Bristol-Myers Squibb

[redacted]

28 March 2019

Transparency Reforms and Evaluation Support Section
Prescription Medicines Authorisation Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

RE: TGA Consultation Response.

Bristol-Myers Squibb Australia Pty Ltd

Whether the TGA should publish that a prescription medicine is under evaluation.
Transparency reforms.

Dear Sir/Madam,

Bristol-Myers Squibb (BMS), a diversified global BioPharmaceutical company, is pleased to have the opportunity to offer comments on the TGA consultation on whether or not the Therapeutic Goods Administration (TGA) should in future, disclose earlier that a prescription medicine is under evaluation and what types of prescription medicines should be published.

BMS EXCUTIVE SUMMARY

BMS supports Option 2 (list all applications accepted for evaluation) as it best delivers against TGA's stated objective of transparency and does not distinguish between new prescription medicines, new or amended indications, new dose forms, biosimilar medicines or generic medicines. BMS believes that the publication of information should be applied consistently across all applications for medicines including that of biosimilars and generics. Option 2 also aligns the TGA with other major health authorities which have successfully implemented schemes for publishing information on applications under evaluation. Indeed, BMS suggests that the TGA should align with the extent of information published by other major health authorities which have effectively implemented such schemes.

Option 2 is also an effective means for Australia to meet its obligations under the World Trade Organisation Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and the US-Australia Free Trade Agreement (AUSFTA) which require Australia to implement a system by which patent holders receive advance notice of third party applications for marketing approval. Option 2 improves the ability of patent holders to determine patent infringement issues related to the potential launch of a generic product compared to the status quo (Option 1).

BMS does not support any of the other proposed options from TGA as they do not equitably align with the TGA's goal of increasing transparency of regulatory activities.

Detailed answers to the specific TGA consultation questions follow.

Q1: Please specify your preference in terms of information that should be included in a potential published list (e.g. active ingredient, tradename, therapeutic area versus indication, sponsor name)?

Q1 BMS RESPONSE

BMS believes that the TGA should align with the extent of information published by other major health authorities where schemes for publishing information on applications under evaluation have proven successful. Thus, BMS supports alignment with the application details publicly disclosed by the European Medicines Agency (EMA), Health Canada and Medsafe at the time of acceptance of a dossier for evaluation. This includes the date the application is accepted for evaluation by the TGA, name of the Sponsor, the active ingredients, the therapeutic and disease area, but not the proposed specific indication wording.

BMS does not support the publication of the proposed indication wording. Indication wording is a key aspect of an application that is evaluated by the TGA and can be subject to change through the evaluation process. No other major international health authority publishes this extent of information on indication wording (e.g. FDA, EMA, Japan, Singapore, Health Canada). A description of the therapeutic and disease area would be appropriate to achieve a goal of transparency.

OPTION 1: Maintain TGA's current publication arrangements

Q2: Do you support Option 1?

a). yes

If yes, provide the reasons why you support the option

b). no

If no, provide the reasons why you don't support the option

c). with modification

What changes to option 1 do you propose?

Q2 BMS RESPONSE TO OPTION 1

BMS does not support Option 1 (maintain TGA's current publication arrangements) as it does not align with the TGA's goal of increasing transparency of regulatory activities.

Q3: What would be the impact of maintaining Option 1 on you individually, or for your organisation (if affiliated)?

Q3 BMS RESPONSE TO OPTION 1

Under present arrangements (Option 1), an innovator company (patent holder) is only alerted to a potential patent infringement at the time the generic medicine is listed on the Australian Register of Therapeutic Goods (ARTG) or the Pharmaceutical Benefits Scheme (PBS) notifies the company of a reduction of price due to the PBS listing. At this point, companies have little or no time to make a considered decision regarding a patent enforcement action, therefore, forcing a rapid decision to proceed with an interlocutory injunction.

Under a Commonwealth policy approach since 2012[1], a patent holder may be subject to the pursuit of damages by the Commonwealth in patent infringement actions. This Commonwealth policy overlaid on the existing Option 1, exposes the patent holder to additional risks, potential costs and resources associated with the inability to make a more considered decision on litigation proceedings. BMS believes this is an unintended consequence of these two distinct Commonwealth practices and may be a disincentive for innovator pharmaceutical companies in making decisions to invest in Australia. Option 2 would assist to provide a more stable and equitable regulatory environment in Australia from an investment perspective (see Q4).

Additionally, in an environment where submission dates are not published, individual companies are reluctant to disclose this information for competitive reasons. This may result in a perception of a lack of transparency by external stakeholders (e.g. healthcare providers, patients, media, etc.), and it also makes it more difficult to counteract misinformed/misplaced assumptions about access to BMS medicines.

OPTION 2: list all applications accepted for evaluation

Q4: Do you support Option 2?

a). yes

If yes, provide the reasons why you support the option

b). no

If no, provide the reasons why you don't support the option

c). with modification

What changes to Option 2 do you propose?

[1] BMS notes TGA's intent to not reconsider issues already addressed by the Pharmaceutical Patents Review Report 2013 and Chapter 10 of the Productivity Commission's September 2016 report into Intellectual Property Arrangements. Both these reports largely address issues relating to the *timeframe around patents including Extension of Term, lifecycle management and other issues relating to data protection*. The specific point raised in Q3 is not addressed in the two reports, or elsewhere.

Q4 BMS RESPONSE TO OPTION 2

BMS supports the introduction of Option 2 based on the following reasons:

1. The approach is consistent with international approaches of key overseas health authorities to the publication of submissions under evaluation.

2. BMS supports an approach that is similar to the EMA and Health Canada. Specifically BMS considers the TGA should adopt the practice of publicly listing when an application to register a new prescription medicine, new or amended indication, new dose form, biosimilar medicine or generic medicine has been accepted for evaluation.

3. A bona fide transparency initiative should not distinguish between new prescription medicines, new or amended indications, new dose form, biosimilar medicines or generic medicines.

4. The community, patients and health-care providers should have access to information on when an application to register a new prescription medicine, new or amended indication, new dose form, biosimilar medicine or generic medicine have been accepted for evaluation.

5. BMS considers that this will assist Australians in determining upcoming treatments in a given therapeutic area and options for treatment which include the availability of generics or biosimilars. The publication of such information enables the public to have better informed expectations on access and timing to new innovative, generic and biosimilar medicines.

6. The availability of this information would permit more timely education and engagement for patient groups, physicians and patients on potential new/additional treatment options.

7. Publication of applications accepted for evaluation would more effectively meet Australia's obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and the Australia-United States Free Trade Agreement (AUSFTA), which requires Australia to implement a system by which patent holders receive advance notice of third party applications for marketing approval. This would afford patent holders more time to assess the risks of defending their patent than the current requirements under subsection 26B of the *Therapeutic Goods Act 1989.*

Q5: What would be the impact of implementing Option 2 on you individually, or your organization (if affiliated)?

Q5 BMS RESPONSE TO OPTION 2

Implementation of Option 2 would have the following impact on BMS:

- More transparency for patients, healthcare professionals and peak bodies on likely access and timing to BMS medicines
- For BMS, the information would offer greater visibility and predictability of the market landscape thus facilitating business decisions and planning
- Provides more time to assess whether the activity of a generic company may be infringing on a BMS patent
- Improve confidence of pharmaceutical companies to invest in Australia if there is a more balanced and equitable environment for intellectual property

In the current environment, sponsors can submit an application and withdraw it prior to receipt of the Delegate's request for Advisory Committee of Medicines (ACM) advice without any information on the fact that an application has been submitted entering the public domain. Under Option 2, knowledge of all submitted applications will come into the public domain.

OPTION 3: list all applications at two different time points

Q6: Do you support Option 3?

a). yes

If yes, provide the reasons why you support the option

b). no

If no, provide the reasons why you don't support the option

c). with modification

What changes to Option 3 do you propose?

Q6 BMS RESPONSE TO OPTION 3

BMS does not support Option 3 (list all applications at two different time points). This option does not fully serve the public interest and the interest of patients since the provision of information for different types of medicine (new versus generic) will be published at different time points. The inequity of publishing information at different time points for new medicines versus generic or biosimilar medicines is not justifiable and does not align with an objective of transparency, which should apply equally to all types of medicines. Additionally, this option would not be an effective solution to meeting Australia's obligations under TRIPS and AUSFTA.

Q7: What would be the impact of implementing Option 3 on you individually, or your organization (if affiliated)?

Q7 BMS RESPONSE TO OPTION 3

An unbalanced approach to the disclosure of information between the innovative medicines sector versus generics or biosimilars has the potential to be a disincentive for innovator pharmaceutical companies to invest in Australia.

OPTION 4: list applications of innovator medicines of highest public interest, but not generic or biosimilar medicines

Q8: Do you support Option 4?

a). yes

If yes, provide the reasons why you support the option

b). no

If no, provide the reasons why you don't support the option

c). with modification

What changes to Option 4 do you propose?

Q8 BMS RESPONSE TO OPTION 4

BMS does not support Option 4 (list applications of innovator medicines of highest public interest, but not generic or biosimilar medicines). This option does not fully serve the public interest and the interest of patients since the provision of information for different types of medicine (new versus generic) will be different. The inequity of publishing information for new medicines only versus none for generic or biosimilar medicines is not justifiable and does not align with an objective of transparency, which should apply equally to all types of medicines. Additionally, this option would not be an effective solution to meeting Australia's obligations under TRIPS and AUSFTA.

Q9: What would be the impact of implementing Option 4 on you individually, or your organization (if affiliated)?

Q9 BMS RESPONSE TO OPTION 4

An unbalanced approach to the disclosure of information between the innovative medicines sector versus generics or biosimilars has the potential to be a disincentive for innovator pharmaceutical companies to invest in Australia.

Sincerely

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