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Press Office

Press release

European Medicines Agency updates treatment recommendations because of continued Fabrazyme shortage

Doctors advised to consider switching patients to alternative treatment

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has been obliged to revise its previous recommendations on the use of Fabrazyme (agalsidase beta). This follows information from the manufacturer, Genzyme, stating that the current supply of Fabrazyme will not address the medical needs of the nearly 600 patients receiving Fabrazyme in Europe today.

The CHMP is recommending that in situations where alternative treatment is available, no new patients should be started on Fabrazyme. For patients receiving a dose of Fabrazyme less than 1 mg/kg every other week, physicians should consider switching to an alternative treatment, such as Replagal.

These recommendations are temporary and do not change the currently approved product information for Fabrazyme.

The supply shortage of Fabrazyme began in June 2009 and was caused by a series of manufacturing problems at the production site in Allston Landing, in the United States of America. Because the current productivity at Allston Landing is still lower than expected, supply of Fabrazyme will not return to normal before the end of this year, according to Genzyme.

Fabrazyme is used to treat the rare, inherited enzyme-deficiency disorder, Fabry disease. Temporary treatment recommendations to manage patients relying on these medicines have been in place since the start of the manufacturing problems and have been regularly updated.

The CHMP remains concerned about the continued supply shortages of Genzyme's medicines. It is currently assessing proposals for improvement measures put in place by Genzyme to prevent similar manufacturing and quality problems in the future, and is closely monitoring the implementation of these measures. The Agency will make further updates as appropriate.

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Notes

1. The updated temporary treatment recommendations for Fabrazyme are as follows:
   - In situations in which alternative treatment is available:
     - Newly identified Fabry patients should not be treated with Fabrazyme. Treatment with an alternative treatment, such as Replagal should be considered.
     - Patients currently treated with Fabrazyme at the recommended dose of 1 mg/kg every other week should continue on this dosing regimen.
     - Patients treated with a dose of Fabrazyme lower than 1mg/kg every other week should be evaluated for switch to an alternative treatment, such as Replagal.
   - In situations where alternative treatment is not available or where (continuation of) treatment with Fabrazyme is deemed medically necessary, patients and prescribers are advised that a deterioration of the condition has been observed in patients on lowered dose. Pain, cardiac manifestations and deafness are usual manifestations of a progression of Fabry disease.
   - All patients, especially those with adjusted dose regimens, should be under close clinical surveillance. A medical examination, including all relevant clinical parameters, should be performed every two months. Doctors are in particular advised to monitor the plasma GL-3 or urinary GL-3 levels, as for the moment the GL-3 level is the most sensitive parameter.
2. The previous treatment recommendations of the CHMP were made on 23 April 2010, following continued supply shortage due to a problem with Genzyme's production site's water system. See here: http://www.ema.europa.eu/humandocs/PDFs/EPAR/fabrazyme/25762810en.pdf.
3. For Cerezyme, used to treat the rare, inherited enzyme-deficiency disorder, Gaucher disease, the temporary treatment recommendations following supply shortage, given on 22 October 2009, are still valid and can be found here: http://www.ema.europa.eu/humandocs/PDFs/EPAR/Cerezyme/Cerezyme_66511209en.pdf.
4. Initially the supply shortages for Cerezyme and Fabrazyme were caused by the shutting down of Genzyme's production site in Allston Landing, in the United States of America, for the sanitisation of the bioreactors due to a viral contamination. See here: http://www.ema.europa.eu/pdfs/human/press/pr/38999509en.pdf.
5. More information on Fabrazyme, including the currently approved product information, is available in the European public assessment report: http://www.ema.europa.eu/humandocs/Humans/EPAR/fabrazyme/fabrazyme.htm.
6. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: www.ema.europa.eu.

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