

# Patents, access to drugs is the issue

*THE Geneva-based International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) comprises 55 global pharmaceutical associations and 26 pharma companies including developing countries like India, China, Russia, and the OECD countries. IFPMA works with international organisations like the WHO, WTO, UNAIDS, the World Bank and the Medicines for Malaria Venture (MMV) on healthcare issues, and is an interface between the industry and international institutions. Dr Harvey E. Bale, Director General, IFPMA, spoke to M G ARUN on the Indian healthcare and pharma sector, during his recent visit to Mumbai.*

**Why should multinational companies feel that the issues regarding patentability and compulsory licensing are n't well addressed in the new Indian patent system? Don't developing countries like India require such safeguards to ensure drug availability at affordable prices?**

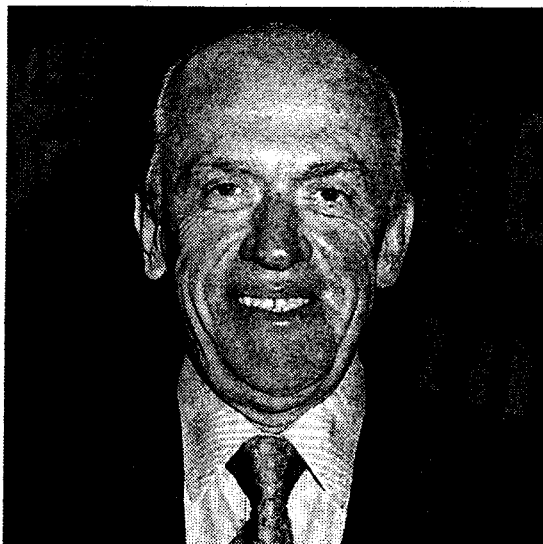
All countries have patent safeguards and have the right and ability to implement compulsory licensing in emergency circumstances. In the mid-1980s, Korea became one of the first countries in Asia to develop an effective patent legislation. Now, countries like China, Mexico and Chile have taken this up. Singapore has initiated a good bio-sciences programme.

It is important for India and the rest of the world to have a good balance between implementation of innovation policies and those that give better access to medicine. There is no conflict between a patent system and the public's access to medicines. The Indian pharma industry has been debating this point for a few years.

**India has a good generics base. Now product patents have also been introduced.**

**Is this a good progression?**

Different countries have moved at different speeds. For India, the patent regime goes well beyond the pharma sector, and encompasses agriculture and food sectors. Every country has to look at their own situation. The lesson learned globally is that you can have a strong patent system and a very strong generic sector as well. India has built a strong chemistry base, and also a generic base.



The future of the world is in information sciences and technology. This is where the value add for India is. I have worked with Hewlett-Packard, and we were outsourcing software from India even in the 1980s. Based upon a very good recognition of contract and copyright laws, the IT sector has grown here. IT and the film industry are the leading high technology sectors for India.

**Is the lack of protection of ideas pushing Indian scientists to work in the US to develop pharma and biotech products?**

Proper balance between innovation and generics is re-

quired. Countries such as China, parts of Latin America, Mexico and Chile have jumped into the innovation bandwagon more aggressively. India needs to do that not just in pharma, but also in agro business, chemistry, food, biotechnology and environmental technology, where the issues are similar to the pharma sector.

**The companies that pursued NCEs have failed right**

where the focus is not on just NCEs, but also modifications of the drug, significant inventions that are not obvious from the point of view of the original compound. There is a tremendous need for patients to have better versions of existing drugs, not only new molecules like what Dr Reddy's is trying to develop. Some time earlier, Ranbaxy came up with a modified molecule, a one-a-day ciprofloxacin licensed to Bayer, and it was successful. That is a good model.

The Indian population needs new and better antibiotics, better pain medicines, psychiatric or diabetes drugs. Most innovation is incremental. We need to allow the gradual evolution to take place.

**Incremental innovation or evergreening of drugs is going to benefit the MNCs only, who are the original innovators. How do you think Indian companies will benefit?**

There have been a few cases in the US and the Bush administration undertook a review of certain cases that it felt were in line with strict patentability issues. But sometimes evergreening is also applied to incremental innovations, which is a mistake. Today, there are 20 anti retroviral drugs in the market for HIV AIDS. This is because patients are increasingly developing resistance to existing therapies, and you need incremental innovations to give patients more options.

**in the clinical trials of the molecules developed. This high-risk, high investment business requires companies to have deep pockets. The industry feels it should focus on the generic sector. What is your view?**

Generics business should not become like commodities, where there is not too much difference between products of competitors. India should be wary of China in generics, and in another 15 years, other developing countries like Bangladesh will have strong generic business that will undercut Indian business.

India has to look at what has been made possible in China, Singapore and Malaysia,

Evergreening is often a minor modification. Here, the original compound can go generic regardless of the new improved compound. When the legal status of the original compound expires, generic companies are free to manufacture the compound. This issue needs more understanding, and will neither be a barrier to Indian companies nor a huge benefit to multinational corporations. ◆