

19 February 2016

MSAC Reform Team
MSAC Reform Section
MSAC.Reform@health.gov.au

Dear MSAC Reform Team

Re: Medical Services Advisory Committee (MSAC) Reform Consultation

AusBiotech would like to thank the department for the opportunity to comment on the draft MSAC Reform consultation documentation and the proposed streamlining of MSAC health technology assessment (HTA) processes.

AusBiotech is a well-connected network of over 3,000 members in the life sciences industry, which includes bio-therapeutics, medical technology, and agricultural biotechnology sectors. The industry consists of an estimated 900 biotechnology companies and employs in excess of 45,000 Australians.

The AusMedtech Health Economics Expert Panel (the Panel) is an expert group of practicing health economists from amongst AusBiotech's member organisations who provide advice on matters including the reimbursement of medical devices.

The Panel members have reviewed the consultation documents on behalf of AusBiotech and have provided feedback that has formed the basis of this submission.

The advice from the Panel is that the reforms, which have focused on the efficiency, transparency, accountability and consistency of processes, have not resulted in processes that are materially different to existing MSAC processes and that they may lead to less efficient and less consistent outcomes.

The key concerns that have been raised with AusBiotech are:

Lack of emphasis on technical HTA Guidelines

AusBiotech has previously stated the importance of clear HTA guidelines to efficiently support applicants through the assessment process and to minimise the administrative burden of the HTA process on the Secretariat.

If the HTA guidelines are given primacy within the MSAC process then, the development of protocols becomes less onerous (or sometimes unnecessary), segmentation becomes less important and the MSAC system becomes much more sustainable because it is built around a clear, generalisable and transparent set of principles which can apply to every application and every stakeholder.

AusBiotech is concerned that the detailed MSAC processes in the reform are being designed to accommodate the fact that the existing draft Guidelines are not being used, not followed or not understood.

AusBiotech strongly recommends that the MSAC Reform Team place greater emphasis on enhancing, and ensuring applicants awareness of, and compliance with the HTA guidelines, and less emphasis on segmentation, additional assessment and decision making within the Secretariat.

Removal of applicants from the protocol development

AusBiotech members are concerned that elements of the reform which propose to reduce applicants' input into the development of protocols may increase the workload on the already stretched resources of the Secretariat. It is worth noting that applicant preparation of protocols evolved out of a desire for applicants to be in greater control of the timeliness of the assessment. Timeliness could not be guaranteed by the department largely because it could not guarantee the availability of skilled assessors within the Secretariat.

While agreeing with the desire of the Department and PASC to ensure a consistent standard of protocols, removing applicants from the process is not necessarily the most efficient manner in which to do so. Rather, we propose this consistent standard can be achieved by requiring protocols to be written according to a clear set of protocol guidelines.

To some extent the Application Form guidelines may help the department achieve a more consistent standard of protocol. However, the Application Form guidelines support the completion of a form which will later be turned into a protocol. AusBiotech members are concerned that this is less efficient and may result in less overall consistency than would be achieved if clear guidelines for the applicant preparation of protocols were in place.

AusBiotech believes the applicant preparation of protocols is a good initiative that should be encouraged and expanded upon in order to meet the MSAC reform objectives of efficiency, accountability and sustainability.

AusBiotech believes the reforms could be used as an opportunity to seek more, not less, input from the applicants. AusBiotech would encourage the Department to further draw upon the skills already present in industry, rather than requiring more from the already overly-stretched resources of the Secretariat.

The relatively recent initiative to invite applicants to the PASC meetings is welcomed. In many respects this initiative could be expanded to include applicant attendance – in a controlled and efficient manner – at ESC and MSAC meetings.

MSAC Resources

The draft Segmentation Framework appears to outline a process requiring additional assessment and decision making within the Secretariat. AusBiotech members have expressed concern that this would likely require a substantial increase in skilled resources within the Secretariat to absorb the additional work that this would entail. Members have reported to AusBiotech for the last few years the Secretariat has largely been constrained to providing basic administrative support and that already many questions requiring clinical or economic assessment have had to be referred to other sources.

The proposed Segmentation Framework with the additional steps and decision points may exacerbate this situation.

A stated aim of the MSAC reforms was to facilitate a “repeatable” and “sustainable” process. AusBiotech cautions the department to limit initiatives that require additional input from the Secretariat as reliance on a small number of key personnel within the Secretariat may actually compromise the repeatability and sustainability of the process.

Segmentation Framework Timelines

AusBiotech members have expressed concern that although the Segmentation Framework details

additional steps and processes in excess of those already employed in the current MSAC processes, there are no timelines incorporated in the Framework. A key strength of the current MSAC processes is the definitive timelines that give certainty to both the applicant and the MSAC. While it may be the intention of the Framework to include specific timelines in the finalised process, there is no indication of this except that 'indicative' PASC and MSAC meeting dates will be identified.

Certainty and transparency of review timelines is critical for business planning. Initiatives that undermine an applicant's ability to forward plan would not be acceptable to industry. It is also in the interests of government, providers and patients that transparent timelines are set and then followed.

Recommendations

AusBiotech thanks the HTA Assessment team for considering this submission and would like to make the following suggestions based on feedback from its members:

- AusBiotech welcomes the focus of the Reform on the entire HTA process, but strongly urges the Reform Team consider increasing the focus on expanding and refining the HTA guidelines. Members believe that efforts to expand and improve the HTA guidelines will minimise the administrative burden on the Secretariat, improve consistency of HTA process and help provide certainty for applicants.
- AusBiotech cautions the Reform Team recommending changes that may lead to additional administrative burden for the secretariat; in particular, changes that require skilled assessment that can only be undertaken by a highly-skilled assessor.
- AusBiotech urges the Reform Team to consider boosting initiatives that draw upon skilled resources within industry both in the development of protocols (supported by expanded HTA guidelines) and in the inclusion of applicants at ESC and MSAC meetings in the same way that PASC meetings have been expanded to include applicant attendance.
- AusBiotech assumes that it is the intention of MSAC to include clear timelines in the Segmentation Framework, but would like to emphasize that certainty and transparency is critical for business planning and any initiative that undermines an applicant's ability to forward plan would be unacceptable to industry. Clear and transparent timelines are a critical aspect of forward planning for applicants.

If you have any questions regarding this submission or would like to arrange a time to meet, please contact the AusBiotech National Programs Manager, Dr Mick Blake mblake@ausbiotech.org (ph: (03) 9828 1425).

Yours sincerely



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