



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 October 2018
EMA/CHMP/727925/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Kalydeco

ivacaftor

On 18 October 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Kalydeco. The marketing authorisation holder for this medicinal product is Vertex Pharmaceuticals (Europe) Ltd.

The CHMP adopted an extension to the existing indication of Kalydeco 50 and 75 mg granules as follows:²

“Kalydeco granules are indicated for the treatment of children with cystic fibrosis (CF) aged ~~2 years~~ **12 months** and older and weighing **7 kg** to less than 25 kg who have one of the following gating (class III) mutations in the *CFTR* gene: *G551D*, *G1244E*, *G1349D*, *G178R*, *G551S*, *S1251N*, *S1255P*, *S549N* or *S549R* (see sections 4.4 and 5.1).”

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

² **New text in bold, removed text as strikethrough**

