THE HON SUSSAN LEY MP
MINISTER FOR HEALTH
MINISTER FOR AGED CARE
MINISTER FOR SPORT

Ref No: MC16-008892

Senator the Hon Michaelia Cash
Minister for Women, Minister for Employment, Minister Assisting the Prime Minister for the Public Service
Senator for Western Australia
PO Box 1966
WEST PERTH WA 6872

Dear Senator the Hon Cash

Thank you for your representations of 10 March 2016 on behalf of s22(1) [redacted] regarding concerns about the lack of TGA clinical testing for Champix.

Champix (varenicline) has been approved in Australia “as an aid to smoking cessation in adults over the age of 18 years" since 15 February 2007. Champix was listed on the Pharmaceutical Benefits Scheme (PBS) on 1 January 2008. Champix was approved on the basis of comprehensive clinical and scientific data, provided by the Sponsor, to support the quality, safety and effectiveness of the product for its intended use. This data was reviewed by the TGA before making a decision about whether or not to approve the new product.
I note that in the correspondence provided by your constituent, there appears to be a confusion in relation to the responsibility for regulatory decision making. While the TGA seeks the advice and input from independent experts, such as the Advisory Committee on the Safety of Medicines (ACSOM), the ACSOM does not have a role in approving any medicines, nor does it have responsibility for placing of warning labels on medicines. These decisions are made by the authorised officers, who are decision makers within the TGA.

Further, ACSOM does not have any role in the listing of medicines on the Pharmaceutical Benefits Scheme (PBS). This is the responsibility of the Australian Government, based on advice from the Pharmaceutical Benefits Advisory Committee (PBAC).

The membership of the ACSOM is publically available, and members are required to declare any interests in considering and providing advice to the TGA with respect to medicines such as Champix.

Like all medicines, those used to treat smoking cessation, such as Champix, can have side effects. Consequently, as with any prescribing decision, the potential benefits of treatment must be balanced against the potential risks while taking into account the particular clinical circumstances of each patient.

The decision to use a particular medicine should be made between the patient and their doctor, and involve discussion of the relative risks and benefits of the therapy compared to other possible treatments or no treatment at all. For medicines that have shown benefit in assisting individuals to quit smoking, the risks of continued smoking also need to be taken into account.

Prescription medicines such as Champix are required to have a Product Information (PI) document approved by the TGA and a Consumer Medicine Information (CMI) document that is consistent with the PI to provide information to health care professionals and consumers about the safe and effective use of the medicine.

The Champix PI and CMI documents contain warnings about neuropsychiatric adverse events such as self-harm and suicidal tendencies and these have recently been re-enforced by highlighting the information in the PI and CMI.

Full versions of PIs and CMIs are available on the TGA website at www.tga.gov.au and pharmacists will have this information for consumers.

Finally, the TGA further ensures the continued safety of the Australian public through post-market monitoring and regulatory activities for prescription, non-prescription and complementary medicines. The primary focus of the TGA is to capture and investigate safety issues related to marketed medicines and to ensure product sponsors have appropriate mechanisms in place to identify safety concerns that may arise once a prescription medicine receives approval for supply in Australia.

Thank you for raising your constituents' concerns.

Yours sincerely

The Hon Sussan Ley MP

Minister	**Sussan Ley**
PDR Number	**MC16-008892**
Subject	**URGENT - concerns about lack of TGA clinical testing for Champix.**
Initiator	**Senator the Hon** Michaelia **Cash**
Action Officer	s22(1) [redacted]
Clearance Officer	s22(1) [redacted]
Division/Branch	**Medicines Regulation**

Adviser/DLO Comments:

Return to Dept for:

Redraft ☐

NFA ☐