

POLICY FORMULATION

The Health Ministry has almost finalised norms and rules to introduce a new Schedule under the Drugs and Cosmetics Rules to exclusively regulate the antibiotics and it is likely to go to the Drug Technical Advisory Board soon. As per the draft regulations, a new Schedule HX will be added to the Drugs & Cosmetics Act to make it compulsory to carry duplicate prescriptions.

About 70 drugs including antibiotics will come under the new Schedule HX. Violations will be punished with a fine of Rs. 20,000 or upto 2 years imprisonment. The whole purpose of the move is to check the abuse of antibiotics. Currently, the antibiotics are included in the Schedule H of the Act.

GROWTH STRATEGY

US-based Merck & Co is looking at in-licensing and co-marketing arrangements with Indian pharma companies as it wants to realise its ambitions to become one of the top five drug companies in the Indian market by 2015. "We are in talks with Indian companies for marketing arrangements as well as closely studying opportunities to roll out generics," said Mr. K.G. Ananthakrishnan, President and Managing Director, MSD India.

Merck operates in countries outside the US and Canada under the name of MSD Pharmaceuticals. In India, there are three separate legal entities – MSD Pharma, Organon India and Fulford

Based on the recommendations of the Task Force set up by the DCGI in this regard, a system of colour coding of third generation antibiotics and all newer molecules like Carbapenem will be introduced. Besides, all types of surveillances will be done for antimicrobial resistance. Apart from this, the Task Force had also called for conducting a study on prescription patterns, setting up of an Antibiotic Management Team with experts from different clinical and pharmaceutical streams, and conducting environmental surveillance as an interface between veterinary, industrial and human health, etc. The ministry is also considering some of these recommendations to streamline the antibiotics sector.

India. The last two entities came under Merck's fold by virtue of their global acquisition. At present, Merck has some 1% share in the Indian market and ranked 29th in the list of pharma companies operating in the country.

The world's second largest drug company said it wants to launch at least five to six new medicines every year in the Indian market from its global portfolio. It is also eyeing the area of branded generics in segments like cardiovascular, diabetes, women health and respiratory. Merck currently has some 75 brands in 13 therapeutic areas in the Indian market across the three entities. While the company locally manufac-

NEWS IN BRIEF

Ipsca Laboratories has said that its formulations manufacturing unit at a Special Economic Zone in Indore has received approval from the UK health regulator – UK Medicines and Healthcare Products Regulatory Agency – for good manufacturing practices. Ipsca Laboratories is one of the leading manufacturers and exporters of active pharmaceutical ingredients (APIs) in the country.

The Department of Pharmaceuticals (DoP) in the Government of India is in the process of examining a proposal to set up a Venture Fund for promoting pharma drug discovery and innovation.

"Details including size etc. are being worked out with the help of National Institute of Public Finance and Policy," the Minister of State for Chemicals and Fertilizers, Mr. Srikant Kumar Jena said in a written reply in the *Rajya Sabha* recently.

tures drugs with 13 contract manufacturers, accounting for almost 60% of its total sales volume, Merck has no immediate plans to set up its own unit.

COMBATING COUNTERFEITS

Counterfeiting has always been a contentious issue within the pharma industry. Right from the definition of the word, the size of the problem, the measures to tackle it effectively, through to the regulatory aspects – everything is subject to debate and usually the stakeholders seldom concur on any one viewpoint. According to some estimates, 12% to 25% of drugs in the Indian market are fake, whereas government estimates put the proportion of outright fakes at a much lower 0.4% and substandard medicines at 8%.

On a basic level, the lack of a universally accepted definition of what a counterfeit is underpins many problems. In India, the descriptions fake, spurious and counterfeit convey the same meaning. However as per WHO definition counterfeit drugs are those that have “been deliberately and fraudulently mislabelled with respect to identity and/or source.” In US, counterfeit drugs could include genuine, foreign medicines/brands not approved by the United States Food and Drug Administration (USFDA). Lately, big pharma MNCs are said to be equating fake drugs as those violating intellectual property protection. Now, regulations recently announced by the Indian authorities to tackle this menace have become a vexing issue for the Indian pharma sector. In January this year, the Directorate General of Foreign Trade (DGFT) made it mandatory for Indian drug makers to carry a barcode on every product exported out of the country from 1 July 2011. This barcode will enable authorities to track each and every medicine exported out of the country. The ‘trace and track’ surveillance system would enable consumers

to track the movement of products up to their manufacturer and thereby establishing their originality. However, the industry has said the proposal is not practical, would add to costs and even questioned the need for the barcode system given that the problem of counterfeits is highly exaggerated going by the Government’s own estimates. It was in this background that a one-day forum on pharmaceutical anti-counterfeiting in emerging regions was organised by a US and India based management and pharmaceutical consulting/training company, FDASmart Inc in association with NLinks Marketing & Promotional Services P. Ltd. in Mumbai recently. The forum discussed the latest developments in global drug counterfeiting scenario and the root causes driving counterfeiting in underdeveloped regions.

Anti-counterfeiting models

According to the experts who spoke at the event, the three anti-counterfeiting models in use today across the world include ‘e-pedigree’, ‘track & trace’ and ‘product authentication’.

A ‘drug pedigree’ is a statement of origin that identifies each prior sale, purchase or trade of a drug. It includes the date of transactions, as well as names and addresses of all parties involved in the transactions. As a drug moves from the manufacturer through the supply chain, each company along the process adds to the pedigree. As paper pedigrees can be fairly easy to counterfeit, manually tedious and cost-prohibitive, more pedigrees are now being provided by electronic documents called e-pedigrees. These must contain a digital signature created via only government-approved technology and

verified by an automated system. The ‘track-and-trace’ process keeps tabs on the serial numbers, product master data and distribution channel information over the product’s lifecycle. Serialised and non-serialised events are managed along with the master data in an open framework to allow internal and external trusted parties access to product identification, status, location and event data at any point in the supply chain. Serialised tracking & tracing radio frequency identification (RFID) and 2D barcode technology are used to identify an individual pack of drugs, and trace its entire lifecycle from manufacturing to wholesaling, distribution, retailing and dispensing.

Authentication is generally done at the consumer end and doesn’t give any information on the supply chain. A customer is typically asked to send a SMS to a number mentioned on the pack by the manufacturer to know the authenticity of the product.

Need for flexible solution

Commenting on the recent DGFT announcement, Mr. Joseph Ringwood, Chief Operating Officer, Systech International, said, “This emerging regulation in India is different than that being implemented in Turkey and actually resembles California legislation. A key point to be made is that the track and trace requirements do not specify infrastructure or the need to capture data and maintain it in any type of database for queries. This



type of serialisation is useless unless the product can at the very least be authenticated." According to him, the key to a successful serialisation system is the need to maintain integrity of data, irrespective of data carriers employed.

In his presentation, Mr. Ringwood took an in-depth look at the global serialisation landscape and spoke about the factors to be considered when selecting a serialisation approach. His advice to Indian companies was to anticipate and prepare for such regulations, which would be better served by having a global perspective. He gave examples of companies like AstraZeneca to illustrate the business benefits of implementing a configurable and flexible serialisation solution.

Bilcare's Chief Scientific Officer, Mr. Praful Naik's take on the counterfeit problem

was that the number of fakes in the Indian drug market is negligible, but the percentage increase over the recent past has taken endemic proportions. He pointed out the equally disturbing trend of expired drugs finding their way into the system and wondered how the regulatory and even tracking system would know if the drugs, which are stolen and repacked, is an expired drug. He also sought to downplay concerns – especially with regard to compliance requirement in importing countries – expressed by the Indian firms with regards to the new track & trace system mandated by the authorities. "If you are putting a track and trace solution on the drug pack, it does not call for any regulatory change clearance in most countries," he observed.



According to Mr. Daryll Mascarenhas, General Manager (Supply Chain), Glaxo-Smith-



Kline Pharmaceuticals Ltd, implementing a track and trace system off-the-shelf would be very difficult in a place like India. "Security of information related to the products is vital for companies and putting this information in the open domain is a major concern for them. So they are not enthusiastic of a mass serialisation measure," he said. Mr. Mascarenhas observed that most of the counterfeits made in India are not sold in the country. "As most drugs are under price control, the drug prices are about 30% less than in the international markets and so leakages happen," he said. Mr. Mascarenhas pointed out that most anti-counterfeiting initiatives taken up by drug firms around the world are in response to a mandate by the regulatory authorities. Moreover companies are also circumspect, as there is generally no standardisation of future mandates. However, his advice to companies was not to just consider the value of the brand as the key driver when taking up anti-counterfeiting measures. "Anti-counterfeiting should be seen as an umbrella solution for all brands," he added.

Dr. Milind Antani, Head-Life Sciences Practice, with the international law firm, Nishith Desai & Associates, had an entirely different view on the size of the counterfeit problem. He said that based on experience of practising medicine in the past in Gujarat, he would tend to believe the industry estimate of 10-30% of drugs to be counterfeits, rather than the Government's estimates. However, he said that the onus of tackling the menace would

lie with the industry, as he felt that not many patients would use technologies like SMSes to ensure authenticity of the drug product. He urged the industry to be vigilant as there were instances when companies were asked to prove that fake drugs confiscated by regulators were not manufactured by them.

Price of drugs immaterial for counterfeiters

In his presentation, Mr. Ram Banarse, Asst. Commissioner, FDA-Maharashtra, informed that antibiotics, antipyretics, analgesics and anti-diarrhoeal were popular targets for spurious drug makers. He said that even though high priced drugs were mostly counterfeited, even cheap drugs like chloroquine can also be targeted. He saw a key role for medical representatives and sales force of pharma companies in tackling spurious drugs. "A company's field force should act as the ear and ears of the organisation. The company should train them to investigate and verify genuineness of products available at chemists," he noted.

Mr. Alden Zecha, CFO/Strategist of Sproxil spoke about Sproxil's consumer based anti-counterfeiting solution that is in pilot stage with National Agency for Food & Drug Administration & Control in Nigeria and being considered for use in Haiti and other regions. The event was used by Tata Teleservices Ltd. to announce the pre-launch of its mobile health solutions as part of their nationwide value-added services in India.

Even as the various stakeholders professed widely varying viewpoints and estimates, all the speakers at the event agreed that counterfeiting ultimately takes its toll on the global pharmaceutical industry thus affecting stakeholders everywhere, but most specially consumers who bear the most dire of all consequences possibly leading up to life threatening situations or death.

INDUSTRY GROUSE

The pharma industry in the country, especially the small and medium scale units, has asked the Drug Controller General of India (DCGI) not to amend the Drugs & Cosmetic Act to make the implementation of 2D barcode/UID (unique identity code) mandatory for the domestic market. Instead of making the 2D barcode/UID mandatory, the industry asked the DCGI to implement the track and trace system for which there is already a provision in the Act. At a meeting convened by the DCGI on the issue recently, the industry is learnt to have apprised the authorities that as a concept there should be track and trace of medicines from manufacturing to retail using software

system, but practically it is not possible in India till the time the whole supply chain along with the manufacturing is automated through web and related software. Industry representatives said that even in USA, where most of the pharmacies (retail) are automated, the authorities have not been able to achieve the same and it is not mandatory. They have done the same in the state of California (2D and UID) on trial basis and the result is that drugs have become more expensive due to shortages as manufacturers are not equipped with 2D and UID and cannot supply the medicines. The industry also pleaded that as the implementation of the new system involves an investment of about

Rs.1 to 2 crores, it should be done on a trial basis or in stages. They suggested that larger companies who are already using such systems share their experience on how effective it is to control spurious drugs and the costs. The industry is learnt to have categorically told the authorities that if the Act is amended to make 2D barcode/UID mandatory, most of the small and medium companies will have no other option but to shut down as they will not be able to comply with the new system as the current manpower, packaging machines, computer hardware and software have to be upgraded and new equipment to implement 2D and UID have to be purchased.

QUALITY CONCERNS

Glenmark Pharmaceuticals has initiated voluntary recall of a skin ointment from the US after the drug exceeded the permissible impurity level. The company's US arm Glenmark Generics started recalling a total of 16,968 tubes of alclometasone dipropionate ointment in three dosage 15-gms, 45-gms and 60-gms as

per a notification on the US Food and Drug Administration's website. Glenmark said the company initiated the recall after it detected out of specification results during its routine stability tests during its shelf life. The drug is made at the company's Baddi plant in Himachal Pradesh and expires between October

2010 and March next year. In August 2009, the US-based Glenmark Generics had launched the generic version of GlaxoSmithKline's 'Aclovate', used to treat inflammatory and eruptions in skins. The company started withdrawing its cream after informing the American drug regulator in December last year.

UNETHICAL PRACTICES

The government said it is examining the possibility of framing a uniform code of pharmaceutical marketing practices (UCPMP) in order to prevent "unethical marketing practices" by pharma firms. In a written reply to a query in *Lok Sabha*, Minister of State in the Ministry of Chemicals and Fertilizers, Mr. Srikant Kumar Jena said, "The Department of Pharmaceuticals is examining the possibility of framing UCPMP, which would

be in the first instance be adopted voluntarily." He was responding to a query on whether the companies were luring doctors to "prescribe costly and unwanted drugs" and what steps were being taken by the government to check the situation. The minister said there were reports in newspapers that some unethical marketing practices were being followed by certain pharma companies. "Keeping in view the allegations made in the media

reports, this Department felt the need to take up the matter in the interest of the consumers/patents as such promotional expenses being extended to doctors had direct implications on the pricing of drugs and its affordability," Mr. Jena said. He added that after discussing the issues with the pharma associations/industry, the Department has been able to persuade most of the associations to have code of ethics.

INVESTING IN INFRASTRUCTURE

Grace Davison Discovery Sciences, a product line of W.R. Grace & Co, has announced the opening of a new technical service knowledge centre in Genome Valley (close to Hyderabad). The Centre was opened to support Grace's customers in the areas of laboratory separations, bulk purification, excipients and pharmaceutical intermediates. Grace's expertise in these areas assists pharmaceutical companies to bring potentially life-

saving medications to market sooner. The centre will serve as a resource for Indian customers, as well as being an Asia Pacific support hub for the region. In addition, it will be a global knowledge centre for product development and applications support for Grace Davison Discovery Sciences. Other services provided will include customer training, validation and testing for a variety of products and product demonstrations.

The new centre complements existing application laboratories in the US, Europe and China. In the last seven months, the company has opened new facilities in Chongqing, China and Hai Duong, Vietnam, and completed the acquisition of a manufacturing company in Wuhan, China. In addition, at the end of 2010, Grace began expansions at existing manufacturing facilities in Sorocaba, Brazil and Kuantan, Malaysia.

ADVANCED RESEARCH

research

The Department of Biotechnology (DBT) is putting in Rs. 200 crores to establish a centre called 'iStem', which will focus on stem cell training and basic research. The centre will be set up at the Bangalore campus of National Centre for Biological Sciences (NCBS).

This first-of-its-kind dedicated institute for stem cell forms a part of the

national 'bio-cluster' or an industry interaction platform of which NCBS and the Centre for Cellular and Molecular Platforms (C-CAMP) are part. It will work in co-ordination with the NCBS and C-CAMP to form the Bangalore biocluster where it will develop technology and enable entrepreneurship initiatives. The effort would also be to comprehend the mechanism of

stem cells and its potential to treat degenerative diseases. Stem cell therapy holds considerable promise as an adjunct if not as an alternate therapy. But the medical fraternity needs to offer therapy backed by scientific data proving its safety and efficacy. Therefore setting up of 'iStem' will give a boost to research and training, according to experts.

INTELLECTUAL PROPERTY

Academy of Intellectual Property Studies (AIPS) – an institute set up in affiliation with the Indian Drug Manufacturers Association (IDMA) – will be organising a one-day seminar on 'European patent prosecution' on April 15 at AIPS, Mumbai. The seminar will focus on the patent claims vis-à-vis Article 19 and 34 amendments. It will focus on

the amendments to Articles 19 and 34, and comment on how they influence the patent prosecution process.

Filing of patent applications at the European Patent Office (EPO) had to take into consideration a variety of amendments in the recent past. The seminar will discuss issues that are

often raised while patenting certain specific types of subject matter in the pharmaceutical, chemical field, such as polymorphs and formulations, patenting of biotech inventions, etc. Strategic tips and techniques that can be employed to successfully prosecute patent applications at the EPO will also be provided at the event.