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): skimmed cow's milk powder

Invented name: Diallertest

Latest Decision number(s): 1) P/208/2009 2) P/107/2008 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-000201-PIP01-08-M01 2) EMEA-000201-PIP01-08 3) EMEA- 4) EMEA-

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

cow's milk allergy

☒ 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:

The development of Diallertest, a diagnosis patch for cow's milk allergy with skimmed cow's milk powder as active substance, has been discontinued for strategic reasons. Instead, DBV has decided to initiate the development of a new diagnosis patch with cow's milk protein extract as active substance. It is important to note that Diallertest was intended to be developed and marketed in children only.

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

Date: 23 Mars 2017

Contact for inquiries from interested parties: ClinDev@dbv-technologies.com

Telephone: +33 1 55 42 78 78

Email: +33 9 72 36 49 71