Australian Government
Department of Health

Australian Government Department of Health submission to the Senate Community Affairs References Committee Inquiry into support for Australia's thalidomide survivors

Thalidomide

Thalidomide was developed by a German pharmaceutical company (Chemie Grünenthal now Grünenthal GmbH) and was sold between 1957 and 1961 in almost 50 countries. The drug was marketed as a tranquilliser and pain killer that was effective for treating insomnia and headaches as well as nausea and morning sickness during pregnancy.

Based on the claims of the manufacturer, thalidomide was considered to be safe: in contrast to older tranquilisers, as an overdose did not result in death, but simply an extra-long sleep.[1] However, no studies had been conducted to investigate the safety of thalidomide for the unborn child.[1]

It was not until the establishment of the Australian Drug Evaluation Committee in 1963, following the thalidomide experience, that expert, independent advice on the quality, safety and effectiveness of prescription medicines was available in Australia.

Thalidomide was marketed and distributed in Australia under the brand name 'Distaval' by Distillers, a British alcohol and pharmaceutical products company (Distillers was subsequently absorbed into the multinational alcoholic beverages company, Diageo, in 1997). Thalidomide was sold 'over the counter' in Australia, rather than upon prescription.

When taken during pregnancy thalidomide was found to cause severe birth defects, with approximately 40 per cent of all babies affected by thalidomide dying during their first year of life. Those who survived suffer from birth defects, which can include:

- the absence of ears, resulting in deafness;
- defects of the muscles of the eye and of the face;
- absence or underdevelopment of the arms;
- thumbs with three joints;
- defects of the femur and tibia;
- malformations of the heart, bowel, uterus and gallbladder.

Toward the end of 1961, Australian obstetrician, Dr William McBride and the German Dr Widukind Lenz separately identified the likely cause and effect relationship between thalidomide use in early pregnancy and birth defects.[1] The observation that there was a high incidence of abnormalities in babies delivered by

women who had taken thalidomide during pregnancy was reported in The Lancet in December 1961.[1]

There are conflicting reports regarding the timeline for the prohibition of the importation of thalidomide into Australia. However, there is broad agreement that it was withdrawn from the market in Australia, Germany and the United Kingdom by the end of 1961, and that Distaval was no longer available for purchase in Australia by August 1962.

The circumstances relating to thalidomide varied between countries, including the identity of the distributors, the degree of government involvement, and the timing of withdrawal from the market, which occurred some months earlier in Australia than in some other countries, including Canada and Ireland.

Since 2008 thalidomide has been authorised to be used to treat a particular type of bone marrow cancer (multiple myeloma) and it is now also authorised for the treatment of a complication of leprosy (erythema nodosum leprosum).[1] Today thalidomide is supplied under strictly controlled conditions, and with a clear warning stating that even a single dose can cause severe birth defects.[1]

The regulation of therapeutic goods in Australia

At the time that thalidomide was sold in Australia, the Commonwealth 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 attempt to ensure that therapeutic substances proposed to be imported or sold in Australia were proven to be efficacious and had undergone clinical trials or other testing to ensure that they were safe to use.

- The Commonwealth did however have the power, under Section 18 of the *Therapeutic Substances Act*, to take steps to prevent the importation and distribution of thalidomide once the Commonwealth knew that there was a problem with, or at least a health risk, associated with use of the drug.

Prior to the thalidomide experience, the safety of medicines was not monitored in Australia. However, as part of the Australian response to the thalidomide tragedy an independent committee was established to monitor the safety of new medicines as well as medicines already available.[1] The Australian Government established the Australian Drug Evaluation Committee (ADEC) in June 1963.

Subsequently the Australian Government established a Therapeutic Goods Branch within the Department of Health in 1967. The Therapeutic Goods Administration (TGA) as it now stands was formed in 1989.

The TGA today carries out a range of assessment and monitoring activities to ensure therapeutic goods supplied in Australia are of the highest standards. It provides a

national framework to ensure medicines and medical devices are safe, manufactured according to international quality standards and perform as intended.

Compensation to thalidomide survivors

The Australian Government has received a submission for compensation from Thalidomide Group Australia (a group representing approximately 35 survivors in Australia). The Government's response to this submission is that it would be the funder of last resort, and the distributor should consider options for further compensation beyond what has been provided to date.

Thalidomide survivors have previously received compensation payments from the distributors, as recently as 2010 or 2013-14.

- About 36 survivors initially received modest compensation from Distillers Company and their parents waived their rights to further compensation in the 1970s. Over 20 years between 1974 and 1994, this group shared in $3,560,383.00 from Distillers Company (at varying amounts dependent on a survivor's level of disability). This funding was provided as survivors reached 25 years of age.
- In 2010 it is understood this group of 36 (along with New Zealand survivors) negotiated a further goodwill payment from Diageo (successor to Distillers) of approximately $51 million over 18 years to be administered and distributed through the Thalidomide Australia Fixed Trust as annuity payments shared between the Australian and New Zealand thalidomide survivors (45 in total). The current component of the Australian income is understood to be $2,190,260 per annum distributed annually to the 36 Australians on a sliding scale according to level of assessed disability. This payment process ceases in 2028.
- Separately, a class action against Diageo through the Victorian Supreme Court was settled in 2014 with $89 million shared between another group of approximately 100 Australian survivors who had received no previous compensation.

Compensation has not been provided to any survivors globally from Grünenthal GmbH.

The Australian Government has supported Australia's thalidomide survivors by allowing these payments to be exempt from income tax and social security income tests.

The Australian Government is considering options to formally recognise Australia's thalidomide survivors and their families through a plaque mounted in a place of significance.

Commonwealth assistance to persons with a disability

There is a range of government benefits which could potentially be accessed by persons with a disability. Of particular relevance to Australian thalidomide survivors are the Disability Support Pension and the National Disability Insurance Scheme.

Disability Support Pension (DSP)

The DSP offers financial help in the form of a pension for persons with a permanent physical, intellectual or psychiatric condition that prohibits them from being able to work. Pension payments under the DSP depend on an individual's circumstances such as age and living conditions.

National Disability Insurance Scheme (NDIS)

The NDIS provides support for Australians under the age of 65 who have a permanent and significant disability, including people with intellectual, physical, sensory and psycho-social disabilities. The NDIS provides support related to a person's disability across a range of areas, such as education, employment, social participation, independence, living arrangements and health and wellbeing, so the person with the disability can lead a better quality and independent as possible lifestyle.

Thalidomide survivors have varying levels and types of disabilities. Access to the NDIS and DSP are dependent upon individual eligibility, however the nature of thalidomide survivors' physical and permanent impairments are likely to meet the eligibility requirements for these initiatives.

Other benefits available

Thalidomide survivors are also entitled to the rebates available to all members of the public under Medicare, and to listed pharmaceuticals through the Pharmaceutical Benefits Scheme, subject to payment of the applicable co-payment.

The amount and nature of these benefits will vary considerably depending on the medical needs of the individual, and on eligibility for other benefits, such as the DSP, which qualify them for a lower co-payment.

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[1] Australian Government – Department of Health Therapeutic Goods Administration. Fifty years of independent expert advice on prescription medicines [Internet]. Canberra, ACT: Australian Government [cited 31 August 2018]. Available from: https://www.tga.gov.au/book/fifty-years-independent-expert-advice-prescription-medicines-02