

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 19<sup>th</sup> 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).

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]

[REDACTED]

[REDACTED]