

EFPIA Data Demonstrates the Challenges Confronting Companies

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Brian P. Sharkey



The Seventeenth Annual Pharmaceutical and Medical
Device Compliance Congress

Washington, DC
October 19, 2016

Pharmaceutical industry spends £340.3m on working in partnership with leading UK health experts and organisations to improve patient care



The ABPI has today published for the first time details of payments or benefits in kind – made to doctors, nurses and pharmacists, as well as other health professionals and healthcare organisations in the UK on a publicly accessible database - Disclosure UK.

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



Association of International Pharmaceutical Manufacturers

Ассоциация международных фармацевтических производителей

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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.

News of 6 June

Press release – The Belgian Transparency Register went live

22 June 2016

Non classé @en

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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



News

Doctors getting biggest payments from drug companies don't declare them on new website

BMJ 2016 ; 354 doi: <http://dx.doi.org/10.1136/bmj.i3679> (Published 01 July 2016)
Cite this as: BMJ 2016;354:i3679

UK Website Of The Year

Hi 15°C | Lo 10°C Belfast | WEATHER



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

PUBLISHED
30/06/2016



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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

By PRESS ASSOCIATION and SOPHIE BORLAND, HEALTH EDITOR FOR THE DAILY MAIL
PUBLISHED: 17:24 EST, 30 June 2016 | UPDATED: 12:03 EST, 1 July 2016



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55% of HCPs agree to release of pharma company payments

July 13, 2016 by [admin](#) [Leave a Comment](#)

Ireland

Pharma association defends payments of €27m to doctors



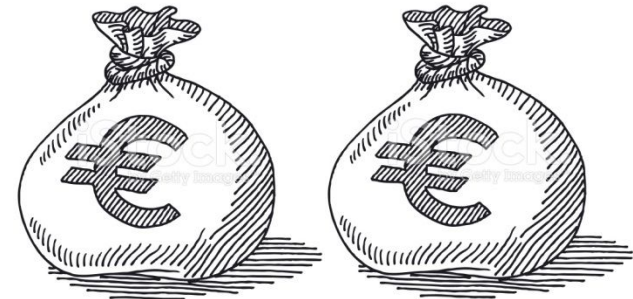
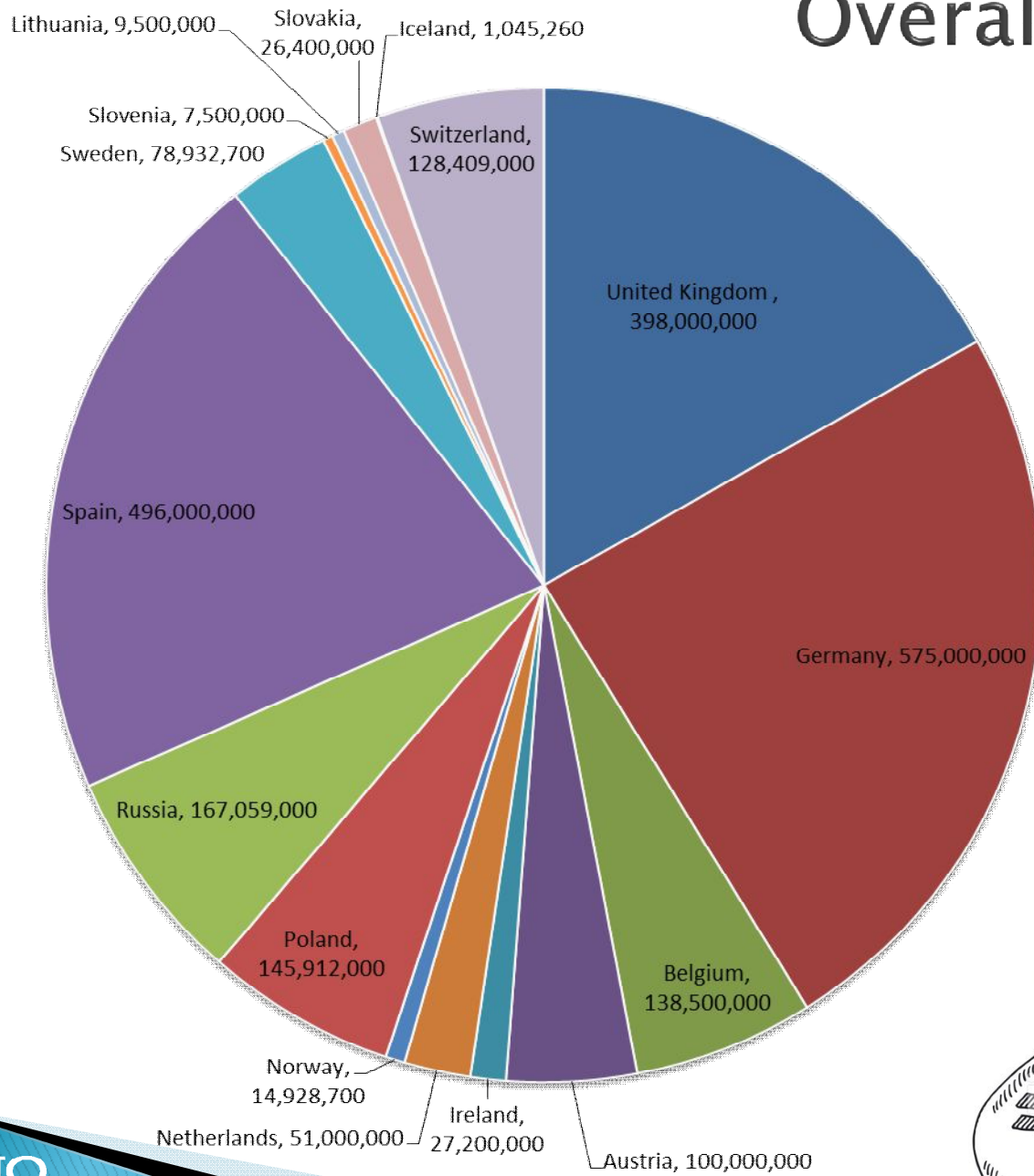
Monday 11 July 2016 09.14

Trends

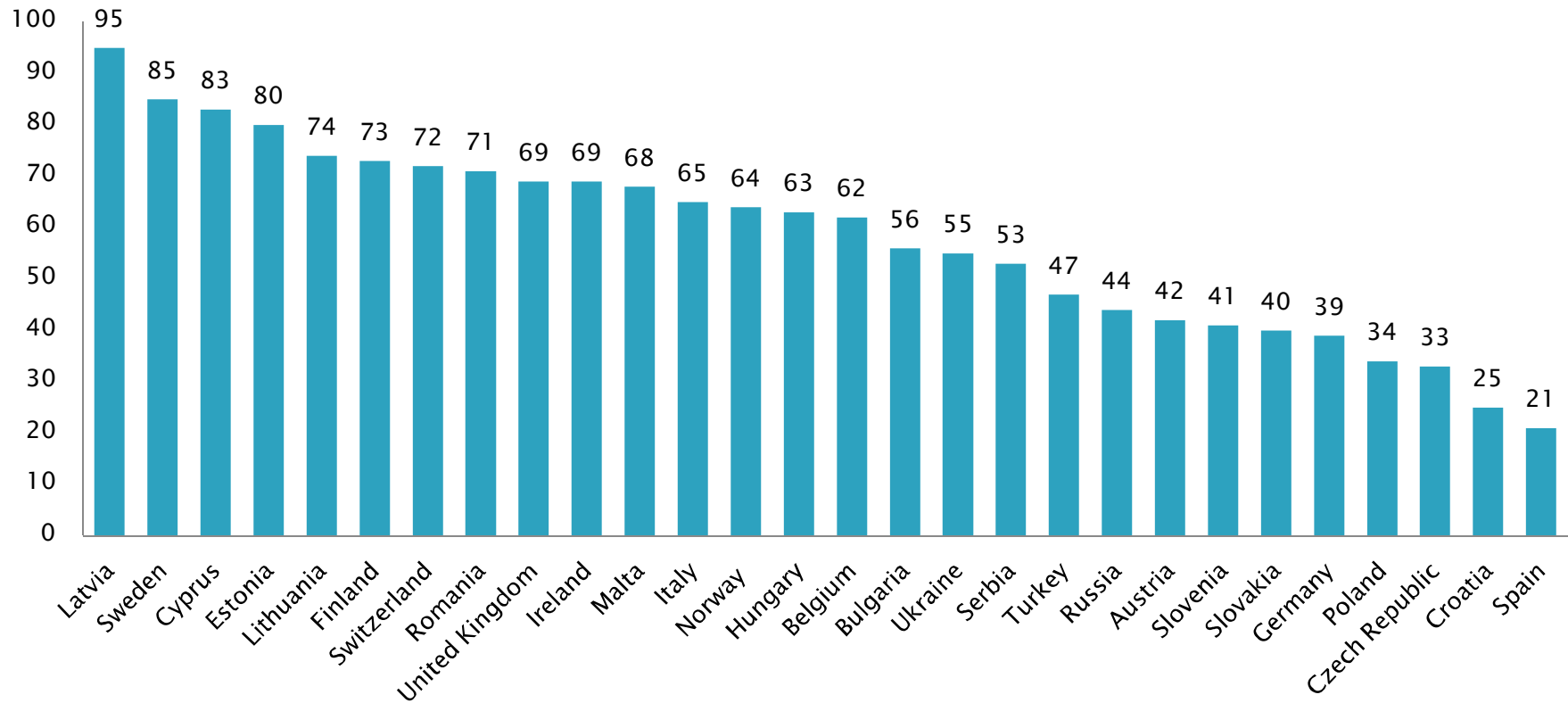
- ▶ “Consent rates” ranged across countries, and even within countries for different types of spend.
- ▶ Consistently across Europe, the largest category of spend was for Research and Development.
- ▶ The second highest category of spend was generally for consulting fees, but there was variation.
- ▶ 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.



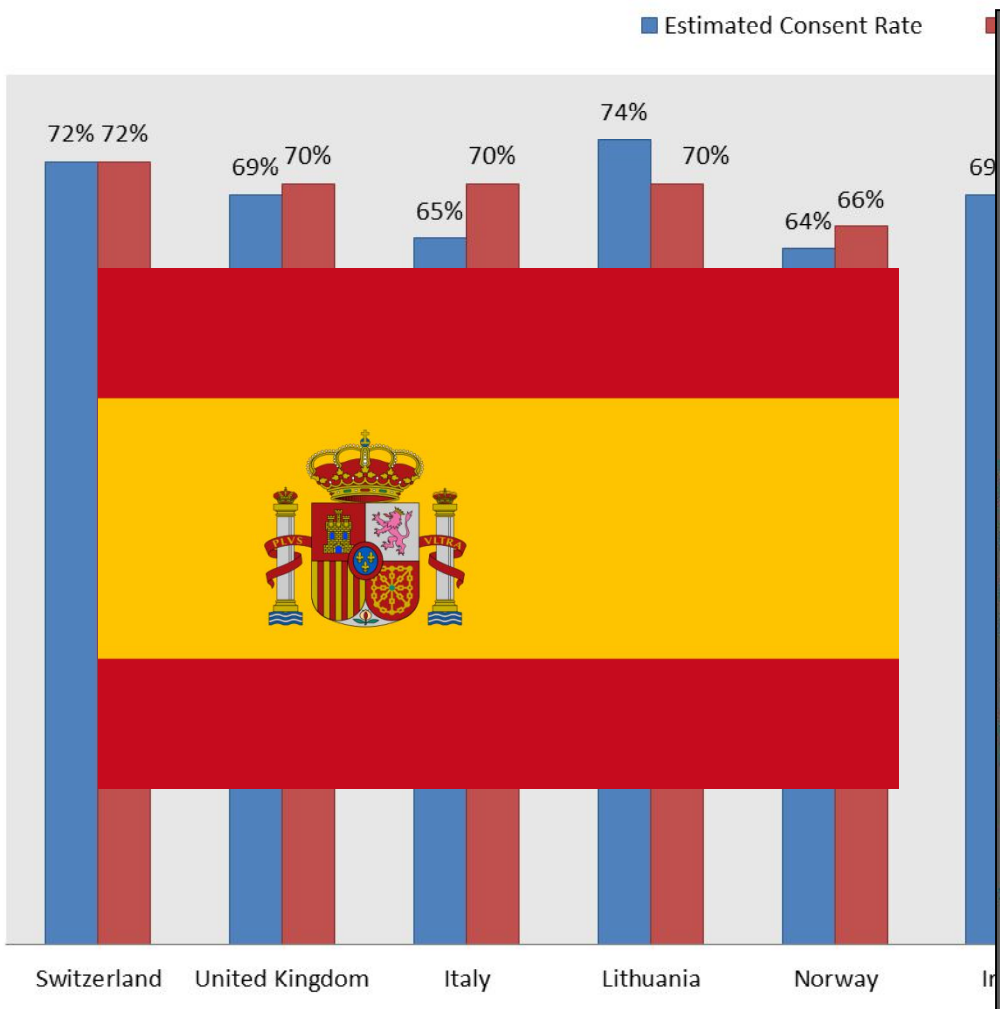
Overall Total Spend (in Euros)



Country Consent Rates – Percentages of HCPs expected to grant their consents *before disclosure*





■ Percentages of HCPs expected to grant their consents before disclosure



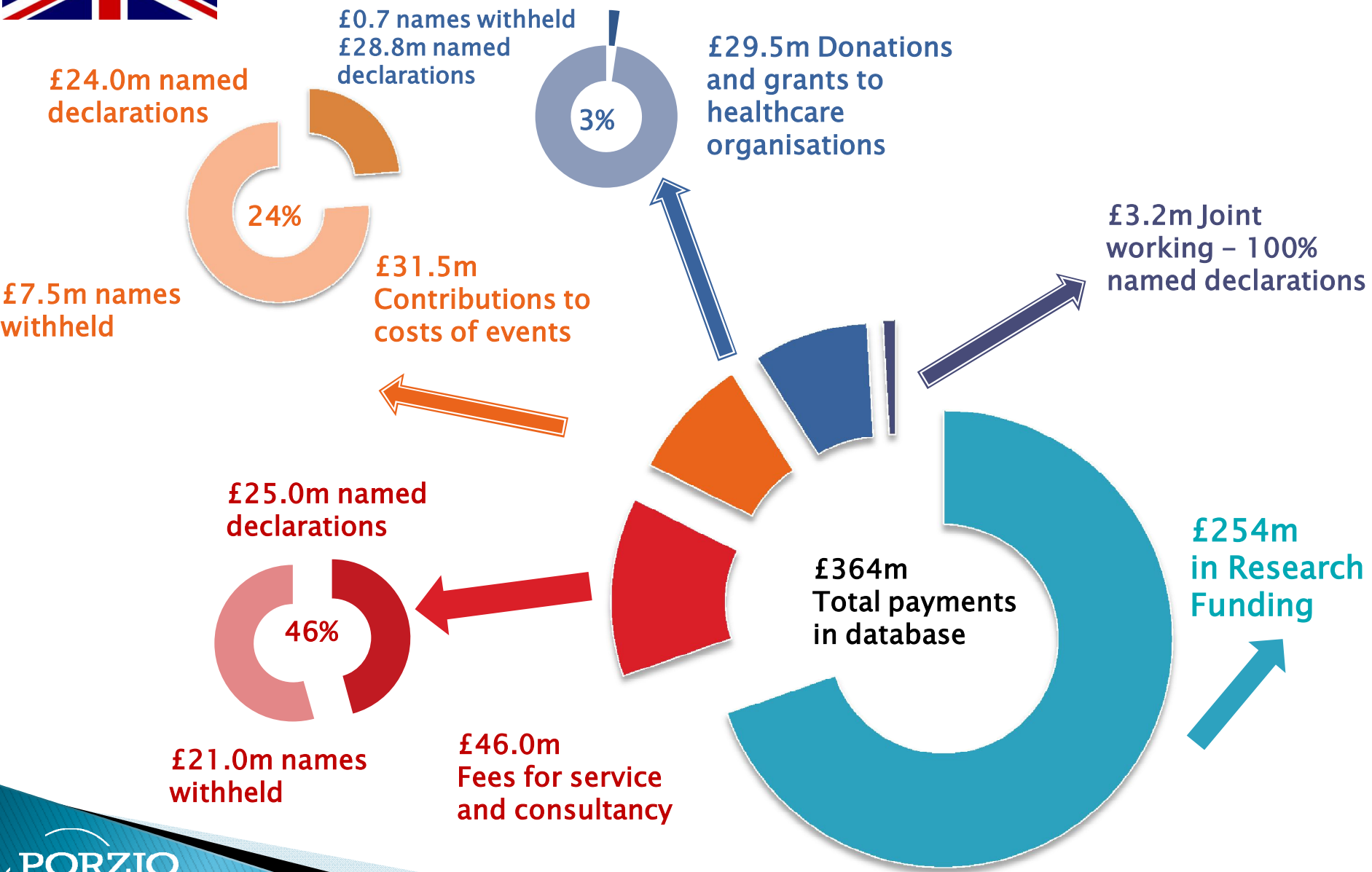
Code of Practice for the Pharmaceutical Industry

2016

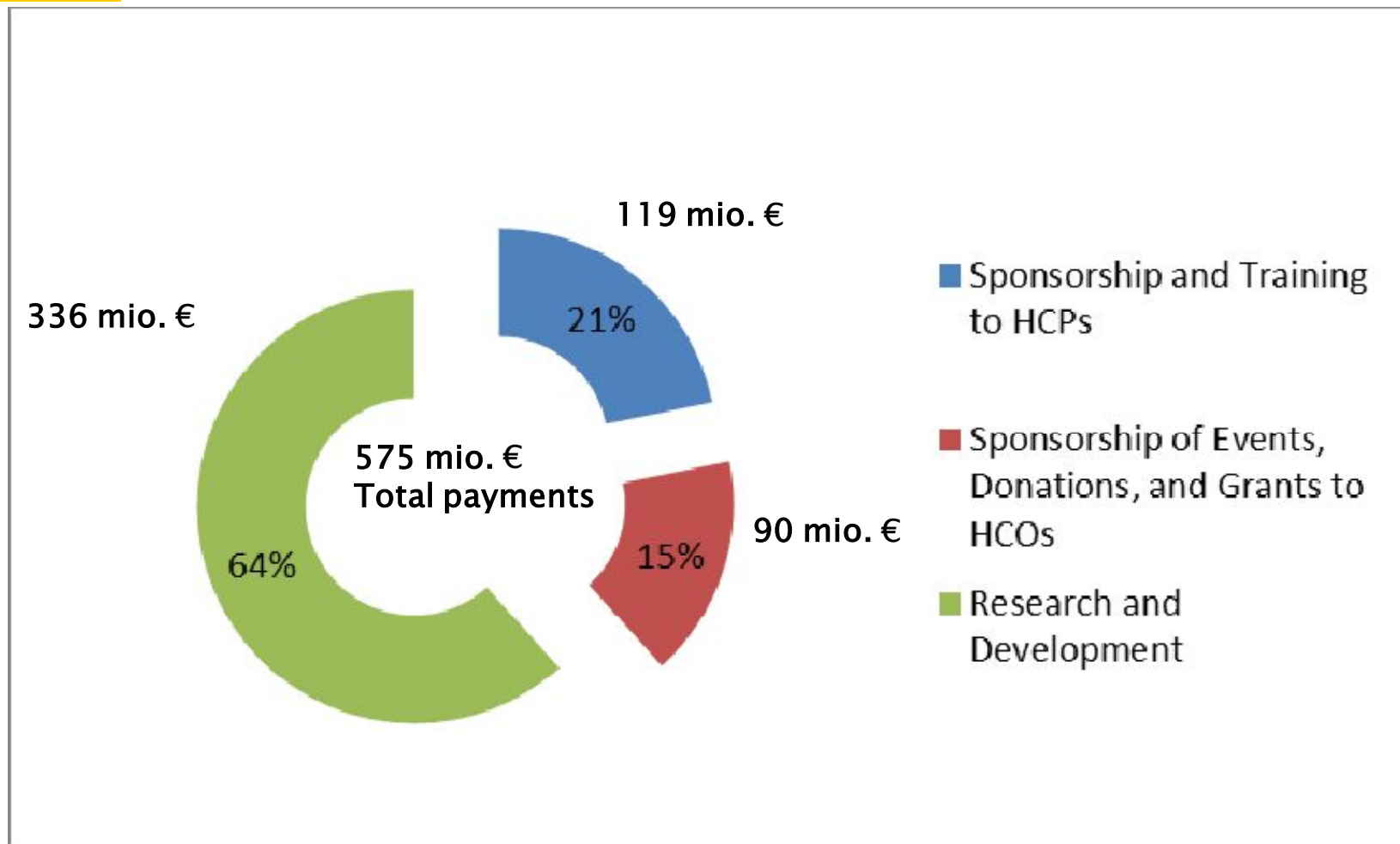


Summary of data included in the database



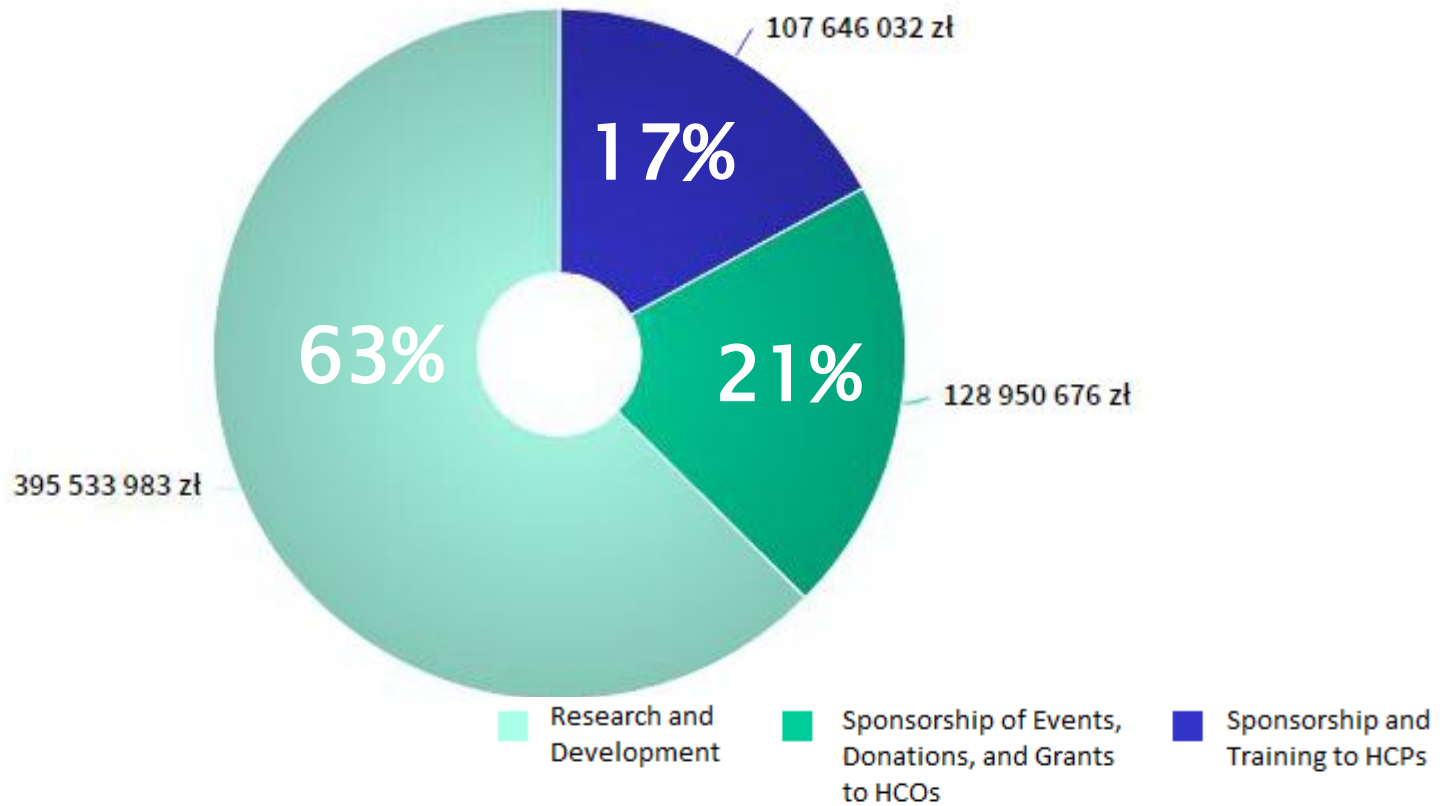


Germany Data



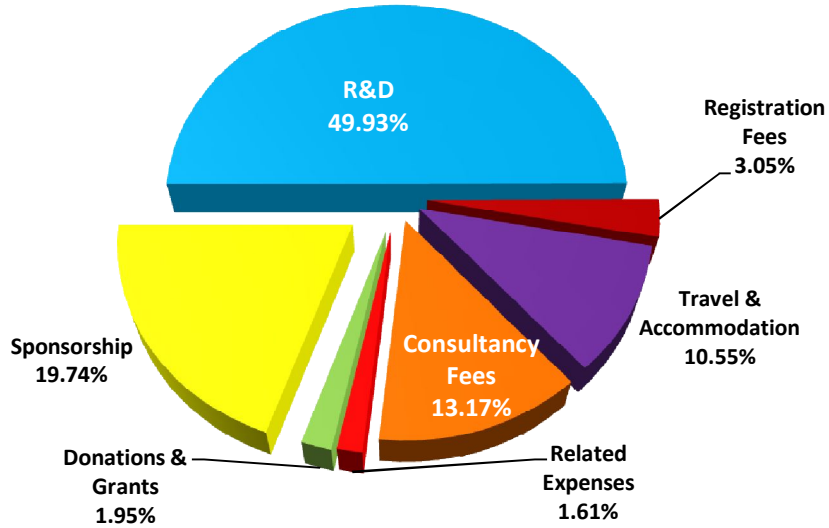


Poland Data

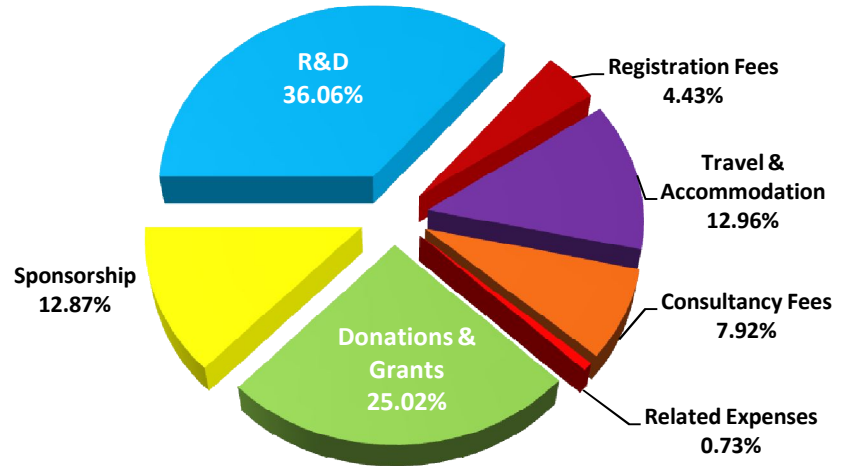


Total Spend by Category

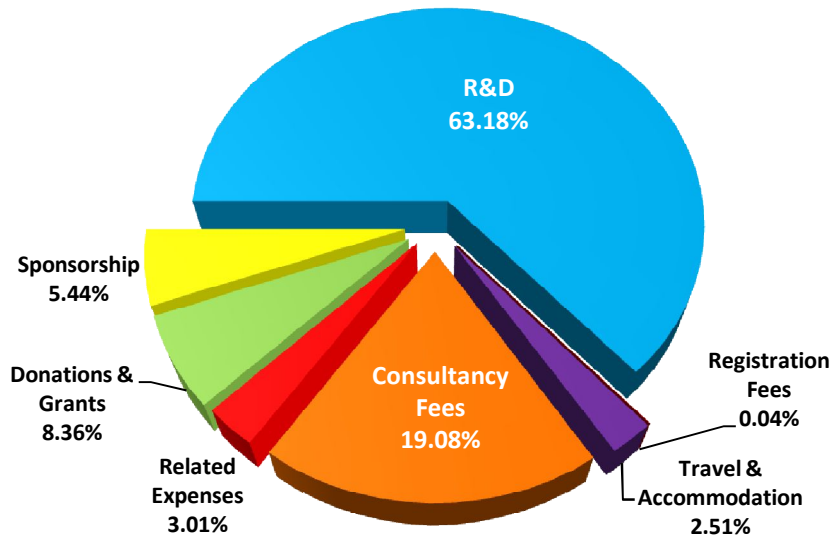
Finland



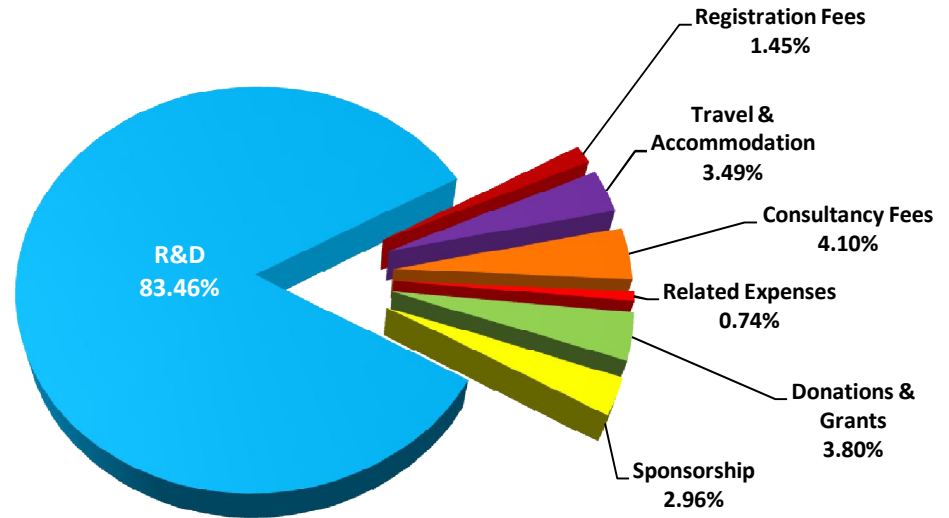
Ireland



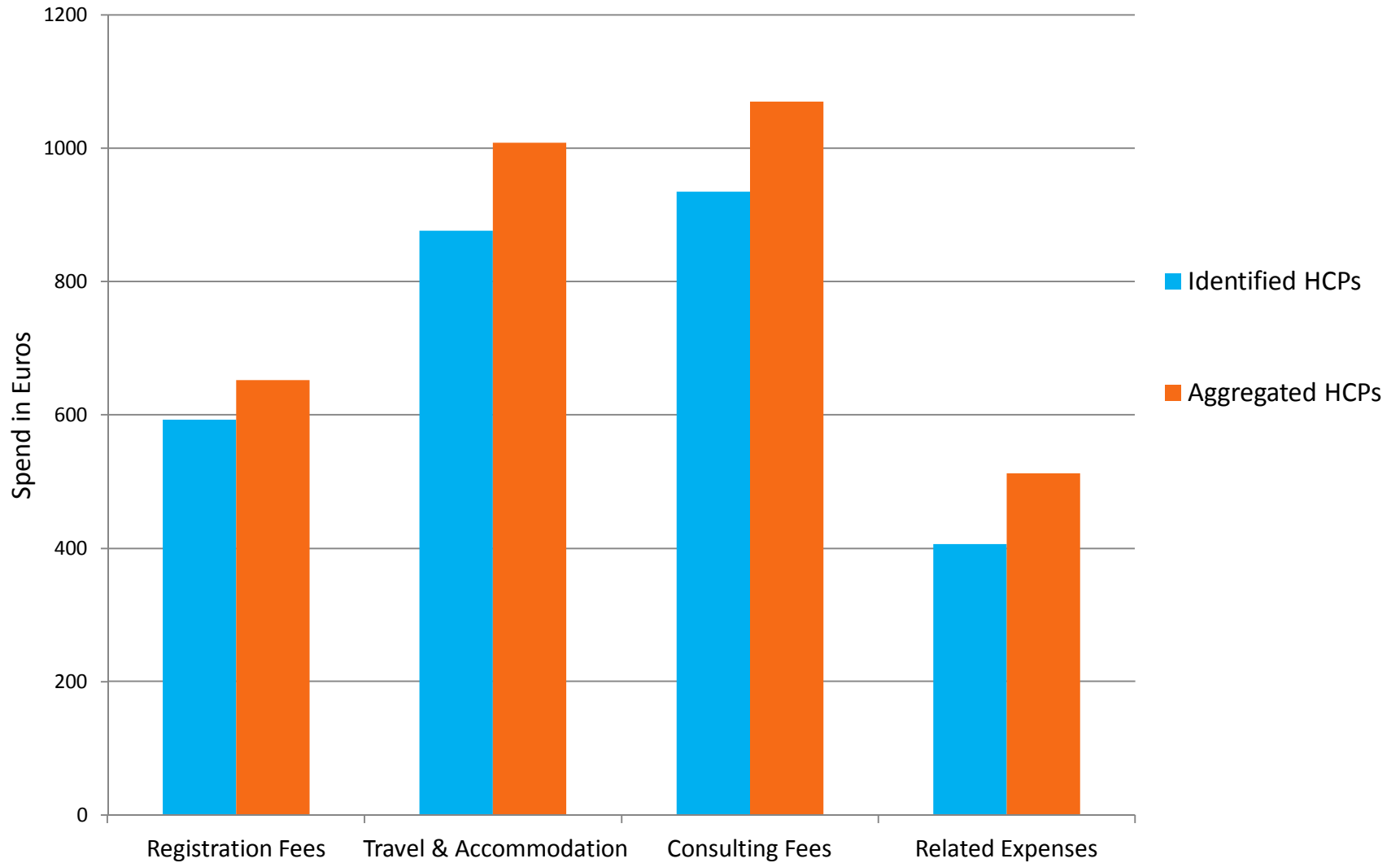
Norway



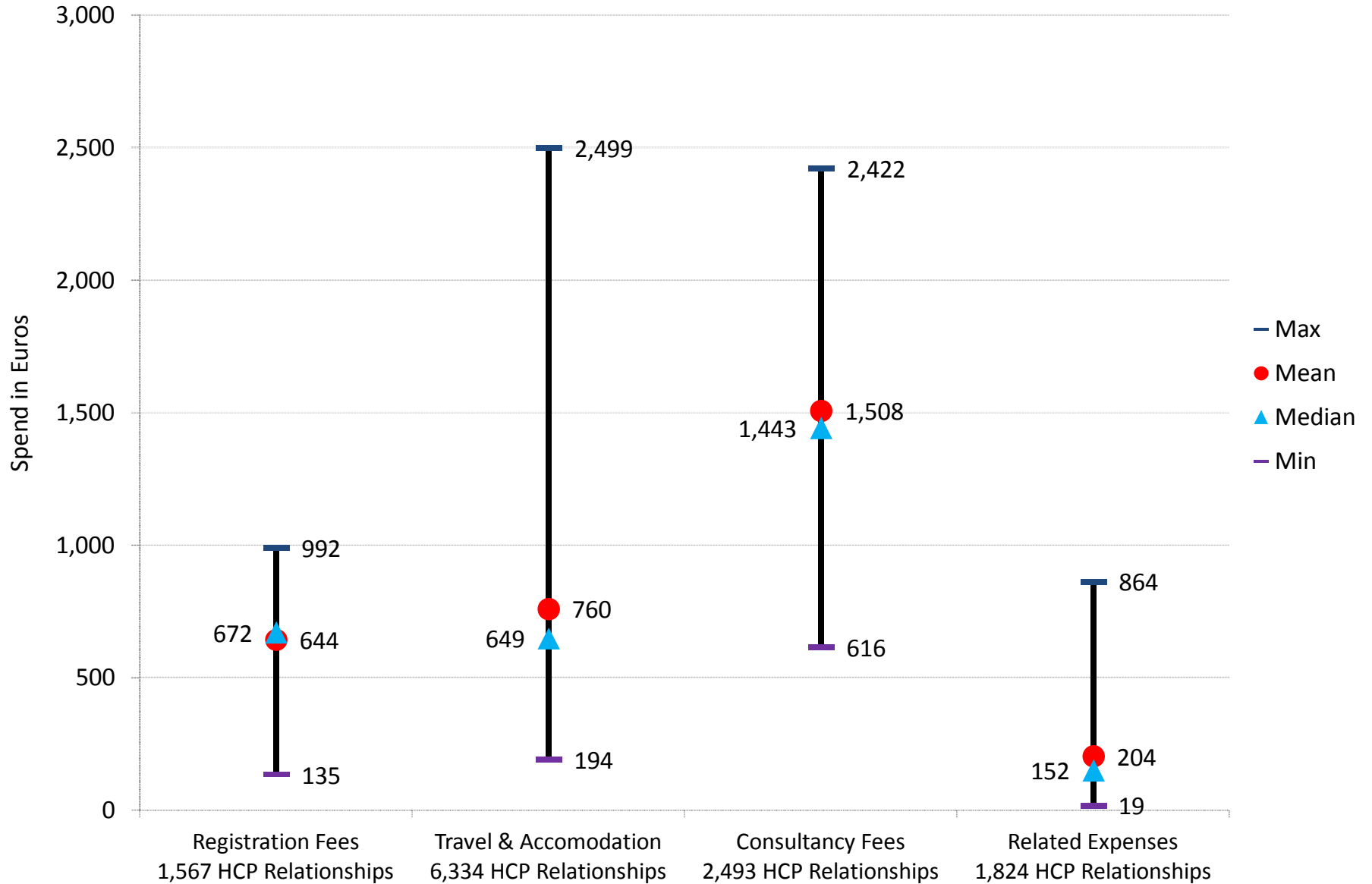
Ukraine



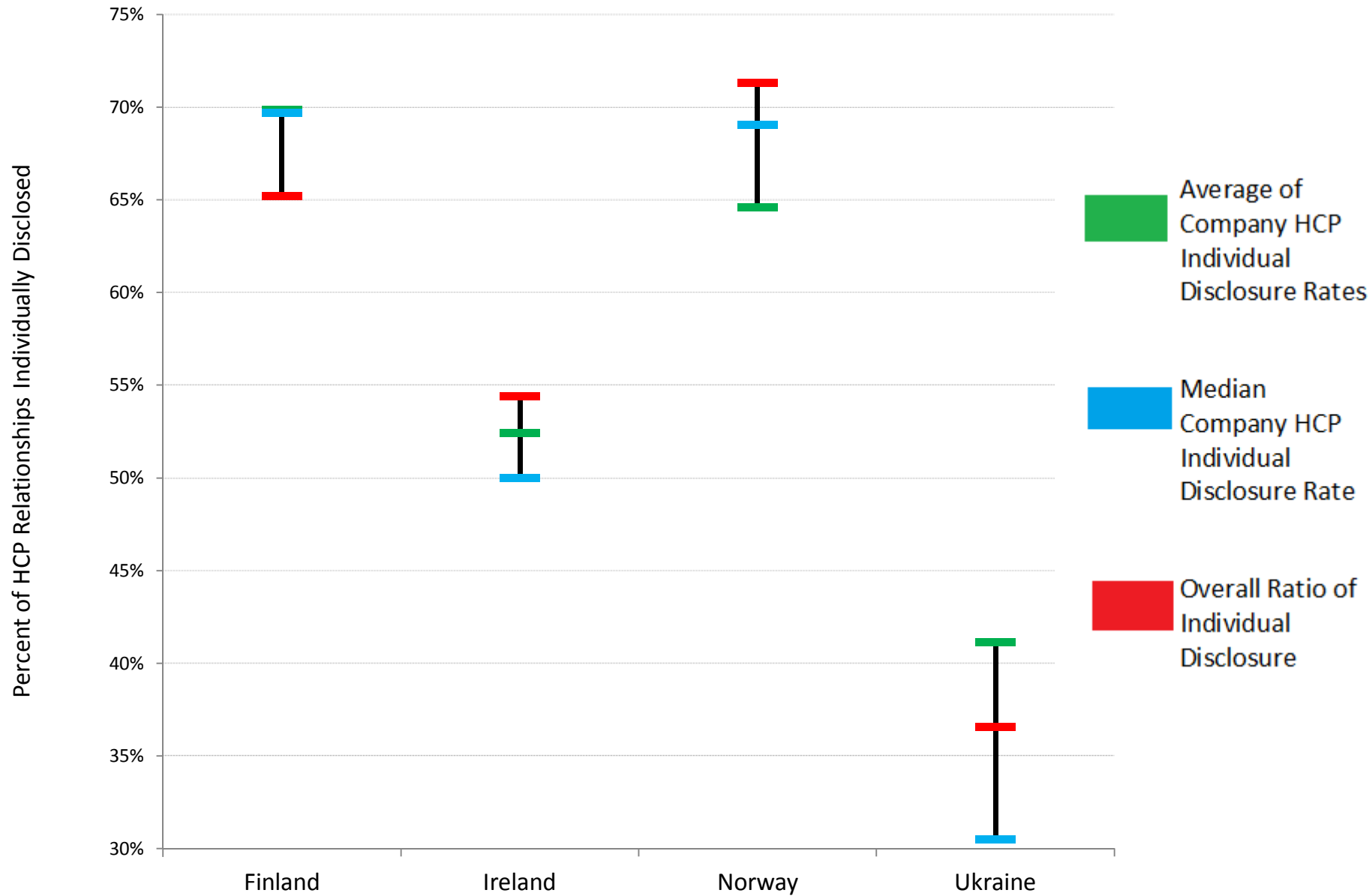
Average Spend per HCP Relationship in Ireland



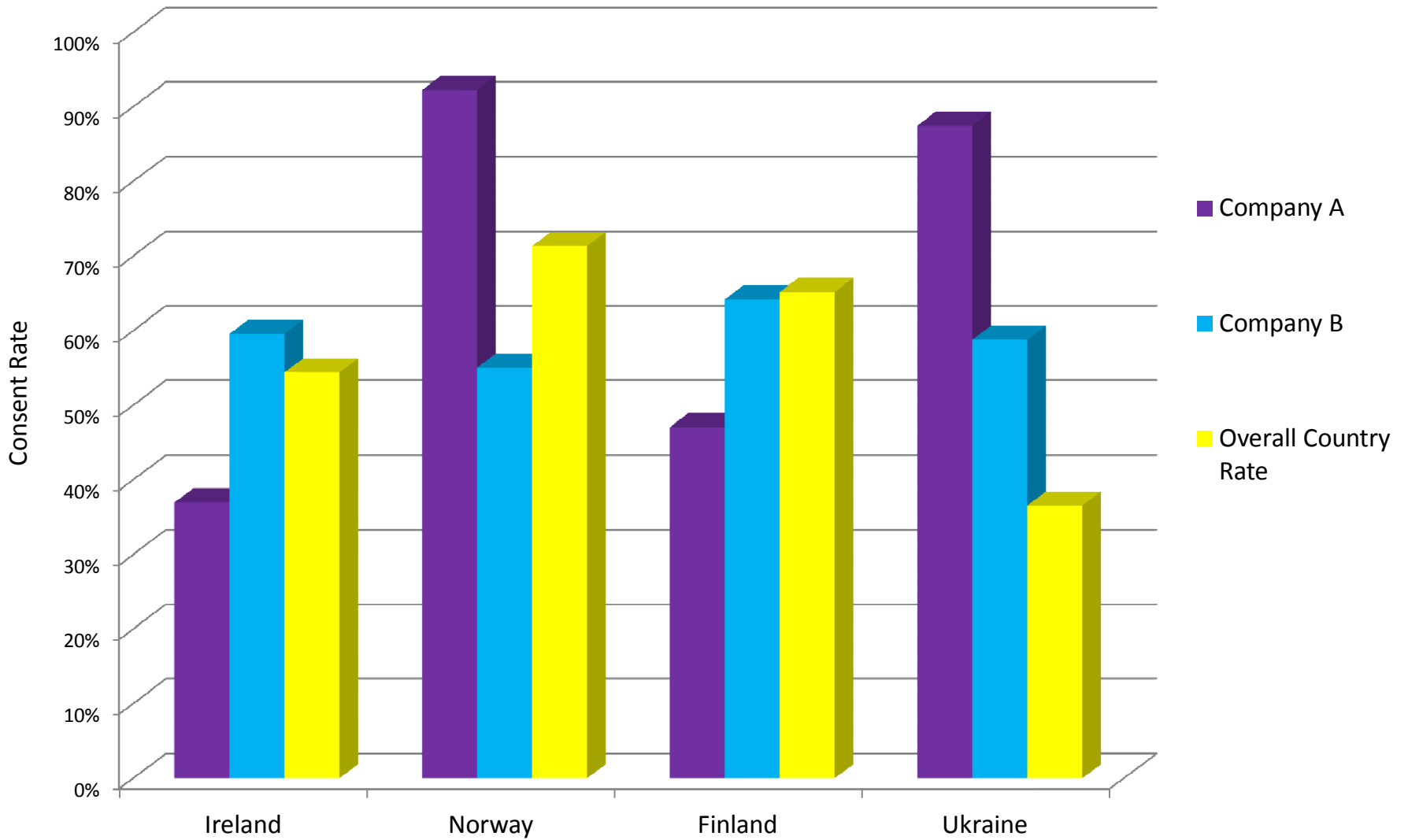
Finland per Capita HCP Spend Range per Company with Mean and Median



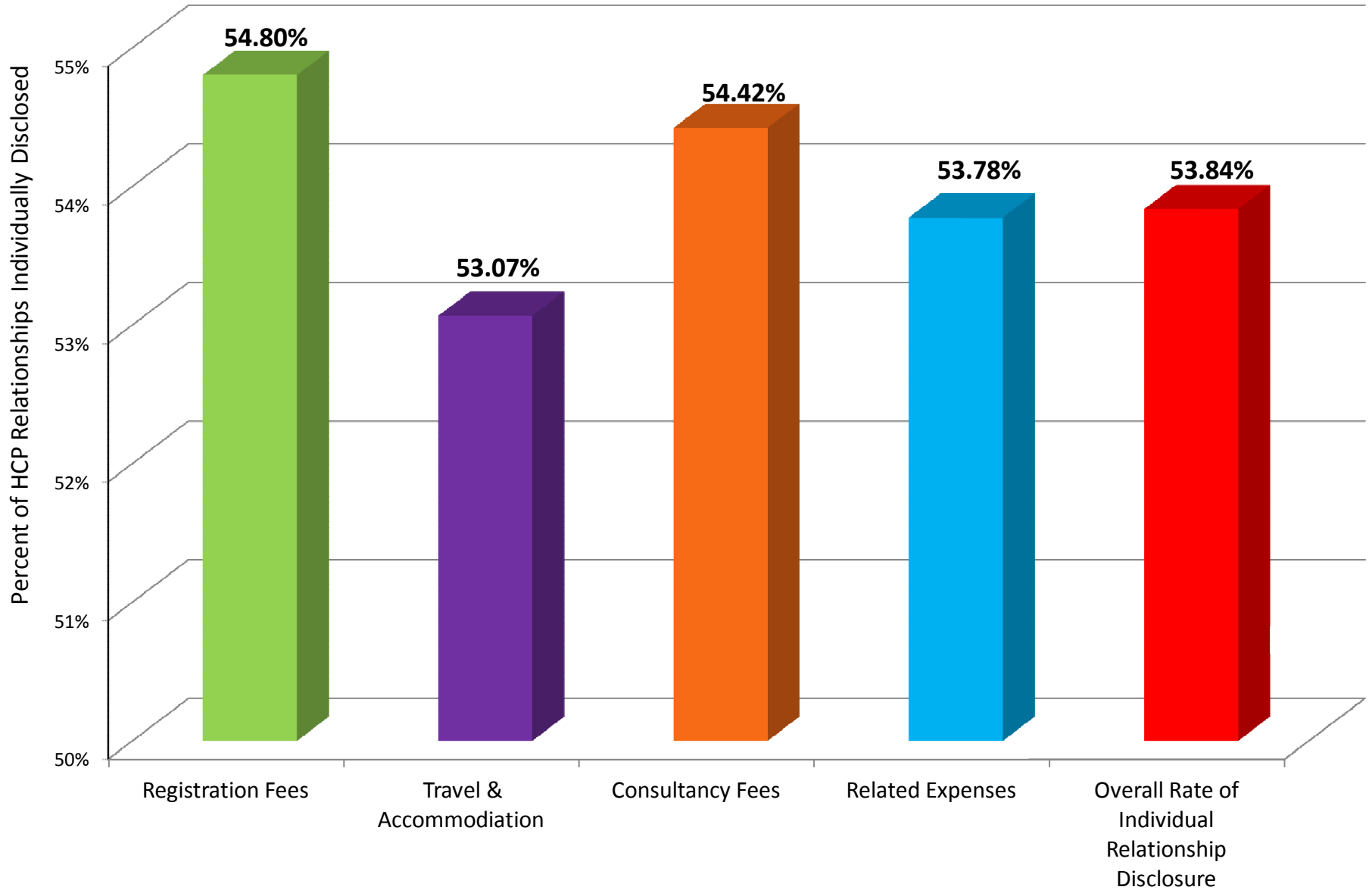
Rates of Individual Disclosure for HCP Service/Consultancy Fees



Consent by Company for HCP Service/Consultancy Fees



Ireland HCP Relationships Individually Identified by Category



Company Comparisons

Spend in Thousands of Euros

Consent Rate



- Company 1 - 32,230
- Company 2 - 29,854



- 25%
- 38%



- Company 3 - 14,495
- Company 4 - 16,875



- 50%
- 55%



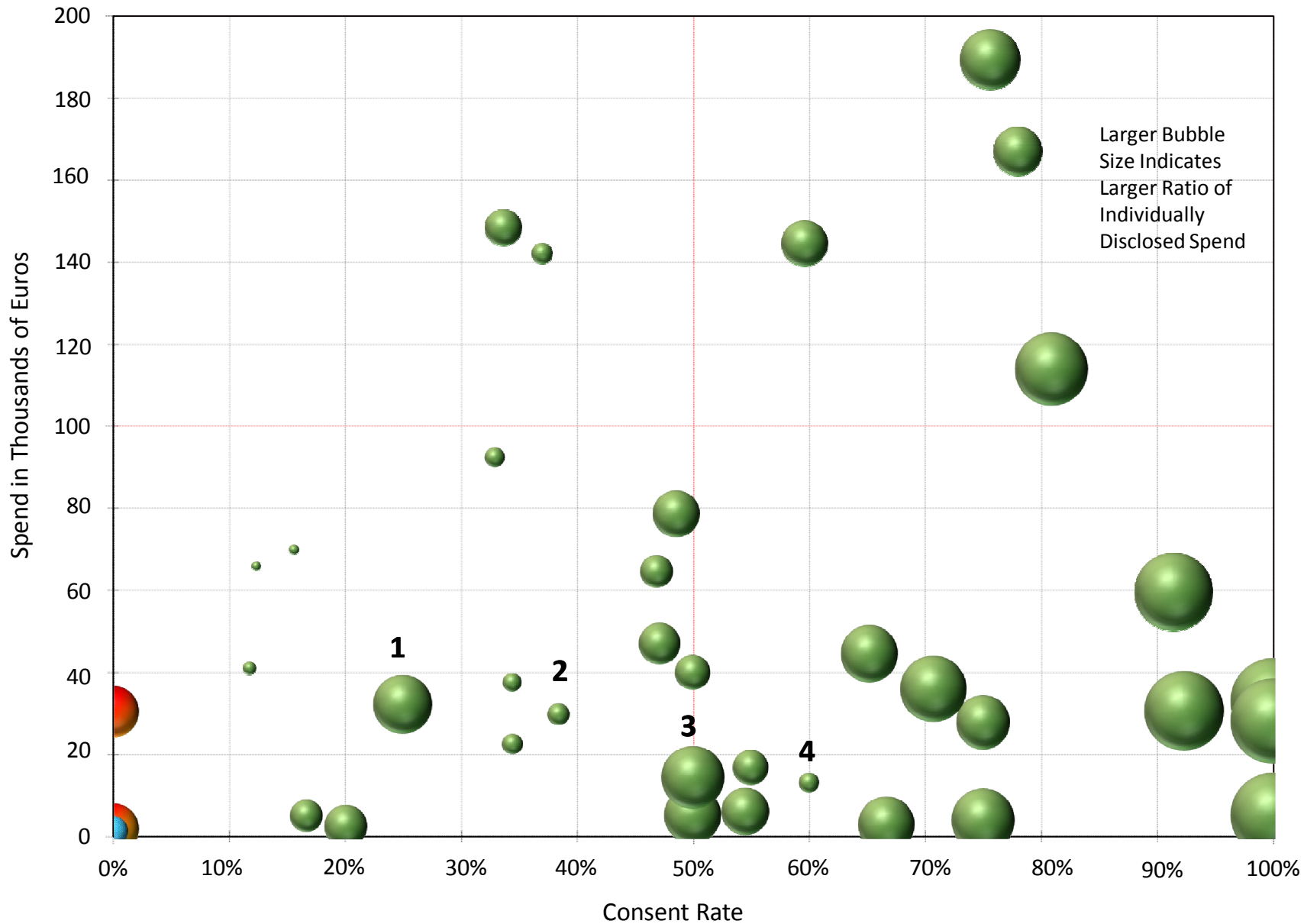
- Company 5 - 328,754
- Company 6 - 328,545



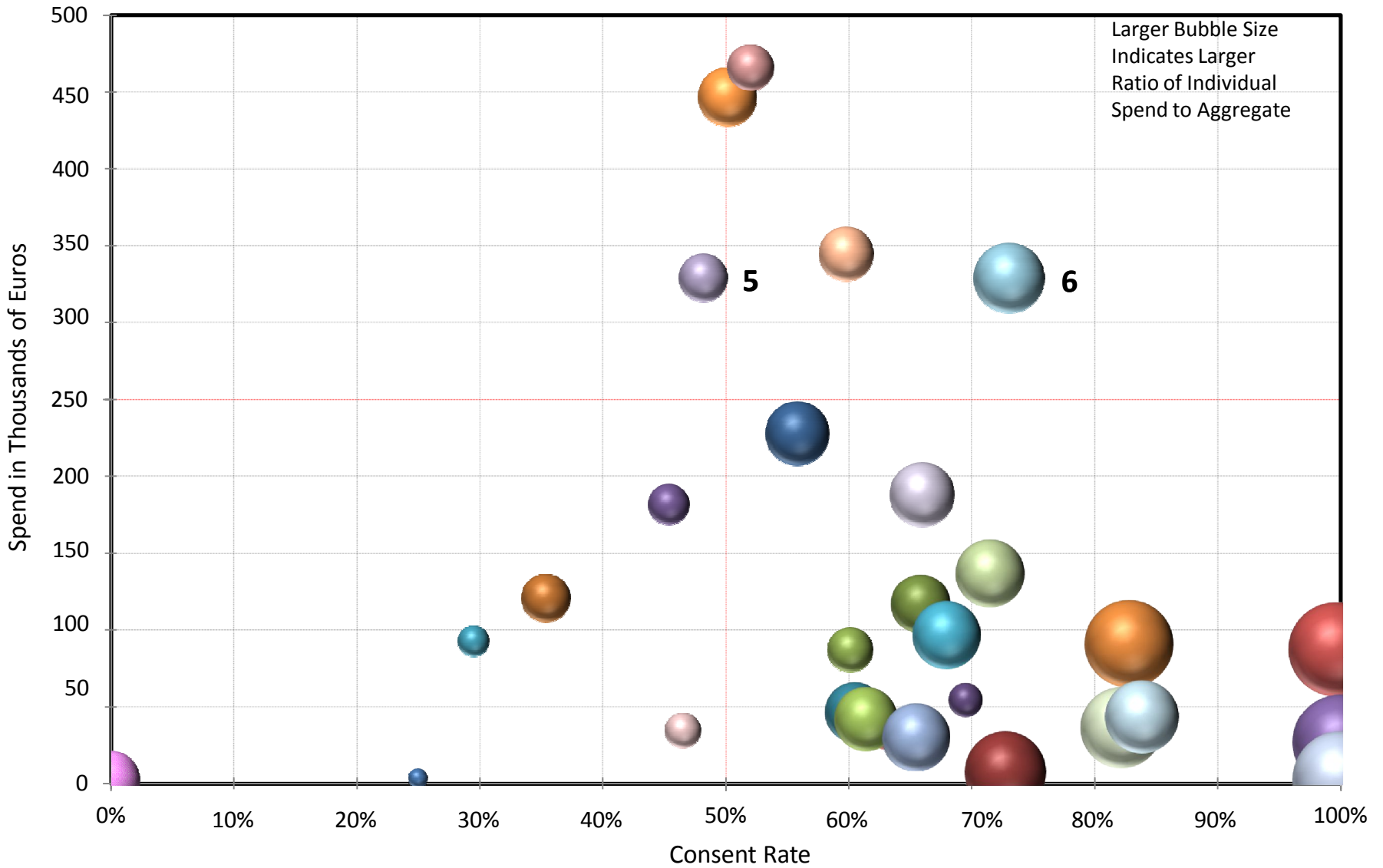
- 48%
- 73%



Ireland HCP Consultancy Fee Spend per Company by True Consent Rate



Finland Travel & Accommodation Spend per Company by True Consent Rate



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



Ireland – Consent

▶ 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.



Ireland – Consent

▶ **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 signing a roster of attendees to the event.



Ireland – Pre-Disclosure & Disputes

▶ 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 it's 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.



Ireland – Pre-Disclosure & Disputes

▶ **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.

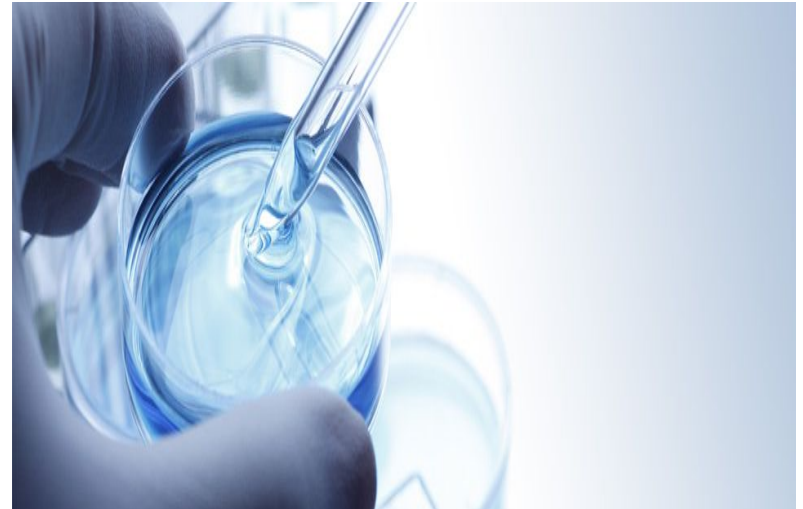
Different Approaches



or



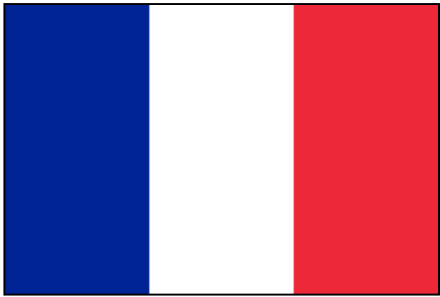
Different Approaches



More Laws?

NHS
England

**Managing Conflicts of
Interest in the NHS:
A Consultation**





Australia

8.5 million Aus. Dollar
66% Consent Rate





Canada

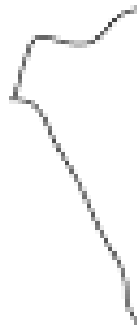


Abbvie, Amgen, Bristol–Myers Squibb, Gilead, Eli Lilly, Merck, Novartis, Purdue, Roche, and GlaxoSmithKline



Saudi Arabia

المملكة العربية السعودية
الهيئة العامة للغذاء والدواء 



Pharmaceutical Company Payments Disclosure Initiative

Version 1.0

Draft

***[Not for implementation and published
for comment purposes]***



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