



#### WEEKLY EU HEALTHCARE NEWS UPDATE

17 DECEMBER – 23 DECEMBER 2022

### EMA'S BOARD ADOPTED THE MULTIANNUAL PROGRAMME FOR 2023-2025 AND PRELIMINARY PROGRAMMING DOCUMENT FOR 2024-2026

The Management Board adopted Agency's multiannual programming document for 2023-2025, including the EMA's work programme and budget for 2023. The full document will be published on the Agency's website in Q1 2023. Most importantly, it is already clear that the 2023 budget increased by 8.6% compared to 2022, to a total of 458 million euros. The Board also adopted a preliminary programming document for 2024-2026.

One of the pharmaceutical authority's priorities for the coming years includes activities related to the life cycle of medicines, along with public health measures and programmes and projects, and the continued implementation of lessons learned from the COVID-19 pandemic. Furthermore, the EMA's 2023 work programme also contains other key work streams, including enhancements to the Clinical Trials Information System (CTIS), implementation of monitoring activities for medical devices, and a pilot on scientific advice for medical device manufacturers.

By monitoring the development of the COVID-19 workload and based on the availability of resources, the Agency will look for opportunities to gradually resume previously suspended or limited activities. It includes restarting clinical data publication (CDP) for centrally authorised medicines outside the scope of COVID-19 activities. Finally, the 2023 work programme envisages the phasing out of business continuity measures after the Agency had to move its headquarters from London to Amsterdam as a result of Brexit.

Source: https://www.ema.europa.eu/en/news/ema-management-board-highlights-december-2022-meeting



## DEADLINE FOR COVID-19 DIAGNOSTICS & THERAPEUTICS WAIVER MOST LIKELY TO BE EXTENDED

A recent recommendation from the World Trade Organisation (WTO) Council on Trade-related aspects of Intellectual Property Rights (so-called TRIPS) urges all the member states to prolong the deadline for deciding whether to have a waiver for COVID-19 diagnostics as well as therapeutics.

Initially, the deadline for a decision was last Saturday (December 17) – this date was set in the WTO ministerial decision of June 17, in which WTO members only agreed on a TRIPS waiver only for vaccines. More than a week before, on December 6, the U.S. Trade Representative issued a statement in support of delaying the decision on an extension of the waiver to COVID-19 diagnostics and therapeutics. On the very same day, the delegations of Argentina, Bangladesh, Bolivia, Egypt, India, Indonesia, Pakistan, South Africa, and Venezuela issued their communication calling on the General Council to extend the waiver to COVID-19 diagnostics and therapeutics.

During the informal TRIPS meeting preceding the initial deadline on Thursday (December 15), the countries were not even able to decide on a report detailing how the discussions on a potential extension had taken place, according to rumours from trade officials. The next day, countries finally agreed to postpone the deadline, passing the matter to the WTO General Council, which later approved the recommendation.

Source: <a href="https://www.jdsupra.com/legalnews/wto-trips-council-recommends-that-5642776/">https://www.jdsupra.com/legalnews/wto-trips-council-recommends-that-5642776/</a>



#### **EUROPE AND THE WESTERN WORLD FEAR A NEW COVID WAVE IN CHINA**

Global health experts around the globe are closely watching a COVID-19 surge in China, worried that a country with 1.4 billion inhabitants is not vaccinated adequately. Moreover, it may not have sufficient healthcare tools to tackle a wave of illness which is expected to kill more than one million people through 2023.

Some European and American officials are making efforts to find out a way how, or if it would be feasible to help avoid a crisis they fear will severely hurt the global economy and public health, but also constrain global supply chains and spawn new coronavirus variants. As a result, Western governments find themselves in an awkward situation diplomatically, as they want to help stem a deteriorating crisis with global as well as domestic health and economic implications.

At the same time, the Chinese government has been willing to accept the expert's proposals. Parallelly, some European and US officials participated in delicate behind-the-scenes discussions with their Chinese counterparts, while presenting deliberately worded official statements intended to make clear that it is Beijing's turn to act. On the other hand, the rivalry between the US and China has intensified recently, with the American administration trying to influence China's semiconductor sector and push Beijing aside in Asia and Africa. Nevertheless, both countries are still deeply intertwined and interdependent, with China as the largest US trade partner.

Source: https://www.dw.com/en/chinas-soaring-covid-numbers-raise-global-fears/a-64164666



# Thank you for your attention!

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