

14 May 2014

Proposal to amend the subsidies for various non-steroidal anti-inflammatory drugs (NSAIDs)

PHARMAC is seeking feedback on a proposal to make a number of changes to subsidies for various NSAIDs in the community. In summary the proposal is to:

From 1 August 2014:

- Fully fund sulindac 100 mg and 200 mg tablets (Aclin), which are currently only partly funded.
- Remove the “for continuation only” restriction from the listing of sulindac in the Hospital Medicines List (HML).
- Add the following rule to diclofenac 50 mg dispersible tablets (Voltaren D), which are currently partly funded: “Additional subsidy for a patient who cannot swallow whole tablets and in whom ibuprofen oral liquid is ineffective or not tolerated and where the prescription is endorsed accordingly”.
- Remove the “Special Authority for Manufacturers Price” that provides a small group of patients with approvals granted prior to 1 September 2010 with full subsidy for all NSAID preparations that are currently partly funded in the community (diclofenac tab 50 mg dispersible, ibuprofen tab 400 mg and 600 mg, mefenamic acid cap 250 mg and sulindac tab 100 mg and 200 mg). The proposal would mean that existing approvals would be cancelled.

From 1 November 2014:

- Delist ibuprofen 400 mg and 600 mg tablets (Brufen), which are currently partly funded by reference to the subsidy of the equivalent number of ibuprofen 200 mg tablets. Ibuprofen 200 mg tablets and 800 mg long-acting tablets would remain fully funded.

Further details and background to the proposal can be found on the following pages.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **5 pm on Wednesday, 28 May 2014** to:

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All feedback received before the closing date will be considered by PHARMAC’s Board (or its delegate) prior to making a decision on this proposal.

Feedback we receive is subject to the Official Information Act 1982 (OIA) and we will consider any request to have information withheld in accordance with our obligations under

the OIA. Anyone providing feedback, whether on their own account or on behalf of an organisation, and whether in a personal or professional capacity, should be aware that the content of their feedback and their identity may need to be disclosed in response to an OIA request.

We are not able to treat any part of your feedback as confidential unless you specifically request that we do, and then only to the extent permissible under the OIA and other relevant laws and requirements. If you would like us to withhold any commercially sensitive, confidential proprietary, or personal information included in your submission, please clearly state this in your submission and identify the relevant sections of your submission that you would like it withheld. PHARMAC will give due consideration to any such request.

Details of the proposal

- The subsidy for sulindac 100 mg and 200 mg tablets would be increased in Section B of the Pharmaceutical Schedule from 1 August 2014 as follows (prices and subsidies expressed ex-manufacturer, excluding GST):

Chemical	Presentation	Brand	Pack size	Current subsidy (and price)	Proposed subsidy and price
Sulindac	Tab 100 mg	Aclin	50	\$2.66 (\$8.55)	\$8.55
Sulindac	Tab 200 mg	Aclin	50	\$3.36 (\$15.10)	\$15.10

- The restriction that currently applies to sulindac 100 mg and 200 mg tablets in Part II of Section H of the Pharmaceutical Schedule (the HML) would be removed from 1 August 2014 as follows:

~~Restricted: for continuation only~~

- The following rule would be added to the listing of diclofenac sodium tab 50 mg dispersible (Voltaren D) in Section B of the Pharmaceutical Schedule from 1 August 2014:

Higher subsidy of \$8.00 per 20 tab with Endorsement
Additional subsidy by endorsement for a patient who cannot swallow whole tablets and in whom ibuprofen oral liquid is ineffective or not tolerated, and the prescription is endorsed accordingly

- The Special Authority for Manufacturers Price (SA1038) that currently applies to all the NSAID preparations that are partly funded in the community (diclofenac tab 50 mg dispersible, ibuprofen tab 400 mg and 600 mg, mefenamic acid cap 250 mg and sulindac tab 100 mg and 200 mg) would be removed from 1 August 2014 as follows:

~~SA1038 Special Authority for Manufacturers Price
Note: Subsidy for patients with existing approvals prior to 1 September 2010. Approvals valid without further renewal unless notified. No new approvals will be granted from 1 September 2010.~~

- Ibuprofen 400 mg and 600 mg tablets (Brufen), which are currently only partly funded, would be delisted from Section B of the Pharmaceutical Schedule from 1 November 2014. Ibuprofen 200 mg tablets and 800 mg long-acting tablets would remain listed fully funded. No changes to HML listings for ibuprofen 400 mg or 600 mg tablets are proposed.

Background

Increased subsidy for sulindac

The recent supplier discontinuation of tiaprofenic acid (Surgam), which was delisted from the Pharmaceutical Schedule from 1 May 2014, and earlier supplier withdrawals of indomethacin and piroxicam from the market, has resulted in a reduced range of fully funded NSAIDs. The Rheumatology Subcommittee of PTAC advised PHARMAC that while the majority of patients can be managed adequately using the current range of fully funded NSAIDs, responses to NSAIDs are highly idiosyncratic and it is important to have as large a range of fully funded options as possible to meet patients' needs.

This proposal would increase the range of fully funded NSAIDs by fully subsidising sulindac.

Full subsidy of diclofenac by endorsement

Currently the only fully subsidised non-tablet NSAID is ibuprofen oral liquid 20 mg per ml. We have been advised by the Rheumatology Subcommittee that there is a need for an additional non-tablet NSAID option, particularly for use in children.

Two suggested options for consideration were naproxen oral liquid and/or fully subsidising diclofenac 50 mg dispersible tablets. We have been unable to source a registered version of naproxen oral liquid so are proposing to fully fund diclofenac 50 mg dispersible tablets for a specific patient group.

Diclofenac 50 mg dispersible tablets (Voltaren D) are currently subsidised at \$1.50 per pack of 20 tablets, but the manufacturer's price is \$8.00 per pack meaning that patients must pay a surcharge of approximately \$12.10 per pack if they are prescribed this formulation.

Given the high cost of diclofenac 50 mg dispersible tablets versus both ibuprofen oral liquid 20 mg per ml (\$1.89 per 200 ml) and diclofenac 50 mg EC tablets (\$16.00 for 500 tablets) we are proposing to fully fund diclofenac 50 mg dispersible tablets only as a second-line treatment option after ibuprofen oral liquid in patients who cannot swallow whole tablets.

Removal of the NSAID Special Authority for Manufacturers Price

If the proposals relating to sulindac and diclofenac 50 mg dispersible tablets are approved, we consider that the Special Authority that provides full subsidy for any partly-funded NSAID for patients with an approval prior to 1 September 2010 would no longer be needed. Fully funded options (from 1 August 2014) for the small number of patients who currently have fully funded access via Special Authority to the currently partly funded NSAIDs are outlined in the table on the following page:

Pharmaceutical	Presentation	Approximate number of patients currently gaining full subsidy via Special Authority	Alternative fully funded options
Diclofenac sodium	Tab 50 mg dispersible	10	If patients did not meet the proposed endorsement criteria, options would be diclofenac tab EC 50 mg, ibuprofen oral liquid 20 mg per ml, or another fully funded NSAID or analgesic
Ibuprofen	Tab 400 mg Tab 600 mg	10 8	Ibuprofen tab 200 mg or another fully funded NSAID or analgesic
Mefenamic acid	Cap 250 mg	0	N/A

The full list of fully funded options can be found in the Pharmaceutical Schedule, available at www.pharmac.govt.nz/Schedule

Delisting of ibuprofen 400 mg and 600 mg

The subsidy for ibuprofen 400 mg and 600 mg tablets is currently set at the level of the subsidy for the equivalent mg amount of ibuprofen 200 mg tablets, as shown in the following table:

Chemical	Presentation	Brand	Pack size	Current subsidy	Current price
Ibuprofen	Tab 200 mg	Arrowcare	1,000	\$12.75	\$12.75
Ibuprofen	Tab 400 mg	Brufen	30	\$0.77	\$4.56
Ibuprofen	Tab 600 mg	Brufen	30	\$1.15	\$6.84

Due to price reductions over time on ibuprofen 200 mg tablets via the tender, a pattern which we anticipate is likely to continue, the subsidy for the higher strengths is now very low, both in real terms and compared with the price. This means that any patients currently prescribed the higher strengths are paying close to the full price of the medicine.

Given the relatively high price of the higher strengths, and the availability of alternative fully funded treatment options, including ibuprofen 200 mg tablets, our view is that there is little clinical or financial justification for ibuprofen 400 mg or 600 mg tablets to remain listed on the community Pharmaceutical Schedule.

This proposal would not prevent us from re-listing either of these strengths of ibuprofen in the future if we were to receive an acceptable commercial offer.