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Public statement

Pemetrexed Pfizer

Cessation of validity of the marketing authorisation in the European Union

On 26 April 2020, the marketing authorisation of Pemetrexed Pfizer (pemetrexed) 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 Pemetrexed Pfizer 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 for commercial reasons.

Pemetrexed Pfizer was granted marketing authorisation in the EU on 26 April 2017 and was indicated

- in combination with cisplatin for the treatment of chemotherapy naïve patients with unresectable malignant pleural mesothelioma and for the first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology;
- as monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy and for the second-line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology.

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

Pemetrexed Pfizer is a generic medicine of Alimta. There are other generic medicinal products of Alimta authorised and marketed in the EU.

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Public Assessment Report (EPAR) for Pemetrexed Pfizer will be updated to indicate that the marketing authorisation is no longer valid.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