Consensus Statement on Medical Affairs Activities

Japan Pharmaceutical Manufacturers Association (JPMA)

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I. Introduction

This consensus statement on medical affairs activities has been developed to promote common understanding of medical affairs (MA) between member companies, health care professionals (HCPs) and other stakeholders, and to contribute to medical care that is highly beneficial for patients, by standardizing organizational structures, activities and guidelines. Although this statement assumes the existence of MA activities or functions, it does not require all member companies to engage in all of the activities and operations described. For member companies with existing MA functions, this statement is expected to be used, for example, to formulate action guidelines and plan activities. For member companies planning to introduce MA functions in the future, this statement is expected to be used as a reference material at that time.

II. Mission

In order to deliver optimal medical care to all patients, MA should:

1) Generate medical and scientific evidence to fulfill unmet medical needs, and disseminate information to HCPs and other stakeholders.

2) Engage in medical and scientific interactions with external experts using high-level and/or the latest scientific knowledge.

III. Roles and functions

The roles MA should play to achieve the above mission include (A) identifying unmet medical needs in real-world clinical settings; and, (B) developing a “medical plan” to optimize the value of the company’s products to patients and HCPs by addressing those unmet needs. Subsequently, based on the medical plan, MA should (C) generate evidence and (D) disseminate medical and scientific information, including the generated evidence, as appropriate. Sophisticated two-way medical and scientific interactions with external experts are essential in order to fulfil roles (A)-(D) above, and the establishment of personnel known as medical science liaisons (MSLs) provides one means to achieve such interactions. To ensure the reliability, transparency and objectivity of MSL activities, a separate “Consensus Statement and Q&As on Medical Science Liaison activities” has been developed based on

the present statement and is included as an appendix.
Major MA activities split according to the roles (A)–(D) are listed below. Just as the different roles of MA interconnect and overlap, so too do the individual activities that are associated with each role. The activities listed are examples only; accordingly not all activities need to be managed exclusively by MA, with the final decision left to individual member companies. Moreover, the intensity of the different activities varies according to the drug life cycle. Member companies shall develop internal standards or a procedural manual to clarify the roles and responsibilities of MA within the company.

(A) Examples of activities related to the identification of unmet medical needs
- Medical and scientific interactions with external experts
- Planning and execution of consultations and advisory board meetings
- Gathering information from research papers and scientific congresses
- Identification of clinical questions and research questions

(B) Examples of activities related to the development of the medical plan
- Conducting gap analyses
- Developing strategies for evidence generation
- Developing strategies for health economic and outcomes research (HEOR)
- Developing publication plans

(C) Examples of activities related to evidence generation
- Planning and execution of company-proposed studies
- Planning and execution of medical database and epidemiology research
- Planning and execution of post-hoc analyses and meta-analyses of clinical trial data
- Supporting and serving as the point of contact for investigator-initiated studies.

(D) Examples of activities related to the dissemination of medical and scientific information
- Providing advanced medical and scientific information to HCPs
- Providing off-label information in response to requests from HCPs
- Planning, support, and execution for the publication of research papers and presentations at scientific congresses
- Disease awareness campaigns (satellite symposiums at scientific congresses, dissemination of medical and scientific information)
- Planning and execution of medical booth activities at scientific congresses

Conducting internal medical education

Medical and scientific review of promotional materials

IV. Ensuring reliability, transparency and objectivity

Member companies shall ensure the reliability, transparency and objectivity of MA activities, paying attention to the following points.

1) MA activities should not be aimed at product promotion..

2) Independence should be maintained between MA activities and commercial activities.

3) Evaluation indices for MA activities should not be linked to commercial activities such as sales targets, instead focusing on activities such as evidence generation and the dissemination of scientific information.

4) Those who engage in MA activities should comply with regulations related to MA activities (legal regulations including the Pharmaceuticals and Medical Devices Act and the Clinical Trials Act, Guidelines on Pharmaceutical Product Communications, the fair trade code, and the JPMA code of practice), internal standards and procedural manuals.

V. Definitions of terminology

The following terms are defined:

1) Unmet medical needs: Medical needs of HCPs or patients that are not adequately fulfilled. For example, needs relating to diseases for which an effective treatment has not yet been found or needs for new therapeutic drugs and therapeutics.

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

3) Medical Plan: An activity plan that aims to optimize the usage of individual products for medical treatment. The plan usually includes environmental analyses, targets, strategies, plans for clinical trials and clinical studies, plans for the publication of research papers and presentations at scientific congresses, plans for interactions with external experts, and plans for education programs that aim to raise awareness of disease.

4) Medical booth: A display space at a scientific congress that is planned and operated by the MA division. Unlike booths planned by the commercial division that aim to explain products, medical booths aim to achieve medical and scientific interactions with the HCPs

that are participating in the congress.

5) Internal medical education: Medical education implemented by the MA division for other internal divisions. Is not limited to information related to company drugs and covers topics such as disease information and, pathophysiology.

[Background to the development of this consensus statement]

The environment faced by pharmaceutical companies in Japan has changed significantly. In particular, drastic changes have been required in how pharmaceutical companies relate to HCPs and in how information is provided to HCPs. There appear to be two major environmental factors. First, distrust towards the activities of pharmaceutical companies has increased due to improper conduct in clinical research and inappropriate provision of information as described in reports monitoring advertising activities. Second, a trend towards evidence-based diagnosis and treatment, and progress in individualized medical care, means that HCPs are required to provide appropriate diagnosis and treatment based on high value medical and scientific information, and thus HCP information needs have increased considerably. Accordingly, there is now an urgent need for evidence generation and dissemination for the benefit of patients via the accurate identification of unmet medical needs through medical and scientific interactions with external experts, while ensuring reliability, transparency and objectivity.

To resolve these issues, in addition to the usual activities conducted by the commercial section including dissemination of sales information and information gathering, Japan has seen a heightened need for medical affairs (MA) activities. MA activities generate and disseminate evidence regarding company products, diseases and their diagnosis and treatment, and having high medical and scientific value. The activities also enable medical and scientific interactions with external experts. The relevance and outcome of such MA activities by pharmaceutical companies is a contribution to improved medical care for the benefit of patients. In other words, outside of pharmaceutical companies, information obtained from MA activities leads to better diagnoses and treatment decisions in real-world medical practice and to progress in medicine and science, contributing to medical care that is of high benefit to patients. Moreover, within pharmaceutical companies, MA contributes to the improvement in patient benefit through evidence generation and dissemination of evidence in response to unmet medical need information obtained from medical and scientific interactions with external experts and input to related functions such as medical strategy or research & development. With the ever increasing importance of the Health Economics and Outcome Research field and real world data including medical payment

data (receipt data) and medical records (including electronic chart data) in recent years, MA is expected to identify unmet medical needs and generate evidence in these areas as well.

The history of the MA function is longer in the U.S. and Europe than it is in Japan, with many pharmaceutical companies having established MA divisions. The background to this is tightened regulations regarding communications between pharmaceutical companies and HCPs enacted by the U.S. Department of Health and Human Services Office of Inspector General (OIG) and Food and Drug Administration (FDA), among others[1]. Specifically, in 2003 the OIG published compliance guidance for pharmaceutical manufacturers in the U.S. to encourage separation of the communication with HCPs regarding educational grants and research funding from commercial divisions[2]. Furthermore, in 2009 the FDA published guidance for off-label publication, proposing that materials containing off-label information should not be provided to HCPs as commercial activities, and clearly instituting multiple stipulations concerning the provision of materials containing off-label information[3]. While an important role of the MA function is to appropriately manage the provision of materials containing off-label information, this guideline clarified the standards and procedures that MA functions should follow to ensure that the exchange of scientific information using off-label information is conducted appropriately[1]. Moreover, since the establishment of MA functions in the U.S., there has been increasing demand for MSL functions that are responsible for high-level medical and scientific interactions with external experts. In fact, since 2000, despite a trend in the U.S. towards decreasing promotional budgets and reducing numbers of employees in commercial sections, the number of MSL employees and the budget for MSL programs has been increasing[1]. In Japan, influenced by head offices located in the U.S. and Europe, global pharmaceutical companies took the lead and started establishing MA sections from around 2005, followed by Japanese pharmaceutical companies from around 2012. Moreover, there was an increasing trend in the number of MSL employees at pharmaceutical companies in Japan between 2011 and 2017 [4], suggesting that Japan is likely to follow a similar pattern as the trend in the U.S. and Europe. Since the establishment of organizational structures to accommodate MA functions at pharmaceutical companies, each company has examined and formulated responses to various issues. Specifically, items examined include the ideal organizational structure, definitions of activities, action guidelines, evaluation indices, outcomes, stakeholder awareness, operating requirements, personnel development, and cooperation with global counterparts. On the other hand, these topics have been addressed by each company without clear guidance, giving rise to variations in approach between pharmaceutical

companies. There are two possible causes for this. The first is insufficient industry guidelines regarding MA. In Japan, the Japanese Association of Pharmaceutical Medicine (JAPhMed) commenced activities as a third-party accreditation organization for the MSL authorization system for pharmaceutical companies in 2014, publishing “Certification standards for the MSL authorization system third-party certification operations.” In October 2015, the European Federation of Pharmaceutical Industries and Associations Japan (EFPIA-J) published the “Status of the MSL and action guidelines” with the goal of achieving common understanding between pharmaceutical companies, medical personnel and other stakeholders. Furthermore, in February 2016 the Pharmaceutical Research and Manufacturers of America (PhRMA) published the “PhRMA guidelines for MSL activities”, presenting guidelines for pharmaceutical companies to engage in appropriate MSL activities and contribute to scientific progress in Japan. On the other hand, the Japan Pharmaceutical Manufacturers Association (JPMA), a large-scale industry body with 71 member companies with substantial influence on participating companies, has not yet published a consensus statement on MA. The second possible cause is an insufficient exchange of information between pharmaceutical companies. Although some seminars and meetings for exchanging information are held currently, there are insufficient opportunities and networking for many pharmaceutical companies to be able to agree on an ideal approach and share knowledge, leaving them to determine their approach to MA on their own and on the basis of little information.

Due to these differences between pharmaceutical companies, there is a risk of confusion surrounding the recognition and awareness of MA among stakeholders including HCPs. As a result, it is possible that the relevance and roles of MA are not fully understood and that there is incomplete engagement in MA activities. In these circumstances, there are concerns that failing to provide necessary information to HCPs could have a negative impact on the diagnosis and treatment of patients and on progress in medical care. Against this background, this consensus statement has been developed to facilitate a common understanding of MA and to contribute to medical care that is of high benefit for patients.

References

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3) FDA, Good Reprint Practices for the Distribution of Medical Journal Articles and

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4) The Japanese Association of Pharmaceutical Medicine (JAPhMed). The eighth annual meeting. JAPhMed Medical Affairs (MA) Committee: Hirohisa Mizuno, Koji Iwasaki, Hideyuki Shiba, Yukio Moritsugu, Koichi Konno.