



Australian Government

Medical Services Advisory Committee

Public Summary Document

Application No. 1679 – Improved medication management for Aboriginal and Torres Strait Islanders Feasibility Study (IMeRSe Feasibility Study)

Applicant: Pharmacy Guild of Australia

Date of MSAC consideration: 31 March – 1 April 2022

1. Purpose of application

An application requesting Medicare Benefits Schedule (MBS) listing and public funding of an Indigenous Medication Review Service (IMeRSe) for Aboriginal and Torres Strait Islander peoples with potential for medication-related problems (MRPs) was received from the Pharmacy Guild of Australia.

2. MSAC's advice to the Minister

After considering the strength of the available evidence in relation to comparative safety, clinical effectiveness and cost-effectiveness, MSAC did not support the public funding of the Indigenous Medication Review Service (IMeRSe). MSAC considered the evidence presented did not demonstrate the comparative effectiveness and cost-effectiveness of the proposed service with existing services. MSAC advised that there is an unmet need for culturally appropriate medication review services for Aboriginal and Torres Strait Islander peoples and that the IMeRSe Feasibility Study identified limitations and gaps with existing medication review services. MSAC suggested the Department could consider reforms to existing Pharmacy Programs, with a focus on improving access to these programs for Aboriginal and Torres Strait Islander peoples.

Consumer summary

This is an application from the Pharmacy Guild of Australia (PGA) requesting Medicare Benefits Schedule (MBS) listing and public funding of an Indigenous Medication Review Service (IMeRSe) for Aboriginal and Torres Strait Islander peoples who may have medication-related problems.

Medication review services are intended to support the quality use of medicines and reduce medication misadventure, by assisting patients to better manage and understand their medicines. There are different types of medication review services that are publicly funded through a [Community Pharmacy Agreement](#) between the Commonwealth Government, Pharmacy Guild of Australia and the Pharmaceutical Society of Australia. This includes the

Consumer summary

[Home Medicine Review](#), [Residential Medication Management Review](#), [MedsCheck and Diabetes MedsCheck](#).

The IMeRSe study was specifically co-designed through a partnership between the PGA and the National Aboriginal Community Controlled Health Organisation (NACCHO) to be a culturally responsive medication review service, delivered by community pharmacists in conjunction with local Aboriginal Health Services (AHSs) staff, to address an important gap in the health services delivered to Aboriginal and Torres Strait Islander patients.

MSAC noted a single, small feasibility study tested whether this service could be provided in a safe, clinically effective and cost-effective manner. The study found that IMeRSe led to improvements in patient concern with their medicines, medication adherence, growth and empowerment, and treatment satisfaction after participating in the program. However, the study reported that IMeRSe did not result in a change (reduction) in potentially preventable medication-related hospitalisations or serious medication-related problems. MSAC considered the clinical effectiveness was uncertain and as a result the cost-effectiveness of IMeRSe was uncertain.

Further, MSAC raised a number of concerns with the way IMeRSe was proposed to be implemented and was concerned that IMeRSe would not be implemented in a way that would provide a coordinated and integrated multidisciplinary medication review service for Aboriginal and Torres Strait Islander peoples.

Overall, MSAC did not support MBS listing and funding for IMeRSe. However, MSAC considered that there is an unquestionable clinical need for better culturally aware and culturally safe medication review services that are delivered to Aboriginal and Torres Strait Islander peoples using an integrated and collaborative multidisciplinary model of care. MSAC suggested the Department could consider reforms to existing Pharmacy Programs, with a focus on improving access, applicability and cultural safety of these programs for Aboriginal and Torres Strait Islander peoples.

MSAC's advice to the Commonwealth Minister for Health

After considering the strength of the available evidence in relation to comparative safety, clinical effectiveness and cost-effectiveness, MSAC did not support MBS funding of an IMeRSe for Aboriginal and Torres Strait Islander peoples with potential for medication-related problems. MSAC considered that there was a need for better culturally aware and culturally safe medication review services and suggested the Department could consider reforms to existing Pharmacy Programs, with a focus on improving access, applicability and cultural safety of these programs for Aboriginal and Torres Strait Islander peoples.

3. Summary of consideration and rationale for MSAC's advice

MSAC noted the application was from the Pharmacy Guild of Australia (PGA) requesting MBS listing and public funding of IMeRSe for Aboriginal and Torres Strait Islander peoples with potential for MRPs.

MSAC noted that medication management reviews (MMR) for all Australians are currently funded under the Seventh Community Pharmacy Agreement (7CPA) MMR programs: the Home Medicines Review (HMR) program, the Residential Medication Management Review (RMMR) program, and the MedsCheck and Diabetes MedsCheck programs. MSAC recalled that in 2017 it had appraised the MMR programs and at that time considered there was insufficient evidence to

determine the clinical and cost-effectiveness of the MMR programs. MSAC also recalled it had considered that the design of these pharmacy service programs could be improved by including formal collaboration with General Practitioners (GPs), by being targeted to appropriate patient populations, and by a reduction in the unit cost of providing each pharmacy service coupled with an incentive to increase this cost if adequate evidence can be furnished to justify it. Further enhancement of these programs might better justify the provision of continued funding of these services.

MSAC noted that the IMeRSe study was co-designed to be a culturally responsive medication review service for Aboriginal and Torres Strait Islander people, delivered by community pharmacists in conjunction with local Aboriginal Health Services (AHSs). The feasibility of delivering IMeRSe was tested in the IMeRSe Feasibility Study. However, rather than using the same model of funding as existing MMRs (i.e. under a Community Pharmacy Agreement), the applicant has proposed to implement the IMeRSe intervention by creating three new MBS item descriptors: one for participating pharmacists (with two follow-ups), one for Aboriginal Health Workers (AHW, with two follow-ups) and one for general practitioners (GPs).

MSAC noted the implementation and item descriptor issues raised by ESC and agreed that consequently the proposed approach for implementing IMeRSe does not align with primary health reforms aiming to provide coordinated and integrated multidisciplinary health care. MSAC acknowledged the expertise, knowledge and value of the pharmacist's role in providing medication reviews, which is enhanced by training in medication review and cultural awareness and safety. MSAC also agreed that involvement of an AHW is integral to IMeRSe. However, MSAC noted the proposed model for implementing IMeRSe does not incorporate vital activities from IMeRSe Feasibility Study that supported training, engagement and collaboration. MSAC noted that the proposed implementation of IMeRSe does not require GP referral. MSAC considered that flexibility in referral may reduce access barriers but agreed with ESC's concerns there would be a lack of engagement and collaboration with GPs. MSAC considered that without referral from and collaboration with a GP the pharmacist may not have the necessary information to understand prescribing intentions. Furthermore, the lack of referral could impede implementation of the actions required from the GP that arise from the medication review. MSAC noted that the IMeRSe Feasibility Study relied on shared infrastructure and technology to create a shared clinical record that was accessed by the pharmacist. This infrastructure and technology are not part of current clinical practice and it is unclear whether or how it would be used for implementation of IMeRSe. MSAC considered this could result in a suboptimal medication review, inefficient communication and reduced implementation of its recommendations. MSAC also considered the proposed MBS fees need to be comparable to existing HMR service fees to avoid disincentivising the referral process. Overall, MSAC considered that the proposed funding model for IMeRSe would not lead to successful implementation of a coordinated and integrated medication review service for Aboriginal and Torres Strait Islander people.

MSAC noted consultation feedback was generally supportive of the proposed culturally appropriate medication review service but raised a number of concerns. In particular, the feedback highlighted concerns around the inclusion/availability of AHW to attend; differences in the qualifications for AHW (Certificate III qualification) and Aboriginal Health Practitioners (Certificate IV qualification) and the implications of this; the role of GPs and the proposed MBS fees.

MSAC noted the nominated comparator was usual care (ad-hoc medication management advice from any health professional). MSAC noted that for the identified population (Aboriginal and Torres Strait Islander peoples with at least one chronic health condition and at risk of MRPs), the service most likely to be substituted by IMeRSe is a formal MMR such as an HMR. MSAC

considered HMR is a more appropriate comparator but acknowledged there are barriers for Aboriginal and Torres Strait Islander people to access existing MMR services, including HMRs.

MSAC noted that the IMerSe Feasibility Study was proposed to obtain the necessary clinical data from which to establish the parameters for a larger randomised controlled trial. MSAC noted the pre-post study had no concurrent control group, a small opportunistic sample size, limited duration of the follow up and was associated with a high degree of bias. MSAC also noted it was uncertain whether the AHS sites, community pharmacists and participants in the study are representative of the broader intended AHS sites, community pharmacists and patients expected if the program is implemented. MSAC noted that these sites undertook significant preparatory and implementation work which was facilitated by a trial coordinator.

MSAC considered IMerSe had non-inferior safety relative to usual care. However, MSAC noted that there was uncertainty regarding the comparative effectiveness of IMerSe versus usual care. MSAC noted that there were statistically significant differences, favouring the post-intervention results, in validated surveys regarding concern with medicines, medication adherence, growth and empowerment and treatment satisfaction. However, no differences in potentially preventable medication-related hospitalisations (PPMRHs) and no differences in the primary outcome of serious MRPs (at the 5% level of significance) were observed. Overall, MSAC considered IMerSe to have non-inferior safety and uncertain effectiveness compared to usual care.

MSAC noted the ADAR presented a cost-effectiveness analysis that focussed on MPR and estimated the incremental cost per MRP avoided (e.g. base case estimated IMerSe cost \$1,822 per MRP avoided). MSAC noted the challenges evaluating the cost-effectiveness of IMerSe and noted ESC advice that a cost-consequence analysis that presents all relevant benefits and costs would be more appropriate. MSAC noted that the limitations and uncertainty in the clinical evidence created uncertainty in the economic analysis. MSAC also noted that the ADAR attributed cost-offsets in terms of observed reduction in hospital admissions and emergency department (ED) presentations to the intervention but that this cannot be reasonably justified. MSAC noted that this offset assumed causality but this is in direct contradiction to the IMerSe Feasibility Study which reported zero difference in the pre- and post-intervention rates of PPMRH. Overall, MSAC considered the cost-effectiveness of IMerSe was highly uncertain.

MSAC noted the ADAR financial estimates predicted that the IMerSe would be cost-saving (ranging from a saving of \$0 to < \$10 million per year up to \$30 million to < \$40 million per year) due to reduction in inpatient and ED costs. However, as noted for the economic analysis, MSAC considered that the estimated cost savings based on hospital inpatient costs and ED costs to be unreliable. MSAC also noted there are no clear criteria to determine eligibility and therefore it is difficult to predict utilisation. MSAC questioned the 5% uptake estimated in the ADAR and considered that the actual uptake will depend on implementation. MSAC noted the uptake in the IMerSe Feasibility Study was 5% but that the study included intensive support and engagement roles/activities (e.g. study coordinator) that are not proposed as part of implementing IMerSe. Overall, MSAC considered the financial estimates for IMerSe were highly uncertain.

Overall, MSAC did not support MBS listing and funding for IMerSe on the basis that the evidence presented did not demonstrate the comparative effectiveness and cost-effectiveness of the IMerSe with existing services. Further, MSAC had significant concerns that the proposed approach to funding and implementing IMerSe would not lead to the successful implementation of a coordinated and integrated multidisciplinary medication review service for Aboriginal and Torres Strait Islander people. MSAC also noted that implementing the proposed IMerSe could conflict with, confuse and duplicate existing HMR services.

MSAC considered that there is an unquestionable clinical need for better culturally aware and culturally safe MMR services that are delivered to Aboriginal and Torres Strait Islander peoples

using an integrated and collaborative multidisciplinary model of care. Further, MSAC noted that this application highlighted that there are a number of barriers for Aboriginal and Torres Strait Islander peoples to access existing MMR services. MSAC suggested the Department could consider reforms to existing Pharmacy Programs, with a focus on improving access and cultural appropriateness of these programs for Aboriginal and Torres Strait Islander people. MSAC noted that some of the barriers could be reduced by considering policy reforms to existing MMR services to provide flexibility in referral pathways and location where the services are conducted for Aboriginal and Torres Strait Islander people. MSAC considered the role of the AHW was integral to IMeRSe and the policy reforms could consider how AHW inclusion in MMR services for Aboriginal and Torres Strait Islander peoples can be supported. MSAC also noted that the requirement for pharmacist accreditation was described as a barrier. MSAC suggested the Department could explore whether pharmacist accreditation is a barrier and consider ways to reduce this barrier. MSAC considered that pharmacists delivering MMR services to Aboriginal and Torres Strait Islander peoples should be encouraged to have undertaken cultural awareness and safety training.

4. Background

The IMeRSe Feasibility Study was funded under the Department of Health, Pharmacy Trials Program (PTP, Tranche 2) as part of the Sixth Community Pharmacy Agreement (6CPA) that sought to assess the feasibility of a culturally responsive Indigenous Medication Review service, delivered by community pharmacists, supported by cross-cultural training and mentoring integrated (and in conjunction) with local AHSs staff.

\$50 million was provided over the Term of the 6CPA to fund the PTP as a whole. Once finalised, consistent with the 6CPA, the outcomes of each PTP trial were to be evaluated by an independent health technology assessment body to determine the effectiveness and cost-effectiveness of the trial intervention and inform decisions about any broader rollout. A decision to fund any future programs would be a matter for Government.

MSAC review of 6CPA Medication Management Review (MMR) Programs

In April 2017, MSAC appraised the evidence for MMR Programs: HMR (also referred to as Domiciliary Medication Management Review [DMMR]), RMMR and MedsCheck/Diabetes MedsCheck Program (refer to [MSAC Minutes](#)).

MSAC advised that there was insufficient evidence to determine the clinical and cost-effectiveness of the continuing 6CPA MMR programs, and thus a weak basis upon which to recommend that funding should be supported or ceased. MSAC advised that further research would be required to make a more robust assessment of the comparative clinical and cost-effectiveness of the MMR programs.

With respect to the HMRs, MSAC advised that there is no clear evidence that HMR reduces hospitalisations and mortality or improves quality of life. MSAC also advised that there is low level of evidence to suggest that HMR increased time to next hospitalisation, although the evidence on the effect of HMR on reduction in health care resource use is conflicting. There is also insufficient evidence to assess patient satisfaction with pharmacist-led HMR.

MSAC considered that the design and value of these pharmacy service programs could be improved by including formal collaboration with GPs and other healthcare networks, by being targeted to more appropriate patient populations, and by a reduction in the unit cost of providing each type of pharmacy service coupled with an incentive to increase this unit cost if adequate

new evidence can be furnished to justify an increase. Further enhancement of these programs might better justify the provision of continued funding of these services.

5. Intervention

The ADAR described IMeRSe as a six-step collaborative intervention that reflects a primary healthcare team approach involving: the consumer, AHS staff (AHW and/or AHS clinician), community pharmacist and a GP. IMeRSe consists of a community pharmacist-led medication management review with a consumer participant, supported by an AHW, and finalised by a GP-led medication plan in consultation with the consumer, AHW and community pharmacist.

Both the intervention in the IMeRSe Feasibility Study and in the ADAR are described as the same six-step collaborative intervention:

1. Consumer identification, recruitment and informed consent
2. Referral, information exchange and appointments
3. Medicines Talk
4. Medicines Report
5. My Medicines Plan
6. Structured follow-up and monitoring over the next 6-months.

The commentary noted that in the IMeRSe Feasibility Study, prior to step 1, there was a large degree of community engagement and training of staff in both the AHS (GPs, AHW, AP, administration) and the community pharmacy to create a 'community of practice, relationship and specific recruitment strategies for different communities. These activities were reported in the IMeRSe Feasibility Study as vital to establishing the relationships to facilitate the intervention. However, none of these activities are described as being part of the intervention for implementation in the ADAR.

The commentary also noted that in the IMeRSe Feasibility Study, step 1 of the intervention described a complex team based approach to identifying likely participants that involved opportunistic recruitment occurring during scheduled/unscheduled appointment, at specialist clinics, outreach visits, community barbeques, when dispensing medication and self-referral, as well as targeted identification through review of clinical databases, participants assessing other services and via recall lists. In addition, specially trained Study Coordinators (who were recruited from the AHS) were reported to play a critical role in the implementation and facilitation of the Intervention. For example, Study Coordinators facilitated consumer consent, access to clinical information for eligibility and sharing with pharmacists. The commentary noted it was not demonstrated which approach was most successful at identifying participants. Further, the complex team-based approach does not appear to be supported by the proposed implementation of IMeRSe and there is a lack of clarity on the pathway for identification, referral to a pharmacist and communication of clinical information.

The commentary noted that the ADAR proposed that it is feasible to implement IMeRSe across the 247 organisations that provide primary health services Aboriginal and Torres Strait Islander peoples as well as mainstream GP clinics. The commentary considered the IMeRSe Feasibility Study did not provide evidence to support this assumption. It was noted that only one mainstream primary health clinic was included, and as reported in the IMeRSe Feasibility Study, the 15 Medicines Plans that were not reviewed and finalised by GPs came from one study site, where mainstream (private) medical practices were responsible for the clinical care of the participants.

The pre-ESC response clarified that there are a number of ways that a consumer’s clinical information could be provided to the pharmacist prior to an IMeRSe service, for example, an AHW, nurse, or GP could provide the information, or arrangements could be made for the pharmacist to have access to clinical records at the health service. The pre-ESC response noted that this may not necessarily require an MBS Item number but could be possible via access through the new Indigenous Health Services Pharmacy Support Program (which was introduced after this MSAC submission). It was also claimed that failure for GPs to follow up can occur with existing MMR services and therefore referral by a GP does not guarantee any subsequent pharmacist report will be reviewed by the doctor. The pre-MSAC response reiterated that GP referral is a barrier for Aboriginal and Torres Strait Islander peoples to access existing MMR programs and that the IMeRSe was specifically designed with flexibility in the referral process to address this barrier.

MSAC considered that flexibility in referral may reduce access barriers but agreed with ESC’s concerns there would be a lack of engagement and collaboration with GPs and that it is important to ensure the proposed service aligned with primary health reforms aiming to provide coordinated and integrated multidisciplinary health care.

6. Proposal for public funding

The ADAR requested funding for IMeRSe by proposing three new MBS item descriptors: one for participating pharmacists (with two follow-ups), one for AHWs (with two follow-ups) and one for GPs. In addition, block funding was proposed to support the training and mentoring of all health practitioners and support staff involved in the delivery of IMeRSe and clinical mentoring of participating pharmacists, similar to that undertaken in the IMeRSe Feasibility Study.

The proposed MBS item and block funding are presented in Table 1.

Table 1 Newly proposed MBS item

Category 8 – Miscellaneous Services Group-M3- Allied Health Services
Aboriginal and Torres Strait Islander medication review service (IMeRSe)
<p>Participation by a pharmacist in a culturally responsive medication management review with a consumer living in a community setting, in which the pharmacist, with the consumer’s consent:</p> <p>(a) assesses and confirms the consumer is:</p> <ol style="list-style-type: none"> i. a self-identified Aboriginal or Torres Strait Islander Australian; ii. aged 18 years or over; iii. at risk of medication-related problems (as identified by any treating health professional, or family member, or self-identified) including but not limited to: <ul style="list-style-type: none"> ▪ being diagnosed with at least one chronic condition, which is current, and/or is pregnant, and/or is within 2 years post partum; ▪ instability of health status and/or medication therapy; ▪ using high-risk medication(s); ▪ likelihood of compromised adherence; ▪ new therapeutic goals; ▪ potentially incomplete understanding of medication use; or ▪ failure to respond to treatment in an expected way <p>(b) following assessment, undertakes a medication management review (Tier 1), at a location agreed upon by the consumer, in conjunction with a recognised support worker (AHW or other clinic staff), and family member or carer as requested by the consumer;</p>

- (c) develops a written medication report for submission to the consumer's usual GP within 2 weeks of undertaking the medication review;
- (d) undertakes any follow-up (Tier 2) required by the consumer or GP, with up to 2 interactions in the subsequent 12 month period.

For any particular consumer – applicable not more than once in each 12 month period, except if there has been a significant change in the consumer's condition or medication regimen requiring a new medication plan. Ineligible if a Domiciliary Medication Management Review (DMMR), Residential Medication Management Review (RMMR), or MedsCheck service has been provided in the previous 12 months.

Fee: \$ 222.77 Benefit: 100% = \$222.77

First follow-up service

Fee: \$ 111.39 Benefit: 100% = \$111.39

Second follow-up service

Fee: \$ 55.70 Benefit: 100% = \$55.70

Rural loading allowance

Up to \$125 – to contribute to travel costs or the cost of locum hire as required, to allow participation by the pharmacist.

Category 8 – Miscellaneous Services
Group-M3- Allied Health Services

Aboriginal and Torres Strait Islander medication review service (IMeRSe)

Participation by an Aboriginal Health Worker (AHW) in a culturally responsive medication management review for a consumer living in a community setting, in which the AHW, in conjunction with a pharmacist, with the consumer's consent,

- (a) assesses and confirms the consumer is:
 - i. a self-identified Aboriginal or Torres Strait Islander Australian;
 - ii. aged 18 years or over;
 - iii. at risk of medication-related problems (as identified by any treating health professional, or family member, or self-identified) including but not limited to:
 - being diagnosed with at least one chronic condition, which is current, and/or is pregnant, and/or is within 2 years post partum;
 - instability of health status and/or medication therapy;
 - using high-risk medication(s);
 - likelihood of compromised adherence;
 - new therapeutic goals;
 - potentially incomplete understanding of medication use; or
 - failure to respond to treatment in an expected way
- (b) following assessment, participates in a medication management review, at a location agreed upon by the consumer, in conjunction with the AHW (or other clinic staff), and family member or carer as requested by the consumer;
- (c) participates in a subsequent review with the consumer and GP and assists with finalisation of a medication plan for the consumer, as requested by the consumer.
- (d) participates in any follow-up (Tier 2) required by the consumer or GP, with up to 2 interactions in the subsequent 12 month period.

For any particular consumer – applicable not more than once in each 12 month period, except if there has been a significant change in the consumer's condition or medication regimen requiring a new medication plan. Ineligible if a Domiciliary Medication Management Review (DMMR), Residential Medication Management Review (RMMR), or MedsCheck service has been provided in the previous 12 months.

Fee: \$50.00 Benefit: 100% = \$50.00

First follow-up service

Fee: \$25 Benefit: 100% = \$25

Second follow-up service

Fee: \$12.50 Benefit: 100% = \$12.50
Category1 – Professional Attendances Group A17 – Domiciliary and residential medication management reviews
Aboriginal and Torres Strait Islander medication review service (IMeRSe)
<p>Participation by a general practitioner (GP) in a culturally responsive medication management review for a consumer living in a community setting, in which the pharmacist, with the consumer's consent,</p> <ul style="list-style-type: none"> (a) assesses and confirms the consumer is: <ul style="list-style-type: none"> i. a self-identified Aboriginal or Torres Strait Islander Australian; ii. aged 18 years or over; iii. at risk of medication-related problems (as identified by any treating health professional, or family member, or self-identified) including but not limited to: <ul style="list-style-type: none"> i. being diagnosed with at least one chronic condition, which is current, and/or is pregnant, and/or is within 2 years post partum; <ul style="list-style-type: none"> ▪ instability of health status and/or medication therapy; ▪ using high-risk medication(s); ▪ likelihood of compromised adherence; ▪ new therapeutic goals; ▪ potentially incomplete understanding of medication use; or ▪ failure to respond to treatment in an expected way (b) following assessment and submission of the medication management review by the pharmacist, develops a medication plan in consultation with the consumer, including the AHW, and family member or carer as appropriate, within 2 weeks of receiving the medication review; and (c) submits the medication plan to the pharmacist who undertook the medication review, with suggestions for further follow up as deemed appropriate; (d) reviews any documented follow-up actions submitted by the pharmacist (up to 2 interactions in the subsequent 12 month period) and updates the medication plan as required. <p>For any particular consumer – applicable not more than once in each 12 month period, except if there has been a significant change in the consumer's condition or medication regimen requiring a new medication plan. Ineligible if a Domiciliary Medication Management Review (DMMR), Residential Medication Management Review (RMMR), or MedsCheck service has been provided in the previous 12 months.</p>
Fee: \$ 75.05 Benefit: 100% = \$75.05
B. Additional block funding to support implementation in Years 1-5
Aboriginal and Torres Strait Islander medication review service (IMeRSe)
<p>To support the implementation of IMeRSe for Years 1-5, the following services will be provided, subject to the identification of a suitable provider:</p> <ul style="list-style-type: none"> (a) provide cultural capability training for pharmacists, pharmacy staff and mainstream health clinic staff involved in the delivery of IMeRSe, consisting of: <ul style="list-style-type: none"> i. an online training module (already developed and accredited); and ii. a face-to-face or video-conference interactive session with an appropriate provider of cross-cultural training; (b) an ongoing support line for cultural mentoring of any health practitioners or support staff involved in delivering the IMeRSe service, to be provided by a suitably qualified Aboriginal and Torres Strait Islander person/people; (c) an ongoing clinical support line for pharmacists, provided by a clinical pharmacist with extensive medication review expertise; (d) development and moderation of a secure chat line for pharmacists and other health professionals involved in the delivery of IMeRSe; (e) documentation of all services provided for the purpose of external evaluation.
Total: \$ 1,179,550 (\$235,910 per year for 5 years)

Source: Table 1, p8 of the ADAR

The commentary noted that the IMeRSe intervention reflected in the requested funding appears to be a reduced intervention compared to what was delivered in the IMeRSe Feasibility Study. That is, the proposed intervention will provide for a pharmacist-initiated MMR, with an AHW support service and a follow-up GP service for review of the pharmacist's report. The collaborative and preparatory aspects of IMeRSe in the IMeRSe Feasibility Study are not included.

The pre-MSAC response noted there could be an argument for IMeRSe to be delivered as an HMR, provided there was relaxation of the HMR requirements for Aboriginal and Torres Strait Islander peoples to allow the following conditions:

- the service is conducted at a mutually agreed location according to consumer preference
- a more flexible referral pathway (with an established referral relationship between pharmacist and health service to support access to clinical records)
- the involvement of an AHW according to consumer preference
- mandating all pharmacists providing IMeRSe are required to have undertaken an accredited cross-cultural training program (rather than Australian Association of Consultant Pharmacy requirements).

The commentary noted the following points regarding the proposed MBS item pharmacist participation in IMeRSe:

- The proposed MBS item does not specify any further training for the pharmacist either to be accredited to deliver an MMR or to have completed cross-cultural training.
- The proposed MBS item is requesting the same fee (\$222.77) as is received by an accredited pharmacist for doing a HMR and not the fee that was provided in the IMeRSe Feasibility Study (\$128). The ADAR argued that if there is not an equivalent fee a perverse incentive may exist to pharmacists to preferentially undertake HMR services rather than IMeRSe, and the time taken to do the Medicines Talk would be similar to an HMR.
- The proposed MBS item has a limit of three services per patient per calendar year (two follow-up services are provided). It does not provide a cap on the number of medication reviews able to be performed by the pharmacists unlike what currently exists with HMR (30 per month). Only one item is applicable once in 12 months.
- The proposed MBS item includes travel allowance but provides no specifics on how this will be calculated or triggered in the MBS item. This cost is not usually a separate provision in an MBS item.
- It does not require a formal referral for the pharmacist to conduct the IMeRSe.
- Currently, pharmacists are not considered eligible health professionals able to provide services under the MBS.

The commentary noted the following points regarding the MBS item proposed for the AHW to participate in IMeRSe:

- A payment will be triggered for participating in an MMR. Any prior activities to determine a patient's eligibility for IMeRSe will not trigger a payment. The fee requested is the same as what was paid in the IMeRSe Feasibility Study.
- MBS items for AHW currently require the AHW to provide a service under the direction of the Medical Practitioner, or if a practice client has an Extended Care Plan. This item implies that the AHW will be operating outside these constraints. It will need to be determined if this meets their terms of registration as an eligible health professional for MBS purposes.

The commentary noted the following points regarding the MBS item proposed for the GP to participate in IMeRSe:

- The fee is equivalent to a Level C consultation.
- The proposed MBS item requires that the GP develop a medication plan within two weeks of receiving the medication review from the pharmacist. The IMeRSe Feasibility Study reported that the average time between the pharmacist submitting their Medicines Report and the GP submitting the corresponding Medicines Plan was 89.4 days. The two week requirement is unlikely to be met based on the results from the IMeRSe Feasibility Study. The ADAR does not indicate what the consequence would be for the patient if the GP does not follow-up the Medicines Report. It was unclear whether this will mean that a patient will not be able to access other formal MMR in the current 12-month period.
- The proposed MBS item suggest the GP will document and update the medication plan in response to follow-up actions from the pharmacist, but no fee for the GP is proposed for this service.

The commentary noted the following points regarding the proposed block funding:

- The request for block funding to support the delivery of the MBS items may be problematic as the MBS items are ongoing whereas block funding will need to be requested again in another five years' time. This could leave the intervention, if it is successful in getting listed, without the requested support.
- The block funding item is subject to the identification of a suitable provider.
- Due to inconsistencies in the description of the block funding, there was uncertainty whether and how the activities/support listed in the item would be delivered with this funding, the role of primary health clinics and whether there may be barriers to AHS accessing these activities/support.

Overall, the commentary noted that the requested MBS items and block funding did not appear sufficient to replicate the primarily institutional training and relationships required to deliver the requested intervention similar to what occurred in the IMeRSe Feasibility Study to other primary health clinics nationally. The commentary considered that it is unlikely that a service-for-fee model is the appropriate funding model, even with the addition of some block funding for mentoring primarily for pharmacists and delivery of a cross-cultural module. As noted from the IMeRSe Feasibility Study over half of the Medicines Talks occurred at the AHS. This is not provided for under this funding model.

The pre-ESC response clarified that block funding will facilitate training delivery and access to cultural and clinical mentoring in the initial five-year period when IMeRSe is new and limited pharmacy workforce are delivering the service. A cultural capability training package has been developed and accredited. Initial block funding is likely to facilitate more rapid implementation and creation of a workforce that can support or mentor others. The need for additional block funding can then be mitigated through a growing workforce, policy, and health education strategies.

Comparison of IMeRSe structure and funding with existing formal MMR

The ADAR argued although IMeRSe has similarities to formal MMR, IMeRSe is unique in its application providing a culturally responsive MMR to facilitate interaction with Aboriginal and Torres Strait Islander people. The ADAR stated that from a consumer perspective, the biggest difference lies in the cultural safety aspects of IMeRSe. The pre-ESC response reiterated that IMeRSe is a strengths-based, culturally responsive medication review service developed in recognition of the limitations of a 'one-size fits all' approach and sustained access barriers for

Aboriginal and Torres Strait Islander peoples to mainstream medication management programs, e.g., Home Medicines Review (HMR). A comparison of IMeRSe and HMR is presented in Table 2.

Table 2 Comparison of IMeRSe and HMR

	IMeRSe	HMR
Funding source(s)	MBS funding only	Combination of MBS (referring medical practitioner) and 7CPA (pharmacist) funding.
Pharmacist	\$222.77 \$111.39 for first follow-up service \$55.70 for second follow-up service	\$222.77 for initial HMR \$111.30 first follow-up service \$55.70 second follow up service
GP	\$75.05	\$161.10 (MBS Item 900)
AHW	\$50 \$25 for first follow-up service \$12.50 for second follow-up service	N/A
Referral	Identified by any treating health professional, or family member, or self-identified	Referral by a medical practitioner
Pharmacist accreditation	Not required	Required
Pharmacist cross-cultural training	Was a requirement for the IMeRSe Feasibility Study but not included as a requirement in the proposed MBS items	Not required
Location of medicine review	At a mutually agreed location between the pharmacist and the client	Occur in patient's home except in the following circumstances if a Program Variation request has been submitted and approved: <ul style="list-style-type: none"> • For cultural reasons as specified by the Patient • If there are concerns about the safety of the Pharmacist relating to being inside the Patient's home.
Service claiming	No cap on the maximum number of services per pharmacist or service. Two follow-up services are provided. If a HMR, RMMR, Diabetes MedsChecks or MedsChecks have been provided in the past 12 months, the consumer will be ineligible for IMeRSe.	Maximum of 30 HMR service claims per calendar month (applies to individual accredited pharmacist, and the Service Provider). Two follow-up services are provided.
Activities	<ul style="list-style-type: none"> • Recruitment and consent • Collection of baseline data and referral for Medicines Talk • Medicines Talk with participant and involving an Aboriginal Health Worker (AHW)/support person • Completion of Medicines Report • Response from GP and completion of My Medicines Plan with participant and/or AHW/support person • Structured clinical follow-up and monitoring 	<ul style="list-style-type: none"> • Identification of patient requiring a medication management review and referral by GP • Patient interview • Clinical assessment • Written initial HMR report to referring doctor and nominated community pharmacy • Structured clinical follow-up and monitoring

Source: Compiled for the ESC report.

Abbreviations: AHW=Aboriginal Health Worker; HMR=Home Medicines Review; IMeRSe=Indigenous Medication Review Service; GP=General Practitioner; MBS=Medicare Benefits Schedule; RMMR=Residential Medication Management Review; 7CPA=Seventh Community Pharmacy Agreement

7. Population

The proposed population is:

- self-identified Aboriginal or Torres Strait Islander Australians
- aged 18 years and over and living in the community
- at risk of medication-related problems (as identified by any treating health professional, family member or self-identified) including but not limited to:
 - being diagnosed with at least one chronic condition and/or is pregnant and /or is within 2 years post-partum
 - instability of health status and/or medication therapy
 - using high-risk medication(s)
 - likelihood of compromised adherence
 - new therapeutic goals
 - potentially incomplete understanding of medication use or
 - failure to respond to treatment in an expected way.

The commentary noted as the proposed population is not limited to the listed criteria from the IMeRSe Feasibility Study, this implies that the population may be greater than those that meet the nominated criteria.

The commentary also noted that the IMeRSe Feasibility Study relied on two definitions of medication-related problems (MRPs) and suggested it should be clarified in the proposed MBS item which definition will be relevant to triggering the need for the MMR.

8. Comparator

The ADAR nominated usual care as the comparator which was defined as *ad-hoc* medication management advice by a range of health practitioners involved in the consumer's care. Further, usual care, as defined in the ADAR, specifically excluded formal MMR services such as HMR/DMMR, RMMR, Diabetes MedsChecks or MedsChecks.

The commentary highlighted that the most relevant comparator for IMeRSe is the medical service(s) that is most likely to be substituted if IMeRSe is listed on the MBS. The commentary considered that in the proposed population, patients identified as requiring an MMR, the appropriate comparator is the currently available formal MMR. The commentary also considered the fact that a pharmacist does not need to be accredited to conduct an IMeRSe does not preclude the identified population from being able to access formal MMR, if they are identified as requiring a medication management review.

The commentary considered that the type of formal MMR that is likely to be substituted would depend on who identified the patient/client as potentially being at risk of a MRP and requiring a medication management review and what options are available to them:

- If it's the patient's GP, and the patient resides in the community, then usual care is MBS item 900, an HMR/DMMR.
- If it is the community pharmacist, then usual care is a MedsCheck or Diabetes MedsCheck or an Indigenous Dose Administration Aid (funded under the Seventh Community Pharmacy Agreement [7CPA]). If a more formal review is required, then the pharmacist could recommend the GP refer the patient for an HMR/DMMR.

- If a patient self-identifies or a carer identifies or if another health professional identifies, then usual care will be determined by whether they take their concerns to the GP or the primary health clinic or the community pharmacy.

The pre-MSAC response reiterated that IMerSe is a unique culturally responsive medication review service and the choice to nominate usual care instead of HMR was due to:

- evidence of significant access barriers for Aboriginal and Torres Strait Islander peoples to existing mainstream MMR services, including HMRs;
- a disconnect between the population need for HMR services and the current level of service provision which is exacerbated in rural and remote areas;
- the differences between IMerSe and HMRs including:
 - no requirement for GP referral,
 - different eligibility criteria,
 - use of a share clinical record system,
 - no requirement for the service to be conducted by an accredited pharmacist.

MSAC considered HMR is a more appropriate comparator but acknowledged there are barriers for Aboriginal and Torres Strait Islander peoples to access existing MMR services, including HMRs.

9. Summary of public consultation input

Prior to MSAC consideration, consultation feedback was received from eight organisations, and one health professional individual (pharmacist). The seven organisations that provided input on the application were:

- Australian Indigenous Doctors' Association (AIDA)
- Australian Pharmacy Council
- Australian Medical Association (AMA)
- National Association of Aboriginal and Torres Strait Islander Health Workers and Practitioners (NAATSIHWP)
- National Rural Health Alliance (NRHA)
- Northern Territory Department of Health (NT Health)
- Pharmaceutical Society of Australia (PSA)
- Rural Doctors Association of Australia (RDAA).

Consultation feedback was generally supportive of the of the proposed service. The AMA expressed mixed concerns related to pharmacy services but also acknowledged the need for culturally appropriate medication management reviews for Aboriginal and Torres Strait Islander people. The RDAA was supportive of the service but expressed concerns about implementation in rural areas.

Proposed service model

- PSA and the pharmacist were supportive of removing the age restriction limiting the service to adults.
- NT Health considered transitions of care should be included as a key area of risk for medication misadventure.
- NT Health considered the service should not exclude people who have received other medication management reviews in the past 12 months. The reason for this was that there is no mechanism to ensure a review under alternate programs has been conducted in a culturally appropriate way, which may limit the direct outcomes for a consumer.

- PSA considered fee-for-service models were not always appropriate and can be a barrier to access in rural and remote areas. NT Health also considered that for this program to be viable, sustainable and incorporated into practice, particularly in the remote setting, there needs to be consideration of how a fee for service can allow a pharmacist to integrate into a care team.
- NAATSIHWP considered opportunistic availability of the service would be acceptable to patients.
- PSA considered other models, such as an integrated model and may be more suitable in setting where Aboriginal Community Controlled Health Services (ACCHSs) are available.
- PSA considered the flexibility to deliver the service using technology should be considered.
- RDAA considered that the proposed service will have limited applicability in rural areas unless underlying workforce challenges in rural areas are addressed. RDAA considered that there is a significant risk that this type of service could become metro centric and not address the significant need in rural areas. RDAA highlighted that it was not clear how the service would operate in areas where outreach into communities is necessary.
- RDAA considered there are a broad range of factors, beyond economic factors and cost analysis, that should be considered to develop and implement a program successfully in rural Australia. This includes access to the broader health, social and community services, workforce issues (not just pharmacy workforce), physical and technological infrastructure, and what other programs and services may be impacted.
- NT Health considered the term 'community pharmacist' should be replaced with 'pharmacist' as professional registration does not differentiate by location of practice. NT Health considered the focus should be the training required by a pharmacist to undertake culturally responsive medication management reviews.

Cultural awareness and safety

- Most respondents supported the values of empowerment, self-determination, and culturally safe health care underpinning the study and the proposed intervention.
- Australian Pharmacy Council and PSA discussed the importance of cultural safety training and other initiatives to provide culturally appropriate health services.
- AMA and NT Health expressed support for cultural awareness training to be required for pharmacists providing the service. RDAA considered it was critical that all health professionals involved in the intervention are trained in culturally aware, safe and responsive care. NT Health considered additional requirements should include ongoing reflective cultural learning and quality assessment of medication review reports.
- AIDA and PSA emphasised the importance of the community controlled health sector.
- NT Health noted that family member structures are not always the same as the western family units and as such family member could be a very broad definition not reflected in the item descriptor.
- RDAA highlighted that rural communities are diverse and have additional geographic, socio-economic, demographic, climatic and cultural factors that can make the delivery of health, social and community services more difficult than in more urban areas.
- NT Health proposed a safe and confidential mechanism for Aboriginal and Torres Strait Islanders to identify practice which was conducted in a manner that did not make the participants feel culturally safe.

Existing services

- PSA considered Home Medicines Review Program rules such as prior approval to provide the service outside the patient's home compound cultural and geographical barriers and do not allow for opportunistic service provision when needed.
- PSA expressed concerns that the IHSPS program had reduced funding provided for remote area health services.
- RDAA considered rural health is complex and characterised by fragmented and siloed approaches where health care is provided by a complicated network of public, private and non-government professionals and services providing health, social and community services.

Aboriginal Health Worker/Aboriginal Health Practitioner involvement

- Most respondents were supportive of collaboration between pharmacists and Aboriginal Health Workers (AHWs)/Aboriginal Health Practitioners (AHPs) and considered this would improve cultural appropriateness of the service. The pharmacist highlighted the importance of AHWs where English was not a client's strongest language and the follow-up care performed by AHWs.
- PSA and the pharmacist raised concerns about the availability of AHWs/AHPs to participate due to competing demands for their time. PSA noted that it was unclear what the model would look like in the absence of AHW/AHP attendance.
- NAATSIHWP highlighted differences in the qualifications for AHW(Certificate III qualification) and AHP (Certificate IV qualification). AHWs undertake training to work under instructions to support safe use of medications, whereas AHPs undertake training to administer medications and support the safe use of medications.
- NAATSIHWP suggested lifting the criteria for AHWs to have a Medicare provider number to include Certificate IV qualification and training to support the safe use of medications.

Role of GPs

- AMA expressed the importance of the prescriber being the ultimate decision maker for their patient's care. NT Health proposed the inclusion of remote medical practitioners.
- The pharmacist considered not needing a GP referral was helpful, but may reduce GP engagement as this can be difficult for HMRs where GP referral is required.
- PSA considered GPs may not be able to complete follow-up within two weeks of receiving the pharmacist report.

Reimbursement

- RDAA raised several concerns related to funding. RDAA considered the overall level of investment, structure and allocation of funding, and mechanisms to ensure equitable distribution of funding were important to ensure funding allocated to rural programs is actually spent on rural programs.
- NT Health emphasised the need for rural and remote loading to be sufficient determined if this program will be available for Aboriginal and Torres Strait Islanders residing outside of the urban setting. NT Health proposed an allowance for accommodation as a subset of rural loading allowance.
- AMA stated it was supportive of pharmacy services being funded in ways that are more consistent with other primary health services but was not supportive of MBS funding. Other organisations were supportive of MBS as a mechanism for accessing health services.

- PSA noted the lower reimbursement for general practitioners (GPs) than for HMRs. PSA considered the required GP output could be similar to HMRs. PSA considered clarity is needed where there are different fees provided for different services.
- The pharmacist and NT Health supported separate funding support for AHWs to attend a medication review. NT Health considered AHWs receives the same benefit as the GP subsidy with a fee of \$75.

10. Characteristics of the evidence base

The ADAR included a single study, the IMeRSe Feasibility Study, a non-randomised, pre-post experimental trial. Participants, investigators and assessors were not blinded to the treatment allocation. The IMeRSe Feasibility Study was designed to develop and test the feasibility of both the intervention and use of the selected study outcome measures across a range of settings, to inform a future randomised clinical trial.

The primary outcome, serious MRPs (medication-related problems) and one of the secondary outcomes, PPMRHS (potentially preventable medication-related hospitalisations), used administrative claims data from the Pharmaceutical Benefits Scheme (PBS) and MBS sourced from Services Australia. Although data was matched for 250 of the 255 participants who completed the intervention, no PBS records were available for 43 participants and no MBS data for three of these participants. The majority of these participants (n=41) were in remote sites, suggesting that PBS medicines had been provided through the Section 100 Remote Area Aboriginal Health Service program. Therefore, results for the primary outcome (serious MRPs), and secondary outcomes (PPMRH and adherence) could be biased by these data limitations.

The commentary considered that it was inappropriate that the ADAR did not conduct a risk of bias assessment of the IMeRSe Feasibility Study using an appropriate tool. During the evaluation, a risk of bias assessment using the NIH Quality Assessment Tool for Before-After (Pre-Post) Studies With No Control Group was conducted.

The commentary considered the IMeRSe Feasibility Study to be at a high risk of bias for the following reasons:

- Although the objectives of the study were well defined, it was designed as a feasibility study to inform a randomised controlled trial and not a study to estimate the effectiveness of IMeRSe.
- Eligibility criteria for AHSs and community pharmacies was not clearly defined, with the exception that the AHS shared electronic clinical records and that the pharmacies had existing relationships with an AHS.
- Not all eligible patients were enrolled (sites recruited 311 consumers, of whom 291 consented).
- The number enrolled (n=291) fell short of the required sample size (n=540).
- The outcome measures were prespecified, clearly defined, and apparently reliable and assessed consistently across all study participants. However, the ADAR does not report whether the outcomes were validated.
- Outcome assessors were not blinded to participants' exposures/interventions.

Additionally, as the IMeRSe Feasibility Study did not have a concurrent control group, the attribution of any differences to the intervention alone is uncertain (there may have been temporal changes, other changes in treatment, etc).

The ADAR did not provide any assessment of the comparability of the AHS sites, community pharmacists and consumers participating in the Feasibility Study to a broader Australian context,

other than stating “[the study] only included one site (of nine included sites) where consumers accessed a mainstream general practice, rather than an AHS. The commentary considered this to be important as not all Aboriginal and Torres Strait Islander peoples have access to AHSs. As such, there is limited evidence of the success of IMeRSe in mainstream general practice settings”.

Thus, the commentary considered that it was unknown whether the AHS sites, community pharmacies (and pharmacists) and consumers participating in IMeRSe are representative of the intended Australian population and whether the results reported for the study would be generalisable to the broader population and setting.

11. Comparative safety

Four participants died during the study period – one prior to receiving the intervention and three after. All deaths were assessed for any possible association with the IMeRSe intervention and found not to be associated. All deaths were reported to the relevant Human Research Ethics Committee (depending on the jurisdiction of the participant) as well as to the clinical trials registry.

Redacted. No other safety concerns were identified during the IMeRSe Feasibility Study.

12. Comparative effectiveness

The results of the IMeRSe Feasibility Study are presented in Table 3 and Table 4.

Table 3 Results of serious MRP (primary outcome) and PPMRHs from IMeRSe

Outcome	N	Count pre	Count post	Rate pre (95% CI)	Rate post (95% CI)	IRR (95% CI)	p value
Serious MRPs	207	1,267	1,184	4.11 (3.14-5.38)	3.85 (2.93-5.03)	0.93 (0.86-1.01)	0.09
Serious MRPs Sensitivity*	122	766	725	4.75 (3.44-6.54)	4.49 (3.25-6.19)	0.95 (0.86-1.05)	0.29
PPMRH	207	21	21	0.06 (0.02-0.15)	0.06 (0.02-0.15)	1.00 (0.55-1.83)	1.00
PPMRH Sensitivity*	122	13	10	0.08 (0.03-0.21)	0.06 (0.02-0.17)	0.77 (0.33-1.75)	0.53

Source: Adapted from Table 11 and 12 of the ADAR.

Abbreviations: CI=confidence interval; IRR=incidence rate ratio; MRP=medication-related problems; PPMRH=preventable medication-related hospitalisations

* Sensitivity analysis was performed using urban and rural participants only to test the sensitivity of the primary outcome to incomplete PBS for remote participants due to Section 100 Remote Area Aboriginal Health Service supply.

The commentary noted that no statistically significant differences were observed for MRPs (primary outcome) and PPMRH (secondary outcome) post-intervention compared with pre-intervention at the conventional 5% level, although a reduction in serious MRPs was statistically significant at the 10% level.

Although the ADAR claimed that “A reduction in serious MRPs is clinically significant as it represents the preventable criteria for PPMRHs”, the commentary noted that there is no clinical meaning in the MRP metric *per se*. A serious MRP was constructed for study purposes as meeting the criteria of sub-optimal patterns of care with or without causing a hospitalisation; a secondary outcome - PPMRH is the sub-set of MRPs for which a hospitalisation is realised.

Therefore, the MRP metric is relevant to patient management (e.g., quality of medication prescription assessed with the risk of hospitalisation) and is not a substitute for the measurements that directly relate to a clinical condition (e.g., blood pressure, blood sugar level etc.) and for which established, meaningful clinical thresholds exist.

Table 4 Results of secondary outcomes from IMeRSe

Outcome	N	Pre-score mean (SD)	Post-score mean (SD)	Difference (95% CI)	p value
BMQ-necessity	215	20.68 (3.62)	20.56 (3.57)	0.12 (-0.40, 0.65) ^a	0.65
BMQ-concern	215	13.80 (4.54)	13.00 (3.79)	0.8 (0.18, 1.42) ^a	0.01*
RAM	215	15.27 (3.29)	15.84 (3.09)	-0.57 (-1.04, -0.09) ^a	0.02*
MPR	599	0.83 (0.59-0.99)	0.92 (0.62-1.02)	NR	0.03*
MPR Sensitivity*	368	0.83 (0.50-0.99)	0.92 (0.57-1.05)	NR	<0.01*
GEM total	96	88.83 (16.93)	92.96 (16.22)	-4.13 (-7.19, -1.06) ^a	0.009*
GEM - Inner peace	96	31.5 (6.41)	33.03 (6.09)	-1.53 (-2.82,-0.24) ^a	0.02*
GEM - Self-capacity	96	20.1 (4.35)	21.04 (4.22)	-0.94 (-1.82,-0.05) ^a	0.04*
GEM - Healing & growth	96	21.33 (5.72)	22.61 (4.81)	-1.28 (-2.39, -0.17) ^a	0.02*
GEM - Connection & purpose	96	11.57 (2.73)	11.95 (2.56)	-0.38 (-0.95, 0.20) ^a	0.20
K10 total score	94	19.04 (9.01)	17.80 (7.95)	1.24 (-0.47, 2.96) ^a	0.15
TSQ - Effectiveness	220	80.51 (20.7)	86.74 (15.93)	-6.24 (-9.24, -3.23) ^a	<0.001*
TSQ - Side effects	10	81.88 (28.02)	75.63 (31.52)	6.25 (-21.23, 33.73) ^a	0.62
TSQ - Convenience	220	82.88 (22.76)	89.72 (15.18)	-6.84 (-9.73, -3.96) ^a	<0.001*
TSQ - Global satisfaction	220	110.44 (30.5)	118.87 (20.28)	-8.43 (-12.48, -4.38) ^a	<0.001*

Source: Adapted from Table 13, 14, 15, 16 and 17 of the ADAR.

Abbreviations: BMQ=Beliefs about Medicines Questionnaire; CI=confidence interval; GEM=Growth and Empowerment Measure; K10=Kessler 10-item scale for psychological distress; MRP=Medication Possession Ratio; RAM=Reported Adherence to Medicine; SD=standard deviation; TSQ=Treatment Satisfaction Questionnaire

* Sensitivity analysis was performed using urban and rural participants only to test the sensitivity of the primary outcome to incomplete PBS for remote participants due to Section 100 Remote Area Aboriginal Health Service supply.

^a As reported in the ADAR. The directionality of the reported results was not consistent with the pre study and post study values.

Other consumer-relevant secondary outcomes showed statistically significant improvements including the Growth and Empowerment measure, beliefs about medicines, self-assessed and objective measures of medication adherence (RAM and medication possession ratio) and treatment satisfaction.

Overall, the evidence suggested that participants in the IMeRSe Feasibility Study felt more empowered, had fewer concerns about their medicines, showed improved medicines adherence

and improved treatment satisfaction. The commentary noted that the ADAR did not provide information regarding whether scores above or below a certain value represent “good” or “bad” results; there was also no information provided regarding what magnitude of change would be clinically significant. Additionally, results reported for each of these outcomes, being self-reported, may have been subject to bias given participants were not blinded to the intervention received.

The summary of key findings is shown in Table 5.

Table 5 Balance of Clinical Benefits and Harms of IMeRSe, Relative to Usual Care, and as Measured by the Critical Patient-Relevant Outcomes in the Key Studies

Outcomes	Participants (studies)	Quality of evidence (GRADE) a	Incidence rate ratio (95%CI)	Pre rate/score (95%CI/SD)	Post rate/score (95%CI/SD)	Comments
Serious medication related problems (count/rate)	IMeRSe (2020), n=207	⊕⊕⊕⊕○	0.93 (0.86-1.01)	4.11 (3.14 – 5.39)	3.85 (2.94-5.04)	p=0.09
Potentially preventable medication-related hospitalisations (count/rate)	IMeRSe (2020), n=207	⊕⊕⊕⊕○	1.00 (0.55-1.83)	0.06 (0.02-0.15)	0.06 (0.02-0.15)	P=1.00
Medication adherence (MPR)	IMeRSe b (2020), n=599	⊕⊕⊕⊕○		0.83 (0.55-0.99)	0.92 (0.62-1.02)	p=0.03
Empowerment (GEM)	IMeRSe (2020), n=96	⊕⊕⊕⊕○		88.83 (16.93)	92.96 (16.22)	p=0.01

Source: Table 2, p15 of the ADAR.

a GRADE Working Group grades of evidence [1]

b n = 599 is the number of paired comparisons for a particular medicine and individual from 207 participants with available data.

GEM=Growth and Empowerment; MPR=medication possession ratio; CI=confidence interval; SD=standard deviation

⊕⊕⊕⊕ High quality: We are very confident that the true effect lies close to that of the estimate of effect.

⊕⊕⊕⊕○ Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

⊕⊕⊕○ Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.

⊕○○○ Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Clinical claim

On the basis of the evidence profile (summarised above in Table 5), the ADAR suggested that, relative to usual care (*ah-hoc* medication review), IMeRSe had non-inferior safety and uncertain effectiveness based on the primary outcome (serious MRPs). Due to the overall confidence in the effect estimate for the reduction in the primary outcome, the evidence for serious MRPs was classified as moderate quality. The ADAR also suggested IMeRSe had a superior outcome compared to usual care for medication adherence and empowerment.

The commentary considered that the non-inferiority claim regarding comparative safety is reasonable, but to the extent that the IMeRSe intervention demonstrates improved adherence to medications, then it will be superior to usual care.

The commentary also considered the claim regarding uncertain comparative effectiveness to be reasonable. Statistically significant differences, favouring the post-intervention results, in validated surveys regarding concern with medicines, medication adherence, growth and empowerment and treatment satisfaction were observed. However, no statistically significant differences in PPMRHs were observed, nor were any differences in the primary outcome of MRPs (at the 5% level of significance). However, the commentary considered that the results should be interpreted with the study aim (feasibility), study design (lack of a concurrent control group), short study duration, small sample size and lack of information regarding the representativeness of the AHSs, community pharmacists and study participants to the intended population, in mind.

ESC considered that the lack of statistically significant differences in clinical outcomes were problematic, but considered a focus on this for an intervention like IMeRSe with other health benefits to be inappropriately narrow. ESC noted that the service resulted in positive patient-reported outcomes, and ESC agreed with the pre-ESC response that these outcomes are valuable for a service such as the one proposed. MSAC agreed with ESC and considered IMeRSe to have non-inferior safety, uncertain effectiveness compared to usual care but could have superior medication adherence and empowerment.

13. Economic evaluation

The ADAR presented an economic evaluation estimating the incremental cost per serious MRP avoided (i.e., a cost-effectiveness analysis) using the cost and effectiveness data collected during implementation of IMeRSe Feasibility Study and also obtained from the PBS, MBS, hospital and emergency admission administrative datasets. The economic evaluation was undertaken from the Australian government perspective and did not include patient out-of-pocket costs (e.g., travel and over-the-counter medications).

A summary of the economic evaluation is presented in Table 6.

The commentary noted that the ADAR indicated that IMeRSe had uncertain comparative effectiveness but also claimed IMeRSe would provide cost-savings, which would suggest a cost-minimisation approach would be appropriate. MSAC noted and agreed with ESC advice that cost-minimisation analysis was not considered appropriate, that cost per MRP avoided does not fully capture the health benefits of the IMeRSe and that a cost-consequence analysis would be more appropriate to handle multiple complex outcome measures (e.g., adherence, hospitalisation, medication errors).

Table 6 Summary of the economic evaluation

Component	Description
Perspective	Australian government
Population	Indigenous population aged 18 years and over and living in the community and identified (including self-identified) at risk of medication-related problems
Comparator	Usual care, <i>ad-hoc medication advice provided by health care professionals</i>
Type(s) of analysis	<i>Cost-consequence. Cost-effectiveness analysis</i>
Outcomes	Serious medication-related problems avoided
Time horizon	12-months (trial-based analysis), [^]
Computational method	Statistical modelling of the number of MRPs pre- and post IMeRSe
Generation of the base case	<i>Statistical modelling of trial based data</i>
Discount rate	Not applicable (one year time horizon)
Software	Excel, STATA

Source: Table 3, p16of the ADAR with commentary in italics

Abbreviations: MRP=medication-related problem; IMeRSe= Indigenous Medication Review Service

[^] The commentary noted that the statistical analysis converted the observed 6-month MRP data into an annual per-person rate, thus the corresponding time horizon is one year. The evaluation-conducted cost effectiveness analysis for the cohort of 291 patients assumed a 12-month horizon.

The commentary raised the following concerns with the inputs to the economic analysis:

- The difference in pre-post study health care resources was estimated using data from the PBS, MBS, hospital and emergency admission administrative datasets, which raised serious attribution concerns.
- The fluctuations in the number of medication prescriptions, investigative services and GP attendances could be influenced by multiple confounding factors over and above the pharmacist-initiated medication reviews
- Attributing cost-offsets in terms of the observed reduction in hospital admissions and emergency department presentations to the intervention cannot be reasonably justified. Irrespective of the difference in health care resource use, it can be argued that the lack of statistical significance in the primary outcome at the pre-set level of 0.05 is entirely due to the study being underpowered and in the anticipated large cluster-randomised trial the difference in per-person rates of MRPs might have attained the required degree of statistical significance.
- Results of the pharmacists' reviews of medications recorded in Medicines Reports (N=255), which produced recommendations to review, or change, pharmacotherapy (44.4%); were not costed. Unlike the change in the PBS and MBS counts, that could not be unequivocally associated with intervention, the pharmacists' recommendations that were accepted by GPs (84.1%) (IMeRSe Report, p.xviii) are directly attributable to the intervention and should have been added to the total cost.
- In some instances, the calculations of the total cost of intervention included the observed use of health care resources with trial-based unit costs, while in other instances, universal participation was assumed with the proposed MBS item fees used as unit costs.
- The size of the cohort was inconsistent throughout the calculations. In some instances, the ITT sample of 291 was used as the denominator, while in other instances the 255 of IMeRSe "in-study" cohort applied, or, alternatively, 207 participants with complete pre- and post-

data were used in the statistical modelling to estimate the rate of MRP per person per year. The evaluators revised the calculations in the ADAR using the ITT (i.e., 291 clients).

- The statistical analysis converted the observed 6-month MRP data into an annual per-person rate, thus the corresponding time horizon is one year. The evaluation-conducted cost effectiveness analysis for the cohort of 291 patients assumed a 12-month horizon. However, since the intervention is limited to one per person per year, the cost estimates are not significantly affected (with exception of ongoing cost of pharmacist mentoring and the number of the observed follow-ups, which could have been larger over the extended time interval).

Table 7 shows cost-estimates presented in the ADAR with the commentary's revised cost-estimates in italics. The total costs per person per year are firstly, reported with average overheads across the areas (e.g., across urban rural, and remote areas) and secondly, separately for each of these areas.

Table 7 Cost estimates (per person per year) produced in the economic evaluation presented in the submission (with the commentary's revised cost-estimates in italics)

Cost item	Cost per year (IMeRSe in-trial) (\$)	Cost per year (\$) <i>(commentary's corrections**)</i>	Cost per year (\$) <i>(commentary's corrections***)</i>
Software, training and implementation (annuitised)*	46,509	<i>62,159</i>	<i>62,159</i>
Pharmacist mentoring	18,766	<i>18,766</i>	<i>18,766</i>
Pharmacist service fees – medicines review	32,640	<i>37,248</i>	<i>64,826</i>
Pharmacist services fees – follow-up	6,784	<i>7,742</i>	<i>32,416</i>
Pharmacist services fees travel	1,482	<i>1,482</i>	<i>1,482</i>
Aboriginal Health Worker service fees	6,250	<i>7,132</i>	<i>7,132</i>
General Practitioner fees	21,840 ³	<i>21,840</i>	<i>46,458</i>
Sub-total (\$)	134,271	<i>156,370</i>	<i>233,240</i>
Services (<i>number of participants in the cohort</i>)	291	<i>291</i>	<i>291</i>
Cost per person per year (less overheads)	461	<i>537</i>	<i>801</i>
Overhead costs (per person)			
<i>urban</i>	16	<i>16</i>	<i>16</i>
<i>rural</i>	36	<i>36</i>	<i>36</i>
<i>remote</i>	40	<i>40</i>	<i>40</i>
Cost per person per year (average)	492	<i>568</i>	<i>832</i>
<i>urban</i>	<i>477</i>	<i>553</i>	<i>817</i>
<i>rural</i>	<i>498</i>	<i>573</i>	<i>837</i>
<i>remote</i>	<i>501</i>	<i>577</i>	<i>841</i>

Source: Adapted from Table 24, p54 of the ADAR with commentary revisions in italics

* Annuity factor = $(1/r) - (1/r(1+r)^t)$ and assuming no salvage value at the end of the time horizon

1 The rate of follow-up from IMeRSe has been assumed, that is 77/255 (30.2%) participants had a follow-up; 50.6% of those that did had one follow-up and 49.4% had two or more follow-ups.

2 The travel cost per participant from IMeRSe was used (i.e. \$1,482/291 participants) and applied to the MSAC funding scenario.

3 Assumes an MBS Item 36 Level C consultation fee (\$75.05).

** corrected for ITT sample, which applied consistently as a denominator; capital service time assumed at 5 rather than 7 years, in-trial unit costs used

*** corrected for ITT sample, capital service time assumed at 5 rather than 7 years, MBS/6PCA unit costs were used

Table 8 shows results of the economic evaluation presented in the ADAR along with the commentary's revised CEA result. The estimated decrease in serious MRPs (primary outcome) from 1,267 to 1,184 post-intervention observed in 207/255 (81.2%) participants was translated into a 7% reduction in the modelled rate of serious MRPs per person per year (risk reduction from 4.11 to 3.85) and remained unchanged. The costs were as in Table 7 for the ADAR and revised cost-effectiveness analyses respectively. For completeness, the CEA conducted during the commentary is replicated using the requested unit costs rather than the unit costs used in the IMeRSe Feasibility Study.

Table 8 Cost Effectiveness Analysis for One Serious Medication-Related Problem Avoided (with commentary revised estimates in italics)

Scenario	Pre-rate (95%CI)	Post-rate (95%CI)	Difference (95% CI)	p-value	Cost per person	Cost per MRP avoided	Assumption
ADAR base case CEA	4.11 (3.14,5.39)	3.85 (2.94,5.04)	0.27 (-0.05,0.59)	0.10	\$432	\$1,598	IMeRSe cost at MSAC fees; no cost usual care
<i>Corrected ADAR study-based CEA¹</i>	<i>4.11 (3.14,5.39)</i>	<i>3.85 (2.94,5.04)</i>	<i>0.27 (-0.05,0.59)</i>	<i>0.10</i>	<i>\$492</i>	<i>\$1,822</i>	<i>IMeRSe in-trial costs Sample size varies, useful service life of initial capital outlay is 7 years</i>
<i>Study-based commentary's CEA</i>	<i>4.11 (3.14,5.39)</i>	<i>3.85 (2.94,5.04)</i>	<i>0.27 (-0.05,0.59)</i>	<i>0.10</i>	<i>\$568</i>	<i>\$2,104</i>	<i>ITT sample of 291 participants; useful service life of initial capital outlay is 5 years, unit costs as in the trial</i>
<i>Alternative unit costs in commentary's CEA</i>	<i>4.11 (3.14,5.39)</i>	<i>3.85 (2.94,5.04)</i>	<i>0.27 (-0.05,0.59)</i>	<i>0.10</i>	<i>\$832</i>	<i>\$3,082</i>	<i>ITT sample 291 participants; useful service life of initial capital outlay is 5 years, MBS/6PCA unit costs</i>

Source: Adapted from Table 4, p16 of the ADAR with commentary in italics

Abbreviations: ADAR=applicant developed assessment report; CEA=cost-effectiveness analysis; CI=confidence interval; ED=emergency department; IMeRSe= Indigenous Medication Review Service; ITT=intention to treat; MBS=Medicare Benefits Schedule; MRP=medication-related problems; 6CPA=Sixth Community Pharmacy Agreement

Note: The rate is reported as a rate per person per 6 months, estimated using a mixed effects Poisson model. Although the incidence rate ratio was found to be statistically significant at the 10% level, the difference between rates, computed using the Stata nlcom command (for on-linear combinations of estimators) was not statistically significant.

Using in-study unit costs, the various denominators as in the original calculations and an assumption of 7 years of useful life of the initial investment, the ADAR estimated the incremental cost per additional serious MRP avoided at \$1,822. After adjusting for the size of the ITT cohort, and under the more conservative assumption of 5 years of useful life of the initial investment, the incremental cost per additional serious MRP avoided is estimated at \$2,104. Applying the MBS/6PCA unit costs to the resource use as recorded in the IMeRSe Feasibility Study produced even a higher ICER estimate of \$3,082.

The key drivers of model are summaries in Table 9.

Table 9 Key drivers of the model (with commentary revisions in italics)

Description	Method/Value	Impact Base case: \$2,104 per MRP prevented
Variation around the effectiveness estimate	95% CI values (-0.05,0.59) in the estimated difference in the per-person per year rate of MRPs of 0.27 were used as point estimates in the sensitivity analysis.	<i>High, but uncertain, since the 95% CI is large and includes zero.</i> <i>Application of -0.05 means that the comparator is a dominant alternative;</i> <i>Application of 0.59 decreases ICER to per MRP prevented to \$963</i>
Assumption about the useful life of the initial investment into IMeRSe	Increasing the useful life of the initial investment into IMeRSe from 5 to 7 years	<i>High, favors intervention</i> <i>Increasing the useful life of the initial investment into IMeRSe from 5 to 7 years decreased the ICER to \$1,791</i>

Source: Compiled from p56 & 57 of the ADAR with commentary in italics.

Abbreviations: CI=confidence interval; ICER = incremental cost-effectiveness ratio; MRP = medication-related problems; IMeRSe= Indigenous Medication Review Service

The commentary noted that the results of the revised CEA are likely to underestimate the actual cost and should be interpreted with caution. Omitted from the total costs were not just the GP approved changes in the medication prescriptions, as discussed above, but also laboratory investigations and referrals to other health professionals. The extension of the time horizon from 6 months to one year would not affect the per-person cost of intervention (it is limited to one per-person per year) but may nevertheless underestimate the ongoing cost of pharmacist mentoring and the number of the observed follow-ups per person conducted by the pharmacists. Also, as discussed above the successful implementation of IMeRSe would require a special funding of the role that was performed by study coordinators selected from AHS staff. The value of this cost outlay is uncertain. Finally, there is uncertainty in relation to the appropriateness of exclusion of IT devices, considered as research-related costs. Laptops and mobile devices may be needed to maintain the exchange of information between pharmacists, AHW and GPs and assist during the ongoing training, this is particularly relevant in the context of the magnitude of the technological problems, particularly with respect to the GuildCare NG™ software.

The results of key sensitivity analyses are summarised in Table 10.

Table 10 Sensitivity analyses

Scenario	Pre-rate (95%CI)	Post-rate (95%CI)	Difference (95% CI)	p- value	Cost per person	Δ Cost per MRP avoided	Assumption
Evaluator- conducted CEA	4.11 (3.14,5.39)	3.85 (2.94,5.04)	0.27 (-0.05,0.59)	0.10	\$568	\$2,104	Cohort of 291 participants; useful life of initial outlay is five years
1	4.11 (3.14,5.39)	3.85 (2.94,5.04)	0.27 (-0.05,0.59)	0.10	\$484	\$1,791	Cohort of 291 participants; useful life of initial outlay is seven years
2	4.11 (3.14,5.39)	3.85 (2.94,5.04)	-0.05	0.10	\$568	Comparator dominates	The comparator is both more effective and less expensive
3	4.11 (3.14,5.39)	3.85 (2.94,5.04)	0.59	0.10	\$568	\$963	Results are sensitive to the variations in the incremental rate of MRPs

Source: Table 28A, p90 of the commentary

Abbreviations: CI=confidence interval; CEA=cost-effectiveness analysis; MRP=medication-related problems;

14. Financial/budgetary impacts

The ADAR used an epidemiological approach to estimate the financial implication of the introduction of the IMerSe for adult Aboriginal and Torres Strait Islander peoples with chronic illness at risk of an MRP. As noted in the ADAR, 'at risk of MRP' is a subjective measure. The ADAR financial estimates used the level of polypharmacy as a proxy for the definition of MRP, but this was not the definition used in the IMerSe Feasibility Study. The commentary noted that it is not possible to estimate whether using this definition is likely to over or underestimate the eligible population. The net financial implications to the MBS/other funding source resulting from the proposed listing of IMerSe for Aboriginal and Torres Strait Islander peoples with potential for MRPs are summarised in Table 11.

Table 11 Net financial implications of IMeRSe to the MBS and other government agencies

Parameter	2021-22	2022-23	2023-24	2024-25	2025-26
Estimated use and cost of the proposed health technology					
Number of people eligible for IMeRSe	96,597	99,654	102,773	106,016	109,324
Number of people who receive IMeRSe	redacted	redacted	redacted	redacted	redacted
Number of services ADAR	redacted	redacted	redacted	redacted	redacted
<i>Number of services of MMR [multiple health professionals deliver the service] (average 2.792 services per person)</i>	redacted	redacted	redacted	redacted	redacted
Cost to the [MBS and government program*] (with appropriate co-payments excluded)	\$redacted	\$redacted	\$redacted	\$redacted	\$redacted
Corrected costs for first year to the MBS** block funding excluded	\$redacted	\$redacted	\$redacted	\$redacted	\$redacted
Change in use and cost of other health technologies					
Block Funding *	\$redacted	\$redacted	\$redacted	\$redacted	\$redacted
Change in use of hospital inpatient services Costs	\$redacted	\$redacted	\$redacted	\$redacted	\$redacted
Net financial impact to government budgets (Sensitivity 1)	-\$redacted	-\$redacted	-\$redacted	-\$redacted	-\$redacted
Change in use and costs of ED visits	\$redacted	\$redacted	\$redacted	\$redacted	\$redacted
Net financial impact (Sensitivity 2) to government budgets	-\$redacted	-\$redacted	-\$redacted	-\$redacted	-\$redacted

Source: Compiled from Tables 29-33 of ADAR, with commentary in italics.

Abbreviations: ADAR=Applicant developed assessment report; ED=emergency department; MBS=Medicare Benefits Schedule; MMR=medication management review

*block funding will need to be provided by a government agency other than the MBS.

**these costs are corrected for the appropriate number of services required to deliver the MMR, the correct requested item fee for GP of \$75 (which substantially reduced the estimated costs), some errors in the excel spreadsheet and the exclusion of travel costs and block funding.

The commentary noted the following regarding the financial estimates:

- The commentary revised average cost of IMeRSe is **\$redacted** per client per year to the MBS. This is a lower figure than estimated by the ADAR, **\$redacted**, because it excludes the requested block funding, travel costs for pharmacists, and only estimates the costs for a GP service at \$75, which is the MBS item fee requested in the ADAR (and not the MBS item 900 fee) and which the GPs that participated in the IMeRSe Feasibility Study had stated was the fee they charged; a Level C consult.
- The commentary revised average number of services per person receiving IMeRSe is **redacted**, a total of **redacted** for Year 1 increasing to **redacted** by Year 5. This is higher than estimated in the ADAR (**redacted**) which is the number of services for the pharmacist but excludes the additional services by the AHW and GP that also are required to deliver the service.

- If the requested MBS fee reimbursement is consistent with MBS Item 900 then patients are unlikely to have out-of-pocket costs for the delivery of this service.
- The requested block funding will need to be sourced from a government agency other than the MBS.

The ADAR reported that the uptake of the IMerSe in the IMerSe Feasibility Study was only 5%, which the commentary considered to be low given the intensive support provided to implement the program. When this uptake it is increased to 10%, it results in a doubling of patient numbers, and almost a doubling of cost.

The commentary also noted that the ADAR reported that the IMerSe Feasibility Study showed no statistically significant differences in MBS or PBS use pre- and post-intervention, and reported no difference between pre-and post-intervention in the number of medication related hospitalisations. However, the ADAR included hospital cost savings based on the inpatient costs of a subgroup of study participants in NSW. The costs are based on emergency department use and inpatient hospitalisations. Although for the MBS, PBS and emergency department use, costs increase with increasing numbers or decrease with decreasing numbers this does not occur with the hospital inpatient costs. The increased number of admissions post-intervention (555 vs 581) have resulted in lower costs (**redacted** vs **redacted**). These costs have been included as a “saving” to the government of **\$redacted** per person per year. However, the IMerSe Feasibility Study reported that it is unclear if the IMerSe intervention will result in a net cost or a net saving to government health budgets due to limitations of the study and the data available on hospitalisations and emergency department use. Therefore, the estimated cost savings are uncertain.

15. Other relevant information

The ADAR provided some information around:

- Equitable access to healthcare.
- Comparison between IMerSe and the existing Domiciliary Medication Management Review Service (MBS Item number 900).
- Pharmacy workforce considerations.

16. Key issues from ESC to MSAC

ESC key issue	ESC advice to MSAC
Claim of cost saving to the Australian health system	There potentially is a cost saving to the Australian health system, but the estimates are uncertain because of assumptions in costs used, effects on resource use (hospitalisation, PBS, MBS), and uptake of the program including substitution of HMR. ESC advises that the applicant provides a more accurate estimate of the proposed cost savings.
Appropriateness of economic evaluation for program evaluations	The proposed cost-effectiveness analysis does not sufficiently capture the benefits of IMerSe, as it only focuses on MRPs avoided for which the IMerSe Feasibility Study did not demonstrate sufficient evidence. ESC considered that a cost-consequence analysis that presents all relevant benefits and costs would be more appropriate.
Uncertainty that proposed implementation will	Realising the program benefits largely depends on the program implementation. ESC considered the involvement of an AHW is integral to the IMerSe. ESC noted engagement and coordination activities from the trial are not included in the implementation of IMerSe. ESC also

provide integrated healthcare	considered the lack of GP involvement in the referral process to be problematic. ESC considered this may not align with primary health reforms aiming to provide coordinated and integrated multidisciplinary health care team. ESC considered that MSAC could benefit from advice on how IMeRSe could be implemented successfully to provide coordinated and integrated multidisciplinary health care without duplicating existing services.
Proposed MBS item claiming and fee	The proposed fee for GP involvement in the IMeRSe is lower than GP involvement in other MMR services (i.e., HMR). The proposed MBS fees need to be compared to HMR service fees to avoid unwanted (dis-)incentives to request the appropriate service.
Population	The population needs to be better defined. The population is likely to be greater than anticipated as eligibility is not limited to the listed study criteria and creates uncertainty in the size of eligible population, estimated uptake and financial estimates.
Comparator	The proposed comparator is usual care, which was described as “ad-hoc medication management advice from any health professional”; however, ESC considered that an HMR is a more appropriate comparator. Comparison with the incorrect comparator has flow on consequences that potentially result in overestimating the incremental costs of the IMeRSe.

ESC discussion

ESC noted that this was a new application from the Pharmacy Guild of Australia (PGA) for Medicare Benefits Schedule (MBS) listing and public funding of an Indigenous Medication Review Service (IMeRSe) for Aboriginal and Torres Strait Islander peoples with potential for medication-related problems (MRP).

ESC recalled that in 2017, MSAC appraised the Sixth Community Pharmacy Agreement (6CPA) Medication Management Review (MMR) programs: the Home Medicines Review (HMR) program, the Residential Medication Management Review (RMMR) program, and the MedsCheck and Diabetes MedsCheck programs. At that time, MSAC considered that there was insufficient evidence to determine the clinical and cost-effectiveness of the continuing 6CPA MMR programs, and thus a weak basis to recommend that funding should be supported or ceased. MSAC considered that the design of these pharmacy service programs could be improved by including formal collaboration with General Practitioners (GPs), by being targeted to appropriate patient populations, and by a reduction in the unit cost of providing each pharmacy service coupled with an incentive to increase this cost if adequate evidence can be furnished to justify it. Further enhancement of these programs might better justify the provision of continued funding of these services.

ESC noted that the IMeRSe was designed to be a culturally responsive medication review service, delivered through community pharmacists in conjunction with local Aboriginal Health Services (AHSs) staff, to address an important gap in the health services delivered to Aboriginal and Torres Strait Islander patients.

ESC considered a culturally responsive medication review service could be very beneficial for Aboriginal and Torres Strait Islander people. ESC considered that it was important for that the service is provided in a culturally acceptable manner and not doing so could have adverse impacts. ESC considered a better service could be provided to Aboriginal and Torres Strait Islander peoples if cultural awareness training was a requirement. ESC considered that for successful implementation in remote areas there would need to be adequate funding for fuel, flights, and potentially accommodation.

ESC also noted that the IMerSe Feasibility Study was a non-randomised, pre-post experimental trial co-designed and conducted by PGA in partnership with the National Aboriginal Community Controlled Health Organisation (NACCHO). However, ESC was concerned that the way IMerSe was proposed for implementation may fail to achieve coordinated and integrated medication management for Aboriginal and Torres Strait Islander patients.

ESC considered that the involvement of an Aboriginal Health Worker (AHW) is clearly an integral component of the IMerSe Feasibility Study and for successful implementation. However, ESC noted that engagement and coordination activities in the IMerSe Feasibility Study that appeared vital to the study, and that would also be important for achieving integrated healthcare in the real world, do not appear to be supported in the proposed implementation of IMerSe. ESC noted that it cannot be guaranteed that the IMerSe will be implemented in all 247 Indigenous primary health services, or in GP clinics. Further, ESC noted that a referral from a General Practitioner (GP) is not required (as with other MMR programs) but a GP is required to finalise a Medication Plan within 2 weeks of receiving a Medicines Report from a pharmacist. ESC considered 2 weeks is not feasible given the IMerSe Feasibility Study reported the average time for finalising a Medication Plan was 89 days and it was unclear what the consequences are for a patient are if the GP does not follow-up. In addition, ESC noted that clinical information would need to be provided to the pharmacist and that the pre-ESC response stated that there were several ways for a pharmacist to receive this information without GP referral. However, ESC considered the lack of GP involvement in the referral process to be problematic as it could lead to disengagement of GPs who are responsible for the patient's treatment. ESC considered it appropriate to include a GP in the referral process for the IMerSe; however, ESC noted that the resulting service would then be similar to the existing HMR service, but with the option of reimbursed AHW involvement. However, ESC considered GP referral would ensure the proposed service aligned with primary health reforms¹ aiming to provide coordinated and integrated multidisciplinary health care team.

ESC noted the three proposed MBS item descriptors for participation of a pharmacist, AHW and a GP in the proposed Aboriginal and Torres Strait Islander medication review service. ESC noted that pharmacists are not currently eligible to claim on the MBS and that the proposed MBS item descriptor for the pharmacist participation does not specify any further training for the pharmacist, either to be accredited to deliver an MMR or to have completed cultural awareness training, and considered that this should be included. ESC noted that the number of services a pharmacist may perform is not capped (as it is for the HMR; capped at 30 per month). ESC also noted that it was not clear how the "Rural loading allowance" would be claimed, as this is not usually a separate cost.

ESC noted that current MBS items for AHWs require the AHW to provide a service under the direction of the medical practitioner if a client has an extended care plan. ESC noted that the proposed MBS item for the AHW participation in IMerSe implies that the AHW could be operating outside these constraints. ESC considered that it will need to be determined if the proposed item meets the AHW terms of registration as an eligible health professional for MBS claiming purposes.

ESC noted that the proposed reimbursement for GP participation (equivalent to a Level C consultation) is lower than the MBS fee for GP involvement in other MMR services (i.e., HMR), and considered that the proposed MBS fees need to be compared to existing HMR service fees to avoid unwanted (dis-) incentives to request the appropriate service.

¹ Report from the Primary Health Reform Steering Group: [Recommendations on the Australian Government's Primary Health Care 10 Year Plan](#) (September 2021)

ESC noted that there was little consumer feedback for ESC consideration and considered it crucial that input from Aboriginal and Torres Strait Islander peoples or relevant organisations should be sought. ESC noted the consultation responses expressed support for IMeRSe highlighting the essential role of involving AHWs and suggesting that the community pharmacists conducting the MMR would need access to a support line. ESC also noted that one consultation response expressed that while referral without a GP is helpful there was concern this may lead to difficulties in engagement and communication with GPs.

ESC noted the proposed population was “Aboriginal and Torres Strait Islander patients (aged 18 years and over) identified as at risk of MRPs by a treating health professional, family member or self-identified who meet the listed criteria but are not limited by these criteria”. ESC queried the age restriction to adults only and noted that MRP is not well defined. ESC considered that due to the current wording of the proposed population, the service may not be targeted to those most likely to benefit and the population may be greater than anticipated as eligibility is not limited to the listed criteria.

ESC noted that the proposed comparator was usual care, which was described as “ad-hoc medication management advice from any health professional” and that participants in the IMeRSe Feasibility Study had not received any formal MMR service. However, ESC considered that an HMR is a more appropriate comparator due to the structural similarities between the proposed services and as the proposed population was eligible to access this service.

ESC noted that the IMeRSe Feasibility Study was designed as a feasibility study to inform a randomised controlled trial. ESC noted 23 pharmacies participated in the study, integrated across nine AHS sites throughout Queensland, New South Wales and the Northern Territory. ESC noted it was unknown whether the AHS sites, community pharmacies and participants are representative of proposed population and therefore whether study results are generalisable. ESC considered one of the strengths of the IMeRSe study was that it was co-designed with input from Aboriginal and Torres Strait Islander communities. ESC also noted that the number of participants was relatively low ($n = 255$ received the intervention) and there was no concurrent control group instead the trial provided pre and post intervention comparison.

ESC noted the primary outcome was a difference in the incidence of serious MRPs for the six months after IMeRSe introduction (post-intervention) compared with six months before (pre-intervention). ESC also noted the secondary outcomes across several person-centred factors, including confidence, satisfaction, psychosocial wellbeing, beliefs about use of medicines, adherence with medication regimens, empowerment and psychological stress. ESC noted that there was a 7% reduction in the modelled rate of serious MRPs per person per year, which was not statistically significant ($P = 0.09$), and that there was no reduction in medication-related hospitalisation rates. However, ESC noted that study participants reported decreased concern about their medicines and superior medication adherence and considered these to be valuable outcomes that were not considered. ESC noted that for some of the medication use outcomes and the Growth and Empowerment scale, the reported direction of change did not align with the baseline and post-intervention outcomes (such as a negative change when scores increased). ESC considered that the lack of statistically significant differences in clinical outcomes was problematic, but considered a focus on this for an intervention like IMeRSe with other health benefits to be inappropriately narrow. ESC noted that the service resulted in positive patient-reported outcomes, and ESC agreed with the pre-ESC response that these outcomes are valuable for a service such as the one proposed. Overall, ESC considered IMeRSe to have non-inferior safety, uncertain effectiveness compared to usual care but that it could have superior medication adherence and empowerment.

ESC noted that a similar program, the Integrating Pharmacists within Aboriginal Community Controlled Health Services (ACCHS) to Improve Chronic Disease Management (the IPAC Project), will be considered at the same MSAC meeting as this application for IMeRSe. ESC also noted that the Department had information on common outcomes from IPAC and IMeRSe which ESC recommended the Department include for MSAC's consideration.

ESC noted that the applicant-derived assessment report (ADAR) estimated the cost-effectiveness of IMeRSe as a cost per MRP avoided (e.g. base case estimated \$1,822 per MRP avoided). ESC considered that cost per MRP avoided does not fully capture the health benefits of IMeRSe. ESC disagreed with the commentary's statement that uncertain effectiveness and cost-savings would suggest a cost-minimisation analysis would be appropriate, as ESC noted that uncertain effectiveness does not equate to non-inferiority. ESC considered that a cost-consequence analysis would be more appropriate to handle multiple complex outcome measures (e.g. adherence, hospitalisation, medication errors). ESC noted that an implication of using the incorrect comparator meant the incremental costs of IMeRSe in the cost-effectiveness analysis would be overestimated because the comparator group did not incur costs or benefits from an intervention.

ESC noted that the ADAR financial estimates predicted that the IMeRSe would be cost-saving, with estimates ranging from a saving of \$0 to < \$10 million per year up to \$30 million to < \$40 million per year, due to reduction in inpatient and emergency department costs. However, ESC considered the estimated savings to be optimistic given there is uncertain evidence from the IMeRSe Feasibility Study about the reduction in preventable hospitalisations and MRPs. As such, ESC agreed with the commentary that attributing cost-offsets in terms of the observed reduction in hospital admissions and emergency department presentations to the intervention cannot be reasonably justified and such cost-saving claims should be very rigorous. ESC also noted that the higher GP benefit fee (from HMR) was used instead of the proposed GP fee, the ADAR did not consider substitution of services (i.e., from HMR to IMeRSe), and the time horizon in the study was 6 months, but the budget impact used 12 months and assumed constant per-person annual rates. Further, medication adherence was not included, and ongoing costs beyond the first year were not included. ESC also noted that a consequence of the broad population definition (i.e., not being limited to the listed criteria) was that it created difficulty in estimating the eligible patient population for the service, which created uncertainty in the predicted uptake and financial estimates. Further, uptake of IMeRSe was assumed to be 5%, however ESC considered that the actual uptake could vary depending on implementation of the IMeRSe (i.e., engagement of an AHW). ESC advised that the applicant should better explain and justify these proposed cost savings.

17. Applicant comments on MSAC's Public Summary Document

The Indigenous Medication Review Service (IMeRSe) intervention is a flexible and feasible culturally responsive pharmacy service for Aboriginal and Torres Strait Islander peoples that addressed longstanding institutional and cultural barriers to medication management review services, reduced medication related problems and promoted adherence, health, and wellbeing. The IMeRSe Feasibility Study was designed to evaluate the feasibility of a consumer-led, collaborative medication review service and the measures needed to assess impact, to then inform a more traditional clinical trial that would assess impact and economic benefit. The project team accept that the evidence collected informs future more robust study to meet the level of evidence for an MSAC submission. Although the study was not intended to measure impact, there were clear measures of success even as a feasibility study trial. The collaborative nature of the service was evidenced by the degree of involvement of Aboriginal Health Workers (AHWs) in service delivery, uptake of pharmacists' recommendations by GPs at a level exceeding

that of more traditional GP-led medication management review services, and involvement of allied health professionals. Participant feedback highlights the benefits of a more encompassing, flexible approach to referral pathways that included referral by GPs, pharmacists, nurses, AHWs, family members, carers, and self-referral. IMeRSe represents an opportunity to optimise coordinated care from multiple perspectives. Flexibility in the location of IMeRSe and inclusion of the AHW as a key provider were also integral to removing sustained access barriers to traditional HMR services. The unique culturally responsive approach of IMeRSe, underpinned by collaborative care and building relationships aligns with elements of an equity driven, rights-based approach to healthcare to promote available, accessible, acceptable, high-quality services. The IMeRSe Feasibility Study assessed the feasibility of how this approach to pharmacy services addressed limitations of the existing Home Medicines Review (HMR) program from multiple perspectives with positive impacts on access, collaborative care, individual empowerment, and community trust in services. Further, pharmacists delivering IMeRSe were not required to be HMR accredited, and 32 of 39 were not, thereby addressing a disconnect between population need for medication review services and available workforce, particularly in rural and remote areas where access to the HMR-pharmacist workforce is reported to be inadequate. To encourage access to, and uptake of culturally responsive medication review services, the existing 'one-size fits all' approach of the HMR Program and the numerous HMR Program Rules need to be modified to remove existing barriers. This highlights the need for multiple services that accommodate the diversity of First Nations peoples, systems of healthcare access and non-Indigenous Australians. It is not guaranteed that any one service will supplant another, more that they may increase appropriate healthcare access overall. Finally, it is important to note key differences between the research infrastructure or processes needed in a feasibility trial and more routine service delivery as part of broader implementation, for example the study coordinator role of the AHW which would not exist in routine service delivery.

18. Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website: [visit the MSAC website](#)