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Press Office

Press release

European Medicines Agency gives further interim recommendations on dealing with shortcomings in quality assurance at Ben Venue Laboratories

Precautionary recall of batches of Ecalta and Luminity manufactured at Ben Venue. Doctors are advised to visually inspect vials of Ceplene and Torisel prior to administration.

The European Medicines Agency has recommended a precautionary recall at pharmacy level of 14 batches of the anti-fungal medicine Ecalta used to treat invasive candidiasis. This is part of the continuing review of the shortcomings in quality assurance identified during a good manufacturing practice (GMP) inspection at Ben Venue Laboratories' manufacturing site in Ohio, USA, and their impact on centrally authorised medicines manufactured at this site.

For the diagnostic medicine Luminity, the Agency recommended a precautionary recall of one batch already quarantined at the level of the marketing authorisation holder. For the two anti-cancer medicines Ceplene and Torisel the Agency advised that healthcare professionals should visually inspect the vials for the presence of particles before administration.

The inspection of Ben Venue highlighted several shortcomings in the quality-management system, particularly in relation to the sterile filling process and possible particle contamination during the manufacturing process.

For each product, the Agency's Committee for Medicinal Products for Human Use (CHMP) considered whether supply from Ben Venue remained essential to meet clinical needs, whether alternative treatment options were available, current EU stock levels and the possibility of sourcing the product from alternative manufacturing sites.

Recall of Ecalta

Following its review, the CHMP considers the supply of Ecalta with the diluent manufactured by Ben Venue no longer essential. Recalling batches of this medicine supplied by Ben Venue would not lead to

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a product shortage since an alternative presentation without diluent vial is available on the EU market. Therefore, the CHMP recommends the recall of batches of Ecalta manufactured at Ben Venue as a precautionary measure.

Recall of Luminity

The CHMP considered the supply of Luminity not essential. Therefore, the CHMP recommends the recall of the quarantined batch of Luminity manufactured at Ben Venue as a precautionary measure.

Advice on Ceplene

The CHMP considers Ceplene, for which Ben Venue is the only manufacturing source, to be essential for certain cancer patients and it recommended that supplies should be available to patients. The CHMP advised that healthcare professionals should visually inspect the vials for the presence of particles before administration.

Advice on Torisel

Ben Venue is the only manufacturing source for the diluent of Torisel. The CHMP considers Torisel to be essential for certain cancer patients and it recommended that supplies should be available to patients. The CHMP advised that healthcare professionals should visually inspect the diluent vials for the presence of particles before administration.

For Angiox, Cayston, Mepact, Soliris and Vibativ, centrally authorised medicines also manufactured at Ben Venue, the CHMP does not recommend any precautionary measures since they are either not marketed within the EU, no batch manufactured at the affected Ben Venue facility is currently on the EU market or the medicines undergo filtration prior to administration.

The Agency is in contact with the regulatory authorities of the EU Member States on the impact of this issue on non-centrally authorised products. There is a co-ordinated national approach to these products, taking the same principles into account as for the centrally authorised medicines.

The inspection process and the review for all centrally authorised medicines manufactured at the Ben Venue Laboratories plant is still ongoing and the Agency will make further updates as appropriate.

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[*] Inclusion of the words “affected … facility” in the third to last paragraph

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The European review of the centrally authorised medicines Angiox, Busilvex, Caelyx, Cayston, Ceplene, Ecalta, Luminity, Mepact, Soliris, Torisel, Velcade, Vibativ, Vidaza and Vistide, manufactured at the Ben Venue site in Ohio, is being conducted in the context of a formal review, initiated at the request of the European Commission under Article 20 of Regulation (EC) No 726/2004, on 17 November 2011. More information on these medicines can be found in the relevant European public assessment reports (EPARs).
3. The press release on the interim recommendations for medicines manufactured at Ben Venue dated 22 November 2011 is available on the Agency's website.

4. The medicines Ecalta and Torisel have two components: powder or concentrate and diluent. For both medicines only the diluent is manufactured at Ben Venue.

5. The Agency is working closely with international regulatory partners and in particular the US Food and Drug Administration, the Australian Therapeutic Goods Administration and Health Canada, to coordinate actions to address the GMP deficiencies at the Ben Venue Laboratories manufacturing site and to share information on the impact of these quality findings for the global product supply.

6. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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