

Japan Voluntary Transparency Guidelines Update

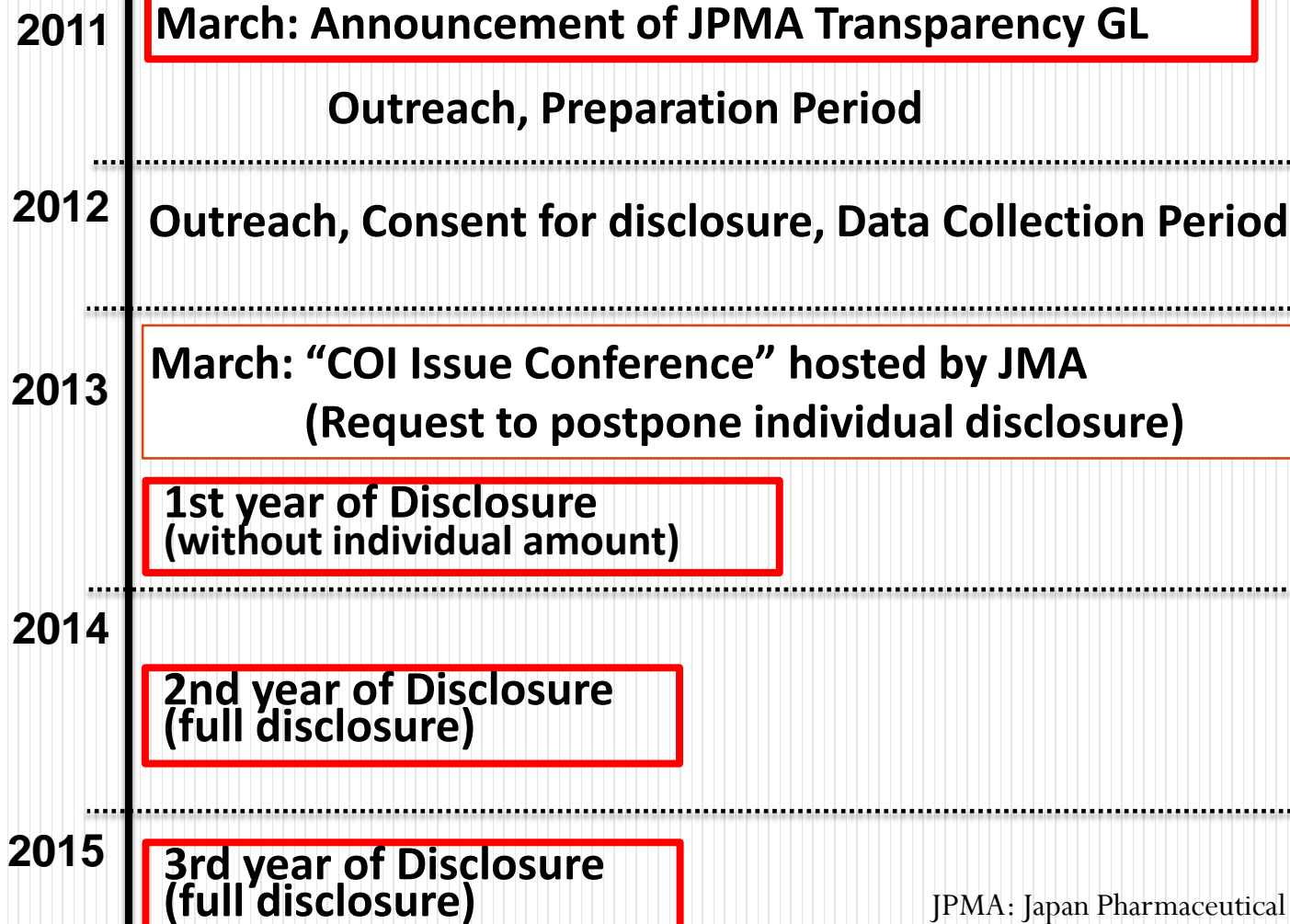
The Fifth Asia Pacific Pharmaceutical Compliance Congress
August 17, 2015

Yota Kikuchi
Manager, Compliance Japan, Sanofi

Agenda

1. Background
2. 2014 Disclosure
3. Environment Change
4. 2015 Disclosure
5. New requirements
6. Conclusion

Background



JPMA: Japan Pharmaceutical Manufacturers Association
JMA: Japan Medical Association

Background

Scope of Disclosure

Category	Expenses for disclosure	Form
A. R&D expenses	1 Joint research	[Amt. / yr]
	2 Research commissioning	[Amt. / yr]
	3 Clinical study	[Amt. / yr]
	4 Post-marketing clinical study	[Amt. / yr]
	5 ADR / infection case reporting	[Amt. / yr]
	6 PMS	[Amt. / yr]
B. Academic research support expenses	1 Scholarships to medical schools	[Inst. name] [Freq.] [Amt. / yr]
	2 Donation to academic societies	[Org. name] [Freq.] [Amt. / yr]
	3 General donation	[Org. name] [Freq.] [Amt. / yr]
	4 Co-sponsoring (at academic societies)	[Event & seminar name] [Amt. / yr]
C. Manuscript / writing fee, etc.	1 Lecture	[HCP's name, position, affiliation] [Freq.] [Amt. / yr]
	2 Manuscript writing / supervising	[HCP's name, position, affiliation] [Freq.] [Amt. / yr]
	3 Consulting/commissioning	[HCP's name, position, affiliation] [Freq.] [Amt. / yr]
D. Information provision-related expenses	1 Lecture meeting	[Freq.] [Amt. / yr]
	2 Explanation meeting	[Freq.] [Amt. / yr]
	3 Medical / pharmaceutical literature, etc supply	[Amt. / yr]
E. Other expenses	Hospitality, etc as social courtesy ⁴	[Amt. / yr]

Started disclosure from 2014

2014 Disclosure of Payments

- 2 step disclosure for individual payments
(1st: Name only 2nd: Name, amount and frequency)
- HCP resistance to individual disclosure
- Confusion within companies for disclosure method of individual payments.
- Initial media articles were only on disclosure method and amount.

Environment Change - 1

- Scandal of companies' improper involvement in investigator initiated studies (2013~).
- Criticism on cozy relationship between pharma and HCPs.
- No HCP resistance to disclosure after the incident.

Environment Change - 2

- April 1, 2015 newspaper article:
“Honoraria paid by 72 companies towards 100,000 HCPs for 350,000 times amounted 30 billion Yen (25 billion USD)”
- HCPs scrutinized for the payments by pharma.
- Government request to companies to confirm COI of Committee members.
- National Hospitals also started their own disclosure.

2015 Disclosure of Payments

- Same method as 2014, except no on-site visit disclosure.
- Most companies expected to publish during August and September.

New Requirements

Start of detailed disclosure of R&D payments

- Request from medical associations for more transparency in R&D payments.
- Companies will disclose annual amount of money by individual names of institution, department, HCP.
- 2016 data to be published in 2017.

Summary

- Voluntary disclosure contributed to reputation
- Disclosure requires further justification of the interactions with HCPs
- Provide contextual information with the published data to get more public understanding
- Further stakeholder involvement to build consensus on sustainable pharma - HCP interactions

Thank you