

# Language Challenges in the Developing World

## Gary Muddyman at Conversis outlines the key issues for biopharma companies entering developing world markets

As biopharma makes up an increasing proportion of the global pharmaceutical market, so it will follow into the world's emerging economies too. The opportunities in these markets are well-known, but what are the risks and challenges involved in working in developing countries with unique cultures and little understanding of Western medical concepts?

The global pharmaceutical market is now worth almost \$900 million and is expected to grow to \$1,100 billion by 2014 (1). Much of this growth is expected to come from emerging markets, with IMS Health predicting that what it calls 'pharmerging markets' will grow at a rate of 14 to 17 per cent until 2014, while developed markets grow by just three to six per cent.

At the same time, biotech medicines are expected to make up an increasing proportion of the overall global pharma market. In fact, an estimated 50 per cent of all new medicines originate from biotechnologies and this number grows when it comes to the most innovative treatments, such as growth hormones, recombinant growth factors, vaccinations, monoclonal antibodies for the treatment of cancers and inflammatory or infectious diseases, and cell therapy (2).

Healthcare biotechnology is growing annually at a rate of 15 per cent. It is now seven times larger than it was 15 years ago. There are currently more than 600 biotech medicines being tested to treat more than 100 diseases (2).

In fact, the latest IMS health report states: "Leading up to 2020, IMS expects to see a continuing shift toward biopharmaceuticals, speciality-driven products, and changes in the mix of disease areas of interest."

### **BIOPHARMA OPPORTUNITIES & RISKS IN THE DEVELOPING WORLD**

What becomes clear from this evaluation is that biopharmaceuticals are on the rise. With increasing acceptance from healthcare payers and a higher profile in society at large, the biopharmaceutical industry is set for terrific growth over the next decade. Like the rest of the pharmaceutical industry, much of this growth will come from new markets in the developing world. This presents both huge opportunities and challenges for the biopharma industry.

The opportunities offered in the developing world are now well-documented: large treatment-naïve populations; quick

patient recruitment and high retention rates for clinical trials; lower costs; larger markets for end-products; and the ability to gather data on epidemiological and demographic disease profiles.

Among the infinite opportunities, however, there are also risks. One of the most common is the risk of misunderstanding. Communication to new partners, patients, investigators, payers and institutions must be as clear and effective in the developing market's native language as it is in English.

What's more, because of the emphasis in biopharma on treating rare diseases, raising a drug's profile and gaining access to the right patients in the right way may be even more important than it was for the big blockbuster drugs of the past. Often, it is the small to medium-sized biotech firms that manufacture orphan drugs, and they simply do not have the big budgets of the global players to launch large-scale marketing and communication programmes across the globe. But doing it right is better than doing it big.

It would be a mistake to assume that launching a drug in a developing nation is the same as launching it in an established Western market, even when that Western market does not share the same language. There are many issues involved when working in developing markets; not least of which is that the pharmaceutical market in general – and the biopharmaceutical market in particular – in these nations are both new, and in many instances, unknown concepts. A basic understanding of the issues involved in communicating to developing markets should give biopharma companies the basic knowledge required to choose a good language partner to help them along the way.

### **CULTURAL DIFFERENCES CALL FOR LOCALISATION**

It goes without saying that the emphasis on accuracy in medical translations cannot be overstated. Any activity associated with testing, marketing or selling your product must be translated accurately while simultaneously tailored to meet the needs of the host country. A basic, literal translation is usually insufficient; it is essential to capture cultural differences and local sensitivities.

This attention to detail is known as localisation – a term that describes the overall task of adapting products, services, websites and all other marketing materials in accordance with linguistic, cultural, technical and other locale-specific requirements of the target market.

To be truly localised, all communication must be presented to the participants in a way that demonstrates an understanding of the market into which it is being introduced. All communication – patient recruitment and retention flyers, posters and fact sheets, packaging, marketing materials, information leaflets, websites and the like – must be mindful of the cultural and social norms within the target market. Of course, translations must also be accurate and comply with local legal and regulatory requirements.

This process involves a careful mix of local knowledge and medical expertise. An agency with proven experience in the region, which has a network of local medical translators, should be used to help with this process. Tone, terminology and accuracy are all of paramount importance. Communication must be informative but without giving false hope. The excitement and hope that has surrounded biopharma developments in the past can build expectations that biotech healthcare products can provide ‘miracle cures’. Translations must be extremely careful to avoid giving this impression; it is a mistake that companies cannot afford to make in new markets and is the reason why a thorough understanding of the local culture is necessary.

To understand why localisation – rather than simply translation – is necessary, it may be helpful to explain the difference between high-context and low-context cultures. The anthropologist Edward T Hall developed a theory that the world’s languages fall into two largely different language groups: high-context and low-context cultures. High-context cultures use many non-verbal cues to communicate. A lot of information is implicit in the situational context since these communities have traditionally had very close connections. Most countries in Asia, Africa, Latin America, southern Europe and the Middle East are considered high-context cultures.

In low-context cultures, information is explicit and formal. Communication is verbal and linear. Northern Europe and North America are considered low-context cultures (3).

It is because of these different styles of communication that complex translations, such as medical translations, require highly specialised care. Local medical experts in the new market must always be involved in medical translation. To add to the

complexity of this equation, many Western medical concepts, such as the placebo and informed consent, are completely unfamiliar concepts in the markets that pharma is now starting to penetrate. It is all very well to capitalise on the opportunity to trial ground breaking products on treatment-naïve patients, but drug sponsors must accept that these patients are also naïve in their understanding of Western medicine. There has been a call in Europe to improve information about medicines to empower patients. No doubt this will soon follow in emerging markets, but it will come with the additional responsibility of communicating in a completely different way to an audience with a very different understanding and value judgement of Western medicine.

Furthermore, because of the complex nature of biotech healthcare products, much of the information that will need to be communicated to patients, and indeed to society at large, must be carefully crafted to take this into account.

### **CHOOSING PARTNERS IN DEVELOPING NATIONS**

When choosing partners with which to conduct clinical trials, drug sponsors should look for research centres that conform to the International Conference on Harmonisation (ICH) Guideline of Good Clinical Practice. Currently, India is well advanced, with many research centres and investigators well-acquainted with the guidelines, as are some south-east Asian countries such as Singapore. China, on the other hand, still lags behind in this area.

Informed consent will also form a vital part of the translation and localisation process when conducting clinical trials in developing countries. Different cultures will have different rules with regards to who makes decisions within the family or community. While these social norms must be respected in gaining informed consent, they can never replace the consent of an individual. The process of gaining informed consent can therefore be particularly onerous on the part of the investigator, and there may be a case for producing appropriate literature for the family and community explaining the purpose and importance of informed consent.

Varying levels of literacy in the developing world will also affect the traditional Western method of collecting informed consent through a printed form with signature. It will also have an impact on patient information leaflets, dosage information and so on. The World Medical Association’s Declaration of Helsinki is the leading guidance on ethical issues in conducting clinical trials in developing countries, and drug sponsors should

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make sure that, in addition to following the ICH Guideline of Good Clinical Practice, investigators have a good understanding of the ethical principles involved in collecting informed consent, as well as the regulatory requirements to properly document it.

A good knowledge of the Declaration of Helsinki in general should help biopharma companies understand the risks and challenges in operating in developing nations, but there are other tools that can help too. The EuroQol EQ-5D questionnaire is a standardised instrument for international clinical trials that measures health outcomes. It is currently available in 83 languages and makes collecting patient reported outcomes easier in various languages.

### WHICH EMERGING MARKETS?

Looking at the world's emerging markets, Asia seems to have the strongest long-term growth prospects, according to a report by the Economist Intelligence Unit on behalf of UK Trade & Investment. This does include China and India, but the rest of Asia also presents itself as a highly favourable investment location for various industries for the next five years (4).

For companies wishing to capitalise on regional economies of scale, it might be an idea to look to Asia for an investment strategy, but they should not be fooled into thinking that geographic closeness equals cultural closeness. These countries speak different languages (indeed, often more than one within their own borders), and have different exposure levels to Western medicine and medical concepts; clinicians will have varying authority and knowledge of the principles of Good Clinical Practice; and although there has been a move towards more regional cooperation, these countries all have their own regulatory requirements for registering new medicines for marketing or clinical trials.

India has a good infrastructure for both testing and marketing drugs, but the Indian population speaks nine official languages. While it is acceptable for some business information to be in English in India, it is definitely not acceptable for pharmaceutical product information to be solely in English. In clinical trials, the languages required will depend on trial protocol (and therefore the target patient population). When launching a product or communications campaign, an analysis will need to be undertaken to determine which of those nine languages documentation must be produced in.

In Malaysia, most pharmaceutical documentation is produced in Malay, simplified Chinese and Tamil. In the Philippines, documentation would normally be translated into Tagalog and Cebuano, both considered rare or specialised languages. In the large Indonesian archipelago, however, it is usually sufficient to translate into Bahasa Indonesia and, similarly, Thai alone is sufficient for Thailand.

China is another story altogether. Like India, there are many languages spoken, with no one individual language having enough prominence to be acceptable for all communication. In

### About the author



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additional to standard Chinese or Mandarin (known as Putonghua, based on the Beijing dialect) and Yue (Cantonese), Wu (Shanghainese), Minbei (Fuzhou), Minnan (Hokkien-Taiwanese), Xiang, Gan and Hakka dialects are all official languages of China. There are also many other minority languages spoken within the nation.

Unlike India, China does not yet have a mature infrastructure for operating clinical trials or marketing Western medicine. This makes the process of working inside China all the more difficult. However, because of the opportunities, many pharmaceutical companies are already operating in China and progress is being made. In fact, there are currently 1,601 trials taking place in China on the FDA register, so it is clear that plenty of companies are managing well there.

### CONCLUSION

This is not meant to make the task of entering developing markets daunting. In fact, the aim is quite the opposite. It is inherently exciting to live in an age where great advancements in medical technology can be shared around the globe so quickly, but sharing success does entail some responsibilities and effective communication is chief among those. Do not fear, however, translation and localisation will be a small part of your overall project when you plan to launch a trial or medicine in a new market. An expert language services agency will be able to help you through the translation process every step of the way, and take that burden off your shoulders.

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