European Medicines Agency
Press Office

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European Medicines Agency statement following seizure of Avandamet tablets by US Food and Drug Administration

The US Food and Drug Administration has informed EMEA of its action in relation to the seizure of a number of batches of Paxil CR and Avandamet due to continuing good manufacturing practice (GMP) violations at GlaxoSmithKline manufacturing site in Puerto Rico.

Avandamet is a centrally authorised product used for the treatment of diabetes and is available in all European Union Member States.

The EMEA scientific committee, CHMP, is already aware of problems relating to the manufacture of Avandamet at the Puerto Rico manufacturing site. The Committee had extensive discussions during its 14-17 February 2005 meeting concerning an earlier voluntary recall of a number of other batches in the EU and US. The Committee also discussed proposals for a potential inspection by European GMP inspectors of the Puerto Rico site. It is envisaged that this inspection will take place shortly.

The European Medicines Agency shares the FDA view that these products do not pose a significant risk to patients and no recall of products is envisaged in Europe at this time.

Patients are advised to continue taking their tablets and to consult their health care professional in case of concern. A number of alternative therapies, including both active components of Avandamet, are available on the EU market.

GlaxoSmithKline has informed the EMEA that none of the batches seized by the FDA have been supplied to the European market.

However, the EMEA considers that the GMP violation allegations referred to by FDA potentially raise serious compliance issues. The Agency will continue to monitor the situation and its implications for patients in Europe.

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NOTES:

1. This press release, together with other information about the work of the EMEA, may be found on the EMEA web site at http://www.emea.eu.int

2. The European public assessment report for Avandamet, including information for patients and healthcare professionals, is available [here]. Avandamet is a combination of Rosiglitazone maleate and metformin hydrochloride; both components are available individually in Europe.

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