Practice of the Association of International Pharmaceutical Manufacturers (AIPM), which is a member of EFPIA, international pharmaceutical companies had published data on transfers of value to healthcare professionals and organizations in 2015.

Press release – The Belgian Transparency Register went live

22 June 2016

Pharmaceutical companies drive transparency and underline industry investment in European Healthcare

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Drugs firms should refuse to pay doctors who won't declare earnings, says NHS

30% of health professionals refuse to be named on drug firm payments database

What are they hiding? A THIRD of health workers including top doctors refuse to admit if they've been given lavish perks or payments by drug firms

55% of HCPs agree to release of pharma company payments

Pharma association defends payments of €27m to doctors
Trends

- “Consent rates” ranged across countries, and even within countries for different types of spend.
- Consistently across Europe, the largest category of spend was for Research and Development.
- The second highest category of spend was generally for consulting fees, but there was variation.
- Companies took a variety of approaches to many reporting issues, as demonstrated by their methodology notes.
- Those different approaches impacted how the data was reported and, therefore, affects the overall analysis of the data.
Country Consent Rates – Percentages of HCPs expected to grant their consents *before disclosure*

<table>
<thead>
<tr>
<th>Country</th>
<th>Consent Rate</th>
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<tbody>
<tr>
<td>Latvia</td>
<td>95</td>
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<tr>
<td>Sweden</td>
<td>85</td>
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<tr>
<td>Cyprus</td>
<td>83</td>
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<tr>
<td>Estonia</td>
<td>80</td>
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<tr>
<td>Lithuania</td>
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<td>Finland</td>
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<tr>
<td>Switzerland</td>
<td>72</td>
</tr>
<tr>
<td>Romania</td>
<td>71</td>
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<tr>
<td>United Kingdom</td>
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<td>Ireland</td>
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<tr>
<td>Malta</td>
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<td>Italy</td>
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<td>Norway</td>
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<td>Hungary</td>
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<td>Belgium</td>
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<td>Bulgaria</td>
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<td>Ukraine</td>
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<td>Serbia</td>
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<td>Turkey</td>
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<td>Russia</td>
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<td>Austria</td>
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<td>Slovakia</td>
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<td>Germany</td>
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<td>Poland</td>
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<td>Czech Republic</td>
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<td>Croatia</td>
<td>25</td>
</tr>
<tr>
<td>Spain</td>
<td>21</td>
</tr>
</tbody>
</table>

*Percentages of HCPs expected to grant their consents before disclosure*

Summary of data included in the database chart taken from the BMJ.
Germany Data

Total payments: 575 mio. €

- Sponsorship and Training to HCPs: 119 mio. € (21%)
- Sponsorship of Events, Donations, and Grants to HCOs: 90 mio. € (15%)
- Research and Development: 336 mio. € (64%)
Poland Data

Note: 1 Polish Zloty = 0.23 Euro as of 9/29/2016

Data taken from http://www.kodeksprzejrzystosci.pl/raporty/.
Finland per Capita HCP Spend Range per Company with Mean and Median

Spend in Euros

- Registration Fees: 1,567 HCP Relationships
  - Max: 992
  - Mean: 760
  - Median: 644
  - Min: 135

- Travel & Accommodation: 6,334 HCP Relationships
  - Max: 2,499
  - Mean: 2,422
  - Median: 1,508
  - Min: 194

- Consultancy Fees: 2,493 HCP Relationships
  - Max: 1,443
  - Mean: 616
  - Median: 1,508
  - Min: 19

- Related Expenses: 1,824 HCP Relationships
  - Max: 864
  - Mean: 204
  - Median: 204
  - Min: 19
Rates of Individual Disclosure for HCP Service/Consultancy Fees

Percent of HCP Relationships Individually Disclosed

Average of Company HCP Individual Disclosure Rates

Median Company HCP Individual Disclosure Rate

Overall Ratio of Individual Disclosure

Finland
Ireland
Norway
Ukraine
Consent by Company for HCP Service/Consultancy Fees

- **Company A**
- **Company B**
- **Overall Country Rate**
Ireland HCP Relationships Individually Identified by Category

<table>
<thead>
<tr>
<th>Category</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registration Fees</td>
<td>54.80%</td>
</tr>
<tr>
<td>Travel &amp; Accommodation</td>
<td>53.07%</td>
</tr>
<tr>
<td>Consultancy Fees</td>
<td>54.42%</td>
</tr>
<tr>
<td>Related Expenses</td>
<td>53.78%</td>
</tr>
<tr>
<td>Overall Rate of Individual Relationship Disclosure</td>
<td>53.84%</td>
</tr>
</tbody>
</table>
## Company Comparisons

<table>
<thead>
<tr>
<th>Spend in Thousands of Euros</th>
<th>Consent Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company 1 – 32,230</td>
<td>25%</td>
</tr>
<tr>
<td>Company 2 – 29,854</td>
<td>38%</td>
</tr>
<tr>
<td>Company 3 – 14,495</td>
<td>50%</td>
</tr>
<tr>
<td>Company 4 – 16,875</td>
<td>55%</td>
</tr>
<tr>
<td>Company 5 – 328,754</td>
<td>48%</td>
</tr>
<tr>
<td>Company 6 – 328,545</td>
<td>73%</td>
</tr>
</tbody>
</table>
Ireland HCP Consultancy Fee Spend per Company by True Consent Rate

Spend in Thousands of Euros

Consent Rate

Larger Bubble Size Indicates Larger Ratio of Individually Disclosed Spend
Finland Travel & Accommodation Spend per Company by True Consent Rate

Larger Bubble Size Indicates Larger Ratio of Individual Spend to Aggregate
Consent Management

Annual Contractual Consent
Contractual consent obtained for all payments over a given year.

Contract by Contract Consent
Written consent obtained for every qualifying interaction, consulting, event, etc.

No Contract/Sponsorship Consent
Written consent obtained solely for the purpose of disclosure.

Pre-Disclosure

Review and Dispute
Company X
- HCPs received a consent package including a letter explaining Company X's commitment to Transparency and the options and rights they have in accordance with data protection legislation... Company X's approach is to seek indefinite consent. If an HCP would like to withdraw a consent already provided, they can do so in writing to Company X or through _____@CompanyX.com.

Company Y
- Consent was obtained on Recipient level for all ToVs during a given period of time not shorter than one full year. Company Y does not accept partial consent or split disclosure.

Company Z
- Company Z is collecting consent at the first point of first engagement for a 1 or 3 year fixed period with all HCPs and HCOs based on local requirements.
Company M
- Company M makes sure to obtain consent of individual healthcare professionals prior to the actual disclosure. Company M preferred approach for consent collection is on a contract by contract basis.

Company P
- In Ireland written consent is collected activity per activity using the Company corporate template which has been modified to include reference to the IPHA Code of Practice.

Company W
- Company W will obtain the consent, as required, of each HCP... via a separate consent statement or via a consent statement in an invitation letter supported by singing a roster of attendees to the event.
Company 1
- At any time, a HCP/HCO may request a copy of the information Company 1 holds about them, including the information on ToV which the company may publish against their name. A HCP or HCO can request data they believe to be inaccurate be corrected. ... To access their data, a HCP/HCO can contact Company 1 via the contact details mentioned in their contract with Company 1 or by contacting our Global Privacy Office via e-mail: xxxx. Company 1 will follow its internal processes to ensure all requests to access personal data are handled within the timelines specified by the relevant country data protection authorities.

Company 2
- During April, HCPs and HCO’s that granted consent to disclose on individual level, received a statement with the details of ToVs to be reported to provide an opportunity to verify and review the information to ensure it is accurate, prior to disclosure on 30 June 2016. Company 2 will review and investigate disputes with HCPs/HCOs relative to our transparency reports. Subject to Company 2's internal review and approval, any changes resulting from disputes will be published from time to time.
Company 3
- Company 3 wishes to offer to HCPs and HCOs the possibility to individually review their own Transfers of Value before disclosure and is notifying them during a pre-disclosure phase before the information is made public. During this phase, recipients are allowed to request access to their detailed information and can dispute the information Company 3 is intending to publish.

Company 4
- In order to be compliant with the data privacy regulation, Company 4 has implemented a responsive dispute process. Each question or claim is centralized and followed up. After a thorough analysis of the inquiry, all applicants will receive a response via a letter signed by Company 4. ... The dispute process is available to all HCP/HCO only through the “Dispute letter template” that is downloadable from the Company website.
Different Approaches

or
Different Approaches
More Laws?

Managing Conflicts of Interest in the NHS: A Consultation
Australia

8.5 million Aus. Dollar
66% Consent Rate
Canada

Abbvie, Amgen, Bristol–Myers Squibb, Gilead, Eli Lilly, Merck, Novartis, Purdue, Roche, and GlaxoSmithKline
Saudi Arabia

Pharmaceutical Company Payments Disclosure Initiative

Version 1.0

Draft
[Not for implementation and published for comment purposes]

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