

16 May 2002

To: All Suppliers and Interested Parties

PROPOSED RE-RESTRICTION OF LIPITOR (ATORVASTATIN) UNDER SPECIAL AUTHORITY CRITERIA

PHARMAC has signed a provisional agreement with Pfizer Laboratories Limited which relates to the continued supply of Lipitor (atorvastatin) on the Pharmaceutical Schedule. Key aspects and effects of the provisional agreement are as follows:

- From 1 July 2002 Lipitor (atorvastatin) would be re-restricted under the same Special Authority criteria as those that applied prior to the widening of access to statins on 1 April 2002. These criteria are appended to this letter as attachment one.
- The widening of access to statins under the current Prescribing Guidelines introduced 1 April 2002 would remain in place for simvastatin (Zocor and Lipex) and for fluvastatin (Lescol and Vastin), therefore no Special Authority applications would need to be made for these chemicals.
- All patients with an active Special Authority number prior to 1 April 2002, would not need to apply for a new number these numbers in addition to any new Special Authority approvals will have a lifetime approval.
- Those new patients that have started treatment with Lipitor (atorvastatin) without a Special Authority since 1 April 2002 will need to have an application approved under the proposed Special Authority criteria in order to receive subsidy for Lipitor (atorvastatin) from 1 July 2002.
- Those patients that were not eligible for subsidised statins under the previous special authority criteria and who would remain ineligible for atorvastatin from 1 July 2002 would have the option of changing to simvastatin or fluvastatin or incurring the full cost of atorvastatin.
- Applications made to Health Benefits under the proposed Special Authority criteria between now and 1 July 2002 will be processed but will not be required until 1 July 2002.
- Lipitor (atorvastatin) will remain listed on the Pharmaceutical Schedule at a higher price than the reference price for statins until 1 June 2004 at which point the reference pricing protection expires.
- Lipitor (atorvastatin) will remain subject to expenditure caps and weighted average daily cost rebates.

PHARMAC also wishes to invite responses from interested parties if they consider that there could be other clinically identifiable groups of patients that may require subsidised access to Lipitor (atorvastatin) in addition to those covered under the proposed Special Authority. Responses should provide any clinical evidence that should be considered by PHARMAC in order to qualify and quantify the proposed group.

If you wish to comment on this proposal so that your comments can be considered by the PHARMAC board please respond no later than 5pm Thursday 30 May 2002.

Yours sincerely

Sarah Schmitt
Therapeutic Group Manager

Attachment One

The proposed Special Authority criteria for Lipitor (atorvastatin) only, from 1 July 2002 would be as follows:

“Special Authority

- a) Applications can be made by a general practitioner or relevant specialist.
- b) Approvals will be granted if the patient fulfills at least one of the criteria outlined in (i) and (j).
- c) Prescriptions for all patients can be written either by the general practitioner or the relevant specialist.
- d) All information requested on the application must be supplied.
- e) Prescribers are required to certify on the Special Authority application that the patient has been offered 3–6 months of counselling and an opportunity to modify lifestyle in the direction which current knowledge suggests would further reduce their risks of cardiovascular morbidity and mortality.
- f) Attach the results of at least two laboratory tests completed within 12 months of the Special Authority application. At least one of these tests must be fasting (with the exception of patients with IDDM). If a computerised record of cholesterol levels is used, it must be signed by the prescriber.
- g) Approvals are valid indefinitely.
- h) General practitioners or relevant specialists may make applications for patients who are in the following risk groups:

NHF A1:	Patients with proven cardiovascular disease	
	A1:1 - (Patients with clinically proven ischaemic heart disease	total cholesterol > 5.5
	A1:2 - (Patients post coronary artery bypass graft (CABG) or angioplasty	total cholesterol > 4.5
	Patients post heart transplant, regardless of cholesterol level.	
NHF B:	Patients with > 20% 5-year cardiovascular disease risk	total cholesterol > 9.0
NHF C:	15-20% 5-year cardiovascular disease risk	total cholesterol > 9.0
NHF D:	10-15% 5-year cardiovascular disease risk	total cholesterol > 9.0
NHF E:	Patients with < 10% 5-year cardiovascular disease risk	total cholesterol > 9.0
- i) Relevant specialists may make applications for patients in the following risk groups:

NHF A1:	A1:3 - Patients with proven ischaemic stroke or unequivocal history of transient ischaemic attack due to atherosclerosis	total cholesterol > 6.0
	A1:4 - Patients with unequivocal history of intermittent claudication	total cholesterol > 6.0
NHF A2:	Patients with Genetic Lipid Disorders: Familial Hypercholesterolaemia, Familial Defective Apo B, Familial Combined Dyslipidaemia, Combined Dyslipidaemia (Type III)	total cholesterol > 6.0
NHF A3:	Patients with insulin and non-insulin dependant diabetes, and established nephropathy (albumin excretion greater than 300mg/day)	total cholesterol > 6.0
- j) Risk Groups sourced from the 1996 NHF Guidelines for the assessment and management of dyslipidaemia, NZ MED J 1996; 109: 224–32.

Note:

 - Patients with a total cholesterol level greater than 9 mmol/l should have their initial assessment undertaken by a specialist.