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Withdrawal of the marketing authorisation application for Fyzoclad (adalimumab)

On 5 December 2018, Pfizer Europe MA EEIG officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Fyzoclad, for the treatment of a number of inflammatory diseases.

What is Fyzoclad?

Fyzoclad is a medicine that contains the active substance adalimumab. It was to be available as a solution for injection.

Fyzoclad was developed as a 'biosimilar' medicine. This means that Fyzoclad was intended to be highly similar to another biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Fyzoclad is Humira. For more information on biosimilar medicines, see here.

What was Fyzoclad expected to be used for?

Fyzoclad acts on the immune system and was to be used to treat the following inflammatory conditions:

- rheumatoid arthritis (a disease causing inflammation of the joints);
- juvenile idiopathic arthritis (disease causing inflammation in the joints);
- axial spondyloarthritis (inflammation of the spine causing back pain);
- psoriatic arthritis (a disease causing red, scaly patches on the skin with inflammation of the joints);
- psoriasis and paediatric plaque psoriasis (both are diseases causing red, scaly patches on the skin).
- uveitis (inflammation of the layer beneath the white of the eyeball) and paediatric uveitis.

How does Fyzoclad work?

Fyzoclad was expected to work in the same way as the reference medicine, Humira. The active substance in Fyzoclad and Humira, adalimumab, is a monoclonal antibody (a type of protein) that has

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been designed to recognise and attach to a substance in the body called tumour necrosis factor (TNF). This substance is involved in causing inflammation associated with the diseases that adalimumab is intended to treat and is found at high levels in patients with these diseases. By attaching to TNF, adalimumab blocks its activity, thereby reducing inflammation and other symptoms of the diseases.

What did the company present to support its application?

The company presented laboratory studies comparing Fyzoclad to its reference medicine Humira in terms of structure, purity and biological activity. In addition, a study in patients with rheumatoid arthritis compared Fyzoclad with Humira.

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

The application was withdrawn while the CHMP was still evaluating the initial documentation provided by the company.

What was the recommendation of the CHMP at that time?

As the CHMP was evaluating the initial documentation provided by the company, it had not yet made any recommendations.

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 the withdrawal was due to a change in the company's strategy.

The withdrawal letter is available here.

What consequences does this withdrawal have for patients in clinical trials?

The company informed the CHMP that there are no ongoing clinical trials with Fyzoclad.