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WEEKLY EU HEALTHCARE NEWS UPDATE

21 MAY – 27 MAY 2022

EMA ISSUED NEW FINAL GUIDELINES ON THE EVALUATION OF HUMAN MEDICINES FOR THE TREATMENT OF MICROBIAL INFECTIONS

European Medicines Agency has published its revised guidelines for evaluating medicines for human use in the treatment of microbial infections. The aim is to help develop new drugs and new treatments.

As the Agency's website explains, the implementation of the new rules is one of the measures to support global efforts to develop new antimicrobial treatments. The EMA highlights that antimicrobial resistance (AMR) directly influences human and animal health and represents a major economic burden worldwide. Only in the European Union alone, AMR is responsible for approximately 33,000 deaths per year. Anti Microbial Resistance, as indicated by the European Medicines Agency, also reduces the efficiency of healthcare in EU member states. What is more, the fight against AMR costs the EU as a whole approximately €1.5 billion per year.

The updated provisions were published alongside a document on the evaluation of medicinal products indicated for treating bacterial infections in children. According to the EMA, the effectiveness of some medicines among children can be predicted from efficacy results obtained from adults. An appendix to the guidance sets out where this rationale can be applied and where it cannot.

Source: https://www.ema.europa.eu/en/news/ema-guidance-supports-development-new-antibiotics

EU TIGHTENS RULES ON IN VITRO SCREENING

As of 26 May 2022, the new rules governing the commercialisation and marketing of in-vitro diagnostic medical devices (IVDR) will be applicable. These include, among others, pregnancy tests, but also COVID-19 and HIV tests.

In summary, the Regulation on in vitro diagnostic medical devices introduces three important changes:

- It improves the quality, safety and reliability of the devices with a new risk-based classification system, more detailed rules on the evaluation of device performance, and greater involvement of independent conformity assessment bodies (so-called 'notified bodies').
- Moreover, the new law strengthens transparency and access to information for patients so that crucial data is easier to find. The European database of medical devices (Eudamed) will contain information about all in vitro diagnostic medical devices on the market, including economic operators and certificates issued by notified bodies.
- Once devices are available on the market, manufacturers will have to gather data about their performance, and 27 EU countries will closely coordinate their vigilance and market surveillance activities, thus enhancing vigilance and market surveillance.

The Regulation on in vitro diagnostic medical devices replaces an earlier Directive on this matter and significantly reinforces the regulatory framework for medical tests. It is estimated that around 70% of clinical decisions are made using in vitro diagnostic medical devices.

Source: https://ec.europa.eu/commission/presscorner/detail/en/QANDA_22_3289

EUROPEAN PARLIAMENT TO CONSIDER PETITION SUBMITTED BY THE POLISH ASSOCIATION OF NATIONAL MEDICINES MANUFACTURERS

A petition tabled in May by the National Pharmaceutical Manufacturers (PL: *Krajowi Producenci Leków*) to the European Parliament, calling to bolster the production of active substances for medicines within the EU has been approved and will be debated at the Petitions Committee meeting in Autumn.

The authors of "Petition on the need to support the production of active substances for medicinal products within the EU" have stressed the need for national and EU institutional bodies to develop mechanisms supporting the production capacity of pharmaceutical substances, in line with the Parliaments resolution from November 2021 on the pharmaceutical strategy.

The other direction - according to *National Pharmaceutical Manufacturers* - could be the establishment of a system of subsidies for the production of active substances, similar to the EU subsidies for agricultural production. The scheme would reduce manufacturing costs and enable the price of the pharmaceutical substance to be lowered and to compete with Asian products.

Source (in Polish): https://cowzdrowiu.pl/aktualnosci/post/krajowi-producenci-lekow-skladaja-petycje-do-parlamentu-europejskiego

Thank you for your attention!

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