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Public statement

Imatinib Teva B.V.

Withdrawal of the marketing authorisation in the European Union

On 8 May 2018, the European Commission withdrew the marketing authorisation for Imatinib Teva B.V. (imatinib) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Teva B.V., which notified the European Commission of its decision not to market the product in the EU for commercial reasons.

Imatinib Teva B.V. was granted marketing authorisation in the EU on 15 November 2017 for treatment of Philadelphia chromosome positive chronic myeloid leukaemia (CML); Philadelphia chromosome positive acute lymphoblastic leukaemia (ALL); myelodysplastic/myeloproliferative diseases (MDS/MPD); hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukaemia (CEL); gastrointestinal stromal tumours (GIST); and dermatofibrosarcoma protuberans (DFSP).

Imatinib Teva B.V. is a generic medicine of Glivec. There are other generic medicinal products of Glivec authorised and marketed in the EU.

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(EPAR) for Imatinib Teva B.V. will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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