Department of Health and Ageing
2009-10 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 2008 to 30 June 2009); and
- activities planned in the current financial year (1 July 2009 to 30 June 2010) which could lead to changes to business regulation.

What regulation does a regulatory plan cover?

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

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

A regulatory plan does not include information about the following:

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

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

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

How up to date is information in this regulatory plan?

This plan was last updated on 30 September 2009.

Past Regulatory Activity

Title	***Aged Care Amendment (2008 Measures No. 2) Act 2008* and amendments to the Aged Care Principles**
Description of issue	Amendments to the *Aged Care Act 1997, Aged Care (Bond Security) Act 2006* and Aged Care Principles to address legislative inadequacies and maintain effective regulatory safeguards for ensuring high quality care for older Australians. This included expanding the requirement for aged care staff to undergo police checks, and requiring services providing residential care to report to the Department of Health and Ageing when residents go missing.
Date of effect	1 January 2009
Contact details	Debbie Miller Legislation Unit Department of Health and Ageing Ph (02) 6289 1044 Email: debbie.miller@health.gov.au

Title	***Australian Organ and Tissue Donation and Transplantation Authority Act 2008***
Description of issue	The Act established the Australian Organ and Tissue Donation and Transplantation Authority as an independent statutory agency within the Health and Ageing portfolio from 1 January 2009, and also established the governance structure comprising an Advisory Council and a number of expert advisory committees.
Date of effect	25 November 2008 (Royal Assent received)
Contact details	Jenny Hefford Blood, Organs and Regulatory Policy Branch Department of Health and Ageing Phone: (02) 6289 1478 Email: jenny.hefford@health.gov.au

Title	***Health Care (Appropriation) Amendment Act 2008***
Description of issue	Paragraph 4(3)(b) of this Act was amended by the *Federal Financial Relations (Consequential Amendments and Transitional Provisions) Act 2009* on 27 March 2009 to enable additional payment of Health Care Grants to the states and territories in 2008-09. It was repealed by the *Federal Financial Relations (Consequential Amendments and Transitional Provisions) Act 2009* with effect from 1July 2009. Despite the repeal, subsections 4(5), 5(2) and 5(3) of the *Health Care (Appropriation) Act 1998*, and any delegations under section 7 of that Act of powers under subsection 5(2) or (3), continue to apply, in relation to grants of financial assistance paid during the appropriation period (within the meaning of this Act) starting on 1 July 2003, as if this repeal had not happened.
Date of effect	25 June 2008
Contact details	Gail Yapp Assistant Secretary Acute Care Strategies Branch Department of Health and Ageing Phone: 02 6289 7601 Email: gail.yapp@health.gov.au

Title	***Industrial Chemicals (Notification and Assessment) Amendment Regulations 2008***
Description of issue	A number of regulations implemented outstanding Low Regulatory Concern Chemicals reforms providing incentives to industry to introduce safer chemicals while incorporating safeguards to ensure the protection of the Australian people and the environment.
Date of effect	4 December 2008
Contact details	Matt Gredley Reform National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8873 Email: matthew.gredley@nicnas.gov.au

Title	***Industrial Chemicals (Notification and Assessment) Amendment Regulations 2009***
Description of issue	The Regulations increased New Chemical assessment fees and charges for the National Industrial Chemicals Notification and Assessment Scheme for 2009-10 by 4.15% (Consumer Price Index/Wage Cost Index) Available at www.nicnas.gov.au
Date of effect	1 July 2009
Contact details	Dr Roshini Jayewardene Regulatory Strategy & Reform National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8860 Email: roshini.jayewardene@nicnas.gov.au

Title	**Private Health Insurance (Benefit Requirement) Rules**
Description of issue	The Rules provide for the minimum benefit requirement for psychiatric, rehabilitation and palliative care and other hospital treatment and the minimum level of benefits payable for hospital treatment. Various amendments to the Rules were made in respect of these minimum requirements or benefit levels.
Date of effect	June 2008, July 2008, September 2008, October, December 2008, February 2009, March 2009, May 2009
Contact details	Penny Shakespeare Private Health Insurance Branch Department of Health and Ageing Ph: (02) 6289 9490 Email: penny.shakespeare@health.gov.au

Title	***Private Health Insurance (National Joint Replacement Register Levy) Act 2009***
Description of issue	This Act established the National Joint Replacement Register Levy for the purpose of funding the National Joint Replacement Registry (NJRR). The NJRR collects data on the implementation of prosthetic joint replacement devices, reports revision rates, complications and other outcomes, and monitors mortality rates. The Act enables the costs of operating the NJRR to be recovered by a levy imposed on each joint replacement prostheses sponsor.
Date of effect	1 July 2009
Contact details	Penny Shakespeare Private Health Insurance Branch Department of Health and Ageing Ph: (02) 6289 9490 Email: penny.shakespeare@health.gov.au

Title	**Private Health Insurance (Prostheses) Rules**
Description of issue	Various amendments to the Rules were made to update prostheses benefits, as required through the year.
Date of effect	August 2008, February 2009, August 2009
Contact details	Penny Shakespeare Private Health Insurance Branch Department of Health and Ageing Ph: (02) 6289 9490 Email: penny.shakespeare@health.gov.au

Title	***Private Health Insurance Legislation Amendment Act 2009***
Description of issue	The *Private Health Insurance Act 2007* was amended to enable private health insurers to allow insurers to permanently offer extended family policies that cover 'dependent child non-students'. 'Dependent child non-students' are people aged from 18 to 24 with no partner where defined in a private health insurer's fund rules. Family policies, or policies with more than one person including a 'dependent child non-student', may be offered at an additional premium cost. Consequential amendments were also made consistent with the introduction of the *Private Health Insurance (National Joint Replacement Register Levy) Act 2009*, which imposes a levy to fund the National Joint Replacement Registry. Amendments were made to the *Age Discrimination Act 2004* to provide that compliance with provisions concerning 'dependent child non-students' does not breach age discrimination requirements.
Date of effect	1 July 2009
Contact details	Penny Shakespeare Private Health Insurance Branch Department of Health and Ageing Ph: (02) 6289 9490 Email: penny.shakespeare@health.gov.au

Title	**Social Security and other Legislation Amendment (Pension Reform and Other 2009 Budget Measures) Act 2009 (Schedule 17)**
Description of issue	Amendments to *Aged Care Act 1997* and the Aged Care Principles ensured that the increase in the pension flowed appropriately and equitably to both the care recipient and the approved provider.
Date of effect	20 September 2009
Contact details	Debbie Miller Legislation Unit Department of Health and Ageing Ph (02) 6289 1044 Email: debbie.miller@health.gov.au

Title	***Therapeutic Goods Amendment (Medical Devices and Other Measures) Act 2009***
Description of issue	This Act amended the *Therapeutic Goods Act 1989* to: 1. exempt medical devices in certain circumstances from provisions in the Act, as currently are medicines. This will allow medical devices to be stockpiled to deal with possible national emergencies or be made available quickly in the case of actual emergencies; 2. allow for a wider range of therapeutic goods information to be provided to the public and for the Therapeutic Goods Administration to release information to Commonwealth agencies or international authorities under a wider range of circumstances to support safety and quality in therapeutic goods; 3. apply the same requirements to both pre-approved and other advertisements that contain restricted representations; 4. allow for medicines and other therapeutic goods, that are not medical devices, to meet the requirements of the European Pharmacopoeia or the United States Pharmacopoeia as alternatives to the British Pharmacopoeia; 5. revise the existing 'fit and proper person' test (for the granting of manufacturing licences for therapeutic goods other than medical devices and for issuing conformity assessment certificates for the manufacture of medical devices) with a test that is narrower and more transparent and which is expected to be easier to administer.
Date of effect	Items 1, 2 and 3 - 18 June 2009; item 4 - 1 July 2009; item 5 - expected to be proclaimed on 1 December 2009
Contact details	Charles Maskell-Knight Principal Adviser, Regulatory Reform Therapeutic Goods Administration (02) 6232 8454 Email: charles.maskell-knight@tga.gov.au

Title	***Therapeutic Goods (Medical Devices) Amendment Regulations 2008 (No. 2)***
Description of issue	These Regulations amended the *Therapeutic Goods (Medical Devices) Regulations 2002* to exempt medical devices that are to be used for emergency purposes from certain requirements of the *Therapeutic Goods Act 1989*. This exemption is part of a framework which allows for the stockpiling of therapeutic goods and supports Australia's preparedness to deal with a potential threat in a public health emergency.
Date of effect	19 December 2008
Contact details	Marlene Keese Office of Legal Services Therapeutic Goods Administration Ph: (02) 6232 8398 Email: marlene.keese@tga.gov.au

Title	***Therapeutic Goods Amendment (2009 Measures No. 1) Act 2009***
Description of issue	This Act amends the *Therapeutic Goods Act 1989* to: 1. allow the registration or listing of medicines and therapeutic devices to be suspended rather than fully cancelled in certain circumstances; 2. allow the taking of video and other recordings and taking of samples of things related to therapeutic goods on premises; 3. ensuring consistency of the powers that can be exercised by an authorised person under the Act in relation to the entry, inspection of and the taking of samples from specified premises; 4. clarify the definition of accessory to a medical device and require that medicine labels not make claims that are inconsistent with the claims approved for the product; 5. apply technical amendments to existing provisions referring to legislative instruments in the Act; 6. incorporate a new framework for the regulation of homoeopathic and anthroposophic medicines. Details of the framework will be set out in regulations and other subordinate legislation made under the Act. Further consultation with industry will occur on the development of this detail; 7. clarify that manufacturing licenses cover single sites, except in certain circumstances, and enabling variation and transfer of licenses to another manufacturer; 8. allow the Minister to determine lists of ingredients that are permitted and prohibited to be included in listed medicines. Applications will be able to be made to ask that an ingredient be included in the permitted ingredients list; and 9. include other amendments including clarification of the way conditions are set on registered and listed goods and clarifying the Advertising Code as a legislative instrument. These amendments will also require the making of legislative instruments for the purposes of specified provisions under this Amendment Act.
Date of effect	Items 1, 2, 3 and 4 – 28 August 2009; item 5 - 1 July 2011; item 6 – to be proclaimed to commence on 25 February 2010; item 7 – to be proclaimed to commence on 5 February 2010; item 8 – to be proclaimed on 25 January 2010, and others to commence on 28 August 2009.
Contact details	Charles Maskell-Knight Principal Adviser, Regulatory Reform Therapeutic Goods Administration (02) 6232 8454 Email: charles.maskell-knight@tga.gov.au

Title	***Therapeutic Goods Legislation Amendment (Annual Charges) Act 2008***
Description of issue	This Act amended both the *Therapeutic Goods Act 1989* and *Therapeutic Goods (Charges) Act 1989* to provide for transparency, accountability and clarity in relation to the granting of exemptions from liability to pay annual charges for goods that have low value and low volume turnover. It also provided for the manufacturing licence fee to be set to zero to enable transition to new single site manufacturing licenses and the payment of fees and charges to be made at the same time.
Date of effect	1 January 2009, however the changes to the payment of annual charges and the exemption apply to financial years commencing 2009-2010 and afterwards.
Contact details	Marlene Keese Office of Legal Services Therapeutic Goods Administration Ph: (02) 6232 8398 Email: marlene.keese@tga.gov.au

Title	***Therapeutic Goods Amendment Regulations 2009 (No. 3)*; and *Therapeutic Goods (Charges) Amendment Regulations 2009 (No. 1)***
Description of issue	These Regulations amended the *Therapeutic Goods Regulations 1990* and *Therapeutic Goods (Charges) Regulations 1990* as a consequence of the amendments made by the *Therapeutic Goods Legislation Amendment (Annual Charges) Act 2008*. The amendments include: • setting out dates when certain annual charges become payable; • clarification of requirements in relation to the low value turnover exemption from annual charges, such as the making of an application for the exemption, deadlines for the making of an application and provision of relevant statements and information, lapsing of an application, the granting of an exemption, the cancellation of an exemption, application fee, the requirement relating to the provision of statements certified by an approved person in relation to an application for exemption, the obtaining of additional information or documents from applicants for an exemption or persons granted exemption, and merits review; and • other consequential and technical amendments.
Date of effect	1 July 2009
Contact details	Marlene Keese Office of Legal Services Therapeutic Goods Administration Ph: (02) 6232 8398 Email: marlene.keese@tga.gov.au

Title	***Therapeutic Goods Amendment Regulations 2009 (No. 5)*; *Therapeutic Goods (Medical Devices) Amendment Regulations 2009 (No. 1)*; and *Therapeutic Goods (Charges) Amendment Regulations 2009 (No. 2)***
Description of issue	These Regulations amend the *Therapeutic Goods Regulations 1990*, *Therapeutic Goods (Medical Devices) Regulations 2002*, and *Therapeutic Goods (Charges) Regulations 1990* to increase by 4.3% most annual product charges and fees payable for the regulation of therapeutic goods.
Date of effect	9 July 2009
Contact details	Marlene Keese Office of Legal Services Therapeutic Goods Administration Ph: (02) 6232 8398 Email: marlene.keese@tga.gov.au

Title	***Therapeutic Goods Amendment Regulations 2009 (No. 5)***
Description of issue	These Regulations amend the *Therapeutic Goods Regulations 1990* to include a new part to administer and implement an infringement notice scheme. This scheme was incorporated into the *Therapeutic Goods Act 1989* in 2006 but its implementation was delayed due to Australia New Zealand Therapeutic Products Authority reforms.
Date of effect	11 September 2009
Contact details	Marlene Keese Office of Legal Services Therapeutic Goods Administration Ph: (02) 6232 8398 Email: marlene.keese@tga.gov.au

Planned Regulatory Activity

Title	Amendments to *Health Insurance Regulations 1975*
Description of issue	The policy intent is to amend the *Health Insurance Regulations 1975* (HI Regulations) to broaden the scope of the Diagnostic Imaging Accreditation Scheme to cover all diagnostic imaging services in the Health Insurance (Diagnostic Imaging Services Table) Regulations from 1 July 2010. Regulation 12AA of the HI Regulations operates to exclude certain non-radiology services from the Scheme and will be repealed so that a Medicare benefit will only be payable for non-radiology services currently prescribed in regulation 12AA, when they are provided from an accredited site.
Consultation opportunities	Consultation regarding the decision to broaden the scope of the Scheme, and proposals for transitioning providers of non-radiology services into the Scheme by 1 July 2010, commenced in February 2009. Feedback about the proposed arrangements to broaden the Scheme has been received from professional and industry organisations representing providers of both radiology and non-radiology services.
Date of effect	1 July 2010
Contact details	Anthony Butler Diagnostic Services Branch Department of Health and Ageing Phone: (02) 6289 7315 Email: anthony.butler@health.gov.au
Date last modified	August 2009

Title	Amendment to *National Health (Pharmaceutical Benefits) Regulations 1960*
Description of issue	These Regulations will establish the requirements and conditions for the supply of pharmaceutical benefits for prescriptions written by midwives and nurse practitioners in accordance with the Schedule of Pharmaceutical Benefits.
Consultation opportunities	While the legislation is before Parliament, the Department is actively consulting with midwife and nurse practitioner professional groups and other interested parties (such as clinicians, pharmacologists and the Pharmaceutical Benefits Advisory Committee).
Expected timetable	The amendments will be finalised following passage of the Health Legislation Amendment (Midwives and Nurse Practitioners) Bill 2009. Following further consultation with stakeholders, the Regulations are proposed to be made prior to 1 July 2010 to allow for all systems and implementation changes to be in place prior to the scheduled commencement date of 1 November 2010.
Contact details	Linda Jackson Pharmaceutical Evaluation Branch Department of Health and Ageing Ph: (02) 6289 7085 Email: linda.jackson@health.gov.au
Date last modified	September 2009

Title	Amendments to *Private Health Insurance (Benefit Requirement) Rules 2009*
Description of issue	The Rules provide for the minimum benefit requirement for psychiatric, rehabilitation and palliative care and other hospital treatment, and the minimum level of benefits payable for hospital treatment. Various amendments to the Rules are planned in respect of these minimum requirements or benefit levels.
Consultation opportunities	The Rules are developed in consultation with the Second Tier Advisory Committee which includes equal representation from both private hospital and private health insurance sectors, and with relevant state government health departments.
Expected timetable	Amendments will occur at various times during 2009-10

Contact details	Penny Shakespeare Private Health Insurance Branch Department of Health and Ageing Ph: (02) 6289 9490 Email: penny.shakespeare@health.gov.au
Date last modified	29 July 2009

Title	**Amendments to *Private Health Insurance (Complying Product) Rules 2009***
Description of issue	To remove temporary provisions for extended family policies that are no longer required following amendments to the *Private Health Insurance Act 2007* which introduced permanent provisions for such policies.
Consultation opportunities	The amendments are consequential to the amendments to the *Private Health Insurance Act 2007,* contained in the *Private Health Insurance Legislation Amendment Act 2009*. Consultation occurred with the private health insurance industry.
Expected timetable	September 2009
Contact details	Penny Shakespeare Private Health Insurance Branch Department of Health and Ageing Ph: (02) 6289 9490 Email: penny.shakespeare@health.gov.au
Date last modified	16 July 2009

Title	**Amendment to *Therapeutic Goods (Medical Devices) Regulations 2002***
Description of issue	An amendment to the Regulations to implement the new regulatory framework for *In vitro* diagnostic (IVD) devices. Consequential amendments will also be required in relation to applicable fees and charges.
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. Extensive stakeholder consultation on draft IVD Rules for the Trans-Tasman Joint Agency occurred in May/June 2007.
	Implementation was expected with the commencement of the now suspended joint regulatory scheme with New Zealand. The development of the IVD framework has progressed in an Australia-only context. The IVD regulatory framework is expected to come into effect on 1 March 2010.
Contact details	Marlene Keese Office of Legal Services Therapeutic Goods Administration Ph: (02) 6232 8398 Email: marlene.keese@tga.gov.au
Date last modified	September 2009

Title	**Amendment to *Therapeutic Goods Regulations 1990* – Committees**
Description of issue	Changes are required to the *Therapeutic Goods Regulations 1990* regarding membership, terms of reference and processes of Therapeutic Goods Administration committees.
Consultation opportunities	The proposed committee changes were developed and consulted on as part of the broader Australia New Zealand Therapeutic Products Authority reforms.
Expected timetable	December 2009
Contact details	Mick O'Connor Executive Support Therapeutic Goods Administration Ph: (02) 6232 8197 Email: mick.o'connor@tga.gov.au
Date last modified	September 2009

Title	**Amendment to *Therapeutic Goods Regulations 1990* – definition of complementary medicines**
Description of issue	Changes are required to the *Therapeutic Goods Regulations 1990* to incorporate a new definition for complementary medicines which would more clearly define the boundaries for regulation of complementary medicine products.
Consultation opportunities	Consultation undertaken in the lead up to the establishment of the previously proposed Australia New Zealand Therapeutic Products Authority.
Expected timetable	March 2010
Contact details	Mick O'Connor Executive Support Therapeutic Goods Administration Ph: (02) 6232 8197 Email: mick.o'connor@tga.gov.au
Date last modified	September 2009

Title	**Amendment to *Therapeutic Goods Regulations 1990* – implementation of a new regulatory framework for biologicals**
Description of issue	Changes are required to the *Therapeutic Goods Regulations 1990* consequent to amendments to the Act through the Therapeutic Goods Amendment (2009 Measures No. 3) Bill 2009 for the new regulatory framework for biologicals.
Consultation opportunities	There have been a number of public consultations with all states, territories, Acute Care Division of the Department of Health and Ageing and key professional groups which have continued to further clarify the development of the proposed framework.
Expected timetable	In November 2006 the Australian Health Ministers' Conference (AHMC) endorsed 4 classes of biologicals (according to risk level) for the proposed biological regulatory framework. Implementation was planned to coincide with the commencement of the Australia New Zealand Therapeutic Products Authority (ANZTPA), however negotiations to establish ANZTPA were suspended in July 2007. The Government has agreed that the Therapeutic Goods Administration progress the implementation of the AHMC-endorsed biologicals regulatory framework in an Australia-only context. The Regulations will commence on the day the amendments to the Act giving effect to the framework commence. The amendments to the Act will commence on a day to be proclaimed within 12 months of the Act receiving Royal Assent, expected to be early to mid 2011.
Contact details	Marlene Keese Office of Legal Services Therapeutic Goods Administration Ph: (02) 6232 8398 Email: marlene.keese@tga.gov.au
Date last modified	September 2009

Title	**Amendment to *Therapeutic Goods Regulations 1990* – implementation of a new regulatory framework for homoeopathic an anthroposophic medicines**
Description of issue	Changes are required to the *Therapeutic Goods Regulations 1990* to incorporate the detail of the regulatory framework for homoeopathic and anthroposophic medicines making therapeutic claims, to ensure they meet appropriate standards of safety, quality and efficacy.
Consultation opportunities	Consultation took place as part of the broader Australia New Zealand Therapeutic Products Authority process. Consultation with key Australian stakeholders on implementation in an Australia-only context is continuing.
Expected timetable	July 2011

Contact details	Marlene Keese Office of Legal Services Therapeutic Goods Administration Ph: (02) 6232 8398 Email: marlene.keese@tga.gov.au
Date last modified	September 2009

Title	**Amendment to *Therapeutic Goods Regulations 1990* – revised scheduling framework**
Description of issue	Changes are required to the *Therapeutic Goods Regulations 1990* to implement separate arrangements for the scheduling of medicines and chemicals
Consultation opportunities	The proposed scheduling model was developed in close consultation with the National Coordinating Committee on Therapeutic Goods. 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 has also occurred.
Expected timetable	1 July 2010
Contact details	Mick O'Connor Executive Support Therapeutic Goods Administration Ph: (02) 6232 8197 Email: mick.o'connor@tga.gov.au
Date last modified	September 2009

Title	**Amendments to Private Health Insurance (Prostheses) Rules 2009**
Description of issue	Various amendments to the Rules are planned to update prostheses benefits, 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.
Expected timetable	February 2010, August 2010
Contact details	Penny Shakespeare Private Health Insurance Branch Department of Health and Ageing Ph: (02) 6289 9490 Email: penny.shakespeare@health.gov.au
Date last modified	September 2009

Title	**Development and implementation of Private Health Insurance (National Joint Replacement Register Levy) Rules 2009**
Description of issue	Rules will be developed to enable the operating costs of the National Joint Replacement Registry to be recovered on each day specified (expected to be twice per year). The Rules will impose the levy on each joint replacement prostheses sponsor according to the number of prostheses they sponsor, at specified rates.
Consultation opportunities	The Department consulted with sponsors of joint replacement prostheses sponsors and with the National Joint Replacement Registry, to develop implementation models for the imposition of the levy. .
Expected timetable	October-November 2009 (development), February 2010 (collection)
Contact details	Penny Shakespeare Private Health Insurance Branch Department of Health and Ageing Ph: (02) 6289 9490 Email: penny.shakespeare@health.gov.au
Date last modified	16 July 2009

Title	**Health Insurance (Diagnostic Imaging Accreditation) Determination 2010**
Description of issue	This Determination will succeed the *Health Insurance (Diagnostic Accreditation) Determination 2008* which expires on 30 June 2010. The Determination will establish the ongoing scheme under which all practices providing diagnostic imaging services in the Health Insurance (Diagnostic Imaging Services Table) Regulations can be accredited for diagnostic imaging procedures. The Determination will have no end date.
Consultation opportunities	Consultation about the ongoing arrangements for the Scheme commenced in February 2009 and included state and territory health departments, around 30 key professional and industry groups as well as the four Stage I approved accreditors. Qualitative and quantitative research regarding the impact of arrangements on practices and accreditors has also been conducted to inform the development of future arrangements for the Scheme.
Date of effect	1 July 2010
Contact details	Anthony Butler Diagnostic Services Branch Department of Health and Ageing Phone: (02) 6289 7315 Email: anthony.butler@health.gov.au
Date last modified	August 2009

Title	**Health Insurance (Diagnostic Imaging Accreditation – Approved Accreditors) Determination 2010**
Description of issue	This Determination will succeed the *Health Insurance (Diagnostic Imaging Accreditation – Approved Accreditors) Determination 2008* which expires on 30 June 2010. The Health Insurance (Diagnostic Imaging Accreditation – Approved Accreditors) Determination 2010 will: i) designate the persons who can receive notices from proprietors of diagnostic imaging practices who are seeking accreditation; and ii) approve the accreditors who can receive and make decisions on applications from proprietors of diagnostic imaging practices seeking accreditation. The Determination will have no end date.
Consultation opportunities	Consultation about the ongoing arrangements for the Scheme commenced in February 2009 and included state and territory health departments, around 30 key professional and industry groups as well as the four Stage I approved accreditors. Qualitative and quantitative research regarding the impact of arrangements on practices and accreditors has also been conducted to inform the development of future arrangements for the Scheme.
Date of effect	1 July 2010
Contact details	Anthony Butler Diagnostic Services Branch Department of Health and Ageing Phone: (02) 6289 7315 Email: anthony.butler@health.gov.au
Date last modified	August 2009

Title	Health Insurance (Diagnostic Imaging Services Table) Regulations 2010
Description of issue	The proposed amendments to the Health Insurance (Diagnostic Imaging Services Table) Regulations would trial the listing of four new 'image only' items for three years. This proposal anticipates an eighteen-month lead time prior to the introduction of the new items, with Medicare implementation effective 1 November 2010
Consultation opportunities	A communication strategy will be developed and implemented to communicate the terms and conditions for the new items to all requesters including GPs, practice managers and allied health professionals.
Date of effect	1 November 2010
Contact details	Anthony Butler Diagnostic Services Branch Department of Health and Ageing Phone: (02) 6289 7315 Email: anthony.butler@health.gov.au
Date last modified	August 2009

Title	Health Insurance Amendment (Compliance) Bill 2009
Description of issue	To give effect to the Increased MBS Compliance Audits initiative announced in the 2008-09 Budget by introducing: • a requirement for persons (practitioners and specified third parties) to produce information to substantiate a Medicare benefit amount paid in respect of a professional service; • a civil penalty for specified third parties (such as corporate practices) who refuse to produce information relevant to substantiating services provided by a practitioner for which a Medicare benefit has been paid; and • a financial administrative penalty for certain practitioners who are unable to substantiate a Medicare benefit which has been paid in respect of a service.
Consultation opportunities	Significant consultation has been and continues to be conducted with a broad range of stakeholders including medical profession, specialist colleges, allied health professionals, privacy and consumer organisations. An exposure draft of the Bill and Privacy Impact Assessment were published in March 2009. In addition the Senate Community Affairs Committee held an Inquiry into Compliance Audits in April 2009.
Expected timetable	The Bill is before Parliament
Contact details	Samantha Robertson Assistant Secretary Medicare Benefits Branch Department of Health and Ageing Ph: (02) 6289 6945 Email: samantha.robertson@health.gov.au
Date last modified	September 2009

Title	Health Insurance Amendment (Diagnostic Imaging Accreditation) Bill 2009
Description of issue	The Bill would amend the *Health Insurance Act 1973* to include transitional provisions to allow practices providing non-radiology services (cardiac ultrasound and angiography; obstetric and gynaecological ultrasound; and nuclear medicine imaging services) to enter into the Diagnostic Imaging Accreditation Scheme by registering for 'deemed accreditation' from 1 April 2010 to 30 June 2010.
Consultation opportunities	Consultation regarding the decision to broaden the scope of the Scheme and proposals for transitioning providers of non-radiology services into the Scheme by 1 July 2010 commenced in February 2009. Feedback about the proposed arrangements to broaden the Scheme has been received from professional and industry organisations representing providers of both radiology and non-radiology services.

Date of effect	1 April 2010
Contact details	Anthony Butler Diagnostic Services Branch Department of Health and Ageing Phone: (02) 6289 7315 Email: anthony.butler@health.gov.au
Date last modified	August 2009

Title	**Health Insurance Amendment (Extended Medicare Safety Net) Bill 2009 and Health Insurance (Extended Medicare Safety Net) Determination 2009**
Description of issue	The Extended Medicare Safety Net (EMSN) provides an additional rebate for Australian families and singles who have out-of-pocket costs for Medicare eligible out-of-hospital services once an annual threshold in out-of-pocket costs has been met. In 2009, the annual threshold for concession cardholders and people who receive Family Tax Benefits (Part A) is $555.70. For all other singles and families the annual threshold is $1,111.60. Out-of-hospital services include GP and specialist attendances and services provided in private clinics. Once the relevant annual threshold has been met, Medicare will pay for 80% of any future out-of-pocket costs for Medicare eligible out-of-hospital services for the remainder of the calendar year. However, as announced in the 2009-10 Budget, from 1 January 2010 for a limited number of Medicare items there will be an upper limit (EMSN cap) on the amount of benefit that will be paid under the EMSN. The new caps will be placed on the following items: obstetrics, Assisted Reproductive Technology (ART) including In-Vitro Fertilisation, hair transplantation for alopecia, one type of cataract operation and one type of varicose vein treatment. The Bill amends the *Health Insurance Act 1973* to allow the Minister for Health and Ageing to determine, by legislative instrument, the Medicare items that will be subject to an EMSN cap and the level of the EMSN cap. The Determination sets out the Medicare items that will have an EMSN cap and the EMSN cap applying to each of the items. This legislation has been assessed as having a low regulatory impact on business. EMSN entitlements are calculated and paid by Medicare Australia.
Consultation opportunities	The Bill was referred to the Senate Committee for Community Affairs for Inquiry and report. The Committee invited submissions from the public, including medical stakeholders, for consideration. The Committee reported on 5 August 2009 and recommended that the Bill be passed. The Department is currently working with the ART profession to restructure the Medicare items for ART. The Department will also work with the obstetrics profession on new obstetrics items
Expected timetable	The Bill and Determination have been drafted to commence on 1 January 2010. The Bill was passed by Parliament on 17 September 2009 and was granted Royal Assent on 7 October 2009.
Contact details	Samantha Robertson Medicare Benefits Branch Department of Health and Ageing Ph: (02) 6289 6945 Email: samantha.robertson@health.gov.au
Date last modified	September 2009

Title	**Import, export and monitoring arrangements for controlled drug substances**
Description of issue	The Office of Chemical Safety and Environmental Health will review the relevant parts of the *Customs (Prohibited Imports) Regulations 1956* and *Customs (Prohibited Exports) Regulations 1958* that relate to narcotic, psychotropic and precursor substances. It is expected that this process will identify opportunities to update or clarify the substances that are controlled under these Regulations, which will ensure consistency with Australia's international treaty obligations and assist with the reduction of supply of precursor substances used for the manufacture of illicit drugs.
Consultation opportunities	Specific consultation mechanisms are yet to be determined, however initial discussions have commenced and will continue with the Australian Customs and Border Protection Service and the Attorney-General's Department. It is expected that further consultation will be conducted with stakeholders and relevant state/territory government agencies. Regulation impact statements will be developed where required.
Expected timetable	It is intended that an internal review of the Regulations will be conducted in the first half of 2009-10 and a more formal arrangement to review and consult on potential regulatory changes may be initiated after that. A specific timetable is yet to be determined.
Contact details	Darren Jones Treaties and Compliance Office of Chemical Safety Ph: (02) 6289 2500 Email: darren.jones@health.gov.au
Date last modified	July 2008

Title	**Industrial Chemicals (Notification and Assessment) Amendment Regulations 2010**
Description of issue	Amendments to reflect first tranche of agreed outcomes of the Review of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) Existing Chemicals Program. These relate to streamlining the secondary notification process and the development of new assessment products. A regulatory impact analysis will form part of the process.
Consultation opportunities	Consultation with stakeholders will occur in accordance with the protocols and principles in the NICNAS Community Engagement Charter, with consultation continuing in 2009-10. The implementation steering group, comprising government, industry and community representatives, which has guided the implementation of the Existing Chemicals Review recommendations, will also be consulted.
Expected timetable	It is intended that modifications to the Regulations will occur as each requirement for secondary notification processes and new assessment products is developed in step with legislative changes.
Contact details	**Technical:** Graham Harvey Existing Chemicals National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8880 Email: graham.harvey@nicnas.gov.au **Policy:** Donald Ward Chemical Policy Section Office of Chemical Safety and Environmental Health Department of Health and Ageing Ph: (02) 6289 2662 Email: donald.ward@health.gov.au
Date last modified	August 2009

Title	Industrial Chemicals (Notification and Assessment) Amendment Regulations 2010
Description of issue	The Regulations will increase fees and charges for the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) for 2010-11. The exact percentage increase is yet to be determined. Office of Best Practice Regulation will be consulted on the need for a Regulation Impact Statement.
Consultation opportunities	The NICNAS Industry Government Consultative Committee will be consulted.
Expected timetable	Expected to be 1 July 2010 for New Chemical assessment fees and charges, and 1 September 2010 for registration fees and charges.
Contact details	Dr 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 2009

Title	Industrial Chemicals (Notification and Assessment) Amendment Regulations 2010
Description of issue	The Regulations will introduce conditions or restrictions to allow the controlled introduction of a chemical subject to section 106 of the *Industrial Chemicals (Notification and Assessment) Act 1989*. Office of Best Practice Regulation will be consulted on the need for a Regulation Impact Statement.
Consultation opportunities	Established consultative mechanisms will be used including the NICNAS Industry Government Consultative Committee.
Expected timetable	30 June 2010
Contact details	Lewis Norman Compliance and Reporting National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8807 Email: lewis.norman@nicnas.gov.au
Date last modified	August 2009

Title	Industrial Chemicals (Notification and Assessment) Amendment Regulations 2010
Description of issue	Minor amendment of regulation 11C is required to clarify the conditions relating to the *Fuel Quality Standards Act 2000* Office of Best Practice Regulation will be consulted on the need for a Regulatory Impact Statement (RIS).
Consultation opportunities	Established consultative mechanisms, including the NICNAS Industry Government Consultative Committee. The Australian Government Department of the Environment, Water, Heritage and the Arts will also be consulted.
Expected timetable	30 June 2010
Contact details	Sneha Satya Existing Chemicals National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8880 Email: sneha.satya@nicnas.gov.au
Date last modified	August 2009

Title	Industrial Chemicals (Notification and Assessment) Amendment (Disinfectants) Bill 2010
Description of issue	The amendments will provide for changes to the *Industrial Chemicals (Notification and Assessment) Act 1989* to enable the transfer of responsibility of some chemicals in low risk hard surface disinfectant products from the Therapeutic Goods Administration (TGA) to the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). The Bill will make amendments that deliver on the Government's commitment to reforming the regulation of disinfectants, 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 analysis will be undertaken.
Consultation opportunities	Both NICNAS and the TGA are consulting widely with a broad range of stakeholders, including the disinfectants industry and its industry bodies, and worker and community representatives, on a set of reform options prepared by an independent consultant for NICNAS and the TGA.
Expected timetable	Agreed position by December 2009 to meet COAG deadline, with date of introduction of Bill to Parliament to be determined.
Contact details	**Technical:** Dr Matthew Gredley Reform Team Leader National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8873 Email: matthew.gredley@nicnas.gov.au **Policy:** Donald Ward Chemical Policy Section Office of Chemical Safety and Environmental Health Department of Health and Ageing Ph: (02) 6289 2662 Email: donald.ward@health.gov.au
Date last modified	August 2009

Title	Industrial Chemicals (Notification and Assessment) Amendment Bill 2010
Description of issue	Amendments to reflect first tranche of agreed outcomes of the Review of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) Existing Chemicals Program. These relate to streamlining the secondary notification process and the development of new assessment products. A regulatory impact analysis will form part of the process.
Consultation opportunities	Consultation with stakeholders will occur in accordance with the protocols and principles in the NICNAS Community Engagement Charter, with consultation continuing in 2009-10. The implementation steering group, comprising government, industry and community representatives, which has guided the implementation of the Existing Chemicals Review recommendations, will also be consulted.
Expected timetable	A specific timetable for legislative change is yet to be determined
Contact details	**Technical:** Graham Harvey Existing Chemicals National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8880 Email: graham.harvey@nicnas.gov.au **Policy:** Donald Ward Chemical Policy Section Office of Chemical Safety and Environmental Health Department of Health and Ageing Ph: (02) 6289 2662

	Email: donald.ward@health.gov.au
Date last modified	August 2009

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 *Therapeutic Goods Regulations 1990* are required to improve the existing arrangements for the advertising of therapeutic products
Consultation opportunities	Extensive consultation was undertaken with the development of the advertising arrangements for implementation as part of the now suspended Australia New Zealand Therapeutic Products Authority. Further consultation on revised arrangements that will improve the existing advertising scheme for therapeutic goods by streamlining requirements and reducing regulatory burdens is expected to occur before the end of 2009.
Expected timetable	July 2011
Contact details	Charles Maskell-Knight Principal Adviser, Regulatory Reform Therapeutic Goods Administration (02) 6232 8454 Email: charles.maskell-knight@tga.gov.au
Date last modified	September 2009

Title	**National Health (Australian Community Pharmacy Authority Rules) Determination 2010**
Description of issue	New pharmacy location rules to be determined by the Minister under section 99L of the *National Health Act 1953*, as part of the Fifth Community Pharmacy Agreement between the Commonwealth and the Pharmacy Guild of Australia.
Consultation opportunities	Consultation to occur with a range of stakeholders, including the Pharmacy Guild of Australia, through an external review of the Rules to be undertaken late 2009.
Expected timetable	To commence from 1 July 2010
Contact details	Chris Forsey Community Pharmacy Branch Department of Health and Ageing Ph: (02) 6289 2368 Email: chris.forsey@health.gov.au
Date last modified	13 August 2009

Title	**National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009**
Description of issue	These Regulations will establish the requirements and conditions for cost recovery fees to be applied to the evaluation, pricing and listing medicines and vaccines on the Schedule of Pharmaceutical Benefits.
Consultation opportunities	While still under development, consultation drafts have been provided to the pharmaceutical industry and other interested parties (including professional bodies such as the Pharmacy Guild of Australia and the Australian Medical Association) in August 2008 and July 2009. Further consultation with stakeholders may occur on particular aspects of the Regulations, prior to their finalisation.
Expected timetable	The Regulations are currently in the final phase of preparation and are proposed to be made in late 2009.

Contact details	Linda Jackson Pharmaceutical Evaluation Branch Department of Health and Ageing Ph: (02) 6289 7085 Email: linda.jackson@health.gov.au
Date last modified	September 2009

Title	***National Health Amendment (Pharmaceutical and Other Benefits – Cost Recovery) Act 2009***
Description of issue	The amendments in this Act were required to implement a 2008-09 Budget measure to cost recover 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	Consultations with the pharmaceutical industry and other key stakeholders occurred in November 2005, June 2006 and May 2007. Further consultations occurred following the announcement of this measure in June 2008 and June and July 2009, and will continue prior to implementation. The Department has established an ongoing consultative forum on cost recovery with Medicines Australia and Generic Medicines Industry Australia.
Expected timetable	The Bill, as amended, was passed by Parliament on 16 June 2009 and received Royal Assent on 22 July 2009. Commencement of fees is subject to Regulations being made. The Minister for Health and Ageing is yet to announce an implementation date, although it is expected to be in 2009-10.
Contact details	Linda Jackson Pharmaceutical Evaluation Branch Department of Health and Ageing Ph: (02) 6289 7085 Email: linda.jackson@health.gov.au
Date last modified	27 July 2009

Title	**NICNAS Cost Recovery Impact Statement 2010**
Description of issue	In accordance with guidelines issued by the Department of Finance and Deregulation, cost recovery arrangements for National Industrial Chemical Notification and Assessment Scheme (NICNAS) must be reviewed in 2009-10. The previous review of NICNAS's cost recovery arrangements was in 2004-05.
Consultation opportunities	Established consultative mechanisms including the NICNAS Industry Government Consultative Committee and wider stakeholder consultation.
Expected timetable	To be undertaken through 2009-10
Contact details	Dr 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 2009

Title	**NICNAS Data Requirements for new sunscreens – Administrative Changes 2010**
Description of issue	Revised data requirements and procedures for new chemicals notification and assessment of sun filters
Consultation opportunities	Established consultative mechanisms including the NICNAS Cosmetic Advisory Group, as well as broader stakeholder consultations. A regulatory impact analysis will form part of the consultation process.

Expected timetable	2009-10, with potential changes to regulations in 2010-2011
Contact details	Hana Hamdan Notification and Assessment Team Leader National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 88 Email: hana.hamdan@nicnas.gov.au
Date last modified	August 2009

Title	**NICNAS Nanomaterials Administrative Changes 2010**
Description of issue	Updating data requirements and procedures for new chemicals notification and assessment of industrial nanomaterials
Consultation opportunities	Established consultative mechanisms including the NICNAS Nanotechnology Advisory Group, as well as broader stakeholder consultations will be undertaken. A Regulatory Impact Analysis will form part of the consultation process
Expected timetable	2009-10, with potential changes to regulations in 2010-2011
Contact details	Dr Matthew Gredley Reform Team Leader National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8873 Email: matthew.gredley@nicnas.gov.au
Date last modified	August 2009

Title	**Pathology and Diagnostic Imaging Prohibited Practices Regulations and market value**
Description of issue	These Regulations 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.* The Regulations will prescribe a method for determining the amount that is to be the market value of property, goods or services; and a method of working out whether the amount of a payment or of consideration for property, goods or services is substantially different from the market value of the property, goods or services
Consultation opportunities	Extensive consultation with key stakeholder groups, including medical colleges and professional associations, to inform them of the Regulations were undertaken.
Expected timetable	September 2009
Contact details	Hilary Metcalf Diagnostic Services Branch Department of Health and Ageing Phone: (02) 6289 8657 Email: hilary.metcalf@health.gov.au
Date last modified	July 2009

Title	**Private Health Insurance Legislation Amendment Bill (No. 2) 2009**
Description of issue	The *Private Health Insurance Act 2007* will be amended to allow for conditional listing of certain prostheses on the Commonwealth Prostheses List and allow the Minister for Health and Ageing to make Private Health Insurance (Prostheses) Rules to specify criteria for listing prosthetic devices on the Commonwealth Prostheses List.
Consultation opportunities	The Department has consulted with health insurers, private hospitals, clinicians, prostheses and medical device suppliers, consumer organisations and the Department of Veterans' Affairs through the Prostheses Devices Committee. The Department has also consulted with Diabetes Australia.
Expected timetable	September 2009

Contact details	Penny Shakespeare Private Health Insurance Branch Department of Health and Ageing Ph: (02) 6289 9490 Email: penny.shakespeare@health.gov.au
Date last modified	September 2009

Title	**Revised Pathology Accreditation Standards for Inclusion in the Pathology (Approved Laboratory) Principles**
Description of issue	Schedule 1 of the *Health Insurance (Accredited Pathology Laboratories – Approval) Principles 2002* [made under subsection 23DNA (1) of the *Health Insurance Act 1973*] set out the materials that form the pathology accreditation standards that Australian pathology laboratories have to be assessed as meeting in order to be eligible to provide Medicare-funded services. The materials are reviewed on a regular basis and Schedule 1 will need to be updated to include 6 revised documents.
Consultation opportunities	Consultation was undertaken by National Pathology Accreditation Advisory Council with key professional and industry stakeholder groups, as well as individual laboratories and their owners, who would be potentially affected by proposed changes to these accreditation standards. This consultation occurred during 2008-09 and consultation feedback was taken into account in the finalisation of the revised standards.
Expected timetable	November-December 2009
Contact details	Debbie Stanford Diagnostic Services Branch Department of Health and Ageing Phone: (02) 6289 4038 Email: debbie.stanford@health.gov.au
Date last modified	25 August 2009

Title	**SSBA Regulatory Scheme**
Description of issue	The Council of Australian Governments (COAG) Review of Hazardous Biological Materials and its associated Report were considered and agreed by COAG on 13 April 2007. COAG agreed to the Report's recommendations which include the establishment of a national regulatory regimen to minimise the security risks posed by specific security-sensitive biological agents (SSBAs). The Department of Health and Ageing is responsible for implementing these recommendations. Part 3 of the *National Health Security Act 2007* established controls to regulate handling of SSBAs. The SSBA regulatory scheme includes the following elements: • establishment of a List of SSBAs; • determination of Standards for SSBAs; • the collection, and recording on a National Register of information about the nature and location of SSBAs handled by entities/facilities in Australia; • restrictions in relation to the secure handling of SSBAs; and • monitoring of compliance with Part 3 through an inspection regimen. The List of SSBAs is not a legislative instrument and will be made by the Minister. The SSBAs are divided into 2 tiers; with Tier 1 agents being assessed by COAG as being more security sensitive. Regulation of Tier 1 agents commenced January 2009 and Tier 2 agents will be regulated from January 2010. With commencement of the regulatory scheme, entities that handle SSBAs are required to report their handlings to the Department and comply with the SSBA Standards which include standards relating to physical security, personnel security and transport.

Consultation opportunities	States and territories and Australian Government agencies were consulted on development of the Act. An Implementation Advisory and Consultative Committee was established in January 2008 with representation from Australian government agencies, counter-terrorism and intelligence agencies. This is the primary mechanism for consultation and input to the development of the scheme. The implementation of the regulatory scheme, which included roadshows in all capital cities in 2008, identified measures to enhance the scheme. To address that feedback, the SSBA Standards will be revised to clarify and update the requirements. In addition, amendments to the Act, to be made by the National Health Security Amendment Bill 2009 (the Bill), will introduce: 1. provisions to address emergency disease situations; 2. regulation of presumed SSBAs; 3. provisions for additional search and seizure powers for inspectors and enabling them to seek police assistance; 4. reporting of certain SSBA related events to law enforcement agencies in additional to the requirement to report those events to the Secretary (of Department of Health and Ageing); 5. provisions enabling the Secretary to decide that an entity need not continue to be a 'registered entity'; and 6. minor and technical amendments to clarify the definition of 'biological agents' and to enable 'nil' reports of reportable events. The Bill will enable the SSBA Standards and the regulations to provide further operational detail. The suspected SSBA measures were assessed to have medium impact on business regulation. Consultations have also occurred with the Australian Federal Police, jurisdictional state and territory law enforcement agencies and counter-terrorism agencies. More information is available at www.health.gov.au/ssba
Expected timetable	The Bill was passed by Parliament on 17 September 2009 and was granted Royal Assent on 7 October 2009. Amendments to the List of SSBAs, SSBA Standards and regulations will commence in January 2010.
Contact details	Peter Kaylock Laboratory Capacity and Regulation Section Health Emergency Management Branch Department of Health and Ageing Ph: (02) 6289 7477 Email: peter.kaylock@health.gov.au
Date last modified	28 August 2009

Title	**Therapeutic Goods Amendment (2009 Measures No. 2) Bill 2009**
Description of issue	This Bill amends the *Therapeutic Goods Act 1989* to: 1. implement new separate scheduling arrangements for medicines and chemicals; 2. enable the Secretary of the Department of Health and Ageing (under which the Therapeutic Goods Administration operates) to declare purposes for which a kind of medical device cannot be included in the Australian Register of Therapeutic Goods and thus made available; 3. extend the circumstances in which consultation can occur with the Gene Technology Regulator to therapeutic goods that are or contain genetically modified organisms (in addition to genetically modified products currently provided for under the Act); 4. clarify the advertising provisions to provide that it is an offence for any person to advertise a therapeutic good inappropriately for a purpose that has not been accepted in relation to the product; 5. revise delegation provisions to enable the regulations to specify a relevant

	person for the purposes of exercising delegation under section 19A of the Act; and 6. introduce provisions to enable the Minister to specify, by legislative instrument, advisory statements required to be included on the labels of specified medicines. These amendments will also require the making of legislative instruments for the purposes of specified provisions under this amending Act, e.g. items 2 and 6.
Expected timetable	Bill passed both Houses of Parliament on 9 September 2009 and received Royal Assent on 29 September 2009. Item 1 – 1 July 2010; items 2 to 5 – to commence the day after the Act receives Royal Assent; item 6 – to commence on a day to be proclaimed within 6 months of Royal Assent.
Contact details	Charles Maskell-Knight Principal Adviser, Regulatory Reform Therapeutic Goods Administration (02) 6232 8454 Email: charles.maskell-knight@tga.gov.au
Date last modified	September 2009

Title	**Therapeutic Goods Amendment (2009 Measures No. 3) Bill 2009**
Description of issue	This Bill amends the *Therapeutic Goods Act 1989* to: 1. incorporate a new framework for the regulation of human cellular and tissue based therapy products (biologicals); 2. introduce requirements for product information documents to ensure that all such documents for the same chemical entity are consistent; 3. expand information gathering powers to enable information to be sought from previous sponsors or manufacturers of therapeutic goods; 4. provide that the Department, Therapeutic Goods Administration and officers are not able to be compelled to provide information that is commercial in nature; 5. enable recall of therapeutic goods without the good needing to be suspended or cancelled first (such as where a problem only affects an isolated batch); and 6. make other changes including an amendment to support post-market pharmacovigilance.
Expected timetable	Bill expected to be introduced during the Spring 2009 sitting of Parliament
Contact details	Charles Maskell-Knight Principal Adviser, Regulatory Reform Therapeutic Goods Administration (02) 6232 8454 Email: charles.maskell-knight@tga.gov.au
Date last modified	September 2009