

座談会

〈Round table discussion〉

## 「サンシャイン条項」の夜明け — 利益相反対応の新局面

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### Dawning of the “Sunshine Act”: Towards a new phase of conflict of interest management

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#### Abstract

The “Sunshine Act” of the United States Patient Protection and Affordable Care Act is to be implemented at the end of March 2013, and following it, Japan Pharmaceutical Manufacturers Association (JPMA) is to implement the “Transparency Guidelines” at the same time. The Sunshine Act requires pharmaceutical companies to submit to the regulatory authority any information of payment or other transfer of value to medical practitioners and institutions except less than 10 dollars, and the regulatory authority will make such information open to public. The range of information defined in JPMA’s Guidelines is limited, however, some Japanese doctors’ groups express objections and related people have been negotiating about the style and range of “transparency”.

Here we discussed about the related issues such as (1) contents and impact of Transparency Guidelines; (2) donation and research agreement and collaborative clinical development among pharmaceutical companies and research institutes/hospitals; (3) study seminars and marketing promotion; (4) activities of medical representatives (MR) and medical scientific liaison (MSL); (5) infrastructure development of clinical trial and clinical research; and (6) education and human resource development. We are now still in the dawning of the “Sunshine Act”, so continuous discussion and efforts for reformation of the clinical trial and healthcare system would be desired.

#### Key words

Sunshine Act, Patient Protection and Affordable Care Act, Transparency Guidelines, promotion code, research agreement

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