What is new?

Pharma & Market Access News Digest

4 ARTICLES YOU SHOULD KNOW ABOUT

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NEWS DIGEST

Germany Speeds Up Access to Advanced Therapies

On June 11th the German Parliament approved legislation that will accelerate access to transformative cell and gene therapies. The legislation addresses bureaucratic barriers by enabling NUB (new diagnostic and treatment method) inquiries to the InEK* to take place twice a year (instead of only once) for advanced therapy medicinal products: by 31st of October and by 30th of April. The NUB pathway provides for early reimbursement and supplements the diagnosis related group (DRG) system.

If the InEK does not reply within two months of the relevant deadline, NUB payment negotiations can by concluded without a decision from the institute.

The legislation also allows such inquiries to be made before the market authorisation of a therapy, in which case the NUB agreement comes into place on the date of the product's market authorisation.

Read more:
https://bit.ly/3xzuywI

*InEK: Institute for the Hospital Remuneration System

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NEWS DIGEST

China's Draft Patent Linkage System

Known for facilitating the growth of generics, China has drafted plans for new systems that will encourage the launch of innovative drugs in the country. The patent linkage system creates a link between approval for generic drugs and patent protection for the relevant innovative drug.

Under the new system, generic drug companies will be required to submit a statement on the patent issues alongside their marketing authorisation applications. The statement will be categorised upon submission, if it's a type IV statement* then:

1. The generic drug company will have 45 days to start a lawsuit or apply for administrative ruling
2. If the company holding the patent responds, a 9 month holding period will be triggered during which the NPMA will not authorise the drug unless the generic drug company wins. If the case is ruled in favour of the patent holder, the generic drug application will be deferred until the patent expires

Read more:
https://bit.ly/2TR076w

*Type IV statement: the relevant patent should be invalidated, or the generic drug would not fall within the scope of the patent.

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NEWS DIGEST

Australia Reclassifies Active Medical Devices for Therapy

From 25th November 2021 active medical devices for therapy with a diagnostic function will be required to meet regulatory requirements demonstrating the safety and performance for Class III medical devices (high-risk), a change to their current classification of Class IIa / Class IIb (low-medium/medium-high risk).

Requirements for the classification include:

- more detailed assessment of the manufacturer's quality management systems and assessment of technical documentation related to each device
- conformity assessment documents demonstrating procedures appropriate for a Class III device
- mandatory audit assessment by the TGA for device inclusion applications, including assessment of clinical evidence.

Continuous positive airway pressure devices (CPAP) will not be reclassified.

Read more:
https://bit.ly/2SGOyyT

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NEWS DIGEST

NICE Encourages Patients to Have Bigger Input in Choice of Care

UK HTA, The National Institute for Health and Care Excellence (NICE), has released new decision making guidance advising HCPs to discuss treatment options with their patients so that decisions are always made collaboratively.

The guidance suggests that resources should be provided before, during and after appointments to support and inform patient decisions. The guideline also advises a patient director be appointed, where possible, to ensure that the voice of the patient is heard.

It will be interesting to observe what impact on securing market access this has and whether more focus will be placed on the medicine's ability to solve patient concerns during assessments.

Read more:
https://bit.ly/3q88DtS

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