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Your questions to the PBAC

Patent expiry and 'new' drug approvals

The February issue of *Australian Prescriber* contains a review of desvenlafaxine with a comment on the expiry of the patent of modified-release venlafaxine (*Aust Prescr* 2009;32:22-3). There are other examples of 'new' drugs which are just small variations on the original molecule. These include perindopril erbumine becoming perindopril arginine and omeprazole becoming esomeprazole.

It appears that these small variations on a successful molecule are not great therapeutic advances. They seem to be produced only for commercial reasons. I would like to know why such products are added to the Pharmaceutical Benefits Scheme. They are unlikely to be more cost-effective than the old drugs already in use.

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PBAC response:

As the Schedule of Pharmaceutical Benefits is not a limited formulary, a 'new' drug such as these can be added even though several similar products are already listed.¹ As mentioned by your correspondent, these drugs are 'not great therapeutic advances' and are 'unlikely to be more cost-effective than the old drugs already in use'.

Perindopril arginine was accepted by the Pharmaceutical Benefits Advisory Committee (PBAC) as being bioequivalent to perindopril erbumine, while esomeprazole and desvenlafaxine were accepted on a cost-minimisation basis, where the evidence indicates that the new drug is no worse than an existing comparator (in this case, omeprazole and venlafaxine respectively). Once the new drug is considered to provide similar health outcomes to the comparator, the PBAC then makes a recommendation about the therapeutically equivalent

doses of the two drugs, based on all the evidence submitted at the time of listing, from which pricing is determined by the Pharmaceutical Benefits Pricing Authority. In the case of desvenlafaxine for major depressive disorders it was recommended on a cost minimisation basis with the parent drug venlafaxine, with the equi-effective doses being desvenlafaxine 50 mg and venlafaxine 75 mg. The PBAC considered that desvenlafaxine would provide a further treatment option for major depressive disorders, however, no evidence was presented to suggest that desvenlafaxine would offer an advantage for any particular patient group over the parent drug venlafaxine.²

In addition, the relative prices are adjusted depending on the actual prescribed daily doses in the marketplace. Both esomeprazole and perindopril arginine are in 'weighted average monthly treatment cost' groups of drugs regarded as therapeutically equivalent (the proton pump inhibitors and the ACE inhibitors). Pricing information using relative volumes of use and prescribed daily doses are compared across the group to determine the lowest priced drug in the group. The PBS subsidy is only provided at this lowest price.³

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