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Questions and answers on the supply shortage of Vfend (voriconazole)

The European Medicines Agency has been notified of supply problems with Vfend, mainly affecting the solution for infusion (drip into a vein) and to a lesser extent the tablet form. This will lead to a temporary shortage of these forms 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) has agreed that a letter should be sent to healthcare professionals, explaining the supply situation in their country and the temporary treatment recommendations to cope with the supply shortage.

What is Vfend?

Vfend is an antifungal medicine that contains the active substance voriconazole. It is available as tablets, an oral suspension and a powder to be made into a solution for infusion.

Vfend is intended for patients over the age of two years with worsening, possibly life-threatening, fungal infections, which include infections called 'invasive aspergillosis', 'candidaemia', 'serious invasive *Candida* sp. infections that are resistant to treatment with fluconazole', and 'serious *Scedosporium* sp. or *Fusarium* sp. infections'.

The active substance in Vfend, voriconazole, is an antifungal medicine that belongs to the group of the triazoles. It works by preventing the formation of ergosterol, which is an important part of fungal cell membranes. Without ergosterol, the fungus is killed or prevented from spreading.

Vfend has been authorised in the EU since 19 March 2002 and is marketed in all EU Member States, as well as Iceland and Norway.

The current European public assessment report for Vfend can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports.

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

In January 2012 the company that makes Vfend, Pfizer Limited, informed the European Medicines Agency of several technical issues at a manufacturing site for Vfend. These problems led to several batches of the infusion form of the medicine being rejected for not meeting quality requirements. Additional problems were then reported on 21 February 2012 also involving another manufacturing site and affecting the tablet form. As a result, supply shortages of Vfend infusion are anticipated in most

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7129
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
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EU countries from the beginning of March 2012, with fewer countries affected by tablet shortages. These shortages are expected to last several weeks. There are no concerns over the quality and safety of Vfend currently available on the market.

What are the recommendations of the CHMP?

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

In order to manage the impact on patients, the CHMP has recommended that prescribers take note of whether Vfend infusion and/or tablets may potentially be in short supply in their country, and rationalise prescribing accordingly. In those countries affected by shortages of both formulations, Vfend should only be given to patients for whom no suitable alternatives are available. Treatment of aspergillosis and serious *Scedosporium* sp. and *Fusarium* sp. infections might have to be prioritised. Patients may be switched to the oral suspension form of Vfend if possible and if considered necessary, as this form is not expected to be affected by the supply shortage.

Alternative treatments to Vfend include liposomal amphotericin B, other amphotericin B formulations, anidulafungin, caspofungin, micafungin, fluconazole, itraconazole and posaconazole. The possibility of starting or switching patients to alternative treatments will need to be assessed individually by the treating doctor. Factors such as a patient's underlying condition, the pathogen causing the infection, the patient's risk factors and previous exposure to these alternatives need to be considered. The most current therapeutic guidelines can offer further support.

What are the recommendations for prescribers?

- Healthcare professionals will receive information on the supply situation of Vfend in their country.
- If a national shortage is anticipated, doctors should rationalise prescribing accordingly. Consideration should be given to reserving Vfend for use in patients for whom no suitable alternatives are available.
- If possible and necessary, doctors can switch patients to Vfend oral suspension, subject to availability.
- When considering alternative treatments, doctors should consider the patient's underlying condition, the pathogen causing the infection, the patient's risk factors and previous exposure to these alternatives to Vfend.

What are the recommendations for patients?

- Patients are informed that alternative treatments to Vfend are available, and the treating doctor will select the best treatment for each patient based on individual needs. Some patients will be able to use Vfend oral suspension.
- Patients who have any questions should speak to their doctor or pharmacist.