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WEEKLY EU HEALTHCARE NEWS UPDATE

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EU REVAMPS DRUG LEGISLATION TO BOOST ACCESS TO AFFORDABLE PHARMACEUTICALS AND INVESTMENT

The European Union is proposing a significant overhaul of the pharmaceutical industry's laws to revive investment and boost access to affordable drugs. The reforms aim to address problems caused by declining manufacturing in Europe, complicated supply chains, and a lack of preparedness for global public health emergencies.

The proposals include shortening the period of intellectual property protection and offering companies an option to gain back at least one year of exclusivity for a product if they launch it at the same time in all 27 member states. The EU also plans to increase transparency by obliging companies to disclose research and development (R&D) costs and public funding received for a new drug when filing for regulatory approval.

Other proposals include streamlining the European Medicines Agency (EMA) and cutting the time the regulator takes to review new medicines, potentially easing the path to market for companies with novel products. Companies may be required to notify the EMA earlier of shortages or withdrawals of their products and hold larger stocks of medicines deemed essential.

However, the proposals have faced criticism from big pharma and biotech firms, who argue that they could damage research and development and innovation. The proposals could also disrupt the generic drugs market, according to some member states. Lawyers representing industry do not expect legislation to be adopted before 2025, and EU elections next year could further delay the changes becoming law.

Source: https://www.reuters.com/business/healthcare-pharmaceuticals/after-covid-drug-shortages-eu-revamps-drug-laws-2023-04-03/

WHO: 1 IN 6 PEOPLE WORLDWIDE IS AFFECTED BY INFERTILITY

A new report published by the World Health Organization (WHO) reveals that around 17.5% of the adult population, or roughly 1 in 6 people worldwide, experience infertility in their lifetime.

The report shows limited variation in the prevalence of infertility between regions, indicating that this is a major health challenge globally. The prevalence was found to be 17.8% in high-income countries and 16.5% in low- and middle-income countries. Infertility is defined by the failure to achieve a pregnancy after 12 months or more of regular unprotected sexual intercourse, and it can cause significant distress, stigma, and financial hardship, affecting people's mental and psychosocial well-being. Despite the magnitude of the issue, solutions for the prevention, diagnosis, and treatment of infertility, including assisted reproductive technology such as in vitro fertilization (IVF), remain underfunded and inaccessible to many due to high costs, social stigma, and limited availability.

Furthermore, the report calls for greater availability of national data on infertility disaggregated by age and by cause to help quantify infertility, identify who needs fertility care, and how risks can be reduced. Additionally, new research funded by WHO and the United Nations' Special Programme of Research, Development and Research Training in Human Reproduction (HRP) and published in the journal Human Reproduction Open found that the direct medical costs paid by patients for a single round of IVF in low- and middle-income countries are often higher than the average annual income, indicating prohibitive costs for most people in these parts of the world. The WHO highlights the urgent need to widen access to fertility care, ensuring this issue is no longer sidelined in health research and policy, and safe, effective, and affordable ways to attain parenthood are available for those who seek it.

Source: https://www.who.int/news/item/04-04-2023-1-in-6-people-globally-affected-by-infertility

EMA RECOMMENDS 9 NEW DRUGS FOR APPROVAL IN THE EU

The Committee for Medicinal Products for Human Use (CHMP EMA) has recommended the approval of 9 new drugs for use in the European Union. The committee's recommendations include a COVID-19 booster vaccine, Bimervax, for individuals over 16 who have already been vaccinated with an mRNA COVID-19 vaccine. This marks the eighth COVID-19 vaccine approved for use in the EU.

Additionally, the committee has given a positive opinion on Briumvi for the treatment of relapsing multiple sclerosis, Omvoh for ulcerative colitis, and Pedmarqsi for the prevention of ototoxicity caused by cisplatin chemotherapy in children. The biosimilar drug Epysqli was also recommended for use in treating paroxysmal nocturnal hemoglobinuria, while Qaialdo was recommended for the treatment of edema resistant to diuretic treatment and sodium restriction.

Finally, the CHMP EMA has issued positive opinions for three generic drugs: Dabigatran Etexilate Accord for the prevention of venous thromboembolism, Lacosamide Adroiq for the treatment of epilepsy, and Sugammadex Adroiq for reversing neuromuscular blockade caused by rocuronium or vecuronium.

The committee has recommended expanding the therapeutic indications for six drugs: Breyanzi, Entresto, Neparvis, Tenkasi, Ultomiris, and Wegovy. Three applications for market authorization have been withdrawn: Feraheme, Onteeo, and Raltegravir Viatris.

Source: https://www.ema.europa.eu/en/news/meeting-highlights-committee-medicinal-products-human-use-chmp-27-30-march-2023

Thank you for your attention!

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