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Press Office

Press release

European Medicines Agency recommends precautionary recall of batches of clopidogrel-containing medicines from Acino Pharma GmbH

Recall due to good manufacturing practice (GMP) failure at active substance manufacturer site

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) recommended the recall of all batches of eight centrally-authorised generic clopidogrel-containing medicines, for which the active substance was manufactured by Glochem Industries Ltd in its factory in Visakhapatnam (India). The medicines concerned are Clopidogrel A1 Pharma, Clopidogrel Acino, Clopidogrel Acino Pharma, Clopidogrel Acino Pharma GmbH, Clopidogrel Hexal, Clopidogrel Ratiopharm, Clopidogrel Ratiopharm GmbH and Clopidogrel Sandoz. The Marketing Authorisation Holder of all these medicines is Acino Pharma GmbH.

While neither the regulatory authorities nor the marketing authorisation holder have received reports raising concerns about these medicines from patients, pharmacists or prescribers, the CHMP recommended, as a precautionary measure, that all batches using clopidogrel made at the Glochem Visakhapatnam factory be recalled from the supply chain starting at the level of pharmacists. The Committee also recommended that the Glochem Visakhapatnam manufacturing site be removed from the list of sites allowed to supply clopidogrel to Acino Pharma GmbH for their generic medicines.

The Committee's recommendation follows an inspection of the Glochem Visakhapatnam manufacturing site, which identified failings in Good Manufacturing Practices (GMP). The GMP failings raised concerns about the processes used to manufacture the active substance and the Committee was not reassured about the quality of medicines made with clopidogrel from this manufacturing site.

Clopidogrel is an antiplatelet medicine that is used to prevent problems with blood clots such as heart attacks or strokes.

The CHMP's opinion has now been forwarded to the European Commission for the adoption of a legally binding decision.

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Notes

1. A question-and-answer document with more information is available here: http://www.ema.europa.eu/humandocs/PDFs/EPAR/clopidogrel1Apharma/Clopidogrel_Q&A_179698 10en.pdf

2. The CHMP reviewed the marketing authorisation of Clopidogrel-containing medicines from Acino Pharma GmbH on the request of the European Commission under Article 20 of Regulation (EC) No 726/2004. This type of procedure is initiated in cases where there are public health concerns with a centrally authorised medicine.

3. More information is available in the European Public Assessment Reports (EPAR) at http://www.ema.europa.eu/humandocs/Humans/EPAR/clopidogrel1Apharma/clopidogrel1Apharma.htm, http://www.ema.europa.eu/humandocs/Humans/EPAR/clopidogrelacino/clopidogrelacino.htm, http://www.ema.europa.eu/humandocs/Humans/EPAR/clopidogrelacinopharma/clopidogrelacinopharma.htm, http://www.ema.europa.eu/humandocs/Humans/EPAR/clopidogrelacinopharmagmbh/clopidogrelacinopharmagmbh.htm, http://www.ema.europa.eu/humandocs/Humans/EPAR/clopidogrelhexal/clopidogrelhexal.htm, http://www.ema.europa.eu/humandocs/Humans/EPAR/clopidogrelratiopharm/clopidogrelratiopharm.htm, http://www.ema.europa.eu/humandocs/Humans/EPAR/clopidogrelratiopharmgmbh/clopidogrelratiopharmgmbh.htm, http://www.ema.europa.eu/humandocs/Humans/EPAR/clopidogrelsandoz/clopidogrelsandoz.htm.

4. 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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