Drug Information Bulletin

Drug Information Centre (DIC)
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Bengal Branch

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Content

Editorial

Schedule H1 has been introduced in the Drugs & Cosmetics Rules effective from 30th August 2013, and includes 46 Drugs including antibiotics, drugs having potential for misuse etc. Out of 46 drugs, 20 drugs were shifted from Schedule H and 26 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.

Schedule H1 notified by the Govt. of India vide GSR 588 (E) dated 30th August 2013

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The notification is available at http://www.cdsco.nic.in/588E30thAug2013.pdf

Indian gets top post in WHO Southeast Asian Region after 44 years

India's Dr Poonam Khetrapal Singh was elected the regional director of the WHO's Southeast Asian region.

An Indian has regained the post after a gap of 44 years. The post was last occupied by an Indian in 1968.

The present incumbent Dr Samlee Plianbangchang is from Thailand and has served for 10 years now.
Dr Khetrapal Singh was elected here during the ongoing meeting of the health ministers of the Southeast Asian countries, an official release said.
The election of the regional director is an opportunity to strengthen India's commitment to perform its role in health and development with the WHO as a key partner, Health and Family Welfare Minister Ghulam Nabi Azad said.
He said: "Poonam Khetrapal Singh is an acknowledged public health specialist and administrator with vast experience and recognition in the UN system. She would be able to contribute to regional as well as global initiatives."
Dr Khetrapal Singh has experience at global level in the WHO as executive director sustainable development and healthy environments and member of the cabinet of the director general in Geneva.
At the national level she has been the advisor, international health, in the health ministry.
Prior to joining WHO, Dr Poonam Singh was a career member of the Indian Administrative Service (IAS) since 1975. In that capacity she held several important portfolios with the Punjab government, including secretary, health, family welfare and medical education. She also worked as a specialist in population, health and nutrition in the World Bank.
Dr Poonam Khetrapal Singh has a PhD in Public Health and is a Fellow of the Royal College of Physicians (FRCP), Edinburgh.
The Southeast Asian region of the WHO comprises of 11 countries — India, Nepal, Bhutan, Bangladesh, Myanmar, Thailand, Indonesia, Sri Lanka, Maldives, Timor-Leste and Democratic People's Republic of Korea.
SEARO is headed by a Regional Director (RD) who is elected by the members of the SEARO countries. The RD has a term

of five years and, though elections are held, customarily, the RD gets a second term.

Persons who have held this post in the past are Dr C Mani (1948-68; India), Dr V T H Gunaratne (1968-81; Sri Lanka), Dr U KoKo (1981-94; Myanmar) and Dr Uton Muchtar Rafei (1994-2004; Indonesia).

Source: IANS

What to do about unsafe medicines?

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Because buyers cannot be aware of deceit in the sale of drugs, regulators need to balance the scales

"Let the buyer beware," lawyers have cautioned since medieval times.1 This is good advice when buying grain or livestock, but for as long as there have been markets people have recognized that some products' defects are not readily apparent to even the savviest shopper. This problem, now called information asymmetry, is perhaps most acute in the medicines market, where falsified and substandard drugs blend almost perfectly with good ones. Because buyers cannot be aware of the deceit in the sale of drugs, regulators need to step in and balance the scales. In much of the world, however, the regulation of drugs is neglected. In this vacuum, drug quality declines and patients suffer.

It is difficult to measure the human suffering caused by unregulated medicines, a recent Institute of Medicine report concluded.2 Whereas the burden of specific diseases can be expressed in disability adjusted life years, quality adjusted life years, morbidity, or mortality, poor quality drugs go unnoticed by design. Some contain no active ingredient
or reduced doses of the labeled drug. Others may mimic a therapeutic effect, disguising, for example, paracetamol in antimalarial packaging. Only through postmarketing surveillance do these problems come to light. Pharmacovigilance data give an understanding of what drugs are compromised and where they circulate. A better understanding of such trends could inform estimates of how much ineffective drugs cost society, translating the threat into concrete terms that compel governments and donors to act.

The irony of the problem is that the very data that could motivate investment in drug regulation depend on market surveillance. In a 2010 assessment, the World Health Organization found that only five of 26 drug regulatory authorities in sub-Saharan Africa had functional pharmacovigilance systems.3 The situation in major drug producing nations is no better. In China and India, for example, short staffed regulatory agencies struggle to inspect and license thousands of manufacturers, with little staff time left for market surveillance. A 2012 Institute of Medicine report identified poor surveillance as one of the main barriers to developing drug safety systems in low and middle income countries.4 The report recommended that the US government and international organizations invest in pharmacovigilance in these countries. In a larger sense, the report argued for more donor investment in medicines regulation in the developing world.

Donor countries stand to benefit from this investment as well. Modern drug manufacturing relies on ingredients sourced from around the world.

Supervising multinational supply chains is an insurmountable job, even for well funded regulatory authorities. Drug importing nations would welcome investments in the technical skills of regulators in drug producing nations, because these regulators have the first responsibility for manufacturing oversight. Building health systems, especially drug regulatory systems, also protects donors' interests in global health. Development agencies have invested heavily in reducing maternal and child mortality and in treating major infectious diseases. These programs depend on effective medicines, something that cannot be ensured without a commensurate investment in drug regulation.

Regulators in developing countries should help initiate these investments. Their agencies have many competing needs: equipment, training, staffing, reference standards, and infrastructure. The scope of the needs can be overwhelming, leading to inaction. The Institute of Medicine report on falsified and substandard drugs recommended that regulators in low and middle income countries draft strategic plans for agency development.2 This plan would identify the agency's priorities and guide decisions about where to invest first, a manageable first step even for a small agency. Regulators could then use the plan to advocate for better support from their ministers and to identify places where donors could contribute.

Investment in regulatory systems could bring about meaningful improvements in the health of the world's poorest people. These improvements are already well under way. The past 20 years have seen great advances in global health, but disease treatment programs may soon face the prospect of diminishing marginal returns. Their continued success depends on corresponding investments in health systems, of which the drug regulatory system is an important part. Until governments can ensure that the drugs in their countries are safe and reliable, patients face a hopeless disadvantage in navigating the drug market alone. Life saving drugs, although apparently plentiful, will remain out of reach for many.

References:

1. LeViness CT. Caveat emptor versus caveat venditor. Md L Rev 1943;7(177).
2. Institute of Medicine. Countering the problem of falsified and substandard drugs. National Academies Press, 2013. www.nap.edu/catalog.php?record_id=18272.
3. WHO. Assessment of medicines regulatory systems in sub-Saharan African countries: an overview of findings from 26 assessment reports. 2010. www.who.int/healthsystems/Assessment26African_countries.pdf.
4. Institute of Medicine. Ensuring safe foods and medical products through stronger regulatory systems abroad. National Academies Press, 2012. www.nap.edu/catalog.php?record_id=13296. (Copied for fair use)

Forthcoming Event

PHARMACISTS DAY CELEBRATION

25th November 2013

Organizer:
IPA, Bengal Branch

Programme:

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