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Review on Drug Regulatory Science Promoting COVID-19 Vaccine Development in China

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ABSTRACT

Regulatory science is a discipline that uses comprehensive methods of natural science, social science, and humanities to provide support for administrative decision-making through the development of new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of regulated products. During the pandemics induced by infectious diseases, such as H1N1 flu, severe acute respiratory syndrome (SARS), and Middle East respiratory syndrome (MERS), regulatory science strongly supported the development of drugs and vaccines to respond to the viruses. In particular, with the support of research on drug regulatory science, vaccines have played a major role in the prevention and control of coronavirus disease 2019 (COVID-19). This review summarizes the overall state of the vaccine industry, research and development (R&D) of COVID-19 vaccines in China, and the general state of regulatory science and supervision for vaccines in China. Further, this review highlights how regulatory science has promoted the R&D of Chinese COVID-19 vaccines, with analyses from the aspects of national-level planning, relevant laws and regulations, technical guidelines, quality control platforms, and post-marketing supervision. Ultimately, this review provides a reference for the formulation of a vaccine development strategy in response to the current pandemic and the field of vaccine development in the post-pandemic era, as well as guidance on how to better respond to emerging and recurring infectious diseases that may occur in the future.

1. Introduction

Vaccines are one of the greatest achievements in the medical field in the history of humankind. Vaccination is the most effective and economical method for preventing infectious diseases. Since China began nationwide implementation of planned immunization in 1978, and after several adjustments and expansions, China's national immunization programs include 14 vaccines to prevent 15 diseases, with a vaccination rate greater than 90% [1,2]. Vaccines have played an irreplaceable role in responding to public health emergencies, such as the pandemic H1N1 flu [3] and hand–foot–mouth disease [4,5]. Chinese vaccination has not only improved the overall health of Chinese people but also contributed to the progress of public health worldwide [1,2,6]. Since 2018, the vaccine management system, laws, and regulations in China have undergone major reforms. Further, vaccine supervision has become more scientific and stricter, effectively promoting the development of the vaccine industry.

The coronavirus disease 2019 (COVID-19) pandemic has undoubtedly increased the speed of global vaccine research and development (R&D), including in China. In one year after the beginning of the epidemic, more than one dozen COVID-19 vaccine candidates entered phase 3 clinical trials. Among them, massage RNA (mRNA) vaccines developed by BioNTech (Germany)/Pfizer (USA) and Moderna, Inc. (USA); adenovirus vectored vaccines by CanSino Biologics Inc. (China) and AstraZeneca (UK); and inactivated vaccines by Sinopharm (China) and Sinovac Biotech Co., Ltd. (China) were approved for conditional marketing. However, multiple variants of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) have emerged successively and have spread rapidly worldwide since the beginning of the COVID-19 pandemic. Accordingly, this virus continues to challenge the vaccine industry and health system. As of 2021, five variants of concern (VOCs) were reported worldwide, including Alpha (B.1.1.7 and Q lineages), Beta

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