



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

17 February 2011  
EMA/126688/2011  
EMA/H/C/000992

## Questions and answers on the supply shortage of Simponi pre-filled pens

The European Medicines Agency has become aware of supply problems with Simponi pre-filled pens, which will lead to a temporary shortage of this pharmaceutical form of the medicine in some European Union (EU) Member States. To deal with the shortage, the Agency's Committee for Medicinal Products for Use (CHMP) is recommending that affected patients should be switched to the other pharmaceutical form of Simponi, the pre-filled syringe. In those countries where the pre-filled syringe is not available, there are other treatments that patients can be switched to.

### What is Simponi?

Simponi is an anti-inflammatory medicine that is used to treat adults with active rheumatoid arthritis (a disease causing inflammation of the joints), active and progressive psoriatic arthritis (a disease causing red, scaly patches on the skin and inflammation of the joints) and severe active ankylosing spondylitis (a disease causing inflammation and pain in the joints of the spine).

Simponi is registered as pre-filled pens and pre-filled syringes. Only the pre-filled pens are affected by the current supply problems.

Simponi has been authorised in the EU since 1 October 2009 and is marketed in 19 Member States<sup>1</sup>, as well as Iceland and Norway.

The current European public assessment report for Simponi can be found on the Agency's website: [ema.europa.eu/Find\\_medicine/Human\\_medicines/European\\_Public\\_Assessment\\_Reports](http://ema.europa.eu/Find_medicine/Human_medicines/European_Public_Assessment_Reports).

### What is the supply problem with Simponi and how long will it last?

In February 2011, the company that makes Simponi, Janssen Biologics B. V. (previously known as Centocor B.V.), identified a manufacturing defect affecting some batches of pre-filled pens. This defect could prevent patients from injecting the full dose of Simponi. As a result, the defective batches were not released onto EU markets. A part of a batch that had been released in Germany before the defect

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<sup>1</sup> Simponi is marketed in Austria, Belgium, Czech Republic, Denmark, Estonia, Finland, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxemburg, the Netherlands, Norway, Portugal, Slovakia, Slovenia, Spain and Sweden. Simponi is also available in the United Kingdom under a physician access program.



was identified is currently being recalled. All other pens currently on the EU market are not affected and should continue to be used.

The company will start to make new pre-filled pens available by the end of February 2011, but it is expected that not all European countries where they are available will have regular supplies of the pre-filled pens until May 2011.

### **What are the recommendations of the CHMP while the shortage is ongoing?**

In order to minimise the risk of interruption of treatment with Simponi, the CHMP has recommended that no new patients should start treatment with pre-filled pens until the supply problems are resolved. In addition, patients currently taking the medicine who need a new prescription can be switched to Simponi pre-filled syringes if needed. In those countries where the syringes are not available, patients should be switched to an alternative treatment, according to availability and the advice of their doctor. Other treatments are currently authorised in the EU for the conditions that Simponi is used for.

The Committee has also agreed that the company should provide a letter to the healthcare professionals in those countries affected by the shortage, explaining the supply situation in their country and the temporary treatment recommendations.

### **What are the recommendations for patients and prescribers?**

- Patients currently using Simponi pre-filled pens may need to be switched to Simponi syringes or an alternative medicine over the next few months.
- Healthcare professionals will receive information on the supply situation of Simponi in their country as appropriate, which will enable them to switch patients to either the pre-filled syringe or other available treatments.
- Patients who will need to switch to an alternative treatment, including Simponi syringes, will need training on the injection technique by a doctor or nurse.
- Patients who have any questions should speak to their doctor or pharmacist.