全球瞭望

新冠候選疫苗之緊急授權：對疫苗臨床試驗的影響*

The Granting of Emergency Use Designation to COVID-19 Candidate Vaccines : Implications for COVID-19 Vaccine Trials

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摘 要

疫苗是目前全球領先的研究重點，有些國家表示，如若在疫苗獲得許可之前，就有令人信服的疫苗試用案例，這些國家將準備授權其緊急使用、或是以公共衛生為由，有條件地進行批准。截至2020年12月1日，數間領先開發新冠疫苗的廠商表示已申請或打算申請其疫苗的緊急授權。假如候選疫苗在指定使用範圍內獲得緊急授權，並於第三期試驗結束前有計畫地部署接

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種，這種策略可能會對新冠疫苗研究和有效控制新冠肺炎的大流行產生深遠的影響，而這些影響值得我們小心斟酌。

An efficacious COVID-19 vaccine is currently the world's leading research priority. Several nations have indicated that if there is a compelling case for use of a vaccine before it is licensed, they would be prepared to authorise its emergency use or conditional approval on public health grounds. As of Dec 1, 2020, several developers of leading COVID-19 candidate vaccines have indicated that they have applied, or intend to apply, for emergency authorisation for their vaccines. Should candidate vaccines attain emergency use designation and be programmatically deployed before their phase 3 trials conclude, such a strategy could have far reaching consequences for COVID-19 vaccine research and the effective control of the COVID-19 pandemic. These issues merit careful consideration.

壹、引言

疫苗作為現代公共衛生的基礎，傳統而言，為產出能通過疫苗許可的有效證據的黃金標準，是針對臨床相關的預定義終點進行雙盲及安慰劑對照的隨機試驗，以評估疫苗效力[1]。截至2020年12月1日，至少有四個新冠疫苗的試驗已經宣布其中期結果相當的有希望[2]。鑑於許多國家迫切地需要對新冠肺炎

1 Johan Vekemans et al., *The Role of Immune Correlates of Protection on the Pathway to Licensure, Policy Decision and Use of Group B Streptococcus Vaccines For Maternal Immunization: Considerations from World Health Organization Consultations*, 37(24) VACCINE 3190-3198 (2019).

2 Pfizer, *Pfizer and Biontech conclude phase 3 study of COVID-19*

採取有效對策，法規規範較為嚴格的幾個國家[3]或地區[4]表示，如果在獲得許可之前，有令人信服的使用案例，他們將準備授權其緊急使用[5]或以公共衛生為由、有條件地批准其上市許可。在這類情況下，頒布上市許可的主管機關可能認為患者風險利益的平衡，能夠正當化在上市許可頒發前對易受影響的特定人群提供臨時疫苗。當只有少數利益或沒有足夠的數據來評估一個疫苗的安全性時，是無法做出有效的風險利益決策

vaccine candidate, meeting all primary efficacy endpoints, Nov. 18, 2020, https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-conclude-phase-3-study-covid-19-vaccine (last visited Nov. 18, 2020); Gamaleya Research Institute of Epidemiology and Microbiology, Russian Direct Investment Fund, *The First Interim Data Analysis of the Sputnik V Vaccine against COVID-19 Phase III Clinical Trials in the Russian Federation Demonstrated 92% Efficacy*, Nov. 11, 2020, https://sputnikvaccine.com/newsroom/pressreleases/the-first-interim-data-analysis-of-the-sputnik-v-vaccine-against-covid-19-phase-iii-clinical-trials-/ (last visited Nov. 17, 2020); Moderna, *Moderna's COVID-19 Vaccine Candidate Meets Its Primary Efficacy Endpoint in the First Interim Analysis of the Phase 3 COVE Study,* Nov. 16, 2020, https://investors.modernatx.com/node/10316/pdf (last visited Nov. 17, 2020); AstraZeneca, *AZD1222 Vaccine Met Primary Efficacy Endpoint in Preventing COVID-19*, Nov. 23, 2020, https://www.astrazeneca.com/media-centre/press-releases/2020/azd1222hlr.html (last visited Nov. 23, 2020).

3 Food and Drug Administration, *Emergency Use Authorization for Vaccines to Prevent COVID-19. Guidance for Industry,* October, 2020, https://www.fda.gov/media/142749/download (last visited Nov. 1, 2020); The UK Government, *Consultation Document: Changes to Human Medicine Regulations to Support the Rollout of COVID-19 Vaccines,* Oct. 16, 2020, https://www.gov.uk/government/consultations/distributing-vaccines-and-treatments-for-covid-19-and-flu/consultation-document-changes-to-human-medicine-regulations-to-support-the-rollout-of-covid-19-vaccines (last visited Nov. 1, 2020).

4 European Medicines Agency, *Authorisation Pprocedures*, 2020. https://www.ema.europa.eu/en/authorisation-procedures (last visited Nov. 1, 2020).

5 WHO, *List of Stringent Regulatory Authorities (SRAs)*, Jun. 22, 2020, https://www.who.int/medicines/regulation/sras/en/ (last visited Nov. 17, 2020).