s 42 - legal professional privilege

From: Maxine Freeman-Robinson s 47F - personal privacy
Sent: Monday, 29 June 2015 10:22 AM
To: PLATONA, Adriana
Subject: Fwd: possible study of the decision-making process underpinning the Deeds of Agreement/RSAs in Australia [SEC=No Protective Marking]

Hi Adriana

I phoned this morning to follow up on the email below. Left a message on your voice mail. Can I follow up with you this week re getting a review of the Deeds for the Department and for my PhD?

When would be suitable?

s 22 - irrelevant

Regards
Maxine

Begin forwarded message:

From: Maxine Freeman-Robinson s 47F - personal privacy
Subject: possible study of the decision-making process underpinning the Deeds of Agreement/RSAs in Australia
Date: 4 June 2015 12:27:48 pm AEST
To: Adriana Platona <adriana.platona@health.gov.au>
Cc: s 22 - irrelevant

Hi Adriana

Thanks for meeting with me a couple of weeks ago regarding the possibility of studying the Australian experience of risk sharing agreements operating since 1997. As we agreed there are some significant advantages for the PBAC and the Government in policy development and consistency in decision-making as well as a good opportunity to provide a clearer and

more transparent view of the process for the other stakeholders in health in Australia (health professionals, health administrators and, significantly, consumers)
You asked for some additional information about the elements required for the study that could be considered confidential or commercially sensitive - particularly from the Deeds of Agreement which are commercial documents between the Government and manufacturers.
I consulted with s 47F - personal privacy last week.
Following a review of the documentation that I think will be required for a thorough evaluation of the decision-making process, the structure of the resulting RSA and evaluation of the conduct of the RSA the following documents will be needed for my research:

- PBAC documentation relating to the submissions for listing the drug for that indication to determine the decision-makers uncertainty with respect to listing and what informed the subsequent negotiation with the company preparing the submission (the manufacturer)
- the establishment Minute for the Deed (providing an overview of the deed for the Government)
- Sections of the Deed relating to description of the type of rebate or reimbursement (principally found in Clause 3 of most deeds)
- the lapsing Minute (providing any significant issues relating to the conduct of the deed)
- any Predicted versus Actual Reports undertaken by DUSC for the drug/indication (providing any significant issues in relation to the drug/indication during the life of the deed).

The Deed describes the confidential information in Appendix A for both parities to the Deed - the Government and the manufacturer.
a) information the Government considers confidential (clauses A.1.1 the amount reimbursed and A.1.2 information about Special Pricing Arrangements). At this time the existence of a Special Pricing Arrangement is notified in the published schedule as an astrix. No additional details regarding the actual price negotiated and agreed are published. For the purposes of my research I do not require the actual price, only that a SPA exists. I also do not require information on the amount of any reimbursement. Only that there was a potential for reimbursement or rebate.
b) information the Manufacturer considers confidential (clauses B.1.1 the amount reimbursed and B.1.2 the rebate formula.
Maxine Robinson) As stated these pieces of information do not necessarily need to be recorded.
The focus of the research is to link the decision with the existence of a deed and the describe how the deed operates to address. The operation of each deed is not required as the formulas can be described in general terms under a classification system.
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Regards
maxine
s 47F - personal privacy
Maxine Robinson
s 47F - personal privacy

Maxine Robinson
s 47F - personal privacy

s 22 - irrelevant

From: Maxine Freeman-Robinson s 47F - personal privacy
Sent: Tuesday, 13 October 2015 11:23
To: s 47F - personal privacy
Cc: PLATONA, Adriana
Subject: s22 - irrelevant [SEC=No Protective Marking]

Categories: Purple Category, Yellow Category

Hi s 47F - personal priva

s22 - irrelevant

Approval of this action would provide two benefits
a) the necessary security to access documents required for a report for the Department on access to medicines using Deeds of Agreement (also referred to as managed entry schemes). This report will be prepared at the same time as work on a PhD therefore the Department will obtain the report at no cost and
s22 - irrelevant

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Departmental documents required for the research will remain on Departmental servers and none will be removed from the Department.

The following is part of my research proposal and might help to frame the argument for why the Government should support my access to the documentation. Hope it saves you some work on the Minute.

s 22 - irrelevant

Regards
Maxine

How will this research contribute to Government policy?

Governments and other payers for health technologies have a commitment to sustainable health system expenditure and responsible fiscal management while providing efficient and beneficial medicines to their population. It is important the assessment of health technology for reimbursement is consistently applied ensuring that the population covered by the reimbursement has confidence in the new technology providing 'value for money' and justifying the additional net cost; particularly where expenditure on the medicine removes funding from other medicines, technologies or interventions (1).

If the medicine is reimbursed the payer may need to reassess that decision in the future if;

- there are unexpected harms or adverse events associated with a reimbursed medicine that are seen when used in a larger population than those in the clinical (28, 29),

- the expected health outcome is not achieved (1, 9, 11, 15), or

- there is wastage of health resources and expenditure for technologies that do not provide the expected benefit (26).

Following a review of the reimbursement decision the payer may seek a lower price for the medicine, limit access to the medicine or consider removing the medicine from reimbursement. Seeking a lower price is strongly resisted by the Pharmaceutical Industry (25, 34). Limiting access to medicines that are reimbursed is strongly resisted by clinicians and consumers (18). Ceasing reimbursement (disinvestment) has a number of economic, ethical and political issues for payers (11, 18).

If the medicine is not reimbursed access will generally be limited by cost of the medicine and the Payer risks denying access to a medicine that may provide a meaningful health benefit for their population, even if the benefit is less than expected or limited to a small number of people (28, 29). Even without reimbursement new technologies, including medicines, may diffuse into the market, especially where they are included in guidelines for treatment and promoted to clinicians and consumers; adding cost to the healthcare system and social and political pressure on Payers (29). The population may consider that a medicine is a breakthrough (27) and therefore not reimbursing a medicine is evidence of promoting inequity in healthcare delivery that may be opposite to Government commitments (26). In Australia equity of access for medicines is an important principle (2).

The use of outcome-based MEAs in Australia is increasing. There has been only one Australian outcome-based MEA bosentan that has been evaluated. Since 2014 the Government has announced an additional three MEAs involving collection of outcomes and a future review by the PBAC. s 47G - Business Information s 47G - Business Information critzotinib for non-small cell lung cancer (4) s 47G - Business Information s 47G - Business Information

It is therefore timely that a review of the MEAs be undertaken to examine the relationship between critical uncertainties identified by the PBAC, and consider what other factors are important for the Australian Government. The lessons learnt from such a review will provide the PBAC with guidance for decision-making, provide other stakeholders with greater understanding of the reasons for managing access. The results of this work could also provide confidence to the pharmaceutical industry in order to include acceptable and useful proposals for MEAs in submissions to the PBAC thereby reducing delays in negotiations between the industry and Government and facilitating earlier access to necessary medicines.

Maxine Robinson
s 47F - personal privacy

Australian Government
Department of Health

To:	Adriana Platona	**Deadline:**	30 October 2015
From:	s 47F - personal privacy	Contact officer:	s 22 - irrelevant
		Phone:	s 22 - irrelevant
Date:	28 October 2015		

s 22 - irrelevant

Purpose

s 22 - irrelevant

s 22 - irrelevant

- facilitate access to departmental documents to enable Ms Freeman-Robinson to prepare a report on the effectiveness of Risk Sharing Arrangements between the Government and manufacturers of pharmaceutical medicines listed on the Pharmaceutical Benefits Scheme (PBS).

Timing

s 22 - irrelevant

Background

s 22 - irrelevant

Issues

Providing support to the Evaluation Branch

s 22 - irrelevant

Access to documents for preparation of a report on effectiveness of Deeds of Agreement

10. Ms Freeman-Robinson is undertaking an extensive review of the effectiveness of Risk Sharing Arrangements as part of her PhD. These Risk Sharing Arrangements are in the form of contracts used by the Australian Government to support access to medicines on the PBS where the PBAC has some uncertainty about the evidence supporting a recommendation to the Minister for Health to list a medicine on the PBS. These agreements have been in place in various forms since 1997.

11. To date there has been no systematic review of whether these agreements are an effective tool for the Government in managing the risk of listing medicines on the PBS. A review of these tools for access is timely as the Government relies on these agreements to manage the risks associated with listing medicines on the PBS and has expanded the scope of these Deeds, through its Memorandum of Understanding with medicines Australia, to include Managed Entry Agreements s 47G - Business Information s 47G - Business Information critzotinib and s 47G - Business Information for non small cell lung cancer).

12. It is my view that a review of the Risk Sharing Arrangements would be of benefit to the Department and the Government. The lessons learnt from such a review will provide the PBAC with guidance for decision-making and provide other stakeholders with greater understanding of the reasons for managing access. The results of this work could also provide confidence to the pharmaceutical industry in order to include acceptable and useful proposals for Risk Sharing Arrangements and Managed Entry Schemes in submissions to the PBAC, thereby reducing delays in negotiations between the industry and Government and facilitating earlier access to necessary medicines.

13. Given that there are approximately 80 Risk Sharing Arrangements the workload is extensive and many of the documents contain some commercially sensitive material. To have this work undertaken by a contractor would be problematic given the scope and content of the material required for such a review. Ms Freeman-Robinson has extensive experience in this area and will be able to identify and extract information, prepare a detailed report for the Department that addresses issues of confidentiality and commercial sensitivity, at the same time as completing her PhD research.

Ms Freeman-Robinson has a current security clearance at the s 47F - Personal privacy , which is supported by the Department.

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15. In my view the department will gain the benefit of a comprehensive and useful report at no additional cost.

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Consultation

PBD HR, Recruitment and Legal Services Branch have provided advice on this matter.

Recommendation

s 22 - irrelevant

Approved / Not Approved / Please Discuss / Noted

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Adriana Platona
Assistant Secretary
19 October 2015