

Evolving role of pharmaceutical physicians in medical evidence and education

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Abstract: The role of pharmaceutical physicians who are the experts working in pharmaceutical companies has progressed over the last few decades, from supervising research and development (R&D) studies and/or providing support to marketing teams to serving an independent critical function. In this review, we focus on pharmaceutical physicians serving medical affairs functions in the pharmaceutical industry. Historically, members of the medical affairs team mainly provided a bridge between commercial teams and the R&D sector and between the organization and external stakeholders. Such teams may even have been managed by other departments, with an emphasis on acquiring and generating data for regulatory purposes. In recent years, the role of medical affairs has broadened due to a change in focus and the increasingly stringent regulatory landscape. Strict regulations require the detachment of commercial from medical activities within pharmaceutical organizations. This change provides an opportunity for a different type of partnership, allowing scientifically minded and medically driven initiatives. This article summarizes the key role of pharmaceutical industry-based physicians in medical affairs and discusses the emerging and evolving role of medical affairs for value creation in evidence generation and medical education.

Keywords: medical affairs, medical education, pharmaceutical physicians, pharmaceutical industry

Role of medical affairs in the pharmaceutical industry

Internal: bridge between research and development (R&D) and commercial functions

As regulatory bodies increase scrutiny on the promotion of therapeutic products, the medical affairs department has played an important role in separating R&D and commercial functions to reduce the commercial influence on R&D efforts.^{1,2} Medical affairs serves as a liaison between the two functions, facilitating the transition of drugs from R&D to commercial.³ Although the marketing department designs and provides pharmaceutical sales representatives (PSRs) with visual aids to engage physicians, medical affairs play a vital role in approving and providing feedback on such information tools.⁴ Pharmaceutical industry-based physicians play an important role in ensuring that key messages are backed by sound scientific evidence and no misleading claims are made.⁵ The medical affairs department is also involved in training PSRs to be knowledgeable about the company's products.⁶ This is relevant because one of the roles of physician-PSR interactions is to inform time-poor physicians about the latest

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therapeutic area and drug data, although these interactions generally tend to be more promotional.⁷

External: bridge between the organization and external stakeholders

Although PSRs have historically been considered valuable sources of medical information, their perceived importance to physicians has been steadily decreasing. Many physicians now choose to rely on other sources, such as manufacturer websites and peer-reviewed journals, for their information.⁸ This may have been one of the reasons why almost half of all new drug launches over the last 8 years have failed to fulfill their financial expectations.⁹ One approach used by pharmaceutical companies to address this underperformance has been to bolster their medical affairs teams.⁵ Given that evidence-based information is of high interest to physicians, medical affairs will play an important role in gathering and presenting scientific data alongside information about potential patient outcomes. There has also been a shift in focus from broad therapeutic areas covering large patient groups to therapy involving smaller populations, targeted therapy, and personalized medicine.¹⁰ This shift has placed more emphasis on the role of medical affairs in establishing connections with health care professionals and providing education about potential individualized therapeutic options.¹⁰ In essence, the external-facing role of medical affairs can be summarized using the medical affairs external communication cycle (Figure 1).¹⁰

Companies are increasingly deploying Medical Science Liaisons (MSLs) in the field to communicate scientific

information to key stakeholders, including physicians, and to capture relevant medical insights.¹¹ The academic qualifications of MSLs range from medical and pharmacy degrees to PhDs, although most companies prefer postgraduate, doctorate, or specialist qualifications.¹² Senior positions in medical affairs, eg, medical manager/medical director roles, generally require at least a basic medical degree and offer dynamic and challenging careers for physicians beyond patient interaction.¹³ Effective communication skills and commercial acumen as well as management and leadership skills are the key attributes required to be successful in these roles.¹³

Medical affairs may also be involved in organizing medical advisory boards, Phase IV clinical trials, preparation of medical responses to enquiries, and preapproved early drug access programs.⁶ Medical affairs departments also play an important function in providing responses to off-label enquiries, which must be handled independently of commercial teams.¹⁴

Medical advisory boards provide pharmaceutical companies with valuable insights on various topics, ranging from trial protocols to regulatory submissions.¹⁵ Advisory boards can be held at any stage during product development and facilitate the generation of data, the development of products, and the creation of trustworthy educational content.¹⁶ However, to make sure that advisory boards provide a return on investment, medical affairs teams need to ensure the optimal allocation of resources.¹⁷ This includes having a clear objective for the meeting, selecting the appropriate key opinion leaders (KOLs) or therapeutic area experts, ensuring adequate preparation, and facilitating the implementation of meeting action points.¹⁸



Figure 1 Overview of medical affairs as a bridge between organization and external stakeholders.

Early access programs (EAPs)

EAPs are one way in which pharmaceutical companies can facilitate access to newer, unapproved therapies for patients with rare and/or severe diseases in an ethical manner.^{19,20} Adoption of EAPs in pharmaceutical companies is becoming increasingly prevalent due to the variety of benefits of these programs.²⁰ In Europe, there are two main types of EAPs: Compassionate Use Programs (CUPs) and Named Patient Programs (NPPs).²¹ In CUPs, patients in selected health care institutions with severe, debilitating, or life-threatening illnesses who cannot be treated adequately with existing medical treatments are granted access to compassionate (free of cost) use of preapproved drugs by pharmaceutical companies.²¹ In contrast, NPPs grant access to preapproved drugs to specific “named” patients in response to requests

from physicians who ultimately bear the costs of these treatments.²¹ The emergence of EAPs means that there is a greater need for the mobilization of medical affairs teams to oversee their planning and execution.²¹ The importance of EAPs cannot be underestimated. For example, the WHO approved the provision of the investigational monoclonal antibody, ZMapp, to six Ebola patients for therapeutic purposes and to prevent the spread of the virus; four of the six patients were saved.²⁰

Investigator-initiated research (IIR)

An IIR is a research led by an independent investigator and that is related to a pharmaceutical company's area of interest.²² In IIR, the principal investigator is involved in the execution of the study and oversees its regulatory management; the latter is otherwise often the responsibility of pharmaceutical or biotechnology companies.²² However, the investigator may request support from pharmaceutical companies in the form of funding and/or product supply without the company assuming the responsibilities of a "sponsor", as defined by the International Conference on Harmonization-Good Clinical Practice (ICH-GCP).^{22,23} Medical affairs teams within pharmaceutical companies are tasked with overseeing IIRs, with an increasingly large proportion of companies using MSAs to support IIR initiatives.²⁴

Evolving role of medical affairs in generating medical evidence Phase IV real-world clinical studies

Randomized controlled trials (RCTs) are the gold standard for the comparison of different clinical interventions.^{10,25} Systematic reviews and meta-analyses may also be conducted later to combine results from multiple studies in an effort to increase the statistical power of the results.²⁶ However, RCTs are performed in clinical settings with stringent controls on many variables because they are designed to establish a causal relationship between an intervention and an outcome.²⁵ In addition, RCTs may not be able to detect long-term adverse events.²⁷ Therefore, there is some skepticism about the real-world clinical practice applicability of data from RCTs.

Real-world data (RWD) include information on patients' health status and outcomes that are obtained regularly from sources such as electronic health records (EHRs) and disease registries. RWD can aid in identifying long-term adverse events and guide the development of specific guidelines in clinical practice.²⁸ Obtaining RWD from pragmatic clinical

trials and observational studies is important for demonstrating the "worth" of health care solutions to the various stakeholders.

Medical teams are also increasingly involved in the execution of postlaunch clinical trials, including Phase IV real-world studies.⁶ The scope of this work is still evolving but is currently the subject of increased attention and may allow the exploration of new questions such as potential new drug indications for smaller patient groups.²⁹

Health economics and outcomes research

As the complexity of the medical landscape increases and the number of treatment options available to patients continues to expand, there is growing demand for the value of medications to be demonstrated.³⁰ This emphasis on the "value" of health care solutions, rather than just the price, has put pressure on pharmaceutical companies to demonstrate the worth of their health care solutions in terms of cost-effectiveness as well as direct and indirect benefits.³¹ Thus, there is an increased focus on health economics and outcomes research (HEOR) that requires relevant data. Medical affairs, in collaboration with market access colleagues, may conduct HEOR to understand and communicate the value of products to external stakeholders, including Health Technology Assessment (HTA) bodies.³¹

HTA

There are a number of different HTA bodies around the world, and these are highly relevant to pharmaceutical companies (Figure 2).³¹⁻³⁹ The role of HTA organizations is to enable efficient allocation of finite resources to meet the almost infinite demands for better medical technologies, including pharmaceuticals, medical devices, and other medical interventions.^{34,40}

The HTA-driven global shift toward evidence-based value analysis has seen the expansion of the medical affairs function to consider HEOR aspects. Medical affairs plays an important role in ensuring that HTA requirements are met, sometimes even before the medical therapy has been approved for marketing.^{41,42} For example, the UK HTA agency, the National Institute for Health and Care Excellence (NICE), receives information about potential new therapies up to 20 months before they have been authorized to enter the market.⁴² This liaison with HTA bodies ensures that pharmaceutical companies are able to fulfill the criteria required to meet increasingly stringent HTA requirements. This is beneficial because earlier collaboration will decrease delays

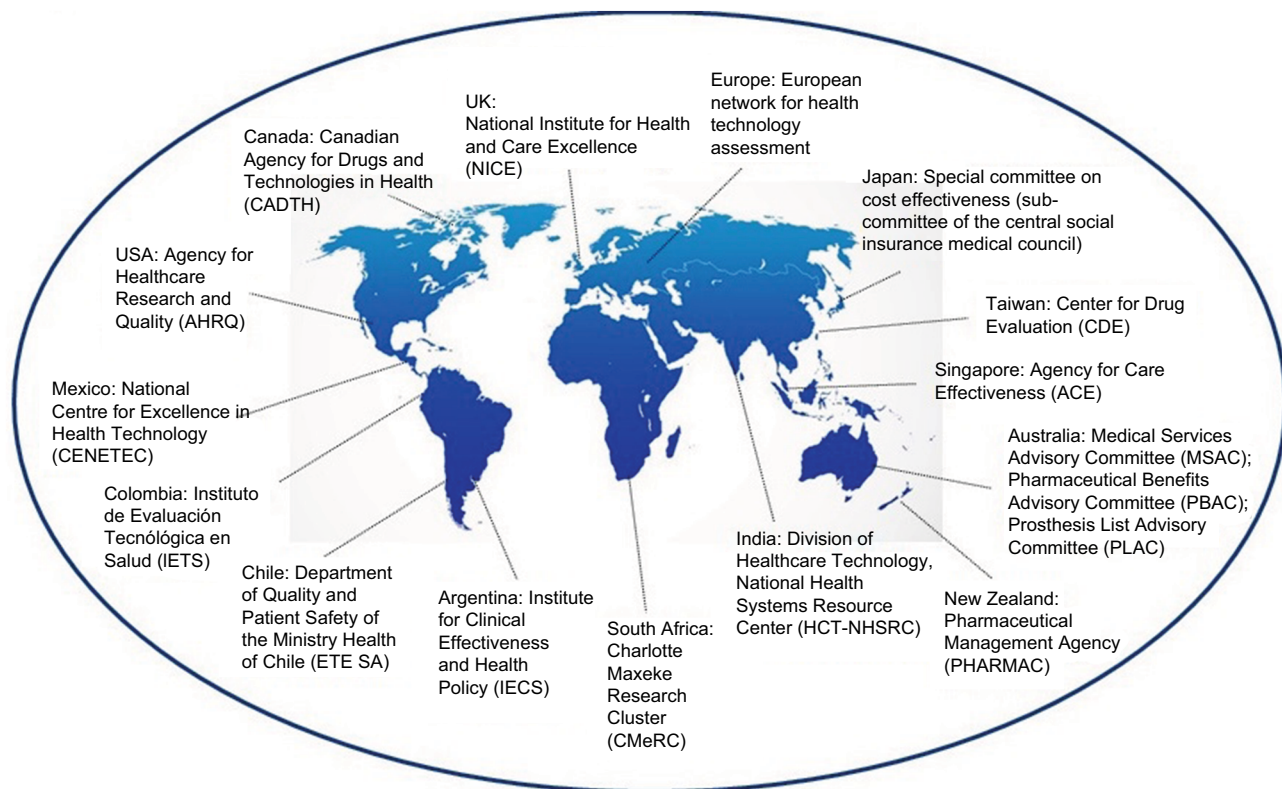


Figure 2 Worldwide Health Technology Assessment agencies.

to market access for products, thereby allowing patients to have timely access to new therapies.

Scientific publications

Medical affairs teams are increasingly being involved in the communication of nonpromotional scientific content via a variety of channels, including scientific publications.^{3,43} Original articles (eg, from RWD, market research on educational needs, and practice gaps), review articles, pharmaceutical-independent consensus/expert opinions, and letters to editors are key types of publications authored or led by medical affairs personnel.

Several studies have highlighted gaps between actual practice and scientific evidence in the clinical setting.⁴⁴⁻⁴⁷ Narrowing of these gaps has proven beneficial in reducing patient morbidity and mortality and decreasing the cost of health care.⁴⁸⁻⁵¹ Medical affairs professionals may be involved in identifying and communicating these gaps through cross-sectional research.⁵²⁻⁵⁵ They can also collaborate with health providers on narrative review manuscripts that address gaps in current clinical practice or educational needs.⁵⁶⁻⁵⁸ Identifying and communicating practice gaps could provide support

to convince government health divisions to take action and update clinical practice guidelines.⁵⁹

Addressing inconsistencies in trial results by combining data using systematic review and/or meta-analysis techniques is another important approach to facilitate better understating of clinical data.²⁶ Medical affairs has an important, and currently under-utilized, role in leading these publications in collaboration with health providers.

In the absence of local guidelines, pharmaceutical-independent consensus/expert opinion publications play an important role in bridging existing knowledge and practice gaps.⁶⁰ A “medical consensus” document is generally regarded as a credible and evidence-based publication by health professionals.⁶¹ Medical affairs teams can lead the publication of consensus papers (eg, based on medical advisory board meetings and clinical forums) to support the adoption of evidence-based practices in local clinical settings.⁶²

However, it is extremely important for medical affairs personnel to adhere to good publication practice standards while leading such activities. A series of reporting guidelines has been developed and motivated primarily by concerns about the quality of publications (Table 1).⁶³

Table I Recommendations from key guidelines for drafting scientific publications

Abbreviation	Scope	Key guidance
General publication guidelines		
ICMJE ^{14,137}	<ul style="list-style-type: none"> Recommendations for appropriate ethical standards and best practices for the preparation and layout of scientific manuscripts to be published in journals 	Authorship <ul style="list-style-type: none"> Provides the definition, roles, and responsibilities of an “author” during submission and throughout the peer-review process Defining, handling, and reporting “conflict of interests” of authors
GPP3 ¹³⁸	<ul style="list-style-type: none"> Developed by the ISMPP to ensure responsible and ethical publishing of RCTs sponsored by pharmaceutical companies Most recent 2015 revision emphasizes on transparency in publications sponsored by pharmaceutical companies 	Publication processes <ul style="list-style-type: none"> Formation of publication steering committees to oversee publication planning Specifies the studies that should be published, ie, those from every clinical trial involving human participants including those with negative findings Specifies limits on premature and redundant publications and severity of plagiarism Procedure in the registration of clinical trials and limits of public posting of data Steps in the documentation of the publication process Authorship and principles of authorship Roles and responsibilities of professional medical writers Handling of “disclosures”, ie, conflict of interests with various commercial and noncommercial parties
Specific publication guidelines according to design of study		
CONSORT ¹³⁹	<ul style="list-style-type: none"> Used to guide the reporting of RCTs including 1) CONSORT statement and 2) CONSORT explanation document that elaborates the statement 	<ul style="list-style-type: none"> CONSORT statement: comprises a 25-item checklist classified into title, abstract, introduction, methods, results, discussion, and other data. This checklist focuses on the design, analysis, and interpretation of the trial Comprises a flow diagram allowing the adaptation of a general flow of the stages a patient will go through in a trial. This includes guidance on the enrolment, allocation, and follow-up of patients and analysis of data obtained
STROBE ¹⁴⁰	<ul style="list-style-type: none"> Guide for reporting observational studies 	<ul style="list-style-type: none"> Guidance comprises 22 items classified into title and abstract, introduction, methods, results, discussion, and other data Specifies differences in requirements of reporting of participants in cohort, case-control, and cross-sectional studies Specifies differences in requirements of statistical methods in the above three study types
PRISMA ¹⁴¹	<ul style="list-style-type: none"> Guide for reporting the systematic reviews and meta-analyses of RCTs 	<ul style="list-style-type: none"> Guidance comprises 27 items classified into the following seven categories: title, abstract, introduction, methods, results, discussion, and funding Guidance also consists of a flow diagram that depicts the general flow of clinical trial records during the course of the meta-analysis
MOOSE ¹⁴²	<ul style="list-style-type: none"> Guide for reporting MOOSE 	<ul style="list-style-type: none"> Guidance consists of a 35-item checklist with the following categories: background, search strategy, methods, results, discussion, and conclusion Specifically and precise guidance on usage of graphs and tables for representation and description of statistical methods
TREND ¹⁴³	<ul style="list-style-type: none"> Guide for reporting the non-RCTs 	<ul style="list-style-type: none"> Guidance comprises a 22-item checklist with the following headings: title and abstract, introduction, methods, results, and discussion Requires the inclusion of methods undertaken by authors and investigators to reduce potential bias arising from nonrandomization

Abbreviations: CONSORT, Consolidated Standards of Reporting Trials; GPP3, Good Publication Practice 3; ICMJE, International Committee of Medical Journal Editors; ISMPP, International Society for Medical Publication Professionals; MOOSE, Meta-analysis of Observational Studies in Epidemiology; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analysis; RCTs, randomized controlled trials; STROBE, Strengthening the Reporting of Observational Studies in Epidemiology; TREND, Transparent Reporting of Evaluations with Nonrandomized Designs.

Evolving role of medical affairs in medical and public education

Continuing medical education (CME) for health providers

CME is a cornerstone of current medical practice.⁶⁴ Although CME assessments and regulations differ between countries, almost all require physicians to undergo some form of continuous education during their practice.^{65,66} In countries that mandate CME for physicians, regulatory institutions stipulate the expected standards and practices for such activities. Should a physician fail to meet these requirements, the consequences depend on the regulations of each specific country.⁶⁶⁻⁶⁸

Despite often being mandatory, the costs of attending CME events are usually high and can act as a deterrent to physician participation.⁶⁹ It is therefore not surprising that commercial support contributes to a large percentage of CME funding.⁷⁰ While the proportion of total commercial funding has decreased from more than half in 2006 to slightly above a quarter in 2016, it still makes a sizeable contribution (\$704 million in 2016).^{71,72} This commercial funding is vital because many CME events could not proceed without financial backing.⁷³ Pharmaceutical companies see this as a key opportunity to present the latest findings and to educate physicians about new products or even established therapeutic areas.⁷⁴ Physicians benefit by gaining insight into medications and therapy options that may be useful for their clinical practice.⁷⁵ However, it is important to note that there is a major difference between industry-led and industry-independent CME events. The former includes events where a pharmaceutical company has substantial influence over the presented content, and these are generally not allowed to contribute to CME credit in most developed countries.⁷⁶ These events are also often perceived as marketing ventures by companies to introduce new drugs or studies to physicians.⁶⁸

The pharmaceutical industry supports independent CME events through unrestricted educational grants and sponsorships.⁷⁷ Most of these may still relate to education about a specific drug or treatment area of commercial relevance.⁷⁸ Sponsorships differ from educational grants in that they generally provide direct, tangible benefits to the sponsor while grants have no strings attached.⁷⁸ For example, sponsorship may be provided to subsidize the cost of entry to CME events for physicians, where permitted by law. In addition, conference sponsors are often able to set up booths and promote their brand through the placement of product logos, promotional materials, and handouts directly outside the event venue. In contrast, independent grants come with

no requirement for the payer's direct benefit.^{79,80} Many companies offer independent grants to a variety of official institutions.⁸¹⁻⁸³ These include universities, medical schools, patient associations, and professional bodies.^{82,84} Grants are given with the goal of ensuring continuous improvement in health care provision and patient outcomes.⁸⁵ The defining difference between independent grants and sponsorship is that grant recipients have full control over the content of their communications.⁸⁶ This means that grant-supported events are less likely to be under industry influence and more likely to promote the communication of unbiased information. As a result, grant-funded events are often perceived as having greater credibility than sponsored events.⁸⁷ In fact, many have suggested that industry grants should be overseen and managed by independent committees that would be responsible for decisions about which specific course or event this funding would be disseminated to.⁸⁸⁻⁹⁰

In the pharmaceutical industry, there has been a recent trend for responsibility for CME activities to be transferred from the marketing department to medical affairs.⁹¹ This reflects the shift in pharmaceutical strategy driven by stakeholder demand for credible, accurate, and evidence-based information. The growing role of medical affairs in the management of CME activities is an important step toward mitigating the "stigma" associated with industry-sponsored events and building trust between the pharmaceutical industry and its key stakeholders.

Public education

The internet has become one of the primary sources for consumers to access medical information.^{92,93} It provides a cost- and time-efficient avenue for seeking medical advice without having to consult a physician. One study found that about 35% of people who search for medical information online use this as a tool to self-diagnose their ailments.⁹⁴ More alarmingly, over a third of these people do not double-check their self-diagnoses with a health care professional.⁹⁴

While there are many credible sources of information on the internet,⁹⁵ a large portion of online resources provide low quality information and can thus pose harm to consumers' health.^{96,97} The widespread availability of noncredible medical information is a danger to society, and pharmaceutical companies have a civic duty to protect consumers by being sources of trustworthy information. The European Union (EU) took this into account when they decided to loosen the policy against allowing prescription medication information to be posted online by their manufacturing companies.⁹⁸ In addition to posting information about their products online,

pharmaceutical companies provide health education to the public and carry out real-world public health initiatives.^{99,100} The importance of medical affairs personnel in these ventures will only grow as more and more patients go online to source health and medical information.

Another pertinent issue is direct-to-consumer advertising (DTCA) of prescription medicines. This is prohibited in most countries, with notable exceptions being Hong Kong, New Zealand, and the USA.^{101–103} In the USA, the Food and Drug Administration (FDA) imposes restrictions on advertising and mandates that no misleading or misrepresented information is to be provided to consumers.¹⁰⁴ While DTCA provides a potential avenue for pharmaceutical companies to educate the general public about their products, many also see a potential risk for public harm.^{105,106} In fact, the perceived risk is so high that in 2008, 22 of the 27 EU members voted to prohibit even the provision of limited information to consumers via DTCA.¹⁰⁷ These fears are largely due to the perception that pharmaceutical companies do not consider public education as the main aim of their advertising but, instead, strive to gain a larger profit margin by acquiring more paying customers.¹⁰⁸ As the importance of consumers as stakeholders increases (aptly demonstrated by the rising prominence of patient associations in Europe), medical affairs will have an ever-expanding role in ensuring that patient centricity is at the forefront of any initiative that their company undertakes.¹⁰⁹

Collaborations with patient associations

More recently, companies have extended medical engagement activities to patient associations in order to fully leverage the valuable patient insights they can provide.⁶ The medical affairs function plays an important role in understanding and integrating patient perspectives into the organization. According to the US FDA, patient involvement in drug development is a priority and, therefore, medical affairs should aim to involve patients earlier in the drug development process to better facilitate the identification of meaningful clinical trial endpoints.¹¹⁰ Medical affairs departments also help to educate patients and health care professionals on the organization's R&D pipeline and current clinical trials. In addition, reaching out to patients can increase the possibility of obtaining funding for orphan drugs from charitable patient organizations given the shift in focus to smaller therapeutic areas.¹¹¹ Such engagements provide pharmaceutical companies with the opportunity to develop more scientific, accurate, and patient-centric programs to engage their key stakeholders,

giving them a competitive edge in the changing pharmaceutical landscape.

Unique conflicts of interest (COIs) for medical affairs professionals

Medical affairs physicians themselves face many challenges in terms of COIs. These arise when a physician's ability to make decisions in the best interests of their patients becomes affected by their relationship with the pharmaceutical company that employs them.¹¹² Their position within the company is noncommercial in nature and could potentially conflict with marketing objectives.¹¹³ However, as both an employee of a company and a physician who has a duty to act in a patient's best interest, a pharmaceutical physician needs to ensure that his/her obligations to both parties have been fulfilled.¹¹⁴ Therefore, it is important to understand and adhere to the key internal and external check systems that control the quality and credibility of internal compliance governance by medical affairs personnel and their external stakeholder interactions.

Control systems in pharmaceutical industry

In today's ever-changing world, controls on pharmaceutical industry practices have to evolve to keep pace with its dynamic nature. The four main pillars of control systems are regarded to be internal company protocols, industry codes of practice, regulations, and laws.¹¹⁵ Table 2 summarizes the different control systems governing pharmaceutical communication around the world. These are of increasing importance to medical affairs departments given that they have an expanding role in communicating both directly and indirectly with physicians, patients, and other key stakeholders.

Laws and regulations

Laws and regulations relating to the communications between the industry and their stakeholders are governed by national and potentially even regional regulatory organizations. For example, member nations of the EU are required to follow European Medicines Agency (EMA) laws.¹¹⁶ However, individual nations within the EU may also impose additional local laws or regulations that they deem necessary to meet the main directives set by the EMA.¹¹⁷

Local laws and regulations are upheld by the regulatory bodies of individual countries. Both the laws and their enforcement can vary from country to country. For example, the advertising of medicines is regulated by the FDA in the United States and by the Therapeutic Goods Administration in Australia.^{104,118} Furthermore, laws that govern other com-

Table 2 Summary of control systems governing pharmaceutical practices around the world

Control system	USA	UK	Canada	Rest of Europe	APAC
External regulators	FDA ¹⁴⁴	MHRA ¹⁴⁵	Health Canada ¹⁴⁶	EMA ¹¹⁶	Singapore: HSA ¹⁴⁷ Australia: TGA ¹¹⁸ New Zealand: Medsafe ¹⁴⁸ Japan: MHLW ¹⁴⁹ India: CDSCO ¹⁵⁰ China: CFDA ¹⁵¹
Laws	FCPA ¹¹⁵	Ant-bribery act ¹¹⁵	The Canadian Privacy Act ¹⁵² Personal Information Protection and Electronic Documents Act ¹⁵²	The Medicines (Advertising) Regulations 1994 ¹⁵³ Community code relating to medicinal products for human use (Directive 2001/83/EC) ^{2,154}	Singapore: Health Products Act ¹⁵⁵ Australia: Therapeutic Goods Act ¹⁵⁶ New Zealand: Medicines Act 1981, Medicines Regulations 1984 ¹⁴⁸ Japan: Pharmaceutical Affairs Law, Standards for Fair Advertising Practices ^{157,158} India: Drugs and Cosmetics Act 1940; Drugs and Magic Remedies (Objectionable Advertisements) Act 1954; Consumer Protection Act 1986 ¹⁵⁹ China: Advertisement Law, Drug Administration Law ¹⁶⁰⁻¹⁶²
Industry codes ¹¹⁵	PhRMA	ABPI	Rx&D	EFPIA	Singapore: SAPI Australia: Medicines Australia Japan: JPMA India: OPPI China: RDPAC

Abbreviations: ABPI, Association of the British Pharmaceutical Industry; APAC, Asia Pacific; CDSCO, Central Drug Standard Control Organization; CFDA, State Food and Drug Administration; EC, European Commission; EFPIA, European Federation of Pharmaceutical Industries and Associations; EMA, European Medicines Agency; FCPA, Foreign Corrupt Practices Act; FDA, Food and Drug Administration; HSA, Health Sciences Authority; JPMA, Japan Pharmaceutical Manufacturers Association; Medsafe, Medicines and Medical Devices Safety Authority; MHLW, Ministry of Health, Labor & Welfare; MHRA, Medicines and Healthcare Products Regulatory Agency; OPPI, Organization of Pharmaceutical Producers of India; PhRMA, Pharmaceutical Research and Manufacturers of America; RDPAC, Research and Development-based Pharmaceutical Association in China; Rx&D, Research-Based Pharmaceutical Companies; SAPI, Singapore Association of Pharmaceutical Industries; TGA, Therapeutic Goods Administration.

mercial entities within the country also apply to pharmaceutical companies. For example, the Foreign Corrupt Practices Act in the USA and the Bribery Act in the UK affect the commercial behavior of local companies' subsidiaries that are abroad.^{119,120} Laws and regulations in individual countries can differ greatly, as seen in the above example of DTCA. Relevant laws are usually taken as the basis for which industry and internal policies or guidelines are enacted, although these policies can often be more comprehensive than the rules and regulations of governmental agencies.¹¹⁵

Industry codes

Local trade associations specific to the pharmaceutical industry have been established all over the world and fall under the jurisdiction of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA).¹²¹ Members of the IFPMA adhere to a strict set of regulatory measures that ensure high standards of quality and promote ethical practices among pharmaceutical companies.¹²² Examples of member associations include the Pharmaceutical Research and Manufacturers of America in the USA, the Association of the British Pharmaceutical Industry in the UK, the Singapore

Association of Pharmaceutical Industries, Medicines Australia, and the European Federation of Pharmaceutical Industries and Associations, which represents EU nations.¹²³ These member associations determine regulations based on the IFPMA Codes of Practice. All member associations and companies implement these codes. In particular, the IFPMA regulates companies' interactions with health care professionals, medical institutions, and patient organizations.¹²⁴

Internal policies

International pharmaceutical companies have a set of global internal policies that govern their communications with stakeholders worldwide.¹²⁵⁻¹²⁷ These are the first point of reference because employees are expected to adhere to company policies by following industry-, national-, or international-level regulations.^{128,129} These policies often incorporate higher-level regulations and are, thus, more stringent and detailed.¹¹⁵

Additional control systems for medical affairs

The goal of the medical affairs department is to communicate medical data about products with a high level of integrity, so

they are seen by key stakeholders and the general public as a credible and transparent source of medical information.⁶ This could contradict with the promotion-minded approach of marketing colleagues and needs to be managed effectively because both departments have to work together to ethically and informatively educate physicians about their products.¹¹³ In order to achieve this balance, there has to be a clear separation between medical affairs and commercial functions. Approaches such as having separate reporting structures (ie, medical affairs does not report to commercial) and separating the funding of both departments (ie, medical affairs does not rely on commercial sales for their funding) help to ensure that medical affairs remains independent of commercial pressures and is able to focus on working in an ethical and patient-centric manner.¹³⁰ Medical affairs physicians needed to be commercially independent and be able to function without consideration of commercial objectives.

Continuous professional development for medical affairs professionals

The rapidly changing pharmaceutical industry and the health care sector landscape have increased the importance of medical affairs in pharmaceutical companies. This is reflected by the growing proportion of clinicians entering the pharmaceutical industry,¹³¹ with some companies viewing a specialty medical qualification, a PhD, and/or a business-related qualification such as an MBA as helpful additions to a primary medical qualification.¹³¹ This shift calls for medical affairs personnel to undertake their own continuing education to address knowledge or experience gaps to be able to respond effectively and efficiently to the dynamic nature of the industry. While traditional roles such as MSL interaction with stakeholders and publishing scientific material remain important, several evolving responsibilities (such as pharmacoeconomic considerations, communicating with patient associations, and planning for prelaunch obligations) are gaining increasing prominence. Pharmaceutical industry physicians need to be trained in these important aspects of medical affairs, necessitating participation in robust training to prepare for the dynamic nature of their roles. To meet these challenges, many educational programs are in place for pharmaceutical physicians to enhance career progression and prepare for their increasingly complex roles.^{131–133}

One example is the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP)-Kings College Medical Affairs in Medicines Development Certification Program. This year-long

e-learning program was designed by the IFAPP academy in collaboration with industry, professional association, and academic personnel.^{134,135} The aim of the program is to enhance the skills of medical affairs professionals who have at least a year of experience working in their specific function.^{135,136} The Duke-National University of Singapore (NUS) Medical School in Singapore also offers the Joint Alliance Duke-NUS Education (JADE).¹³³ JADE provides a similar e-learning platform to the IFAPP-Kings College Program and is designed to develop medical affairs professionals to suit the evolving needs of their roles.¹³³ This program caters not only to medical affairs professionals but also to health care professionals who are keen to develop a career in medical affairs.¹³³

Although the modular, e-learning model is popular in today's internet age, many medical affairs professionals have limited time to pursue such ventures. Thus, programs offered in the form of short, traditional lecture models do have a role. The Center for Executive Leadership for the Pharmaceutical Industry (C.E.L.forpharma) offers short workshops (1–2 days) with expert speakers and educators.¹³² These programs are specifically for the betterment of medical affairs executives, enable personnel to develop new skills, and stay relevant in a changing environment.¹³²

The Pharmaceutical Medicine Specialty Training in the UK offers a more intensive, selective, and rigorous program. This 4-year training program for pharmaceutical physicians is overseen by the Joint Royal Colleges of Physicians Training Board and offers physicians the opportunity to be listed on the General Medical Council's specialist register for pharmaceutical medicine. This program is specifically offered to upgrade licensed medical doctors with positions within the pharmaceutical industry and is more selective than most other programs on offer.¹³¹

Conclusion

Pharmaceutical companies are allocating more resources to the medical affairs function in order to increase new product development and postlaunch execution activities. This is vital in addressing the need to improve R&D productivity within the scrutiny of ever-increasing HTA standards and the tightening of laws and regulations globally. The traditional role of pharmaceutical physicians in the medical affairs function is evolving well beyond the usual support to internal commercial functions and collaboration with KOLs. In the future, the focus of medical affairs may be on generating and communicating medical evidence, leading medical education, and empowering patient associations. Increasing

responsibility for various facets of the industry, such as CME, public health initiatives, and HEOR, make the field of medical affairs a dynamic venture. A career in medical affairs may offer the right niche, progression, and fulfillment to many health professionals, including physicians, by enabling them to challenge global unmet needs in medical and health communication and education in this exciting and expanding field, with the ultimate goal of improving patient care and outcomes.

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Author contributions

All authors were involved in conception, design, analysis, and interpretation of data. All authors were also involved in the preparation of the manuscript, revising it for scientific content, final approval before its submission for publication, gave final approval of the manuscript version to be published, and agree to be accountable for all aspects of the work.

Disclosure

Dr Sajita Setia was an employee of Pfizer Pte Ltd at the time of submission of this manuscript and Dr Kannan Subramaniam is an employee of Pfizer Australia. Mr Prasad S Nair and Ms Elma Ching underwent indirect patient care pharmacy training for 3 months at Pfizer, Singapore. The authors report no other conflicts of interest in this work.

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