PHARMAC
Pharmaceutical Management Agency

Consultation document

PHARMAC's Implementation of Trans-Pacific Partnership (TPP) provisions and other Amendments to Application Processes

September 2016

Message from Steffan Crausaz, Chief Executive, PHARMAC

During September and October we're visiting towns across New Zealand to talk about the work that PHARMAC does. All New Zealanders are in some way, and at some time, affected by the decisions we make.

We get applications from a wide range of people asking for PHARMAC to fund particular medicines and soon we expect to be asked about funding particular medical devices.

We want to talk with you about changes we're proposing to this process.

Some of these changes are required to meet New Zealand's obligations under the Trans-Pacific Partnership (TPP), but we're also using this opportunity to improve the way we do things. In order for us to keep making the best decisions for New Zealanders, we need your feedback on all these proposed changes, outlined below:

TPP changes for eligible applications

- PHARMAC would make a final decision within a specific period of time – we are calling this the 'TPP track'.
- At the end of the specific period of time, if a TPP track application is declined a review process would be available.

Other changes affecting all applications

- A Product Application Assessment Record would continuously publish information for all new medicines and medical device applications. This would develop over time to provide comprehensive links to all information collected from all sources, including consultations.
- A new decision-type "decline as proposed" would complement the existing "decline" decision type to make it clearer that PHARMAC remains interested in the pharmaceutical even where the application details were not satisfactory.

We attach supporting information explaining our current and proposed future processes. The proposed changes include amendments to our Operating Policies and Procedures which would be necessary for New Zealand to comply with the TPP when it enters into force for New Zealand. It is important to note that the TPP requirements only affect certain medicines funding applications, and not medical devices funding applications.

New Zealanders can be assured that neither the TPP nor the other proposals change the heart of the PHARMAC model—we'll still be seeking expert clinical advice and undertaking rigorous value for money assessment, carefully applying our factors for consideration when making our decisions and taking part in the usual round of robust commercial processes. Funding applications on the TPP track would not 'queue-jump' ahead of other applications and we will take care that we continue to secure the best health outcomes for New Zealanders.

I hope you take this opportunity to help shape the way PHARMAC responds to the TPP obligations the Government has directed us to address as well as other changes we are proposing to make and I look forward to reviewing your feedback.

Steffan Crausaz
Chief Executive

Contents of this consultation document

1. Introduction

The Trans-Pacific Partnership (TPP) Agreement was signed in Auckland by the twelve TPP members on 4 February 2016. Since then TPP signatories have focused on their respective domestic processes necessary to ratify the Agreement. For New Zealand, this has involved the Foreign Affairs Defence and Trade Committee examining TPP and New Zealand's National Interest Analysis (which addresses the implications of TPP for New Zealand), and more recently the introduction of the Trans-Pacific Partnership Agreement Amendment Bill to New Zealand's House of Representatives. The Bill does not propose any changes to the legislation under which PHARMAC operates.

New Zealand has obligations under Annex 26-A (Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices) to Chapter 26 of TPP (Transparency and Anti-Corruption) that will, in practice, apply to PHARMAC. In this consultation paper, references to TPP requirements or obligations are references to those found in Annex 26-A (the **Annex**).

As part of New Zealand's domestic processes, the Minister of Health has issued a direction that from the date that the TPP enters into force for New Zealand, PHARMAC shall, in carrying out its functions, have regard to the need for New Zealand to comply with the obligations in the Annex.

It is important to note that the TPP-related proposed amendments would only take effect when the TPP comes into effect in New Zealand. The date for this is currently unknown.

With respect to New Zealand, the TPP Annex applies to formal and duly formulated applications from suppliers for new pharmaceuticals, completed in accordance with the *Guidelines for Funding Applications to PHARMAC*, seeking reimbursement and listing on the Pharmaceutical Schedule[i].

However, a number of PHARMAC's activities are not subject to TPP, including:

- funding decisions for medical devices
- funding decisions for any medicines not included on the *Pharmaceutical Schedule* (such as under policies like Named Patient Pharmaceutical Assessment)
- funding decisions for medicines that are purchased directly by the Government (e.g. hospital cancer treatments or other hospital administered medicines)
- funding decisions based on any proposal that has not been submitted in accordance with the *Guidelines for Funding Applications to PHARMAC.*

A number of the TPP requirements reflect existing PHARMAC processes and therefore no changes are necessary. PHARMAC has developed a proposed approach to ensure New Zealand meets the remaining TPP obligations that relate to PHARMAC's work. These obligations require PHARMAC to:

1. set a timeframe for consideration of all formal and duly formulated proposals for listing of new pharmaceuticals[ii]; and
2. provide a review process for decisions to not list applications[iii]. Note, the Minister of Health has directed that this be an internal process (that is, managed by PHARMAC).

The nature of these obligations was set out in the Government's factsheet *Pharmaceutical and Medical Device Purchasing (Reimbursement)*, released shortly after the conclusion of TPP

negotiations in October 2015. The Government estimated that implementing these provisions was expected to involve up to $4.5 million in one-off establishment costs for PHARMAC, and $2.2 million per year in operating costs. The Government published the analysis behind these estimated costs in November 2015. The TPP National Interest Analysis released by the Government in January 2016 further assessed the implications of these obligations for New Zealand.

While these TPP obligations for New Zealand relate solely to new medicine funding applications from suppliers, PHARMAC has taken into consideration the impact of the proposed approach on all funding applications, including for other medicine and medical device applications and those made by clinicians, consumers and others.

Applicants already engage with PHARMAC before making an application and through to any consultation stage. Further increasing the visibility of this engagement may be helpful to applicants and others interested in PHARMAC's decision-making processes. We are also mindful that in addressing the TPP requirements, PHARMAC has an opportunity to make positive changes for all other funding applications from suppliers, clinicians and consumers.

PHARMAC commenced a rolling review of its Operating Policies and Procedures (OPP) in 2012. Details on that work can be found on our website www.pharmac.govt.nz. The OPP are PHARMAC's framework for how we carry out our statutory role of deciding which pharmaceuticals and related products are subsidised for use in the community and by public hospitals. They provide guidance to suppliers, people and groups about what to expect when working with us, and they steer us internally as we consider funding proposals and policy changes. Due to the potential time delay between deciding on any changes to our OPP and when they might come into effect, it is possible that future changes may be required to ensure alignment with other aspects of PHARMAC's operations in effect at that time. Depending on the significance of any such changes, consideration would be given to whether consultation was appropriate and any change would be notified by PHARMAC at the time.

The proposed changes do not change the fundamentals of the PHARMAC model and would not lead to increases in the amount people pay for pharmaceutical co-payments.

PHARMAC will continue to fulfil its statutory objective of securing, *"…for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided."*

Section 7 on page 26 contains a glossary of the commonly used terms in this consultation paper.

1.1. Seeking your feedback

This document outlines PHARMAC's proposed approach to addressing the TPP obligations through administrative changes to our processes and OPP and how you can get involved and have your say.

We have provided supporting information to describe the current process and how we expect to amend it. The information covers:

- the current process;

- the proposed changes to implement the TPP obligations (note PHARMAC has not determined the detailed internal processes to manage any proposed review process and as such these are not the subject of this consultation);
- other proposed changes and specific consultation questions;
- the sections of the OPP proposed for amendment being 2.1, 4.1 and 4.5 and specific consultation questions; and
- a summary of all specific consultation questions.

Because the date of TPP's entry into force is currently unknown, the technical aspects of the processes would be adjusted according to the time available within which to implement them. This has particular relevance to information technology solutions for example. We have described at a high-level what we intend to achieve, while we anticipate that the specific detail would become available nearer the date that TPP enters into force for New Zealand.

1.2. Submitting your response

Comments can be submitted through our online consultation form at http://consult-pharmac.objective.com/portal/ or via email, fax or letter by **5pm Friday, 28 October 2016** to:

Sarita Magan
PHARMAC
PO Box 10-254
Wellington 6143

Email: opp@pharmac.govt.nz
Fax: (04) 460 4995

We also invite interested people or groups to meet with PHARMAC staff to present their views in response to this consultation. Please contact Sarita Magan on (04) 9013232 by **Friday, 30 September 2016** if you would like to arrange a time to meet with us. If several groups are interested in meeting we may organise larger group meetings.

We will be holding community forums as part of this consultation. To find out more about these go to our website.

Information requested under the Official Information Act

Feedback we receive is subject to the Official Information Act 1982 (OIA) and we will consider any request to have information withheld in accordance with our obligations under the OIA. Anyone providing feedback, whether on their own account or on behalf of an organisation, and whether in a personal or professional capacity, should be aware that the content of their feedback and their identity may need to be disclosed in response to an OIA request.

We are not able to treat any part of your feedback as confidential unless you specifically request that we do, and then only to the extent permissible under the OIA and other relevant laws and requirements. If you would like us to withhold any commercially sensitive, confidential proprietary, or personal information included in your submission, please clearly state this in your submission and identify the relevant sections of your submission that you would like withheld. PHARMAC will give due consideration to any such request.

1.3. Next steps

After the consultation period closes, we will consider all submissions, release a summary of the submissions received, consider whether further consultation is appropriate and recommend any changes to PHARMAC's OPP to the PHARMAC Board for a final decision. This would be published on our website although TPP-related changes would not come into effect until the date TPP enters into force.

[i] The TPP Annex states (at footnote 11):

> [11] This Annex shall not apply to government procurement of pharmaceutical products and medical devices. If a public entity providing health care services engages in government procurement for pharmaceutical products or medical devices, formulary development and management with respect to that activity by the national health care authority shall be considered an aspect of such government procurement.

The Appendix to the TPP Annex also defines **national health care authorities** as follows:

> For New Zealand, the Pharmaceutical Management Agency (PHARMAC), with respect to PHARMAC's role in the listing of a new pharmaceutical[18] for reimbursement on the *Pharmaceutical Schedule*, in relation to formal and duly formulated applications by suppliers in accordance with the *Guidelines for Funding Applications to PHARMAC*.
>
> [18] For the purposes of New Zealand, "pharmaceutical" means a "medicine" as defined in the *Medicines Act 1981* as at the date of signature of this Agreement on behalf of New Zealand.

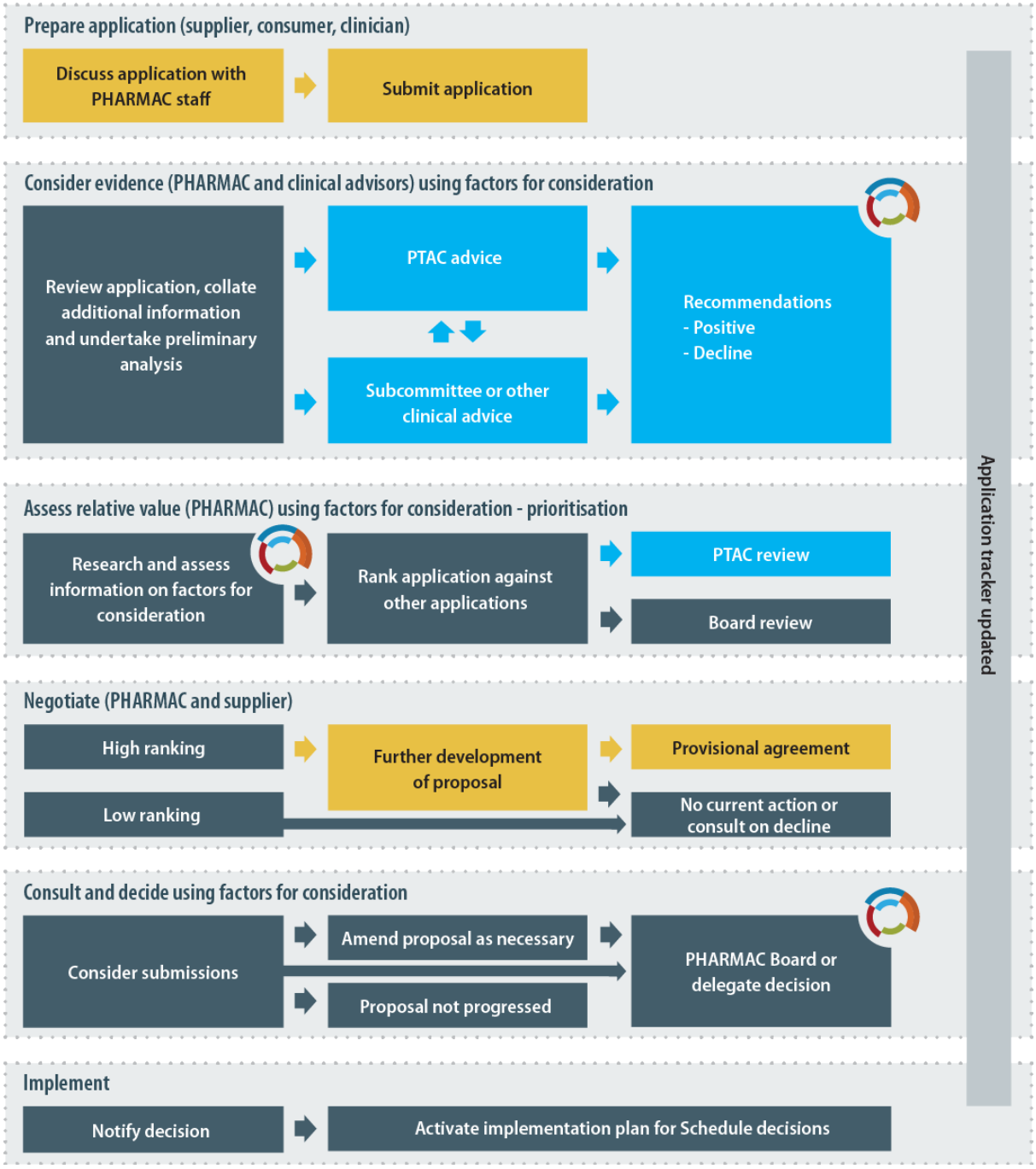
[ii] Article 3(a) of the TPP Annex requires Parties to the TPP to:

> ensure that consideration of all formal and duly formulated proposals for such listing of pharmaceutical products or medical devices for reimbursement is completed within a specified period of time[13]
>
> [13] In those cases in which a Party's national health care authority is unable to complete consideration of a proposal within a specified period of time, the Party shall disclose the reason for the delay to the applicant and shall provide for another specified period of time for completing consideration of the proposal.

[iii] Article 3(e) of the TPP Annex states requires parties to the TPP to:

> make available:
>
> (i) an independent review process; or
>
> (ii) an internal review process, such as by the same expert or group of experts that made the recommendation or determination, provided that the review process includes, at a minimum, a substantive reconsideration of the application,[15] and
>
> that may be invoked at the request of an applicant directly affected by a recommendation or determination by a Party's national health care authorities not to list a pharmaceutical product or a medical device for reimbursement;[16]

2. Supporting information — current process for considering an application for funding



The diagram of the current process reflects section 4.5 of the OPP. PHARMAC is not bound to follow the process set out in the diagram and may vary this process or adopt a different process where appropriate. The current process is further explained below:

2.1. Prepare application (supplier, consumer, clinician)

Before submitting to PHARMAC, the applicant is encouraged to talk with staff. This helps to ensure that the appropriate information is included with the application.

2.2. Consider evidence (PHARMAC and clinical advisors) using factors for consideration

PHARMAC reviews and collates additional information before submitting the application for consideration by the Pharmacology and Therapeutics Advisory Committee (PTAC). In some cases, the application is also considered by one of the specialist PTAC Subcommittees.

The supporting information collated includes consideration of the nature of the disease, condition or illness for which the pharmaceutical is to be used, and the treatments already available in New Zealand for that disease, condition or illness. PHARMAC also completes a preliminary analysis of the cost of funding the new pharmaceutical and comments on any supplier-provided cost-utility analysis.

PTAC is an expert group of clinicians providing objective advice to PHARMAC regarding pharmaceuticals use, benefits and overall value for New Zealanders. Committee members are all senior practising clinicians who help in the process of deciding which pharmaceuticals may be subsidised by making recommendations to PHARMAC. PTAC uses the same Factors for Consideration as PHARMAC when considering applications.

2.3. Assess relative value (PHARMAC) using factors for consideration - prioritisation

Following PTAC advice, PHARMAC completes research and assessment of information on the factors for consideration. This is wide ranging and includes health need, populations experiencing health disparities, Māori health, economic assessment consisting of a cost-utility analysis and budget impact analysis. A positive PTAC recommendation to fund a pharmaceutical does not necessarily mean that it will be funded. These recommendations are taken into account when PHARMAC assesses the relative value of each new application. This is because PHARMAC looks at all the applications together before ranking each new application against other applications using the factors for consideration to determine what the best health outcomes are likely to be.

From time to time PHARMAC reviews applications, which can result in a reordering of the relative ranking of applications: some pharmaceuticals may shift down the list, others may move up. The aim of determining the relative ranking of each application is to identify potential changes to the Pharmaceutical Schedule that would provide the best health outcomes.

Both PTAC and the PHARMAC Board regularly review the full list of ranked pharmaceutical applications.

2.4. Negotiate (PHARMAC and supplier)

Negotiation may occur at any stage of an application. However, PHARMAC usually considers whether an application should proceed to commercial negotiations after it has been ranked. Generally the applications towards the top of the list are those which PHARMAC negotiates. PHARMAC staff negotiate with the supplier which may result in both parties reaching a provisional agreement.

Before an application proceeds to a provisional agreement, funding needs to be potentially available. Where negotiations take some time to conclude, it is possible that funding may no longer be available. This may be for a range of reasons such as a new funding position, other negotiations concluding, or better health outcomes becoming available with newer applications that have been ranked potentially higher than the one under active negotiation.

2.5. Consult and decide using factors for consideration

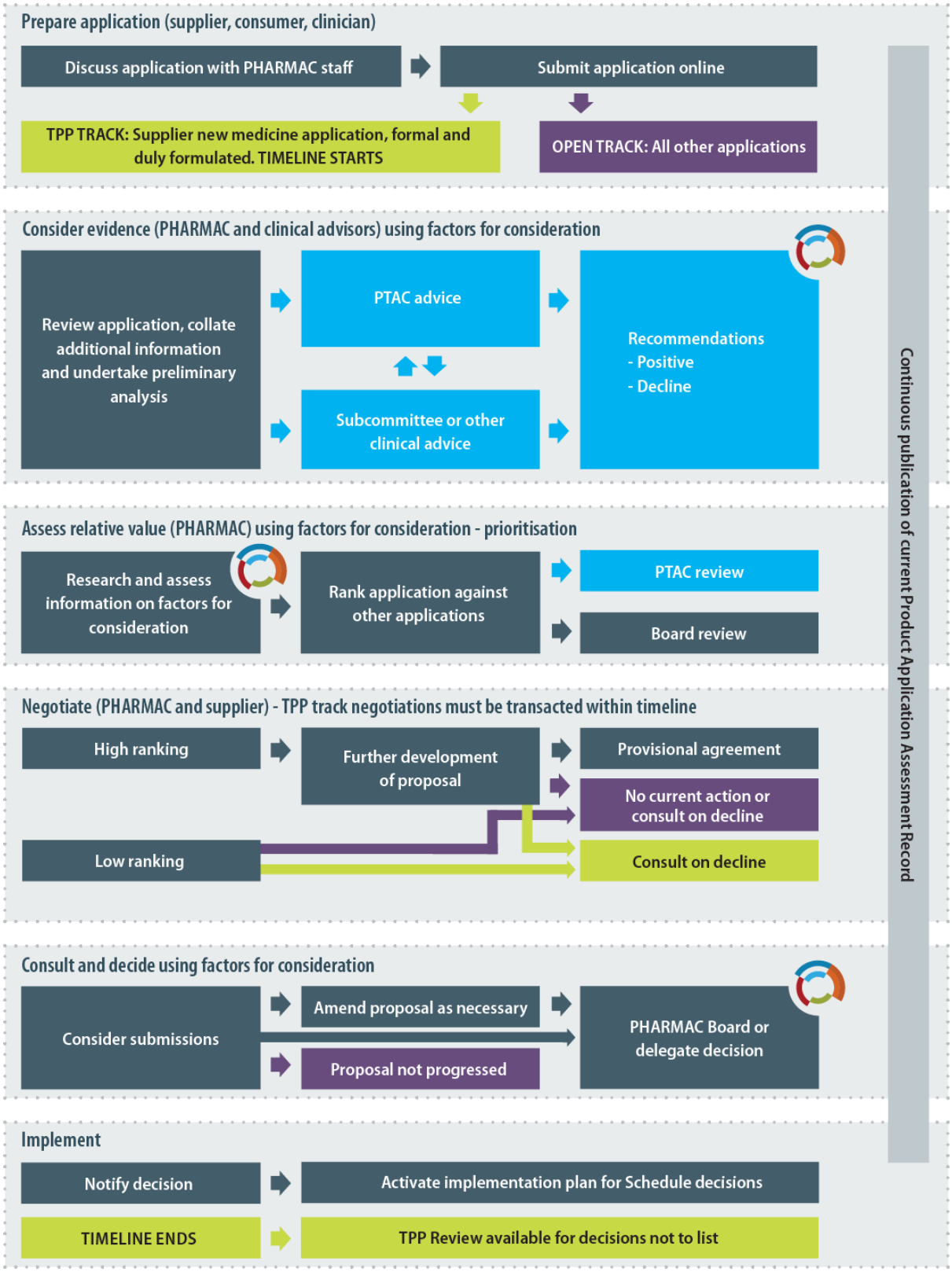
If PHARMAC considers it appropriate to do so, PHARMAC will then consult with relevant stakeholders on the proposal, taking this feedback into account before a decision is made. Final decisions are made by the PHARMAC Board or by the Chief Executive or other staff acting under delegated authority of the Board.

2.6. Implement

PHARMAC manages implementation of its funding decisions beginning with the notification of a decision. PHARMAC liaises with others in the sector with similar responsibilities for implementation (for example, the Ministry of Health in respect to changes to the National Immunisation Schedule). This can include support for consumers, District Health Boards, prescribers, pharmacists and other clinicians, and consideration of distribution and funding arrangements.

3. Supporting information
— proposed process for considering an application for funding

Note: The same stages apply to all applications. However, there are some differences in processing steps within each stage for each track. For TPP track applications differences are shown in green, and Open track differences are shown in purple, otherwise all other processing steps are in common.



Proposed process diagram

This diagram provides a simplified, indicative guide to the proposed process that PHARMAC would usually follow when considering applications for funding that might result in a listing on the Pharmaceutical Schedule. As with our current OPP, PHARMAC is not bound to follow the process set out in the diagram and may vary this process or adopt a different process where appropriate.

3.1.1. Prepare application (supplier, consumer, clinician)

Before submitting to PHARMAC, an applicant would be encouraged to talk with staff. This would help to ensure that the appropriate information is included with the application.

PHARMAC is proposing to introduce a website for electronic submission of funding applications. This is referred to as the funding application website. Development and launch of this web interface would be subject to resourcing and having sufficient development time within the TPP implementation process.

We propose establishing a formal process for supplier applications that meet the TPP requirements.

Two application 'tracks' would operate:

- a TPP track for certain supplier applications that satisfy the TPP criteria (set out in section 3.1.2 below); and
- an Open track for all other applications (supplier, clinician, consumer generated applications).

The key differences between a TPP track application, and an Open track application, would be:

- PHARMAC will need to make a Final Determination on a TPP track application within a specified period of time (PHARMAC's proposal set out in this consultation document is 36 months from submission of the application) of when the duly formulated application is submitted, unless PHARMAC is unable to do so, in which case it shall disclose the reason for delay to the supplier, and provide for another specified period (or periods) of time for completing consideration of the application; and
- If PHARMAC makes a Final Determination not to list a new medicine that is the subject of TPP track application, PHARMAC will make available an internal review process (a TPP Review) which the supplier may choose to invoke. There are limitations to the scope of this review. For example, when reviewing an application, the reviewer will not need to consider any assessment related to any other proposal for listing by PHARMAC. In this way, a review will not require, for example, querying the prioritisation of one application over another.

All applications would be made online. Key information would allow the system to identify applications eligible for the TPP track.

3.1.2. TPP track for eligible supplier applications

Section 1, Introduction, references the specific TPP requirements. In New Zealand, and in the context of PHARMAC's funding processes this means that the TPP track would be for applications for reimbursement and listing on the Pharmaceutical Schedule:

- from a pharmaceutical supplier (meaning an entity with the necessary rights in connection with the medicine for PHARMAC to be willing to enter into a contract for supply with that entity). The country of origin of that supplier would be irrelevant (that is, while it is called the TPP track, it would not be necessary for a supplier to establish they were actually from a TPP country);

- 'formal and duly formulated' in terms of the *Guidelines for Funding Applications to PHARMAC* (these would be updated to reflect the proposed TPP track process);

- for a medicine (not a medical device);

- where the application is that supplier's first application to PHARMAC for that chemical or biological entity;

- where the medicine is registered for all indications cited within the funding application with Medsafe; and

- where the medicine is for use in the community (including oral cancer medicines).

The TPP track would not be available for:

- hospital-only medicines including 'PCT-only' medicines as these are not 'reimbursed' medicines in terms of the TPP - most vaccines would also not qualify as these are not currently reimbursed;

- applications for new indications, formulations, presentations, combinations, or any other use of a chemical or biological entity that has been the subject of a previous application by that supplier (or a 'Predecessor Company' as defined in the Glossary) for reimbursement or listing on the Pharmaceutical Schedule (whether that application was successful or not); or

- applications by 'Successor Companies' (as defined in the Glossary) where a previous application for that chemical or biological entity was made by a Predecessor Company.

Applications would be required to identify whether the chemical or biological entity that is the subject of the application had previously been applied for by that supplier.

- Supplier applications may still proceed down the TPP track if PHARMAC has previously considered that medicine through an application made by another supplier. However, if the previous application was made by a Predecessor Company, then the Successor Company's application must proceed down the Open track.

- Following a decision on a medicine application made under the TPP track, any future application for that medicine would not be possible on the TPP track and would need to be made under the Open track.

The Guidelines for Funding Applications to PHARMAC would be amended to make clear that a duly-formulated application for a new medicine would require compulsory fields to be completed. As well as being that supplier's first application for that medicine in any form, the supplier's product must have been registered for the proposed indication/s with Medsafe. To be considered 'duly formulated' the formal application would have to include sufficient information for the parties to be able to enter into a contract. This would include acceptance of PHARMAC's standard terms and conditions (Annexes 3a and 3b) and any proposed additional terms and conditions (Annex 4).

The supplier's application would be able to be amended within a brief 'period of grace' window after submission to PHARMAC. Following this period, the application would be locked and fully considered in its entirety until the point of negotiation is reached.

By the end of this period of grace, PHARMAC would confirm to the supplier whether the application is eligible to proceed down the TPP track. If it is not eligible, the application would progress on the Open track.

The period of grace is proposed to be 10 working days.

If the application progresses down the TPP track the supplier's application would be assessed 'as is' as duly-formulated and taken to its conclusion within the specified timeframe. PHARMAC proposes that this timeframe is 36 months from submission of the application; see further explanation in the following section. Suppliers would not be permitted to provide supplementary information or additional applications for the new medicine until the negotiation stage; see section 3.4.2 below. This would avoid inefficiencies such as PTAC having to add to its workload by reconsidering multiple applications for the same medicine from a supplier.

We anticipate that around 40-50% of supplier applications to PHARMAC would be eligible for the TPP track (and therefore subject to the specified timeline and option of TPP review).

3.1.3. Timeframe for completion applies to TPP track only

The TPP timeframe commences from the point of submission of a duly formulated application on the TPP track. The period of grace is included within the timeframe.

The TPP timeframe concludes when the applicant is notified of PHARMAC's Final Determination.

Following the consultation commenced by this document, PHARMAC's Board will determine the standard timeframe for TPP track applications. As set out in this document, the proposed timeframe for these formal and duly formulated supplier applications for new medicines is 36 months from submission of the application.

This period of time (36 months) is similar to the current median processing time for applications from submission to ranking, plus additional time to enable negotiation to occur and the impact of any amendments to be considered, together with the time necessary for consultation on a proposed Final Determination (if PHARMAC considers it appropriate to do so), including reviewing and responding to submissions, and making and notifying a Final Determination. This proposed time would mean PHARMAC committing to completing its assessment for TPP track applications more quickly than the current process, and as a result PHARMAC would need to find further efficiencies in its processes.

There may be some situations where PHARMAC would need to extend the standard timeframe. Section 1, Introduction, outlines the circumstances in which the TPP requirements (including completing consideration within a specified period of time) will apply. Footnote 3 in the Introduction refers to the section of the Annex that provides, in effect, that where PHARMAC is unable to complete consideration of the proposal within a specified period (or periods) of time, the reason for the delay needs to be disclosed to the supplier, and PHARMAC needs to provide another specified period of time for completing consideration of the proposal.

Therefore, PHARMAC would notify the supplier of the reasons for a delay and the new timeframe that applies. It is envisaged that extensions would be notified where PHARMAC's regular processes were not able to be completed within the regular timeframe. For example, where a TPP track application was not able to be accommodated on a PTAC agenda, it would be moved to the next PTAC meeting – an extension of a further four months. Or where additional subcommittee advice was sought an extension relating to the next meeting cycle would be notified. Other possible reasons for an extension would be where consultation responses required additional analysis and further clinical advice to be sought. The length of time of such an extension would vary depending on the complexity of the issues raised. Suppliers would not be able to apply for an extension.

3.1.4. Open track

The Open track is for all other supplier applications to list medicines or medical devices on the Pharmaceutical Schedule, and for all applications submitted by clinicians, consumers, PHARMAC and other interested parties. The proposed funding application website would be available for all Open track applications. Guidelines would be available to support these applications. This track would process a wide range of applications including hospital medicines and an expanding area of PHARMAC activity - medical devices. PHARMAC is unable to offer a standard timeline for applications made under the Open track as these will rarely be applications made in a standard form that represents fully-formed contracts for supply with that entity. For example, Open track applications may vary in terms of the level of evidence available, commercial terms proposed, level of negotiation required or involve unregistered products. Applicants generally make use of the flexibility of this assessment track to provide further evidence and revised terms which may be proposed at any time, including innovative arrangements and bundled proposals with other products.

3.2. Consider evidence (PHARMAC and clinical advisors) using factors for consideration

No change is proposed.

3.3. Assess relative value (PHARMAC) using factors for consideration - prioritisation

No change is proposed.

3.4. Negotiate (PHARMAC and supplier)

3.4.1. Open track

No change is proposed.

3.4.2. TPP track

During the negotiation stage, provided there is sufficient time remaining within the standard timeframe, a supplier on the TPP track could suggest amendments to the application. PHARMAC would indicate whether there was sufficient time remaining within which to process such a change (taking into consideration the time required to issue and respond, if necessary, to any consultation and to make a Final Determination). Generally such change would relate to a response to the assessment, including clinical advice, or involve proposals for alternative commercial arrangements.

3.5. Consult and decide using factors for consideration

No change is proposed.

3.6. Implement

3.6.1. Open track

No change is proposed.

3.6.2. TPP track - Review Process

A supplier with a TPP track application may seek a TPP Review of PHARMAC's Final Determination of that application, if PHARMAC's decision is not to list the medicine on the Pharmaceutical Schedule. The TPP does not require reviews to be completed within a specified period of time. There are limitations to the scope of this review. For example, when reviewing an application, the reviewer will not need to consider any assessment related to any other proposal for listing by PHARMAC. In this way, a review will not require, for example, querying the prioritisation of one application over another.

The Ministerial Direction that this be an internal review means that PHARMAC would oversee the entire review. This would include a substantive reconsideration of the application by PHARMAC staff, and may use the input of an external reviewer to assist in reviewing PHARMAC's use of its processes in reaching its Final Determination. In circumstances where PHARMAC had consulted on the proposed Final Determination, feedback from that consultation would be considered as part of the TPP Review.

While a new application may be made at any time under the Open track following completion or withdrawal from the TPP track, this is not available for a medicine for which an application is undergoing a TPP Review. A supplier may make a new application under the Open track at the completion of a TPP Review.

If a supplier makes a new application, PHARMAC would enable the original application to be linked to a separate application under the Open track, meaning that any relevant information and assessment could be utilised. PHARMAC may choose to reissue a proposed final Determination and proceed to consultation and Final Determination.

4. Proposed Operating Policies and Procedures (OPP) to support TPP changes

PHARMAC proposes the following Operating Policies and Procedures (OPP) to take effect from the date the TPP enters into force for New Zealand.

Following Board decision and notification of OPP changes, non-material changes may occur to ensure consistency and alignment with PHARMAC's OPP (which remains subject to a rolling review) in effect at the date TPP enters into force for New Zealand. This may include changes to section number, headings and wording.

Proposed additions are shown in bold, deletions in strikethrough:

OPP Section 2.1 Amendments to the Pharmaceutical Schedule

PTAC, pharmaceutical suppliers, **clinicians, consumers,** DHBs and other interested parties may approach PHARMAC to suggest possible amendments to the Schedule**, using the process described in the relevant funding application Guidelines**. PHARMAC may amend the Schedule as it considers appropriate, including initiating amendments of its own accord. Possible amendments to the Schedule include (but are not limited to):

(a) listing new pharmaceuticals~~, including listing community pharmaceuticals and listing hospital pharmaceuticals that are subject to national contracts for supply to DHB hospitals;~~

(b) changing ~~guidelines or restrictions on the prescribing and dispensing of~~ **the terms on which a pharmaceutical is** listed ~~pharmaceuticals~~ including;

~~(c)~~ **i) changing guidelines or restrictions on prescribing and dispensing**

ii) changing the subsidy levels of pharmaceuticals as a result of PHARMAC adopting one of the strategies set out in section 3 or by any other means;

~~(e)~~ **iii)** delisting pharmaceuticals or delisting part or all of a therapeutic group or sub-group;

~~(f)~~ **iv)** changing packaging sizes and brand names;

v) changing the indications, formulations, presentations or any other feature of a listed pharmaceutical;

~~(d)~~ (c) amending the basis on which pharmaceuticals are classified into therapeutic groups and sub-groups; **or**

~~(g)~~ (d) publishing of information or requirements relating to the implementation of contracts for supply to DHB hospitals**.**~~, including in relation to pharmaceuticals that may be purchased by DHB hospitals other than those which are the subject of a national contract; or~~

~~(h) publishing of information about applications in respect of hospital pharmaceuticals that are undergoing or have undergone assessment by PHARMAC and/or DHBs.~~

OPP Section 4.1 General

4.1.1 ~~Before seeking to initiate an amendment to the Schedule, the party seeking the amendment should contact PHARMAC to discuss the nature of its proposed amendment and establish what the appropriate procedure is in its particular case and what sort of information it needs to provide to PHARMAC. Further details about procedures for making submissions may be found in PHARMAC's guidelines for submissions, available on request from PHARMAC.~~**All applicants are encouraged to contact PHARMAC prior to making an application for funding to discuss their application.**

4.1.2 The procedure to be followed in respect of an **application for an** amendment to the Schedule may vary depending on a number of factors, including (but not limited to):

(a) the nature of the amendment (e.g., new listing, delisting, classification);

(b) who has initiated the amendment (e.g., PHARMAC, PTAC, supplier, interested parties) **and whether it is the first time they have made this application**;

(c) the type of pharmaceutical being listed (e.g., a new ~~pharmaceutical~~ **medicine** or a generic ~~pharmaceutical~~ **medicine or a medical device)**;

(d) whether the amendment would result from an RFP, tender, listing contract or some other arrangement; or

(e) whether the amendment is a result of PHARMAC adopting a new strategy.

4.1.3 PHARMAC may require a party initiating an amendment to the Schedule to provide **in their application** relevant information, including (but not limited to):

(a) pharmacological information (forms, strength, indications, dosages, contra-indications etc);

(b) therapeutic information (main therapeutic claims, advantages/ disadvantages when compared with other pharmaceuticals etc);

(c) price information (proposed price, price overseas, other pricing proposals);

(d) epidemiological information (number of people with the particular condition, number likely to be prescribed the pharmaceutical etc);

(e) market information (expected sales etc);

(f) detailed information on the costs and benefits of the pharmaceutical (e.g., reductions in expenditure; improvements in longevity and/or quality of life etc); and

(g) information regarding packaging and pack sizes.

PHARMAC will decide what information it requires on a case by case basis. For example, less information may be required where a party proposes that PHARMAC list a generic pharmaceutical, as opposed to the listing of a new pharmaceutical.

4.1.4 Subject to PHARMAC's right to prioritise its consideration of proposed amendments, PHARMAC is not bound to consider any proposed amendment until the party initiating the amendment has complied with all the conditions set by PHARMAC, including (but not limited to):

(a) providing non-biased information;

(b) setting out the basis for any estimates or assumptions made;

(c) providing a synopsis on all material issues; and

(d) providing comprehensive and detailed cost/benefit information.

4.1.5 Supplier applications for amendments to the Pharmaceutical Schedule must be made in accordance with the *Guidelines for Funding Applications to PHARMAC*. For the avoidance of doubt, the Guidelines do not apply to responses to tenders, RFPs or other commercial proposals issued by PHARMAC.

4.1.6 PHARMAC will operate a TPP track for applications that meet the eligibility criteria in 4.1.7 and an Open track for all other applications for amendments to the Pharmaceutical Schedule.

4.1.7 An application for reimbursement and listing on the Pharmaceutical Schedule will only be eligible for the TPP track if it is:

4.1.7.1 an application from a pharmaceutical supplier (meaning an entity with the necessary rights in connection with the medicine for PHARMAC to be willing to enter into a contract for supply with that entity);

4.1.7.2 "formal and duly formulated" in terms of the *Guidelines for Funding Applications to PHARMAC*;

4.1.7.3 for a medicine (not a medical device);

4.1.7.4 the first application to PHARMAC by that supplier (or a Predecessor Company) for that chemical or biological entity, and is NOT an application for a new indication, formulation, presentation, combination, or any other use of a chemical or biological entity that has been the subject of a previous application by that supplier (or its Predecessor Company) for reimbursement or listing on the Pharmaceutical Schedule;

4.1.7.5 where the medicine is registered with Medsafe for all indications cited within the funding application; and

4.1.7.6 where the application is seeking reimbursement for use of the medicine in the community (including oral cancer medicines).

4.1.8 The following applies to applications on the TPP track:

4.1.8.1 The supplier may make amendments to its application within 10 working days of initial submission. After that time, no further changes may be made to the application until the assessment stage has been completed. PHARMAC may choose whether to accept any changes proposed by the supplier after the assessment stage has been completed, taking into consideration whether there is likely to be sufficient time to make a Final Determination within the time specified under 4.1.8.2 as a consequence of the processing required.

4.1.8.2 A final decision will be made by PHARMAC within 36 months of an application meeting the requirements set out in 4.1.7 above being submitted unless an extension (or extensions) to the specific period of time is notified by PHARMAC to the supplier with reasons for the delay stated.

4.1.8.3 A supplier may apply for a review of a decision not to list a medicine where the application has been made under the TPP track ("TPP Review").

The TPP Review is to be conducted by PHARMAC in accordance with the process determined by PHARMAC for this purpose.

4.1.8.4 No additional application will be accepted from a supplier for a medicine undergoing review until the TPP Review is completed.

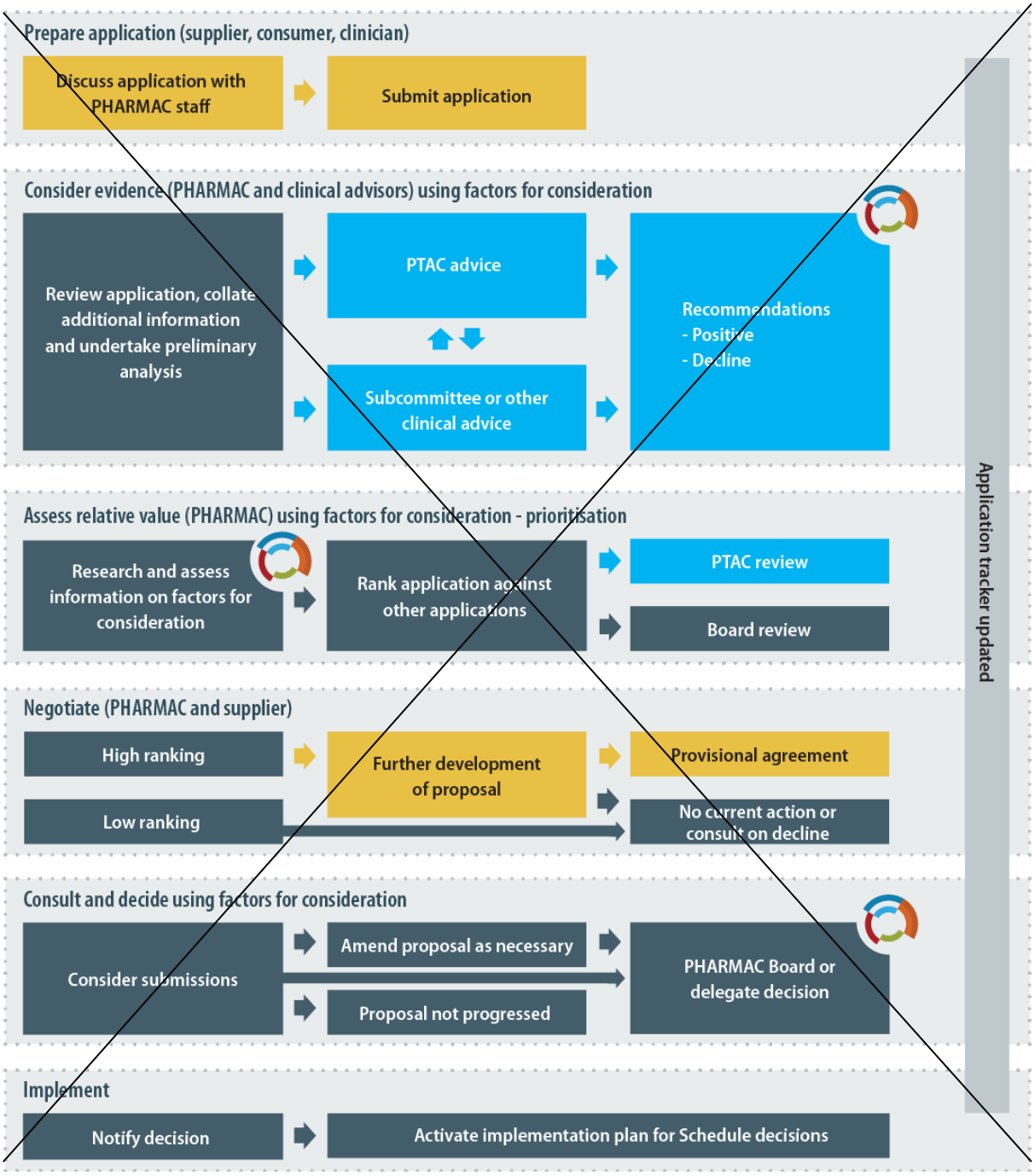
4.1.8.5 A supplier which has an application on the TPP track can withdraw its application at any time. Any subsequent application from that supplier in relation to the same chemical or biological entity would be dealt with as an Open track application.

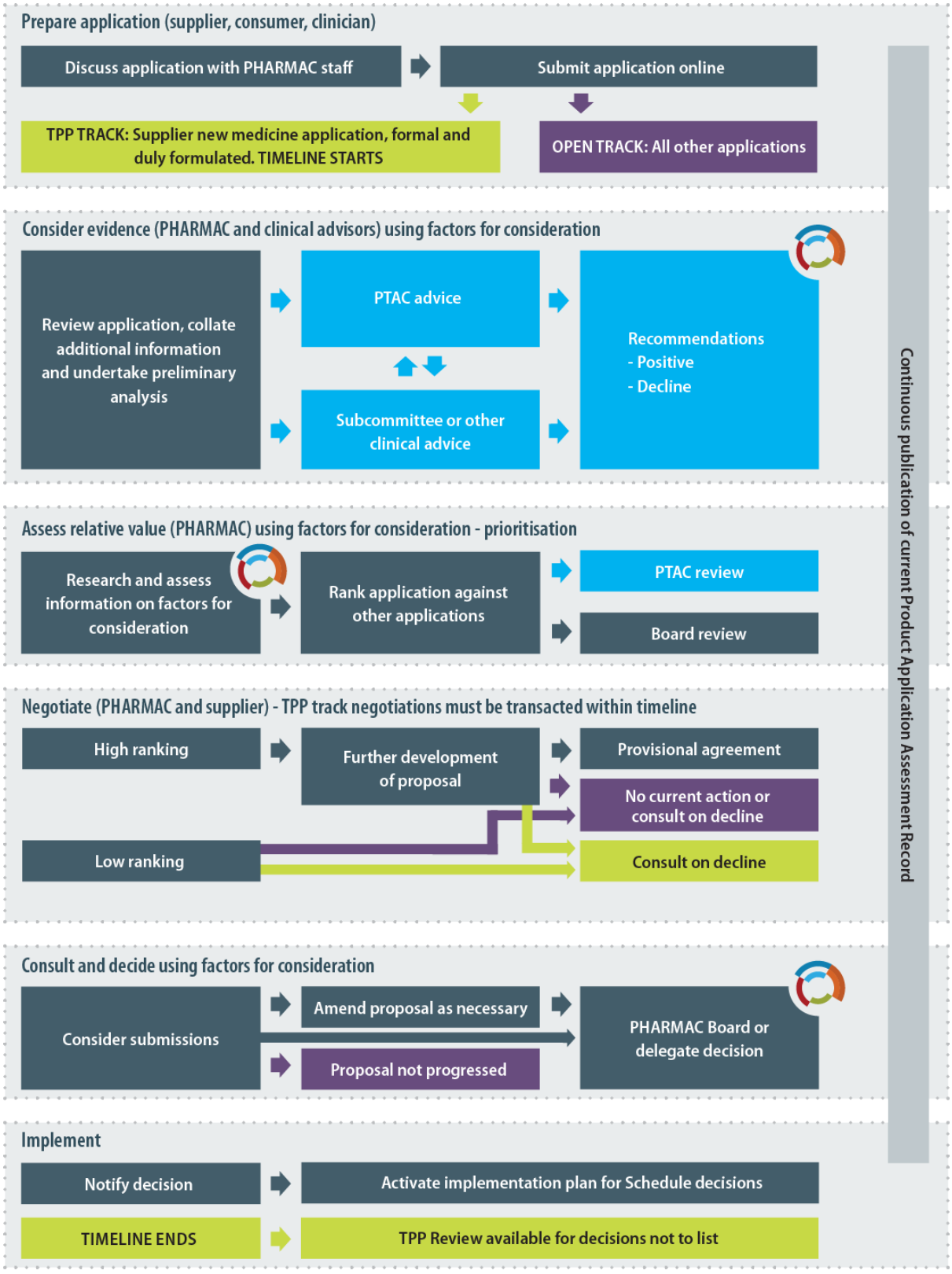
4.1.9 Supplier applications not eligible for the TPP track are processed under the Open track, as are all applications from all other applicants.

4.1.9.1 Once an application is submitted under the Open track, PHARMAC may request further information. PHARMAC may decide not to consider an application until all requested information has been provided.

4.1.10 PHARMAC will make available information on the progress of applications in a timely and transparent manner.

OPP Section 4.5 Procedure for Listing a Pharmaceutical on the Pharmaceutical Schedule





Note: This diagram provides a simplified, indicative guide to the process that PHARMAC will usually follow when listing a pharmaceutical on the Schedule. PHARMAC is not bound to follow the process set out in the diagram and may vary this process or adopt a different process where appropriate. **PHARMAC provides a range of opportunities for applicants and other interested parties to engage with it regarding an application which is under assessment.**

4.1. TPP-related Consultation questions

1. How well does the proposed OPP section 2.1 reflect the proposed TPP-related changes?
2. How well does the proposed OPP section 4.1 reflect the proposed TPP-related changes?
3. How well does the proposed OPP section 4.5 reflect the proposed TPP-related changes?
4. How workable is the proposed TPP track and what issues or concerns might you have with its implementation?
5. How reasonable is 36 months as the proposed timeframe within which PHARMAC should make its Final Determination for TPP track applications?
6. How reasonable is the proposed period of grace of 10 working days within which supplier TPP track applications may be amended?
7. What level of detail would it be reasonable to publish following a TPP Review?
8. What other thoughts do you have on the proposed OPP changes?

5. Other proposed PHARMAC changes

5.1. Product Application Assessment Record

A new Product Application Assessment Record (PAAR) would be developed for all new medicines and medical device applications that would be available on the funding application website, regardless of which track they were filed on. Development and launch of the online PAAR is subject to resourcing and sufficient timeframes within which to develop it and the necessary security and privacy provisions that would give users confidence that sensitive information would be protected and not inadvertently disclosed. PHARMAC would proceed with a document-based PAAR until such time as the technology solution was in place.

Content (subject to the level of restriction indicated by the content provider or the requirements of the relevant funding application Guidelines) would include:

- Supplier application details
- Clinical information (PTAC, subcommittees, other expert advice)
- PHARMAC information (factors for consideration information including some aspects of cost utility analysis, technology assessment report, implementation)
- Timeframe (for TPP track)
- Consultations, and consultation responses (members of the public would have the opportunity to note which of their content they wished to be restricted (such as personal health information) and which they would consider unrestricted)
- Review findings (for TPP track)
- Assessment status and whether the application is still current or complete.

Over time the PAAR would replace the current application tracker as the same functionality would be contained in the PAAR. The proposed continuous disclosure process via the PAAR would mean the replacement of current processes around publication of clinical advice (such as PTAC and subcommittee minutes).

Content from a closed PAAR may be able to be re-used to populate a related new application's PAAR, although the original application would still be viewed as closed.

5.2. Unrestricted versus restricted information

The funding application website would have clear delineation of information that is 'unrestricted', such as general product descriptions and published research, and that which is 'restricted', such as the commercial aspects of an application, for example pricing, some aspects of cost-utility analysis and budget impact analysis.

An ability to provide general feedback on applications would be offered. However, information provided would only be added to PHARMAC's formal assessment process where it was able to be accommodated within the process' timeframes. Note that TPP track applications may not have further information added until following completion of the assessment stage. Only PHARMAC could access the restricted information submitted, with a copy provided to the applicant for their records. As with all information currently held by PHARMAC any restricted information would be subject to the Official Information Act and may still be published; however, it would not automatically be published to the funding application website.

5.3. PHARMAC Determinations

The TPP refers to Draft Final Determinations and Final Determinations. PHARMAC's funding decisions involve changes to the Pharmaceutical Schedule. Notified decisions are its Final Determinations on each application. The TPP Review process would only be available for Final Determinations on TPP track applications.

We expect that the requirement to make decisions on TPP track applications within a timeframe would most likely lead to an increase in decline decisions, as PHARMAC currently tends to keep open applications that it might otherwise decline at that time in case new information or funding becomes available.

There is sometimes public confusion about the nature of these decline decisions. These decisions relate to a specific application and may represent a decline of the pharmaceutical itself due to the availability of suitable alternatives, the level or certainty of clinical benefits or in other cases, where the application's pricing means the value for money is very low or the overall cost exceeds the available funding. In the vast majority of cases, PHARMAC remains interested in funding treatments where they offer a measurable and clinically-meaningful health gain. A future positive listing decision would remain dependent on receiving a further application with improved clinical evidence or commercial terms, and available funding. In such situations, under the proposed approach suppliers would be able to make a new application on the Open track and propose alternative terms or arrangements. In a very small number of cases, PHARMAC concludes, based on the available evidence, that it is unlikely to fund a particular pharmaceutical in the foreseeable future in which case a 'decline' would have a different impact.

To assist in better understanding the nature of decline decisions, PHARMAC proposes to maintain its current 'Decline' category and also establish a new category of decision: 'Decline as Proposed'. This decision type would make it clearer that the application itself was declined, rather than the pharmaceutical being declined.

Should an application be 'Declined as Proposed', the pharmaceutical would remain as a potential future funding option. If a future application for the pharmaceutical or a similar pharmaceutical is received PHARMAC would then be in a better position to identify those likely to offer good health gains.

Should a proposal be 'Declined', it would indicate that PHARMAC is unlikely to contemplate listing the pharmaceutical in the absence of new information. The pharmaceutical is therefore unlikely to be considered as an option for investment.

5.4. Other consultation questions

9. What comments do you have on the proposed new funding application website?
10. What information should be published and why?
11. What comments do you have about the processes for publishing information?
12. What is your view on the proposal to distinguish a decision to "Decline" from a decision to "Decline as Proposed"? How useful would you consider such a distinction?
13. What other general comments do you have regarding this consultation?

6. List of all consultation questions

1. How well does the proposed OPP section 2.1 reflect the proposed TPP-related changes?

2. How well does the proposed OPP section 4.1 reflect the proposed TPP-related changes?

3. How well does the proposed OPP section 4.5 reflect the proposed TPP-related changes?

4. How workable is the proposed TPP track and what issues or concerns might you have with its implementation?

5. How reasonable is 36 months as the proposed timeframe within which PHARMAC should make its Final Determination for TPP track applications?

6. How reasonable is the proposed period of grace of 10 working days within which supplier TPP track applications may be amended?

7. What level of detail would it be reasonable to publish following a TPP Review?

8. What other thoughts do you have on the proposed OPP changes?

9. What comments do you have on the proposed new funding application website?

10. What information should be published and why?

11. What comments do you have about the processes for publishing information?

12. What is your view on the proposal to distinguish a decision to “Decline” from a decision to “Decline as Proposed”? How useful would you consider such a distinction?

13. What other general comments do you have regarding this consultation?

7. Glossary

Decision-types

- List – details of the Schedule change notified
- Decline as proposed – the application itself is declined, rather than the pharmaceutical itself being declined.
- Decline – the pharmaceutical is unlikely to be funded without new information.

Draft Determination
The view formed by PHARMAC following the completion of assessment of a funding application.

Formal and Duly Formulated Application
For a supplier's new medicine application to be eligible for the TPP track it must complete the compulsory information required under the *Guidelines For Funding Applications to PHARMAC.*

Final Determination
The final funding decision notified by PHARMAC to the applicant.

Funding Application Guidelines
Guidance for applicants seeking amendments to the Pharmaceutical Schedule. Includes *Guidelines For Funding Applications to PHARMAC* for suppliers and other forms of guidance for clinicians, consumers and other applicants.

Funding Application Website
The method by which TPP track and Open track applications would be made. Suppliers would indicate at point of submission, which content was restricted and which was unrestricted. PHARMAC would consult the supplier on any proposal to remove restrictions placed by suppliers on content. Content forms part of the Product Application Assessment Record.

Medicines

Where this document uses the term "medicine" it carries the current meaning under the Medicines Act 1981.

Open track
The proposed application method for all applications that are not eligible for the TPP track.

Product Application Assessment Record
The online resource whereby all information relevant to an application to list a medicine or medical device on the Pharmaceutical Schedule can be viewed by PHARMAC. Those adding to the Product Application Assessment Record would indicate at point of submission, which content was restricted and which was unrestricted. Only unrestricted content would be able to be viewed outside PHARMAC.

Pharmaceuticals
The New Zealand Public Health and Disability Act 2000 (NZPHDA) defines 'pharmaceutical(s)' as "medicines, therapeutic medical devices, related products and related things."

The TPP requirements for New Zealand state "'pharmaceutical' means a 'medicine' as defined in the Medicines Act 1981 as at the date of signature of this Agreement…" [4 February 2016]

Where this document uses the term "pharmaceutical" it carries the NZPHDA meaning.

Predecessor Company
A company of which at least 51% of its equity share capital, or 51% or more of its business and assets (by value), or the rights in relation to the chemical or biological entity in question, have been acquired by another company (that company being a Successor Company).

Proposed Final Determination
The view formed by PHARMAC prior to consideration of consultation on a funding decision.

Successor Company
A company that has acquired either 51% or more of the equity share capital, 51% or more of the business and assets (by value), or the rights in relation to the chemical or biological entity in question, of a Predecessor Company.

TPP Review
The PHARMAC review invoked by a TPP track applicant following a decision not to list a medicine.

TPP track
The proposed application method for all applications for reimbursement and listing on the Pharmaceutical Schedule that are:

- from a pharmaceutical supplier (meaning an entity with the necessary rights in connection with the medicine for PHARMAC to be willing to enter into a contract for supply with that entity). The country of origin of that supplier would be irrelevant (that is, while it is called the TPP track, it would not be necessary for a supplier to establish they were actually from a TPP country);
- 'formal and duly formulated' in terms of *The Guidelines for Funding Applications to PHARMAC*;
- for a medicine (not a medical device);
- where the application is the first application to PHARMAC by that supplier (or a Predecessor Company) for that chemical or biological entity, and is NOT an application for a new indication, formulation, presentation, combination, or any other use of a chemical or biological entity that has been the subject of a previous application by that supplier (or its Predecessor Company) for reimbursement or listing on the Pharmaceutical Schedule;
- where the medicine is registered with Medsafe for all indications cited within the funding application; and
- where the application is for use of the medicine in the community (including oral cancer medicines).

8. Introduction to PHARMAC

The Pharmaceutical Management Agency (PHARMAC) is the New Zealand Crown entity that decides which pharmaceuticals and related products are subsidised for use in the community and public hospitals.

Our key obligations are set out in the New Zealand Public Health and Disability Act 2000 (NZPHD), which states that our core objective is:

To secure for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided

NZPHD section 47(a)

Our key statutory functions are, within the funding provided to us, to:

a) *Maintain and manage a pharmaceutical schedule that applies consistently throughout New Zealand, including determining eligibility and criteria for the provision of subsidies*
b) *Manage incidental matters arising out of paragraph (a), including in exceptional circumstances providing for subsidies for the supply of pharmaceuticals not on the pharmaceutical schedule*
c) *Engage as [we see] fit, but within [our] operational budget, in research to meet our objective*
d) *Promote the responsible use of pharmaceuticals*
e) *Any other functions [we are] for the time being given by or under any enactment, or authorised to perform by the Minister by written notice to the board of PHARMAC after consultation with it.*

NZPHD section 48

As a Crown entity, PHARMAC has a commitment to upholding the principles of the Treaty of Waitangi. PHARMAC's Māori Responsiveness Strategy, Te Whaioranga, provides a framework for ensuring that PHARMAC responds to the particular needs of Māori in relation to pharmaceuticals.

We carry out our responsibilities through a wide range of activities, including, among others, the clinical and pharmacoeconomic assessment of pharmaceuticals, commercial procurement strategies, negotiations with pharmaceutical suppliers, access and optimal use of medicines strategies, and contributing to advice to the Government on relevant matters.

PHARMAC does not decide which pharmaceuticals are able to be used in New Zealand. This is the role of Medsafe, the New Zealand Medicines and Medical Devices Safety Authority. It is responsible for the regulation of medicines and medical devices in New Zealand. It ensures that medicines and medical devices are acceptably safe. PHARMAC is responsible for deciding which pharmaceuticals should be subsidised by Government for use in New Zealand.

New Zealand Government

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