Indian bulk drugs manufacturing in peril

India's active pharma ingredient requirements were till recently met through domestic manufacturing. But China's subsidies, tax incentives and infrastructural investments have led to a dramatic increase in Chinese imports

RAMESH ADIGE

India can easily hope to be known as the 'pharmacy of the world'. Already, Indian generic pharmaceuticals are finding their way into all the markets across the globe and are known for their quality and affordability. India ranks 13th in value terms and 3rd in volume terms in the global pharmaceutical market. Drugs from India are exported to more than 200 countries. According to a report by PwC, India is expected to join the league of the top 10 global pharmaceuticals markets in terms of sales by 2020, with the total value reaching $50 billion. Factors like expanding medical infrastructure, health insurance, rising healthcare spending, a huge untapped healthcare market and changing disease patterns will provide a surge in growth of the Indian generic industry in the domestic sector. In exports, the impending patent expiries will make an over $100 billion market available (at innovator price). India is poised to rise to greater heights as the provider of high-quality, affordable generic medicines for the whole world, given that all countries are taking cost containment measures in healthcare.

Our country can be proud of the fact that we have around 169 USFDA-approved facilities in India and around 153 EDQM (Europe) certified manufacturing units. Almost 35% of all active drug master file (DMF) filings with the USFDA are from India (2,759 DMF filings as of December 2011). On the manpower side, the growth of the generic pharma industry in India is underpinned by the availability of a large talent pool of English-speaking technical and scientific personnel. Every year around 300,000 post-graduates and around 1,500 PhDs qualify in Biosciences. In chemistry alone, around 150,000 Masters in Science qualify every year.

Fully-integrated manufacturing is one of the key strengths of the Indian pharmaceutical sector. Manufacturing costs in India are competitive in comparison to the western countries. India is Trade-Related Aspects of Intellectual Property Rights (TRIPS) compliant. Our scientists are adept at working around patents and going up the value chain in generics manufacturing, by providing differentiated formulations based on novel drug delivery systems. The cost of innovation is a fifth or a seventh that of Europe/US. But it is important that we are not overtaken by China.

The Chinese threat

The requirement of bulk drugs, also known as the active pharmaceutical ingredient (API), for the Indian pharmaceutical industry was till recently met by API manufacturing in India. API is the principal product that is used in dosage forms such as tablets, capsules, liquids, and injectables, on the basis of safety, efficacy & quality parameters. However, in the last few years, large-scale imports from China have impacted API manufacturing in India. Chinese imports are cheaper and highly subsidised. Approximately ₹8,000 crore of Chinese API, and intermediates (the raw material for manufacture of API), are being consumed by the Indian pharmaceutical industry. China presently supplies over 30% of India's requirements of APIs.

China has emerged as the dominant player in the global API industry due to its large-scale manufacturing capabilities of APIs and intermediates, with strengths in fermentation technology. There is a challenge of quality and supply consistency. Importers are managing this by judiciously identifying right sources in China and monitoring the supplies/deliveries.

Globally, innovator companies do not outsource APIs for their products till they

are protected by patents. However, after the patent expires, innovator companies gradually begin outsourcing APIs in order to achieve greater cost efficiencies to compete with generics. Companies like Pfizer, AstraZeneca, GSK and others are partnering with API suppliers in China to fulfill their bulk drug requirements.

It is evident that the API manufacturing base is shifting to China globally, not only for generic manufacturers, but also in the case of innovator companies for post-patent molecules. Of late, even formulation manufacturing is starting to shift to China.

Where China scores

The Chinese government provides support to its intermediate and API manufacturers via export benefits (7% of FOB value), tax benefits (incentives for R&D, reduced level of income tax) and direct funding (plan to invest $750 million for promotion of intermediates and API manufacturing). In addition, it has bio-medical parks and 5 SEZs—Shenzen, Hainan, Zuhai, Xiamen and Shantau. Apart from this, a two-year tax holiday, followed by three years of 50% tax, coupled with excellent infrastructure, goes a long way in boosting the Chinese pharma industry.

There is also a systematic focus on quality. The New Drug GMP 2010 programme, published in February 2011 mandates: (i) Stringent quality systems in manufacturing (in line with international standard) and (ii) all manufacturing plants must comply with the New Drug GMP 2010 programme. The Health Reform Plan of 2009—with a $125 billion investment in overall Chinese healthcare—is ongoing.

China also has advantages in human resources with a disciplined labour supply. The Chinese government is encouraging overseas Chinese PhDs to return home. Around 80,000 persons with PhD have already returned. Coupled with this, low power tariffs and low capital costs further boost the industry.

India had displaced Italy as the major global source of API, but China has now taken the lead. Policy interventions must happen so that India regains and retains its position as the top provider of APIs and formulations for global requirements. One can recall that during the Beijing Olympics in 2008, China closed most of its API plants to reduce pollution. This resulted in an almost 20% increase in Chinese API prices. We had no alternative since China has a near-monopoly in several APIs.

Basic chemicals and early-stage intermediates do not require a Current Good Manufacturing Practice (CGMP) compliant facility and manufacturing of intermediates is not environment-friendly. It may therefore be desirable to encourage Chinese intermediates and discourage Chinese APIs for import into India.

How to meet this threat

The import duty structure can be changed so that APIs fall in the highest bracket (increase from present level of 7.5%) and intermediates fall in the lowest bracket (reduce from present level of 7.5% to less than 5%). As far as fiscal support is concerned, we can provide export benefits for APIs and formulations similar to China, additional tax holiday zones and extensions of SEZ benefits for API manufacturing plants, increased R&D incentives, low interest rate loans and dedicated API parks with incentives, common infrastructure, etc, to avoid duplication of investment.

Other areas of support include a subsidy for effluent treatment plants and other similar investments, subsidised power for fermentation-based intermediate facilities to support the fermentation based pharma industry, a robust vendor registration process for imports, including overseas plant inspection by the Drug Controller General of India, similar to what USFDA & MHRA do. Inspectors should be posted in Beijing and Shanghai in our embassy or consular offices.

Public sector units should be revived, not really to meet competition from China, but in order to provide an assured manufacturing base for intermediates and APIs. We should encourage PSUs to get back into business. This is so as to meet national health security needs. Considering the high volumes and usage in manufacture of API, to start with, the following advanced intermediates can be manufactured by Indian PSUs: Erythromycin Thiocyanate (used in manufacturing antibiotics), 7 ACA (used in manufacturing antibiotics), OTBN (used in manufacturing anti-hypertensive drugs), Penicillin/CAPA/FADCS (used in manufacturing antibiotics), Menthyl 5R Hydroxy-1, 3 Oxathiolone, HME (used in manufacturing anti-HIV/AIDs drugs), Beta Thymidine (used in manufacturing of anti HIV/AIDS drugs), RIFA-S (used in manufacturing anti-TB drugs), Cystofer base (used in manufacturing anti-ulcer drugs) and Iso Buty benzene & sodium dichromate (used in manufacturing Non-steroidal anti-inflammatory drugs)

Similarly, the following APIs can be considered for manufacture by Indian PSUs: (a) ARVs—Lamivudine, Nevirapine, Zidovudine, Efavirenz, (b) Anti-malaria—Artemether, Lumefantrine, (c) Anti-TB—Rifampicin, Ethambutol, Isoniazid, Pyrazinamide, (d) Anti-inflammatory—Ibuprofen, (e) Anti-ulcer—Ranitidine, (f) Antibiotics—Amoxycillin, Ampicillin, Cloxacillin, Cephalexin, Ciprofloxacin and (g) Combination with antibiotics—Potassium Clavulanate.

When the government makes investments in PSUs for the manufacturing of important advance intermediates and/or APIs, profits should not be anticipated in the initial years, since this is a long-term strategy to meet public health needs, especially in emergencies.

If we take harsh steps against China, it is likely that China may take retaliatory measures to prevent generic formulations being exported from India into China. It must be kept in mind that China will be a huge market for formulations. As per an IMS report, it is predicted that China will be the third-largest market after the US and Japan in the next 2-3 years. India must take advantage of this market. India must take definite and calibrated steps. The world has seen trade wars fought for beef, bananas and basmati. Once we have our priorities clear, India and China can also engage with each other in a spirit of 'co-opetition'—competition and also cooperation in the pharmaceutical space.

The author is former executive director, Ranbaxy Labs Ltd