EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 April 2010
EMA/CHMP/110267/2010
Press Office

Press release

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

19-22 April 2010

Update on pandemic medicines

The Committee reviewed further results from clinical studies and post-marketing experience for the centrally authorised pandemic influenza vaccines **Celvapan, Focetria** and **Pandemrix**. Marketing authorisations for these vaccines had been given under specific conditions. The Committee concluded that the additional data from clinical and non-clinical studies, from post-marketing surveillance and from the use of these vaccines in at least 40 million people in the European Economic Area since September 2009 was sufficient to allow these vaccines to be given full marketing authorisations for their use outside a declared influenza pandemic. Under the terms of their current authorisations ('exceptional circumstances') they can only be used in the context of a WHO-declared pandemic. The Committee will continue to keep the vaccines under close surveillance. The product information of the three vaccines has been updated accordingly.

For Focetria, the CHMP recommended further changes to the product information to include data on the immunogenicity and safety in children aged 6 to 35 months and in children aged 3 to 7 years. The available data indicate that a single full dose of Focetria vaccine triggered a good immune response in children aged 6 to 35 months, but that the second dose further increased the immune response. Furthermore, immunogenicity data in children aged 3 to 7 years old suggests that a single dose may be sufficient.

The Agency will continue to evaluate all information that becomes available and make further recommendations as necessary. The most recent pandemic influenza pharmacovigilance update report was published on 21 April 2010 and can be found here.

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Positive opinion for a new medicine adopted

The Committee adopted a positive opinion, recommending the granting of a marketing authorisation for **Daxas** (roflumilast), from Nycomed GmbH, intended for maintenance treatment of severe chronic obstructive pulmonary disease associated with chronic bronchitis in adult patients as an add-on to bronchodilator treatment. The review for Daxas began on 27 May 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 opinions for extensions of indication adopted

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

- **Reyataz** (atazanavir), from Bristol Myers Squibb Pharma EEIG, to extend the therapeutic indication to include the treatment of HIV-1 infected paediatric patients above 6 years of age.
- **RoActemra** (tocilizumab), from Roche Registration Ltd, to extend the therapeutic indication to include a statement that RoActemra has been shown to reduce the rate of progression of joint damage and to improve physical function, when given in combination with methotrexate.

The summary of opinion for these medicines, including their full indications, can be found here.

Review of bufexamac concluded

Finalising a review of medicinal products for topical use containing **bufexamac**, a non-steroidal anti-inflammatory drug (NSAID), and the risk of contact allergic reactions, the Committee concluded that the benefits of these medicines do not outweigh their risks for patients in any of their indications and therefore recommended that the marketing authorisations be revoked.

More information about this review is available in a separate press release and a question-and-answer document.

Arbitration on Seroquel XR concluded

The Committee completed an arbitration procedure initiated at the request of the marketing authorisation holder following the refusal of an extension of the therapeutic indications of **Seroquel XR** prolonged release tablets (quetiapine), from AstraZeneca AB, in a mutual recognition procedure.

The CHMP concluded that the benefit-risk profile of this medicine was positive as an add-on medication for major depressive episodes in major depressive disorder patients who have had sub-optimal response to treatment with other antidepressants, and recommended that an extension of the therapeutic indication should be granted.

More information about this review is available in a separate question-and-answer document.

Review of live attenuated vaccines started

The Committee has begun looking at the overall impact of the detection of genomic fragments of viral origin in batches of live attenuated vaccines. This follows the publication of an article in which a highly sensitive new polymerase chain reaction technique was used to detect these genomic fragments.

The review was started at the request of the Executive Director of the European Medicines Agency under Article 5(3) of Council Regulation (EC) No 726/2004. The CHMP will give an opinion on whether there is any potential public health concern arising from the findings and whether new test methods should be considered for the development and routine testing of live attenuated vaccines. The Committee will also review the need to update existing guidance on this matter and the need for appropriate guidance for other vaccines and other biological products. This review will be conducted in close co-operation with the EDQM (European Directorate for the Quality of Medicines & Healthcare) and international partners.

No safety concern with Myozyme

The Committee was informed by Genzyme Europe B.V. of a production problem at one of its manufacturing sites, the Flanders facility in Geel, Belgium, of **Myozyme** (alglucosidase alfa). During routine maintenance Genzyme discovered a faulty pump seal that could have potentially contaminated Myozyme batches with hydraulic oil. After reviewing all available data, including results of the analysis of samples of the concerned batches using enhanced analytical methods that did not reveal any contamination, the Committee concluded that there was no concern about the safety of Myozyme. The production problem has now been corrected and production is resuming. While currently no shortage of Myozyme is expected, the CHMP will be monitoring the availability of Myozyme on the market. Myozyme is used to treat patients with Pompe disease, a rare, inherited enzyme-deficiency disorder.

New temporary treatment recommendations for Fabrazyme

The Committee was informed that the supply shortages for Genzyme's medicinal products, **Cerezyme** and **Fabrazyme**, are continuing for longer than expected and that Genzyme has not yet resumed full production. The supply shortages are likely to continue at least until the end of September 2010.

For Fabrazyme, the CHMP decided to revise the recommendations made on 25 September 2009, since, based on information supplied by the manufacturer, at least 12% of patients on the reduced Fabrazyme dose regimen have already experienced a worsening of their disease. For Cerezyme the interim recommendations made by the Committee on 22 October 2009 remain valid.

More information about the continued shortage of these products and the new treatment recommendations for Fabrazyme is available in a separate press release.

Harmonisation referrals concluded

The Committee recommended harmonisation of the prescribing information for three medicinal products. The reviews were initiated because of differences in the summaries of product characteristics, labelling and package leaflets in the countries where the products are marketed. The products reviewed are:

- **Famvir** and associated names (famciclovir), from Novartis and associated companies. The medicine is authorised to treat herpes zoster and acute genital herpes simplex and to suppress recurrent genital herpes.
- **Valtrex** and associated names (valaciclovir) from GlaxoSmithKline and associated companies. The medicine is authorised to treat herpes zoster, herpes simplex and genital herpes and to prevent cytomegalovirus infections and disease.
- **Vascace** (cilazapril), from Roche and associated companies. The medicine is authorised to treat hypertension and heart failure.

Question-and-answer documents with more information about these referrals can be found here.

A more detailed CHMP meeting report will be published shortly.

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