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CMOs: A robust growth trend

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CMOs: A robust growth trend

The extent to which outsourcing can be done is quite extensive, so much so that there have been propositions of a virtual company where the company will be in the sole possession of intellectual property and run by a handful of people. This actually is not a farfetched idea, in a few years it maybe a reality. For now, CMOs in Asia are on a rollicking growth path

The pressure to reduce or maintain costs, while increasing productivity, has been the driving force in outsourcing in the life sciences sector. Outsourcing is happening across the whole spectrum- in the pharmaceuticals and biotechnology sector right from drug discovery research, preclinical studies, clinical trials, manufacturing, packaging, distribution to even sales and marketing. In the medical devices area outsourcing is happening in design, component manufacturing, device assembly, (from individual components) and supply chain management (in the form of packaging, warehousing, sterilization).

The contract manufacturing outsourcing (CMO) market growth continues to be driven by its attractiveness to the small and emerging biopharmaceutical companies, which do not have the resources to invest in manufacturing capacity. Global biopharmaceutical contract manufacturing is poised to grow from $2.45 billion in 2007 at a CAGR of 14.9 percent between 2007 and 2014, according to market analyst firm Frost & Sullivan.

North America continues to remain the primary demand driver for contract manufacturing. Europe and Asia are emerging as strong contenders, with significant new capacity being added in Asia, states Amit Ghosh, pharmaceutical consultant at Frost & Sullivan.

Asia Pacific offers a significant cost advantage with outsourced research or manufacturing savings that can range from 50 to 80 percent. This is likely to boost the volume of outsourced work to this region.

Ghosh forecasts a definite growth in the CMO for all sectors primarily generics, biopharmaceuticals and medical devices. Asia will continue to hold its lure with low production costs; increasing reliant manpower; local governments' incentives to lure CMOs in their respective countries; implementing stronger IP laws to assure companies of the viability of producing /outsourcing to their countries; and expanding healthcare markets in the growing economies.

In the ensuing pages BioSpectrum brings you an overview of some of the key countries in Asia Pacific region where the companies engage to outsource and do contract manufacturing.

Coming to specific outsourcing areas, both pharmaceutical and medical devices companies outsource heavily in the manufacturing, packaging and distribution but areas like R&D, sales and marketing-activities which are considered to be their core competencies-are kept under close control. In fact, most of the big pharma companies find that offshore outsourcing in some areas like manufacturing or packaging, distribution or clinical research has a synergistic effect in their overall vision of entering newer markets faster with minimal investments.

The extent to which outsourcing can be done is quite extensive, so much so that there have been propositions of a virtual company where the company will be in the sole possession of intellectual property and run by a handful of people. This actually is not a far fetched idea, in a few years that level of sophistication maybe a reality.

Systemic catalysts for growth of outsourcing in Asia are stable government regimes, rising healthcare funding by the governments, better IP protection being promised and implemented by the governments.

China

In the last decade, China has begun undergoing a series of changes with which, healthcare provision must keep-up in order to ensure that the patient population needs' are satisfied. The Chinese population is aging; hence there is an increase in the number of patients solely dependent on government healthcare funding. The Chinese government is attempting to invest in the state-of-art medical devices and pharmaceuticals. The biggest issue for companies outsourcing manufacturing to China is intellectual property protection, which the Chinese government seeks to address through implementing tighter controls when introducing better IP laws. China's move to join WTO encourages a positive perception of the country among the foreign companies.

The CMO sector in China is set to increase by leaps and bounds in the coming years, showing a very rapid increase in the number of players. It could pose a serious challenge to India in the coming years. The Chinese government has begun to support and encourage this sector, through implementation of a solid regulatory framework to instill confidence among outsiders.

Generics

Chinese bulk drugs and API producers are among the largest in the world and are known for their lower prices, but in terms of generics they are still quite far behind India. This is because India started quite early in the generics production scenario, whereas the Chinese drug manufacturers concentrated on APIs. In this sector of CMOs for generics, China though a late bloomer is poised for a rapid growth in the next 10 years, serious enough to pose a challenge to India. Zhejiang Huahai

Pharmaceutical was the first Chinese company to get FDA approval in 2007 and will be exporting its finished drug to the US by 2012-when the patent held by Boehringer Ingelheim GmbH for the AIDS drug nevirapine expires. By charting its development, we can safely say that it will take a long time before China can catch-up with India, which is about 10 times bigger in terms of exporting generics. But given China's expertise as the world's largest producer of raw materials for drugs and manufacturing, this is surely a stepping stone for the country to make waves in generics outsourcing. Also, looking at the fact that about 40 percent of the existing production capacity of pharmaceutical producers remains unutilized at the moment, it can be said that the capacity to become an outsourcing powerhouse for generics does exist in China.

Biopharmaceuticals

At present about 40 percent of the production capacity of pharmaceutical producers with China is lying idle. These companies need newer sources of revenue to expand and remain viable, which can be used for biopharmaceuticals manufacturing. The demand for biopharmaceuticals is growing within China and elsewhere in the world. So, the venture into biopharmaceutical production is an option being considered by many of these producers now.

Though the output of biopharmaceuticals from China is insignificant at the moment, the potential market in the near future is expected to be large. While considering exports to western countries, the primary challenge faced by the Chinese companies right now is the stringent quality norm requirements of western companies and governments. They have to modify their facilities and train their staff to meet the requirements of the western companies and agencies, including the FDA cGMP or EU COS certification. As of now, very few Chinese contract manufacturers have managed to get this kind of certification. The Chinese government and the industry is pushing for these standards, which will lead the players to quickly capture the growing segment, not just in China, but worldwide as contract manufacturing of other companies looking to produce cheaply in China.

Some of the companies at the forefront of the biopharmaceutical uptake are Beijing BaiAo Pharmaceutical, Beijing WanTai Biological Pharmacy Enterprise, National Vaccine & Serum Institute, Shanghai CITIC GuoJian Pharmaceutical, and Shenzhen Neptunus Interlong Biotechnology.

Medical devices

China is one of the fastest growing areas for medical devices; both in terms of domestic and foreign sales into China and production from within China for export purposes. China became the eleventh largest market globally for medical devices in 2004, accounting for approximately $3.5 billion. The medical devices industry is mainly located in the eastern cities of China. These include Beijing, Guangzhou, Shanghai and Tianjin. High levels of demand in these areas further promote the industry. It is thought that over 250 medical devices companies have operations in China, yet are headquartered remotely across the globe. The Chinese government has set up Special Economic Zones (SEZs), which encourage establishment of businesses by foreign companies by offering tax reductions.

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The CMO sector for medical devices in China is also set to increase in the near future, with companies adopting and understanding the high levels of sophistication required for production of medical devices. There are a good number of companies already doing contract manufacturing for exports, but the exact figures are difficult to come by. The problems faced by the western companies are similar to pharmaceutical producers of west, such as the issue of IP protection, and quality issues, however, as costs take precedence the rise of contract manufacturing in China is inevitable. Also, lowering profit margins of other machineries and toy manufacturers is forcing these players to look at medical devices as a future source of revenues.

Malaysia

Malaysia has one of the highest government expenditure on healthcare, which is about three percent of the GDP. Its healthcare industry is considered to be one of the best in the region and attracts a substantial number of medical tourists. Country's 90 percent of the expenditure on public healthcare is funded by the government, clearly presuming that generics in Malaysia is also on the rise. This doesn't seem to be the picture in reality though. Both prescriptive drugs and generics don't seem to illustrate growth due to lack of regulations and enforcements. Generics sold in pharmacies in Malaysia are quite regularly found to be counterfeits, causing a great deal of concern within the government. In order to regulate and control the use of pharmaceuticals the government has come out with standards and guidelines such as the use of particular holograms

for drugs approved by the government. There is also encouragement to the companies with "standard of practice" and incentives to set up base in Malaysia, some of which are:

- Income tax exemption of 70% or 100% on the statutory income for five years, or
- Investment Tax Allowance of 60% or 100% on the qualifying capital expenditure for five years, or
- Reinvestment Allowance of 60% on the qualifying capital expenditure for 15 years

Some other General Incentives

- Industrial Building Allowance
- Infrastructure Allowance
- Import duty exemption for: raw materials/components; and equipment and machinery.

Generics & biopharmaceuticals

Currently, CMO for biopharmaceuticals is minimal in Malaysia as most drugs (both branded and generics) are mostly imported, even with the presence of some mid-sized pharmaceutical producers in the country. In February 2006, Malaysia got its first biopharmaceutical plant with current Good Manufacturing Practice approval. The company Inno Biologics Sdn Bhd was a turnkey project from Malaysia, a plant built in Germany with assembly done in Malaysia. Contract manufacturing to other pharmaceutical companies is one of the many services offered here.

The future of CMOs is likely to improve in Malaysia, as the government is encouraging the use of generics in its healthcare system. The expected outcome in the coming years will be contract manufacturing mostly for local consumption in Malaysia, and export to a few neighboring countries, because most pharmaceutical companies will find it prudent to outsource to countries like India or China, because of costs.

Medical devices

Malaysia is a well-known name in the medical devices sector, with current revenues estimated at $1.4 billion, and is expected to grow at eight percent for some years to come. It happens to be the highest exporter of surgical gloves and catheters. Medical device companies use Malaysia as their global base for developing, manufacturing and marketing a wide range of products and services-from single use products, equipment and diagnostics to packaging and sterilization. Malaysia offers the lower end spectrum of medical devices, using rubber and plastic components in the majority of the manufacturing done here, although being a net importer of high-end medical devices. There are about 170 medical devices companies in Malaysia, with a handful of them carrying out contract manufacturing for export purposes. The CMO sector for these products is set to rise in Malaysia with a decent procurement from global players. Also another parallel trend seen in the devices manufacturing in Malaysia is the setting up of wholly owned manufacturing units by global manufacturers like Braun, 3M, Ansell and others. Thus Malaysia is poised to offer a bright future for both company owned manufacturing and CMOs in the years to come.

Singapore

Regionally, Singapore offers the best benefits to companies willing to outsource in terms of experience, track record, IP protection, regulatory compliance and strong incentives. On the manpower front, Singapore excels in the region and this can be gauged from the country's serious focus on managing skilled talent pool, comprising researchers, scientists, engineers and technicians. This makes up about 93 full-time equivalent researchers per 10,000 labor force, which is on par with many developed countries like Sweden, Japan and the US. Singapore has attracted numerous leading medtech companies to its economy and has encouraged them to establish commercial operations, R&D centers and manufacturing facilities. Some of the notable names in the Singapore contract manufacturing scenario are CEI Contract Manufacturing Limited, Encus International, Eng Tic Lee Achieve, Forefront Medical Technology, Interplex Singapore, Inzign, John While Springs, Nano

Technology Manufacturing, Racer Technology and Rayco Technologies.

Generics

Generics form 10 percent of the pharmaceutical industry in Singapore. Due to its small population, the consumption of generics as a whole is quite insignificant. With the progression of aging population and decrease in government funding being two crystal clear incentives to develop more generic drugs, nevertheless overall uptake of generics is not very lucrative for most companies in the country. Existing companies are facing tight competition in margins. The contract manufacturing sector for generics is not poised for a growth in Singapore, since it will be for the local market.

Biopharmaceuticals

Singapore has some of the big names in contract manufacturing like A-Bio and Lonza, manufacturing for the likes of GSK, Genentech, and Novo Nordisk. Some pharma giants like Schering Plough and GSK are pretty convinced by the investment incentives in Singapore, and they have moved forward to set up their own manufacturing base here.

Singapore already has a reputation as a trusted site for bulk drugs and secondary products, and the country now aims to become the outsourcing hub for biologics. And its basics serve Singapore well on its path to achieve that status. Many outsourcing majors in developed countries will unhesitatingly come to Singapore as compared to India or China as they are convinced with Singapore's IP protection laws. The CMO scene for biopharmaceuticals in Singapore is set to grow with the recent government initiatives and also the growing confidence of manufacturing companies in the technical capability of its skilled manpower. Companies will also be sold on the strong IP protection provided and the close proximity to ASEAN countries.

Medical devices

Singapore always had a very advanced electronic manufacturing base. This has augured well in its becoming a center for medical device manufacturing. With increasing sophistication in medical devices, in the form of small electronics components being introduced into every kind of medical device, Singapore was well positioned to take up the challenge in its stride. As contract manufacturers from Singapore have been very aggressive in promoting their services abroad, medical devices' CMOs may find that Singapore fits their requirements for producing highend devices. However, high cost of production in Singapore is a cause of concern for people looking to outsource.

Most medical devices companies have their regional offices and distribution centers in Singapore, also proximity to big markets in the ASEAN region was very well suited as a base for exports into these countries. But, the trend for medical devices' CMOs in Singapore is not towards growth, the growth expectations can at best be described as modest. Singapore government's own agenda of becoming a big player in the medical tourism market will lead to Singapore being a vibrant market for medical devices, but how much of that will lead to contract manufacturing in Singapore remains a big question. It is quite likely, that the CMO sector for medical devices in Singapore will remain confined to hi-end devices requiring a good degree of technical manpower.

Australia

ustralia is one of the richest healthcare markets in the Asia Pacific region and ranks as the 11th largest in the world. Per capita spending is on a par with European markets such as Germany and the Netherlands. Local manufacturing is high tech, but tends to be fragmented and small-scale. A few multinationals, such as GSK, have major facilities in the country. Much of the market, however, is supplied by imports. The contract manufacturing outsourcing in Australia is not a major force in Australia, primarily because of the small size of the market and its lack of appeal of being an export hub, vis-Ã -vis, the Asian CMO scene.

Biopharmaceuticals and generics

The Australian government has supported and encouraged the development of contract manufacturing; Australia is not a big market for generics, though the generics are priced very competitively. The cost of branded drugs in Australia is not very high, so it is an impediment for the generics market. There are a few big local players in the generics market in Australia, so the trend of CMO for generics is very low growth. For biopharmaceuticals the government wants to encourage the local production of biological drugs. In 2006, the government granted $10 million for the establishment of mammalian cell production facility, where local companies can produce their small batches of complex biological material for clinical and pre-clinical studies. Prior to that, these used to be done in Singapore or even the UK and the US. So, the trend for CMO, in

Australia is for local consumption, instead of exports.

Medical devices

The medical devices sector in Australia, comprises local small-to-medium sized enterprises (which often possess a niche product), including both domestic initiatives and subsidiaries of global companies, importers and distributors, the players are not very active in CMO, whatever manufacturing is done, is for the local consumption in Australia.

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