

Role of Medicine Information in Pharmaceutical Industry

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Medicine information is the provision of unbiased, evidence-based and critically evaluated information about medicines. Medicine information pharmacists have a wide spectrum of activities, i.e., answering enquiries, proactive provision of information, adverse drug reaction reporting, provision of a medicine helpline for public, support for drug and therapeutic committees and training and education. Apart from these usual responsibilities, medicine information pharmacist now provides information to drug discovery and development departments in the pharmaceutical industry. This article illustrates various roles of medicine information in the pharmaceutical industry.

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Medicine Information (MI) is the provision of unbiased, evidence-based and critically evaluated information about medicines in an attempt to improve patient care. This discipline, often referred to as “drug information”, was developed in the late 1960s and early 1970s¹. The need for such information was felt not only when the number of new medicines increased enormously but also when they were more potent; the therapies used were also more complex than the previous ones. With developments in medical sciences, it became a big challenge to keep abreast with the most recent developments in order to make appropriate decisions in health care delivery. The Medicine Information Centre (MIC) services were established to meet the demand for evaluated independent information. It is to be appreciated that the importance attached to Evidence-Based Medicine (EBM) is fast growing.

MI is a resource-intensive sector. As a result, it has gradually slipped to “low priority” area. However, the departments of pharmacy and/or pharmacy practice in the country have established such services, and it has become a priority area. Such departments often offer training to the students who manage a MIC.

MI pharmacists have a wide spectrum of activities that include answering enquiries, proactive provision of information, adverse drug reaction reporting, provision of a medicine helpline for public, support for drug and therapeutic committees (DTCs) and training and education. The key roles of an MIC are to provide information to the physician(s) and patient(s), but now the paradigm is shifting to provision of information to drug discovery and development departments in the pharmaceutical industry. The end users of medicine information, therefore, are also the pharmaceutical industry’s own staff, notably in Research and Development, sales, marketing and medical functions. The responsibilities and activities vary considerably from company to company and from country to country.

The MIC services in the pharmaceutical industry are well established in many countries, notably, USA, UK, EC, Canada and Japan. In Europe, the industry is bound to provide non-promotional information services about the medicines they market. The council directive 92/28/EEC on the advertising of medicinal products for human use requires that “The marketing authorization holder shall establish within his undertaking a scientific service in charge of information about the medicinal products which he places on the market”. These departments may be

identified by other names such as drug information, product information, medical communications and medical services². Further, some companies, for example, Eli Lilly, have very well-established MIC. “MI Services” was initiated at Eli Lilly in 1993, which slowly turned into the Global Medicines Information (GMI) department. GMI helps the affiliates by reducing duplication of effort, increasing consistency in responses and providing higher quality and more timely information to requesting customers in support of Lilly pharmaceuticals³.

In India, the graduates of library science have traditionally managed this area. It is an emerging discipline with great potential for the pharmacy graduates. At present, there are over 15 medicine information centres providing clinical pharmacy services in India, and they could be classified as independent or otherwise. Some of the independent centres like Pharma Information Centre (PIC) provide information to drug manufacturers. The hospitals at Chennai and Coimbatore also have a similar program⁴. To the best knowledge of the authors, full-fledged medicine information departments in pharmaceutical companies in India are still not functional. Often the responsibilities are assigned to the department looking after product management and/or the clinical activities. A responsible company would not venture into any misinformation and would expect its MIC to provide information which is in perspective of the product in question. However, criticism cannot be prevented because it is an in-house service. Since the MICs have only been in active existence for less than a decade, independent centres will have to face the litmus test regarding the superior and balanced information provided to the industry. This article outlines the responsibilities of MI professionals in the pharmaceutical industry. For the sake of clarity, they have been split into 12 sections:

First and foremost is answering enquiries. Health professionals using or planning to use a drug or vaccine may need extensive information about its efficacy, safety and cost-effectiveness. Interestingly, although these departments can be a valuable source of detailed and helpful information, relatively few health professionals seem to be aware of their existence or their role. When referring to contact with companies, doctors, in particular, mention the sales representative as their source of information. In fact, the MIC often deals with the enquiries that representative receive from doctors. Questions from health care professionals can be patient specific also, such as drug use in pregnant women, children or the elderly¹.

Next is to provide current awareness. It is a valuable proactive service of an MIC. A company's medical, marketing, sales and other departments must be up to date with latest news and publications about their own products and those of competitor companies. The awareness about current developments can be provided in a variety of forms, like printed bulletin alerts, but it is still arguable that the most effective form of current awareness is direct word of mouth, either face to face or over the telephone. The current awareness bulletins can be simply the photocopies of the content page of a medical journal or cut-and-paste bulletins consisting of photocopied extracts from articles or sometimes even whole articles. It may include comments from the MIC about the significance of the findings of specific reports. The red alerts may include new findings from clinical trials, reports of side effects, claims made about competitor products or other new developments for which some response is needed quickly⁵.

Maintenance of databases is the next responsibility. Most MICs will have significant collections of published and unpublished information about their company's products. Much of the published information will be in the form of articles from medical and scientific journals, textbooks, symposium proceedings, abstracts and other publications. Unpublished information may include clinical trials reports, adverse event reports, expert reports, regulatory dossiers, formulation details, stability data and a variety of other pharmaceutical and clinical information. Maintaining this information in an easily accessible form in filing systems, databases, internet is an essential and demanding activity. It is also important to maintain a bibliographic database of reports about the company's products. Government authorities impose legal obligations on companies to monitor the literature, especially reports of possible side effects of the medicines that they produce. Maintenance of an up-to-date database is therefore a crucial role².

Providing support for marketing and sales is also a responsibility of MI professionals, who with their knowledge of the company's products and their skills in finding and evaluating information can play a major role in supporting members of medical/marketing team in developing marketing plans, launch plans for new products and evaluating new clinical data².

Reviewing promotional materials such as advertisements, brochures, package inserts and slide packs that are used to promote the use of a company's products. Such material must comply with legal regulations and codes of

practices. The MIC in many companies has the important role to check such materials before they are approved for use².

Internet "home pages" created by many MICs serve as product and disease-state resources for the rest of the company. Many of these home pages contain information on staff responsibilities, frequently asked questions, policies and procedures, therapeutic presentations and responses to medical information enquires. Internet home pages may also serve as training tools and as repositories for project updates and team communications⁶.

MI professionals also provide competitor analysis. Good MI skills in searching literature, analyzing data from clinical trials and synthesizing this information into a well-structured report or briefing provide an invaluable service to a company. It is also important to keep track of what is said about the company's medicines and competitors' products at congresses, in news reports, in market analysts' reports and through market research activities. The MI professional can play a role here by attending key congresses, monitoring newswires and other specialized sources and through its links with the sales force².

Another major responsibility of an MI professional is to provide information to patients. Patients are becoming increasingly knowledgeable about their condition and their treatments. A lot of information and misinformation about medicines is now easily available to patients through the internet, and the company's MIC has the opportunity to provide factually accurate and meaningful information to the patients².

Some MICs play an active role in pharmacovigilance by collecting and following up reports of adverse events associated with company's products. Many companies have separate pharmacovigilance or safety departments, but the MIC may still be the first point of contact for doctors, pharmacists or even patients when reporting adverse events².

To be effective in their work, MI professionals must build up an extensive network of contacts within the company. They must be aware of the expertise and information available in other departments. For example, the regulatory dossier put together by the regulatory affairs department is a very valuable collection of information and knowledge about a medicine. MI professional should include it as key source of information².

MICs also offer student and residency training programmes. Under these programmes, training can be provided through rotation to professionals in other areas of the company, such as regulatory, safety and health economics, and they can learn how to use medicine and drug information in these various settings. Apart from this, regular training can also be provided to students of pharmacy, who might ultimately take up careers in MI².

MI professionals, in particular, have a role throughout the research and development process in providing scientists with the tools and services to obtain and manage external and internal information. In today's environment, the role of research and development information is to provide current (proactive) literature and updated patent services, retrospective literature search services, competitive information, provision of end user training/support about databases, access to full text information via electronic journals and document delivery and finally the management of internal chemical and biological information².

The information-intensive pharmaceutical industry will continue to need the skills of information professionals,

but MI staff must ensure that their companies understand their role, the skills they have and the value that they can provide. MI professionals must be recognized as professionals; and to be able to do that, they have to appreciate that "the true professional commands a body of knowledge - a discipline that must be updated constantly."

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