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S&A PHARMA NEWSLETTER

EDITORIAL

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The drug regulatory authority of any country should be robust as it is responsible for taking all necessary regulatory action in research, manufacturing, and distribution to ensure the quality of drugs. It forms the backbone in running the health care system of the country. Therefore, time to time surveillance and monitoring of regulatory guidelines should be encouraged to prepare for the healthcare challenges as and when they arrive.

We are pleased to present this Vol. III Issue VIII of S&A – Pharma Newsletter. Through this newsletter, we aim to share recent information allied to regulatory reforms and updates from pharmaceutical sector in India as well as from foreign jurisdictions, based on information collated through research and appraisal of applicable statutory provisions.

In the present issue, we start with an article on a notice issued by Department of Pharmaceuticals to 22 defaulting drug companies for launching drugs in the market without prior approval from NPPA. Going forward, the issue throws some light on the draft amendment of the Drug and Cosmetic Rule, 1945 related to mandatory QR code on bulk drug packaging. Further, this issue discusses the Health Ministry proposal to amend Drugs and Cosmetics Rule, 1940, to include e-Cigarettes under the definition of drug for its regulation. This issue then covers the Surrogacy Amendment Bill, 2019 cleared by Lok Sabha; the amendment seeks to ban commercial surrogacy and to promote ethical altruistic surrogacy in the country. Going forward, the current volume mentions the expansion of India Hypertension Control Initiative (ICHI) programme to 100 districts in India by ICMR together with WHO. Next this volume also covers an important announcement of ICMR launching a clinical trial on tuberculosis vaccine, which aims to prevent the spread of TB in the family or caretaker of TB patients. The issue goes on to discuss the revised 'Consumer Awareness, Publicity and Price Monitoring Scheme' of NPPA to strengthen price monitoring and enforcement system at central and state level.

The volume then discusses the recent Indian regulations in the health care sector in a separate section as 'Indian Health Care Highlights 2019'.

From the international arena, the issue has a separate section which discusses recent announcements from US FDA for August 2019. Along with this, we also included a separate new section for WHO to discuss the major regulation taken by WHO in August 2019.

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Trust you enjoy reading this issue as well. Please feel free to send your valuable inputs / comments at newsletter@singhassociates.in

Thank you.

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Launching a new drug in market requires nod from drug pricing authority

On July 23, 2019, the Union Minister for the Chemicals & Fertilizers, Mr. D .V. Sadananda Gowda, in a written reply to Lok Sabha informed that 22 drug formulations were introduced in the market without prior approval of the National Pharmaceutical Pricing Authority (NPPA). Consequently, the NPPA issued demand notices for an amount of INR 101 crore against defaulting companies. Out of this, an amount of INR 5.56 crore has been recovered and demand notices amounting to INR 89.31 crore are under litigation[1].

The NPPA ('Authority') is an independent agency under the Department of Pharmaceuticals (DoP), Ministry of Chemicals & Fertilizers to regulate the availability of medicines in the country at affordable prices. The Authority functioning as per provisions of the Drugs (Prices Control) Order, 2013 (DPCO) of Essential Commodities Act, 1955, regularly monitors the market activities for DPCO compliances and takes action against violators.

The DPCO, 2013[2] has precisely mentioned the applicability of prior price approval for different drugs:

- that when an existing manufacturer launches a new drug other than the listed drug (drug + dosages + strengths) in National List of Essential Medicines, shall need to apply for prior price approval of such new drug from the Government (NPPA) in Form-I of Schedule-II of this Order. Non-compliance of this provision requires existing manufacturer to deposit the overcharged amount along with the interest calculated from the launching period, in addition to penalty as per Para15(5) of this order[3].

In certain cases the approval of pricing authority is not required, namely:

- No prior approval is required in case the manufacturers increase the maximum retail price (MRP) of scheduled formulations once in a year (April), on the basis of the wholesale price index.
- As per para 12(1) a manufacturer, launching a scheduled formulation, shall be free to fix the price of the scheduled formulation equal to Price list; to or below the ceiling price fixed for that schedule formulation by the Government. (2) Where an existing brand is re-launched by another manufacturer the provisions of paragraph 13 shall be applicable.
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However, the provisions of this order are not applicable in certain cases, where:

- a new drug patented and produced in India, if developed through indigenous research and development, are exempted for price regulation under this Order for a period of five years from the date of commencement of its commercial production in the country.
- a new drug is produced by a new patented process in India, if developed through indigenous research and development, are exempted for price regulation under this Order for a period of five years from the date of the commencement of its commercial production in the country.
- a new drug involving a new delivery system developed through indigenous research and development, are exempted for price regulation under this Order for a period of five years from the date of its market approval in India, if proof of approval of such new drugs from Drugs Controller General (India) is produced before the Government.

Note – NPPA regularly analyzes market-based information to monitor the status of new drug launches and drug overcharging. Apart from this, a consumer may lodge a complaint directly to NPPA, if he observes pricing of medicine over and above the printed MRP of a medicine.

1 http://pib.nic.in/PressReleseDetail.aspx?PRID=1579896

2 http://www.nppaindia.nic.in/wp-content/uploads/2018/12/DPCO2013_03082016.pdf

3 Para 15(5) Where existing manufacturer of scheduled formulation fails to apply for prior approval of the price of the new drug in Form-I, such manu fac turer shall be liable to deposit the overcharged amount over and above such price fixed and notified by the Government, if any, along with inter est thereon from the date of launch of the new drug, in addition to the penalty.

Health Ministry to mandate Quick Response code on packaging of bulk drugs

The central government proposes the amendment in Drugs and Cosmetic Rule, 1945 to mandate that every Active Pharmaceutical Ingredient (API) or bulk drugs manufactured or imported in India should have Quick Response (QR) code on its label at each level packaging, to facilitate tracking and tracing. QR code stores the information in certain forms which can only be read through software application. The draft amendment also proposes that following minimum information shall be stored in the QR codes:

- Unique product identification code,
- Name of the API,
- Brand name (if any),
- Name and address of the manufacturer,
- Batch no.,
- Batch size,
- Date of manufacturing,
- Date of expiry or retesting,
- Serial shipping container code,
- Manufacturing license no. or import license no.
- Special storage conditions required (if any)[1].

API is the crucial component of any drug formulation, therefore a safe and secure supply chain and storage condition will play important role in maintaining the quality and integrity of API or bulk drugs. The Drug Technical Advisory Board (DTAB), in its 82nd meeting, to enhance the quality supply of APIs, has recommended to include provisions under the Drugs and Cosmetics Rules, 1945 for mandatory QR coding on labels of APIs for tracing the origin and movement of APIs from manufacturers to formulators through a system of networking.

Apart from this, the Union Ministry of Commerce, through the Centre for Development of Advanced Computing (C-DAC), is planning to roll out online tracing and authentication system from April 1, 2020, for pharmaceutical export packages. The online system aims to help manufacturers and merchant traders to adopt integrated system that will enable the tracing of an exported pharmaceutical product.

The online system also has the provision to create virtual tertiary and secondary packages and generation of unique identification for manufacturers, merchant exporters, products, and packages to simplify the workflow of both manufacturers and merchant exporters.

Conclusion

The labelling requirement will not directly affect the quality, safety and efficacy of drug products. But it is expected to improve the quality of supply chain and facilitate the tracing and tracking of bulk drugs labeled with QR code.

1 http://www.egazette.nic.in/WriteReadData/2019/210445.pdf

Confusion around the status of Electronic Nicotine Delivery Systems: Drug or Poison?

The Electronic Nicotine Delivery Systems (ENDS) are electronic devices that heat a glycol and/or glycerin-based solution containing nicotine or other flavoured substances to create an aerosol, which is then inhaled by a user. ENDS use chemical solutions and emissions process. Variation in chemicals produce known and unknown toxicity which raises red flags about the safety and efficacy of this system. The most commonly known ENDS is electronic cigarettes or E-cigarettes which include heat-not-burn devices, vape, e-sheesha, e-nicotine flavoured hookah and similar other devices that enable nicotine delivery. At present more than 460 brands of e-cigarettes with varied configuration are available in the market.

ENDS are being promoted by some industry bodies and smokers as a smoking cessation aid, but lack of evidence to support its safety and efficacy as a quitting aid has left their statement vague. Moreover, a few ex-smokers who reported discontinuation of their cigarette usage with the help of ENDS have been found to be addicted to the ENDS itself to satisfy their nicotine addiction during periods of temporary or forced restraint.

The usability of ENDS was questioned by the state Government of Punjab, Haryana and Union Territory of Chandigarh, who have declared ENDS or e-cigarettes as an unapproved drug under the Drugs and Cosmetics Act, 1940 and Rules made thereunder. Further, the State Governments of Karnataka, Kerala, Mizoram, Maharashtra, Jammu & Kashmir, Uttar Pradesh and Bihar have banned the manufacture, distribution and sale of e-cigarettes in their jurisdictions.

In the year 2018, Government of India had issued an advisory on ENDS, which advised youth especially non-smokers to not use ENDS and the like devices. Moreover, it also advised State/UT governments to restrict the manufacturing sale, distribution, trading, advertisement of ENDS in their jurisdiction, except for the purpose and in the manner, as may be approved under the Drugs and Cosmetics Act 1940 and Rules made thereunder.

Subsequently, the Central Drugs Standard Control Organization in February 2019, issued an order to all State/ UT Drug Controllers stating that no ENDS and like products had yet been approved under the Drugs and Cosmetics Act 1940 and Rules made thereunder and requested them to therefore, direct the Controller to ensure that ENDS and like devices shall be monitored and restricted for sale, manufacturing, import, distribution, trade and advertisement in their jurisdictions.

In May 2019, the Indian Council of Medical Research on the eve of 'World *No Tobacco*' Day released a white paper on regulation of ENDS and like devices.

Tobacco Control Law and Related Laws in India

1. Drugs and Cosmetics Act, 1940('Act') and Rules made thereunder regulate the nicotine and few of its formulations.
    - The Act defines Nicotine as 'Drug' under section 3(b).
    - Smoking cessation aids like chewing gums and lozenges up to 2 mg of 'Nicotine' are exempted from sale license under chapter IV of Act, but manufacturing of these formulation requires drugs manufacturing license issued by DCGI.
    - Various "Nicotine" preparations indicated to reduce withdrawal symptoms associated with quitting the smoking such as Nicotine Transdermal Patches 36 mg/78 mg/ 114 mg; Nicotine Lozenges 2mg/4mg; Nicotine ploacrilex lozenges are approved by DCG(I) under Act.

Nicotine is defined as 'drugs' and any product intended to be used as aid for smoking cessation has to be approved under the provisions of the Act. Therefore the Drug Consultative Committee (DCC) in its 48th meeting, recommended that since Electronic Nicotinic Delivery Systems (ENDS) and the like products are used as a tobacco [especially smoking forms such as cigarettes] cessation product and functions for nicotine delivery for reasons including nicotine de-addiction, these devices and products fall under the definition of "drug" as defined under Section 3(b) of the Drugs and Cosmetics Act, 1940[1]. Now the Health ministry proposes an amendment in Drugs and Cosmetics Rule, 1940 to define e-cigarettes as drug for its regulation.

2. Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003 (COTPA 2003), is a comprehensive legislation passed by Ministry of Health & Family Welfare to regulate the advertisement, trade and commerce, production, supply and distribution of cigarettes and other tobacco products in India. Overall it aims to protect the population from the health hazards associated with the use of tobacco products.

3. Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011 ('Regulation') issued under the Food Safety and Standards Act, 2006 by the Food Safety & Standards Authority of India (FSSAI). The Regulation 2.3.4 states that no tobacco and nicotine products shall be used as ingredients in any food products e.g Gutkha is banned accordingly.

4. The Insecticide Act, 1968 listed out 'Nicotine' as insecticide

5. Juvenile Justice (Care and Protection of Children) Act, 2015. Section 77 of the said act discourages the use of any intoxicating liquor or any narcotic drug or tobacco products or psychotropic substance to any child, except for the medical reason. Any person enforcing any child to use the said substances shall be punishable by rigorous imprisonment.

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1 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/common_download.jsp?num_id_pk=OTE1

Central Government to Ban Commercial Surrogacy

The Lok Sabha on August 05, 2019 cleared the Surrogacy (Regulation) Bill, 2019, which seeks to ban commercial surrogacy and to promote ethical altruistic surrogacy with the due clearance from appropriate authorities to only eligible couples and mother as defined under this Bill[1].

The bill is yet to get approval from Rajya Sabha and the President's assent to become a law. Once it is approved, it will be announced by the Central government for enforcement purpose.

The bill only allows permitted surrogacy to be ethical surrogacy, where (i) the intending couple has been proven infertile; (ii) the nature of surrogacy is altruistic, means no monetary compensation is made to the surrogate mother except medical expenses and insurance coverage; (iii) not for commercial or marketable purposes; (iv) not for producing children for sale, prostitution or other forms of exploitation; and (v) for any condition or disease specified through regulations.

Highlights of Surrogacy Regulation Bill 2019

The bill is seeking to regulate the surrogacy procedure by appointing an appropriate authority in center and state; the said authority will be responsible to recommend any amendments to the rules and regulations related to surrogacy.

The bill also empowers the central and the state governments to constitute the National Surrogacy Board (NSB) and the State Surrogacy Boards (SSB), respectively. Functions of the NSB include (i) advising the central government on policy matters relating to surrogacy; (ii) laying down the code of conduct of surrogacy clinics; and (iii) supervising the functioning of SSBs.

The appropriate authority shall also regulate:

1) **Surrogacy clinic**
The appropriate authority will be responsible to issue, cancel or suspend the registration of surrogacy clinic, and also monitor the regulatory compliance of these clinics.

2) **The intending couple**
The appropriate authority will issue the '*certificate of essentiality*' to the intending couples on the basis of:

- a certificate of proven infertility of one or both partners of the intending couple from a District Medical Board;
- an order of parentage and custody of the surrogate child passed by a Magistrate's court; and
- Insurance coverage for a period of 16 months covering postpartum delivery complications for the surrogate.

The appropriate authority will issue the '*certificate of eligibility*' to the intending couples on the basis of:

- the couple being Indian citizens and married for at least five years;
- between 23 to 50 years old (wife) and 26 to 55 years old (husband);
- they do not have any surviving child (biological, adopted or surrogate); this would not include a child who is mentally or physically challenged or suffers from life threatening disorder or fatal illness; and
- Other conditions that may be specified by regulations.

1 http://164.100.47.4/BillsTexts/LSBillTexts/PassedLoksabha/156-C_2019_LS_Eng.pdf

3) **The surrogate mother**

The appropriate authority will also issue the '*certificate of eligibility'* to the intending surrogate mother, for this the surrogate mother has to be -

- a close relative of the intending couple;
- a married woman having a child of her own;
- 25 to 35 years old;
- a surrogate only once in her lifetime; and
- possess a certificate of medical and psychological fitness for surrogacy.

Apart from this the appropriate authority empowers the surrogate mother that she has an option to withdraw from surrogacy before the embryo is implanted in her womb. She can also give her written consent to abortion of surrogate child. The surrogate child is deemed to be the biological child of the intending couple.

Non-compliances of the Bill like participating in commercial surrogacy; exploiting the surrogate mother; abandoning, exploiting or disowning a surrogate child; and selling or importing human embryo or gametes for surrogacy, will result in imprisonment up to 10 years and a fine up to 10 lakh rupees.

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Indian Council of Medical Research to expand India Hypertension Control Initiative (IHCI)

On July 31, 2019, Indian Council of Medical Research (ICMR) announced expansion of their programme India Hypertension Control Initiative (ICHI) together in collaboration with WHO and Ministry of Health and Family Welfare.[1]

Background

The first ICHI was launched in November 2017 with the aim to control the cases of heart attack and other serious disorder related to high blood pressure or hypertension. The programme also aimed to reduce death and disability related to cardiovascular diseases. According to data published by ICMR, Hypertension is the major reason of up to 10.8% of all deaths in India. Prior to this expansion of ICHI the programme enrolled about three lakh patients with hypertension as their present condition. The programme was initiated in 25 selected districts of India in states of *Punjab, Madhya Pradesh, Kerala, Telangana, and Maharashtra*. However, the current expansion programme will extend to 100 districts in India. This expansion will cover almost *all the states of India*. The major goal/objective of the expansion is to improve the quality of hypertension treatment among 15 crore population over the period of next 4 years.

Major contributions of expanded IHCI in strengthening the health system

- **Hypertension treatment protocols** to simplify quality patient care in the primary care facilities, prioritizing adequate quantity of quality medicine and blood pressure monitors
- **Comprehensive training** for healthcare workers (doctors, nurses, pharmacists, ANM, mid-level health care providers) on latest practices on hypertension.
- **Focusing on team-based care** to involve nurses, health workers and ASHAs for counseling and follow up of the patients and to improve adherence to treatment.
- **Patient-centered services** to improve patient support, reduce reliance on bigger hospitals far away from the patient's home, increase the utilization of "Health and wellness centers" and primary health centers and reduce the travel and expenditure on medicines.
- **Easy-to-use information** systems strengthen the culture of accountability and continuous improvement which can be applied to other health conditions as well.
- **Monitoring of all the health facilities and prompt feedback** to the program managers to bridge the gaps in a timely manner. [2]

Note: According to Dr. Balram Bhargava, Secretary, Department Health Research and Director General ICMR "Government of India has adopted a national action plan for the prevention and control of non-communicable diseases and has set a target for a 25% reduction in high blood pressure by 2025. With approximately 20 crore adult patients with hypertension in India, more support from all quarters will be needed to help the Government achieve this target.

Conclusion

Heart attacks and strokes contribute to maximum number of deaths and high blood pressure or hypertension is the major cause all cardiovascular diseases. Hence, to minimize the related death rate and to provide better treatment option, the government organization is taking control initiatives that can prevent the severity and death cases due to this disease. Expansion of ICHI programme of ICMR is one of its kind of control initiative taken to improve the quality of hypertension treatment.

1 https://www.icmr.nic.in/sites/default/files/press_realease_files/IHCI_op.pdf

2 https://www.icmr.nic.in/sites/default/files/press_realease_files/IHCI_op.pdf

Indian Council of Medical Research launched vaccine trial to prevent spread of Tuberculosis

On July 15, 2019, Indian Council of Medical Research (ICMR) has launched a vaccine trial ('Trial') to prevent the occurrence of Tuberculosis (TB) among close contacts of TB patients. The main purpose of the trial is to prevent the spread of the disease among people in close contact with TB patients.[1]

Background of Tuberculosis in India:

India accounts for about a quarter load of the Tuberculosis around the globe with highest number of Multi Drug Resistance TB (MDR-TB) patients. Also, India is the second highest country after South Africa for HIV- TB co-infections. Moreover the lack of awareness, social stigma, limited availability of diagnosis and treatment is making Indian population vulnerable to TB infection. Therefore, there is a need that the health bodies should come with an easy vaccine option which is cost effective and can easily prevent the disease from spreading. ICMR conducted landscape analysis of the two potential vaccine candidates *VPM 1002* and *MIP* and took forward the phase 3 clinical trial in healthy caretaker/attendees of sputum smear positive TB patients. The main purpose of the phase 3 trial was to evaluate the safety and tolerability of VPM1002 compared to BCG in newborn infants with TB.[2]

About the vaccines

VPM1002 is the recombinant bacille Calmette–Guerin (BCG) which is more effective in the treatment of tuberculosis. Bacillus Calmette-Guérin (BCG), an attenuated strain of Mycobacterium bovis was the only vaccine which has been used in treatment of tuberculosis in young children. However several TB cases are still observed in children after the use of BCG. The protective efficacy of BCG against pulmonary TB is even less certain and yet pulmonary TB comprises >75% of the disease burden. This was the major reason for the development of the more efficacious and safer drug for treating TB. VPM1002 vaccine was developed to enhance MHC-I-related immune responses. Moreover the drug was more safe and effective in comparison to the conventional BCG and can be given to adults for treatment of TB whereas BCG is only used in children.

Objective of the Trial

The vaccine trial for Tuberculosis was performed with two vaccines VPM 1002 produced by Serum Institute of India, Pune and MIP (Mycrobacterium Indicus Pranii). The aim of the trial was to evaluate the safety and efficacy of the above two vaccines in single trial against control group with no vaccine. The study enrolled 1200 healthy individuals in contact with smear positive TB cases that are at high risk of contracting the disease. These individuals were selected from 7 sites in 6 states (Delhi, Karnataka, Maharashtra, Orissa, Tamil Nadu and Telangana) of the country. The study has the approval from all the regulatory bodies of India.

Conclusion

Since TB is highly prevalent disease there is an imperative need that the health bodies and ministry should come up with a vaccine or treatment remedies which can prevent the disease effectively without any side effects. To achieve the goal ICMR has conducted the trial on various vaccines stains which have the potential to prevent the disease more effectively as compared to the conventional vaccine options.

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1 https://www.icmr.nic.in/sites/default/files/press_realease_files/Press_Release_Launch_of_vaccine_trial.pdf

2 https://www.tbfacts.org/tb-india/

NPPA revised the existing monitoring and enforcement system to Consumer Awareness, Publicity and Price Monitoring scheme

On August 8, 2019, the National Pharmaceutical Pricing Authority (NPPA) declared that they have revised the existing 'price monitoring and enforcement system' with the approval of Department of Pharmaceuticals (DoP), and renamed it as 'Consumer Awareness, Publicity and Price Monitoring' to strengthen the monitoring and enforcement system. The revised/modified scheme will be implemented at the Central level by the National Pharmaceutical Pricing Authority (NPPA) and at the State level by the registered societies of Price Monitoring and Resource Units (PMRUs)[1].

Background

The main purpose of NPPA was to always have a check on the ceiling price of the medicines and make them available at a very affordable price to public. However, majority of the public was not aware of the price control of various branded medicines available in the market and as a result they used to purchase the medicines at higher price even though the medicine is available at cheaper rate in market. Moreover, due to growth in the pharmaceutical industry there is a shift in the pricing control from economic criteria to essential and market-based criteria. Based upon this changing scenario and lack of the field units which can have link between activities of state drug controllers and state drug inspectors, NPPA has revised the existing scheme by renaming it as Consumer Awareness, Publicity and Price Monitoring.

Objectives of the scheme

The main objective of the scheme was to deliver the information to the public regarding:

- Ceiling prices of scheduled medicines notified by the Government;
- Permissible price increase for scheduled and non-scheduled medicines;
- Availability of medicines at reasonable prices and promotion of generic medicines;
- Precautions to be taken while purchasing medicines from chemists/retailers such as checking the MRP (which includes all taxes), manufacturing and expiry dates, price list of medicines, obtaining bill for the medicines bought, etc.;
- Requirement for prescription of medicines by their generic names also;
- Price control and monitoring and enforcement activities of NPPA;
- Lodging complaints to NPPA for any violation of DPCO, 2013 as well as unethical practices in the Pharma sector[2]

The new revised scheme will be implemented by NPPA and Price Monitoring and Resource Units (PMRUs).

NPPA: The NPPA will create general awareness among public regarding the ceiling prices of medicines fixed by the Government and precautions to be taken while purchasing the drug. Moreover, they should also organize conferences and seminars for spreading awareness.

1 http://www.nppaindia.nic.in/wp-content/uploads/2019/01/CAPPM-SCHEME-GUIDELINES.pdf

2 http://www.nppaindia.nic.in/wp-content/uploads/2019/01/CAPPM-SCHEME-GUIDELINES.pdf

PMRUs: PMRUs will be formed both at the center and state level and will perform the activities like market-based data collection, compilation; analyzing and management of scheduled/non-scheduled formulations; monitoring of price movement of scheduled/non-scheduled formulations; collection/purchase of test samples of medicines; and miscellaneous activities like advertisement and publication of newsletter, etc.

Conclusion

The changing trend in the price control monitoring system and lack of monitoring centers raised an alarm among the experts of NPPA to form or revise their existing scheme which creates awareness among public regarding the ceiling prices fixed by the Government and about controlled medicines. The revised scheme will help in creating awareness amongst the people about the availability of medicines and their prices, which will help them in choosing quality medicines at reasonable price.

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India Healthcare Highlights August 2019

This segment of the newsletter shares recent information associated with regulatory reforms from *Healthcare and Pharmaceutical* sectors from Indian jurisdiction. This segment collates information on a monthly basis via conducting research and appraisal of applicable statutory provisions. Below are the highlights for August 2019.

Annual increase in ceiling prices of knee implants should not be more than 10% - NPPA[1]

The drug price regulator, National Pharmaceutical Pricing Authority (NPPA) has notified that the annual ceiling price of orthopaedic knee implants should not be increased beyond 10 per cent. Two years ago the orthopaedic knee implants were brought under price regulation under the provision of Drug Price Control Order (DPCO), 2013. Price regulation make these devices affordable and therefore available to the common man. NPPA has categorized knee implants into two types; primary knee replacement systems and revision knee replacement systems, which is again classified into subtypes according to feature and types of material it is made of. Therefore the features, types of material used and newness of technology of implants are considered by drug regulators while calculating the ceiling pricing.

Cabinet approves merger of National Institute of Miners' Health (NIMH) with ICMR-National Institute of Occupational Health (NIOH)[2]

The Union Cabinet on July 24, 2019, has approved to merge National Institute of Miners' Health (NIMH), an autonomous Institute under Ministry of Mines (MoM) with National Institute of Occupational Health (NIOH) of Indian Council of Medical Research (ICMR), Ministry of Health & Family Welfare (MoH&FW). The merger will transfer all assets and liabilities, all the employees of NIMH to NIOH in similar post/pay scale as the case may be and their pay will be protected. The merger will benefit both the institutes in terms of enhanced expertise in occupational health, and also benefit government to manage the merged institute cost effectively. In future, government may merge more autonomous organizations in order to improve the performance of autonomous institutes, and management of expenditure of these institutes.

India-U.S. Collaborative Research Grants on Vaccine Adjuvant Development[3]

National Biopharma Mission (NBM) is Industry-Academia Collaborative mission to promote indigenous innovative research and development with the main focus on vaccine and biopharmaceuticals. The mission is implemented by Biotechnology Industry Research Assistance Council (BIRAC), and supported by the Department of Biotechnology (DBT). Under this mission the DBT had collaborated with National Institute of Allergy and Infectious Diseases (NIAID) - National Institute of Health (NIH). The collaboration under the aegis of Indo-US Vaccine Action Programme (VAP) is now inviting proposals for the in-vitro/in-vivo research and preclinical trials of vaccine adjuvants development. This call invites consortia-based concept proposals from academia (with/without industry) with already established/identified leads and explicitly outlined deliverables for further validation. The programme will not support the proposals related to cancer-related adjuvant discovery/development and clinical trials.

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1 http://www.nppaindia.nic.in/en/whatsnew/notification-in-respect-of-knee-implants/

2 http://pib.gov.in/PressReleseDetail.aspx?PRID=1580068

3 http://dbtindia.gov.in/sites/default/files/7-8-2019_Adjuvant_RFA_0.pdf

US FDA Highlights August 2019

US FDA approves the first therapy for rare joint tumor[1]

On August 2, 2019, US Food and Drug Administration granted approval to Turalio (pexidartinib) capsules for the treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not responsive to improvement with surgery. The FDA granted the approval of Turalio to Daiichi Sankyo. TURALIO is a drug used to treat adults with a tumor in the protective layer surrounding the tendons called Tenosynovial Giant Cell Tumor or TGCT. The drug approval was given based on the results of a multi-center international clinical trial of 120 patients, 59 of whom received placebo.

US FDA approves Baqsimi nasal powder for severe hypoglycemia[2]

On 24 July, 2019, US FDA approved the Baqsimi nasal powder, the first glucagon therapy approved for the emergency treatment of severe hypoglycemia that can be administered without an injection. The FDA granted the approval of Baqsimi to Eli Lilly and Company. Severe hyperglycemia is the condition in which patients' blood sugar levels fall to a level where he or she becomes confused or unconscious or suffers from other symptoms that require assistance from another person to treat. The drug Baqsimi is a nasal powder indicated for the treatment of severe hypoglycemia in patients with diabetes ages 4 years and above. The efficacy of the drug was studied in two studies with 83 and 70 adults with diabetes and compared a single dose of Baqsimi to a single dose of glucagon injection.

US FDA warns public about the side effect of Miracle Mineral Solution[3]

US FDA has warned the consumers on the purchase of the products sold online for medical treatment. According to the resource information FDA has cautioned about the dangers of Miracle or Master Mineral Solution, Miracle Mineral Supplement, MMS, Chlorine Dioxide (CD) Protocol, Water Purification Solution (WPS) and other similar products. Miracle Mineral Solution and similar products are not FDA-approved, and ingesting these products is the same as drinking bleach. Consumers should not use these products, and parents should not give these products to their children for any reason.

FDA approves first generics of Lyrica[4]

On July 19, 2019, the US FDA approved the first generics of lyrica for the treatment of neuropathic pain associated with diabetic peripheral neuropathy and postherpetic neuralgia. The FDA granted approvals for the generic versions of Lyrica to Alembic Pharmaceuticals, Alkem Laboratories, Amneal Pharmaceuticals, Dr. Reddy's Laboratories, InvaGen Pharmaceuticals, MSN Laboratories Ltd., Rising Pharmaceuticals, Inc., Sciegen Pharmaceuticals Inc., and Teva Pharmaceuticals. The first approved generic is widely used in the treatment of the neurological disorder. Pregabalin is an anticonvulsant drug used for neuropathic pain, epilepsy and generalized anxiety disorder. Pregabalin achieves antihyperalgesic activity by binding to the α2δ subunit of the voltage-dependent calcium channels.

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1 https://www.fda.gov/news-events/press-announcements/fda-approves-first-therapy-rare-joint-tumor

2 https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-severe-hypoglycemia-can-be-administered-without-injection

3 https://www.fda.gov/news-events/press-announcements/fda-warns-consumers-about-dangerous-and-potentially-life-threating-side-effects-miracle-mineral

4 https://www.fda.gov/news-events/press-announcements/fda-approves-first-generics-lyrica

WHO Highlights August 2019

WHO launches new report on Global tobacco epidemic[1]

On July 26, 2019, World Health Organization has launched its seventh report on global tobacco epidemic in process to implement the most effective methods/measures from the WHO Framework Convention on Tobacco Control (WHO FCTC) which are proven to effectively reduce the tobacco demand. MPOWER intervention is one of its kind of measures, launched in 2007 and together with WHO FCTC, promoted various preventive actions on tobacco use. The recent report emphasizes more upon various steps taken by the developed countries in cessation of Tobacco activities. The report was launched in Brazil which became the second country after Turkey to implement MPOWER intervention to achieve better results in ceasing tobacco activities. MPOWER provides a very strong tool to Government in helping people ceasing the tobacco use.

Co-sponsors of Ebola trial declared two drugs more effective in treating disease[2]

On August 12, 2019, co-sponsors of Ebola trial have announced advances that will bring patients a better chance of survival. According to the resource information two out of the four drugs being tested are more effective in treating Ebola. Moving forward, these are the only drugs that future patients will be treated with. Details of the changes are available in this WHO/NIAID/INRB release.

WHO study revealed baby products high in sugar and marketed incorrectly[3]

On July 15, 2019, Two new studies performed by WHO in Europe have shown that baby products contain inappropriately high levels of sugar. Apart from this the products are also marketed incorrectly. WHO's long-standing recommendation states that children should be breastfed, exclusively, for the first 6 months. Its 2016 global Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children explicitly states that commercial complementary foods should not be advertised for infants under 6 months of age.

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1 https://www.who.int/news-room/detail/26-07-2019-who-launches-new-report-on-the-global-tobacco-epidemic

2 https://www.who.int/news-room/detail/12-08-2019-update-on-ebola-drug-trial-two-strong-performers-identified

3 http://www.euro.who.int/en/media-centre/sections/press-releases/2019/whoeurope-studies-find-baby-foods-are-high-in-sugar-and-inappropriately-marketed-for-babies