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PhRMA Guiding Principles for use of Medical Science Liaisons (“MSLs”)

Background

- The purpose of these Guiding Principles is to set forth the guiding principles for pharmaceutical companies to promote appropriate activities of MSLs in a compliant manner and contribute to scientific advances in Japan.
- Recently pharmaceutical companies have increased medical affair activities by Medical Scientific Liaisons (MSLs). MSLs focus on medical and science-based discussions with Thought Leaders (“TLs”) to improve health care of the patients.
- MSLs’ activities are possible only if the MSLs are qualified to engage in high level medical and science discussion with TLs. Lack of consensus on the qualification and the standards of activities of MSLs would create inconsistent approach among pharmaceutical companies.

Suggested Principles for Use of MSLs

A. Roles and Responsibilities

- MSLs discuss medical/scientific information with TLs based on advanced scientific knowledge related to the company’s therapeutic areas of interest as peer to peer interactive discussion.
- The activities of MSLs should be strictly non-promotional.

B. Qualification

- Pharmaceutical companies must clearly provide qualification/requirements for MSLs, such as post-graduate degrees in the areas of medicine, science or pharmacy, credentials by academic societies, achievements in academic activities (e.g. publication of paper in reputable scientific journal), years of experience, etc.
- These qualification or requirements must be sufficient to select qualified personnel who can properly engage in advanced scientific discussion with TLs.

C. Independence from Commercial Activities

- The activities of MSLs must be independent from the activities of MRs. Pharmaceutical companies should create policies/SOPs to clearly distinguish the roles and responsibilities of MSLs and MRs, and to separate materials to be used by MSLs and MRs.

- MSLs should not report to Sales, Marketing functions or Business Strategy planning function and should not disclose contents of interaction with TLs other than aggregated TLs insight to MRs to avoid raising any doubt that the purpose of the activities are promotional, except for sharing of names of TLs and dates of visit for scheduling purposes.
- MRs should not be present when MSLs have scientific discussion with TLs.

D. Scope of Information Provision by MSLs

- MSLs may provide latest scientific information relating to products prior to approval or off-label use to TLs only upon unsolicited requests from TLs. Such information must be complete, accurate, balanced and based on evidence, and should not relate to promotion of specific products.
- MSLs must make own judgement to provide such latest scientific information without any influence by Sales or Marketing functions.

E. Performance Evaluation

- Performance evaluation of MSLs must be conducted independent from Sales or Marketing functions and in a fair, transparent and objective manner.
- Key performance indicators for evaluating MSLs' activities should not include items related to Sales, e.g. sales target or number of detail calls, and compensation for MSLs should not be directly linked to amount of sales or promotion outcomes.