

To:

Head of Paediatric Medicines  
European Medicines Agency  
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**Notification of discontinuation of a paediatric development which is covered by an agreed PIP Decision**

Actives substance(s): (S)-Pyrrolidine-2-carboxylic acid compound with (2S,3R,4R,5S,6R)-2-(3-((2,3-dihydrobenzo[b][1,4]dioxin-6-yl)methyl)-4-ethylphenyl)-6-(hydroxymethyl)tetrahydro-2H-pyran-3,4,5-triol (2:1) ( LIK066)

Invented name: NA

Latest Decision number(s): 1) P/0183/2014 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-001527-PIP01-13 2) EMEA- 3) EMEA- 4) EMEA-

Please note that development of the medicinal product above in the [condition(s)/indication(s)]:

Treatment of type 2 diabetes mellitus

has been discontinued

has been suspended/put on long-term hold (with possible re-start at a later time)

for the following reason(s): (tick all that apply)

(possible) lack of efficacy in adults

(possible) lack of efficacy in children

(possible) unsatisfactory safety profile in adults

(possible) unsatisfactory safety profile in children

commercial reasons (please specify: )

manufacturing / quality problems

other regulatory action (please specify: ) (e.g. suspension, revocation of M.A.)

other reason (please specify: strategic reasons)

Please add a brief description (max 2000 characters) of the reason(s) for the discontinuation / suspension:

Novartis has decided to discontinue development of LIK066 in the treatment of type 2 diabetes mellitus based on strategic considerations.

Name and signature of the PIP contact point: Signature on file

Date: 13-Nov-2018

Contact for inquiries from interested parties: Please see contact details below

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