News Digest

Pharma & Market Access News Highlights

4 ARTICLES YOU SHOULD KNOW ABOUT

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What's inside:

Aduhelm's label is backtracked and investigations into its approval launch

A "New Era" UK MHRA shares delivery plan for 2021-2023

Biden signs executive order impacting prescription drug pricing

NICE to publish guidance for treatment of blood clots associated with COVID-19 vaccines

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NEWS DIGEST

Aduhelm’s label is backtracked and investigations into its approval launch

Aduhelm is the first drug to be approved by the FDA that claims to treat Alzheimer's disease rather than solely address its symptoms. However, since the announcement on June 7th the decision has been met with much scrutiny.

Recently, the approval has been backtracked. The drug is no longer labelled for use in all Alzheimer’s patients. The updated label states that Aduhelm should only be used to treat patients with mild cognitive impairment due to Alzheimer’s disease or mild Alzheimer’s dementia - the patient population that was studied across the three clinical trials that supported the approval.

Additionally, following reports of off the books meetings between the drugmaker's staff and FDA, investigations into the drug’s approval have been launched by the FDA’s acting commissioner and the Committee on Oversight and Reform.

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

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NEWS DIGEST

A "New Era" UK MHRA shares delivery plan for 2021-2023

The UK's Medicines and Healthcare products Regulatory Agency (MHRA) has released a 2 year delivery plan for what it refers to as the "new era", following departure from the European regulatory system.

The delivery plan consists of 14 objectives which fall into 6 core areas: patient safety, healthcare access, scientific innovation, collaborative partnerships, dynamic organisation and financial stability.

The plan is underpinned by the introduction of a new business model, said to provide a financially sustainable future. The model is key to "preparing for the end of (MHRA's) operation as a Trading Fund and inclusion within the Department of Health and Social Care's accounting boundary."

Read more:
https://bit.ly/2VQwCD1

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NEWS DIGEST

Biden signs executive order impacting prescription drug pricing

On July 9th, Joe Biden signed an executive order with the aim of promoting competition in America. Initiatives contained within the order include:

- Production of a comprehensive plan to combat high prescription drug prices by the Department of Health and Human Services. The plan is to be produced within the next 45 days.
- Formulation of plans to safely import medicines from Canada (where they're sold at lower prices).
- Increasing the supply of generics and biosimilars by urging the Federal Trade Commission to ban drugmakers from paying their generic counterparts to delay entry/
- Encouraging over the counter sale of hearing aids in pharmacies which the president anticipates will lower their cost.

Read more:
https://wapo.st/36BH2sm

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NEWS DIGEST

NICE to publish guidance for treatment of blood clots associated with COVID-19 vaccines

Cases of blood clots are thought to be associated with COVID-19 vaccines. Such cases of vaccine-induced immune thrombocytopenia and thrombosis (VITT) and low blood platelet counts are rare, occurring in around 14.2 individuals for every 1 million vaccinated.

NHS England has requested that NICE produce guidelines to aid clinicians in treating patients with these rare occurrences effectively as although rare, these side effects are considered very serious.

Currently, there is no official guidance regarding the diagnosis and treatment of VITT. NICE is collaborating with a panel of experts to develop such guidance. No date for when the guidance will be ready has been revealed yet.

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

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