Department of Health and Ageing
2007-08 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 2006 to 30 June 2007); and
- activities planned in the current financial year (1 July 2007 to 30 June 2008) 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 20 August 2007.

Past Regulatory Activity

Title	Private Health Insurance Act 2007 and Private Health Insurance Rules 2007
Description of issue	This Act regulates the private health insurance industry. The new legislation allows flexibility for health insurers to partner with doctors and other health care practitioners to provide treatment that best suits the needs of the patient, and to reduce the growing burden of disease through targeted prevention and disease management programs.
Date of effect	1 April 2007
Contact details	Veronica Hancock Private Health Insurance Branch Department of Health and Ageing Ph: (02) 6289 9490 Email: veronica.hancock@health.gov.au

Title	Private Health Insurance Complaints Levy Regulations 1995
Description of issue	The Regulations provide for a levy payable by registered health insurers for the funding of the Private Health Insurance Ombudsman (PHIO). The amendments provided for an increase of $200,000 in the levy collected to compensate for additional costs to the PHIO to undertake expanded functions as a result of the *Health Legislation Amendment (Private Health Insurance) Act 2006*.
Date of effect	3 November 2006
Contact details	Veronica Hancock Private Health Insurance Branch Department of Health and Ageing Ph: (02) 6289 9490 Email: veronica.hancock@health.gov.au

Title	Aged Care Amendment (Residential Care) Act 2006	
Description of issue	Amendments to the *Aged Care Act 1997* to give effect to the further harmonisation of aged care and pension assets assessments; and changes in respect of delegations for approvals of care needs assessments conducted by Aged Care Assessment Teams.	
Date of effect	The new gifting arrangements were implemented on 1 January 2007, affecting gifts made from 10 May 2006. The income stream changes take effect on 20 September 2007.	
Contact details	Harmonisation of assets assessments	Jacquie Maycock Resident Liaison Section Department of Health and Ageing Ph: (02) 6289 7909 Email: jacquie.maycock@health.gov.au
	Aged care approvals delegations	Judy Bartholomew Assessment Section Department of Health and Ageing Ph: (02) 6289 5200 Email: judy.bartholomew@health.gov.au

Title	Aged Care Amendment (Residential Care) Act 2007
Description of issue	Amendments to the *Aged Care Act 1997* to give effect to the implementation of the new aged care funding instrument.
Date of effect	The Minister formed an Industry Reference Group in 2004 to assist in the development of the new funding model. This Group, which consists of industry peak bodies, industry professionals, aged care providers and consumer representatives, meets at least quarterly.
Contact details	Keith Tracey-Patte Funding Model Implementation Department of Health and Ageing Ph: (02) 6289 1578 Email: keith.tracey-patte@health.gov.au

Title	Residential Care Subsidy Amendment Principles 2006 (No 1)
Description of issue	This amendment made a number of technical amendments to the Residential Care Subsidy Principles to ensure the efficient operation of the Conditional Adjustment Payment (CAP). This amendment also extends the 2006 financial reporting date for CAP by one month. The extra reporting time is provided in recognition of the need for providers to adopt the Australian Equivalents to International Financial Reporting Standards in their 2005-06 General Purpose Financial Reports.
Date of effect	7 July 2006
Contact details	Iain Scott Office of the Prudential Regulator Department of Health and Ageing Ph: (02) 6289 4145 Email: iain.scott@health.gov.au

Title	National Health (Australian Community Pharmacy Authority Rules) Amendment Determination 2007 (No. 1)
Description of issue	Amendment of the pharmacy location rules to address shopping centre "backfilling" that was causing clustering of pharmacies in areas already well serviced by existing pharmacies.
Date of effect	27 March 2007
Contact details	David Pearson Pharmacy Access Section Community Pharmacy Branch Department of Health and Ageing Ph: (02) 6289 8984 Email: david.pearson@health.gov.au

Title	National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007
Description of Issue	The *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007* gives effect to the new pricing arrangements associated with major reforms to Pharmaceutical Benefits Scheme which enable the benefits of competition to be captured where drugs have multiple brands.
Date of effect	Royal Assent was received June 2007; Act commenced 1 August 2007.
Contact	Sue Campion Assistant Secretary Policy and Analysis Branch Department of Health and Ageing Ph: (02) 6289 7585 Email: sue.campion@health.gov.au

Title	Gene Technology Amendment Act 2007
Description of issue	The *Gene Technology Amendment Act 2007* amended the *Gene Technology Act 2000* to implement the policy agreed by all jurisdictions in response to the Statutory Review of the *Gene Technology Act 2000* and the Gene Technology Agreement, conducted in 2005-06. The amendments to the Act provide an efficient and effective regulatory system for the application of gene technology. This will ensure that the regulatory burden is commensurate with the risks.
Date of effect	1 July 2007
Contact details	Davis Lemke Health & Environmental Regulatory Policy Section Regulatory Policy & Biotechnology Branch Regulatory Policy & Governance Division Department of Health and Ageing Ph: (02) 6289 7045 Email: davis.lemke@health.gov.au

Title	Gene Technology Amendment Regulations 2007 (No.1)
Description of issue	The *Gene Technology Amendment Regulations 2007* (Amendment Regulations) amend the Gene Technology Regulations 2001 to give effect to the recommendations of the Statutory Review of the *Gene Technology Act 2000* and the Gene Technology Agreement, conducted in 2005-06. The Amendment Regulations reduce the regulatory burden of low risk dealings with genetically modified organisms (GMOs) and the timeframe for the Gene Technology Regulator to assess applications for field trials to conduct research under limited and controlled conditions. The Amendment Regulations also remove legislative requirements on exempt dealings.
Date of effect	1 July 2007
Contact details	Davis Lemke Health & Environmental Regulatory Policy Section Regulatory Policy & Biotechnology Branch Regulatory Policy & Governance Division Department of Health and Ageing Ph: (02) 6289 7045 Email: davis.lemke@health.gov.au

Title	Health Insurance Amendment (Diagnostic Imaging Accreditation) Act 2007
Description of issue	This amends the *Health Insurance Act 1973* to create an overarching framework for the establishment of accreditation schemes for diagnostic imaging linked to the payment of Medicare benefits. The Act prescribes that Medicare benefits are only payable when rendered from an accredited site. The operational and administrative details of accreditation schemes will be set out in legislative instruments.
Date of effect	1 July 2008
Contact details	Margaret Curran Diagnostic and Technology Branch Department of Health and Ageing Phone: (02) 6289 7315 Email: margaret.curran@health.gov.au

Title	Health Insurance Amendment (Inappropriate and Prohibited Practices and Other Measures) Act 2007
Description of issue	This legislation amends provisions of the *Health Insurance Act 1973* relating to pathology and diagnostic imaging services funded under Medicare. The majority of the changes clarify and strengthen existing provisions of the Act that prohibit inducements to secure referrals for pathology and diagnostic imaging services. The Act also makes other more minor, technical amendments relating to the delivery of pathology services. The changes enable more efficient and effective implementation of the policy intent of the current provisions.
Date of effect	1 March 2008
Contact details	Debbie Stanford Diagnostics and Technology Branch Department of Health and Ageing Ph: (02) 6289 4038 Email: debbie.stanford@health.gov.au

Title	Health Insurance (Eligible collection Centres) Principles 2007
Description of issue	This replaces the 2005 Principles. The Principles regulate the allocation of Approved collection Centres to pathology providers. A regulatory impact statement was prepared and approved.
Date of effect	1 July 2007
Contact details	Hilary Metcalf Diagnostics and Technology Branch Department of Health and Ageing Ph: (02) 6289 8657 Email: hilary.metcalf@health.gov.au

Title	Food Standards Australia New Zealand Amendment Act
Description of issue	Amendments to the *Food Standards Australian New Zealand Act 1991* (the FSANZ Act) to: • reform the assessment and consultation process to match the process with the nature and scope of the application or proposal under consideration and create more meaningful opportunities for consultation with stakeholders • harmonise as far as possible the processes for the assessment of applications and proposals • allow for alignment of the policy setting process of the Council and the standard development and approval process of FSANZ • align the processes of the Australian Pesticides and Veterinary Medicines Authority and of FSANZ for the cooperative setting of Maximum Residue Limits • recognise the potential need to develop urgent standards due to unforseen negative impacts on trade • remove the ability for the Council to request a second review while maintaining appropriate oversight of standards by the Council – this amendment is subject to changes to the Food Treaty between Australia and New Zealand • create a process for expert scientific assessment of future high level health claims – the later commencement of this provision allows time for finalisation of the Nutrition, Health and Related Claims Standard currently under development.
Date of effect	Royal Assent received on 28 June 2007; Proclamation of Schedule 1 on 1 July 2007
Contact details	Catherine Gay Food and Health Living Branch Department of Health and Ageing Ph: (02) 6289 5133 Email: catherine.gay@health.gov.au

Title	**Medical Indemnity (Run-off Cover Claims and Administration) Protocol 2006 (No.2)**
Description of issue	The Protocol allows for the reimbursement of costs incurred by insurers as a result of administering the run-off cover scheme (ROCS) and establishes a claim handling fee.
Date of effect	4 December 2006
Contact details	Sonya Kelly Medical Indemnity Branch Department of Health and Ageing Ph: (02) 6289 9213 Email: sonya.kelly@health.gov.au

Title	**Medical Indemnity (Prudential Supervision and Product Standards – Notice of Provision of Run-off Cover) Determination 2007**
Description of issue	The purpose of the Determination is to set out the data to be provided to Medicare Australia by insurers in a written form in order to facilitate the management of the run-off cover scheme (ROCS).
Date of effect	13 July 2007
Contact details	Sonya Kelly Medical Indemnity Branch Department of Health and Ageing Ph: (02) 6289 9213 Email: sonya.kelly@health.gov.au

Title	**Medical Indemnity (IBNR Claims) Protocol 2006**
Description of issue	The Protocol establishes eligibility criteria for payment of claim handling fees, sets out the process and timing of such payments, and contains a provision dealing with the recovery of overpayments.
Date of effect	4 December 2006
Contact details	Sonya Kelly Medical Indemnity Branch Department of Health and Ageing Ph: (02) 6289 9213 Email: sonya.kelly@health.gov.au

Title	**Medical Indemnity Legislation Amendment Act 2006**
Description of issue	The Act amends the Medical Indemnity Act 2002 and the Medical Indemnity (Prudential Supervision and Product Standards) Act 2003 in order to simplify the administration of run-off cover scheme (ROCS) for the medical insurers and Medicare Australia. The changes introduced by the Act also allows insurers to clarify indemnity arrangements and provide cover under ROCS for eligible doctors based on the doctors' last contract of insurers and removes the requirement for doctors to have had a medical indemnity cover at the time of the incident.
Date of effect	4 November 2006
Contact details	Sonya Kelly Medical Indemnity Branch Department of Health and Ageing Ph: (02) 6289 9213 Email: sonya.kelly@health.gov.au

Title	**Industrial Chemicals (Notification and Assessment) Amendment Regulations 2007 [No 1]**
Description of issue	The Regulations increased fees and charges for the National Industrial Chemicals Notification and Assessment Scheme for 2007-08 by 3.83% (Consumer Price Index/Wage Cost Index). Available at www.nicnas.gov.au
Date of effect	1 July 2007
Contact details	Roshini Jayewardene Regulatory Strategy & Reform National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8860 Email: roshini.jayewardene@nicnas.gov.au

Planned Regulatory Activity

Title	Amendments to Private Health Insurance Rules 2007
Description of issue	Various amendments to the Rules are planned to update default hospital benefits, enact updated prostheses benefits, etc as required through the year.
Consultation opportunities	Prostheses List benefits are developed in consultation with industry and other stakeholders through Prostheses and Devices Committee processes. Amendments to default hospital benefits flow on changes made to the MBS.
Expected timetable	November 2007, June 2008
Contact details	Veronica Hancock Private Health Insurance Branch Department of Health and Ageing Ph: (02) 6289 9490 Email: veronica.hancock@health.gov.au
Date last modified	2 August 2007

Title	Health Legislation Amendment (Pharmaceutical Benefits Entitlement) Bill – relating to arrangements for approving a pharmacist to supply pharmaceutical benefits
Description of issue	Minor, technical and consequential amendments identified during the development of the new pharmacy location rules, including: • providing for special supply arrangements for private hospitals; • enabling the Secretary and Minister to attach conditions to particular approvals; • ensuring flexibility in the recovery of payment for pharmaceutical benefits in certain circumstances.
Consultation opportunities	Ongoing consultation (discussions, meetings and workshops) with Medicare Australia and the Pharmacy Guild of Australia. Potential for consultation (meetings and discussions) with private hospital authorities in August-December 2006.
Expected timetable	Drafting instructions issued
Contact details	David Pearson Community Pharmacy Branch Department of Health and Ageing Ph: (02) 6289 8984 Email: david.pearson@health.gov.au
Date last modified	2 August 2007

Title	**Health Emergency Planning and Response Branch – COAG Review of Hazardous Materials**
Description of issue	The Council of Australian Governments (COAG) Review of Hazardous Biological Materials and its associated Report was considered and agreed by COAG on 13 April 2007. COAG agreed to the Report recommendations which include the establishment of a national regulatory regime to minimise the security risks posed by specific security-sensitive biological agents. The Department of Health and Ageing is responsible for implementing these recommendations. The COAG Review of Hazardous Chemicals is currently ongoing given the complexity and number of chemicals involved. The Chemicals Review is being managed by PM&C with the involvement of Health portfolio agencies (DoHA and Office of Chemical Safety).
Consultation opportunities	States and Territories and Australian Government agencies have been consulted on the development of the supporting legislation associated with this new regime – the *National Health Security Bill 2007.* An Implementation Advisory Committee will be established in late 2007 with representation from Australian government agencies, states and territory agencies, scientific and technical experts, industry representatives and intelligence agencies. This will be the primary mechanism for consultation and input to the development of the scheme. There will also be significant consultation and education and awareness undertaken by the department with the sector prior to the regulations coming into effect. There has been significant consultation throughout the COAG Biological Agents Review with governments and sector stakeholders (including peak bodies, universities, public and private diagnostic laboratories and facilities).
Expected timetable	The draft Bill is expected to be considered in the Spring Session of parliament 2007. The regulatory arrangements will be 'phased-in', with particular provisions commencing at different times. There will be an 18 month implementation period before the regulation commences. The National Register and reporting requirements are expected to come into effect on 1 January 2009, following the establishment of an administrative unit within DoHA, development of a computer-based National Register and an extensive education and awareness raising campaign for stakeholders. At that time, facilities will be required to report on their holdings of security sensitive biological agents (SSBA). For the first 12 month period only facilities holding a specific 12 (of the total 22 SSBA) will be regulated. After approximately 12 months facilities with holdings of any of the 22 SSBA will be regulated.
Contact details	Director Biological Regulation Section Health Emergency Management and Biosecurity Branch Department of Health and Ageing Ph: (02) 6289 7220 (or 6289 4539)
Date last modified	20 July 2006

Title	Proposed amendments to restrict advertising of tobacco products on the internet
Description of issue	Proposed amendments to the *Tobacco Advertising Prohibition Act 1992* and the Tobacco Advertising Prohibition Regulations, Statutory Rules 1993 No. 129 to clarify the legislation's intent in respect of advertising on the internet. Amendments will clarify that the prohibition on the advertising of tobacco products applies to advertisements on the internet. These changes will impact upon businesses selling tobacco products over the internet.
Consultation opportunities	There will be opportunity for public comment during the preparation of a Regulation Impact Statement.
Expected timetable	Preparation of a Regulation Impact Statement is estimated to occur in late 2007.
Contact details	Penny Marshall Drug Strategy Branch Department of Health and Ageing Ph: (02) 6289 7688 Email: penny.marshall@health.gov.au
Date last modified	23 July 2007

Title	Therapeutic Goods Amendment Bill 2007
Description of issue	Amends section 9B of the Therapeutic Goods Act to substitute the existing requirement for medical device sponsors to have their product entered in the Australian Register of Therapeutic Goods as "included" medical devices by 4 October 2007 with a requirement to lodge an application by 4 October 2007.
Consultation opportunities	Progressed following concerns raised by industry. Key stakeholder groups advised of the proposal to progress the Bill.
Expected timetable	Introduced 20 June 2007; expected debate August 2007.
Contact details	Dr Graeme Harris Deputy Director Office of Devices, Blood and Tissues Therapeutic Goods Administration Ph: (02) 6232 8809 Email: graeme.harris@health.gov.au
Date last modified	July 2007

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 (IVD) devices.
Consultation opportunities	This proposal has been agreed 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	Initial date of implementation early 2006. Extensive stakeholder consultation on draft IVD Rule for trans-Tasman Joint Agency in May/June 2007. Due to recent postponement of the joint agency this is being reviewed.
Contact details	Rita Maclachlan Office of Devices, Blood and Tissues Therapeutic Goods Administration Phone: (02) 6232 8700 Email: rita.maclachlan@tga.gov.au
Date last modified	July 2007

Title	Implementation of a new regulatory framework for human cellular and tissue therapies
Description of issue	A new regulatory framework for Human Cellular and Tissue Therapies (HCTs).
Consultation opportunities	There have been a number of public consultations with all States, Territories, Acute Care Division of the Department of Health and Ageing, New Zealand Ministry of Health and Medsafe, and key professional groups which have continued to further clarify the development of the proposed framework.
Expected timetable	AHMC endorsement of Classes 2, 3 and 4 for the framework obtained in November 2006. Implementation was planned to coincide with the commencement of the Australian New Zealand Therapeutic Products Agency. Due to the recent postponement of the joint agency this is being reviewed.
Contact details	Rita Maclachlan Office of Devices, Blood and Tissues Therapeutic Goods Administration Phone: (02) 6232 8700 Email: rita.maclachlan@tga.gov.au
Date last modified	July 2007

Title	Implementation of a new framework for the regulation of Biologicals
Description of issue	Development of a separate regulatory scheme for Biologicals to include blood components, blood products and human cellular and tissue therapies (incorporating the HCT framework listed above).
Consultation opportunities	The Acute Care Division of the Department of Health and Ageing, the Jurisidictional Blood Committee, the National Blood Authority and New Zealand's Medsafe and Ministry of Health have been consulted.
Expected timetable	Implementation was scheduled to coincide with the commencement of the Australian New Zealand Therapeutic Products Agency. Due to the recent postponement of the joint agency this is being reviewed.
Contact details	Rita Maclachlan Office of Devices, Blood and Tissues Therapeutic Goods Administration Phone: (02) 6232 8700 Email: rita.maclachlan@tga.gov.au
Date last modified	July 2007

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 Government have agreed by means of a treaty to establish the Australia New Zealand Therapeutic Products Authority (ANZTPA) to harmonise therapeutic goods regulation between both countries. On 16 July 2007 the New Zealand Government announced that it would not be proceeding at this time with the legislation designed to enable the establishment of a joint agency with Australia for the regulation of therapeutic products. This was in recognition that New Zealand Government did not have sufficient support in the New Zealand Parliament to ensure the passage of its Bill at this time. Both the Australian and New Zealand Governments remain committed to the vision of a joint trans-Tasman therapeutics authority. However, negotiations between the two countries are postponed for the time being.
Consultation opportunities	
Expected timetable	The Agreement between the Governments of Australia and of New Zealand for the establishment of a Joint Scheme for the Regulation of Therapeutic Products remains in place and is able to be revisited at some future time.
Contact details	Alice Creelman Regulatory Reform Group Therapeutic Goods Administration Ph: (02) 6232 8189 Email: alice.creelman@tga.gov.au
Date last modified	August 2007

Title	Therapeutic Goods (Charges) Amendment Regulations
Description of issue	An amendment to the Therapeutic Goods (Charges) Regulations to implement fees for a new regulatory framework for *In vitro* diagnostic (IVD) devices. Amends schedules of charges applying to therapeutic goods, listed, registered and included medical devices, to include charges for IVDs.
Consultation opportunities	The IVD fees and charges model has been developed in close consultation with industry and in accordance with the Australian Government's cost recovery policy. TGA consultation on IVD fees and charges included: • Ongoing stakeholder consultation on cost recovery proposals undertaken through a TGA/industry working group involving representatives from the Medical Industries Association of Australia (MIAA) and members from the IVD industry who represent both large and smaller IVD suppliers; and • A Cost Recovery Impact Statement (CRIS) identifying the changes and incorporating stakeholder views was completed in March 2006 in accordance with Australian Government Cost Recovery Guidelines and has been published on the TGA's website.
Expected timetable	The drafting of legislation for the new IVD regulatory framework commenced in March 2006. The Therapeutic Goods (Charges) Amendment Regulations will coincide with implementation of the IVD regulatory framework.
Contact details	Vinod Mahaian Business and Services Branch Therapeutic Goods Administration Ph: (02) 6232 8216 Email: vinod.mahaian@tga.gov.au
Date last modified	July 2007

Title	Therapeutic Goods (Medical Devices) Amendment Regulations
Description of issue	An amendment to the Therapeutic Goods (Medical Devices) Regulations to implement fees for a new regulatory framework for *in vitro* diagnostic (IVD) devices. Amends schedules of fees applying to therapeutic goods, listed, registered and included medical devices, to include fees for IVDs.
Consultation opportunities	The IVD fees and charges model has been developed in close consultation with industry and in accordance with the Australian Government's cost recovery policy. TGA consultation on IVD fees and charges included: • Ongoing stakeholder consultation on cost recovery proposals undertaken through a TGA/industry working group involving representatives from the Medical Industries Association of Australia (MIAA) and members from the IVD industry who represent both large and smaller IVD suppliers; and • A Cost Recovery Impact Statement (CRIS) identifying the changes and incorporating stakeholder views was completed in March 2006 in accordance with Australian Government Cost Recovery Guidelines and has been published on the TGA's website.
Expected timetable	The drafting of legislation for the new IVD regulatory framework commenced in March 2006. The Therapeutic Goods (Medical Devices) Amendment Regulations will coincide with implementation of the IVD regulatory framework.
Contact details	Vinod Mahaian Business and Services Branch Therapeutic Goods Administration Ph: (02) 6232 8216 Email: vinod.mahaian@tga.gov.au
Date last modified	July 2007

Title	Implementation of a new regulatory framework for homoeopathic, medicines and related remedies which make therapeutic claims
Description of issue	In March 2005, the Australian Government accepted the recommendation from the Expert Committee on Complementary medicines in the Health System, to implement regulations for homoeopathic medicines and related remedies making therapeutic claims, to ensure they meet appropriate standards of safety, quality and efficacy. The TGA has developed the regulatory framework for these medicines, within the context of the previously proposed Australia New Zealand Therapeutic Products Authority (ANZTPA). However, given that the ANZTPA has now been indefinitely postponed, the Australian Government has indicated it will move to introduce these regulatory requirements within the Australian context.
Consultation opportunities	Consultation (including a Regulation Impact Statement) took place in both Australia and new Zealand during May – August 2006. On-going consultation with key stakeholders was undertaken as part of the broader ANZTPA process. Consultation with key Australian stakeholders is continuing following the postponement of the ANZTPA given the Governments intention to introduce legislation within the Australian context.
Expected timetable	June 2008
Contact details	Dr David Briggs Office of Complementary Medicines Therapeutic Goods Administration Ph: (02) 6232 8439 Email: david.briggs@tga.gov.au
Date last modified	July 2007

Title	**Implementation of legally enforceable quality standards for ingredients in complementary medicines.**
Description of issue	In March 2005, the Australian Government accepted the recommendation from the Expert Committee on Complementary medicines in the Health System, to introduce legally enforceable quality standards for ingredients in complementary medicines. As part of the proposed move to the ANZTPA, the TGA had developed an Order to provide legal underpinning for the quality standards to apply to new complementary medicine substances and those substances which currently have quality parameters outlined in TGA Compositional Guidelines where there is no mandatory standard. Whilst the TGA has undertaken this work within the context of the proposed ANZTPA, given that the ANZTPA has now been indefinitely postponed, the Australian Government has indicated it will move to introduce these regulatory requirements within existing Australian legislation.
Consultation opportunities	On-going consultation with key stakeholders was undertaken as part of the broader ANZTPA process. Consultation with key Australian stakeholders is continuing following the postponement of the ANZTPA given the Governments intention to introduce legislation within the Australian context.
Expected timetable	June 2008
Contact details	Dr David Briggs Office of Complementary Medicines Therapeutic Goods Administration Ph: (02) 6232 8439 Email: david.briggs@tga.gov.au
Date last modified	July 2007

Title	**Implementation of a legally enforceable standard for the levels and kinds of evidence to support indications and claims for Listed complementary medicines.**
Description of issue	In March 2005, the Australian Government accepted the recommendation from the Expert Committee on Complementary medicines in the Health System, to prescribe in the Therapeutic Goods Regulations 1990, the TGA's *Guidelines for Levels and Kinds of Evidence to Support Indications and Claims for Listed medicines* (the Guidelines) as the requirement for the level and kind of evidence to support the indications and claims for Listed complementary medicines. The TGA has reviewed the existing Guidelines with the intent of developing an Order to provide legislative underpinning as part of the move to the Australia New Zealand Therapeutic Products Authority (ANZTPA). However, given that the ANZTPA has been indefinitely postponed, the Australian Government has indicated it will move to introduce these regulatory requirements within existing Australian legislation.
Consultation opportunities	On-going consultation with key stakeholders was undertaken as part of the broader ANZTPA process. Consultation with key Australian stakeholders is continuing following the postponement of the ANZTPA given the Governments intention to introduce legislation within the Australian context.
Expected timetable	June 2008
Contact details	Dr David Briggs Office of Complementary Medicines Therapeutic Goods Administration Ph: (02) 6232 8439 Email: david.briggs@tga.gov.au
Date last modified	July 2007

Title	**Legislative change to implement a revised framework for the advertising of therapeutic products**
Description of issue	Changes to the *Therapeutic Goods Act 1989* and the Therapeutic Goods Regulations 1990 are required to improve the co-regulatory scheme for the advertising of therapeutic products It was planned that a revised advertising co-regulatory model would be implemented with the trans-Tasman therapeutic products regulatory scheme. With the decision in July 2007 to postpone negotiations on the establishment of the trans-Tasman therapeutic products regulatory scheme, there still is a need to finalise advertising arrangements in an Australian-only context.
Consultation opportunities	The proposed trans-Tasman advertising co-regulatory model was substantially based on the report of the Interim Advertising Council (IAC), which included broad membership of all key stakeholder groups. Stakeholders also participated extensively in the consultation process in both Australia and New Zealand on issues that were considered by the IAC. More recently an Advertising Implementation Steering Group had been established to guide the implementation of the operational aspects of the new regulatory model for the advertising of therapeutic products in Australia and New Zealand. It comprised of similar membership to the IAC. Face-to-face stakeholder meetings were held in February 2007 following the release of the draft Australia New Zealand Therapeutic Products Regulatory Scheme Advertising legislation. A number of submissions have been received and considered. These submissions will need to be reconsidered in an Australian-only context.
Expected timetable	Work to adapt the joint scheme provisions for the advertising co-regulatory framework in Australia is planned to commence in the last quarter of 2007.
Contact details	Dr Fiona Cumming Regulatory Reform Group Therapeutic Goods Administration Ph: (02) 6232 8184 Email: fiona.cumming@tga.gov.au
Date last modified	August 2007

Title	Legislative change to implement a revised medicines scheduling framework
Description of issue	Changes are required to the *Therapeutic Goods Act 1989* and the *Therapeutic Goods Regulations 1990* to implement one of the key recommendations of the National Competition Policy *Review of Drugs and Poisons and Controlled Substances Legislation* (the 'Galbally Review'); namely that the National Drugs and Poisons Schedule Committee be disbanded and replaced with two separate committees – the Medicines Scheduling Committee (MSC) and the Chemicals Scheduling Committee (CSC). There will be separate legislative arrangements to establish the MSC and CSC as expert advisory committees and to provide for their respective scheduling procedures. It was intended to realise the proposed scheduling arrangements with the implementation of the trans-Tasman therapeutic products regulatory scheme. With the decision in July 2007 to postpone negotiations on the establishment of the trans-Tasman therapeutic products regulatory scheme, there still is a need to progress this Galbally recommendation in an Australian-only context.
Consultation opportunities	The proposed medicine scheduling model has been developed in close consultation with the National Coordinating Committee on Therapeutic Goods. Widespread consultation on the proposed scheduling model for medicines has also occurred with face-to-face stakeholder meetings in August 2005 and more recently in November 2006 following the release of the relevant draft Australia New Zealand Therapeutic Products Regulatory Scheme legislation. A number of submissions have been received and considered. These submissions will need to be reconsidered in an Australian-only context. Stakeholder consultation on other aspects of the proposed scheduling model including the *Standard for the Uniform Scheduling of Medicines and Poisons* and the Scheduling Policy Framework have recently (July 2007) occurred. These submissions should assist in the finalisation and implementation of these documents.
Expected timetable	Work to adapt the joint scheme provisions for the new medicines scheduling framework in Australia is planned to commence in the last quarter of 2007.
Contact details	Mick O'Connor Regulatory Reform Group Therapeutic Goods Administration Ph: (02) 6232 8197 Email: mick.o'connor@tga.gov.au
Date last modified	August 2007

Title	Diagnostic Imaging (Radiology) Accreditation Scheme Regulations and Ministerial Determination
Description of issue	The purpose of the subordinate legislation is to set out the administrative arrangements for implementing an accreditation scheme for practices providing radiology services linked to the payment of Medicare benefits.
Consultation opportunities	Consultation with key stakeholder groups, including medical colleges and professional associations, to inform these arrangements will be undertaken from July – October 2007.
Expected timetable	November 2007
Contact details	Margaret Curran Diagnostic and Technology Branch Department of Health and Ageing Phone: (02) 6289 7315 Email: margaret.curran@health.gov.au
Date last modified	July 2007

Title	**Pathology and Diagnostic Imaging Prohibited Practices Regulations and Ministerial Determinations**
Description of issue	These Regulations and Ministerial Determinations will set out details relating to specific elements of the pathology and diagnostic imaging prohibited practices provisions of the *Health Insurance Act 1973* resulting from the *Health Insurance Amendment (Inappropriate and Prohibited Practices and Other Measures) Act 2007.*
Consultation opportunities	Consultation with key stakeholder groups, including medical colleges and professional associations, to inform the regulation will be undertaken from July 2007– October 2007.
Expected timetable	November 2007
Contact details	Debbie Stanford Diagnostic and Technology Branch Department of Health and Ageing Phone: (02) 6289 4038 Email: debbie.stanford@health.gov.au
Date last modified	30 July 2007

Title	**National Health Amendment (Pharmaceutical and Other Benefits – Cost Recovery) Bill 2007**
Description of issue	The amendments in this Bill are required to implement a 2005-06 Budget measure for cost recovery of processes relating to evaluating and pricing medicines, vaccines and other products for listing on the Pharmaceutical Benefits Scheme and National Immunisation Programme. Fees will be charged to sponsors (generally, the pharmaceutical industry) who bring submissions for listing products to the Pharmaceutical Benefits Advisory Committee for consideration. Details of the cost recovery scheme, including a schedule of fees, will be specified in regulations.
Consultation opportunities	Rounds of consultation with the pharmaceutical industry and other key stakeholders occurred in November 2005, June 2006 and May 2007. Further consultations are expected prior to implementation.
Expected timetable	Commencement of fees is expected in 2008.
Contact details	Stephen Dellar Pharmaceutical Evaluation Branch Department of Health and Ageing Ph: (02) 6289 7085 Email: stephen.dellar@health.gov.au
Date last modified	7 August 2007

Title	National Health Amendment (Pharmaceutical Benefits Prescribing – Optometrists) Bill 2007
Description of issue	The amendments in this Bill are required to implement a 2007-08 Budget measure to allow optometrists to prescribe a limited list of medicines under the Pharmaceutical Benefits Scheme (PBS). Amendments to regulation and legislative instruments will also be required.
Consultation opportunities	Implementation processes for this initiative include consultation with optometrist, ophthalmology, medical, pharmacy and consumer peak bodies, State/Territory registration boards, optometrist training and accreditation bodies, and medical software vendors.
Expected timetable	Introduction of the Bill in the Spring 2007 Parliamentary sitting period. Commencement of the new PBS prescribing arrangements for optometrists from 1 January 2008.
Contact details	Stephen Dellar Pharmaceutical Evaluation Branch Department of Health and Ageing Ph: (02) 6289 7085 Email: stephen.dellar@health.gov.au
Date last modified	7 August 2007

Title	National Health Amendment (Pharmaceutical Benefits Access) Bill 2007
Description of issue	The Bill proposes amendments to the National Health Act 1953 to provide for Australian Government employees (including spouses and/or dependants) to access medicines subsidised under the Pharmaceutical Benefits Scheme (PBS) whilst working overseas.
Consultation opportunities	Planning and implementation processes for this initiative include consultations with the Department of Foreign Affairs and Trade and other government agencies with government-employed staff posted overseas.
Expected timetable	Introduction of the Bill in the Spring 2007 Parliamentary sitting period.
Contact details	Stephen Dellar Pharmaceutical Evaluation Branch Department of Health and Ageing Ph: (02) 6289 7085 Email: stephen.dellar@health.gov.au
Date last modified	7 August 2007

Title	Health Legislation Amendment Bill
Description of Issue	To amend provisions which were unintentionally narrowed by the National *Health Amendment (Pharmaceutical Benefits Scheme) Act 2007.* The amendments will enable current practice to continue through allowing pharmacists to continue to substitute other brands of other pharmaceutical items of the same drug that are flagged as being equivalent and interchangeable in the Schedule of Pharmaceutical Benefits.
Consultation opportunities	Consultations will be carried out with Medicines Australia and the Pharmacy Guild prior to introducing the amendments.
Expected Timetable	The amendments will be introduced in the sitting week of 13 August 2007.
Contact	Sue Campion Assistant Secretary Policy and Analysis Branch Department of Health and Ageing Ph: (02) 6289 7585 Email: sue.campion@health.gov.au
Date last modified	13 August 2007

Title	Classification Amendment Principles 2007 (No. 1)
Description of issue	In the 2004 Budget as part of the Australian Government's *Investing in Australia's Aged Care – More Places, Better Care* initiative, measures were announced to implement a new funding model for residential aged care with a reduced number of basic funding categories. To initiate these changes these Amending Principles will replace the Resident Classification Scale (RCS) with the Aged Care Funding Instrument (ACFI) as the means of allocating subsidy to providers of residential aged care.
Consultation opportunities	The Minister formed an Industry Reference Group in 2004 to assist in the development of the new funding model. This Group, which consists of industry peak bodies, industry professionals, aged care providers and consumer representatives, meets at least quarterly.
Expected timetable	The new funding model will commence on 20 March 2008. This amendment will be made in September 2007.
Contact details	Keith Tracey-Patte Funding Model Implementation Department of Health and Ageing Ph: (02) 6289 1578 Email: keith.tracey-patte@health.gov.au
Date last modified	13 August 2007

Title	Aged Care Amendment (Securing the future of aged care for Australians) Bill 2007 and Amendments to the Aged Care Principles 1997	
Description of issue	Amendments to the *Aged Care Act 1997* and the *Aged Care Principles* to give effect to the Securing the future of aged care for Australians reform package.	
Consultation opportunities	The reform package is the Australian Government's final response to Professor Warren Hogan's *Review of Pricing Arrangements in Residential Aged Care*. The changes are being implemented in consultation with industry.	
Expected timetable	The majority of the Securing the future for aged care for Australians initiatives will be implemented on 20 March 2008. Amendments to the Aged Care Principles are consequential to passage of the Bill.	
Contact details	Increasing investment in high care; and fairer income-tested care fees	Jacquie Maycock Resident Liaison Section Department of Health and Ageing Ph: (02) 6289 7909 Email: jacquie.maycock@health.gov.au
	More and better community care	Kate McCauley Community Care Branch Department of Health and Ageing Ph: (02) 6289 7930 Email: kate.mccauley@health.gov.au
	Better updating approved providers	Prue Karmel Capital and Approved Provider Section Department of Health and Ageing Ph: (02) 6289 5523 Email: prue.karmel@health.gov.au
Date last modified	14 August 2007	

Title	**Food Standards Australia New Zealand Amendment Regulations 2007**
Description of issue	Amendments to the *Food Standards Australia New Zealand Amendment Regulations 2007* are necessary following amendments to the *Food Standards Australia New Zealand Act 1991* by the *Food Standards Australia New Zealand Amendment Act 2007* that received Royal Assent on 28 June 2007.
Consultation opportunities	Extensive consultation was undertaken with stakeholders in the development of the *Food Standards Australia New Zealand Amendment Act 2007*.
Expected timetable	Regulations to be made by 1 October 2007.
Contact details	Mary Jordan Senior Legal Adviser, Office of Legal Counsel Food Standards Australia New Zealand Ph: (02) 6271 2231 Email: mary.jordan@foodstandards.gov.au
Date last modified	26 July 2006

Title	**National Health Amendment (National HPV Vaccination Program Register) Bill 2007**
Description of issue	This Bill establishes the operation of the National Human Papillomavirus (HPV) Vaccination Program Register.
Consultation opportunities	The Bill was consulted on by the Attorney General's Department and the Office of the Federal Privacy Commissioner.
Expected timetable	Passed by Parliament 9 August 2007; to commence on Royal Assent (expected by September 2007).
Contact details	Letitia Toms Director, Immunisation Policy Section Targeted Prevention Programs Branch Department of Health and Ageing Ph: (02) 6289 8572 E-mail: letitia.toms@nicnas.gov.au
Date last modified	August 2007

Title	**Industrial Chemicals (Notification and Assessment) Amendment (Cosmetics) Bill 2007**
Description of issue	The amendments represent an extension of the existing approach by enabling the Minister to make standards for cosmetic products as a whole, that are imported into, or manufactured in, Australia. The second objective of the Bill is the making of minor technical amendments to improve clarity and consistency within the *Industrial Chemicals (Notification and Assessment) Act 1989*. The Bill presents amendments that deliver on the Government's commitment to reforming the regulation of cosmetics, providing more effective and streamlined regulation while also ensuring the continued safeguarding of health, safety and the environment. Will be made available at www.nicnas.gov.au A Regulatory Impact Statement was prepared.
Consultation opportunities	Both NICNAS and the TGA consulted widely with a broad range of stakeholders including the cosmetics industry and its industry bodies, government and non-government organisations, and worker and community representatives.
Expected timetable	Passed by Parliament 9 August 2007; to commence 28 days after Royal Assent
Contact details	Roshini Jayewardene Regulatory Strategy & Reform National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8860 Email: roshini.jayewardene@nicnas.gov.au
Date last modified	August 2007

Title	Industrial Chemicals (Notification and Assessment) Amendment Bill 2008
Description of issue	Amendments to reflect any agreed outcomes of the Review of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) Existing Chemicals Program. Recommendations that are likely to result in adjustments to regulation may include the identification of downstream use information, streamlining the secondary notification process, the development of new assessment products, a scoping study on monitoring of adverse effects and possible powers to ban, restrict or control certain chemicals A Regulatory Impact Statement will form part of the process.
Consultation opportunities	The implementation of the recommendations will be guided by an Implementation Steering Group comprising government, industry and community representatives. Consultation with stakeholders will occur in accordance with the protocols and principles in the NICNAS Community Engagement Charter, with consultation scheduled for 2007-08.
Expected timetable	It is intended that consultations will occur in stages over the next several years, with a specific timetable yet to be determined.
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	August 2007

Title	Industrial Chemicals (Notification and Assessment) Amendment Regulations 2007
Description of issue	Amendments to reflect any agreed outcomes of the Review of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) Existing Chemicals Program. A Regulatory Impact Statement will form part of the process.
Consultation opportunities	The implementation of the recommendations will be guided by an Implementation Steering Group comprising government, industry and community representatives. Consultation with stakeholders will occur in accordance with the protocols and principles in the NICNAS Community Engagement Charter, with consultation scheduled for 2007-08.
Expected timetable	It is intended that consultations will occur in stages over the next several years, with a specific timetable yet to be determined.
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	August 2007

Title	**Industrial Chemicals (Notification and Assessment) Amendment Regulations 2007**
Description of issue	A number of regulations are required for implementing outstanding Low Regulatory Concern Chemicals (LRCC) reforms. No specific Regulation Impact Statement (RIS) for regulations is required as it is covered in the RIS prepared for the LRCC amendment to the *Industrial Chemical (Notification and Assessment) Act 1989.*
Consultation opportunities	Consistent with the NICNAS Community Engagement Charter, established consultative mechanisms will be used including the NICNAS Industry Government Consultative Committee and the Community Engagement Forum. In addition, public consultation on the proposed changes occurred in October 2006.
Expected timetable	December 2007
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	August 2007

Title	**Industrial Chemicals (Notification and Assessment) Amendment Regulations 2008**
Description of issue	The Regulations will increase New Chemical assessment fees and charges and registration fees for the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) for 2008-09. The exact percentage increase is yet to be determined. Office of Best Practice Regulation will be consulted on the need for a Regulatory Impact Statement (RIS).
Consultation opportunities	Established consultative mechanisms will be used including the NICNAS Industry Government Consultative Committee.
Expected timetable	Expected to be 1 July 2008 for New Chemical assessment fees and charges and 1 September 2008 for registration fees.
Contact details	Roshini Jayewardene Regulatory Strategy & Reform National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8860 E-mail: roshini.jayewardene@nicnas.gov.au
Date last modified	August 2007

Title	**Cosmetic Standard 2007**
Description of issue	To enable the Minister, by legislative Instrument, to determine standards for cosmetics imported into or manufactured in Australia, having regard to Australia's international obligations. A Regulatory Impact Statement was prepared for the amendments to the Act that provided for establishment of a Cosmetic Standard.
Consultation opportunities	No separate consultation required.
Expected timetable	28 days from Royal Assent for the *Industrial Chemicals (Notification and Assessment) Amendment (Cosmetics) Act 2007.*
Contact details	Roshini Jayewardene Regulatory Strategy & Reform National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8860 E-mail: roshini.jayewardene@nicnas.gov.au
Date last modified	August 2007