

1 February 2002

To: All Pharmaceutical Suppliers and Interest Parties

**FURTHER CONSULTATION ON THE MERCK SHARP AND DOHME PROPOSAL FOR SIMVASTATIN**

Further to our consultation letter of 24 December 2002, the following letter relates to:

- the proposed prescribing guidelines for statins following the proposed removal of the current Special Authority criteria;
- the application of reference pricing to other members of the HMG CoA Reductase Inhibitors (statins).

**Proposed Prescribing Guidelines**

Further to the consultation letter issued on 24 December 2001, the provisional agreement with MSD includes widening subsidised access to statins by removing the current Special Authority Criteria, replacing these with statin prescribing guidelines no longer requiring application to Health Benefits.

PHARMAC intends the proposed statin prescribing guidelines will provide prescribers with appropriate information to assess whether a statin would be a suitable for each patient.

PHARMAC's recent discussions with interested parties, clinicians and with the Cardiovascular sub-committee of the Pharmacology and Therapeutics Advisory Committee (PTAC) have resulted in the preliminary recommendation that the the statin prescribing guidelines be based on the current National Heart Foundation (NHF) guidelines for treatment of cardiovascular disease. PHARMAC understands, however, that the NHF guidelines are also currently under review.

Attached is a summary of the results of cost utility analysis, prepared by PHARMAC, for statin treatment at a weighted average daily cost (WADC) of \$0.45. This analysis applies to additional patients treated with simvastatin priced at this level. It does not however apply to current patients taking other statins, which may have a higher WADC. Based on this analysis, PHARMAC currently considers that the appropriate levels for treatment of 5-year absolute cardiovascular risk are 10-15% and higher.

## Application of reference pricing

Reference pricing of statins is based on the weighted average daily dose (WADD) of each chemical which in turn effects the weighted average daily cost (WADC) and the subsidy per tablet of each of the strengths.

Based on the current WADD for simvastatin, fluvastatin and atorvastatin, PHARMAC considers that the tables below estimate the subsidy reductions that would result from reference pricing to simvastatin, as proposed in the provisional agreement with MSD.

If the proposal is accepted by the PHARMAC Board, notification of the actual subsidies would occur prior to each subsidy reduction.

### *Fluvastatin (Vastin)*

Vastin is currently reference priced to simvastatin and incurs a manufacturers surcharge, as the price is higher than the subsidy paid.

Chemical (Brand)	Presentation and (Pack Size)	Current subsidy and (price) as listed in the Pharmaceutical Schedule 1 January 2002	Subsidy at 1/4/02	Subsidy at 1/1/03	Subsidy at 1/1/04	Subsidy at 1/1/05	Subsidy at 1/1/06
Fluvastatin (Vastin)	20mg Capsule (30)	\$12.93 (\$23.10)	\$6.38	\$5.94	\$5.50	\$5.28	\$5.06
Fluvastatin (Vastin)	40mg Capsule (30)	\$15.12 (\$27.00)	\$7.51	\$6.99	\$6.47	\$6.22	\$5.96

### *Fluvastatin (Lescol)*

Lescol is currently reference priced to simvastatin and there is currently no manufacturers surcharge on this product.

Chemical (Brand)	Presentation and (Pack Size)	Current subsidy and (price) as listed in the Pharmaceutical Schedule 1 January 2002	Subsidy at 1/4/02	Subsidy at 1/1/03	Subsidy at 1/1/04	Subsidy at 1/1/05	Subsidy at 1/1/06
Fluvastatin (Vastin)	20mg Capsule (30)	\$12.93 (\$12.93)	\$6.38	\$5.94	\$5.50	\$5.28	\$5.06
Fluvastatin (Vastin)	40mg Capsule (30)	\$15.12 (\$15.12)	\$7.51	\$6.99	\$6.47	\$6.22	\$5.96

*Atorvastatin (Lipitor)*

Lipitor is protected from reference pricing as a result of a previous agreement until 1 June 2004. PHARMAC proposes that the following approximate subsidies would take effect from that date.

Chemical (Brand)	Presentation and (Pack Size)	Current subsidy and (price) as listed in the Pharmaceutical Schedule 1 January 2002	Subsidy at 1/6/04	Subsidy at 1/1/05	Subsidy at 1/1/06
Atorvastatin (Lipitor)	Tab 10 mg	\$32.99 (\$32.99)	\$4.72	\$4.53	\$4.34
Atorvastatin (Lipitor)	Tab 20 mg	\$48.09 (\$48.09)	\$6.85	\$6.58	\$6.31
Atorvastatin (Lipitor)	Tab 40 mg	\$66.69 (\$66.69)	\$9.55	\$9.16	\$8.78

PHARMAC welcomes submissions on both the reference pricing of statins and the structure, content and application of prescribing guidelines for statins. **The closing date for submissions is 5pm Monday 18 February 2002.** Submissions can be made by post, facsimile or e-mail.

Please note a copy of this consultation letter, the attached summary of the results of the cost utility analysis, the detailed cost utility analysis, and related documents referred to the analysis are available on the PHARMAC website [www.pharmac.govt.nz](http://www.pharmac.govt.nz).

Yours sincerely

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**ATTACHMENT:**

**SUMMARY OF RESULTS OF UPDATED COST UTILITY ANALYSIS FOR STATINS**

PHARMAC estimates the cost-utility of providing statins to everyone with dyslipidaemia and > 10% 5-year absolute risk of cardiovascular events, at a proposed price of \$0.45/day, is \$1,630/QALY if statins are used over patients' remaining lifetimes, or \$1,445/QALY if statins are used for 5 years and then use is reassessed.

In particular, those with established coronary heart disease (CHD) and total cholesterol > 5.5 mmol/l are estimated to have remaining lifetime and 5-year cost/QALYs of \$1,285/QALY and \$1,155 respectively. Others with a >10% 5-year absolute cardiovascular risk and total cholesterol > 5.5 mmol/l have \$2,110 and \$1,860 cost/QALYs for the same analyses. Only one group has cost/QALYs greater than \$5,000 - those with <10% 5-year absolute risk (giving less value with much higher cost/QALYs at >\$13-15,000/QALY):

**Cost/QALYS for statins Rx, lifetime use at 10% discount rate**

discount rate:	10.0%								
population group			Undiscounted values	Discounted 5-year costs, QALYs per patient					
group	5-year absolute CHD risk	potential no. pts	undiscounted QALYs	discounted QALYs	Rx costs	net other costs	% offsets	cost/QALYs	
					Vote:Health costs				
Average daily cost/patient (ADC)					\$0.60 current price simvastatin	\$0.60	\$0.60	<b>\$0.60</b>	\$0.45 future contracted price simv
Average cost/patient/year (AYC)					\$219	\$219	\$219	<b>\$219</b>	\$164
past CHD >=7.5	61.6%	16,388	3.73	<b>1.09</b>	\$1,362	-\$397	29%	<b>\$888</b>	<b>\$575</b>
past CHD 6.5-7.4	43.9%	39,281	3.49	<b>0.93</b>	\$1,450	-\$447	31%	<b>\$1,076</b>	<b>\$688</b>
past CHD 5.5-6.4	31.7%	66,949	2.53	<b>0.54</b>	\$1,501	-\$383	25%	<b>\$2,090</b>	<b>\$1,389</b>
past CHD <5.5	23.8%	54,690	1.34	<b>0.26</b>	\$1,502	-\$236	16%	<b>\$4,950</b>	<b>\$3,482</b>
genetic LDs	35.3%	2,936	5.13	<b>0.66</b>	\$1,843	-\$1,149	62%	<b>\$1,047</b>	<b>\$352</b>
at risk >=20%	22.5%	25,369	1.92	<b>0.54</b>	\$1,472	-\$387	26%	<b>\$2,010</b>	<b>\$1,329</b>
at risk 15-19%	17.5%	46,187	1.80	<b>0.45</b>	\$1,562	-\$362	23%	<b>\$2,661</b>	<b>\$1,795</b>
at risk 10-14%	12.5%	107,860	1.64	<b>0.36</b>	\$1,683	-\$311	18%	<b>\$3,815</b>	<b>\$2,645</b>
low risk <10%	3.6%	1,319,776	1.05	<b>0.10</b>	\$2,034	-\$168	8%	<b>\$18,768</b>	<b>\$13,654</b>
past CHD	32.6%	177,308	2.49	<b>0.59</b>	\$1,477	-\$353	24%	<b>\$1,913</b>	<b>\$1,285</b>
others >10% risk	10.3%	182,352	1.77	<b>0.41</b>	\$1,626	-\$348	21%	<b>\$3,096</b>	<b>\$2,111</b>
total	21.3%	359,660	2.13	<b>0.50</b>	\$1,552	-\$350	23%	<b>\$2,409</b>	<b>\$1,631</b>

### Cost/QALYS for statins Rx, 5-year use at 10% discount rate

discount rate:	10.0%										
population group	5-year absolute CHD risk		potential no. pts	undiscounted QALYs	Undiscounted values	Discounted 5-year costs, QALYs per patient	Rx costs	net other % offsets	cost/QALYs		
group	5-year absolute CHD risk	potential no. pts	undiscounted QALYs	discounted QALYs				Vote:Health costs			
Average daily cost/patient (ADC)							\$0.60 current price simvastatin	\$0.60	\$0.60	<b>\$0.60</b>	\$0.45 future contracted price simv
Average cost/patient/year (AYC)							\$219	\$219	\$219	<b>\$219</b>	\$164
past CHD >=7.5	61.6%	16,388	1.49	<b>0.63</b>	\$758	-\$243	32%	<b>\$823</b>	<b>\$520</b>		
past CHD 6.5-7.4	43.9%	39,281	1.28	<b>0.51</b>	\$770	-\$263	34%	<b>\$986</b>	<b>\$612</b>		
past CHD 5.5-6.4	31.7%	66,949	0.78	<b>0.28</b>	\$773	-\$228	29%	<b>\$1,948</b>	<b>\$1,257</b>		
past CHD <5.5	23.8%	54,690	0.39	<b>0.13</b>	\$773	-\$141	18%	<b>\$4,746</b>	<b>\$3,294</b>		
genetic LDs	35.3%	2,936	1.52	<b>0.41</b>	\$800	-\$467	58%	<b>\$817</b>	<b>\$326</b>		
at risk >=20%	22.5%	25,369	0.75	<b>0.30</b>	\$771	-\$223	29%	<b>\$1,806</b>	<b>\$1,171</b>		
at risk 15-19%	17.5%	46,187	0.63	<b>0.24</b>	\$783	-\$202	26%	<b>\$2,405</b>	<b>\$1,595</b>		
at risk 10-14%	12.5%	107,860	0.52	<b>0.18</b>	\$797	-\$166	21%	<b>\$3,475</b>	<b>\$2,378</b>		
low risk <10%	3.6%	1,319,776	0.14	<b>0.04</b>	\$825	-\$72	9%	<b>\$21,129</b>	<b>\$15,343</b>		
past CHD	32.6%	177,308	0.83	<b>0.32</b>	\$771	-\$210	27%	<b>\$1,760</b>	<b>\$1,155</b>		
others >10% risk	10.3%	182,352	0.60	<b>0.22</b>	\$790	-\$188	24%	<b>\$2,769</b>	<b>\$1,861</b>		
total	21.3%	359,660	0.71	<b>0.27</b>	\$781	-\$199	25%	<b>\$2,176</b>	<b>\$1,446</b>		

PHARMAC's analysis is based on clinical trial data on the effectiveness of statin treatment, applied to models of natural history of cardiovascular disease, quality of life scores for each health state, and costs of treating with pharmaceuticals and to other parts of the health sector.

This analysis applies to additional patients treated with simvastatin priced at this level (weighted average daily cost (WADC) of \$0.45). It does not however apply to current patients taking other statins, which may have a higher WADC.

Details of methods and results can be found in PHARMAC document #61344, available on PHARMAC's website [www.pharmac.govt.nz](http://www.pharmac.govt.nz) at <http://www.pharmac.govt.nz/download/statin02.pdf> or freephone 0800 66 00 50.

Supporting documents referred to in the detailed document are also available on-line at <http://www.pharmac.govt.nz/download/statin97methods.pdf>, <http://www.pharmac.govt.nz/download/statin97results.pdf>, and <http://www.pharmac.govt.nz/download/statin97A2FH.pdf>.