14 December 2018

The Secretary
MDP 952
Department of Health
GPO Box 9848, Canberra ACT 2601

Dear Sir/Madam

Re: Minor Application for consideration at the March 2019 PBAC meeting

Please find enclosed a minor application seeking a PBAC recommendation to list a bioequivalent brand of tiotropium capsule containing powder for oral inhalation.

The proposed brand is Braltus® tiotropium (as bromide) 13 microgram powder for inhalation capsule. Braltus capsules are inhaled with a Zonda inhaler. The Zonda inhaler is supplied with every pack of Braltus.

The relevant reference product is Spiriva® tiotropium (as bromide monohydrate) 18 micrograms powder for inhalation capsule. Spiriva capsules are inhaled with the HandiHaler. The Handihaler is available with the Spiriva pack (in some cases) or more commonly supplied separately, as it is reusable.

Based on advice requested from the PBAC Secretariat earlier this year (enclosed for reference), we understand that PBAC consideration is required in this instance due to the difference in metered dose of the two products and the different inhalation devices. Both products provide the same delivered dose of 10 micrograms and are demonstrated to be bioequivalent.

The suitability of Braltus as an alternate substitutable brand of tiotropium powder for inhalation is justified within the application, based upon:

1. TGA acceptance of established bioequivalence
2. The attributes of the delivery device and product presentation which will offer increased choice to patients and prescribers
3. Quality Use of Medicine measures in place to support a clear understanding and correct use of the product in the community
4. The cost saving opportunity for government to list a quality, bioequivalent alternative brand of an important and extensively used COPD treatment.

Please do not hesitate to contact the undersigned should you require and further information

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