



ASIA PAC TRANSPARENCY AND DISCLOSURE UPDATES - Update from JAPAN -

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DISCLAIMER

- The views and comments I will present are of my own and do not reflect the views of my employer Sanofi or the Japanese Pharmaceutical Manufacturers Association.

Agenda

- Overview of Transparency in Japan
- Latest Updates

Overview of Transparency in Japan

- NO Transparency Law. Governed by voluntary code.
- Expanding voluntary transparency guidelines.
 - Provider: Pharma (2011), Device (2012), Generic (2012), etc.
 - Recipients: Public medical institution (2014).
 - Scope: HCP, HCO and Patients/Patients Group.
- Data Privacy issue.
 - Obtaining comprehensive written consent.



The Japanese Pharmaceutical Manufacturers Association

- JPMA is a voluntary association comprising of 73 research-oriented pharmaceutical companies (as of 1 April 2016).
- As a member of the IFPMA.
- In a world first, JPMA disclosed HCPs spending data in 2012.



The Japanese Pharmaceutical Manufacturers Association

- Purpose: To demonstrate clearly
 - the pharma sector's contribution to life science.
 - how corporate activities are conducted with high ethical standards.

JPMA Transparency Guideline

- Disclosure method
 - Company's website.
- Timing of disclosure
 - The payments in each fiscal year shall be disclosed in the following fiscal year.
 - e.g. Payments made during the fiscal year 2015 will be disclosed in the fiscal year 2016.
 - Frequency: Once a year.

JPMA Transparency Guideline

- Targets of disclosure
 - A. R&D expenses
Annual total amount
 - B. Academic research support expenses
Individual amount
 - C. Manuscript/writing fees, etc.
Individual amount
 - D. Information provision-related expenses
Annual total amount
 - E. Other expenses
Annual total amount



NEW!

Latest Information

- Revised JPMA Transparency Guidelines
 - Item A. Research and development expenses
 - Total annual amount will change to individual amount
 - From 2016 financial data
- Clinical Research Bill
 - Submitted by Ministry of Health, Labor, Welfare (MHLW):
 - Transparency report requirements:
 - the amount provided for a certain clinical research financial support
 - Detailed scope will be determined by the MHLW order

Questions ?

