5. Accelerating the Growth of Generic Pharmaceutical Industry

5.1 Paucity of Funds to Move to the Next Orbit

Most organisations in India, China and developing countries have begun their journey recently. Establishing a regulatory compliant manufacturing infrastructure and developing a quick product portfolio to run these manufacturing engines is quite expensive and consumes most of the borrowing power. The availability of funds for long gestation but high return projects, building broad product / market portfolio, entering into new technologies, etc., is an important issue which deserves attention of the government.

5.2 Complex Technologies

India's presence in injectible dosage forms, steroids/hormones, sustained or controlled release drugs, poor solubility drugs with difficult bioequivalence, dermatologicals, ophthalmologicals, etc., is almost negligible. India has a number of DMFs and ANDAs in conventional vanilla generic products either for off patented products or patented products. Typically, an immediate release generic ANDA could cost around US$1million to develop and register. A specialty generic such as sustained release formulation could cost more than US$3-4mn. Neither small companies nor public companies with huge pressure from stock markets can build large or specialty portfolio in the current circumstances.

Many of the untapped opportunities are not impossible to capture as several corporations like Impax, Schwarz Pharmaceutical, Abrika, Skye Pharmaceutical and scores of companies have hugely benefited from the focus on specialty generic APIs and formulations. With stretched balance sheets a new initiative has to be conceived to push the industry into the next orbit. India with significant lower costs of innovation and testing is better placed to capture these opportunities.

5.3 Creating Broad Portfolio

It is a known fact that broad portfolios are crucial for success. Broad portfolios come either through mergers or through significant manufacturing and R&D investments. The product portfolios of most Indian companies are insignificant in size as compared to competitors. The R&D costs, being revenue expenditure, by and large in generics, to create such a product portfolio further stretches the profitability and market capitalisation of the companies. Novel financing concepts to fund intangible assets are practically non existent.

5.4 Building Market Portfolio

Commercialisation of intellectual property across several markets enables enough profitability in the current competitive context. Most Indian companies are not having financial muscle to file drug registration applications in all target countries. Unlike India, the drug registration costs in Europe, Australia, Canada, etc., are prohibitively expensive (the registration costs are at least 50 to 200 times more than Indian costs) leave alone other costs such as meeting their country requirements like bioequivalence with local reference product, etc. Once again neither alliances exist between local players to penetrate several countries nor are venture capital concepts prevalent to push innovation to several markets. (Refer Appendix VI for Mergers & Acquisitions scenario of India.)

Building Portfolio for Untapped Highly Attractive Opportunities

Prioritised funding by institutions like EXIM Bank through Special Purpose Vehicles (SPVs) has to be pursued aggressively. Such SPVs shall contract product development work for excellent but high initial cost opportunities such as specialty generics, topicals, steroids, hormones, biopharmaceuticals, non infringing process based DMFs/formulations, ANDAs, etc. Obviously, such funding is not a loan stretching the balance sheets of companies nor an equity dilution in the current company. An agreed percentage of revenues from the SPV funded projects will go back to the funding bank towards the investment and Internal Rate of Return (IRR). Once the funding BANK recovers its investment and IRR, the ownership of the products will flow back to the company without complications. Public and private initiative on a mega scale in this area is essential for jumpstarting India's pharmaceutical industry into a higher orbit achieving quantum growth.

5.5 Access to International Markets- Need for a Policy Environment

Inter & intra country competition is significant to capture the opportunity in pharmaceutical intermediates, APIs and formulations. The intermediate, API and generic formulators from India, China and established European API/formulator firms are facing three challenges:

a. Growing consolidation of large generic marketing organisations
b. Consolidation of pharmacies termed as pharmacy chains and distributors and
c. High cost of developing ANDAs/DMFs and subsequent registration at key markets.

Hence, the number of players sourcing APIs or formulations is coming down giving way to tremendous bargaining power in the hands of large generic firms or distributors/pharmacy chains, obviously causing price erosion and pressures on profitability. The financial power and business wisdom in developed world ensured significant consolidation in the generic marketing organisations and distribution/pharmacy chains fronts.

At the same time new players like India and China had very little consolidation or mergers between the native firms causing heavy crowding of markets and price erosions. Consolidation between native companies could create large corporations who in turn either can with stand the pressure of consolidated buyers or buy access through purchase of relevant marketing/distribution organisations. The costs saved in duplicated research efforts and the avoidance of capital expenditures can boost the financial muscle while at the same enabling them to compete with the global generic conglomerates. However, as at present, fragmentation is the order of the day in developing countries. Institutional approaches for encouraging consolidation need to be examined. A consortia approach to creation of a special purpose vehicle adequately supported by venture funds, exclusively charged with accessing developed markets could be considered as a means of breaking market monopolies in these countries.

Developed country players are using these opportunities to vertically integrate through acquisitions and there by compete with the emerging third world players. As the opportunity to become “big” comes down, the opportunity to be self reliant through native companies’ drug discovery programmes extinguishes, exposing large population economies such as India to western inventions only. The per capita income differential being very high, the affordability of international drugs can become a significant issue. Limited resources of fragmented companies do not allow M & A activity to buy access into other countries. In several countries, governments have initiated, through policy action, strategic Mergers & Acquisitions in national interests.

Engineer Alliances to Protect Strategic Interests of the Country

Alliance initiatives between domestic companies funded through a venture capital concept by Exim bank, etc., should be promoted. Prioritizing funds to promote internal M&A is necessary in creating large Indian companies to counter the increased bargaining power of consolidated buyers.

The recent takeover of controlling interest in Pharmaceutical major Ranbaxy by the Japanese multi-national Daiichi has raised several questions. India has witnessed in the last five years several takeovers by Indian companies of brands, equity holdings, controlling interests, intellectual properties etc., all over the world. These efforts have been consequences of realization that economies of scales have to be achieved, difficult markets have to be accessed, monopolies of multi-nationals in holding patents have to be breached and strong research and development initiatives have to be taken. Companies like Ranbaxy, Dr. Reddy, CIPLA and others have for a long time been at the vanguard of this ‘movement’ and represented the new belligerence of the Indian pharmaceutical industry.

Ranbaxy takeover appears to be a ‘perfect fit’ at the firm level. Ranbaxy needed huge doses of capital, to meet high costs of patent challenges, R&D and high entry costs in foreign markets; Daiichi on the other hand required large network of markets and proven capacities and know-how both in research and manufacturing. Over 11% of the global pharmaceutical demand is generated in Japan. The national health commitments in Japan due to a variety of reasons including the rise of old age population is causing Japan to look at generics to reduce their national health spending. Therefore, it fits well with the perspective of a Japanese multi-national to acquire a company like Ranbaxy. Some other companies at the top end of Indian pharmaceutical industry have also been vulnerable, lately.

However, these developments need to be seen in a perspective which is not constrained by market dynamics alone. Indian generics are addressing typical concerns of developing countries in their larger national health commitments. The generic requirements of developed countries are somewhat different from those of developing countries for a variety of reasons. Indian generics operate at very low margins which make them quite competitive.

Some contemplate that a multi-national innovator like Daiichi may not look at Ranbaxy acquisition in the same perspective as we do. They apprehend that over time Daiichi might like to re-orient Ranbaxy to serve the needs of its Japanese generics market. Secondly, in order to take advantage of better realization from developed markets, Ranbaxy might re-orient its production basket more specific to the developed country needs. Thirdly, Daiichi may use Ranbaxy's excellent R&D infrastructure to developed country requirements rather than the larger public health based developing country requirements. Fourthly, Ranbaxy's passing over to an innovator parent, may dampen the 'spirit' of Indian pharmaceutical industry.

This may increase the vulnerability of Indian companies. It is noteworthy that most of the big Indian companies are small by global standards. It may be worth recalling that controlling interest in Ranbaxy could pass on to Daiichi in a deal worth US $ 4.6 billion. There may be several other companies in the same league where controlling interest may require much lesser investment. In such cases a take-over would be even easier. It is apprehended that a few more takeovers of this kind may neutralize the sting out of India's generics revolution. This may even be a good strategy for the 'innovators' to 'silence' the generics frontrunners, thereby retaining their innovation foundations while acquiring huge generic potential.

It is no surprise that hurdles have been coming in the way particularly accentuated in the last five years. Whether it was the debate on ever greening and data protection; patent challenges in the US; a variety of subterfuges on 'counterfeiting', including the debate in WHO general assembly or the regulatory biases reflected in some markets in Africa or other developed countries or hasty efforts at developing a multilateral regime, which have been confronted with a sustained and consistent approach adopted by the government and the domestic industry. Government of India has withstood these challenges with determination. But it is time to consolidate the progress in comprehensive manner.

Companies, even in the top league in India have been finding the going tough due to difficult and complex access regimes in developed markets such as US and Europe; and limited financial, technical and human resources at their command. Even if India is able to take a 10% slice in the emerging market in developed countries it will open an opportunity of around $50bn. at current prices of patented and branded drugs. In terms of generics it will be much lesser yet huge in proportion to our present exposure. In order to catapult this sector into the next orbit of growth, strategic investments in research and development, technology and market penetration are necessary.

Access to developed markets cost a fortune in terms of product dossier development expenses, regulatory filing costs and potential litigation costs. It is estimated that preparation and registration of a Drug Master File or an Abbreviated New Drug Application (ANDA) cost (product dossier development cost) between $ 1 million to $ 5 million in the US. Similar expenses are incurred in other developed markets. Developing a non infringing process to come around the IP bottle necks is another huge expense. Breaking the complex maze of IP woven by multinationals requires deep understanding of law and practice and it costs large doses of money. Most developed markets are now under tight grip of a few distribution entities across the world. Even the larger Indian companies have found it difficult to meet these costs as great risks are associated with them.

A very liberal domestic entry regime and a fragmented structure of industry make India vulnerable and it is therefore suggested the country needs consolidation of domestic industry.

All of this throws up challenges of unique financing mechanisms and institutional forms besides investments in creating capacities in research, law and science and technology.

Indian pharmaceutical industry has reached its enviable position with no less contribution from an encouraging domestic policy and legal environment. The sector has been nurtured through government policies and a strong human resource base particularly in chemical sciences, supported lately by contributions from bio-technology. Huge opportunities are awaiting Indian pharmaceuticals in potential space to be created by drugs going off patent, contract research services and manufacturing, etc. The industry does not need hand holding but would need in place, strategic controls and directions in national interest and for exploring global opportunities. Therefore, it may be questionable to believe that pharmaceutical sector in India does not require adequate props from the establishment. One takeover may not shake the confidence of the industry; however a few of them could have potential to do so and might change the entire course of pharmaceutical movement in India. Some might suspect the need of regulatory additions in the modern market-driven environment, but it may be opportune time to reflect if we need greater policy intervention to help pharmaceutical industry catapult to the next orbit.

5.6 Promoting Internationally Competitive Manufacturing

Currently, there are considerable efforts in various countries for developing pharmaceutical exports. There are countries which have specialised in contract manufacturing for global markets. Pharmaceutical industry for international generic markets is capital intensive as several varieties of products need dedicated high cost facilities. Profitability can be achieved only when the product penetrates various markets across the world. Further, different countries have different packaging specifications.

1. Transfer pricing to EOUs or SEZs is another issue which needs consideration. The Indian entrepreneurs have invested in huge capacities in the recent past. Appropriate capacity utilization in multi-product facilities takes a long period of time. Under the current excise rules, the transfer price from one unit of the company to other unit is well defined. However, in the initial phases of development, the transfer price from a new unit could be far more than the available market price or export price to outside customers. In such cases the tax benefit offered by SEZ or EOU suffers. Hence for inter unit transfers, for the purpose of exports, either the transfer price as calculated by department or price sold to the market (as was under earlier law) should be considered. Although the anomaly looks trivial, it has serious consequences as it will have impact on make or buy decisions affecting the domestic growth.

Streamlining Inter-unit Transfer Pricing for Export Purpose

Pharmaceutical manufacturers should be given the option for determination of transfer prices for internal movement of goods based on cost price as calculated or price charged to external customers.

The list of key cities where inter-unit transfers are smoothened by excise department needs to be expanded realistically.

2. Recently some inputs such as steel are attracting export duty. As per the recent law, SEZ s when they buy steel, should pay export duty. Pharmaceutical facilities consume lot of steel and such duties increase the capital expenditure of the unit as compared to domestic unit. While the intention of every SEZ is to capture exports, there is often a need to sell certain portion in domestic and capital cost differentials due to such export duties suffered by units in SEZs will work against the interests of the policy.

Exemption from Export Duties to SEZ Units

Export duties applicable to exports should not be charged to SEZ purchases.

3. Pharmaceutical establishments take considerable time for designing, constructing with advanced air handling systems and containments, validation of each and every equipment, facility, taking test batches, consequent documentation, testing of bioequivalence, waiting for inspections and consequent product approvals. This is quite a slow process often taking more than 48 months to achieve meaningful commercialization. Considering the nature of the industry, the law should provide additional time for commercialization of facility and availing of tax benefits. In addition, a fixed percentage of capacity should be allowed to be sold in domestic market instead of fixed percentage of annual sales to allow the units to gain experience and recover overheads. In a knowledge intensive industry, it is very difficult to retain people during the period of testing and waiting for various approvals. Allowing production for domestic market firstly ensures good quality drugs being available for domestic market and secondly, it helps the work force and managers to have sufficient experience for successful inspections and approvals. Consequently the year of commencement of tax benefit should be computed from the year of profits. The nature of the industry is time consuming and hence such an exception is rational.

Formulating Practical Norms for Pharmaceutical SEZs

Domestic sales up to a fixed percentage of capacity installed should be allowed for export oriented pharmaceutical units.

First year of profits should be considered for beginning the tax holiday period.

5.7 Promoting Competitive R&D

4. R&D conducted in house enjoys weighted deduction as an incentive. However, there are a few ambiguities in the definition of R&D itself in the context of pharmaceuticals R&D. For example, when a R&D unit develops a formulation, it has to be tested for bioequivalence. Such a bioequivalence testing gets out sourced. Similarly, an R&D may develop a production process. Such process has to be scaled up in commercial facilities and often some rework is needed. Such production batches in scale up have to be outsourced in commercial facilities, as R&D in general may not have large manufacturing facilities for scale up and process refinements. Outsourcing of scale-up operations cannot be performed at universities, etc. Such outsourcing costs in pharmaceutical R&D are common and should be allowed for weighted deduction.

Treatment of R&D Expenditure for Tax Purposes

Outsourcing done by approved R&D, for example bio-equivalence studies which are integral part of R&D should be considered for weighted deduction.

5. The law to develop commercial R&D firms is very restrictive. It is stipulated that these should be independent companies managed by significant number of outside directors having significant sales to third parties. Setting up large bioequivalence centers, or large contract research firms, etc., are extremely capital intensive. Such centers have long pay-back period and will dilute the Return on Capital Employed (ROCE) of many companies. In this context, the incentive to build such contract research centers by large companies wanes. Only upon the guarantee of promoting companies they will be able to raise funds enough to meet the capital intensive nature of the segment. It is therefore necessary to give tax incentives to such subsidiaries for engaging in commercial R&D. The external component targets should be liberal as it takes considerable time to shift contract research from developed economies to India. For example a firm doing bioequivalence testing should keep records for several years to enable the auditors of government agencies to inspect and audit. Failure in inspections means the product withdrawal or non approval. As pharmaceutical business is extremely regulated, lot of effort goes into establishing credibility and then acquiring business. The outsourcing decisions of corporates consider such things as financial stability of testing centers in addition to the competence. Considering the exceptional nature of industry, the rules should enable large corporates to set up divisions for commercial R&D availing tax deductions or holidays.

Permitting Commercial R&D Subsidiaries for Tax Exemption

Commercial R&D firms promoted by established firms as subsidiaries should be allowed for the purpose of tax holidays in pharmaceutical industry.

5.8 Overcoming Cost Escalation in Human Resource

Skill set is strong only in limited number of organisations pushing up the costs of innovation and manufacturing. India traditionally enjoyed the benefits of low costs coupled with committed skills. Costs are rapidly increasing in the relevant manpower base such as scientists, regulatory affairs personnel, manufacturing personnel, pharmaceutical lawyers and international business development personnel.

Availability of right talent at meaningful costs should remain India's strength for some more years and it is feasible to achieve this if some initiatives are taken now. There are no formal and significant efforts to diffuse innovation capabilities due to lack of linkages between academia, public institutions and industry. It is generally not in the interest of the country for select players only to continue to enjoy the competence of a large skilled pool of human resource. The industrial growth and continuity is dependent on the creation of large skilled population. Intense public initiatives have to be conceived and implemented in this area.

In most parts of the world relevant innovations take place at all three key centres such as universities, public institutions and industry. In India, beyond initial beginnings given by public sector and public institutions, the linkages were not established sufficiently between these three centres of innovation. There is a strong case for developing several centres of excellence in leading universities and scientific and technical institutions dedicated to specialised sub-sectors of the pharmaceutical sector and focussed on advanced research and dissemination. A Research and Development Fund of Rs. 150 crores alone may not be adequate enough to deal with challenges mentioned above. A strong public-private initiative involving institutions at all levels is of immediate relevance.

Exports and globalisation capability is enjoyed by a few large players in India. Competency in APIs/ formulations, intellectual property creation, facility design and maintenance, knowledge of global regulatory affairs, legal acumen, and expertise in managing international executives and understanding of global markets is not available beyond a few players.

In the pharmaceutical industry, the government machinery dealing with bioequivalence, site inspections, GMPs, etc., is often a big resource to the industry. One can often see scores of consultants or managers who were earlier on the rolls of Food & Drug Authorities contributing to the development of the private sector. Foreign site inspections to approve imports by government agencies are a means of gathering immense knowledge in various countries. India by and large does not capture this benefit as the Indian regulatory bodies are not focussed on international site inspections of APIs or formulators to evaluate cGMP and the data submissions.

The work force in India beyond the internationally approved plants reportedly, has a different set of experience in manufacturing processes. The present drug regulatory regime does not mandate bio equivalence at the time of registration of a new drug. The Indian drug registration process is not only less expensive but is also less demanding. The need for bio equivalence does not merely increase the demands over the applicant but also helps in qualitative improvement of drugs, creation of superior infrastructure, better skilled manpower and encourages investments in these areas. It has a multiplier effect on the entire drug production and regulation process. The drug registration regulatory regime, therefore, in India can adopt bio equivalence as an important criterion of new drug registration. As there is no mandatory bioequivalence testing (apart from a few exceptions) or research to prove equivalence in case of changes in processes or sites or machineries in production, the attitude in manufacturing may become lax and counter productive, sometimes even in internationally oriented Indian facilities. Hence though thousands of firms exist, there is shortage of relevant skill set raising the costs. If the need to align with international norms becomes mandatory, the industry will produce large number of skilled people in manufacturing, regulatory affairs and R&D at least in the medium term beating the wage cost escalation.

Enhancing Pool of Trained Professionals

The country has to facilitate Learning and Development vigorously through public initiatives in enlarging the pool of skilled population in the areas of:

- **Law**
- **Regulatory affairs**
- **Knowledge of market environment at the global level**
- **Patent procedures & filing**
- **Non Infringing Processes -concepts & strategies**

Pharmexcil should facilitate L&D for pharmaceutical professionals to enhance the learning opportunity and available pool of talent.

Treatment of Investments in Quality on Par with R&D to Enhance Quality and Skilled Scientific Personnel

Insisting on stringent cGMP (current GMP) and bioequivalent drugs for key drugs can turn the table in enhancing the skilled population. Only when organizations have a need for higher quality, employees in such organizations will have incentive to learn, update and join the elite trained pool of scientific personnel. While it directly benefits in increasing the skilled population, it also benefits in assuring quality drugs to Indian population. This is also a progressive step in controlling spurious drugs. Considering investments for Quality Control equipment at par with R&D capital goods purchases is a crucial step in rejuvenating Indian quality environment.

5.9 Reducing Dependence on China in Intermediates

Indian pharmaceutical sector has been sourcing its requirements of chemical intermediates and bulk drugs in large quantities from China over sometime. This has been necessitated due to cost competitive supplies from China acquired by them *inter-alia*, due to economies of scales and diversity of portfolio. A situation has come when almost 60 to 70% of our requirement of intermediates is sourced from China. Recently China cracked down on its chemical industry in order to enforce environmental legislation leading to short supply of chemical intermediates, increasing their prices uneconomically for Indian drug manufacturers. On one hand, this severely affected bottom lines of Indian companies while on the other their supply schedules were also disturbed.

India must reduce its dependency for these intermediates on China. This would be possible if we identify other alternative markets in our vicinity which can be equally competitive if their scales could be increased. Alternatively, there is a strong need to review domestic capacities for supply of drug intermediates so that Indian drug industry is not over dependant on one country. It may be appropriate to examine production capacities in neighbouring countries to suit our industry requirements. India must create a policy environment for its small and medium chemical industry to position itself appropriately to address back-end needs of the pharmaceutical industry.

Reviving Indian Drug Intermediate Industry

The energy and labour costs differential has virtually eroded. In the past intermediate industry migrated to China due to these reasons. India is emerging as a significant supplier of finished APIs and formulations to regulated markets and ROW. China can capture our market with the strength in intermediates if India does not pay attention to building intermediate industry. Every year, several new chemical entities loose patent protection and the corresponding opportunity for several intermediates and finished APIs emerges. An expert panel needs to study the potential intermediates that can come back to Indian manufacturing arena. Genuine foreign site inspections, analysis of imported samples of every consignment, in-depth review of regulatory submissions will put Indian industry on par with imports at least in strategic intermediates.

5.10 Hurdles in Tapping Narcotics based APIs and Formulations

Drugs like codeine, etc., classified as narcotics have a very significant presence in the global market. As per IMS Health, over US$9 billion opportunity exists in global narcotic pharmaceutical market. While certain countries have severe restrictions in the imports of scheduled drugs, there exists an opportunity for certain sub classes of narcotic drugs. While safety has to be kept in the mind always, the opportunity can not be ignored.

For contract manufacturing of pharmaceutical products requiring narcotics DMF material, the same has to be obtained from vendors approved by respective drug regulatory authorities of importers' country who (vendors) are often situated abroad. To cater to this segment, Indian manufacturers will have to necessarily import from these vendors and export the finished pharmaceutical product to the foreign buyer. Indian manufacturers requiring narcotic DMF have to apply for annual quota for importation to DCGI, New Delhi. The application has to be made in the month of April, one year in advance and quotas are granted in the month of March of subsequent year.

Currently, the procedure for imports of narcotics is cumbersome creating avoidable hurdles to genuine manufacturers resulting in abandoning of this opportunity. Imports of narcotics material is permitted only through Government Opium & Alkaloids Works (GOAW) which is the canalizing agency established in this regard.

The manufacturers have to apply to Government Opium & Alkaloids Works (GOAW), Delhi for importing the same by them. The importer has to deposit the entire purchase cost with GOAW in advance. GOAW in turn would seek approvals from Ministry of Finance involving approvals from Internal Finance Unit (IFU), expenditure department and revenue department. The approvals require passing through several layers of hierarchy including submission to finance minister before it is finally returned with approval to GOAW. The entire process will be repeated from stage-1 if the application is returned to GOAW due to any query raised at finance ministry.

NOC & import permit is also mandatory from Narcotics Department, Gwalior. After receiving such permits, GOAW issues purchase order to the manufacturer based on which the manufacturer can place order on foreign vendor. Usually foreign vendors also require additional time to obtain necessary permissions and export licenses to supply narcotic DMF material. The narcotic material thus imported will have to again travel to GOAW by road from port of importation for quality control clearance by them before it is finally released to the domestic manufacturer.

The production at the manufacturers' premises is also strictly regulated requiring manufacturer to account for every single gram leaving no room for errors. Production records have to be maintained and narcotic materials are required to be stored in cages and vaults as per specifications under the law in this regard.

The entire process imposes the challenge of risk on the manufacturers and is fraught with huge delays and consequent financial costs. GOAW imposes service charges besides duties and CST to the tune of 20%. A further 8 to 10% cost escalation occurs due to financial cost for the period required for obtaining the approvals which is reported to be between 7 to 8 months. In addition to this inventory carrying and handling costs of 8-10% on the stocks maintained under quota system has to be borne rendering Indian manufacturer uncompetitive in the international market.

India, therefore, loses export opportunity of this sector. Moreover, due to the stringent regulation & control of narcotic materials, the domestic manufactures are unable to undertake product development for international markets. The opportunity is thus killed in its nascent stage itself. This is evident from the fact that India thus far has not filed a single DMF for narcotic substance with US FDA or any other drug regulatory authorities abroad and has thus barely penetrated this market.

It is therefore, necessary for clear, simplified time bound guidelines for importing narcotic materials for drug development and contract manufacturing when DMF materials can not be offered by narcotics board. The concerns against the use of narcotics and their illegal trade are very genuine and must be respected. However, within premise of this broad understanding, there is need to examine the present procedure under the concerned legislation to make narcotics based drug manufacturing relatively simpler and growth generating.

Many firms are averse to participate in this opportunity due to very difficult conditions and delays in adhering to current procedures and controls. For example, contract development services will need import of DMF approved narcotics. Such dossiers or technologies may be licensed to markets for production at foreign sites. There is an advantage for India in this sector as the country produces significant quantities of narcotic raw materials and this competitive advantage can be better utilized by introducing some reforms in the present regulatory procedures..

Looking At Narcotics Formulations as an Important Opportunity and Not Just A Menace

In view of the above, it is therefore necessary, to simplify the procedure and to capture the global narcotics business in certain classes of narcotics. The entire process of approvals from multiple agencies such as DCGI, INCB, Ministry of Finance, State Narcotics Boards, the quota systems and canalization should be relooked at for promoting export production. The genuine manufacturer exporters may be permitted to directly import narcotic substances based on risk profiling and past records with minimal regulatory constraints.

The quota system should be done away for export production as it is difficult to assess import requirements one year ahead especially when the country desires to capture a bigger share.

Obtaining INCB permission for each consignment of the same material for same importer and by the same vendor for certain classes of narcotics is not present even in developed countries such as Europe where the regulation is very stringent and can be done away with.
Online submissions, approvals and clearances should be considered.

5.11 New Technologies

Biocatalysis, Organocatalysis, Nanotechnology, etc., are some of the new technologies that will have significant influence on the industry. Development of biocatalysts requires a significant interface and cross functional understanding between chemistry and biology. Developing micro organisms which act as enzyme catalysts accelerating certain chemical reactions which otherwise take multiple steps or cause lot of environmental issues is an essential technology.

Being one of the largest producers of APIs, the country needs to develop biocatalysts either to reduce load on environment as also to reduce cost of manufacturing. As most of the API production is being shifted to India and China, the incentive to develop this science with respect to APIs will be less in developed world. Europe, US and other key countries are focusing on biocatalysts for significant gains in food processing, environment management, etc. Companies working on biocatalysts like ‘Codexis’ have succeeded significantly, licensing the technology/ biocatalysts with out incurring huge capital expenditures in setting up production units. Technologies based on biocatalysis helped European and US firms to cut several steps in chemical process and compete comfortably with low cost countries.

Typically, many API companies in India have insignificant understanding of biology and managing of micro organisms. The task should be evaluated and should be focussed as industry projects at premier institutes and universities.

In general, China is stronger in biology and rapidly improving its skills. API companies in China are similar to India except that China is a dominant force in fermentation technology. Potential opportunities if harnessed only by China in this area may mean loss of business in such APIs.

Large state investment has changed the landscape in China thwarting Indian attempts to succeed in bio-generics. Most of the biotech research in China is underwritten by the government (China participated in human genome project) enabling Chinese firms to produce hepatitis vaccines, recombinant insulin, interferon and other generic therapeutic biologics. Department of Biotechnology in India is working with industry and has contributed significantly in bringing out several vaccines for growth. Biotechnology has vast implications in agriculture, environment, pharmaceuticals, etc., and obviously overlap of projects takes place. The biotech industry in the world is characterised by small firms founded by former professors or scientists with funding from either venture capital or by government. Substantial growth in the knowledge of biology and chemistry is essential for success. The strong determination of government of China aggressively promoting the institutions in this sector and experts believe that China may overtake India significantly in spite of India's advantages of English speaking employees, regulatory and manufacturing competence, etc. The current strategy of developing projects and subsequently trying to market or commercialise them should be suitably amended. Instead identifying projects in a consultative mode with the industry in relation to global developments and opportunities may produce more useful results. Associating universities and technical institutions in research and development work and licensing of consequent benefits to domestic firms may be a sound strategy. While the Departments concerned have more or less similar approach a certain amount of industry interface and aggressive approach in a global setting is essential.

Focusing on Immediately Commercialisable technologies By Government Institutions

One or two Indian scientific institutions should work along with domestic firms to identify target products which can benefit from these new technologies and take up projects. A small percentage of costs should be shared by industry firms and the technology may be licensed by them with out bottlenecks.

Banks should provide capital for taking up commercialisable R&D

R&D being a revenue expenditure, certain new technologies are taking a back seat in corporates that are already struggling for profits. Competing countries are investing in new technologies like biocatalysts, etc. forging ahead of India. Banks should develop SPV concepts to fund these technologies.

5.12 Reviving Fermentation Products

India has lost large volumes of fermentation business such as Pen G, 7 ACA, etc. to China with its low costs in energy. China has gone for huge capacity expansion and captured global market with very aggressive pricing. It enjoys substantial profitability, after the global capacities were shut down. Power interruptions are fatal for fermentation industry. Fermentation skills are essential as several APIs come from fermentation industry. Several biotech products need fermentation. Although it is difficult to assure the quality of power, the capital required for back up power plants should be evaluated with a priority focus in fermentation industries. It is essential that the skills in this key segment should not be lost forever to competing nations.

Reviving Fermentation Capabilities of India

As the cost disadvantage is disappearing between China and India in energy and labour, the country should relook at fermentation R&D, Lyophilised pharmaceuticals, etc., Soft funding for fermentation projects as a kick off to bring back select intermediate industry especially in biopharmaceuticals and certain recent fermentation based intermediates/ APIs may be considered.

5.13 The Linkage with Educational System

a. A number of young students are moving away from pure sciences like chemistry, biology, etc. to other non-science disciplines as science education loses its attraction in the present socio-economic milieu. Premier institutions like IITs, NITs, etc., capture students for engineering and do not have adequate schemes to attract students in sciences especially after 10+2. Integrated courses in these institutions are considered only second option for aspiring engineers.

b. Most law students coming from good law schools have back ground of humanities and combination of life sciences with law are almost non existent. Lately some National Law institutions have adopted combined courses of science and law but they are very few in numbers and not yet very popular. A majority of law graduates in India are from arts disciplines and are finding difficulties in relating to the life sciences industry requirement. Legal understanding is a key component of international pharmaceutical business. Hence, India must develop law and life sciences connect urgently.

c. Educational institutions lack relevant exposure to industry due to almost non existent interface between academia and industry.

d. Similarly, there is a strong need for content oriented updates or programmes in regulatory affairs, IPR matters, legal issues, scientific developments, etc. for existing professionals. As the industry is nascent, the limited skilled manpower is becoming expensive and the pool is not enlarging as the efforts to enhance the pool through learning and development programmes are insignificant.

Attracting Talent to Chemistry and Biology

An integrated postgraduate course in chemistry could be offered in NITs, IITs, NIPER, and leading universities at the 10+2 level. Most bright students prefer engineering streams. Pure science in local colleges has become an unattractive destination. While chemistry is fancied to some extent, biology has much less attraction. Integrated courses in biology could be introduced at leading institutes focusing on microbiology, biotechnology and pharmacy. The quality of education in some of the private institutions offering these courses requires in-depth examination.

Integrated courses in law and life sciences should be introduced in premier law schools and universities.

A legal frame-work should be developed for tapping and developing the student potential while employing them for project works. However, as industry is not willing to offer projects in view of confidentiality issues, the legal framework should provide for confidentiality agreements by students and professors of universities. The confidentiality agreement should carry particulars such as passport details, permanent address of the student, etc. to trace them in the event of violations of such confidentiality agreements. Further, government should also make it mandatory for Universities Professors to produce a minimum number of projects/research works each year. Patentable research should be the drive at Institutions and universities. Increments and promotions may be linked to the research output and industrially commercialisable projects undertaken by their students/ departments. Grants etc could be linked to the requirements of projects in terms of equipments/ space rather than mere capacity expansion, etc.

5.14 Capturing Opportunity in Emerging Markets

In the context of pharmaceutical exports because, as shown by the examples of Thailand[9] and South Africa[10], there are situations when patented pharmaceuticals become too expensive for developing countries and consequently, they import cheaper copies of these drugs. Indian companies such as *Cipla*

[9] The Economist, "A Gathering Storm", June 7th, 2007. This mentions initiatives by Malaysia and Brazil to pursue compulsory licensing.
[10] The Economist, "The Price of Africa's Cheap Drugs", April 19th, 2001.

and *Aurobindo* have been at the forefront of exporting drugs in these situations. It is an acknowledged fact that India has requisite manufacturing capacity, internationally approved quality and regulatory infrastructure in several companies. Diseases like AIDS etc are national emergencies. Since India is one of the countries which has significant manufacturing capacity as well as a past record of providing for such situations, an important opportunity as well as social responsibility emerges. [11]. For example India has offered various ARVS (Antiretroviral) such as NRTIs, NNRTIs, PIs at a breathless speed and at affordable price. Various international organisations and governments which did not dream of providing medicine except for campaigning prevention could benefit from India and are able to provide relief to millions in Africa etc. A simple look at WHO approved ARVs or PEPFAR approved ARVs clearly illustrates the undeniable contribution of India in controlling AIDS internationally at affordable cost. Indian organisations like Aurobindo have been felicitated at White House and at UN for such contributions.

Emerging markets pose several challenges to exporters. A. cost of reaching them to start businesses, registering products etc., B. low volume requirements for several products, necessitating a large portfolio for commercial viability. C. several varying technical and non technical barriers D. credit risk. On the contrary the advantages are also many. A. the domestic industry in several countries is weak B. the current financial and skill requirements for setting up cGMP facilities does not justify viability. C. the regulatory aspirations are increasing and there is a room for high quality companies to replace old firms with dated technologies and systems. D. the market achievements can be sustained over a longer period.

India should assess each country opportunity and develop a strategic plan in terms of, a. Required product portfolio, b. suitable export firms portfolio to register and produce these products, c. credit strategy that can be incorporated in bilateral trade relations as a country credit instead of credit risk being taken at firm level, d. procurement strategy to facilitate registrations and govt purchases. The fragmented industry with several small firms finds each opportunity unviable at a firm level and the nation misses the opportunity as a whole. Hence, Banks or pharmexcil , may facilitate cooperation at firm level to pool the products and share costs in overcoming the initial costs before exports commence.

The issue of capital and output ratio is a national subject. The capacity building has taken place with funds from Indian Banks and Indians as share holders. From a highly centralised license permit regime, we have moved to a free economy very rapidly. However our firm level capabilities to understand the markets, global demand, legal issues, etc are highly skewed. While leading firms employ international consultants and obtain knowledge, majority of other firms do not have access to requisite knowledge . For example, due to such lack of global market intelligence and dynamics, in some categories like cephalosporin's, Indian firms have built large capacities where the global demand is a fraction of what we have built .These are natural perils in a free economy with inadequate evolution of modern business systems. The fragmented industry can ill afford modern business practices at firm level. While it is unthinkable to monitor investments in each sector in our free economy, it is a national requirement to

[11] Duncan Matthews, "WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?", 7 J. Int'l. Econ. L. 73, (2004).

overcome the economic weakness at firm level through shared concepts facilitated by govt bodies in the interim.

Thrust in developing Economies

Neglecting less developed markets may prove unwise in medium term. We should develop customised promotional programmes for markets in Africa, CIS, South East Asia and Latin America more vigorously. Non tariff barriers are constantly mounting in various parts of world. Although these markets are less regulated, the regulatory requirements and aspirations are escalating. Many current exporters in various countries with compromised infrastructures will find uneconomical to reinvest in businesses paving way for growth of Indian Pharmaceutical industry with high quality investments in manufacturing.

One key barrier is cost of product registration and consequent follow up for our highly fragmented industry. We have to go out of box and facilitate a shared structure to provide skilled registration services for our fragmented industry to capture the skill set , minimise costs through economies of scale . This will provide a breather to SMEs who have already invested heavily in manufacturing and finding it difficult to economically register and reach various markets. Learning the skill set and regulatory compliance issues for each and every country across world are prohibitively expensive for a SME. However such a draw back can be overcome with a public initiative in providing such service. The skill set achieved can be available for multiple organisations. Further procuring RLDs (Reference Listed Drugs) or Innovator samples across world is a very expensive and time consuming process for a SME. A shared service set up can overcome this barrier.

Pharmexcil can organise India trade meets in several countries bringing together Indian SMEs and corporates and local buyers aggressively.

Shared Regulatory Services

Pharmexcil should develop an umbrella regulatory services department wherein each SME or small corporate need not liaise with the local governments independently for drug registration. Such a cooperative setup will be nodal point to register products for various companies into the destination country on a shared cost basis and help acquire strong skill set, utilizing local experts in the country, avoiding duplication of resources by our highly fragmented industry. Such an entity can help do quality filings and hasten the exports at minimal cost.

Shared Marketing Services

Where feasible, Pharmexcil can facilitate marketing co-operatives in destination countries, wherein a common co-operative entity can market the products for its members at a small

marketing fees while remitting the entire revenues to the respective exporting member companies. This will help the co-operative enjoy larger product portfolio, large capacity as a backbone, economise of scale in distribution and warehousing, etc. and minimise the overall investments in the marketing.

Identifying Strategies to Participate In Regional Clusters

In each regional cluster in the global pharmaceutical trade there exists a country in each cluster which supports all the neighbouring countries. Currently India competes with these regional champions in exports to the countries in the cluster. Over a period of time as regional champions emerge our exports could dry up. Pharmexcil should organise a study with the objective of finding practical strategies in utilizing these regional strengths for the furthering of our exports.

Anti-diversion Mechanism

Indian companies should be careful to have anti-diversion mechanisms in place i.e. mechanisms to ensure that the medicines are consumed in the market for which they have been manufactured (the market which has declared the national emergency) and are not re-exported, as this would tarnish their reputation irretrievably. Pharmexcil should initiate a system with exporters wherein it creates awareness and promotes compliance.