

日本におけるメディカルアフェアーズの歴史

—過去, 現在, 将来—

前田 英紀*

(受付: 令和2年1月27日, 受理: 令和2年4月21日)

The Establishment of Medical Affairs Functions in Japan

— History, Current Status, and Future Perspective —

Hideki MAEDA*

Summary

Medical affairs has rapidly attracted a great deal of attention in recent years. It is also a function that is often misunderstood or poorly understood within the pharmaceutical industry. In the US, the medical affairs function has been established for a long time however, it has relatively short history in Japan. Back in 2012, during the Diovan clinical trials, questionable ties between medical researchers and pharmaceutical companies resulted in serious misconduct. These incidents triggered the separation of the functions of conducting post-marketing clinical studies and evidence generation from the functions of sales department, leading to the establishment of independent medical affairs departments in the pharmaceutical industry.

The definition of medical affairs may vary among companies. In principle, the aim of medical affairs departments is to fulfill unmet medical needs through the generation of scientific evidence and to deliver scientific value to key stakeholders and patients. People engaged in medical affairs functions need to be able to engage in scientific exchange activities with key opinion leaders independently of the sales department, in order to help ensure that patients can receive optimal medical care.

Medical affairs includes various roles, for example,

1. Liaison functions, in which field-based medical affairs experts engage in scientific discussions with key opinion leaders and identify unmet medical needs.
2. Planning post-marketing medical strategy for drugs in order to maximize value.
3. Planning and conducting post-marketing clinical studies and surveillance, database studies and pharmaco-epidemiological studies with real-world data, and supporting investigators to initiate clinical studies.
4. Delivering unbiased scientific information to key opinion leaders and responding to inquiries from healthcare professionals, for example by means of booths at scientific or medical conferences and/or call-centers.

Our understanding of the roles and responsibilities of medical affairs functions in Japan is still evolving. In this paper, I present an overview of medical affairs in Japan, covering its history, current status and future prospects.

Key words

Medical affairs, Medical Science Liaison, MSL, Clinical trials