The Hon Tanya Plibersek MP
Minister for Health
Minister for Medical Research

The Hon John Murphy MP
Chair
Standing Committee on Petitions
PO Box 6021
Parliament House
CANBERRA ACT 2600

Dear Mr Murphy

Thank you for your letter of 3 June 2013 on behalf of the Standing Committee on Petitions, regarding improving consumer safety in pharmaceutical products.

Thank you for the opportunity to provide a submission. Please find enclosed my response to the issues raised in the petition (Attachment A).

Once again, thank you for writing.

Yours sincerely

Tanya Plibersek

8-7-13

Encl

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The Hon Tanya Plibersek MP
Minister for Health, Minister for Medical Research
Response to Standing Committee on Petitions

All clinical trials that meet the WHO/ICMJE 2008 definition of a clinical trial are required to be registered on the Australian New Zealand Clinical Trials Registry. This must occur before the first patient is enrolled in the trial.

In Australia, publicly funded research funded by funding bodies such as the National Health and Medical Research Council (NHMRC) must be conducted in accordance with the Australian Code for the Responsible Conduct of Research, 2007 (the Code), and, for research involving humans, with the National Statement on Ethical Conduct in Human Research, 2007 (the National Statement). These documents establish robust standards for the approval and conduct of research in Australia.

The Code guides institutions and researchers in responsible research practices. The National Statement promotes ethically sound human research by providing guidance on the design, review and conduct of human research.

While neither document provides a legislative mandate, the conduct of NHMRC funded research is tied to a funding agreement such that any funded research must be carried out in accordance with the Code and the National Statement.

In relation to the provision of negative results from clinical trials, Section 4 of the Code acknowledges that dissemination of research findings is an important part of the research process and that researchers have a responsibility to their colleagues and the wider community to disseminate a full account of their research as broadly as possible. It also states that the account should be complete, and, where applicable, include negative findings and results contrary to their hypothesis.

The National Statement provides guidance for interventions and therapies, including clinical and non-clinical trials and innovations. In addition, the National Statement provides guidance on reporting requirements in relation to adverse events that may occur during research involving humans such as clinical trials. The events must be reported to the Human Research Ethics Committee by those conducting the trial.

In order for a new prescription medicine to be approved in Australia it is necessary for a sponsor to make an application to the Therapeutic Goods Administration (TGA). The application must be accompanied by supporting data to establish the quality, safety and efficacy of the medicine for its intended use.

A comprehensive evaluation of the submitted clinical and other scientific data is undertaken by the TGA and it is expected that all relevant data is submitted. Sponsors submitting an application for registration are required to provide a summary of the adverse events which occurred or worsened in the clinical trial patient populations. These are required to be summarised in tables listing each event, the number of subjects in whom the event occurred and the frequency of the events in the patients treated with the drug under investigation, with comparator drugs and with placebo. A separate section is included which details any deaths which may have occurred during the trial or post-trial completion which may have resulted from a process that began during the trial. It should be noted that adverse events occurring in a clinical trial are not necessarily causally related to the drug.

Where people with particular characteristics have suffered serious or life threatening side effects, these characteristics can be documented in the contraindications and precaution section of the Product Information (PI). For example, the clinical trial may highlight that people of a certain age and gender or people with conditions such as high blood pressure or particular organ diseases have suffered side effects to the point that the PI will provide advice to medical practitioners about the use of the medicine by these particular people.

Further, when advice about a prescription medicine application for registration is sought by the TGA from the Advisory Committee on Prescription Medicines, sponsors are required to submit tabulation of any serious unexpected adverse drug reactions that are not mentioned in the proposed Australian Product Information and have not been submitted previously. This can also lead to precautionary advice being included in the PI.

The PI document provides health professionals with a summary of the essential scientific information to allow the safe and effective use of a medicine under nearly all circumstances. As a condition of registration, certain medicines, mainly those prescribed by a doctor, are required to have a product information document which provides information relating to the safe and effective use of the medicine, including information regarding the medicine's potential side effects and interactions with other medicines. PI documents are agreed with the TGA as part of the medicine's approval process before it can be made available in Australia.

The Consumer Medicines Information (CMI) is a leaflet that contains information on the safe and effective use of a medicine, including relevant and extensive information on side effects and interactions with other medicines. The information has been written by the pharmaceutical company responsible for the medicine. TGA regulations require that the CMI must be made available to consumers either in the pack or in another manner that will enable the information to be given to the person to whom the medicines are administered or otherwise dispensed.

The information in both these documents assists doctors, pharmacists and other health professionals in prescribing and dispensing medicines and also in their consultations with patients, such as to better educate a patient on the medicine they are being given.

The TGA recognises that not all adverse events which may be related to a medicine will occur within the context of a clinical trial. Therefore it conducts extensive post-market monitoring activities on medicines and regularly reviews adverse event signals which appear to be extra ordinary. This may lead to further information on adverse events being included in the PI and CMI documents.