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Emerging Markets Mean Financial Rewards for the Life Sciences Industry

Peter Rose, Managing Director
******@***maetrics.com

Managing Director - Maetrics

New Challenges for Regulatory Compliance

With healthcare spending on home soil drying up, and the UK National Health Service (NHS) set to achieve unprecedented efficiency savings of £50bn by 2020 (NHS England 2013), savvy UK life sciences firms are looking to emerging markets for growth. Unlike the UK, emerging markets are becoming increasingly appealing, due to a growing middle class that expects a better standard of living and enjoys higher life expectancy rates than ever before. All this is driving the demand for new medical products.

Specifically, whilst the global pharmaceutical market is expected to grow 4.5 percent a year on average to 2016, emerging markets are expected to grow at three times that pace (Grunwald 2014; Ward and Waldermeir 2014). The most bullish emerging market of all, China, aims to have total healthcare coverage of its 1.35 billion population by the year 2020, equivalent to an over $180 billion growth in the market over four years (IMS Institute for Healthcare Informatics 2013). IMS additionally suggests that pharmaceutical sales alone will exceed $1 trillion by 2017, making it a rich market for life sciences firms. The increased spending on medicines in emerging markets and new drugs for cancer and orphan diseases are identified as the main drivers for this growth, and given the figures, markets such as China, Brazil, India and Russia are a bountiful source of future revenue.

Changing demographics clearly play a big part in the opportunity presented by emerging markets. For example, in China, the number of people aged 65 and over is expected to nearly treble from 123m to 330m by 2050. This increase, along with chronic diseases rising by 20-30 percent, 300m people being added to the urban population by 2025, and the Chinese economy expected to reach the number one spot at $73.5 trillion by 2020, has resulted in healthcare spending growing by 7 percent (Sagentia 2011). Indeed some companies have already begun to reap the rewards of entering emerging markets. France's biggest drug-maker has increased its revenues by 20 percent since 2010 (Ward 2014) by entering emerging markets, despite revenues stalling in the developed world.

In December 2011 the UK government launched a ten-year Strategy for UK Life Sciences, setting out the long-term vision to support the growth of small and mediumsized British life sciences enterprises. The aim of this strategy is to help bring further investment into the UK life science industry, helping allay fears about the economy and funding gaps whilst supporting innovation in the sector. Furthermore, to encourage innovation in the UK, Patent Box tax legislation has been introduced to provide UK businesses with an incentive to perform R&D. However, latest research commissioned by Maetrics, a full-service life sciences consulting company, confirms that 43 percent of UK life sciences businesses say that reduced healthcare spending will be one of the main challenges they face this year. Additionally, a quarter (26 percent) say they are concerned about the stability of the UK economy, and that the predicted £30bn funding gap set to hit the NHS by 2020 (Illman 2013) is therefore a major concern.

Research and development (R&D) in the pharmaceutical area reportedly accounts for approximately £11.5 million spent every day, according to the Association of the British Pharmaceutical Industry (ABPI). The majority of this expenditure is funded from within the industry, highlighting the integral importance of the sector to the nation's growth and economy, but also how self-reliant it is. In 2013, 22 percent of the entire R&D activity in the UK was in the pharmaceutical sector alone, and UK companies funded 66 percent of their R&D while 23 percent of investment came from abroad (ABPI n.d.). But with cost pressures continuing to increase, the recent downturn has left many life sciences companies fundamentally reassessing their business model, increasing their efforts on factors such as safety, personalised and targeted medicines, and network-based collaborations (Capgemini 2009).

So with businesses expanding abroad, away from the UK, it is important for them to be aware that with potential comes risk, as they then face the challenge of navigating varying complex national regulatory systems. The Maetrics research highlights the concerns respondents have when facing regulatory compliance, with 50 percent revealing this as their biggest challenge.

Regulatory compliance is of the utmost importance, as fines can not only cripple smaller businesses, but can also expose any sized business to reputational damage, patient safety issues, and criminal sanctions, not to mention the negative impact on investor confidence.

This is particularly significant, as the Maetrics study revealed that another key challenge for 2015 is new product launches, with 46 percent citing it as a top obstacle. With increased global competition, price pressures and the growing demands of ageing populations, there is a significant burden on firms to meet consumer needs all over the world. In addition drug safety, counterfeiting, good laboratory practices (GLP) and government policies mean that all new drugs must be carefully planned to ensure they meet the varying regulations in all markets in which they will be sold. Regulatory diversity in these areas means there is no 'onesize-fits-all' solution.

To emphasise the importance of GLP, the World Health Organization (WHO) outlines five points that companies must take note of in their Good Laboratory Practice report: resources (organisation, personnel, facilities and equipment); characterisation (test items and test systems); rules (study plans, or protocols, and written procedures); results (raw data, final report and archives); and quality assurance (World Health Organization 2001).

UK life sciences businesses also report that they face an industry skills shortage, with 43 percent of respondents agreeing that finding specialised staff will be difficult this year. This specialised staff shortage was initially highlighted by the Association of the British Pharmaceutical Industry in 2008, but since then the issue has worsened, and in 2012 the industry topped PWC's talent challenge poll (PWC 2012). Indeed one

core aim for the Strategy for UK Life Sciences is to attract, develop and reward talent in the industry (HM Government 2012).
A more recent report by recruitment firm Hays highlighted the ongoing challenges still faced by employers recruiting in the life sciences industry, with 55 percent of their respondents saying they expect to encounter a shortage of experienced applicants in the next 12 months (Hays 2014). With businesses entering new emerging markets, it is important that their staff have the necessary skills, knowledge and experience to successfully navigate compliance issues abroad.
Finally, one in five respondents in the Maetrics study reported that merger and acquisition (M&A) activity will pose a challenge in 2015. It is widely accepted that M&A transactions almost doubled in 2014 compared to 2013, and this trend shows no sign of abating with activity still buoyant in early 2015. In particular, larger pharmaceutical companies are continuing to focus on building capability in specific diagnostic areas in order to maintain a strong pipeline. The hunt for so-called blockbuster drugs is keeping interest in smaller, specialised outfits and laboratories very much alive.
Whilst concerns remain for the life sciences industry in regard to emerging market expansion, the opportunity for growth is unprecedented. Key to successfully entering these markets is a strong quality and compliance team, whether internally or externally through a consulting partner. It's clear that to take full advantage of the opportunities the emerging markets present, confidence in understanding, interpreting and implementing regulations will play a critical role.

Key Points

- UK life science businesses are continuing to focus on emerging markets and therefore face the challenge of navigating a variety of complex national regulations.
- Five points that companies must take note of in their Good Laboratory Practice report: resources (organisation, personnel, facilities and equipment); characterisation (test items and test systems); rules (study plans, or protocols, and written procedures); results (raw data, final report and archives); and quality assurance.
- The hunt for so-called blockbuster drugs is keeping interest in smaller, specialised outfits and laboratories very much alive.
- There is a need for skilled and experienced staff, yet respondents also highlight a skills shortage in the life sciences industry.

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