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WEEKLY EU HEALTHCARE NEWS UPDATE

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CLINICAL TRIALS IN THE EU: THE WORKPLAN FOR 2022-2026

The European Commission (EC), the Heads of Medicines Agencies (HMA), and the European Medicines Agency (EMA) have published the 2022-2026 Workplan of the initiative Accelerating Clinical Trials in the EU (ACT EU).

ACT EU was set up in January 2022. It strives to transform the way clinical trials are initiated, designed, and coordinated to further develop the EU as a focal point for clinical research, promote the development of high-quality, safe, and at the same time effective medicines, as well as to better integrate clinical research in the European healthcare system.

The ACT EU Workplan is based on the Clinical Trials Regulation (CTR), applicable from January 2022, as well as on the activities of the European regulatory network to support clinical trials. The document is focused on key areas, such as innovation in clinical trials, robust methodologies, and collaboration among the stakeholders.

It is structured in line with the ten priority actions for ACT EU and has been prepared based on the recommendations of the European medicine agencies network strategy to 2025 and the European Commission's Pharmaceutical Strategy for Europe.

Source: https://www.ema.europa.eu/en/news/accelerating-clinical-trials-eu-publication-2022-2026-workplan

A GREENLIGHT FOR THE FIRST COVID-19 VARIANT-ADAPTED BOOSTER VACCINES

Two adapted mRNA COVID-19 vaccines targeting the original strain of COVID-19, as well as the BA.1 Omicron subvariant have got the nod of the European Medicines Agency (EMA).

These vaccines are Comirnaty from Pfizer/BioNTech and Spikevax from Moderna. They were approved during an extraordinary meeting of EMA's Committee for Medicinal Products for Human Use (CHMP) on 01 September.

Earlier EU Health Commissioner Stella Kyriakides informed in a statement that „they will proceed with an accelerated authorization of these vaccines to ensure that they can be rolled out quickly across the EU." She added that the above-mentioned vaccines are developed to offer broader protection against current and future variants.

In her statement Kyriakides also called for EU member states to make sure to include the adapted booster vaccines in their vaccination campaigns, emphasizing the importance of vaccination in the fight against coronavirus.

As informed, the Commission will shortly present actions related to COVID-19 vaccination strategies and come out with measures against its surge in the upcoming months. Furthermore, EMA and the European Centre for Disease Prevention and Control (ECDC) will also publish their considerations on the roll-out of the adapted vaccines.

Source: https://ec.europa.eu/commission/presscorner/detail/en/STATEMENT_22_5272

A GUIDELINE TO AVOID MEDICAL DEVICES SHORTAGE

The European Commission (EC) presented a guideline and agreed on a list of actions to facilitate the transition into the new framework for medical devices. The list was approved by the Medical Device Coordination Group (MDCG) chaired by the European Commission on 29 August and aims to tackle the issues raised at the Employment, Social Policy, Health and Consumer Affairs EU Council in June.

During the aforementioned meeting, the EU health minister Stella Kyriakides warned about the existing difficulties for medical devices manufacturers related to meeting the deadlines for implementing the two key regulations for medical devices (MDR) and in vitro diagnostics (IVDR), respectively, entered into application on May 2021 and May 2022. Delays in complying with the regulations could result in issues with getting certification for medical devices, threatening shortages on the market.

As explained, the barriers to implementing these new frameworks are mainly connected with the fact that many devices need to be registered, alongside the limited capacity of medical device authorities. In line with the data provided by Medtech Europe, the medical device certificates required under the new rules have not been issued yet for more than 85% of the over 500,000 devices registered under the previous regime. The association also estimates that 15-30% of small and medium-sized enterprises (SMEs) in the sector still have no access to a notified body under the new MDR rules. As for the IVDR, only seven designated notified bodies are available for manufacturers, who keep facing issues registering both current and innovative devices.

Source: https://www.euractiv.com/section/health-consumers/news/commission-presents-guideline-to-avoid-medical-devices-shortage/

Thank you for your attention!

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