EDITORIAL

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Founding Partner

Dear Friends,

It is a proven scenario that socioeconomic status affects an individual's health outcomes and the health care they receive. People with lower socioeconomic status are more likely to face health issues and are more uncomfortable to report problems arising due to health issues. The socioeconomic health is not only for individuals but it is also relevant for a developing country with poor economy. As a result, the national health strategies and plans of governments and other health partners in these countries also gets affected by socioeconomic status.

We are pleased to present Vol. IV Issue II 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 a year review on Regulatory Action by CDSCO on treating COVID-10 disease. The present issue also throughs light on Personal Protective equipment's which are essential for healthcare workers in treating the disease. The present issue also provides a review on price fixation of the coronary stents by NPPA and its use. The current volume also provides an overview price revision of ringer lactate solution with special packaging instructions.

The present issue primarily focus on COVID-19 disease and various government schemes useful in treating and eradicating the diseae.

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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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Contents

Ministry of AYUSH expedites the process for grant of approval /new/renewal of license for manufacturing of ASU immunity boosting healthcare products and sanitizers

The regulatory and quality control provisions for the manufacturing of Ayurvedic, Siddha and Unani drugs/ medicines, under the Drugs and Cosmetics Act, 1940, has expedited the process for granting the license to manufacture ASU drugs which can boost immunity to fight COVID-19 disease.[1]

Background

Due to COVID-19 outbreak, the need for public use of ASU-based immunity boosting products for healthy people and hand sanitizers has been significantly emphasized upon and their demand has increased manifold. In this regard, some drug manufacturers engaged in or interested in producing ASU ingredients-based such products have represented to the Central Government about the problems being faced in the States/UTs for grant or renewal of license/approval in the current situation.

The government, during interaction with stakeholders, has suggested ASU medicines manufacturers to utilize their resources for producing essential items like sanitizers and has highlighted that the impact of traditional practices for boosting immunity of healthy people is set to play an important role in India's fight against COVID-19.

According to the resource information, during the urgent need to manufacture essential healthcare products at the time of emergency all the State AYUSH Licensing Authorities/Drug Controllers and Expert Committees thereunder, have been directed to complete the licensing/approval/renewal process expeditiously and dispose off the applications of the manufacturers maximum within a week's time provided the prescribed standards and relevant provisions of the Drugs & Cosmetics Rules, 1945, in terms of use of ingredients and permitted excipients in accordance with the authoritative books including Pharmacopoeias and Formularies, are fulfilled. It is also been appealed that the list of manufacturers and details of such ASU products being licensed /approved under respective jurisdiction be sent to Drug Controller and AYUSH Licensing Authorities ….

Conclusion

At the time of emergency when all the departments of health ministries are coming forward to combat or stop the aggravation of this pandemic disease, Ayush ministry has taken a welcome forward step in producing the immune booster products which can be considered as a preventive measure against COVID-19.

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1 *http://ayush.gov.in/ev ent/expediting-process-grant-approval-license-renewal-license-manufacturing-asu-immunity-boosting*

To fight COVID-19, Government allows manufacturers of industrial oxygen to produce oxygen for medical use

In a letter by the Drug Controller General of India (DCGI), released on April 7, 2020, stated that oxygen therapy is a part of clinical management of COVID-19 patients and therefore, it is of vital importance to ensure the availability and supply of oxygen for medical use across the country.

Background

According to the information published by WHO, patients suspected with COVID-19 or with severe acute respiratory infection (SARI) are recommended with supplemental oxygen therapy. In response to this, the All India Industrial Gases Manufacturers Association has proposed for manufacturing of medical oxygen by manufacturers of industrial oxygen. The Drug Controller General of India (DCGI) has decided to grant license to manufacturers of industrial oxygen to produce oxygen for medical use in public interest in the wake of the coronavirus outbreak.[1]

The DGCI has asked all state and union territory drug controllers to take action for granting license to manufacturers of industrial oxygen to make oxygen for medical use. To ensure proper availability of medical oxygen, the license will be granted to all the manufacturers having the facility to supply oxygen. The license should be supplied within 24 hours of receiving the application, fee etc. as per the Drugs & Cosmetic Act 1940 & Rules thereunder and an undertaking in writing to manufacture the medical oxygen in compliance with the standard prescribed in Indian Pharmacopoeia and labelling requirement as per the said act and rules.

Conclusion

Since WHO has already declared oxygen as important for clinical management in patients with COVID-19, Indian government has requested all manufacturers with the facility to manufacture oxygen required to manage to come forward COVID-19 patients. Moreover, the Government has also waived-off the time period for providing licenses to the manufacturers, which will help the manufacturers to initiate the production at immediately.

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1 *https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTgzNQ==*

Government lifts restrictions on export of 24 API pharma ingredients with immediate effect

The government, with immediate effect, has lifted the restrictions on export of 24 API pharma ingredients including Tinidazole, Metronidazole, Acyclovir, Vitamin B1, B6 and B12, Progesterone, Chloramphenicol, Ornidazole, formulations made of Vitamin B1.[1]

Background

On March 06, the Union Minister of State for Shipping, and Chemical and Fertilizers, had said that the government has imposed short term restrictions on some active pharmaceutical ingredients (API) with regards to coronavirus preparedness. The ease on curbs on export 24 APIs assumed significance as some pharma companies had raised concerns over these restrictions. The total number of COVID-19 positive cases in India has reached 10k+ according to the latest government estimates. However, export restriction on paracetamol, a common fever and pain reliever, and its formulations would remain, as per the resource information.

Note: Earlier, there were no restrictions on outbound shipments of these products. APIs are raw material for pharmaceuticals. India has exported APIs worth approx. USD 225 million last year. The country's API imports stood at around USD 3.5 billion per year. Out of this, about USD 2.5 billion is from China. Besides Vitamin B1, B6 and B12, the other APIs and formulations over which the export restrictions have been eased include tinidazole, metronidazole, acyclovir, progesterone, chloramphenicol, ornidazole, formulations made of chloramphenicol, formulations made of clindamycin salts, and formulations made of neomycin. The restricted APIs and formulations included common antibiotics and vitamins.

Conclusion

Due to continuous request form pharmaceutical sector to remove the ban on the expot of API, central government has finally lifted the ban on assuraane given by the companies that they have enough stock and there will be no shortage of these formulations in India amid the coronavirus outbreak. The Indian Pharmaceutical Alliance (IPA), which represents the country's biggest drug makers, and the Indian Drugs' Manufacturer's Association (IDMA) have written to the government seeking withdrawal of that notification as, according to them, they have surplus to meet the global demand and such a restriction would adversely affect their image.

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1 *https://www.livemint.com/politics/policy/govt-lifts-export-curbs-on-24-pharma-ingredients-medicines-11586230962483.html*

GSK announced the completion of merger with Hindustan Unilever Limited for various healthcare products in India

On April 01, 2020, GSK announced the completion of its divestment of Horlicks and other Consumer Healthcare nutrition products in India, to Unilever, including the merger of its Indian listed entity, GlaxoSmithKline Consumer Healthcare Limited ("GSK India"), with Hindustan Unilever Limited ("HUL").[1]

Background

India provides a large market to various healthcare products of the GSK company. As part of the transaction, HUL will distribute these Consumer Healthcare brands, which include market leaders like Sensodyne, Crocin, Otrivin and Eno, for GSK in India. GSK will continue to be responsible for demand generation, portfolio strategy, R&D and marketing for these brands. GSK also completed the divestment of Horlicks brands rights and other Consumer Healthcare nutrition products to Unilever in other markets for cash proceeds equivalent to £397 million. Bangladesh closing is expected to follow later this quarter, subject to local procedures. GSK India is not part of the GSK Consumer Healthcare Joint Venture with Pfizer and the merger of GSK India and HUL therefore does not impact the Joint Venture.

GlaxoSmithKline Consumer Healthcare Limited (GSKCH) brands such as Horlicks, Boost, and Maltova will now be part of the company's food and refreshments business falling under the nutrition category. As part of the merger, 3,500 employees of GSKCH will now become part of the Indian arm of the Anglo Dutch giant Unilever. Under the deal, HUL will distribute GSK's brands like Eno, Crocin, Sensodyne etc in the country.

About GSK Consumer Healthcare India

GSK Consumer Healthcare India is a leading fast-moving consumer healthcare company with over 500 employees in India and category-leading brands such as Sensodyne, Eno, Crocin and Otrivin. Its Mission Health program touches the lives of approximately 90,000 people by focusing on health and well-being with projects dedicated to neglected tropical diseases, dengue management, cleft and palate surgeries and plastic waste management.

Conclusion

GSK merger with HUL will certainly increase the sales of its nutritional products in the Indian market and will help common public in India to get within reach of the nutritional products with beneficial effects, with HUL being the distributor. It will boost the Indian pharmaceutical market in the field nutritional products.

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1 *https://www.gsk.com/en-gb/media/press-releases/gsk-completes-divestment-of-horlicks-and-other-consumer-healthcare-nutrition-products-in-india-and-certain-other-markets/*

NPPA FIXES/ REVISES CEILING PRICES OF 2 SCHEDULED FORMULATIONS UNDER DRUGS (PRICES CONTROL) ORDER, 2013

National Pharmaceutical Pricing Authority has revised the prices of 2 scheduled formulation of Paciltaxel used in chemotherapy under the Drugs Price Control Order, 2013.

Background

In view of the Drug Price Control Order and all the instructions mentioned in the order, NPPA has revised the ceiling price of the formulation (paciltaxel) exclusive of all goods and service taxes applicable, if any in respect of the Scheduled formulation(s).[1] The table below gives the complete information of price revision:

S No	Scheduled Formulation	Dosage strength	Unit	Ceiling price	Review order number and date	Existing SO number and date
1	Paciltaxel	Injection 100mg/16.7ml	1 ML	205.04	31015/33/2016-PI.I dated 19.09.2016	1213(E) dated 25.03.2020 (at Sl. No. 613)
2	Paciltaxel	Injection 30mg/5ml	1 ML	205.04	31015/33/2016-PI.I dated 19.09.2016	1213(E) dated 25.03.2020 (at Sl. No. 613)

Note:

(a) All manufacturers of scheduled formulations, selling branded or generic or both versions of scheduled formulations at a price higher than the ceiling price (plus goods and services tax as applicable) so fixed and notified by the Government, shall revise the prices of all such formulations downward not exceeding the ceiling price specified in column (5) in the above table plus goods and services tax as applicable, if any.

(b) All existing manufacturers of above mentioned scheduled formulations having MRP lower than the ceiling price specified in column (5) in the above table plus goods and services tax as applicable, if any, shall continue to maintain the existing MRP in accordance with paragraph 13 (2) of the DPCO, 2013 which states that there will be an annual increase in maximum retail price which may be carried out as per the increase in the wholesale price index with respect to previous year.[2]

(c) The manufacturers may add goods and services tax only if they have paid actually or if it is payable to the Government on the ceiling price mentioned in column (5) of the above said table.

(d) The ceiling price for a pack of the scheduled formulation shall be arrived at by the concerned manufacturer in accordance with the ceiling price specified in column (5) of the above table as per provisions contained in paragraph 11 which states that the average price to retailer calculated as per the provisions in paragraphs 4, 5 and 6 shall be on the dosage basis, (per tablet, per capsule or injection in volume as listed in first schedule) and the ceiling price or retail price of a pack shall be reached by multiplying the same with the number or quantity in the pack as the case may be. The manufacturer shall issue a price list in Form–V from date of Notification as per

1 http://www.nppaindia.nic.in/wp-content/uploads/2020/04/3-2.pdf

2 http://www.idma-assn.org/pdf/drug-price-control-order-2013.pdf

paragraph 24 of the DPCO, 2013 to NPPA through IPDMS and submit a copy to State Drug Controller and dealers.

(e) As per para 24(4) of DPCO 2013, every retailer and dealer shall display price list and the supplementary price list, if any, as furnished by the manufacturer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.

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NPPA sets up PMRU in J&K to track drug price ceiling violation

The National Pharmaceutical Pricing Authority (NPPA) has set up Price Monitoring and Resource Unit (PMRU) in Jammu & Kashmir Union Territory, taking the total number of PMRUs in the country to 12, to track drug price ceiling violation by pharma companies.[1]

Background

PMRU is a government body which is designed to help NPPA and State Drug Controllers in ensuring availability and accessibility of medicines at affordable prices. It is NPPA funded body and has already been setup in 11 states including Kerala, Odisha, Gujarat, Rajasthan, Punjab, Haryana, Nagaland, Tripura, Uttar Pradesh, Andhra Pradesh and Mizoram. PMRU has been setup to monitor price control due to lack of a field-level links between the NPPA and the State Drugs Controllers to monitor drug prices.

Objectives of PMRU are:

- To monitor notified prices of medicines
- To detect violation of the provisions of the DPCO
- To look at price compliance, collect test samples of medicines
- To collect and compile market-based data of scheduled as well as non-scheduled formulations.

The PMRU, a registered society, shall function under the direct control and supervision of State Drug Controller of Jammu & Kashmir. The unit shall be funded by NPPA for its recurring and non-recurring expenses. The PMRU shall help NPPA and State Drug Controller in ensuring availability and accessibility of medicines at affordable prices. It is also expected to organise seminars, training programs and other information, education and communication (IEC) activities in the areas of availability and affordability of medicines for all.

PMRU will also collect samples of medicines, collect and analyse data and make reports with respect to availability and over-pricing of medicines for taking action under the provisions of Drug Price Control Order (DPCO). This assumes added significance as PMRU, J&K, will assist NPPA and Government in checking overpricing and identifying causes & addressing local issues of shortages/hoarding in the current situation when country is fighting the COVID-19 pandemic.

Conclusion

NPPA has set up different PMRU units in different states in order to maintain the price control on medicines between the customers and manufacturers and make them available to the public at an affordable price.

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1 *https://pib.gov.in/newsite/PrintRelease.aspx?relid=200878*

US FDA Pharma Highlights April 2020

This section of the newsletter discusses recent drug approvals from U.S. Food and Drug Administration (USFDA) for various serious diseases. The section outlines the role of new drugs in the treatment of serious diseases such as cancer, heart disease and from tobacco products. The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices.

FDA Requests Removal of All Ranitidine Products (Zantac) from the Market[1]

The U.S. Food and Drug Administration has announced that it is requesting manufacturers to withdraw all prescription and over-the-counter (OTC) ranitidine drugs from the market immediately. This is the latest step in an ongoing investigation of a contaminant known as N-Nitrosodimethylamine (NDMA) in ranitidine medications (commonly known by the brand name Zantac). Ranitidine belongs to a group of drugs called histamine-2 blockers. It works by reducing the amount of acid your stomach produces. Ranitidine is used to treat and prevent ulcers in the stomach and intestines.

FDA Approves Additional Treatment for Adults and Adolescents with Hemophilia A or B with Inhibitors[2]

The U.S. Food and Drug Administration has approved Sevenfact [coagulation factor VIIa (recombinant)-jncw] for the treatment and control of bleeding episodes occurring in adults and adolescents 12 years of age and older with hemophilia A or B with inhibitors (neutralizing antibodies). Sevenfact contains an active ingredient expressed in genetically engineered rabbits. Hemophilia A or B is a congenital bleeding disorder caused by a dysfunction or deficiency of Coagulation Factor (F) VIII or IX, respectively. People with hemophilia may bleed for a longer time than others after injury or surgery. They may also have spontaneous bleeding in muscles, joints and organs, which may be life-threatening. The FDA granted approval of Sevenfact to Laboratoire Francais du Fractionnement et des Biotechnologies S.A.

FDA Provides Updated Guidance to Address the Urgent Need for Blood During the Pandemic[3]

As part of the U.S. Food and Drug Administration's ongoing commitment to fight the COVID-19 pandemic, the agency issued guidance for immediate implementation to address the urgent and immediate need for blood and blood components. The COVID-19 pandemic has caused unprecedented challenges to the U.S. blood supply. Donor centers have experienced a dramatic reduction in donations due to the implementation of social distancing and the cancellation of blood drives.

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1 *https://www.fda.gov/news-events/press-announcements/fda-requests-removal-all-ranitidine-products-zantac-market*

2 *https://www.fda.gov/news-events/press-announcements/fda-approves-additional-treatment-adults-and-adolescents-hemophilia-or-b-and-inhibitors*

3 *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-updated-guidance-address-urgent-need-blood-during-pandemic*

WHO Pharma Highlights April 2020

This segment of the newsletter focuses on sharing the recent regulatory reforms and updates on Healthcare and Pharmaceutical domain from World Health Organization (WHO). This segment collates information periodically via conducting research and review of pharmaceutical updates from the WHO. Below are the highlights for the month of April 2020.

WHO and UNICEF collaborate on pandemic response through COVID-19 Solidarity Response Fund[1]

On April 03, 2020, WHO and UNICEF announced an agreement to work together on COVID-19 response, through the historic COVID-19 Solidarity Response Fund powered by the United Nations Foundation and Swiss Philanthropy Foundation. The COVID-19 Solidarity Response Fund has been set up to facilitate an unprecedented global response by supporting the WHO Strategic Preparedness and Response Plan. As part of the agreement, an initial portion of the money from the fund – which currently stands at more than $127 million – will flow to UNICEF for its work with vulnerable children and communities all over the world.

WHO releases guidelines to help countries maintain essential health services during the COVID-19 pandemic[2]

The COVID-19 pandemic is straining health systems worldwide. The rapidly increasing demand on health facilities and health care workers threatens to leave some health systems overstretched and unable to operate effectively. Previous outbreaks have demonstrated that when health systems are overwhelmed, mortality from vaccine-preventable and other treatable conditions can also increase dramatically. During the 2014-2015 Ebola outbreak, there were increased number of deaths caused by measles, malaria, HIV/AIDS, and tuberculosis, all attributable to health system failures; the numbers exceeded deaths from Ebola.

New WHO recommendations to prevent tuberculosis aim to save millions of lives[3]

New World Health Organization (WHO) guidance will help countries accelerate efforts to stop people with tuberculosis (TB) infection becoming sick with TB by giving them preventive treatment. A quarter of the world's population is estimated to be infected with TB bacteria. These people are neither sick nor contagious. However, they are at greater risk of developing TB disease, especially those with weakened immunity. Offering them TB preventive treatment will not only protect them from becoming sick but also cut down on the risk of transmission in the community.

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1 *https://www.who.int/news-room/detail/03-04-2020-who-and-unicef-to-partner-on-pandemic-response-through-covid-19-solidarity-response-fund*

2 *https://www.who.int/news-room/detail/30-03-2020-who-releases-guidelines-to-help-countries-maintain-essential-health-services-during-the-covid-19-pandemic*

3 *https://www.who.int/news-room/detail/24-03-2020-new-who-recommendations-to-prevent-tuberculosis-aim-to-save-millions-of-lives*

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