From: [redacted]
To: Exemptions
Subject: AA1000592 – Juno & Ors – Submission - [redacted]
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Submission

As mentioned over the phone, one key aspect of lenalidomide is Risk Management Plan. As part of this plan that was approved by TGA for the Celgene product, the patient needs to get a pregnancy test conducted in the presence of a healthcare practitioner prior to any scripts being given (initiation or subsequent). Once the results are okay (patient not pregnant), then the prescriber can generate the script and the records are updated in the proprietary Celgene software. The software runs different instances for Prescribers and Pharmacists. Once the patient details are in the system from prescriber the pharmacist can also update that product has been dispensed.

This way the patient details are kept updated by the prescribers and the pharmacists.

Now, coming to the scenario where there are generics for this product. Each generic supplier will need to have their own Risk Management Plan which will need to run at all prescribers and pharmacies. The challenge for something like this is that Prescribers are already adept in using the Celgene software for Lenalidomide and Pomalidomide. There is no incentive for them to have 3-4 more systems for same molecule for no benefit to them.

Unless the Celgene system is made open to all generic entrants, there will be either very limited to no substation from prescribers and pharmacists will need to then maintain one patient in 2 systems (if they do switch). The risk in such scenario is the efficacy of the database from a patient safety perspective.

Allowing all generics to enter with their own software has the potential of a notional competition in the market with no big benefit for PBS as there will be very limited competition.

TGA probably will not be able to mandate this as their remit is to ensure an adequate risk management plan (which all generics will have). The “management” of competition is something that probably falls under ACCC, hence this submission.