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Amendment Bill 2002

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I N F O R M A T I O N A N D R E S E A R C H S E R V I C E S

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No. 178 2001-02

Therapeutic Goods and Other Legislation Amendment Bill
2002

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26 June 2002

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Therapeutic Goods and Other Legislation Amendment Bill 2002

Date Introduced: 21 March 2002

House: House of Representatives

Portfolio: Health and Ageing

Commencement: Most substantive provisions will commence on Royal Assent

Purpose

To attempt to secure the constitutional validity of the conferral of powers and functions on Commonwealth officers under the co-operative scheme between the Commonwealth and States in relation to therapeutic goods.

The Bill also provides for the implementation of a mutual recognition agreement between Australia and Singapore.

Background

The *Therapeutic Goods Act 1989* (the Principal Act) seeks to establish a uniform national system of controls on the availability within Australia of therapeutic goods. The system is administered by the Therapeutic Goods Administration (TGA), which is located within the Department of Health and Aged Care. The Secretary of the Department exercises the powers of the TGA.

The basic scheme of the legislation is that, unless exempt, therapeutic goods must be entered as either 'registered' goods (for example pharmaceutical benefit drugs or implantable devices) or 'listed' goods (for example over the counter medicines, vitamins) in the Australian Register of Therapeutic Goods before they may be supplied in, or exported from Australia.¹ Before goods are listed or registered they are assessed by the TGA to determine their quality, safety and conformity with relevant Australian and international standards.²

Due to constitutional limitations in the Commonwealth's power the Principal Act does not comprehensively regulate therapeutic goods. For example, the legislation does not

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generally cover activities of unincorporated manufacturers who do not trade interstate. All States and Territories have pledged to introduce legislation to produce a national scheme to overcome these deficiencies in Commonwealth power. Thus far however only New South Wales³ and Victoria⁴ have followed through on this commitment. The State legislation provides that the Commonwealth's therapeutic goods laws apply as the law of New South Wales and Victoria. Further the State laws confer on the Commonwealth officers the same functions and powers under the State law as they have under the Commonwealth legislation.

Section 6A of the Principal Act currently provides that if a corresponding State law⁵ confers a function or power on the Secretary, the Secretary may, with the written approval of the Minister, perform the function or exercise the power, as the case may be. The constitutional validity of co-operative schemes of this nature was thrown in doubt by the decision of the High Court in *R v Hughes*.⁶

Co-operative Legislative Schemes and the Constitution⁷

The idea of a national co-operative scheme is that the States will plug the constitutional gaps by:

- regulating behaviour in an identical fashion where Commonwealth legislation cannot reach, and
- conferring administrative responsibilities for the scheme on a single national body.

The *Hughes* case concerned the co-operative scheme that underpinned the corporations law. The central question in *Hughes* was whether Commonwealth law could pass a law 'consenting' to the conferral of functions and powers on its officers by State law. In particular, the High Court examined whether the Commonwealth Parliament could consent to the Western Australian *Corporations Act* conferring prosecution functions on the Commonwealth Director of Public Prosecutions.

The Court upheld the validity of the consent provisions in the Commonwealth *Corporations Act 1989* but it did so on the narrowest of grounds, consigning many future cases with just slightly different facts to the category of 'constitutionally suspect'. The legal basis for the decision in *Hughes* is that for a Commonwealth law to be valid, one must be able to point to a head of legislative power in the Constitution which supports it.

The question exposed by the litigation in *Hughes* and which now must be considered in relation to all other co-operative legislative schemes is this:

when a *Commonwealth* law states that a Commonwealth body may or must exercise a function or power conferred on it by State legislation, what head of power does it rely on?

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This seems clear and straightforward. Unfortunately, while the High Court managed to forge unanimous agreement on the outcome in *Hughes* and 6 out of 7 judges merged their reasoning into a single joint judgment, the precise implications of *Hughes* remain clouded by questions about what the Court did and did not say.

We can probably extract from the decision in *Hughes* the following propositions and implications:

1. **If a State law confers functions on a Commonwealth entity then a Commonwealth law may permit it to exercise those functions, by relying on what is called the 'incidental power'.⁸** The incidental power exists by implication in relation to most heads of power (eg trade and commerce, defence etc) as well as standing as an independent and express head of power in section 51(xxxix) of the Constitution. Basically the incidental power supplements a head of Commonwealth power, broadening it out beyond the immediate subject matter in a limited way to authorise laws which are, for example, necessary to give proper effect to the exercise of that bit of the Commonwealth's constitutional authority. An example of using the 'incidental power' might be giving the Australian Federal Police a power to investigate allegations which could lead to prosecution for a quarantine offence. The law granting such a power might not be centrally about quarantine, but it is reasonably necessary and incidental to the effective exercise of the Commonwealth's constitutional authority over quarantine matters.
2. **If, however, the Commonwealth law effectively imposes a duty on the Commonwealth entity to exercise the function or power then the search for a source of constitutional authority intensifies.** This is particularly so, perhaps, if the duty is to exercise powers 'adversely to affect the rights of individuals'.⁹ Clearly carrying out prosecutions adversely affects the rights of individuals; presumably a wide range of other official functions carried out by Commonwealth agencies under co-operative schemes would equally answer that description.
3. **It is possible that the incidental power may support a Commonwealth law which imposes such a duty.** It has been suggested in the High Court that an implied power, the 'nationhood power', might also plug the gap where no other relevant Commonwealth powers can be identified, although this is speculative and perhaps overly optimistic in the present judicial climate.
4. **Sometimes other heads of constitutional power can be readily identified as supporting a Commonwealth law imposing a duty on its officials.** *Hughes* is such a case—Mr Hughes engaged in an overseas commercial transaction and thus the DPP's prosecutorial role was authorised by the Commonwealth's powers in relation to overseas trade and commerce (section 51(i)) and external affairs (section 51(xxix)).
5. **But co-operative schemes are usually devised because it is hoped that the States can plug a perceived gap in the Commonwealth's constitutional armoury.** It seems quite likely that several co-operative schemes have a real constitutional question mark

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hanging over them after *Hughes*, specifically over the constitutional authority of Commonwealth agencies to carry out duties apparently conferred by State law and 'authorised' by Commonwealth law.

6. **The existence of a *duty* on the DPP to exercise its functions was implied rather than express in the case of *Hughes*.** The co-operative scheme involved State laws disavowing any role in corporate law offences for their own State prosecution authorities. The only prosecution authority under the co-operative scheme was the Commonwealth DPP, and this *exclusive* role seems to have been relevant to the High Court's finding that a *duty* was imposed on the DPP to carry out its prosecutorial functions under the corporations scheme. The significant thing about *Hughes* picked up in this Bill is that the High Court found that a duty was imposed there *not by State law but by the Commonwealth law* (a point further discussed below). Whether the reasoning in *Hughes* means that an absence of exclusiveness equates to the absence of a duty is unclear. If a Commonwealth law does not impose a duty but merely *permits* additional (State-conferred) functions to be exercised by a Commonwealth entity, then presumably proposition 1 (above) applies and the Commonwealth law is valid, supported by the incidental power.
7. **But even the proposition in the last sentence is complicated by a question left unanswered in *Hughes*. If a particular co-operative scheme involves a duty being imposed on a Commonwealth entity, the High Court left open whether it would have to be imposed by the Commonwealth law as a 'constitutional imperative'.¹⁰** In other words the High Court was unwilling to commit itself in *Hughes*, but may decide in future that the only legislature which can impose a duty under a co-operative scheme on a Commonwealth body is the Commonwealth Parliament. If that last possibility transpires then the constitutional situation might look like this:
 - a co-operative scheme may operate, relying on the incidental power of the Commonwealth, but only where multiple Commonwealth, State and Territory agencies retain responsibilities for its administration (thus surrendering one of the major perceived advantages of such schemes: the single national regulator)
 - any scheme which compels a single national body to assume exclusive regulatory functions can only survive constitutional scrutiny if a supporting head of Commonwealth power for its activities can be identified (thus in many cases rendering the whole idea of a co-operative scheme redundant, because the Commonwealth could have legislated to that effect without the agreement of the States).

The Commonwealth, in drafting this Bill, keeps hope alive that the possibility mentioned in proposition 7 may not transpire. In other words, it maintains the hope that the High Court will not insist that duties on Commonwealth bodies can only be imposed by Commonwealth law (ie there is no such 'constitutional imperative'). As will be seen below,

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the Bill contemplates the possibility that *State* laws may also impose duties on Commonwealth bodies.

Interpretative Statements

The High Court is the ultimate arbiter of whether a law of the Commonwealth Parliament is constitutionally valid or not. The Parliament cannot, by legislative assertion, talk its laws into being constitutionally valid if, when properly interpreted, they exceed the powers available to Parliament. Similarly, if a law is *partly* invalid, it is ultimately up to the High Court (if asked by litigating parties) to state what part survives constitutional scrutiny and what part does not.

That said, there is nothing wrong with Parliament attempting to shape the High Court's perception of these issues by inserting interpretative statements into an Act, statements which push a Commonwealth argument that a particular law is valid or has a particular constitutional impact.¹¹

Schedule 1 of the Bill:

- caters to a variety of judicial interpretations of the Therapeutic Goods scheme, based on the High Court's statements in *Hughes*, and
- attempts by expression of Parliamentary intention, to save as much of those schemes as possible from any finding of constitutional invalidity.

State Action

The Parliamentary Secretary's second reading speech states that the Government will encourage Victoria and NSW to validate past actions under the co-operative scheme.¹² In 2001 Victoria and NSW passed *Co-operative Schemes (Administrative Actions)* legislation to provide a mechanism to validate past actions undertaken by Commonwealth officers or authorities under certain State laws relating to various cooperative schemes. The legislation seeks to give actions the same effect as they would have had if they had been taken by duly authorised State officers or authorities.

The co-operative schemes legislation initially validated actions undertaken by Commonwealth officers operating under the national registration scheme for agricultural and veterinary chemicals however the legislation also provides a mechanism whereby other cooperative schemes can be dealt with by a proclamation of the Governor-in-Council.

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Main Provisions

Schedule 1: Remedying the *Hughes* problem

Item 5 of Schedule 1 repeals section 6A which purports to allow the Secretary to perform functions and powers conferred by State Law and inserts a new consent provision in the form of **proposed section 6AAA**.

The new provision is broader than existing section 6A in that it explicitly provides for the imposition of duties rather than simply functions and powers on Commonwealth officers and authorities.

The High Court's willingness to imply the existence of a duty in *Hughes* despite the absence of language to that effect puts the Commonwealth on notice that duties may be found to exist in other co-operative legislative schemes which also refrain from using the word 'duty'. If it turns out that *State* laws *can* impose such duties (an unanswered question from *Hughes*, see proposition 7 above) then to ensure validity the Commonwealth 'consent' to that conferral will need to cover duties as well functions and powers.

Proposed subsection 6AAA(2) restricts the 'consent' to the limits of the Commonwealth's power. **Proposed subsection 6AAA(3)** provides a mechanism by which the regulations can 'carve out' certain types of functions, powers or duties from the consent provisions.

Proposed section 6AAB is an interpretation provision designed to apply when a corresponding state law purports to impose a duty on a Commonwealth officer or Commonwealth authority. It caters to two possibilities:

- State legislative power is sufficient to impose the duty, and
- Commonwealth powers can support the duty but State powers can not.

In the first case **proposed subsection 6AAB(2)** provides that the duty is not to be taken as being imposed by the Commonwealth (ie by the Therapeutic Goods Act). The Commonwealth will be taken to have consented to the State imposing this duty under **proposed section 6AAA**.

However as discussed above, without deciding the issue, the High Court entertained the possibility that where a co-operative scheme imposes a duty on a Commonwealth entity, that duty must be imposed *by Commonwealth law*. **Proposed subsection 6AAB(3)** caters to the possibility that this proves to be the case. It says that if the Constitution requires that a duty be imposed by Commonwealth law then this Act expresses such an intention, to the extent necessary to secure constitutional validity. **Proposed subsection 6AAB(4)** merely confirms that in doing so the Parliament relies on the widest array of powers available to it under the Constitution.

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Proposed section 6AAC applies where the Principal Act is picked up and applied by a corresponding state law eg by the *Therapeutic Goods (Victoria) Act 1994*. In such cases **proposed subsection 6AAC(2)** provides that duties imposed on a Commonwealth officer or authority are taken to be imposed by State law to the extent that it is constitutionally permissible and within the legislative powers of the State.

Proposed subsection 6AAC(3) expresses a legislative intention that the State law does not impose a duty that is unconstitutional or outside State powers.

Where the imposition of duty would be unconstitutional, the State law is, under **proposed subsection 6AAC(4)**, to be taken as conferring a discretion rather than a duty.

A 'band aid' approach?

In the case of the Corporations Law national scheme, the Commonwealth decided to seek a referral of powers from the States under section 51(xxxvii) of the Constitution to enable it to enact the *Corporations Act 2001*¹³ rather than seek to prop up the national scheme by remedial legislation. It may be asked why the Commonwealth has decided against seeking a similar reference of power from the States in relation to therapeutic goods.

Even with the passage of this legislation it remains possible that aspects of the therapeutic goods scheme could be invalidated on *Hughes* grounds. The High Court could hold that the scheme requires the imposition of duty to act on Commonwealth officers by the Commonwealth but that the Constitution does not provide a head of power to support such legislation.

Schedule 2 Industrial Chemicals

The *Industrial Chemicals (Notification and Assessment) Act 1989* (the ICNA) established a national scheme, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), which assesses all new chemicals imported or manufactured in Australia.

The objectives of NICNAS are defined in section 3 of the ICNA and include:

- aiding in the protection of the Australian people and the environment by finding out the risks to occupational health and safety, to public health and to the environment that could be associated with the importation, manufacture or use of the chemicals
- providing information, and making recommendations, about the chemicals to Commonwealth, State and Territory bodies with responsibilities for the regulation of industrial chemicals
- giving effect to Australia's obligations under international agreements relating to the regulation of chemicals, and
- collecting statistics in relation to the chemicals.

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Currently the National Occupational Health and Safety Commission (NOHSC) supplies staff to the Director of NICNAS to implement the scheme. NOHSC is located within the Department of Employment and Work Place Relations portfolio.

Items 1-8 of schedule 2 effect changes that are consequential on the transfer of responsibility for the administration of the ICNA from Minister for Employment and Workplace Relations to the Minister for Health and Ageing. References to the National Occupational Health and Safety Commission, its Chairperson and CEO are replaced with references to the Department and the Secretary of the Department.

There may be some concern that the expertise possessed by NOHSC will be lost by the transfer however the TGA has stated that essentially the same staff will be involved in the administration of the scheme after the transfer of portfolio responsibility.¹⁴

Item 9 inserts new provisions governing financial arrangements.

Proposed section 100A establishes a ‘Special Account’ called the Industrial Chemicals Account (the Account). A ‘Special Account’ is an account established either by a determination of the Finance Minister or (as in this case) by an Act, for certain identified purposes. It is a way of setting aside money in a notional separate ledger within the Consolidated Revenue Fund for a particular purpose, and ensuring that the money is used only for those purposes.¹⁵ **Proposed section 100B** lists a range of funds that must be credited to the account, this list includes fees and charges collected under the INCA.

Items 10-12 propose amendments to the *National Occupational Health and Safety Commission Act 1985* which are consequential on the transfer of responsibility for the ICNA to the health portfolio. NOHSC will no longer have a role in making payments and providing staff for the purposes of the ICNA.

Schedule 3: Conformity Assessments

In 1997 Australia entered into a mutual recognition agreement with the European Community.¹⁶ In order to implement part of the agreement the Parliament passed the *Therapeutic Goods Amendment Act 1997*. In brief, the legislation allowed the Secretary of the Department of Health and Aged Care to accept ‘conformity assessment certificates’ issued by conformity assessment bodies in the European Community (EC). These documents state that therapeutic goods manufactured in the EC member states to which the certificates apply meet all Australian regulatory requirements relating to good quality, safety and efficacy. Acceptance of these certificates precludes the need for further evaluation or assessment of the products before they are included in the Australian Register of Therapeutic Goods and approved for general marketing.¹⁷

In 2000 the Principal Act was again amended to extend this regime to apply to members of the European Free Trade Association (EFTA) namely; Iceland, Liechtenstein and Norway.

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The amendments proposed by **schedule 3** revise the conformity assessment framework to accommodate the new mutual recognition agreement (MRAs) signed between Australia and Singapore¹⁸ as well as future MRAs.

Items 13, 15, 17 amend the assessment criteria for inclusion in the register of therapeutic goods relating to registrable therapeutic goods¹⁹, listable therapeutic devices²⁰ and listable medicines.²¹ In each case where the good or medicine is manufactured outside Australia, the Secretary of the Department of Health and Aged Care must determine whether the manufacturing and quality control procedures used in the manufacture of the goods are acceptable. Under the proposed amendments, in making this determination the Secretary may take into account an 'EC/EFTA attestation of conformity' or a 'non EC/EFTA attestation of conformity'. These terms are defined in subsection 3(1) by amendments made by **items 6 and 9**.²² The new framework gives increased flexibility to the conformity assessment process. The Minister is empowered by **new section 3B** to declare that a country is covered by a non-EC/EFTA mutual recognition agreement.

Blood Products

The Bill strengthens the ability of the Government to regulate blood products. Licences to manufacture blood or blood components will be subject to the condition that licensees comply with the requests of the Secretary for information on the steps involved in production (**new paragraph 40(4)(a)**).

Schedule 4: Conditions on Listing Therapeutic Goods

Schedule 4 amends the *Therapeutic Goods Act 1989* to allow the Minister to place conditions on the listing of goods on the Register. According to the Explanatory Memorandum²³ this will allow goods to be listed in certain circumstances such as where specified ingredients are below a certain level or where there is a warning statement.

Items 1 and 2 are identical. The inclusion of both provisions reflects uncertainty about the commencement of the *Therapeutic Goods Amendment (Medical Devices) Act 2002*²⁴ (the Medical Devices Act). That legislation repeals section 17 of the *Therapeutic Goods Act 1989*, which establishes the Australian Register of Therapeutic Goods, and replaces it with a new section 9A. The relevant provisions of the Medical Devices Act commence on Proclamation or 6 months after Royal Assent. In the event that the Medical Devices Act commences before this Bill, **item 2** will not commence at all.

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Endnotes

- 1 Following the commencement of the *Therapeutic Goods Amendment (Medical Devices) Act 2002*, the register will also include a part for medical devices included in the Register. See: [Bills Digest No. 104, 2001-2002](#) for background on this measure.
- 2 The relevant assessment criteria is listed in sections 25, 25B-26A. Schedules 3 and 4 of the *Therapeutic Goods Regulations 1990* specify whether goods required to be included in the register should be classified as 'listed' or 'registered'.
- 3 In the form of the *Poisons and Therapeutic Goods Act 1966 (NSW)* and the *Poisons and Therapeutic Goods Regulations 1994 (NSW)*.
- 4 In the form of the *Therapeutic Goods (Victoria) Act 1994*
- 5 The NSW and Victorian legislation are declared to be 'corresponding state laws' by the *Therapeutic Goods Regulations 1990 (Cth)*.
- 6 (2000) 171 ALR 155.
- 7 This section on the constitutional issues raised by the *Hughes* case draws substantially on Sean Brennan, Agricultural and Veterinary Chemical Legislation Bill 2001, [Bills Digest No.133, 2000-01](#)
- 8 *R v Hughes* (2000) 171 ALR 155 pp. 163/164.
- 9 *ibid.*, at pp. 167/168.
- 10 *ibid.*, at p. 164
- 11 An example of such a provision is found in section 15A of the *Acts Interpretation Act 1901* which states:

Every Act shall be read and construed subject to the Constitution, and so as not to exceed the legislative power of the Commonwealth, to the intent that where any enactment thereof would, but for this section, have been construed as being in excess of that power, it shall nevertheless be a valid enactment to the extent to which it is not in excess of that power.
- 12 The Hon P. Worth, 'Therapeutic Goods and Other Legislation Amendment Bill 2002', Second Reading Speech, House of Representatives, *Hansard*, 21 March 2002, p. 1847.
- 13 Background on the referral of powers can be found in [Bills Digest No.140 2000-01](#).
- 14 This information is based on a briefing provided to author by officers of the TGA.
15. The 'Special Account' provisions in the *Financial Management and Accountability Act 1997* provide that when an amount of money is appropriated for the purposes of the Special Account, that money is set aside within the Consolidated Revenue Fund and can only be spent for those purposes. All funds appropriated and amounts spent are deemed to have gone into or come from the Special Account which notionally exists within the Consolidated Revenue Fund. See sections 20 and 21 of the *Financial Management and Accountability Act 1997*.

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- 16 Agreement on Mutual Recognition in Relation to Conformity Assessment, Certificates and Markings between Australia and the European Community.
- 17 Therapeutic Goods Amendment Bill 1997, Senator the Hon. Ian Campbell, *Second Reading Speech*, Senate Hansard 26/3/1997, p. 2465.
- 18 This mutual recognition agreement was examined by the Joint Committee on Treaties in 2001. See <http://www.aph.gov.au/house/committee/jsct/Reports/Report39/report%2039.pdf>
- 19 This includes all prescription drugs and implantable therapeutic devices. A summary of the classification of therapeutic goods is available at the following link:
<http://www.health.gov.au/tga/docs/pdf/summary.pdf>
- 20 Eg Over the counter medicines.
- 21 This includes predominantly over-the-counter drugs, herbal preparations and vitamins that are described in schedule 4 of the Therapeutic Goods Regulations. Where such products are supplied for use in Australia section 26A applies. Listable drugs that are exported from Australia must be processed under section 26 along with listable therapeutic devices.
- 22 They replace the term ‘conformity assessment certificate’ which is used in the current mutual recognition regime.
- 23 p. 19.
- 24 The Medical Devices Act restructures the *Therapeutic Goods Act 1989* into Chapters and Parts. It changes a number of headings and cross-references in the Act. The Register will continue to exist although the sections dealing with it will be grouped together in a new Chapter 2 and renumbered.

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