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Public statement

Imatinib Koanaa (imatinib)

Withdrawal of the marketing authorisation in the European Union

On 31 August 2023, the European Commission withdrew the marketing authorisation for Imatinib Koanaa (imatinib) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Koanaa Healthcare GmbH, which notified the European Commission of its decision not to market the product in the EU for commercial reasons.

Imatinib Koanaa was granted marketing authorisation in the EU on 22 September 2021 for the treatment of adults and children with:

- chronic myeloid leukaemia (CML), in patients who are 'Philadelphia chromosome positive' (Ph+),
- Ph+ acute lymphoblastic leukaemia (ALL).

This medicine is also used for treating adults with:

- myelodysplastic or myeloproliferative diseases (MD/MPD),
- advanced hypereosinophilic syndrome (HES) or chronic eosinophilic leukaemia (CEL),
- gastrointestinal stromal tumours (GIST),
- dermatofibrosarcoma protuberans (DFSP).

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

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Public Assessment Report (EPAR) for Imatinib Koanaa will be updated to indicate that the marketing authorisation is no longer valid.

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