Drug Information Bulletin

Drug Information Centre (DIC)
Indian Pharmaceutical Association
Bengal Branch
Tele fax: 033 24612776, E-mail: ipabengal.dic@gmail.com
Web Site: http://www.ipabengal.org
Contact: 09830136291

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Regulatory Affairs Division (RAD), IPA

UHC-Day celebrated on 12th December. Theme- "Keep the Promise"

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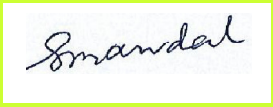
Content

Editorial

Three days back the International Universal Health Coverage (UHC) Day was celebrated throughout the Globe with a theme-**"Keep the Promise".**

It is a fact that about half of the world population does not have full coverage of essential health services and about 100 million people are still being pushed into extreme poverty because they have to pay for health of their own. In this premise all UN member states have agreed to try to achieve universal health coverage (UHC) by 2030. In 2005 WHA adopted the term Universal Health Coverage (UHC) and defines UHC as- "ensuring that all people have access to needed health services (including prevention, promotion, treatment, rehabilitation and palliation) of sufficient quality to be effective while also ensuring that the use of these services does not expose the user the financial hardship". On 12 December 2017, United Nations General Assembly declared 12th December as International Universal Health Coverage Day (UHC Day) by resolution, making it an official UN-designated day. UHC Day aims to raise awareness of the need for strong and resilient health systems and universal health coverage for the people. Each year on 12th December, UHC advocates raise their voices to share the stories of the millions of people still waiting for health, to call on leaders to make bigger and smarter investments in health, and to remind the world that Health for All is imperative to create the world we want. This year also this day was celebrated throughout the globe on 12.12.2019 with a theme **"Keep the Promise".**

Hope all stake holders and the policy makers will keep the promise to extend UHC by 2030.



Dr. Subhash C. Mandal
Editor
E mail: subhash.mandaldr@gmail.com
Mob. 9830136291

Key medicines likely to get costlier soon

Prices of widely used medicines—key antibiotics, anti-allergics, anti-malarial drugs, BCG vaccine and Vitamin C—will increase soon.

Invoking for the first time a provision "in public interest'', the drug prices regulator NPPA on Friday revised prices of 21 formulations, allowing a one-time increase of 50% from the existing ceiling price. The decision, "in exercise of extraordinary powers in public interest" under paragraph 19 of the Drugs Prices Control Order, 2013, has been taken to ensure their availability, official sources say. Till now, this provision has only been used to reduce prices, for example, to bring cardiac stents and orthopaedic implants under price control.

The NPPA's move is in response to the pharma industry's requests over the last two years to allow upward revision in prices. The industry had sought a hike in the wake of rising prices of active pharmaceutical ingredients (raw materials), and fluctuation in exchange rates, resulting in "unviable and unsustainable production''.

Prices of key APIs imported from China have jumped as high as 200% in certain cases due to a shake-up in Chinese factories in the wake of environmental concerns.

According to DPCO, prices of scheduled formulations can be revised only once a year—in April, based on the change in the wholesale price index of medicines in the preceding calendar year. The decision, taken in the NPPA meeting held on December 9, includes 21 scheduled formulations (12 drugs) which are low-priced drugs, and have been under repeated price control.

Elaborating on its decision, NPPA says most of these drugs are used as the first line of treatment, and are crucial to the country's public health programme. Also, many companies have sought permission to discontinue their products, on account of the market being unviable.

Further, "its mandate is to ensure availability of drugs at affordable prices. But while ensuring affordability, access cannot be jeopardized and life-saving essential drugs must remain available to patients. Therefore, NPPA is of the considered view that unviability of these formulations should not lead to a situation where these drugs become unavailable in the market, and patients are forced to switch to costly alternatives", the order says.

As per policy, pricing of drugs cannot be cost based, and is market determined, but this is an "exceptional measure'' being undertaken to address the situation that's arisen due to repeated price control, it adds. Earlier in January, NPPA deliberated upon 49 such industry applications involving 72 formulations, seeking an upward revision of ceiling prices under paragraph 19 of DPCO, 2013, and shortlisted 19 formulations. It also constituted a committee under senior health and pharma ministry officials, including the drugs controller general, to examine the issue based on parameters of essentiality, market share and available alternatives.

The revision under Para 19 of DPCO 2013, 'should be undertaken only in exceptional circumstances as there is neither a precedent nor any formula prescribed for upward revision of ceiling prices'', a NPPA order said. Further, after short listing the 12 formulations, NPPA referred the issue to the standing committee on affordable medicines and health products, Niti Aayog, for the modalities to be followed for such cases. The panel recommended that there was a need to revisit the prices of the 12 formulations presented to it for upward price revision under para 19 of DPCO 2013 by allowing one-time 50% increase from the present ceiling price. It was also recommended that NPPA may examine any other additional formulations/ molecules for upward price revision and present to the Authority.

Recently, a PwC India report which noted the increase in API prices as high as 100%, also said 'While the market-based methodology of annual revision in ceiling prices is a welcome feature of DPCO 2013 (as compared to the method followed in DPCO 1995), certain anomalies call for swift interventions from the government to allow an appropriate one-time increase of affected scheduled formulations'.

SOURCE: THE TIMES OF INDIA

Low enrollment impedes studies of treatments for rare diseases

Thirty percent of clinical trials for rare-disease treatments registered on ClinicalTrials.gov from January 2010 through December 2014 were discontinued, and the results from 31.5% of those that were completed remained unpublished four years later, due primarily to inadequate enrollment, according to a study published in the journal PLOS Medicine. The results suggest that new models and better networks are needed for rare-disease treatment studies, says senior investigator Florence Bourgeois.
Ref.: Medical Xpress

Scientists compete to develop pigs that resist hemorrhagic virus

Scientists in China have used CRISPR-Cas9 gene editing to make pigs that can serve as models for studying human diseases as well as pigs that resist cold weather, and now, along with scientists in Scotland and the US, they are intensifying efforts to genetically engineer pigs that resist African swine fever. Scientists in the US have also used CRISPR to develop pigs that resist porcine reproductive and respiratory syndrome and can pass the trait to offspring.
Ref.: Bloomberg (tiered subscription model)

Health Ministry plans new unit to regulate all Medical Devices

The Union health ministry is gearing up to establish a dedicated unit to regulate all medical devices under the Central Drugs Standard Control Organization (CDSCO), according to a ministry official.
The Union finance ministry last month sanctioned 750 posts in different capacities for the unit's headquarters in Delhi and three laboratories. The health ministry has recruited 25 inspectors last month to examine medical devices, and will be coming up with three dedicated laboratories for the same, said the same official cited above.
In October, the health ministry put out a draft notification to regulate all medical devices in the country under the Drugs and Cosmetics Act, 1940. According to the draft regulation, it is mandatory for all medical devices to get CDSCO certification for manufacture, sale, and distribution within India.
However, since drugs are different from medical devices, government think tank Niti Aayog had in October proposed a separate act for such devices. For the time being, the health ministry will regulate devices under the Drugs and Cosmetics Act, 1940, said another official in the know of things.
Only 23 of at least 5,000 medical devices available in the market at the moment are regulated by CDSCO, mainly due to lack of infrastructure, according to government estimates.
The new draft expands the scope to include all devices -- instruments, apparatus, appliances and implants -- whether they are used alone or in combination for use in humans as well as animals.
"The ministry is in the process of recruiting experts who will be adequately trained to manage a dedicated medical devices vertical. The devices were being regulated in batches earlier, but after stakeholders' consultation, it was decided to regulate all the devices in one go," a senior health ministry official said on condition of anonymity.
"Most countries go by the 'one Act, one regulator' practice for regulating both drugs and medical devices. There are different regulatory verticals, and it has been working quite effectively. The ministry has already begun preparations necessary for regulating devices," said the health ministry official quoted above.
Advocacy groups have been demanding stringent regulatory measures for medical devices in the country.
"CDSCO lacks adequate expertise and capacity to regulate medical devices as is obvious from its failure to effectively regulate the devices that are already under the regulatory ambit. Mere expansion of the scope of regulation does nothing to satisfy patient safety needs," according to Malini Aisola, co-convenor of the NGO, All India Drug Action Network (AIDAN).
"We have asked for systemic reforms on many fronts and for consultation with civil society and patient groups. Neither the initiative under Niti Aayog to bring out a new law nor CDSCO's counter efforts to regulate more devices are responsive to user needs and patient-oriented process," she said.

Medical devices are divided into four categories based on their risk assessment -- A, B, C and D. The first two are low-risk devices such as x-ray, CT, MRI etc, while stents and other implantable devices fall in the C and D categories.
Source: Hindusthan Times

Report of RAD & HPD National Seminar at Ranchi

HPD and RAD have jointly arranged National Seminar on **"Recent Amendment in Regulatory Affairs Related to Drug Industry and Hospital Pharmacy"** in collaboration with Dept. of Pharm.Sc.& Technology, Birla Institute of Technology. Ranchi on 14th October 2019.

Inaugural Session:

Inaugural programme was started at 10.00 am. Dr. S.Samanta HOD, Dept. of Pharmaceutical Sciences & Technology, BIT, extended hearty welcome to the guest and participants and extended thanks to IPA for holding this National seminar at BIT. Dr. M.P.Chopra, read out the messages received from Dr. B. Suresh, President PCI and Dr. T.V.Narayana, National President, IPA and President SEARPharm Forum.

Dr Paminipadnabhan Offi. Vice Chancellor, BIT, Mesra, Ranchi Chief Guest in inaugural function expressed his satisfaction for organizing this Joint national seminar at BIT and she also requested to all stakeholders to work hard for the developing health care services.

Mrs. Ritu Sahay, Director Drugs Control, Jharkhand spoke on the important role performed by the regulatory officers for ensuring good quality medicines. She also highlighted on recent developments in the regulatory field. Dr. Subhash C. Mandal, Chairman, RAD extended whole hearted thanks to the BIT administration for providing all supports in holding the joint National seminar. He also explained how regulatory officers can ensure safe, efficacious and affordable medicines to the people for improving access to health care. Dr. Mandal also emphasized on strengthening the regulatory infrastructure in both the Centre and state/UT lavel. Prof. S.L.Nasa, President, IHPA, Dr. Hari Kumara, Registrar, Central University of Jharkhand and Dr M.P.Rana, Hon. Treasurer, RAD was special Guest on the occasion. About 400 delegates participated in the programme. Dr. B.N.Sinha, CEC Member, IPA, and Vice President of IPA Jharkhand State branch spoke in this occasion.

Scientific session:

After inaugural session there was scientific session having 5 speakers who spoke on the following topics-

1. **Dr. Subhash C. Mandal Chairman, RAD, IPA** delivered lecture on "Glimpses of Regulatory Milestones in India".
2. **Prof. S.L.Nasa, President, IHPA** delivered a lecture on "Development of Hospital Pharmacy in India".
3. **Dr. Hari Kumar Registrar Central University of Jharkhand** delivered a lecture on "Holistic Development & Role of Education".
4. **Dr. Sujit Kumar, Jt. Director, Drugs Control, Jharkhand state & Joint Secretary RAD, IPA** delivered a lecture on "Regulatory Amendments Required for Cosmetics Formulations".
5. **Dr. R.N.Gupta, Chairman, HPD, IPA** delivered lecture on "Recent Amendment in Regulatory Affairs Related to Drug Industry and Hospital Pharmacy".

   Dr. M.P.Chopra, Secretary of HPD, IPA very nicely and masterly coordinated the entire programme and extended vote of thanks.

   In a poster session 83 posters were presented and three best prizes were awarded in the valedictory session.