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# WEEKLY EU HEALTHCARE NEWS UPDATE

**25 MARCH – 31 MARCH 2023**

# REVISION OF THE EU GENERAL PHARMACEUTICAL LEGISLATION DELAYED AGAIN DUE TO COMMISSION'S BUSY AGENDA

**The European Commission has delayed the unveiling of its regulatory framework for pharmaceuticals for the third time in a few months, pushing back the reform's presentation to a later date due to the commission's busy schedule.**

The EU's general legislation on medicines for human use is the last major health file to be announced by the EU executive before the end of the current legislative term in the second half of 2024. Initially expected by the end of last year, the proposal was then delayed to mid-March, and then to the end of March. Although the EU's health chief, Stella Kyriakides, confirmed that the proposal would be set for March 29th, a commission spokesperson later mentioned the 'very busy agenda' of the College of Commissioners as the main reason behind the latest postponement.

There is currently no expected timing for the proposal's presentation, but another indicative date could be put forward on the next College agenda. EU co-legislators, the European Parliament and the EU-27 ministers, are unlikely to start discussing the proposal for new rules as there is an unofficial cut-off point for inter-institutional talks around February 2024. The reform aims to ensure a future-proof and crisis-resistant medicines regulatory system for Europe that can solve problems highlighted by the industry in recent years.

Source: https://www.pinsentmasons.com/out-law/news/eu-pharma-law-reform-faces-further-delay

# NEGOTIATIONS ON THE PANDEMIC AGREEMENT RESUME WITH FOCUS ON PROPOSALS CONCERNING „ONE HEALTH" AND „COMMON GOOD"

**Negotiations on a global pandemic agreement will resume next week, with calls for more attention to be paid to the One Health approach and less to organised misinformation campaigns. The meeting will focus on continuing text-based negotiations, with member states working to meet the deadline for submitting proposals.**

The Quadripartite Group, which includes WHO, FAO, UNEP and WOAH, has urged all countries and stakeholders to prioritize the One Health approach on the international policy agenda and accelerate its implementation. They have also called for the prevention of pandemics and health threats by targeting activities and places that increase the risk of zoonotic transmission between animals and humans. The European Union, on the other hand, has emphasized "common good" proposals and "legal provisions" in its initial proposals for a pandemic accord, according to a statement published alongside the proposals. The documents were initially posted on the Delegation of the European Union to the UN and other international organizations in Geneva website on Monday but were taken down on Tuesday.

Before the negotiations resume, WHO's Intergovernmental Negotiating Body (INB) has held several informal meetings to address a number of thorny issues, including global supply chains, technology transfer and pathogen sharing.

Source: https://healthpolicy-watch.news/pandemic-accord-talks-soldier-on/

# EU MEDICINES AGENCY REITERATES COVID VACCINE SAFETY AMID SIDE EFFECTS MONITORING

**The European Medicines Agency (EMA) chief, Emer Cooke, has reassured the public that COVID-19 vaccines are safe, and side effects are still being closely monitored. The EMA played a crucial role in ensuring all 27 EU countries could receive safe, high-quality vaccines through evaluating them to obtain EU marketing authorisation.**

In an exchange with European Parliament on Monday (March 27), many questions focused on the development, distribution, and side effects of vaccines. Cooke emphasized that COVID-19 vaccines underwent clinical trials with 15,000 to 20,000 subjects, a sample size five to ten times larger than most vaccine trials. She noted that the EMA published 50 monthly reports since the pandemic's onset with figures on vaccine side effects and deaths. Vaccine manufacturers also need to provide monthly safety reports to the EMA. Cooke promised to send all reports and studies requested by MEPs and emphasized that pharmacovigilance specialists continue to evaluate vaccine data to determine if problems exist and how to address them.

During a Wednesday exchange of views, the European Commission's Vice President, Margaritis Schinas, declared the purchase of COVID-19 vaccines a "small European miracle" and a success story. The discussion included a heated debate on vaccine side effects and how the EMA monitors them now that the majority of the European population is vaccinated. Some lawmakers accused the EMA of withholding information regarding vaccine side effects and deaths.

Source: https://www.euractiv.com/section/coronavirus/news/eu-drug-agency-covid-vaccine-side-effects-still-being-monitored/

# Thank you for your attention!

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