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 substances(s): solithromycin

Invented name:

Latest Decision number(s): 1) P/0119/2016 2) P/0180/2016 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-01581-PIP01-13-M02 2) EMEA-01581-PIP01-13-M03 3) EMEA- 4) EMEA-

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

Treatment of bacterial pneumonia, treatment of tularaemia, treatment of anthrax

☐ 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: lack of sufficient funding to progress the adult program)

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

A decision by the U.S. Biomedical Advanced Research and Development Authority (BARDA) not to support the conduct of a large safety study required by the U.S. FDA has resulted in a halt development of the adult program. The sponsor has also withdrawn the EMA marketing authorization application for the adult indication for treatment of bacterial pneumonia. Based on these decisions, the paediatric program has been discontinued.

Name and signature of the PIP contact point: Triskel EU Services, Ltd.

Date:

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