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Mega Ace Consultancy

# Pharma focus

MONTHLY REVIEW OF THE INDIAN PHARMA SECTOR

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## Stem Cell Research in India

# Calling for Balanced Regulations

Perhaps, the one of the earliest applications of stem cell therapy was in the 1950s when bone marrow was used to treat blood cancer. However, despite this early application not much progress was made in this sphere as global pharmaceutical companies busied themselves in the discovery of New Chemical Entities and Molecules. While many of these were evolved from the basic medicines / drugs already in use the new discoveries contributed in terms of curing / controlling major ailments, these had limitations in addressing the needs of certain incurable diseases / debilities and terminally ill patients.

Over the past decade and a half realization has dawned that stem cell therapy could be the next major stride taken by the pharmaceutical / healthcare industry in addressing the set of incurable diseases / debilities. However, this renewed interest has been mired in controversy especially as a lot of attention and advertisement has

been given to the use of 'embryonic stem cell' technology that raised the ethical issue of deriving the stem cell from an embryo in the process of which it 'died'. Though in the meanwhile a retinue of stem cell sources have been identified and understood, this debate slowed down stem cell research particularly in the US and some European countries. Moreover, another important ethical issue is the 'unknown' impact of this technology on 'humans' used is clinical trials as certain applications have led to the generation of tumours. The latter has led to the demand for a regulated environment for companies involved in research / research organisations / Organisations, individuals and entities delivering stem cell therapy. Since knowledge in this area is in the nascent stage there is danger of instituting 'regulations' that this may thwart progress in this technology, Therefore, the real challenge at this stage is to create regulations that do not asphyxiate research and progress in the application

of stem cell therapy.

The field of stem cell research / therapy, owing to this background of controversy, is relatively virgin and open to most countries that have the requisite skilled labour force including India. Though in recent years, Korea, Japan and certain European countries have made headway in this field and the US government has enhanced funding for stem cell research, the Indian government has been paying attention to this area with as much as Rs 300 crores having been allocated by the Department of Bio-technology of the government of India over the last five years.

The major objective of the Indian government in promoting research in this field has been to understand the fundamentals of how stem cells work and to conduct clinical trials to gauge the effectiveness of the therapy. The leading organisation in this context is the National Centre of Biological Sciences at Bangalore (NCBS). Besides



this, among others, important work / supplementary work is being executed by institutes like National Centre for Cell Science (Pune), National Institute for Research in Reproductive Health (Mumbai), All India Institute of Medical Sciences (New Delhi), Rajiv Gandhi Centre for Biotechnology (Trivandrum), Centre for Cellular and Molecular Biology (Hyderabad), The Stem Cell Institute (Bangalore) and LV Prasad Eye Institute (Hyderabad).

Apart from the government initiatives there are over 40 Companies / Hospitals / collaborative research organisations which have emerged in India in the past decade that are focused on research / clinical trials / therapy in the field of stem cell this number is multiplying fast.

Besides, this year over 60 permissions are likely to be obtained for clinical trials from the Drug Controller General of India. Though Guidelines for Stem Cell Research and Therapy have been issued by the Department of Biotechnology and the ICMR in 2007, these, perhaps, do not have a legal binding.

While most companies / research

institutions are going through the process of obtaining permissions from the DGCI and institutionalized processes to grapple with ethical issues, there is so far an environment of relative *laissez faire* in the area of stem cell research in India.

It is as a result of this recent systematic profusion of research / therapy that some companies like Reliance Life Sciences and Life Cell International Pvt Ltd, Regenerative Medical Services Pvt Ltd and Cryo-Save India Pvt Ltd have created facilities for culturing / storing / supplying stem cells. Besides several companies / organisations have reached advanced stages of clinical trials for regenerative medicine using stem cells like Stempeutics Research Pvt Ltd, Nichi-In Centre for Regenerative Medicine (Chennai), Centre for Cellular and Molecular Biology (Hyderabad), L. V., Prasad Eye Institute, National Centre for Cell Science (Pune) and Manipal Hospital.

In the trail of these successes have emerged skepticism and concern about the profusion of hospitals and clinics offering stem cell therapy in India, with a clientele that surprisingly comes from

the US. Such criticism has emerged because it is felt that sometimes therapies may be being administered more as 'experiments' than as an outcome of possession of certain knowledge. Therefore, patients would be risking unknown adverse outcomes. As such there is a growing demand for greater regulation.

However, considering the fact that most of such therapies are being administered to terminally ill patients or those with incurable diseases this concern may be somewhat misplaced.

Nevertheless, there is a strong case for 'practitioners of stem cell therapy' to record and make available to a regulator all necessary data / outcome of each case handled by them. This would help improve the scanty information available in the area of stem cell therapy and provide the foundation for improving upon the regulatory framework.

Over-regulation would asphyxiate the development of a technology that has the promise of revolutionizing therapeutic capabilities of medical sciences and banishing old age.

## Data Exclusivity and Patent Extension

Data exclusivity has been the subject matter of heated debates between big pharma on the one hand and public health groups and generic drug manufacturers on the other. It is based on the claim of big pharma that the data it generates from clinical trials and submits to the regulatory authorities should be considered the exclusive property of the drug companies and cannot be used even by the regulatory authorities. If data exclusivity is accepted, the generic companies who

want approval from the drug regulator for their generic version – chemically identical to that of the earlier patent protected ones — they have to conduct new drug trials and generate the same data that is there already with the regulatory bodies. This data monopoly is generally claimed for a further period of 5 years, effectively stopping cheaper generic versions of the patented products therefore for another five years. The EU has not specified the number of years it wants data

exclusivity, but given what we are seeing elsewhere, it will be for at least a five year period. In effect, the EU is asking for the patent protection of all medicines to be extended five years for delays in patenting and another undefined number of years on account of data exclusivity [article 18, para 2]. The EU draft asks also for what is known as "patent linkage". Patent linkage is a system in which the Drug Controller refuses to grant or delays a marketing approval to a generic drug



manufacturer if the drug is already patented. This 'linkage system' requires that the generic manufacturer prove to the drug regulator that the drug for which approval is sought is not covered by a valid patent. The aim is to create a second tier of protection for patent monopoly. In India, there is no patent linkage and the courts have rejected attempts by big pharma to create such linkages. The patent system and the drug regulatory system in India are two separate and independent mechanisms created under different laws and this is the legislative intent. If introduced, the patent linkage system would seriously impact the early entry of generic drugs

into the market. Some feel that the government should not proceed any further on the India-EU FTA and all other FTAs unless all current proposals, negotiating drafts are debated and discussed in parliament and with state governments. This segment contends that the Government has no right to negotiate away peoples' rights to

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violation of patent laws of the European countries.

Once Brazil, which had jointly raised its voice with India against EU's customs regulations, gets the required approval domestically for filing the case, both countries would request the WTO for setting up of a panel to hear the dispute. India has appointed intellectual property experts to prepare the case against the EU and is confident of a favourable verdict at the WTO. Indian officials feel that customs officials in the EU countries bent WTO rules when they seized good quality off patent medicines being shipped from India and as such it would not be difficult proving the case.

For extension of patents, the EU argument is that patent life needs to be extended in India by another five years beyond TRIPS as Indian patent office takes time for approving patents [Article 17.3, para 1,2, 3]. This would require a new legislation.

Indian officials have contended that they were not aware of any patent office that did not take time for processing patent applications and in any case the law could not be changed for procedural delays. They felt that in case EU feels its companies are losing money due to long delays in the patent office, the correct procedure would be to ask the Commerce Ministry to streamline this procedure and not ask the Indian Parliament to change the law! Further, it was argued that extension of patents was more the promotion of 'monopoly' rather than 'free trade', which the EU stands by. Since India and EU are eager to have a Free trade Agreement (FTA), it is important for both to interpret 'free trade' identically. Perhaps, a major stumbling block would be the way EU interprets 'free trade' in the area of patent extension in the pharma sector.

## Pros & Cons Debate

# Confiscation of Indian made drugs in Europe

Over the past one year, a number of reputed Indian drug producers including Dr Reddy's Laboratories Ltd and Aurobindo Pharma Ltd had their consignments seized in countries like Netherlands and France, following complaints made by European pharmaceutical companies that hold European patents to these medicines. In their defence Indian companies have pointed out that such seizures violate the provisions of Trips (international intellectual property law) agreement, because while the European countries had granted patents for those medicines to global pharma companies, they were off-patent in India. Moreover, the drugs that were confiscated were life-saving medicines being exported to countries in Latin America and Africa, which did not have enough capacities to manufacture these

and such transactions are permitted under the Trips and public health agreement. Africa and Latin America, incidentally, are major markets for India's low cost drugs used for treatment of diseases like HIV/AIDS, tuberculosis and malaria. The two continents account for around 15% of India's total pharmaceutical exports of nearly Rs 40,000 crore. It has also been stated that EU's former trade commissioner Katherine Ashton, during her visits to India last year, had given assurances that the EU would sort out the issue bilaterally with India. Following on the promise, in January this year, the EU had said that it would make alterations in its customs regulations or its application in a way that shipments of generics from India on the way to third countries would not get confiscated at European ports for



# Industry News Updates

## Elder Pharma ties up with Gelnova Laboratories

Indian drug maker Elder Pharmaceuticals plans to enter the nicotine replacement therapy, or anti-smoking segment, with chewable jelly cubes, that reproduces the sensation of tobacco chewing while providing nicotine to addicts. Growing rate of tobacco-related cancer and awareness is prompting doctors to prescribe drugs to shed the habit. The market is currently estimated at around Rs 720 crore of which around Rs 200 crore is from prescriptions, while the rest is sold over-the-counter. Sun Pharmaceuticals, Pfizer, Cipla and GSK are leading players in the segment at present, marketing solutions in the form of transdermal patches, chewing gums, inhalers, nasal sprays and lozenges. According to the Economic times the Director of Elder Pharma Alok Saxena plans around Rs 18-20 crore revenue from this product in three years. The operating margin on the product is likely to be between 18-20%, he added. Elder Pharma has entered into a manufacturing agreement with Gelnova Laboratories to manufacture the product. According to the Company Sources Elder Pharma is planning more drugs that can be delivered in gel form, and will outsource to Gelnova. Elder Pharma will offer the nicotine pastilles in mint and pan masala flavours. The products will be launched in three strengths-

1mg, 2mg and 4 mg. The product lasts for around 30-40 minutes in the mouth.

## Government mulls bringing cancer drug under price control

The government is considering bringing cancer drugs under price control to provide relief to patients in the country, senior officials reported to the Hindustan Times. As per the officials, a move is already on to make cancer drugs a part of the National List of Essential Medicines (NLEM), which would make it easier to bring them under the Schedule I of the Drug Price Control Order of 1995. Schedule I drugs are under price control in the country at present. "Currently, we are collecting data from pharma companies on the market size of cancer drugs, cost of production, packaging and other expenses. Only after analyzing these data, The Government will start the process of bringing cancer drugs under price control," Another senior official said the Health Ministry has also mooted a proposal to amend the NLEM in order to accommodate cancer drugs in the list. NLEM is a list of 354 drugs drawn up by the government in 2003 aimed at addressing the priority healthcare needs of the country. The Supreme Court had asked the government to put in place a policy that would bring medicines under the essential list under price control.

However, an attempt to bring the NLEM under price control through National Pharmaceutical Policy 2006 did not materialise due to the difference of opinion between the various ministries. At present, most of the cancer drugs sold in India are manufactured by multinationals such as Novartis, Roche and GSK. These can cost up to Rs 1.25 lakh for a month's treatment. NGOs and other social organisations have been demanding for long that the government should act to bring down the prices of cancer drugs. It is estimated that there are nearly 1.5-2.0 million cancer cases at any given point of time in India and over 3 lakh die annually due to the dreaded disease.

## Orchid to acquire US-based marketing company Karalex Pharma

Orchid Chemicals & Pharmaceuticals Ltd announced that it had entered into an agreement to acquire Karalex Pharma, LLC, a US-based generic marketing and sales services company head-quartered in New Jersey, USA through an all-cash deal for an undisclosed amount. The transaction is expected to close by this month subject to customary closing conditions. Karalex Pharma launched in 2007 is a provider of generic pharma focused exclusively on the US healthcare market in a company committed to becoming a leading provider in the generic segment.

*Mega Ace Consultancy Research Group: Prof. Poonam Kumar & Mr. Rajiv Channa*  
*Research Support: Vaishali Padake & Vaithianathan Ganesan*

*For Research Queries Contact:*

**Mega Ace Consultancy [India] Pvt. Ltd.**

68-B, Mittal Tower, Nariman Point, Mumbai 400021

Tel: +91-22-22812298, 22812302; Fax: +91-22-22812305

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