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# Withdrawal of application for the marketing authorisation of ABP 710 (infliximab)

Amgen Europe B.V. withdrew its application for a marketing authorisation of ABP 710 for the treatment of inflammatory diseases.

The company withdrew the application on 27 May 2019.

## What is ABP 710 and what was it intended to be used for?

ABP 710 is an anti-inflammatory medicine that was intended to be used to treat the following inflammatory diseases:

- rheumatoid arthritis (an immune system disease causing inflammation of the joints);
- Crohn's disease (a disease causing inflammation of the digestive tract);
- ulcerative colitis (a disease causing inflammation and ulcers in the lining of the gut);
- ankylosing spondylitis (a disease causing inflammation and pain in the joints of the spine);
- psoriatic arthritis (a disease causing red, scaly patches on the skin and inflammation of the joints);
- psoriasis (a disease causing red, scaly patches on the skin).

ABP 710 contains the active substance infliximab and was intended to be given by infusion (drip) into a vein.

ABP 710 was developed as a 'biosimilar' medicine. This means that ABP 710 was intended to be highly similar to another biological medicine already authorised in the EU (the 'reference medicine'). The reference medicine for ABP 710 is Remicade. For more information on biosimilar medicines, see here.

## How does ABP 710 work?

The active substance in ABP 710, infliximab, is a monoclonal antibody, a type of protein that has been designed to recognise and attach to a specific structure (called an antigen) in the body. Infliximab has been designed to attach to a chemical messenger in the body called tumour necrosis factor-alpha

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(TNF-alpha). This messenger is involved in causing inflammation and is found at high levels in patients with inflammatory diseases. By blocking TNF-alpha, infliximab improves the inflammation and other symptoms of the diseases.

## What did the company present to support its application?

The company presented results from laboratory studies to show that the active substance in ABP 710 is highly similar to that in Remicade in terms of structure, purity and biological activity.

In addition, the company presented results of a study to show that ABP 710 produces similar levels of the active substance in the body to giving an infusion of Remicade. Finally, the company provided results from a study of 558 patients with moderate to severe rheumatoid arthritis intended to confirm that ABP 710 was as safe and effective as Remicade in patients with this condition.

Because ABP 710 was developed as a biosimilar medicine, studies on effectiveness and safety of Remicade for all its uses did not need to be repeated for ABP 710.

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

The application was withdrawn while the European Medicines Agency was still evaluating the initial information provided by the company.

## What did the Agency recommend at that time?

As the Agency was still evaluating the initial information from 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 linked to a change in its strategy for ABP 710.

## Does this withdrawal affect patients in clinical trials?

The company informed the Agency that there are no ongoing clinical trials with ABP 710.