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Public statement

Imatinib Actavis (imatinib)

Withdrawal of the marketing authorisation in the European Union

On 16 May 2022, the European Commission withdrew the marketing authorisation for Imatinib Actavis (imatinib) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Actavis Group PTC ehf., which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Imatinib Actavis was granted marketing authorisation in the EU on 17 April 2013 for treatment of:

- paediatric patients with newly diagnosed Philadelphia chromosome (bcr-abl) positive (Ph+) chronic myeloid leukaemia (CML) for whom bone marrow transplantation is not considered as the first line of treatment;

- paediatric patients with Ph+ CML in chronic phase after failure of interferon-alpha therapy, or in accelerated phase or blast crisis;

- adult patients with Ph+ CML in blast crisis;

- adult and paediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) integrated with chemotherapy;

- adult patients with relapsed or refractory Ph+ ALL as monotherapy;

- adult patients with myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene re-arrangements;

- adult patients with advanced hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukaemia (CEL) with FIP1L1-PDGFRα rearrangement;

- adult patients with unresectable dermatofibrosarcoma protuberans (DFSP) and adult patients with recurrent and/or metastatic DFSP who are not eligible for surgery.

The marketing authorisation was initially valid for a 5-year period. It was then granted unlimited validity in 2017.

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Imatinib Actavis 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Public Assessment Report (EPAR) for Imatinib Actavis will be updated to indicate that the marketing authorisation is no longer valid.