Preliminary impact and risk assessment

Purpose of the PIRA: A preliminary impact and risk assessment (PIRA) is intended to:

- Help agencies determine whether Cabinet's Regulatory Impact Analysis (RIA) requirements apply to a policy initiative for which they are responsible.
- Help agencies identify the potential range of impacts and risks that might be presented by the policy options for a policy initiative or review, in order that these can be appropriately addressed in the regulatory impact analysis undertaken.
- Provide an initial plan for RIA processes and identify milestones, timeframes, and who to consult.
- Help Treasury policy teams determine the level and sort of policy engagement they wish to have with the lead agency on this policy initiative.
- Help Treasury confirm whether the nature and size of the potential impacts and risks warrant early RIAT engagement on RIA elements and involvement in providing independent quality assurance (QA) on the quality of the regulatory impact statement (RIS) that informs the policy proposals.

When to complete a PIRA: It should be started as early as possible in the policy development process (as soon as policy work commences). This includes processes such as reviews of policy or legislation where it is not known at the outset whether a regulatory option will ultimately be selected or preferred, but is one of the available policy options being considered.

How to complete it: Provide as much information as possible given the stage of policy development. **This may not require definitive answers to all questions**, and you may need to apply your judgement. Relevant supporting information may be attached. If there is insufficient information to enable Treasury to confirm "significance" at the initial stages of the policy process, the final confirmation of this may be deferred until later in the process.

Who to send it to: The PIRA should be provided to your Treasury policy team and copied to RIAT (email ria@treasury.govt.nz). Please also liaise with your agency's RIA team or panel (if you have one).

Who to contact if you have any questions: Your Treasury policy team is your first point of contact for enquiries about completing the PIRA.

Section 1: General information

Name of the responsible (or lead) government agency:

Ministry of Health

Title of policy work programme or proposal:

Therapeutic Products Regulation

If known, the title(s) of the main Act and/or Regulations that could be amended or created:

Amendment to Medicines Regulations 1984

Agency contact name and phone number:

Susan Martindale until 5 December (ph. (04) 819 6892; email: susan_martindalel@moh.govt.nz)

email:

Date completed: 25 November **2014**

Section 2: Do the RIA requirements apply?

Do the RIA requirements apply?	**Yes/No/Not sure**
Is this policy initiative expected to lead to a Cabinet paper?	**Yes** (a LEG paper in Jan / February2015)
Will this policy initiative consider options that involve creating, amending or repealing legislation (either primary legislation or disallowable instruments for the purposes of the Legislation Act 2012)?	**Yes** (amending the Medicines Regulations 1984)

If you can answer "no" to **either** of these two questions, the RIA requirements do not apply. There is no need to complete a PIRA (though the questions might still provide useful prompts).

Additional exemptions from the RIA requirements	**Yes/No/Not sure**
If this initiative includes legislative options, are they covered by one or more of the following exemptions?	
• Technical "revisions" or consolidations that substantially re-enact the current law in order to improve legislative clarity or navigability (including the fixing of errors, the clarification of the existing legislative intent, and the reconciliation of inconsistencies)	**Yes**
• Suitable for inclusion in a Statutes Amendment Bill (if not already covered by the point above).	**No**
• Would repeal or remove redundant legislative provisions.	**No**
• Provides solely for the commencement of existing legislation or legislative provisions (this does not include changing the existing commencement date).	**No**
• Needs to be authorised in an Appropriation Bill, an Imprest Supply Bill.	**No**
• Is for a Subordinate Legislation (Confirmation and Validation) Bill relating to regulations that have already been made	**No**
• Implements Deeds of Settlement for Treaty of Waitangi claims, other than those that would amend or affect existing regulatory arrangements.	**No**
• Brings into effect recognition agreements under the Marine and Coastal Area (Takutai Moana) Act 2011	**No**
• Essential (the minimum necessary) in order to comply with existing international obligations that are binding on New Zealand.	**No**
• Has no or only minor impacts on businesses, individuals or not-for-profit entities (such as might be the case for certain changes to the internal administrative or governance arrangements of the New Zealand government, like the transfer of responsibilities, staff or assets between government agencies)	**Yes – the planned amendment does not change current policy or practice settings, but is intended to provide legal clarity as recommended by Crown Law**

If all the legislative options associated with this policy initiative qualify for one of these exemptions, then the RIA requirements do not apply.

If claiming a full exemption, please confirm this assessment with your Treasury policy team. You do not need to submit a PIRA for this purpose, but you will need to provide information in support of this claim.

If some aspects of the legislative options for this initiative can stand independently from the rest, and qualify for one of these exemptions, then the RIA requirements do not apply to those aspects. Since a PIRA will still need to be completed and submitted to your Treasury policy team, it should note any important aspects of the initiative for which an exemption is claimed.

Section 3: Description and context

The policy issue

What is the intended scope of the policy initiative?

No policy change is proposed. The amendment is being progressed on the recommendation of the High Court and Crown Law in order to provide legal certainty.

What are the main underlying policy issues/problems to which this policy initiative is responding (ie, the root cause of the problem)?

The Crown has recently been involved in two court proceedings involving attempts by the same litigant to prevent fluoridation of public water supplies:

a. *New Health Inc v South Taranaki District Council* (Attorney-General was an intervening party in the High Court). New Health has now appealed the High Court decision upholding the legal basis for fluoridation, including the finding that provision of fluoride in drinking water was not mass medication. **That appeal has been set down for 12 March 2015**

b. *New Health Inc* v *Attorney-General* (High Court, Wellington). New Health sought declarations that the Ministry take steps to ensure that fluoride compounds are approved as medicines before they can be supplied for use in fluoridating water. The Court dismissed New Health's application, finding that the fluoride compounds are not medicines at the concentrations used in drinking water. **The judge went on to recommend that to provide more legal clarity, the Ministry pursue an amendment to the Medicines Regulations to exempt these fluoride compounds from the definition of *medicine* when they are used to fluoridate water.**

What is known about the magnitude of these policy issues/problems?

See above

What is the type or nature of the evidence supporting the problem definition?

See above

The policy process

Who has commissioned this work (ie, a portfolio Minister, an agency at the request of industry or the public, etc)? Is this initiative in your current regulatory plan? Who is responsible for its delivery?

Recommended by the High Court and Crown Law. The Minister of Health has accepted Crown Law's recommendation to pursue an amendment to the regulations

The policy process

What is the expected policy process, and expected timing of key milestones?

Are there any process or timing commitments, existing obligations, constraints, or previous Cabinet decisions that are relevant?

The Court of Appeal has given the Crown leave to vacate the fixture set down for 12 March 2015 if, by 6 February the Crown is in a position to satisfy the Court that the recommended regulation change **will be** implemented. This would have the effect of rendering the appeal moot, an outcome that would save considerable legal costs for the Crown and free up valuable Court time for other fixtures. Officials consider that such an amendment could be sufficiently progressed by 6 February if the streamlined process described below is adopted.

Proposed action and timing

This is a technically simple amendment that does not involve a change in policy or practice settings in view of the recent High Court decisions. For this reason, and to move with urgency, the Minister has agreed that officials can consult on the proposed regulation change and issue drafting instructions to Parliamentary Counsel for the new regulation to be drafted without first taking the issue to Cabinet.

Officials released a consultation document on 25 November and will shortly issue drafting instructions to the Office of Parliamentary Counsel so that consultation and drafting can occur in parallel. This will enable the analysis of submissions to be completed around mid to late January 2015 and a paper seeking Legislation Committee approval for the regulation change to be considered around 6 February. At that time officials would recommend that the Minister seek a waiver of the 28 day rule on the grounds that it would be beneficial to provide early legal certainty. It should then be possible to have the new regulation come into force by the end of February 2015.

What consultation process is planned, and who will be consulted?

2. Before making or amending a regulation, the Act requires that there be consultation with organisations or bodies that appear to be representative of persons likely to be substantially affected by the regulation. For this regulation change, the Ministry is consulting with local bodies and with the lawyers representing the parties to the recent litigation, and oral health groups and has placed the consultation document on its Medsafe website. Given the narrow scope of the proposed amendment, Crown Law has advised that a five week consultation period would be appropriate.

The policy process

If any established methodology or form of analysis is to be followed or incorporated, please identify

N/A

The policy options

Are there feasible non-regulatory options to consider? Is it possible that legislation is not required?

Absolutely not (see above).

If the range of policy options to be considered is already constrained by existing government commitments, Ministerial directions, or previous Cabinet decisions, what are those constraints?

N/A

If this involves only delegated legislation, what is the legislative authority under which it must be made?

Section 105(1)(i) of the Medicines Act 1981

Which groups are might be noticeably affected (either positively or negatively) by the policy options being considered?

N/A

Section 4: Are the significance criteria met?

A regulatory initiative if considered to trigger the significance criteria if any of the options being considered are likely to have:

- Significant direct impacts or flow-on effects on New Zealand society, the economy, or the environment, or
- Significant policy risks, implementation risks or uncertainty.

Are there significant impacts?	Yes/No/Not sure
Will any policy options that may be considered, potentially:	
• Take or impair existing private property rights?	**No**
• Affect the structure or openness of a particular market or industry? *For example, assist or hinder businesses to provide a good or service; establish or remove a licence, permit or authorisation process; create or remove barriers for businesses to enter or exit an industry?*	No
• Impact on the environment, such as regulations that affect the use and management of natural resources?	**No**
• Have any significant distributional or equity effects? *For example, where significant costs are imposed or significant benefits conferred on different sectors of the population?*	No
• Alter the human rights or freedoms of choice and action of individuals?	No
• Have any other significant costs or benefits on businesses, local or central government, individuals or not-for-profit organisations etc? *For example impose additional compliance costs; introduce or alter government cost recovery arrangements; impact on New Zealand's international capital flows or trade including the flows of goods, services, investment and ideas to and from New Zealand; impact on the incentives to work or the mobility of labour, or to invest in education or skills; impact on resource allocation, saving or investment, fiscal costs to government?*	**Potential cost savings to the Crown and possibly local government from reduced risk of litigation initiated by anti-fluoride groups**

For the major types of impacts you have identified, please provide brief information about the nature and likely magnitude of the impacts (in whatever dimensions seem most useful and available).

Savings on legal costs (quantum unknown) and court time if the appeal set down for March is rendered moot. The risk of further litigation involving local bodies may be reduced.

Are there significant policy, design or implementation risks?	Yes/No/Not sure
Are any of the legislative options likely to be novel, or unprecedented?	**No**
Is the evidence-base for the size of the problem or the effectiveness of different policy options weak or absent?	**No**
Are the benefits or costs of the policy options likely to be highly uncertain? Are there obvious risks that need to be managed?	**No**
Is the success of any of the options likely to be dependent on other policy initiatives or legislative changes?	N/A
Are any of the legislative options likely to have flow-on implications for the future form or effectiveness of related legislation?	No
Are there other issues with the clarity or navigability of, or costs of compliance with, the current legislation that it might be good to address at the same time?	No- a major and separate review is planned over a longer timeframe
Do any of the legislative options have the potential to be inconsistent with or have implications for New Zealand's international obligations?	**No**
Are there any issues arising in relation to New Zealand's commitment toward a single economic market with Australia? Please check with the Ministry of Business Innovation and Employment. There may be, for instance, issues relevant to the Trans-Tasman Mutual Recognition Agreement (TTMRA).	**No**
Are any of the legislative options likely create or extend a power to make delegated legislation, or grant a broad discretionary power to a public body?	**No**
Are any of the legislative options likely to include provisions that depart from existing legislative norms for like issues or situations? *These may include Bill of Rights Act and Privacy Act issues, fundamental common law principles, retrospective rule-making, creation of strict liability offences or burden of proof reversals, and matters affecting civil or criminal immunity. Please see the Legislative Advisory Committee Guidelines on Process and Content of Legislation.*	No
Are any of the options likely to create, amend, or remove offences or penalties (including pecuniary penalties), the jurisdiction of a court or tribunal, or impact on court-based procedures and workloads?	No
Has implementation testing and operational expertise been integrated into the plan for evaluating options?	N/A
Is there a possibility that local government will be expected to implement, administer, or enforce any options?	**No**
Are implementation timeframes likely to be challenging?	**No**
Are the actual costs or benefits highly dependent on the capability or discretionary action of the regulator?	**No**

Section 5: Agency assessment and Treasury confirmation

Agency's preliminary assessment **Treasury's Assessment**

Do the RIA requirements apply to this policy process or proposal?

No

Would any resulting regulatory proposal be likely to have a significant impact or risk and therefore require RIAT involvement?

No