Appendix 1: Current Operating Policies and Procedures (OPP)

Operating policies and procedures of the Pharmaceutical Management Agency ("PHARMAC")

Third edition
(Update effective from 2 August 2016)

1. Introduction

1.1 PHARMAC's objective

PHARMAC's principal 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.

1.2 PHARMAC's role

1.2.1 PHARMAC's role is to manage the Government's expenditure on subsidies for pharmaceuticals used in the community and on the procurement of pharmaceuticals provided to patients for use while in hospital. Its role includes activities relating to the supply of pharmaceuticals (for example, negotiating with pharmaceutical companies over the subsidisation or procurement of their products) and activities influencing the demand for pharmaceuticals (for example, promoting appropriate prescribing and best practice initiatives). PHARMAC's role encompasses any activity that is within PHARMAC's statutory powers, objectives and functions. Under the Crown Entities Act 2004 PHARMAC must act consistently with its objectives in performing its functions. PHARMAC may be given additional objectives and functions under sections 47(b) or 48(e), respectively, of the New Zealand Public Health and Disability Act 2000 (**NZPHD Act**). PHARMAC's role in managing the purchasing of hospital pharmaceuticals is undertaken pursuant to a Ministerial authorisation under section 48(e) of the NZPHD Act. Clause 3.2 of these operating policies and procedures outlines certain strategies that PHARMAC may use in carrying out its core activities in relation to the subsidy and purchase of community and hospital pharmaceuticals. These operating policies and procedures mainly address matters relating to PHARMAC's role in managing expenditure on community and hospital pharmaceuticals but in doing so they are not intended to limit any other PHARMAC activities.

1.2.2 As part of its role, PHARMAC manages the Pharmaceutical Schedule (**Schedule**). The Schedule is a list of pharmaceuticals and related products (**pharmaceuticals**) that sets out the criteria for access to subsidy for community pharmaceuticals. It also lists some of the pharmaceuticals purchased by DHBs for use in their hospitals and includes hospital pharmaceuticals for which national contracts have been negotiated by PHARMAC. When PHARMAC makes amendments to the listing of pharmaceuticals in the Schedule, it uses the Factors for Consideration as set out in clause 2.2 of these operating policies and procedures.

1.2.3 As an agency of the Government, PHARMAC has obligations under public law. Public law controls the exercise of power by governmental or other public authorities that make public decisions in New Zealand. Public law is particularly concerned with ensuring that fair processes are followed in reaching decisions. PHARMAC's obligations regarding consultation are an example of the way in which public law governs PHARMAC's decision-making processes. The courts have certain powers to review PHARMAC decisions where it is alleged that PHARMAC has breached its public law obligations.

1.3 Operating policies and procedures

1.3.1 The operating policies and procedures contained in this document are intended to provide guidance on the way in which PHARMAC carries out its role. Pharmaceutical suppliers, pharmacists, medical practitioners and other interested parties should consult the Schedule for information about the pricing of pharmaceuticals and other matters relating to the prescription and supply of subsidised pharmaceuticals. Further details about PHARMAC's operations may be found on its website at www.pharmac.govt.nz.

1.3.2 The operating policies and procedures were originally published in July 1993, the second edition was published in January 2001 and the third edition in January 2006. In 2012, PHARMAC began a rolling review of the operating policies and procedures. Further information about the rolling review is on PHARMAC's website at www.pharmac.govt.nz.

1.4 The Pharmacology and Therapeutics Advisory Committee (PTAC)

PTAC and its subcommittees provide independent and objective advice to PHARMAC, including in relation to community and hospital pharmaceuticals. PTAC comprises medical practitioners with broad general experience and a particular interest in pharmaceuticals and their therapeutic indications. Further details about PTAC and its subcommittees may be found in the PTAC Guidelines, which are available on request from PHARMAC.

1.5 Other advisory committees

1.5.1 PHARMAC will maintain a Consumer Advisory Committee to provide input from a consumer or patient point of view.

1.5.2 PHARMAC may maintain a hospital pharmaceuticals advisory committee, whose role may include advising PHARMAC in relation to national procurement strategies for hospital pharmaceuticals.

1.5.3 PHARMAC's Board may establish any other advisory committees that it considers appropriate.

1.6 The Treaty of Waitangi

1.6.1 PHARMAC recognises:

(a) the Treaty of Waitangi as one of New Zealand's founding constitutional documents;

(b) the principles of the Treaty of Waitangi; and

(c) the special relationship of partnership between Maori and the Crown.

1.6.2 PHARMAC will endeavour to ensure that its policies and procedures are responsive to the particular characteristics, special needs and cultural values of Maori communities.

1.6.3 To avoid any doubt, nothing in this clause 1.6:

(a) entitles a person to preferential access to services on the basis of race; or

(b) limits section 73 of the Human Rights Act 1993 (which relates to measures to ensure equality).

2. The Pharmaceutical Schedule

2.1 Amendments to the Pharmaceutical Schedule

PTAC, pharmaceutical suppliers, DHBs and other interested parties may approach PHARMAC to suggest possible amendments to the Schedule. 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 listed pharmaceuticals;

(c) 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;

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

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

(f) changing packaging sizes and brand names;

(g) 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.

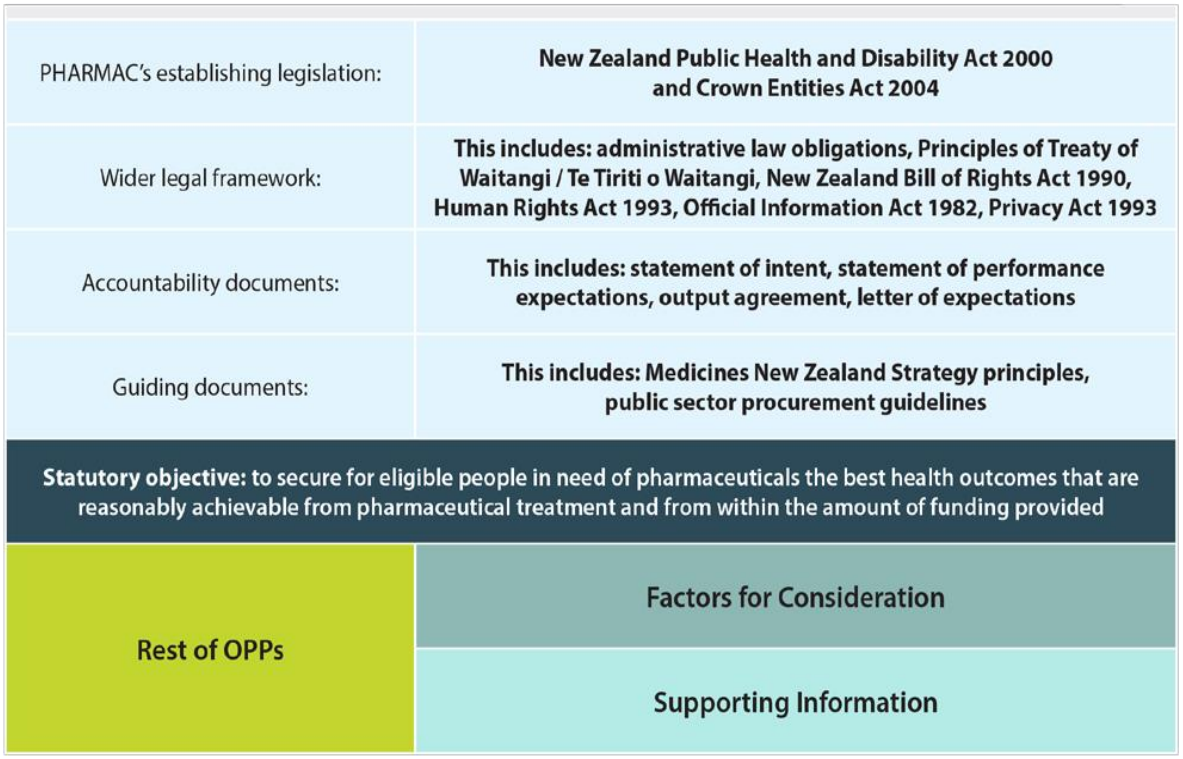
2.2 Factors for Consideration

PHARMAC uses the factors for consideration, set out in this clause, to inform decisions about changes to the Schedule and decisions relating to treatments for named patients. These factors help PHARMAC determine whether any decision or proposal helps PHARMAC achieve its statutory objective.

Where PHARMAC makes decisions that do not involve changes to the Schedule (for example, about promoting the responsible use of medicines), it endeavours to use these factors, to the extent that they are relevant to those decisions. If PHARMAC takes into account a factor in addition to the “factors for consideration” listed below when making a decision, it will consult on the use of that additional factor where it is appropriate to do so.

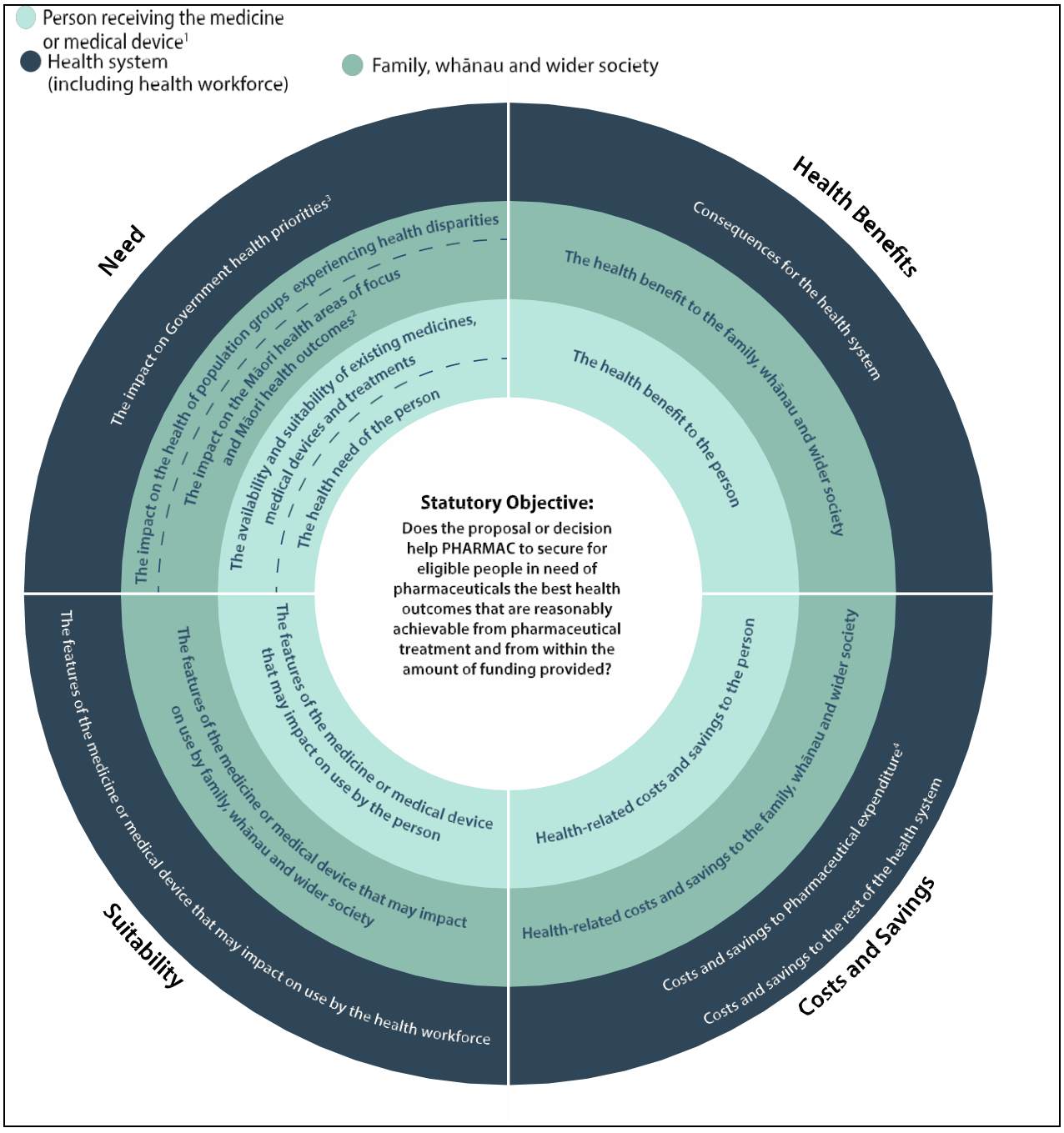
The factors for consideration should be considered within the context of the broader legal framework within which PHARMAC operates, as set out below:

PHARMAC's legal framework and guiding documents



Factors for Consideration

The extent to which any one particular factor is relevant, if at all, and the influence of each factor is for PHARMAC to determine on each occasion within the context of its legal obligations. PHARMAC considers the relevant factors when making a funding decision to determine if, at that given point in time and relative to other funding decisions being considered, the decision would help PHARMAC to meet its statutory objective.



[1] The person receiving the medicine or medical device must be an eligible person, as set out in *Health and Disability Services Eligibility Direction 2011* under Section 32 of the *New Zealand Public Health and Disability Act 2000*.
[2] The current Maori health areas of focus are set out in PHARMAC's Te Whaioranga Strategy.
[3] Government health priorities are currently communicated by the letter of expectations.
[4] Pharmaceutical expenditure includes the impact of the Combined Pharmaceutical Budget (CPB) and / or DHB hospital budgets (as appropriate).

The factors for consideration are supplemented by a 'supporting information' document that provides more information about how PHARMAC interprets the factors and what they include. It is a 'living document' that will be updated as required over time, in light of changes such as PHARMAC's increasing role in relation to medical devices. This supporting document does not form part of the OPP and is provided for explanatory purposes only.

Named Patient Pharmaceutical Assessment (NPPA) decisions for individual named patients and Pharmaceutical Tender decisions also have supplementary considerations that provide an additional level of specificity:

- NPPA applications: Prior to the above factors being taken into consideration, NPPA funding applications must meet specified prerequisites as outlined in the NPPA policy.

- Tender decisions: Specific matters taken into account are annually consulted on and published in the 'Matters for evaluation' section of the annual Invitation to Tender document.

Individual requests for proposals (RFPs) may also have additional prerequisites or evaluation considerations, which would be notified and published by PHARMAC accordingly.

3. PHARMAC strategies

3.1 General

PHARMAC may adopt a range of strategies in order to achieve the core objective described in clause 1.1 or in pursuit of any other objective or its functions. These strategies are generally used to assist PHARMAC in determining the price or subsidy at which pharmaceuticals are to be listed on the Schedule. PHARMAC is not bound to pursue any particular strategy. PHARMAC may also modify or depart from a strategy previously adopted, including not applying the strategy the same way in all situations, or may adopt new strategies, provided that PHARMAC complies with its public law obligations, including consultation, and that any new decision is made in accordance with PHARMAC's statutory objectives, functions and powers, including any additional objectives and functions that may be given to PHARMAC under the NZPHD Act.

3.2 PHARMAC's strategies

3.2.1 Subject to clauses 3.1 and 3.2.3, strategies that PHARMAC may adopt in relation to the subsidisation of community pharmaceuticals include (but are not limited to):

(a) reference pricing (as defined in clause 3.3);

(b) entering into contracts with pharmaceutical suppliers which detail the terms of listing of a pharmaceutical on the Schedule (**listing contracts**);

(c) entering into arrangements which involve the sharing of financial or other risks between PHARMAC and a pharmaceutical supplier, including (but not limited to) rebate arrangements for a particular pharmaceutical or market;

(d) cross deal or bundling arrangements whereby a composite decision may be made entailing amendments to the Schedule in respect of more than one pharmaceutical (whether or not those pharmaceuticals are in related therapeutic groups or sub-groups);

(e) tendering, or issuing requests for proposals (**RFPs**), or entering into arrangements for the supply of one or more subsidised brands of a chemical entity or one or more members of a sub-group, which may entail the delisting of other brands of a chemical entity or other members of a sub-group;

(f) tendering, or issuing RFPs, or entering into arrangements whereby pharmacists may be obliged to dispense a particular brand of a pharmaceutical;

(g) issuing RFPs in relation to other subsidy arrangements for particular pharmaceuticals or therapeutic groups or sub-groups;

(h) two-part pricing arrangements whereby PHARMAC may make an up-front payment (in addition to any ongoing subsidy) in return for the listing of a pharmaceutical on specific terms;

(i) parity pricing, whereby PHARMAC may reduce the subsidy payable for a pharmaceutical in a particular therapeutic sub-group to the level of the subsidy payable for a pharmaceutical in any other sub-group; or

(j) making subsidies available for pharmaceuticals to particular patient groups.

3.2.2 Subject to clauses 3.1 and 3.2.3, strategies that PHARMAC may adopt in relation to the management of hospital pharmaceuticals include (but are not limited to):

(a) strategies outlined in clause 3.2.1; and

(b) any other strategy developed and notified by PHARMAC.

3.2.3 PHARMAC may enter into an express contractual agreement with a supplier not to apply one or any of the strategies set out in clauses 3.2.1 and 3.2.2 to a particular pharmaceutical supplied by that supplier.

3.2.4 Other strategies that PHARMAC may adopt include (but are not limited to):

(a) contracting and other arrangements that encourage cost-effective prescribing or otherwise relate to PHARMAC's demand side activities;

(b) promotions or communications regarding the prescription of particular pharmaceuticals or groups of pharmaceuticals, or prescribing in general;

(c) taking an active role in other issues (such as the extension of patent terms, the monitoring of pharmaceutical advertising and the distribution of pharmaceuticals) that may affect the demand for, supply of, or access to pharmaceuticals; or

(d) evaluating the outcomes, and processes used by PHARMAC, in relation to any amendment to the Schedule.

3.3 Definitions of reference pricing and therapeutic groupings

3.3.1 Subject to clause 3.1, reference pricing means that all pharmaceuticals in any given therapeutic sub-group to which PHARMAC decides to apply reference pricing are subsidised at the level of the lowest priced pharmaceutical in that sub-group. Reference pricing is based on the classification of pharmaceuticals into different therapeutic groups and further into sub-groups.

3.3.2 A **therapeutic group** is defined as a set of pharmaceuticals that are used to treat the same or similar condition(s). A **therapeutic sub-group** is defined as a set of pharmaceuticals that produce the same or similar therapeutic effect in treating the same or similar condition(s).

3.3.3 PHARMAC will carry out appropriate consultation on the classification of pharmaceuticals into therapeutic sub-groups and its application of reference pricing in respect of a particular sub-group.

3.3.4 PHARMAC is not bound to apply reference pricing in every situation, or in the same way in every situation, where pharmaceuticals have been classified into a therapeutic sub-group. PHARMAC may also provide exemptions from reference pricing to certain pharmaceuticals, or groups of pharmaceuticals or to groups of patients, provided that PHARMAC consults on any proposed exemption before making its decision.

3.3.5 PHARMAC may, on the advice of PTAC, change the status of a pharmaceutical within a particular therapeutic sub-group, or revise the composition of a therapeutic sub-group, in light of new knowledge about that pharmaceutical or the pharmaceuticals within that sub-group.

3.3.6 In the event that PHARMAC decides to apply reference pricing to any particular hospital pharmaceuticals it would envisage (subject to consultation if any alternative is proposed) using existing definitions of these terms and existing classifications used for community pharmaceuticals.

3.4 Contracting and tenders

3.4.1 The majority of the pharmaceuticals in the Schedule are listed pursuant to a listing contract between the supplier and PHARMAC. PHARMAC has standard terms of listing for both community and hospital pharmaceuticals, which are updated periodically and are available on request from PHARMAC. Listing contracts may also include special terms relating to particular pharmaceuticals, including (but not limited to) rebates and risk sharing arrangements, restrictions on access, and protection against delisting or price reduction. The special terms of any given contract will depend on the commercial arrangement negotiated between the supplier and PHARMAC.

3.4.2 Pharmaceuticals may also be listed subject to the contractual terms of PHARMAC's annual tender. The tender includes listing terms similar to the terms in PHARMAC's standard community and hospital listing contracts. However, PHARMAC's tenders also include special terms which reflect the fact that the successful tenderer's brand of a particular pharmaceutical has sole or other special supply status in the community or hospital market for a period of time. PHARMAC consults on the annual tender before it is issued.

4. PROCEDURE

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.

4.1.2 The procedure to be followed in respect of 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);

(c) the type of pharmaceutical being listed (e.g., a new pharmaceutical or a generic pharmaceutical);

(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.

The procedure followed in any particular case will be guided by the principles set out in this section. PHARMAC may adopt procedures that are different from those followed in previous and/or similar cases. The attached flow-diagram provides a simplified, indicative guide to the process that PHARMAC will usually follow when listing a community pharmaceutical on the Schedule.

4.1.3 PHARMAC may require a party initiating an amendment to the Schedule to provide 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.

4.2 Consultation

4.2.1 Submissions received during consultation assist with PHARMAC's decision-making. PHARMAC will consult when it considers appropriate with any sections of the public, groups, or individuals that, in the view of PHARMAC, may be affected by its proposals (which may, according to the circumstances, include suppliers, PTAC and other advisory committees, health professionals, community or patient groups, Maori, Pacific peoples and other groups):

(a) to amend and update the operating policies and procedures pursuant to clause 1.3.2

(b) to amend the Schedule in a manner described in clause 2.1;

(c) to adopt new Factors for Consideration;

(d) to adopt a new strategy pursuant to clause 3.1; or

(e) that otherwise relate to the management of pharmaceutical expenditure.

4.2.2 Where PHARMAC consults with relevant third parties about any of the matters set out in clause 4.2.1 or about any other matters, it will take such steps as it considers appropriate to:

(a) provide sufficient information to enable the consulted parties to make a reasonably informed submission on the matter; and

(b) give the consulted parties a reasonable opportunity to make a submission, including allowing them adequate time to respond.

4.2.3 PHARMAC will consider the submissions provided by consulted parties with an open mind.

4.2.4 PHARMAC will, when it considers it appropriate to do so, take measures to inform the public, groups and individuals of PHARMAC's decisions concerning the Schedule.

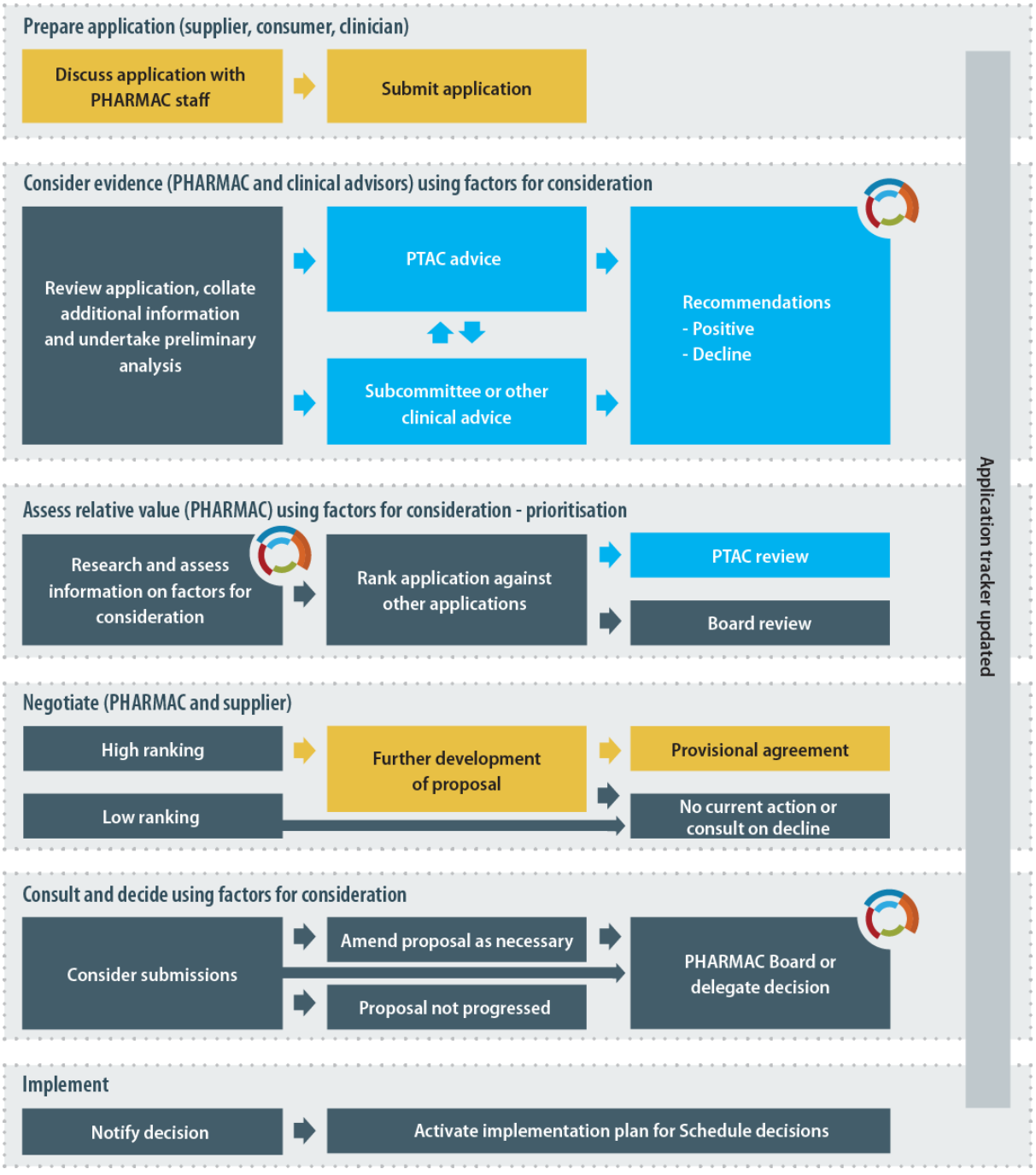
4.3 Confidential information

PHARMAC recognises that certain information held by it may be regarded as confidential and commercially sensitive. PHARMAC respects the confidentiality and commercial sensitivity of this information, but must balance this against the need to provide information during its consultation processes. In addition, PHARMAC is subject to the Official Information Act. PHARMAC will at all times act in good faith where it considers it necessary or appropriate to release information, including in any consultation with affected parties.

4.4 Prioritisation process

PHARMAC uses a prioritisation process. The description of that process forms part of this OPP.

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.