Department of Health and Ageing
2003-04 Regulatory Plan

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 2002 to 30 June 2003); and
- activities planned in the current financial year (1 July 2003 to 30 June 2004) 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 22 August 2003.

Past Regulatory Activity

Department of Health and Ageing

Title	Research involving human embryos and prohibition of human cloning
Description of Issue	The Research Involving Embryos and Prohibition of Human Cloning Bill 2002 was introduced into Federal Parliament on 27 June 2002. The Bill was developed to implement the 5 April 2002 Council of Australian Governments' (COAG) decision that all jurisdictions would enact nationally consistent legislation to ban human cloning and other unacceptable practices, and regulate research involving embryos created by assisted reproductive technology (ART) that are no longer needed by the couple for whom they were created and would otherwise be destroyed.
Consultation Opportunities	The legislation to ban human cloning and establish a new regulatory regime was developed by the National Health and Medical Research Council (NHMRC) in consultation with the COAG Implementation Working Group (CIWG) – which contains representatives of Premiers/Chief Ministers Departments and health authorities from all jurisdictions - and with the NHMRC's principal committees, experts in related fields and interested parties in all capital cities, with the aim of implementing the 5 April 2002 COAG decision. The NHMRC also took account of submissions made to the House of Representatives Standing Committee on Legal and Constitutional Affairs during a two-year inquiry prior to the release of its report entitled 'Human Cloning: scientific ethical and regulatory aspects of human cloning and stem cell research' (August 2001).
Timetable	On 27 June 2002, the Prime Minister introduced the Research Involving Embryos and Prohibition of Human Cloning Bill 2002 into the House of Representatives. On 21 August, the Bill was referred to the Senate Community Affairs Legislation Committee, which presented its report to the President of the Senate on 24 October 2002. Following extensive debate in both Houses of Parliament, the *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002* were passed on 11 December 2002 (the original Bill having been split into two parts during the House of Representatives debate) and became law in Australia on 19 December 2002. The *Prohibition of Human Cloning Act 2002* comprehensively prohibits human cloning and a range of other unacceptable practices relating to assisted reproductive technology (ART) and contains strong penalties for non-compliance. The *Research Involving Human Embryos Act 2002* establishes a strict licensing system to regulate the use of excess ART embryos. The legislation establishes a new Principal Committee of the NHMRC, the NHMRC Licensing Committee, and contains conditions that must be satisfied prior to obtaining a licence to use an excess ART embryo. The NHMRC Licensing Committee will administer both pieces of legislation.

Contact Details	Nicholas Duell Executive, Policy & Communications National Health and Medical Research Council Ph: (02) 6289 9426 E-mail: nicholas.duell@nhmrc.gov.au
Date Last Modified	21 August 2003

Title	Amendments to referral arrangements for diagnostic imaging services funded through Medicare
Description of Issue	Amendments to the *Health Insurance Act 1973* have implemented the recommendations arising from the Diagnostic Imaging Referral Arrangements Review. Specifically, the amendments have: • introduced an accountable substitution model for diagnostic imaging services, which enables the imaging service provider to substitute a more appropriate imaging service when a patient is referred to the service provider for an inappropriate diagnostic imaging service; • excluded services requiring referral by a specialist from being performed without a referral, by radiologists as an additional necessary service; • extended to all service providers prohibitions against stationing diagnostic imaging equipment or employees at the premises of another practitioner so that diagnostic imaging services may be rendered (these measures only previously applied to radiologists); and • exempted the above prohibition for services in defined areas of need as defined in the regulations.
Date of Effect	Legislation was introduced into Parliament on 11 December 2002. The Bill received Royal Assent on 15 April 2003, and the new requirements took effect on 1 July 2003.
Contact Details	Samantha Robertson Diagnostics and Technology Branch Department of Health and Ageing Ph: (02) 6289 7315 E-mail: samantha.robertson@health.gov.au
Date Last Modified	14 August 2003

Title	Introduction of registration requirements for diagnostic imaging and radiation oncology premises and mobile facilities
Description of Issue	Amendments to the *Health Insurance Act 1973* require the registration of premises that render diagnostic imaging procedures and radiation oncology services for Medicare benefits to be payable and the allocation of Location Specific Practice Numbers (LSPNs) to registered sites.

	The information collected through registration and the use of LSPNs will assist the Government, in conjunction with the diagnostic imaging and radiation oncology professions, to better manage and monitor the provision of these services under Medicare. The requirement to apply and maintain registration lies with the proprietor operating the diagnostic imaging or radiation oncology services at the premises or mobile facility. Medical practitioners are responsible for including a LSPN on accounts, receipts and direct billing assignment forms so that patients can claim Medicare benefits. The detail of information included under the registration requirements is included in the Health Insurance Regulations 1975.
Date of Effect	Legislation was introduced into Parliament on 11 December 2002. The Bill received Royal Assent on 15 April 2003, and the new requirements took effect on 1 July 2003.
Contact Details	Samantha Robertson Diagnostics and Technology Branch Department of Health and Ageing Ph: (02) 6289 7315 E-mail: samantha.robertson@health.gov.au
Date Last Modified	14 August 2003

Title	Recognition of osteopaths as a professional group under the *Health Insurance Act 1973*
Description of Issue	Amendments to the *Health Insurance Act 1973* now recognise osteopaths as a separate professional group to chiropractors and have the effect of allowing osteopaths to request diagnostic imaging services.
Date of Effect	Legislation was introduced into Parliament on 11 December 2002. The Bill received Royal Assent on 15 April 2003.
Contact Details	Samantha Robertson Diagnostics and Technology Branch Department of Health and Ageing Ph: (02) 6289 7315 E-mail: samantha.robertson@health.gov.au
Date Last Modified	14 August 2003

Title	Health and Ageing Legislation Amendment Bill 2003
Description of Issue	The Bill includes the following measures: • gives express power to the Secretary to suspend, rather than cancel, an approval to supply pharmaceutical benefits; and • makes explicit the Minister's discretion to suspend, rather than cancel, an approval to supply pharmaceutical benefits by dispensing doctors and hospital authorities.

Date of Effect	June 2003.
Contact Details	Catherine Farrell Pharmaceutical Access and Quality Branch Department of Health and Ageing Ph: (02) 6289 8984 E-mail: catherine.farrell@health.gov.au

Title	Ministerial Determination (under subsection 99L (1) of the *National Health Act 1953*) PB 9 of 2002
Description of Issue	The Third Community Pharmacy Agreement (2000-2005) between the Australian Government and the Pharmacy Guild of Australia sets out the arrangements for the location of pharmacies approved to supply pharmaceutical benefits. These arrangements provided for an incremental and targeted easing of the pharmacy location restrictions, together with the introduction of provisions aimed at improving access to pharmaceutical benefits for people in rural and remote Australia.
Date of Effect	Ministerial Determination PB 9 of 2002, an amendment to Ministerial Determination PB 8 of 2000, was published in Gazette No 25 on 26 June 2002 and took effect from 1 July 2002.
Contact Details	Catherine Farrell Pharmaceutical Access and Quality Branch Department of Health and Ageing Ph: (02) 6289 8984 E-mail: catherine.farrell@health.gov.au

Title	Ministerial Determination (under subsection 99L (1) of the *National Health Act 1953*) PB 15 of 2002
Description of Issue	The Third Community Pharmacy Agreement (2000-2005) between the Australian Government and the Pharmacy Guild of Australia sets out the arrangements for the location of pharmacies approved to supply pharmaceutical benefits. These arrangements provided for an incremental and targeted easing of the pharmacy location restrictions, together with the introduction of provisions aimed at improving access to pharmaceutical benefits for people in rural and remote Australia. Subsequent to the amending Determination PB 9 of 2002, an anomaly was identified which was inconsistent with the provisions set out in the Third Agreement. A minor amendment to the Determination was required to correct the anomaly.
Date of Effect	Ministerial Determination PB 15 of 2002, an amendment to Ministerial Determination PB 8 of 2000, was published in Gazette No 45 on 13 November 2002 and took effect immediately upon gazettal.
Contact Details	Catherine Farrell Pharmaceutical Access and Quality Branch Department of Health and Ageing Ph: (02) 6289 8984

	E-mail: catherine.farrell@health.gov.au

Title	Changes to the Health Insurance (General Medical Services Table) Regulations 2001
Description of Issue	The changes are associated with the implementation of the Outer Metropolitan (Other Medical Practitioners) Relocation Incentive Program (Program). This Program was announced as part of the More Doctors for Outer Metropolitan Areas Measure in the 2002-03 Budget. The area of the regulation affected is Schedule 1 of the Health Insurance (General Medical Services Table) Regulations 2001. The specific amendment is to the definition of 'eligible non-vocationally recognised medical practitioner'. The purpose of the regulatory change is to allow doctors in the Program to claim Medicare A1 rebates once they have relocated from an inner metropolitan area to an outer metropolitan area of workforce shortage. The Program is also applicable to eligible doctors already practising in outer metropolitan areas of workforce shortage.
Date of Effect	4 November 2002
Contact Details	Bronwen Dowse Workforce and Quality Branch Department of Health and Ageing Ph: (02) 6289 3120 E-mail: bronwen.dowse@health.gov.au
Date Last Modified	15 August 2003

Title	Private Health Insurance Levy Bills 2003 and National Health Amendment (Private Health Insurance Levies) Bill 2002
Description of Issue	These Bills removes any constitutional doubt in relation to four extant private health insurance industry levies by re-imposing them in compliance with section 55 of the Constitution.
Consultation Opportunities	The action was taken in response to concerns raised by the Australian Nation Audit Office Report 'Management of Commonwealth Non-Primary Levies'. Industry and key stakeholders have already been consulted in relation to this proposed legislation.
Expected Timetable	This package of legislation was passed by Parliament on 26 June 2003 and received Royal Assent on 15 July 2003. Regulations consequential to these Acts will be made before 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
Date Last Modified	18 August 2003

Title	Review of *Health Legislation Amendment Act (No 1) 2001* as specified under Section 5E of the *National Health Act 1953*
Description of Issue	Section 5E of the *National Health Act 1953* (the Act), inserted by the outreach services legislation *(Health Legislation Amendment Act (No 1) 2001)* requires that an independent review of the operation of the outreach legislation be undertaken and a report be tabled in both Houses of Parliament by 30 June 2003.
Consultation Opportunities	Industry and key stakeholders were consulted as part of the review.
Expected Timetable	The report was tabled in both Houses of Parliament on 30 June 2003.
Contact Details	Julie Marr Hospitals Branch Department of Health and Ageing Ph: (02) 6289 9825 E-mail: julie.marr@health.gov.au
Date Last Modified	18 August 2003

Title	Establishment of the National Blood Authority to provide a national management framework for the Australian blood and blood products sector
Description of Issue	Establishment of the National Blood Authority to coordinate and manage Australia's blood supply to ensure that supply levels are sufficient to meet Australian demand.
Consultation Opportunities	Extensive consultations with stakeholders were conducted by the Review of the Australian Blood Banking and Plasma Product Sector, completed on 3 June 2001. Stake holders consulted included: • Australian Red Cross Blood Service; • Therapeutic Goods Administration; • CSL Limited; • National Health and Medical Research Council; • National Institute of Clinical Studies; • Pharmaceutical Benefits Advisory Committee • Australian Council for Safety and Quality in Health Care • Pharmaceutical Benefits Pricing Authority; • Medical Services Advisory Committee; • Haemophilia Foundation Australia; and • other pharmaceutical industry players. In developing an implementation strategy for the Review's recommendations, including the establishment of a National Blood Authority, consultations have been held with relevant stakeholders.

Expected Timetable	Legislation to establish the National Blood Authority was introduced into Parliament on 11 December 2002. The National Blood Authority was established on 1 July 2003.
Contact Details	Robin Boyce Blood Organ and Tissue Policy and Financing Department of Health and Ageing Ph: (02) 6289 8888 E-mail: robin.boyce@health.gov.au
Date Last Modified	18 August 2003

Title	Health Legislation Amendment (Private Health Industry Measures) Bill 2002
Description of Issue	The Bill includes the following measures: • enables health funds to offer discounts for payments made quarterly; • enables the Minister to approve Employee Health Benefits Schemes when the Scheme is part of a Certified Agreement; • enables the Health Insurance Commission (HIC), consumers and the Department to access a range of information from health funds; and • transfers responsibility for Billing Agents from the Private Health Insurance Administration Council to the HIC.
Date of Effect	This Bill received Royal Assent on 8 October 2002.
Contact Details	Neil Smith Private Health Industry Branch Department of Health and Ageing Ph: (02) 6289 9434 E-mail: neil.smith@health.gov.au

Title	Health Insurance Commission Amendment Regulations 2002 (No 2)
Description of Issue	This regulation has the effect of requiring the Health Insurance Commission (HIC) to maintain a Register (consisting of two parts): GPs eligible to participate in the *Better Outcomes in Mental Health Care* initiative (Part A); and GPs permitted to provide Focussed Psychological Strategies services as part of the *Better Outcomes in Mental Health Care* initiative (Part B). To be eligible to participate, GPs must be registered with the HIC. The General Practice Mental Health Standards Collaboration (GPMHSC) notifies the HIC of GPs eligible to participate, based on GPs demonstrating to the GPMHSC that they have the appropriate mental health skills. The GPMHSC is the body responsible for setting skills and training standards.
Date of Effect	1 November 2002
Contact Details	Paul McGlew

	General Practice Access Branch Department of Health and Ageing Ph: (02) 6289 8647 E-mail: paul.mcglew@health.gov.au

Therapeutic Goods Administration

Title	Changes to *Industrial Chemicals (Notification and Assessment) Act 1989* and regulations regarding the definition of synthetic polymers of low concern in relation to assessment of industrial chemicals
Description of Issue	The legislative amendments extend the definition of synthetic polymers of low concern to include more low hazard polymers, including certain polyesters of low molecular weight. This reduces the fees and data requirements from industry as these polymers currently attract a full examination fee, while their chemical composition and level of risk are consistent with similar polymers of low concern.
Date of Effect	The Act came into effect on October 2001. The regulations came into effect on March 2002
Contact Details	Bob Graf New Chemicals Assessment 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 Act (No 1) 2003*
Description of Issue	Reform of the commercial evaluation permit category will ensure that all sectors in the chemical industry can access a fast, low-cost permit to commercially evaluate new industrial chemicals.
Consultation Opportunities	Consultation with industry stakeholders took place in 2000-01, with a period of public comment and consultation in 2001-02. A Regulation Impact Statement was prepared in 2002. The final report was released in February 2003.
Date of Effect	The Bill received Royal Assent on 15 July 2003.
Contact Details	Bob Graf New Chemicals Assessment National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8850 E-mail: bob.graf@nicnas.gov.au
Date Last Modified	18 August 2003

Title	*Industrial Chemicals (Notification and Assessment) Amendment Act (No 1)*

	2003
Description of Issue	Proposals were developed in response to the formal evaluation of the company registration program in 2000, with the aim of streamlining administration and delivering reform. Areas of change include: • introduction of late fees into the Act and regulations and the alignment of the annual renewal deadline with the registration expiry date; and • moving the fee setting power from the Act into the regulations to take into account consumer price indexing and allow greater flexibility in adjusting fees to fully recover costs in administering the Act and regulations. Costing arrangements under the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) were reviewed with an activity based costing model using 2001-02 data. It was determined that New Chemical activities were under-recovered, Australian Inventory of Chemical Substances (AICS) searches were a significant cost burden on NICNAS and there was insufficient company registration funding for remaining activities.
Consultation Opportunities	Extensive consultations took place in relation to the proposed changes. All key stakeholders, including industry associations and registered companies, were consulted. Results of the activity-based costing model were presented to the Industry Government Consultative Committee (IGCC) in the form of a proposal for increased fees and charges at the November 2002 meeting. Subsequently a draft Regulation Impact Statement was prepared and presented to IGCC for comment in January.
Date of Effect	The Bill received Royal Assent on 15 July 2003.
Contact Details	Eileen Tso Compliance National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8832 E-mail: eileen.tso@nicnas.gov.au 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	Changes to the *Industrial Chemicals (Notification and Assessment) Act 1989* to put into effect the new Administrative Arrangements Order
Description of Issue	Changes were required to reflect the new Administrative Arrangements Order dated 26 November 2001, under which portfolio responsibility for the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) moved from the then Minister for Employment, Workplace Relations and Small Business to the Minister for Health and Ageing. Under the amendments, the Department of Health and Ageing, rather than the National Occupational Health and Safety Commission, will supply staff to the Director of NICNAS to implement the *Industrial Chemicals (Notification and*

	Assessment) Act 1989.
Date of Effect	The Bill came into effect on 3 July 2002.
Contact Details	Deborah Willcocks Existing Chemicals Assessment National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8890 E-mail: deborah.willcocks@nicnas.gov.au

Title	*Therapeutic Goods Amendment (Medical Devices) Act 2002*
Description of Issue	A new medical device regulatory scheme that is internationally accepted best practice. This Act was passed by Parliament on 21 March 2002. It improves medical device safety and brings Australia into line with international best practice by adopting the global regulatory model for medical devices based on the principles of the Global Harmonisation Task Force. Medical device safety will be improved under the new framework, as all devices will have to meet quality, safety and performance requirements for the protection of patients and users.
Date of Effect	Schedule 1 – 4 October 2002. Schedule 2 – 5 years after schedule 1
Contact Details	Rita Maclachlan Conformity Assessment Branch Therapeutic Goods Administration Ph: (02) 6232 8700 E-mail: rita.maclachlan@health.gov.au

Title	Therapeutic Goods and Other Legislation Amendment Bill 2002
Description of Issue	New provisions to: • Address constitutional issues raised by the High Court's decision in *R v Hughes* (provisions to enable persons, other than the Secretary of the Department of Health and Ageing (the Secretary) and delegates of the Secretary, to exercise powers and functions under State laws). • Give effect to the transfer of portfolio responsibilities for the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) to the Health and Ageing portfolio. • Enable Mutual Recognition Agreements (MRA) with Singapore and other countries to be implemented. The amendments will allow the Secretary to accept conclusions of Good Manufacturing Practice (GMP) inspections and manufacturing certificates issued from Singapore as evidence that the manufacturing processes employed in Singapore in the manufacture of medicines that are exported to Australia meet with Australian requirements. The Minister may declare other countries with which Australia may have a MRA, similar to the MRA with Singapore, to be countries from which certificates of GMP will be accepted.

	• Enable the Secretary to obtain information about blood or blood component manufacturing processes to monitor the manufacturer's compliance with new standards for blood, and new manufacturing standards for the manufacture of blood and blood products. • Clarify when the Secretary may recover the balance of evaluation fees, payable for the evaluation of registrable medicines that are, in the main, prescription medicines, owing for evaluation work that has that has been completed by the Therapeutic Goods Administration. • Allow the Minister, when determining what therapeutic goods may be treated as 'listable' goods for the purposes of being entered into the Australian Register of Therapeutic Goods, to impose conditions for the treatment of those goods as listable goods.
Date of Effect	3 July 2002
Contact Details	Rita Maclachlan Conformity Assessment Branch Therapeutic Goods Administration Ph: (02) 6232 8700 E-mail: rita.maclachlan@health.gov.au

Title	Therapeutic Goods Amendment Regulations 2002 (No 3) Statutory Rule 2002 No 143
Description of Issue	Amends Schedule 9 and Regulation 45 to increase annual fees and discounted fees.
Date of Effect	1 July 2002
Contact Details	Michel Lok Business and Services Branch Therapeutic Goods Administration Ph: (02) 6232 8216 E-mail: michel.lok@health.gov.au

Title	Therapeutic Goods (Charges) Amendment Regulations 2002 (No 4) Statutory Rule 2002 No 144
Description of Issue	Sets the level of charges chargeable by the Therapeutic Goods Administration for maintaining registrations and listings in the Australian Register of Therapeutic Goods for the period 1 July 2002 to 30 June 2003.
Date of Effect	1 July 2002
Contact Details	Michel Lok Business and Services Branch Therapeutic Goods Administration Ph: (02) 6232 8216 E-mail: michel.lok@health.gov.au

Title	Therapeutic Goods Order No 66A

Description of Issue	Therapeutic Goods Order No. 66A – Standards for Blood Components – amends the existing Therapeutic Goods Order No 66 by updating the edition of a key reference document that prescribes the minimum standard to be met by blood and blood components in Australia. Specifically, it requires that blood and blood components must meet the requirements of the Council of Europe document titled 'Guide to the preparation, use and quality assurance of blood components' 8th edition.
Date of Effect	17 July 2002
Contact Details	Albert Farrugia TGA Laboratories Branch Therapeutic Goods Administration Ph: (02) 6232 8539 E-mail: albert.farrugia@health.gov.au

Title	*Therapeutic Goods (Charges) Act 1989*
Description of Issue	Annual charges flowing from the new medical device regulatory scheme. This Act was passed by Parliament on 21 March 2002. As a consequence of the Therapeutic Goods Amendment (Medical Devices) Bill 2002, the *Therapeutic Goods (Charges) Act 1989* has been amended to provide for annual charges to be imposed in respect of medical devices 'included in the Register'.
Date of Effect	4 October 2002.
Contact Details	Rita Maclachlan Conformity Assessment Branch Therapeutic Goods Administration Ph: (02) 6232 8700 E-mail: rita.maclachlan@health.gov.au

Title	*Therapeutic Goods Amendment Act (No 1) 2003* (previously Therapeutic Goods Amendment Bill (No 2) 2002)
Description of Issue	Contains the following measures: (i) Increase in maximum penalties for a range of existing offences under the Act where there has been a failure to comply with standards, false statements made in applications for entry of goods on the Register, breach of conditions of a manufacturing licence, false statements made in a conformity assessment declaration and the counterfeiting of therapeutic goods. (ii) New offences for falsification of any document that has been created, retained or issued for the purposes of the Act and for supplying goods originating from a manufacturer or manufacturing site that has not been notified to the Secretary of the Department of Health and Ageing. (iii) Expansion of the compulsory public notification and recall provisions

	which may be used where there is a problem with a product or its manufacture. (iv) Insertion of a 'fit and proper person' test into the provisions for granting a manufacturing licence or conformity assessment certificate and suspending or revoking a manufacturing licence or conformity assessment certificate. (v) New statutory conditions of licence to ensure compliance with manufacturing principles and reporting of adverse effects known to a manufacturer. (vi) Requirement for sponsors of therapeutic goods to maintain records of all manufacturers involved in the manufacture of each batch of therapeutic goods and have them available for inspection at any time. (vii) Provision for better identification of therapeutic goods in the event of a recall or where a sponsor applies for re-entry of previously cancelled goods on to the Register. (viii) Adverse event reporting for listed goods. (ix) Amend the definition of 'therapeutic goods' to enable s.7 Determination to be made that will allow therapeutic goods to be regulated as such, and not as food. (x) Transfer the administrative provisions for obtaining approval to publish advertisements about therapeutic goods through broadcast media from the Broadcasting Services Act to the Therapeutic Goods Regulations. (xi) Transfer advertising offence provisions from the regulations to the Act and create new offences for publishing, through broadcast media, advertisements and generic information that do not comply with Therapeutic Goods Advertising Code.
Date of Effect	27 May 2003 for Amendments i – viii Amendments ix to xi in this Act will have effect at a date to be later proclaimed.
Contact Details	Amendments i – viii: Rita Maclachlan Office of Devices, Blood and Tissues Therapeutic Goods Administration Ph: (02) 6232 8700 E-mail: rita.maclachlan@health.gov.au Amendments ix –xi Pio Cesarin Non Prescription Medicines Branch Therapeutic Goods Administration Ph: (02) 6232 8660 E-mail: pio.cesarin@health.gov.au

Title	*Therapeutic Goods Amendment Regulations 2002 (No 4) Statutory Rule 2002 No 234*
Description of Issue	These regulations contain consequential amendments to the existing Therapeutic Goods Regulations resulting from changes to the Act required

	to implement the new medical devices scheme. The Therapeutic Goods Regulations, as amended, will now include regulations made for the purposes of sections that are in all parts of the Act except for Chapter 4, which deals with medical devices. The regulations for Chapter 4 are found in the new Therapeutic Goods (Medical Devices) Regulations 2002.
Date of Effect	4 October 2002
Contact Details	Rita Maclachlan Office of Devices, Blood and Tissues Therapeutic Goods Administration Ph: (02) 6232 8700 E-mail: rita.maclachlan@health.gov.au

Title	*Therapeutic Goods (Charges) Amendment Regulations 2002 (No 2) Statutory Rule 2002 No 235*
Description of Issue	Makes consequential amendments to the Charges Regulations to provide for the inclusion of medical devices in the Register under Chapter 4 of the *Therapeutic Goods Act 1989*. These regulations also provide for a 'deemed refusal' of an application for declaration of low volume and low value if an applicant is not notified within 40 days.
Date of Effect	4 October 2002
Contact Details	Michel Lok Business and Services Branch Therapeutic Goods Administration Ph: (02) 6232 8216 E-mail: michel.lok@health.gov.au

Title	Therapeutic Goods Amendment Regulations 2003 (No 2) Statutory Rule 2003 No 151
Description of Issue	Amends schedules of fees and charges.
Date of Effect	1 July 2003
Contact Details	Michel Lok Business and Services Branch Therapeutic Goods Administration Ph: (02) 6232 8216 E-mail: michel.lok@health.gov.au

Title	Therapeutic Goods (Charges) Amendment Regulations 2003 (No 1) Statutory Rule 2003 No 152
Description of Issue	Sets the level of charges for maintaining registrations and listings in the Australian Register of Therapeutic Goods for the period 1 July 2003 to 30 June 2004.

Date of Effect	1 July 2003
Contact Details	Michel Lok Business and Services Branch Therapeutic Goods Administration Ph: (02) 62328216 E-mail: michel.lok@health.gov.au

Title	*Therapeutic Goods Amendment Regulations 2002 (No 5) Statutory Rule 2002 No 315*
Description of Issue	Amendments relating to: (i) the Complaints Resolution Panel and other aspects of the regulation of advertisements; (ii) permitting medicines containing L-arginine to be listable medicines in the Australian Register of Therapeutic Goods (ARTG); and (iii) requiring patient information documents to be included in all prescription medicines.
Date of Effect	19 December 2002 for 1 and 2, 1 January 2003 for 3.
Contact Details	i and ii Pio Cesarin Non Prescription Medicines Branch Therapeutic Goods Administration Ph: (02) 6232 8660 E-mail: pio.cesarin@health.gov.au iii Dr Leonie Hunt Drug Safety & Evaluation Branch Therapeutic Goods Administration Ph: (02) 6232 8100 E-mail: leonie.hunt@health.gov.au

Title	*Therapeutic Goods (Medical Devices) Amendment Regulations 2003 (No 1) Statutory Rule 2003 No 153*
Description of Issue	Sets the level of charges chargeable by the Therapeutic Goods Administration for maintaining registrations and listings in the Australian Register of Therapeutic Goods for the period 1 July 2003 to 30 June 2004.
Date of Effect	1 July 2003
Contact Details	Michel Lok Business and Services Branch Therapeutic Goods Administration Ph: (02) 6232 8216 E-mail: michel.lok@health.gov.au

Title	*Therapeutic Goods Amendment Regulations 2002 (No 6) Statutory Rule 2002 No 345*
Description of Issue	Consequential amendments resulting from the implementation of the new emergency exemption power under section 18A of the *Therapeutic Goods Act 1989*. Provision has been made for stockpiling goods previously exempt under the regulations (Schedule 5A, items 9 and 10 dealing with autoinjectors and smallpox vaccine) when these goods are exempted under section 18A. Defunct provisions in the regulations and Schedule 5A have been removed.
Date of Effect	20 December 2002 and 1 January 2003
Contact Details	Dr John McEwen Acting Principal Medical Officer Therapeutic Goods Administration Ph: (02) 6232 8210 E-mail: john.mcewen@health.gov.au

Title	*Therapeutic Goods (Emergency) Exemption 2002*
Description of Issue	Relates to the stockpiling of Therapeutic Goods for the purposes of an emergency under paragraph 18A(2)(a) – vaccinia (smallpox) vaccine.
Date of Effect	19 November 2002
Contact Details	Dr John McEwen Acting Principal Medical Officer Therapeutic Goods Administration Ph: (02) 6232 8210 E-mail: john.mcewen@health.gov.au

Title	*Therapeutic Goods (Emergency) Exemption (No 2) and (No 3) 2002*
Description of Issue	Stockpiling of Atox ComboPen and AtroPen autoinjectors for the purposes of an emergency.
Date of Effect	12 December 2002
Contact Details	Dr John McEwen Acting Principal Medical Officer Therapeutic Goods Administration Ph: (02) 6232 8210 E-mail: john.mcewen@health.gov.au

Title	*Therapeutic Goods (Emergency) Exemption (No 4) 2002*
Description of Issue	Stockpiling of amoxycillin antibiotic suspension for the purposes of an emergency.

Date of Effect	17 December 2002
Contact Details	Dr John McEwen Acting Principal Medical Officer Therapeutic Goods Administration Ph: (02) 6232 8210 E-mail: john.mcewen@health.gov.au

Title	*Therapeutic Goods (Excluded Goods Order) No 1 of 2002*
Description of Issue	Amendment of the Excluded Goods Order made under subsection 7(1) in relation to substances and equipment for use in the purification or treatment of drinking water where no therapeutic claims are made.
Date of Effect	20 December 2002
Contact Details	Dr John McEwen Acting Principal Medical Officer Therapeutic Goods Administration Ph: (02) 6232 8210 E-mail: john.mcewen@health.gov.au

Title	Medical Device Standards Order No 1
Description of Issue	Specifies medical device standards relevant to medical devices that require clinical evidence in order to demonstrate compliance with essential principles.
Date of Effect	5 March 2003
Contact Details	Rita Maclachlan Office of Devices, Blood and Tissues Therapeutic Goods Administration Ph: (02) 6232 8700 E-mail: rita.maclachlan@health.gov.au

Title	Medical Devices Standards Order No 2
Description of Issue	Specifies relevant medical device standards for risk analysis and risk management methods concerning medical devices.
Date of Effect	5 March 2003
Contact Details	Rita Maclachlan Office of Devices, Blood and Tissues Therapeutic Goods Administration Ph: (02) 6232 8700 E-mail: rita.maclachlan@health.gov.au

Title	Medical Devices Standards Order No 3

Description of Issue	Specifies medical device standards for medical devices that are required to be sterile, whether the device is sterilised by the manufacturer prior to release or supplied in a non-sterile state but packaged in such a way that it can be sterilised at a later stage following supply.
Date of Effect	5 March 2003
Contact Details	Rita Maclachlan Office of Devices, Blood and Tissues Therapeutic Goods Administration Ph: (02) 6232 8700 E-mail: rita.maclachlan@health.gov.au

Title	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.
Date of Effect	5 March 2003
Contact Details	Rita Maclachlan Office of Devices, Blood and Tissues Therapeutic Goods Administration Ph: (02) 6232 8700 E-mail: rita.maclachlan@health.gov.au

Title	Conformity Assessment Standards Order No 2
Description of Issue	Specifies quality assurance techniques for the analysis and management of risk, sourcing, collection, handling, viral and transmissible agent elimination and/or activation of animal materials and their derivatives used in manufacturing medical devices.
Date of Effect	5 March 2003
Contact Details	Rita Maclachlan Office of Devices, Blood and Tissues Therapeutic Goods Administration Ph: (02) 6232 8700 E-mail: rita.maclachlan@health.gov.au

Title	Office of Gene Technology Regulator - introduction of new guidelines for certification of facilities/physical containment requirements (certain PC2 facilities)
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 in the guidelines manage risks to human health and safety and the environment associated with the performance of dealings with GMOs inside laboratories and other facilities. The Regulator has issued new Guidelines for Certification of Facilities/Physical Containment Requirements. The new guidelines affect certification of PC2 animal houses and PC2 plant houses.
Date of Effect	7 August 2003
Contact Details	Andrew Keal Review 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	August 2003

Planned Regulatory Activity

Department of Health and Ageing

Title	Health Insurance Commission New Simplified Claiming Model – Contained in a Health and Ageing Portfolio Bill
Description of Issue	The Bill provides for a new Health Insurance Commission (HIC) simplified billing claiming model. The model will enhance Informed Financial Consent and facilitate increased simplified billing.
Consultation Opportunities	The HIC is responsible for the consultation in relation to this matter.
Expected Timetable	Introduced in the Senate 27 March 2003, and passed by the Senate on 26 June 2003. To be considered by the House of Representatives – passage is expected by the end of 2003.
Contact Details	Neil Smith Private Health Insurance Branch Department of Health and Ageing Ph: (02) 6289 9434 E-mail: neil.smith@health.gov.au
Date Last Modified	18 August 2003

Title	Health Legislation Amendment (Private Health Insurance Reform) Bill 2003
Description of Issue	The proposed legislation will implement reforms to the regulation of the private health insurance industry.

	The legislation will aim to produce increased value for money in private health insurance products by allowing funds to be more efficient and responsive to members' needs, through: • decreasing the current regulatory burden on health funds; • strengthening consumer protection as a result of increased powers for the Private Health Insurance Ombudsman and better information on the relative performance of funds; and • improving the effectiveness of Lifetime Health Cover arrangements.
Consultation Opportunities	The Department has undertaken consultation with key stakeholders, in particular with the industry participants who will be effected by the proposed reforms. The Regulation Impact Statement has been made available with the introduction of the draft legislation. The Senate Community Affairs Legislation Committee inquiry into this Bill enabled both public hearings and submission in relation to the Bill. The Report of the Committee recommended that the Bill proceed.
Expected Timetable	This legislation was introduced in the Senate on 6 March 2003. Debate is expected during August/September 2003, with passage is expected by the end of 2003. Regulations detailing performance indicators will be prepared with a view to commencement by the end of 2003.
Contact Details	Neil Smith Private Health Insurance Branch Department of Health and Ageing Ph: (02) 6289 9434 E-mail: neil.smith@health.gov.au
Date Last Modified	18 August 2003

Title	Health Legislation Amendment (Medicare and Private Health Insurance) Bill 2003
Description of Issue	The proposed legislation will implement elements of the 'A Fairer Medicare' package. The Bill amends the: *Health Insurance Act 1973*, *National Health Act 1953* and *Private Health Insurance Incentives Act 1998* to enable registered private health funds to offer insurance plans to cover all out-of-pocket expenses for out-of-hospital Medicare eligible services in excess of $1,000 in a calendar year.
Consultation Opportunities	The Department has undertaken consultation with key stakeholders, in particular with the industry participants who will be effected by the proposed change.
Expected Timetable	This legislation was introduced to the House of Representatives on 28 May 2002, and passed in the House of Representatives on 16 June 2003.

	It is expected that this legislation will pass through Parliament by the end of 2003. Regulations detailing portability arrangements for the new product will be prepared with a view to commencement from 1 January 2003.
Contact Details	Neil Smith Private Health Industry Branch Department of Health and Ageing Ph: (02) 6289 9434 E-mail: neil.smith@health.gov.au
Date Last Modified	18 August 2003

Title	Amendment to *User Rights Principles 1997* to remove cap on maximum amount of daily resident fees for approved care recipients in unfunded places
Description of Issue	An amendment to the *User Rights Principles 1997* made under the *Aged Care Act 1997* is being considered to remove the cap on the maximum daily amount of resident fees that an approved provider can charge an approved care recipient in an unfunded place. This will allow the approved provider to charge an amount agreed beforehand with the care recipient. An approved provider wishing to charge such an amount will be required to notify the care recipient of certain prescribed matters. An approved provider will not be able to ask a care recipient who is already receiving care in an unfunded place to leave a residential care service simply because the care recipient does not agree to pay an additional amount. The proposed amendment will allow an approved provider with spare capacity to offer places that may have otherwise been unavailable to approved care recipients. The proposal also offers an incentive for approved providers to build spare capacity before they receive an allocation of places. This will decrease the time lag between the allocation of places and those places becoming available for the provision of funded care. Except for this amendment, an approved provider will continue to have the same responsibilities towards approved care recipients, regardless of whether they are receiving care in funded or unfunded places.
Consultation Opportunities	Extensive consultation has been carried out with industry representatives. The Department has also written to consumer representatives on the Aged Care Advisory Committee, inviting comments on the proposed legislative amendment. The results of this consultation will contribute to the development of a Regulation Impact Statement (RIS) in relation to the proposal. The Office of Regulation Review (ORR) has been informed of the proposal and a draft RIS has been submitted to ORR.

Expected Timetable	Subject to the completion of the consultation process referred to above, it is anticipated that the amendment will commence on 31 August 2003.
Contact Details	Jane Bailey Quality Outcomes Branch Department of Health and Ageing Ph: (02) 6213 4800 E-mail: jane.bailey@health.gov.au
Date Last Modified	19 August 2003.

Title	Amendment to the Health Insurance Regulations 1975 to allow the creation of a new workforce program under section 3GA of the *Health Insurance Act 1973*
Description of Issue	The outer metropolitan areas of Australia's cities have undergone considerable growth over recent years, putting additional pressure on services provided by medical practitioners. In the 2002-2003 Federal Budget the Government announced the More Doctors for Outer Metropolitan Areas Measure to improve access to medical services in outer metropolitan areas. The measure was implemented in January 2003. Consultations with key stakeholders have continued since the implementation of the measure to determine how the measure can be further enhanced. Consultations have shown that the utilisation of a select group of permanent-resident, overseas-trained doctors, who are currently living in metropolitan areas, could further increase the number of doctors working in outer metropolitan areas of workforce shortage. An amendment to Part 2 of Schedule 5 of the Health Insurance Regulations 1975 is required in order for this new component of the More Doctors for Outer Metropolitan Areas Measure to become an approved program under section 3GA of the *Health Insurance Act 1973*.
Consultation Opportunities	The Outer Metropolitan Workforce Working Group will develop and implement a pilot program in Perth, on the Department's behalf. The Outer Metropolitan Workforce Working Group will undertake consultations with a number of key stakeholders including: • Western Australian Centre for Rural and Remote Medicine; • WA Medical Registration Board; • General Practice Divisions of Western Australia; • General Practice Department of the University of Western Australia; • WA Department of Health; and • general practice training bodies. Consultation has been undertaken with the Office of Regulation Review and it has advised that a Regulation Impact Statement is not required.
Expected Timetable	It is expected that this legislation will be introduced into Parliament in the Spring Sittings 2003.
Contact Details	Caragh Cassoni Workforce and Quality Branch

	Department of Health and Ageing Ph: (02) 6289 3122 E-mail: caragh.cassoni@health.gov.au
Date Last Modified	15 August 2003

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 have taken 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 will benefit rural and remote communities by requiring those doctors who have taken advantage of the anomaly to relocate from metropolitan areas.
Consultation Opportunities	Consultation has not been considered necessary on this matter. The intention was to restore arrangements that had been in place prior to the introduction of regulatory changes in October 2001. These changes inadvertently allowed some overseas-trained doctors to access Medicare for assistance at operations in metropolitan areas. The Government intention was that overseas-trained doctors only be able to access Medicare in rural and remote districts of workforce shortage, not metropolitan areas.
Expected Timetable	It is expected that this legislation will be introduced into Parliament in the Spring sittings. A draft Regulation Impact Statement (RIS) has been has been sent to Office of Regulation Review for consideration. It is expected that the RIS will be completed by the end of October.
Contact Details	Barny Lee Workforce Distribution Programs Department of Health and Ageing Ph: (02)6289 5632 E-mail: barny.lee@health.gov.au
Date Last Modified	13 August 2003

Title	Changes to the regulations relating to the location of pharmacies approved to supply pharmaceutical benefits
Description of Issue	The Third Community Pharmacy Agreement (2000-2005) between the Australian Government and the Pharmacy Guild of Australia, which sets out the arrangements for the location of pharmacies approved to supply pharmaceutical benefits, specified that these arrangements be reviewed June 2004. Also, Determination PB 9 of 2002 has resulted in various administrative and legal difficulties with parts of the Determination no longer consistent with the intent of the Third Agreement. The Department has been negotiating with the Pharmacy Guild of Australia to correct this matter.
Consultation Opportunities	Consultations between the Department, the Pharmacy Guild of Australia and the Office of Legislative Drafting will occur during 2003/2004 concerning the review of existing arrangements and the development of replacement legislation.
Expected Timetable	June 2004 – reporting of the review of the pharmacy location arrangements; June 2004-June 2005 – development of arrangements taking into account the results of the review; June 2005 - Third Community Pharmacy Agreement expires, possibly to be followed by the Fourth Community Pharmacy Agreement.
Contact Details	Catherine Farrell Pharmaceutical Access and Quality Branch Department of Health and Ageing Ph: (02) 6289 8984 E-mail: catherine.farrell@health.gov.au
Date Last Modified	29 July 2003

Title	The Health Legislation Amendment Bill (No 1) 2003 (Part 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. This program is administered by the Health Insurance Commission (HIC) 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 follows a Federal Court ruling which questioned the capacity of the HOSC Act's ability to recover Medicare and Residential Care moneys paid to compensation claimants in certain circumstances.
Date of Effect	Passed by the Senate on 26 June 2003, but awaiting passage through the House of Representatives.
Contact Details	Mark Burness

	Financing and Analysis Branch Department of Health and Ageing Ph: (02) 6289 7015 E-mail: mark.burness@health.gov.au

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 may require mandatory professional association membership and specify the requirements for a professional association to become an approved professional body under the Rules of Conduct.
Consultation Opportunities	Initial comment has been invited from all contracted service providers and practitioners who currently provide services under the Hearing Services Voucher System, as well as with the Audiological Society of Australia (ASA), the Australian College of Audiology (AC*Aud*), the Hearing Aid Audiometrists Society of Australia (HAASA) and consumer representatives. Comment will be sought from the above groups on the final proposal.
Expected Timetable	Submission of proposed changes for Ministerial approval – November 2003 Tabling of proposed changes – February 2004
Contact Details	Judi Sutton Office of Hearing Services Ph: (02) 6289 5411 E-mail: judi.sutton@health.gov.au
Date Last Modified	18 August 2003

Title	Future of the Voluntary Agreement for the Disclosure of the Ingredients of Cigarettes
Description of Issue	A Voluntary Agreement for the Disclosure of the Ingredients of Cigarettes was signed by the previous Minister for Health and Aged Care, Dr Michael Wooldridge, and the three tobacco companies - Philip Morris Ltd, British American Tobacco Australia Ltd and Imperial Tobacco Australia Ltd - on 20 December 2000. Four rounds of public disclosure have occurred to date, with data posted on the Department's web site in 2000, 2001, 2002 and 2003. The present agreement expires in December 2003, however negotiations are under way

	to extend the life of the agreement until December 2004. Under the auspices of the agreement, companies also provided one-off cigarette emissions data that were posted on the Department's web site in early 2002.
Consultation Opportunities	Consultations between the Department and stakeholders are currently occurring regarding the extension of the current voluntary agreement.
Expected Timetable	May 2004 – final disclosure under extended Voluntary Agreement. December 2004 – extended Voluntary Agreement expires.
Contact Details	Penny Marshall Tobacco Control & Drug Prevention Strategies Department of Health and Ageing Ph: (02) 6289 9321 E-mail: penny.marshall@health.gov.au
Date Last Modified	14 August 2003

Title	Review of the *Tobacco Advertising Prohibition Act 1992*
Description of Issue	The review will consider whether *Tobacco Advertising Prohibition Act 1992* (the Act) has met its objective of limiting the exposure of the public to messages and images that may persuade them to start or continue smoking, and whether the objectives of the Act should be expanded to take into account new and emerging advertising and sponsorship practices. After ten years of administration, the review will also consider areas of the Act that are not effective and whether corrective action is necessary. A panel comprising legal, public policy, public health, broadcasting and tobacco control expertise has been established to provide the Department with advice throughout the course of the review.
Consultation Opportunities	The Department, in collaboration with the advisory panel, has developed a discussion paper for publication. This will be released in late August/early September 2003 to provide opportunities for consultation with stakeholders and the public. Availability of the discussion paper and details regarding submissions will be advertised in major newspapers and on the Department's web site at www.health.gov.au/tobacco.
Expected Timetable	Issues paper to be released for public consultation late August/early September 2003. Report to Parliamentary Secretary by November/December 2003.
Contact Details	Penny Marshall Tobacco Control & Drug Prevention Strategies Department of Health and Ageing Ph: (02) 6289 9321 E-mail: penny.marshall@health.gov.au
Date Last Modified	14 August 2003

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 is an action identified under the National Tobacco Strategy as a measure to strengthen public awareness of the harm caused by tobacco use. The review of health warnings is being conducted jointly by the Department of Health and Ageing and the Department of Treasury, with the assistance of a technical advisory group.
Consultation Opportunities	The general public and key stakeholders, including the public health lobby and the tobacco industry, will be consulted at various stages of the review. Consultation to date includes the release in May 2001 of a discussion paper for public comment and consultation with industry during August 2003. There will be further opportunities for public consultation at a later stage in the review, with the release of a consultation paper during October 2003.
Expected Timetable	A consultation paper is planned for release in October 2003, with new regulations expected to be approved by December 2003. This will be followed by a phase-in period for the industry, with new health warnings appearing on tobacco products by July 2004.
Contact Details	Penny Marshall Tobacco Control & Drug Prevention Strategies Group Department of Health and Ageing Ph: (02) 6289 9321 E-mail: penny.marshall@health.gov.au
Date Last Modified	14 August 2003

Title	World Health Organisation proposed Framework Convention on Tobacco Control
Description of Issue	The World Health Organisation (WHO) has developed a 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.
Consultation Opportunities	Consultation has occurred with other Federal agencies, State and Territory Governments, non-government organisations and industry groups throughout the FCTC process. The World Health Assembly unanimously adopted the text in May 2003 and it is now open for signature. The Government has yet to decide whether to sign and/or ratify the convention. That decision will be taken in accordance with the treaty-making practices agreed by the Council of Australian Governments.
Expected	May 2003: Text of FCTC finalised for consideration by World Health

Timetable	Assembly. Consideration by the Joint Standing Committee on Treaties and Federal Executive Council will follow on a timetable to be determined.
Contact Details	Klaus Klaucke Tobacco Control and Drug Prevention Strategies Group Department of Health and Ageing Ph: (02) 6289 8059 E-mail: klaus.klaucke@health.gov.au
Date Last Modified	14 August 2003

Title	Food safety management in Australia - risk profiling and food safety programs
Description of Issue	Results from a national two-year program of work on food safety clearly identify that contaminated food is a significant health problem in Australia. The 5.4 million cases of food poisoning which occur in Australia each year cost the community an estimated $3.75 billion. The Food Regulation Standing Committee (FRSC) has developed draft policy guidelines for food safety management in Australia, based on the program of work on food safety. These draft guidelines discuss the use of risk-profiling and make recommendations as to which food business sectors should develop and implement food safety programs as a preventative approach to food safety. The FRSC is responsible for coordinating policy advice to the Australia New Zealand Food Regulation Ministerial Council and ensuring a nationally consistent approach to the implementation and enforcement of food standards. It also advises the Ministerial Council on the initiation, review and development of standing committee activities.
Consultation Opportunities	Public consultation on the draft document 'Food Safety Management in Australia - Risk Profiling and Food Safety Programs' commenced on 20 March 2003 and ended on 17 April 2003. The Australian Government, with state and territory collaboration, collated an e-mail list of 1,060 interested parties. An e-mail announcing the consultation and the location of the consultation documentation was sent to industry organisations, community groups, government agencies and all local government areas on 20 March 2003. Advertisements appeared in the Government Gazette on 20 March 2003 and *The Australian* and local newspapers as chosen by each state and territory on 22 March 2003, and again in *The Australian* on 19 March 2003. A total of 69 submissions was received from the following groups: local government (30), food consultants (4), industry (13), industry associations (13), research organisations (2), government agencies (4), community groups (1), stakeholder groups (1) and unknown (1). The consultation summary is available at

	http://www.foodsecretariat.health.gov.au/consult.htm.
Expected Timetable	The revised policy guidelines and a summary of submissions will be recommended to the Australia New Zealand Food Regulation Ministerial Council in December 2003. If approved by the Ministerial Council, the policy guidelines will be provided to Food Standards Australia New Zealand to form the framework within which the new food standards will be developed. Additional consultation will take place as part of the process.
Contact Details	Dr Ian McKay Food Safety and Surveillance Department of Health and Ageing Ph: (02) 6289 5155 E-mail: ian.mckay@health.gov.au
Date Last Modified	19 August 2003

Title	Nutrition, health and related claims
Description of Issue	A policy framework for nutrition, health and related claims to allow manufacturers and distributors of foods to make claims, in the context of advertising and labelling their products, that the foods contain certain nutritional substances and thereby provide health benefits from consumption of the product.
Consultation Opportunities	A consultation paper on the introduction of health claims was circulated to stakeholders during 2002. The outcome of this consultation process was considered by Ministers prior to a decision to implement a risk-based approach to health claims, and the endorsement of principles to guide the policy development framework. As a result of the Ministers' decision, the Food Regulation Standing Committee (FRSC) agreed that a Policy Advisory Group (PAG) be established to develop a policy guideline for regulating food advertising and labelling involving nutrient, health and related claims. The PAG had government, industry, consumer, and expert nutrition representation and met regularly during the period October 2002 to May 2003 to work on development of the guideline. FRSC will consider the details of the package before presenting it to the Ministerial Council later this year.
Expected Timetable	It is expected that the Food Regulation Standing Committee will provide final advice on this issue to the Ministerial Council in December 2003.
Contact Details	Catherine Gay Food and Environmental Health Branch Department of Health and Ageing Ph: (02) 6289 5133 E-mail: catherine.gay@health.gov.au
Date Last Modified	18 August 2003

Title	Novel foods

Description of issue	A policy guideline is to be developed to clarify the 'novel food' framework. The issue of food novelty is linked both to 'new' or innovative foods and to foods with a history of use in other countries but not in Australia and New Zealand and which may require specific knowledge or skills in order to be used safely.
Consultation opportunities	Consultation has already been conducted. Public comment was invited the Food Regulation Standing Committee (FRSC) secretariat web site, and supplemented by targeted consultation with key stakeholders. Stakeholders were asked to make a submission commenting on the principles and options in the paper, including a preferred option and any related considerations. The consultation period closed on 1 April 2003.
Expected timetable	It is anticipated that the Food Regulation Standing Committee (FRSC) will provide policy advice on this issue to the Australia New Zealand Food Regulation Ministerial Council at its December 2003 meeting.
Contact details	Catherine Gay Food and Environmental Health Branch Department of Health and Ageing Ph: (02) 6289 5133 E-mail: catherine.gay@health.gov.au
Date last modified	18 August 2003

Title	Food-type dietary supplements
Description of Issue	An increasing number of products is being manufactured in or imported into New Zealand under the New Zealand Dietary Supplements Regulations 1984 and from there enter into the Australian market under the Trans-Tasman Mutual Recognition Arrangement. These foods represent a growing sector of the global food market and present challenges in terms of the boundaries that exist between food-type and therapeutic-type dietary supplements. A policy guideline will be developed to articulate overarching principles for dealing with this issue, considering the need to protect consumer health and safety, the requirement for flexibility to allow industry innovation and the need to clarify the food-drug interface.
Consultation Opportunities	Stakeholder consultation has occurred. Public comment was invited via the Food Regulation Standing Committee (FRSC) secretariat web site. This was supplemented by targeted consultation of key stakeholders; a paper developed by the FRSC Dietary Supplements Working Group encouraged comment by stakeholders on policy principles and options for the regulation of food-type dietary supplements.
Expected Timetable	A FRSC Working Group has been formed and it is anticipated that FRSC will provide policy advice on this issue to the Australia New Zealand Food Regulation Ministerial Council early in 2004.
Contact Details	Catherine Gay Food and Environmental Health Branch Department of Health and Ageing

	Ph: (02) 6289 5133 E-mail: catherine.gay@health.gov.au
Date Last Modified	18 August 2003

Therapeutic Goods Administration

Title	New regulations under the *Industrial Chemicals (Notification and Assessment) Act 1989* to give effect to Australia's obligations under the Rotterdam Convention on the Prior Informed Consent procedure for certain hazardous chemicals and pesticides in international trade, if ratified and if Australia becomes a party
Description of issue	Regulations have been made for the voluntary procedure for the Prior Informed Consent (PIC) Scheme. New regulations will be required to regulate exports of PIC chemicals to countries that are parties to the convention when the convention comes into force (if ratified by Australia).
Expected Timetable	A National Interest Analysis (NIA) and a Regulation Impact Statement (RIS) are to be released for public comment in 2003. New regulations in place in 2004.
Consultations	Opportunities for public comment will be provided by the NIA and RIS.
Contact details	Sneha Satya Existing Chemicals Assessment National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8880 E-mail: sneha.satya@nicnas.gov.au
Date Last Modified	18 August 2003

Title	NICNAS new chemicals – Low Regulatory Concern Chemicals
Description of Issue	The introduction of a new Low Regulatory Concern Chemicals (LRCC) notification category will assist the chemical industry with faster and lower cost assessment for the introduction of these chemicals. Criteria are likely to involve low hazard chemicals, chemicals similar to those already assessed under the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and/or chemicals assessed by another recognised agency.
Consultation Opportunities	NICNAS established an LRCC Task Force to oversee the process. The task force includes representatives from government, the community and industry. In addition, a number of NICNAS/industry/community working groups have been established to develop options. The LRCC Task Force provided its final report to the Parliamentary Secretary for Health in June 2003, following a public consultation period. The Final Report and Recommendations for the LRCC Reform Initiative and Implementation Strategy have been agreed to in-principle, subject to further technical

	development, consultation and cost benefit analysis.
Expected Timetable	Legislation to amend the *Industrial Chemicals (Notification and Assessment) Act 1989* is expected to be introduced in the Autumn Sittings 2004.
Contact Details	Dusanka Sabic Reform Activities National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8870 E-mail dusanka.sabic@nicnas.gov.au
Date Last Modified	18 August 2003

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). National Industrial Chemicals Notification and Assessment Scheme (NICNAS) New Chemicals input under the OECD New Chemicals program includes 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 New Chemicals has finalised such an arrangement with Environment Canada and is working towards recognition of the Canadian scheme as an approved foreign scheme.
Consultation Opportunities	Through the Industry Government Consultative Committee and with key industry stakeholders during 2002-03.
Expected Timetable	Bilateral Arrangement with Canada – signed late 2002. Recognition of Canadian scheme - Dec 2003. Other foreign scheme activities ongoing.
Contact Details	Bob Graf New Chemicals Assessment National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8850 E-mail: bob.graf@nicnas.gov.au
Date Last Modified	18 August 2003

Title	Review of legislative requirements for synthetic polymers of low concern under the *Industrial Chemicals (Notification and Assessment) Act 1989*
Description of Issue	The notification and assessment of synthetic polymers of low concern (PLC) are being reviewed during the Low Regulatory Concern Chemicals (LRCC) project. It is most likely that changes to the *Industrial Chemicals (Notification and Assessment) Act 1989* and the regulations will be required.
Consultation	Consultation with industry through the Industry Government Consultative

Opportunities	Committee and LRCC Task Force during 2002-2003. Public consultation was conducted during 2002-03 during LRCC activities.
Expected Timetable	June 2004
Contact Details	Bob Graf New Chemicals Assessment National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8850 E-mail: bob.graf@nicnas.gov.au
Date last modified	18 August 2003

Title	Review of the NICNAS guidelines for confidential listing on the Australian Inventory of Chemical Substances
Description of Issue	New guidelines for confidential listing on the Australian Inventory of Chemical Substances (AICS) were endorsed by the Industry Government Consultative Committee (IGCC) in 2000. The guidelines included that a review should take place after two years' of operation, for appropriateness and effectiveness. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and the Technical Advisory Group commenced the review in mid-2002.
Consultation Opportunities	Consultation meetings were held with industry and the public in Sydney and Melbourne in 2002. A progress report was presented to IGCC in November 2002. The public comment period on the draft guidelines closed in July 2003.
Expected Timetable	Revised guidelines are expected to be released in Dec 2003. These guidelines were placed on the NICNAS web site and comments sought.
Contact Details	Venky Krishnamurthy Existing Chemicals Assessment National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8834 E-mail venky.krishnamurthy@nicnas.gov.au
Date Last Modified	18 August 2003

Title	Review of the Existing Chemicals Program
Description of Issue	Objectives of the review of the Existing Chemicals Program are to consider how to set priorities, examine industry and public input into the assessment process and to review process and procedures.
Consultation Opportunities	Stakeholder consultation will include seminars with industry, public and government departments and release of a discussion paper. Proposed

	changes to the program will be presented to the Industry Government Consultative Committee.
Expected Timetable	A scoping exercise, including focussed consultation, has recently been completed. Background information and an on-line questionnaire are available on the National Industrial Chemicals Notification and Assessment Scheme web site at www.nicnas.gov.au. A public consultation period is expected to take place from January to March 2004.
Contact Details	Jane Weder Existing Chemicals Assessment National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8895 E-mail: jane.weder@nicnas.gov.au
Date Last Modified	18 August 2003

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 improvements has been identified.
Consultation Opportunities	Draft revised guidelines were released for public comment in 2002. Comments were sought by 30 September 2002. Copies of the draft revised guidelines were sent to key stakeholders and all accredited organisations. The draft revised guidelines can be found at the Office of Gene Technology Regulator's web site: www.ogtr.gov.au or obtained via e-mail: ogtr@health.gov.au or telephone 1800 181 030.
Expected Timetable	Following consideration of public comments on the draft revised guidelines, the Regulator issued new revised guidelines in connection with PC2 plant and animal facilities in August 2003. New revised guidelines covering PC1, PC3, PC4 and remaining PC2 facilities (for example, insectaries and aquariums) are anticipated to be issued by the Regulator before the end of 2003.
Contact Details	Andrew Keal

	Review 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	August 2003

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 2003. These guidelines are intended to improve the guidelines dated June 2001.
Consultation Opportunities	The draft will be available for public consultation for at least four weeks later this year. A copy will also be placed on the Office of Gene Technology Regulator's web site: www.ogtr.gov.au, and copies will also be available via e-mail: ogtr@health.gov.au or by telephoning 1800 181 030.
Expected Timetable	Final Guidelines are expected to be issued by the Gene Technology Regulator before the end of 2003.
Contact Details	Andrew Keal Review 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	August 2003

Title	Office of Gene Technology Regulator – review of gene technology regulations
Description of Issue	In response to stakeholder comments, as well as the Office of Gene Technology Regulator's (OGTR) administration of the regulations during its first 18 months of operation, OGTR is considering possible revisions to the regulations.
Consultation Opportunities	Institutional Biosafety Committees have been asked for suggestions of possible amendments to the regulations. Comments have been sought by 30 September 2003. Before any decision is made to amend the regulations, the proposed amendments would be circulated to the Gene Technology Technical Advisory Committee and the Ministerial Council for Gene Technology.
Expected Timetable	Amended regulations will be tabled in the first half of 2004.
Contact Details	Michael Munro-Mobbs Legal Unit

	Office of Gene Technology Regulator Ph: 1800 181 030 Web site: www.ogtr.gov.au E-mail: ogtr@health.gov.au
Date Last Modified	August 2003

Title	Development and implementation of a trans-Tasman regulatory scheme for therapeutic products
Description of Issue	Until 1 May 2004, 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, the Australian and New Zealand Governments have agreed 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.
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 two 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. 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 – October 2003 Legislation introduced – early 2004 Legislation passed – mid 2004 Agency commences operations in 2005

Contact Details	Jeff Ibbotson Trans Tasman Group Therapeutic Goods Administration Ph: (02) 6232 8198 E-mail: jeff.ibbotson@health.gov.au
Date Last Modified	13 August 2003

Title	Therapeutic Goods Amendment Regulations 2004
Description of Issue	Amends schedules of fees and charges.
Expected Timetable	1 July 2004
Contact Details	Michel Lok Business and Services Branch Therapeutic Goods Administration Ph: (02) 6232 8216 E-mail: michel.lok@health.gov.au

Title	Therapeutic Goods (Charges) Amendment Regulations 2004
Description of Issue	Sets the level of charges for maintaining registrations and listings in the Australian Register of Therapeutic Goods for the period 1 July 2004 to 30 June 2005.
Expected Timetable	1 July 2004
Contact Details	Michel Lok Business and Services Branch Therapeutic Goods Administration Ph: (02) 6232 8216 E-mail: michel.lok@health.gov.au

Title	Therapeutic Goods (Medical Devices) Amendment Regulations 2004
Description of Issue	Sets the level of charges for maintaining registrations and listings in the Australian Register of Therapeutic Goods for the period 1 July 2004 to 30 June 2005.
Expected Timetable	1 July 2004
Contact Details	Michel Lok Business and Services Branch Therapeutic Goods Administration Ph: (02) 6232 8216 E-mail: michel.lok@health.gov.au

Title	Review of the arrangements for access to unregistered therapeutic goods under Clinical Trial and Special Access Scheme arrangements

Description of Issue	A review of the Australian and New Zealand arrangements for access to unapproved therapeutic products is under way and due to report in late 2003 on best practice for Australia and in the context of the establishment of a trans-Tasman agency.
Expected Timetable	The review is due to report in late 2003. Any regulatory changes arising from the outcome may be incorporated into the existing Australian therapeutic goods legislation and/or into trans-Tasman legislation.
Contact Details	Dr Leonie Hunt Drug Safety & Evaluation Branch Therapeutic Goods Administration Ph: (02) 6232 8100 E-mail: leonie.hunt@health.gov.au

Title	Amendments to Quarantine Proclamation to require permits for commercial quantities of human blood and blood components
Description of Issue	In March 2001, the previous health Minister, Dr Michael Wooldridge, gave an undertaking to the Chair of the Joint Committee on Public Accounts and Audit (JCPAA) that arrangements to protect human blood supplies from contamination from overseas sourced blood would be pursued. This was in response to JCPAA recommendations relating to an audit of the Therapeutic Goods Administration's (TGA) management of blood fractionation processes in 2001. Overseas sourced blood is processed (for export) in the same facilities as Australian sourced blood. 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 s.28 of the Quarantine Proclamation. Before deciding to issue a permit, a Director of Quarantine will be required to be satisfied of certain matters which will indicate that the blood or blood products will not endanger the health of the Australian community by carrying infectious material which could contaminate Australian blood supplies. 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	Currently with the Office of Legislative Drafting. Implementation as soon as possible.

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