Australian Government

Department of Health

Secretary

Ms Jeanette Radcliffe
Committee Secretary
Standing Committee on Community Affairs References Committee
PO Box 6100
Parliament House
CANBERRA ACT 2600

Dear Ms Radcliffe

Thank you for forwarding the correspondence from Ms Lisa McManus, Thalidomide Group Australia, providing comments and information in response to several answers provided by the Department to questions on notice resulting from the 2 November 2018 hearing of the inquiry of the Senate Community Affairs References Committee into support for Australia's thalidomide survivors.

Ms McManus makes claims against the Department's response to three questions on notice.

With regard to the response to question number 4, Ms McManus has stated the following:

> *The Federal Health Council [the precursor to the National Health and Medical Research Council (NHMRC) was established in 1926 following a Royal Commission's recommendations. The NHMRC was active from 1937 – 1961. Its goal was to develop a uniform approach to labelling and standards and emphasised the need for independent laboratory testing of pharmaceuticals released onto the Australian market.*
>
> *It was evident that the Australian government was negligent in following their own guidelines.*

This statement appears to have been adapted from the book, A History of Therapeutic Goods Regulation in Australia, written by John McEwen and published September 2007. The exact quote from this book is as follows:

> *During the period 1939-1961, the National Health and Medical Research Council (NHMRC) was active in developing a more uniform national approach to labelling and standards and emphasised the need for independent laboratory testing. The federal government moved to enact legislation to regulate the standards for medicines, particularly to require that Pharmaceutical Benefits were of good quality.*
>
> *The Industry was rapidly evolving both in the sophistication and variety of products and in the multinational nature of many companies.*

> *Further, the National Biological Standards Laboratory (NBSL) was established in 1958 to independently test medicines on the Australian market and regulate their manufacture.* (page vi)

The Department agrees with Ms McManus' assertion that the NHMRC was active in developing a more uniform approach to labelling and standards of medicines in Australia. The NHMRC facilitated discussions between the states and the Commonwealth through regular conferences on matters related to uniform standards for food and medicines. However, while recommendations were made by the conferences that could then be adopted by the states in their own legislation, due to differences in legislation and local factors they did not seem to have been practically implemented.

The NBSL was established in the Commonwealth Department of Health in 1958 but there is no evidence to suggest its role was to evaluate drug safety. Any testing which was conducted focussed on determining the pharmaceutical quality of the medicine and its conformance with international pharmacopeial standards (e.g. did the medicine have the stated active ingredient). These tests did not measure the effects of the medicine on the human body, and were not designed to investigate teratogenicity (the tests which could have predicted the effect of thalidomide on the developing human foetus). Additionally, noting this drug was not listed on the Commonwealth's Pharmaceutical Benefits Scheme at the time, we cannot identify any reason the Commonwealth would have sought international data or undertaken any testing to determine safety.

The legislation governing therapeutic substances was the *Therapeutic Substances Act 1953 (Cth)*, as amended by the *Therapeutic Substances Act 1959 (Cth)* (Therapeutic Substances Act). The Therapeutic Substances Act was concerned largely with labelling and manufacturing quality standards. It did not outline a role for the Commonwealth in ensuring therapeutic substances to be imported or sold in Australia were proven to be efficacious and had undergone clinical trials or other testing to ensure they were safe to use.

As the Department indicated in its response to the question on notice, the Australian Government established the Australian Drug Evaluation Committee in June 1963 to monitor the safety of new medicines as well as medicines already available. There is no evidence to suggest the Australian Government was negligent in following its own guidelines in relation to monitoring drug safety prior to June 1963.

With regard to the response to question number 7 and the two pharmaceutical products identified by Ms McManus as being Chemie Grunenthal products trademarked and licensed for sale in Australia, I can advise the following:

- Palexia SR® (tapendadol) is supplied to the PBS by Seqirus Pty Ltd (formerly bioCSL Australia Pty Ltd). The Department interacts with Seqirus on all matters relating to the PBS listing and supply of this product in Australia under the PBS and not with Chemie Grunenthal.
- Versatis® (lignocaine %) patch is not listed on the PBS. The Australian sponsor of Versatis is also Seqirus (bioCSL). The Pharmaceutical Benefits Advisory Council considered a submission from bioCSL in 2015 but did not recommend listing.

With regard to the response to question number 15, Ms McManus states the 107 publicly reported thalidomide survivors who received compensation in 2014 from the Gordon Legal class action does not represent the total number of recognised survivors in Australia. The Department reiterates its response citing these 107 survivors was only referring to the number of claimants involved in the class action, and was not intended to represent the total number of thalidomide survivors recognised in Australia.

Yours sincerely

Glenys Beauchamp

5 February 2019