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# Questions and answers on Okrido (prednisolone sodium phosphate, oral solution, 6 mg/ml)

Outcome of a procedure under Article 29 of Directive 2001/83/EC as amended

On 27 June 2013, the European Medicines Agency completed an arbitration procedure following a disagreement among Member States of the European Union (EU) regarding the authorisation of the medicine Okrido. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that the benefits of Okrido outweighs its risks, and the marketing authorisation granted in the United Kingdom can be recognised in other Member States of the EU.

## What is Okrido?

Okrido is a medicine that contains the active substance prednisolone sodium phosphate. It is available as an oral solution (6mg/ml).

The active substance in Okrido, prednisolone sodium phosphate, belongs to a group of medicines called glucocorticoids, which are substances that help to reduce inflammation.

Okrido is used to treat a range of inflammatory and auto-immune conditions (diseases caused by the body's own defence system attacking normal tissue) including:

- allergies, including severe allergic reactions;
- diseases of the lungs (including asthma), upper airways (croup), blood vessels and heart, bowel or kidneys, muscles and joints (including rheumatoid arthritis) or the eye or nervous system;
- skin conditions;
- some cancers, including leukaemia, lymphoma and myeloma;
- organ transplantation.

Okrido is a generic medicine based on a 'reference medicine' already authorised in the EU. The reference medicine was Prednisolone 5 mg soluble tablets by Sovereign.

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## Why was Okrido reviewed?

Pharmapol Arzneimittelvertrieb GmbH submitted Okrido for mutual recognition on the basis of the initial authorisation granted by the United Kingdom's Medicines and Healthcare products Regulatory Agency on 19 April 2010. The company wanted the authorisation to be recognised in Germany and the Netherlands (the 'concerned Member States'). However, the Member States were not able to reach an agreement and the United Kingdom referred the matter to the CHMP for arbitration on 5 March 2013.

The grounds for the referral were that sufficient data had not been provided to show that Okrido produces comparable levels of the active substance in the body to Prednisolone 5 mg soluble tablets by Sovereign. In particular, as the two medicines contain different excipients (inactive ingredients), the Netherlands considered that further studies were needed to show that these differences did not result in relevant differences in the way the two medicines are absorbed by the body.

## What are the conclusions of the CHMP?

Based on an evaluation of the currently available data and the scientific discussion within the Committee, the CHMP concluded that, based on the data submitted, Okrido is expected to produce comparable levels of the active substance in the body to the reference medicine. The CHMP therefore concluded that the benefits of Okrido outweigh its risks, and therefore the marketing authorisation for Okrido should be granted in all concerned Member States.

The European Commission issued a decision on 5 September 2013.