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Public statement

Paglitaz

Cessation of validity of the marketing authorisation in the European Union

On 27 March 2015, the marketing authorisation of Paglitaz (pioglitazone) ceased to be valid in the European Union (EU).

The cessation of validity is due to the fact that the marketing authorisation holder, Krka d.d. Novo mesto, had not marketed Paglitaz in the EU since its initial marketing authorisation in March 2012. 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.

Krka d.d. Novo mesto confirmed that the product had not been marketed due to commercial reasons.

Paglitaz was granted marketing authorisation in the EU for the treatment of type 2 diabetes mellitus. The marketing authorisation was initially valid for a 5-year period.

Paglitaz is a generic medicine of Actos. There are other generic medicinal products of Actos authorised and marketed in the EU.

The European Public Assessment Report (EPAR) for Paglitaz will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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

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