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WEEKLY EU HEALTHCARE NEWS UPDATE

11 APRIL – 15 APRIL 2022

EUROPEAN MEDICINES AGENCY AND THE EUnetHTA 21 CONSORTIUM PUBLISHED THE JOINT WORK PLAN UNTIL 2023

The European Medicines Agency is relaunching its collaboration with the European Network for Health Technology Assessment. The joint tasks of the plan are intended to prepare the European Union for entry into force of the regulation on health technology assessment (HTA) by January 2025.

EMA and HTA bodies, facilitated through the previous EUnetHTA cooperation, have jointly identified several focus areas of their European regulatory-HTA post-Joint Action collaboration. It is recognised that the implementation of the activities needs to be flexible, so that such collaborative work can provide a transition into a legislative framework on European HTA cooperation, once adopted.

Four bilateral meetings are planned until September 2023, and each meeting will have a different theme to allow in-depth discussions on the items listed on the work plan. Priority areas in the joint programme include joint scientific consultation for evidence generation, generation of patient-relevant data and information to support decision making, and methodologies to engage patients and healthcare professionals.

Source: https://www.ema.europa.eu/en/news/ema-eunethta-21-consortium-set-priorities-their-collaboration

EFPIA PRESENTS PROPOSALS TO ADDRESS HEALTH INEQUALITIES IN MEDICINE ACCESS

On Monday (11 April), the European Federation of Pharmaceutical Industries and Associations (EFPIA) announced its proposals to address the issue of unequal access to medicines in Europe. The new pledge aims to increase the availability of innovative medicines and decrease the time patients must wait for new medicines.

At the same time, the EU pharmaceutical industry represented in EFPIA commits to file pricing and reimbursement applications in all EU countries as soon as possible and no later than two years from the central EU market authorisation, provided that local systems allow it.

According to Nathalie Moll, director general at EFPIA, the newly adopted set of proposals is a big step forward towards „*making progress now rather than waiting for everybody else because clearly nobody has found the silver bullet*". The industry's commitment is accompanied by the introduction of the European Access Portal, where marketing authorisation holders can provide information about the timing and processing of these applications in all EU countries. As a result, it will enable tracking the reasons for delays in certain markets or indicate why marketing authorisation holders may not have filed in a particular market.

Source: https://efpia.eu/news-events/the-efpia-view/efpia-news/new-proposals-from-the-research-based-industry-can-reduce-inequalities-in-patient-access-to-medicines/

THE EU ENSURES A LONG-TERM SUPPLY OF MEDICINES FROM GREAT BRITAIN TO NORTHERN IRELAND, IRELAND, CYPRUS & MALTA

On Tuesday (12 April), the EU Council adopted a directive and a regulation to ensure a continued supply of medicines to Northern Ireland, and to Cyprus, Ireland and Malta. The measures will apply retroactively from 1 January 2022.

The aim of the EU institutions is to preserve the uninterrupted supply of medicinal products for human use in Northern Ireland after the withdrawal of the United Kingdom, under the protocol on Ireland/Northern Ireland.

The newly adopted directive will also, exceptionally and for a transitional period of three years, allow medicinal products from the UK to be placed on the market in Ireland, Malta and Cyprus under derogations from the requirement for authorisation holders to be established in the EU. The regulation is closely linked to the directive and focuses on ensuring the supply of investigational medicinal products to the same markets.

At the end of 2022, the EU Commission will also make proposals to revise the bloc's pharmaceutical legislation. The revision will seek to provide solutions to the problems with access to medicines, enhancing the security of supply and addressing the risks of shortages in the smaller markets of the Union.

Source: https://ec.europa.eu/commission/presscorner/detail/en/ip_22_2385

Thank you for your attention!

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