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Questions and answers on the review of Conbriza (bazedoxifene), PecFent (fentanyl) and Torisel (temsirolimus)

Outcome of procedures under Article 20 of Regulation (EC) No 726/2004

On 19 July 2012, the European Medicines Agency completed a review of three centrally authorised medicines, Conbriza (bazedoxifene), PecFent (fentanyl) and Torisel (temsirolimus), following concerns over the conduct of certain studies submitted as part of their marketing authorisation applications, which were conducted at the Cetero Research facilities in Houston, Texas, USA. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that the findings have no impact on the benefit-risk balance of these three medicines, and that the marketing authorisations should be maintained across the European Union (EU). The CHMP is continuing to review the potential impact of the findings on four other centrally authorised medicines.

Which medicines are affected by the Agency's review?

The Agency's review covers centrally authorised medicines whose marketing authorisation applications included studies conducted at the Cetero Research facilities in Houston, Texas, USA. The review has been concluded for the following three medicines:

- Conbriza, containing the active substance bazedoxifene, used for the treatment of osteoporosis (a disease that makes bones fragile) in women who have been through the menopause;
- PecFent, containing the active substance fentanyl, used for the treatment of 'breakthrough' pain in adults with cancer. 'Breakthrough pain' is when a patient experiences additional, sudden pain in spite of ongoing treatment with painkillers;
- Torisel, containing the active substance temsirolimus, used for the treatment of advanced renal cell carcinoma (a type of kidney cancer) and mantle cell lymphoma (an aggressive cancer of a type of white blood cell called B-lymphocytes).

The CHMP is also reviewing four other concerned centrally authorised medicines: Temodal (temozolomide), Tygacil (tigecycline), Ribavirin Teva (ribavirin) and Ribavirin Teva Pharma (ribavirin). The review of these medicines is still ongoing.

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More information on these medicines can be found in the relevant European public assessment reports (EPARs) for each medicine: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports.

Why were these medicines reviewed?

The EMA was informed by the US Food and Drug Administration that a recent inspection of the Cetero Research facilities had raised concerns over the way certain studies, called 'bio-analytical' studies, were conducted at these facilities in the period from April 2005 to June 2010.

To assess the potential impact on medicines on the European market, the EMA identified the seven centrally authorised medicines whose marketing authorisation applications included data from such studies conducted at the Cetero Research facilities. A number of non-centrally authorised medicines for which the marketing authorisation dossiers also included data generated at the Cetero Research facilities are being assessed by EU Member States.

Consequently, on 16 July 2012 the European Commission asked the CHMP to assess whether the identified issues have an impact on the benefit-risk balance of the seven centrally authorised medicines, and to issue an opinion on whether the marketing authorisation for these medicines should be maintained, varied, suspended or withdrawn across the EU.

Which data has the CHMP reviewed?

The CHMP reviewed the studies performed at the Cetero Research facilities, which were submitted as part of the marketing authorisation applications for Conbriza, PecFent and Torisel. The Committee considered the importance of the study data in the context of the overall data submitted in support of the marketing authorisation applications for these medicines.

What are the conclusions of the CHMP?

The CHMP noted that the data from the studies conducted at the Cetero Research facilities represented a small proportion of the overall set of data submitted to support the authorisations of Conbriza, PecFent and Torisel. For Conbriza and Torisel, the study results were confirmed by other studies not conducted at Cetero. In the case of PecFent, the results were re-evaluated and found similar to data from studies not conducted at Cetero and data from the scientific literature.

The Committee therefore concluded that the deficiencies identified at the Cetero Research facilities do not have an impact on the benefit-risk balance for the three medicines and that the marketing authorisations should be maintained across the EU.

A European Commission decision on this opinion will be issued in due course.