2 April 2020

Louise Clarke
Assistant Secretary,
Office of Health Technology Assessment - Policy
Department of Health,
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Woden ACT 2601
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Dear Louise

Thank you for our recent discussions on Medicines Australia's concerns regarding the proposed changes to the Public Summary Documents (PSD) process.

Medicines Australia remains supportive of the Pharmaceutical Benefits Advisory Committee's (PBAC's) objective for the publishing of PSDs to be efficient, consistent, and reflective of the committee's decision-making deliberations. We also wish to acknowledge the level of engagement and consultation afforded to industry on these important proposed changes, both the PSD processes and the PSD redaction criteria.

Medicines Australia notes that our most recent discussions with the Department resulted in the following outcomes:

- **Implementation timeframe:**
  - The single opportunity for review will begin from the July 2020 PBAC meeting.
  - Agreement from the Department of Health to delay implementation of the proposed changes to the PSD redaction criteria until the November 2020 PBAC meeting.
  - The delay to implementation of the PSD redaction criteria is essentially an extension of the pilot under which:
    - The trial process will be conducted in parallel with the current process to enable applicants to test the criteria,
    - Where there is a difference between the trial version and the version developed under the existing arrangements, applicants choose which version of the PSD they wish to have published.
- The department intends to publish **the finalised procedure guidance** in April 2020, to allow sufficient time for applicants to understand the new rules ahead of the July 2020 cut off for the November 2020 PBAC meeting.

- **Redaction criteria**: Strong support from the Department of Health for Medicines Australia to proactively monitor this issue and that the AMWG Transparency and Efficiencies sub-group should review and discuss at 6 months and 12 months post implementation. As MA has continually noted, we remain extremely concerned that the clinical data redaction criteria are still too narrow and may have the adverse impact of applicants not including all potentially relevant data in PBAC submissions. Additionally, applicants may not be able to take advantage of the parallel process and/or be significantly de-prioritised by the global organisation as a launch market if these proposed changes were implemented and confidentiality of data was not assured.

Medicines Australia also notes that significant administrative burden for applicants (both locally and globally) is associated with the proposed redaction criteria and processes.

Medicines Australia welcomes the inclusion of the "disclaimer" statement and the revision of the ICER and Budget impact ranges to ensure that back-calculation of a confidential price cannot occur. MA believes it would be prudent to seek some legal advice on the words of the disclaimer, and will be seeking some advice in due course.

Medicines Australia has reviewed the revised Procedure Guidance provided to us on Sunday March 29, 2020 and our comments and suggested changes are attached.

While Doh has advised that Attachment A is the guidance document which supports the information in the Procedure Guidance, Medicines Australia believes it is a critical part of the guidance, particularly because it was part of the original consultation document, and is referred to on pages 1 and 3 of the draft Procedure Guidance. Medicines Australia believes that consultation on the PSD Procedure Guidance documents are not complete until MA has been able to comment on Attachment A.

Medicine Australia seeks a response from the Department of Health as to the broader transparency issues raised in our submission on the 16 December and elsewhere, in particular:

- Greater transparency with regards to PBAC decision making in PSDs to include further detail to assist readers in understanding the basis for each PBAC determination of interchangeability.
- Greater transparency with regards to PBAC decision making in PSDs to include further detail to assist readers in understanding the clinical expert advice that has been sought by PBAC and how that advice has informed the PBAC recommendation.
- Greater transparency of the intra-cycle PBAC meeting agendas

Medicines Australia re-iterates its thanks for the open and constructive dialogue on this topic and requests the Department/ PBAC to continue to engage to ensure the changes benefit all stakeholders. If you would like to discuss any aspect of this submission further, please feel free

to contact Greg Cook on 0417-105746, who is leading the Medicines Australia response on this issue.

Yours sincerely,

Elizabeth de Somer
CEO
Medicines Australia

Attachments: Medicines Australia comments on the revised Procedure Guidance provided to MA on Sunday March 29, 2020.

Cc: Andrew Mitchell, Amanda Aldred, Zoe Spry