NEWS DIGEST

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- A proposed German health data sharing act could benefit industry, but they must be prepared to give back
- The Nordic Pharmaceutical Forum strengthens its collaboration on medicines
- EU aims to revamp European pharmaceutical laws
- Are companies looking to expedite reimbursement processes to prioritise speed to market over price optimisation?

Remap

A proposed German health data sharing act could benefit industry, but they must be prepared to give back

The traffic light coalition wants to create a central data access and coordination point in the federal government that will enable access to research as part of the Health Data Utilisation Act (GNDC). Approved data from the electronic patient file (ePA) are planned to be included there.

IQWiG boss Dr Thomas Kaiser, in a recent interview, spoke about the planned Health Data Utilisation Act (GNDC). He said" I personally have nothing against the data also being used or business interests as long as they lead to significant improvement in care" he added that he would " only grant data release to those who, in return also release their data for research". Therefore, under certain conditions, the pharmaceutical industry may have access to the large amounts of data collected following the act.

In a separate recent interview, Kaiser called for tougher sanctions when outcomes of clinical trials are not published. It is repeatedly reported that clinical trial results in Germany are not published or not published in a timely manner. Kaiser said that "patients consent to studies because they are supposed to improve care. And then you don't keep this promise, that can't be! Something like that is completely unacceptable and would need far more far-reaching consequences".

Source

Remap

The Nordic Pharmaceutical Forum strengthens its collaboration on medicines

The Nordic Pharmaceutical Forum (NPF) has just published a new joint Nordic strategy for pharmaceuticals through till 2025, bringing together the procurement bodies of Denmark, Finland, Iceland, Norway and Sweden. Set up in 2015 to address several common challenges across the Nordic countries affecting patient access to medicine, the NPF's new joint strategy focuses on three areas: Innovative procurement cooperation; Security of supply; and a strong Nordic voice.

By focusing on innovative procurement cooperation, the NPF hope to ensure that patients continue to have access to both new and older medicines, as national procurers of hospital medicines are experiencing increasing pressure on budgets due to rising prices for innovative pharmaceuticals. Therefore, the key areas that will be addressed by the current strategy are new and often promising medicines, common Nordic tendering procedures and Horizon Scanning. The NPF will draw on the past 7 years' worth of experience with joint price negotiations to produce new guidelines, with a particular focus on ATMP's. Tommy Juhl Nielsen, Director, Pharma Division at Sykehusinnkjøp HF in Norway was optimistic "We will learn from our experience and continue to work on developing common guidelines for common negotiations".

Security of supply is the second strategic area moving forward for the NPF and in this vein countries will primarily focus on the difficulties in supplying medicines. The NPF identified production of medicines by hospital pharmacies for individual patients as an important element in securing supplies. So, for this reason the member states have agreed to work towards consistent knowledge sharing on the development and production of these magistral pharmaceuticals.

Finally, a strong Nordic voice to increase visibility, was identified as a key aspect of achieving the NPFs ambition of being recognised as an organisation that effectively develops and delivers sustainable healthcare solutions for medicine supply to the public sector.

Source

EU aims to revamp European pharmaceutical laws

The European Union (EU) has been under increasing pressure to address problems faced across Europe with access to medicines. Recent shortages of essential drugs such as antibiotics and painkillers as well as the COVID-19 pandemic have highlighted issues faced in Europe and the EU plans to reform pharmaceutical laws in an attempt to revive investment and boost access to affordable treatments.

With country health budgets drained following the pandemic, the European Commission aims to publish a draft of the reforms on April 26th, which will address the following:

Shorter intellectual property protection:

- The period of time that a company has to develop and sell drugs under IP protection will be decreased from 10 years.
- Companies will be able to gain an extra year of exclusivity by launching in all 27 EU member states simultaneously.

Greater transparency:

- Companies will be obliged to be more transparent with costs of research and development and level of public funding received when submitting for regulatory approval

Expedited regulatory process:

- Aims to streamline the EMA regulatory approval process by reducing the number of scientific committees and cutting the time regulator takes to review medicines.
- “Regulatory sandbox” for testing of innovative technologies to achieve rapid approval.

Drug shortages:

- Shorter notification periods for companies to disclose shortages or withdrawals of products.

Antibiotic development:

- Incentives for investment in antibiotics to combat the problem of antibiotic resistant “superbugs”.

Once the draft has been published, details will have to be finalised by the European Parliament, Commission and member states. The final legislation is not likely to be adopted before 2025.

Source

Remap

Are companies looking to expedite reimbursement processes to prioritise speed to market over price optimisation?

BeiGene have undertaken a novel approach to pharmaceutical access with their BTK inhibitor Brukinsa for patients with chronic lymphocytic leukaemia. Focussing on the speed of access to patients rather than achieving a premium price versus comparator drugs, BeiGene have been able to truncate the time it takes to gain access.

Josh Neiman, the company's chief commercial officer for North America and Europe, has described it as: "we want to get access to our patients as quickly as we can".

To achieve this, the company have targeted a price parity approach, aiming to equal the cost of comparator products despite showing superiority in clinical trials. The hope is that by aiming for price parity, BeiGene will avoid long cumbersome pricing negotiations. This approach helps the company to get their medicines to patients faster and build healthy relationships within the market, with both patients and doctors alike.

According to recent evidence shared by the company, the strategy is working. In Denmark, Brukinsa achieved the fastest access compared to 22 other big-name drugs. In Belgium, the company took just 9 months (270 days) compared to the national average of 500 days to gain access, and in Italy they were third best in achieving access the fastest with a 10-month reimbursement process.

Amidst a background of pricing pressures, clawbacks and tax increases across Europe, will other pharmaceutical companies follow suit in forgoing premium prices in favour of achieving expedited access?

Source

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Paul Craddy

MANAGING DIRECTOR
& FOUNDER

Graham Foxon

MANAGING DIRECTOR
& FOUNDER

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