



Therapeutic Goods Amendment (Poisons Standard) Bill 2008

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Therapeutic Goods Amendment (Poisons Standard) Bill 2008

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House: House of Representatives

Portfolio: Health and Ageing

Commencement: Royal Assent

Links: The [relevant links](#) to the Bill, Explanatory Memorandum and second reading speech can be accessed via BillsNet, which is at <http://www.aph.gov.au/bills/>. When Bills have been passed they can be found at ComLaw, which is at <http://www.comlaw.gov.au/>.

Purpose

To amend the [Therapeutic Goods Act 1989](#) to address the decision of the Federal Court in [Roche Products v National Drugs and Poisons Schedule Committee](#) [2007] FCA 1352 (30 August 2007) (the Roche Products decision).

Background

Xenical (orlistat) was registered in the Australian Register of Therapeutic Goods under the *Therapeutic Goods Act 1989* (TGA) on 11 April 2000. Roche Products Pty Limited (Roche) is a sponsor of orlistat within the meaning of the TGA, a sponsor being a person who imports goods into Australia or manufactures or arranges the manufacture of goods in Australia.

Since 1 May 2004 orlistat has been able to be supplied over the counter to a consumer from a pharmacy without the need for a prescription from a medical practitioner. In February 2006 the National Drugs and Poisons Schedule Committee (the Committee) decided to include orlistat into Appendix H of the Poisons Standard, which meant in effect that orlistat could be advertised to consumers.

According to the judgement of Branson J in the Roche Products decision:

The decision to include orlistat in Appendix H was confirmed by the Committee in June 2006 and took effect from 1 September 2006. On or about 12 October 2006, following its receipt of complaints concerning the advertising of Xenical, the Committee decided to reconsider orlistat's inclusion in Appendix H. On 22 February 2007, the Committee decided to remove orlistat from Appendix H. On 26 June 2007 the Committee confirmed that decision with effect from 1 October 2007.

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At the time of the decision to ban the advertising of Xenical Roche expressed disappointment and frustration¹:

“We won’t be able to advertise yet products with dubious ingredients largely based on green tea extract, eye of newt, wing of bat and guinea pig tails can,” Mr Nadjarian said in a veiled attack on leading complementary weight loss brand, Fatblaster, which has under 3 per cent of the total market.

On 8 June 2007 Roche commenced proceedings to challenge the decisions of the Committee 12 October 2006, 22 February 2007 and 26 June 2007 under the *Administrative Decisions (Judicial Review) Act 1977* (ADJR Act) and the *Judiciary Act 1903*.

The Court held that decisions of the Committee under the relevant part of the TGA are legislative decisions, and as such are not reviewable under the ADJR, which, as its name suggests, provides for the review of administrative decisions. It is this aspect of the decision that this Bill is addressing. The Court also held, in relation to the challenge pursuant to the Judiciary Act that the decisions of the Committee were valid and the application by Roche Products was accordingly dismissed.

Part 6-3, sections 52A-52E of the TGA establish the Committee and sets out the functions of the Committee. In particular section 52D provides for the Poisons Standard and gives the Committee power to amend the Poisons Standard or prepare a new Poisons Standard and the mechanisms of how to do this. Section 52E sets out the matters the Committee must take into account when exercising its powers under section 52D.

In reaching this decision the Court quoted a passage that assists the sometimes difficult task of determining whether a decision is of an administrative or legislative character, as follows²:

In *Commonwealth v Grunseit*, Latham CJ expressed...the distinction in these terms: ‘The general distinction between legislation and the execution of legislation is that legislation determines the content of a law as a rule of conduct or a declaration as to power, right or duty, whereas executive authority applies the law in particular cases’.

There is a list of matters which can be relevant in deciding the character of decisions such as³:

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1. ‘Regulator halts ads for weight for loss drug’, *Sydney Morning Herald*, 27 February 2007, p.21.
 2. *Roche Products Pty Limited v National Drugs and Poisons Schedule Committee*[2007]FCA 1352 at paragraph 27.
 3. *ibid* at paragraph 29.

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- Whether the decisions determined rules of general application or whether there was an application of rules to particular cases.
- Whether there was Parliamentary control of the decision.
- Whether there was public notification of the making of the regulation.
- Whether there has been public consultation and the extent of any such consultation.
- Whether there were broad policy considerations imposed.
- Whether the regulations could be varied.
- Whether there was power of executive variation or control.
- Whether provision exists for merits review.
- Binding effect.

In a detailed consideration of these matters, Branson J. came to the view that decisions of the Committee fell into the ‘legislative’ side of the equation.

According to the Explanatory Memorandum⁴ to the Bill the Therapeutic Goods Administration had been relying on:

an earlier external legal advice and statements made by the Federal Court in *Pro Health Products Pty Limited v McEwen* [2004] FCA 1790 (11 October 2004) (Pro Health), which categorised and treated decisions of the Committee as administrative in character.

Roche also relied on this judgement in its submissions to the Court but Branson J. was of the view that the question of the character of a scheduling decision of the Committee was not squarely before the court, and that the decision was decided under significant time restraints so he expressly rejected the judgement⁵.

The finding that the decisions were legislative, not administrative, means that because they had not met the requirements of the *Legislative Instruments Act 2003* (the LIA), the Poisons Standard, and any amendments, may have been unenforceable. The Bill seeks to address this problem.

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4. Explanatory Memorandum, Therapeutic Goods Amendment (Poisons Standard) Bill 2008, p.1.
 5. op. cit. paragraph 38.

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This is not the only legislative amendment resulting from the Federal court's decision in *Roche*. In 13 February, the Trade Practices Amendment (Access Declarations) Bill 2008 was introduced into Parliament. That Bill proposes to make similar retrospective amendments to the Part XIC into the *Trade Practices Act 1974* (TPA) in order to ensure past declarations by the Australian Competition and Consumer Commission regarding the access regime for the telecommunications industry remain enforceable. More detail is available in the relevant [Bills Digest no.59, 2007–08](#). It is possible that more Bills across a potentially wide range of Commonwealth regulation might be introduced in the near future in reaction to the *Roche* decision.

Committee consideration

The Bill has a retrospective aspect in that it validates all previous decisions that have been made and reschedules decisions that may have been repealed. According to the Second Reading Speech⁶ the retrospective element will not add any new regulatory requirement but:

Rather, the retrospective effect of the amendments is necessary to preserve the status quo of the Poisons Standard, and amendments made to it, before the *Roche* decision.

This explanation is also present in the Explanatory Memorandum and so the Scrutiny of Bills Committee will have these matters before it at the time it considers the Bill.

Position of significant interest groups/press commentary

Pharma in Focus⁷ has reported on the Bill, outlining aspects of the Federal Court decision which has led the Government to make the amendments and stating:

The irony of the situation is that it was the NDPSC's (*the Committee's*) argument in court that caused the anomaly to arise, undermining the legal standing of its own decisions and forcing the government to step in.

It reports that the decision 'created a legal nightmare that cut the ground from under most committee decisions since 2000 and may have made the Poisons Standard itself unenforceable.'⁸

It would appear that the first Poisons Standard was inserted into the TGA in 1999 and the only Poisons Standard prepared by the Committee under paragraph 52D(2)(b) was the

6. Hon. N. Roxon, Minister for Health, Second Reading Speech, *House of Representative Debates*, 14 February 2008.

7. Pharma in Focus, *News*, 18–24 February 2008.

8. *ibid.*

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Poisons Standard registered on 19 December 2007. All other instruments before that date were amendments to the First Poisons Standard⁹.

Main provisions

Item 2 adds **new subsection 52D(4A)** to specify that an instrument amending the Poisons Standard or creating any new Poisons Standard is a legislative instrument but that the Poisons Standard (the instrument) is not disallowable by Parliament.

Item 3 adds two **new provisions** to Part 6-3 of the TGA. **New section 52EA** is to validate past registration of the Poisons Standard and instruments made amending the Poisons Standard in the past ('the instruments'), and to ensure that such instruments were not and are not disallowable by Parliament (**new subsections 52EA (1) and (2)**). It also provides that the instruments are deemed to be registered under the *Legislative Instruments Act 2003* (LIA) if they were required to be registered but were not (**new subsection 52EA(3)**) and instruments that were not lodged for registration on or before the last lodgement day under the LIA are deemed to be lodged and registered in accordance with the requirements of the LIA (**new subsection 52EA(4)**). One of the effects of failing to lodge an instrument for registration is that such an instrument is not only unenforceable it is repealed by subsection 32(2) of the LIA. The effect of the latter subsections is to make all such instruments registered and enforceable.

New section 52EB provides that if the effect of **new section 52EA** is to acquire property from a person otherwise than on just terms, the Commonwealth is liable to pay a reasonable amount of compensation to that person. In the event of disagreement as to quantum, proceedings can be commenced in the Federal Court. This provision is a constitutional safety net, and adopts the meaning of 'acquisition of property' and 'just terms' in section 51(xxxi) of the Constitution.

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9. See Explanatory Memorandum at p. 4.

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