

## 再探公共衛生與智慧財產保護之調和：探討《IHR 2024》 以及《大流行病協定》草案對WTO/TRIPS之影響與衝擊

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### 摘要

新冠肺炎疫情所引發的全球公共衛生緊急事件，以及隨之而來之醫藥用品及資源近用問題，再度讓世界貿易組織（World Trade Organization, WTO）下的《與貿易有關之智慧財產權協定（Agreement on Trade-Related Aspects of Intellectual Property Rights, TRIPS）》與公共衛生及健康相關權利調和之爭再次受到注意。本文擬檢視 WTO 自 2000 年間「杜哈公共衛生宣言（Declaration on the TRIPS Agreement and Public Health）」及 TRIPS 協定第 31 條之 1 制定後對智慧財產權保護與公共衛生需求間之調整，並希望檢視在經歷新冠肺炎疫情期間全球醫藥產品緊張以及部分國家再次呼籲放寬對醫藥產品智慧財產權保護後，世界衛生組織（World Trade Organization, WHO）在後疫情時代所推動之《國際衛生條例（International Health Regulations 2005）》修正以及新制定之《國際大流行病預防、防範和應對公約（International Treaty on Pandemic Prevention, Preparedness and Response）》談判中，運用哪些規範手段與工具促進醫藥產品之近用狀況，並檢視相關規範之修正與制定對既有智慧財產權與公共衛生保護調和之影響，以及該等條款可能存在之疑義與問題。

關鍵字：大流行病協定、國際衛生條例、TRIPS 協定第 31 條之 1、杜哈公共衛生宣言

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## Abstract

The urgent and unprecedented global public health emergency triggered by the COVID-19 pandemic, coupled with the subsequent challenges of accessing medical supplies and resources, has once again thrust the debate between the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) under the World Trade Organization (WTO) and the reconciliation of rights related to public health and health into the limelight. The pharmaceutical industry's heavy reliance on intellectual property rights protection under the TRIPS Agreement has led to exorbitant prices and restricted access to medical products, failing to meet the needs of public health governance. Despite the national emergencies caused by major public health diseases such as AIDS, malaria, tuberculosis, and anthrax in the late 1990s, which led to the Doha Declaration in 2000 and the formulation of Article 31bis of the TRIPS Agreement, the global pandemic induced by COVID-19 has once again resulted in shortages of epidemic prevention materials, medical products, and vaccines. Over the course of the pandemic, neither the Doha Declaration on the TRIPS Agreement and Public Health nor Article 31bis of the TRIPS Agreement has effectively balanced the access to medical products and the needs of public health governance across countries.

Post-pandemic, the World Health Organization (WHO) has taken a proactive stance in strengthening global resilience to pandemics. It has done so by advocating for amendments to the International Health Regulations (2005), hereinafter referred to as IHR 2005, and by formulating the International Treaty on Pandemic Prevention, Preparedness, and Response, hereinafter referred to as WHO CA+. These efforts have called on contracting parties to expand technology transfer and apply compulsory licensing to promote a rebalancing of trade and public health interests. This study will focus on the re-evaluation of international public health needs prompted by COVID-19, analyzing the evolution and development of the TRIPS Agreement through the Doha Declaration and Article 31bis, and examining sections of the current IHR 2005 amendment drafts and the WHO CA+ drafts that may conflict with TRIPS or WTO regulations, particularly regarding the expansion of medical technology transfer and the application of compulsory licensing.

**Keywords:** Pandemic Agreement, International Health Regulations, Article 31bis of the TRIPS Agreement, Declaration on the TRIPS Agreement and Public Health