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Research Article

IMPACT OF COVID-19 PANDEMIC ON MARKETING AUTHORIZATION PROCEDURE OF MEDICAL DEVICES IN DIFFERENT COUNTRIES

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ABSTRACT

Medical devices have been used to treat and diagnose diseases. Due to the current pandemic, the medical device industry has been under tremendous pressure to deliver, innovate and be able to handle the sudden surge in demand for equipment and perform further research. The article is an attempt to describe that, how, in the present COVID-19 situation, regulatory authorities of major countries temporarily allowed the market, to follow-up the emergency authorization policies to help the industry and the population to fight against the virus. Globally, Pharmaceutical sector is endlessly involved to cope-up with the current situation by providing high-quality medical devices such as ventilators, PPE kit, masks for the betterment of the occupiers.

Keywords: Fast-track approval, Emergency use authorization and Interim order.

INTRODUCTION

The era of newer development & technology has always attempted to decrease the morbidity and mortality rate due to various diseases. Currently the impact of Coronavirus (COVID-19) on manufacturing companies of drugs and medical devices has been unique as, not only they have to set up emergency management systems, practically overnight in order to maintain their normal business operations but also they have to make available diagnostic and therapeutic medical devices to diagnose and respond to public health emergency.

As a result of the COVID-19 pandemic, protective medical equipment including masks, gowns, and medical devices for use in testing and treating COVID-19 patients are in high demand. Manufacturers of these medical devices are attempting to scale up production in the face of supply shortages while industry and government are innovating to tackle the issue[1].

When there is a public health emergency or an extensive potential for a public health emergency that will impact national health, medical devices needed for emergency use shall be reviewed and authorised in time to effectively prevent, control, and eliminate the hazards.

Respiratory assist devices such as life-support machine, atomizer, oxygen generator and monitor are the primary clinical treatment medical devices. Thus, from diagnosis to cure, the need for instruments for measuring temperature, nucleic acid diagnostic kit, antiviral medical products and life-support machine has kept on increasing[2].

The objective of the paper is to study the marketing authorization procedures of different countries for the medical devices at time of declared medical emergency of novel coronavirus pandemic[3].

USA

To address the COVID-19 pandemic, the US Food and Drug Administration (FDA) is committed in providing timely access to critical medical devices. During this pandemic emergency around the globe, the USFDA is using its Emergency Use Authorization (EUA) authority to permit the utilization of non-certified medical

products, or unauthorised uses of approved medical products so as to diagnose, treat and prevent serious or life-threatening disease where aren't any adequate, approved, and available alternatives present. The allocation of a EUA is different than FDA approval. In determining whether to issue a EUA, the FDA evaluates the available evidence and punctiliously balances any known or potential risks of any erroneous products with any known or practicable advantages of making them available during the emergency.

The devices that are eligible for inclusion under this EUA are those that are not currently marketed in the U.S., or that are currently marketed in the U.S. but a modification is made to the device that would trigger the requirement that a manufacturer submit a new premarket notification (510(k)) to the FDA under FD&C Act. The Secretary of Health and Human Services must make a declaration of emergency or threat justifying authorization of emergency use for a product before the grant of EUA. Meanwhile, CDRH will conduct its analysis as quickly as possible. When the emergency is over, the EUA assertion is discontinued, and will no longer prevail[4].

EUROPE

For the protection of healthcare providers who are tackling the COVID-19 crisis, the European Commission has recommended to allow deprecation from conformity assessment procedures of the medical devices or personal protective equipment (PPE), surgical masks, ventilators, respiratory equipment and IVD test kits to detect coronavirus infections. Conformity assessment, the CE mark, or formerly EC mark, is a mandatory conformity marking for certain products sold within the European Economic Area (EEA) since 1985.

Under normal circumstances, CE Marking certificate in Europe for a medical device, IVD or PPE can be obtained either from a Notified Body or a self-declaration for low-risk products as stipulated under the European Medical Devices Directive (93/42/EEC, or MDD), Active Implantable Medical Devices Directive (90/385/EEC, or AIMDD); the In Vitro Diagnostic Medical Devices Directive (98/79/EEC, or IVDD) for IVD devices; and Regulation (EU) 2016/425. Conformity assessments of these devices can range from several months to year or longer for high-risk medical devices and IVDs.

However, in emergency public health situations both the European Commission as well as EU member states individually have the ability to momentarily permit access to EU markets for devices and PPE products that have not gone through or have not yet completed the required conformity assessment based on the applicable legislation, and thus have not yet received the CE Marking certificate or are not yet able to affix the CE mark to the device (for self-declared products)[5].

CANADA

The importation and sale of medical devices used to diagnose, treat or prevent COVID-19 in Canada is accelerating day by day. In order to expedite the review of these medical devices, inclusive of test kits an interim order (IO)[6] has been approved by the Minister of Health. An interim order is one of the fastest mechanisms accessible to tackle nationwide public health emergencies.

If an application for the marketing authorization to import and sell a COVID-19 related medical device is approved under the Interim Order, the importer would be exempt from the requirements of Part 1 of the Medical Device Regulations[7], except for the provisions relating to distribution records and recalls. Further, if the device is already approved by a overseas regulatory authority and has no longer been suspended, the applicant is exempt from including any known information related to the quality, safety and effectiveness of the device.

The government will also publish a list of marketed medical devices that have been approved for expanded uses based on urgent need and a determination that the health or safety of patients, users or other persons will not be unduly affected by the expanded use. If these medical devices are also accredited for import and sale, importers will moreover be exempt from meeting the requirements of Part 1 of the Medical Device Regulations[8].

AUSTRALIA

Substantially, any vaccine, medicine or medical device need to be accredited by the Therapeutic Goods Administration (TGA) before it could be marketed in Australia. However, whilst the TGA has an essential role to play in ensuring quality, safety and efficacy, there are some fast-track mechanisms that could apply in light of the public health emergency that is presently going through in regard of COVID-19[9].

The TGA has greater flexibility to facilitate the rapid approval of diagnostic medical devices which are used to detect COVID-19 infection. Concerning the COVID-19 outbreak, the TGA has emergency exemptions that permit the importation and sale of some devices, including COVID-19 IVD test kits, and products without the standard registration requirements, or expedited registrations, where applicable.

The standard process includes providing evidence of conformity assessment from the TGA, or acceptable overseas regulator, to obtain an Australian Register of Therapeutic Goods (ARTG) listing number (TGA approval). The approval process timeframes vary primarily based on device classification and generally range from a few weeks to several months[10].

CHINA

In response to the outbreak of a pneumonia-like ailment induced by coronavirus (COVID-19), Chinese regulatory authorities adopted a few emergency measures under certain "Special Review and Approval Procedures" to fast-track the evaluation and approval process for developing diagnostic kits, vaccines and therapies for combating COVID-19 infections.

Chinese Center for Drug Evaluation (CDE) in collaboration with China National Medical Products Administration (NMPA) has proclaim guidelines for filing new drug applications (NDA) for anti-COVID-19 drugs and technical guidelines on filing investigational new drug (IND) applications for anti-COVID-19 therapies and preventive vaccines. These guidelines ensure the time for acquiring an IND or NDA approval could be significantly reduced[11].

Besides the fast track approval for urgently required devices, "Notice of Importing Unapproved Medical Devices in Urgent Need" was published by NMPA that allow the import of urgently needed devices without NMPA approval however with FDA/CE/Japan certification and recognized testing reports and Quality Management System. Provincial NMPA along with National Health Commission and Chinese Customs work collectively to facilitate the smooth importation and customs clearance in order to ensure product delivery such as protective masks, clothing, sterilization and ventilation devices to the hospitals as quickly as possible[12].

INDIA

Several notices had been published by Central Drugs Standard Control Organisation (CDSCO) in response to the ongoing pandemic that addresses new measures to expedite access to devices intended to prevent or treat COVID-19 and to safeguard supply of other indispensable IVDs[13].

Taking into account the rapid spread of COVID-19 in international locations and the need for immediate research and product development, CDSCO has determined to fast track the regulatory approval process in consultation with DCGI to deal with the applications for development of vaccines, diagnostics, prophylactics and therapeutics for COVID-19. Review Committee on Genetic Manipulation (RCGM) will approve the application fulfilling criteria within 7 days from the date of receipt of application along with IBSC recommendation on IBKP portal[14].

As part of the expedited approval process, data requirements (e.g., for clinical performance evaluations) may be condensed, deferred, or waived on a case-by-case basis. The CDSCO issued temporary modified release procedures for other critical imported IVDs to be followed throughout the course of the COVID-19 pandemic, which has caused typical sampling and testing processes to be disrupted. Port offices holding consignments of these IVDs may release them based on a review of documents, protocol, the manufacturer's batch release certification, and the history of compliance[15].

CONCLUSION

In response to the COVID-19 outbreak, medical device market regulators of different countries are releasing Emergency Use Authorizations (EUAs) and expedited regulatory pathways for devices which healthcare providers need most, like ventilators, face masks and PPE, test kits and so on. Some authorities are redirecting products to streamline marketplace entry and avoid shortages. The state of affairs is changing rapidly; every country is committed to monitor the developments to deliver regulatory news and intelligence that helps medical device companies respond quickly to COVID-19 pandemic.

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