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Public statement

Leflunomide Teva

Cessation of validity of the marketing authorisation in the European Union

On 10 March 2014, the marketing authorisation of Leflunomide Teva ceased to be valid in the European Union (EU).

The cessation of validity is due to the fact that the marketing authorisation holder, Teva Pharma B.V., had not marketed Leflunomide Teva in the EU since its initial marketing authorisation in March 2011. 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.

Leflunomide Teva was granted marketing authorisation in the EU on 10 March 2011 for the treatment of adult patients with active rheumatoid arthritis.

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

Leflunomide Teva is a generic medicine of Arava which is authorised in the EU to treat adult patients with active rheumatoid arthritis and active psoriatic arthritis. Leflunomide Teva was a duplicate application to Repso, which is marketed in the EU. The marketing authorisation holder will maintain the marketing authorisation for Repso.

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Report (EPAR) for Leflunomide Teva will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.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