Print ISSN: 2319-2003 | Online ISSN: 2279-0780

IJBCP International Journal of Basic & Clinical Pharmacology

DOI: http://dx.doi.org/10.18203/2319-2003.ijbcp20164153

Educational Forum

The emerging role of MD Pharmacology postgraduate in pharmaceutical industry

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Received: 27 January 2016
Revised: 28 September 2016
Accepted: 03 October 2016

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ABSTRACT

Patient-benefit is a shared goal of the pharmaceutical company and the treating doctor. At the same time, the pharmaceutical company- in order to recur its R and D costs has to balance patient centricity with making profits. Consequently, the commercial benefits from prescription of a product and education about optimal use of product both become the responsibilities of same organization. This often leads to allegations of bias by the regulators. We are in an era where regulatory bodies closely monitor the promotional method of drugs, the validity of information being communicated, to what audience the information is shared, who all can share the information from the company's end. Thus the pharmaceutical companies split the two functions and allocated a set of medical professionals for handling the scientific interactions. The larger objective of the pharmaceutical company is optimum product utilization via educating the potential prescribers about efficacy and safety data of the product, and not just generates sales. Medical affairs serves as a link of pharmaceutical company who intends to develop a peer-to-peer relationship with HCP, through-out the life-cycle of product and provides a scientific interface of the prescribing clinicians and the pharmaceutical industry. Medical affairs role encompasses scientific, informational, communications and interpersonal activities. This article emphasizes on the evolving role of medical affairs in the pharmaceutical industry so as to provide a clear idea to the pharmacology post graduates.

Keywords: Career, Medical affairs, Pharmacology, Pharmaceutical industry, Regulatory

INTRODUCTION

Patient-benefit is a shared goal of the pharmaceutical company and the treating doctor. At the same time, the pharmaceutical company- in order to recur its R and D costs has to balance patient centricity with making profits.

Consequently, the commercial benefits from prescription of a product and education about optimal use of product both become the responsibilities of same organization. This often leads to allegations of bias by the regulators.

The pharmaceutical industry is under challenging circumstances. The scrutiny over commercial practices are increasing, the reimbursement clauses, the drug-pricing regulations, the regulatory obligations of clinicians while taking favours from company, is all resulting in critical situation.

We are in an era where regulatory bodies closely monitor the promotional method of drugs, the validity of information being communicated, to what audience the information is shared, who all can share the information from the company's end.

Thus the pharmaceutical companies split the two functions and allocated a set of medical professionals for handling the scientific interactions. The larger objective of the pharmaceutical company is optimum product utilization via educating the potential prescribers about efficacy and safety data of the product, and not just generates sales.[1-3]

The evolving importance of medical affairs in pharmaceuticals

Medical affairs serves as a link of pharmaceutical company who intends to develop a peer-to-peer relationship with HCP, through-out the life-cycle of product and provides a scientific interface of the prescribing clinicians and the pharmaceutical industry.

Medical affairs role encompasses scientific, informational, communications and interpersonal activities. A typical day in medical advisors routine is varied starting, with answering some of the product related queries, followed by meetings with marketing, then reviewing the data and simplifying it for sales field force, and then attending a teleconference for global collaboration of projects. The role demands working in teams. It is required to envision medical information from entrepreneurial angle, in order to understand the wants and needs of colleagues on the marketing side.[4]

The process of straitening of the regulatory requirements mandated a clear demarcation of medical and commercial activities of pharmaceutical companies. Pharmaceutical physician have a tough job of playing the balancing act. [5]

Table 1: Skill set requirement of medical affairs professional.

Scientific understanding of drugs, biological, biosimilars, bioidenticals, medical devices.
Medical writing skills
Pharmacovigilance
ICH GCP, clinical research site management, clinical trial designing, critical analysis and interpretation
Disease epidemiology and pipeline
Regulation governing Pharma and HCP practices worldwide
Statistics
Familiarity with digital tools – Microsoft PowerPoint, excel,
Cross-funtional partnership, team-management, team-work, negotiation skills, influence
Literature search
Time management skills, work prioritisation
Written and verbal communication skills, soft skills,
Regulatory
People management
Intellectual property rights understanding to deal with issues like infringement, patent searching, patent filing, royalties and damage exemptions for clinical trials.
Familiarity with basic management concepts – strategy, economics, finance, marketing, operations
Pharmacoethics – to deal with ethical issues related to the development, promotion, sales, prescription, and use of pharmaceuticals [6]
Pharmacoeconomics – Health Economic Outcome Research (HEOR), market identification and research, supporting promotional activities, contributing to pricing decisions, crucial go or no go decisions in drug development
Ability to provide and receive constructive feedback

The medical expertise requirements for companies differ in terms of academic qualification. Most companies hire an MD in pharmacology. An additional experience of clinical trials, MBA, or clinical experience may serve as an added advantage but is not mandatory.

Table 2: Role of medical affairs through various phases of drug life cycle.[9]

Phase of drug life cycle	Value provided by medical affairs function
R and D	Designing clinical trials Strategizing on end point so as to optimize efficacy Build wealth of evidence by publishing data
Regulatory approval	Medical support to regulatory affairs department Medial presentations focusing on safety and efficacy data to regulatory authorities Provide the required medical rationale
Pre-launch	Educational activities disseminating the efficacy and safety data Conducting advisory boards, expert panel meets, Medical positioning – Focus on inclusion of drug in guidelines and recommendations based on evidence
Marketing	Training of internal stakeholders – sales, marketing Promotional material input and review Drug related and therapy area related query resolution Participation in HCP meetings Designing educational scientific initiatives around the drug/therapy area Provide competitive intelligence To ensure that scientific developments in the field are identified and passed on to internal and external stakeholders Execution of post marketing surveillance study Partnering with HCPs to generate real world evidence Pharmacovigilance Drug administration /any other drug related assistance Building KOL advocacy groups Liaise with multiple stakeholders involved in end-user utilization of drug

Journey from MD Pharmacology to medical affairs

The professional opportunities for MD pharmacologists are diverse. Most commonly pharmacologists opt for either the academic posts in a medical college, pharmacovigilance, medical writing, clinical research, or join the medical affairs division of a pharmaceutical industry. While the former is an extension of the teaching and experimentation components of post-graduate curriculum, joining the medical affairs in pharmaceutical

organization involves a transition from healthcare functions to corporate responsibities.[7] Having good knowledge of the job profiles of individual roles enable the post graduate to make well informed career decision. This blog focuses on the latter career option and gives a broad stroke overview of the core competency requirement of a pharmaceutical post graduate for having a successful career in medical affairs of pharmaceutical industry.

Currently the medical advisors have to have on-the-job learning, where on-going training happens under various requirements. However a broad map of the some skill sets that provide you an edge can guide the post graduate to dedicate some time to sharpen the skills.

Pharmacologists in the industry play a major role in selecting the scientific content of drug promotional materials. A student should be well versed about the ethical, legal and regulatory guidelines regarding drug advertisement, promotions and marketing.

Current role of medical affairs

The journey from drug development to drug commercialization involves disseminating the product related information and educating the clinicians and raising their scientific awareness so that it can be prescribed to the right set of potential beneficiaries (patients) of the drug. [8]

Evolution in role of medical affairs

There is continued expansion in how much value medical affairs can offer to a pharmaceutical industry.

Table 3: Areas of evolution in work environment of pharmaceutical physician.

Implementation of strict regulations on HCP-pharma interaction
Increase in variety of stakeholders eg. Government bodies, patient advocacy groups
Expansion in digital media
Emergence of newer technological platforms
Evolving code of ethics applicable to HCPs, pharmaceuticals, clinical research
Narrowing R and D pipeline
Niche therapy areas
Need of 'real world' comparative efficacy safety data

The increase in the opportunities is a result of expanding array of stakeholders with whom medical affairs professional interacts. More-so with the existing stakeholders the demand for efficacy and safety data challenges are on the surge which makes the role of peer-to-peer interaction crucial.

Table 4: Stakeholders for a pharmaceutical physician.

Internal stakeholders	External stakeholders
Marketing	Health care practitioners
Sales	Patients
Regulatory	Patient groups
Clinical research	General public
Business development	Regulatory authorities
Strategic alignment	External agencies
Training	Medical societies
Global and regional counterparts	Government bodies
Market research	Insurance oranisations
Compliance	External agencies
Legal	Clinical research site

Across therapeutic areas, the focus is increasing on gaining clinical insights about the drug from 'real-world' data, conducting 'head-to-head' trials for better comparative conclusions, health economic outcome research surveys, and more advanced clinical interpretation of the clinical trials.

Table 5: Current responsibilities of medical affairs viz-a-viz evolving roles for future preparedness.[10]

Current role of medical affairs	Evolving roles for future preparedness
Medical scrutiny of drug promotional practices	Proactive medical input for shaping product strategy
Medical information	Medical value preposition through evidence (EBM)
Advisory boards	KOL advocacy development through peer-to-peer knowledge sharing
Medical review	Medical governance with solution providing
Sales force training	Exploring new platforms for scientific learning and recall
Key customer interaction	e-education and use of modern digital channels
Reactive query addressal	Risk assessment and mitigation strategy
Support to regulatory and clinical research activities	Strategic inputs to design and conduct of study, to optimize drug lifecycle management
Checking approach as per local norms	Balancing approach through cross-functional, local as well as global interaction
Pharmacovigilance – reporting of adverse events	Partnering with HCP in management of adverse drug reaction and providing medical support for future prevention/better management of such events
Medical strategy	Suggest synergies with other products, provide go-no go decisions for new drugs, aligning companies strategies to leading developments in the field globally

Measured indicators of medical personnel's performance in a company

In any organization, employee's contributions are quantified in numbers and medical team is no different. The commercial growth of the drug as a brand does not feature in job responsibility of the medical advisor.

The efforts of a medical affairs team is quantified and features as measurable variables on basis of which the employees performance is assessed at the mid and end of year and also to judge areas of improvement.

Table 6: A general template of key performance indicators for medical affairs professional.

Activities
Number of medical initiatives planned and executed Number of visits to new or established experts Number of and timely resolution of consumer queries Number of conferences planned and supported Number of publications supported Number of training sessions conducted for field force and qualitative feedback received Number of innovative suggestions provided
Soft end points
Positive remarks from the marketing department Positive remarks from the sales force reps Positive remarks from external experts Positive remarks from other stakeholders Encouraging conclusions in publications Incorporation of new substances in guidelines

Patient interaction – a thin line between educating and drug promotion

With the rise of consumerism in healthcare, and remarkable economic pressures, the patient is an integral decision maker in therapy decisions. The new-age patients prefer to go well prepared to a doctor's consultation, and the internet serves as a vast resource for recent medical updates. Most pharmaceutical companies have a web based domain where patient can access medical information about drug in simple language.[11]

Needless to say the content of the information is solely the responsibility of medical affairs. The department of pharmaceuticals, regulatory body governing the practices of pharmaceuticals, mandates that the interaction with patients from a pharmaceutical company can be done only by a medical professional.

With the use of social media and innovative data collection, patients are also a source of valuable insight generation for the pharmaceutical industry. The means and ways are always run through medical scrutiny.

Educating the Health care professionals and KOLs

Post Sunshine Act, the financial disclosures are under public scrutiny and renounced KOLs who used to be constant source of clinical sights for pharmaceutical industry , now are being cautious with interacting with and participating in advisory boards and educational meetings, as they do not want to be perceived as the paid spokespersons of the pharmaceutical industry. This complex situation demands that drug related messages are conveyed and discussed with them in an unbiased scientific manner, which is the purview of a medical professional.

Common enquiries/queries encountered by medical affairs professional

Product/therapy area related queries consume average 40-50% of a medical advisors time. The time fraction may vary depending upon how new the product is and extent of scientific involvement as a nature of the pharmaceutical company.

The competencies required to fulfil this role in accomplished manner requires extensive literature search and command on therapy area.

The role demands resolution of product/therapy-area related enquiries which may fall into any of the below categories:

Results of latest trials

- Interpretation and clinical application of clinical trial results
- Comparative analysis of the products data vis-à-vis competitors data
- An understanding of global practitioner opinion about product, specially from regulated countries
- Safety profile in the 'real-world setting' - from clinician-interaction based or post-marketing surveillance based
- Possibility of new data generation from the existing clinical practices for authorship and academic stature elevation
- Efficacy profile of drug in specific organ compromise setting – based on pharmacokinetic and pharmacodynamics.

Assessment of KOL query addressal

Key performance indicators capture the KOL query addressal in qualitative and quantitative parameters. The qualitative parameters include completeness of the answer, validation from indexed publication, clinical application and lastly, feedback generation. Quantitative parameters include time required to query resolution and number of queries resolved annually. Frequency of future

product related enquiries reflects on degree of engagement of clinician, thereby enhancing his knowledge and advocacy of the drug.

The responses are appreciated maximum by a clinician when they are evidence based, duly referenced, organized, to-the-point and includes a summary. One may make an attempt to suggest the clinical implication of the compiled database; however one can leave the final call to the discretion of the clinician.

Clinical research – an excellent platform to define the optimal use of a drug

The medical affairs team is in the capacity of contributing to clinical research operations department at the strategic level – clinical trial protocol designing, with special focus on end points, case report form defining, analysis intervals decision, publication plan, identifying platforms for disseminating data at time points, site feasibility analysis, investigator selection, medical monitoring, adverse drug reporting and finally submission to regulatory authorities and publication.

When the initiatives for study come from health care professionals, medical advisors are one-point contact for the same, and can provide forementioned scientific help and assistance in designing and executing study around the research question with optimal utilization of resource. Such studies can be for approved indication for the drug in respective country, or for other indication, which only the medical team can support from the company's end. [12]

Develop strategic vision

The transition from pharmacology post graduate to medical affairs professional requires learning agility. One is required to work beyond his immediate work experience – gain basic commercial understanding, planning the product lifecycle and learning the knack of interpreting the clinical data for the commercial colleagues. In the process, the learning curve evolves and one gains a strategic vision for the product, the business unit and for the organization, at large. One is required to be open to learning, by undertaking regional and global projects, and by making cross functional shifts and gaining experience of collateral functions like regulatory affairs, commercial and RandD. Some pharmaceutical companies include regular field based interaction in 'Key Performance Indicators (KPIs)' of medical affairs. This serves as an excellent opportunity for gaining real world insights and taking clinically relevant inputs for shaping the strategy for the company. Medical affairs are in an excellent position to provide the most relevant strategic insights to the company. [13]

Importance of soft-skills

Communication is equally important as much as knowledge. However valid your medical information is, if your way of communication with internal/external stakeholders is not adequate, it will fall on deaf ears. An MSL recruitment firm conducted an analysis and concluded that 83% of the medical professionals were rejected on grounds of 'poor communication skills' by recruiters.[14]

The structure and hierarchy

While there is some variation in segmentation and structure, most pharmaceutical companies have two kinds of scientific teams: research / development and medical affairs. While R and D defines the scientific direction and early stage development, medical affairs provides scientific support for late stage development and post market support for drugs and devices. In small companies, the same team may be responsible for both kinds of activities.

CONCLUSION

Medical Affairs is the essential link between HCP and the pharmaceutical industry and this interaction is based purely on scientific evidence. Another recent addition to the therapy decision makers is the; patient' whose benefit is at the centre of interest of both pharmaceutical industry and the patients. Medical affairs personnel needs to demonstrate risk-appetite as well as agility to extend and learn additional skill sets which are the need of the hour, with the patient sentiments, critical economic situation, emerging complexity of data around the product and increase in variety of stakeholders gaining access to medical data, the role of medical affairs is leading in a very important direction. Medical affairs need to make complementary changes in their skill sets and attitudes to emerge as partners to array of stakeholders. With this changing landscape where the bar for medical due diligence is high; we can expect the pharmaceutical industries to have a medical affairs -led future. Medical affairs as a function has become more relevant than before, although more complex. We as pharmaceutical physicians need to evolve accordingly to play this crucial role.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: Not required

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Cite this article as: Chaudhari PB. The emerging role of MD Pharmacology postgraduate in pharmaceutical industry. Int J Basic Clin Pharmacol 2016;5:2706-11.