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Dear Sir/Madam

MEDICINES STATUS WEBSITE: CONSUMER VIEW CONSULTATION

Medicines Australia (MA) appreciates the opportunity to provide comment on the consultation paper specific to the introduction of a consumer-friendly Medicines Status Website (MSW). MA fully supports greater transparency for consumers, and in doing so, stresses the importance of providing relevant information that meets the needs of consumers.

Overall, MA agrees that publication on the consumer-friendly MSW of: i) Submission Type, ii) PBAC Meeting Date and Closing Date for Consumer Comments, iii) PBAC Outcome, iv) Link to Public Summary Document (PSD), and v) Date PBS Listed will be valuable for consumers. However, MA has some concerns as to the value of the information specific to: i) Date the Notice of Pricing Intent was submitted, ii) Positive Recommendation Pathway selected by the Sponsor, iii) Pricing Offer submitted, and iv) Pricing Agreement Accepted. There may be competition law issues associated with publishing pricing information. MA is seeking legal advice on this matter, and recommends the Department of Health (DOH) also seeks legal advice on the publication of such information.

From an industry perspective, MA believes that publication of any material on the consumer-friendly MSW should observe the following principles:

- Respect commercial-in-confidence documents, commercial arrangements, competition and patent issues, and any publication should not undermine the process or engagement. To that end, MA requests that the following fields not be part of the MSW, until MA and the DOH have sought legal advice regarding compliance with competition law to enable an informed decision:
 - o date that “Notice of Intent for Pricing” form submitted
 - o date on which the current pricing offer was submitted
 - o date on which the Department accepted the price proposal
- Publication should be aligned with current publication dates and should not involve any earlier disclosure than is provided for by the existing process, i.e. the status of “*Pending PBAC*” should not be revealed earlier than its disclosure on the PBAC agenda; if included, none of the pricing milestones should be made public before the PBAC outcomes are published.
- A timetable for publication of the different milestones should be agreed with industry to avoid any unintended consequences.

- Should be integrated with TGA information.
- Should enable sponsor comment, particularly where there are unresolved issues which are delaying completion of the listing process.

As we have flagged previously, industry needs to consider the implications of the online portal for consumers and compliance with the MA Code of Conduct. The Code is the final guidance on public communication from sponsors of medicines. MA has previously received advice from the TGA that linking a specific medicine with its indication on a public facing website is a form of promotion to consumers as an interpretation of the *Therapeutic Goods Act*. MA strongly recommends that fields published on the MSW is consistent with all legislation that the Department of Health administers.

To help shape MA's views on the proposed consumer-friendly MSW, MA recently organised a consultation with a range of patient organisations to understand their information needs. The list of organisations consulted is at Attachment A and their detailed feedback is at Attachment B.

The key observations from the patient organisation consultation were:

- Consumers need to have knowledge of indicative timelines for them to make sense of the information being posted and to assist with management of their expectations. For example, consumers sought a simplified diagram of PBS processes with expected timelines for each milestone.
- Simplified language, a user guide and clear definitions are required for the process, for each of the relevant milestones, and for such terms as "discussant", "responsible person", and "secretariat listing".
- Understanding the interactions across different pathways and processes, e.g. Life Saving Drugs Program (LSDP), Medical Services Advisory Committee (MSAC), as well as including end-to-end alignment with Therapeutic Goods Administration (TGA) processes is important for consumers, and
- The ability to search by therapeutic area in addition to medicine name.

MA understands that the DOH has met with and sought feedback from the Consumer Consultative Committee (CCC), and requests that this important feedback from the CCC be shared as part of the joint activities of the AMWG Streamlined Pathways Subgroup. MA believes that the views across a wide range of patient organisations is important given the different levels of knowledge and experience of each patient organisation with the health technology assessment process.

In conclusion, while information and search functionality at the level of a medicine and disease area are certainly welcomed, MA questions whether the information presented in the proposed MSW truly addresses consumer needs. It is proposed that the initial MSW contain basic, relevant information which can then be enhanced following further education and development of the new IT system. The current proposal has the potential to lead to information overload for consumers who, based on recent feedback from patient organisations, often find the existing PBS information difficult to follow, with the use of complex terminology that is hard to understand. User-friendly language and diagrams within the MSW are key.

Please find below MA's detailed comments on the draft guidance paper:

Page / Form	Area	Medicines Australia (MA) Comment
1/ Features of the MSW Consumer View	Embedded table	While MA acknowledge that the initial launch of the MSW will be a relatively basic view in the form of an Excel spreadsheet, it is requested that through the development of an upgraded IT system that the technology and functionality improve in a timely way to ensure efficiencies, timeliness and accuracy in the information posted.
	Definitions and user guide	The inclusion of definitions of the stages and the meaning of each field and a user guide are a welcome inclusion.
	Timing of record creation	'A new record for a medicine will be created in the MSW consumer view following the publication of the PBAC Agenda'. This is welcomed. It is important that the first piece of information to be published remains the PBAC meeting agenda, aligned with status quo.
	New fields for presentation and strength	Include medicine presentation and strength in table.
	New field for Recommendation with Variation	Given the new terminology used by the PBAC around verbal outcomes to sponsors that are positive but with variations to the sponsor proposal, how will this be captured in the MSW fields?
	PBAC meeting date field	What does the link in the PBAC meeting date field take the reader to? The PBAC agenda or the PBAC web outcomes? Is a separate field required for PBAC web outcomes?
	Definitions of 'withdrawal' and 'completed'	Current status 'withdrawn': MA requests a clear definition of "withdrawn". Current status 'completed': replace with 'PBS listed' to improve clarity.
	'Notice of Intent for Pricing Submitted', 'Current Price Offer Submitted', 'Price Accepted'	There may be competition law issues associated with publishing the date of Notice of Intent for Pricing, Current Price Offer and Price Accepted. It is recommended that MA and the Department of Health both seek legal advice on the publication of such information.

Figure 1	Excel table	Does the information presented address consumer needs? It could become complicated by multiple submissions / pathway options. It is proposed that the initial MSW contain basic, relevant information which is then built upon. The current proposal has the potential to lead to information overload for consumers who already find the PBS calendar complex and difficult to follow, with the use of complex terminology that is hard to understand. User-friendly language and diagrams are encouraged.
		The ability to search based on medicine name is an important benefit for consumers.
		For consumers, a common search will be for a particular disease area. Currently, based on the use of the Excel table, a search based on therapeutic area will require consistent use of terminology.
		It will be important for the functionality to improve over time.
		How would the MSW capture a medicine that has a positive PBAC recommendation but the sponsor re-submits an updated proposal to PBAC (i.e. not a positive pathway)?
		PHARMAC have condensed their process differently and Medicines Australia recommended the Department considers this approach. See 'Application Tracker': https://www.pharmac.govt.nz/

If you would like to discuss any aspect of this submission further, please feel free to contact me on vgardiner@medaus.com.au.

Yours sincerely



Dr Vicki Gardiner
 Director, Policy and Research
 Medicines Australia

ATTACHMENT A: MEDICINES AUSTRALIA CONSULTATION WITH PATIENT ORGANISATION – ATTENDEES

There were a total of 38 patient organisation attendees that participated in the Medicines Australia webinar on Monday 15th April. However, as attendees were not required to register their company name, many registered for the event using their first names only. The following list of patient organisations were able to be identified as participating.

- Heart4hearts
- Cancer Council of Australia
- Brain Foundation
- Stroke Foundation
- Centre for Community Driven Research
- Rare Voices
- Leukaemia Foundation
- Lung Foundation
- MS Australia
- National Asthma
- Breast Cancer Network Australia
- Pain Australia
- Asthma Australia
- National Asthma Council Australia
- Unicorn Foundation
- Creaky Joints
- Ovarian Cancer
- Lymphoma Australia
- Rare Cancers Australia

ATTACHMENT B: MEDICINES AUSTRALIA CONSULTATION WITH PATIENT ORGANISATIONS

Medicines Status Website Webinar – 15th April 2019

MA representatives:

- Petrina Keogh, Manager Stakeholder Relations, Medicines Australia
- Carlene Todd, Director of Market Access & Public Policy, Roche
- Bronwyn Underwood, Associate Director Market Access, Biogen

Department of Health representatives (silent observers):

Sally Roberts, PBS Process Improvements Project

Sally Wortley, Lead for the HTA Consumer Evidence and Engagement Unit

Comments from Healthcare Organisation attendees

Response 1:

- A link on how to make a Consumer Comment would be helpful from the MSW; ie the date for Consumer Comments needs to be a hyper link to the Public Comments website.

Response 2:

- No link between the agenda item, the outcomes date and when the PSD can be expected. It would be helpful for there to be a joined up view across the entire calendar.
- A simplified diagram of PBS processes with expected timelines for each milestone would be helpful. The generic calendar is too complex for most consumers.
- The generic calendar is too complex for most consumers. Simplified language is required; most consumers don't know who a 'discussant' or 'responsible person' is, or what a 'Secretariat listing' is.
- What is the 'Notice of Intent for Pricing'? What are the timelines for each stage of the process?
- People need an understanding of the time between each stage.
- Consumers are needing a knowledge for timelines; it is understood that these are variable; however, there is a need for indicative timelines and ranges based on statistics and experience.
- Awareness that a medicine is taking longer than normal due to issues that impact on variability of timeline.
- Where do stakeholder meetings fit in? How can consumer groups be aware of them within the MSW?
- Ministerial announcements about the Government listing every medicine recommended by the PBAC places pressure on patient organisations from patients wondering why medicines aren't moving through to listing in a more timely way.
- Managing consumer expectations is important, and requires an increased understanding of the process and timelines (ie if the process takes up to x months on average, that is helpful for a consumer to know).
- Commended workshops that Jo Watson conducts, valuable to consumer groups, enormous benefit to the advocacy community, confidence in what they are saying.

- Carlene shared that the DoH is setting up a new Consumer Unit, which may lead to more educational opportunities for HCOs in the future.

Response 3:

- A graphic on the process would be helpful.
- The PBAC is only one part of a longer reimbursement pathway, there is a need to include MSAC and LSDP pathways also.
- Patients want to understand what the pathway is and when they can be active.
- Also noted the need for including indicative timelines.
- Recommend visual timeline and diagram of key steps, especially if LSDP candidate.
- PBAC calendar as a visual - ARROW TIMELINES.
- Simple diagram of process will be important.
- Excited that patients will be able to search by product view.

Response 4:

- Can you search for therapeutic use as well as HCOs are often interested in multiple medicines? A manual search for therapeutic use is time-consuming.
 - Carlene: Search function is possible however requires a consistent use of terminology.
- Will the Excel spreadsheet be updated regularly? What is the frequency of updates? Why can it not be a live website?
- Page could be more inviting for consumers, more “user friendly” language and engaging (very wordy).
- Patients understand there is a positive PBAC recommendation but don’t understand that a medicine still cannot be accessed and why.
- Reiterated the need for explanations around timelines to listing and who is responsible to progress the application.

Response 5:

- There is a need for end to end consultation and alignment with respect to the recent TGA transparency consultation. Consumers interested in where they can access the information across both the regulatory and reimbursement process.
- This enables informed decision making support for consumers and potential efficiencies.
- A TGA submission from Pain Australia is available on their website as an example.
- Similar process with TGA - limited capacity to provide submissions for various consultations, co-ordination at the other end, struggle to put comments in with the time commitments and resource constraints.

Response 6:

- Locating consumer information on the current PBS website is very confusing and therefore we welcome any upgrades or changes to this. However, will this be a new website or be part of the current PBS website?
- Currently when we ask our community to make a submission to PBAC we have to send them the link to the submission page so that they can access this section easily otherwise they don’t find the section relevant to them on the website.

- Regardless of whether it is a new site or part of the existing one I think we have an opportunity to plan the navigation so that the consumer takes in the amount of information that is relevant to their needs. Let's not assume that they all want to know everything. However, some consumers will, and patient organisations will definitely benefit from all of the information being in one place. Navigation will be the key.
- Back to the start though – we could benefit from a process whereby an alert is sent to all HCO's when a new meeting agenda is available.
- When a consumer or organisation lands on the site it is very clear with visuals and text friendly information about the process and how to navigate to the section that they are looking for.
- When making a submission it would be good if there are some guidelines and examples here of what can make up a valued submission. If petitions are worthless this should be stated, and this may help lessen the workload for PBAC. Also, in this section it should be explained to consumers that not all submissions will meet the requirements that underpin the approval process and that they can check back to this site to see how the progress of their medicine is going.
- Educate users of this site that not all submissions will be approved and give some examples as to why this is the case.
- Potentially seek feedback from users of the current submission form (via a survey) to learn more about the experience of completing this form.
- Explain in this section that the form may not suit patient organisations as the questions are not relevant to them, but they can email a separate submission to PBAC.
- The current PSD is not very patient friendly so is difficult to use when providing feedback to patients.
- Organisations can / do make a submission on behalf of all our consumers, but we only know what is being considered for approval. Meaning we have no idea what is in the sponsor's submission. This does mean our submission is in dependent of the sponsor's, which is great, but it also means it is hard for us to explain the success or failure of a submission to our consumers if we haven't seen this document. It also means we have no idea which comparators have been used.
- Is the price disclosure that was listed on the excel spreadsheet, new to this process? If yes, what is the reasoning behind this?
- The hearings with consumer groups prior to a PBAC meeting have been very beneficial for all parties.