

# Plenary presentation: Group 1

## Group 1: Earlier engagement in the HTA process (led by Hayley Anderson, Melanoma Patients Australia)

### Idea description

Earlier engagement of patients in the process for reimbursement of medicines means that they are an integral part of the entire journey in the process of funding medicines via the PBS, from the time a reimbursement application is first identified, rather than at the end of the process once the PBAC are imminently making the recommendation.

### Why was this idea recommended at the Sydney, Brisbane and Melbourne workshops

There need to be earlier access points for patients in the process for making funding decisions for medicines. Current opportunities for engagement include Public Comments (10 weeks prior to PBAC meeting) and Consumer Hearings for select diseases and medicines (immediately prior to the PBAC meeting). Consistent feedback from multiple stakeholders is that these timeframes are not earlier enough, and that patients/patient organisations need to be involved much earlier in the submission process.

### Elements of the idea (put forward by participants of Syd, Bris, Melb workshops)

1. Calendar for patient interaction/touchpoints
2. Development of registry of patient organisations that PBAC can contact for early input
3. Patient organisation Liaison Officer in Pharmaceutical Evaluation Branch at DOH
4. Patient organisations alerted when submissions are posted on PBAC agenda

# Earlier engagement in HTA process: who plays a role?

Elements	Who will play the major role in making this happen?
Calendar for patient interaction/touchpoints	Department of Health in coordinating a central calendar from registration through to reimbursement which includes the TGA, PBAC, MSAC, PLAC. Links to additional patient training/activity/meeting sessions
Development of registry of patient organisations that PBAC can contact for early input	The DoH in creating an opt in, online register of patient organisations, individuals and carers that can be contacted by DoH to provide insights, advice and experience with condition or disease and/or the medicine. DoH to manage register with other advisors to ensure register is applicable, acceptable and measurable.
Patient organisation Liaison Officer in Pharmaceutical Evaluation Branch at DOH	The DoH in providing a Patient Liaison Unit of people to ensure a consistent approach to reimbursement submissions, and to facilitate patient organisations or individual patients to be actively involved in the process to improve awareness, collaboration and better input.
Patient organisations alerted when submissions are posted on PBAC agenda	DoH to publish and send alerts to patient organisation and/or individuals on the register or who have requested alerts for PBAC (or other) agenda

# Earlier engagement in HTA process: main success factor?

Elements	What is the main factor that will make this element successful in practice?
Calendar for patient interaction/touchpoints	A 'how to' be involved link providing instructions/information at each calendar date on how patients can be involved and become part of the process. Details need to be kept up to date and should be user friendly, easy to find and understand.
Development of registry of patient organisations that PBAC can contact for early input	Patient awareness and accessibility to a register for patients to list their details/disease/interest. Provide clear information on the area/disease specific inputs and types of engagement that is available to the patient. Expand or collaborate on what already exists within patient organisations. Formalising a register may increase confidence of patients of their value/preferences in access to medicines. Register needs to be plain language, accessible, with ethical protocols, governance and independence.
Patient organisation Liaison Officer in Pharmaceutical Evaluation Branch at DOH	DoH would require a dedicated Patient Liaison Unit. Look to O/S models for current processes e.g. NICE and learn from their set-up. Buy-in from the DoH as a priority for Govt.
Patient organisations alerted when submissions are posted on PBAC agenda	DoH would require dedicated resources to manage the alerts and improve the website to be patient oriented including information/context on the submission process. Recognise that patients have different needs to that of industry. 'Buy-in' from the DoH.

# Earlier engagement in HTA process: main barrier?

Elements	What is the main barrier in the way of this element getting off the ground?
Calendar for patient interaction/touchpoints	A lack of resources and funding. Current limitations with the MA code of conduct.
Development of registry of patient organisations that PBAC can contact for early input	The language/complexity/privacy issues. Government liability – reaching out to patients prior to registration. Current limitations with MA Code of Conduct.
Patient organisation Liaison Officer in Pharmaceutical Evaluation Branch at DOH	Ensure that the position does not become a secretariat as it may miss the mark. Increased capacity, funding. Not a priority area for Govt.
Patient organisations alerted when submissions are posted on PBAC agenda	Resources. Lack of willingness by DoH.

# Earlier engagement in HTA process: resources needed?

Elements	What are the major resources that are needed?
Calendar for patient interaction/touchpoints	DoH commitment. Funding. Pilot testing of new site/calendar with patients.
Development of registry of patient organisations that PBAC can contact for early input	DoH commitment. Funding.
Patient organisation Liaison Officer in Pharmaceutical Evaluation Branch at DOH	DoH commitment. Funding. Capacity.
Patient organisations alerted when submissions are posted on PBAC agenda	Resources. DoH commitment.

# Earlier engagement in HTA process: leadership role

Idea	Who should lead the project/who else should be involved?
Formation of a Consumer and Patient Liaison Unit within Government to act as an interface between patients/consumers and the HAT Process	Governance committee that involves key stakeholders e.g. patients, patients advocacy groups, industry, professional associations and Department of Health.

# Earlier engagement in HTA process: next steps

Idea	What are our recommended next steps to get the project off the ground?
	Form a working group to develop a proposal to go to DoH.
	Seek interested parties to work with the Steering Committee on this initiative. Time frame: meet 2017 budget process
	<p>This proposal will include the formation of a Governance committee. The governance committee will work with the DoH to appoint a Consumer and Patient Liaison Unit that provides an interface to all HTA bodies to:</p> <ul style="list-style-type: none"><li data-bbox="575 882 1754 1005">• Implement a calendar that has touchpoints which includes information/explanations on how to engage with the system. Compare to NICE</li><li data-bbox="575 1016 1412 1051">• Table a pilot calendar to be tested with consumers.</li><li data-bbox="575 1062 1503 1096">• Implement and manage a register for patients and carers</li><li data-bbox="575 1108 1754 1188">• Responsible for ensuring alerts at every milestone delivered in an easy to use, plain language format.</li></ul>

# Plenary presentation: Group 2

## Group 2: A new consumer portal for HTA information (led by Leanne Wells CHF)

### Idea description

A dedicated consumer portal on the PBS website explains in plain language what the PBAC is, its processes, how to be involved, with comprehensive links to tools and linkages to advocacy groups

### Why was this idea recommended at the Sydney, Brisbane and Melbourne workshops

There is a need for user-friendly information, tools and awareness of the HTA system for patients, advocacy groups, clinicians and other stakeholders. All stakeholders need to have timely access to information that they readily understand and to fit-for-purpose, self-explanatory tools to be able to effectively share their stories and perspectives.

### Elements of the idea (put forward by participants of Syd, Bris, Melb workshops)

1. Guidelines document for consumer involvement in the PBAC process (e.g. opportunities to interact such as hearings)
2. Briefing document for consumers and clinicians on preparing for hearings
3. Training tool (e.g. video) for advocates to become experts in the PBAC process and experts in evidence collection
4. Submission component dedicated to consumer input that can be downloaded from the portal by patient organisations
5. Development of case studies of successful patient involvement stories for the portal
6. Registry of patient organisations on the portal

# New consumer portal for HTA: who plays a role?

Elements	Who will play the major role in making this happen?
Guidelines	Consumers to co lead and co write with DoH
Briefing Doc	Consumers, market research and consultation
Training tool	As above
Submission component	As above
Case Studies	As above
Registry	As above

# New consumer portal for HTA: main success factor?

Elements	What is the main factor that will make this element successful in practice?
Guidelines	<ul style="list-style-type: none"><li>• Buy in from critical stakeholders (MAP stakeholders and brief key advocates)</li><li>• Expertise and conviction from Govt</li><li>• Effective consumer engagement and participation in development and design</li><li>• Continued patient group/industry /academic/govt collaboration</li><li>• Portal utility (multi media, simplicity etc) as evaluated by consumers recognised internationally as best practice</li></ul>
Briefing doc	Portal needs to include more general info about HTA , health literacy and reasons to be involved (call to action)
	Benefits that patient and community participation
	Specific guidance around participation in PBAC

# New consumer portal for HTA: main barrier?

Elements	What is the main barrier in the way of this element getting off the ground?
<p>Collaborative all inclusive approach</p> <p>Devel of case studies short succinct multi-media and multi lingual –</p> <p>additional leverage Health Direct role (both state and federal support)</p>	<ul style="list-style-type: none"><li>• DoH expertise and conviction to commit to it and to resource it</li><li>• Driving traffic to an already over burdened system (need to develop a risk management plan)</li></ul>
<p>Other languages</p> <p>Linking of all</p> <p>Health literacy CALD ATSI</p> <p>Optimising info pathways</p> <p>Fit for purpose</p>	

# New consumer portal for HTA: resources needed?

Elements	What are the major resources that are needed?
<b>Near Term</b>	People with right expertise, time and commitment to sit on the working group
	An entity that takes the coordination and mandate to drive forward e.g Industry fund a grant to the entity to employ a coordinator to write the business case to be ratified by all interested parties
	Implementation plan with appropriate governing group to provide oversight, expert review and advice
	In addition Consumer panel will provide oversight
<b>Final Stage</b>	Secured dedicated funding for the portal Capacity to evaluate, maintain, improve and continuously promote

# New consumer portal for HTA: leadership role

Idea	Who should lead the project/who else should be involved?
Project Lead	<ul style="list-style-type: none"><li>• Health Direct - Uber portal to utilise</li><li>• Proven track record and infrastructure</li><li>• Consumer facing</li></ul>
Tasks	<p>Working group to develop business case and implementation plan for the portal</p> <p>Seek advice and interest from Health Direct</p> <p>Funding sources to be identified</p> <p>Blended funding model Government Industry</p>
	<p>Audit of existing resources, co design workshops that develop specifications for the portal to be given to architect e.g health direct</p>

# New consumer portal for HTA: next steps

Idea	What are our recommended next steps to get the project off the ground?

# Plenary presentation: Group 3

## Group 3: Consensus on methodologies and approaches to capture patient perspective (led by Colman Taylor Optum Consulting)

### Idea description

There is an agreed, standardised and systematic approach to the capture and interpretation of evidence that is relevant to patients in the decision-making process for the funding of medicines.

### Why was this idea recommended at the Sydney, Brisbane and Melbourne workshops

There is a need for evidence that is relevant to patients to be systematically collected and deemed of value to the PBAC in their decision making.  
This evidence may be in the form of consolidated surveys across a large number of patients or individual patient stories that capture their unique experiences.  
There is a need to agree on how this valuable information is to be collected, consolidated, shared and used in the decision-making process to fund medicines.

### Elements of the idea (put forward by participants of Syd, Bris, Melb workshops)

1. Development of a patient survey for medicines entering the PBAC process to accompany submissions
2. Update of Public Comments Form to ensure patient relevance
3. Component of the submission dedicated to consumer input that is available for patient organisations to complete and submit alongside the submission
4. How to capture patient narratives effectively.
5. Weighting of criteria that are important to patients

## Consensus on methodologies: who plays a role?

Elements	Who will play the major role in making this happen?
Patient survey for medicines entering PBAC process to accompany submissions	Patient groups, need willingness from DOH Others to assist with implementation Differs for design vs collection aspects
Update of Public Comments Form to ensure patient relevance	DOH Steering committee: incl medical grps, IT experts, consumer reps
Component of submission dedicated to consumer input for patient org. to complete & submit alongside submission	Patient groups, Industry, DOH Decision-makers clear on what is informative
How to capture patient narratives effectively	Patient groups, ind-led patient services via independent 3 <sup>rd</sup> party – to collect data Industry & physician support
Weighting of criteria important to patients	System-wide: patients, pt groups, consumers, endorsed by PBAC/DOH in Guidelines

# Consensus on methodologies: main success factor?

Elements	What is the main factor that will make this element successful in practice?
Patient survey for medicines entering PBAC process to accompany submissions	Willingness, simplicity, communication
Update of Public Comments Form to ensure patient relevance	Accessibility Capturing patient-relevant information Simple and easy to understand: drop-down boxes and multi-lingual
Component of submission dedicated to consumer input for patient org. to complete & submit alongside submission	Buy-in from industry, clinicians & DOH Decision-makers to be clear on what will improve decision-making process
How to capture patient narratives effectively	Flexibility in medium & format; e.g. video/audio, case studies, qualitative data & free-text; overview & detail
Weighting of criteria that are important to patients	Simplicity, communication, accessible, representative

# Consensus on methodologies: main barrier?

Elements	What is the main barrier in the way of this element getting off the ground?
Patient survey for medicines entering PBAC process to accompany submissions	Consensus on content Who does it? Priority of this idea vs others Ability to implement
Update of Public Comments Form to ensure patient relevance	Current lack of accessibility – finding it! Access to good information on trial drug
Component of submission dedicated to consumer input for patient org. to complete & submit alongside submission	Commercial-in-confidence – timing of agendas/overlapping PBAC cycles MA code, resourcing, awareness Govt buy-in
How to capture patient narratives effectively	Value of narratives in evaluations Ability for industry to engage with patients (legislative and MA code)
Weighting of criteria that are important to patients	Funding & cost, awareness, education/training, high levels of uptake

## Consensus on methodologies: resources needed?

Elements	What are the major resources that are needed?
Patient survey for medicines entering PBAC process to accompany submissions	\$\$\$ , coordination, development Data analytics
Update of Public Comments Form to ensure patient relevance	Funding Facilitation Testing
Component of submission dedicated to consumer input for patient org. to complete & submit alongside submission	People & \$\$\$
How to capture patient narratives effectively	Varied/flexible formats for narrative collection
Weighting of criteria that are important to patients	Community groups, DOH staff with expertise and administration to endorse. Need qualitative data to lead into quantitative approach with ranking of key features

# Consensus on methodologies: leadership role

Idea	Who should lead the project/who else should be involved?
Lead and Involvement	Patient-group responsible? Do patients have the resources? Consumer Health Forum – association of patient groups that coordinates patient input (but doesn't represent all) Other patient organisations/patient groups?
	<b>Umbrella organisation/steering committee covering multiple stakeholders to run pilot: 'tripartite'</b>
	Clear role for DOH – involved from the outset
	Clear role for Industry
	Getting committee consumer reps together from federal/state level – in decision-making roles already – key influencers
	Medical groups & colleges

# Consensus on methodologies: next steps

Idea	What are our recommended next steps to get the project off the ground?
Business Case	<p>Work up a proposal/business case to DOH, including:</p> <ul style="list-style-type: none"><li>• Share existing best practice examples across patient groups</li><li>• Proposed methodologies – both qualitative &amp; quantitative</li><li>• Identify case study, and undergo pilot(s) with multiple stakeholders. Refine along the way – partnership approach</li><li>• Evaluate learnings from pilot(s) – it develops the evidence base</li></ul>
	Determine how we would know when we have been successful
	<p><b>Two buckets:</b></p> <ul style="list-style-type: none"><li>• <b>Current process improvements to ensure equity across disease groups – proactive approach smaller patient groups</b></li><li>• <b>Upskilling in collecting the best patient-relevant evidence</b></li></ul>
	<p>Working alongside other international groups – don't re-invent the wheel (e.g. look to NICE to identify relevant patient groups and processes)</p>
	Workshop involving committee consumer reps – work with them to help us

# Plenary presentation: Group 4

## Group 4: Increased transparency and feedback about how patient input is used in decision making (led by Catherine Holliday, Centre for Community-Driven Research)

### Idea description

It is important that patients have a good understanding of the HTA processes, decision-making and outcomes from PBAC meetings, and that feedback is proactively provided to patients on the value of the evidence contributed.

### Why was this idea recommended at the Sydney, Brisbane and Melbourne workshops

There needs to be increased transparency to patients and patient organisations on how their perspectives are included in the PBAC decision-making process.  
This includes how feedback is provided to patients and patient organisations on their submissions to PBAC following the PBAC decision to enable further learnings and continuous improvement.  
It also includes timely and proactive two-way communication between the PBAC/Department of Health and patients/patient organisations.

### Elements of the idea (put forward by participants of Syd, Bris, Melb workshops)

1. Public Summary Documents and Guidelines documents that meet the needs of patients and consumers
2. Formalised feedback from PBAC to patients/consumers following decisions on what patient evidence was valuable and supported decision-making
3. More resources for PBAC consumer rep to enable feedback on patient/consumer submissions

# Transparency/feedback on patient input: who plays a role?

Elements	Who will play the major role in making this happen?

# Transparency/feedback on patient input: main success factor?

Elements	What is the main factor that will make this element successful in practice?
Alert	<ul style="list-style-type: none"><li>• More proactive</li><li>• Add “register” for Consumer/patient groups</li><li>• GAP: individual patients – how to reach them</li> <li>• Assumption: % pts that are interested?</li></ul>
Guidance	<ul style="list-style-type: none"><li>• Previous example/response</li><li>• Check list/fact sheet (guide)</li><li>• Map of process</li><li>• What do PBAC want to hear</li><li>• What do patients want to tell</li><li>• What are the factors that trigger a hearing? Or potentially a community forum – what are the rule</li></ul>
Acknowledgement of submissions	<ul style="list-style-type: none"><li>• Timeline</li><li>• How it will be used</li><li>• What happens next – we will get back to you</li><li>• Link to PSD</li></ul>

# Transparency/feedback on patient input: main success factor?

Elements	What is the main factor that will make this element successful in practice?
Opportunity to qualify the information received	<ul style="list-style-type: none"><li>• This is what the PBAC understood (e.g. themes)</li><li>• Opportunity for patient groups to clarify if this is right/add anything else</li><li>• Opportunity for Department/PBAC to ask questions of areas they would value further input</li><li>• Setting – does it always need to be written – couldn't PBAC/Department go to patients, hold consumer forums earlier in the process (resource: would need more "patient liaisons" to do this)</li></ul>
Hearings	<ul style="list-style-type: none"><li>• How are they offered</li><li>• How invited in?</li><li>• Resources?</li><li>• Provide questions prior to hearing so patients can prepared</li></ul>
Outcomes	<ul style="list-style-type: none"><li>• Communication of process and debrief (what was understood and what was the response by PBAC)</li></ul>
PSD	<ul style="list-style-type: none"><li>• Response by PBAC to all patient groups/patients who make a comment</li><li>• Plain language</li><li>• Explain consumer feedback – themes – lived experience, limitations and gaps of what is available</li><li>• How did that information get used in the decision – weighting – how is it valued</li><li>• What is next (for the submission)</li></ul>

# Transparency/feedback on patient input: main success factor?

Elements	What is the main factor that will make this element successful in practice?
Guidance	<p>Map of the process and timelines so groups and patients can prepare, know when to provide input</p> <p>What do PBAC want to hear</p> <p>What do Patients want to tell</p> <p>Opportunity to respond/clarify if that is what meant</p> <p>Hearings – guidance on process but also what information would be helpful; how are they chosen;</p> <p>Links to where information is/will be (assumption group#2 portal is present)</p>
Two way feedback and multiple opportunity to respond and clarify	<p>Consumer “commentaries” capturing what was understood (themes?) from the consumer input</p> <p>PBAC can post questions/areas during evaluation process where they would value further patient input perspective</p>
Setting and method of feedback	<p>Written submission/feedback</p> <p>Verbal Consumer “reps/liasons” go to patients to discuss themes/clarify etc</p> <p>PSDs – plain language of themes and outcome/decision</p>
Acknowledgement	<p>Acknowledgement of when submission made, responses received, outcomes available etc</p>
Decision making	<p>How was the information used/factored into the decision – weighting vs other factors</p>

# Transparency/feedback on patient input: main barrier?

Elements	What is the main barrier in the way of this element getting off the ground?

# Transparency/feedback on patient input: resources needed?

Elements	What are the major resources that are needed?

# Transparency/feedback on patient input: leadership role

Idea	Who should lead the project/who else should be involved?
Patient Led	<p>Patient led</p> <ul style="list-style-type: none"> <li>• Not developing these things FOR patients</li> <li>• Developing these things WITH patients</li> </ul> <p>Need department, PBAC present/involved            Industry            Minister's office            ACCN</p>
	<ol style="list-style-type: none"> <li>1. Map what has been done and what needs to be done               <ul style="list-style-type: none"> <li>• Feedback – check assumptions</li> </ul> </li> <li>2. Delegation/coalition from this forum to present recommendations to Department AND Minister's office               <ul style="list-style-type: none"> <li>• divide into short term and long terms</li> <li>• achievable but \$\$</li> <li>• make it easy to uptake (benefits to all parties)</li> </ul> </li> </ol> <ul style="list-style-type: none"> <li>• Need evaluation/feedback loop</li> <li>• Communication plan and advocacy</li> </ul>
Government	<p>Need department, PBAC present/involved            BUT Plan B - What can we do without DoH</p> <ul style="list-style-type: none"> <li>• E.g Register of group: Centre of Community Driven Research has begun this with alert system – how to broaden register and advertise this as opportunity</li> </ul>

# Transparency/feedback on patient input: next steps

Idea	What are our recommended next steps to get the project off the ground?