Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 13 & 15 February 2013

Question: E13-125

OUTCOME 2: Access to Pharmaceutical Services

Topic: Price Reductions

Type of Question: Written Question on Notice

Senator: Senator Fierravanti-Wells

Question:

The number of cases since the introduction of the different formularies where an originator company with a product in F1 – and which is not subject to generic competition – has introduced a new mechanism that will actually trigger a statutory price reduction and moving to F2? Please provide a list of where that might have happened.

Answer:

The criteria for application of a 16 per cent statutory price reduction are set out in the *National Health Act 1953* (the Act).

The criteria in the Act do not limit the 16 per cent reduction to situations where the drug has come off patent and has generic competition. The relevant criteria are:

- a new brand of pharmaceutical item lists on the Pharmaceutical Benefits Scheme (PBS);
- the new brand is bioequivalent or biosimilar to an existing brand of pharmaceutical item; and
- the new and existing brands have the same drug and manner of administration.

To be clear, the new and existing brands can be the same, and it doesn't matter if they have the same or a different sponsor. This is clarified in a 'note' published in the Act with the relevant provision (section 99ACB(1)).

Issues around originator sponsors listing bioequivalent brands that trigger a price reduction and move to F2 are broader than the introduction of specific presentations of a product. Single sponsor listings of bioequivalent brands may occur for a range of reasons, including maintaining market share and pricing advantages for affected or related drugs.

For example, the 16 per cent reduction was applied for the combination drug amlodipine and valsartan when the single brand sponsor listed a second brand of one strength of its tablets. In that case, the drug avoided taking a 40.09 per cent price disclosure reduction to one component (amlodipine) by taking a 16 per cent reduction on the other component (valsartan). Although the combination drug is now in F2 and subject to price disclosure, both brands are supplied by the same sponsor so there is unlikely to be discounting or price disclosure reductions.

The Department of Health and Ageing is aware of a few instances since 2007 PBS Reforms where a company has stated that it decided not to proceed with an application to list a new presentation of a medicine already available under the PBS when it was informed that the listing was considered as a 16 per cent reduction trigger under the criteria in the Act. These examples include both biologic and non-biologic medicines (eg: a dispersible tablet or a different injection delivery device). It is not appropriate for the Department to make public a list of affected medicines as these listing decisions are a commercial matter for the companies concerned.