[redacted]

From: [redacted]@health.gov.au> on behalf of RMP Coordinator <rmp.coordinator@health.gov.au>
Sent: Tuesday, 6 June 2017 11:08 AM
To: [redacted]
Cc: [redacted]
Subject: RE: Tiotropium Dry Powder Capsules for Inhalation 10 microgram - Request for RMP waiver [SEC=UNCLASSIFIED]

[redacted]

No RMP is required for your product tiotropium dry powder for inhalation.

Please attach this email with your PPF.

Regards [redacted]

[redacted]
Risk Management Plan Evaluation
Pharmacovigilance and Special Access Branch
Health Products Regulation Group
[redacted]

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

[redacted]

From: [redacted]
Sent: Tuesday, 6 June 2017 10:53 AM
To: RMP Coordinator
Cc: [redacted]
Subject: Tiotropium Dry Powder Capsules for Inhalation 10 microgram - Request for RMP waiver [SEC=No Protective Marking]

ATTENTION: TGA RMP COORDINATOR

[redacted] on behalf of Teva Pharma Australia Pty Ltd [redacted] would like to request a Pharmacovigilance Risk Management Plan (RMP) waiver with reference to a planned Category 1 application to the TGA of Tiotropium Dry Powder Capsules for Inhalation (10 microgram).

The proposed generic formulation is for the same indication as the Australian innovator product Spiriva® (tiotropium bromide) Capsules for inhalation, via the same route of administration (oral administration), in the same dosage form.
[redacted] are planning to submit the Pre-Submission Planning Form (PPF) in August 2017.
Attached is a report supporting the justification for a waiver.

[redacted] on behalf of Teva Pharma Pty Ltd, seek approval for a waiver for a Risk Management Plan prior to submitting the Pre-submission Planning Form for Tiotropium Dry Powder Capsules for Inhalation (10 microgram).

Many thanks and kind regards,

[redacted]

[redacted]

[redacted]

[redacted]