

# India as a hub for ethical and evidence-based medical communications

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## Abstract

Ethical and evidence-based medical communications are gaining increasing importance in emerging pharmaceutical markets, outside of North America and Western Europe. In large pharmaceutical companies resources are limited, and small and mid-sized companies may lack the infrastructure and technical knowhow to provide these services for emerging markets. Required skills and competencies include scientific knowledge, communication skills, analytical skills, and awareness of global as well as regional legal and ethical requirements for pharmaceutical product information. India is already a preferred destination for outsourcing medical writing for regulatory documents and has the potential to become a 'hub' for medical communications services. Skilled medical writers in India can help global pharmaceutical companies to reach out to healthcare professionals and patients in the emerging markets with evidence-based information related to their products.

**Keywords:** Medical communications, Emerging markets, India, Medical information, Medical writers, Evidence-based

## Emerging markets and the pharmaceutical industry

The focus of the pharmaceutical industry is steadily shifting towards the emerging markets of India, China, South East Asia, Latin America, Africa, Russia, Eastern Europe, and the middle-eastern countries.<sup>1</sup> These markets, with their growing economies, large patient pools, increasing middle-class populations, expanding healthcare coverage (governmental and personal) and improving healthcare facilities are increasingly attractive to global pharmaceutical companies. The stagnation of developed markets (North America, Western Europe, and

Japan), due to expiring patents and generic competition, together with the challenges of new drug innovation, is also pushing the pharmaceutical companies (both big and small) towards the emerging economies. It is expected that, despite the lower spending capacity of patients, the emerging markets will contribute 30% of the global spend on medicines by 2016, primarily due to larger patient numbers.<sup>2</sup>

As a result, most innovator companies have established dedicated units for research and development, sales, marketing, and medical affairs in some of the countries that represent emerging markets. Alternatively these companies may have partnerships with contract research organisations (CROs) or other specialist outsourcing organisations within such countries. Pharmaceutical companies are positioning themselves in the emerging markets by marketing their established products, which have gone off-patent, at lower prices or through the acquisition of existing generic brands in these markets. Several established and not-so-old products (new to these markets) are being launched every year. These product launches require medical communications and medical information support. Additionally, clinical and observational studies and medical surveys are being undertaken in many of these countries with the prospect of a large number of journal articles that need to be drafted. Delivery of this new medical communication requires effective compliance standards, operating procedures, guidelines, and work instructions specific to the emerging markets.

## Scope of medico-marketing and medical information services for emerging markets

Ethical and evidence-based communication for promotional (medico-marketing) and non-promotional

(medical information services, publications) material is needed to support the effective and successful launch of established or new products in emerging markets and to report clinical trials in peer-reviewed international journals. To launch new products in new territories, companies may use either a 'group of countries at the same time' or a 'one country at a time' approach. In either case, they need to create materials to inform and educate local healthcare professionals (HCPs) about the key features, benefits, and risks of the products specifically with reference to the local or regional population. This information may be gathered from local clinical or observational studies and medical surveys, and can be communicated through product monographs, brochures, slide kits, leave-behind literature, sales aids, continuous medical education (CME) slides, training modules, key opinion leader documents, conference posters, abstracts, and journal articles.

Following the launch of a product, pharmaceutical companies require a dedicated team of medical information scientists to answer unsolicited inquiries from HCPs through standardised or customised responses to inquiries about labelled or off-label use,<sup>3</sup> efficacy and safety of the product. This requires a strategy-based literature search in peer-reviewed literature databases<sup>4</sup> to identify relevant articles and create customised responses. Appropriate medical communication is based on fit-for-purpose material customised both to the scientific and ethical positioning of the product and to the local requirements.

### Challenges faced by pharmaceutical companies in emerging markets

Major challenges faced by pharmaceutical companies while catering to the emerging markets are:

- Diversity in demography, culture, and language
- Variations in local government health policies and regulations
- Differences in medical infrastructure (healthcare facilities, insurance policies) in different countries
- Paucity of local staff with up-to-date domain knowledge
- Gaps in infrastructure and technological support
- Lack of knowledge of disease profiles of the population

There is also competition between innovators amongst themselves, and between innovators and

generic companies for a share of the market. Pharmaceutical companies with no previous experience in these markets need to understand the business and healthcare requirements of each country. Large pharmaceutical companies have established marketing and sales departments in many emerging countries but these may not be adequately staffed and the existing staff may also be involved in other essential activities. Medium-sized and small companies face additional challenges since they may not wish to invest in building a captive operation with a fairly comprehensive skill set in these countries. Pharmaceutical companies are trying to find ways to reduce their marketing expenditure. One useful approach is to create a central hub (a 'centre of excellence') for medical communications to produce a repository of common material for all products and to disseminate the material across all markets, with customisation for local marketing needs (e.g. translation).

### 'Hub in India' model for emerging markets

In India, medical writing started in the late nineties against the backdrop of economic liberalisation, the boom in information technology and potential for growth in the field of clinical research services.<sup>5</sup> This was helped by English being one of the official languages and the only language of science in India.<sup>6</sup> These factors, along with the cost-effectiveness of services delivered from India, encouraged several pharmaceutical companies to open their first offices here (e.g. Pfizer, Novartis, Sanofi Aventis, GSK). CROs, IT-based business process outsourcing organisations, medical communications agencies, and specialised service providers also followed.<sup>7</sup> At this juncture, India did not have its own innovator products and the drug regulatory body of India was evolving. Indian companies initially contributed to the fields of medical communications and health journalism. They increased their presence by drafting peer-reviewed journal articles and then entered the field of regulatory writing (e.g. clinical study reports and other clinical trial-related documents and aggregate safety reports for post-marketed products) for innovator companies, based on data that were primarily from the developed world. In the initial years Indian outsourcing companies lacked adequate experienced personnel and training programs, and showed a lack of clarity and perspective among medical writers.

Over the past few years, however, Indian companies have increased their status as a preferred destination for all categories of medical writing, along

with related activities (such as biostatistics and drug safety).<sup>8</sup> Accurate estimates of the scope and volume of medical writing done from India are not available, but several hundred medical writers are now based in India. These writers produce substantial numbers of regulatory, clinical, and scientific trial reports and post-marketing documents both for innovator and generic drugs, and for all the developed markets. Indian medical writers have more recently entered the fields of medical information, CME, product labelling, pharmaceutical research analytics, and health economics.

A survey of Indian medical writers (49 respondents; 2008) provides preliminary information on educational qualifications and job profiles of medical writers in India.<sup>9</sup> The recently formed All India Medical Writers Association accounts for about 250 registered medical writers from all over the country.<sup>8</sup> However, accurate information is not yet available about the number of medical writers in India, their distribution in full-time jobs versus freelancing, their engagement in regulatory, clinical, or medical domains, their qualifications and experience or their career progression. Another survey of medical writers in India is needed to provide insight into some of these aspects.

In the past few years, many Indian and international professionals with higher education and work experience from North America or Europe have been returning to India or joining firms based in India, and are thus contributing to the development of specialised domains.<sup>10</sup> Collaborations and professional networks with such individuals are creating stronger bridges between the medical writing community in India and those in other countries.

In addition, medical writers in India are learning from and working closely with their international colleagues, and are instrumental in timely submissions of regulatory documents to the FDA, EMEA, and other regulatory agencies. They are part of international medical communications teams and participate in writing manuscripts and other clinical documents mostly for North American and European markets. Of late, generic companies, with a bigger focus on developed markets, are also bringing their writing projects to Indian writers.

Both promotional and non-promotional medical communications in emerging markets require significant background work to identify, analyse, and present health-related data in local populations. This involves collecting epidemiological data for different diseases in emerging markets to determine whether the needs of the local population differ

from those of the established markets, collecting information about local regulatory requirements and health economics, and finding innovative yet simple and cost effective ways to reach HCPs and patients. Medical communications demand strong engagement of medical writers with HCPs from different countries working in a range of settings (e.g. hospitals, private clinics). Medical information services require high-quality standards because even small errors could have serious consequences for patients. Indian medical writers can play an important role in providing medical information and communications support because of their medical/scientific knowledge, analytical skills, experience with literature databases, exposure to data management systems, and global experience. Their experience of working with the most mature regulatory bodies of the world has assisted the development of appropriate and efficient quality control and quality assurance strategies.

Writers in India understand the needs of non-native English-speaking countries. Due to the global influence and awareness of opportunities, many Indians also learn other languages, including those of some of the emerging market countries. Thus translations of English documents into local languages of emerging nations may also be a future area of opportunity for India. They have experience of working in a range of environments (pharmaceutical companies or specialist service providers) and have acquired expertise in different types of medical writing through job transitions. In the early part of their careers, medical writers in India typically start with service provider organisations on specific and well-defined writing assignments or preparing documents with stringent style guides and time lines through collation of contributions from several clinical and regulatory personnel from pharmaceutical companies. The complexity, quality, and variety of medical writing in India have consistently increased.

## Conclusion

The central hub model is ideal for the medical communications documents that are the subject of this article. Tremendous synergies can be realised by preparing common material that can be customised for local consumption. Considering the progress made and the experience gained by medical writers in India, the pharmaceutical industry may strongly consider the 'hub in India' model for reaching out to HCPs and patients in emerging markets with information about clinical trials and information required for product launches. Over the last decade medical writers in India have developed

the capability to meet this challenge through their training and work experience. They can add value in reaching out to emerging markets through their knowledge of the culture and infrastructure of such markets.

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## Conflicts of interest and disclaimers

The author declares no conflicts of interest. The views expressed by the author in this article are personal and do not necessarily represent the views of the organisation with whom the author is associated.

## References

1. Pharma Emerging Markets 2.0. How emerging markets are driving the transformation of the pharmaceutical industry. Booz & Company Inc; 2013. [cited 2013 Aug 12]. Available from: [http://www.booz.com/media/file/BoozCo\\_Pharma-Emerging-Markets-2.0.pdf](http://www.booz.com/media/file/BoozCo_Pharma-Emerging-Markets-2.0.pdf).
2. The global use of medicines: outlook through 2016, Report by the IMS Institute for Healthcare Informatics. 2012. [cited 2013 Aug 12]. Available from: [http://www.imshealth.com/deployedfiles/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/Global%20Use%20of%20Meds%202011/Medicines\\_Outlook\\_Through\\_2016\\_Report.pdf](http://www.imshealth.com/deployedfiles/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/Global%20Use%20of%20Meds%202011/Medicines_Outlook_Through_2016_Report.pdf).
3. Guidance for industry: responding to unsolicited requests for off-label information about prescription drugs and medical devices. 2011 [cited 2013 Aug 12]. Available from: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM285145.pdf>.
4. Keary E, Byrne M, Lawton A. How to conduct a literature review? *Irish Psychol* 2012;38(9-10):239-45.
5. Basrur R. Medical writing in India. *Write Stuff* 2006; 15(2):50-1.
6. Pal C. It is a critical issue, the topic of outsourcing: Commentary on 'What price quality?' *Write Stuff* 2011;20(2):96-7.
7. Bose S. Medical writing in India at a crossroads. *Medical Writing* 2013;22(2):94-5.
8. Das N, Das S. The changing face of medical writing in India. *Medical Writing* 2013;22(2):91-3.
9. Samulack D, D'Souza E. Medical writing outside the US: challenges and opportunities – the Indian perspective. Presented at the 68th Annual Conference of the American Medical Writers Association; 2008 October 25; Louisville, KY. 2008 [cited 2013 Feb 12]. Available from: <http://www.cactusmed.com/files/amwa-presentation-68th-annualconference.pdf>.
10. Pal C. From researcher in Europe to medical writer in India. *Medical Writing* 2012;21(1):39-41.

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