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Dear Sir/Madam

Public consultation on standardised redaction of Public Summary Documents

Medicines Australia (MA) welcomes the opportunity to provide comment on the PBS Process Improvements consultation on the standardised redaction of Public Summary Documents (PSDs). This feedback has been consolidated based on input from the MA representatives on the Streamlined Pathways Subgroup of the Access to Medicines Working Group (AMWG), the Health Economic Working Group and have also included wider perspective from the Medicines Australia membership.

Overall, Medicines Australia is supportive of the Pharmaceutical Benefit Advisory Committee's (PBAC) objective for the publishing of PSDs to be efficient, consistent and reflective of the committee's decision-making deliberations in order to enhance transparency with stakeholders. We are also supportive of a consistent approach across the regulatory and reimbursement processes of bringing new medicines and therapies to Australia. Notwithstanding, we are also in favour of this approach being consistent with Australian legislation, in place to protect Australian industries and the global environment in which our industry operates.

One of Medicines Australia's gravest concern is the **unintended consequences** of the proposed definitions of Academic-in-Confidence (AiC) and Commercial-in-Confidence (CiC) which are many-fold including;

- delays in new medicines submissions to the PBAC in Australia, due to the disproportionate risk of indiscriminate publication of confidential clinical material that may jeopardise the companies' commercial interests elsewhere, or harm future academic publication plans. This means that sponsors may choose to delay submitting to Australia until they are confident about how the confidential clinical data will be secured, and
- delays in PBAC decision making as local sponsors may not be permitted by their parent companies to undertake post-hoc, subgroup analysis requested by the PBAC, which may lack the scientific rigor and statistical validity required to support publication. Medicines Australia has proposed that a qualitative summary of the additional analyses could be included to explain the decision rather than exposing the analyses themselves.

In alignment with the *Freedom of Information Act 1982*, the Therapeutic Goods Administration (TGA) is required to provide open access to information held by government and transparency about government decision making. As we have outlined in our submission, Section 47G of the Act provides for a public interest conditional exemption for documents which concern a person in respect of their business, commercial or financial affairs. This section provides for a potential exemption from disclosure when the disclosure of such information would unreasonably affect that business adversely or could be expected to prejudice the future

supply of information to the Commonwealth or an Agency for the purpose of administration of a law. Medicines Australia strongly believes that it is possible to develop AiC and CiC criteria consistent within this Act to avoid the untended consequences listed above.

Medicines Australia's submission also addresses the issue of introducing process and content changes, in **timelines that do not allow for reasonable business planning**. It is our firm view that the proposed timelines for implementation of the content changes are unacceptable. The need to consider business planning has previously being recognised by the Department, resulting the a more appropriate introduction of new government policy.

Medicines Australia is supportive of the Department's proposed revised standard ranges for presenting economic and financial information in PSDs on the condition that there is no possibility of **back-calculating to derive the confidential effective price**. It also wishes to flag its early and strong opposition to any additional proposals to further minimise redactions to economic and financial information (as proposed by the Department for consideration post-March 2020). To disclose such confidential commercial information would have a significant impact on the price levels offered and the ability of sponsors to seek and gain reimbursement in Australia.

With these three key concerns in mind, the following submission recommends the following:

- widening of criteria for AiC to realistically represent the diversity and complexity of the publication process;
- developing balanced CiC criteria, aligned with existing Government standards, in consultation with industry to ensure that the most relevant data is available to inform decision making;
- including the option of a qualitative summary of the redacted clinical data to explain the PBAC decision rather than the actual analyses;
- Introducing an independent review or appeals process to ensure procedural fairness prior to PSD publication;
- Introducing revised ranges for presenting economic and financial information in PSDs on the condition that there is no possibility of back-calculating to derive the confidential effective price, and
- Delaying implementation until at least July 2020 to ensure appropriate consultation and co-creation of AiC and CiC criteria and to allow for appropriate business planning, consistent with the approach taken to other changes, such as Cost Recovery.

Thank you for the opportunity to provide feedback on the proposed standardised redactions of public summary documents and we look forward to working with you once you have reviewed all submissions.

If you would like to discuss any aspect of this submission further, please feel free to contact Betsy Anderson-Smith on banderson-smith@medaus.com.au.

Yours sincerely

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Director, Policy and Research
Medicines Australia

Medicines Australia Submission

Public Consultation – Standardised Redactions of Public Summary Documents

Executive Summary

Medicines Australia is supportive of the Pharmaceutical Benefit Advisory Committee's (PBAC) objective for the publishing of Public Summary Documents (PSDs) to be efficient, consistent, and reflective of the committee's decision-making deliberations, as well as transparency efforts that have a clear benefit for patients, healthcare practitioners and other relevant stakeholders. To ensure that changes to the PSD redaction process have no unintended consequences of delays in medicines access for patients, Medicines Australia requests:

- widening of criteria for academic-in-confidence (AiC) to realistically represent the diversity and complexity of the publication process
- developing balanced commercial-in-confidence (CiC) criteria, aligned with existing Government standards, in consultation with industry to ensure that the most relevant data are available to inform decision making
- including the option of a qualitative summary of the redacted clinical data to explain the PBAC decision rather than the actual analyses
- introducing an independent review or appeals process to ensure procedural fairness prior to PSD publication
- introducing revised ranges for presenting economic and financial information in PSDs on the condition that there is no possibility of back-calculating to derive the confidential effective price.
- delaying implementation until at least July 2020 to ensure appropriate consultation and co-creation of AiC and CiC criteria and to allow for appropriate business planning, consistent with the approach taken to other changes, such as Cost Recovery.

Summary of Medicine's Australia's position and recommendations

Key issues and concerns

Medicines Australia is supportive of the PBAC's objective for the publishing of PSDs to be efficient, consistent, and reflective of the committee's decision-making deliberations. Industry shares the view that transparency is in general helpful, and must be conducted in a way that improves outcomes for stakeholders. However, Medicines Australia believes that the proposal to publish all clinical evidence relied upon by the PBAC to inform its decision-making process will lead to either significant omissions of unpublished clinical data from PBAC submissions or potential delayed lodgement of submissions. Australian affiliates will not submit analyses as their parent companies will not permit publishing of confidential clinical data. This will lower the level of relevant information relevant for decision making, which, in turn, may lead to an increased risk of initial submissions being delayed, greater uncertainty for the PBAC in their deliberations if important data are missing, increased rejections, submission churn and resultant delays to Australian patients accessing new medicines via the PBS. All stakeholders should anticipate detrimental effects to the system and delayed patient access to innovative therapies if all clinical data is made transparent.

Limiting the scope of the Academic-in-Confidence (AiC) redaction criteria and no Commercial-in-Confidence (CiC) exemption criteria do not represent 'process improvements', as defined in the Strategic Agreement. The proposal does not meet existing Government standards for confidential information.

Content-related recommendations

To remove the risk of delayed access to medicines for patients, Medicines Australia recommends that i) the proposed AiC redaction criteria for clinical data be broadened to realistically represent the diversity and complexity of the publication process, and ii) CiC redaction criteria be developed, and agreed with Medicines Australia, so that a more balanced approach can be taken. This more balanced approach should recognise the need for the PBAC to support its recommendations with evidence, and the data owner's right and/or licensee's obligation to maintain confidentiality.

Medicines Australia requests the Department of Health (Department) further consults to ensure the CiC criteria are consistent with Australian legislation and with other Government agencies, including the Therapeutic Goods Administration (TGA). Medicines Australia believes any proposed changes be considered in the context of the Strategic Agreement and wider agreements such as the Australia-US Free Trade Agreement (Aus-US FTA) which provides context about the treatment of confidential information.

Process-related recommendations

Medicines Australia requests that a review or appeals process be implemented for sponsors who are not able to agree with the redaction decisions of the Department. Sponsors must have sight of the finalised PSD to facilitate this review or appeal process prior to publication. The procedure guidance should clearly articulate the review process, including roles and responsibilities and timeline, as well as acceptable criteria for justifying redactions. It is assumed that this process will respect the data owner's right and/or licensee's obligation to maintain confidentiality.

Implementation-related recommendations

For the process changes, it is requested that the education process and updated procedure guidance be provided well in advance of the November 2019 PBAC outcomes. Given the concerns raised by Medicines Australia, it is proposed that the Department provide an adequate notice period for implementation of the content changes. Implementation should be no earlier than for submissions lodged in March 2020 for the July 2020 PBAC meeting, given feedback from sponsors lodging in November 2019 for the March 2020 meeting that they are well advanced with these submissions, and have already committed to redacting unpublished clinical data in order to gain approval from their parent companies or via agreements with 3rd party data owners (for in-licence products) to include particular analyses. Furthermore, the proposed July 2020 implementation date is only agreed on the condition that all areas of concern have been addressed prior to October 2019.

While the Strategic Agreement does not specifically foreshadow PSD standardised redactions as a 'process improvement', it does state that "*any new agreed initiatives will be enacted through collaborative effort between the Department and Medicines Australia, recognising the important role of individual sponsors in supporting these goals*" (clause 10.3.2). Medicines Australia respectfully requests that the Department and the PBAC recognise the important role of medicines sponsors in supporting these proposed PSD redaction changes.

Background

On 30 July 2019, the Department of Health held an information forum on process improvements to standardise the redactions of PBAC PSDs. Subsequently, a consultation paper was posted on the Department's website, stating the PBAC's preference for greater transparency to be introduced into PSDs through a phased approach: phase 1 focuses on changes to the negotiation process and phase 2 aims to introduce standardised redactions of PSD information.

PHASE 1 – Changes to Negotiation Process

From the **November 2019 PBAC meeting**, it is proposed by the Department that sponsors will have one (**single**) opportunity to review and seek redaction of PSD information prior to publication (Consultation Paper, page 2). This initial change is aimed at increasing efficiency through improving negotiation processes between the Department and sponsors in relation to PSD redactions.

Medicines Australia is supportive of the Department's proposal to streamline the PSD redaction process. It understands that the current process for identifying and agreeing the redaction of information within a PSD in some cases diverts resources from other important PBS-related activities for both sponsors and the Department, such as post-PBAC listing steps, and importantly has led to potential inconsistencies in the information published in PSDs. However, Medicines Australia is concerned that sponsor companies will not be afforded due process or procedural fairness should a dispute arise as a result of their one opportunity to seek redaction of PSD information prior to publication.

Therefore, Medicines Australia calls for an independent review/appeals mechanism to be established and that guidance on how and when to access this review mechanism be clearly defined and incorporated into all educational and PSD guidance material. Sponsors must have sight of the finalised PSD to facilitate this review or appeal process prior to publication. Sponsors must also have a clear understanding of what best practice looks like in terms of the required approach to justifying PSD redactions. It is important for sponsors to be fully aware of changes to the PSD processes well before submission to ensure a reasonable opportunity to plan for the changes.

For the process changes, it is requested that the education process and updated procedure guidance be provided well in advance of the November 2019 PBAC outcomes. To aid both education and implementation Medicines Australia proposes delaying the introduction of changes to the PSD processes until July 2020.

PHASE 2 – Introduction of Standardised Redactions

Publication of all clinical evidence relied upon to inform PBAC decision-making represents a changed approach to publication of data in the clinical trials, comparative effectiveness, comparative harms, benefits/harms, and clinical claim sections of the PSD. The Department have proposed that an exception may apply where sponsors meet the criteria for 'academic exceptions' (Consultation Paper, page 4). During consultation with the Access to Medicines Working Group Streamlined Pathways Subgroup (AMWG-SPS), concerns were raised regarding disclosure of information considered to be commercial-in-confidence; however, the PBAC does not consider 'commercial-in-confidence' issues apply to the publishing of clinical data used for deliberations, a position with which Medicines Australia disagrees.

Publication of all clinical evidence relied upon by the PBAC to inform its decision-making process: 'Academic exception'

Medicines Australia has received extensive feedback from sponsors who are extremely concerned that the proposed AiC exception criteria are too narrow and do not allow for many of the publication scenarios that local sponsors face when attempting to gain global approval to include clinical data within PBAC submissions. Furthermore, the proposed AiC criteria must recognise that it is not just the clinical data in the manuscript that are commercial-in-confidence but also that the intent of the data in the manuscript are also captured. For example, if the manuscript includes the point estimate for the primary efficacy endpoint but not the 95% confidential interval around it, this does not mean that the confidence interval remains unredacted in the PSD.

The consequences associated with a narrow approach to AiC exceptions include the risk that parent companies reject Australian affiliates' request for inclusion of particular efficacy and safety data in a PBAC submission. The submission may not be able to proceed, or otherwise proceeds with a lower level of evidence relevant for reimbursement decision making. The implication of both scenarios is potential delayed access for patients to medicines.

The academic exception criteria need to realistically represent the complexity and diversity of the publication process. Medicines Australia has attempted to categorise the various scenarios described by member companies and details them in Table 1 below.

Table 1: Potential Academic-in-Confidence scenarios that do not fit the proposed exception criteria

Examples of data which may not be included in PBAC submissions because they don't fit the proposed AiC redaction criteria	***Reason***
Efficacy and safety data from key clinical studies that have not been submitted for publication at time of PBAC submission.	• The ability of sponsor companies to submit a reimbursement application in Australia in parallel with their registration dossier means that key clinical trial data for a new medicine/ indication may not yet to be submitted for publication in a journal. • As this situation does not meet the exception criteria for AiC, parent companies may reject Australian affiliate requests for inclusion of particular efficacy and safety data in a PBAC submission, and the submission may not be able to proceed, delaying access for patients. • This would not be informative for the PBAC where certain data or analyses are excluded in a submission because of the risk of publication in a PSD.
Patient reported outcomes from key clinical studies that have not been submitted for publication at time of PBAC submission.	• Often, patient reported outcomes (PROs) are classified in clinical trials as secondary or subsequent endpoints and not part of the primary journal publication. • As this situation does not meet the exception criteria for AiC, parent companies may reject Australian affiliate requests for inclusion of PRO data in a PBAC submission.
Indirect treatment comparison (ITC) specific to comparators in the Australian healthcare system, using unpublished data.	• Rarely are these ITC data analyses published, and for the small percentage that are, they are usually published in a journal well after PBAC consideration.

	• As this situation does not meet the exception criteria for AiC, parent companies may reject Australian affiliate requests for inclusion of ITC data in a PBAC submission. • In contrast, if the ITC analysis was based on published data for both the proposed medicine and comparator, publication of this ITC in the PSD would be acceptable given that the analysis could be re-created by other parties using other sources.
The sponsor is not responsible for relevant clinical trial data – e.g. a clinical organisation may be running the relevant clinical study.	• In this situation, sponsors are unlikely to know, or be able to find out, the publication plans and status of any manuscripts that the clinical organisation may be working on. • As this situation does not meet the exception criteria for AiC, local affiliates may need to exclude relevant clinical data.
Data may only be published in a conference poster or oral presentation but not in a manuscript (or not in a manuscript for a long time).	• This would not meet the current AiC criteria and thus sponsors would not be able to present these data in the PSD, impairing the PBAC's decision making ability, and potentially preventing sponsors from making a submission.

Presently, parent companies recognise and welcome the benefits of a parallel reimbursement process where early consideration of clinical data and resulting PBAC decisions can deliver earlier access for Australian patients. In supporting the parallel process, there is a recognition that PSDs will be published early as part of a global launch sequence. Companies manage this benefit/risk by allowing inclusion of clinical trial data in line with the scenarios outlined in Table 1 above, on the understanding that unpublished data is able to be redacted.

Should the strict AiC exception criteria be implemented as proposed, PBAC submissions are likely to contain little more clinical data than that in the key study trials' primary publication. As a result, clinical data relevant to HTA decision making may be reduced, uncertainty increased, PBAC rejection rates likely to escalate and patient access to medicines that improve health outcomes placed at risk. In some cases, the submission will not proceed or will occur much later, because it will not be possible to adequately articulate the unmet need and the clinical value of the medicine for Australian patients with a suboptimal dataset.

As such, Medicines Australia strongly urges the Department to broaden the proposed clinical data 'academic exception' criteria rule, such that the clinical data described in many of the scenarios in Table 1 above can be included in future PBAC submissions and remain redacted. Medicines Australia believes that submissions should include as much data as possible to help inform the PBAC and so that potential areas for uncertainty can be reduced.

Medicines Australia requests several potential options for AiC redaction criteria, given the varied approaches taken by sponsors to the publication process. Medicines Australia understands that some sponsors have extensive publication plans for medicines which may run over many years. As such, Medicines Australia would like to jointly explore with the Department that criteria for data redaction based on AiC be expanded to include data that is planned for submission to a journal. In this situation, the sponsor could submit the publication plan as evidence in support of any AiC exception claim, where possible, or the Medical Affairs Lead for the medicine could outline the plans for publication. It is important to note that the Department would need to acknowledge that this information in the publication plan remain confidential. It is important for the Department to also recognise that for some sponsors or medicines the publication plan may not be controlled by the sponsor company.

Alternatives to this proposal, where a publication plan is not available, is for sponsors to proactively alert the Department when the clinical analysis is published and in the public domain (which would then trigger unredaction of previous unpublished clinical data) or redacted AiC data are automatically unredacted at 12 months after publication of the PSD.

Publication of all clinical evidence relied upon by the PBAC to inform its decision-making process: 'Commercial exception'

Medicines Australia believes the meaning within the Australian legal context of 'commercial-in-confidence' (CiC) could include unpublished clinical data or analyses and where disclosure may undermine the economic interest or competitive position of the sponsor. Medicines Australia urges the Department to consult widely, including obtaining a legal view if not previously sought, before any implementation of this proposal. In particular, Medicines Australia requests the Department seek further advice on the appropriate definition of 'commercial-in-confidence' such that its application in a PSD is comparable to other areas of the Australian Government, including agencies, legislation and agreements. Medicines Australia has received legal advice on these matters.

Sponsors often present unique, Australian HTA-specific clinical analyses within their PBAC submissions – either proactively or in response to the Evaluator, Economic Subcommittee (ESC) or PBAC's request for specific data (see Table 2). Parent companies understand that publication of any post-hoc analyses conducted to assist country-level HTA decision-making may not be generalisable outside of particular jurisdictions and settings. They are, however, concerned that these data may be misinterpreted outside of the local context and as such present potential commercial risks that may undermine economic interests in other countries. These data may be context specific and should remain redacted from the PSD documents. Sponsors have experienced that publication of such data can be misleading and unnecessarily cause concern for patients and prescribers. An example of this is the German IQWIG publication of a finding of 'hint of harm' in girls from a statistically non-significant post-hoc analysis of an insulin product where a subgroup of N=18 was analysed (http://www.pmlive.com/pharma_news/iqwig_unimpressed_with_tresiba_for_children_749773).

Some Global sponsor organisations currently allow inclusion of what they view as commercial-in-confidence data within PBAC submissions as they have been assured by their local affiliate that these data can be redacted to mitigate this commercial risk. Should this change, parent companies would not provide clearance for post-hoc data to be included in a PBAC submission and local sponsors would need to prove the cost-effectiveness of their medicine without this sometimes important data to inform reimbursement decision making, or submissions would not proceed. This would likely lead to a significant delay with regards to PBAC approval and patient access to new medicines.

Table 2: Potential Commercial-in-Confidence scenarios relating to clinical data

Examples of data which may not be included in PBAC submissions because they are considered commercial in confidence	***Reason***
Post-hoc subset data analyses specific to the Australian HTA system and/or in response to Evaluator or PBAC requests.	• Rarely are these post-hoc subset data analyses published, as they are often not considered statistically robust. Publication of these exploratory results would not be accepted or suitable under the journal peer-review process, and could be reputationally damaging for sponsors. For the small percentage that are, they are usually published in a journal well after PBAC consideration, having typically been developed during the submission development phase or while the submission was under evaluation. • As this situation does not meet the exception criteria for AiC, parent companies may reject Australian affiliate requests for inclusion of post-hoc subset data analyses in a PBAC submission.
Post-hoc data analyses (e.g. subgroup analysis) conducted by the Evaluator and/or Department during the evaluation process.	• These post-hoc data analyses are not published. • This situation does not meet the exception criteria for AiC, with parent companies in the past requesting redaction of this data on the basis of CiC – i.e. not wanting post-hoc data analyses that are specific to the Australian HTA system and conducted by non-applicant people being published and potentially causing confusion or commercial risk in other jurisdictions.
Post-hoc, non-pre-specified interim analyses which are performed for HTA purposes.	• These analyses are often not published as they are not pre-specified and thus, this would preclude presentation of such data in a submission unless there were CiC exceptions.
Unpublished safety data	• It is possible that the PBAC will see/review emerging safety data prior to the Regulator reviewing/taking a position on the data.

While not called out in the proposed criteria for clinical data redaction, Medicines Australia believes there is a need for criteria to be developed and agreed with Medicines Australia to allow for redaction of clinical data for 'commercial-in-confidence' reasons. Any agreed criteria will need to be specific to the preparation of a PSD and not relevant to other areas of the reimbursement process, such as pricing, risk-share negotiations and other post-PBAC recommendation processes.

From a legal perspective, the concept 'commercial in confidence' encompasses:

- the quality of confidentiality; i.e. the information is not publicly available or readily discoverable and has been disclosed by one person to another on a confidential basis; and
- the concept of harm; i.e. if released, there would be potential or likely harm or competitive detriment to the commercial interests of the owner of the confidential information.

Medicines Australia requests that the Department consider the definition of 'commercial-in-confidence' in the context of Australian legislation, agencies as well as wider Government agreements such as the Australia-US Free Trade Agreement (Aus-US FTA). It is important to be consistent with how other Government departments deal with commercially-sensitive material.

The following approaches are used within the Australian Government to ascertain what is believed to be commercial in confidence (Table 3). It seems reasonable that these definitions of commercial-in-confidence would be deemed appropriate to apply to unpublished clinical data, post-hoc ITC or subgroup analyses conducted solely for the purposes of a PBAC evaluation.

Table 3. Definitions of commercial in confidence within Australian Government agencies, legislation and agreements

Australian Government agency/legislation	**Definition of commercial in confidence and implications**
Free of Information (FOI) Act	Although the FOI Act does not use the term "commercial-in-confidence", section 47 of the Act provides an exemption from disclosure in response to a freedom of information application, where a document discloses: • *trade secrets; or* • *any other information having a commercial value that would be, or could reasonably be expected to be, destroyed or diminished if the information were disclosed.* Documents that meet either of these criteria do not need to be disclosed, and are not subject to weighing against the public interest to determine if the document should be released. Section 47G of the FOI Act also provides for a public interest conditional exemption for documents which concern a person in respect of their business, commercial or financial affairs. This section provides for a potential exemption from disclosure when the disclosure of such information would unreasonably affect that business adversely or could be expected to prejudice the future supply of information to the Commonwealth or an Agency for the purpose of administration of a law.
Therapeutic Goods Administration (TGA)	The TGA has published the *TGA Approach to disclosure of commercially confidential information*, which *"provides guidance as to how official information of a business or commercial nature, provided to the TGA, is treated" (*https://www.tga.gov.au/sites/default/files/regulation-basics-disclosure-cci-140514.pdf.) The TGA has adopted the definition of "commercially confidential information" used by the European Medicines Agency (EMA), being: *"Any information which is not in the public domain or publicly available, and where disclosure may undermine the economic interest or competitive position of the owner of the information".* The TGA guidance describes the following as the kind of information that is likely to be "commercially confidential information": "*1. certain kinds of information about therapeutic goods - depending on the nature of the product, this might include (but is not limited to), information or data about the formulation or the active ingredient, methods of extraction and manufacture, certain information about clinical trials, testing methods and*

	validation of manufacturing processes, "trade secrets", design information, the outcome of testing of a product or investigations into its performance, information about the manufacture of particular batches, information about the manufacturing processes applied to batches, aspects of adverse event reports and related information, information provided as part of a recall, post-market studies/performance/safety information about the product. *2. certain kinds of information about a manufacturer or supplier – this might include information provided for the purpose of obtaining a manufacturing licence or conformity assessment certificate, information about manufacturing and product processes obtained in the course of, or for the purposes of, Australian or overseas inspections and clearances, site master files etc, and* *3. financial or commercial information including about a sponsor or manufacturer and its business (provided for instance in an application to pay by instalments or for an exemption from annual charges, or evaluation or assessment fees), the identity of suppliers, marketing information and business strategies etc, information provided as part of a procurement process including for instance, about the financial viability of a company, pricing structure and profit margin."* The Consultation Paper has made no reference to these considerations, focussing solely on principles 1 and 2 (at Attachment A to the TGA guidance) which relate to open access to information and transparency of decision-making. TGA Guidance Principle 3 (not cited in the Consultation Paper) relates to appropriate protection of trade secrets and intellectual property rights, and highlights that: *"Therapeutic goods regulators hold information that has a significant commercial value that may have involved a considerable investment in resources and effort to compile. Disclosure of information that would discourage future investment and innovation in the therapeutic goods industry without clear public health benefits could have long term effects on investment in public health*." In addition, the Consultation Paper refers to the TGA's AusPAR guidance (https://www.tga.gov.au/book/appendix-2-0.) focussing on section 7 of Appendix 2 - the principles to be applied for the deletion of commercially confidential information and personal information, in respect of clinical and nonclinical data. This section of the AusPAR guidance makes it clear that detailed information about study methods could be regarded as trade secret, upon justification from a sponsor, and, development plans relating to other indications in development could also be commercially confidential information in specific cases. Having regard to the balance of the guidance, **it is clear that detailed data which are not directly necessary for the purposes of the TGA's decision-making will be more likely to be considered commercially confidential**. It is also important to have regard to the TGA's general approach to commercially confidential information expressed in that AusPAR guidance. In section 1 of Appendix 2 to the AusPAR guidance, the TGA states that *"Openness and transparency of the regulatory process is important in the promotion of public health. However, unless there is an overriding public interest in disclosure, the TGA will refrain from disclosing* [commercially confidential information] *CCI or personal information."* That is, **the view of the sponsor is a relevant consideration in determining whether certain**

	commercially sensitive information should be protected from publication. It is important to note that the timeframe to publication of AusPAR's tends to be significantly longer than the time taken to publish PSDs, and that the clinical data published in PSDs may not have comprised part of the regulatory package submitted to the regulator for marketing authorisation, especially if the analysis has been requested specifically by the PBAC in their assessment of the cost-effectiveness of the medicine.
Australia-US Free Trade Agreement	Consideration should be given to the provisions of the Australia-US Free Trade Agreement, which were the impetus for introduction of PSDs. Annex 2-C: Pharmaceuticals to Chapter 2 - Chapter 2 - National Treatment and Market Access for Goods (including Pharmaceutical Benefits Scheme) (https://dfat.gov.au/about-us/publications/trade-investment/australia-united-states-free-trade-agreement-guide-to-theagreement/Pages/2-national-treatment-and-market-access-for-goods-including-pharmaceutical-benefitsscheme.aspx.) (dated 6 March 2004) provides, at 2-C(2): *"To the extent that a Party's federal healthcare authorities operate or maintain procedures for listing new pharmaceuticals or indications for reimbursement purposes, or for setting the amount of reimbursement for pharmaceuticals, under its federal healthcare programs, it shall:* *(a) ensure that consideration of all formal proposals for listing are completed within a specified time;* *(b) disclose procedural rules, methodologies, principles, and guidelines used to assess a proposal;* *(c) afford applicants timely opportunities to provide comments at relevant points in the process;* *(d)* ***provide applicants with detailed written information regarding the basis for recommendations or determinations regarding the listing of new pharmaceuticals or for setting the amount of reimbursement by federal healthcare authorities****;* *(e)* ***provide written information to the public regarding its recommendations or determinations, while protecting information considered to be confidential under the Party's law****; and* *(f) make available an independent review process that may be invoked at the request of an applicant directly affected by a recommendation or determination."* Any proposal which does not permit consideration (and appropriate protection) to be given to confidential information is contrary to the Australia-US Free Trade Agreement. That Free Trade Agreement provided the basis for the principles of transparency adhered to today, including the publication of PSDs as a way of communicating PBAC outcomes to the public.

It is Medicines Australia's belief that unpublished clinical data or analyses prepared for a submission be considered 'commercial-in-confidence' data since the primary purpose is to inform the PBAC about the cost-effectiveness and subsequent pricing of a proposed new medicine. These analyses are often not published elsewhere and therefore could be considered a trade secret. If these data or analyses are relied on by the PBAC for the purposes of reaching its decision whether or not to recommend a particular listing, Medicines Australia proposes that a qualitative summary of the additional analyses be included to explain the decision rather than the analyses themselves.

Publication of revised standard ranges for presenting economic and financial information

Specific values for certain types of information such as incremental cost-effectiveness ratios (ICERs), patient numbers and financial implications are currently replaced within PSDs with a selection from a standardised set of ranges. Sponsors and Medicines Australia deem this necessary as publication of specific values will lead to direct derivation of commercially-sensitive information such as effective prices (disclosing confidential discounts and rebates) and market projections.

Medicines Australia is supportive of the Department's proposed revised standard ranges for presenting economic and financial information in PSDs on the condition that there is no possibility of back-calculating to derive the confidential effective price. It also wishes to flag its early and strong opposition to any additional proposals to further minimise redactions to economic and financial information (as proposed by the Department for consideration post-March 2020). In introducing revised standard ranges and to reinforce its strong concerns with any further redactions to economic and financial information, Medicines Australia believes the proposed revision must be underpinned by the principle that disclosure will not reveal any sensitive commercial information (such as confidential effective price, discount, rebate or market estimates).

To disclose such confidential commercial information would have a significant impact on the price levels offered and the ability of sponsors to seek and gain reimbursement in Australia.

In addition, Medicines Australia believes that any proposed ranges be tested with current PSDs to ensure confidential information will not be revealed and such that no other unintended consequences are observed.

Timing of the proposed changes

Following the August consultation Medicines Australia has raised significant concern that sponsors who lodged submissions in July 2019 for the November 2019 PBAC meeting did so without knowledge of the proposed process change and therefore had no opportunity to change course, should they have concerns and wish to do so. For the process changes, it is requested that the education process and updated procedure guidance be provided well in advance of the November PBAC outcomes.

Further, sponsors lodging in November 2019 for the March 2020 PBAC meeting are well advanced with regards to data inclusion for their submissions. That is, they have already made decisions about what to include in the submission and committed to redacting data in order to gain approval for data inclusion from their parent companies. These sponsors do not have finalised criteria for redaction exceptions and do not have a reasonable opportunity to revise plans with a clear understanding of the revised criteria. Therefore, it is requested that the Department provide an adequate notice period and that, given feedback from many sponsors, implementation of the content changes should be no earlier than for submissions lodged in March 2020 for the July 2020 PBAC meeting.

This timeline would then be aligned with the introduction of Stage 2 PBS Process Improvements and all stakeholders could align and work towards this common date. However, the July 2020 implementation is only agreed on the condition that all areas of concern have been addressed in October 2019. Sponsors require at least one cycle to develop a submission, including the clinical data required for an application

While the Department has consulted Medicines Australia on the proposed changes, it is crucial that adequate notice and guidance is publicly available. It is important that sponsors are provided with ample notice of any changes well before any submission cut-off for a particular PBAC meeting date proposed for implementation.

Conclusion:

Medicines Australia is supportive of the PBAC's objective for the publishing of PSDs to be efficient, consistent, and reflective of the committee's decision-making deliberations, as well as transparency efforts that have a clear benefit for patients, healthcare practitioners and other relevant stakeholders. However, Medicines Australia believes the proposal to publish all clinical evidence relied upon by the PBAC to inform its decision-making process will lead to significant omissions of unpublished clinical data from PBAC submissions. This will, in turn, lead to an increased risk of initial submissions being delayed, as well as greater uncertainty for the PBAC in their deliberations if important data are missing, rejections, submission churn and resultant delays to Australian patients accessing new medicines via the PBS.

To ensure that changes to the PSD redaction process have no unintended consequences of delays in medicines access for patients, Medicines Australia requests:

- widening of criteria for AiC to realistically represent the diversity and complexity of the publication process
- developing balanced CiC criteria, aligned with existing Government standards, in consultation with industry to ensure that the most relevant data are available to inform decision making
- including the option of a qualitative summary of the redacted clinical data to explain the PBAC decision rather than the actual analyses
- introducing an independent review or appeals process to ensure procedural fairness prior to PSD publication
- introducing revised ranges for presenting economic and financial information in PSDs on the condition that there is no possibility of back-calculating to derive the confidential effective price.
- delaying implementation until at least July 2020 to ensure appropriate consultation and co-creation of AiC and CiC criteria and to allow for appropriate business planning, consistent with the approach taken to other changes, such as Cost Recovery.

The Consultation Paper cites the "overarching commitment" found in the Strategic Agreement to improving the *"efficiency, transparency and timeliness of PBS listing processes"*. While the Strategic Agreement does not specifically foreshadow PSD standardised redactions as a 'process improvement', it does state that "*any new agreed initiatives will be enacted through collaborative effort between the Department and Medicines Australia, recognising the important role of individual sponsors in supporting these goals*" (clause 10.3.2). Medicines Australia requests that the Department and the PBAC recognise the important role of medicines sponsors in supporting these proposed PSD redaction changes.