To:

Head of Paediatric Medicines
European Medicines Agency
30 Churchill Place
London E14 5EU
United Kingdom
paediatrics@ema.europa.eu

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

Actives substances(s): omarigliptin

Invented name: ZIMGLYSTO

Latest Decision number(s): 1) P/0266/2012 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-001234-PIP01-11 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: Discontinuation of PIP EMEA-001234-PIP01-11 is founded in the sponsor's (Merck Sharp & Dohme (Europe), Inc.) notification to the EMA and (co)rapporteurs dated 07-April-2016 declaring its intention to no longer pursue the submission of the marketing authorisation application pertaining to omarigliptin H0004034 (reference MAA) and its related products H0004259, H0004260 and H0004261 (duplicate MAAs), previously notified to meet the EMA-published submission deadline of 26 April 2016. This decision has been made for business reasons only and is not due to safety concerns or the efficacy of omarigliptin.)

☐ manufacturing / quality problems

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

☐ other reason (please specify:)

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

Please refer to the statement above under "commercial reasons".

Name and signature of the PIP contact point: Kolade Majekodunmi

Date: 09 August 2016

Contact for inquiries from interested parties: Merck Sharp & Dohme (Europe) Inc.

Netherlands

Telephone: +31(0)412663179

Email: pip.information@merck.com