

The positioning and activity principles of MSL

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– Introduction –

More and more pharmaceutical companies in Japan are now starting to have Medical Affairs (hereinafter referred to as MA) or Medical Science Liaison (hereinafter referred to as MSL) teams in place. Multinational pharmaceutical companies are growing the MSL function to enhance information provision for Healthcare Professionals (HCPs) while domestic ones are following similar trends. In reality, however, the requirements for MSL are not necessarily the same for all the companies. Given this background, the Corporate Ethics Committee has decided to establish the positioning and the activity principles to share the basic stance on how MSLs should be.

1. The background and history of MA and MSL

Pharmaceutical products demonstrate their value only when they are properly used for patients in need of treatment. There is therefore a need to provide efficacy and safety information in a balanced manner; communicating this information appropriately with HCPs will be of benefit to patients.

Information on pharmaceutical products can come from information gained during investigational clinical trials, and also come from medical needs analyses based on a huge amount of prescribing information obtained from post-launch clinical studies and clinical practice. It is becoming increasingly important to provide this latest information to HCPs when they judge the benefits and risks of pharmaceutical products for their patients.

Given this background, pharmaceutical companies have created Medical Affairs (MA) functions and the Medical Science Liaison (MSL) role, consisting of employees who have a high level medical and scientific expertise. MA and MSLs help advance healthcare by compiling higher quality drug information and delivering it to HCPs in a timely manner.

2. The positioning and role of MA and MSL

The role of MA is to generate evidence based on medical needs, communicate information with internal stakeholders, and provide scientific support for the

preparation of materials used for information provision while MSLs actually interact with HCPs for such activities.

■ About MA

The MA function is independent of Commercial activities (Sales, Marketing), and engages in non-promotional scientific activities. Staff members who belong to MA have medical and scientific expertise, and provide medical and scientific support for disease prevention, treatment and diagnosis etc. through Medical activity plan development, product data and evidence accumulation, and scientific exchange with HCPs. These activities are not influenced by Commercial functions.

■ About MSL

The MA function often has MSL roles, who generate information described above and interact with HCPs. MSLs are appointed from those who have taken training based on a curriculum to acquire advanced scientific knowledge and skills appropriate for scientific exchange with HCPs. They are required to attend continuous training to acquire further expertise after their appointment. MSLs are not evaluated with commercial factors including sales and market share etc.

As described above, MA and MSL activities will be closely associated with the lifecycle of pharmaceutical products and greatly help maximize their medical and scientific value.

3. MSL activity principles

CEC has developed the following “MSL activity principles” based on the positioning and role described in 2:

- (1) MSLs visit specialists in each disease area, build/ maintain sound and good relations of trust while respecting the independence of HCPs, and have substantial discussion.
- (2) MSLs provide accurate, objective, and scientific data based information in a non-biased manner.
- (3) Information on off-label use or unapproved drugs should only be given reactively in response to a question or request from an HCP.
- (4) MSL activities are not for sales promotion, and information to be provided does not contain sales messages.
- (5) MSLs engage in activities in accordance with Medical plans that are not associated with sales or market share etc.

- (6) In principle, when MSLS provide information with HCPs from a medical/scientific perspective or exchange information with HCPs, they should not sit with MRs.
- (7) MSLS do not share the details of providing information with MRs from a commercial perspective.

END