Drug Information Bulletin

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Content

Editorial

Schedule H1 has been introduced in the Drugs & Cosmetics Rules vide a notification dated 30th August 2013, which is effective from 1st March 2014, and includes 46 drugs including antibiotics, drugs having potential for misuse etc. Out of 46 drugs, 26 drugs were shifted from Schedule H and 20 more drugs have been included in this schedule.

The main aim was to reduce irrational use of antibiotics, which is a major cause of developing resistance to antibiotics. It was noted that all medicines including antibiotics are available from community pharmacy over the counter in India. Thereafter some more medicines were included in this list as their irrational use created health hazards and social problems.

The sale of these drugs has made regulated imposing additional conditions. Firstly the label of the drugs should bear a warning-

"SCHEDULE H1 DRUG-WARNING
-it is dangerous to take this preparation except in accordance with the medical advice.
-not to be sold without the prescription of a registered medical practitioner"

Label should contain RX symbol in red color at the left top corner. Supply of a drug included in Sch. H1 requires to be recorded in a separate register at the time of supply including the Name & address of the prescriber, Name & address of the patient, Name of the drug and quantity supplied. The record requires to be preserved for 3 years and made ready for inspection.

Experts feel that the restrictions prescribed for dispensing of Schedule H drugs are not being implemented properly, leading to irrational and misuse of medicines. They expect stricter enforcement of the restrictions imposed in case of dispensing of Schedule H1 medicines by the regulatory mechanism for the sake of public health.

New business model of Jan Aushadhi increases the scope of Pharmacists as Entrepreneur

The Department of Pharmaceuticals (DoP) hopes to infuse fresh blood into the sluggish Jan Aushadhi campaign by revising the business plan to enable the pharmacists also to run the generic outlets that seek to make drugs affordable to the common man.

As per the new business plan, pharmacist, trust or society can run the generic outlet and the process for identification of operating agencies has been simplified. As per the old pattern, individual pharmacists were not allowed to operate the outlet.

Another change in the guidelines is that the stores would now be opened even outside the hospital premises. Basket of drugs will also be widened to 361 drugs covering all therapeutic categories.

"This will give chance to unemployed pharmacists to set up generic outlet and is expected to give a big boost to the campaign. Besides, the process of selection has also been simplified," sources said.

Since the launch of the ambitious campaign in 2008, 157 Jan Aushadhi stores have been opened, with Rajasthan leading the tally. However, only 93 of them are currently functional, according to official sources.

The government has already put the new business plan by inviting expression of interest from the aspiring persons/agencies to open Jan Aushadhi stores in Odisha and Uttar Pradesh. In Odisha, there are already 14 outlets while UP is yet to have its first store.

"The operating entity will get a minimum of 16 per cent margin on MRP on scheduled products and 20 per cent margins on non-scheduled products as per government regulations. This will change as per changes made by government in future from time to time," said the notification for EOI.

Though still running behind the schedule, the DoP's ambitious target is to set up 3150 Jan Aushadhi stores by the end of the current Five Year Plan. However, the apathy on the part of the state governments has failed the campaign.

Sources said the Bureau of Pharma Public Sector Undertakings of India (BPPI), which is spearheading the campaign, has been regularly writing to all the state governments, where the Jan Aushadhi campaign is yet to make inroads.

Sweeping drug reforms endorsed by expert panel in India

An expert committee led by Ranjit Roy Chaudhury endorsed sweeping reforms for clinical trials and the processes for approving and banning drugs in India. Their proposals include limiting clinical trials to accredited institutions. The panel also endorsed the establishment of a Central Accreditation Council for research institutes, ethics committees and clinical researchers. Detailed report is available at http://www.cdsco.nic.in/Report_of_Dr_Ranjit_Roy.pdf

Higher cataract risk appears associated with statin use

An increased risk of cataracts, a main cause of poor vision and blindness, appears to be associated with the use of statins, the popular cholesterol-lowering medications, according to a report published by JAMA Ophthalmology, a JAMA Network publication.

Cataracts are a clouding of the lens of the eye. They can affect quality of life, and with a growing elderly population the incidence of cataracts is likely to increase.

Therefore, understanding the modifiable risk factors for the condition needs to be a public health priority, the authors write in the study background.

Jessica Leuschen, M.D., of the San Antonio Military Medical Center, Texas, and colleagues analyzed data from a military health care system from October 2001 to March 2010. Their analysis matched 6,972 pairs of statin users and nonusers.

In the researchers' primary analysis, the risk for cataract was higher among statin users compared with nonusers, a finding that held up when accounting for other factors that could explain the result (odds ratio, 1.27).

The authors note that prior studies of the association between statins and cataracts have yielded different results, with some suggesting an increased risk and others finding no, or inconsistent, associations.

"In conclusion, this study found statin use to be associated with an increased risk for cataract," the study concludes.

Ref. JAMA Ophthalmol. Published online September 19,, 2013.

GSK signs $196 million contract with US Government for Anthrax treatment

The Raleigh (NC) News & Observer ".biz" blog reports that GlaxoSmithKline and the US government have entered into $196 million contract "to provide 60,000 doses of the [anthrax] treatment, raxibacumab, over four years." Part of a larger five-year government contract, the anthrax agreement is with the Department of Health and Human Services Biomedical Advanced Research and Development Authority (BARDA). GSK announced a public-private agreement it had entered into "with the BARDA to support the development of antibiotics to fight antibiotic resistance and bioterrorism."

The Triangle (NC) Business Journal reports that raxibacumab received FDA approval last December, and was "developed by Human Genome Sciences," acquired by GSK in July 2012. The US government "hopes to use the medicine as a counter-measure against a potential bioterrorist attack."

Google announces Calico, a new company focused on health and well-being

Google today announced Calico, a new company that will focus on health and well-being, in particular the challenge of aging and associated diseases. Arthur D. Levinson, Chairman and former CEO of Genentech and Chairman of Apple, will be Chief Executive Officer and a founding investor.

Announcing this new investment, Larry Page, Google CEO said: "Illness and aging affect all our families. With some longer term, moonshot thinking around healthcare and biotechnology, I believe we can improve millions of lives. It's impossible to imagine anyone better than Art—one of the leading scientists, entrepreneurs and CEOs of our generation—to take this new venture forward." Art said: "I've devoted much of my life to science and technology, with the goal of improving human health. Larry's focus on outsized improvements has inspired me, and I'm tremendously excited about what's next."

Art Levinson will remain Chairman of Genentech and a director of Hoffmann-La Roche, as well as Chairman of Apple.

Commenting on Art's new role, Franz Humer, Chairman of Hoffmann-La Roche, said: "Art's track record at Genentech has been exemplary, and we see an interesting potential for our companies to work together going forward. We're delighted he'll stay on our board."

Tim Cook, Chief Executive Officer of Apple, said: "For too many of our friends and family, life has been cut short or the quality of their life is too often lacking. Art is one of the crazy ones who thinks it

doesn't have to be this way. There is no one better suited to lead this mission and I am excited to see the results."

Wireless health market poised for growth

The global wireless health market has hit growth mode, according to new report findings, which project the market will expand more than 20 percent within a five-year period.

The report, conducted by Research and Markets, pegs the wireless health market currently at $23.8 billion, expected to reach $59.7 billion by 2018, the growth being attributed to the uptick in remote patient monitoring applications and diagnostics, aging populations and growing hospital deficits.

Wireless network technologies represent the largest market segment and will continue to be the largest contributor over the next five years, researchers say.

The mobile devices and mobile apps segment, however, is also growing rapidly and will continue to grow at a similar pace over the next few years due to its wide applications and increased adoption by various healthcare professionals, pharmaceutical companies and research laboratories.

However, some say consumers, not healthcare organizations, are contributing most significantly to market growth. According to a recent IMS Research report, wireless health devices utilized by the consumer will actually prove the biggest part of the market. An estimated 50 million wireless health devices will be distributed for consumer monitoring applications over the next five years, with a fewer number of devices being used by telehealth patients.

"Due to the relatively slow deployment of managed telehealth systems, which is in part due to a reluctance from health providers to move past trials, issues with reimbursement and stringent regulations related to the use and storage of medical data, medical devices used by the consumer to independently monitor their health will provide the biggest uptake of wireless technology in consumer health devices over the next five years," said Lisa Arrowsmith, senior analyst at IMS Research, when releasing the 2012 IMS Research report.

Despite the market growth projected by Research and Markets, the industry needs to deal with issues such as uncertainty about security, privacy, lack of standards and reimbursements, to name a few.

North America is the biggest market for wireless health in 2013, followed by Europe and APAC. However, increasing demand from Asian countries has attracted players such as Qualcomm, Verizon, Hewlett Packard and GE Healthcare. China is the leading market and Japan shows promising growth opportunities in this region, according to the report.

Maharashtra FDA cancels 52 retail licenses, suspends 243 licenses for violation of D&C Act

The Maharashtra Food and Drug Administration (FDA) has cancelled the licenses of 52 retailers and suspended another 243 retailers during its crackdown on the offending chemists for the last four months from April to July 2013. The FDA has also issued show cause notices to another 450 retailers in the state.

According to senior FDA officials, stringent enforcement of the Drugs and Cosmetics (D&C) Act, 1940 has yielded results and 20 per cent cases have revealed that chemists in most of the cases were found to be absent. It was also observed during inspections that bills were not issued to the customers and medicines were sold without proper prescriptions.

Maharashtra FDA had embarked on an action plan to implement 100 per cent billing inspections to help in the recall of products which are not of standard quality and also help to trace products with adverse drug reactions (ADRs).

According to a senior FDA official, Rule 65 of the D&C Act mandates that the retail licensee should issue the bill in compliance with the Act related to it. Having an electronic facility of bar coding provided by the retail licensee ensures that manufacturing date, expiry date, batch number and other relevant details are checked for the sake of authenticity.

The crackdown on retailers was part of the FDA's action plan to implement the D&C Act strictly in the state. Earlier, the senior FDA officials deliberated on the regulator's role in facilitating the need for counseling pharmacists on following areas like reading prescriptions regarding incompatibility of drugs, patient counseling, correct dosage and medication errors which lead to adverse side effects in patients.

It has been learnt that 50 per cent of the state's sales establishments mostly located in the interior parts of Maharashtra still face the challenge of implementing the electronic system of issuing bills due to lack of knowhow, intermittent power supply and other technical issues.

Forthcoming Events

PHARMACISTS DAY CELEBRATION

25th September 2013

Organizer:
IPA, Bengal Branch

Programme:

- Wearing of Badge at Hospitals, Colleges, Universities, Pharmaceutical Industries during the day
- Seminar on "Concept and implementation of Ward Pharmacy" at IPA Auditorium at 6.30 pm.

52nd National Pharmacy Week

17th -24th November 2013

Theme:
Pharmacist: A Health Care Professional

Organizer:
Indian Pharmaceutical Association, Bengal Branch

Inauguration:
17th November 2013 at 10.00 am.

Inaugural Venue:
Shril Sikshayatan Auditorium.
11, Lord Sinha Road, Kolkata – 700071