

28 September, 2018

Electronic Submissions
Therapeutic Goods Administration
136 Narrabundah Lane
Symonston ACT 2609

Response to Milestone 5 Request for Information – Delegate's File Note

**BRALTUS Tiotropium (as tiotropium bromide)
Dry Powder for Inhalation, hard capsules
13 microgram
Submission No.: PM-2017-03103-1-5
eSubmission Identifier: e002646
Coordination file number E17-28754**

Dear Sir/Madam,

[REDACTED] on behalf of Teva Pharma Australia Pty Ltd
(Client ID 61006) submits a response to the Milestone 5 (File Note), dated 19th
September 2018:

| | |
|-------------------------|--|
| Trade name: | BRALTUS |
| Sponsor: | Teva Pharma Australia Pty Ltd |
| Active ingredient: | Tiotropium (as tiotropium bromide) |
| Dosage form: | Dry Powder for Inhalation, hard capsules |
| Strength/s: | 13 microgram |
| eSubmission Identifier: | e002646 |
| Sequence Number: | 0005 |

The issues have been addressed in a response document (Module 1.0.3).

[REDACTED]

This eCTD sequence is being provided via email only. The eCTD submission consists of approximately <10MB of data. The electronic copy has been scanned using antivirus software (Kaspersky Endpoint Security) and is free of known viruses.

For any questions regarding the submission (regulatory or IT), please contact [REDACTED]
[REDACTED] by telephone on [REDACTED] or by e-mail at [REDACTED]

Yours sincerely,

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]