OPPI

Daily News Monitor

April 20, 2016

1. Indian drug control weakest, need to bolster it: Pharma Secy – PTI Flash

Terming Indian drug control as the "weakest in the world", a top government official today acknowledged that the industry is saddled with many issues and departments work at cross-purposes on key matters.

"In the entire world, I think our drug control system probably is the weakest today. It needs to be strengthened," Department of Pharmaceuticals (DoP) Secretary V K Subburaj said at an event here.

Batting for quality, he said the health ministry is already seized of the matter and working on improving specific parameters, increasing the number of inspectors as well as drug control staff.
Putting out a ballpark figure, the secretary noted that the domestic industry -- both pharma and medical devices put together -- has a potential to grow up to USD 300 billion by 2030, from the existing USD 32 billion, but would require a proactive approach to solve various issues.

"Very tall targets unless we take proactive steps... The problem solving in this sector takes a long time... various sectors pull in different directions," Subburaj said.

He singled out drug industry associations for working in opposite directions, adding that "if we take one decision, it is appreciated by one but the other one criticises us".

There are various organisations such as IPA, OPPI and IDMA, among others, which represent various sections of the drug industry in the country.

Citing an example, Subburaj pointed to divergent views of various bodies, because of which the government took one year to come up with Uniform Code of Pharmaceutical Marketing Practice (UCPMP).

"To take example of uniform marketing code, we thought we could arrive at a common solution. But even after 7-8 meetings, we failed to come to a conclusion. It's only now that we have arrived at a code," he added.

According to the secretary, it may take years to implement the bulk drug policy.

"We created the bulk drug policy, but before we could get necessary approvals, to implement it takes years. It is not that overnight decisions are taken because various departments pull in different directions," Subburaj said.

He dubbed revival of PSUs as a difficult task despite the willingness shown by the government. On the pricing front, he said -- albeit in a lighter vein -- that all departments have worked closely to "strangle" the drug industry.

"Pricing is one important issue which is bothering all the industry... I think all departments have worked very closely to see that the sector gets strangled," Subburaj said.
He also spoke of guidelines on the bulk drug policies, which are expected to come out shortly.

"The idea is that in another 10 years, we should see there is no dependence (on bulk drug imports). We are moving towards that, coordinating with departments and the industry so that there is a good ecosystem in place for this sector," Subburaj explained.

He wanted the drug industry to sharpen focus on various other streams apart from generic drugs to further boost profitability of the sector.
"Not only generics, but also focus on other sectors like phytochemicals, blood products, proteins, monoclonal antibodies and veterinary medicines," he said.

Also appeared in Economic Times & Business Standard

2. The real story behind drug approvals – Hindu Business Line
   Whistle blower, Dinesh Thakur stresses on why the Indians need to know how approvals for the FDCs and the drugs mentioned by the standing committee were granted. Typically, before a drug is approved, it is required to be supported by clinical trials conducted by independent medical experts. If the Government is now banning these drugs, clearly there never was any evidence to support their use to begin with.

3. Indian drug firms can ill-afford to be slack in clinical studies – Hindu Business Line
   The latest action on Alkem comes at a time when Indian drugmakers are already dealing with regulatory action from the United States Food and Drug Administration. As the Indian drug industry grows in foreign markets, companies need to get their act together and ensure that quality systems are not just put in place, but also followed, rigorously.

4. 'India has come a long way in public health' – Hindu Business Line
   Lelio Marmora, Executive Director of Geneva-based UNITAID, which works under the aegis of the World Health Organisation, has many aces up his sleeve. The organisation appears to be liaising successfully with big pharma companies to make life-saving drugs cheaper. However, that hasn't kept criticism off its door. In a conversation with BusinessLine, Marmora addresses questions over transparency, ethics, IP and the rights of companies as well as developing nations.

5. Indian Drug makers Target Niche Markets – Wall Street Journal
   India's leading pharmaceutical companies, which have grown to dominate the generic-drug market, are hoping to squeeze billions in additional sales out of gaps in the U.S. market by developing niche treatments for ailments ignored by industry leaders.

   While the companies still make most of their money selling inexpensive generic drugs, they are trying to climb the profitable product ladder by spending more on research and development to create their own bespoke mixtures of drugs, new delivery systems and even improving on blockbuster drugs that have gone off patent.

6. Patent box regime: Time for a market-oriented approach – Financial Express
   Government has brought a concessional tax regime for patent income, with a view to encourage indigenous research & development activities and to make India a global R&D hub. Under this

concessional tax regime, any company, which has registered any patent, would be able to reduce the tax on the royalty earned out of that patent, from 30% to 10%, besides applicable surcharge and cess; the only condition being that the patent should have been developed and registered in India under Patents Act, 1970.

7. BAN ORDER ENDS UP IN COURT - Pharmabiz
   As the unexpected ban order can seriously affect the sales of several high turnover products of leading pharma companies, challenging that order was not at all unexpected. By obtaining stay orders by the pharma companies and IDMA, a major confusion has been created among the trade and physicians with regard to the sale and prescription of these products. Considering the ban covers a huge number of fast moving products of several top companies, the office of DCGI should have anticipated legal hurdles before issuing such an order and took appropriate steps to avoid this confusion.

8. India makes all Mylan HIV drugs for developing world – Times of India
   Rajiv Malik is president of Mylan, the $9.5- billion, Nasdaq-listed global generic and speciality pharmaceuticals company. Malik became part of Mylan in 2007 when the latter acquired India-based Matrix Laboratories, where he was CEO. That deal also transformed Mylan, which till then operated only in the US, into one of the world's largest manufacturers of active pharmaceutical ingredients (APIs).

9. Government working on recommendations to reduce bulk drug imports – Economic Times
   The government is working on the recommendations of Katoch Committee in order to reduce import of bulk drugs. Many state governments have shown interest in setting up bulk drug manufacturing units and soon the country will have many such hubs, Pharmaceuticals Secretary V K Subburaj said.

10. Lack of independent regulatory system stifling growth in medical devices: AdvaMed - Mint
    The Advanced Medical Technology Association (AdvaMed), an international lobby group, says the lack of an independent regulatory system and price controls have impeded the growth of the medical devices industry in India.

    The medical devices sector in India is highly import-dependent and fragmented with limited indigenous manufacturing; imports constitute over 75% of the estimated market valued at Rs.60,000-70,000 crore. Not having separate regulation appropriate for medical devices is a stumbling block companies to design, develop, test and launch a product in India.