13 December 2011
EMA/CHMP/964006/2011
Press Office

Press release

European Medicines Agency recommends precautionary recall of remaining batch of Vistide manufactured at Ben Venue Laboratories

The European Medicines Agency has recommended a precautionary recall at pharmacy level of one batch of the antiviral medicine Vistide, which is used to treat cytomegalovirus infections of the retina. 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.

During its initial review in November 2011, the Committee for Medicinal Products for Human Use (CHMP) considered that supplies of Vistide manufactured by Ben Venue could continue to be used, as this medicine is sterilised at the end of the manufacturing process and thus there is no risk of lack of sterility. However, the GMP inspection has now revealed a possible contamination with particles and the CHMP concluded that the sterilisation at the end of the manufacturing process could not guarantee the absence of particles in the vial. Recalling one batch of this medicine supplied by Ben Venue will not lead to a product shortage since an alternative manufacturer of Vistide is now supplying the European Union market. Therefore, the CHMP now recommends the recall of the remaining batch of Vistide manufactured at Ben Venue as a precautionary measure.

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

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. A question-and-answer document on shortcomings in quality assurance at Ben Venue Laboratories is available on the Agency's website.
3. Press releases on the interim recommendations for medicines manufactured at Ben Venue dated 22 November 2011 and 9 December 2011 are available on the Agency's website.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8427 **Facsimile** +44 (0)20 7418 8409
E-mail press@ema.europa.eu **Website** www.ema.europa.eu

4. 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).

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

Contact our press officers

Monika Benstetter or Sabine Haubenreisser

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu