European Federation of Pharmaceutical Industries and Associations

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EFPIA Japan

EFPIA Japan institutes MSL guideline for the purpose of sharing the common understanding among HCP and other stakeholders as to MSLs' role and activities

TOKYO—30 October 2017— EFPIA Japan announced today that MSL guideline has been instituted for members of EFPIA Japan.
(http://www.efpia.jp/link/Final_EFPIA_MSL_Guideline_201710_E.pdf)

Recently, many pharmaceutical companies started to employ individuals who primarily undertake information exchange with healthcare professionals from the medical, pharmaceutical and other scientific perspectives in a department independent from the departments conducting the sales activities of drugs. These individuals are called as "Medical Science Liaisons (MSL)".

In the Japanese pharmaceutical industry, a system has been established for assigning personnel called "Medical Representative (MR)", who have been undertaking the sales activities of his/her company's own drugs, post-marketing safety control, post-marketing surveillance, etc. With a focus on these activities, the self-regulations have been implemented on pharmaceutical companies' promotion activities targeting healthcare professionals, medical institutions, etc.

On the other hand, except regulations pertaining to clinical trials and studies, no public or self-regulations have been established concerning information exchange aimed at the research and development of drugs with healthcare professionals, etc., or concerning the collection, provision and exchange of information aimed at the accumulation of advanced medical and pharmaceutical knowledge concerning existing drugs.

Therefore, in the actual medical/clinical practice, there were some cases where the fairness and transparency could be hardly secured, because all activities were assessed/judged in the framework of the codes and regulations governing promotion activities, or, for the activities never fitting into such framework, they were assessed/judged simply by each person involved on case-by-case basis.

Given this situation, EFPIA-J published the "Principal regarding MSL's Roles and Activities" ("Principal") in October of 2015 for the purpose of sharing the common understanding among HCP and other stakeholders. In order to advance the Principal, hereby establishes an MSL Guideline as a reference for each pharmaceutical company to institute their own guideline.

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Ole Mølskov Bech, Chairman of EFPIA Japan said: “It is crucial that the pharmaceutical industry is able to engage healthcare professionals in discussion about the research and development of new drugs and about post-marketing safety controls – but society must have confidence that these discussions are appropriate. The EFPIA MSL Guideline will help create that confidence. In doing so, it will contribute to advances in treatments, and will ultimately benefit patients who suffer from disease. By providing a practical guideline that defines the role of MSLs, EFPIA Japan will contribute to patients and to scientific development in Japan”

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About EFPIA Japan:
Established in April 2002, EFPIA Japan represents 24 R&D-based European pharmaceutical companies operating in Japan. In 2016, combined sales from the member companies accounted for roughly 22% of the pharmaceutical market in Japan.
Mission of EFPIA Japan is to “Contribute to healthcare and patients in Japan by early introduction of innovative medicines and vaccines”. EFPIA Japan aims to strengthen dialogue with decision-makers in order to improve Japanese healthcare for all.

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