EFPIA Japan MSL Guideline (Translation)

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Preamble

In consideration of the nature of pharmaceutical companies conducting their business activities under the public medical insurance system as a part of human life-related industry, pharmaceutical companies (i), by being well-aware of sublime ethic, have to comply with the Law concerning Securement, Etc. of Quality, Efficacy and Safety of Pharmaceutical Drugs and Medical Devices, Etc. ("PAL"), the Act on Prohibition of Private Monopolization and Maintenance of Fair Trade , other applicable laws and regulations, and the Fair Competition Code in Ethical Pharmaceutical Drugs Marketing Industry , the JPMA Code of Practice, and other self-regulations established by other pharmaceutical industrial associations, (ii) contribute to the improvement of people's health and welfare in Japan and other parts of the world through the development of innovative, highly useful and safer drugs, and the dissemination activities and, for this purpose, pharmaceutical companies have responsibilities (a) to appropriately exchange information with healthcare professionals ("HCP" as defined in the paragraph 2 "Definition" below), medical institutions, patient groups and other stakeholders, (b) to work for researches and developments to satisfy unmet medical needs, and (c) to collect and provide information concerning the proper use and dissemination of drugs.

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.

Recently, many pharmaceutical companies started to employ individuals who primarily undertake information exchange with HCP, etc. 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”). 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 (“Guideline”) as follows.

1. General Provisions

The Guideline summarizes the items which each pharmaceutical company should take into consideration when MSL, who belongs to a department independent from the departments conducting the sales activities of drugs, appropriately exchange information with HCP, medical institutions, patient groups and other stakeholders, respond to unmet medical needs, facilitate the proper use of drugs, and collect and provide information for facilitating the optimization of product value. Therefore, this Guideline does not intend to refer to any activities of pharmaceutical company’s employees other than MSL.

2. Definitions

- Pharmaceutical companies

“Pharmaceutical Companies” refers to companies that hold drug marketing authorization under Article 12 of the PAL, and that currently engage in manufacturing/marketing or importing/marketing ethical drugs.

- HCP (Healthcare Professionals)

“HCP” refers to medical doctors, dentists, pharmacists, nurses, etc., who engage in a medical/pharmaceutical research and/or medical services.

- KOL (Key Opinion Leader)

"KOL" refers to HCP, who have plenty of clinical experience and advanced academic knowledge in the respective specialized areas.

- Unmet Medical Needs

"Unmet Medical Needs" refers to medical needs which have yet to be satisfied.

- Sales Activities

"Sales Activities" refers to activities of inducing HCP's proper prescription of company's own products (defined below) and drive the sales of such drug in order to make available such drug to patients.

- Proactive Information Provision

"Proactive Information Provision" refers to proactively providing information without any request from HCP.

- Reactive Information Provision

"Reactive Information Provision" refers to providing information in response to a voluntary request from HCP.

- Advisory Board

"Advisory Board" refers to a meeting held for the purpose of receiving specialized information and professional advice from an appropriate number (one or more) of KOL or other stakeholder(s) engaging in each specialized area.

- Medical Plan

"Medical Plan" refers to a plan necessary for maximizing the contribution of drugs' value to medical treatment and each specific activity to realize such plan. Such plan and conducting such activity shall not be affected by Commercial departments.

- Medical Seminar

"Medical Seminar" refers to a seminar or an event planned and held by a company from a medical, pharmaceutical, or other scientific perspective and "not for the purpose of sales", and is not affected by departments engaging in Sales Activities.

- Regarding the Company's Own Products

"Regarding the company's own products" refers to matters concerning the efficacy, safety and quality of the company's own products, as well as matters concerning medical treatment for the relevant disease by said products.

3. Purposes and Responsibilities of MSL

1) MSL identifies and verifies potential unmet medical needs for drugs and appropriate standard treatments from the medial, pharmaceutical and scientific perspectives and conducts activities for the purpose to maximally contribute to the medical treatment with the value of drug.

2) MSL must satisfy the qualifications specified by his/her company.
3) MSL must belong to a department independent from the departments engaging in the Sales Activities of his/her company's own products.
4) MSL must not be reviewed/evaluated based on the sales revenue of his/her company's own products.
5) MSL must take continuous education by taking the educational opportunities provided by his/her company and/or by external organizations in accordance with his/her company's rule.

4. Responsibilities of Pharmaceutical Companies Employing MSL

1) A pharmaceutical company must specify the responsibilities of its MSL.
2) Since MSL is required to provide and exchange opinions to or with KOL and other stakeholders from medical, pharmaceutical and other scientific perspectives, the qualifications of MSL has to be so specified as to enable each pharmaceutical company to select individuals who have a sufficient sense of ethics required to play a part of healthcare as well as adequate knowledge and capability.
3) A pharmaceutical company must not review/evaluate MSL based on the sales revenue of his/her company's own products.
4) A pharmaceutical company must provide the opportunity of continuous education to MSL.

5. Enhancement of Awareness, Information Collection and Opinion Exchange regarding Disease

With relation to the disease areas of his/her company's own products and drugs that his/her company plans to market in the future, MSL may enhance disease awareness collect and provide information, and exchange opinions from, to and with HCP, patients and other stakeholders from the medical, pharmaceutical and other scientific perspectives.

6. Provision of Information and Exchange of Opinions concerning Drugs

1) MSL must not engage in any Sales Activities of his/her company's own products.
2) MSL act to perform the responsibilities which are different from the ones to be taken by the departments engaging in Sales Activities. In order to avoid any misunderstanding that MSL engages in the Sales Activities, in principal, MR shall not be present when MSL provides information to, or exchanges information with, HCP.
3) MSL may occasionally exchange information with MR regarding the collection and provision of safety information or the treatment measures of the relevant HCP, however, any details of information provided by MSL shall not be shared with MR for a sales purpose.
4) MSL may provide information to and exchange opinions with HCP concerning his/her

company's own products from the medical, pharmaceutical and other scientific perspectives.

5) MSL must comply with JPMA's Code of Practice and other laws and self-regulations regarding the pharmaceutical companies' promotion matters even in the cases of Proactive Information Provision concerning his/her company's approved products. In addition, in the cases of the Proactive Information Provision, MSL must use the materials consisting with the purpose of MSL activities in order to avoid any misunderstanding that MSL engages in any Sales Activities. MSL is allowed to use only the materials which have passed his/her company's internal material review process.
6) MSL may reactively provide the published articles and other scientific literature upon a request from HCP concerning unapproved drugs and then, based on such articles and literature, may exchange opinions from the medical, pharmaceutical and other scientific perspectives. Provided, however, MSJ must comply with the following:
    A) In the cases of any information provision or opinion exchange concerning off-label use, even if it is reactive one, it is advisable that MSL uses the generic name in order to avoid any misunderstanding that MSL engages in any Sales Activities.
    B) In the cases that MSL engages in any drug development activities, MSL must comply with GCP and other applicable laws and regulations.
    C) Prior to the approval of drugs, from the medical, pharmaceutical and other scientific perspectives, MSL may exchange opinions with appropriate number of HCP including the clinical trial investigators, KOLs and other individuals who have knowledge concerning the proper use of drugs. In this case, the purpose of information collection must be clearly explained and the details of opinion exchange should be recorded. Even in this case, in order to avoid any misunderstanding that MSL engages in any Sales Activities for unapproved drugs, MSL may not conduct any Proactive Information Provision to HCP. Especially, during the period from NDA to the approval when the information and the opportunities of communication with HCP tend to increase, further careful attention is required.

7. Advisory Board

1) MSL may plan and operate an Advisory Board from the medical, pharmaceutical and other scientific perspectives, regardless of whether it is before or after the approval and whether it relates on-label information or off-label information of his/her company's own drugs or other drugs.
2) When MSL convenes an Advisory Board, he or she has to clarify its purpose and prepare its minutes.
3) Professional advice given by KOL or other stakeholders shall be reflected in the medical plans.

4) The MSL activities set forth in this paragraph shall be conducted in a manner to satisfy the requirements set forth in the item 1 through item 5 of the paragraph "6. Provision of Information and Exchange of Opinions concerning drugs".

8. Seminars and Other Events

1) MSL may at a Medical Seminar held by the Company, plan and operate said seminar on the prevention, diagnosis and treatment of diseases from a medical, pharmaceutical, or other scientific perspective. In such case, MSL may refer to the drugs for said disease areas, however, shall give due consideration not to make any explanation solely towards the company's own products. The same shall apply with regard to seminars co-held with scientific congresses. (This is a rule on planning of events held by Medical.)
2) MSL may make a presentation from the medical, pharmaceutical and other scientific perspectives in the seminars held by the department conducting any Sales Activities of his/her company's own products (including the seminars jointly held with other pharmaceutical company). Provided, however, he or she must not make any presentation containing any Sales Activities of his/her company's products but may provide only the medical, pharmaceutical or scientific knowledge. The same rule applies to the seminars co-held with scientific congresses. (This is the rules for making a presentation at the seminars held by the marketing/sales departments)
3) MSL may, at an exhibition booth at a scientific congress, plan and operate said exhibition booth on prevention, diagnosis and treatment of diseases from a medical, pharmaceutical, or other scientific perspective. In such case, MSL may comment on pharmaceuticals for said disease areas, but shall give due consideration not to make any biased explanation solely towards the company's own products. (This is a rule on planning of events held by Medical.)
4) The MSL activities set forth in this paragraph shall be conducted in a manner to satisfy the requirements set forth in the paragraph "6. Provision of Information and Exchange of Opinions concerning his/her Company's Own Drugs".

9. Research concerning Drugs

MSL may support clinical trials, clinical studies and other research activities in compliance with the applicable laws and regulations, and self-regulation.

End

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