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Ms Susie Back
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Subject: AA1000592 – Juno, Natco and Celgene - submission

Dear Ms Back

[redacted]

- The pharmaceutical development process of bringing a new medicine to market from discovery through clinical trials to approval is extremely costly.
- Pharmaceutical companies have a strong commercial incentive to examine ways of protecting market share and maximising profitability when their patent protection of a new medicine approaches expiry.
- Historically, pharmaceutical companies have undertaken a range of different "evergreening" strategies to maintain their market share upon the expiry of their patent. These strategies have varying degrees of success and typically involve long drawn-out legal processes that delay or prevent the entry of new competitors.
- In general terms, there is no real incentive for sponsors of patented molecules/products to offer a lower price for their originator brand if no generic/biosimilar competitor brands are available.
- Although price reductions rarely occur with originator brands where there is no generic competition, pharmaceutical companies may offer other incentives apart from price to win contracts/tenders, such as offers of annual rebates depending on a customer's

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expenditure on their product/s [redacted]

- The arrival of generic/biosimilar competitor brands once a new medicine's patent expires typically significantly reduces the price of the medicine. This price reduction is driven both by competition and the Commonwealth's legislated price disclosure mechanism that implements cycles of mandated reductions in the price the Commonwealth pays for a medicine.
- Although the expiry of a patent and subsequent entry of generic/biosimilar competitive brands typically drives the price of the medicine down, profit margins typically remain sufficiently attractive to generate strong competition for market share amongst pharmaceutical companies.
- Occasionally, a pharmaceutical company with an originator brand enters into a mutually profitable licensing arrangement with another pharmaceutical company to introduce a generic medicine on the market either in direct competition to, or in place of, the originator brand on expiry of the patent.
- A commercial arrangement where the sponsor of an originator brand provides exclusive access to another pharmaceutical company to manufacture and distribute a generic competitor brand to its product (in Australia) for a time period before the patent expires may provide a "first mover" advantage. This advantage is magnified if there are complexities associated with the medicine (such as the manufacturing process or data required for regulatory submissions) that may delay the market entry of competitors.
- There is a very limited incentive to offer generic products at the best price when only one generic product is on the market, especially when a commercial agreement between the supplier of the originator product and the only available generic product is in place while other suppliers of generic products are competitively disadvantaged. Bigger savings and hence higher economic efficiency can be expected when the real competition starts, unless the suppliers of alternative generic products have withdrawn from the Australian market by then.
- A listing of a generic brand on the Australian Register of Therapeutic Goods (ARTG) is not a definitive indicator of market entry. A well-established generic medicine may deter other generic competitor brands from entering the Australian market if the cost of entry is high relative to potential market share.
- The pharmaceutical industry typically responds rapidly to changes in the regulatory environment. Any authorisation provided to a pharmaceutical company that is commercially favourable may increase the likelihood of similar authorisations being sought by other pharmaceutical companies.
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- [redacted]
- [redacted]
- The patient co-payment fee for a PBS-eligible prescription to be dispensed will be the same (i.e. for either the originator or a generic brand if 'a flagged' as being bioequivalent on the PBS) unless specified on the PBS that a therapeutic group premium has been applied to a particular item (brand).
- The Commonwealth and sponsor may agree to a lower price being offered than that shown as the PBS list price for the product. This commercial-in-confidence pricing is referred to as a "Special Pricing Arrangement" and is not publicly available.