Drug Information Bulletin

Drug Information Centre (DIC)

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Content

Editorial

Scientific studies show, that an estimated 4.8 million people suffering from moderate to severe cancer pain do not receive treatment. Similarly, about 1.4 million people suffering from moderate to severe pain at terminal stages of HIV annually, remain untreated. In India, a million people with cancer and an unknown number of people with other incurable and disabling diseases like HIV/AIDS, need opioids for pain relief and only a minute fraction (0.4%) of the population in need of opioids have access to the drugs. Major barriers to gain access to opioids are complicated regulations and problems related to attitude and knowledge among health professionals, regulators, administrators and the public regarding pain relief and opioids. As a result of collaborative efforts among the WHO, certain Palliative Care Organizations and Pain & Palliative care activists, the Government of India has taken some steps like - asking all state governments to modify the narcotic rules & regulations following a model, extended schedule K exemption to Morphine Tablets. Currently, more than 15 states and union territory in India have simplified regulations, but opioid availability for medical use has improved only in a minority of these states. Establishment of simple standard operating procedures to implement the simplified regulations, advocacy, and aggressive and improved education of professionals are essential for further improvement of the situation.

In the mean time Govt. of India has amended NDPS Act 1985 to improve access to opoids for medical purpose vide THE NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES (AMENDMENT) ACT, 2014 dated 10th March 2014. It is expected that the same will help to improve palliative care of millions of patients suffering from pain.

Dr. Subhash C. Mandal
Editor

Prohibition of testing of Cosmetics on Animals

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 21st May, 2014

G.S.R. 346(E).—Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 was published, as required by section 12 read with section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health & Family Welfare) number G.S.R. 16(E) dated the 13th January, 2014 in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i) dated the 13th January, 2014, inviting objections and suggestions from all persons likely to be affected thereby before the expiry of a period of forty five days from the date on which the copies of the Official Gazette of the said notification were made available to the public;

And whereas copies of the Gazette were made available to the public on the 16th January, 2014;

And whereas, objections and suggestions received from the public on the said rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred under section 12 read with section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:—

1. (1) These rules may be called the Drugs and Cosmetics (2nd Amendment) Rules, 2014.

(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945, after rule 148-H, the following rule shall be inserted, namely:—

"148-C. *prohibition of testing of cosmetics on animals.*—*No person* shall use any animal for testing of cosmetics."

[F. No. X-11014/7/2013-DFQC]

ARUN K. PANDA, Jt. Secy.

Note.—The principal rules were published in the Gazette of India vide notification No. F.28-10/45-H (1) dated the 21st December, 1945 and last amended by notification published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R. 153(E) dated the 5th March, 2014.

Indian firm develops inexpensive vaccine for battle with Cholera

Hilleman Laboratories Pvt., an Indian biotechnology non-profit, says it has developed an affordable and rugged cholera vaccine which could change how the battle with deadly disease is fought.

New Delhi-based Hilleman Laboratories Pvt. — which is backed by Merck & Co. and the Wellcome Trust charity — said Tuesday that it has created an inexpensive vaccine that can survive without refrigeration in the far-flung tropical villages where it is most needed.

Cholera kills over a hundred thousand people, mostly young children, and infects millions every year.

"Cholera is a huge public health burden," said Hilleman Chief Executive Davinder Gill. "The disease is endemic in over 50 countries across the world but it especially huge in the subcontinent and especially in the Bengal delta."

The vaccine is a dry power, capable of surviving temperatures of 45 degrees Celsius and is produced in a way which dramatically reduces the cost of manufacturing. One dose of the vaccine should eventually cost "significantly less than one U.S. dollar," Mr. Gill said. He hopes to start clinical trials next year.

Cholera infections are caused by drinking water infected with the bacteria. If left untreated, cholera bacteria cause severe diarrhea, dehydration and sometimes death. Diarrhea kills 800,000 children under the age of five every year, according to Unicef. A quarter of those deaths are in India.

While there are already other vaccines to ward off the bacterial infection, they are often in short supply and poorly suited for use in impoverished areas of the world where the disease is most prevalent.

The two vaccines used today, Dukoral and Shanchol, are not widely enough used to be effective in helping eradicate the disease.

Dukoral is too expensive for most poor countries, costing between $4 and $9 per dose, according to data from the World Health Organization. It is complicated to deliver, requiring a large amount of water, a problem in cholera-stricken areas with limited access to clean water. The vaccine also has to be refrigerated or it ceases to be effective after a few weeks in storage.

Shanchol costs around $1.85 a dose, according to WHO data, but it also requires refrigeration.

The need for a cold storage chain makes these vaccines less than ideal to fight cholera outbreaks, which usually follow natural disasters like the 2010 earthquake in Haiti. Because of the prices and need for refrigeration, demand for the vaccines has been limited considering the global size of the problem.

"All of us in public health said we needed a cholera vaccine, but until (the companies) actually see the orders it was kind of a vicious circle of low demand leading to low supply," said David Sack, a professor at Johns Hopkins Bloomberg School of Public Health who has been studying how to fight cholera since 1975.

The maker of Shanchol, pharmaceutical giant Sanofi SA, said that while it is working on creating a dedicated manufacturing facility for its vaccine, the demand from cholera-affected countries remains limited.

To have a chance at eradicating cholera, the world needs around 100 million doses of a cholera vaccine at around 50 cents a dose, said Dr. Sack.

"Now, we have three million doses at the cost of $1.85 per dose — and currently we need two doses," he said. "It's a problem."

Ref. The Wall Street Journal

435 drugs for seniors are in trials or under FDA review

A report by the Pharmaceutical Research and Manufacturers of America found that 435 drugs for seniors are either being reviewed by the FDA or are in clinical studies. The list includes 61 possible new treatments for heart disease, 62 for arthritis, 67 for Alzheimer's disease and 110 for diabetes. Not all of the experimental drugs will reach the market; products that reach clinical studies have a 16% chance of approval, PhRMA said.

Source: AARP.org/AARP Blog

AIDCOC wants govt. to appoint only technically qualified person in drugs dept

With a view to ensure better implementation of Drugs and Cosmetics Act and Rules, the All India Drugs Control Officers' Confederation (AIDCOC) recently made a strong appeal to health ministry demanding appointment of only technically qualified person in the drugs control organizations. The confederation stressed that posts at central and state level should be headed by only technically qualified person having qualification and experience as prescribed under Rule 49(A) and 50(A) of the D&C Rules.

This demand comes in the wake of repeated attempts by Centre to fill in top post by appointing people who either do not have any technical background or are not experienced to take over the post. Citing examples, AIDCOC pointed out that in the past Dr Surender Singh, a doctor by profession and Dr G N Singh, a pharmacist without any experience in the drug department were chosen over other eligible candidates to handle the drug controller general of India's (DCGI's) post.

Ravi Uday Bhaskar, secretary general, AIDCOC informed that by selecting candidates who do not fulfill the eligibility criterion as mentioned in the D&C Rules, the CDSCO is not only violating the Act & Rules but is also setting a wrong precedence.

"We fail to understand Centre's rationale, behind appointing people from outside for top post such as that of DCGI and state drug controllers, when we have qualified and experienced experts within the organization. These people have been in the system from a long time, gradually rising to the senior level to head the organization through hard work. Unfortunately, it seems that none of these matters as they prefer appointing only outsiders with MBBS degrees, IAS and IPS

candidates for the top job when pharmacists with years of experience slogging in the office."

Bhaskar pointed out that this is not only affecting the morale of the pharmacists working within the organization but also is jeopardizing the job prospects of pharmacists eying top job in the drug regulatory system. He added that apart from bringing major changes in their approach to appointments in the organization the centre should also focus on strengthening the same in terms of manpower and infrastructure through communication, networking and human resources development.

AIDCOC pointed out that massive training programmes specially designed to meet the existing situation is a much needed requirement to meet the impending challenges due to changing market dynamics. Bhaskar further added that key focus should be given to creating specialists in each area handled by the regulatory agencies for better and effective implementation of the Act and Rules.

Ref. Pharmabiz.com

Health Minister plans to give 50 essential medicines free

After recently prescribing the need for 'bitter medicine' to resuscitate the ailing economy, the Narendra Modi government is, seemingly, working on contours of a social welfare healthcare project to sweeten the deal for the citizenry. For starters, the health ministry's vision is to provide 50 essential generic medicines, free of cost, from "birth to death" to all Indians across the nation.

"Fifty basic essential drugs address 75% of the healthcare needs of the majority, and we plan to make these available free to everyone, from birth to death," Union health minister Harsh Vardhan told this reporter.

The programme will be rolled out in phases, beginning with select hospitals across India, with the objective of reaching every citizen.

"A standard list of medicines will ensure that for the same amount of money, 35% more medicines of superior quality can be procured to meet the healthcare needs of the majority," said Dr Vardhan.

"The programme will focus on efficient procurement, quality control and rational use – 50% medicines are wasted or overused, leading to complications and drug- resistance," the minister added.

Notably, as the Capital's health minister between 1993 and 98, Dr Vardhan implemented the 'Delhi model' of World Health Organization's "Essential Drug Programme" that drew up an essential drugs list with relevance to India's healthcare needs.

"Today, the out-of-pocket expenditure on health is 60% mainly because of two factors, medicines and diagnostics. Providing free medicines coupled with their rational prescription and use will lower cost to patients tremendously," said Ranjit Roy Chaudhury, national professor of pharmacology and chair of the committee for preparing the city's essential medicines list.

The Delhi model has been duplicated in 12 states in India and is promoted as a case study for developing nations by WHO.

Source: Hindusthan Times

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