Notification of discontinuation of a paediatric development which is covered by an agreed PIP Decision[i]

Actives substances(s): Dalcetrapib

Latest Decision number(s): 1) P/28/2010

Corresponding PIP number(s): 1) EMEA-000580-PIP01-09

If the PIP has been submitted as part of a marketing authorisation application in order to comply with the requirements of Article 7 of the Paediatric Regulation (as a condition of the validation of the respective application) and a marketing authorisation was granted based on this application, then there is a legal obligation to complete that PIP. The same applies if there has been a successful post-authorisation application, where the PIP was included in order to comply with the requirements of Article 8 of the Paediatric Regulation.

Please confirm if any of the above applies:

Yes ☐ No ☒

If yes, it means that based on the Marketing Authorisation obtained at the end of that initial procedure or the successful post-authorisation application, as applicable, you are obliged to complete that PIP. That obligation cannot be cancelled by a unilateral decision, including by withdrawing the MA. Such PIP must be completed, unless it is modified in agreement with the PDCO by removing all outstanding PIP measures or granting a full product-specific waiver instead (upon relevant circumstances in accordance with the Paediatric Regulation). Non-completion of a binding PIP establishes noncompliance with the requirements of the Paediatric Regulation, which the European Medicines Agency has an obligation to report to the European Commission.

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

Lipoprotein deficiency

☒ has been discontinued

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:)

☐ other reason (please specify:)

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

Product development of dalcetrapib was terminated in 2012.

Based on the results of the second interim analysis of the dalcetrapib dal-OUTCOMES trial and the resulting recommendation by the independent Data and Safety Monitoring Board (DSMB) to stop the trial due to lack of clinically meaningful efficacy, Roche concluded that the drug was well tolerated, but given the lack of benefit, the overall benefit-risk of dalcetrapib is assessed to be neutral.

As a consequence, Roche does not intend to initiate the clinical studies as specified in the agreed PIP, on the grounds that dalcetrapib is also likely to show a neutral benefit-risk profile in all subsets of the proposed paediatric population.

Date:	11 December 2025
Contact for inquiries from interested parties:	Roche Registration GmbH
Telephone:	+49 7624142892
Email:	global.eu_regulatory_office@roche.com

[i] This form will be published to the corresponding decision available on the website of the European Medicines Agency.