Department of Health and Ageing
2005-06 Regulatory Plan

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Explanatory Note

The Department of Health and Ageing, like other Australian Government agencies which have responsibility for business regulation, is required to publish a regulatory plan on its web site early in each financial year.

The regulatory plan deals with changes within the Department's area of responsibility and contains information about:

- changes to business regulation which have occurred since the beginning of the previous financial year (1 July 2004 to 30 June 2005); and
- activities planned in the current financial year (1 July 2005 to 30 June 2006) which could lead to changes to business regulation.

What regulation does a regulatory plan cover?

A regulatory plan covers business regulation. This includes primary legislation, subordinate legislation, quasi-regulation or treaties that directly affect business, have a significant indirect effect on business, or restrict competition.

Quasi-regulation refers to rules or arrangements where governments influence businesses to comply, but which do not form part of explicit government regulation.

A regulatory plan does not include information about the following:

- regulations of a minor or machinery nature that do not substantially alter existing arrangements;
- regulations that involve consideration of specific government purchases;
- regulations of a state or self-governing territory that apply in a non-self governing territory; and
- anticipated activity about which it would be inappropriate to publish information on grounds of confidentiality.

In addition, there may be regulatory activities that have not been included in the regulatory plan because they could not be foreseen when the plan was prepared at the start of the financial year.

In view of these exclusions, users should not take a regulatory plan to be a comprehensive source of information on past or potential changes to business regulation.

How up to date is information in this regulatory plan?

This plan was last updated on 30 January 2006.

Past Regulatory Activity

Department of Health and Ageing

Title	**National Health Amendment Regulations 2004**
Description of issue	Established performance indicators for the private health insurance industry.
Date of effect	1 July 2004
Contact details	Neil Smith Private Health Insurance Branch Department of Health and Ageing Ph: (02) 6289 9434 E-mail: neil.smith@health.gov.au

Title	***Private Health Insurance Incentives Amendment Act 2005***
Description of issue	Increased the private health insurance rebate to 35% for people aged 65 to 69 years and to 40% for people aged 70 years and over.
Date of effect	1 April 2005
Contact details	Neil Smith Private Health Insurance Branch Department of Health and Ageing Ph: (02) 6289 9434 E-mail: neil.smith@health.gov.au

Title	***Health Legislation Amendment (Australian Community Pharmacy Authority) Act 2005***
Description of issue	Amended the *National Health Act 1953* to provide for the pharmacy location rules, and their administration by the Australian Community Pharmacy Authority, to remain in effect until 31 December 2005. It also made a technical amendment to correct a misdescription in the *Health Legislation Amendment (Podiatric Surgery and Other Matters) Act 2004.*
Date of effect	26 June 2005
Contact details	Kim Richter Pharmaceutical Access and Quality Branch Department of Health and Ageing Ph: (02) 6289 8195 E-mail: kim.richter@health.gov.au

Title	**National Health (Pharmaceutical Benefits) (Application to supply pharmaceutical benefits following the death of approved pharmacist – documentary evidence) Determination 2005**
Description of issue	Determined the documentary evidence which must accompany an application by a person who is, or likely to become, an executor or administrator of the estate of a deceased approved pharmacist, to supply PBS medicines.
Date of effect	24 January 2005
Contact details	Kim Richter Pharmaceutical Access and Quality Branch Department of Health and Ageing Ph: (02) 6289 8195 E-mail: kim.richter@health.gov.au

Title	**Determination under subsection 99L(1) of the *National Health Act 1953,* No. PB 14 of 2004**
Description of issue	Prevented pharmacies which are directly accessible from within supermarkets

	from being approved to supply PBS medicines.
Date of effect	12 August 2004
Contact details	Kim Richter Pharmaceutical Access and Quality Branch Department of Health and Ageing Ph: (02) 6289 8195 E-mail: kim.richter@health.gov.au

Title	**Determination under subsection 99L(1) of the *National Health Act 1953*, No. PB 14 of 2005**
Description of issue	Prevented pharmacies which are directly accessible from within supermarkets from being approved to supply PBS medicines (previous determination ceased to have effect after 30 June 2005).
Date of effect	1 July 2005
Contact details	Kim Richter Pharmaceutical Access and Quality Branch Department of Health and Ageing Ph: (02) 6289 8195 E-mail: kim.richter@health.gov.au

Title	**Rules for the location of pharmacies approved to supply pharmaceutical benefits**
Description of issue	The pharmacy location rules are determined by the Minister under section 99L of the *National Health Act 1953* and will currently cease to have effect after 31 December 2005 in accordance with Division 4B. Depending on the outcomes of a review of the rules a new determination will be made by the Minister.
Date of effect	1 January 2005
Contact details	Kim Richter Pharmaceutical Access and Quality Branch Department of Health and Ageing Ph: (02) 6289 8195 E-mail: kim.richter@health.gov.au

Title	***National Health Amendment (Prostheses) Act 2005***
Description of issue	Amended the *National Health Act 1953* to require health funds to provide no gap cover for the cost of appropriate, clinically necessary prostheses and medical devices for each Medicare Benefits Schedule (MBS) admitted to hospital procedure.
Date of effect	21 March 2005
Contact details	Jen Nixon Private Health Insurance Branch Department of Health and Ageing Ph: (02) 6289 9850 E-mail: jen.nixon@health.gov.au

Title	**Health Legislation Amendment (Podiatric Surgery and Other Matters) Bill 2004**
Description of issue	Enabled registered health benefits organisations to pay benefits for accommodation and nursing associated with procedures performed on admitted patients by accredited podiatrists from their hospital tables. It also enabled a person who was, or was likely to become, an executor or administrator of the estate of a deceased approved pharmacist to supply medicines subsidised under the pharmaceutical benefits scheme at or from the deceased pharmacist's approved premises, and receive payment for that supply. It included a provision for day surgeries to provide Hospital Casemix Protocol

	data to the Department of Health and Ageing. It also made some minor updates and technical amendments.
Date of effect	13 July 2004
Contact details	Peter Callanan Private Health Insurance Branch Department of Health and Ageing Ph: (02) 6289 9840 E-mail: peter.callanan@health.gov.au

Title	**Medical Indemnity Legislation Amendment (Run-off Cover Indemnity and Other Measures) Bill 2004** **Medical Indemnity (Run-off Cover Support Payment) Bill 2004**
Description of issue	Implemented a Run-off Cover Scheme (ROCS) to indemnify doctors when they cease private medical practice and expand the Exceptional Claims Scheme (ECS) to include some overseas treatment. Imposed a Run-off Cover Support Payment on medical indemnity insurers to fund the ROCS. Expanded the ECS to include some overseas treatment.
Date of effect	ROCS provisions 1 July 2004. ECS provisions 5 December 2003 consistent with commencement of ECS legislation.
Contact details	Susan Rogers Medical Indemnity Branch Department of Health and Ageing Ph: (02) 6289 9246 E-mail: susan.rogers@health.gov.au

Title	**Medical Indemnity Amendment Regulations 2004** **Medical Indemnity (Run-off Cover Support Payment) Regulations 2004**
Description of issue	Implemented aspects of the Run-off Cover Scheme (ROCS) which provides indemnity to cover claims against doctors when they cease private medical practice and to expand the Exceptional Claims Scheme (ECS) indemnity to some overseas events. Implemented the Run-off Cover Support Payment which imposes 8.5% tax on medical indemnity insurers of a proportion of premium income to fund the ROCS (9.5625% for United Medical Protection (UMP)). Sets UMP Support Payment imposition day of 1 November each year for UMP members as UMP operates on a calendar year basis.
Date of effect	ROCS provisions 1 July 2004. ECS provisions 5 December 2003 consistent with commencement of ECS legislation.
Contact details	Susan Rogers Medical Indemnity Branch Department of Health and Ageing Ph: (02) 6289 9246 E-mail: susan.rogers@health.gov.au

Title	***Medical Indemnity Legislation Amendment Act 2005***
Description of issue	Addressed a number of anomalies and unintended consequences in current legislation.

Date of effect	21 March 2005
Contact details	Susan Rogers Medical Indemnity Branch Department of Health & Ageing Ph: (02) 6289 9246 E-mail: susan.rogers@health.gov.au

Title	**Changes to *Health Insurance Act 1973* to restore restrictions on access to Medicare for assistance at operations for overseas-trained doctors**
Description of issue	Changes that came into effect on 18 October 2001 varied the *Health Insurance Act 1973* to allow all overseas-trained doctors to access Medicare for assistance at operations. This included procedures in metropolitan areas. Overseas-trained doctors are normally required under restrictions in the *Health Insurance Act 1973* to work in rural and remote districts of workforce shortage if they wish to access Medicare benefits for services provided. Prior to this change, the only overseas-trained doctors able to access Medicare benefits were those on occupational trainee visas who were required as part of their training courses to assist at operations. However, a number of doctors on ordinary medical practitioner visas took advantage of this change to work in metropolitan areas. The changes, which came into effect in 2001, allowed this anomaly to occur. The legislative change benefited rural and remote communities by requiring those doctors who have taken advantage of the anomaly to relocate from metropolitan areas.
Date of effect	21 April 2004
Contact details	Jeanette Hill-Burgess Health Workforce Branch Department of Health and Ageing Ph: (02) 6289 7999 E-mail: jeanette.hill-burgess@health.gov.au

Title	**Determination under subsection 98B(1)(a) of the *National Health Act 1953***
Description of issue	This determination affected the annual indexation of the dispensing fee paid to pharmacists for the supply of ready-prepared and extemporaneously prepared pharmaceutical benefits.
Date of effect	1 July 2004
Contact details	Brenda White Pharmaceutical Access and Quality Branch Department of Health and Ageing Ph: (02) 6289 8984 E-mail: brenda.white@health.gov.au

Title	**Determination under subsection 84C(7) of the *National Health Act 1953***
Description of issue	This determination affected the allowable additional amounts which pharmacists can charge for pharmaceutical benefits less than the patient contribution, as agreed with the Pharmacy Guild.
Date of effect	1 August 2004
Contact details	Brenda White Pharmaceutical Access and Quality Branch Department of Health and Ageing Ph: (02) 6289 8984 E-mail: brenda.white@health.gov.au

Title	**Determination under subsection 84HA(1) of the *National Health Act 1953***
Description of issue	This determination affected the fee paid to pharmacists for the issue of a concession/entitlement card.
Date of effect	1 January 2005
Contact details	Brenda White Pharmaceutical Access and Quality Branch Department of Health and Ageing Ph: (02) 6289 8984 E-mail: brenda.white@health.gov.au

Title	**Amendment to the National Health (Pharmaceutical Benefits) Regulations 1960**
Description of issue	The definition of an approved pharmacist was amended in accordance with the amendments which were made under the Health Legislation Amendment (Podiatric Surgery and Other Matters) Bill 2004. Following legal advice, this amendment was not a necessity however it will remove any uncertainty.
Date of effect	16 December 2004
Contact details	Brenda White Pharmaceutical Access and Quality Branch Department of Health and Ageing Ph: (02) 6289 8984 E-mail: brenda.white@health.gov.au

Title	**Determination under subsection 91(2) of the *National Health Act 1953* (relates to provisions proposed under the Health Legislation Amendment (Podiatric Surgery and Other Matters) Bill 2004)**
Description of issue	This determination set out the documentary evidence required in order for the Secretary to make a decision in respect of an application to permit a person, in the event that an approved pharmacist dies, to continue to supply pharmaceutical benefits and to receive payment for that supply.
Date of effect	24 February 2005
Contact details	Brenda White Pharmaceutical Access and Quality Branch Department of Health and Ageing Ph: (02) 6289 8984 E-mail: brenda.white@health.gov.au

Title	**Ministerial Determinations (under subsection 3C of the *Health Insurance Act 1973)***
Description of issue	The Ministerial Determinations created new Medicare items under the Medicare Benefits Schedule to allow benefits to be payable for certain allied health and dental services on referral by a GP. Allied health professionals and dental practitioners providing services under this measure are required to register with Medicare Australia.
Date of effect	1 July 2004
Contact details	Kathy Trembath General Practice Programs Branch Department of Health and Ageing Ph: (02) 6289 7829 E-mail: kathy.trembath@health.gov.au

Title	**World Health Organization proposed Framework Convention on Tobacco Control**
Description of issue	The World Health Organization (WHO) developed the Framework Convention on

	Tobacco Control (FCTC) which aims at developing international consensus on measures to contain the health, social and economic costs of tobacco use. Australia was actively involved in negotiations on the convention and attended all six negotiating sessions, with the final session held in February 2003.
Date of effect	27 February 2005
Contact details	Penny Marshall Drug Strategy Branch Department of Health and Ageing Ph: (02) 6289 7688 E-mail: penny.marshall@health.gov.au

Title	**Amendments to Health Insurance (General Medical Services Table) Regulations 2003 – Rural Other Medical Practitioners (ROMPs) Program**
Description of issue	The Rural Other Medical Practitioners (ROMPs) Program was introduced in January 2001. The Program is implemented through Schedule 1, Part 2, paragraph 3(3)(a) and paragraph 3(4)(a) of the Health Insurance (General Medical Services Table) Regulations 2003. This Program provided patients with access to the higher A1 Medicare rebate for services provided in rural or remote areas under the Rural, Remote and Metropolitan Areas (RRMA) classification by non-vocationally recognised medical practitioners who express an interest in achieving vocational recognition. Through the enhancements to the Medicare package, announced on 10 March 2004, the Government agreed to extend certain general practice workforce programs, including the ROMPs Program, to "areas of consideration". The areas of consideration included RRMA 1-2 locations. The regulations restricted eligibility of areas under the Program to RRMA 3-7 locations.
Date of effect	1 July 2004
Contact details	Ms Tuija Uotila GP Programs Branch Department of Health and Ageing Ph: (02) 6289 3645 E-mail: tuija.uotila@health.gov.au

Title	**Amendments to Health Insurance (General Medical Services Table) Regulations 2003 – The Pre-vocational General Practice Placements Program**
Description of issue	On 18 November 2003, the Australian Government announced changes to Medicare. One of the initiatives included in the announcement was the Pre-vocational General Practice Placements Program (the Program), designed to provide junior doctors with an opportunity to undertake a supervised general practice placement in outer metropolitan, regional, rural and remote areas. The Program encouraged doctors to take up general practice, particularly in these areas. The proposed Regulations amended the definition of "general practitioner" in the Rules of Interpretation contained in Part 2 of Schedule 1 to the Principal Regulations, in order to expand the current definition of "general practitioner" to include medical practitioners in the Program. The purpose of the proposed regulations was to allow services provided by a medical practitioner who undertook a placement in general practice as part of the Program, to attract the full Medicare rebate, being the same rate as that for services provided by practitioners who are vocationally registered under Section 3F of the Act.

Date of effect	1 July 2004
Contact details	Ms Tuija Uotila GP Programs Branch Department of Health and Ageing Ph: (02) 6289 3645 E-mail: tuija.uotila@health.gov.au

Title	**Amendments to Health Insurance Regulations 1975 – The Pre-vocational General Practice Placements Program**
Description of issue	On 18 November 2003, the Australian Government announced changes to Medicare. One of the initiatives included in the announcement was the Pre-vocational General Practice Placements Program (the Program), designed to provide junior doctors with an opportunity to undertake a supervised general practice placement in outer metropolitan, regional, rural and remote areas. The Program encouraged doctors to take up general practice, particularly in these areas. The proposed regulations included the Program in Part 2 of Schedule 5 to the Principal Regulations specified the Program for the purposes of the Register of Approved Placements. The proposed regulation included three bodies in Part 2 of Schedule 5 to the Principal Regulations for the purpose of separately administering approved placements under the Program. The administering bodies are the Australian College of Rural and Remote Medicine, the Royal Australian College of General Practitioners and General Practice Education and Training Ltd.
Date of effect	1 July 2004
Contact details	Ms Tuija Uotila GP Programs Branch Department of Health and Ageing Ph: (02) 6289 3645 E-mail: tuija.uotila@health.gov.au

Title	***Aged Care Amendment (Transition Care and Assets Testing) Act 2005***
Description of issue	This Act incorporated two sets of amendments to the *Aged Care Act 1997* ("the Act"). The first set of amendments introduced a number of measures to enable the Secretary of the Department of Health and Ageing to conduct assets assessments for new residents entering aged care homes and to delegate this power. Under the previous arrangements, assets assessments were undertaken by an approved provider at the time a person entered residential care. Approved providers could claim concessional resident supplement or assisted resident supplement, based on assets information provided by a resident at the time of entry. The new arrangements provide a process by which the Secretary of the Department of Health and Ageing is able to determine the value of a person's assets and their eligibility for concessional resident status or assisted resident status. It also enables the Secretary to delegate this power to the CEO of the Service Delivery Agency (Centrelink) and to the Secretary of the Department of Veterans' Affairs. Providers have been relieved of the administrative burden of conducting assessments. Residents are better placed to make decisions about their care needs because they will have greater certainty about their financial situation prior to entry. There was a 12-month transitional period, during which approved providers continued to undertake assets assessments in certain circumstances. This avoided delays for people seeking to enter care immediately and also avoided having a high volume of assessments to be completed at commencement. This Act also provided leave arrangements for existing recipients of residential care to receive transition care (a type of flexible aged care) following a hospital stay.
Date of effect	1 July 2005
Contact details	Stephen Dellar Residential Program Management Branch Department of Health and Ageing Ph: (02) 6289 5500 E-mail: stephen.dellar@health.gov.au

Therapeutic Goods Administration Group of Regulators

Title	**Industrial Chemicals (Notification and Assessment) Amendment Regulations 2005 [No 1]**
Description of issue	The Regulation increased the New Chemical assessment fees and charges for the National Industrial Chemicals Notification and Assessment Scheme for 2005-06 by 3.63% rounded to the nearest dollar.
Date of effect	1 July 2005
Contact details	Nick Miller Business Management and Communication National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8810 E-mail: nick.miller@nicnas.gov.au

Title	**Industrial Chemicals (Notification and Assessment) Amendment Regulations 2004 [No 239]**
Description of issue	The Industrial Chemicals (Notification and Assessment) Amendment (Low Regulatory Concern Chemicals) Act 2004, made a number of changes to the Act. These have a bearing on the Industrial Chemicals (Notification and Assessment) Regulations 1990 with regard to the definition of synthetic polymer of low concern to be replaced by a new definition of polymer of low concern.
Date of effect	6 August 2004
Contact details	Bob Graf Reform National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8850 E-mail: bob.graf@nicnas.gov.au

Title	***Industrial Chemicals (Notification and Assessment) Amendment (Rotterdam Convention) Act 2004***
Description of issue	Amendments to the *Industrial Chemicals (Notification and Assessment) Act 1989* were made to enable implementation of the obligations of the Rotterdam Convention. Amendments were required to enhance the information gathering powers of the Director and to facilitate information exchange and provision of information on domestic regulatory actions to the Secretariat and other parties to the Convention.
Date of effect	18 August 2004 (day on which the Rotterdam Convention entered into force for Australia).
Contact details	Sneha Satya Review and Treaties National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8880 E-mail: sneha.satya@nicnas.gov.au

Title	**Industrial Chemicals (Notification and Assessment) Amendment Regulations 2004 [No 246]**
Description of issue	To meet Australia's obligations under the Rotterdam Convention in relation to exports, it was proposed that the Regulations be amended to provide that specific chemicals cannot be exported without prior authorisation from National Industrial Chemicals Notification and Assessment Scheme.
Date of effect	18 August 2004 (day on which the Rotterdam Convention entered into force for Australia).
Contact details	Sneha Satya Review and Treaties National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8880 E-mail: sneha.satya@nicnas.gov.au

Title	**Industrial Chemicals (Notification and Assessment) Amendment Regulations 2004 [No 388]**
Description of issue	The Regulation amended the fees for self-assessment and permit renewals under the National Industrial Chemicals Notification and Assessment Scheme.
Date of effect	23 December 2004
Contact details	Bob Graf Reform National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8850 E-mail: bob.graf@nicnas.gov.au

Title	**Therapeutic Goods (Excluded Goods) Order No. 1 of 2004**
Description of issue	An amendment to the 1998 Excluded Goods Order to remove any products that fit the definition of a medical device under the new regulatory system implemented on 4 October 2002.
Date of effect	4 October 2004
Contact details	Rita Maclachlan Office of Devices, Blood and Tissues Therapeutic Goods Administration Ph: (02) 6232 8700 E-mail: rita.maclachlan@health.gov.au

Planned Regulatory Activity

Department of Health and Ageing

Title	**The Health Legislation Amendment Bill (No _) 200_ (relates to the *Health and Other Services (Compensation) Act 1995*)**
Description of issue	Proposed amendments to the *Health and Other Services (Compensation) Act 1995* (HOSC Act) to clarify the legislation's original intent and repeal section 33AA. This program is administered by Medicare Australia and recovers all Medicare and residential care benefits paid to a claimant in the event of a successful compensation settlement from a personal injury case. The proposed amendment to the legislation will clarify the original intent of the legislation and repeal section 33AA which will allow a continuation of the Advanced Payment Option beyond 1 July 2006.
Expected timetable	Drafting has not yet begun.
Contact details	Mark Burness Medicare Benefits Branch Department of Health and Ageing Ph: (02) 6289 7015 E-mail: mark.burness@health.gov.au
Date last modified	July 2005

Title	**Notification of amendments to the Hearing Services Rules of Conduct 2000**
Description of issue	The Rules of Conduct under the *Hearing Services Administration Act 1997* set out the requirements for contracted providers of hearing services in their dealings with voucher holders under the Commonwealth Hearing Services Voucher System. They include the qualification requirements of persons registered to practice in the Voucher System. There may be changes to Part 3 of the Hearing Services Rules of Conduct 2000 concerning the rules about qualifications for hearing health practitioners who provide services to eligible clients under the Hearing Services Voucher System. The changes will be necessitated by the outcome of a review of the regulation professional qualification requirements of the Hearing Services Program.
Consultation opportunities	The review is to be conducted by an independent organisation and will include consultation with all stakeholder groups.
Expected timetable	The review is to be completed by January 2006. The timing of changes will be dependent on Ministerial approval of a revised framework.
Contact details	Judi Sutton Office of Hearing Services Department of Health and Ageing Ph: (02) 6289 5411 E-mail: judi.sutton@health.gov.au
Date last modified	21 July 2005

Title	**Review of health warnings on tobacco products in Australia as specified under the Trade Practices (Consumer Product Information Standards) (Tobacco) Regulations**
Description of issue	A review of health warnings on tobacco products commenced in 2000. The review was an action identified under the previous National Tobacco Strategy 1999 - 2004 as a measure to strengthen public awareness of the harm caused by tobacco use. The review of health warnings was conducted jointly by the

	Department of Treasury and the Department of Health and Ageing, with the assistance of a technical advisory group. The review was completed in August 2004, with the amended Trade Practices (Consumer Product Information Standards) (Tobacco) Regulations gazetted on 26 August 2004. The ACCC, in consultation with the Department are presently drafting further amendments to the regulations.
Consultation opportunities	The general public and key stakeholders, including the public health lobby and the tobacco industry, have been consulted at various stages of the review. Consultation to date includes: • the release in May 2001 of a discussion paper for public comment; • a meeting in August 2003 with tobacco industry representatives outlining the government proposal for new health warnings; • meetings in late 2003 involving the Department and industry representatives; • meetings in late 2003 involving the Parliamentary Secretary and industry representatives; • the release in February 2004 of an initial Regulation Impact Statement; • the release in May 2004 of a revised Regulation Impact Statement; • a one day presentation in May 2005 to Australian tobacco manufacturers and importers on the application of the health warnings to tobacco products retailed in Australia; and • the release of an exposure draft of the revised amendments to tobacco product manufacturers and importers in June 2005.
Expected timetable	All tobacco products are expected to display the new health warnings from 1 March 2006.
Contact details	Penny Marshall Drug Strategy Branch Department of Health and Ageing Ph: (02) 6289 9321 E-mail: penny.marshall@health.gov.au
Date last modified	28 June 2005

Title	**Proposed amendments to the *Food Standards Australia New Zealand Act 1991***
Description of issue	Since the implementation of the new bi-national food regulatory system in 2001, it has become apparent that there are a number of areas in which the food regulatory process may be streamlined and clarified, while protecting public health and safety. In order to address the areas of concern, it will most likely be necessary to amend the *Food Standards Australian New Zealand Act 1991* (FSANZ Act). However, if simpler mechanisms are identified in the implementation process, these will be considered. The proposed amendments to the FSANZ Act will seek to: • eliminate unnecessary duplication of regulations; • streamline the food regulatory process; • improve the clarity and consistency of the operations of Food Standards Australia New Zealand (FSANZ); and • in some cases, to implement recommendations of the Senior Officials Working Group report on the new food regulatory system, as endorsed by the Council of Australian Governments (COAG).

	In summary the proposed amendments seek to: • grant the Australian Government Minister for Health the power to implement a national food recall in an emergency situation (as endorsed by COAG); • harmonise the setting of Maximum Residue Levels in foods by FSANZ and the Australian Pesticides and Veterinary Medicines Authority; • improve alignment of the standard setting processes of FSANZ with the policy development processes of the Australia New Zealand Food Regulation Ministerial Council; • allow FSANZ to partially approve applications, rather than having to reject an entire application where there is a problem with only one part; and • allow exemptions from the requirement to undertake consultation in both Australia and New Zealand where a draft food standard will only apply in one country.
Consultation opportunities	Public consultation on the proposed amendments is planned for November 2005. Submissions are invited from all interested individuals or organisations. Consultation documents, including a Regulation Impact Statement, will be available to the public on the Food Regulation Secretariat website at: http://www.foodsecretariat.health.gov.au/ A range of consumer, industry and public health organisations will be contacted directly about the consultation process. Individuals or organisations that wish to be contacted regarding the consultation process may contact the Food Regulation Secretariat on (02) 6289 4073, to be added to the stakeholder list.
Expected timetable	It is expected that the amendment bill will be introduced to Parliament in the Autumn 2006 sitting.
Contact details	Catherine Gay Food and Healthy Living Branch Department of Health and Ageing Ph: (02) 6289 5133 E-mail: catherine.gay@health.gov.au
Date last modified	July 2005

Title	**Review of the *Gene Technology Act 2000***
Description of issue	The *Gene Technology Act 2000* states that the Gene Technology Ministerial Council must cause an independent review of the operation of the Act, including the structure of the Office of the Gene Technology Regulator, to be undertaken as soon as possible after the fourth anniversary of the commencement of the Act.
Consultation opportunities	A first call for submissions was initiated in May 2005 with submissions due 15 July 2005. It is expected that issues papers will be released in October 2005 followed by national consultations in October-November 2005.
Expected timetable	The review is to commence as soon as possible after 21 June 2005 and the report is to be tabled in both Houses of Parliament by 21 June 2006.
Contact details	Elizabeth Flynn Review Secretariat Department of Health and Ageing Ph: (02) 6289 4571 Email: elizabeth.flynn@health.gov.au
Date last modified	20 July 2005

Title	**National Health Amendment (Fourth Community Pharmacy Agreement) Bill 2005**

Description of issue	Will amend the *National Health Act 1953* to implement measures contained in the Fourth Community Pharmacy Agreement between the Commonwealth and the Pharmacy Guild of Australia
Expected timetable	Proposed to have effect from 1 January 2006.
Contact details	Kim Richter Pharmaceutical Access and Quality Branch Department of Health and Ageing Ph: (02) 6289 8195 E-mail: kim.richter@health.gov.au
Date last modified	20 July 2005

Title	**Amendment to Division 4B of the *National Health Act 1953***
Description of issue	Division 4B provides for the Minister to determine rules regulating the location of pharmacies approved to supply PBS medicines and gives effect to the Australian Community Pharmacy Authority (ACPA) and provides for their functions and administration. This Division will cease to have effect after 31 December 2005. Changes to Division 4B will depend on the outcome of a review of the location rules.
Expected timetable	Must receive Royal Assent by 31 December 2005.
Contact details	Kim Richter Pharmaceutical Access and Quality Branch Department of Health and Ageing Ph: (02) 6289 8195 E-mail: kim.richter@health.gov.au
Date last modified	July 2005

Therapeutic Goods Administration Group of Regulators

Title	**Industrial Chemicals (Notification and Assessment) Amendment Regulations 2005 [No _]**
Description of issue	The purpose of the Regulation is to list Tetra ethyl lead and Tetra methyl lead in regulations relating to s106 of the *Industrial Chemicals (Notification and Assessment) Act 1989* to give effect to Australia's obligations under the Rotterdam Convention. No specific Regulatory Impact Statement (RIS) for regulations as changes to the *Industrial Chemicals (Notification and Assessment) Act* and regulations to be made under "the Act" were covered in the RIS prepared during the ratification process.
Consultation opportunities	Opportunities for public comment provided via National Interest Analysis and RIS during ratification process.
Expected timetable	December 2005
Contact details	Sneha Satya Review and Treaties National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8880 E-mail: sneha.satya@nicnas.gov.au
Date last modified	July 2005

Title	**Proposed Therapeutic Goods Order (TGO) No. 71 – Tamper-Evident Packaging of Therapeutic Goods**
Description of issue	TGO 71 will adopt the document *Code of Practice for the Tamper-evident Packaging (TEP) of Therapeutic Goods* (Edition 1, June 2003), published by the Therapeutic Goods Administration on behalf of the Industry Government Crisis Management Committee, as a standard for therapeutic goods in Australia.
Expected timetable	This Order is expected to come into effect in Australia from 1 July 2006, with a one-year transition period during which sponsors should ensure full compliance.
Contact details	Rita Maclachlan Office of Devices, Blood and Tissues Therapeutic Goods Administration Phone: (02) 6232 8700 E-mail: rita.maclachlan@health.gov.au
Date last modified	July 2005

Title	**Industrial Chemicals (Notification and Assessment) Amendment Regulations 2005 [No _]**
Description of issue	The purpose of the Regulation is to amend the current regulation for Octabromobiphenyl and decabromobiphenyl to cover import aspects under the Rotterdam Convention.
Expected timetable	December 2005
Contact details	Sneha Satya Review and Treaties National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8880 E-mail: sneha.satya@nicnas.gov.au
Date last modified	July 2005

Title	**Review penalties and improve comprehensibility of the *Industrial Chemicals (Notification and Assessment) Act 1989***
Description of issue	The low regulatory concern chemicals reform initiative identified a range of issues, which require regulatory amendment. While the majority of these reforms are contained in the Industrial Chemicals (Notification and Assessment) Amendment (Low Regulatory Concern Chemicals) Bill 2004, a number of issues

	remain outstanding. The review will also consider the current range of penalties and offences under the Act and address anomalies and improve comprehensibility.
Consultation opportunities	Public consultation on the proposed changes occurred in September 2004.
Expected timetable	December 2005
Contact details	Bob Graf Reform National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8850 E-mail: bob.graf@nicnas.gov.au
Date last modified	July 2005

Title	**Industrial Chemicals (Notification and Assessment) Amendment Regulations 2006 [No _]**
Description of issue	A number of regulations are required for ongoing implementation of Low Regulatory Concern Chemicals (LRCC) reforms. No specific Regulatory Impact Statement (RIS) for regulations is required as it is covered in the RIS prepared for the LRCC amendments to the *Industrial Chemicals (Notification and Assessment) Act 1989.*
Consultation opportunities	Via NICNAS Industry Government Consultative Committee and established engagement strategies.
Expected timetable	February 2006
Contact details	Bob Graf Reform National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8850 E-mail: bob.graf@nicnas.gov.au
Date last modified	July 2005

Title	**Industrial Chemicals (Notification and Assessment) Amendment Regulations 2006 [No _]**
Description of issue	Various amendments to reflect any agreed outcomes of the current review of Existing Chemicals Program that requires legislative change. A Regulatory Impact Statement will form part of the process.
Consultation opportunities	Via a RIS to be prepared as part of the review.
Expected timetable	June 2006
Contact details	Bob Graf Reform National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8850 E-mail: bob.graf@nicnas.gov.au
Date last modified	July 2005

Title	**NICNAS new chemicals – approved foreign schemes**
Description of issue	The *Industrial Chemicals (Notification and Assessment) Act 1989* provides for recognition of approved foreign schemes (section 43) and use of an assessment report generated under the approved foreign scheme (section 44). The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) participated in the OECD New Chemicals program which included work-sharing activities designed to assist in harmonisation of assessments, new chemicals notification procedures and reporting. The work aims to reduce regulatory burden for industry and governments, while maintaining health and environmental standards. Bilateral arrangements between national new

	chemicals regulators are encouraged under the program. NICNAS has finalised such an arrangement with Environment Canada and is working towards recognition of the Canadian scheme as an approved foreign scheme under the legislation.
Consultation opportunities	Through the Industry Government Consultative Committee and with key industry stakeholders initially during 2002-03 and the Low Regulatory Concern Chemcials (LRCC) consultation process in 2003-04.
Expected timetable	Bilateral Arrangement with Canada – signed late 2002 renewed August 2004. Recognition of Canadian Scheme – estimated June 2006. Other foreign scheme activities ongoing.
Contact details	Bob Graf Reform National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8850 E-mail: bob.graf@nicnas.gov.au
Date last modified	July 2005

Title	**Proposed consequential amendments to the *Industrial Chemicals (Notification and Assessment) Act 1989***
Description of issue	Consequential amendments to the *Industrial Chemicals (Notification and Assessment) Act 1989* are proposed to give effect to the changed administrative arrangements arising from the establishment of the Trans-Tasman Agency on 1 July 2006.
Expected timetable	1 July 2006
Contact details	Alice Creelman Trans Tasman Group Therapeutic Goods Administration Ph: (02) 6232 8189 E-mail: alice.creelman@health.gov.au
Date last modified	July 2005

Title	**Conformity Assessment Standards Order No 1 of 2005 – Amendment to Conformity Assessment Standards Order No 1**
Description of issue	Specifies the quality management standards for manufacturing medical devices requiring conformity assessment and in particular, quality assurance techniques for medical devices supplied in a sterile state. This Standards Order will be amended to include references to the new ISO 13485-2003 which replaces the previous ISO 13485-1996.
Expected timetable	Order expected to be made and registered in the Federal Register of Legislative Instruments in October 2005.
Contact details	Rita Maclachlan Office of Devices, Blood and Tissues Therapeutic Goods Administration Ph: (02) 6232 8700 E-mail: rita.maclachlan@health.gov.au
Date last modified	July 2005

Title	**Medical Device Standards Order – Sterilants and Disinfectants for Medical Devices**
Description of issue	Proposed standards for sterilants and disinfectants for medical devices.
Expected timetable	Due to be completed by December 2005.
Contact details	Rita Maclachlan Office of Devices, Blood and Tissues Therapeutic Goods Administration Ph: (02) 6232 8700 E-mail: rita.maclachlan@health.gov.au
Date last modified	July 2005

Title	Therapeutic Goods Amendment Bill 2005
Description of issue	The Amendment Bill proposes a new suite of regulatory sanctions under the *Therapeutic Goods Act 1989* which includes higher level penalties with specified aggravating circumstances, strict liability provision with aggravating circumstances, civil penalty, enforceable undertaking, infringement notices and extension of liability to executive officers. The Bill also includes amendments to provisions relating to the release of information and a minor amendment to the advertising provisions to remove a regulatory requirement.
Expected timetable	The Bill is currently being drafted and is proposed to be introduced in the Spring sittings 2005.
Contact details	Ms Terry Lee Legal Services Group Therapeutic Goods Administration Ph: (02) 6232 8230 E-mail: terry.lee@health.gov.au
Date last modified	July 2005

Title	Development and implementation of a Trans-Tasman regulatory scheme for therapeutic products
Description of issue	Therapeutic goods have a special exemption under the Trans-Tasman Mutual Recognition Arrangement (TTMRA). The TTMRA seeks to lessen regulatory and trade barriers between Australia and New Zealand. To resolve the special exemption, which must be renewed each year, the Australian and New Zealand Governments have agreed by means of a treaty to establish a Trans-Tasman Therapeutic Goods Agency to harmonise therapeutic goods regulation between both countries. The move towards a single market for therapeutic goods, with a common regulatory system, will facilitate trade and reduce compliance costs for industry. The agency will assume the role of the Therapeutic Goods Administration in Australia and Medsafe in NZ for ensuring the quality, safety, efficacy and timely availability of therapeutic products manufactured or supplied in Australia and/or New Zealand or exported from the Australia/New Zealand market. The regulatory activities of the agency will include pre-market assessment or evaluation, product licensing, post-market surveillance, licensing of manufacturers, setting of standards and communicating decisions and information. The agency will provide staff and services in Australia for the Gene Technology Regulator and in the area of chemical safety.
Consultation opportunities	Australian and New Zealand officials have developed the agency proposals in consultation with a range of stakeholder groups, including industry and consumer representatives and professional associations, over the past three years. A discussion paper, 'A Proposal for a Trans-Tasman Agency to Regulate Therapeutic Products' was issued in June 2002 for comment. Further meetings followed with major interest groups to refine the proposals and to develop the operational detail. Public consultation also occurred on the Treaty. As part of a communication strategy for the project, a web site www.jtaproject.com keeps stakeholders informed of progress. An exposure draft of the legislation that establishes the agency will be released for consultation before legislation is introduced.

Expected timetable	Exposure drafts of legislation – late 2005 Legislation introduced – early 2006 Legislation passed – mid 2006 Agency commences operations in 2006
Contact details	Alice Creelman Joint Agency Establishment Group Therapeutic Goods Administration Ph: (02) 6232 8189 E-mail: alice.creelman@health.gov.au
Date last modified	July 2005

Title	**Amendments to Quarantine Proclamation to require permits for commercial quantities of human blood and blood components**
Description of issue	This measure involves removing the current exemption under the Quarantine Proclamation for human blood and blood products intended for human therapeutic use. The effect of the amendment will be to make human blood or blood products in commercial quantities prohibited biological materials unless a permit to import them has been granted under s28 of the Quarantine Proclamation. A new permit will be required for each act of importation. The purpose of this requirement will be to ensure that the source of each shipment of blood is checked before permission is granted for its importation.
Consultation opportunities	Consultation has occurred with relevant stakeholders, including CSL Limited, the Australian Red Cross Blood Service, peak industry associations, the AMA, the Society of Hospital Pharmacists of Australia, the Fertility Society of Australia and the Australian Bone Marrow Registry.
Expected timetable	Implementation early 2006.
Contact details	Glenn Smith Office of Devices, Blood and Tissues Therapeutic Goods Administration Ph: (02) 6232 8291 E-mail: glenn.smith@health.gov.au
Date last modified	July 2005

Title	**Amendment to the Therapeutic Goods (Medical Devices) Regulations 2002**
Description of issue	An amendment to the Medical Devices regulations to implement the new regulatory framework for *In vitro* diagnostic devices.
Consultation opportunities	This proposal has been agreed to by the Australian Health Ministers' Conference and the Australian Health Ministers' Advisory Council. There has been ongoing consultation with stakeholders including industry, professional bodies and consumers since 2003.
Expected timetable	Proposed date of implementation early 2006
Contact details	Rita Maclachlan Office of Devices, Blood and Tissues Therapeutic Goods Administration Ph: (02) 6232 8700 E-mail: rita.maclachlan@health.gov.au
Date last modified	July 2005

Title	**Included as part of the trans Tasman Joint Agency legislation, the implementation of a new regulatory framework for tissues, cellular therapies and emerging biological therapies.**
Description of issue	A new regulatory framework for tissues, cellular therapies and emerging biological therapies.
Consultation	Two rounds of public consultation with all States and Territories followed by

opportunities	ongoing consultation with key professional groups.
Expected timetable	Proposed date of implementation 1 July 2006.
Contact details	Rita Maclachlan Office of Devices, Blood and Tissues Therapeutic Goods Administration Ph: (02) 6232 8700 E-mail: rita.maclachlan@health.gov.au
Date last modified	July 2005

Title	**New Therapeutic Goods Order 73 Standards for Haematopoietic Progenitor Cells (HPCs) Derived from Cord Blood. (TGO 73)**
Description of issue	TGO 73 prescribes the Netcord and the Foundation of the Accreditation of Cell Therapy (FACT) document *International Standards for Cord Blood Collection, Processing, Testing, Banking, Selection and Release (*2nd Edition, July 2001) as the standard for HPCs derived from cord blood.
Consultation opportunities	The Australian HPC sector support the Netcord/FACT standard as the preferred standard. The adoption of the standard was recommended by the Therapeutic Goods Committee, a statutory committee established under the Therapeutic Goods Regulations.
Expected timetable	Proposed date of implementation early 2006.
Contact details	Rita Maclachlan Office of Devices, Blood and Tissues Therapeutic Goods Administration Ph: (02) 6232 8700 E-mail: rita.maclachlan@health.gov.au
Date last modified	July 2005

Title	**Office of Gene Technology Regulator - review of guidelines for certification of facilities/physical containment requirements**
Description of issue	Certain dealings with genetically modified organisms (GMOs) may be conducted in laboratories and other facilities if those facilities comply with containment conditions that are set out in guidelines issued by the Regulator. The containment conditions manage risks to human health and safety and the environment associated with the performance of dealings with GMOs inside laboratories and other facilities. A review of the relevant guidelines by the Regulator in 2002 identified a range of technical improvements to the guidelines that are necessary or desirable to ensure that they more effectively manage risks to human health and safety and the environment associated with dealings with GMOs that may be conducted in them. As a result, the Regulator has implemented a process to amend the guidelines in those areas where the need for improvement has been identified.
Consultation opportunities	In the coming period revised guidelines are expected to be released for public comment in respect of certification of: • laboratories to physical containment level PC3; and • large scale containment facilities to physical containment level PC 1 and PC 2. Copies of the draft revised guidelines are expected to be sent to key stakeholders and all accredited organisations. Revised guidelines for aquaria physical containment level PC 2, arthropod physical containment level PC 2 and Drosophila physical containment level PC 2 are expected to be issued in the near future.
Expected timetable	Following consideration of public comments on the draft revised guidelines; the

	Regulator is expected to issue new guidelines before the end of 2005.
Contact details	Ian Coleman Licence and Application Management Section Office of Gene Technology Regulator Ph: 1800 181 030 Web site: www.ogtr.gov.au E-mail: ogtr@health.gov.au
Date last modified	June 2005

Title	**Office of Gene Technology Regulator – review of guidelines for accreditation of organisations conducting dealings with genetically modified organisms**
Description of issue	Draft Revised Guidelines for Accreditation were prepared in the first half of 2004. These guidelines are intended to improve, streamline and simplify the June 2001 version of the guidelines which set out core criteria for organisations and for the establishment and maintenance of Institutional Biosafety Committees by organisations that propose to conduct dealings with GMOs.
Consultation opportunities	Draft guidelines were released for comment from December 2004 until March 2005.
Expected timetable	Final guidelines are expected to be issued by the Gene Technology Regulator before the end of 2005.
Contact details	Ian Coleman Licence and Application Management Section Office of Gene Technology Regulator Ph: 1800 181 030 Web site: www.ogtr.gov.au E-mail: ogtr@health.gov.au
Date last modified	July 2005

Title	**Office of the Gene Technology Regulator – review of the Gene Technology Regulations 2001**
Description of issue	After more than three years of operational experience the Gene Technology Regulator has identified aspects of the Regulations that require re-examination and has initiated a review to address these issues.
Consultation opportunities	The Gene Technology Regulator has sought feedback from Institutional Biosafety Committees (IBCs) regarding potential amendments that, while consistent with the object of the *Gene Technology Act 2000*, would improve their effectiveness, efficiency and clarity. The final draft of the proposed amended regulations will be circulated for public comment in the second half of 2005.
Expected timetable	It is anticipated that the proposed regulations will be operational by the end of 2005 or early 2006.
Contact details	Matt Lemm or Will Tucker Policy, Communication Secretariat Office of the Gene Technology Regulator Ph. 1800 181 030 Web site: www.ogtr.gov.au E-mail: ogtr@health.gov.au
Date last modified	July 2005

Title	**Office of the Gene Technology Regulator – review of the *Gene Technology Act 2000***
Description of issue	Section 194 of the *Gene Technology Act 2000* (the Act) stipulates that the Ministerial Council for Gene Technology must cause an independent review of the operation of the Act, including the structure of the Office of the Gene Technology Regulator (OGTR), as soon as possible after the fourth anniversary of commencement of the Act. The Act states that the review must be undertaken by people the Ministerial Council agrees possess appropriate qualifications and

	include people who are not employed by the Commonwealth or a Commonwealth authority.
Consultation opportunities	The independent panel appointed by the Ministerial Council to conduct the review has called for submissions addressing the Terms of Reference.
Expected timetable	The report is due to be tabled in each House of Parliament by 21 June 2006.
Contact details	Elizabeth Flynn Department of Health and Ageing Ph: (02) 6289 4571 E-mail: elizabeth.flynn@health.gov.au
Date last modified	July 2005