SHPA response to ACCC request for information - Juno & Ors application for authorisation – April 2022

1. **Please explain how Celgene's risk management plan operates and what is required to be done by prescribers / pharmacists in order to prescribe / supply lenalidomide and pomalidomide products?**

Patients who require treatment with pomalidomide or lenalidomide must be registered with the Celgene i-access program. The prescribers and pharmacists must also be registered with the program.

When dispensing, the pharmacist must submit the dispensing online via i-access program, and either obtain an automated approval, or if it goes under review, wait for it to be assessed and verified by Celgene before proceeding to supply to the patient. The first dispensing usually takes the longest for approval as it is a new patient, thereafter the process is quite streamlined if no queries or issues arise with the supply.

2. **Would both the prescriber and pharmacy be required to operate the same risk management plan in order for a patient to obtain and dispense their script of the same brand of lenalidomide and pomalidomide?**

Yes, both prescriber and pharmacists would need to be registered for the same program and the prescribers must be kept up to date with which program the pharmacy is currently using based on the brand of medicine.

3. **Would prescribers / pharmacies be willing to switch to, or operate, a second or subsequent generic risk management plan if generic products of lenalidomide and pomalidomide were introduced? What factors would generally be taken into account, and to what extent would additional switching costs, IT interface changes or training costs act as a barrier to prescribers/pharmacies deciding to switch.**

At present, use of the i-access program by pharmacists represents significant administrative burden and is onerous to operate, and thus, there is a strong preference to only use a singular risk management plan at any one point in time. Pharmacists and prescribers would not want to swap brands constantly due to stock outages or tender brand changes as this would require pharmacists and prescribers to learn a new risk management program or operate concurrent programs, increasing the risk of the requirements of the program not being fully carried out by prescribers or pharmacists.

If there were multiple un-integrated risk management programs being used with multiple brands being supplied over the course of a patient's treatment, this would create more work for prescribers and pharmacists in having to explain to each risk management program a patient did not miss a dispensing, just rather that they had the other product/brand which is logged on the other risk management program. This scenario not only has additional training costs and administrative costs that take up pharmacist resourcing, it will also present a risk to the safety and quality use of these medicines if prescribers and pharmacists had to use multiple programs in an environment where healthcare demands and healthcare resourcing has been extremely challenging.

We would anticipate hospitals would not switch brands of these medicines without significant Director of Pharmacy/Pharmacy Manager engagement and assessment of an equivalent risk management solution to deem whether switching brands is appropriate for their hospital.

From a logistics point, it is strongly preferred by prescribers and pharmacist to minimise brand swapping for individual patients, especially if the risk management programs are un-integrated, it will make it difficult or impossible to track patients, this is a huge barrier that likely needs to be resolved by sponsors. If pharmacists

were to keep multiple brands, significant work could be created in ensuring communication of what brand a patient on was performed and maintained, to avoid scenarios such as accidentally entering in a dispensing in the wrong risk management program.

4. **How many separate risk management plans would prescribers / pharmacies be willing establish and operate at any given time? Please explain why.**

There is a strong preference to only use a singular risk management plan at any one point in time, for various reasons described above. A summary of these reasons are below:

- Significant administrative burden which detracts from patient care
- Significant increased training requirements for any risk management program
- Multiple programs being used concurrently will also necessitate increased IT upkeep, keeping track of multiple users for multiple systems and their login details
- These systems are un-integrated and cannot display information from one program in another, which is administratively onerous to check if patients are supplied multiple brands over the course of their treatment, and also increases the risk of wrong information being entered
- Risk to safety and quality use of medicines given the need to explain to patients who have varying levels of health literacy
- Increased stockholding leading to increased risk of expired stock and wastage