Amendments to PHARMAC's Operating Policies and Procedures document section 2.3 that come into effect when the Trans-Pacific Partnership comes into force for New Zealand.

To replace in full

Section 2.3 Procedure for considering an application for funding

All applicants are encouraged to contact PHARMAC prior to making an application for funding for a chemical or biological entity to discuss that application.

a) 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):
   i. the nature of the amendment (e.g., new listing, delisting, classification);
   ii. who has initiated the amendment (e.g., PHARMAC, supplier, interested parties) and whether it is the first time they have made this application;
   iii. the type of pharmaceutical being listed (e.g., a new medicine or a generic medicine, a medical device, related product, or related thing);
   iv. whether the amendment would result from an RFP, tender, listing contract or some other arrangement;
   v. whether the amendment is a result of PHARMAC adopting a new strategy; or
   vi. any current funding arrangements in place for the same or competitor product.

b) PHARMAC may require a party initiating an amendment to the Schedule to provide in their application relevant information, including (but not limited to):
   i. pharmacological information (forms, strength, indications, dosages, contra-indications etc);
   ii. therapeutic information (main therapeutic claims, advantages/ disadvantages when compared with other pharmaceuticals etc);
   iii. price information (proposed price, price overseas, other pricing proposals);
   iv. epidemiological information (number of people with the particular condition, number likely to be prescribed the pharmaceutical etc);
   v. market information (expected sales etc);
   vi. 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
   vii. 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.

c) 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):

   i. providing non-biased information;

   ii. setting out the basis for any estimates or assumptions made;

   iii. providing a synopsis on all material issues; and

   iv. providing comprehensive and detailed cost/benefit information.

d) All 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.

e) PHARMAC will operate a TPP track for applications that meet the eligibility criteria in 2.3.f and an Open track for all other applications for amendments to the Pharmaceutical Schedule.

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

   i. 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);

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

   iii. for a medicine as defined in the Medicines Act as at 4 February 2016 (not a medical device, related product, or related thing);

   iv. the first application to PHARMAC by that supplier (or a Predecessor Company) for that chemical or biological entity, and is NOT an application for an additional indication, or for a 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;

   v. for a medicine registered with Medsafe for all indications cited within the funding application; and

   vi. for an application seeking reimbursement for use of the medicine in the community (including oral cancer medicines).

g) The following applies to applications on the TPP track:

   i. The supplier may make amendments to its application within 20 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 2.3.g)ii as a consequence of the processing required.

   ii. A final decision will be made by PHARMAC within 30 months of an application meeting the requirements set out in 2.3.g)i 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.

   iii. 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 must be requested within 20 working days following notification of a decision not to list. The TPP Review is to be conducted by PHARMAC in accordance with the process determined by PHARMAC for this purpose.

   iv. No additional application will be accepted from a supplier for the same or a related indication for a medicine undergoing review until the TPP Review is completed. For the avoidance of doubt, a supplier can make an Open track application for an unrelated indication while a TPP Review is underway.

   v. 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.

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

   i. 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.

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

j) The diagram below 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.