Consensus Statement on Medical Science Liaison Activities

Japan Pharmaceutical Manufacturers Association (JPMA)

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I. Introduction

In recent years, to contribute to progress in medical science and the development of medical care, pharmaceutical companies have increased their focus on activities that aim to disseminate high-level and/or cutting-edge scientific knowledge to external experts by establishing a position known as medical science liaison (MSL), which involves participating in medical and scientific interactions with HCPs.

Based on the “Consensus statement on medical affairs (MA) activities”, we have compiled our basic thinking on MSL activities into this “Consensus statement on medical science liaison activities”. Although this statement assumes the existence of MSL functions, it does not require all member companies to appoint MSLs. For member companies with existing MSL functions, this statement is expected to be used, for example, to formulate action guidelines and plan activities. For member companies planning to introduce MSL functions in the future, this statement is expected to be used as a reference material at that time.

II. Purpose

This consensus statement is intended to set out the requirements that should be observed to ensure that medical and scientific communication between the MSLs of member companies and external experts[QA1 QA2] is appropriate and that MSL activities contribute to progress in medical science and the development of medical care.

If a member company establishes the position of MSL, that company’s MSLs will engage in interactions with external experts based on this statement while fulfilling the requirements specified in this statement, and while complying with the relevant regulations and the JPMA code of practice.

Even if referred to by a name other than MSL, personnel whose role involves engaging in medical and scientific interactions with external experts[QA3] are required to engage in activities according to this statement.

III. Roles and responsibilities

Member companies shall develop internal standards or procedural manuals to clarify the roles and responsibilities of MSLs, paying attention to the following points.

1. MSL activities should aim to contribute to the improvement in the quality of medical care and the maximization of patient benefits.
2. Based on the latest scientific knowledge in their disease area, MSLs should engage in peer-to-peer exchanges of medical and scientific information and opinions with external experts as fellow scientists[QA4].
3. MSLs should try to develop and maintain robust and positive relationships while respecting the independence of external experts[QA5].
4. MSL should engage in activities in accordance with the medical plan

IV. Requirements

Member companies shall specify the conditions necessary to fulfill the role of MSL, paying attention to the following points.
1. Conditions should ensure that MSLs can exchange information and opinions appropriately and scientifically based on the latest expertise in their disease area.
2. Conditions shall be fulfilled by, for example, obtaining a license in medical care such as that of physician or pharmacist, or a degree from an educational institution[QA7 QA8] in the field of natural science[QA6], such as a degree in medicine or pharmacy.
3. MSLs should fully understand the relevant regulations[QA9], internal standards and internal procedural manuals, and also acquire the necessary knowledge of medicines relevant to their disease area.
4. Before commencing activities as an MSL, MSLs should complete the necessary internal training program[QA10 QA11]. Moreover, to maintain the latest knowledge ongoing training is required.

V. Independence from commercial activities

MSL activities should ensure independence from commercial activities, paying attention to the following points.
1. MSLs should belong to a division that maintains independence from commercial divisions[QA12].
2. MSL activities should not be aimed at promoting sales of the company's drugs[QA13].
3. When engaging in medical and scientific interactions with external experts, MSLs should clarify the purpose of the interaction and decide whether the attendance of personnel from commercial divisions is appropriate[QA14].
4. MSLs should share information that is provided to or obtained from external experts with commercial divisions of the company to the extent that it does not compromise their

independence[QA15].

5. When the MA division conducts advisory board meetings[QA16 QA17] to obtain medical and scientific opinions, they should clarify the purpose of the meeting and run the meeting independently from the commercial divisions[QA18].

6. Key performance indicators (KPI) for MSL activities[QA19] should not be linked to commercial activities such as sales targets.

VI. Scope of information dissemination

MSLs shall disseminate information[QA20], paying attention to the following points.

1. Information provided by MSLs[QA21] should be accurate and objective based on scientific evidence. Moreover, information should be provided based on fair scientific judgement.

2. MSLs should provide information based on their independent judgement and not be influenced by commercial divisions.

3. Information provided by MSLs should not include content that is intended to promote sales of the company's drugs[QA22].

4. Materials used by MSLs for providing information should be distinguished from commercial materials and should be reviewed[QA23] in advance.

5. Pre-approved drug or off-label information should be provided only in response to an unsolicited request from external experts in a fair manner that is in accordance with Guidelines on ,Pharmaceutical Product Communications, internal standards, and procedural manuals.

6. At the pre-approval stage, to gather opinions about the interpretation of results of developmental clinical trials, clinical research plans and medical plans, undisclosed information should only be provided to contracted external experts[QA24].

VII. Definitions of terminology

The following terms are defined.

1. "Medical Science Liaison" refers to a person who belongs to a division independent from commercial divisions and whose main role is to interact with external experts in the field of medicine or science. See Note 1.

2. "External experts" refers to external specialists who have outstanding expertise in a particular medical or scientific area and who occupy positions of leadership in the field or in academic societies. See Note 2.

3. "Medical and scientific interactions" refer to exchanges of information and opinions to resolve specific issues in the medical or scientific field, which could in turn contribute to

medical progress and the development of medical care.

Note 1: While “MSL” is used as a representative term, the use of this term is not binding. Even if referred to by a different term, personnel whose role fits this definition shall be considered equivalent to MSLs.

Note 2: To clearly distinguish them from HCPs who are engaged for commercial purposes, some companies refer to external experts who interact with MSLs as key opinion leaders (KOLs), key external experts (KEEs), thought leaders (TLs) or scientific thought leaders (STLs).

Q&As regarding the Consensus Statement on Medical Science Liaison Activities

Q1 How are external experts selected?

A1 External experts should be selected based on MA independent selection criteria such as medical/academic record, social status such as board membership of an academic society, and relevance of their expertise to the company. Interactions should be conducted with external experts selected in advance in order to draw a clear distinction between commercial activities relating to the company's products.

Q2 Are MSL interactions limited only to external experts ?

A2 A premise of the MSL role is that MSLs interact with external experts. There is no restriction on MSLs responding passively to request from HCPs other than external experts for high-level and/or the latest information, but each company is expected to deal with these requests appropriately in line with internal standards and procedural manuals. Requests for information from HCPs should to be voluntary, and must not be solicited or invited by the company.

Q3 Does the consensus statement also apply to R&D and pharmacovigilance personnel?

A3 Interactions with external experts that are conducted by R&D and pharmacovigilance personnel are beyond the scope of this statement. If an MSL engages in R&D or pharmacovigilance related activities, the MSL needs to ensure that they meet the requirements stipulated under GCP and GVP/GPSP regulations and that they follow the prescribed procedural manuals.

Q4 What is meant by "fellow scientist" (in the context of peer-to-peer interactions)?

A4 Fellow scientist refers to having the same level of scientific knowledge regarding the topic of the information exchange with an external expert, and being able to have discussions as a scientific equal. It does not necessarily require the possession of a specific qualification or degree. It does not relate to social status.

Q5 What is meant by "respecting the independence of external experts"?

A5 When a conflict of interest arises, for example when the company is supporting clinical research, the MSL should not provide information or exchange opinions in such a way as to unduly influence the research plan or to bring about a result in favor of the company.

Q6 What kinds of fields of study are included in “natural science”?

A6 Fields of study such as medicine, pharmacy, veterinary medicine, dentistry, nursing, clinical examination, science, engineering, agricultural science, and psychology (aspects related to medical care or medicine).

Q7 What level of academic degree should be required of MSLs?

A7 While it is up to the each company to determine what level of degree should be required (e.g. doctor, master, or bachelor), a bachelor’s degree should be the minimum requirement.

Q8 Is it possible to set an equivalent standard in place of qualifications or degrees?

A8 It is possible to set a standard other than qualifications or degrees if it can guarantee the ability to engage in scientific discussions with external experts. However, because the acquisition of a scientific grounding is essential to enable scientific discussions, systematic participation in external or internal educational programs and/or regular competence checks are required.

Q9 What are the regulations relevant to MSL activities?

A9 The relevant regulations include legal regulations such as the Pharmaceuticals and Medical Devices Act and the Clinical Trials Act; regulations self-imposed by the industry including Guidelines on Pharmaceutical Product Communications, the fair competition code, the JPMA code of practice; guidelines set by academia and internal rules.

Q10 Are there any provisions regarding training content?

A10 While there are no particular provisions stipulated, each company should set training contents appropriately according to the duties required of the MSL. Training content may include statutory regulations, internal operational manuals, information on diseases and medical care in the MSL’s field, procedures for clinical research and research paper submission, and various business skills.

Q11 What training formats can be considered?

A11 Training may include internal and external education programs, participation in seminars and/or attendance at scientific congresses.

Q12 What is meant by “commercial divisions”?

A12 Commercial divisions are those in which performance is evaluated in terms of sales

volume of the company's products, and correspond to those comprised of sales strategy, marketing and medical representative (sales) personnel.

Q13 What activities are considered to be "promoting sales of the company's drugs"?
A13 "Promoting sales of the company's drugs" refers to activities that induce the prescription, supply, purchase, or use of the company's products, the results of which are evaluated by commercial indicators such as the volume of prescriptions or sales.

Q14 In what kind of situations are commercial personnel unable to accompany MSLs?
A14 These situations include interactions involving off-label use or undisclosed data, and interactions related to clinical studies or the publication of research papers. It is desirable for each company to stipulate limits on the participation of commercial personnel in advance.

Q15 What specific limits should be set to ensure independence of MSL activities?
A15 Information or discussions involving off-label use, undisclosed data, clinical studies and the publication of research papers should not be shared with commercial divisions. However, there is no restriction on sharing the visit schedule for a particular external expert. It is desirable for each company to stipulate the scope of possible information sharing in advance.

Q16 What is an advisory board meeting?
A16 A meeting of an advisory committee that consists mainly of external experts, and which is held to collect a broad range of professional opinions. When organized by a MA division, an advisory board meeting usually involves inviting external experts based on the content regarding which opinions are to be collected. The aim of these meetings is to collect opinions; advisory board meetings are not held with the primary aim of providing information.

Q17 Are there provisions regarding the implementation of advisory board meeting hosted by the MA division?
A17 While there are no particular provisions prescribed, individual contracts with each advisory board member are required. Each company should determine procedures and implement meetings according to those procedures.

Q18 Which specific aspects of meeting operation must be conducted independently of the commercial division?
A18 When the MA division hosts an advisory board meeting, commercial divisions should not be involved in the deciding the purpose of the meeting, the selection of advisors, providing notice of the meeting, meeting procedures, or preparation of meeting records. However, there are no restrictions on the involvement of commercial divisions in aspects of the meeting that do not affect meeting content, such as arranging the meeting venue and transportation for the attendees.

Q19 Is it acceptable to set performance indicators for MSLs such as the number of external expert visits or the number of clinical questions gathered?
A19 As long as they are not linked to commercial activities, it is acceptable to set numerical targets for MSL activities. However, personnel from commercial divisions should not be involved in the evaluation of MSLs.

Q20 Which regulations should be followed with regard to the provision of information? Are there any particular points of caution?
A20 The relevant regulations are the Pharmaceuticals and Medical Devices Act and the Guidelines on Pharmaceutical Product Communications, both of which should be followed closely. In the Guidelines on Pharmaceutical Product Communications, the provision of sales information is defined as the dissemination of information (including via disease awareness campaigns) that is expected to lead to an increase in sales by raising awareness of product name, efficacy or safety, regardless of whether the information dissemination is active or passive. This consensus statement stipulates that provision of information on a company's own products by MSLs should not be conducted for promotional purposes. However, it is possible that, from the perspective of HCPs, some MSL information sharing could be construed as having commercial purpose, and because at the current point in time (April 1, 2019) no method has been established across member companies to guarantee that such activities do not have commercial intent, it is difficult to completely exclude the possibility that cases arise in which information provision is suspected to have commercial intent. Accordingly, with regard to MSL information dissemination activities, each member company should comply with the Guidelines on Pharmaceutical Product Communications.

Q21 Is the information that can be provided by MSLs limited to that on their company's products?

A21 Information on a company's own products will not always be sufficient to contribute to improvement in the quality of medical care and the maximization of patient benefit. Rather, it should be noted that scientific fairness may be lost if information on a company's products alone is provided in a biased manner. The information provided should have a clear scientific basis, such as being based on peer-reviewed scientific publications. Moreover, the information should not include content intended to recommend a company's own drugs or to denigrate or slander other companies' drugs.

Q22 Is referring to a company's own drugs by their product names considered to be sales promotion?

A22 In principle, it is preferable to use general product names to avoid content being mistaken for sales promotion. However, cases where using product names has validity do not fall into this category, including cases where it is necessary to distinguish a product from generic drugs, or cases where each product has different efficacy or effect despite having the same ingredients.

Q23 From what perspective is internal review conducted?

A23 Review should be conducted from the perspective of not including elements that could lead to sales promotion of the company's drugs, of maintaining scientific fairness, and of following internal and external compliance regulations.

Q24 In cases where a confidentiality agreement or similar contract has already been concluded between external experts and the company for a clinical trial or other reasons, is it still necessary for MSLs to conclude a new contract?

A24 If an appropriate contract with external experts already exists, there is no need to conclude a new contract.