Introduction

Mylan Australia welcomes the Therapeutic Goods Administration's (TGA) focus on the important issue of the naming of biological medicines and appreciates the opportunity to make a submission to the *Consultation: Nomenclature of Biological Medicines*.

Mylan is one of the world's leading global pharmaceutical companies and in Australia is the No. 1 supplier by volume of medicines to the Pharmaceutical Benefits Scheme (PBS). About one in six PBS prescriptions is dispensed with a Mylan product*****. Our medicines include prescription, generic, brand-name and over-the-counter products in a variety of dosage forms and therapeutic categories, including tablets, capsules, injectables, topicals and transdermal patches. We also manufacture medicines right here in Australia. Of our 720 employees nationally, about 500 work at our state-of-the-art manufacturing plant in Carole Park, Queensland, where last year we produced close to 3 billion doses of tablets and capsules for the local and more than 50 export markets. Mylan Australia is a member of the Generic and Biosimilar Medicines Association (GBMA) and concurs fully with the GBMA submission to this consultation.

The consultation

TGA states that the issue it is addressing in the consultation is the *need to be able to capture accurate information about a medicine that is associated with an adverse event*. It further states that *a unique product name, or combination of details that together give the required specificity, would meet the objective*, as well as batch number information.

TGA also states that it is considering the issue in the policy context of the government commitment to support a viable and competitive market for biological medicines in Australia through the implementation of a biosimilar medicines uptake policy. The uptake of biosimilars is predicated on the regulatorily-demonstrated similarity between biosimilars and their reference medicine. Distinct non-proprietary names generally communicate product differences. In the case of biosimilars, they will suggest that there are meaningful structural and clinical differences between biosimilars and their reference medicines. This is contrary to the regulatory requirement that biosimilars must demonstrate sufficient similarity to the reference medicine in physicochemical, biological and immunological characteristics, efficacy and safety, such that clinically meaningful differences between the biosimilar and the reference product are not expected when used for approved indications. Any artificial construct of a difference between a biosimilar and its reference product, through inappropriate nomenclature, would thwart the government's efforts to fulfil its commitment to the uptake of biosimilars.

The conundrum then is that the nomenclature system must not compromise the simultaneous achievement of each of the above two outcomes.

In other markets, such as the US and Europe, the consideration of nomenclature differences between originators and biosimilars is stated to be pursued for the purposes of improved pharmacovigilance and to prevent the substitution of non-interchangeable biosimilars. Mylan Australia submits that nomenclature changes will not achieve either of these outcomes and that they are irrelevant in Australia in any case because of other policy settings.

Mylan Australia agrees that accurate, specific adverse event reporting is crucial to robust pharmacovigilance practices for both small molecule medicines and for biological medicines.

***** *Expenditure and Prescriptions Twelve Months to 30 June 2016, PBS Information Management Section Pharmaceutical Policy Branch*

However, changes to the nomenclature of biological medicines should not be advocated for based on misguided belief that they will strengthen pharmacovigilance practices and outcomes. Such changes should only be implemented if there is clear evidence and expectation such would be the case.

Mylan Australia contends that robust pharmacovigilance practices are already in place and, other than minor tweaking, there is no need for major change. Detailed information about medicines, identifying them to batch, is already present on medicine labels. The capture of this information is already possible through the TGA's online adverse event reporting system. Fields identifying a medicine to batch number already exist in the online form but are not mandatory to complete. A simple education/awareness initiative directed at prescribers, pharmacists and patients could mandate that all fields in the online form be completed.

As for inappropriate and inadvertent interchange of originators with biosimilars, Australia has a clearly defined system of "a-flagging" that prevents any confusion about what is substitutable and what is not. Inadvertent substitution therefore should not occur.

On the other hand, changes to the nomenclature of biological medicines could have significant impact on the success of the Government's policy to encourage the uptake of biosimilar medicines, and therefore on accessibility for Australians to this important, developing area of therapeutics. Biosimilar medicines are by TGA definition highly similar and their appropriate use enables more widespread access to biological medicines because of the competition they provide in the market and the resulting price reductions.

The nomenclature of biological medicines in Australia does not need to change *to be able to capture accurate information about a medicine that is associated with an adverse event*. What is needed is education about an enhanced way of completing adverse event reports. This will result in the *required specificity* being provided to the regulator *to be able to capture accurate information about a medicine that is associated with an adverse event.*

The Options

Based on the above, Mylan Australia's view on each of the options is as follows.

Option 1: The status quo has resulted in an effective and robust pharmacovigilance system. However, Mylan Australia acknowledges that minor enhancements can make it even better.

Option 2: This is the best option to be followed. Minor enhancements along the lines of better education/information/awareness about the online adverse event reporting system, together with mandatory requirement for information to batch level to be included would make an already good system even better. Most importantly it would not counter the government's biosimilars uptake policy.

Option 3: We do not believe such an elaborate system needs to be implemented in Australia when only slight enhancement of the existing system outlined in option 2 will result in the same information being made available to the regulator. If a 2D barcode system is advocated for on broader grounds, such as quality use of medicines or in anticipation of uptake of electronic prescribing and dispensing linked to patients' electronic health record, then that is not the subject of this consultation and should be considered separately. The regulatory effort and cost of implementing a 2D barcode system would be burdensome and would not address the issue of this consultation any better than enhancing the existing system as described in option 2.

Option 4: This option would not result in a greater improvement to pharmacovigilance practices than option 2 would. Yet it would counter the government's biosimilars uptake policy by inappropriately delineating biosimilars and their reference medicines as different. The use of distinguishable non-proprietary names suggests to prescribers and pharmacists that there are significant and/or clinically relevant differences between a reference product and its biosimilar when, in fact, the TGA has made a scientific and regulatory decision that there are none.

In any case, a four-letter meaningless suffix would not be particularly memorable to health care professionals and thus their usefulness in effectively identifying products would be diminished.

Conclusion

In conclusion, Mylan Australia supports Option 2 as the only option that will enable the capture of accurate information about a medicine that is associated with an adverse event, without obstructing the government's delivery on its policy commitment to support a viable and competitive market for biological medicines in Australia through increased uptake of biosimilar medicines.