



Australian Government

Department of Health and Aged Care

Consultation Paper 7 - Proposed measures for compliance, assurance and information sharing

Stakeholder feedback analysis report



Introduction

The purpose of this report is to provide an analysis of stakeholder feedback received in response to the Consultation Paper on the proposed Compliance, Assurance and Information sharing measures for the Prescribed List (PL). Submissions were open to stakeholders between 12 July 2023 and 10 August 2023. A total of 19 submissions were received (Figure 1). The submissions represented the medical technology sector, private hospitals, private health insurers, clinical experts, government departments and individual consultants. In addition to this, feedback was also received from other areas in the department.

Evaluation of the submissions considered feedback about the proposed measures in preparation for the drafting of the compliance, assurance and information sharing legislation.

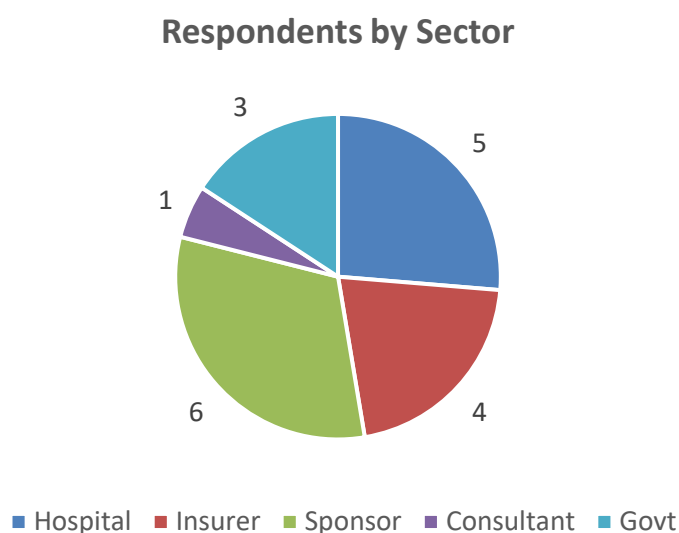


Figure 1: Number and industry sector of respondents to the proposed measures for compliance, assurance and information sharing.

Key feedback

Most stakeholders supported the proposed measures and acknowledged that measures were required to uphold the integrity of the PL. Some of the key feedback that was received included:

- Record keeping and notification obligations needed clarity about what was required and who was required to keep these records.
- The Information sharing measures seemed appropriate. However, stakeholders would not like to see these expanded to areas outside of the regulatory environment.
- The department should explore using any existing reporting and notification requirements and collaborate with other areas within the department such as TGA, to minimize the overall regulatory burden.
- Stakeholders would like to be included in further consultation on the proposed measures, including the exposure draft of the legislation.

Key concerns

Some of the concerns raised by stakeholders about the proposed measures included:

- Record keeping and notification obligations for hospitals, as it is unclear what records these would be and that any records about devices and human tissue products should be the responsibility of sponsors.
- Maintaining a gifts and benefits register by hospitals. This would be quite a burden for hospitals to maintain, and some stakeholders questioned whether this was actually an issue that needed to be remedied.
- Disproportionate sanctions for some offences, including the revocation of a hospital declaration and the removal of an item from the PL due to false and misleading information.

The key issues raised and the department's response are listed in Table 1 below. In addition, the feedback that was received in response to the 18 questions that were asked in the consultation paper can be found in Table 2 below.

Table 1: Key feedback and concerns about the proposed measures for the Compliance, Assurance and Information sharing legislation and the department’s accompanying response to address stakeholder concerns.

This table outlines the key themes that were raised by stakeholders in their feedback during the consultation on the proposed measures for the compliance, assurance and information sharing legislation. Using this feedback, the department has outlined the response that we are proposing to undertake, as well as identifying the key risks associated with these themes. However, note that this is not final and may change during the drafting process for the legislation or resulting from any further consultation.

Issue	Stakeholder feedback	Department response	Risk
<p>Public Summary Documents (PSD)</p>	<p>Stakeholders made a wide range of suggestions on what information should be included in PSDs. Some of the suggestions included a document that was completed by sponsors during the application process, or a summary of the considerations undertaken by the relevant Expert Clinical Assessment Groups (ECAGs) or Medical Devices and Human Tissue Advisory Committee (MDHTAC).</p> <p>Suggestions on which listed devices or human tissue products should be prioritised for PSDs included items that have conditions associated with them, items that have high use, or for applications for items that would fall into a new group in which feedback on the decisions made would be useful.</p> <p>Some stakeholders do not believe that sponsors should draft the PSDs as this could be a potential conflict of interest or may have issues with the Therapeutic Goods advertising code.</p>	<p>The department acknowledges the feedback provided by stakeholders and will explore the various options about what information could be included on a PSD, including who would be responsible for completing the PSD, as well as the feasibility of any collaboration with the Therapeutic Goods Administration (TGA) about a combined PSD.</p>	<p>Inclusion of PSDs would provide stakeholders and patients with more information than they otherwise would have about medical devices and human tissue products. However, not including PSDs at this time, will result in very little detriment to either patients or stakeholders while the inclusion of PSDs are being further considered.</p>

Issue	Stakeholder feedback	Department response	Risk
<p><i>Record keeping and notification obligations for sponsors</i></p>	<p>Some sponsors acknowledged and supported the requirement to keep accurate and current information about their devices and human tissue products, and that they were the most suited to retain this information.</p> <p>Other stakeholders supported the idea that sponsors should play an active role in assisting the department to manage the PL given its size and variability. This may include, but is not limited to, advising the department of any changes to their listed devices and human tissue products, and maintaining accurate and current information.</p> <p>Some stakeholders deemed the enforcement powers to be excessive and disproportionately weighted towards sponsors, and that there was a lack of clarity about what records were required to be kept.</p>	<p>The department agrees with stakeholders that sponsors should be responsible for maintaining records about their listed devices and human tissue products. The department also acknowledges that at this stage there is some uncertainty about what records are required to be kept. The details of any record keeping and notification obligations will be outlined in the MDHTP (Medical Device and Human Tissue Product) Rules in the future.</p> <p>Notification obligations are required so the department can be made aware of any new information in relation to a device or human tissue product that may potentially affect its suitability to be listed on the PL. For this reason, sponsors are best placed to be responsible for providing this information to the department.</p>	<p>This measure will give the department further access to information if required about listed devices and products. This will aid in helping to solve any queries or disputes involving stakeholders and devices, and the department will be well informed of any adverse events or relevant changes related to listed devices and products resulting in a more accurate and reliable PL.</p>
<p><i>Record keeping and notification obligations for hospitals</i></p>	<p>Many stakeholders stated that it was unclear what records would be required to be kept outside of their current HCP/PHDB obligations. Hospitals stated that they already kept records about the costs and provision of listed devices and human tissue products, but many hospitals would find the extraction of that information from their existing database systems costly and</p>	<p>Any information about a listed device or human tissue product that the department would require a hospital to keep would already be kept by hospitals within their existing database systems. Requiring hospitals to keep additional records would be unnecessary.</p> <p>Notification obligations outlined in the</p>	<p>This measure has been removed from the proposed measures.</p>

Issue	Stakeholder feedback	Department response	Risk
	<p>onerous.</p> <p>Hospitals did not believe that it was their responsibility to notify the department of events about listed devices and human tissue products, such as when they were no longer on the ARTG.</p>	<p>consultation paper would mostly fall under the responsibility of sponsors and have been removed for hospitals.</p>	
<p><i>Hospital gifts and benefits register</i></p>	<p>Some stakeholders questioned whether this was an issue that needed to be remedied and that this was an extra burden on hospitals to record these items.</p>	<p>The department is undertaking further consultation on this proposed measure to help understand stakeholder concerns and further refine the measure. Part of the consultation is to ask stakeholders if they believe that sponsors, instead of hospitals, would be better placed to be responsible for maintaining this gifts and benefits register.</p> <p>The register would only be for items that are on the PL, that were received free of charge or where a discount was given that does not fall below a nominal threshold (yet to be determined).</p> <p>This measure is not intended to impinge on normal commercial arrangements between sponsors and hospitals.</p>	<p>This measure will help the department identify the scale and role that discounts and gifted items on the PL play in the procurement of medical devices and human tissue products. This will then help to determine if there is an issue where listed devices and products that are received with very little outlay are then used to claim a benefit from the PL, which could ultimately affect insured patients through higher premiums.</p>
<p><i>Record keeping and notification obligations for</i></p>	<p>There were very little comments from stakeholders regarding recording keeping for insurers about listed devices and human tissue products. However, most comments</p>	<p>Any information about a listed device or human tissue product that may be required to be kept by an insurer, would already be held by an insurer. Requiring</p>	<p>This measure has been removed from the proposed measures.</p>

Issue	Stakeholder feedback	Department response	Risk
<i>insurers</i>	regarding insurers suggested that they should be required to justify and report each non-payment, or even each claim that is questioned on an annual basis for items listed on the PL.	<p>insurers to keep additional records would be unnecessary.</p> <p>Notification obligations outlined in the consultation paper would fall under the responsibility of sponsors and have been removed for insurers.</p> <p>The department is currently undertaking a review of what information is being provided by insurers and assessing whether there is scope to bring in a requirement for insurers to record and report any denied benefit claims.</p>	
<i>Clinical effectiveness of medical devices and human tissue products</i>	<p>Stakeholders had concerns over what the definition of 'clinical effectiveness' was and how they were to demonstrate this for their listed devices and products. They were also unsure how this would work over the longer term as the consultation paper seemed to suggest that it was the responsibility of the sponsor to constantly demonstrate their clinical effectiveness. Stakeholders questioned whether sponsors would be required to demonstrate constant clinical effectiveness or would this only be at particular points in time.</p> <p>There were also suggestions that it was the assessment of clinicians who determined the clinical effectiveness.</p> <p>Some stakeholders questioned how the</p>	The department will provide further clarification on the record keeping requirements closer to the implementation date - including providing more education about what is meant by clinical effectiveness. More specific details of what is required will be included in the MDHTP Rules in due time.	<p>There is a risk that medical devices and human tissue products will be used for procedures where that item would not be deemed to be clinically effective, resulting in patients potentially not receiving the medical treatment that they are entitled to.</p> <p>Misuse of medical devices and human tissue products may also result in costs for patients and benefit claims made to insurers being higher than they need to be.</p>

Issue	Stakeholder feedback	Department response	Risk
	<p>clinical effectiveness could be demonstrated if listed devices and human tissue products were not used for what they were originally assessed for.</p> <p>Information that demonstrates the clinical effectiveness should be clarified.</p>		
<p>Cost effectiveness of medical devices and human tissue products</p>	<p>Stakeholders had concerns over what the definition of 'cost effectiveness' was and how this could be demonstrated. Some questioned whether cost effectiveness should only be assessed in relation to the Australian market, or whether it should also be in comparison with the costs of devices and products provided overseas as well.</p> <p>Some stakeholders questioned how cost effectiveness would work in relation to devices and products that were used for procedures which they were not originally assessed for.</p>	<p>The department will provide further clarification on the record keeping requirements closer to the implementation date - including providing more education about what is meant by cost effectiveness. More specific details of what is required will be included in the MDHTP Rules in due time.</p>	<p>There is a risk that medical devices and human tissue products are being used for procedures where the use of that device is not cost effective for that type of procedure. This results in higher costs and ultimately, higher patient insurance premiums.</p>
<p>Administrative sanctions for providing false and/or misleading information – sponsors</p>	<p>Many stakeholders raised concerns about the potential impact on patient outcomes if a device or human tissue product was removed from the Prescribed List, and that additional punitive measures should be considered before this occurs.</p> <p>The removal of a listed device or human tissue product seemed like a disproportionate response for providing false or misleading</p>	<p>The proposed measure that allows for the removal of a listed device or human tissue product if a sponsor was to provide false or misleading information has been removed. This may have had a detrimental effect on patients and would be disproportionate to the offence. Sanctions for providing false and/or misleading information can be enforced in other ways.</p>	<p>This measure has been removed from the proposed measures.</p>

Issue	Stakeholder feedback	Department response	Risk
	information.		
Administrative sanctions for providing false and/or misleading information – hospitals	<p>Stakeholders raised concerns that revoking a hospital declaration seemed like a disproportionate response in the context of the regulations.</p> <p>Stakeholders strongly supported that other measures should be considered before a hospital declaration is revoked, as this would have a detrimental effect on patients whose welfare should be the key priority.</p>	<p>The proposed measure that allows for the revoking of a hospital declaration if the hospital was to provide false or misleading information has been removed. This would have had a detrimental effect on patients that would be inconsistent with the severity of the offence. Sanctions for providing false and/or misleading information can be enforced in other ways.</p> <p>The Minister already has the power to revoke a hospital declaration if needed.</p>	This measure has been removed from the proposed measures.
Information sharing	<p>Most stakeholders stated that the proposed information sharing measures outlined in the consultation paper appeared appropriate. There was endorsement to share with other government agencies and departments, but stakeholders were less supportive of the suggestion to share information with other professional associations for health care providers.</p> <p>Concerns were also raised over the protection of protected and commercially sensitive information.</p>	The department is going to make no changes from those proposed in the consultation paper. Information is proposed to be shared with the Independent Health and Aged Care Pricing Authority, the Therapeutic Goods Administration, the Australian Competition and Consumer Commission, the Chief Executive Medicare and any Commonwealth, State or Territory authority that has functions relating to health care providers or has functions relating to human tissue products.	This measure allows other regulatory agencies to be better informed to undertake their respective duties, resulting in a more compliant and transparent regulatory environment.
Object of the Act	Most stakeholders supported the suggested changes to broaden the object	The department will broaden the object of the Act to include objects consistent with	This will ensure that compliance activities are

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	of the Act.	the new obligations.	consistent with the object of the Act.
Clarity on the proposed measures	<p>Stakeholders sought clarity on the roles and expectations of each of the stakeholders, and also commented about the lack of clarity in regard to some of the proposed measures.</p> <p>There was particular concern from some stakeholders about what sort of information was required for record keeping, or the types of information that could potentially be requested by the department under the measures.</p>	<p>The department recognises that the consultation paper lacked specific detail around some measures – particularly with regards to record keeping. More details about the specifics of these measures will be provided closer to the commencement of the scheme. Details about what is required will be updated in the MDHTP Rules shortly.</p> <p>Closer to the implementation of these proposed measures, there will be further information provided by the department to clarify requirements.</p>	Clarity will ensure that stakeholders can more accurately comply with the obligations and reduce the likelihood of non-compliance and any associated sanctions.
Conditions of listing	<p>Many stakeholders support the idea of introducing conditions of listing, but there is some confusion with the current term ‘conditions for the provision of a listed device or product’. Some stakeholders suggested that perhaps these could even be combined or amalgamated into the MDHTP Rules.</p> <p>Other stakeholders suggested that as pharmaceuticals are subject to specific indications, there is no reason that medical devices and products should be treated any differently.</p>	<p>The department understands that there is the potential for confusion between the two similar names, and if the ‘condition of listing’ was instituted, it would be named in a way to avoid confusion.</p> <p>The department needs further investigation into how it would work, what devices or products it could be used for, and the process for how any conditions would be determined.</p>	Conditions of listing would assist in tightening the use of medical devices and human tissue products on the PL by reducing the likelihood of any inefficient use.

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	It was suggested that the use of conditions would help with low value care and that there is room to tighten usage for devices and human tissue products.		
TGA collaboration	Some stakeholders suggested that there were areas within the proposed measures that could potentially be combined with TGA. Some of the areas that have been suggested where the potential for collaboration exists between the two areas includes public summary documents, conditions of listing, notification obligations, record keeping, TGA's medical device unique device identification and ARTG listings.	There has already been discussions with the TGA regarding some of the measures and there are plans to further investigate the feasibility of combining some of the measures over the longer term.	Collaboration with TGA on some notification or reporting measures will reduce the likelihood of inaccurate records and ensure a more accurate and reliable PL.
Enforceable undertakings and injunctions	Stakeholders did not have any comments in relation to the use of enforceable undertakings and injunctions as a compliance tool.	Enforceable undertakings and injunctions are a sophisticated compliance tool to use for enforcement. Due to the infancy of this compliance scheme, the department is not intending to include these at this time. However, in the future after operating under the scheme for several years, there will be a review of all compliance measures to determine if any additional measures or changes may be required.	This measure has been removed from the proposed measures.

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<p><i>Changes to existing reporting requirements</i></p>	<p>Some stakeholders suggested that there is the potential to change some of the existing reporting requirements to incorporate some of the new proposed measures. Modification to existing HCP or PHDB data could incorporate some of the new requirements, or provide information that would be useful to manage compliance of the PL.</p>	<p>The department acknowledges that information is already being provided by stakeholders to the department which may be useful for managing compliance of the PL. The team is currently undertaking an assessment of the feasibility to use or modify existing data, or at a minimum ensuring that there is no repetition in the requirements.</p>	<p>There is negligible risk for patients or the PL.</p>

Table 2. Key feedback from the questions proposed in the consultation paper for the proposed measures for the Compliance, Assurance and Information sharing legislation.

This table outlines the 18 questions that were asked during the consultation on the proposed measures for the compliance, assurance and information sharing legislation and the stakeholder feedback that was received in relation to each of those questions. Using this feedback, the department has outlined the response that we are proposing to undertake. However, note that this is not final and may change during the drafting process for the legislation or resulting from any further consultation.

Consultation Question	Stakeholder response	Department response
<p>1. Do you support the concept of a ‘shared responsibility’ for safeguarding the Prescribed List? If not then why not?</p>	<p>The majority of stakeholders supported the concept of ‘shared responsibility’ for the Prescribed List (PL), but would like to see a balanced approach, with no stakeholder taking on the majority of the burden. Stakeholders should also not be responsible for areas or decisions outside of their control.</p>	<p>The department is working towards involving each of the stakeholder groups in becoming active participants in safeguarding the Prescribed List, and is conscious of not requiring stakeholders of being responsible for areas not relevant for them.</p>
<p>2. Do you consider that the role of insurers, sponsors and hospitals in safeguarding the Prescribed List needs to be expanded? If so, what additional obligations do you consider are necessary and why?</p>	<p>Some stakeholders suggested that the role of insurers could be expanded by documenting and reporting any decisions in relation to refusing to pay a benefit claim, whilst hospitals could do more to identify potential fraudulent use of the PL by suppliers and sponsors. Others stated that there should be more accountability for sponsors in ensuring that their devices and products are listed correctly, there should be more transparency around discounts and rebates, and the commercial impacts of non-compliance activities should be considered with corresponding penalties.</p> <p>Stakeholders believe that obligations should be well defined for each stakeholder group, with some stating that they would like to see</p>	<p>The department is currently undertaking a review of what information is being provided by insurers and assessing whether there is scope to bring in a requirement for insurers to record and report any denied benefit claims.</p> <p>Part of the role of compliance going forward will be to use the powers the legislation will provide to try and identify any instances of fraudulent or non-compliant behaviour related to the PL. Additionally, as part of the compliance strategy, there will also be a program of education and training in any areas that are identified where knowledge could be improved to help with the operation of the PL.</p>

Consultation Question	Stakeholder response	Department response
	<p>the department provide education and training to those who engage with the PL.</p>	<p>Some reform measures, including regrouping of the PL and the new assessment pathways aim to improve the integrity and accuracy of the PL. Through the newly implemented assessment pathways, sponsors will have more clarity and accountability on the evidence they must provide. The HPP will also provide some functionality for sponsors to keep information up to date.</p> <p>Implementing a system where penalties corresponded with the commercial impacts would be very difficult to operationalise and would be open to interpretation.</p> <p>The department is currently looking into the feasibility of introducing a measure that would require hospitals/sponsors to report any discounts or free devices or products that they received/given for items on the PL.</p>
<p>3. Do you agree with the policy principles used for developing the proposed measures?</p>	<p>Most stakeholders agreed with the policy principles used for developing the proposed measures. In particular, some stakeholders supported the principles of proportional response to the issue being addressed, extra clarification in the obligations, and aligning with other data keeping and regulators such as the TGA to minimise regulatory burden and duplication.</p> <p>Some stakeholders believed there was a lack of detail around the rationale supporting some</p>	<p>The department has tried to align offences with a proportional penalty and has removed some sanctions from the measures such as revoking of a hospital's declaration as they were deemed disproportionate to the offence.</p> <p>Prior to the measures coming into force, the department will be looking to provide further guidance and education about the measures and will ensure that obligations for stakeholders are clearly defined.</p>

Consultation Question	Stakeholder response	Department response
	<p>of the principles and the measures underpinning them.</p>	<p>The department has been involved in discussions with other areas around the department to discuss similar record keeping and data requirements to ensure that there were no requirements that were being asked to be repeated.</p> <p>There are plans to have further discussions with the TGA regarding possible collaborations on any data or notification requirements.</p>
<p>4. What additional resources would be useful to consider in developing the proposed measures?</p>	<p>Some stakeholders suggested that there could be some extra clarity on which medical devices and human tissue products were covered by the PL if product numbers were included for each billing code.</p> <p>Discussions with other departments and areas within the department would be useful to ensure that there is a consistent approach to data collection.</p> <p>Stakeholders would like to be included in further consultation on the proposed measures, including the exposure draft of the legislation.</p> <p>The provision of standardised reporting templates would also be useful for stakeholders.</p>	<p>With over eleven thousand medical devices and human tissue products already on the PL, expanding this list to include product or catalogue numbers for each billing code, as well as maintaining the accuracy of the product numbers, would be a considerable task.</p> <p>Discussions have already been held with some areas of the department about what requirements they have for stakeholders and what records they keep and need to report. There are plans to hold further discussions about requirements with other agencies and areas within the department such as the TGA.</p> <p>The department is holding further consultation on the proposed measures. There will be further consultation on the proposals for hospitals/sponsors to record any listed items they receive/give free of charge, or at discounted prices,</p>

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		<p>and on the measure that limits sponsors from charging higher than the PL benefit. Additionally, there will be further consultation on the exposure draft of the legislation once the legislation is drafted.</p> <p>There are plans to create templates where feasible to assist with any record requirements.</p>
<p>5. What are the likely impacts of each proposed measure from your perspective?</p>	<p>Stakeholders questioned why they were being asked to keep additional records when there was an active push from government to reduce the collection of sensitive information and minimise the cyber risk.</p> <p>Stakeholders stated that these measures will increase the regulatory burden with an increase in administrative and regulatory costs, which increases the risk for hospitals who are already operating with minimal resources. Extracting the information out of hospital systems may also be difficult, and there could be significant costs to implement the record keeping requirements.</p> <p>Some stakeholders stated that these measures would lead to an increase in the confidence of the PL listings and their clinical application, although actively managing PL listings will add additional costs.</p> <p>Removal of an item from the PL or revocation of a hospital declaration will have a significant impact on patients.</p>	<p>The department understands that there are additional risks when maintaining sensitive information, which is why the department has explored the feasibility of incorporating any record keeping requirements into existing requirements for stakeholders. Some record keeping measures proposed in the consultation paper have been removed.</p> <p>To reduce some of the regulatory burden and costs associated with record keeping, the department is looking to provide templates which may assist with some of the data requirements.</p> <p>The department recognises that revoking a hospital's declaration or removing an item from the PL would not be a proportionate response to providing false or misleading information and has removed these sanctions for this offence.</p>

Consultation Question	Stakeholder response	Department response
<p>6. How might these impacts be mitigated?</p>	<p>Clear guidelines and lines of communication channels should be established, including the department providing adequate examples of what would be expected to be required.</p> <p>Any duplication in regulatory requirements or data collection with other areas of the department such as TGA should be minimised. Some stakeholders would like to see the creation of a connection between the PL and the TGA, particularly in relation to reporting requirements and ARTG numbers.</p> <p>The PL could look at the way the PBS scheme works with regards to accountability mechanisms etc. which are very effective at ensuring accuracy and quality of information provided by sponsors.</p>	<p>Prior to the implementation of the legislation, the department is planning on providing some further educational guidance on the requirements and what is expected. Included in this, will be the provision of any templates if applicable.</p> <p>As stated above, the department continues to explore regulatory requirements that are imposed by other areas of the department with the intention of reducing any duplication. Additionally, avenues where requirements could be combined are also being looked into.</p> <p>Public summary documents will not be brought in at this stage. Further work is needed to be undertaken into what information they would hold, who would complete that information and if it is feasible to provide a public summary document for all listed products on the PL.</p>
<p>7. What do you think of the concept of introducing ‘conditions of listing’ as a means of introducing new obligations on sponsors? In your view, is it possible to readily differentiate these ‘conditions of listing’ from the current ‘conditions for the provision of a listed device or product’?</p>	<p>Most stakeholders either supported the concept of introducing ‘conditions of listing’ or were neutral in their stance.</p> <p>Introducing conditions of listing would clearly outline obligations for sponsors. However, if it was implemented, stakeholders would like there to be a clear distinction between the two sets of conditions, or perhaps they could even be combined.</p>	<p>The department would need to undertake further investigation before potentially bringing in conditions of listing for medical devices and human tissue products.</p> <p>Future discussions with the TGA are planned to discuss how the PL and TGA requirements could possibly be combined, including investigating new</p>

Consultation Question	Stakeholder response	Department response
	<p>Additional conditions will lead to an increase in accountability of sponsors for their listings.</p> <p>Stakeholders also suggested that the department could work in conjunction with the TGA about developing a consistent set of conditions of listing.</p>	<p>and more efficient ways of undertaking common requirements and notifications.</p>
<p>8. One point that stakeholders may wish to comment on would be the use of different 'Rules' for specifying the record keeping and notification requirements in Proposed Measures 1, 2 and 3. Should these requirements for listed devices and products be specified in the MDHTP Rules for <u>all</u> stakeholders, or should different Rules include these obligations?</p>	<p>Generally, stakeholders supported the concept of combined rules or were neutral. It would be easier for stakeholders to identify their requirements and reduce some of the administrative burden if the requirements were all in the same Rules.</p>	<p>All record keeping and notification requirements will be specified in the same document for all stakeholders – the MDHTP Rules.</p>
<p>9. Should additional considerations apply before removing a listed device or product or revoking a hospital declaration for providing either false or misleading information or not complying with record keeping obligations? For example, should any detriment to insured persons from removing a listed device or product or revoking a hospital declaration be considered?</p>	<p>Most stakeholders agreed that the potential impact on insured individuals should be carefully weighed against any compliance measures. If the removal of a listed device or product compromises standards of patient care, then other punitive measures should be considered.</p>	<p>The department understands that revoking a hospital declaration or removal of a device or product from the PL may be an excessive sanction for providing false or misleading information. These sanctions have been deemed to be disproportionate to the offence and have been removed.</p>
<p>10. Should the offences in the Criminal Code continue to be relied on as the only means for dealing with false or misleading information?</p>	<p>There was no clear preference for stakeholders regarding the Criminal Code. Some stakeholders believe that the fines included in the Criminal Code are comparatively small in relation to the size of</p>	<p>The department will look to include new offences which can also be relied on which will allow for larger penalties if required.</p>

Consultation Question	Stakeholder response	Department response
	some stakeholder companies, and that the penalties should be proportional.	
<p>11. In Proposed Measure 7, what is the value of a new strict liability offence and a new underlying offence for providing false or misleading information when the Criminal Code already applies?</p>	<p>Some stakeholders were supportive of creating a new strict liability and underlying offence, while others were against it. One of the main concerns from stakeholders was that the penalties under the criminal code were relatively small in relation to the size of some of the companies and the benefit amounts for devices on the PL. New offences would allow a larger sanction to be placed on a person if required.</p>	<p>The department will look to include the new offences and will consult with the Office of Parliamentary Counsel during the drafting of these new offences.</p>
<p>12. Should additional compliance measures be considered? Please provide the basis for these additional measures.</p>	<p>Some stakeholders suggested that the current proposed measures were adequate and that further measures should not be considered at this time until their effect could be evaluated. Additional compliance measures that were suggested during consultation included independent audits and standardised reporting mechanisms, expansion of PHDB data collection and the requirement for insurers to document and report the benefit claims that they questioned or declined.</p>	<p>The department is currently looking into the possibility of insurers reporting their declined benefit claims and may bring this measure in in a future amendment.</p> <p>One new measure that has been proposed to be included in the measures that was not outlined in the consultation paper is a measure that limits the amount that sponsors can charge. This measure would limit the cost of devices and products sold to hospitals and clinicians to the benefit amount on the PL.</p>
<p>13. Do you think there are other agencies that should be authorised for disclosure of protected information? For example, professional associations for health care providers?</p>	<p>Some stakeholders were concerned about the protection of sensitive information and the risk of sharing this information with other agencies. Generally, stakeholders were happy to disclose protected information to the agencies listed in the consultation paper, or other government bodies such as the Australian</p>	<p>There is no plan to extend the list of agencies beyond that that was mentioned in the consultation paper.</p>

Consultation Question	Stakeholder response	Department response
	Taxation Office, but did not want to see that list expanded to professional associations or clinical bodies.	
<p>14. Do you think the objects of the Act should be amended to recognise the expanded scope contemplated in the proposed measures? What do you think of the proposed additional object for the PHI Act?</p>	<p>Most stakeholders agreed with or were neutral towards the proposed amended object of the Act.</p>	<p>The objects of the Act will be amended to recognise the expanded scope contemplated in the proposed measures.</p>
<p>15. How might Public Summary Documents (PSDs) be introduced in an incremental manner? For example, what kinds of devices or products should first be required to have a Public Summary Document?</p>	<p>Stakeholders suggested that PSDs for listed devices or human tissue products could be incrementally introduced by prioritising items that have conditions associated with them, items that have high use, or for applications for items that would fall into a new group in which feedback on the decisions made would be useful.</p>	<p>Further work needs to be undertaken by the department in relation to PSDs before they can be introduced. This includes exploring the various options on what information could be included on a PSD, including who would be responsible for completing the PSD, as well as the feasibility of any collusion with the Therapeutic Goods Administration (TGA) about a combined PSD.</p>
<p>16. What do you think of the proposed incremental implementation of the proposed measures?</p>	<p>Stakeholders supported the incremental implementation of the proposed measures as they acknowledged that they would need time to adjust to the new measures.</p>	<p>The department will continue with the planned staged implementation, beginning with Schedule 1 after Royal Assent and concluding with Schedule 4 commencing on the tentative date of 1 July 2026.</p>
<p>17. The department is considering whether a statutory review should be provided for in the PHI Act so that there is an independent review of the measures</p>	<p>Most stakeholders either supported the idea of a statutory review or were neutral about it. Several stakeholders supported a statutory review, not just on the measures introduced</p>	<p>At this stage, a statutory review will not be undertaken. However, one may occur</p>

Consultation Question	Stakeholder response	Department response
<p>introduced as part of the reforms. Would you support such a review and what would be important elements of the review from your perspective?</p>	<p>as part of the reforms, but on the whole of the PHI Act.</p>	<p>in the future once the measures have been operating for a period of time.</p>
<p>18. Do you consider that disqualifying criteria should apply for sponsors of listed devices or products in that if the sponsor has been convicted of a criminal offence then should the sponsor be disqualified from being a sponsor for a listed device or product?</p>	<p>Stakeholders generally agreed that there should be some disqualifying criteria for sponsors. However, most of those that agreed, believed that it should be linked with the sponsor's ability to operate within the Australian market and not in relation to individual PL listings.</p>	<p>While agreeing with stakeholders that removing an item from the PL due to providing false or misleading information was a disproportionate sanction in relation to the offence, the department is reconsidering leaving in the ability to remove an item from the PL if needed. This would be a potential sanction to act as a deterrent for sponsors acting in or encouraging non-compliant or criminal behaviour.</p>