

PHARMACEUTICAL INDUSTRY UPDATE

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BY



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PHARMA INDUSTRY – AT A GLANCE (Jan. '05 to Mar. '05)



1. EXCISE DUTY ON MRP TO HIT SSIS: IDMA

The government's decision to levy Excise Duty on MRP with an abatement of 35 per cent has come as a big shock to the pharma industry, said the Indian Drug Manufacturers' Association (IDMA). At a conference the Indian Drug Manufacturers' Association stated their concerns that if this were to get implemented it would be the Small Scale Industry (SSI) that would be the worst hit.

There was no need to rush into the revised mode of charging excise as that will create a lot of difficulties for the industry as the stocks lying in the factories would have to be repackaged with the revised prices as required under DPCO, said IDMA. "The budget may also bring in some changes, we cannot keep changing things like packaging, etc," said N I Gandhi, chairman of the Pricing Committee, IDMA.

The change over from Excise on transfer price to Excise on MRP would be a death knell for small and medium size pharma industry which has been surviving on doing job-work for large manufacturers. The SSIs will not be sure of the future business prospects if this abatement stays, as the companies that so far were relying on getting products outsourced from them will now start producing in-house.

The IDMA is concerned that most companies may not be able to sustain the inadequate abatement of 35 per cent. Further, IDMA president, Suresh Kare, said that the prices for drugs falling under the non scheduled category will rise upto ten per cent and would take into account about 40-50 per cent of the drugs in the non scheduled category. This would also lead to increased requirement of cash flow to pay higher excise duty.

The IDMA executive committee said that the Association has already sent an SOS to the finance as well as C&PC ministry requesting them to keep the notification in abeyance at least till the budget is presented.

"Unfortunately, the business environment for small and medium units is becoming extremely discouraging with the onslaught of government notifications such as the Patents third amendment bill, Schedule M amendment, etc. the writing is on the wall that the closure of the National Sector small and medium pharma companies would pave the way for monopolistic situation thereby resulting in increased cost of medicines as well as shortages," said Kare.

2. SCOPE FOR INDIAN COS TO STOP OUTLICENSING OF MOLECULES

Once a common code on good clinical practices comes into effect in the country, Indian pharma companies focusing on research, can stop outlicensing their molecules to MNCs, according to Dr Anji Reddy, chairman, Dr Reddy Laboratories.

Speaking at a press conference here Dr Reddy said industry related bodies are already in the process of finalising the blueprint, which would be ready within the next few months.

Once this is done, the infrastructure would be standardised for the companies to conduct their own trials, within the next three to four years, he said. "Most of the domestic companies would not have to outlicence their molecules and in the next three to four years most of the drug trials could be done in India itself. This will bring down R&D costs and enable many Indian companies to do discovery by themselves without outlicensing," he said.



As clinical trials form a significant portion of the drug development costs, conducting tests within India would drastically bring down R&D expenditure by pharma Cos, Reddy said and added that the benefits would in turn be passed on to the consumers by bringing down the prices.

India currently lacks the infrastructure required for conducting these trials and are generally done in regulated markets. Consequently domestic companies have to approach global pharma giants for taking these molecules to the markets as they cannot bear the heavy costs involved.

Already many Indian companies pursuing drug discovery have stopped outlicensing their molecules to MNCs, he said. "For example we have not outlicensed a single molecule after 2001".

Dr Reddy said that contract research would be another opportunity for Indian Pharma firms. "The trend has already started. India has nearly 100 drug manufacturing units which are approved by the United States Food and Drug Administration and it has the research capabilities. Indian pharma can leverage on this.

Talking about his own company's plans, Dr. Reddy said DRL was setting up a new drug research facility in China within the coming one year. He said that with India becoming a part of the WTO patent regime from January 1, there would be a lot of opportunities for pharma companies in contract research and manufacturing. China, which is also a signatory to the WTO regime has become a potential destination for drug research, he said and added "India and China have together a population of over 200 crore people. There is potential in developing new drugs especially for these two countries. These drugs will have patent protection so there is no room for others copying these drugs".

3. SSIS SEEK EXCLUSION FROM PROPOSED DUTY SYSTEM

The national small scale industry (SSI) committee of Indian Drug Manufacturers' Association (IDMA) is seeking the exclusion of SSIs from the purview of the proposed duty system. This was one of the proposals made at a meeting held recently (January 20, 2005) between a delegation led by S V Veeramani, chairman of the national SSI committee of IDMA, and the government officials Chandrasekhar (Revenue Secretary, Finance Ministry) and C K Singh (Chairman, Central Board of Excise and Duty).

Following the outcome of this meeting, IDMA is now preparing a report on this account for re-submitting within next week. Several state and national level associations of pharma SSIs are scheduled to meet senior government officials in the finance department with a detailed account on how the MRP-based excise duty will affect the small scale units.

The IDMA SSI committee feels that the 35 per cent abatement, in any case, does not take into account most of the cash discounts and incentives such as retail margin (20 per cent), wholesale margin (10 per cent), distributor margin (5 per cent), C&F commission (2 to 3 per cent), bonus offer (10 per cent), expiry and breakage discounts (3 per cent), delivery and forwarding discounts (4 per cent), amongst others.

A large number of pharma SSIs face an imminent threat of losing their contract manufacturing orders from large pharma companies on account of the proposed duty system removing the transfer price advantage.

Veeramani said that the proposed MRP-based duty system would undoubtedly deal a death blow to SSIs. "Not having the marketing muscle, most of the units are into contract manufacturing. And once the MNCs find that there will be no transfer price advantage for them, they will stop giving business to SSIs and instead go for expanding their own capacity," he said.

Similarly, the Confederation of Indian Pharmaceutical Industries (CIPI) is preparing a comprehensive report on the excise duty being paid by the SSI contract manufacturers, which will help the officials arrive at the likely adverse impact on the business of the proposed system. "The units that have already invested in Schedule M feel deceived as they are now stand to lose MNC business. Hence the abatement has to be increased to 60 per cent immediately," said T S Jaishankar, Chairman, CIPI. "With VAT coming into force in the next six months, the trade is not lifting goods, to avoid tax complications. They are just taking one week stock. Definitely February and March are going to be worse for the industry," he said.



S Lakshmi Narayanan, secretary of Pharmaceutical Manufacturers Association (PMA), Chennai, said that it is the demand of most of the SSIs that government should consider increasing the SSI limit from the present Rs one crore to Rs three crore as the industries will quickly cross the one-crore mark.

In his personal view the proposed system is a simplified central excise duty structure that should be welcomed. "However, the abatement should be nothing less than 50 per cent." The Executive Committee of PMA, which met on January 20, did not take any stand on the MRP-based excise duty proposal. It is likely that it might join other associations in the subsequent deliberations, he said.

4. SCHEDULE M IMPLEMENTATION GETS SIX MONTHS EXTENSION

The government has given in again to the demands of the small scale sector and extended the implementation of Schedule M by another six months to June 30, 2005. The SSI players have been strongly lobbying with the government to get additional time as they are yet to upgrade their facilities to the new Schedule M requirement.

The notification says that in view of the representations received from SSI associations it was decided that the cut off date in case of manufacturers existing as on 11/12/2001 will be further extended by six months, i.e., up to 30/06/2005.

The government had previously also extended the deadline from December 31, 2003 to December 31, 2004, owing to pressure from industry segments. Once it was clear that the government is keen to implement the norms starting January 1, 2005, the SSI associations collectively took up the issue with the Health Minister and sought support from several MPs as well.

The Confederation of Indian Pharmaceutical Industry (CIPI) was leading in the group seeking delay in Schedule M implementation and it went ahead to demand the assessment of real need in the Indian context before going ahead with Schedule M. Rather than exploring options to upgrade the units SSIs have been buying time and continuously pestering the government to extend Schedule M deadline. It may be noted that in the notification dated November 8, 2004 had relaxed space requirements for SSI segment.

The notification said that the requirement of ancillary area shall not apply to units registered before January 1, 2002, and manufactures external preparations, oral liquids preparations, tablets, powders, capsules, ophthalmic preparations and parenteral preparations. The Schedule gives general and specific requirements for factory premises and materials, plant and equipment and minimum recommended areas for basic installation for certain categories of drugs.

5. GOVT. OPEN TO REVISIT AMBIGUOUS PROVISIONS OF PATENT ORDINANCE, RULES

The Government agreed to revisit the ambiguous provisions of the Patents Ordinance and Rules to make the product patent regime credible and protect the interests of consumers and producers.

This assurance was held out by the Secretary, Department of Industrial Policy & Promotion (DIPP), Ashok Jha, while addressing an interactive session on Amendments to the Patents Act, 1970, organised by the Federation of Indian Chambers of Commerce and Industry (FICCI) here. Jha said, the amendments had been discussed in detail, debated by an inter-ministerial group for over a year and carefully scrutinized by the Joint Parliamentary Committee (JPC) to carefully calibrate the interests of consumers and stakeholders. Even so, the government was open to new suggestions, for which a brain-storming meeting with the stakeholders and patent lawyers would be convened shortly.

"I am in a position to effect changes to reflect ground realities but I cannot change perceptions, especially those that are based on uninformed comment," the Secretary said, and added that the timelines for grant of patents had been reduced from a maximum period of 104 months to 52 months and the minimum period from 27 months to 5 months.



Jha said interactive sessions like the one organised by FICCI would be held in other cities to elicit the views and suggestions of the parties who had to deal with the new product patent regime.

He said, the entire issue of flexibility, public health, pre and post-grant opposition to patents, ever-greening, compulsory licensing, and royalty had been examined by the JPC and attempt made to see that the Patent Act reflected the TRIPs agreement.

While the government had erred on the side of the Indian companies and public health insofar as local working issues were concerned, Jha said, certain provisions that were exercising the minds of patent attorneys such as new use, patenting of software, fees, etc. would be looked at afresh to address the concerns of industry.

6. PATENT ACT WILL NOT AFFECT DRUGS EXPORT : KAMAL NATH

The Union Minister of Commerce & Industry Kamal Nath has said that export of drugs from India will not in any way be affected by the amendment to the Indian Patents Act. “The global market for generic drugs is currently estimated at US \$ 40 billion and the impending expiry of patents on drugs worth US \$ 60 billion during the next five years offers huge opportunity to India”, the Minister said while participating in the World Economic Forum (WEF) Session in Davos (Switzerland) on “India Meets Doha” which discussed the WTO Agreement on Trade-Related Intellectual Property Rights (TRIPs) in the context of the healthcare industry and its implications for India’s research & development (R&D) and intellectual property rights.

Kamal Nath reiterated that the new patents regime would not affect domestic prices as 97 per cent of the drugs in the Indian market were already off-patent, including 350 life-saving essential drugs. “The 12 ARVs (anti retro-viral drugs) most used for AIDS and manufactured in India, cannot be patented, as they are pre-1995 inventions. India will continue to manufacture, use and export them without hindrance”, Kamal Nath stated.

Underlining the possibility of India taking centre stage in drug development in the near future, Kamal Nath stressed that India had a 10 billion dollar pharmaceutical industry, which was the 4th largest in terms of volume and the 13th largest in terms of value. There were 300 pharma companies in India of large and moderate size and 5500 small pharma companies, while the largest number of units approved by the US-FDA outside America were in India. Although at present less than 0.25 per cent global spending in Pharma R&D was being done in India, Shri Kamal Nath said that “with higher patent protection, it is expected that more medical research would take place in India, given the cost advantage and large pool of technical and scientific talents in India”.

Stressing the emergence of India as a low cost centre for medical research, Shri Kamal Nath said: “India will – in fact, is already emerging – as a low cost centre for medical research. Many multinational companies from Europe and America have tied-up with local ‘Indian Multinationals’ (such as Nicolas Piramal, CIPLA, Dr. Reddy, Ranbaxy, Wockhardt) to carry out research for new molecules. India has world-class talent with requisite training. Our manufacturing and R&D Labs are well equipped.

There is synergy between fields of IT, biotechnology and medicine. The cost of Basic Research and Drug Discovery in India is much lower as compared to the Western counterparts. For a new drug to come in to the market, the average cost is 810 million dollars and takes 10-15 years in the Western countries. The global Pharma industry, therefore, desperately needs strategies to bring down the cost. Therefore, outsourcing in India has become an option. While outsourcing in India provides cost-benefit to the giant pharma companies, it is also a huge opportunity for smaller international companies which do not have well developed drug discovery programmes, to get a foothold, making it a win-win strategy. The first steps into Drug Discovery have already been taken by many pharma companies in India through in-house research as well as partnership with global players. The Patent Law in India, complying as it does with international norms for intellectual property, establishes India’s credibility and enormous strength in basic research and drug discovery is not a far-fetched dream”.

7. FICCI MOOTS SETTING UP OF BIOTECH COUNCIL OF INDIA

The Federation of Indian Chambers of Commerce and Industry (FICCI) has proposed establishment of a Biotechnology Council of India (BCI), an independent statutory national body, mandated to ensure standardisation in biotechnology education and training.

The proposed Council, on the lines of the Medical Council of India or the Bar council, should be empowered to grant recognition to those institutions that meet such standards, set with reference to qualified and trained teaching staff, infrastructure, adequately equipped laboratories, etc, that are essential for a focused education in biotechnology.

While lauding the efforts of the Department of Biotechnology in identifying human resource development as an area of high priority during the 10th Plan in order to generate trained/skilled human resource in the critical and high tech area of biotechnology, FICCI has underlined the need for creating a specific policy framework.

For instance, at present, there are four categories of M Sc. course in biotechnology in the country supported by the UGC, Department of Biotechnology, AICTE (in engineering colleges) and the university system. This has resulted in lack of uniformity in requirements, the quantum of financial support and the consequent lowering standards of education.

Estimates are that Indian biotech industry is expected to grow to US\$1.45 billion in 2005-06, US\$ 4 billion in 2006-07 and more than double that figure, US\$ nine billion in 2007-08. Over the next few years, India is slated to become a major centre for custom research, and clinical and biological services. It is already the second largest manufacturer of vaccines used by children and these are exported to over 100 countries.

With the challenge of GATT looming large, biotech firms in India are preparing themselves for an intense phase that would test the ultimate enterprise and intuitive knowledge of Indian scientific and industrial community. FICCI has therefore emphasised that it is important to create a learning programme in the area of biotechnology and its ancillary fields. The need of the hour is to envisage a multidisciplinary curriculum that will cover all aspects of Biotechnology including understanding process principles, experimentation, animal & plant technologies, bioinformatics, basics of project management, IPR issues, business values and finances in BT.

Separate modules could be created for students and corporates, which will focus on different themes. The student course will emphasize on practical hands-on training, teaching the ethics of GLP and a fundamental know-how of BT management. The suggestions in this regard are:

- Create courses on biotech equipments & technology
- Create short-term & long-term courses on bio-safety
- Create specific specialisations on patents & IPR
- Increase courses content on regulatory frameworks
- Include biotech in marketing and allied subjects

With regard to vocational courses, the chamber has proposed that that the State Governments and the Department of Biotechnology, with the certainly feasible support from and collaboration with the industry, establish instrumentation and training centres in a few key locations in different states, where students can get trained and research workers can get instrumentation services, on payment of prescribed charges, so that expensive facilities required for most of education and training in biotechnology need not be duplicated.

Going a step further, it is imperative to create educational opportunities for professionals from related fields such as pharma to hone the necessary skills for creating their career path with biotechnology industry. The proposed Biotechnology Council could actively create educational resources, self-training modules, information about advanced courses, research and fellowship opportunities, and links to various conferences and meetings around the world. Each of these tools for continuing education has its own advantages and disadvantages. For example while online tools provide the benefits of a self-paced environment for learning, conferences allow discussion and generation of new ideas.



The Council could also take up popularisation of Biotechnology in a big way by increasing awareness through seminars, symposia, conferences, workshops, popular lecture series, biotechnology publications in various languages, organize biotechnology exhibitions, national science day celebrations in universities and institutions.

FICCI has also suggested the creation of a course in Bioentrepreneurship, as this decade, which is all set to see a biotechnology boom, will belong to those who have the power to convert their dreams into reality. It will see the rise of the bioentrepreneur. The ones who will move away from the safe waters of the laboratory and convert a patentable/testable research dream into a viable business proposition. Every bioentrepreneur must, therefore, thoroughly understand the grassroots features of the biotechnology sector such as research, collaboration, infrastructure, technology and commercialisation capital and come up with an alternative business model to achieve success.

8. NEW INDIAN IPR REGIME TO BUG GLOBAL GENERICS INDUSTRY

"Every time a new drugs enters the market, it is a wait of long 20 years before you could get access to it," said William Haddad, father of US generics & generic biotech industries. "I am damn angry," he said while talking at a press conference on the impact of Patent Amendment Ordinance 2004 in Delhi organized by Indian Drug Manufacturers Association.

The Ordinance 2004 will impact the growth of global generic drug industry adversely. The generic drug industry in the US that is depended on off-shoring its API requirements to countries like India would feel the pinch, Haddad pointed out. Of the 7000 odd mail box applications at least 400 are patent filings for APIs and this will deny access to cheap raw material to developed world.

Haddad said that he would strongly advise Indian government against any commitment that go beyond TRIPs. "The Ordinance should be placed in the Parliament for discussion and should not be passed in its current form," asserted Haddad.

India should join hands with Brazil and other countries to get exemption from implementation of TRIPs till 2016. "It should not be economic indicators that decide but we need to redefine the eligibility criteria for participation in the 2016 exemptions".

According to Haddad, those nations which have traditionally supplied essential medicines to poor countries of the world should be exempted. By 2016 many of the smaller nations will be able to develop their own pharmaceutical industry, but in the interim the manufacturing nations should be put back into the equation, he said.

In his testimony in the European Parliament hearing on TRIPs and Access to Medicines, last month, Haddad called for reconvening a mini-Doha to explore the failures for the past attempts leading towards a WTO meeting this summer to correct these flaws.

He also urged to clarify and simplify the methodology for poor nations to use compulsory licensing. Right now the generic industry and the NGOs believe the process is too cumbersome for most nations. "I believe that CL should be part of the WHO process so that each nation does not have to reinvent the wheel," he said.

Unveiling certain truths about the research based pharmaceutical industry he said, "The R&D cost of a drug put at \$800 million is a big lie and studies show that the actual cost is only \$250 per drug. Moreover, since most of the approved medicines entering the market are not truly new or novel or are acquired from other sources, according to Dr Marcia Angell, who was the editor of the New England Journal of Medicine, the real time cost is a mere \$100 million. Angell wrote that were the figure been anywhere near the claimed \$802 million, the industry would not have been so secretive about its data.

9. IDMA URGES FOR UNIFORM IMPLEMENTATION OF VAT BY ALL STATES

The Indian Drug Manufacturers' Association (IDMA) has urged all state governments to ensure the implementation of value added tax (VAT) in a uniform manner at the same time. In a statement issued to all



state governments and the finance minister, the association has put forward certain suggestions for implementation of VAT:

- With the implementation of VAT there should be a single point tax based on MRP only at the manufacturer's level for all medicines. This will ensure full realisation of VAT in one step, ensure early receipts by states, minimise VAT collection/assessment costs and avoid unnecessary work and harassment of intermediary traders.
- No other tax and levies should be charged by any state.
- The month of March being the financial year closing for most of publicly-held member companies, the implementation of VAT needs to be postponed by three months and make it effective from 1st July 2005.

The association has ensured full support for close cooperation in the successful transition from the current system to the single point tax system of VAT.

10. BUDGET 2005 A DAMP SQUIB, QUIPS INDUSTRY

The Union Budget 2005-06 has failed to trigger much enthusiasm among the pharmaceutical industry. Industry expressed disappointment on the incentives announced by finance minister at both the R&D and manufacturing level.

In his budget speech the Finance Minister (FM) has announced keenness to enhance the Rs 150 crore R&D corpus for the industry and said, "The corpus deserves to be increased and I propose to do so in phases beginning next year." However, going by the experience so far it doesn't cheer up the industry. Because, even after announcing it a couple of years back as well as sanctioning last year, the R&D fund is yet to go operational and the beneficiaries identified are yet to get the disbursement.

According to Satish Reddy of Dr Reddy's the budget is quite disappointing. Pharma major Ranbaxy Laboratories said that the budget announcements fall short of industry expectations. The Indian Drug Manufacturers Association also expressed disappointment over the budget announcements.

The Finance Minister in his speech said that India has also the potential to become an attractive destination for outsourcing in drug discovery and clinical research, and for co-development of drugs and manufacturing. In biotechnology, the industry has the potential to be a global leader supplying novel technologies and products to the health and agriculture sectors. The FM assured that the government would provide a stable policy environment and necessary incentives to help the two industries become world leaders.

Although the industry looked unhappy and dissatisfied over the incentives provided sector analysts said that the R&D benefits will be key to pegging up research activities in the new patent regime. The FM has announced weighted deduction of 150 per cent of expenditure on in-house research and development facilities of companies engaged in the business of biotechnology, pharmaceuticals, electronics, telecommunication, chemicals or any other notified product.

Moreover, there would be 100 per cent deduction of profits of companies carrying on scientific research and development and approved by the Department of Scientific and Industrial Research. These have been a few long standing demands by the industry which are materializing in the budget this year. The budget has proposed to bring down custom duty on nine equipment for pharma and biotech industry to five per cent level. The cut in corporate tax is welcomed by the industry as well.

The Finance Minister has a major focus on building up quality human resource and this is reflected in the proposal to upgrade IISC to the standards of global universities. In his speech, P Chidambaram said that on January 6, 2005, the Prime Minister spoke about his intention to set up a Knowledge Commission to look into the issue of building quality human capital. Government believes that investments in institutions of higher education and Research and Development organizations are as important as investments in physical capital and physical infrastructure.

He said, "What we need are world class universities, and we must make a beginning with one institution. We must have a university that will be ranked alongside Oxford and Cambridge or Harvard and Stanford. I am

happy to inform the House that we have selected the Indian Institute of Science (IISc), Bangalore, which enjoys a high reputation as a centre of excellence in research and development. We shall work to make IISc, in a few years, a world class university. I propose to provide an additional sum of Rs.100 crore as a grant for this purpose."

Although the FM has not given in to the demand of industry for excise duty cuts, he has promised to set up an advisory committee to advise the Government on the extent of abatement for both excise duty and service tax. He said that as many goods are chargeable to excise duty on a value with reference to their maximum retail price after allowing suitable abatement, there is need for making the system of quantifying the abatement transparent. There should also be a mechanism to review the rate of abatement to reflect changed circumstance, he said.

11. ALLIANCES AND OUTSOURCING HAVING MAJOR IMPACT ON PHARMA INDUSTRY

The modern pharmaceutical company faces numerous challenges in its efforts to improve productivity and to strengthen the product portfolio. In an attempt to counteract the pressures of operating in a global pharmaceutical market, companies have sought to establish relationships with external partners such as biotechnology companies and Clinical Research Organizations (CROs) as a means to remaining competitive and profitable.

Alliances and external collaborations have provided companies with the opportunity to gain access to new technological breakthroughs and novel expertise regardless of national or geographical boundaries. Evidence of the growing emphasis on alliances and external collaborations as a route to success is highlighted by the fact that partnerships within the biopharmaceutical sector are currently being formed at the rate of \$5 billion per year.

This new report from Arrowhead Publishers is designed to provide information, insight and in-depth analysis of alliance and licensing activity within the pharmaceutical industry in order to identify the challenges faced by members of the pharmaceutical community; current trends in partnering activity; an understanding of the dynamics of the buyer-supplier relationship and best practices for managing external collaborations. The report is aimed at providing an appraisal of the partnering process, and insights into the current environment of pharmaceutical discovery and development.

Strategies for Innovation in Pharmaceutical R&D includes the following features:

- A thorough market analysis of the global pharmaceutical industry, including the challenges faced by pharmaceutical manufacturers and the technological developments currently affecting innovation
- Guidelines for partnership management, with profiles of market leaders in the areas of pharmaceuticals, biotechnology and clinical research
- An informative and vital source of reference that provides practitioners with easy to access case studies, tabular data, key competitor profiles and a glossary of key pharmaceutical terms and definitions, with details of alliance and licensing deals within the biopharmaceutical sector
- A review of key developments taking place in the environment of pharmaceutical R&D and an evaluation of possible strategies for facilitating the drug discovery and development process
- Analysis of the significance of biotechnology to the pharmaceutical industry, including key trends in pharmaceutical alliance and licensing agreements
- An assessment of the importance of outsourcing to the drug development process, and an overview of the market for contract research, including key trends in pharmaceutical licensing agreements

12. A WAVE OF CHANGE HITS PHARMA INDUSTRY, TRIGGERS HOPE FOR BETTER GROWTH

Faced with at least three regime changes simultaneously giving the initial impression of total chaos for the Indian pharmaceutical industry, experts feel that this will lead to a better regime for overall growth.



The past couple of months have seen fast changes for the pharmaceutical sector, starting from the MRP-based excise duty structure to WTO Patent regime and the latest in all, the VAT regime. Express Pharma Pulse talked to industry players across the country to get a feel of their anticipations and strategies in this context.

While all the three new regimes are apprehended to be the death knell for small-scale sector, the medium to large companies are looking at the regime change positively. However, with regard to both patents and VAT, companies are keeping a wait and watch approach and says, "There is need to actually analyse the Patent Act Amendment and see how the government implements the VAT structure across the country".

Kewal Handa, ED-Finance, Pfizer India, said, "Manufacturers will not be affected much by the new VAT regime, rather all trade related issues will be sorted out". According to Rajiv Gulati, CMD, Eli Lilly, "VAT is a good move though there are many implementation ambiguities. There is no mechanism to recover tax paid on inventory as on April 1, 2005 and many others could pop up once the regime takes off". Pfizer's Handa thinks that this could facilitate for uniform prices for drugs across the country by having MRP inclusive of VAT and printing the same on medicine packs from April 1. For this, the government will have to amend DPCO to effect this on controlled drugs and the Excise Authority will have to notify the abatement inclusive of VAT.

D B Mody, director, J B Chemicals & Pharmaceuticals, says, "While the system is good, there are still many imponderables with regard to the system coming into force whether in all the states or in some of the states effective from 1st April 2005". According to the domestic drug major Ranbaxy Laboratories, "The VAT regime will prove to be good for manufactures, traders and consumers at large. The system will bring in more transparency and reduce bureaucratic hurdles".

Owing to uncertainties of the new regime in the past couple of months the trade has cut down intake by at least 25 per cent and in line with this manufacturers reduced production. This has caused for dip in sales for almost all the pharmaceutical manufacturers. Ideally VAT would have reduced the tax incidence on drugs by about 3.5 per cent thereby benefiting users had not the MRP-based excise duty structure is put in place that will see increase in tax by around 8 per cent, says experts.

"Sales of our company like others has been affected during Feb-March 2005," Mody pointed out. Some of the states are yet to fall in line with the VAT regime and there is uncertainty about how the sales tax on closing stock as on March 31, 05 will be offset and when.

Overall it is positive sign as the rate for medicines is agreed upon at 4 per cent. Ranbaxy said that VAT is a welcome move and that the company does not see any rise in medicine prices. "With the 4 per cent uniform VAT structure, the prices will either come down in the states having a higher tax rate or will become stable," says Ranbaxy.

"The government should introduce eight digit HSN for VAT as well as it has been proposed for levy of customs and excise duty in the Union Budget. This would not only align tariff practices to global standards, but will simplify implementation. There would be less litigation as far as the classification issues are concerned," pointed out Kewal Handa of Pfizer. There is also need to remove the Union Sales Tax and ensure that VAT is a single taxation system as it is in other countries.

According to Sun Pharma, "VAT and MRP based excise are issues that affect across the sector as they have a direct impact on the bottom-line". Pfizer's Handa opines, "The excise on MRP is a good move and this will bring all parallel trade into VAT chain". "Although some companies may like to neutralise the cost increase due to the MRP based excise and may be forced to take marginal price increase, with the price reduction owing to VAT, ultimately consumers will stand to benefit," he adds.

At abatement of 40 per cent and under the current excise duty at 16 per cent, an MRP-based excise regime will see less of contract manufacturing outsourcing by pharma majors thus hitting the small scale sector directly, say analysts. It will also double the pace of shifting plants to tax havens. Collectively the industry is seeking an abatement of at least 45 per cent and excise duty reduction by 8 per cent from the current 16 per cent.

Mody puts it as, “The new system has been hurriedly put into force without seeing the implications on the pricing front and more particularly the very survival of SSI units”. “SSI and mid-size units may not be able to survive and quite a few units in the industry will migrate to the excise exemption areas like Himachal Pradesh, Uttaranchal & J&K,” Mody adds. Companies like Nicholas Piramal are now betting on their manufacturing plants in tax free areas such as Himachal.

The strong IPR regime is unleashing a new era that will put domestic players in the global turf. The new regime opens up avenues for growth and economic prosperity given the scientific strength and biodiversity of the country. Genuine innovative R&D and a strategic patent portfolio management policy are the key to long term growth of the drug industry in India.

Although the WTO Patent regime should ideally trigger growth and innovation, there is much apprehension that the small player will be compelled to down shutters. However, experts point out that if used the regime to their advantage by aligning themselves to global standards in manufacturing the regime will open up new areas of collaboration.

Further, the government is coming out with more and more innovation support schemes and building up infrastructure facilities that will help small companies do original R&D in collaboration with public funded institutions. The new era is not the end of business, but a new path to prosperity if positioned appropriately, says a pharma expert.

According to Indian Pharmaceutical Alliance, the new regime will encourage international companies to leverage India’s intellectual and cost advantages to establish research centres here and encourage reverse brain drain to make the country a global centre of pharmaceutical research.

H Khorakiwala, chairman, Wockhardt, and President, IPA, said, “The new patent regime will help the domestic industry meet its ambitious target of acquiring one-third of the global generic market”. Sun Pharma, said, “We support the IPA stand which in brief supports TRIPs but with adequate safeguards against ever-greening. We think it is very important to see that we do not go beyond the purview of the law, and ensure appropriate redressal mechanisms in place”.

The foreign MNCs with their subsidiaries doing roaring business in India are upbeat about the WTO patent regime, although with a little apprehension as to how good the enforcement would be here. The new regime will see more of simultaneous clinical trials in the country for the MNC parent pipeline drugs and leveraging the strength of Indian markets.

Kewal Handa, ED-Finance, Pfizer, said, “In the short term there wouldn’t have much impact, but it will be benefiting in the medium to long term”. Domestic pharma biggie Ranbaxy says it is quite happy if a patent is granted to a pharmaceutical product based only on the criteria of novelty, innovation and commercial utility”.

“There would be a testing period for IPR, and companies will be cautious in taking strategic decisions mainly due to the ambiguity in the law and the IPR not being TRIP compliant. More R&D will move to India only in a stable IPR regime with Data Protection norms and good infrastructure in place,” Handa says.

Ranbaxy is quite sure about the generics and says, “We don’t see any products actually being withdrawn from the market in the new patent regime. There will however be a progressive decline in the number of new launches. This will not be immediate, but will be gradual”.

Companies like Ranbaxy, Dr Reddy’s, Nicholas Piramal, Wockhardt, Cadila, Dabur, Sun, etc., have been readying themselves to meet the challenges in the WTO regime. According to Krishna Ella, Bharat Biotech, Hyderabad, “Long term interests of the drug industry in India will be served by turning to genuine R&D and a strategic patent portfolio management policy would establish themselves as competent players in the global arena”.

Over the past many years, domestic companies diverted money to R&D, developing both new drugs and delivery systems and built up sustainable pipeline. Some of the drugs are in the Phase II and Phase I trials



while there are many in the early stages of development, thereby positioning the companies to benefit in the strong IPR regime.

The Indian Pharma industry fragmented with around 20,000 players will see in the new Patent regime, many a structural changes in the industry and the marketplace over a period of time. A re-emergence of ORCs (Original Research Companies) will take place, says Ranbaxy.

Top bracket companies with a strong focus on R&D will be able to innovate cost-effectively and deliver better value to the consumer. Such companies will emerge stronger. At the middle level, companies surfing the generics-wave offering a wide range of products will continue to flourish.

Some of these will focus on the export of generics but will have to transform themselves into research oriented organisations, as growth momentum through generics alone will not be sustainable in the long run due to the prevailing wafer thin margins. Finally at the bottom rung, outsourcing companies, contract suppliers and those capable of delivering economies of scale, will survive by supplying to larger Indian and global players.

Mody feels that the WTO regime in the present form is likely to slow down growth of the domestic industry and create monopolistic situations for the MNCs for their patented products, as and when marketed in India. Mody, a little apprehensive, states, "With the three simultaneous regime changes there will certainly be chaos in the next few months in the industry". However, he is optimistic that in the medium to long term the industry will benefit.

13. INDIAN PHARMA INDUSTRY: CHALLENGES AND OPPORTUNITIES

The academia-industry collaboration can work wonders for the growth of pharma industry says Prof. V B Gupta

Challenges and opportunities come together. They are like two faces of one coin, two poles of one magnet. The challenges and opportunities that Indian pharma industry is encountering currently have never been so gigantic. It is time we think how we could make maximum out of this opportunity, taking up the challenge - boldly.

In the changing game acquisitions, mergers and segmentations are getting central place. The R&D in itself is emerging as a rapidly growing industry with an estimated annual revenue of Rs 500 crore India - the emerging global driver:

Because of its large and youthful human resource, low-cost, diversity and democracy now almost everybody is consolidating that this century is 'India's Century.' It's not only that most of the jobs are coming to India; even for most of the developed countries it is essential to keep attracting Indian human resource for their survival. Hence, India is going to drive the world, whether on its own land, or on the land of others.

The economy is roaring, FDI is close to that of China and in this quarter employees' salaries have witnessed a sharp climb. Privatisation of education has added another exponent to the situation by making the work force professionally trained.

Pharma industry - in mid life crisis:

Dr Reddy's Labs' Q3 net profit is down by 93 per cent, Ranbaxy Q4 by 30 per cent and Sun Pharma's by 10 per cent. New patent regime is putting high pressure on R&D, hence the expenses are increasing and the soaring competition in generics is keeping the profit margins at the minimal. The Indian pharma industry is rated as the fourth largest by volume and 13th largest by value. There are 6,000 to 20,000 pharma companies, of which several of them do not have enough or even minimum required R&D skill, and hence, are liable to close down unless they find a way out.



The cost of developing a new drug is huge (Rs 4,000 crore) and may take around 12-15 years. Even the cost for filing aNDAs is enormous from Indian viewpoint (Rs 2.2 crore); perhaps many companies are filing aNDAs. This is the challenge, and it is reshaping the industry.

Contract Research and Manufacturing (CRAM) - the new mantra:

In the changing game acquisitions, mergers and segmentations are getting central place. The R&D in itself is emerging as a rapidly growing industry with an estimated annual revenue of Rs 500 crore. Boston Consulting Group projects the R&D revenue to touch Rs 2,200 crore by 2010. Similar is the case of contract manufacturing; perhaps, it has already taken a sizable shape. Because of the simple reason of economics, India is destined to emerge as the global hub for Contract Research and Manufacturing (CRAM) with patenting and certification activities taking a more prominent place.

Green pharmacy - Think green:

As per the estimates of WHO the market of Greens would soar to \$five trillion by 2050 due to diversion of masses from Red Pharmacy because of latter's ill-effects. India, by virtue of its plethora of ancient knowledge and time-tested holistic systems of medicine, again has all the reasons to become the global leader in Greens, another green optimism.

Trading (retailing) - a sharp twist ahead:

The retailing of medicine, which now by and large is limited to commodity trading, will take a more radical twist, making the much-needed pharmacy practice a reality. It is expected that soon chain pharmacies would sprout putting the existence of retail traders in danger and creating huge job possibilities for pharmacy professionals.

Academia industry collaboration - blockbuster for the challenge:

It's the academic institutions that in fact guide the economy of any country. They are considered as the engines of growth. And it is only when academia and industry work hand-in-hand, the real development of a nation takes place. Now because of increased importance of R&D and increased protection for Intellectual Property, the academia-industry collaborations are inevitable.

The simple reason is this that it is compulsory for the academia to pursue research and the same has now become life saving for the industry. Take the example of the BRNSS Contract Research Centre, the basis of this CRC is this that the institute is required to do research for fulfilling the requirements of M Pharm and Ph D degrees, only added factor is this that the IP would now be used for its commercial applications too. Look at the economics – if industry has to do its research by itself, then it has to have building, instruments and scientists, all of which costs a lot. We already have all of these and are, as a matter of fact, in a position to provide the R&D to the industry for free. In other words, it is in the academia-industry collaboration, where the life saving blockbuster for the pharma industry is hidden.