



Drug Information Bulletin

Drug Information Centre (DIC)

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Editorial

Use of generic medicines is gradually getting popularity throughout the globe. Several countries have already passed suitable legislation to reduce Govt. health expenditure and the cost to individuals of their medicines. Use of generic medicines is also considered as one of the tools of propagating concept of Rational Use of Medicines

It may be noted that several state Governments and the Govt. of India has directed the doctors working under the Government health care system to prescribe in generic name. The Medical Council of India has also directed all prescriber to prescribe in generic name as far as possible. In spite of such instructions prescribing in generic name could not be ensured in several cases especially in private settings. Experts believe that awareness needs to be created amongst the prescriber in addition to issuing orders.

Hope all health care providers will be serious about this issue for proper implementation!!!



Dr. Subhash C. Mandal
Editor

Schedule Q & Schedule S of Drugs and cosmetics Rules amended vide GSR.203 (E) dated 18th March 2015

"Resorcin Brown" & "Solvent Red 1" have been omitted from the Schedule Q vide this notification.

Standards for Six more finished forms have been added to Schedule S after sl. No. 30, which are-

31. Liquid foundation make-up IS 14318
32. Cold Wax-Hair remover IS 15152
33. Face pack IS 15153
34. Kajal IS 15154
35. Oxidation Hair Dyes (Emulsion Type) IS 15205
36. Cream Bleach IS 15608

Most countries woefully unprepared to fight resistant superbugs: WHO

Only 34 countries have national plans to fight the global threat of antibiotic resistance, meaning few are prepared to tackle "superbug" infections which put even basic healthcare at risk, the WHO said on Wednesday.

In a survey of government plans to tackle the issue, the World Health Organization said only a quarter of the 133 countries that responded were addressing the problem.

"This is the single greatest challenge in infectious diseases today," said Keiji Fukuda, the WHO's assistant director-general for health security. "All types of microbes, including many viruses and parasites, are becoming resistant."

"This is happening in all parts of the world, so all countries must do their part to tackle this global threat."

Antimicrobial drugs such as antibiotics and antivirals are used to treat conditions such as bloodstream infections, pneumonia, tuberculosis, and HIV.

But superbug infections -- including multi-drug-resistant forms of TB -- already kill

hundreds of thousands of people a year, and the trend is growing.

Yet according to the WHO, few countries have plans to preserve antibiotics. Those that do are largely in wealthier regions such as Europe and North America, where health systems are better organized and funded and scientific capabilities are more advanced.

"Many more countries must ... step up" with comprehensive strategies to "prevent the misuse of antibiotics and reduce spread of antimicrobial resistance", the WHO report said.

Monitoring is key for controlling antibiotic resistance, the WHO said, but it is currently not effective. In many countries, poor laboratory capacity, infrastructure and data management are preventing effective surveillance, making it difficult to discern patterns of resistance and identify disease trends and outbreaks.

At the same time, non-prescription over-the-counter sales of antimicrobial drugs are common, increasing the risk for overuse and abuse by the public and by unscrupulous doctors.

Commenting on the WHO's report, Mike Turner, head of infection and immunobiology at international health charity The Wellcome Trust, described drug-resistant infections as "one of the biggest threats to the future of global health".

"Yet in most areas of the world we have no idea which drugs are being sold to whom and for what purpose. This is an appalling state of affairs," he said.

"We cannot hope to stop bacteria becoming resistant to drugs unless we have simple, basic information in place."

Asian generic companies focus more on market expansion

Singapore: A Frost & Sullivan (F&S) analysis finds that the Asian generic market is expected to grow at a

compound annual growth rate of 17-18 percent between 2014 and 2018. The team said that in Asia, India is a major market for generic drug manufacturing, followed by South Korea and Japan. Indonesia, Malaysia and Taiwan also offer immense promise. The analysis elaborated that with blockbuster drugs expected to go off-patent post 2015, generic drug manufacturers in the region are looking beyond the patent cliff to focus on market expansion and improving the quality of existing drugs. Mr Siddharth Dutta, healthcare industry manager, F&S, said, "Large drug brands have also opened their own generics division to counter the patent cliff and sustain global market shares. Pharmaceutical companies are expected to particularly invest in new chemical entities (NCE) and super generics in the next three to five years and generic manufacturers in countries like Malaysia are looking for new markets like Brazil and other Latin American countries." Mr Dutta added that manufacturers must adopt both long and short-term strategies to position themselves in the local and global markets and boost revenue. While big manufacturers need to focus on therapeutics and products with limited active pharmaceutical ingredients (API) availability, mid-sized manufacturers should focus on products with relatively higher profit margins.

For <http://www.biospectrumasia.com> Details:

Pharma looks to reduce R&D costs of \$5B per treatment

An analysis by Forbes found that major drugmakers spend \$5 billion for every new drug. Drugmakers can reduce costs by getting help from foundations or pursuing abandoned drug programs, Matthew Herper writes.

For details: [www. forbes.com](http://www.forbes.com)

Indian drug companies contest government's "brand" definition

India's pharmaceutical companies have complained that the government is slashing prices excessively in implementing its new drug pricing control order by mixing the definitions of "brand" and "product" to lower the ceiling on many drug prices. The alliance of domestic drugmakers contends that the government is unfairly including cheaper generics in its brand definitions, while the government argues that companies often market the same drug under different names. "This could compromise availability of some products in the long term," said the Indian Pharma Alliance in a statement.

For details: [The Economic Times \(India\)](http://www.economictimes.com)

Malaria vaccine demonstrates early promise

A small Phase 1 test of the PfSPZ malaria vaccine at the U.S. National Institute of Allergy and Infectious Diseases showed that the vaccine appeared to be safe and effective in generating an immune response in healthy adults. The vaccine is composed of live but weakened sporozoites of the most deadly malaria parasites. The study appears in the journal Science.

For details: [PharmaTimes \(U.K.\)](http://www.pharmatimes.com)

Online sale of medicines: Maharashtra FDA orders FIR against Snapdeal CEO

Maharashtra's Food and Drugs Administration (FDA) on Friday said it has ordered filing of FIR against e-commerce major Snapdeal.com's CEO Kunal Bahl and directors of the company in a case related to alleged

online sale of medicines, including prescription drugs.

FDA commissioner Harshadeep Kamble told reporters here that filing of an FIR has been ordered against Bahl as well as directors of Snapdeal.

When contacted, the company spokesperson did not offer any immediate comment.

Last month, FDA had raided the company's premises here in this regard. At that time, Snapdeal had said it was delisting the drugs from its portal and was assisting the regulator in the investigation.

FDA had earlier issued a notice to the company and it was asked to furnish details of the drugs offered for sale, distribution and exhibited for sale on its website Snapdeal.com.

The raid followed FDA receiving information that various medicines, including prescription drugs, were being sold online through Snapdeal.com.

As per the law, only a licensed retailer can sell drugs, and that too on the basis of prescription of a doctor, Kamble said, adding such type of online sale of drugs is not allowed as self medication can be harmful.

Source: The Times of India

ASCI upholds 151 of 201 complaints in January

The Advertising Standards Council of India's Consumer Complaints Council (CCC), a self-regulatory industry body, upheld 151 out of 201 advertisements in January 2015.

Out of the 151 advertisements against which complaints were upheld, 90 belonged to Personal and Healthcare

category, followed by the Education category with 40 advertisements.

For details: http://www.afags.com/news/story/43723_ASCI-upholds-151-of-201-complaints-in-January

Takeda agrees to pay \$2.4 Billion to settle suits over cancer risk of Actos

Takeda Pharmaceutical has agreed to pay \$2.4 billion to settle thousands of lawsuits from patients and their family members who said that the company's [diabetes drug Actos](#) caused [bladder cancer](#), it announced on Tuesday.

Takeda, a Japanese company, said the settlement would resolve most of the product-liability lawsuits related to Actos. It said it would take a \$2.7 billion charge against earnings to cover the settlement and costs for defending the remaining cases.

For details: http://www.nytimes.com/2015/04/29/business/takeda-agrees-to-pay-2-4-billion-to-settle-suits-over-cancer-risk-of-actos.html?_r=0

Forthcoming Event:

IPA CONVENTION 2015

**Venue: Hotel Trident, BKC,
Mumbai**

Date: 05-06 June 2015

**Theme: Indian Pharma Inc.:
Adapting to the
Rapidly Evolving Global
Challenges**