SINGH & ASSOCIATES

FOUNDER MANOJ K SINGH

ADVOCATES & SOLICITORS

Vol. IV, Issue III
March 2020

S&A PHARMA NEWSLETTER

EDITORIAL

Manoj K. Singh
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.

Note: All reasonable precautions have been taken to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the author and/or the firm be liable for damages arising from its use.

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

Thank you.

Contributors to the current issue:
Mr. Manoj K. Singh
Ms. Vijaylaxmi Rathore
Ms. Arnika Sharma

All ©Copyrights owned by Singh & Associates

2020 © Singh & Associates

S&A Pharma Newsletter ®
Volume IV, Issue III
March 2020

SINGH & ASSOCIATES
ADVOCATES & SOLICITORS

NEW DELHI
E-337, East of Kailash
New Delhi - 110065 INDIA

GURUGRAM
7th Floor, ABW Tower, MG Service Road
Sector 25, IFFCO Chowk, Gurugram
Haryana - 122001 INDIA

MUMBAI
Unit No. 101, 10th Floor
Sakhar Bhavan, Plot No. 230
Ramnath Goenka Marg
Nariman Point, Mumbai - 400021, INDIA,

BENGALURU
Condor Mirage, 101/1, 3rd Floor
Richmond Road, Richmond Town
Bengaluru - 560025, INDIA

Ph: +91-11-46667000
Fax: +91-11-46667001

Email: india@singhassociates.in
Website: www.singhassociates.in

Managing Editor
Manoj K. Singh

Published by
Singh & Associates
Advocates and Solicitors

Contents

1. Novel Coronavirus Disease 2019 (COVID-19): Guidelines on rational use of Personal Protective Equipment 04

2. ICMR appoints Metropolis Healthcare for conducting tests for COVID-19 06

3. Notice on regulatory pathway for R&D of IVD kit for diagnosis of COVID-19 07

4. NPPA revises the ceiling price of coronary stent 08

5. Price revision of Ringer Lactate -RL Injection with Special Packaging 09

6. Union health ministry undertakes preventive schemes for effective healthcare delivery to combat COVID-19 11

Novel Coronavirus Disease 2019 (COVID-19): Guidelines on rational use of Personal Protective Equipment

Recently, Ministry of Health and Family Welfare came out with guidelines on use of Personal Protective Equipment for health care workers and those others working in points of entries (POEs), quarantine centers, hospitals, laboratories and primary health care / community settings. The guidelines set an approach to guide on the type of personal protective equipment to be used in different settings.[1]

Background

Coronaviruses are a large family of viruses that circulate among animals, including camels, cats and bats, and some cause illness in people and others. Rarely, animal coronaviruses do evolve and infect people and then spread between people such as has been seen with MERS and SARS. The outbreak of Novel coronavirus disease (now named COVID-19) initially noticed from a seafood market in Wuhan city in Hubei Province of China in mid-December 2019, has spread to more than 185 countries/territories worldwide including India. The causative agent for COVID-19, earlier termed provisionally as novel Coronavirus has been officially named as SARS-CoV-2

Personal Protective Equipment (PPE)

Personal Protective Equipment (PPE) cover protective gears designed to safeguard the health of workers by minimizing their exposure to a biological agent.

Components of PPE

Components of PPE are goggles, face-shield, mask, gloves, coverall/gowns (with or without aprons), head cover and shoe cover:

- **Face shield and goggles:** Contamination of mucous membranes of the eyes, nose and mouth is likely in a scenario of droplets generated by cough, sneeze of an infected person coming in touch with / close proximity of an infected person. Hence, protection of the mucous membranes of the eyes/nose/mouth by using face shields/ goggles is an integral part of standard and contact precautions. The flexible frame of goggles should provide good seal with the skin of the face, covering the eyes and the surrounding areas and even accommodating for prescription glasses.
- **Masks:** Respiratory viruses of coronavirus variety target mainly the upper and lower respiratory tracts. Protecting the airway from the particulate matter generated by droplets / aerosols prevents human infection. Hence, the droplet precautions/airborne precautions using masks are crucial while dealing with a suspect or confirmed case of COVID-19/performing aerosol generating procedures. Different types of relevant masks are:
    - Triple layer medical mask
    - N-95 Respirator mask
- **Gloves**: Nitrile gloves are preferred over latex gloves because they resist chemicals, including certain disinfectants such as chlorine.
- **Coverall/Gowns:** Coverall/gowns are designed to protect torso of healthcare providers from exposure to virus. Coveralls typically provide 360-degree protection because they are designed to cover the whole body, including back and lower legs and sometimes head and feet as well, whereas the design of medical/

1 https://www.mohfw.gov.in/pdf/GuidelinesonrationaluseofPersonalProtectiveEquipment.pdf

isolation gowns does not provide continuous whole-body protection (e.g., possible openings in the back, coverage to the mid-calf only).

Conclusion

With the health ministry developing the Personal Protective Equipment (PPE) it has helped the society to combat the disease effectively at personal level without putting major burden on health care officials. This guidance will help the common man to know the standards of the components of Personal Protective Equipment and methods of their uses as well as the procedure to discharge them effectively.

***

ICMR appoints Metropolis Healthcare for conducting tests for COVID-19

The Indian Council of Medical Research (ICMR), the country's apex biomedical research body, has appointed Metropolis Healthcare Ltd to conduct test for COVID-19 in Mumbai.[1]
Metropolis Healthcare has already begun sample collection from home and testing in Mumbai.

The customer can call Metropolis helpline number 8422801801 for any queries regarding COVID-19 testing. Patients can directly call up the lab but should fulfill ICMR guidelines i.e. they should have doctor's prescription and should WhatsApp the same to them on the number given above.

As per ICMR's guidelines, Metropolis is testing people with travel history and symptoms, people who were in direct contact with positive cases and the ones who have symptoms of fever, cough, difficulty of breathing. Testing is only undertaken upon the prescription of a certified doctor and on furnishing government issued ID proof.

All COVID–19 reports are released within 24 hours. All positive test results are notified to the ICMR immediately. For testing, Metropolis Healthcare has procured kits which ICMR has approved. The test is based on real time PCR technology. It consists of two parts – screening and confirmatory and both the tests are done together for the best possible outcome for the patient.

Metropolis Healthcare's team of technicians has undergone rigorous training for sample collection of COVID – 19. It's laboratory in Mumbai is already specialized for swine flu. The testing and sample collection methodology of COVID-19 is same as swine flu. All technicians are equipped with full protective gear, masks and goggles to their ensure safety and of lab personnel.

Conclusion

Due to increasing number of cases of COVID-19 in India, ministry of health is taking all steps to identify those infected and is giving authorization to various pharmaceutical companies and private labs to develop the COVID-19 kit at a fast pace to ensure proper screening of the disease.

***

1 http://www.pharmabiz.com/NewsDetails.aspx?aid=122029&sid=2

Notice on regulatory pathway for R&D of IVD kit for diagnosis of COVID-19

On March 19, 2020, the Central Drug Standard Control Organization has published a notice regarding the regulatory pathway for R&D of IVD kit for diagnosis of COVID-19 in order to encourage the research and development of the kit. Any individual who wishes to propose any new development should submit the application to CDSCO which will be processed on priority basis. CDSCO will also provide regulatory guidance on such matter.[1]

Following are the details under this provision:

- Any firm having in-vitro diagnostic kit under development for COVID-29 can directly submit the application through Public Relations Office for seeking guidance on regulatory pathways.
- Any firm having in-vitro diagnostic kit under development forCOVID-29 in any other country can directly submit the application through Public Relations Office regarding expedited approval in Indian market.
- Data requirement for clinical evaluation may be waived on case-to-case basis depending on type and nature of diagnostic kit, existing data on the product and evidence of available clinical evaluation data of such kit.
- All applications required for manufacturing, import and evaluation of the COVID-19 kit may be processed on priority within 7 days.
- Application required for manufacturing, import and evaluation of the COVID-19 required for sale and distribution would be processed on priority through accelerated review.

Note: For any additional information contact Public Relations Office through toll-free number 1800 11 1454 & write to startupinnov@cdsco.nicin.

Conclusion

Novel Corona-virus Disease (COVID-19) has spread over 118 countries with now more than 191.127 cases and 7807 people have lost their lives as on 18.03.2020. World Health Organization (WHO) has declared it as pandemic. However, there is no current evidence from randomized clinical trials to recommend any specific treatment for suspected or confirmed patients with COVID-19. In order to make new advancements in treating disease, CDSCO has come up with proposal on submitting application based upon the regulatory pathways in developing COVID-19 kit. This will help the society to identify and tackle the disease in a better way with a positive outcome.

***

1 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTc3MA==

NPPA revises the ceiling price of coronary stent

Drug price regulator NPPA has approved hike in prices of cardiac stents by 4.2 per cent in-line with the wholesale price index (WPI) of the previous calendar year, as per an official statement.[1]

Background

After a notification issued by National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemical and Fertilizers, regarding the fixation of ceiling price of the Coronary Stents and after considering the hike in WPI at 4.26 per cent for the year 2018 over 2017, it has been decided to revise the ceiling prices of coronary stents with effect from April 1, 2019.

As per the new prices notified by the National Pharmaceutical Pricing Authority (NPPA), a bare metal stent (BMS) would now cost Rs 8,261, while the drug eluting stent (DES) will cost Rs 30,080.

The drug pricing authority had earlier revised the prices of stents in February last year. It had increased the prices of bare metal stents from Rs 7,400 to Rs 7,660. On the other hand, it had reduced the price of DES to Rs 27,890 from Rs 30,180. Providing a major relief to lakhs of cardiac patients, the government had for the first time cut prices of life-saving coronary stents by up to 85 per cent in February 2017. Prior to February 2017, BMS used to cost as much as Rs 45,000 and DES Rs 1.21 lakh.

Notes

(a) All the existing manufacturers/importers of Coronary Stents having MRP lower than the ceiling price (plus Goods and Services Taxes as applicable, if any), may revise the existing MRP of Coronary Stent, on the basis of WPI @ 1.88468% for the year 2019 in accordance with Paragraph 16(2) of DPCO, 2013, read with Para 13(2) of DPCO, 2013.

(b) The manufacturers/importers of Coronary Stents may add Goods and Services Taxes only if they have paid it actually or if it is payable to the Government on the ceiling price.

(c) 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/importers, at 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.

(d) The manufacturers not complying with the ceiling price and notes specified herein above shall be liable to deposit the overcharged amount along with interest thereon under the provisions of the Drugs (Prices Control) Order, 2013 read with Essential Commodities Act, 1955.

Conclusion

Coronary stent is a tube-shaped device placed in the arteries that supplies blood to heart. It keeps the arteries open in the treatment of coronary heart diseases. Moreover, after intensive deliberations and after considering the available information and the market statistics at its disposalNPPA took the unanimous decision that cardiac stents being an essential drug under Schedule I of DPCO (drug price control orders) 2013 and part of NLEM (national list of essential medicines) 2015 having paramount importance on public health needs to continue to be kept under price regulation in the larger public interest.

***

1 http://www.nppaindia.nic.in/wp-content/uploads/2020/03/5-1.pdf

Price revision of Ringer Lactate -RL Injection with Special Packaging

On March 25, 2020, the National Pharmaceutical Pricing Authority revised the ceiling price of Ringer Lactate injection in special packaging, by increasing it by 15 percent. The special packaging reduces chances of contamination of the product.

Background

Lactated Ringer's solution, or LR, is one of the two most common intravenous (IV) fluids used for patient care at hospitals. The decision to increase its ceiling price, was recently approved in NPPA's 205th (overall) and 73rd meeting of the authority under DPCO, 2013, after it considered that its committee note on the minor safety innovation in the packaging of the ringer lactate injections.

Price Revision as per 1.88468% increase in Annual Wholesale Price Index (WPI)

S. No.	Formulations	Unit	Ceiling Price excluding GST
1	Ringer lactate injection	100 ml pack (having special features)	Rs. 23.51
2	Ringer lactate injection	250 ml pack (having special features)	Rs. 40.08
3	Ringer lactate injection	500 ml pack (having special features)	Rs. 51.07
4	Ringer lactate injection	1000 ml pack (having special features)	Rs. 89.77

(a) It is reported a group of manufacturers including M/s Albert David Ltd, M/s Aculife Healthcare Pvt. Ltd, M/s B. Braun Medical (India) Pvt. Ltd, M/s Fresenius Kabi India Pvt. Ltd and M/s Ostuka Pharmaceuticals India Pvt. Ltd had filed a review application against ceiling price fixation of Ringer lactate Injection fixed vide S.O. 2401(E) dated 28.07.2017.

The ceiling prices are applicable with effect from 01.04.2020 (ceiling prices are inclusive of Wholesale Price Index (WPI) @1.88468% for the year 2019 over 2018).

(b) The manufacturers of scheduled formulations, selling above mentioned products/ brand name of scheduled formulations at 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 as specified plus goods and services tax as applicable, if any.

(c) The manufacturers of above mentioned scheduled formulations having MRP lower than the ceiling price as specified (plus goods and services tax as applicable, if any), may revise the existing M.R.P. of their formulations,

on the basis of WPI @ 1.88468% for year 2019 in accordance with paragraph 16(2) of DPCO, 2013, read with para 13(2) of DPCO, 2013.

(d) The manufacturers may add goods and services tax only if they have paid it actually or if it is payable to the Government on the ceiling price as fixed.

(e) Any other manufacturer claiming separate ceiling price for ringer lactate injection in pack having special features like:

(i) self-collapsibility and self-sealability

(ii) not having air-vent

(iii) there is no chance of contamination during manufacture/ infusion/ admixing levels

shall apply to NPPA for separate ceiling price approval.

(f) For other special features claimed or any other pack size manufactured, the manufacturer shall approach the NPPA for specific price approval for its formulation.

(g) The ceiling price for a pack of the scheduled formulation shall be arrived at by the concerned manufacturer in accordance with the ceiling price as specified as per provisions contained in paragraph 11 of the Drugs (Prices Control) Order, 2013. The manufacturer shall issue a price list in Form–V from date of notification as per paragraph 24 of the DPCO, 2013, to NPPA through IPDMS and submit a copy to State Drug Controller and dealers.

(h) 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, at 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.

(i) Where an existing manufacturer of scheduled formulation with dosage or strength or both as specified in the above table launches a new drug as per paragraph 2 (u) of the DPCO, 2013 such existing manufacturer shall apply for prior price approval of such new drug to the NPPA in Form I as specified under Schedule-II of the DPCO, 2013.

(j) The manufacturers of above said scheduled formulations shall furnish quarterly return to the NPPA, in respect of theproduction / import and sale of scheduled formulations in Form-III of Schedule-II of the DPCO, 2013 through IPDMS.

Any manufacturer intending to discontinue production of above said scheduled formulation shall furnish information to the NPPA, in respect of discontinuation of production and / or import of scheduled formulation in Form-IV of Schedule-II of the DPCO, 2013 at least six months prior to the intended date of discontinuation.

(k) The manufacturers not complying with the ceiling price and notes specified hereinabove shall be liable to deposit the overcharged amount along with interest thereon under the provisions of the Drugs (Prices Control) Order, 2013 read with Essential Commodities Act, 1955.

(l) Consequent to the issue of ceiling prices of such formulations as specified in column (2) of the above table in this notification, the price order(s) fixing ceiling or retail price, if any, issued prior to the above said date of notification, stand(s) superseded.

***

Union health ministry undertakes preventive schemes for effective healthcare delivery to combat COVID-19

The union health ministry has undertaken various healthcare schemes to ensure healthy life and further improve the average life expectancy of the people in the country to combat COVID-19.[1]

Background

In order to decrease the effect of increasing burden of diseases, National Health Mission (NHM) has initiated various programs like National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS), National Programme for Control of Blindness and Visual Impairment (NPCBVI), National Mental Health Programme (NMHP), National Programme for Healthcare of Elderly (NPHCE), National Programme for the Prevention and Control of Deafness (NPPCD) etc.

The Ayushman Bharat scheme with its two components of Health and Wellness Centres (HWCs) and Pradhan Mantri Jan Arogya Yojana (PMJAY) addresses disparity in access and reduces out of pocket expenditure for secondary and tertiary care hospitalization for 40 per cent of India's population. The scheme provides hospital care for about 1,350 illnesses at secondary and tertiary level empanelled public and private hospitals. HWC encourages healthy choices and behaviours including Yoga and other physical activities. National Health Mission is creating a network of 1,50,000 HWCs by upgrading existing Sub Centres (SCs) and Primary Health Centres (PHCs) to provide comprehensive primary health care (CPHC), which is universal and free to all those who access public health facilities. The CPHC basket of services cover 12 key service areas, which go beyond the reproductive, maternal, neonatal, child and adolescent health (RMNCH+A) services to include screening and care for NCDs etc. National Health Policy, 2017, also emphasises on provision of availability of free, comprehensive primary health care services, for all aspects of reproductive, maternal, child and adolescent health and for the most prevalent communicable, non-communicable and occupational diseases in the population.

Conclusion

In order to prevent the increasing prevalence of the disease government has taken special steps like providing continuous care to elderly above 60 years of age from preventive and promotive up to rehabilitation in geriatric units of district hospitals, community health centres and primary health centres under NPHCE. It also provides financial support in the form of untied funds, annual maintenance grants and Rogi Kalyan Samiti (RKS) funds for development of health facilities and ensuring services.

***

1 http://www.pharmabiz.com/NewsDetails.aspx?aid=121980&sid=2

notes