



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 May 2010
EMA/CHMP/163664/2010
Press Office

Press release

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP)

17-20 May 2010

Positive opinion for a new medicine adopted

The Committee adopted a positive opinion, recommending the granting of a marketing authorisation for **Ozurdex** (dexamethasone), from Allergan Pharmaceuticals Ireland, intended for the treatment of macular oedema. The review for Ozurdex began on 25 March 2009 with an active review time of 210 days.

The summary of opinion for this medicine, including the full indication, can be found [here](#).

Positive opinion for a generic medicine adopted

The Committee adopted a positive opinion recommending the granting of a marketing authorisation for the generic medicine **Leflunomide medac** (leflunomide), from medac GmbH, for the treatment of active rheumatoid arthritis. Leflunomide medac is a generic of Arava.

The summary of opinion for this medicine, including the full indication, can be found [here](#).



Positive opinions for extensions of indications adopted

The Committee gave positive opinions for applications for extensions of the therapeutic indications, adding new treatment options for medicines that are already authorised in the European Union, for:

- **Orencia** (abatacept), from Bristol-Myers Squibb Pharma EEIG, to include treatment of moderate to severe active rheumatoid arthritis in patients who responded inadequately to previous therapy with one or more disease-modifying anti-rheumatic drugs including methotrexate or a TNF alfa inhibitor.
- **Taxotere** and **Docetaxel Winthrop** (docetaxel), from Aventis Pharma S.A., to include adjuvant treatment, in combination with doxorubicin and cyclophosphamide, of patients with operable node-negative breast cancer eligible to receive chemotherapy according to internationally established criteria for primary therapy of early breast cancer.

Summaries of opinion for all mentioned medicines, including their full indication, can be found [here](#).

Restriction of indication for Zeffix adopted

The Committee recommended changes to the product information of **Zeffix** (lamivudine), from Glaxo Group Ltd, to restrict its therapeutic indication in chronic hepatitis B, due to the high risk of resistance to lamivudine, stating that treatment with lamivudine should only be initiated in patients with compensated liver disease when the use of an alternative antiviral agent with a higher genetic barrier to resistance is not available or appropriate. In addition, in patients with decompensated liver disease, lamivudine should always be used in combination with a second antiviral agent without cross-resistance to lamivudine.

The summary of opinion for this medicine, including the full indication, can be found [here](#).

Update on Genzyme's manufacturing quality assurance system

The CHMP heard a presentation given by Genzyme on its manufacturing and quality assurance systems, following a series of manufacturing and quality problems with several of its medicines, including Cerezyme, Fabrazyme and Myozyme. Whilst the Committee acknowledged that these products remain safe for patients and that Genzyme has taken actions to rectify these problems, the CHMP remains concerned about this issue and has requested that Genzyme implement a robust programme of measures to prevent similar manufacturing and quality problems in the future.

In this regard, the CHMP has now requested that Genzyme carry out a risk assessment of its manufacturing processes and use this to prepare a detailed plan for improvement. The plan should aim at proactive identification of potential risks and continuous assurance of quality and supply of Genzyme's medicines. Genzyme has also been requested to provide regular progress reports on the implementation of this plan to the CHMP. The Committee will continue to monitor the situation closely. Further inspections of the manufacturing sites in the USA have been scheduled and will start as of June 2010, as requested by the Committee earlier this year.

Over the past two years, Genzyme has reported several product quality defects, which have led to the ongoing supply shortages for Cerezyme and Fabrazyme, which are used by patients suffering from rare, inherited enzyme-deficiency disorders, and for which no or only limited alternative treatments exist. As a result, the CHMP issued temporary treatment recommendations to ensure that these medicines continue to be available to European patients at greatest need of treatment.

For more information on the temporary treatment recommendations for Cerezyme and Fabrazyme see the Agency's [April press release](#).

No need to restrict use of rotavirus vaccines

The Committee confirmed that there is no evidence that the unexpected presence of porcine circovirus (PCV) in batches of the oral rotavirus live vaccines, **Rotarix** and **Rotateq**, presents a risk to public health. PCV is not known to cause disease in humans.

In the framework of an ongoing formal review of Rotarix, from GlaxoSmithKline Biologicals S.A., initiated in March 2010, the CHMP discussed available data, including new laboratory results, that further clarify and characterise the nature of the presence of PCV in this rotavirus vaccine. Investigations are still ongoing, but the CHMP confirmed its previous position that there is no need to restrict the use of Rotarix. For more information see also the Agency's [March 2010 press release](#).

The Committee is now also reviewing Rotateq, based on information received from the manufacturer (Sanofi Pasteur MSD SNC) that batches of this centrally authorised rotavirus vaccine contained low amounts of PCV DNA fragments. As with Rotarix, there is no need to restrict the use of this vaccine.

The CHMP is awaiting further information from the manufacturers on the root cause of the findings and on measures to manufacture the vaccines free of porcine circoviruses. The CHMP will be reviewing all new data on an ongoing basis. The Committee will consider the need for further recommendations in its meeting in July 2010, as further data emerge.

Notes

1. The review of Rotateq is being conducted in the context of a formal review, initiated by the European Commission under Article 20 of Regulation (EC) No 726/2004/EC. The Committee will make recommendations on whether the marketing authorisation for Rotateq should be maintained, changed, suspended or revoked.
2. A more detailed CHMP meeting report will be published shortly.

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