NORTHERN TERRITORY GOVERNMENT
Top End HEALTH SERVICE

Medicine Management Unit (MMU)

Postal address
GPO Box 41326
Casuarina NT 0811

EDOC2022/109112

15 March 2022

Dear Sir/Madam

Re: Application for authorisation under section 88(1) of the Competition and Consumer Act 2010 (Cth) lodged by Juno Pharmaceuticals Pty Ltd, Natco Pharma Ltd, Celegene Corporation and Celgene Pty Ltd

Thank you for the invitation to provide input regarding Juno Pharmaceuticals Pty Ltd (Juno), Natco Pharma Ltd (Natco), Celegene Corporation and Celgene Pty Ltd (together, Celgene), hereby referred to as 'The Agreement', seeking authorisation to enter certain provisions of a Settlement and Licence Agreement and its expected impact as a result of early market entry of generic Lenalidomide (originator Revlimid®) and Pomalidomide (originator Pomalyst®) in Australia.

From an NT Health perspective, pharmaceutical procurement for NT public hospitals is conducted via public tender. Originator pharmaceutical manufactures may choose not to submit tender offer for a variety of commercial reasons. Where the originator pharmaceutical manufacture does not submit tender offer, we do not enter into contract with them.

Generic pharmaceutical manufactures may choose to submit tender offers, and NT Health will enter into contract if the generic product is of acceptable quality. Generally speaking, NT Health will only stock a single brand of medicine in most instances. Therapeutic Goods Administration (TGA) and Pharmaceutical Benefits Scheme (PBS) approval of the generic as bioequivalent to the originator is sufficient reason for keeping a single brand. NT Health considers a variety of factors beyond cost when assessing tender offers. Consultation with stakeholders, particularly for highly specialised pharmaceuticals such as Lenalidomide and Pomalidomide, would be undertaken and our clinicians may recommend stocking the originator only, the generic only, or stocking both brands depending on the circumstances.

NT Health believes The Agreement will not have a direct impact to consumers who access Lenalidomide or Pomalidomide via the PBS; the majority of patient's access these medicine via the PBS noting some of the issues identified below which may have broader implications for access. It is assumed that Juno/Natco will submit a Pharmaceutical Benefits Advisory Committee (PBAC) application for PBS listings, however, it is noted that the Authorised Launch Date related to PBAC submission per the Agreement is considered confidential and NT Health cannot be sure. Securing a PBS listing offers a way for pharmaceutical companies to obtain market share in Australia.

Assuming PBS listing in which the generics are listed as bioequivalent to the originator, the cost to consumers is not expected to change. The concession co-payment paid by consumers cannot be further reduced from current cost of $6.80, and it is highly unlikely that there would be a significant reduction in the cost for the general co-payment to decrease below the maximum $42.50 at present i.e. the approved ex-manufacture price (AEMP) of Pomalidomide being reduced to below $42.50 from present $6,650. There is the potential that Celgene may request a price premium or brand premium for Revlimid® and

Pomalyst® upon entry of the generics onto the market; this payment is in addition to the co-payment, and would impact consumers should the prescriber, or patient, not allow generic substitution.

Consumers who would be directly impacted are those accessing these treatments privately for indications that are not subsidised by the PBS i.e. self-funded treatment. It is expected that the number of patients who can self-fund their treatment to be small. Availability of a generic option may potentially decrease this cost, but this is subject to community pharmacy mark-ups for dispensing of a private prescription. Improved consumer access in the context of patient choice of dispensing pharmacy is not expected to improve given the high cost of acquisition of these agents and the monitoring requirements per treatment protocols; it is expected that dispensing of these agents will continue to be undertaken by public and private hospital pharmacies with oncology services.

NT Health agrees that early entry of generic Lenalidomide and Pomalidomide, with subsequent PBS listing, will result in an immediate decrease in the cost price i.e. the AEMP. Reduction in the AEMP directly influences the PBS reimbursement to dispensing pharmacies, and thus, contributes to a reduction in PBS expenditure. However, PBS expenditure is reflective of usage, and given the changes in practise observed in haematology, Lenalidomide and Pomalidomide use may decrease in the future with the availability of new, potentially efficacious and/or safer agents, or re-utilisation of currently available agents. NT Health note Celgene has sponsored trials for Iberdomide (CC-220), a new analogue of Thalidomide similar to Lenalidomide and Pomalidomide, in the relapsed or refractory multiple myeloma setting[1].

Further AEMP reductions will occur through mandatory price disclosures following change in the PBS Formulary Allocation from F1 to F2 with the early entry of the generics[2]. The AEMP reduction from first PBS listing of generic Lenalidomide and Pomalidomide is expected to be 25% as part of a 'First New Brand Price Reduction'[3], however, this may be subject to the Sponsor applying for Ministerial discretion for reducing the price reduction by a lower percentage, or not applying the price reduction at all.

A decrease in AEMP as a result of early entry of a generic Lenalidomide and Pomalidomide does benefit hospitals and jurisdictions that are currently subsidising costs to patients via state-government funded mechanisms for off-label or non-PBS indications. There is also a reduced cost to public hospitals where these agents are required as part of inpatient admission in which public hospitals are unable to claim the cost of treatment under the PBS in this setting.

The reduction of cost may have flow on benefits for public health in the context of increasing the number of subsidised PBS indications available. This could occur through increased treatment access for conditions that are not currently PBS subsidised. For example, reduced cost of Lenalidomide may improve the cost-effectiveness proposition to facilitate PBS listing for the treatment of mantle cell lymphoma. NT Health notes a previous submission by Celgene was rejected by PBAC based on uncertain cost effectiveness for this indication[4]. However, this benefit to public health is reliant on the Sponsor to re-submit the PBAC application; the Sponsor may chose not to undergo the PBS listing process, particularly if a generic is available.

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[1] Gao, S., Wang, S. & Song, Y. Novel immunomodulatory drugs and neo-substrates. *Biomark Res* **8,** 2 (2020). https://doi.org/10.1186/s40364-020-0182-y

[2] Generally, F1 formulary allocation is intended for single brand drugs, and F2 are for drugs that have multiple brands. Drugs in F2 are subjected to statutory price reductions, price disclosures and guarantee of supply. PBS Formulary Allocations

[3] Pharmaceutical Benefits Scheme (PBS) | First New Brand Price Reductions

[4] Celegene submission for Section 100 Highly Specialised Drug listing for Lenalidomide for the treatment of relapsed and/or refractory mantle cell lymphoma in adults

NT Health does see potential issues with The Agreement. 'Pay for delay' agreements, where the generic manufacturer acknowledges the patent of the originator pharmaceutical company and agrees to refrain from marketing its generic product for a specific period of time, is a well-known mechanism utilised upon threat of entry of generic medicines into the market in the pharmaceutical industry. Such deals often provide no incentive to the 'first mover' generic manufacture to significantly lower price to gain market share by undercutting costs of the originator. This is particularly the case where the agreement subjects the generic manufacture to annual volume-limited sales amounts, or in the Australian context, determines when submission for PBS reimbursement can be undertaken; a high consideration for gaining market share.

Ultimately, these agreements delay the entry of competitors in the market, reduce competition, and prolongs the introduction of reduced prices. In Australia, reduction in PBS expenditure, and resulting cost savings, could be utilised to subsidise treatment for new agents. It is noted that Celgene and parent company Bristol Myer Squibb, have entered settlement with multiple generic manufactures including Sun Pharma[5], Dr. Reddy[6], and Cipla[7] in addition to Natco[8], in which they have licensed sell volume-limited amounts of generic Lenalidomide in the United States. The full details of The Agreement are not available to the public, to determine if The Agreement shares the same similar qualities as those signed in the United States.

In addition, originators have been deleted from the market due to commercial decisions following entry of generic and biosimilar agents. Examples of originators deleted from the market include Herceptin® (Trastuzumab), Mabthera® (Rituximab) and Neulasta® (Pegfligrastim)[9] which resulted in significant clinical and administrative workload stress and patient dissatisfaction. There is a risk of medication shortages in the event that Revlimid® & Pomalyst® are deleted from the market before maturation of the generic supply chain. Medication shortages in the oncology space have major impact on consumer in relation to commencing, and continue treatment, for their underlying malignancy. Furthermore, consumers accessing treatment through medication access programs would be significantly affected as these programs are often facilitated by the originator manufacturer.

Thank you again for the opportunity to provide input. For any further information or questions, please contact me on [redacted]

Yours sincerely,

[redacted]

Associate Professor Bhavini Patel
Executive Director Medicines Management | Research | NT Executive COVID-19 Vaccine Lead
Top End Health Service
15th February 2022

[5] Sun Pharma Announces Settlement of Patent Litigation for Generic Revlimid (lenalidomide) in US
[6] Bristol Myers Squibb Announces Settlement of U.S. Patent Litigation for REVLIMID® (lenalidomide) With Dr. Reddy's
[7] Bristol Myers Squibb Announces Settlement of U.S. Patent Litigation for REVLIMID® (lenalidomide) with Cipla
[8] Celgene settles Revlimid Patent Litigation
[9] Discontinuations | Medicine Shortages Reports Database | Therapeutic Goods Administration (TGA)