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S&A PHARMA NEWSLETTER

EDITORIAL

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The role of a drug regulatory authority is not only to authorize drugs for marketing and manufacturing, but also to regulate its quality, safety, affordability and availability to the patients. Regulatory authorities with their comprehensive updated guidelines keep regulating the pharmaceutical products globally; however, extra efforts and periodic reviews of guidelines is expected from the health organizations and regional governments in the public interest.

We are pleased to present this Vol. III Issue VI 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 the guidelines for Nipah virus released by the state of Kerala for the proper management of the disease. The article also explains the epidemiology of the virus and disease caused by it. Moving further, this issue discusses the introduction of pharmacovigilance program in India in association with CDSCO for patient safety. Going ahead, the issue throws some light on expected role of government in the growth of Indian Pharmaceutical Industry and its Vision 2030. The issue then discusses the approval of Homeopathy Central Council Amendment Bill 2019 and the Prohibition on the use of ENDS or e-cigarettes by Indian Council for Medical research. The newsletter then reports on CCI penalty on some pharma companies and chemist associations for following anti-competitive practices. This volume also discusses recent regulatory updates in Indian health care sector.

From the international arena, this volume has a dedicated section which discusses the breakthrough US FDA updates and approvals for June 2019.

Trust you will 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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Contents

Nipah Virus infection - a challenge to the Indian health care facility

On June 06, 2019, Directorate of Health Services, Kerala released the first of its kind interim guidelines on management of Nipah Virus (NiV) infection[1]. The guideline describes the disease epidemiology, clinical features, diagnosis, prevention and treatment of the disease. Moreover, it also explains the standard precautions to be followed by health care personnel during patient handling, diagnosis and treatment of disease. However, this is an interim guideline adapted from NCDC interim guidelines, and WHO Bulletins. The situation is still evolving, and the content of this guideline is subject to modifications at regular intervals.

NiV is a highly pathogenic paramyxovirus zoonotic disease where animals like large fruit bats/flying foxes are considered to be the natural reservoirs of NiV. The disease is transmitted by direct contact with infected bats, pigs or their partially consumed fruits, and human to human contact. Fever, inflammation of the brain (encephalitis), altered mental status, severe weakness, headache, respiratory distress, cough, vomiting, muscle pain, convulsion, and diarrhea are the common symptoms of NiV infection.

Challenges to the Indian health care facility

Disease Management

At present, there is no known treatment or vaccine available for humans or animals. Therefore, the disease management is limited to only symptomatic treatment and intensive supportive care of the patients. Some observational reports suggest that Ribavirin may be useful to reduce mortality among patients with encephalitis caused by NiV. Treatment unavailability is the biggest health care challenge and for the time being the focus is limited to preventive measures where bio-safety precautions seem the key to control the spread of the disease.

Strict Precautionary Measures

Standard droplet and bio-safety precautions should be followed by health care personnel during sample collection/transport/ storage/ processing of suspected cases. In addition, all suspect cases of NiV should be segregated from all other patients in an isolation ward/ facility for infection control. This again is a major challenge for Indian hospitals/health care units as most of these facilities are already overpopulated with patient visits where implementation of bio-safety precautions and usability of Personal Protective Equipment PPE(N 95 mask, double surgical gloves, gowns, goggles foot cover, etc.) appears long way to go.

Requirement of Isolated Facility

As per the guideline, the best preventive measure is to isolate the suspected case. It says, "*Sample collection should be done only AFTER ADMISSION in an appropriately secure isolation facility, and ensuring that the staff member doing the collection is using adequate PPE.*" In addition, the guideline limits the movements of caretakers and even staff personnel of the hospital to the isolated ward and recommends to follow '*restriction for essential purposes*' protocol. It means, the Indian health care facilities should upgrade their isolated ward/units not only in numbers but also biosafety standards as a single confirmed case of NiV can give rise to many suspected/probable cases of NiV, which may not be accommodated in few isolation wards.

Transportation and Storage of Samples

Nipah cases are only confirmed through laboratory tests of respiratory secretions, urine or cerebrospinal fluid using a combination of tests either by 1) Nipah virus RNA identification by PCR, or by 2) Isolation of Nipah virus from sample. For this the samples should be collected using adequate bio-safety precautions, then safely packed in triple container packing, and stored/transported under cold chain (2-8°C) condition to the testing laboratory

1 https://www.nhp.gov.in/NHPfiles/adph_06062019.pdf

within 24 hours with prior intimation of testing lab. The hospital facilities should be upgraded in such a manner that fulfills the requirement of cold chain storage and transportation of sample. In addition, the guidance demands countrywide establishment of additional laboratories for testing NiV as a preventive measure.

Pharmacovigilance Programme of India & CDSCO work together for Patient Safety

The Pharmacovigilance Programme of India, (PvPI) was first introduced in the year 2010 to improve safety of Indian population by monitoring drug related Adverse Drug Reactions (ADRs) collected via ADR monitoring centers across the country and the data was further sent to National Coordinating Centre (NCC)-PvPI.

NCC-PvPI receives suspected ADRs from all stakeholders, including Marketing Authorization Holders (MAHs), and reviews the safety information on a regular basis. It supports the Central Drugs Standard Control Organization (CDSCO) for further regulatory actions in the following manner:

I. **Signal Review Panel (SRP)** of NCC-PvPI analyses the suspected ADRs and identifies India specific drug safety signals and recommends its findings to CDSCO for appropriate regulatory action.

II. **Subject Expert Committee (SEC)** of CDSCO reviews the SRP recommendations, and if agreed with SRP, the SEC recommends the same to CDSCO for implementation or for inclusion of the ADRs in prescribing information (package inserts and drug safety labels). In case the SEC is not satisfied with SRP recommendations, it asks the NCC-PvPI to submit more Individual Case Safety Reports/signals to support their recommendation.

III. **CDSCO** after considering recommendation of SEC, requests all State/UT Drugs Controllers to instruct all the manufacturers licensed for the said product/drugs to implement the same in prescribing information.

At present, a total of 47 drug safety signals, as identified and forwarded to CDSCO by SRP[2], are categorized on the basis of their current regulatory status:

1. Action taken by CDSCO
2. Information sent to CDSCO by SRP, and is in process
3. SEC recommended to CDSCO

1. Action taken by CDSCO: CDSCO requested all State/UT Drugs Controllers to instruct all manufacture of said product in their jurisdiction to implement the specified recommendations:

Sr. No.	Suspected Drug	Adverse drug reactions	SRP Recommendations
1	Carbamazepine	Stevens Johnson syndrome (SJS) and Toxic Epidermal Necrolysis (TEN)	For Drug Safety Label Change – Patient may be screened for HLAB*1502 prior to initiating the Carbamazepine treatment.
2	Piperacillin and Tazobactam	Hypokalaemia, Bronchospasm	To include in Prescribing Information
3	Rabies Vaccine	Erythema Multiforme	

2 https://ipc.gov.in/images/pdf/PvPI_Recommendations_to_CDSCO.pdf

2. Information sent to CDSCO by SRP, and is in process:

Sr. No.	Suspected Drug	Adverse drug reactions
SRP Recommendations: To include in Prescribing Information		
1	Mannitol	Hypokalaemia
2	Rota-Virus Vaccine	Intussusception
3	Ranitidine	Cardiac Arrest
4	Pulmonary Surfactant	Pulmonary Haemorrhage
5	Ceftriaxone	Stevens Johnson syndrome
6	Lamotrigine	Stevens Johnson syndrome (SJS) and Toxic Epidermal Necrolysis (TEN)
7	Betamethasone	Photosensitivity Reaction
8	Azithromycin	Acute Generalised Exanthematosus Pustulosis (AGEP)
9	Cloxacillin	Acute Generalised Exanthematosus Pustulosis (AGEP)
10	Itraconazole	Photosensitivity reaction
11	Ibuprofen	Stevens Johnson syndrome (SJS) and Toxic Epidermal Necrolysis (TEN)
12	Amoxicillin/ Clavulanate Potassium	Stevens Johnson syndrome (SJS) and Toxic Epidermal Necrolysis (TEN)
13	Ciprofloxacin	Stevens Johnson syndrome (SJS) and Toxic Epidermal Necrolysis (TEN)
14	BCG vaccine	Lymphadenopathy
15	Docetaxel	Candidiasis
16	Dipeptidyl peptidase-4 (DPP4) Inhibitors	Arthralgia
17	Diclofenac	Nicolau Syndrome
18	Glibenclamide	Palpitation
SRP Recommendations: Signal		
19	Itraconazole	Acute Generalised Exanthematosus Pustulosis (AGEP)

3. Subject Expert Committee recommended CDSCO to direct the concerned manufacturers to incorporate following changes in package inserts/drug safety labels:

Sr. No.	Suspected Drug	Adverse drug reactions
SRP Recommendations: Signal		
1	Cefixime	Acute Generalised Exanthematosus Pustulosis (AGEP)
2	Sulfasalazine	Toxic Epidermal Necrolysis (TEN)
3	Furosemide	Dermatitis Lichenoid
4	Lithium Carbonate	Drug Reaction with Eosinophilia and Systemic symptoms Syndrome (DRESS)
SRP Recommendations: To include in Prescribing Information		
5	Phenytoin	Acute Generalised Exanthematosus Pustulosis (AGEP)
6	Sodium Valproate	Gum Hyperplasia
7	Sulfasalazine	Stevens Johnson Syndrome (SJS)
8	Fluconazole	Hyperpigmentation

Sr. No.	Suspected Drug	Adverse drug reactions
9	Terbinafine	Acute Generalised Exanthematosus Pustulosis (AGEP)
10	Cefotaxime	Angioedema
11	Ofloxacin	Stevens-Johnson Syndrome
12	Tranexamic Acid	Seizure/Convulsion
13	Quetiapine	Urinary Incontinence
14	Sulfasalazine	DRESS Syndrome
15	Tramadol	Hiccups
16	Phenobarbital	DRESS Syndrome
17	Cefepime	Urticaria
18	Meropenem	Hypokalaemia
19	Artemether + Lumefantrine	Stevens Johnson syndrome (SJS)
20	Cefixime	Mouth Ulceration
21	Lamivudine	Hearing Loss
22	Carbamazepine	Drug Reaction with Eosinophilia and Systemic symptoms Syndrome (DRESS)
23	Amlodipine	Alopecia
24	Carvedilol	Hyperkalaemia
25	Amlodipine	Gingival Hypertrophy

Note - The NCC-PvPI also publishes the preliminary analysis of ADRs at regular intervals in the form of *Drug Safety Alert* to inform the health care professionals, patients and consumers to closely monitor the possibility of ADR associated with the suspected drug, and if such reaction is encountered then report it to the NCC-PvPI.

Government role in Indian pharmaceutical industry to achieve vision 2030

On June 17, 2019, a report on '*The Indian pharmaceutical industry – the way forward*[3]' was published by an Indian Pharmaceutical Alliance (IPA) representing research based pharmaceutical companies in collaboration with McKinsey & Co and stakeholders. The report lists the growth ambitions that Indian pharmaceutical industry ('Industry') needs to follow to achieve its targets for year 2030 (Vision 2030). The target envisages the industry to establish India as a global leader in life sciences without compromising its domestic growth including accessibility and affordability.

According to the report the industry at its current pace of 7-8% CAGR is expected to grow about USD 80 to 90 billion in annual revenue by 2030. However, with its bold aspirations of a 11-12%….. CAGR, the industry can expect to grow about USD 65 billion by 2024 and about USD 120 to 130 billion by 2030. The four bold aspirations for the industry to target Vison 2030 are:

1. Growth in domestic market with increased accessibility and affordability.
2. Potential innovations in next generation inventive products.
3. Strong hold in the US market by increasing ANDA filing for upcoming off patent drugs, and potential pricing offers.
4. Grow in unexplored/underutilized markets such as Japan and China.

To achieve this target, the Indian industry requires a huge support from the government and its regulatory bodies either in terms of regulatory policies and a supportive ecosystem or in terms of investment. The government's role is to:

1. **Accelerate universal healthcare access by strengthening the healthcare infrastructure -** Improve healthcare infrastructure and increase usability of digital technologies such as telemedicine facilities, artificial intelligence, healthcare apps and, mobile clinics to accelerate the universal health coverage/access. Improved healthcare access offers a sea of opportunities for health industry including the pharma industry.

   In addition, the government needs to increase healthcare expenditure from its current 1.2 percent to 2.5 in next five years and then to 5 percent by 2030, in line to match the universal health access of developed economies. Moreover, the government is to empower its citizens to bear the costs of medical care either by bringing them under universal health coverage or insuring their health under 'Ayushman Bharat'.

2. **Create a stable and supportive regulatory environment for the industry -** The Government can create a transparent, easy, and coherent regulatory policy which will reduce the uncertainty regarding pricing and drug approval process. Also lowering the frequency of policy revisions or setting up a periodical review framework can help resolve confusion and revive the trust of pharmaceutical companies towards the government.

3. **Create an independent Ministry for Pharmaceuticals -** In order to promote the industry's interest, a dedicated Union Ministry of Pharmaceuticals can be set up by government to simplify policy making, speed-up the product approval and implementation process, and expedite investment approvals. For example, agencies like CDSCO and NPPA can be brought together under a new ministry for better coordination and quicker decision making.

4. **Primary Focus on API manufacturing to reduce the reliance on imports -** The government can provide

3 https://www.ipa-india.org/static-files/pdf/publications/position-papers/2019/ipa-way-forward.pdf

infrastructural and regulatory support to industry for manufacturing APIs by:

a. Constructing large dedicated zones
b. Extending pre-approval of environmental clearance
c. Enabling existing production facilities
d. Lowering cost of borrowing to setup API plants

5. **Promote innovation by creating a research ecosystem via -**
   - Targeted tax interventions, like competitive tax breaks on R&D investments, capital gains, technology transfers, etc. For example, reducing GST on all drugs to a uniform five percent and not just limited to life saving drugs can help reduce the cost of drugs.
   - Regulatory interventions like -
     - Offering a streamlined policy for clinical trials of innovative products.
     - Offering support to health-tech start-ups and create an investor-friendly environment, with ease of doing business policies.
   - Creating anchor educational institutions for research and innovation that initiate research, provide talent to the industry and collaborate on key strategic initiatives with long-term impact.

6. **Expand and consolidate global footprint and collaborate with international regulatory bodies -** The exchange of regulatory best-practices between regulatory agencies of countries will improve the market presence and also help to expedite approvals in large markets like China and Japan. The government can also work closely with the USFDA and other international regulatory bodies to communicate key issues faced by Indian pharma companies and drive the required regulatory changes.

Conclusion

Government support in the form of investments and regulatory interventions is integral to initiate the innovation-led growth of industry. The government has already launched some initiatives that can strengthen the industry but only to some extent; like 18.6 percent increased budgetary allocations for healthcare over five years to boost the domestic market, the launch of Ayushman Bharat Yojana to cover 50 crore beneficiaries under affordable healthcare, attracting pharma investment by intending to set up pharma parks in Andhra Pradesh, Uttar Pradesh and Haryana. Much more intent and application from the government is required for achieving vision 2030.

Indian Council of Medical Research declares complete prohibition of ENDS

Indian Council for Medical Research has recently declared the prohibition of ENDS or e-cigarettes in India due to adverse health related data now available after extensive research. This prohibition from ICMR was for public to prevent them, especially children and pregnant mothers, from the side effects of ENDS or e-cigarettes.

Impact of ENDS on Public Health

ENDS or e-cigarettes are battery operated smoking devices. These products contain nicotine in different concentrations along with other flavoring and vaporizing agents found to be harmful for the health. The products resemble exactly like traditional tobacco products like nicotine cigarettes and cigars.

ENDS are also harmful for non-users especially children and pregnant mothers as it can gravely affect them due to their weak immune system[4]. *Use of ENDS or e-cigarettes has documented adverse effects on humans which include DNA damage; carcinogenesis; cellular, molecular and immunological toxicity; respiratory, cardiovascular and neurological disorders and adverse impact on foetal development and pregnancy*[5]. There are several reports of poisoning due to accidental swallowing by children which is a major reason of concern for all health authorities to take stringent actions on use and manufacturing of ENDS products.

The magnitude of the potential risk caused by the use of ENDS or e-cigarettes is not possible to measure since the products are very recent and come in a variety of forms. It is believed that usage of ENDS or e- cigarettes cannot reduce or cease the use of traditional tobacco products rather it can heighten the dual risk of use of ENDS and promote initiation to tobacco addiction to non-smokers. Use of the ENDS or e-cigarettes can potentially lead to excess tobacco usage and can also cause potential threat to the country's tobacco control laws and on-going tobacco control programmes.

Conclusion

E–cigarettes cannot be used as a safe tobacco substitute due to limited data available on the safety. No e-cigarette has been approved by FDA as a cessation aid. Environmental concerns and issues regarding non-user exposure exist. The health impact of e-cigarettes, for users and the public, cannot be determined with currently available data.

4 https://www.nhp.gov.in/NHPfiles/Press_Release_2.pdf

5 https://www.nhp.gov.in/NHPfiles/Press_Release_2.pdf

CCI penalizes Pharma firms and Chemist associations for anti-competitive practices

The Competition Commission of India (CCI) is an agency under the Competition Act, 2002 (Act), which monitors and eliminates anti-competitive practices, promotes and sustains competitions, protects the interests of consumers and ensures freedom of trade in the Indian markets. The CCI on June 06, 2019, penalized Madhya Pradesh Chemists and Druggist Association (MPCDA), Indore Chemists Association (ICA), Himalaya Drug Company (HDC) and Intas Pharmaceuticals Limited (IPL) along with some of their officials for anti-competitive practices and contravention of the provisions of the Act[6].

The Commission ordered a monetary penalty of Rs. 4, 18,404/- on MPCDA and Rs. 39,142/- on ICA, in addition to cease and desist directions. Monetary penalties of Rs. 18, 59, 58,000/- on Himalaya Drug Company and Rs. 55, 59, 68,000/- on Intas Pharmaceutical Limited with additional penalty on certain officials of these companies.

Apart from this, the MPCDA was directed to organize at least five competition awareness programmes for its members in the state over a period of six months and ICA was directed to organize one competition awareness programme in Indore. The Commission also directed Himalaya and Intas to bring into place a Competition Compliance Programme and file the compliance report with the Commission.

Background

Madhya Pradesh Chemists and Distributors Federation, as informant has alleged contravention of the provisions of Section 3 of the Act by MPCDA and 14 others, including 4 pharma associations and 10 pharmaceutical companies. According to the allegations, the named associations through the practice of mandating No Objection Certificate (NOC)/ Letter of Consent (LOC) prior to appointment of stockiest by the pharmaceutical companies limits the competition as mandating NOC/LOC ensures that only those distributors which are favored by associations are eventually selected by the pharmaceutical companies to do business with them.

The named pharmaceutical companies were also actively participating in the anti-competitive practices carried out by associations, since they willingly adhered to their directives and refused to appoint fresh distributors until the associations gave their consent for such appointment, as a result of which supply of drugs to the consumers was restricted and competition stifled in the market.

The Commission after forming a prima-facie opinion under Section 26(1) of the Act directed the office of Director General (DG) to conduct investigation into the matter. The DG submitted the "Main Investigation Report" upon completion of investigation.

CCI Decision

Main Investigation Report has confirmed the contravention of Act by said associations, where the pharmaceutical companies and certain officer bearers/ officials of the associations were found to be facilitating such anti-competitive practices. The Commission after appreciation of the detailed submission reports and evidence on record, has established contravention of the provisions of Section 3 of the Act by MPCDA, ICA, Himalaya and Intas Pharmaceuticals[7].

6 https://www.cci.gov.in/sites/default/files/press_release/PR22019-20.pdf

7 https://www.cci.gov.in/sites/default/files/64-of-2014.pdf

Cabinet approves Homoeopathy Central Council (Amendment) Bill, 2019

On June 12, 2019, the union cabinet approved the draft Homoeopathy Central Council (Amendment) Bill, 2019. The bill replaces the Central Council (Amendment) Ordinance, 2019, and extends the tenure of the Board of Governors for another year. This amendment will increase the time period of reorganization of the Central Council from the current period of one year to two years, so that the effect of the term of the Board of Governors can be extended by one year.

Background of the Homeopathy Act

The Homeopathy Central Council Act, 1973, was established to deal with the education and practice of homeopathy. Further, to improve the quality and functioning in the colleges, the Central government has introduced technical education. However, the Central Council for Homeopathy was not able to carry its duties in an appropriate manner and hence, the council was suspended; and Homoeopathy Central Council (Amendment) Ordinance, 2018, and the Board of Governors was constituted in its place on May 18, 2018 for a period of one year or till a new Central Council of Homoeopathy was reconstituted.

After the said time period of one year the Central Council for Homeopathy was not reconstituted since the State registrars were not updated for conducting the elections. Hence, the National Commission for Homoeopathy Bill, 2019, was introduced and the period to reconstitute the Central Council for Homeopathy was expanded from one year to two years. Since the house was not in session, the Homoeopathy Central Council (Amendment) Ordinance, 2019, was passed and thereafter, the Homoeopathy Central Council (Amendment) Bill, 2019, was established and approved to replace the said ordinance[8].

Key points of the Bill

- The new amendment came into force from March 2019.
- *The new bill replaces the words 'within a period of one year' section 3 (a) of Homoeopathy Central Council Act, 1973, with words 'within a period of two years'. This will expand the timeline for reconstituting the Central Council of Homeopathy.*[9]
- *The affairs of the Union Homeopathy Council have been entrusted to a Board of Governors, which includes reputed and qualified Homeopathy doctors and eminent administrators until the Council is reorganized.*

Conclusion

In order to reconstitute the Central Council for Homeopathy which includes dignified homeopathy doctors, the Union Cabinet has increased the timeline in the form of Homoeopathy Central Council (Amendment) Bill, 2019, which will help the Government to come out with a council which can work for the upliftment of the Homeopathy profession with transparency and quality.

8 https://www.prsindia.org/sites/default/files/bill_files/Homoeopathy%20Central%20Council%20%28Amendment%29%20Bill%2C%202019.pdf

9 https://www.prsindia.org/sites/default/files/bill_files/Homoeopathy%20Central%20Council%20%28Amendment%29%20Bill%2C%202019.pdf

India Healthcare Highlights June 2019

This segment of the newsletter is focused on regulatory reforms from Healthcare and Pharmaceutical sectors in the Indian jurisdiction with collated information on monthly basis via conducting research and appraisal of applicable statutory provisions. Presenting the highlights for the month of June 2019:

Cabinet passes new initiative to control Foot and Mouth Disease (FMD) and Brucellosis[10]

The Union Cabinet meeting chaired by the Prime Minister on May 31, 2019, cleared a novel initiative to control Foot and Mouth Disease (FMD), and Brucellosis, which is expected to improve the health of livestock and benefit crores of livestock rearing farmers. The Cabinet has allocated a total amount of INR 13,343.00 crores for this initiative with the aim to eradicate these diseases from the country in the next five years.

FMD and Brucellosis are very common amongst the livestock such as cow-bulls, buffaloes, sheep, goats, pigs etc. FMD in cow/buffalo has the potential to cause milk loss up to 100% which could last for four to six months. Brucellosis reduces the milk output by 30%, during the entire life cycle of the animal causing further infertility. The programme so far has been implemented on cost sharing basis between the Central and State Governments. In a rare instance of departure from the norm, the Central Government has decided to now bear the entire cost of the programme to ensure complete eradication of these diseases. The initiative envisages vaccination coverage for FMD to 51 crore animals at six months interval along with primary focus on bovine calves vaccination, while the vaccination coverage for Brucellosis is aimed to cover 100% of 3.6 crore female calves.

Health Ministry proposes implementation guideline for the 'Free Diagnostics Initiative'[11]

The Ministry of Health and Family Welfare under the support of National Health Mission launched the 'Free Diagnostics Initiative' in July 2015. The initiative was to provide the essential quality diagnostics accessible in public health facilities free of cost, which would further help physicians to take an informed decision regarding the treatment of patient. On June 08, 2019, the Health Ministry has proposed a set of implementation guidelines to ensure the availability of basic diagnostic services at public health facilities. This guidance could be useful for the states for rolling out or strengthening the free diagnostic services. Moreover, this document provides guidance about which services could be implemented in in-house laboratory and which services could be outsourced, if required. The guidance also explains the implementation of free diagnostics initiative in public-private partnership mode.

Health Ministry to boost the process of formulating 'National Policy for treatment of Rare Diseases'[12]

On June 11, 2019, the Union Minister for Health and Family Welfare at the high level meeting to review the status of '*National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Strokes (NPCDCS)*' has directed the health officials to speed-up the process of formulating '*National Policy for treatment of Rare Diseases'* and the Non Communicable Diseases (NCD) interventions in consultation of stakeholders as the burden of these diseases is continually rising in the country. The union minister also directed the officials to organize aggressive awareness drives at all levels to encourage public on adopting a healthy lifestyle and availability of nearby NCD Clinics and Day Care Centers.

10 http://pib.nic.in/PressReleseDetail.aspx?PRID=1573020

11 https://www.nhp.gov.in/NHPfiles/Circulation-of-Draft-document-on-BMMP-and-FDI.pdf

12 http://pib.nic.in/newsite/PrintRelease.aspx?relid=190363

Cabinet approves MoC between India and Kyrgyzstan on High Altitude Biology and Medicine Research[13]

On June 12, 2019, the Union Cabinet, chaired by the Prime Minister has approved a Memorandum of Collaboration (MoC) between India and Kyrgyzstan for collaborative research work on High Altitude Biology and Medicine. The MoC is aimed to develop and strengthen the mutual relationship in science and medicine sectors, especially in high altitude biology and medicine. Moreover, it will aim to understand the physical and mental condition of soldiers' system at high altitude, thus, easing the high altitude related maladies with Yoga practices, herbals and neutraceuticals in both Indian and Kyrgyzstan soldiers/population.

BPPI blacklisted 12 pharmaceutical companies for supplying substandard drugs to Jan Aushadhi Kendras[14]

Bureau of Pharma PSUs of India (BPPI), the implementing agency of Pradhan Mantri Janaushadhi Pariyojana (PMBJP), has blacklisted 12 pharmaceutical companies for supplying substandard medicines to Jan Aushadhi Kendras across the country, which are now barred from doing business for two years. The pharmaceutical products from these blacklisted companies were found substandard after testing in government laboratory; the companies being Overseas Health Care, Hanuchem Laboratories, Legen Health Care, Jackson Laboratories, Mascot Health Services, Syncom Healthcare, Osteoplast Wellness, AMR Pharma India Private Limited, Terrace Pharmaceuticals, Cachet Pharmaceuticals Pvt. Ltd., Ravenbhel Healthcare Pvt. Ltd. and Athens Life Sciences.

13 http://pib.nic.in/PressReleseDetail.aspx?PRID=1574103

14 http://janaushadhi.gov.in/Blacklist.aspx

US FDA Highlights June 2019

FDA Finalizes guidance for premarket tobacco product applications to check oversight of tobacco products and health issue

Electronic nicotine delivery systems (ENDS) are new artificial tobacco products which use artificial inhalers as a flavoring agent instead of burning tobacco leaves, such as e-cigarettes or vapes. Recently, U.S. Food and Drug Administration finalized the guidance for manufacturers of electronic nicotine delivery systems (ENDS) in a bid to keep a check on the health issues related to ENDS and to prevent the oversight of these tobacco products.[15] The main objective of the guidance was to protect children from the harmful effects of tobacco products by creating an awareness about the risk and benefit of using the tobacco containing products manufactured via premarket tobacco product applications (PMTA). Moreover, this guidance further explains to the manufacturers about manufacturing conditions, packaging materials accidental exposure to e-liquids, such as child-resistant, exposure-limiting packaging or nicotine exposure warnings on labels. The FDA assures public via this guidance that the FDA will continue to take all necessary actions to protect children as part of their Youth Tobacco Prevention Plan.

FDA approves new treatment for hypoactive sexual desire disorder in premenopausal women

On June 21, 2019, U.S. Food and Drug Administration has approved Vyleesi (bremelanotide) to treat acquired, generalized hypoactive sexual desire disorder (HSDD) in premenopausal women. HSDD is a sexual disorder characterized with low sexual desires in female. The condition is not due to any existing medical condition or any other psychiatric condition with partner. Acquired HSDD can occur in a patient who does not have any prior history of sexual disorder. The drug Vyleesi generally acts on melanocortin receptors, however, the mechanism of action for treating HSDD is still unknown. The drug should not be used for long periods of time and should be stopped within 8 weeks if there is no sign of improvement in sexual desire and associated distress. The effectiveness of the drug was clinically proved in two 24-week, randomized, double-blind, placebo-controlled trials in 1,247 premenopausal women. The end point of the study showed that 25% of the female patients treated with Vyleesi had an increase of 1.2 or more in their sexual desire score (scored on a range of 1.2 to 6.0, with higher scores indicating greater sexual desire) compared to about 17% of those who took placebo.[16] The approval of the drug is a great achievement since from many years FDA is committed to continuing to work with companies to develop safe and effective treatments for female sexual dysfunction.

FDA expands approval of treatment for cystic fibrosis to include patients ages 6 and older.

On June 21, 2019, U.S. Food and Drug Administration today approved the expansion for Symdeko (combination of tezacaftor/ivacaftor), a drug used for the treatment of cystic fibrosis for treatment of pediatric patient of age 6 years and older with cystic fibrosis of certain genetic mutation.

Cystic fibrosis is a serious genetic disorder that results in the formation of thick mucus that builds up in the lungs, digestive tract and other parts of the body leading to severe respiratory and digestive problems along with infections and diabetes. Earlier the drug was approved to be used in patients aged 12 and older with cystic fibrosis and genetic mutation. Expansion in indication of Symdeko provides an important treatment option for younger patients, and also provides more context on the safety and dosing specific to this population. The safety of Symdeko in patients age 6 to less than 12 years was supported by data from a study that included a 24-week, open-label treatment period with 70 cystic fibrosis patients ages 6 to less than 12, and had similar observations of safety to clinical trials in ages 12 and older. This approval was granted to Vertex Pharmaceuticals Incorporated. [17]

15 https://www.fda.gov/news-events/press-announcements/fda-finalizes-guidance-premarket-tobacco-product-applications-electronic-nicotine-delivery-systems

16 https://www.fda.gov/news-events/press-announcements/fda-approves-new-treatment-hypoactive-sexual-desire-disorder-premenopausal-women

17 https://www.fda.gov/news-events/press-announcements/fda-expands-approval-treatment-cystic-fibrosis-include-patients-ages-6-and-older

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