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Withdrawal of application for the marketing authorisation of Dexamethasone Taw (dexamethasone phosphate)

Taw Pharma (Ireland) Ltd withdrew its application for a marketing authorisation of Dexamethasone Taw for the treatment of several inflammatory and other conditions.

The company withdrew the application on 20 January 2021 because it was unable to remove preservatives from the medicine within the timeframe required by EMA.

What is Dexamethasone Taw and what was it intended to be used for?

Dexamethasone Taw was developed as a medicine for treating several inflammatory conditions or conditions where the immune system is overactive.

Dexamethasone Taw contains the active substance dexamethasone phosphate and was to be available as a solution for injection or for infusion (drip) into a vein.

Dexamethasone Taw is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance. The reference medicine is called Fortecortin.

How does Dexamethasone Taw work?

The active substance in Dexamethasone Taw, dexamethasone phosphate, reduces inflammation and can suppress the body's immune response. It does this by activating certain genes, which reduce the activity of immune cells and substances that promote inflammation.

What did the company present to support its application?

The company presented data on the quality of Dexamathasone Taw. It also provided data on the benefits and risk of dexamethasone from the published literature.

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How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after EMA had evaluated the initial information from the company and had prepared questions for the company. The Agency was assessing the company's responses to the questions at the time of the withdrawal.

What did the Agency recommend at that time?

Based on the review of the data, at the time of the withdrawal, the Agency had some concerns and its provisional opinion was that Dexamethasone Taw could not have been authorised.

EMA had concerns about the preservatives (known as parabens) in the medicine, which are not present in the reference medicine and could cause allergic reactions. EMA therefore requested that the company remove these preservatives. The Agency also requested the company to provide a valid certificate of good manufacturing practice (GMP) for its manufacturing site.

At the time of the withdrawal, the Agency's opinion was that the company had not fully addressed its quality concerns.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of the application, the company stated that it was unable to remove preservatives from the medicine within the required timeframe.

Does this withdrawal affect patients treated with dexamethasone medicines?

This withdrawal has no effect on patients receiving other dexamethasone medicines, including patients being treated for COVID-19.