

European Medicines Agency  
Dr Harald Enzmann  
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1083 HS Amsterdam  
Netherlands

**Subject: Withdrawal of CMML indication from the applications to extend the therapeutic indication for Inaqovi - EMEA/H/C/005823/II/02**

5 Aug 2024

Dear Dr Enzmann,

I would like to inform you that, at this point of time, Otsuka Pharmaceutical Netherlands B.V. has taken the decision to withdraw the application to add chronic myelomonocytic leukemia (CMML) indication to the marketing authorisation for Inaqovi tablets, in the treatment of Acute Myeloid Leukemia. The applicant seeks to pursue the myelodysplastic syndrome (MDS) indication and revise it to higher-risk MDS.

This withdrawal is based on the following reasons:

On 25 April 2024, Otsuka Pharmaceutical Netherlands B.V. received a list of requests for supplementary information (RSI) on CMML. The applicant cannot fully address the list of requests on CMML now.

The applicant reserves the right to submit a variation application in the future to include CMML in marketing authorisation for Inaqovi.

I agree for this letter to be published on the EMA website.

Yours sincerely,

CCI

