NEWS DIGEST

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- NICE joins international consortium aimed at improving clinical decision making for lung cancer patients
- EMA phases out extraordinary COVID-19 regulatory flexibilities
- Endometrial cancer patients gain early access to GSK's Jemperli
- The wait times for new medications in France are on the rise

Remap

NICE joins international consortium aimed at improving clinical decision making for lung cancer patients

The National Institute for Health and Care Excellence (NICE) has joined the Integration of heterogenous Data and Evidence towards Regulatory & HTA Acceptance (IDERHA) consortium, which aims to advance digital healthcare data for lung cancer patients and ultimately improve clinical decision making and enhance patient access to health innovation.

Lung cancer is the fourth most frequent cancer in Europe and accounts for 11.9% of all new cancer diagnoses and is the leading cause of cancer relating deaths. To counter this, Europe's Beating Cancer Plan has identified key action areas for the European Union to address: prevention, early detection, diagnosis, and treatment and quality of life. The IDERHA project, announced by the Innovative Health Initiative, aims to address and focus these key areas. IDERHA aims to develop a scalable platform to integrate health data along the patient journey with lung cancer to help healthcare professionals provide bespoke patient care. Moreover, IDERHA also has the objectives of developing policy recommendations for accessing and sharing compliant health data and setting standards for the acceptability of diverse health research findings for regulatory and health technology assessment (HTA) decision making.

The IDERHA team is led by Fraunhofer ITMP and Johnson & Johnson MedTech, and encompasses 29 partners and 4 associated partners throughout Europe, including academic, pharmaceutical, clinical, patient advocacy groups, and public authorities such as NICE. Work in the IDERHA project will be divided over 8 work packages and governed by a steering committee headed by representatives from partner organisations.

Expected outcomes include the extension and elaboration of standards in data quality and ethics, and harmonisation of data sources and health data reuse, the demonstration of the impact of enhanced data management on public health, and the improvement of health care innovation.

Source

EMA phases out extraordinary COVID-19 regulatory flexibilities

The European Medicines Agency (EMA), European Commission and the Heads of Medicines Agencies have announced they are phasing out the extraordinary regulatory flexibilities that were put in place during the COVID-19 pandemic.

The flexibilities had been introduced during the pandemic to address regulatory and supply challenges and had included regulatory, manufacturing and importing aspects. Going forward, flexibilities will no longer be granted. However, for those flexibilities already agreed (for example, English-only labelling for COVID-19 vaccines), application will be extended until the end of 2023 to avoid disruption to access. From 2024, all regular legislations around labelling should be followed.

The EMA has also explained that on-site GMP and GDP inspections have been restarted, however a considerable number of postponed inspections still need to be carried out. Because of this, the validity of existing GMP and GDP certificates has been extended until the end of 2023.

Experiences from the extraordinary COVID-19 regulatory flexibilities are being collated to inform best practice learnings for tackling medicine shortages during future health challenges.

Source

Remap

Endometrial cancer patients gain early access to GSK's Jemperli

GSK has announced that eligible endometrial cancer patients in the UK will gain early access to Jermperli (dostarlimab), an anti-PD-1 therapy, in combination with platinum-containing chemotherapy. The Medicines and Healthcare Regulatory Agency (MHRA) has granted a positive opinion under the Early Access to Medicines Scheme (EAMS).

The therapy has been indicated to treat adult patients with mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) primary advanced or recurrent endometrial cancer). Its access through EAMS has been granted based on positive data from part one of the phase 3 RUBY study researching dostarlimab plus carboplatin-paclitaxel versus placebo plus carboplatin-paclitaxel among patients with primary advanced or recurrent endometrial cancer.

Endometrial cancer is the most common gynaecological cancer in the UK and results in the diagnosis of 10,000 new cases annually, and although it often has better prognosis than other womb cancers if diagnosed early, those with advanced disease have limited options for treatment. EAMS, which aims to give patients with life threatening or seriously debilitating conditions early access to medicines when there is a clear unmet medical need, will allow for treatment for those with advanced endometrial cancer whilst allowing for data collection.

John Fleming, UK oncology medical lead at GSK, stated: "There is a significant unmet need in endometrial cancer and patients don't have time to wait. The recent data from the RUBY clinical trial has shown a clear benefit for this group of patients and we are very pleased to have been able to work collaboratively with the MHRA to provide quick access to dostarlimab for eligible patients in Great Britain with primary advanced or recurrent endometrial cancer."

Source

The wait times for new medications in France are on the rise

The first report from Leem's Observatory on Access to Medicines has raised concerns about France's declining appeal as a pharmaceutical market, as well as the accessibility and availability of new drugs in the country compared to European neighbours like Germany, Italy, and England. The study found that, by the end of 2022, 34% of medicines that gained European marketing authorisation from 2018 to 2021 were not yet available in France, mostly due to extended negotiation periods and unfavourable economic circumstances.

Despite improvement in the High Health Authority's evaluation times, market placement lead times remain well beyond the 180-day target set by the European Transparency Directive, causing French patients to gain access to new drugs months after their German, English, and Italian counterparts. Additionally, supply shortages of common medicines have increased over recent years due to competition and weakening economic balance, further hindering access to necessary treatments.

The survey results highlight that the French pharmaceutical industry is experiencing slow international growth despite considerable investments in production and R&D. Compared to its European counterparts, France lags behind in the production of new drugs, particularly biological originators, generics, and biosimilars. Complex and unpredictable regulation, along with increasing budgetary pressure, has resulted in a less appealing environment for pharmaceutical innovation and growth.

Leem's president, Thierry Hulot, emphasises an urgent need for intervention to realise President Macron's ambition of making France the leading innovative and sovereign European nation in health, stated in the 2030 Health Innovation Plan. The observatory's future reports will monitor these issues over time, allowing for ongoing analysis and response to changing needs.

Source

We always welcome your thoughts and opinions on the topics raised here.

If you'd like to share anything or hear how we can support you in getting your product to market, email Paul and Graham, managing directors, today at: contact@remapconsulting.com.

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