NEWS DIGEST

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Remap

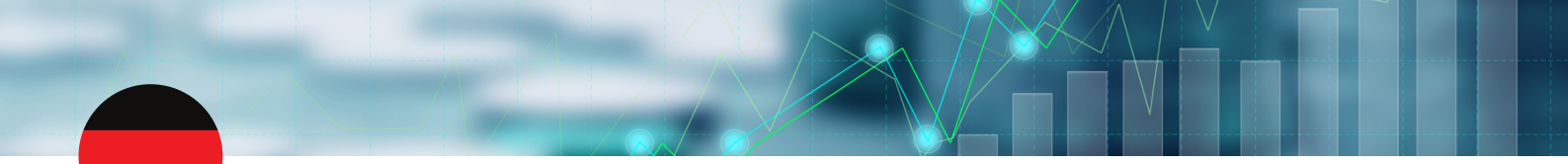
New regulatory pathway set to support safe patient access to innovative medical technology

The development of a new regulatory pathway facilitating the development of innovative technologies is currently underway. The Innovative Devices Access Pathway (IDAP) will be run by The Medicines and Healthcare products Regulatory Agency (MHRA) in conjunction with the National Institute for Health and Care Excellence (NICE), Health Technology Wales (HTW) and the Scottish Health Technology Group (SHTG).

The new regulatory pathway is intended to bring innovative technologies to the National Health Service (NHS) by providing innovators and manufacturers with a multi-partner support service including targeted scientific advice, with the aim of transforming health outcomes for patients with quicker access to these technologies.

The launch of IDAP is set for later in 2023, and once operational, IDAP partners will use the lessons and experience gained from the initial running of the pathway to further develop IDAP in the future, to create a framework that supports innovators in generating the required evidence to obtain regulatory and health technology assessment approval and resulting patient access.

Source



AbbVie joins Roche in launching a constitutional complaint about the GKV financial stabilisation act

On 31st May, AbbVie filed a constitutional complaint about the GKV Financial stabilisation act joining Roche who filed a complaint just last week. According to the company the complaint was filed to close the short-term financing gap in statutory health insurance. They say the new regulation, specifically a 10% discount to current treatment if they have the same scientific benefit, violates the fundamental right to equal treatment before the law.

The Financial Stabilisation Act was passed in Germany in November 2022 and has come under considerable criticism from the pharmaceutical industry due to the range of cost control measures which will be imposed upon them.

vfa President Han Steutel says: "I am not surprised by the legal headwind for the 2022 law. Comprehensible assessments are a constitutional requirement; it cannot be conveyed to anyone that a new drug has the same additional benefit as another drug, nonetheless should cost ten percent less. And that's not the only interference with the established rules of drug reimbursement that goes against the system."

Source

The MHRA's new international recognition framework in the UK is expanded to 7 regulatory agencies

The UK's new international recognition framework (IRF) will have new recognition routes for medicines established using marketing authorisation from agencies in Australia, Canada, the EU, Japan, Switzerland, Singapore, and the US. Expanding on the original announcement of the initiative which stated the US and Japan as partners in the IRF, the new international recognition routes will sit alongside the Medicines and Healthcare products Regulatory Agency's (MHRA) own unique innovation pathway that integrates early regulatory advice with health technology assessment advice.

These recognition routes have been facilitated by existing international partnerships, such as those developed through the Access Consortium and Project Orbis. The MHRA hopes that the IRF will enable patients in the UK to gain faster access to cutting-edge medicines approved in other countries, with cost reductions and streamlined regulatory processes.

As the UK's sovereign regulator, the MHRA will still retain responsibility for approving all "recognition route" applications through the new framework to ensure quality and safety for products entering the UK and will retain rigorous scrutiny and the power to reject applications if supporting evidence is insufficient.

The new IRF for medicines will be in place by the first quarter of 2024, and work is underway to establish similar routes for medical devices, with the MRHA launching a targeted consultation on medical devices to gather views on a wide range of topics.

Source

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Compassionate prescribing framework for Kaftrio and Kalydeco extended to cystic fibrosis patients without an F508del mutation, from the age of six regardless of the severity of the disease

The combination use of Kaftrio (ivacaftor/tezacaftor/elexacaftor), with Kalydeco (ivacaftor) is indicated within its marketing authorisation (MA), for the treatment of patients suffering from cystic fibrosis carrying at least one F508del mutation of the cystic fibrosis transmembrane conductance regulator (CFTR) gene.

The ANSM has established a compassionate prescription framework (CPC) which currently allows the drugs Kaftrio and Kalydeco in combination, to treat patients aged 12 and over, without the F508del mutation and who present with severe respiratory impairment (FEV1 < 40% of the predicted value) or a risk of progression to a lung transplant or a vital prognosis committed in the short term.

From the 1st June this CPC is being extended to patients with cystic fibrosis without an F508del mutation, from the age of 6 years regardless of the severity of the disease. This extension reflects the evolving research in this area.

CPC are developed by the ANSM for a period of three years and are renewable, they allow patient access to drugs for which there is an urgent therapeutic need which is not covered by the respective drug's MA. Further, a presumed favourable benefit/risk ratio, in particular based on published scientific data on efficacy and tolerance must be demonstrated.

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Spain's Access to Oncology Drugs Hindered by Delayed Availability and Reimbursement Restrictions

The availability of oncology drugs in Spain has been a cause for concern, as highlighted by Isabel Pineros, director of the Market Access department at Farmaindustria. According to recent data, only 57% of approved oncology drugs in the European Union (EU) are accessible to patients in Spain. This situation has raised significant challenges for both the public and private healthcare sectors, as the private market's access is contingent upon a drug's reimbursement status in the public healthcare sector. "Pharmaceutical companies refrain from introducing new innovations in Spain until they have a successful reimbursement resolution" explains.

The WAIT indicator survey has revealed a decline in the availability of oncology drugs in Spain over the past year, dropping from 61% to 57%. Additionally, the average time from marketing authorization to patient access has increased significantly, soaring from 469 to 611 days. These statistics paint a worrisome picture, indicating a worsening situation for cancer patients in need of timely access to life-saving treatments.

The combination of delayed availability and reimbursement restrictions based on patient subpopulations has the potential to exacerbate existing inequities in healthcare. Patients who fall into specific subpopulations or possess unique disease biomarkers might face additional obstacles in accessing appropriate medications.

Spain plays a substantial role in the research and development (R&D) of oncology drugs, with over 30% of clinical trials conducted in the country focusing on this therapeutic area. With recent uptake of personalised medicine approaches, which emphasise tailoring treatments to patients based on their underlying molecular diagnoses, it becomes crucial to ensure the availability of precise drugs for each specific disease and biomarker combination. Failing to provide patients with the appropriate medications according to their specific needs undermines the potential benefits of personalised medicine in oncology.

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