Therapeutic Goods Administration

Scientific Evaluation Branch

Pharmaceutical Chemistry Section

Milestone 5 Report: Quality Data

(Chemical Drug Substance, CTD Format Dossier)

New generic medicine (Type D)

(type of submission)

tiotropium bromide

(drug substance – polymorphic form if present)

BRALTUS

(proposed trade name)

13 microgram Dry Powder for Inhalation, hard capsules

(dose form and strengths)

Teva Pharma Australia Pty Ltd

(sponsor/distributor if appropriate)

PM-2017-03103-1-5

(submission number)

E18-211908

(Chemistry file number)

Milestone 3 evaluation report:	D18-10408790
Applicant's response to MS3:	e002646 - (0003)
Milestone 5 evaluation report:	D18-10785551
Applicant's response to MS5:	e002646 (0004)

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Table of Contents

Introduction

The Sponsor's response to matters raised in the pharmaceutical chemistry milestone 5 report is evaluated in this report.

Module 1:

Trade name

Question 1

No objection to the trade name, BRALTUS, has been received from the clinical delegate.

Labels

Question 2

The sponsor has included a statement that 'Each capsule contains 13 micrograms of tiotropium (as bromide) and will deliver 10 micrograms of tiotropium'. ***However, this statement is not prominent enough, therefore it is considered that the labels should be amended to show each strength in similar prominence as below:***

Braltus

Tiotropium (as bromide)

13 microgram metered dose

10 microgram delivered dose

Product Information (PI)

Question 3

The sponsor has included the Vcap under the 'Description' section of the PI and included a statement stating 'BRALTUS and SPIRIVA both deliver 10 micrograms of tiotropium and are equivalent' as requested. This is acceptable.

DHCP letter

The contents of the DHCP letter will be referred for RMP for comment.

Evaluator's recommendation

Approval recommended from a pharmaceutical chemistry and biopharmaceutics perspective.

[redacted]

Pharmaceutical Chemistry Section
Scientific Evaluation Branch

31 August 2018