

## The BioPartner 4th Annual Discussion Forum: is BRIC worth the risk for UK's Life Sciences SMEs?

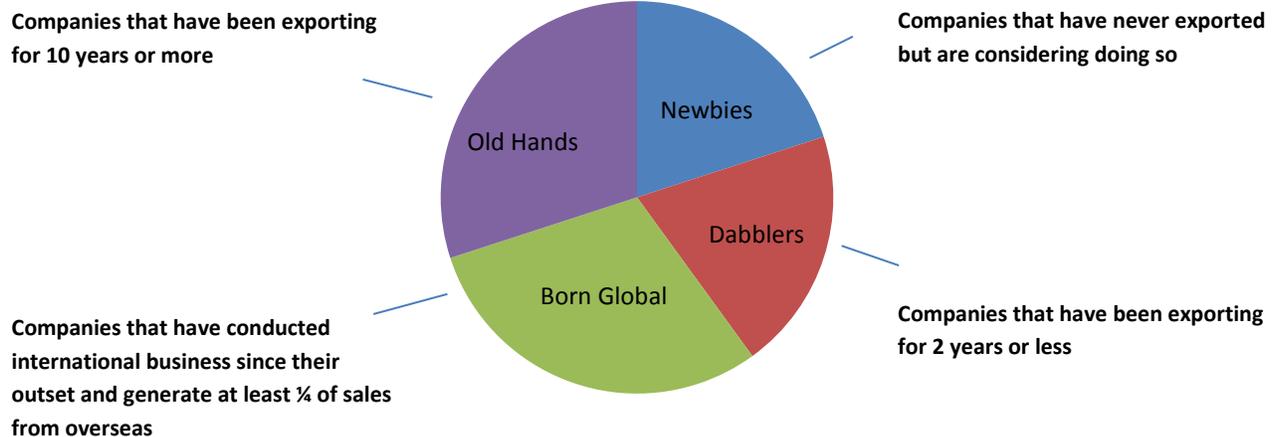
Mottram Hall, Cheshire, 5<sup>th</sup> July 2012.

Panel: **Jenny Murray, Managing Director of Sera Laboratories International**  
**Paul Eadie MBE, UK Trade & Investment Latin America Trade Advisor**  
**Allan Syms, Sector Specialist: Global Value Chain-Life Sciences China, UK Trade & Investment**  
**Dr Nermeen Varawalla, MD, DPhil (Oxon), MBA; Founder & CEO, ECCRO**

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Participants:

UK Trade & Investment, the government arm that works with UK-based businesses to ensure their success in international markets, has identified 4 categories of UK export companies. The distribution of attendees according to these categories was:



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The BioPartner 4th Annual Discussion Forum asked whether BRIC is worth the risk for UK Life Sciences companies. The UK government has highlighted the fast-growing BRIC economies (Brazil, Russia, India, and China) as the principal areas of opportunity for UK business. However, for Life Science Small to Medium Enterprises (SMEs) in the UK, these countries currently account for only a small fraction of international business. Innovative services and products do not seem to have a place even in the more affluent parts of these economies, where the main demand is for high quality goods and medicines. The Panel presented three main points for discussion: opportunity, infrastructure, and IP protection. These were discussed in the context of Brazil, India and China; Russia was not included.

### **Opportunity**

Q: Are UK Life Science SMEs well established enough to do well in BRIC markets? If so, where in these markets do they fit in and is there real value in branching into these markets?

A: It varies from case to case depending on the nature of the SME.

Before trying to enter a BRIC economy, it is up to the SME to identify its goal e.g. whether it is trying to sell or to source. It needs to ensure whether or not its product/service has a place in the BRIC country it is trying to enter i.e. there is no point trying to create a market that doesn't yet exist. Just because a product/service has a place in the UK does not mean it does in a BRIC country – the infrastructure may simply not be in place.

The Chinese market for pharmaceuticals is said to be \$50bn. Chinese traditional medicine and genomics dominate, and biopharma has been a relatively small part of that market, but, for example, contract research has shown recent growth, spearheaded by returning trainees, mainly from the USA, who have started their own companies. Therefore, it may be difficult to sell a CRO service in China, but it is easier to source a CRO there. On the other hand, not many of the increasing non-generic medical compounds available in China can be found anywhere else in the world. However, it may be feasible to provide them with first world CRO expertise to take these products out of China.

One comment was that despite 10 years of established global pharma presence in China, no new molecules have reached the stage of global development, raising a question over the viability of pharma research in China. However, the Chinese government has set a goal of 30 new molecular entities by 2020, which the sector is working hard to achieve. This stretch goal outstrips locally-available skills and capacity, but China has the money to buy in skills, which it does mainly from India. UK providers need to present a 'value purchase'.

Brazil has a long history of policies against the importation of goods, stemming from the debt burden it only turned around in the last decade. However, the way of doing business fits the European model better than most, due to historical ties, and initial input is rewarded with strong business in time. Collaboration is key - it is still very difficult to set up as a foreign-owned business there and expect to compete with local companies; the usual route to 'export' is through local partners or distributors.



Brazil boasts one of the world's most integrated societies – for instance, there are 1m Japanese living in Sao Paulo, and Germany has made extensive investments in Brazil. In terms of trade, however, Brazil is closely aligned with the USA (18% of exports) but a lot of trade is with other tropical regions and China is now Brazil's biggest trading partner. This is reflected to an extent in the kinds of products – including medicines – that will succeed.

India has a strong contract research base. To an extent, its contract research companies are viewed as competition by UK SMEs but there is opportunity to supply British innovation and experience. Formulation and development of biosimilars is an area of interest for numerous Indian pharmaceutical companies.

For Medtech-based SMEs the situation is different and it may be hard to justify the effort needed to tap into BRIC countries. Issues around manufacture, pricing and protection are added to the initial cost and time of setting up. However, there are ways around these additional barriers, in particular by working with local companies as distributors or agents. The justification for biopharma SMEs – particularly those working on small molecules – is that the large market in these countries allows for more potential profit.

*Regarding markets for approved drugs, the growing middle-class in BRIC countries are increasingly interested in buying high-end healthcare. Whereas in first world countries, the primary interest is in high quality healthcare at mid-price, there is an increasing demand in BRIC countries for premium care at high prices. These price points are roughly equivalent across these different markets, and with the UK NHS brand perceived by BRIC citizens to be “first in class”, any company that already sells drugs into the NHS is at an advantage.*

One thing for certain is that the time to grasp opportunity is now. Markets in these places change quickly – an opportunity that exists now may not exist a year or two from now having been snatched up by competitors. For example, the UK has always been good at taking early research forward, but China is learning to do this as well at a much faster pace.

To sum up the opportunity, the example of Shenzhen was brought up. Designated China's first Special Economic Zone in 1979, its population has risen from just 30,000 to nearly 13m today, creating the first of China's 13 megalopolises and an economic powerhouse of manufacturing, electronics and design with its own Stock Exchange. Situated north of Hong Kong, it boasts the country's largest port, which is also the world's fourth busiest. It imports and exports more than any other Chinese city and is home to many producers of Western high tech goods, which tend to locate outside the core districts where labor and land are much cheaper. In terms of innovation its patent output is the highest in China both for domestic patents and PCT applications. Growth continues, with plans for integration with nearby Hong Kong. **Key message: UK companies are encouraged to ‘piggyback’ on the growth of Chinese Centres.**

## **Infrastructure**



Q: How differently is business conducted in the BRIC countries? Will the infrastructure pose problems? What extra input might be required from a UK base?

A: There are definitely cultural and infrastructural differences in BRIC countries, but with the right amount of research beforehand, these should not pose problems. Extra input from a UK base may not necessarily be a burden but rather something to take advantage of.

In terms of language, English is sufficient in most BRIC countries (with the exception of Brazil where it is still better to be able to speak Portuguese).

Cultural differences in terms of business conduct in China are apparent from the outset. Business is rarely conducted at all during initial meetings but negotiations tend to take place around talking and eating the local “delicacy”, and during drinks when it is easier to sweeten the honeypot for one party without the other party noticing. In India, the work ethic is unparalleled and customer service is very highly regarded. Education is at a very high standard, but – as in China also – students are discouraged from questioning. Coupled with a strong hierarchical structure, this can act as a damper to innovation. ‘Keeping face’ is also very important, and people will avoid asking or answering questions to which they don’t know the answer, in order not to look foolish. Critical issues may be overlooked as a result and it is therefore important to make sure all details are covered before making a deal.

Recent revisions to UK law mean that British companies need to be more transparent – and careful – about making and accepting payments, but these business ethics may not necessarily be fully understood in other cultures. The best approach is to state upfront that you are unable to make ‘facilitation’ payments, as this precludes misunderstandings further down the line.

Relationships are key in unfamiliar territories and investing in them is crucial. It is worth paying someone with essential experience of the market to help make connections and open doors. Using Business Development agents to expand your business in these and other countries means getting access to someone with language and cultural fluency, and contacts with the right companies. Increasingly, these agents are likely to have technological proficiency obtained from training in the US or Europe, and experience of working in the sector locally.

Infrastructure may pose problems depending on the nature of the SME. For example, it would be difficult for a UK clinical trial CRO to start up in the BRICs as they lack suitable expertise i.e. research nurses. In India, training schemes for such expertise exist to some extent; however, in Brazil and China, such training is non-existent. Finding individuals suitable for the job or developing training schemes would be extra work for the SME, and some skill-sets are especially difficult to find in certain BRIC countries for cultural reasons e.g. nursing in China is seen as a low-level job. This goes back to the point that market entry research beforehand may identify these hurdles. Hong Kong has the necessary nursing infrastructure so that a clinical trial CRO aiming at the Chinese market may be able to start in Hong Kong first. In this clinical trial CRO example, BRIC countries have access to a much larger pool of people at different stages of relevant disease states to choose from. In India, there is a strong customer service infrastructure, so SMEs with services that require a good customer interface would do well in India.



Surprisingly, a lack of infrastructure may prove to be an opportunity. China is beginning to take medical regulation seriously; however, they have ten times the workload of the US FDA, with a tenth of people to do the job. The Skills required for these tasks are well established in the UK and may provide good service opportunities.

**Key message: Research the infrastructure before BRIC entry, to identify where your best point of insertion lies.**

### **Intellectual Property**

Q: Should there be Intellectual Property concerns and is it necessary to worry about competition?

A: Intellectual property concerns will always be an issue, but no more so than anywhere else in the world.

Once, IP concerns may have been relevant (/justified?), but IP protection is becoming increasingly important in BRIC countries as well.

In China, there is a positive prosecution rate for IP infringement compared to other developing countries. Patent protection is also becoming increasingly important in Brazil. Improved regulation is welcomed, but in China medical registrations can now take up to two years instead of 8-9 months, and there may be a requirement for clinical trials that will require additional funding.

One thing to be cautious of, is the Model Utility Patent. Upon protecting your intellectual property, other parties might try to interfere by setting up MUPs (short term patent protection on the process or usefulness connected with a concept, which can be set up in under 90 days) to block the utility of your IP. So rather than copying you, they block you. Although the utility model patents rarely cause long term trouble, they are still short term interference that should be taken into account.

Counterfeiting is recognised by India and China as a serious global problem and both countries are steadily making progress through legal enforcement and tighter regulation. Penalties for infringement can be severe, but there is also recognition in the therapeutics sector that creating or acquiring one's own IP is key to premium pricing and creating value, thus making generics or 'knock-offs' less attractive. In India's thriving democracy with a vociferous media, with individual protection high on the agenda and a coalition government has had a paralysing effect on the civil service, stalling key aspects of decision-making with respect to regulatory processes.

In terms of competition, it is usually more expensive to produce abroad and import rather than produce at home. Often, partners in BRIC countries will ask to have the production brought into the BRIC country.

Looking briefly at the regulatory landscape, it was agreed that all three countries suffer from overburdened regulatory agencies that are slow to process applications and approvals, are biased strongly to internally-developed medicines and devices, and still have some streamlining to do. The governments of all three countries accept and have committed to addressing the lack of skill sets in this



area, either through supporting training in UK and other Western universities, or by buying in skills. **Key message: Given the pace of change it will not be long before BRIC countries become better at dealing with Western medicines, for which there is high demand.**

### Getting Out There

Q: What is the best way to obtain contacts and information? How much travel will be needed? Are there particular clusters to focus on?

A: All of these, again, depends on the nature of the SME. Doing the necessary research before any attempt to enter BRIC countries will make each of these easier. Fortunately, there are abundant resources for doing so.

In terms of obtaining contacts and information, one good way is to lay as much groundwork as possible from home. Rather than investing in all the initial legwork in the BRIC country to gauge interest, it is possible to set up an attractive website and have initial contacts made by interested parties in BRIC countries. Some members of the audience said that their webstats had shown a high level of interest from BRIC nations – up to 30% of web-traffic – but that in the main this had not converted to real business. Translation into the principal BRIC languages was suggested as one way to encourage more enquiries.

Another means of initiating contact is by going to key international partnering conferences and making contact with BRIC attendees. Their willingness to travel to these conferences, usually under visa restrictions and having overcome bureaucratic hurdles at home, signify their dedication to finding international partners.

The size and scale of the BRIC countries is easily underestimated and they cannot each be regarded in the way that one might think of a single country in Europe. China in particular is vast and diverse; urbanisation has driven up city populations to unprecedented levels. As for choosing particular clusters to focus on, this depends largely on the investigation done on opportunity and infrastructure. These will largely determine where to focus. In China, the traditional focus has been on the East; however, there is increasing government support for expansion into the West and aid might be provided to SMEs looking into expanding into such areas. (Does this mean the East and West of China? If so, can we insert some examples of regions to get bearings? Is the aid referred to, OMIS and P2E?)

UKTrade & Investment's OMIS (Overseas Market Information Service), Passport to Export and Gateway to Global Growth services do help with the early steps of identifying contacts and leads, and they can provide some matched funding for translations and other services. UKTI also organises foreign missions, often with the support of Accredited Trade Organisations (ATOs) such as the BIA and BioPartner, taking UK companies to areas of critical mass. Usually focused around a significant international conference, these missions provide opportunities to meet with local company representatives. There was some opinion from the audience that UKTI does not do enough to make the sector aware of these and other services.



Travel should be taken seriously. Potential BRIC partners want to gauge your commitment and this can be shown by making the necessary face-to-face visits.

Barriers to Commerce came up frequently during the discussion. For example, selling directly into the Chinese market is not permitted for WOFEs (wholly owned foreign enterprises), necessitating either creative export/import or the formation of joint ventures with local firms. The shareholder composition of a JV then becomes an important determinant of the profitability of the venture. A number of agencies and consultancies specialise in assisting UK companies to set up shop in China; the China Britain Business Council (<http://www.cbcc.org>) will act as an agent for UK companies. China also operates the 'Thousand Talents' programme – the equivalent of £10,000 is available as a grant from the Chinese government to start building a business from the ground up. This money is available to individuals as well as companies and can be used to import talent.

Licensing and acquisition are possible routes into China or India, where significant Life Science companies are building global businesses through buying up valuable products, services and technologies – notably Piramal, Dr Reddy's, and WuXi. Chinese companies are increasingly looking externally for both acquisition and licensing. One model is to 'sell' your marketing rights for China, for up to 10% of profits – this can be very attractive for a relatively early stage product as long as it is developed in a correct and timely manner by the licensee.

**Key message: Talk to several advisors about the various options before embarking on a strategy; hiring a local representative, setting up a JV or starting a new entity in a BRIC country may mean the difference between success and failure.**

## **Conclusions**

Dramatic growth that continues despite global financial problems, increasing affluence and an appetite for quality consumer goods and effective medicines mark the BRIC economies – and several others – as trade targets for UK companies with top-drawer products and services. British companies are successful in these markets; for instance, Astra Zeneca's sales in China topped \$1bn in 2010 and continue to grow. For most UK SMEs in the Life Science sector, the majority of international business comes from the USA, followed by a subset of European countries, and there is little evidence of any move to increase BRIC trade or collaboration. It is perhaps no surprise that of all the companies represented at the 2012 BioPartner Discussion Forum, the only ones with a significant presence in BRIC were suppliers of quality research materials, whilst companies in other sectors had either tried and found no traction, or had found no evidence to persuade them to expand outside of their currently successful markets. Our 'show of hands' at the close of this year's discussion demonstrated that no one had been persuaded to reconsider their stance, at least for now.

**Footnote:** One month on from this discussion, 2 of the companies attending had reported significant moves to establish a presence in India and China.