NEWS DIGEST

- Europe: EFPIA-EURORDIS release joint statement on patient access to medicines for rare diseases
- UK: NICE recommends first digital therapeutic Sleepio for treating insomnia
- France: €7.5 billion for Health Innovation Plan 2030
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Europe: EFPIA-EURORDIS release joint statement on patient access to medicines for rare diseases

The European Federation of Pharmaceutical Industries and Associations (EFPIA) and Rare Diseases Europe (EURORDIS) have published a joint statement on Patient Access to Medicines for Rare Diseases outlining recommendations to support accelerated and broader access to both currently approved and future innovative medicines. They came up with six proposals, split into three subgroups, aimed at addressing the key barriers to patient access for orphan medicinal products (OMPs) and rare diseases.

<u>Increasing the equity of access to rare disease medicines</u>

1: Equity Based Tiered Pricing (EBTP)

2: Industry Commitment to File and European Access Portal

<u>Improvement of HTA and P&R processes</u>

3: Supporting enhancement of EU-level and cross-country collaboration for OMPs

4: Adaptive pathways and Real-World Evidence (RWE) in value assessments

5: Adaptation of country-level HTA and P&R frameworks

<u>Support for access today and innovation in the future</u>

6: 'Moonshot' for basic and translational research for adult and paediatric rare diseases

Read in full https://bit.ly/3nleRWY

UK: NICE recommends first digital therapeutic Sleepio for treating insomnia

Sleepio has become the first digital therapeutic to ever receive a positive appraisal from the National Institute for Health and Care Excellence (NICE).

The Institute has recommended the Sleepio app-based treatment for patients suffering from insomnia as an effective alternative to sleeping pills. Clinical evidence has shown that Sleepio reduces insomnia symptoms compared with sleep hygiene and sleeping pills. According to NICE's guidance, Sleepio represents a cost saving at a price of £45 per person compared with usual treatment in primary care, based on an analysis of primary care resource use data before and after Sleepio was introduced in 9 GP practices.

The Sleepio app uses an artificial intelligence (AI) algorithm to provide people with tailored digital cognitive behavioural therapy for insomnia (CBT-I). NICE estimates that up to 800,000 patients in England could benefit from the app.

Sleepio was assessed through NICE's medical technologies assessment. This is the first digital therapeutic ever assessed by NICE and may set a precedent as a result of which many other digital therapeutics may follow.

France: €7.5 billion for Health Innovation Plan 2030

France's Health Innovation Plan 2030, announced by President Emmanuel Macron back in June 2021, will have a budget of €7.5 billion, according to the local press. The Plan is intended to establish France as a leader in healthcare in Europe.

The plan focuses in particular on encouraging innovation across biotherapies, digital health, emerging infectious diseases and medical technologies.

- €2.4 billion to accelerate development in biotherapies, digital health, emerging infectious diseases and medical technologies as well as in chemical, biological, radiological and nuclear risks. €800 million of this will be devoted to the development and production of biological medicines. Indeed, the plan is to develop by 2030 at least 20 biological drugs to treat cancers, emerging diseases and chronic diseases, including age-related diseases. A further €275 million is set aside for "future technologies" including monoclonal antibodies, and CAR-T therapies.
- €2.1 billion to support the emergence, growth and industrialisation of healthcare start-ups by Bpifrance (the French Public Investment Bank)
- €1.5 billion provided to support industrial investments by calls for national projects and an IPCEI (Important Project of Common European Interest) to improve support for the development of healthcare innovations
- €1 billion investment in research focussed to support clusters, translational research, attracting high-level scientists and R&D infrastructures
- €500 million to support the maturation of technologies and clinical trials.

A dedicated committee will oversee the strategic implementation of the plan. It will work closely with the new Health Innovation Agency which is due to be launched later in 2022.

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UK: ABPI responds to launch of IMF

In a recent press release, r. Paul Catchpole, the Association of the British Pharmaceutical Industry (ABPI)'s Director of Value and Access Policy, calls the recently launched Innovative Medicines Fund "good news for patients". However, he also goes on to share his concerns about how the proposed design of the Fund might make it difficult for companies to use it.

For example, pharmaceutical companies must currently pay the full costs of treatment in perpetuity for patients using the fund if the drug does not receive a positive recommendation by NICE after the managed access period. This, according to Dr Catchpole "is challenging because many of the medicines expected to go into the Fund, such as those for rare diseases, need to be used life long and sometimes from childhood". Dr Catchpole goes on to indicate that there are industry concerns about the mandate for manufacturers to pay back any expenditure exceeding the IMF's annual budget. "This requirement duplicates the national cap already in place on annual medicines bill expenditure through the Voluntary Scheme", he states.

Dr. Catchpole also added that the IMF is aimed mainly at providing earlier access to those medicines which lack the evidence base to pass NICE's assessment, but the fund does not offer any benefits to the drugs which do have a sufficient evidence base at the time of appraisal. The IMF should ideally support commercial approaches which would expedite access to new medicines. To be able to do that, NHS England could also leverage innovative payment models to mitigate the long-term uncertainty around products.

Continue reading https://bit.ly/3nn3Lkn

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