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Public statement

Palonosetron Hospira

Withdrawal of the marketing authorisation in the European Union

On 8 April 2019, the marketing authorisation of Palonosetron Hospira (palonosetron) ceased to be valid in the European Union (EU).

The cessation of validity is due to the fact that the marketing authorisation holder, Pfizer Europe MA EEIG, had not marketed Palonosetron Hospira in the EU since its initial marketing authorisation. In accordance with provisions of the sunset clause[1], the marketing authorisation of the medicinal product lapsed as the product had not been marketed in any of the EU Member States within three years of its initial authorisation.

Pfizer Europe MA EEIG confirmed that the product had not been marketed due to commercial reasons.

Palonosetron Hospira was granted marketing authorisation in the EU on 8 April 2016 for prevention of nausea and vomiting associated with cancer chemotherapy.

The marketing authorisation was initially valid for a 5-year period.

Palonosetron Hospira is a generic medicine of Aloxi. There are other generic medicinal products of Aloxi authorised and marketed in the EU.

The European Public Assessment Report (EPAR) for Palonosetron Hospira will be updated to indicate that the marketing authorisation is no longer valid.

[1] Article 14(4) of Regulation (EC) No 726/2004 ("sunset clause")

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