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Date	27 November 2001		
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Message

P242 Foods For Special Medical Purposes – Initial Assessment Report

Thank you for providing for our comments a copy of the Initial Assessment Report for P242 Foods For Special Medical Purposes.

The current draft broadly follows the RIS framework, and contains a useful set of questions to inform the further development of the regulatory impact analysis. Our comments are intended to add further to the development of this analysis.

Problem/Issue

The current statement of the Problem tends to imply that there is a technical issue only, that is, the lack of explicit permission in the Australian New Zealand Food Standards Code (Volume 2) creates a legal impediment.

However, Section 3.2.3 outlines lighter regulatory requirements in the US for "medical foods". The Potential Impact of Regulatory Options at Attachment 5 also suggests that there is potential for future health risks. Is this potential risk from future imports that may come from unregulated countries, and from future FSMP that may be produced domestically, or is it also from countries currently supplying the Australian market? In this regard, do the quality requirements in Australia's

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tendering processes and New Zealand's PHARMAC requirements reduce the impact of this? (I note that the Report asks stakeholders for information/views on health risks and that, on page 17, it states that "to date ANZFA has no evidence of any significant risk to either target or non-target populations from the current unrestricted access arrangements for FSMP.)

The Problems section should also provide the relevant information on the status quo, for example, the extent of voluntary labelling along the lines of "Use under medical supervision", or the extent of confusion that may be caused by the general prohibition on prophylactic and therapeutic claims.

In addition, the Report mentions that there is ambiguity in consumers receiving consistent information. What are the public health or other impacts of this ambiguity?

Does the Problem section also need to pick up the issue identified in Section 3.1.1.1, that FSMP potentially fall in the regulatory interface between therapeutic goods and food? Section 3.1.2 suggests similar ambiguities in the treatment of FSMP under New Zealand's regulatory framework. This issue is not a mere technical issue created by the development of Volume 2, and would seem to be important in distinguishing Option 2, Recognition in Volume 2, from Option 4 – Full Regulation.

Given the above comments, I suggest placing the Problem section after the current Background section.

Objectives

The RIS should not state a specific regulatory objective (such as "the development of joint ... regulation") but rather the objectives of governments as they relate to addressing the specific problem.

In relation to the second paragraph, I suggest replacing "is predicated on fulfilling" with "should not be inconsistent with" (as some changes may not fulfill each of the three objectives).

In the fourth paragraph, the RIS refers to COAG's competition policy requirement that all business regulation be reviewed . This is not specifically relevant to the matter here. The RIS can, however, refer to COAG's *Principles and Guidelines* for good regulatory practice.

The specific objectives include protection of public health and safety. As noted above, this issue should be discussed in the Problem section.

Options

It is not clear why Option 3 has been included. The term "co-regulation" usually refers to a situation where government produces legislative backing to enable the requirements to be enforced. (I refer to *A Guide to Regulation* defines co-regulation on page B2). However, regardless of terminology, it is not clear why for FSMP an Option has been chosen that would be difficult to enforce, if compliance is important for public health reasons. Can the RIS clarify this?

In addition, the description of Option 3 refers to Option 2 and also Option 4, yet the latter has not yet been described. It would assist the readability of the paper if the numbering of Option 3 and 4 were swapped.

A feasible sub-option of Option 4 would be recognition of specific overseas regulatory regimes as equivalent to an Australia New Zealand standard.

It is also not clear why Option 5 has been included, unless there is a high degree of innovation in these products which would require regulatory flexibility. Can the redraft address this?

Affected Parties

Health professionals do not need to be included as an affected party. They are not directly affected, and the group "consumers" covers the interests that health professionals represent.

In terms of industry impacts, the RIS need only cover the impacts on Australian and New Zealand manufacturers and importers.

Impact of Regulatory Options

(With reference to Attachment 5)

Option 1

The assessment of the status quo option is a little tricky, as implementation of Volume 2 will itself create change from the (current) status quo.

The Report notes (Government, Costs) that there may be uneven enforcement between jurisdictions. Given this, some of the stated impacts do not seem plausible. In particular, isn't there some potential costs to consumers in terms of reduced range of FSMP products available? Similarly, isn't there a risk to consumers of some impact on the supply of low volume products? And why will there be greater competition than now?

The Report states (Consumers, Costs) that "there are no restrictions on the composition and quality of products available...[and] no regulatory controls to protect public health and safety". This of itself implies health risks. However, given all imports come from countries with a regulatory regime over at least some of the products, there may not be negative health outcomes. In this regard, the RIS could be more balanced in its assessment.

The Report notes (Industry, Costs) that there is the risk of new market competitors compromising product quality and standards. How is this likely to be more so than now?

Option 2

The Report refers to potential for "future public health risk". Does this refer to imports from current suppliers, to other imports, and to domestically produced FSMPs?

Option 3

Option 3 as assessed seems to relate to co-regulation in a Australian/New Zealand context. It needs to be revised to reflect the limited scope for such an arrangements when all products are currently sourced from overseas, and therefore the limited impacts of such an arrangement, in the short term at least, on consumers and industry.

Further work on this section should also avoid double counting of impacts, as in increased costs for industry and increased prices for consumers.

Option 4

The Report states (Government, Costs) that there may be an increase in prices. In this regard, the RIS seems to be inconsistent in stating here that price effects will impact on Government (through PHARMAC outlays and hospital tenders), but in the assessment of Option 3 that the price effects will be on Consumers (Australian consumers?).

The potential for reduced product range is stated in relation to all affected parties. The RIS should, instead, identify the impacts for each group of this reduction. For Government it may be reduced health benefits from these products and for consumers likewise, so the RIS could possibly only refer to consumer effects. For industry, there may be significant impacts for any specialised producers so affected, or importers, but as noted above, the RIS should only focus on the impacts on Australia/New Zealand producers.

Option 5

The impacts of Option 5 relative to Option 4 seem to hinge on increased flexibility and less prescription. These should be discussed as issues in the Problem section, and identified as objectives.

Consultation

The RIS should identify which groups were consulted, their support or otherwise for the preferred option and, where there was opposition to it, the reasons for this.

I hope these comments assist in your further work on this. Please call me if you wish to discuss them.

In line with the new advising arrangements being established between ANZFA and the ORR, and with COAG's RIS requirements that the ORR assess the RIS prior to consultation, can we be provided please, for our comments, a copy of the draft Draft Assessment Report before it is made public.

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Jane O'Donohue, Assistant Director

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