Review Article

BRIDGING THE GAP BETWEEN R & D AND COMMERCIALIZATION IN PHARMACEUTICAL INDUSTRY: ROLE OF MEDICAL AFFAIRS AND MEDICAL COMMUNICATIONS

Sonal Jain

Senior Medical Writer, Prabhadevi, Mumbai-400025.

ABSTRACT

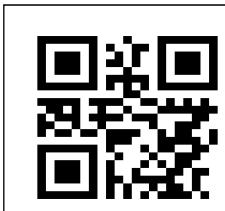
The launch of a new drug into the market requires a unique and complex process initiating from development (R&D) to its commercialization (marketing authorization and selling of these products). Due to increased burden by regulatory authorities, the medical affairs evolved as separate medical organization to bifurcate medical and commercial functions. It is closely associated with development but works mainly on post-approval activities by providing both the scientific and clinical expertise. The core functional areas of medical affairs (MA) include: **medical communications/publications, medical science liaisons (MSLs) and medical information.** In the recent years ethical and evidence-based medical communications has attained increasing importance in emerging pharmaceutical markets. A successful product launch is based on both promotional (medico-marketing) and non-promotional (medical information services, publications) material to support the product and to report clinical trials in peer-reviewed international journals. Local clinical or observational studies and medical surveys can provide sufficient information about the product. Besides, a number of medical communication like product monographs, brochures, slide kits, leave behind literature (LBL), continuous medical education (CME) slides, training modules, key opinion leader documents (promotional inputs) and conference posters, abstracts, and journal articles (research based inputs)are other ways to aid in an effective product launch. In the last 10 years medical writers in India have developed the capability to meet this challenge through their training and work experience making India 'hub' for medical communications services.

KEYWORDS: Key opinion leaders, Medical affairs, Medical communications, Medical science liaisons, Medical writing.

INTRODUCTION

The pharmaceutical manufacturing model has two main splits: a development organization responsible for new product development and getting FDA approval for drug products and a commercial organization responsible for marketing of those products. However, there occurs an additional group, called medical affairs (MA) which act as a bridge between development and commercialization [1].

Healthcare providers (HCPs) have the ability to provide appropriate therapies to sick owing to their medical knowledge. Now-a-days, due to multifaceted therapeutic options there is a necessity of continuous update and expansion of the knowledge base of the HCPs so that they can provide the best treatments possible. MA professionals within the pharmaceutical industry are capable to bridge this information gap because of their scientific and medical expertise background. They can establish themselves with their "physician base" and can act as reliable source for scientifically sound medical communications. In the past 10 years there is an emerging role for the MA as a core competency within the pharmaceutical industry [2]. MA plays a multifunctional role in the pharmaceutical industry like involvement in strategic medical communications planning and implementation across the product lifecycle (lifecycle management post initial indication approval). As the role of MA has increased, there is a need and responsibility to update the medical fraternity for novel treatment approaches and advances from the clinical research stage for an indication. The activities like disease state awareness, publication planning, and product launch communication collaterals, and post-launch phase IV planning frequently require specific medical expertise which can be provided by MA team. Initially the responsibility for strategic planning was exclusively assigned to commercial teams but today there is a task shift in the prelaunch phase to a function started by the MA team. The MA professionals provide their valuable inputs with strict adherence to accurate scientific interpretation of data specific for product or disease state or both. MA teams may provide their contribution to



DOI: 10.5455/ijcbr.2017.33.12

eISSN: 2395-0471
pISSN: 2521-0394

Correspondence: Sonal Jain, Senior Medical Writer, Prabhadevi, Mumbai-400025.
Address: 19/34-A, Alok Nagar, Agra, Uttar Pradesh-282010. E-mail: sonal.jn1@gmail.com.

external thought leaders (key opinion leaders (KOL) and clinicians by providing an in-depth knowledge of specific disease states and the parallel role of pharmaceuticals. In this way MA can aid HCPs remain updated and translate cutting-edge science to fulfil unmet clinical needs and eventually provide better patient care [2].

Definition of MA according to the Accreditation Council for Medical Affairs (ACMA)

"…provides medical support for development stage as well as commercialized products including post-marketing studies (PMS), safety, and surveillance, and product support. The main responsibility for medical or drug based information, is to provide a comprehensive, product compliant, and disease state information to HCPs and consumers" [3].

Key Proficiencies of Medical Affairs: MA has developed into a discrete medical organization that is associated with development organizations but mainly works on post-approval activities by providing support through its scientific and clinical expertise. Some of the important functions of MA are illustrated in Figure 1 [1].

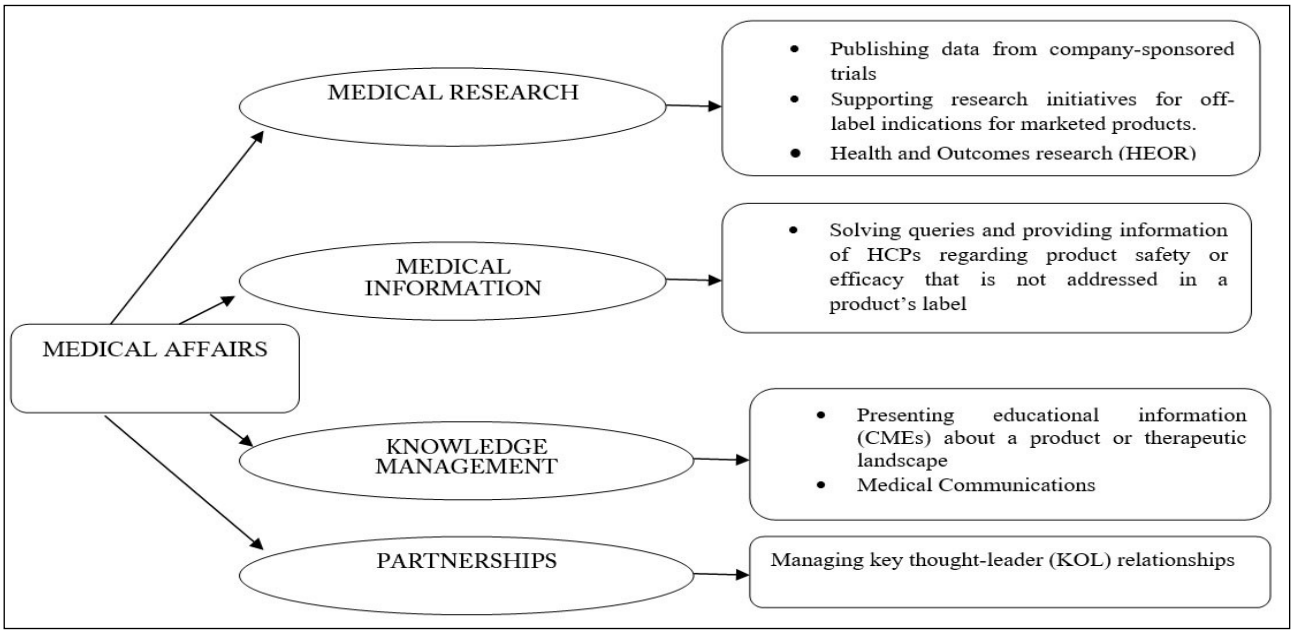


Figure 1. Medical Affairs Functions [1]

A Medical Affairs Portfolio [4]

Medical field teams: including medical science liaisons (MSLs), responsible for relationship management and communication of product information with HCPs, regulators and institutional leaders.

Post-launch clinical trials: involved in planning and conducting of phase IIIb/IV company-sponsored interventional and observational studies and support of investigator-initiated studies (IIS).

Medical information: including the medical staff in centralized call centers to disseminate medical information in response to drug-related queries.

Medical communications: including the writing and support for peer-reviewed journal publications and other medical and scientific inputs.

Medical education: Including the planning and funding support for continuing medical education (CMEs) for HCPs and the sales force training.

Medical strategic activities: The development of the medical-brand strategy for each product by medical directors and to develop the product's cross-functional life-cycle strategy in alliance with development, commercial, regulatory and other departments.

Health economics and outcomes-research (HEOR) activities: including research and communications related to product value like product value dossiers, patient-related outcomes, health technology assessments.

Recognizing the capabilities of MA and the correct time to constitute its respective functional teams is vital for preparing for and executing a successful drug product launch [1-5].

Medical communications/publications [1]

It is a MA group primarily responsible for all clinical research publications such as abstracts, posters, and manuscripts. These types of medical communication input are important for product commercialization. Besides, medical communications is also involved in strategizing the plan that incorporates the timing of clinical trial data with the announcement of main data points at scientific meetings. This plan indicates the timing of abstract submissions and manuscript publications in the years leading up to and following a launch. The publication of interim data (like for either early stage or pivotal trials, which might occur months to years before drug approval (*T* – 24 to *T* – 12; or 24 to 12 months before launch) is a part of this publication planning. The correct interpretation of clinical trial data and presenting it in clear and concise form for the organization as a whole is also one of the primary role of

medical communications group. Besides, the publication of data post-approval of drug is more critical and medical communications propose publication plan to maximize the amount of exposure, and recognition for a new drug product [1].

Medical Science Liaisons (MSLs) [1]

MSLs form field based teams of MA who nurture relationships with both external and internal stakeholders by their scientific and clinical expertise. For external stakeholders, an MSL team functions as the "medical" face of the company in a very distinctive way from sales force. Primarily, it is responsible for maintaining strong relationships with both community and academic physicians and acts an effective channel for a flow of information both to HCPs and into a company itself. For internal stakeholders, an MSL team can use its strong relationships with other major corporate departments to help external stakeholders understand internal infrastructure of the company.

An MSL team is ideally constituted sometime before 24 to 12 months of product launch. This time period helps in gaining in-depth understanding of the disease state and therapeutic landscape, learning all drug-related aspects, and establishing relationships with key external stakeholders (KOLs, important organizations, and payers). The success of the product depends on all these in place at the time of product launch.

Medical information [1]

A medical information group provides answers to all queries related to commercial drug products like safety, efficacy, posology, and administration. This group of MA generally is first recipients of the queries from patients, HCPs, and other interested parties during the product launch. They prepare commercial product launch materials and/or sales training. The group is typically framed before 24-12 months before product launch.

Medical affairs Activities [4,5]

MA is a single point of contact across departments within the organization and outside stakeholders also. As discussed above this organization is important for knowledge collection and dissemination (Figure 2).

Data generation, maintenance and presentation are important for smooth functioning of MA

Data generation and maintenance [5]:

- Finding and outlining of scientific peers

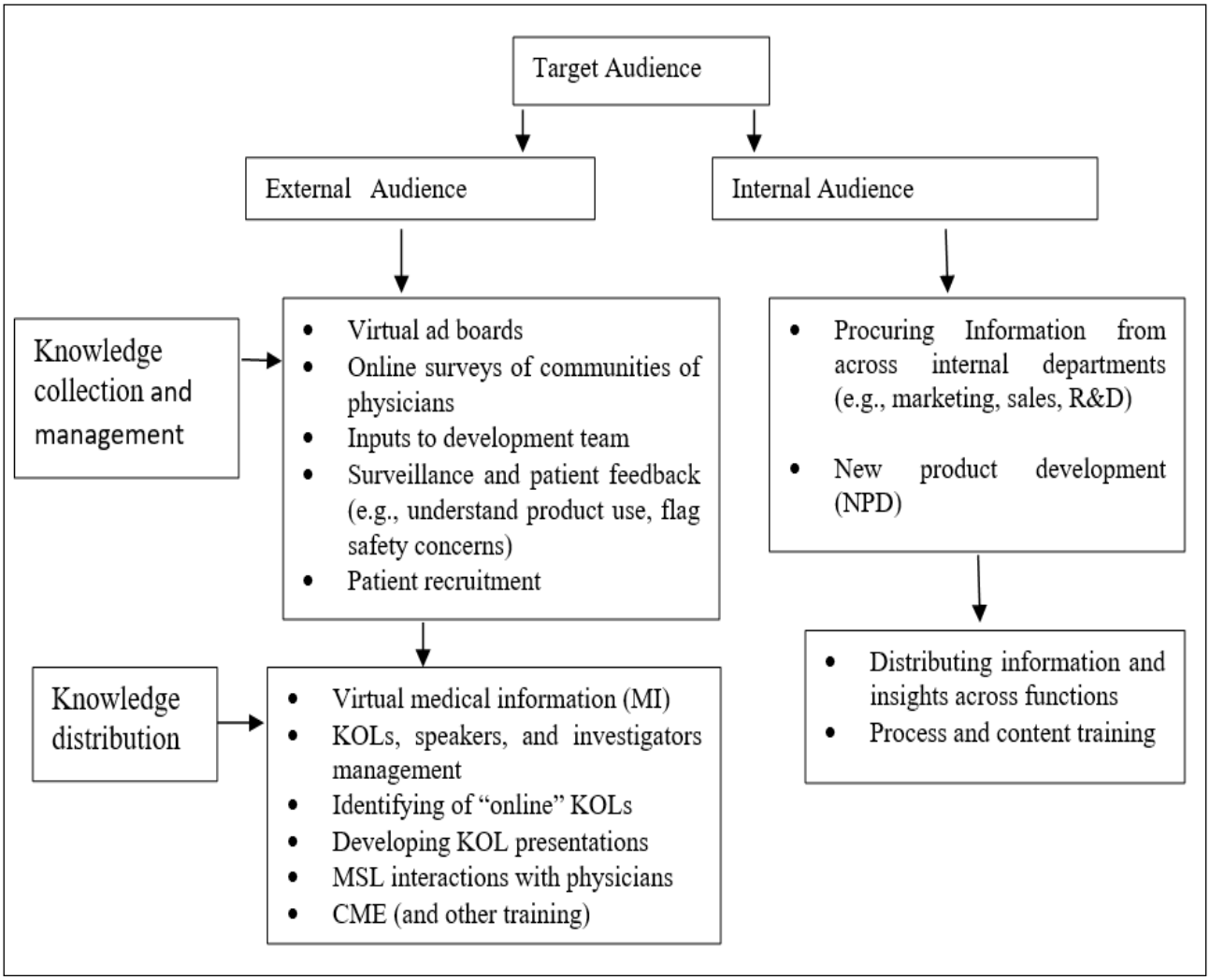


Figure 2. Types of activities by MA for external and internal stakeholders

- Deciding the best possible role is for each of the scientific peers
- Knowledge of the patient flow
- An effective risk management plan for characterizing risks associated with the product
- Clinical and observational studies, drug utilization studies, epidemiological data and HEOR.

Data presentation [5]*:* Developing a market access plan based on clinical evidence of efficacy and safety of the product together with the epidemiological data to explore the unmet medical need.

Essential Driving Forces for Medical Affairs [6]

As the experts speak MA provide medical and scientific advice throughout the drug's life cycle by developing and communicating data that address patients' unmet need and progress in the treatment of the disease. they categorized driving forces for MA in nine broad heads:

1. **Joint Leadership:** Partnerships with internal and external stakeholders.
2. **Customer/ patient Focus:** Strategic develop of solutions for customer requirements
3. **Strategic Visualization:** Application of medical knowledge to a "broad landscape" in strategic planning and decision making
4. **Dexterity:** Decisive, flexible, dynamic approach and entrepreneurial attitude
5. **Business Insight:** Instituting a holistic understanding to bridge a gap between development and commercial phases of drug.
6. **Innovation:** A futuristic projection of environmental needs and independent thinking
7. **Assurance:** Passionate and committed
8. **Scientific Expertise:** A value addition to maintain the scientific integrity of the products by application of medical knowledge.
9. **Compliance Insight:** Explore opportunities and restrictions within the environment by application of compliance expertise.

Emerging markets unmet requirements: Challenges for pharmaceutical sector in emerging markets [7].

The primary challenges for pharma sector for emerging markets are:

- Demographic variation
- Diversity in culture and language
- Differences in local government health policies and regulatory norms
- Variations in medical infrastructure (healthcare facilities, insurance policies) across different geographical regions
- Scarcity of local staff with up-to-date domain knowledge
- Dearth of knowledge of disease profiles of a particular population

Role of outsourcing industry [8]: An outsourcing industry play a vital role in now-a-days effective business strategy for most of the pharmaceutical industry. The difference in the harmonization and its related complexities lead to useless resourcing, operational incompetencies, cost escalation and delayed time-to-market. Outsourcing medical and scientific content development to a proficient "functional service provider" is the best solution to overcome these problems. An efficient outsourcing partner permits pharmaceutical companies to hold the control in-house for maintaining standardization of content and creative design across globe catering to their local affiliates with a country. Besides, attending to queries from local health care provider (HCPs) is also provided by outsourcing industry. This can be done with a team of skilled resources who can attain knowledge on scientific aspects of the sponsor's product portfolio by conducting comprehensive literature search, in-depth understanding of the product and the therapeutic area and comparator treatments and then can create content pertaining to sponsor's portfolio.

Medical writing in pharmaceutical marketing: Medical writing is an integral domain for the pharmaceutical industry. According to the *CenterWatch* estimates the medical writing market has doubled in size in the last five years from 2003 to 2008. Furthermore, medical writing has been reported as fourth most often outsourced service [9]. A competent medical writer should possess skills like correct and accurate interpretation of scientific data, target audience identification, flawless English language skills (editing/proofreading), strong communication skills across different stakeholders in the project (pre-clinical scientists, clinical scientists, marketing department, regulatory affairs, biostatistics, freelancers and consultants and senior management) and ability to work in pressurized conditions to meet deadlines. A medical writer should facilitate rational discussion between different groups to prevent project delays. If there is a key deadline to be kept it may be necessary to raise issues into the open to get a resolution [10-11].

The gamut of medical writing [11]

Medical writing involves writing different types of documents for different target audiences ranging from simple newsletters to complex regulatory submissions (Figure 3).

Common challenges associated with the medical writing : The dearth of aptitude in business and technical writing skills, high attrition rate, quality issues and scarcity of training programs are the main challenges faced by medical writers. These difficulties can be overcome by effective management strategies adopted by an organization. The primary goal of any employer should be to provide effective training, maintaining, developing and retaining its medical writers. An effective recruitment strategy highlighting proper description of job profile and seeking exposure to global experience, motivation and regular appraisals to keep the morale high and effective training programs are some of the prime factors for smooth functioning of a medical writing department [12, 13].

India as a "core" for outsourcing of medical writing [7,13,14]

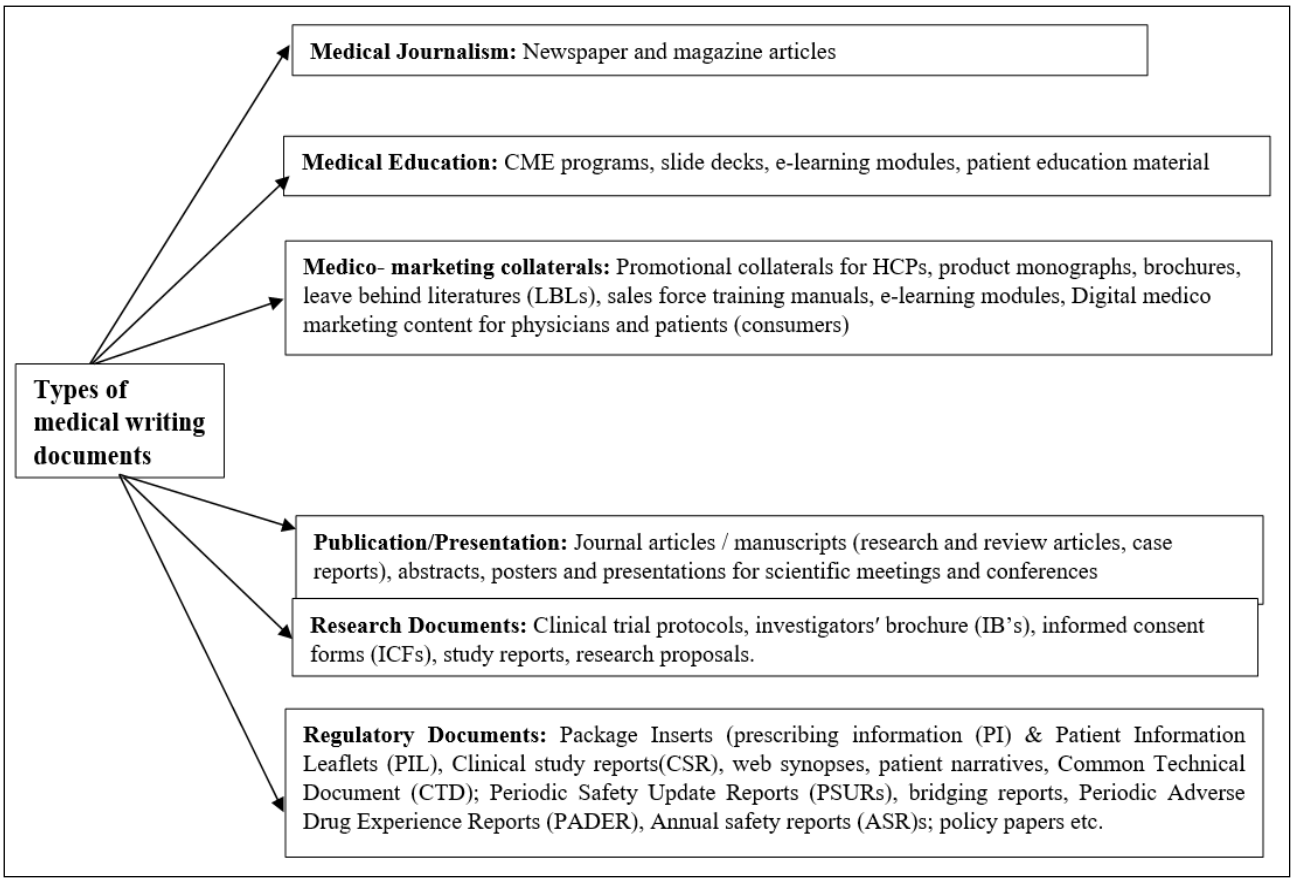


Figure 3. Type of medical writing documents for different stakeholders

During the first few years of development of medical writing, Indian outsourcing companies were restricted by inadequate experienced staff and standardized training programs. However, during the last decade Indian companies have increased their benchmark and are considered as a preferred terminus for all categories of medical writing and related activities (like biostatistics and pharmacovigilance). The complexity, quality, and variety of medical writing in India have constantly increased. The writers now are competent enough to develop considerable numbers of regulatory, clinical, and scientific trial related reports and post-marketing documents both for innovator and generic drugs, and for all the emerged markets(US, Europe and Japan). Besides, Indian medical writers have also taken a step in associating themselves in CME, product labeling, pharmaceutical research analytics, and HEOR. The harmonization with the local populations and regulatory norms is important for developing both promotional and non-promotional medical communications in emerging markets. This requires gathering of epidemiological data for different diseases and identifying whether the needs of the local population differ from the established markets, collecting information about local regulatory norms and HEOR, and finding innovative but cost effective ways to reach HCPs and patients. This is done by medical writers in India as they understand the needs of non native English-speaking countries.

Chief medical writing associations [14]

1. The American Medical Writers Association (AMWA)
2. The European Medical Writers Association (EMWA
3. The All India Medical Writer's Association (AIMWA)
4. The Drug Information Association India Medical Writing Community

CONCLUSION

An efficient MA function depends on capability of organization to hire and nurture the right expertise and skills. An organization should recruit the talent with a vision to its wide range strategic priorities including its focus, structure at business unit (BU) and country level, formal training programs, and performance management systems. An excel in MA requires wide range of skills including medical science liaisons and medical writers to bridge the gap between developmental phase of drug to its commercialization. The best way is to choose a strengths-based leadership strategy to approach for unique talents and encouraging these capabilities among individuals and teams.

CONFLICT OF INTEREST

Nil

FUNDING

Nil

REFERENCES

1. Crowley-Nowick P and Smith J. The Role of Medical Affairs in Moving from R&D to Commercialization. *Bio Process International*. 2013. 11(4):12-16. Available at URL:www.bioprocessintl.com (Accessed on April 2, 2017).
2. Joyce D. Medical Affairs: The Catalyst for Effective Medical Communications. *PharmaVOICE - April 2013.*Available at URL: http://www.pharmavoice.com/article/medical-affairs/ (Accessed on April 2, 2017) .
3. Accreditation Council for Medical Affairs (ACMA). 2016. Available at URL:https://www.medicalaffairsspecialist.org/(Accessed on April 2, 2017).
4. Evers M, Fleming E, Ghatak A,Hartmann J, Nathoo A,andPiervincenzi R. Pharma Medical Affairs 2020 and beyond. 2012. McKinsey & Company. Pp:1-9.Available at URL:file:///C:/Users/LENOVO/Downloads/Pharma_Medical_Affairs_2020.pdf (Accessed on April 2, 2017).
5. Medical Affairs. 2014. pp: 1-19. Available at URL: www.cegedim.com(Accessed on April 2, 2017).
6. The changing face of medical affairs. Trends in Medical affairs. pp: 1-17 Available at URL:http://1.eyeforpharma.com/LP=15649?utm_campaign=4843%2001DEC16%20Content%20Autoresponder&utm_medium=email&utm_source=Eloqua&elqTrackId=7adcc88ba69c4577ae47d66756b1e111&elq=d7ab2c25036c4225aa5ffe001cbafe38&elqaid=23941&elqat=1&elqCampaignId= (Accessed on April 2, 2017).
7. Pal C. India as a hub for ethical and evidence-based medical communications. The European Medical Writers Association. 2013. 22(4):288-291.
8. Medical Communications for Emerging Markets. Safety & Risk Management | Clinical Research & Post Approval Support | Regulatory Affairs & Operations. Available at URL:www.sciformix.com (Accessed on April 2, 2017).
9. Korieth K. The Center Watch Monthly. *The Center-Watch Monthly*. 2008.15(12):8–13.
10. Dawes K and Kauper K. Medical writers in drug development and marketing. *The Journal of the European Medical Writers Association*. 2006. 5(1): 18-19.
11. Sharma S. How to Become a Competent Medical Writer? *Perspect Clin Res*. 2010. 1(1): 33–37.
12. Medical and Scientific Writers in pharmaceutical industry. Available at URL:http://www.jli.edu.in/blog/medical-scientific-writers-in-the-pharmaceutical-industry/(Accessed on May 14, 2017).
13. Sharma S. Development of medical writing in India: Past, present and future. *Perspect Clin Res.* 2017.8:45-50.doi: 10.4103/2229-3485.159934
14. Shirke S.Medical writing on an accelerated path in India. *Perspect Clin Res*. 2015. 6(3): 125–128.

How to Cite this article: Sonal Jain. Bringing the gap between R & D and commercialization in pharmaceutical industry: Role of medical affairs and medical communications. *Int. j. clin. biomed. res.* 2017;3(3): 44-49.