Guidelines for Deeds of Agreement for the Pharmaceutical Benefits Scheme (Version 1.5)

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Preface

These guidelines aim to improve the understanding of and public access to information regarding the requirement for and development of deeds of agreement. They are intended to improve the level of understanding in relation to terminology, timing and risk-sharing components.

These guidelines are also intended to improve sponsor awareness of the processes involved in developing deeds and identify the importance of initiating the negotiations early. These guidelines have been developed to account for experience. This is a living document that will evolve to allow for inevitable change.

Disclaimer

These guidelines have been developed to provide readers with information about deeds of agreements.

Material in these guidelines is made available on the understanding that the Commonwealth is not providing legal or professional advice. While reasonable care has been taken in preparing these guidelines, the Commonwealth provides no warranties and makes no representations that the information contained in these guidelines is correct, complete or reliable. These guidelines are subject to change from time to time and the Commonwealth provides no warranties and makes no representations about the currency of the information contained in these guidelines. The Commonwealth expressly disclaims liability for any loss, however caused, whether due to negligence or otherwise arising from the use of, or reliance on, the information contained in these guidelines by any person.

The information contained in these guidelines is necessarily general and these guidelines may not apply in all circumstances. The Commonwealth may, at its sole discretion, choose not to adhere to these guidelines. If a deed of agreement is entered into between the Commonwealth and a sponsor then that deed of agreement will record the entire agreement between the parties in relation to its subject matter and will not be affected in any way by the content of these guidelines.

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PURPOSE

The purpose of these guidelines is to provide the history, context and processes to assist sponsors when developing deeds of agreement in the context of listing medicines on the Pharmaceutical Benefits Scheme (PBS).

BACKGROUND

What are Deeds of Agreement?

Deeds of agreement are commercial agreements between the Australian Government on behalf of the Commonwealth of Australia and Responsible Persons (pharmaceutical companies, or sponsors), and are designed to help maintain the appropriateness and cost-effectiveness of listed medicines. They may also reduce the Government's exposure to the risks associated when listing particular medicines on the PBS, following a positive Pharmaceutical Benefits Advisory Committee (PBAC) recommendation.

These agreements are negotiated between officers of the Department of Health (the Department), representing the Australian Government, and the sponsor of a medicine, and are formalised in a legal document called a 'deed of agreement'.

Note – While the PBAC may recommend that the Government negotiate a deed, they do not decide on its final content.

History and context

The first agreement between the Commonwealth and a sponsor occurred in 1998, to minimise the Government's exposure to risks associated with the listing of a new medicine on the PBS. Prior to 2003, agreements were formalised via an exchange of letters. Deeds of agreement were introduced by the Department in 2003 to record the negotiated terms of these risk sharing arrangements in clearer detail.

The deed format has evolved since 2003. The deed records the context and terms of the agreement and is intended to be relatively consistent across agreements. It is possible for a standard clause to be amended, where the sponsor's requested change is supported by specific evidence of potential detriment to the company if the standard clause is applied. The amendments must not change the intent of the deed or the arrangements contained within.

Example Deed of Agreement

A de-identified example of a deed of agreement is attached to these guidelines. This attachment contains an example of the standard clauses that are found in a deed. Deeds will generally demonstrate consistency with the attached example.

Why do we have them?

There are two broad types of arrangements which are covered by a deed; Special Pricing Arrangement (SPA) and Risk Sharing Arrangement (RSA).

SPA

The Commonwealth may enter into confidential Special Pricing Arrangements with a sponsor for the supply of a medicinal product formalising a 'published' versus 'effective' pricing component. The difference between the published price in the *Schedule of Pharmaceutical Benefits* and the price actually paid by the Commonwealth (the 'effective' price), is managed through a rebate arrangement.

The main reason for the Commonwealth to enter into a SPA for the supply of a medicine is so that Australia is able to have access to medicines at a lower cost-effective price without affecting the price for the product in other markets.

Sponsors seeking a SPA for a product should refer to the SPA criteria attached to these guidelines for further information.

RSA

RSA deeds have been developed to address multiple types of risk. The most common types of risk are outlined below.

- *Uncertainty in estimating the overall cost to the PBS* — for example this could be the result of uncertainties in the number of patients, daily dose and/or duration of therapy of the medicine.

  Any medicine deemed to be of a high cost nature may be accompanied by a deed. This is to provide the Australian Government with the security that the agreed estimated expenditure for this medicine will not be exceeded, and if it is, any fiscal impact that results from this risk will be shared by the sponsor and not carried entirely by the Government.

- *Cost-effectiveness* - this is affected by the volume of use beyond the restriction(s), and by the volumes of use of categories within the restriction(s) where cost-effectiveness is known to vary across categories.

If a medicine has a high risk of leakage outside the restriction then this means patients may be receiving the medicine for a purpose that is not approved, and therefore it may not be cost-effective. A deed of agreement is required in this case to ensure that if Government expenditure exceeds the estimated costs of a medicine for a particular restriction (an indicator that the medicine may have been prescribed outside of its restriction); the additional costs are shared between the Government and the sponsor and implicitly reflect a lower price to address any concerns that such additional use will be less cost-effective than in the intended population.

- *The extent of overall gain in health outcomes - data monitoring requirements* — these deeds usually call for the collection and provision of data in relation to a specific listing.

  These may include: a request by the PBAC to provide further data; the need for some coverage for a possible future event such as a booster dose of a vaccine at a reduced price; or other pricing arrangement at the request of the Government.

- *Estimating usage* - Usage uncertainty can arise because, despite the best efforts in the construction of the restriction, the restriction may be difficult to enforce. For example, the number of patients expected to receive the therapy might be so large that an authority required listing to reinforce adherence to the restriction would be impractical.

  These are not the only risks addressed under a deed, however, they provide a good indication of the preparation requirements for a deed.

  For these risks, deeds may be recommended by the PBAC (usually in relation to cost-effectiveness and/or health outcomes), or by the Department (usually in relation to overall costs). Alternatively deeds may be proposed by the sponsor to the PBAC to help address areas of uncertainty which, if not addressed, may result in a rejection by the PBAC. Given that deeds typically rely on utilisation data, there are advantages to all parties if a sponsor puts any proposal for such an arrangement forward early in the process of application for a drug listing (e.g. in its submission to PBAC), rather than introducing the proposal later.

  The intent of the financial arrangements in a deed is not to derive income for the Government. Rather, the intent is to provide incentives to pharmaceutical companies to ensure that usage of the medicine is contained within the agreed PBS restriction, that accurate information is being provided to clinicians, and to encourage the company to bring a new submission to the PBAC if new or extended uses in practice emerge.

NOTE - For further information regarding the risk-management approach, including assistance in the decision-making process, please refer to Section 4 of the PBAC Guidelines (v5.0) - https://pbac.pbs.gov.au/

THE DEED OF AGREEMENT PROCESS

The following section is intended to guide the reader through the significant milestones of the deed of agreement process. This begins with an application to the PBAC, followed by the recommendation and subsequent pricing, through to the negotiation, execution and expiry phase of the deed of agreement.

The key message is the importance of initiating discussion and negotiation as early as possible. The negotiation phase can take some time, so it is very important for all stakeholders to be proactive to ensure the earliest possible listing date is reached.

Sponsors are encouraged to approach the Department to discuss the potential requirement for a deed of agreement as early in this process as possible.

1. PBAC Recommendation

The listing process begins with a positive PBAC recommendation.

If the PBAC identifies that one or more of the above risks exist, it will also recommend that the sponsor enter into a deed of agreement with the Government to ensure that the potential impact of these risks can be minimised. In this event, listing **cannot** occur until the deed has been signed and executed.

Alternatively, a sponsor can include in its PBAC submission an offer to enter into a deed of agreement. This approach has become more common as industry has become aware of risk sharing arrangements and of the advantages of beginning these discussions as early as possible.

Following a positive PBAC recommendation, the sponsor is encouraged to contact the PBS Pricing and Managed Access Section to learn more about the deed process and the standard deed of agreement. Discussions at this stage are necessarily general as the type of deed is usually not finalised and the prices have not been agreed in principle. All correspondence in relation to deeds should be addressed to the PBS Pricing and Managed Access Section, Pricing and Policy Branch (see 'Who do you contact?').

2. Negotiation of the deed of agreement

Negotiations first focus on the type of arrangement that is required for each specific listing. The different types of arrangements are discussed in more detail in the next section of these guidelines.

All listings require the agreement of costing estimates. Following agreement of the estimates of utilisation and financial impact between the Department and the sponsor, the other affected Divisions of Health and portfolio agencies are approached to review the costs. A finalised cost to Government is considered by the Department of Finance.

Negotiations of financial-based agreements are based on the finalised financial estimates.

At the same time, a deed is drafted by the Australian Government Solicitor (AGS) and submitted to the sponsor for consideration.

At this stage, the sponsor is welcome to propose amendments to the deed, but only where these are supported by specific evidence of potential detriment to the company if the existing deed is applied.

3. Signing of the deed of agreement

Once in-principle agreement is reached, the deed will be prepared for the sponsor for signature by the appropriate Responsible Person and returned to the Department. Deeds cannot be executed until Government has agreed to the listing.

4. Government Consideration

All PBS recommendations are subject to Government consideration prior to listing.

5. Execution

Once the listing has been approved, the Minister (or Delegate) will execute the deed. A copy of the executed deed will be returned to the sponsor for its records.

If a drug has been recommended by the PBAC to have a deed of agreement, then the drug will not be listed until this deed has been executed.

6. Variations to a deed of agreement

A variation to an existing deed of agreement at the request of the sponsor is possible. However, it is preferred that the sponsor provide an evidenced based submission to the PBAC, outlining and justifying the reasons for the proposed amendment. PBAC agreement is one trigger required by the Department to enter into a re-negotiation of any existing deed.

This is not the only way for a variation to occur. Where agreed in writing by both parties, a variation to the deed can be made. This would generally be for administrative arrangements.

7. Expiry or Termination of a deed of agreement

Deeds are required to cover the period of the forward estimates, generally a period of five years. Towards the end of this period the ongoing need for a deed will be reviewed by the Department. If the financial risks associated with the requirement for the deed are not realised during the term of the agreement, the Department may recommend the deed lapse on expiry.

If it is deemed necessary to continue an agreement, renegotiations will commence between the sponsor and the Department on behalf of the Government. Through this process the sponsor is encouraged to provide any evidence that it considers may have a bearing on the content or expectations of the renewed agreement. If an agreement cannot be reached prior to the expiry of a Deed, the terms of the existing deed remain in force until such time agreement can be reached. This is necessary to ensure the risks associated with the listing can continue to be managed.

Types of Arrangements

There is a basic deed template (as attached to these guidelines) which is then tailored for each specific listing to contain special pricing arrangements and risk sharing arrangements. The following is a non-exhaustive list of some of the general types of arrangements employed:

Special Pricing Arrangement (SPA)

The deeds that cover SPAs are put in place so that Australia is able to have access to medicines at prices recommended by the PBAC as cost-effective, whereby due to international reference pricing or various other commercial reasons, sponsors are not able to supply the medicine at a particular publically available price. The deeds for SPAs involve the Department recovering a

percentage of expenditure (through a rebate) at the listed price to reflect the outcome of the cost-effective recommendation by the PBAC.

The existence of SPAs are made publicly known, however the content of these individual arrangements is confidential and commercially privileged information.

Subsidisation cap and reimbursement arrangements

These arrangements generally involve the Department recovering a percentage of expenditure once an agreed amount or subsidisation cap ('cap') has been exceeded. They are designed to address risks relating to overall expenditure uncertainty and cost-effectiveness and are based upon the agreed estimates. The cap is usually expressed as a dollar amount and the reimbursement percentage will vary depending on the level of risk. These types of agreements may also be 'tiered', that is, they may have more than one cap with different reimbursement payable over each cap. In these cases the reimbursement payable increases once each tier has been exceeded.

In many cases these thresholds are designed to encompass the extent of use estimated for the PBS restriction and the deed will include clauses that allow for the possibility of new medicines entering the market. This ensures fairness and encourages competition.

"Shared" deeds of agreement

The need for shared agreements arises when the PBAC recommends a new medicine for listing, or an extension to an existing listing on the PBS, for the same intended population as an existing medicine that already has a deed in place. In this case, the new medicine becomes a 'New Drug' for the purposes of the original deed and in most cases will join the deed and be subject to the same arrangements that apply in the existing deed.

The definition of a 'New Drug' as contained in the de-identified deed example (see definitions and clause 3.3 in the attached) is designed to assist in the management of multiple deeds, promote fairness and to facilitate the process of listing competing medicines.

When a medicine is to join an existing deed, both sponsors (for the new and existing medicines) are required to agree to the release of certain information that enables the finalisation of the shared deed.

The typical shared deed process commences upon receipt of a positive PBAC recommendation. The Department then sends a letter to the sponsor/s of the current listing, advising them of the release of any necessary confidential information contained in their 'deed' with the Government, for provision to the

new sponsor. Once released this detail is used to establish a deed with the new sponsor, ensuring equity and fairness between listings.

If a new listing is required to 'join' or 'share' an existing arrangement, it will be subject to the timeframes contained in the existing deed.

The new sponsor can choose not to proceed with listing on the basis that it does not wish to join an existing arrangement. However, if a sponsor wishes to list without entering the existing arrangement it may need to return to the PBAC with evidence to support this approach.

Example: A medicine is recommended by the PBAC that will share the market with a currently listed medicine and therefore must join the existing subsidisation cap and reimbursement arrangement. After 12 months, expenditure has exceeded the agreed subsidisation cap. The sponsors of both medicines pay a share of the total reimbursement amount payable, calculated on the basis of each medicine's share of the overall market under the deed.

Data provision arrangements

These agreements are most often employed to provide the PBAC additional evidence regarding the cost-effectiveness of a listing. These can vary in their requirements and can range from the utilisation and provision of existing data, to the establishment of an entirely new process.

Example: A sponsor agrees to the creation of a registry designed specifically to capture data in relation to a particular listing, which would better inform future decision making. This data is then compared with the Department's data to confirm appropriate utilisation.

Certain types of deeds may require amendments or additions to the standard clauses depending on the particular risk they are intended to mitigate. Negotiations and the resulting arrangement required to mitigate risk around the cost of a medicine will contain a different focus to an arrangement requested by PBAC to provide data, or assurances against leakage outside PBS restrictions.

OTHER ISSUES

Confidentiality

Commercial arrangements with the Government are made under a clear legal requirement for transparency, including the requirement to make public the fact

that such arrangements exist, to minimise the extent that an earlier arrangement could slow the listing of a new PBAC-recommended alternative medicine.

Furthermore, unlike arms length commercial arrangements between business entities, arrangements with the Government are subject to statutory requirements controlling release of information. The *Freedom of Information Amendment (Reform) Act 2010, Department of Finance Circulars* and the *Crimes Act 1914* provide explicit procedures for managing information release and also for criminal sanctions of employees who release information in certain circumstances, and these cannot be overridden by contrary contractual clauses. Only in extreme cases where a business entity can convincingly demonstrate to the Government that a release will create significant financial detriment to that Company is the Government in a position to consider identifying information as confidential in a deed.

Possible future competitors

Prior to execution of the deed, the Government also anticipates how the proposed deed could be expanded if other medicines were to be subsequently listed for use in a similar population. This ensures fairness between the competing medicines. A deed should not constitute a barrier to the listing of a subsequent medicine.

Execution

Deed negotiations between the sponsor and the Department are finalised between the time of the PBAC recommendation and PBS listing.

All PBS recommendations are subject to Government consideration prior to listing.

The deed must be executed by both parties either before the medicine is listed on the PBS or before a change in the circumstances in which the medicine is supplied on the PBS becomes effective.

Timeframes

A positive recommendation for listing by the PBAC is an important first step towards PBS-subsidisation of a medicine. However a number of other steps need to be completed before a medicine can be subsidised, and these steps do have a bearing on the time it takes to list.

Medicines that are of a high cost to the Commonwealth are required to undergo a Cabinet consideration process. The deed of agreement negotiations can be progressed during the Cabinet submission process, but a medicine must receive

Cabinet approval before a deed can be executed by the Government and subsequently listed on the PBS.

Listings, including those that require a deed of agreement, may be subject to published listing timeframes that require a Services Australia data transfer. Due to the nature of the data, the transfer process to Services Australia cannot be commenced until all other aspects of the listing have been agreed and completed.

Dispute Resolution

To minimise the time to listing, the process relies on both parties communicating any issues that arise during the negotiation process at their earliest possible convenience. Given the time constraints on this process, it is in each party's best interests to raise issues relevant to the deed of agreement as soon as possible.

In the event that an agreement cannot be reached, formal advice will be provided by the Assistant Secretary of the Pricing and Policy Branch who is the person responsible on behalf of the Commonwealth. Alternatively, the sponsor can approach the Department for clarification or to outline perceived issues at any stage of the process.

Each deed contains a specific clause to outline the obligations of both parties should a dispute arise.

Recovery Action

Where recovery action is required, this action is initiated by the Department, on behalf of the Government. This is a data-driven process based on the number of processed prescriptions and involves the production and dissemination of an invoice when the relevant terms of an arrangement in a deed are triggered. Processed prescription is defined as a pharmaceutical benefit in relation to which a Subsidy is validly paid as reported by the Department.

Where recovery action is required, it is reconciled either monthly or annually depending on the specific arrangements and involves directly invoicing the relevant sponsor.

WHO DO YOU CONTACT?

Responsibility for the development and ongoing management of deeds of agreement resides with the PBS Pricing and Managed Access Section, a part of the Pricing and Policy Branch of the Department of Health. All correspondence in relation to deeds should be addressed to:

The Director
PBS Pricing and Managed Access Section
Pricing and Policy Branch
MDP 900
Department of Health
GPO Box 9848
Canberra ACT, 2601

Email: pbspricing@health.gov.au

ATTACHMENTS

Attachment A – The Deed of Agreement Process

Attachment B – Basic De-identified Deed (example only)

Please note:

- *This template is the basis of all agreements*
- *Negotiations will not be entered into regarding these standard clauses unless the attributes of a particular arrangement associated with a medicine are identified by the PBAC as requiring different treatment or the Commonwealth Delegate determines the change is necessary based on an identifiable detriment to the sponsor if it is not changed.*

Attachment C – Special Pricing Arrangement criteria