Application for changes to the Pharmaceutical Schedule

A form for clinicians, clinical groups and consumer groups to make a funding application to PHARMAC

Foreword

PHARMAC is the government agency that decides, on the behalf of District Health Boards, which pharmaceuticals should be publicly funded in New Zealand.

- Information on the process PHARMAC uses to make its funding decisions and
- how we determine if a proposal to fund a treatment would help us achieve our Statutory objective

PHARMAC's 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".

Each year, PHARMAC receives a large number of applications that contain proposals either to fund new pharmaceuticals or to widen access to pharmaceuticals that we already fund. As PHARMAC must work within a fixed budget, we need to make difficult choices about which applications we should progress to a funding decision at any given time. This involves assessing large amounts of often complex information, to identify those proposals that would provide the best health outcomes.

We have written this funding application form for people, clinicians, clinical groups and consumer groups to use. We recognise that some individuals and groups won't have the same resource as pharmaceutical suppliers to prepare applications. This form is to help you provide the right information in order to progress an application with us.

This form is a guide – you don't have to follow it in detail, or at all, but it will make processing your application much easier and may reduce the time involved. If you don't know some information, please feel free to leave those sections blank; however the form does outline the general information that we need to assess a funding application. Having your application address these points may reduce follow-up questions to you, and could speed up how quickly we consider it.

The *Guidelines for Funding Applications to PHARMAC*, updated in 2019, set out the full information that we need to progress any funding application. We expect pharmaceutical suppliers to follow the full *Guidelines for Funding Applications to PHARMAC* when submitting a funding application. However, as an applicant, please feel free to view them should you wish to have more detailed information on submitting an application.

Send your applications to us at:

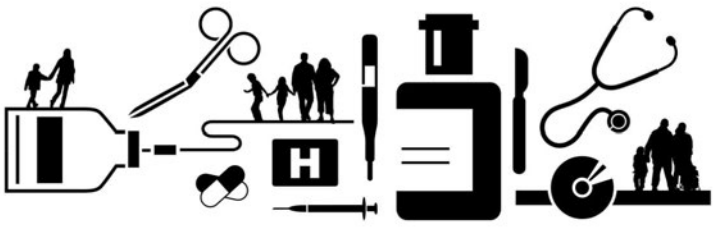
Email: **applications@pharmac.govt.nz**

Post: **PO Box 10254**
The Terrace
Wellington 6143

You may also find it beneficial to talk to the relevant Therapeutic Group Manager at PHARMAC before you make a formal funding application. Please email us as above, and we will contact you.

We will keep you informed of progress. We publish and regularly update a record of all current funding applications via the Application Tracker on our website (**www.pharmac.govt.nz**), which details the current status of applications and any relevant advice that we have obtained on your application.

Please read the notes that can be found at the end of this document before completing your application form. They will help guide you to provide the correct information and provide additional help to complete the form.



PHARMAC
Pharmaceutical Management Agency

New Zealand Government

Application

Product details

1. Please select the type of application you would like to make.

- ☐ New chemical or biological entity
- ☐ New medical device for use in the community
- ☒ New indication for a pharmaceutical already listed in the Pharmaceutical Schedule
- ☐ New formulation or strength of a pharmaceutical listed on the Pharmaceutical Schedule
- ☐ Treatment for a rare disorder
- ☐ Generic or biosimilar pharmaceutical
- ☐ Other

2. If other, please specify.

Click here to enter text.

Pharmacological information

3. What is the registered name of the generic pharmaceutical?

Ferric carboxymaltose

4. What is the brand name of the pharmaceutical?

Ferinject

5. Which therapeutic area does this pharmaceutical fall into?

Alimentary – haematology subcommittee

6. Please provide information on the various forms, strengths, and pack sizes of the pharmaceutical that you are seeking funding for.

500 mg/10 mL

7. Which companies produce and/or supply the pharmaceutical?

Vifor Pharma Pty Ltd

Proposed amendments to the Pharmaceutical Schedule

8. Please provide details on the indications for which funding is sought.

Patients in the community with serum ferritin between 20mcg/L and 50mcg/L where CRP is >5 without having to seek specialist approval

9. Will the pharmaceutical be used in the community, in hospital, or in both the community and hospital?

Community

10. In which wards, departments or settings is the pharmaceutical l kely to be used?

Primary care setting, e.g.; general practice

Dose

11. Please provide details on the course of treatment that would be likely used in New Zealand clinical practice for each indication for which funding is requested. This should include both the dose and the duration of treatment.

2 x 500mg (local recommended dose in Canterbury)

Regulatory status of the product

12. Has the pharmaceutical been registered with Medsafe for all indications for which funding is sought?

- ☒ Yes, the pharmaceutical is registered for all indications that funding is sought
- ☐ No, but registration has been lodged with Medsafe for the requested indication
- ☐ No, registration has not been lodged with Medsafe for the requested indication
- ☐ No, but the pharmaceutical is Medsafe registered for an alternative indication
- ☐ Unknown

The disease and its impacts

13. Please provide an overview of the disease that would be treated by the proposed pharmaceutical.

Iron deficiency anaemia in patients with an inflammatory response, i.e.; ferritin appears 'normal' as it is an acute phase protein but patient is iron deficient. Currently GPs need to obtain specialist approval before administering funded ferric carboxymaltose to these patients. This creates confusion for GP teams and delays for patients.

14. Does the disease impact on the health of the patient's family, whānau or wider society? Please explain and provide sources of information.

The need to obtain specialist approval creates confusion and means some vulnerable patients may either have treated delayed or miss out on care.

15. What is the impact of the disease on Māori health outcomes? Please explain and provide sources of information.

16. Does the disease fall into one of the categories of PHARMAC's Māori health areas of focus?

- ☐ Mental Health
- ☐ Diabetes
- ☐ Heart Health – High blood pressure and stroke
- ☐ Respiratory health
- ☐ Cancer – Lung and breast

17. Does the disease disproportionately affect population groups that may already be experiencing a health disparity?

Yes – these are patients with iron deficiency anaemia and raised CRP from inflammation of chronic disease, i.e.; have comorbidities.

Patient population

18. Who is the target population?

Patients with iron deficiency anaemia and inflammation of chronic disease.

Current treatment options

19. What treatments are currently used in New Zealand to treat the disease? Please describe the current treatment algorithm for the target population and if possible, include a flowchart illustrating the current management of the disease in the target New Zealand population.

Current treatment options

Ferric carboxymaltose is the accepted and recommended treatment for these patients: the issue is the need to obtain specialist approval.

20. Please provide commentary around how well the current treatments work for the disease being treated. In your response, please also provide details of any risks or any tolerability issues associated with the current treatment options.

As above, this is the current treatment. The issue is the need for GPs to obtain specialist approval.

21. Are there any issues regarding the availability or suitability of current treatments for this indication?

No

22. How would the proposed treatment change the current treatment algorithm? Please include a flowchart illustrating the expected changes in clinical management.

It would eliminate the need for general practitioners to phone/write to a hospital specialist for approval: no other changes.

Identification and Selection of Studies

23. Please provide a citation list of the relevant evidence that you have found that details the use of the proposed pharmaceutical in the target population. In addition, please indicate whether these articles have been provided with your application.

As above, only change is that GP wouldn't need to contact specialist first.

Trial Results

24. Are there any factors that may influence the applicability of clinical study results to patients in routine clinical practice in New Zealand? Would the same clinical benefits and adverse effects be expected?

N/a

25. Does the pharmaceutical have similar, greater, or fewer side effects and/or toxicity when compared to current treatment options? Please provide details.

N/a – this is the current treatment option.

Interpretation of the Evidence

26. Please provide a general interpretation of the evidence base, considering the clinically significant health benefits and potential health losses to the patient that could be gained from the pharmaceutical, relative to those of the comparator.

N/a – already funded.

27. Please provide a general interpretation of the evidence base, considering the clinically significant health benefits and potential health losses that could be gained from the pharmaceutical, to the family and whānau of the person receiving the treatment, and to wider society.

N/a – already funded.

28. If the proposed pharmaceutical was funded, what would the consequences to the health system be?

Make life easier for general practice teams and improve ease of access for patients.

Health Related Costs and Savings

29. Please detail whether there are there any additional health-related costs or savings to the person receiving treatment that are likely to be incurred if the pharmaceutical is funded.

No – cost of administering IV ferric carboxymaltose remains the same. Some DHBs (e.g.; Canterbury) have funding in place to reduce or avoid the cost of this to the patient already.

Health Related Costs and Savings

30. Please detail whether there are any health-related costs or savings that may be experienced by the family, whānau and wider society of the person receiving the treatment, if the pharmaceutical is funded.

No

31. Please detail whether there are there any additional costs or savings to the health sector that are likely to be incurred if the pharmaceutical is funded.

Save GP teams having to make phone calls/write letters. Free up specialist time to spend on other things.

Features of the pharmaceutical that impact its use

32. Are there any features of the pharmaceutical that may impact use by the person receiving the treatment? If so, please explain.

No.

33. Are there any features of the pharmaceutical that may have an impact on its use by the family or whānau of the person receiving the pharmaceutical, or on wider society?

No.

34. Are there any features of the pharmaceutical that may have an impact on its use by the health workforce?

No.

35. Are there any other issues or benefits that may arise as a result of the features of the pharmaceutical that have not been covered elsewhere in this section?

No,.

Additional Information

36. Please provide any additional information that is relevant to your application.

The current indication of ferritin below 20 is fine for most patients. However, the issue is for unwell patients with inflammatory stuff going on (i.e.; with a raised CRP), where the ferritin can appear 'normal' but they do in fact still have iron deficiency (As CHP > Iron Deficiency Anaemia put its, 'Conflicting results may occur when iron deficiency is associated with an inflammatory response and ferritin may be normal'.) Currently, for these patients GPs need to phone a specialist (physician, O&G, anaesthetist) to authorise the SA. We have feedback from GPs that this is confusing and time-consuming. One feedback that came through was '95 yr old man with severe IDA - Hb78, MCV22 but ferritin 33 …. How do I prescribe this....how do I endorse the Rx as no SA number to quote? The chemist will not provide the the Rx if they cannot be reimbursed somehow. Urgent response please... otherwise he will end up admitted'. In that instance, we just advised him to get specialist approval, but ideally GPs wouldn't have to do this. Hence our request to add some criteria along the lines of 'patients where ferritin is between 20 and 50 microgram/L if the CRP is greater than 5 mg/L".

Declaration

37. Do you agree with the following statement? "I declare that all known published and unpublished clinical trials relevant to this Application have been disclosed in the Application."

Yes

38. Do you have any potential conflicts of interest relevant to this Application? If so, please provide a description of the potential conflict you may have.

No

39. I agree that the product details information provided in the on-line form can be made publicly available on the Application Tracker.

Yes

40. I confirm the information provided in this Application is correct.

Yes

41. Do you have any comments regarding any of the above declarations?

No

Identification

42. Name of person submitting application.

s 9(2)(a)

43. Date of application

28 July 2020

44. Who is the primary contact for this application?

s 9(2)(a)

45. What is the primary contact's email address?

s 9(2)(a) @cdhb.health.nz

46. What is the primary contact's phone number?

s 9(2)(a)

Use these notes to help you complete the application form

Please read the following notes before you complete your application form. They provide additional information to support you in completing an application form to PHARMAC.

Please note:

- Evidence to support your responses should be referenced in the relevant sections of the application form. We need you to supply copies of referenced articles wherever possible. Please clearly say which (if any) cited publications you cannot provide.
- We prefer funding applications related to medicines that have been registered by Medsafe. While we can consider funding applications for unregistered medicines or unregistered indications, this is determined on a case–by-case basis.
- It is possible to provide pictures, diagrams and graphs. Please copy and paste these at the relevant point in your application.
- We may decide to defer our assessment of your application until we receive a full funding application from the supplier, which they would need to prepare in accordance with the full *Guidelines*. We will let you know if this is the case.

Additional guidance on the questions in the application form

Section		Questions	Guidance
Pharmacological information	1	What is the registered name of the generic pharmaceutical?	Please provide the approved name of the generic medicine or biological entity as specified in the Medsafe datasheet. It is the active ingredient that is contained within the pharmaceutical and is different to the brand name. If the pharmaceutical is not yet registered in New Zealand, please enter the generic name of the pharmaceutical as registered overseas.
	2	What is the brand name of the pharmaceutical?	If known, please state the official brand name(s) of the pharmaceutical as specified in the Medsafe datasheet. If the pharmaceutical is not registered in New Zealand or if you are unsure of the brand name(s), please leave this answer blank.
	3	Which therapeutic area does this pharmaceutical fall into?	Please provide the therapeutic area which the medicine or medical device falls into.

Section		Questions	Guidance
	4	Please provide information on the various forms, strengths, and pack sizes of the pharmaceutical that you are seeking funding for.	Please provide the following information on the pharmaceutical that you wish to be considered for funding; the forms, the strength and the pack size.
	5	Which companies produce and/or supply the pharmaceutical?	If known, please list the organisations that produce or supply the product.
Proposed amendments to the Pharmaceutical Schedule	6	Please provide details on the indications for which funding is sought.	In order to ensure that that we achieve best health outcomes from within the budget allocated, PHARMAC sometimes targets and restricts the funded use of pharmaceuticals to specific indications or diseases. Please provide details of clinical indications you would like the pharmaceutical to be funded for.
	7	Will the pharmaceutical be used in the community, in hospital, or in both the community and hospital?	Please provide details of the setting that the pharmaceutical will be used in, either hospital, community, or both. The Pharmaceutical Schedule is structured so that Community Pharmaceuticals are those pharmaceuticals listed in Sections A to G and Section I of the Pharmaceutical Schedule (https://www.pharmac.govt.nz/tools-resources/pharmaceutical-schedule/). This includes cancer medicines, some blood products and vaccines which may be used in District Health Board (DHB) hospitals. Hospital pharmaceuticals are those pharmaceuticals listed in Section H of the Pharmaceutical Schedule and are available to be provided or dispensed in DHB hospitals. Information on the likely setting that the pharmaceutical will be used in will help determine where in the Pharmaceutical Schedule any listing could occur.
	8	In which wards, departments or settings is the pharmaceutical likely to be used?	Please provide details of the clinical setting that the pharmaceutical will be used in. Information on the likely clinical setting that the pharmaceutical will be used in will help determine where in the Pharmaceutical Schedule any listing could occur and what clinical advice may be required to assess the application.

Section		Questions	Guidance
Dose	9	Please provide details on the course of treatment that would be likely used in New Zealand clinical practice for each indication for which funding is requested. This should include both the dose and the duration of treatment.	Please provide information on the dose for each indication that the medicine is likely to be used to treat. The information provided should be based on the most likely dose regimen used in New Zealand clinical practice. In the case of a pharmaceutical that is not used for chronic therapy, please also provide information on the average length of a treatment course and anticipated frequency of repeat courses of treatment.
Regulatory status of the product	10	Has the pharmaceutical been registered with Medsafe for all indications for which funding is sought?	Applications should be for Medsafe-registered products and indications. If the pharmaceutical is not registered for all indications, please contact PHARMAC to discuss before submitting your application.
The disease and its impacts	11	Please provide an overview of the disease that would be treated by the proposed pharmaceutical.	Please provide an overview of the disease for which funded treatment is sought. Details that you may wish to provide in this overview might include risk factors for developing that disease, diagnosis, symptoms, and prognosis of disease. If you are requesting that the use of the proposed pharmaceutical is restricted to specific subgroup(s) of the New Zealand population with a disease, please indicate whether the usual course of the disease differs for that subpopulation when compared to others with the disease. Please do not describe the impact that the proposed pharmaceutical has, but rather limit to information on the disease or condition and its impact on the patient.

Section		Questions	Guidance
			Please reference all the sources of information that you used to inform your overview.
	13	What is the impact of the disease on Māori health outcomes? Please explain and provide sources of information.	PHARMAC considers how decisions may impact on the health outcomes of Māori in accordance with commitment to te Tiriti o Waitangi (the Treaty of Waitangi). Please describe whether: • the condition disproportionately affects Māori • there are any differences in progression of disease for Māori • there are delayed treatment issues • there are disparities in access to treatment • or whether the condition affects Māori significantly more than it does other New Zealanders. Where feasible, please quantify the disease or disability incidence, prevalence and mortality rates for Māori compared with other New Zealanders. Sources of data may include: • Te Whaioranga • Tatau Kahukura: Māori Health Chart Book • Unequal Impact II (studies on cancer statistics) • Māori Health Review • NZ Burden of Disease, Injuries and Risk Factors Study 2006-2016 • Annual Update of Key Results: New Zealand Health Survey Please reference all sources of information used in your response.

Section		Questions	Guidance
			Please limit your response to the health need of Māori in relation to the disease in question, and not to how the proposed treatment would affect this health need.
	14	Does the disease fall into one of the categories of PHARMAC's Māori health areas of focus?	Please identify whether the disease for which funding has been sought has been identified as one of PHARMAC's current Māori health areas of focus. The Māori health areas of focus and further information can be found in Te Whaioranga - the PHARMAC Māori Responsiveness Strategy.
	15	Does the disease disproportionately affect population groups that may already be experiencing a health disparity?	As part of its Factors for Consideration, PHARMAC considers the impact that a decision could make on population groups that are already experiencing a health disparity. Please provide details on whether the disease disproportionately affects population groups that may already be experiencing a health disparity. Please include a description of the impact of the disease on the identified population. PHARMAC defines health disparities as 'avoidable, unnecessary and unjust differences in the health of groups of people'. Population groups experiencing health disparities will have one or more shared characteristics that mean they experience poorer health outcomes as a result of broader systemic social determinants of health. This disadvantage may mean that the population group may be more susceptible to a given illness, or may experience poorer health outcomes, than the average person with the illness. Population groups that have previously been identified that may have a health disparity include, Pacific peoples, refugees, people living in areas of New Zealand that have been identified to have New Zealand deprivation index scores of levels 9-10; and sub-regionally deprived populations (geographical areas in New Zealand where residents face significantly greater health disparities than other geographical areas). Sources of data may include:

Section		Questions	Guidance
			• Tupu Ola Moui: Pacific Health Chart Book 2012 • Annual Update of Key Results: New Zealand Health Survey Please reference all sources of information used in your response.
Patient population	16	Who is the target population?	Please describe the New Zealand population that would be treated with the proposed pharmaceutical. Details you may wish to provide include age of disease onset, age of diagnosis, ethnicity, prevalence or incidence in other populations experiencing disparities, important comorbidities, and life-expectancy. Please reference all the sources of information you used to answer this question.
Current treatment options	17	What treatments are currently used in New Zealand to treat the disease? Please describe the current treatment algorithm for the target population and if possible, include a flowchart illustrating the current management of the disease in the target New Zealand population.	Please provide details of the comparator treatments available in New Zealand. These are the likely treatments a person with the disease would currently receive in New Zealand. If the pharmaceutical can be used for several diseases and there are different treatments, please provide the likely treatment algorithm for each disease. If there is currently no treatment available, or if palliative care would be the recommended approach, please indicate this in your response. If possible, include a flowchart illustrating the current management of the disease in the target New Zealand population.

Section		Questions	Guidance
	18	Please provide commentary around how well the current treatments work for the disease being treated. In your response, please also provide details of any risks or any tolerability issues associated with the current treatment options.	Please provide commentary on the clinical features of existing treatments - this commentary may include details on effectiveness, tolerability, adverse events etc. In this section please limit your answer to discussing the clinical features of current treatment options only. Please do not discuss any characteristics of your proposed pharmaceutical or any non-clinical or suitability features (size, shape, taste etc) of the existing treatment options.
	19	Are there any issues regarding the availability or suitability of current treatments for the indication?	Please detail any existing non-clinical issues there are with current treatment options. These issues may include issues with availability, taste, size, the practicality and appropriateness for the target population (for example, the suitability of current treatment in groups such as children). Please provide details on the availability of current treatment. This may include details on whether the current treatment is listed on the Pharmaceutical Schedule for the relevant indication or used as part of standard practice within DHB hospitals. For further information on the availability and suitability of current treatment, please refer to the Factors for Consideration.
	20	How would the proposed treatment change the current treatment algorithm? Please include a flowchart illustrating the expected changes in clinical management	Please provide a diagram that demonstrates how the proposed pharmaceutical would impact the treatment of the relevant indications. Summarise the differences between the current and proposed clinical management, as depicted in the algorithms.

Section		Questions	Guidance
Identification and Selection of Studies	21	Please provide a citation list of the relevant evidence that you have found that details the use of the proposed pharmaceutical in the target population. In addition, please indicate whether these articles have been provided with your application.	All evidence cited should be referenced appropriately, and should be numbered in the order in which they first appear in the text. All references should be listed within the requested citation list in the Vancouver style. Where a question requests that all sources of information are included, it is sufficient to include a reference to the source rather than attach each article. However, if you consider that the article is key to the assessment of the proposal, please include it within the attachments.
Trial Results	22	Are there any factors that may influence the applicability of clinical study results to patients in routine clinical practice in New Zealand? Would the same clinical benefits and adverse effects be expected?	When assessing an application, PHARMAC needs to understand whether there are any factors that may affect whether the same results we see in the evidence will occur in clinical practice. For example, if the proposed pharmaceutical is taken with an adjuvant therapy that is not available in New Zealand, this should be highlighted and the potential effect of this should be discussed. Describe any factors that may influence the applicability of clinical study results to patients in routine clinical practice in New Zealand. Consider the geographical and clinical setting of the studies and how these and other factors could affect the reproducibility of finding when the pharmaceutical is used in routine clinical practice. Factors that may differ between the trial and what would be expected were the proposed pharmaceutical funded according to the requested restriction include. • Patient populations (e.g. age, ethnicity, performance status, previous treatments); • Disease (e.g. disease severity); • Clinical management (e.g. dose schedule of comparator, permitted/disallowed concomitant drugs, monitoring or assessment frequency).

Section		Questions	Guidance
			Describe the relevance of the outcomes assessed in clinical studies to clinical benefits and adverse effects expected in New Zealand health sector and pharmaceutical funding environment. Please reference all sources of information.
	23	Does the pharmaceutical have similar, greater, or fewer side effects and/or toxicity when compared to current treatment options? Please provide details.	
Interpretation of the Evidence	24	Please provide a general interpretation of the evidence base, considering the clinically significant health benefits and potential health losses to the patient that could be gained from the pharmaceutical, relative to those of the comparator.	PHARMAC makes decisions based on the available evidence. When considering whether to fund a proposed pharmaceutical, we need evidence to demonstrate how funding it would allow us to get the best health outcomes. Please provide a general interpretation of the evidence base, considering the clinically significant health benefits to the patient of the pharmaceutical, relative to those of the comparator(s). This may include both improvements in extension of life and health-related quality of life. As well as health benefits, also consider any potential health losses because of the funding decision. This includes harm done by adverse effects as well as no longer providing a gain that current treatment delivered.
	25	Please provide a general interpretation of the evidence base, considering the clinically significant	Some diseases and conditions may affect people other than the person who has the condition. For example, during pregnancy, a disease may affect the unborn child as well as the mother or a communicable disease may

Section		Questions	Guidance
		health benefits and potential health losses that could be gained from the pharmaceutical, to the family and whānau of the person receiving the treatment, and to wider society.	have an impact on wider society. Please provide details on whether the proposed pharmaceutical would provide any benefits or potential health losses to people beyond the individual receiving the treatment.
	26	If the proposed pharmaceutical was funded, what would the consequences to the health system be?	As part of making its decision, PHARMAC thinks about the consequences that funding a treatment could have on the wider health system. For example, we need to understand if funding a medicine for a community use would help prevent hospitalisations, or we need to understand the kind of support and training that may be required to maximise the benefits of a treatment. Please detail the potential flow on effects that funding the proposed pharmaceutical could have on the health system.
Health Related Costs and Savings	27	Please detail whether there are there any additional health-related costs or savings to the person receiving treatment that are likely to be incurred if the pharmaceutical is funded.	When we assess an application for funding a medicine, we consider the implications of funding the pharmaceutical and the effect that funding the medicine has on the person receiving the pharmaceutical. This assessment includes reviewing the health-related costs or savings that could be incurred by the person receiving treatment. These costs or savings must be health-related. Please refer to PHARMAC's Prescription for Pharmacoeconomic Analysis - Methods for cost-utility analysis, which can be found here (https://www.pharmac.govt.nz/medicines/how-medicines-are-funded/economic-analysis/pfpa/), for full details of the costs and savings that PHARMAC consider during analysis. To determine if a cost or saving is health related, please consider whether they are partially subsidised by the health system. For example, if funding a pharmaceutical would result in a reduction of the number of GP visits needed by the person receiving treatment, this would reduce their health-related costs. This is because the costs that the person must pay in GP fees would reduce. We do not consider the costs that would be involved of a person privately funding their own medicines as these are not subsidised by the public system.

Section		Questions	Guidance
			Examples of costs to patients include: • pharmacy co-payments • manufacturer surcharges and pharmacy mark-up • GP visits • ambulance part-charge • residential care • travel and accommodation for hospital visits. Where possible, please ensure that quantitative information is provided. For example, an estimate in the reduction or increase of GP visits that may be required, or the type and diagnostic tests that may be required during treatment for the average patient. If quantitative information is unavailable, please provide a full description of the estimated effects.
	28	Please detail whether there are any health-related costs or savings that may be experienced by the family, whānau and wider society of the person receiving the treatment, if the pharmaceutical is funded.	When we assess an application for funding a medicine, we consider the implications that funding the pharmaceutical has on the health-related costs or savings which the family or whānau of the person receiving the pharmaceutical may incur. These costs or savings must be health-related. Please refer to PHARMAC's Prescription for Pharmacoeconomic Analysis - Methods for cost-utility analysis, which can be found here (https://www.pharmac.govt.nz/medicines/how-medicines-are-funded/economic-analysis/pfpa/), for full details of the costs and savings that PHARMAC consider during analysis. To determine if a cost or saving is health related, please consider whether they are partially subsidised by the health system. For example, if a pharmaceutical would reduce the number of hospital visits a person would require, this may reduce the health-related costs to their family if a family member is needed to drive them to hospital, and they are eligible to claim National Travel Assistance, as the cost that a family member would have to pay in car fuel would reduce.

Section		Questions	Guidance
			Where possible, please ensure that quantitative information is provided. However, if quantitative information is unavailable, please provide a full description of the estimated effects.
	29	Please detail whether there are there any additional costs or savings to the health sector that are likely to be incurred if the pharmaceutical is funded.	Please identify and estimate all additional costs and savings to the health sector that may occur if the pharmaceutical is funded – for each item provide the New Zealand price and estimated resource use. All costs should be clearly described, and sources of cost data provided. All price estimates should be obtained from New Zealand. Where feasible, resource use estimates should be based on New Zealand information (e.g. number of GP visits, length of hospital stay, etc.). If New Zealand data is not available, international sources may be used, but should be validated for the New Zealand setting. For details on how to estimate these costs, please refer to the Cost Resource Manual.
	30	Are there any features of the pharmaceutical that may impact use by the person receiving the treatment? If so, please explain.	Please provide information on the features of the pharmaceutical that may have an impact on use by the person receiving the treatment, and the outcome of treatment. Features are particularly relevant if they affect adherence. Examples of features of a pharmaceutical that may impact on use by the patient include (but are not limited to): • size • shape • taste • coating • method of delivery (e.g. oral, infusion, etc.) • ease of use • time required to administer

Section		Questions	Guidance
			• frequency of administration (e.g. once daily versus multiple times per day) • packaging • supporting information • training. If possible, please provide information on the likely magnitude of impact on the outcome of treatment. Consideration should be given to whether there are any subgroups in the target population who are more impacted by the features of the pharmaceutical (for example, elderly, children, people with poor dexterity, poor vision, intellectual impairment, etc.). Please reference all sources of information.
	31	Are there any features of the pharmaceutical that may have an impact on its use by the family or whānau of the person receiving the pharmaceutical, or on wider society?	In cases where the pharmaceutical needs to be administered by someone other than the patient or health workers, please provide information on the features of the pharmaceutical that may impact on use by the family or whānau of the person receiving the pharmaceutical, or on wider society. Features are particularly relevant if they may impact on adherence and health outcomes of the patient. The features identified may influence things such as how difficult the pharmaceutical is to administer, the time it takes to administer treatment, or how much dexterity is required to administer treatment (especially for older caregiver partners). Please note that these examples are not exhaustive. If possible, please provide information on the likely magnitude of impact on the outcome of treatment. Please reference all sources of information.

Section		Questions	Guidance
	32	Are there any features of the pharmaceutical that may have an impact on its use by the health workforce?	In cases where the pharmaceutical needs to be administered by members of the health workforce, please provide information on the features of the pharmaceutical that may affect use by the health workforce. This includes features which: • affect how easy it is for a health worker to use • affect how likely it is a health worker may make (or prevent) an error • dissuade workers from using a product at all even though it could be clinically beneficial. Features particularly relevant to the health workforce could include (but are not limited to): • training in use • confusion with similar products • ease of obtaining patient cooperation • packaging, and • supporting information. Please reference all sources of information.
	33	Are there any other issues or benefits that may arise as a result of the features of the pharmaceutical that have not been covered elsewhere in this section?	Please detail any features of the pharmaceutical that may influence the use and outcomes achieved by the pharmaceutical that have not been covered elsewhere in this section.
Additional information	34	Please provide any additional information that is relevant to your application.	Please provide any further information that has not been provided elsewhere in this application and which you consider is relevant to your application.

Section		Questions	Guidance
Declaration	35	Do you agree with the following statement? “I declare that all known published and unpublished clinical trials relevant to this Application have been disclosed in the Application.”	Please indicate whether you agree that all known published and unpublished clinical trials relevant to the application have been disclosed within it.
	36	Do you have any potential conflicts of interest relevant to this Application?	Please indicate whether you have any potential conflicts of interest. A conflict of interest could be described as a situation where it could be perceived that you are unable to be impartial because of the possibility of a clash of different interests that you have. For example, it may be that you, or a family member have a condition which could be treated by the treatment you are applying for funding for, or you took part in clinical trials for the medicine you are applying for. You may still apply for a medicine or medical device if you have a conflict of interest, however we need to be aware of if you have one.
	37	Provide a description of any conflicts you may have.	
	38	I agree that the product details information provided in the on-line form can be made publicly available on the Application Tracker	We understand that the general public are interested in the work that PHARMAC does and we want to help them understand what we are working on. In order to help with this, we would like to let people know that we have received your application and how it is progressing. We do this by putting information you have provided, and information relating to our assessment of your application on the PHARMAC website. Examples of this can be found on PHARMAC's Application Tracker here. If you have any concerns about this, or would like to discuss it further, please contact us on +64 4 460 4990.
	39	I confirm the information provided in this Application is correct	
	40	Do you have any comments regarding any of the above declarations?	

Section		Questions	Guidance
Identification	41	Name of person submitting application	Please provide the name of the person who is submitting the application.
	42	Date of application	Please indicate the date of submission.
	43	Who is the primary contact for this application?	Please provide the name of the person who should be PHARMAC staff's first point of contact with any questions or information relating to this application.
	44	What is the primary contact's email address?	Please provide the email address of the person who should be PHARMAC staff's first point of contact with any questions or information relating to this application.
	45	What is the primary contact's phone number?	Please provide the phone number of the person who should be PHARMAC staff's first point of contact with any questions or information relating to this application.