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Public statement

Gefitinib Mylan (gefitinib)

Withdrawal of the marketing authorisation in the European Union

On 27 September 2024, the European Commission withdrew the marketing authorisation for Gefitinib Mylan (gefitinib) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Mylan Pharmaceuticals Limited, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Gefitinib Mylan was granted marketing authorisation in the EU on 27 September 2018 for the treatment of non-small cell lung cancer. The marketing authorisation was initially valid for a 5-year period. It was then granted unlimited validity in 2023. The product had not been marketed in the EU since 2023.

Gefitinib Mylan is a generic medicine of Iressa.The European Public Assessment Report (EPAR) for Gefitinib Mylan will be updated to indicate that the marketing authorisation is no longer valid.

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