EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Public statement

Pemetrexed Lilly

Cessation of validity of the marketing authorisation in the European Union

On 1 November 2021, the marketing authorisation of Pemetrexed Lilly (pemetrexed) ceased to be valid in the European Union (EU).

The cessation of validity is due to the fact that the marketing authorisation holder, Eli Lilly Nederland B.V., permanently discontinued marketing of Pemetrexed Lilly in the EU in October 2018. In accordance with provisions of the sunset clause[1], the marketing authorisation of a medicinal product lapses if the product had not been marketed in any of the EU Member States for three consecutive years.

Eli Lilly Nederland B.V. confirmed that it discontinued the marketing of the product due to commercial reasons.

Pemetrexed Lilly was granted marketing authorisation in the EU on 14 September 2015 for treatment of malignant pleural mesothelioma and non-small cell lung cancer.

The marketing authorisation was initially valid for a 5-year period and was renewed with unlimited validity in 2020.

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

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Public Assessment Report (EPAR) for Pemetrexed Lilly will be updated to indicate that the marketing authorisation is no longer valid.

[1] Article 14(5) of Regulation (EC) No 726/2004 ("sunset clause")

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