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INTRODUCTION

India's life sciences and healthcare sector is one of the fastest growing in the world. With the increasing purchasing power of India's middle class, demand for quality healthcare is growing. At the same time, various initiatives to provide effective healthcare for a huge portion of the population that is unable to pay for services are also being explored. The subsectors witnessing significant activity include biotechnology, generic drug manufacture, building new hospitals and medical infrastructure, and medical devices.

Over the last few months the Indian pharmaceuticals subsector has been featured in the news – from sustained growth, R&D collaborations and development of new products, to proposed changes in the foreign investment. The overall growth in the sector has also seen increasing clinical research activities being undertaken in India and the tightening of norms for clinical data management. There has been a significant move towards increasing access to healthcare, whether it is through building new hospitals in smaller urban centres or breakthrough in remote diagnostics as has been unveiled by Philips.

In September, a biopharma focused event, Bio India will take place in Hyderabad, India. UKIBC is supporting UKTI in organising a visit for interested UK companies and there will also be relevant business meetings in Bangalore and Mumbai. Further details can be found at: http://www.ukibc.com/ukibc_events/

India's life sciences and healthcare sector is one of the fastest growing in the world. With the increasing purchasing power of India's middle class, demand for quality healthcare is growing.

FURTHER INFORMATION

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MARKET UPDATE

The Indian Pharmaceuticals industry has been growing at a phenomenal pace. According to a recent Industry Forecast Scenario report by BMI (Business Monitor International), India's pharmaceutical market is expected to grow by 16.4% in 2011. The report also estimates that the industry will keep growing at a compound annual growth rate (CAGR) of around 14.6% until 2015. A recent study by McKinsey estimates that the pharmaceuticals market in India will reach US$55 billion by 2020.

DRIVERS FOR GROWTH IN THE INDIAN PHARMACEUTICAL INDUSTRY

According to BMI, the market expansion will be sustained by a combination of factors over the next decade. The key driver of medicine sales is a booming economy. While economic growth in India remains subject to threats such as higher energy costs and inflation, the country continues to enjoy an outstanding GDP growth at 7.8% FY2011/12 (Apr-Mar). Over the next decade, India's GDP is forecast to more than treble, from INR76,208 bn (U$1,674bn) in 2010 to INR281,108bn (US$7,397bn) in 2020. This is positive news to the pharmaceuticals industry.

Another source of increased demand for medicines in India is greater state involvement in healthcare, which traditionally has been minimal. The FY2011/12 (April-March) budget provides INR26,760 crore (US$5.94bn) for the Ministry of Health & Family Welfare, representing a 20% increase compared with the previous year, when the increase was 18%.

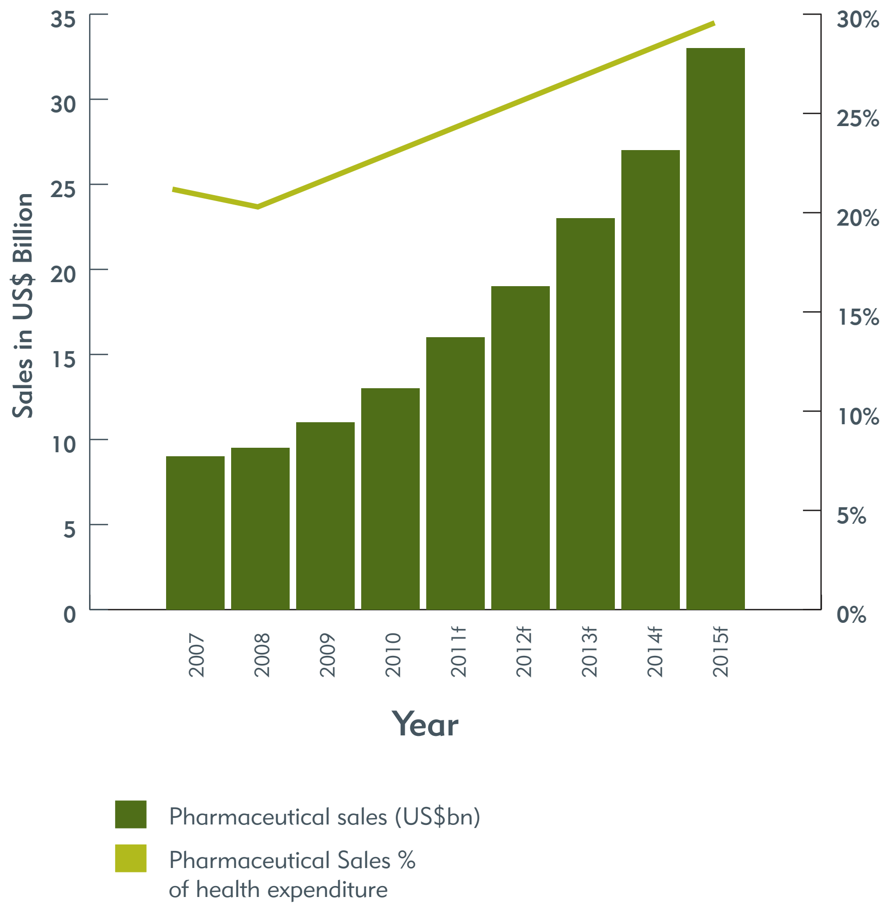
INDIA REPRESENTS ONE OF THE MOST ATTRACTIVE PHARMACEUTICAL MARKETS.

Sales of medicines are expected to post CAGRs of 15.5% and 13.9% through to 2015 and 2020, respectively. Within a decade, the value of the pharmaceutical market will approach US$60bn".

The following chart shows the historical and projected growth of sales of pharmaceutical products in US$ billion and pharmaceutical sales as a % of health expenditure:

Sales of medicines are expected to post CAGRs of 15.5% and 13.9% through to 2015 and 2020, respectively.

SALES OF PHARMACEUTICAL PRODUCTS IN INDIA.



Source: IMS Health, AIOCD Pharmasofttech AWACS, Organisation of Pharmaceutical Producers of India

INVESTMENT UPDATE

India's large, growing and ageing population is an obvious enticement for pharmaceutical firms. According to the UN Population Division, the number of people living in the country will increase from 1.17bn in 2000 to 1.32bn in 2020 - a rise of 36%. The percentage of the population aged 65 and over will increase from 4.3% to 6.3% over the same period. However, we caution that Indian per-capita spending on medicine is, and will remain, relatively low (US$11 in 2010, US$26 in 2015 and US$45 in 2020).

India's large, growing and ageing population is an obvious enticement for pharmaceutical firms. According to the UN Population Division, the number of people living in the country will increase from 1.17bn in 2000 to 1.32bn in 2020 - a rise of 36%.

India stands to gain as global companies are looking to minimize costs from clinical trials and scientific research. The advantages are highly-skilled scientists, cost-efficiency and proximity to an ethnically genetically diverse and growing group of patients. With regulations coming in and domestic and multinational majors looking at increasingly tightening processes for handling clinical and pharmaceutical data, more international companies are likely to include India as a part of their clinical research process. India needs to capitalise on these strengths to be able to significantly contribute to global healthcare. There is also a substantial need to find new innovative solutions to meet local needs.

REGULATORY FRAMEWORK

AN EVOLVING FDI REGIME IN THE INDIAN PHARMACEUTICALS SECTOR[1]

There is an ongoing debate about the level of FDI in the pharmaceuticals sector in India. According to a recent article in the Economic Times, the Planning Commission deputy chairman Mr Montek Singh Ahluwalia recently endorsed allowing 100% foreign direct investment (FDI) in the pharmaceutical sector. "I endorse the view that there should be no case for rollback from 100% FDI," said Mr Ahluwalia.

The FDI debate was sparked by the recent high-profile acquisitions of Indian companies known for their generics manufacturing by large multinationals. An inter-ministerial panel comprising senior officials from the health ministry, commerce ministry, the pharmaceuticals department and the finance ministry was therefore tasked with suggesting measures that could help retain India's competitiveness. The panel's report recommended that the FDI cap for brownfield pharma projects, which would include expansion and M&As, be cut to 49% (on a case-by case basis), while the ceiling for greenfield ventures be retained at 100%.

Following the inter-ministerial panel's recommendation, the government set up a group under Planning Commission member Arun Maira to look at the ideal policy regime for the sector. "The expert group will see whether there is any problem relating to merger and acquisition rules of pharmaceutical companies in the country. I don't think there is any move anywhere to prevent expansion of existing 100% foreign-owned pharmaceutical companies or greenfield investment by foreign companies", Mr Ahluwalia was been quoted as saying.

COMPANY NEWS

INDIA NEEDS INNOVATION IN THE PHARMACEUTICALS SECTOR – OPPI

In an article in Pharma Biz, Mr Ranjit Shahani, President, Organization of Pharmaceuticals Producers of India (OPPI) and Vice Chairman & Managing Director, Novartis India Limited said that the Indian pharma industry needs innovation as the healthcare environment and patient demands are witnessing significant changes.

Sahani said, "The global population is currently going through a period of intense change with three overarching trends: an ageing population, changing lifestyles, and emerging markets. People are living longer. Patients are more demanding, lifestyle diseases are on the rise and standards of safety are higher. Emerging markets are presenting new challenges. All of these necessitate innovation. While the need for innovation is at an all time high, the cost of pharmaceutical research has gone up exponentially with the average expenditure of bringing a new drug to market US$ 2 billion". This is a potential opportunity for large international players as well as niche drug manufacturers to tap into the opportunities that the growth in Indian market has to offer. India too stands to gain as global companies are looking to minimize costs from clinical trials and scientific research. The advantages are highly-skilled scientists, cost-efficiency and proximity to a growing group of patients. OPPI feels that if India could capitalize on these strengths, it could significantly contribute to the global healthcare to meet the patient needs.

"The Indian pharma industry needs innovation as the healthcare environment and patient demands are witnessing significant changes."

Source: Pharmabiz

PHILIPS TO LAUNCH VIRTUAL ICUS IN INDIA[2]

India is exploring options to provide quality affordable healthcare to people across the country. It is clear that with the current state of physical healthcare infrastructure, India would need to explore technologies which will allow remote delivery of healthcare and telemedicine services. Bearing this

1 The Economic Times: http://articles.economictimes.indiatimes.com/2011-07-12/news/29765527_1_fdi-policy-pharmaceutical-sector-sectoral-cap
2 http://www.business-standard.com/india/news/philips-to-introduce-india%5Cs-first-virtual-icu-soon/438858/

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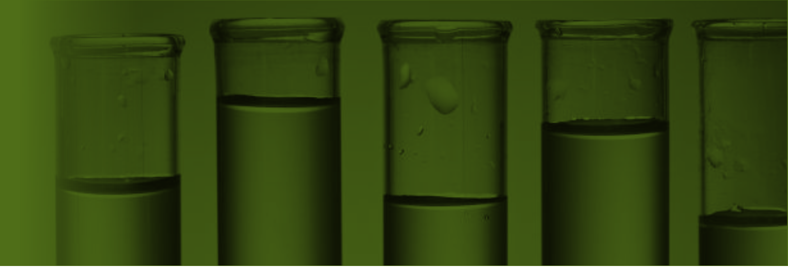

in mind, the announcement by Philips Electronics to launch its virtual intensive care unit (ICU) – the first in the country – will definitely be a welcome move.

This technology will allow patients admitted to intensive care units (ICU) at hospitals in smaller towns and villages to receive treatment from specialists in metro cities. This will be great news for the critical care segment. Philips is already in talks with major multi-specialty tertiary care hospital groups to introduce this technology called eICU over the next few months.

"Like the monitoring process in a traffic control room, an eICU monitors patients in different hospitals 24x7 and makes key interventions at the right time. The technology connects several hospitals' ICUs to a big specialist ICU where critical care specialists monitor and review patients through online data connected from patient monitors and live images of the patient's condition. We are in talks with multi-specialty tertiary care hospitals to implement the technology in India," said Krishna Kumar, vice president and business head of Philips Healthcare in India.

According to Philips, through this technology doctors can centrally monitor patients in multiple ICUs, which would help hospital groups to deal with the talent shortage in the sector.

Philips leads the critical care segment in India, with a 52 per cent share. In 2010, the company had posted 43 per cent growth in this category in India. Healthcare contributes about 40% of Philips' global revenues. The UK arm of company leads on healthcare R&D and technology development. Philips feels that its facility in Cambridge is the key global hub of innovation & entrepreneurship. The facility benefits from the open collaboration with a broad range of academic and commercial organisations in the ecosystem and drives innovations in new applications in health and well being.

FORTIS PLANS LOWER COST HOSPITALS IN SMALLER INDIAN TOWNS[3]

Large private hospital chains providing quality healthcare have started becoming the healthcare providers of choice for the growing middle-class in India's major cities. It is estimated that by 2030 India will have 68 cities with a population of over 1 million. Each of these urban centres will see major investment in high class hospitals and medical centres.

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One of the large Indian hospital chains, Fortis Healthcare, announced last June its plans to expand its existing network of 56 hospitals by establishing a second brand of hospitals aimed at the smaller (Tier 2 and 3) cities. According to news reports, Fortis is planning to set up 25 hospitals in the next three years under the new brand. The main objective is to provide affordable healthcare without compromising on quality.

The UKIBC very much welcomes this development, and it is in line with the UK-India CEO Forum objective of extending affordable healthcare to the Indian population.

Other than setting up hospital infrastructure, opportunities for UK companies include developing health delivery systems, provision of medical devices and equipment, mobile health and applications for remote diagnostics & monitoring.

RESEARCH FINDS NEW LOW COST "POLYPILL" TO HALVE RISKS OF A HEART ATTACK[4]

A study was recently carried out by members of the PILL collaborative group, an international group of researchers based in Australia, New Zealand, Brazil, the Netherlands, India, the UK and the US. It was funded by a range of organisations including **The Wellcome Trust**, the Health Research Council of New Zealand, the National Heart Foundation of New Zealand, the National Health and Medical Research Council of Australia, the Brazilian Ministry of Health (Projeto Hospitais de Excelencia) and the British Heart Foundation.

The clinical research was based on a randomised controlled trial of a polypill in 378 people who all had a slightly increased risk of vascular disease, the researchers found that people who took the medication had improvements in their blood pressure and levels of "bad" LDL cholesterol (equivalent to a 46% reduction in cardiovascular risk) over 12 weeks. According to The Daily Telegraph, "A new 10p-a-day 'polypill' containing aspirin and statins halves the risk of heart disease and stroke, according to the world's first international trial of the drug".

The polypill itself is called the Red Heart Pill and was manufactured and provided free of charge by Dr. Reddy's Laboratories in India.

This research shows the close cooperation and potential in the lifesciences sector between the UK and Indian players. We feel that there is substantial scope for collaboration between the two countries to explore affordable and effective healthcare solutions.

ICRA REPORT SAYS INDIAN PHARMA CONTRACT RESEARCH TO GROW AT HEALTHY PACE[5]

According to a new report by ICRA, the market for outsourced pharma research and manufacturing activities in India is in a strong position and looks set to capture a sizeable chunk of the global outsourcing pie by 2012. The Indian contract research and manufacturing services (CRAMS) sector is expected to almost double to

3 http://articles.economictimes.indiatimes.com/2011-07-01/news/29726109_1_fortis-plans-new-hospitals-hospitals-in-three-years
4 http://www.telegraph.co.uk/health/healthnews/8535957/10p-polypill-halves-heart-disease-and-stroke-risk.html
5 http://www.thehindubusinessline.com/todays-paper/tp-corporate/article2091497.ece

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$7.6 billion in 2012, up from $3.8 billion in 2010. The segment in India will grow at a high 41.4 per cent CAGR during fiscal years 2010-12. In contrast, worldwide, the outsourcing market is expected to grow at a far lower 12.6 per cent CAGR.

Sourcing from Indian companies will also more than halve the spend of global majors on these activities. "Global pharma majors are tying up with Indian companies to get drug discovery and development of new chemical entities with focus on biological skills to take advantage of skilled manpower and scientific talent pool," the ICRA report says.

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Among some significant Indian players in this sector include Jubilant, Biocon, Strides Arcolab, Dishman Pharma and Divi's Labs that have gained from some winning global deals. CRO players grew five-fold in three years, from around 20 in 2005 to around 100 in 2008. The number may reach 150-200 by 2012.

Custom or contract manufacturing will lead the segment. The report says, "The growth will be supported by a high number of US FDA approved plants, skilled manpower coupled with inherent cost advantages, which will enable India to capture a significant chunk of the current $67 billion global pharma outsourcing market".

LARGE INDIAN IT PLAYERS KEEN ON DRUG SAFETY DATA MANAGEMENT[6]

With its large IT base, it is expected that the large Indian players are keen to explore the potential that clinical data management and pharmacovigilance have to offer. Over the last two years, IT majors including TCS, Cognizant , Wipro, Accenture, Genpact, HCL, among a host of others have set up dedicated business verticals entirely for clinical data management and pharmacovigilance (study of side effects of drugs available in the market or being used for clinical trials), catering to pharma majors the world over.

On top of that, the Indian government has announced that by the end of 2011 there would be as many as 100 pharmacovigilance centres in the country. These would be in addition to similar centres that each pharmaceutical company would be required to have. This is good news not only for the IT services companies, but also for multinational and Indian drug manufacturers because they would be able to get reliable data for their clinical research.

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BIOCON LAUNCHES REUSABLE INSULIN PENS[7]

According to a report in Business Line, Indian biopharma company, Biocon, is planning to launch a number of new products during this financial year. Among them is a reusable insulin pen, branded Insupen. Insupen, a high-end and less painful jab for diabetics than their regular injection, will put the Bangalore-based biopharma major in the league of a small but growing domestic market with at least four pen makers. (MNCs Novo Nordisk, Aventis, Eli Lilly, and Wockhardt are already in this segment.

"In India, where we have 51 million people suffering from diabetes, the use of pens has been limited so far, but this is fast changing. There is a growing market for insulin pens. Close to 20 per cent of insulin users administer it with pens.".

According to Mr Rakesh Bamzai, Biocon's President-Marketing, "Insupen would be affordable in keeping with Biocon's philosophy of affordable innovation for the masses". Although diabetics globally prefer the handy pens to regular injections in order to get their daily insulin doses, "in India, where we have 51 million people suffering from diabetes, the use of pens has been limited so far, but this is fast changing. There is a growing market for insulin pens. Close to 20 per cent of insulin users administer it with pens," Mr Bamzai says.

RANBAXY LAUNCHES CANCER DRUG IN EUROPE[8]

Ranbaxy Laboratories has announced the launch of its new breast cancer drug in the UK, Romania and France. It is the bio-equivalent of Femara, the innovator product of Novartis, that has a market size of $58 million in UK (Source: IMS 2010), $95 million in France (Source: GERS May 2011) and $5.5 million in Romania (Source: Cegedim 2010).

The product will be offered through pharmacies, retail and wholesale stores with immediate effect and will benefit the healthcare system in these EU markets. Ranbaxy's subsidiary companies, Ranbaxy (UK) Ltd, Terapia Ranbaxy and Ranbaxy Pharmacie Generiques will be marketing this product in UK, Romania and France respectively.

6 http://articles.economictimes.indiatimes.com/2011-06-24/news/29699025_1_clinical-research-international-clinical-trials-clinical-data
7 http://www.thehindubusinessline.com/companies/article2148035.ece?homepage=true
8 http://www.thehindubusinessline.com/companies/article2293349.ece

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INDIA COMPANY PROFILE - Fortis Healthcare India Ltd.

MAIN ACTIVITIES	Ambulatory Health Care Services; Hospitals; Nursing and Residential Care Facilities
DESCRIPTION	Fortis Healthcare Limited owns, operates and manages multi specialty hospitals and super specialty hospitals in India. The company's multi specialty hospitals and super specialty hospitals primarily provide tertiary and quaternary healthcare services to patients primarily in the areas of cardiac, neuro sciences, orthopedics, cancer, and mother and child care, as well as minimal invasive surgery, renal sciences, and kidney and liver transplants. It operates approximately 51 hospitals. The company was formerly known as Rancare Limited and changed its name to Fortis Healthcare Limited in June 1996. The company was incorporated in 1996 as is based in New Delhi, India. Fortis Healthcare Limited is a subsidiary of Fortis Healthcare Holdings Limited. Main Products: Healthcare Services, Pharmaceuticals, Other Services.
STATE	New Delhi; Delhi
KEY EXECUTIVES	Balinder Singh Dhillon, Director Brian William Tempest, Director Gurcharan Das, Director Harpal Singh, Director P S Joshi, Director
WEBSITE	**http://www.fortishealthcare.com**
IN THE NEWS	Fortis Group to go `cheaper and deeper' http://www.thehindubusinessline.com/companies/article2409352.ece CRISIL assigns valuation grade of 4/5 to Fortis Healthcare http://www.moneycontrol.com/news/crisil-research/crisil-assigns-valuation-grade45-to-fortis-healthcare_581112.html

Sources: ISI Emerging Markets; Fortis Healthcare

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CASE STUDY - ECCRO - NERMEEN VARAWALLA, FOUNDER & CEO

1. Tell us about your business – its origin, offering and coverage?

Emerging Country Contract Research Organisation (ECCRO) is a specialist CRO focussed on International Phase II-IV clinical trials conducted in India. The company delivers clinical trial services for international pharmaceutical and biotechnology companies so they can test the safety and efficacy of their innovative new products.

ECCRO is a specialist in the field because:

1) We focus on India, realising that regional expertise is essential to deliver clinical research to our international clients.

2) We "partner" with clinical trial sites because we believe that investment in site management is essential to deliver ECCRO's standards of ethical integrity, data quality and site productivity. Our operating processes represent industry leading practices that have been customised for the Indian clinical trial environment.

ECCRO's CEO and founder, Dr Nermeen Varawalla, an Indian physician by background is based in London, UK from where she leads corporate affairs and customer liaison. Given the time zone and transport links London is a great base to manage India operations and serve US & European customers. ECCRO's India office is based in Mumbai.

2. When and where did you make the first investment in India? In which cities do you currently have business relationships and/or business activity in India?

ECCRO's India operational team, trial management staff and support services are located in Mumbai. Apart from clinical trial sites in the metropolitan cities, we also work with hospitals in Indian Tier II and III cities (for example in Vadodara, Pune, Ahmedabad, Lucknow and Varanasi). ECCRO's site managers are based in these cities and work at our partner hospitals where they conduct ECCRO's trials.

3. What were the main drivers of your decisions to foray into India?

India has a great potential for clinical trials that has not yet been fully-tapped. India's large population, disease burden, unmet medical need and hospital-centric healthcare system make it very suitable for clinical research. It is because of these factors that India has the potential to contribute some of the world's most productive clinical trial sites. However achieving international standards of data quality and ethical integrity has been a challenge for this relatively nascent industry.

The sheer size of the country and the widespread use of English are an added advantage, as well as the cost effective labour force and robust IT infrastructure.

Stable regulatory framework and a democratic political system also make India an attractive location for international clinical trials.

4. What key factors would you attribute your success in India to?

Our specialized knowledge and the potential of the Indian market are key elements to our success.

In India, relationships are very important, for instance with investigators, hospitals, vendors and regulators.

The Indian workforce has an incredible work ethic. They are very dedicated and motivated, but to enable them to be most effective there is an element of managing

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CASE STUDY - ECCRO - NERMEEN VARAWALLA, FOUNDER & CEO

their communication and client interaction. Again, this is where our knowledge of India comes into play. Other businesses struggle with the management culture in India, but this is not an issue for ECCRO.

5. What have been your biggest practical challenges of entering and operating in India? (Infrastructure, identifying suitable partners, hiring suitable staff, etc.)

Most challenges in India are around infrastructure. There is also a lot of competition for talent and staff.

In our field, we recognize that there are a few challenges because the Indian healthcare clinical trials currently conducted there need a lot of support and handholding. At ECCRO we have made a deliberate decision to invest further to support the sector. We believe India is an emerging country with a lot of potential to become an effective and attractive market for clinical trials.

The nature of our business requires close attention to regulatory compliance. This in itself is not a challenge, however Indian bureaucracy with delayed decision-making can make the regulatory approvals process somewhat difficult.

6. From a regulatory perspective, what have been the main barriers to doing business in India? (Regulatory framework, bureaucratic impediments, legal or taxation issues, corruption). Are any of these impediments specific to the sector you operate in?

India is a democracy currently governed by a hung parliament. This political environment has slowed down the business of government and has had an impact on the regulatory processes.

In India there is great concern that Indian clinical trial subjects should not be exploited by foreign companies. The Indian regulator is therefore under a lot of pressure to protect its population. ECCRO and other players in the field understand these issues and very much welcome the initiative. However, a limitation of resources and expertise to deal with the political pressure and requirements means that the regulator has become very slow. At ECCRO we have a good relationship with the regulator's office and are happy to cooperate in the process, but do get frustrated with unnecessary delays and the associated uncertainty.

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UK Trade & Investment can also support your company to succeed in the Indian market. For more information on the life sciences and healthcare sector in India, you may contact:

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You may also wish to read a recent report by PwC on: **"Healthcare unwired: Health Insurance and Healthcare Access in India"**. You may find a copy of the report at: http://www.pwc.com/en_IN/in/assets/pdfs/publications-2011/health_report.pdf