Drug Information Bulletin

Drug Information Centre (DIC)

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Regulatory Affairs Division (RAD), IPA

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Content

Editorial

Recent controversy regarding fixing of price of medicines not included in the National Essential Medicines List 2011 (NLEM 2011) is a whistleblower to the policy makers. NPPA exerted its power as per the provision of Paragraph 19 of DPCO 2013, which authorizes the NPPA "in extraordinary circumstances, if it considers necessary so to do in public interest, fix the ceiling price or retail price of any drug for such period as it deems fit". Recent withdrawal of the internal guidelines on fixation /revision of prices of scheduled and non-scheduled formulations, under Para 19 of the DPCO 2013 dated 29.05.2014 vide notification dated 22.09.2014 by NPPA has created apprehension that price of medicines will be out of control and emergency medicines especially antiretroviral, anticancer, antidiabetic, cardiovascular, anti TB etc. will be out of reach of the patients.

This situation cropped up due to the several reasons-

Firstly the EML which was prepared in the year of 2011 is not updated, as a result some other strength or dosage form of the existing medicines left out. Some more drugs showed more efficacy over the existing medicines and being prescribed by the doctors frequently are not included in the existing EML.

Secondly it is a tendency of a sector of manufacturers to manufacture and promote medicines in the strength & dosage form not been included in the existing EML to avoid price control. This situation can be avoided by regular updating the NLEM like WHO, who updated the list every two years and strict enforcement of EML. Judicious approval of new strength and dosage form of the medicines already included in the existing EML and restricting aggressive marketing of medicines having no or least therapeutic advantage could be an effective measure.

The recent decision of withdrawal of the internal guidelines on fixation /revision of prices of scheduled and non-scheduled formulations, under Para 19 of the DPCO 2013 dated 29.05.2014 vide notification dated 22.09.2014 by NPPA has created strong reaction amongst the health care providers, who are apprehending uncontrolled price hike of the emergency medicines.

Dr. Subhash C. Mandal
Editor

World's 1st dengue vaccine likely by 2015

MUMBAI: As India deals with increasing number of dengue fever, pharma major Sanofi today said the world's first vaccine against the mosquito-borne viral disease may be available by the second half of 2015.

Sanofi Pasteur, the French drugmaker's vaccine unit, will file for registration of its vaccine candidate and subject to regulatory approval the world's first dengue vaccine could be available by the second half of 2015, the company said in a statement.
Results of the last stage of the clinical study showed that the vaccine gives a 95.5 per cent protection against severe dengue and an 80.3 per cent reduction in the risk of hospitalisation, it said.

Dengue has been a serious challenge to public health as it affects lakhs of people annually in India, Sanofi said.

The company added that its phase III efficacy clinical study programme for the dengue vaccine candidate was conducted in over 31,000 participants across 10 endemic countries in Asia and Latin America.

"We plan to submit the vaccine for licences in 2015 in endemic countries where dengue is a public health priority," Sanofi Pasteur President and CEO Olivier Charmeil said.

Country Head, Sanofi Pasteur, Stephan Barth, said dengue is a serious health concern in India, causing a significant but under-reported burden.

"Over recent months we have seen a worrying increase in cases in many parts of the country, putting a huge strain on healthcare systems. India is part of Sanofi Pasteur's global development strategy for dengue vaccine.

"Results of CYD 15 are very encouraging and in line with the results of the phase III study results in Asia and the Phase II study results in India," he said.

Committed to dengue vaccine research for more than 20 years, Sanofi Pasteur aims to make the tropical ailment the next vaccine-preventable disease, Barth said.

Read more at:
http://economictimes.indiatimes.com/articleshow/45035232.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst

DCVMN International, India Vaccine Manufacturers to Support Vaccine Initiative

The Developing Countries Vaccine Manufacturers Network (DCVMN) International has committed to support a $3.6 million program that will aim to deliver high quality and affordable vaccines in India.
The initiative will enable more vaccine manufacturers in the country to provide a sustainable, secure supply of priority vaccines for the international market. The initiative will primarily focus on pentavalent/ hexavalent, human papillomavirus, measles/rubella, pneumococcal conjugate, rotavirus, typhoid conjugate, and inactivated polio vaccines.

"The three years' project costs of over $3.6 million will be sourced 60 percent by international global health organizations and the remaining jointly by DCVMN members and partners," the group said.

The project will focus on several core areas. These will include adequate training relevant to changing GMP requirements and quality management systems. The program will also try to encourage dialogue on regulatory challenges, as well as widen access to independent experts. Design of manufacturing facilities will also be reviewed. Finally, the initiative will address World Health Organization standards and prequalification. This could help maintain the industry's momentum gained from the WHO's clearance earlier this year stating that India's Central Drugs Standard Control Organization (CDSCO) meets the prescribed international standards for vaccine manufacturing.

DCVMN President Mahendra Suhardono said, "With two out of three children in the world receiving lifesaving vaccines from emerging manufacturers, and as the world's population is growing at the fastest rate in developing countries, it is important to ensure improved manufacturing in every facility we can reach."

India has been working to redeem its reputation in pharmaceutical manufacturing after suffering a series of blows in the form of FDA bans affecting several Indian manufacturing facilities, including Ranbaxy. Several initiatives including the Coalition for Affordable Care and a petition from The Indian Pharmaceutical Alliance (IPA) have been launched in order to improve the quality of generic pharmaceutical manufacturing and increase drug discovery in the country. Earlier this month, India also announced its intention to help in the development of drugs and vaccines for Ebola virus.

Ref.

http://www.outsourcedpharma.com/doc/dcvmn-international-india-vaccine-manufacturers-to-support-vaccine-initiative-0001

Government panel moots clinical trial waive for 2 cancer drugs

The government's top advisory panel on medicines has recommended waiving off of clinical trials for two new cancer drugs, allowing them to be sold without testing on Indian patients. This, according to the panel, is permitted to cater to unmet medical needs.

The move is significant as it comes despite a recent directive from the Supreme Court asking the government to be careful while approving clinical trials as well as new medicines.

The two medicines - Aflibercept and Trastuzumab emtansine - are used in treatment of metastatic colorectal cancer and metastatic breast cancer respectively.

The Drug Technical Advisory Committee, headed by director general of health services Jagdish Prasad, considered that since both the drugs have been tested in various other countries and found to be effective, these can be allowed for sale in India in "public interest".

The law allows waiver of clinical trial in Indian population, only for drugs approved outside India, if there is national emergency, extreme urgency, epidemic, orphan drug or a disease for which there is no therapy.

Forthcoming Event:

IPA's Platinum Jubilee Celebration 15.11.2014 (Saturday)

Inaugural Programme:

1.30 pm: Registration
2.30 pm: Invocation
2.45 pm: Inauguration by lighting of lamp
2.50 pm: Welcome address by President, IPA, Bengal Branch
3.00 pm: Tribute to IPA: Hony. Secretary, IPA, Bengal Branch
3.10 pm: Inaugural Address
3.20 pm: address by Chairman, Platinum Jubilee Celebration & 53rd National Pharmacy
3.25 pm: Release of materials on "Antimicrobial Resistance".
3.30 pm: Address by dignitaries
4.00 pm: Felicitation of Past Presidents & Hony. Secretaries of IPA
4.10 pm: Award ceremony
4.20 pm: APC Ray Memorial Lecture by Mr. Pankaj Patel, Acharya P.C. Ray Memorial Gold Medal Awardee

Scientific Session:

4.35 pm: Key note speaker-Dr. Samir Kumar Brahmachari
5.20 pm: Key note speaker- Prof. R.S.Thakur
5.35 pm: Vote of thanks
5.40 pm Tea Break
6.00 pm: Cultural Programme
7.30 pm: Dinner

Notice:

Attendance in National Workshop on "Redefining the Role of Pharmacists in Health Care System" on 16.11.2014 is against a participation fee, which is as follows: Non Member: Rs. 400, Member: 300 & Students: Rs. 150

National Workshop on Redefining the Role of Pharmacists in Health Care System

Date: 16.11.2014
Time: 10.00 am
Venue: Dr. H.L.Roy Auditorium, Indian Institute of Chemical Engineers, Jadavpur University, Kolkata

9.30: Registration
Sumposium-1: Health care delivery system and role of Pharmacist
10.15: Present health care status and Role of Pharmacists in Health Care Delivery in India: Dr. Guru Prasad Mohanta, Professor, Department of Pharmacy, Annamalai University,
11.00: Tuberculosis and Role of Pharmacist: Dr. D. K. Mitra, Professor, All India Institute of Medical Sciences (AIIMS), New Delhi
11.45: Tea Break
Sumposium-2: Recent issues on pharmaceutical Industry
12.00: Present Trend in Pharmaceutical Industry: Mr. Kaushik Desai, Hony. General Secretary, IPA
12.45: Current Status of FDCs and its regulation in India: Dr. Santanu K Tripathi, Professor & Head, Dept. of Clinical & Experimental Pharmacology, Calcutta School of Tropical Medicine, Kolkata.
1.30: Lunch
2.30: Symposium -3: Recent challenges in health care system
2.30: Role of Pharmacists in controlling Misuse of Drugs with special reference to Schedule H 1: Mr. Sankar Gupta, Former Dy. Drugs Controller (I)
3.15: Role of Pharmacists in Antimicrobial Resistance: Dr. Satadal Das, President, Indian Association of Medical Microbiologists, Bengal Chapter
4.00: Quality Plant Medicines through Regulation: Dr. Soroj Kumar Pal, Inspector of Drugs, Directorate of ISM Drugs Control, West Bengal
4.45: Panel Discussion