

Public Report of the Review of the Quality Use of Medicines Program's
Delivery by
NPS MedicineWise

Review of the Quality Use of Medicines Program's
Delivery by the National Prescribing Service Limited
(NPS MedicineWise)

Public Report

Department of Health

December 2019

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Prepared by:
Emeritus Professor Lloyd Sansom AO

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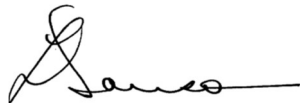
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Acknowledgments

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I also acknowledge the assistance of the Chief Executive Officer (CEO) and the staff of NPS MedicineWise for their openness in engaging with the Review and for their timely responses to the Review's many requests for information.

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Emeritus Professor Lloyd Sansom AO

10 July 2019

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1.3 Glossary

ACNC	Australian Charities and Not-for-profits Commission
ACSQHC	Australian Commission on Safety and Quality in Health Care
ACT PHN	Capital Health Network PHN
AEST	Australian Eastern Standard Time
AHHA	Australian Healthcare and Hospitals Association
AIHW	Australian Institute of Health and Welfare
AME	Adverse Medicines Event
AMR	Antimicrobial Resistance
ANAO	Australian National Audit Office
APAC	Australian Pharmaceutical Advisory Council
ARA	Australian Rheumatology Association
ASTAG	Australian Strategic and Technical Advisory Group on Antimicrobial Resistance
AURA	Antimicrobial Use and Resistance in Australia
CATAG	Council of Australian Therapeutic Advisory Groups
CDM	Chronic Disease Manager
CEO	Chief Executive Officer
CHF	Consumers Health Forum of Australia
CIAG	Clinical Intervention Advisory Group
CINSW	Cancer Institute New South Wales
CIS	Clinical Information Systems
COPD-X	Chronic Obstructive Pulmonary Disease Clinical Practice Guidelines
CPD	Continuing Professional Development
CSS	Clinical Service Specialists
CVD	Cardiovascular Disease
DATIS	Drug and Therapeutic Information Service
DUSC	Drug Utilisation Sub Committee
DVA	Department of Veterans' Affairs
EQ _u IP	Effectiveness of Quality Incentive Payments
EY	Ernst and Young
FBT	Fringe Benefits Tax
FTE	Full Time Equivalent Employees
GP	General Practitioner
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HNELHD	Hunter New England Local Health District
HPRG	Health Products Regulation Group
ISDB	International Society of Drug Bulletins
MBS	Medical Benefits Schedule
MHCP	Mental Health Care Plans
MIMS	Monthly Index of Medical Specialities
MTX	Methotrexate
NCIRS	National Centre for Immunisation Research & Surveillance

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NMP	National Medicines Policy
NPS	National Prescribing Service
NSQUM	National Strategy for Quality Use of Medicines
NSW TAG	NSW Therapeutic Advisory Group Inc.
OECD	Organisation for Economic Co-operation and Development
OHP	Office of Health Protection
PBAC	Pharmaceutical Benefits Advisory Committee
PBO	Parliamentary Budget Office
PBS	Pharmaceutical Benefits Scheme
PGPA Act	The Public Governance, Performance and Accountability Act 2013
PHARM	Pharmaceutical Health and Rational Use of Medicines
PHI	Private Health Insurance
PHN	Primary Health Care Network
PIP- QPI	Practice Incentive Program - Quality Prescribing Incentive
PPI	Proton Pump Inhibitor
PSA	Pharmaceutical Society of Australia
QUD	Quality Use of Diagnostics
QUM	Quality Use of Medicines
QUME	Quality Use of Medicine Education
QUMP	Quality Use of Medicines Program
RACGP	Royal Australian College of General Practitioners
SNOMED	A systematically organized computer processable collection of medical terms providing codes, terms, synonyms and definitions used in clinical documentation and reporting.
SNRIs	Serotonin and Norepinephrine Reuptake Inhibitors (a class of medications that are effective in treating depression)
SSRIs	Selective Serotonin Reuptake Inhibitors (a class of drugs that are typically used as antidepressants in the treatment of major depressive disorder and anxiety disorders)
TGA	Therapeutic Goods Administration
the Department	The Department of Health
MATES	Medicines Advice and Therapeutics Education Services
WAPHA	Western Australian Primary Health Alliance
WHO	World Health Organisation

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2 Executive Summary

Introduction

Quality Use of Medicine (QUM) is one of the central objectives of the National Medicines Policy (NMP) and for 20 years NPS MedicineWise has played a valuable role as a key implementation arm of the Government's National Strategy for Quality Use of Medicines (NSQUM). QUM objectives are a constant but the QUM environment continually evolves. New challenges emerge including the aging population and the complexity of managing people with co-morbidities and multiple medications, while old challenges such as reducing medication related preventable hospitalisations persist.

To meet these evolving challenges, the investment of the Commonwealth Department of Health (the Department) in QUM has expanded and diversified to include providers other than NPS MedicineWise. In the 2017/18 Budget, the Government announced that it would reduce NPS MedicineWise's funding by \$40 million over four years. Despite this reduction, NPS MedicineWise's core Commonwealth funding is still significant, amounting to over \$25 million in 2021/22.

These developments highlight the importance of reviewing delivery of the Government's QUME Program's by NPS MedicineWise.

To address the Terms of Reference, this Review has drawn on 54 external submissions and 26 external interviews, met with Officials from across the health portfolio and also extensively reviewed NPS MedicineWise's documents and met with NPS MedicineWise staff.

Part 1 - Governance, Transparency & Accountability

NPS MedicineWise's governance structures and administrative policies and practices are appropriate for a Company Limited by Guarantee. However, the review identified the need for greater transparency and accountability in the reporting of NPS MedicineWise's performance against the requirements of the Quality Use of Medicine Education (QUME) Grant Agreement.

The Agreement's performance indicators do not reflect all the requirements of the Grant. So, while the annual performance reports show that targets are met, it is not possible to determine whether all the activities funded under the Grant have been delivered.

Accountability would be enhanced by the addition of analytical performance measures enabling decision-makers to better assess policy options and trade-offs. For example, key performance indicators that report the proportion, frequency and distribution of medical practitioners who engage with NPS MedicineWise's programs would be more informative.

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The need for transparent outcome measures was raised by a number of stakeholders. Stakeholders called for NPS MedicineWise's performance against QUM indicators to be published and also noted that the evaluation of NPS MedicineWise's programs was conducted in-house and the outcomes are not publicly available.

Transparency in NPS MedicineWise's financial reporting must also be improved. Reporting would be enhanced by a financial structure that reported the costs of programs including specific elements of multi-faceted programs. The current process of distributing fixed costs and program costs across the six activities meets the Grant's requirements but provides decision-makers with limited information on program implementation costs or the net benefit of a specific program activity. Transparently reporting the costs of interventions is important in determining the efficient allocation of resources and in acquitting grant funds.

One issue the Review identified was the lack of a clear delineation between non-Grant activities, NPS' Grant activities and VentureWise's activities. The same staff are involved in the delivery of all three activities. NPS MedicineWise's use of Grant funded staff to complete non-Grant projects raises the potential for Grant funds to be used for non-Grant activities.

An examination of NPS MedicineWise's financial processes appears to indicate that the QUME Grant underwrites NPS MedicineWise's commercial activities. That would be contrary to the proper use of Commonwealth grant funds. The Review notes that Grant funds cannot be used for any purpose other than the activities listed as funded by the Grant. Commonwealth Grant funds must also not be used to support commercial activities.

The consultation process repeatedly highlighted stakeholders' concerns that the establishment and commercial activities of VentureWise detracted from NPS MedicineWise's mission. There is also evidence that NPS MedicineWise's decision to pursue funding from the pharmaceutical industry has resulted in reputational damage. The Review, however, identified certain VentureWise projects funded by pharmaceutical companies that were of a high quality and provided a public benefit. These projects would have been generally accepted by stakeholders if greater transparency about the programs was available.

Part 2 - Delivery of QUME Grant Program

The Review identified almost universal acknowledgement that NPS MedicineWise produces high quality, valued resources in the delivery of its programs which support the Quality Use of Medicines and Diagnostics. The process of identifying topics for Grant funded therapeutic programs is thorough and combines expert knowledge and opinion with evidence.

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While the NPS MedicineWise process of topic selection is comprehensive, in practice the capacity for a topic to contribute to the delivery of Pharmaceutical Benefits Scheme (PBS) or Medical Benefits Schedule (MBS) savings appears to be the critical factor. These programs may be weighted higher versus those with strong public health justifications but with limited opportunity for cost savings.

The process of selection, design and implementation of specific programs must be transparent and include meaningful engagement with the broader QUM ecosystem. The Review's consultations identified concerns amongst consumer representatives that genuine consumers' involvement in NPS MedicineWise's program design had declined.

The process should also engage earlier and often with the Department, ACSQHC, Royal Australian College of General Practitioners (RACGP) and Primary Health Care Networks (PHNs). Consideration should therefore be given to including Department of Health officials and ACSQHC staff and PHN and RACGP representatives on the Clinical Intervention Advisory Group (CIAG).

Over the past eight years the Government has invested \$33.7 million into the development of MedicineInsight which is a research quality national longitudinal general practice dataset. There are 718 general practices participating, representing more than 4,000 active general practitioners (GPs) enabling the de-identified data of approximately 3.6 million regular patients to be collected.

The Department and associated portfolio agencies are using MedicineInsight for a range of purposes and are highly supportive of its capabilities. Academic researchers and the pharmaceutical industry are also using the resource.

Some stakeholders raised concerns with the commercial use of MedicineInsight data, while others highlighted the Government's investments in multiple GP software extraction tools and doubted MedicineInsight's ability to engage with PHNs who use other GP software extraction tools.

MedicineInsight's governance and management are consistent with best practice privacy, consent and ethics requirements, however, greater transparency with stakeholders would address many of the issues raised.

The Review considers that there is a significant opportunity for an increased use of MedicineInsight data in the area of post marketing surveillance. The system has the capability of collecting data on behalf of sponsors of therapeutic goods to satisfy the requirements of the Therapeutic Goods Administration (TGA) for compliance with Risk Management Plans. MedicineInsight could also be further developed to support the TGA and Pharmaceutical Benefits Advisory Committee (PBAC) requirements for the

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managed entry of new products. Since these data requirements will be specified by a Government agency, any perceived conflicts of interest can be managed in a transparent manner. However, this potential will only be realised when MedicineInsight gains access to medical specialists' data.

Part 3 - Evaluation Methodology

The methods and reporting currently used by NPS MedicineWise to evaluate savings to the PBS and MBS are not considered to comply with the guidance issued by the Department of Finance for the estimation of savings (Appendix I). This requirement to comply with the guidance appears not to have been explicitly communicated to NPS MedicineWise.

NPS MedicineWise uses interrupted time-series analyses to calculate the financial impact of its programs for the purpose of reporting PBS and MBS savings. This is an established methodology for the examination of an intervention when a randomized trial is not feasible. The Review therefore considers an interrupted time-series analysis method which is robustly applied and transparently reported as the appropriate methodology and model to evaluate savings to the PBS and MBS.

However, the interrupted time series analyses submitted by NPS MedicineWise were not sufficiently detailed to validate the PBS and MBS savings claimed. Greater transparency in the method applied including a technical appendix is needed. There is also no explicit statement or evidence provided in regard to any sensitivity analysis. The graphical presentations do not include confidence intervals, making it difficult to determine whether an intervention was the actual cause of the claimed difference in the projected and actual prescription volumes. The limitations of the estimates of savings needs better identification including that of substitution where applicable.

While accepting the adoption of the use of an interrupted time-series approach as an appropriate methodology by which to assess the cost benefits of interventions, the Review acknowledges the need for greater transparency and documentation of the financial impact of NPS MedicineWise's programs. The Review believes there is uncertainty in regard to the magnitude of any net savings to the PBS and MBS systems.

Conclusion

As the national organisation funded by the Commonwealth Government to implement the NSQUM, NPS MedicineWise's actions must embody the Strategy's five Principles which are:

- The primacy of consumers;
- Partnership;
- Consultative, collaborative, multidisciplinary activity;
- Support for existing activity; and
- Systems-based approaches.

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The Review's stakeholder consultations highlighted a view that NPS MedicineWise is withdrawing from its national QUM stewardship responsibilities: increasingly adopting a transactional rather than relational approach to its QUM programs; reducing collaboration and limiting the flow of information about its programs. This is resulting in a lack of co-ordination and duplication of effort.

The growing complexity of the QUM landscape reinforces the need for NPS MedicineWise to promote the five NSQUM principles in the identification, design and implementation of all Commonwealth funded programs.

The Review has identified almost universal acknowledgement that NPS MedicineWise produces high quality valued resources to support the delivery of its therapeutic programs. Many of the submissions to the Review commented that the work of NPS MedicineWise was highly regarded and while many expressed concerns with its recent direction there was a general consensus of support for the work of the organisation

NPS MedicineWise has been a government preferred provider for QUM activities because it is perceived as independent, it has recognised expertise and a record of producing high quality evidence-based resources. To maintain this position, it has to re-establish itself as a steward of QUM in Australia and adopt a more collaborative approach to working with stakeholders. This may result in NPS MedicineWise refocusing its efforts onto under-serviced QUM priorities such as promoting QUM for multi-morbid patients and collaborating more closely with other providers of continuing professional development (CPD).

The Government's investment in MedicineInsight is a strategic asset worthy of continued support.

The method currently used by NPS MedicineWise to evaluate savings to the PBS and MBS needs to be transparently applied and reported in a manner consistent with the requirements of the Government's approach to calculate savings.

Any new Grant Agreement should recognise that NPS MedicineWise's role is greater than just being a provider of education, ensure that program selection is not dominated by the need to deliver PBS and MBS savings and encourage the organisation to take on a greater QUM stewardship role.

3 Recommendations

Governance

Recommendation 1. NPS MedicineWise should review the reputational risks arising from its VentureWise activities in view of the necessity to maintain both the perception and reality of independence in the QUM ecosystem. Such a review should consider whether the continuance of its current relationship with VentureWise is in the best interest of the company in view of the negative perception of the relationship as expressed to the Review by key stakeholders.

If the relationship is to be maintained, further steps should be taken to ensure that there is a clear separation between both entities.

Recommendation 2. Representatives of the Department of Health, PHNs, RACGP and ACSQHC should be included as members of the CIAG. This will enable wider deliberations about prioritisation and better co-ordination while also promoting closer engagement. This will minimise duplication while also ensuring Grant funded activities align with other relevant Department programs.

Recommendation 3. NPS Medicine Wise should strengthen governance of the use of MedicineInsight data including introducing greater transparency to ensure ongoing confidence in the processes and to ensure data are not used in a manner contrary to NPS MedicineWise's mission.

Recommendation 4. The Board of NPS MedicineWise should consider mechanisms for the appointment of Directors and the composition of the Board with a view to include members with specific financial and legal expertise and knowledge of public sector governance.

Recommendation 5. NPS MedicineWise's processes should be refocused to ensure consumer involvement in a genuine collaborative manner in the priority setting, co-design, and where applicable, the delivery of programs.

Embedding QUM across the Health System

Recommendation 6. Consistent with the Quality Use of Medicine Principles of system-based approaches, NPS MedicineWise's topic selection and annual Workplan development must take into consideration the need for better integration of medication management between levels of healthcare services.

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Recommendation 7. In the development of the annual Workplan, NPS MedicineWise and the Department must identify system-based issues that impact on QUM and support collaborative interventions that improve medication use while recognising the potential for NPS MedicineWise to demonstrate its QUM stewardship role.

Recommendation 8. A collaborative working relationship between PHNs and NPS MedicineWise is essential to ensure the efficiency and effectiveness of QUME programs. The Department should consider the necessary incentives and processes to facilitate the development of a productive working relationship between NPS MedicineWise and the PHNs to leverage Commonwealth investments in primary health quality initiatives.

Recommendation 9. To ensure the efficient use of the Commonwealth QUM investments, the relationship between NPS MedicineWise and the ACQSHC should be further developed. The two organisations should have complementary priorities and share expertise to avoid duplication and promote consistent messaging wherever applicable.

Recommendation 10. In line with the Principles of NSQUM, it is recommended that QUM initiatives that relate to specific disease entities be supported in a system based approach. To achieve a system based approach, both NPS MedicineWise and disease specific groups must act collaboratively.

Recommendation 11. MedicineInsight is a valuable primary health care data asset and its use by government agencies should be expanded to support the post marketing requirements including for the reporting required for Risk-Management Plans and for drug approvals under accelerated regulatory approval processes and managed entry schemes recommended by PBAC.

Recommendation 12. The utility of MedicineInsight data should be better promoted to government and non-government agencies including PHNs.

Recommendation 13. The Department should consider options for a refresh of the National Medicines Policy.

Grant Management

Recommendation 14. Commonwealth Grant funds must only be used to support Grant activities. The terms of the Grant Agreement should include a clear requirement that resourcing for non-Grant activities be separated from funds provided through the Grant. To ensure ongoing compliance with the Grant requirements and to improve financial transparency in the future use of Grant funds, NPS MedicineWise should be required to establish financial processes that

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clearly show that Grant funds are not being used to underwrite any aspect of NPS MedicineWise's non-Grant projects. The Agreement should also require that any processes that rely on reimbursing the Grant for the cost of using Grant funded staff and assets for non-Grant activities must first be agreed in writing by the Department.

Recommendation 15. Mechanisms to support greater collaboration between NPS MedicineWise and other key stakeholders need to be built into any new funding Agreement. The Department should ensure QUM performance indicators across government funded activities are harmonised (including ACSQHC and PHNs) to ensure delivery against shared safety and quality goals is optimised.

Recommendation 16. Acceptance of the final topic selection for inclusion in the annual Workplan should reside with the Department of Health. The process of developing and approving NPS MedicineWise's annual Workplan and Budget needs to be better integrated with the Department's QUM priorities in order to avoid duplication and to identify areas of synergy across various initiatives.

Recommendation 17. The terms of the Grant Agreement should be amended to require that costs of each of the elements that constitute an activity under the Grant be reported to the Commonwealth.

Recommendation 18. MedicineInsight should continue to be developed and maintained by the Department and NPS MedicineWise.

Recommendation 19. The Australian Prescriber should continue to be published at current frequency and continue to be a core component of NPS MedicineWise funded programs.

Recommendation 20. NPS MedicineWise should undertake a review of RADAR and consider whether it is the most efficient and effective means of informing pharmacists and prescribers regarding PBS listings. Further, in view of the apparent overlap in the type of material, there is a need to consider whether both RADAR and Australian Prescriber are necessary or whether consolidation of the two publications is an appropriate option.

Recommendation 21. While the MedicineLine service does perform a useful function, the question of whether it could be better integrated into Healthdirect Australia should be considered by the Department. If NPS MedicineWise's service were to be incorporated into Healthdirect's services, consideration will need to be given to increasing Healthdirect's access to expertise on medicines.

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Recommendation 22. Government QUME funding should not be allocated to activities to address Antimicrobial Resistance (AMR) unless it is part of a co-ordinated program endorsed by the Office of Health Protection (OHP).

Recommendation 23. Availability and utility of NPS MedicineWise's Medicine apps should be actively promoted by NPS MedicineWise as part of its services to consumers and health professionals.

Enhancing Transparency

Recommendation 24. The Grant Agreement should require that the outcomes of NPS MedicineWise Grant funded activities are made available in the public domain, so as to enhance transparency. The annual evaluation reports, detailed Economic Evaluation reports and the more detailed financial impact reports on PBS and MBS savings should also be required to be made available in the public domain.

Recommendation 25. The Grant Agreement should require that, at the beginning of each year, NPS MedicineWise is required to make publicly available the Grant activities proposed for the next year including:

- (a) the objectives for those activities;
- (b) the anticipated costs of the programs; and
- (c) the anticipated savings (if applicable).

Enhancing Stewardship

Recommendation 26. Consideration should be given to the importance of a stewardship role for NPS MedicineWise in promoting QUM including fostering a culture that promotes the five principles of the NSQUM across the health system. This should be specified in any new Grant Agreement.

Recommendation 27. The process for the selection of therapeutic topics should include more formal arrangements that enable, as is appropriate, stakeholders including representatives of consumer groups, ACSQHC, and PHNs, to be involved in the selection of the topics to be considered in the final project plan.

Recommendation 28. QUM initiatives for medical specialists must be further developed and delivered by NPS MedicineWise, including delivery through bespoke approaches.

Recommendation 29. Strategic relationships with medical specialists established through Choosing Wisely should be further developed by NPS MedicineWise as QUM initiatives will increasingly be designed for medical specialists.

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Recommendation 30. NPS MedicineWise should use its national networks to facilitate collaborations with consumer groups so that disease-specific groups' priorities and activities are better integrated with the Grant Agreement's QUM objectives.

Recommendation 31. While it is appropriate for the NPS MedicineWise's programs to include the development of CPD materials, consideration should be given to NPS MedicineWise collaborating with professional associations to minimise the duplication of effort and ensure consistent messaging relating to a particular topic.

Performance Measurement

Recommendation 32. PBS and MBS savings targets must be set whilst recognising that the pursuit of QUM will not always result in savings to the MBS and PBS and that public health system based improvements have the potential to deliver savings in other parts of the health system.

Recommendation 33. A QUM performance assessment framework to guide indicator selection, implementation and evaluation should be developed by NPS Medicine Wise and the Department for inclusion in any future NPS MedicineWise-Commonwealth Grant Agreement. This Framework should reflect the requirements of the NSQUM Principles.

Recommendation 34. NPS MedicineWise should undertake a rigorous and detailed evaluation of each component of its programs including their impact on outcomes. This may require enhancing its evaluation methods to include prospectively using a step-wedge trial or similar designs as discussed in the 2018 report *Assessment of Evaluation Methods by NPS MedicineWise* prepared by Roselie Viney, Stephen Jan and Katharina Wagner.

Recommendation 35. A formal financial methodology and process should be agreed between the Department and NPS MedicineWise that addresses the following issues:

- The selection of programs/activities to include in the annual financial impact reports.
- The specifications of a costing methodology that aligns with Australian Government policy costing guidance, particularly on the qualitative explanations to accompany the financial impact report.
- The selection of data sources and the documentation of the source and any limitations it might present.

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- The use of assumptions and the requirement to provide clear and plain English explanations on the impact of those assumptions on the overall reliability of the financial impact.
- Guidance on when savings can be considered ongoing or whether they are temporary in nature.

Recommendation 36. A formal methodology for estimating savings to PBS and MBS should be developed by NPS MedicineWise and agreed with the Department and align with the Australian Government's approach to calculating savings.

Recommendation 37. In the estimation of savings to MBS and PBS using time-series analysis, the issue of substitution must be taken into account. Savings claimed from reduction of one medicine could be offset by substitution to alternate therapies.

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4 Introduction

4.1 *Quality Use of Medicines and NPS MedicineWise*

QUM is one of the central objectives of the NMP and for 20 years NPS MedicineWise has played a valuable role as a key implementation arm of the Government's National Strategy for the Quality Use of Medicines (NSQUM). Quality Use of Medicine (QUM) objectives are a constant but the QUM environment continually evolves. New challenges emerge including the aging population and the complexity of managing people with co-morbidities and multiple medications, while old challenges such as reducing preventable medication-related hospitalisations persist.

In the twenty years since NPS MedicineWise was established, it has received over \$602.4 million in core Commonwealth funding and reported PBS savings of \$1.06 billion. Over this period, it has grown into a large company with over 200 employees. In 2017/18 the NPS MedicineWise Group which includes its wholly owned subsidiary, VentureWise, recorded revenues of \$45 million of which \$38.9 million (86%) were from Commonwealth funding (1).

The 2018-19 Commonwealth Budget included a commitment to undertake a Review of NPS MedicineWise while also reducing the organisation's core Commonwealth funding by \$40 million over four years. NPS MedicineWise's core Commonwealth funding remains significant, amounting to \$110.4 million between 2018/19 and 2021/22

This Review focuses on NPS MedicineWise's role as an implementation arm of the Government's QUM strategy including the efficient and effective use of Grant funds to deliver the greatest positive impact on health outcomes.

4.2 *Terms of Reference*

The Review's Terms of Reference are as follows:

The Review of NPS MedicineWise (NPS) will inform the Department of Health (the Department) and assist NPS on options to deliver an efficient, flexible and innovative delivery of Quality Use of Medicines (QUM) programs.

The review is expected to provide a robust evaluation of the delivery of the QUME programs by NPS, the mechanisms for the evaluation of the effectiveness of these programs, including savings delivered to the health system, and the role of NPS as a delivery arm of QUM activities on the Government's behalf.

The Review will include an examination of the interactions between the NPS and relevant government and non-government agencies and instrumentalities involved in broader QUM activities and their impact on the delivery of the programs.

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The Review will:

- consider whether NPS' governance and administrative policies and practices are accountable and effective, and make recommendations for any improvements to support higher levels of accountability, transparency and performance in the delivery of Grant activities on behalf of the Australian Government;
- evaluate the effectiveness, efficiency and appropriateness of the work delivered by NPS to achieve the objectives and outcomes of the QUME Grant program;
- evaluate the methodology used by NPS for attributing savings from its activities and identify options to ensure the methodology is robust and defensible; and
- provide advice on how to best target NPS activities to deliver value for money, improve linkages with relevant stakeholders and achieve the QUM outcomes expected of Government, taking into consideration the potential impact of the recent decision to reduce funding to NPS and NPS' ability to continue to deliver on the core program objectives.

Scope

The Review will be undertaken in three parts, to develop strategies and recommendations to inform future arrangements for the NPS.

- Part One will focus on governance, transparency and accountability issues, including the impact on the QUME Grant Program of the NPS commercial arm VentureWise;
- Part Two will focus on NPS delivery of the QUME Grant Program and NPS long term sustainability; and
- Part Three will focus on the evaluation of programs delivered by NPS, including savings evaluation methodology and reporting of broader health outcomes.

The Review will also provide options to inform the efficient, flexible and innovative delivery of the QUME Grant Program as well as a robust evaluation of its outcomes and savings.

4.3 External Consultations

The Review included a public consultation from December 2018 to February 2019. Information about the review was:

- Hosted at CitizenSpace
- Advertised on the Department's website and hyperlinked to CitizenSpace

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- Promoted through the Department's social media accounts (Twitter and Facebook)
- Virtually hosted on the Australian Government business consultation website.

126 key stakeholders were notified by email hyperlinking to information about the consultation process. As part of this process, stakeholders and members of the public could request an interview with the reviewers.

All stakeholders interviewed received a document outlining the Department's responsibilities under the *Privacy Act 1988* and the Australian Privacy Principles.

The Review received 54 external submissions by e-mail and/or mail and 26 interviews were conducted with external stakeholders in Canberra, Adelaide, Melbourne, Sydney and Brisbane (Appendices A & B).

4.4 Internal Consultations

The Review was also communicated within the Department. A letter was sent to 11 people in the Department and portfolio agencies as well as an email to the Technology Assessment and Access Division requesting input.

Three internal submissions were received and eight interviews conducted (Appendices A & B)

4.5 NPS MedicineWise Consultations

In December 2018, the reviewers requested information relating to the Terms of Reference from NPS MedicineWise. The details of this request are outlined in Appendix C. In response, a large volume of documents were supplied by NPS MedicineWise which have been reviewed.

Interviews were also conducted with NPS MedicineWise staff in December, January and February 2019.

4.6 Document Review

In addition to studying the 54 stakeholder submissions and the documents provided by NPS MedicineWise, the reviewers assessed past NPS MedicineWise contracts, NPS MedicineWise annual reports, NPS MedicineWise Board papers, and briefing papers on the Department's TRIM filing system and relevant articles available on the internet.

5 National Medicine Policy and Quality Use of Medicine

5.1 *Early Policy Development*

In the late 1980s and 1990s the World Health Organisation (WHO) recommended that governments develop national medicines policies. During this time in Australia, concerns were growing across government, the health sector and the broader community about the spiralling cost of medicines on the PBS, the quality of drug use, inappropriate prescribing, and the high incidence of potentially preventable adverse medicines events (AME) and hospitalisations. In 1991, this culminated in the government forming a working party to review rational use of medicines and drug policy objectives to achieve improved health outcomes. In 1992 a quality use of medicines policy was published and the Commonwealth Government established two major advisory groups: the Australian Pharmaceutical Advisory Council (APAC), and the Pharmaceutical Health and Rational Use of Medicines (PHARM) committee.

APAC brought together all the players to debate national medicines policy. PHARM funded one-off projects that showed promising outcomes but unfortunately proved difficult to sustain. This led to a recommendation that a national centre to co-ordinate the quality use of medicine be established which in 1998 became the National Prescribing Service. (2)

The establishment of NPS MedicineWise was supported by a stakeholder consultation process managed by the then Commonwealth Department of Health and Family Services in collaboration with an advisory group comprising doctors, GP registrars, pharmacists and consumers. Broad consultation built a degree of ownership with stakeholders, and engaged different groups in the work and success of programs implemented by the new entity.

5.2 *National Strategy for Quality Use of Medicine*

In 2002 the Government launched the National Strategy for the Quality Use of Medicines which set out the approach and principles necessary to achieve QUM in Australia. The strategy reaffirmed QUM's place within the National Medicine Policy's framework, and its five principles (listed in Figure 1) are as relevant today as they were in 2002. These principles highlight the critical importance of consumers in achieving QUM through approaches that build on partnerships, include consultative, collaborative and multi-disciplinary activities, promote existing activities and adopt systems-based approaches (3).

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Figure 1 - National Strategy Quality Use of Medicine's Principles (3)

Principles

The five principles underlying the National Strategy were developed in consultation with all partners and recognise the problems Australia currently faces in achieving QUM. They are:

- *The primacy of consumers*

The National Strategy recognises both the central role consumers play in attaining QUM and the wisdom of their experience. Consumers must be involved in all aspects of the National Strategy.

- *Partnership*

Active and respectful partnerships are essential to achieving QUM in Australia.

- *Consultative, collaborative, multi-disciplinary activity*

To attain QUM, activities must be consultative, collaborative and multi-disciplinary. Therefore, key partners must be involved at all stages in designing, implementing and evaluating QUM programs. At the local level, the value of the healthcare team in achieving QUM needs to be promoted and consumers recognised as active members.

- *Support for existing activity*

Wherever possible, initiatives within and across all groups need to be stimulated and supported, and support given to existing groups that are already developing initiatives. Actions taken to improve QUM should heed the ethical and legal rights, obligations and responsibilities of all partners.

- *Systems-based approaches*

To achieve QUM it is necessary to adopt systems-based approaches that will:

- develop behaviours that support QUM; and
- create a supportive environment that encourages QUM.

Multiple activities and strategies are needed to raise awareness about issues related to QUM. Attitudes, knowledge, skills and behaviours that support QUM need to be developed and maintained. We also need to inspire community, organisational, legal and political efforts to create an environment that supports QUM.

Any undertaking related to QUM should reflect these five principles.

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5.3 QUM Principles and NPS MedicineWise

When NPS MedicineWise was established, there was no organisation with a national focus providing evidence-based objective education and academic detailing for GPs although Therapeutic Guidelines were available. Over the ensuing two decades, a complex QUM ecosystem has developed. New structures have been established, such as:

- the Primary Health Networks (PHNs),
- the Veterans Affairs program's Medicines Advice and Therapeutics Education Services (MATES),
- the National Centre for Antimicrobial Stewardship Centre of Research Excellence, and
- the Australian Commission on Safety and Quality in Health Care (ACSQHC).

In addition, the introduction of national registration and continuing professional development requirements for health professionals are furthering the QUM agenda. Despite these advancements, stakeholders raised concerns about the fragmentation of QUM efforts. (Refer to Sections 7.14 to 7.17)

As the QUM landscape becomes more crowded, the five principles of the NSQUM take on even more importance. While a crowded environment might make acting in a manner consistent with these principles more challenging, this is in fact NPS MedicineWise's raison d'être. Not only must the organisation be a steward of QUM, it should also value-add by leading efforts to address the difficult QUM issues like the management of patients with complex co-morbid conditions. This is because the solutions to these QUM challenges are built on actions that are consistent with the five principles. Actions that uphold the primacy of the consumer, require a partnership approach based on consultation, collaboration, multi-disciplinary activity, leverage existing activities and are system based. This highlights the continued need for a national organisation committed to reinforcing the five NSQUM Principles.

The National Medicines Policy (NMP) was written over 20 years ago. The core objectives of the NMP are enduring but the context in which they are applied have changed. A number of key stakeholders indicated that a refresh of the NMP was needed to ensure the ongoing commitment to the principles of the Policy by stakeholders. This may therefore be an appropriate time for the Government to revisit the NMP, to acknowledge developments in healthcare and healthcare delivery in the last two decades and to take the opportunity to reinforce the central role of quality use of medicines and diagnostics.

Recommendation. The Department considers options for a refresh of the National Medicines Policy.

6 Part 1. Governance, Transparency and Accountability

6.1 Governance Structure

NPS MedicineWise is a company limited by guarantee. It is a private, not-for-profit, non-government organisation registered with the Australian Charities and Not-for-profits Commission (ACNC).

It has 45 members, being organisations representing GPs, pharmacists, specialists, nursing, other health professionals, the pharmaceutical industry, government and the Australian community. A list of NPS MedicineWise's members is provided in Appendix D.

In February 2015, NPS MedicineWise established a wholly-owned subsidiary, VentureWise Pty Ltd, to commercially leverage the capability of the organisation and support its financial sustainability. Unlike NPS MedicineWise, VentureWise Pty Ltd is a proprietary limited for-profit company which is subject to the payment of income tax.

The organisational governance structure for the NPS MedicineWise Group including Board, management governance groups, VentureWise and advisory groups is set out in Appendix E.

The Review noted that, while the Board Charter refers to a skills based Board, the current Board does not include specific legal or financial expertise. The addition of these skills to the Board would be appropriate for a Board with responsibility for a Government grant of the magnitude NPS MedicineWise receives from the Commonwealth. Under the NPS MedicineWise Constitution, the Board appoints members to the Board. The Constitution limits the influence of members to the removal of a Director by a resolution of the Voting Members.

Recommendation. The Board of NPS MedicineWise should consider mechanisms for the appointment of Directors and the composition of the Board with a view to include members with specific financial and legal expertise and knowledge of public sector governance.

NPS MedicineWise has established administrative policies and frameworks to support its work. These include a Risk Management Framework, Quality Policy, Management Delegations Policy and Policy Document Framework which are all comprehensive and appropriately structured. Furthermore, NPS MedicineWise's operating/administrative practices, policies and procedures are well designed.

The consultation process of this Review highlighted stakeholders' concerns regarding the perceived conflict of interest between VentureWise's commercial activities and NPS MedicineWise's role as a steward of QUM in Australia. A more detailed discussion of VentureWise's role and its impact is outlined in Section 6.7.

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Apart from the above issues, an examination of the documents provided by NPS MedicineWise indicate the organisation's governance structures and administrative policies and practices are appropriate for a not-for-profit Company limited by guarantee.

6.2 Frequency and nature of reporting to Government

The QUME Agreement requires NPS MedicineWise to provide the Department with Annual Performance Reports. There are four sections to the reports:

- Section 1: Performance measures against defined indicators
- Section 2: Financial reports and contract acquittals
- Section 3: Financial impact of NPS MedicineWise programs
- Section 4: Additional reports.

6.2.1 Section 1 Key Performance Indicators

Section 1 of the 2017-18 Performance Report reports objectives against performance indicators for the six activity areas:

- quality use of therapeutics for prescribers;
- quality use of therapeutics for pharmacists;
- quality use of therapeutics for consumers;
- quality use of diagnostics (QUD);
- information and awareness raising of new therapeutics and therapeutic issues; and
- post-market monitoring.

The indicators listed in the Agreement are descriptive and list activities to be provided or absolute counts with limited context. For example under Activity 1, NPS MedicineWise is required to secure '14,000 unique GPs participants per annum'. The organisation exceeded this target by engaging with 15,071 unique GP participants in 2017-18. This performance indicator would be more informative if it was also presented as a percentage of the total number of GPs and also presented with a percentage increase or decrease compared with previous years.

The performance reports reveal that NPS MedicineWise is meeting the Agreement's key performance indicator requirements for each activity. However, accountability and transparency in the use of Commonwealth money is hindered by the lack of analytical performance measures enabling decision-makers to better assess policy options and trade-offs as part of the development of strategic funding priorities and program selection and design. For example, in a multi-faceted program, it is currently not possible to identify or measure the impact of each facet.

As highlighted in Sections 5.3 and 7.13 of this report, NPS MedicineWise has a critical role as a steward for the QUM arm of the National Medicine Policy. A performance indicator that measures their ability to drive

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collaborative behaviours is therefore needed. This need was highlighted by the Victorian and Tasmanian PHN Alliance submission which argued that:

The intended outputs and outcomes of the Government's investment in NPS MedicineWise's activities is not consistently understood, which challenges the capacity for partners and indeed practitioners to work collaboratively (4).

The need for transparent outcome measures was raised by a number of stakeholders who noted that the evaluation of NPS MedicineWise's programs had shifted from external to internal. Many stakeholders called for NPS MedicineWise's performance against QUM indicators to be published and used to inform collaborative activity at the PHN level and with the Australian Commission on Safety and Quality in Health Care (ACSQHC) (4) (5) (6).

Recommendation. The Grant Agreement should require that the outcomes of NPS MedicineWise Grant funded activities are made available in the public domain, so as to enhance transparency. The annual evaluation reports, detailed Economic Evaluation reports and the more detailed financial impact reports on PBS and MBS savings should also be required to be made available in the public domain.

The Australian Healthcare and Hospitals Association (AHHA) submission referred to the National Strategy for Quality Use of Medicine's Manual of Indicators which was last published in 2004 and the ACSQHC National QUM Indicators for Australian Hospitals and Atlas of HealthCare Variation as important documents which should inform the development of NPS MedicineWise's Grant performance indicators (7) (8) (9). Where applicable, these indicators could be used to inform the development of NPS MedicineWise's performance framework.

An integrated QUM performance measurement framework would assist with the identification of indicators that accounted for the interconnections and complexity in cause and effect relationships in the delivery of healthcare. As the NSW Bureau of Health Information explains:

The integrated performance assessment framework takes as its starting point, well-established elements of performance measurement such as resources, staff, activity, and results. However, it acknowledges the limitations of these standard constructs of inputs, outputs and outcomes – recognising that increases or decreases do not necessarily correspond to an improvement or deterioration in performance. It emphasises the importance of moving beyond measurement of static concepts to a focus on functional, relational and dynamic constructs (10).

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The challenges of measuring performance in addressing QUM issues calls for an integrated framework that can be applied in a systematic and rigorous manner.

Recommendation. A QUM performance assessment framework to guide indicator selection, implementation and evaluation should be developed by NPS Medicine Wise and the Department for inclusion in any future NPS MedicineWise-Commonwealth Grant Agreement. This Framework should reflect the requirements of the NSQUM Principles.

6.2.2 Section 2: Financial reports and contract acquittals 2017-18

The documents provided as part of the performance report include an audited Annual Financial Report for the consolidated Group of National Prescribing Service Limited and its Subsidiary, VentureWise, plus separate Statements of Income and Expenditure for each of the six Grant activities.

6.2.2.1 Financial Statements

The Notes to the Financial Statements include a balance sheet for the Parent Entity, National Prescribing Service. Table 1 compares the balance sheets of the Parent Entity and the Group and indicates that VentureWise's liabilities reduce the total equity of the Group by \$347,550. The impact of VentureWise on the NPS MedicineWise Group is a net liability of \$347,550 comprised of a contribution to the Group of \$152,000 offset by the inter-company loan facility of \$500,000.

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Table 1 - Comparison of NPS MedicineWise Group and National Prescribing Service 2018 Balance Sheets

	Group (NPS MedicineWise + VentureWise) \$	NPS MedicineWise (Parent Entity) \$	Difference \$
Current Assets	12,535,290	12,512,018	23,272
Non-Current Assets	615,716	572,187	43,529
Total Assets	13,151,006	13,084,205	66,801
Current Liabilities	8,135,025	7,575,957	559,068
Non-Current Liabilities	1,209,245	1,353,962	(144,717)
Total Liabilities	9,344,270	8,929,919	414,351
Net Assets	3,806,736	4,154,286	(347,550)
Retained Earnings	3,806,736	4,154,286	(347,550)
Total Equity	3,806,736	4,154,286	(347,550)
Surplus	631,512	378,214	253,298

Source: Created from NPS MedicineWise Consolidated Statement of Financial Position as at 30 June 2018 and Note 23 of Notes to the Financial Statements for the Year Ended 2018, Annual Report 30 June 2018.

Accountability and transparency of reporting to Government in the use of Commonwealth money would benefit from financial reporting that details the related transactions between NPS MedicineWise and its subsidiary, VentureWise Pty Ltd.

6.2.2.2 Income and Expenditure Statements for Grant Activities

Section 2 of NPS MedicineWise's Performance Report includes statements of Income and Expenditure for each of the six activities funded through the Grant. These indicate that income and expenditure are attributed to each activity on a proportional basis, consistent with the Grant Agreement's budget allocations.

Transparency and accountability of Commonwealth monies is also reduced because the costs of programs funded through the Grant cannot be determined from these accounts. NPS MedicineWise has advised that it does not quantify resources on a per program basis, unless a formal cost benefit analysis is undertaken. As NPS MedicineWise explains:

This is because programs span multiple financial years and annual budgets so unless it is formally evaluated it is not routinely calculated. Costs in any given financial year are acquitted against the six schedule activities and audited financial statements provided to the Department of Health (11).

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Performance reporting to the Commonwealth would be enhanced by a financial structure that reported the costs of programs including specific elements of multi-faceted programs. For example, the separate costs of GP visits, a clinical audit and a PBS Feedback letter as part of a therapeutic program should be provided to the Commonwealth. Reporting should also delineate administrative costs from program costs. The Review was unable to determine from the current financial reports what percentage of the total costs are administrative costs.

The current process of distributing fixed costs and program costs across the six activities meets the current Grant requirements but provides decision-makers with limited information on program implementation costs or the net benefit of a specific program activity. Transparently reporting the costs of interventions is important in determining the efficient allocation of resources.

Recommendation. The terms of the Grant Agreement should be amended to require that costs of each of the elements that constitute an activity under the Grant be reported to the Commonwealth.

6.2.3 Section 3 Financial Impact of NPS MedicineWise programs

NPS MedicineWise is required to demonstrate a reduction of \$70 million per annum in PBS expenditure and \$13 million per annum in MBS expenditure related to the delivery of programs funded through the Grant.

NPS MedicineWise's ability to meet these saving objectives will be challenged by the \$40 million over four year budget reductions announced in the 2017/18 budget. A detailed evaluation of the efficiencies of the operation and effectiveness of components of their therapeutic programs will be required.

NPS MedicineWise estimates PBS and MBS savings using interrupted time series analyses of pharmaceutical dispensing and MBS service records to make a projection of what the utilisation of goods and services would have been had the program(s) not taken place. It then estimates the expenditure savings by comparing the projected utilisation in the absence of the intervention with the actual utilisation after the intervention.

The Review's assessment of NPS MedicineWise's method and reporting of financial impact information are discussed in detail in Section 8 of this Report.

6.2.4 Section 4 Additional Reports

The Grant Agreement requires NPS MedicineWise to produce evaluation reports for each of the financial years covered by the Agreement based on the principles established in the organisation's evaluation framework. These reports are a high level summary of the programs delivered and do

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not provide sufficient detail for decision-makers to assess the efficiency, appropriateness and effectiveness of the programs or progress towards a QUM goal or objective.

For example, the 2017 Evaluation Report summarises the outcomes of NPS MedicineWise activities, including six multi-year therapeutic programs, and the financial impact of the programs. The information provided in the annual evaluation report is of such a high level that it is not possible to critically examine the evaluation's methods or findings. This is unfortunate as this is the only publicly released document evaluating NPS MedicineWise's work, as the organisation does not release detailed evaluations of its therapeutic programs. The absence of publicly available evaluations of NPS MedicineWise's activities was highlighted by many stakeholders who called for greater transparency (See Recommendation 24).

The Agreement also requires NPS MedicineWise to provide at least one detailed evaluation of a therapeutic program each year, representing a third of the programs delivered. These evaluations are produced at least three years after the intervention occurred. The following Economic Evaluations have been completed as part of the current funding Agreement:

- Early Use of insulin and oral antidiabetic agents (2014) for a program launched in 2008.
- Balancing Benefits and Harms of Antipsychotics (2015) for a program launched in 2011
- Imaging for Acute Low Back Pain (2016) for a program launched in 2013.
- Exploring inhaled medicines use and asthma control (2017) for a program launched in 2014.
- Chronic Pain: Opioids and Beyond (2018) for a program launched in 2015
- Proton Pump Inhibitors - Too much of a good thing (2018) for a program launched in 2015.

These evaluations are very informative and their findings should be publicly available on the NPS MedicineWise website. The Review has been unable to ascertain why these evaluations are classified as confidential as their publication would not only inform QUM policy but also highlight the quality of NPS MedicineWise's work and its impact on selected outcomes (See recommendation 24).

6.3 Structure and management

NPS MedicineWise is led by a Chief Executive Officer (CEO), Steve Morris, who was appointed in late 2018. The previous CEO, Dr Lynn Weekes had led the organisation for 20 years having been appointed its inaugural CEO.

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The new CEO recently announced a restructure of the organisation. The current Executive Team's expertise and background include medicine, pharmacy, science, health promotion, public health, evaluation, research, public affairs, education, publishing, information technology, administration and finance.

As at 21 January 2019, the MedicineWise Group had 217.2 budgeted full time equivalent employees (FTE).

The organisation's structure is divided into 5 streams:

- Health Insights & Business Delivery
- Program & Product Development
- People & Environment
- Business & Commercial Services
- Corporate Affairs & Communications

The Review has been advised that a revised structure has been implemented since the drafting of this Report

An analysis by the Review of the distribution of FTEs provided by NPS MedicineWise across these business units suggests that, at that time, up to approximately 30 percent of the organisation's QUME funded workforce fulfil corporate (including back-office or support function) roles and approximately 70 percent are engaged in program design and implementation.

6.4 Advisory Groups Role and Input

NPS MedicineWise has informed the Review that it uses advisory groups to provide advice on the focus, design, development, implementation and evaluation of NPS MedicineWise's QUME programs, products and services. These groups include the Consumer Advisory Group, Choosing Wisely Advisory Group, CIAG, Nurses Insight and Data Development Advisory Group. The organisation also draws on the expertise of expert Working Groups, Key Opinion Leaders and internal and external expert reviewers to support the development and implementation of therapeutic programs.

The Review has identified almost universal acknowledgement that NPS MedicineWise produces high quality, valued resources to support the delivery of its therapeutic programs.

Consumers are central to the quality use of medicine. The delivery of the Government's QUME Grant requires NPS MedicineWise to work collaboratively with consumers to deliver a range of consumer specific initiatives. The Consumer Advisory Group is listed as part of the organisation's governance structure outlined in Appendix E and consumers are represented across a number of advisory structures. However, NPS MedicineWise advises that the Consumer Advisory Group was disbanded in

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2018 and in submissions to the Review this was perceived negatively by consumer organisations.

The Review's consultations identified concern amongst consumer representatives that genuine involvement of consumers in NPS MedicineWise's program design had declined over recent years. The Review received seven submissions from individuals, peak organisations and disease specific groups with a consumer focus. While recognising NPS MedicineWise's previously strong partnership record, many of these submissions raised concerns with NPS MedicineWise's commitment to genuine consumer engagement. For example, the Consumer Health Forum's submission stated:

We believe NPS are well positioned, have gained community trust and have well established partnerships with consumer organisations, clinicians, the pharmaceutical industry and government, for the implementation and promotion of QUM. However, from CHF's perspective the scope of the QUM Grant Program is unclear and the consumer-centred approach to the delivery of the NPS programs, including the QUM program has deteriorated in recent years. CHF believes consumer inclusion should be considered a standard part of best-practice and be embedded across multiple levels of NPS; from organisational governance and leadership to point of program delivery (6).

Stakeholders however were encouraged by recent efforts by NPS MedicineWise to address the issue and engage more collaboratively with consumer groups.

Echoing the concerns of the Consumers Health Forum of Australia (CHF), this Review has been unable to identify a clear and consistent consumer-centred approach to the development and delivery of the Grant program.

Recommendation. NPS MedicineWise's processes are refocused to ensure consumer involvement in a genuine collaborative manner in the priority setting, co-design, and where applicable, the delivery of programs.

Recommendation. NPS MedicineWise should use its national networks to facilitate collaborations with consumer groups so that disease-specific groups' priorities and activities are better integrated with the Grant Agreement's QUM objectives.

6.5 Resource Allocation

The Department provides Grant funding to NPS MedicineWise under the QUME Program to support activities that raise awareness and promote behaviour change consistent with the quality use of medicine and medical

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services. This in turn supports the sustainability of the PBS and the MBS as well as optimising clinical outcomes. The activities must be delivered nationally and target prescribers, pharmacists and consumers and include the quality use of diagnostics, raise awareness of new therapeutics and therapeutic issues and cover post market monitoring.

The Program's outcome is to improve the health of Australians through the practice of QUM and services by providing independent, evidence based information and education campaigns and by collecting data from the clinical setting to inform program design and evaluations.

The Agreement also requires NPS MedicineWise to demonstrate through a rigorous and defensible methodology that its activities are associated with savings to the PBS and MBS. Annual milestones for savings of \$70 million for the PBS and \$13 million for the MBS are listed in the Agreement, resulting in projected savings of \$280 million to the PBS and \$52 million to the MBS for the period of the Agreement from 2015/16 to 2018/19. Table 2 and Figure 3 list the Core Commonwealth funding for QUM, the PBS saving targets and NPS MedicineWise's reported PBS savings between 2001/02 and 2018/19. Note: Table 2 does not include any MBS savings.

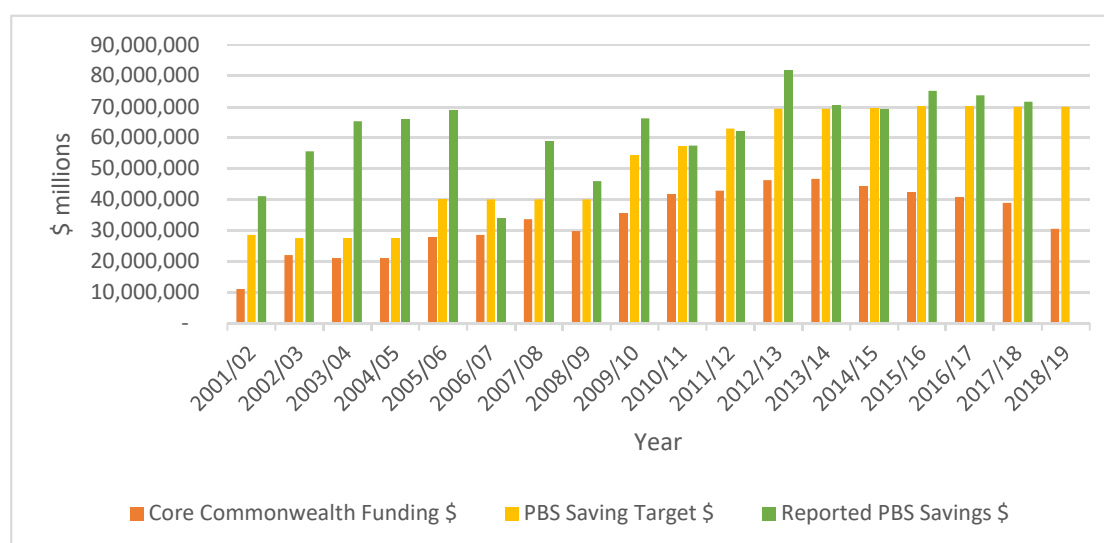
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Table 2 - Core Commonwealth QUME Grant Funding, PBS Saving Targets & Reported Saving 2001-02 to 2018-19 (12)

Year	Core Commonwealth Funding (\$ millions)	PBS Saving Target (\$ millions)	Reported PBS Savings (\$ millions)
2001/02	11.0	28.5	41.1
2002/03	22.0	27.5	55.6
2003/04	20.8	27.5	65.3
2004/05	21.0	27.5	65.9
2005/06	27.5	40.0	68.7
2006/07	28.5	40.0	33.9
2007/08	33.6	40.0	58.8
2008/09	29.8	40.0	45.9
2009/10	35.5	54.1	66.2
2010/11	41.6	57.1	57.4
2011/12	42.8	62.9	62.0
2012/13	46.3	69.3	81.7
2013/14	46.7	69.3	70.4
2014/15	44.0	69.3	69.2
2015/16	42.3	70.0	75.2
2016/17	40.6	70.0	73.7
2017/18	38.9	70.0	71.6
2018/19	30.5	70.0	TBA
Total	602.4(actual)	933.0	1062.6

Figure 2 - Core Commonwealth QUME Grant Funding, PBS Saving Targets & Reported PBS Saving 2001/02 to 2018/19 (13)



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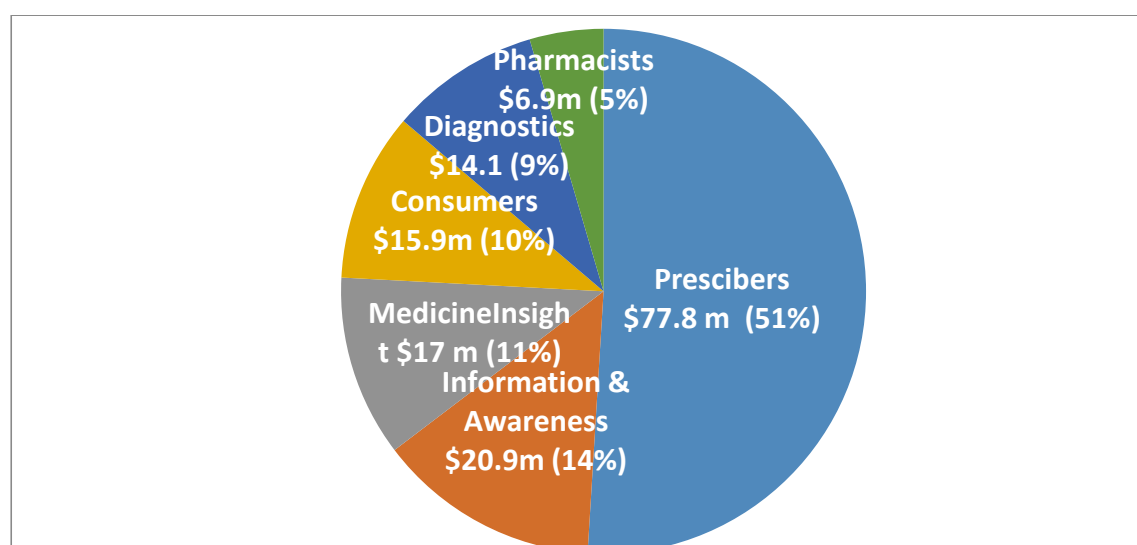
6.5.1 Grant Funding

Over the period 2015/16 to 2018/19 NPS MedicineWise received \$152.7 million (GST exclusive) from the Commonwealth to deliver the QUME Program. The Program is divided into six activity areas: prescribers, pharmacists, consumers, information and awareness, diagnostics and post-market monitoring through MedicineInsight. Table 3 lists this funding by year and activity. Figure 3 illustrates the proportional division of the Grant funding between the six activities. The Review has been unable to determine the basis upon which the Department made this proportional allocation and notes that the majority of funding is associated with GPs both directly and indirectly.

Table 3 - Quality Use of Medicine Program 2015-2019 Funding by Activity (GST Excl.) (14)

	2015-16	2016-17	2017-18	2018-19	Total
Activity 1 Prescribers	\$21,322,066	\$20,658,829	\$20,513,955	\$15,344,784	\$77,839,634
Activity 2 Pharmacists	\$1,823,476	\$1,883,167	\$1,849,453	\$1,389,326	\$6,945,422
Activity 3 Consumers	\$4,294,454	\$4,123,827	\$4,048,086	\$3,422,616	\$15,888,983
Activity 4 Diagnostics	\$4,020,249	\$3,860,405	\$3,700,556	\$2,509,753	\$14,090,963
Activity 5 Information & Awareness	\$6,826,955	\$5,856,889	\$5,101,659	\$3,134,222	\$20,919,725
Activity 6 MedicineInsight	\$3,992,800	\$4,213,882	\$4,150,292	\$4,685,549	\$17,042,523
Total	\$42,280,000	\$40,596,999	\$39,364,001	\$30,486,250	\$152,727,25

Figure 3 - NPS MedicineWise Funding for 2015-16 to 2018-19 by Activity (GST excl.)



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6.5.2 Financial Transparency

In 2017/18 the QUME Grant provided \$39.4 million to NPS MedicineWise to deliver the six activities. In addition to this Grant funding, NPS MedicineWise provided information to the Review that in 2017/18 it received money from the Department for contracted services outside the QUME Grant.

The Review noted that the financials of NPS MedicineWise are independently audited annually.

One issue the Review identified was the lack of a clear delineation between NPS MedicineWise's non-Grant and Grant activities and VentureWise activities. The same staff are involved in the delivery of all three activities.

NPS MedicineWise's use of staff to complete both Grant and non-Grant funded projects raises the potential for Grant funds to be used for non-Grant activities.

NPS MedicineWise has advised that it manages the costs of QUME funded staff working on non-QUME projects through timesheets as follows:

When staff complete timesheets, they indicate the number of hours they spend on specific projects for that week. At the end of the month the time allocated to each project by the staff member is converted into a cost allocated to the project based on the salary band of the staff member working on the project. NPS MedicineWise and VentureWise share the same salary band structure and there are seven bands. The bands range from Band 1 for Executive staff to Band 7 for administrative staff.

All staff are grouped into one of the seven bands based on their role description. Then for each band, an average is taken of the staff cost (salary, superannuation, workers compensation) of each staff member in the band to arrive at an average staff cost for the band. This average is then adjusted to account for actual working days in a year i.e. adjust for leave when calculating an hourly rate from an annual staff cost (e.g. hourly rate increases to ensure that leave costs are included in the rate). This salary band rate is applied to the hours charged to each non-QUME project to arrive at the cost removed from acquittal against the QUME grant and charged to non-QUME projects. (15)

Costs not allocated to non-Grant activities include rent and depreciation. From the documents reviewed it would appear that on-costs are charged to non-government clients and these on-costs are not returned to the Grant but to the equity of NPS MedicineWise.

NPS MedicineWise justifies the Grant funds subsidising NPS MedicineWise non-Grant activities by paying almost all the Group's Fixed Costs on the basis that the costs of the premises has not increased because of these non-

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Grant activities and the asset being depreciated were purchased prior to VentureWise's establishment.

This financial process appears to indicate that the QUME Grant underwrite NPS MedicineWise's commercial activities. That would be contrary to the proper use of Commonwealth Grant funds.

The Review notes that Grant funds cannot be used for any purpose other than the activities listed as funded by the Grant. Commonwealth Grant funds must also not be used to support commercial activities.

Recommendation. Commonwealth Grant funds must only be used to support Grant activities. The terms of the Grant Agreement should include a clear requirement that resourcing for non-Grant activities be separated from funds provided through the Grant. To ensure ongoing compliance with the Grant requirements and to improve financial transparency in the future use of Grant funds, NPS MedicineWise should be required to establish financial processes that clearly show that Grant funds are not being used to underwrite any aspect of NPS MedicineWise's non-Grant projects. The Agreement should also require that any processes that rely on reimbursing the Grant for the cost of using Grant funded staff and assets for non-Grant activities must first be agreed in writing by the Department.

Furthermore, the existence of multiple contracts outside the QUME Grant Agreement between NPS MedicineWise and the Department raises the risk that the Department could double pay for services already funded through the Grant. Health portfolio-wide processes to mitigate this risk should be explored.

6.5.3 Transparency of Program Costs

NPS MedicineWise advised that because its therapeutic programs are multifaceted, the costs of a program are usually split across more than one Agreement activity, based on a determination by NPS MedicineWise as to which target group it considers benefits from the activity. Costs are not reported to the Department based on program deliverables but, rather, on the target group that is determined to benefit.

NPS MedicineWise does not quantify resources on a per program basis, unless a formal cost benefit analysis is undertaken. NPS MedicineWise acquits program costs for each of the six activities at a macro level. Costs are not provided for specific programs or elements of programs, for example GP visits or clinical audits. Fixed costs, or overhead costs, are allocated to each Agreement activity on a proportional basis. Transparency in the reporting of NPS MedicineWise's performance would be enhanced by a financial structure that reported the costs of all programs including specific elements of multi-faceted programs. Specific program costs are contained in the Economic Evaluation of therapeutic programs. However NPS

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MedicineWise is only required to deliver one Economic Evaluation a year and these focus on programs delivered some years before the report is completed.

The Department should require greater visibility of the costs of the programs it funds. Aside from selective and dated costs detailed in Evaluation Reports, it is not possible to calculate what the costs of all the services the QUME Grant has funded. Any future grant agreements should include a requirement for NPS MedicineWise to transparently report the costs of designing and implementing a program separately to the fixed administrative costs of running NPS MedicineWise. The annual activity plans should include budgets for each program.

Recommendation. The Grant Agreement should require that, at the beginning of each year, NPS MedicineWise is required to make publicly available the Grant activities proposed for the next year including:

- (a) the objectives for those activities;
- (b) the anticipated costs of the programs; and
- (c) the anticipated savings (if applicable).

6.6 Program Selection, Development and Implementation

6.6.1 Topic Selection Process

A systematic horizon scanning process is used to identify the potential areas for Grant funded therapeutic programs. Table 4 lists the areas used to identify therapeutic topics as part of the formative research horizon scanning process. The topic selection process combines expert knowledge and opinion with evidence around QUM, medical tests and health technologies. This produces between 40 and 50 potentially relevant topics from which a shortlist of approximately 10 topics is constructed. NPS MedicineWise's formative research team further explores each shortlisted topic including basic cost savings estimates for each shortlisted topic to assess the potential healthcare budget impact on the PBS and/or MBS.

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Table 4 - Areas Assessed in Formative Research Horizon Scanning Activities to Identify Therapeutic Topics (16)

Area	Content
NPS MedicineWise programs	<ul style="list-style-type: none"> • Previous NPS MedicineWise programs including their evaluation
Audience areas of interest	<ul style="list-style-type: none"> • Clinical Service Specialist (CSS) survey of general practitioner (GP) areas of interest • Suggestions from key NPS MedicineWise teams • Previous advisory group meeting feedback • Results from national consumer and GP surveys
Gaps and variation in practice	<ul style="list-style-type: none"> • Practice gaps literature search (Australian and international) • Challenges/ controversies in clinical practice • International Choosing Wisely evaluations and literature • Atlas of Variation • ACSQHC Clinical Care Standards • Australian Institute of Health and Welfare (AIHW) reports • Therapeutic Guidelines (eTG): new, upcoming and revised • Other new and upcoming Australian guidelines • National Institute for Health and Care Excellence: recent reports and guidelines
Current medicine utilisation	<ul style="list-style-type: none"> • PBS volumes and expenditure over time • MedicineInsight data on highest volume original and repeat prescriptions • Choosing Wisely medicines recommendations
Medicine changes on the horizon	<ul style="list-style-type: none"> • Key Therapeutic Goods Administration (TGA) changes of interest • Key Pharmaceutical Benefits Advisory Committee (PBAC) changes of interest • Recent Drug Utilisation Sub Committee (DUSC) analyses • Post-market reviews of PBS subsidised medicines • Safety alerts from the TGA • New medicines on the horizon (including relevant approvals internationally) • Possible Australian patent expiries • Biologicals on the horizon — Food and Drug Administration (FDA) 'purple book'
Current pathology utilisation	<ul style="list-style-type: none"> • MBS pathology services and costs over time • Choosing Wisely pathology recommendations • MedicineInsight data on pathology test utilisation, where available
Current imaging utilisation	<ul style="list-style-type: none"> • MBS imaging services and costs, including changes from previous years • Choosing Wisely imaging recommendations • MedicineInsight data on imaging utilisation, where available
MBS changes on the horizon	<ul style="list-style-type: none"> • MBS review recommendations

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The suggested shortlist, formative research report and cost savings estimates are discussed with the CIAG which is an external multidisciplinary expert advisory group that provides strategic advice on the selection, design, development, implementation and evaluation on NPS MedicineWise programs, products and services. A membership list is provided in Appendix D. The Department is not represented on the CIAG and has no visibility of this process or the documents produced. This is unfortunate as the CIAG provides structured feedback on which topics should be prioritised from the shortlist. NPS MedicineWise advises that, in addition to this process, several stakeholders are consulted to assist in selecting topics for delivery, including other Advisory Groups and key stakeholders as needed and the Department.

NPS MedicineWise's Executive reviews and approves the recommended topics for the year ahead. The need for the Department to be more closely involved in the final selection of programs funded under the Grant is essential to ensure that interventions are more integrated with or complimentary to other Government initiatives in QUM and duplication is minimised. While there is a requirement for the Department to approve NPS MedicineWise's annual Workplan, such a requirement appears to be poorly formalised and implemented.

More co-ordination is needed before programs are agreed and implemented. For example, the selection of a program about proton pump inhibitors (PPI) was recommended by NPS MedicineWise in 2018/2019. This was the third time in 10 years that a program on this topic had been implemented by NPS MedicineWise and it was implemented at the same time as a similar program was being conducted by the DVA through the Veteran's MATES program.

A strong theme emerging from the consultation process was the need for greater collaboration and partnerships between stakeholders within various health systems and settings. A number of stakeholders had noted a change in the approach of NPS MedicineWise in supporting better integration and collaboration across the QUM ecosystem in recent years. Their sentiments are summarised in the following quote.

In the past, NPS has run annual workshops with members and stakeholders. They have been an opportunity for NPS to gather relevant information and strategy advice from frontline clinicians and stakeholders for their programs. In the last few years, the workshops seem to have been more about telling members about NPS programs rather than identifying QUM gaps and program improvement. It is unclear why this change has occurred and whether it is appropriate (17).

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Feedback contained in the RACGP submission highlighted the need for greater interactivity and decision support tools in the selection and design of programs:

Feedback from our members also suggests that they can feel like recipients of information delivered by NPS MedicineWise rather than active participants in a quality improvement activity.

We believe there should be a greater focus on self-directed quality improvement. For example, developing skills in data management, review and analysis and self-directed audits would help build a valuable quality improvement skill set within practices.

Advocacy from the NPS to encourage the integration of high-quality QUM decision support tools into clinical software would also be welcome (18).

NPS MedicineWise's process of program selection must be transparent and include meaningful engagement with the broader QUM ecosystem. The process should also engage earlier and often with the Department, ACSQHC and PHNs. Consideration should therefore be given to including Department officials and RACGP, ASCQHC and PHN representatives on the CIAG.

Recommendation. The process for the selection of therapeutic topics should include more formal arrangements that enable, as is appropriate, stakeholders including representatives of consumer groups, ACSQHC, and PHNs, to be involved in the selection of the topics to be considered in the final project plan.

Recommendation. Representatives of the Department of Health, PHNs, RACGP and ACSQHC should be included as members of the CIAG. This will enable wider deliberations about prioritisation and better co-ordination while also promoting closer engagement. This will minimise duplication while also ensuring Grant funded activities align with other relevant Department programs.

Recommendation. Acceptance of the final topic selection for inclusion in the annual Workplan should reside with the Department of Health. The process of developing and approving NPS MedicineWise's annual Workplan and Budget needs to be better integrated with the Department's QUM priorities in order to avoid duplication and to identify areas of synergy across various initiatives.

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6.6.1.1 Criteria for Topic Selection

The following five criteria are listed by NPS MedicineWise as influencing the design of each therapeutic program:

- Mission: programs must aim to and be likely to improve the QUM and/or QUD.
- Consumers: programs must aim to and be likely to provide a benefit for consumers by contributing to better health outcomes.
- Health professionals: programs must aim to and be likely to attract participation of the health professional target audience (i.e. GPs and pharmacists) by providing educational value.
- Economic impact: programs must support better economic outcomes and each year programs must contribute to PBS and/or MBS savings.
- Evaluation: programs must aim to and be likely to have a demonstrable impact on health professional knowledge, prescribing and/or ordering of tests and/or imaging. (16)

While the NPS MedicineWise process of topic identification is comprehensive, in practice the capacity for a topic to contribute to the delivery of PBS or MBS savings appears to be the critical factor, trumping programs with strong public health justifications. Programs that promote the QUM and QUD will not always translate into PBS and MBS savings. However, economic benefits to the wider society and the broader health system would be expected. The wider QUM benefits were raised by stakeholders who identified the need for initiatives that are not required to deliver PBS savings (17) (19) (20). As the Council of Australian Therapeutic Advisory Group's submission noted:

Any PBS savings achieved through NPS MedicineWise QUM intervention is far surpassed by the savings achieved through price disclosure and therefore it would be more prudent to link QUM interventions to outcomes, which are more relevant to patients and the overall population, or use a combination of outcome measures and PBS/MBS savings (20).

RACGP's submission raised a similar point (18).

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The NSW Therapeutic Advisory Group Inc. (NSW TAG) submission called for a wider QUM lens than just cost-saving to the PBS. In particular, it noted that there is a need for QUM interventions to recognise and address the QUM issues that arise because of the complexity of a patients' health journey. As NSW TAG explains:

...influencers of PBS prescribing include hospital prescribing (not only discharge prescribing but also via discharge summaries in the public health care system or specialist's letters in the private care hospital sector) and hospital services such as antimicrobial (and other) stewardship programs; post hospital discharge services e.g. heart failure and anticoagulation programs; general practice-based pharmacists; and, home and aged care medication review services; Formative training of prescribers is substantially conducted in hospitals, especially now GP training programs have been attenuated (17).

The need for initiatives to address the QUM issues that arise at the transitions of care including serious medication errors are consistently identified as a significant issue. Addressing these issues has the capacity to reduce the costs of medication related avoidable hospital admission and readmissions. The ACSQHC is coordinating a national plan in response to the Global Patient Safety Challenge:-Medication without Harm program of the WHO. The role of NPS MedicineWise in contributing to such a plan needs to be considered in the development of any new funding agreement. The ACSQHC's response to the review highlighted the need for greater collaboration:

Engagement would be enhanced by a greater level of collaboration between NPS MedicineWise, the Commonwealth Department of Health, jurisdictional stakeholders and the Commission. This would allow harmonisation of all stakeholder strategies and work plans to national quality use of medicine objectives (5).

Recommendation. Consistent with the Quality Use of Medicine Principles of system-based approaches, NPS MedicineWise's topic selection and annual Workplan development must take into consideration the need for better integration of medication management between levels of healthcare services.

Recommendation. In the development of the annual Workplan, NPS MedicineWise and the Department must identify system-based issues that impact on QUM and support collaborative interventions that improve medication use while recognising the potential for NPS MedicineWise to demonstrate its QUM stewardship role.

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There was also feedback that the focus on the PBS and MBS savings was too narrow. For example, the submission from the Department's Deputy Secretary of the Health Products Regulation Group (HPRG) asked:

Is the original premise of the NPS, with its focus on better use of PBS medicines, too narrow these days, considering the substantial annual investment by government in the NPS? There are a number of other priority areas, such as medical devices that NPS or similar organisation could pursue (21).

There was a consensus view that the pursuit of PBS and MBS savings should not be the sole determining factor in topic selection.

Recommendation. PBS and MBS savings targets must be set whilst recognising that the pursuit of QUM will not always result in savings to the MBS and PBS and that public health system based improvements have the potential to deliver savings in other parts of the health system.

6.6.2 Annual Workplan and Budget

The QUME Grant requires NPS MedicineWise to submit an updated Activity Workplan and Budget for the Department's approval by 31 July each year. The Workplan and Budget must include an overview by financial year of the Activity 1 to 6 objectives, tasks and timeframes; and details of planned expenditure of Funds by financial year. The Agreement permits the Department to require amendments to the Activity Work plan and Budget before approving either document.

There is limited evidence of the Department's input into the development of NPS MedicineWise's annual Workplan and Budget. The lack of cooperative interaction has led to a perception that approval of the Workplan and Budget is considered to be a process formality.

However, more recently, the reduction in NPS MedicineWise's funding has highlighted areas where the two organisations may have differing priorities. This tension is exacerbated by the breadth of activities and therapeutic topic areas listed in the Grant Agreement combined with lack of transparency related to program costs. Greater collaboration between the Department and NPS MedicineWise during the process of developing the annual Workplan and Budget would assist to resolve these issues.

6.6.3 Neuropathic Pain Program Design Case Study

NPS MedicineWise achieves its PBS and the MBS saving targets through the delivery of its therapeutics programs. There is evidence that this objective has largely influenced the selection and design of programs.

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For example, a visiting program focused on neuropathic pain was delivered in 2018 because of its capacity to deliver PBS savings by reducing the suboptimal use of pregabalin. NPS MedicineWise estimated that:

Assuming a 5% volume change prescribing of pregabalin among people aged 18 years or more following delivery of a targeted neuropathic pain program, the estimated potential PBS savings are \$2.89 million over a 12 month period (22).

The program's description lists the following focus of the intervention:

- Structured approach to diagnosis
- Raising the profile of amitriptyline as a first line agent and the awareness of the limited role of pregabalin in the absence of a diagnosis of neuropathic pain
- Erroneous belief that pregabalin is a more suitable first line option
- Use of pregabalin outside of PBS restrictions
- Using a step-wise guidelines-based approach to selecting medicines
- Clarity on the efficacy and safety of medicines
- Taking a holistic approach to pain management ensuring a focus on function rather than pain (22).

A number of stakeholders commented that the design and implementation of this program, especially its focus on amitriptyline as a first line treatment, did not sufficiently recognise or highlight the appropriateness or otherwise of tricyclic antidepressants such as amitriptyline in elderly patients many with comorbidities and prescribed multiple medicines. This issue is mentioned in the key messages to health professionals under 'consider low dose amitriptyline as a first line agent for neuropathic pain' but no management plans or tools are provided for this significant patient cohort other than to state that caution in the elderly is required.

This program would have benefited from the inclusion of management options and tools to support the treatment of neuropathic pain in this cohort of patients.

While acknowledging the appropriateness of a therapeutic program to address the QUM issues regarding pregabalin, this example suggests that a largely savings focus may be restricting program design and overlooking the complexity of medication management.

6.7 VentureWise Pty Ltd. (VentureWise)

In 2015, the NPS MedicineWise Board established a separate entity – VentureWise - as a wholly owned subsidiary, consistent with the mission of NPS MedicineWise, with the purpose of diversifying its revenue source. NPS MedicineWise has advised the Department that Commonwealth-

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sourced funds have not been used to establish VentureWise. Instead NPS MedicineWise used 'private company equity' and entered a shareholder loan agreement with VentureWise to provide it with financial resources.

Annual reports and correspondence between NPS and the Department on VentureWise's establishment indicate the rationale for adopting a subsidiary model at the time was based on several factors, including:

- NPS MedicineWise is a not-for-profit organisation. This limits commercial activities and the Board perceived the potential for loss of Health Promotion Charity status and associated FBT benefits.
- Funding beyond 2014-15 was highly uncertain at the time. The organisation was advised by the Department of Health in 2014 the likelihood of future competitive funding, and it wasn't until May 2015 funding for 2015-18 was confirmed (non-competitive and subject to reductions).
- A subsidiary model would provide more flexibility to explore opportunities with commercial, non-government funders in new markets (23).

Documents provided by NPS MedicineWise advise that VentureWise operates within a governance framework with its own management and board.

VentureWise has a Management and Operational Agreement in place with NPS MedicineWise as the sole shareholder.

6.7.1 Stakeholder Feedback

The consultation process highlighted stakeholders' concerns that the establishment and commercial activities of VentureWise detracted from NPS MedicineWise's mission. For example, RACGP's submission states:

The RACGP expresses some reservations about the NPS MedicineWise's commercial arm, VentureWise. There is potential for conflict of interest between the two organisations, and this possibility does compromise the NPS MedicineWise's value to GPs. Every effort should be made to ensure the two organisations remain separate. It is particularly important, given recent funding cuts to NPS MedicineWise by the Government, that NPS MedicineWise does not become dependent on commercial funding. VentureWise itself should be subject to a separate and independent review (18).

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This concern was echoed by the NSW TAG Submission:

While it is recognised that value to the Australian healthcare system can be provided by NPS expertise using other funding sources apart from the Australian Government's Department of Health, there is a perception that the profit-making arm of NPS, VentureWise (stated on the website to be part of the MedicineWise Group) compromises NPS independence. It is unclear what the MedicineWise Group is. In other documents VentureWise is described as a wholly owned commercial subsidiary of NPS MedicineWise. We recognise that other funding sources help maintain a critical mass of employees and activity to ensure continued rigour of services and delivery. We also note that the recent staff turnovers and redundancies at NPS may have resulted in a loss of corporate knowledge. It is also recognised that the pharmaceutical and device industry plays a fundamental role in the Australian healthcare system as elucidated in the National Medicines Policy. However, the VentureWise program casts doubt on the independent integrity of NPS programs. Such perceptions can arise (rightly or wrongly) when a useful NPS program that educated healthcare professionals about the tactics employed by the pharmaceutical industry to promote their medicines, 'Evidence vs Hype', appears to be no longer available on the NPS website or via workshops. Issues regarding independence and transparency have also been made with regard to the MedicineInsight program (17).

The submission from the Australian Prescriber Editorial Executive Committee also highlighted the potential impact of NPS MedicineWise commercial arm, VentureWise, on Australian Prescriber's membership of the International Society of Drug Bulletins (ISDB) of which Australian Prescriber is a founding member. From 2019, ISDB members will be prohibited from accepting directly or indirectly funds from the pharmaceutical industry because of potential conflicts of interests (24).

The Victorian and Tasmanian PHN Alliance questioned whether the commercial interests of VentureWise were consistent with the QUME Grant program and NPS MedicineWise, and also noted that there was a risk of it being perceived as being at odds with data use in the public interest (4).

Submissions from some previous Board members and Medicine Australia strongly supported the VentureWise model (25) (26) (27).

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Recommendation. NPS MedicineWise should review the reputational risks arising from its VentureWise activities in view of the necessity to maintain both the perception and reality of independence in the QUM ecosystem. Such a review should consider whether the continuance of its current relationship with VentureWise is in the best interest of the company in view of the negative perception of the relationship as expressed to the Review by key stakeholders. If the relationship is to be maintained, further steps should be taken to ensure that there is a clear separation between both entities.

6.7.2 Transparency and Disclosure of Transactions

The lack of transparency and level of disclosure regarding inter-company arrangements contained within the Financial Accounts of the Group add to Stakeholders' questions.

The documents received from NPS MedicineWise regarding VentureWise's operations indicate that VentureWise commissions services from NPS MedicineWise which then uses existing NPS MedicineWise staff to provide that service. The Management and Operational Agreement between the NPS MedicineWise and VentureWise states in clause 4.1

- a) The Shareholder (NPS MedicineWise) will make available the services of the Shareholder Employees to the Company (VentureWise) on a non-exclusive basis for so long as each of the Shareholder Employees remains an employee of the Shareholder.
- b) The Company will be required to reimburse the Shareholder for the full cost of the Shareholder providing the services of the Shareholder Employees.
- c) In undertaking their roles for the Company, the Shareholder Employees will be under the direction, control and supervision of the Company. The Shareholder will have the sole right to exercise all authority with respect to the conditions of employment (including termination of employment and remuneration of such Shareholder Employees). (28)

The level of transparency in the financial transactions between the two entities make it difficult to assess their financial interactions including the requirement that Grant funds are not used for non-Grant activities.

In the absence of transparent financial statements documenting the interactions between the two entities and the unspecified nature of Item H Assets and Item J Specified Personnel listed in the Agreement, it is difficult to quarantine Commonwealth Grant funds from being used for non-Grant activities.

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6.7.3 Reputational Risk

There is evidence that the decisions of NPS MedicineWise to pursue funding from the pharmaceutical industry to deliver educational programs and to use MedicineInsight data to inform its commercial activities have resulted in reputational damage to NPS MedicineWise.

The Review examined the contract projects funded by pharmaceutical companies that have been undertaken by VentureWise. It was noted that some of the projects were undertaken following requests by the PBAC for information from sponsors regarding utilisation of new listings using MedicineInsight data where the reason for prescribing was relevant and was not available from PBS/MBS data sources.

One project was an educational program for GPs on the treatment of Hepatitis C which complemented the Government's initiative to enhance the uptake by GPs with the view to eradicate the disease by 2030. While sponsored by one company, the educational program was generic in nature and was of a high quality.

Another program, however, appeared to involve raising GPs' awareness of the availability of a new range of biological agents which were restricted to specialists prescribing on the PBS. The contract involved only two of the three sponsors with a product in the class. It was akin to providing the details usually provided by sponsors to GPs for a new product. The activity was a topic which would have been ideally suited to RADAR or the Australian Prescriber. This project could be seen as a potential conflict of interest simply because of the commercial arrangement with sponsors and the nature of the program.

NPS MedicineWise states that a summary of each commercial project undertaken by VentureWise is made available on its Website, but the summaries are minimal and non-informative and therefore contribute to a perception of a conflict of interest by many key stakeholders.

It is considered likely that if greater transparency existed about the programs conducted by VentureWise then the extent of concern expressed by certain key stakeholders may have been reduced.

NPS MedicineWise was established as a source of independent evidence based QUM advice to prescribers. The perceived potential conflicts of interest related to some of VentureWise's commercial activities are a reputational risk. Several stakeholders expressed concern that the organisation's independence is being compromised. Over the same period the organisation's relationship with the Department has become more transactional and less relational. The Review believes that this is an indirect result of the establishment of VentureWise which raises perceived conflicts of interest which must be managed by the Department.

7 Part 2. Delivery of the QUME Program

7.1 Overview of QUME Program Activities

The National Prescribing Service was established in 1998 and was tasked with:

- providing individual GPs with feedback related to their prescribing behaviour compared with their peers and contracting prescribing advisers to liaise with GPs in relation to effective prescribing;
- collecting, analysing and disseminating prescribing data and utilising this data to develop strategies for effective prescribing; and
- managing a Quality Prescribing Research and Innovation Grants programme to identify effective approaches and resources.

During this 20 year period, the range of interventions NPS MedicineWise delivers in support of quality use of medicine and diagnostics has expanded.

Table 5 lists the interventions and initiatives NPS MedicineWise supports. While some programs are stand alone, like the Australian Prescriber and RADAR, most programs are delivered as part of a package of initiatives. NPS MedicineWise's therapeutic programs consist of a suite of activities that can be applied differently depending on the target audience.

Table 5 - NPS MedicineWise Interventions

Intervention	Target	Description
Academic Detailing – Educational visiting	<ul style="list-style-type: none"> • General Practice • Pharmacists • Practice nurses 	NPS MedicineWise Clinical Services Specialists meet with GPS/Pharmacists/ Practice Nurses individually in their practices to discuss evidence-based therapy on a particular therapeutic topic.
Small group case-based discussions facilitated through general practice		Case scenarios depicting real clinical dilemmas are used as the basis of discussion in groups of up to ten participants. These groups are run by NPS MedicineWise Clinical Services Specialists and may include members of a multidisciplinary team such as pharmacists and/or practice nurses. These discussions are an opportunity for GPs and other health professionals to learn from their peers and share information.
Interactive workshops	<ul style="list-style-type: none"> • Nurses • Aged Care Employees • General Practitioners • Pharmacists 	There are two types of workshops facilitated through general practice. Workshops for nurses and other aged-care employees are generally held in residential aged-care facilities. These workshops are used to increase awareness of the quality use of medicines (QUM) and best practice principles of medicine use for the elderly.

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Intervention	Target	Description
Clinical audits (paper-based and electronic)	<ul style="list-style-type: none"> • General Practice 	GPs review their practice, receive individual and peer feedback and implement changes to practice on a specific therapeutic topic. Since 2012, NPS MedicineWise has moved largely to delivering interactive online clinical audits.
Pharmacy practice reviews	<ul style="list-style-type: none"> • Pharmacists 	Similar in process to a clinical audit but completed by pharmacists and interns who review their practice and undertake a reflective learning exercise on a therapeutic topic. These activities help pharmacists enhance their counselling interaction with consumers and provide up-to-date, balanced information. Pharmacists are informed of the key messages provided to medical practitioners to ensure consistency of service provision.
Prescribing practice reviews (PBS Feedback letters)	<ul style="list-style-type: none"> • General Practice 	A prescribing practice review provides recommendations about prescribing and other aspects of patient management for a particular condition. Key information such as recommended target doses for medications is presented in easy reference tables.
Prescribing feedback (MedicineInsight)	<ul style="list-style-type: none"> • General Practitioners 	Provides GPs from participating practices with monthly reports via an online portal and through the NPS MedicineWise team of Clinical Services Specialists (CSS). Reports are tailored for each practice and compare procedures and prescriptions between 'Your Practice 12 months ago', 'Your Practice now', and in comparison to all other participating practices.
Case Studies	<ul style="list-style-type: none"> • Health Professionals 	Case studies take the form of a case scenario accompanied by a set of questions which are completed by GPs, pharmacists and nurses. Participants receive feedback on their own and the aggregated responses, evidence-based practice points and expert commentary on the case. Distributed in print via NPS News until 2012, case studies are now provided online via NPS MedicineWise's learning site and are developed for most therapeutic topics.
Webinar	<ul style="list-style-type: none"> • Health Professionals 	An educational activity for health professionals where a panel discussion on a therapeutic topic is streamed live over the internet. The audience can participate by asking questions during the broadcast. The panel discussion is recorded and is available online after the live broadcast. Participants are eligible

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Intervention	Target	Description
		for a range of continuing professional development.
Choosing Wisely	<ul style="list-style-type: none"> • Clinicians • Consumers • Policy Makers 	Since 2015 facilitating the Choosing Wisely initiative, which encourages health professionals and consumers to question the necessity of tests, treatments and procedures where evidence shows they provide no benefit or, in some cases, lead to harm.
MedicineInsight	<ul style="list-style-type: none"> • General Practitioners • Policy Makers 	Since 2011, the organisation has been receiving Commonwealth funding to develop MedicineInsight, a post-market surveillance data program
Australian Prescriber	<ul style="list-style-type: none"> • Clinicians 	An online journal published every two months that is supported by a podcast and translates evidence about drugs and therapeutics into a form that is relevant to the Australian context
RADAR	<ul style="list-style-type: none"> • Clinicians 	A resource that provides health professionals with timely, independent evidence-based information on new drugs and medical tests and changes to listings on the Pharmaceutical Benefits Scheme and Medicare Benefits Schedule.
MedicineLine & Adverse Event Line	<ul style="list-style-type: none"> • Consumers 	A telephone service providing consumers with information on prescription, over-the-counter and complementary (herbal, 'natural', vitamin and mineral) medicines.
MedicineWise app	<ul style="list-style-type: none"> • Consumers 	A smart phone app designed to help consumers manage their medicines and record why their taking them, as well as record other important health information including measurement and test results.

7.2 Multifaceted Program Components

NPS MedicineWise advised the Review that the programs delivered:

aim to improve the QUM and/or diagnostics (QUD) in specific areas of health care. Whether focused on QUM, QUD or both, they are generally referred to as therapeutic programs. Most of these programs are directed to health professionals but will also usually include components, products or services for use by patients or consumers. These programs are national, largely implemented within primary care and designed to complement or support other National Medicine Policy components. All programs are multifaceted and include more than one intervention strategy. Some programs include educational visiting, where NPS MedicineWise Clinical Service Specialists (CSS) (i.e. field force) provide educational visits to general practices and/or community pharmacies. 'Non-visiting programs' do not include educational visiting (16).

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7.2.1 Visiting Program (Academic Detailing)

NPS MedicineWise maintains a significant workforce to deliver a visiting program (currently 40 FTE). Approximately, 20% of GPs participate in the academic detailing component of a program. While the literature generally supports the effectiveness of academic detailing, the Economic Evaluation Analysis of the Exploring Inhaled Medicines Use and Asthma Control program demonstrated no significant impact of the visiting intervention on prescribing behaviour. This observation should stimulate a critical examination by NPS MedicineWise of its visiting program.

7.2.2 Small Group Discussions

In place of the one-on-one academic detailing, NPS MedicineWise offers small, often multidisciplinary, group discussions. Approximately 15% of the GP workforce participate in small group discussions.

7.2.3 PBS Feedback letters

PBS Feedback letters are common to many NPS MedicineWise programs and appear to involve more than 75 % of active GPs in Australia.

7.2.4 Clinical e-Audits and Case Studies

Programs also include clinical e-audits and case studies, however, the uptake of these components are much lower at approximately 2% of the GP cohort.

7.2.5 Assessing Effectiveness of Program Components

The Review team was unable to determine the relative impacts of each activity. Where there are multiple elements to an intervention, it would be informative to determine if a certain element is likely to have a higher contribution than another. For example, the Economic Evaluation of the *Exploring Inhaled Medicines Use and Asthma Control* (2014) included an analysis of GPs' prescribing behaviour following the program which included a PBS feedback letter to 23,000 GPs and visits to 6,000 GPs. The evaluation suggested that there was little difference in the prescribing behaviour of those GPs who received a visit and the feedback letter compared with those who only received the feedback letter.

A better understanding of the impact of the visiting program over and above the feedback letter is required as this 2017 evaluation raises critical questions about the cost effectiveness of NPS MedicineWise's visiting program. It would also be informative to analyse whether a difference exists in other programs and whether there are variations on a state by state or regional basis. Implementation strategies for each program need to be designed to enable NPS MedicineWise to evaluate the impact of components of its programs. As Roselie Viney, Stephen Jan and Katharina

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Wagner note in their 2018 evaluation - *Assessment of Evaluation Methods Used by NPS MedicineWise*

Ideally, NPS MedicineWise interventions would be implemented in ways that allow evaluation of (a) intervention effects against effects in control or comparison groups not exposed to the intervention; (b) effects of intervention components to identify those that generate the most beneficial impacts most efficiently; and (c) how intervention impacts vary by population subgroups. (29)

Recommendation. NPS MedicineWise should undertake a rigorous and detailed evaluation of each component of its programs including their impact on outcomes. This may require enhancing its evaluation methods to include prospectively using a step-wedge trial or similar designs as discussed in the 2018 *Assessment of Evaluation Methods by NPS MedicineWise* prepared by Roselie Viney, Stephen Jan and Katharina Wagner.

7.3 Australian Prescriber

Australian Prescriber is a government funded independent journal that translates evidence about drugs and therapeutics into a form that is relevant to the Australian context. It is published every two months online. Readers can sign up for a publication e-alert, and can access the full text for free online. It is a flagship product of NPS MedicineWise and has continued to innovate its offering, being one of the first journals to provide free access online, and has created the 'doctors bag' app and produces regular podcasts.

The consultation process of the Review identified the Australian Prescriber as being highly valued by clinicians. As one Medical Specialist commented:

I grew up learning from this journal, and to this day I continue to learn from it. It has improved my prescribing practice substantially by providing current, reliable, and topical information and it is hard to know what would replace it should it go. I have been involved with this journal, but my admiration extended far beyond the start of my involvement and will continue far after its finish. I can only hope that its scope expands, not contracts (30).

This feedback is supported by previous surveys of Australian Prescriber readers.

Responsibility for producing Australian Prescriber was transferred to NPS MedicineWise in 2002. A separate contract between the Department and NPS MedicineWise for the delivery of Australian Prescriber existed up until 2015. The current funding Agreement which has been in place since 2015, requires NPS MedicineWise to continue to publish *Australian Prescriber*

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under Activity five: Information and awareness raising of new therapeutics and therapeutic issues. Between 2015-16 and 2018-19 nearly \$21 million has been provided for this activity which also includes funding for RADAR, Medicine Update and NPS Direct.

The Agreement required Australian Prescriber to be published in print and online in 2016 and to investigate new delivery methods and models to leverage new technologies and digital media channels. The Agreement also stated "This must be targeted to minimise printing and distribution costs in years two and three of this activity."

The decision to transition the publication to an on-line presentation has been criticised because it was not accompanied by an effective communication strategy. (24).

The impact of the transition is concerning. Visits to the australianprescriber.com website declined by 95 percent between April 2016 (343,017 visits) and July 2016 (17,837 visits) and visit numbers did not return to the earlier volume until October 2018. The distribution of the readership has changed over this period with the number of GPs, pharmacists and students growing, while the number of Registrars and Medical Specialists has declined (Figure 4.)

The Australian Prescriber Editorial Executive Committee's submission also noted the following impacts:

- Sixty percent reduction in medical specialists readers from 8,947 print subscribers to 3,493 email subscribers.
- Closure of a distribution channel for quality use of medicine resources eg. Management of anaphylaxis protocol wallchart (24).

An October 2015 NPS MedicineWise high cost drugs scoping report identified a large number of biologic agents currently being reimbursed in Australia as s100 and /or s85 medicines and that many of these can only be prescribed by a medical specialist or under supervision of a specialist. Improving the communication channels to medical specialists regarding QUM and QUD is therefore a strategic priority.

It would appear that the efficiency gains NPS MedicineWise achieved by moving online, came at a high strategic price – the loss of 5,400 medical specialist accessing Australian Prescriber.

In August 2018, NPS MedicineWise advised the Department that it was reviewing Australian Prescriber to see if there is an appetite and opportunity to reshape the publication. It reported a readership of 80,000

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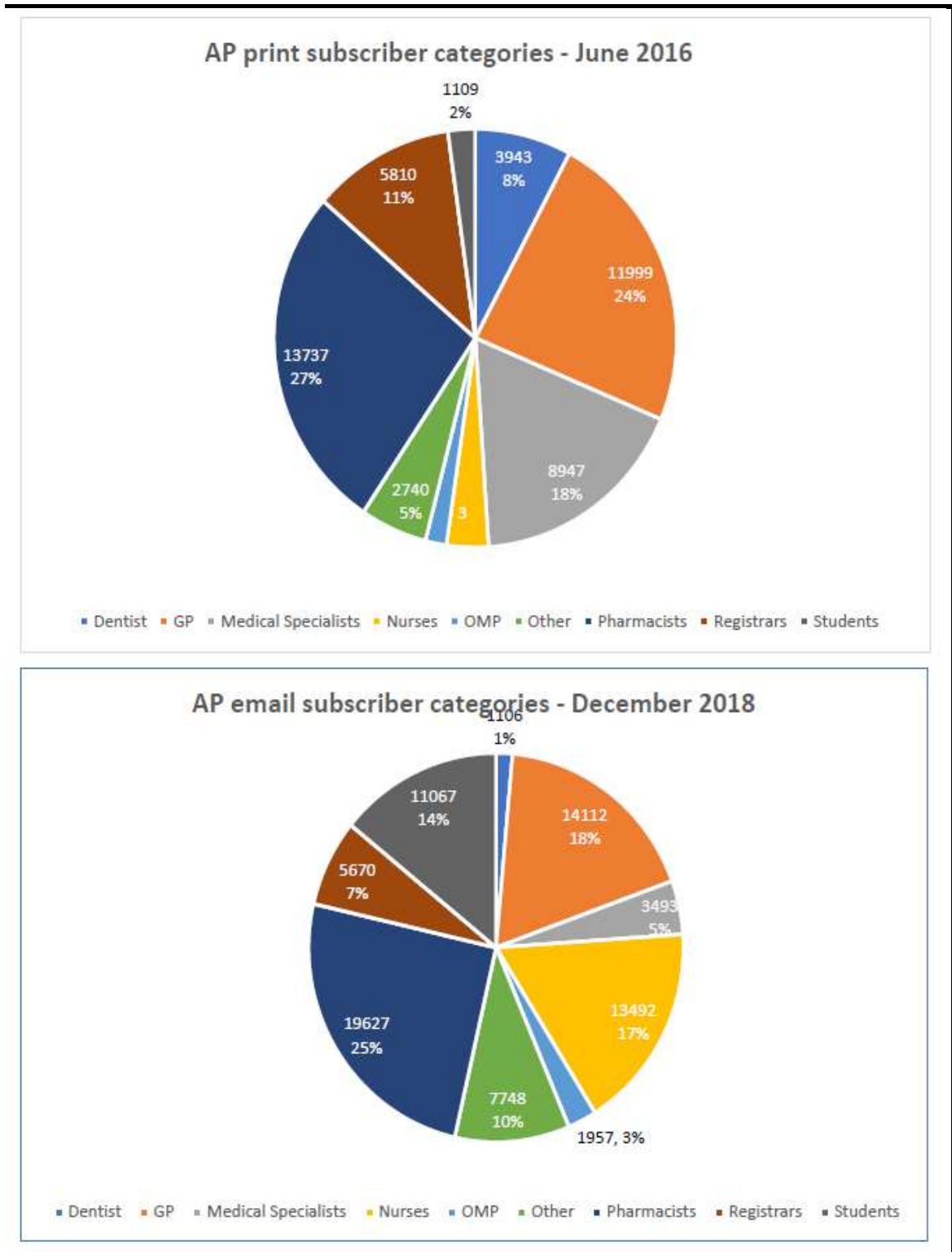
NPS MedicineWise

and its new podcast is becoming increasingly popular with 15,000 subscribers. The number of staff involved in the preparation of Australian Prescriber is 4.7 FTE which appears to be appropriate number for the initiative.

Recommendation. The Australian Prescriber should continue to be published at current frequency and continue to be a core component of NPS MedicineWise funded programs.

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Figure 4 - Changes in readership following the end of print (24)



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7.4 RADAR

RADAR provides health professionals with timely, independent evidence-based information on new drugs and medical tests and changes to listings on the PBS and MBS. As of March 2019 RADAR had over 107,000 subscribers - as listed in Table 6.

Table 6 - Number of RADAR Subscribers by profession

Subscriber	Number
Medical practitioners	31,069
Pharmacists	22,630
Nurses	37,558
Other Health Professionals including Dentists, Midwives, Students	16,307

NPS RADAR outputs range from well prepared detailed pieces highlighting treatment options in the Australian context to very brief articles and PBS updates. The latest full review (10 minute read) was published in July 2018.

It is important that decision-making bodies like PBAC have a communication channel to alert clinicians to changes to PBS and to the potential quality use of medicine implications which may have an impact on health outcomes and the achievement of cost-effectiveness in clinical use.

The Review is concerned that reduction in Government funding may be impacting on the quality and timeliness of RADAR. Continuation of RADAR, therefore, needs to be considered in light of the reduction in Grant funding and the potential overlap with the content contained in Australian Prescriber.

Recommendation. NPS MedicineWise should undertake a review of RADAR and consider whether it is the most efficient and effective means of informing pharmacists and prescribers regarding PBS listings. Further, in view of the apparent overlap in the type of material, there is a need to consider whether both RADAR and Australian Prescriber are necessary or whether consolidation of the two publications is an appropriate option.

7.5 National Curriculum for Quality Use of medicines

NPS MedicineWise has developed and maintained a curriculum on the quality use of medicines which is now used by the majority of the schools of medicine and pharmacy in Australia. This has become a valuable resource and is highly regarded by educators.

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7.6 MedicineLine and Adverse Event Line

NPS MedicineWise's MedicineLine and Adverse Event Line are staffed by 5.31 FTE pharmacists and in 2017-18 answered 7,263 and 146 calls respectively. The service costs \$750,000 per annum to support.

NPS MedicineWise collaborates with Healthdirect Australia to deliver MedicineLine, a telephone service providing consumers with information on prescription, over-the-counter and complementary (herbal, 'natural', vitamin and mineral) medicines. Calls from all states and territories in Australia (except Queensland and Victoria), are connected via Healthdirect to an experienced registered nurse. If the inquiry concerning medicines can't be answered by the registered nurse, the caller may be put through to an NPS MedicineWise pharmacist during the hours of 9am to 5pm AEST. Queensland or Victorian callers are connected directly with an NPS MedicineWise pharmacist during business hours.

The HPRG Submission was highly supportive of the Adverse Events Line as stated below:

Our experience is that consumer reports received via the NPS are of a higher quality than other consumer reports as the NPS pharmacist is able to actively engage with the consumer regarding the patient's history, the adverse reaction (s), all medications taken and other useful information (21).

In August 2018, NPS MedicineWise sought approval to close these lines because alternate sources of information for consumers about medicines like Healthdirect Australia and state-based services like 13 HEALTH existed. The Department did not support the removal of the NPS MedicineWise MedicineLine and Adverse Event Line services from the current contract requirements.

It is important that consumers have access to information on medicines but consideration should be given to NPS MedicineWise's service being better integrated into a 24/7 day service like Healthdirect. However, such a change would require enhancing Healthdirect's access to expertise in medicines as required.

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Recommendation. While the MedicineLine service does perform a useful function, the question of whether it could be better integrated into Healthdirect Australia should be considered by the Department. If the NPS MedicineWise service were to be incorporated into Healthdirect's services, consideration will need to be given to increasing Healthdirect's access to expertise on medicines.

7.7 *MedicineWise App*

In 2014 NPS MedicineWise launched an app, MedicineList+, for both Android and iOS devices. The app was relaunched in 2017 as The MedicineWise App. The free app enables consumers to build, edit and share their medicine list, set dose and appointment alerts, track tests and results, record important information and view relevant medicines information. The app is also capable of keeping track of more than one person's medicines list, supporting parents and people who care for older family members. NPS MedicineWise description of the App is provided in Table 7.

Table 7 - NPS MedicineWise App Description (31)

MedicineWise app is a free app designed to help patients record and manage their medicines and other health information such as medical test results and allergies.

It is powered by a MIMS medicines database and SNOMED condition coding, which reduces the barrier for patients entering their medicines, and increases accuracy of data entered. It aims to support patients to take their medicines as directed and have safe and accurate conversations with their care team.

MedicineWise App sits on a clinical data repository, which allows NPS MedicineWise to provide contextualised information to patients based on their situation.

During the design phase of a therapeutic program, key consumer messages and target cohorts are identified. These messages are developed including the supporting content. Depending on the key message, consumers will receive it as an interruptive push notification, a read later message or be able to find the content as part of their medicine or condition record.

As an example, as part of the rheumatoid arthritis program, it was identified that consumers were unaware of the potential benefits of taking folic acid alongside their methotrexate. An interruptive message was delivered recommending people discuss the benefits with their doctor, and it received 100% engagement.

Another example provided a test for asthma sufferers to complete so they could self-assess if they were well controlled, and this message had 80% engagement.

A 2017 review of 272 medication adherence apps by iMedicalApps, an independent online medical publication, included MedicineWiseApp in its top five medication adherence apps based on three practical features and 17 functional features. The review noted the high quality of MedicineWiseApp

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information and that it was from a credible source, NPS MedicineWise, as its key features (32).

NPS MedicineWise has advised that as of 25 March 2019 the app had been “installed on 30,374 devices. There are 22,265 patient records, with a total of 88,035 medicines and 37,526 health conditions listed. Therefore, there is an average of 4 medicines per patient with [the] largest cohort being people with high blood pressure, followed by those on antidepressants” (31).

According to the Consumer Health Forum, the consumer awareness of the App would have been greater with a more effective promotion (6). Further, no evidence was provided to the Review of a promotion of the App to pharmacists to assist patients with medication management.

NPS MedicineWise also delivers the Doctor's Bag App. This is a free app designed to support health professionals during emergency situations by providing emergency drug doses. It is produced by the Australian Prescriber team and funded from the Information and Awareness Raising contract. There are currently 11,404 installs.

<p>Recommendation. Availability and utility of MedicineWise's Medicine apps should be actively promoted by NPS MedicineWise as part of its services to consumers and health professionals.</p>

7.8 MedicineInsight

Over the past eight years the Government has invested \$33.7 million into developing MedicineInsight to improve post-market surveillance of medicines. Funding of \$16.67 million was provided in the 2011 Budget and an additional \$17 million is included in the current funding Agreement. NPS MedicineWise's description of MedicineInsight is included in Table 8.

The Department and associated portfolio agencies have used, or are currently utilising, MedicineInsight in a range of areas, including:

- Insight reports on post market utilisation of medicines and tests (including for the QUME Agreement deliverable)
- Data to inform policy development in primary care, e.g. for evaluation of the Health Care Homes program and the EQuIP trial
- Insight reports to inform government medicines policy (eg ondansetron prescribing for the Drug Utilisation Sub Committee (DUSC) and opioids and pregabalin use for the TGA)
- Description of national general practice activities through an annual General Practice Insights Report
- Development of methodology to evaluate benefits realisation for the My Health Record
- Informing the development of National Key Performance Indicators
- Use of a 10% data sample to inform the development of the Department's work to improve general practice data

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- Vaccine surveillance as part of the AusVaxSafety Program
- Monitoring of antibiotic prescribing and antimicrobial resistance.

MedicineInsight data are highly valued and widely used. There are other primary care data programs on the market and the Review has not undertaken a comparison of these programs, but notes that the AIHW is undertaking such a review and public consultation is underway. Advice to the Review indicates a strong desire for continuing access to MedicineInsight data. The Review notes the utilization of MedicineInsight by NPS MedicineWise in government and non-government activities. MedicineInsight data complements the work of the DUSC Sub-Committee in that it can provide insight including reasons for prescribing.

Appendix F lists all the projects supported by MedicineInsight Data.

Table 8 - Description of MedicineInsight (33)

MedicineInsight links diagnosis, prescriptions and clinical indicators within a national representative cohort, and addresses gaps in knowledge about how and why medicines are prescribed. It gives local and national perspectives on what treatments have been prescribed for what conditions, against which groups and the impact this has had.

It is the only national general practice dataset in Australia providing longitudinal, de-identified, whole-of-practice data that can be weighted using patient and encounter data to be nationally representative. Data are extracted from the clinical information systems (CIS) of participating general practices to connect patient conditions with treatments and outcomes.

As at the end of January 2019, there are 718 practices participating in the MedicineInsight program. This represents more than 4000 active GPs.

MedicineInsight collects de-identified data of approximately 3.6 million regular (RACGP active) patients attending participating general practices. Recruitment beyond the original 500 practices required under the QUME contract has been supported by funding from non-QUME sources. Practices are able to reidentify their patients at the practice.

MedicineInsight is unique in that it is a research quality national dataset, with potential to support a range of current and future Commonwealth health policy priorities. Its three primary uses are:

- Post market monitoring
- Data and insights to inform research and policy
- Quality improvement in primary care.

The consultation process has raised concerns with how the data collected through the government funded initiative is used by VentureWise and the lack of transparency in data governance (34) (7). For example, AHHA's submission called for:

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there to be transparent requirements regarding intellectual property associated with government-funded activities and commercial activities, including clear data governance requirements, restrictions in access to and use of patient and provider data (particularly for commercial ventures), and open and transparent availability of government-funded data mapping (7).

The Capital Health Network PHN's (ACT PHN) submission stated that:

improved integration with the PHN would not only increase the uptake of practices enrolling in MedicineInsight – as the PHN is a trusted and known entity with practices, it would also reduce duplication of having separate electronic patient data to support improved care and health outcomes (35).

The Victorian and Tasmanian PHN Alliance submission raised the need for wider access to MedicineInsight data:

However, the fact that de-identified and aggregated medicines use data analytics is not openly accessible is inconsistent with the Australian Government's commitment to open government and the manner in which other Government-funded datasets are handled. Moreover, practitioners have reported limited understanding in relation to how primary care data shared with NPS MedicineWise will be used, and sensitivities in relation to potential utility derived by General Practices contributing data to MedicineInsight, compared with the relative utility derived by NPS MedicineWise and its commercial subsidiary VentureWise (4).

While there are widespread concerns with NPS MedicineWise's commercial use of the MedicineInsight data, the Review is confident greater transparency with stakeholders would address many of the issues raised.

The Review considers that there is a significant opportunity for an increased use of MedicineInsight data in the area of post marketing surveillance. The system has the capability of collecting data on behalf of sponsors of therapeutic goods to satisfy the requirements of the TGA for compliance with Risk Management Plans or of the TGA and PBAC for the managed entry of new products. Since the data requirements will be specified by a Government agency, any perceived conflicts of interest can be managed in a transparent manner. However, the capability is limited by the lack of access to the data held by medical specialists. This will limit the ability of NPS MedicineWise to fulfil the potential expansion of the utility of MedicineInsight data.

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Recommendation. MedicineInsight should continue to be developed and maintained by the Department and NPS MedicineWise.

Recommendation. MedicineInsight is a valuable primary health care data asset and its use by government agencies should be expanded to support the post marketing requirements including for the reporting required for Risk-Management Plans and for drug approvals under accelerated regulatory approval processes and managed entry schemes recommended by PBAC.

Recommendation. The utility of MedicineInsight data should be better promoted to government and non-government agencies including PHNs.

Recommendation. NPS Medicine Wise should strengthen governance of the use of MedicineInsight data including introducing greater transparency to ensure ongoing confidence in the processes and to ensure data are not used in a manner contrary to NPS MedicineWise's mission.

Quarterly Evaluation Reports

The Department is entitled to request an evaluation report using MedicineInsight data from NPS MedicineWise every quarter. These reports compliment the work undertaken by the DUSC Secretariat. Recent reports include the prescribing of ondansetron in general practice (June 2018) and the prescribing of direct acting anti-viral medications for Hepatitis C in general practice (Jan 2019). Both of these reports provided important information and were well presented and will enable the PBAC to address the issues raised. It is important for the Department to utilize this facility on an ongoing basis.

7.9 Antimicrobial Resistance

Antibiotic use and prescribing remains a critical QUM issue. NPS MedicineWise has received funding for AMR activities through separate funding agreements to deliver consumer and health professional focused interventions. Between 2012 and 2017 NPS MedicineWise reported an 18 per cent reduction in all antibiotics prescribed by GPs and dispensed under the PBS. It also reported a positive improvement in GP knowledge, attitudes and practice around antibiotic prescribing and antibiotic resistance between 2011 and 2017. Australia continues to record one of the highest rates of defined daily doses of antibiotics per 1,000 inhabitants compared with comparable OECD countries (36).

The submission from the OHP noted that the Department, through OHP, has commissioned the ASCQHC to manage the Antimicrobial Use and

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Resistance in Australia (AURA) Surveillance System. As part of this work, the ACSQHC works with NPS MedicineWise to analyse data on patterns of antibiotic use in primary care through the MedicineInsight program. The aggregated clinical data collected by MedicineInsight is assisting to identify evidence gaps in primary health care (37). In 2015 the Commission also collaborated with NPS MedicineWise on the development of a suite of antimicrobial prescribing modules in a hospital setting. ACSQHC advises that NPS MedicineWise is currently leading a revision of these modules to reflect current therapeutic guidance for prescribing antimicrobials (38).

NPS MedicineWise is also a member of the Australian Strategic and Technical Advisory Group on Antimicrobial Resistance (ASTAG) chaired by the Australian Government Chief Medical Officer and Australian Chief Veterinary Officer. ASTAG develops and provides expert advice to the Australian Government on AMR-related issues. ASTAG includes representatives from across the fields of human health, animal health, food, agriculture and the environment.

As a member of ASTAG, NPS MedicineWise is involved in the development of the next National AMR Strategy for Australia (beyond 2019). The ASTAG members, including NPS MedicineWise, participated in a workshop on 14 August 2018 regarding scope and priorities for the next AMR strategy. This included discussing and mapping the *Increase awareness and understanding of antimicrobial resistance* objective, its implications and actions to address it, through effective communication, education and training.

The OHP is undertaking a review of antibiotic listings on the PBS and, where appropriate, proposing changes to remove or restrict access to repeats. This is an important step to reduce inappropriate antibiotic use and is part of the Australian Government's broader ongoing strategy to reduce the risk of AMR in Australia, as outlined in the National AMR Strategy.

Following discussions with OHP, the Review has identified a potential duplication between the work commissioned by OHP and that undertaken independently by NPS MedicineWise.

Recommendation. Government QUME funding should not be allocated to activities to address AMR unless it is part of a co-ordinated program endorsed by the OHP.

7.10 Choosing Wisely

NPS MedicineWise has become the facilitator of Choosing Wisely in Australia.

NPS MedicineWise facilitation of the Choosing Wisely movement in Australia is an important strategic development. The lists created by the

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medical specialist groups and health professionals are an important resource and greater effort is needed to implement their recommendations. This will not only reduce incidences of low value care, but also has the potential to deliver significant savings.

The Choosing Wisely initiative opens up opportunities to develop important communication channels and linkages with medical specialists which have not been widely developed previously. These strategic relationships need to be further cultivated as the application of new therapeutics and technologies will often be restricted to medical specialists. QUM initiatives will increasingly need to be designed specifically for medical specialists and in many cases will be different from those provided to GPs.

Recommendation. Strategic relationships with medical specialists established through Choosing Wisely should be further developed by NPS MedicineWise as QUM initiatives will increasingly be designed for medical specialists.

7.11 Consumers

Consumers are central to QUM. The first QUM Principle recognises the primacy of the consumer:

“The National Strategy recognises both the central role consumers play in attaining QUM and the wisdom of their experience. Consumers must be involved in all aspects of the National Strategy”
(39)

The QUME Grant has included \$15.88 million between 2015/16 and 2018/19 to support consumers' QUM. The Review has not been able to assess the effectiveness of NPS MedicineWise consumer programs because of the disbursement of these funds across multiple programs and limited availability of outcome information.

One of the deliverables listed in the Grant for consumers is the implementation of Choosing Wisely. Between 2016 and 2018 CHF received funding from NPS MedicineWise to collaborate on a joint program to increase consumer engagement with Choosing Wisely. The experience from CHF's perspective was sub-optimal:

From CHF's perspective, the project began with good intent with regular meetings with personnel from both organisations. However, when the Expert Working Group broke into small groups to complete four identified projects, there appeared different priorities between the two organisations about which projects to progress. CHF's main concern was the overall project appeared to be losing its consumer focus and shifting from its original intent of being activation and translation focused to an information provision and awareness raising focus (6).

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This comment from CHF again highlights the need for NPS MedicineWise to engage in a more supportive and co-operative way with external groups including consumer representatives in a manner which aligns with the principles of national strategy for QUM.

7.12 The National Strategy for Quality Use of Medicines (NSQUM)

7.12.1 The 2009-2015 Grant Agreement

In the 2009 to 2015 QUME Agreement with NPS MedicineWise, the principles of the NSQUM were reinforced by referring explicitly to a partnership approach in the first paragraph of *Schedule*:

To improve the health of Australians through improvements in the Quality Use of Medicines by health professionals in partnership with stakeholders, by:

Supporting nationally coordinated approaches to QUM;

- The collection of clinical use data to inform education programs and evaluations;
- Providing independent information about medicines to health professionals;
- Encouraging and supporting cross-discipline and cross sector collaborations that promote QUM;
- Utilising incentives that support QUM initiatives; and
- Undertaking ongoing evaluation (40).

These principles are not clearly enunciated in the current 2015-2019 QUME Grant Agreement. There are only two requirements for NPS MedicineWise to work collaboratively in this Agreement. Item B3 related to the quality use of therapeutics for prescribers requires NPS MedicineWise:

to work in a highly collaborative and strategic way with PHNs to ensure the efficient and effective use of resources within the primary care environment (14).

Item B6, related to the implementation of QUD, calls for NPS MedicineWise to:

integrate with other relevant activities within the health sector that are designed to reduce pressure on the health system and health budget. Your organisation must bring together the different sectors – government, industry, researchers, health service providers, clinicians, consumer organisations – to establish a platform for effective sharing of information, utilisation of data and knowledge, synthesis or priorities and integration of all of these elements for a common purpose (14).

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7.13 The QUM ecosystem and NPS MedicineWise stewardship role

The growing complexity of the QUM ecosystem underlines the importance of collaboration. In 2019 there are multiple players in the quality use of medicine policy space. For example, community pharmacy has taken on more quality use of medicine initiatives such as Medication Reviews. Primary Health Networks are commissioning quality initiatives and information technology has revolutionised access to information and support. Unfortunately, the feedback from the consultation process suggests that NPS MedicineWise's response to this growth has been to adopt a more transactional and commercially driven approach to delivering QUM programs rather than the relational style defined in the 2002 NSQUM.

A number of submissions and stakeholder interviews commented that, since NPS MedicineWise was established, the QUM environment had evolved into a complex ecosystem. The NSW TAG submission summarises this growth and the challenges it represents:

The importance of QUM (and the challenges in achieving it) have seen a growth in organisations that have varying degrees of involvement and responsibilities. They include national organisations such as The Australian Commission on Safety and Quality in Health Care (and accrediting organisations), the Council of Australian Therapeutic Advisory Groups (CATAG), various jurisdictional organisations such as, for example, in NSW, the pillars of NSW Health such as the Clinical Excellence Commission and the Agency of Clinical Innovation and more local or specific organisations such as Primary Health Networks (previously similar organisations were the Divisions of General Practice) and specific consumer groups. Many of these have grown into large organisations and developed in-house skills but have varying knowledge of the QUM landscape. As a result, there has been some 'siloeing' of QUM activity and a resultant increase in duplicated and wasted effort and money and reduced efficiency.

The challenge for this current review of NPS is that, by only looking at one 'cog', it is unlikely that efficient integrated delivery of healthcare and QUM to all Australians can be achieved. Ideally, there needs to be: (a) identification of current gaps in QUM delivery (and the NMP) that can be prioritised; (b) a determination of existing expertise and experience in NPS and in other parts of the QUM/healthcare system at the state and national level; (c) an understanding of how these various roles and responsibilities fit together; and finally (d) identification of where and how NPS can best apply its expertise or should develop expertise and what it should remove or leave to others (17).

The growth in the number of organisations committed to driving QUM demonstrates the success of the 2002 NSQUM and the Department's long-term QUM investments. The QUME Grant Agreement must nurture the

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QUM ecosystem and include mechanisms to prevent QUM activities becoming 'siloed' and government funded organisations adopting a competitive rather than collaborative approach to delivering QUM initiatives.

Any new Grant Agreement should require NPS MedicineWise to deliver all its Grant funded activities in a manner consistent with the NSQUM five principles.

Recommendation. Consideration should be given to the importance of a stewardship role for NPS MedicineWise in promoting QUM including fostering a culture that promotes the five principles of the NSQUM across the health system. This should be specified in any new Grant Agreement.

7.14 Relationship of NPS MedicineWise with PHNs

The complexity of the QUM ecosystem and the existence of multiple players raises the potential for duplication and the inefficiencies in the delivery of programs. This is apparent in NPS MedicineWise's relationship with Primary Health Networks.

Based on stakeholder feedback, the Review considers the current relationship between NPS MedicineWise and most PHNs as transactional and collaboration between the two entities is limited.

Prior to 2013, NPS MedicineWise worked collaboratively with and through the Divisions of General Practice which later became Medicare Locals. In 2013, NPS MedicineWise changed its operating model. As NPS MedicineWise explains:

In 2013, NPS MedicineWise moved away from service delivery contracts with entities like Divisions of GP and Medicare Locals, moving to a directly-employed workforce force for the delivery of the Educational Visiting Service. This was not a popular decision for some of the contracted service providers, primarily as our programs are highly effective at opening the doors to general practices. However, this more cost-effective and efficient in-house field force model has allowed NPS MedicineWise to continue to provide high quality and valued services to GPs and other health professionals, and this provides NPS MedicineWise the capacity to adapt and respond to changing needs and opportunities quickly (41).

NPS MedicineWise reported a 15 % reduction in the costs of delivering its GP visiting programs from 2014/15 to 2015/16 because of this change (36). Seven PHNs still support the NPS MedicineWise's CSS or 'field force' including giving them access to their facilities, although during the consultations the Review was informed that this access did not necessarily extrapolate to meaningful interactions.

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AHHA's submission claimed NPS MedicineWise's withdrawal of CSS contributed to a 'siloed approach in supporting QUM locally, with confusion and duplication of effort at the general practice level.' They suggest that 'it would be preferable if NPS MedicineWise activities were planned at a regional level in collaboration with PHNs, with funds allocated according to regional needs.' (7)

The Review team met with four PHNs and received submissions from the Northern Territory PHN, the ACT PHN, Victorian and Tasmanian PHN Alliance and Western Australian Primary Health Alliance (WAPHA).

The ACT PHN described the NPS MedicineWise QUME program as 'poorly integrated with the role and work of PHNs supporting general practices'. According to their submission, there is 'no visibility of the NPS MedicineWise QUM information being provided to practices'. The ACT PHN submission highlights the potential for duplication. This PHN provides funding for the employment of pharmacists within the general practice team and by the middle of 2019, eleven general practices will be employing pharmacists.

The Victorian and Tasmanian PHN Alliance supported the strategic alignment of their work with the QUME Grant Program and NPS MedicineWise activities. They note that a lack of coordination is a risk to efficiency and effectiveness. Their submission highlights the growing numbers of entities working in the QUM space and the need for better collaboration:

Recognition of the breadth of quality use of medicines roles – There are a suite of parties and programs that have a role in quality use of medicines. The QUME Grant Program and NPS MedicineWise efforts which are largely therapeutically oriented, would benefit from further recognition of the suite of efforts that are complementary in nature. For example, the breadth of activities that may be undertaken by PHNs in advancing the system issues associated with embedding the principles of quality use of medicine is worthy of recognition. Efforts towards formalising activities, investment (including how activities are managed through PHN funding schedules), and measures of success in relation to these functions is considered essential for longer term sustainability of Australian quality use of medicines interests not otherwise limited to the Grant Program and Australian Government funded NPS MedicineWise activities (4).

Greater collaboration has occurred between NPS MedicineWise and PHNs through a national immunisation project funded through the Department's OHP. As part of this initiative and in partnership with National Centre for Immunisation Research & Surveillance (NCIRS), NPS MedicineWise has brought together staff working at PHNs, state and territory health departments, public health units and other key stakeholders to help to build

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an electronic platform where the latest information and resources are available for PHNs regarding immunisation.

The Department funds both PHNs and NPS MedicineWise to improve the quality of care in the primary health. The relationship between NPS MedicineWise and the 31 PHNs must be improved.

Some PHNs appears to harbour continued and deep resentment towards NPS MedicineWise because of its 2013 decision to centralise its CSS facilitators. This was communicated to the Review during face-to-face meetings and NPS MedicineWise reports that its repeated requests for executive meetings with some PHNs are ignored. The PHNs do not have NPS MedicineWise's QUM expertise and NPS MedicineWise's relationships with GPs should be a strategic asset that PHNs could leverage to improve primary health care.

Recommendation. A collaborative working relationship between PHNs and NPS MedicineWise is essential to ensure the efficiency and effectiveness of QUM programs. The Department should consider the necessary incentives and processes to facilitate the development of a productive working relationship between NPS MedicineWise and the PHNs to leverage Commonwealth investments in primary health quality initiatives.

Recommendation. Mechanisms to support greater collaboration between NPS MedicineWise and other key stakeholders need to be built into any new funding Agreement. The Department should ensure QUM performance indicators across government funded activities are harmonised (including ACSQHC and PHNs) to ensure delivery against shared safety and quality goals is optimised.

7.15 Relationships of NPS MedicineWise with Medical Specialists

NPS MedicineWise prescriber QUM activities are predominately focused on prescribing in general practice. However, a 2015 Formative Research report identified the potential for NPS MedicineWise to expand its QUM activities to prescribing of high cost medicines many of which are covered by the Highly Specialised Drugs program and which are more likely to be prescribed by specialists.

An example of interaction in this area is the Australian Rheumatology Association work with NPS MedicineWise. In 2017, NPS MedicineWise worked collaboratively with the Australian Rheumatology Association (ARA) to improve the quality use of methotrexate (MTX) for the management of rheumatoid arthritis. The ARA described their experience as 'outstanding' and reported that 'the independent nature of NPS MedicineWise means they are rightly perceived as trustworthy and rigorous;' and, that the 'scope of the NPS MedicineWise enables it to reach rural and regional areas that are typically hard for the ARA to engage

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with.' The ARA praised the co-design working model that NPS MedicineWise applied in the development of the program:

The working model that was developed was unique: working together as one from development, to planning, to implementation, through evaluation, and in the future – revisions, other meds (sic). The original idea was to focus on prescribing of biologics. However, the QUMP accepted direction from the ARA – to focus on low dose MTX with early intervention as the predominant issue in inflammatory arthritis (e.g., rheumatoid arthritis), and to specifically target the prescribing, dispensing and patient education behaviours of GPs, pharmacists and specialist doctors.

The educational resources were co-produced by the ARA, and a patient support group – Arthritis Australia, working alongside the NPS MedicineWise staff. The ARA continues to endorse these resources which represent the highest quality use achievable for the Australian clinical context. (42).

This example demonstrates that NPS MedicineWise has the potential to develop high quality QUM initiatives to improve prescribing by medical specialists.

The background documents that NPS MedicineWise produced in support of this program are valuable resources for policy makers. These documents would have been a useful resource for Departmental officials focused on the quality use of rheumatology treatments.

It will be essential for NPS MedicineWise to develop its data resources more comprehensively to engage formally with medical specialists using the approach with specialist societies that has been demonstrated through its interaction with rheumatologists. It is acknowledged that the nature of engagement with medical specialists may need to be different to GPs.

Recommendation. QUM initiatives for medical specialists must be further developed by NPS MedicineWise and delivered, including through bespoke approaches.

7.16 Relationship of NPS MedicineWise with Disease Specific Groups

The delivery of disease specific QUM activities has become an increasingly contested space. One organisation questioned the exclusiveness of NPS MedicineWise's QUME Grant. Another organisation claimed that it had a longer-term commitment, greater expertise and networks to deliver QUM for its specific disease compared with NPS MedicineWise.

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Hepatitis Australia's submission called for 'full competition for large-scale education and campaign services through a tendering or grant processes. Their submission argued that:

with the scope of funded medicines moving further into section 100 realm and the growing need for targeted education rather than broad-brush approaches both on the treatments themselves and the consumers who stand to benefit from them, a significant effort is needed to improve consumer literacy and clinician awareness. The effectiveness of the NPS in this consumer education role should be reevaluated and alternative models considered.

Broad education campaigns have potential wide reach, but the challenge in improving health literacy for increasingly diverse communities requires partnerships, with nuanced messaging, and with sustained and at times local level engagement.

There is more the NPS could be doing to partner with, seek the expertise of, or even subcontract to others with the capacity to engage, influence and improve health literacy for consumers and to adapt messages for different audiences (19).

The Lung Foundation's submission asserted their ownership over QUM initiatives that targeted their stakeholders. This claim was based on the up-to-date nature of their COPD-X guidelines compared with NPS MedicineWise's resources. To overcome the ad hoc nature of collaborations, the Lung Foundation called for a formal agreement with NPS MedicineWise (43).

The Review considers that the QUM agenda would be advanced by NPS MedicineWise collaborating more closely with disease specific groups especially in support of major government initiatives such as the new hepatitis C treatments. The perceived conflict of interests concerns being raised in relation to VentureWise in regards to the perceived influence of the pharmaceutical industry in NPS MedicineWise activities by some stakeholders, are equally applicable to disease specific organisations that receive financial support from the pharmaceutical industry.

NPS MedicineWise is well placed to be a steward of clinician and consumer education on new therapies. For example, disease specific groups' advocacy for patient access to new therapies may not always be consistent with the QUM commitment to the evidence hierarchy of therapeutics or the PBAC's recommendations. This does not preclude the need for NPS MedicineWise to share its intelligence and collaborate more closely with these organisations.

Calls for the Government's QUM investment to be distributed through disease specific groups needs to be balanced against the need to improve QUM for patients with multiple co-morbidities. A more constructive approach would be for NPS MedicineWise in collaboration with disease

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specific groups to develop support tools that helped clinicians apply disease specific guidelines in complex clinical contexts including for patients with multiple co-morbidities.

This may result in NPS MedicineWise refocusing its efforts onto under-serviced QUM priorities such as promoting QUM for multi-morbid patients.

Furthermore, to maintain its high standing in the health sector, it needs to re-affirm itself as the steward of QUM in Australia and adopt a more collaborative approach to working with stakeholders.

Recommendation. In line with the Principles of NSQUM, it is recommended that QUM initiatives that relate to specific disease entities be supported in a system based approach. To achieve a system based approach, both NPS MedicineWise and disease specific groups must act collaboratively.

7.17 Relationship of NPS MedicineWise with Australian Commission on Quality and Safety in Health Care (ACQSHC)

The Australian Commission on Safety and Quality in Health Care (ACQSHC) is a corporate Commonwealth entity that operates under the *National Health Reform Act 2011* and the *Public Governance, Performance and Accountability Act 2013 (PGPA Act)*. The Commission's funding is provided by all governments and its annual program of work is developed in consultation with the Australian, State and Territory health ministers.

The ACQSHC collaborates with NPS MedicineWise on medication safety issues including online modules on antimicrobial prescribing in a hospital setting and is also using MedicineInsight data to inform its work on the appropriateness of antibiotic prescribing (5). The Review is aware the Commission is increasingly extending its work into primary care, where applicable, and recognises the benefits of greater collaboration including the harmonisation of all stakeholder QUM strategies and work plans

Recommendation. To ensure the efficient use of the Commonwealth QUM investments, the relationship between NPS MedicineWise and the ACQSHC should be further developed. The two organisations should have complementary priorities and share expertise to avoid duplication and promote consistent messaging wherever applicable.

7.18 Relationship of NPS MedicineWise with Peak Bodies and Professional Associations

Many peak bodies and professional associations engaged with this Review. It was evident from the submissions received from many peak bodies that the work of NPS MedicineWise is highly regarded.

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NPS MedicineWise's relationship with some professional associations was more complex. Many of the activities provided by NPS MedicineWise to health professionals are eligible for accredited CPD points towards registration requirements. Generally these activities are free of charge and are available as part of programs funded under the QUME Grant. Some professional bodies have commented that this gives NPS MedicineWise an advantage since CPD programs offered by these bodies are developed at a cost resulting in a charge being made to participants.

Many submissions referred to an increasingly competitive relationship with NPS MedicineWise. For example, the Pharmaceutical Society of Australia (PSA) highlighted the duplication of programs that offer QUM CPD points.

To overcome this, the PSA recommended the following approach:

It may be more efficient and effective for: NPS MedicineWise to act as a knowledge bank for QUM messages and resources; QUM programs to be co-designed and co-developed by NPS MedicineWise and other relevant organisations such as PSA, RACGP or Consumers Health Forum; and profession-specific organisations such as PSA or RACGP to be responsible for the implementation of messages, education and practice support through the delivery of those QUM programs (44).

Recommendation. While it is appropriate for the NPS MedicineWise's programs to include the development of CPD materials, consideration should be given to NPS MedicineWise collaborating with professional associations to minimise the duplication of effort and ensure consistent messaging relating to a particular topic.

7.19 NPS MedicineWise Value-add

NPS MedicineWise is recognised as a credible source of QUM expertise. A consistent theme emerging from the consultation process was that the design and delivery of programs resulted in high quality evidence-based resources and QUM education programs. Evidence confirms academic detailing programs like those delivered by NPS MedicineWise can be effective at changing prescriber behaviour (45) (46) and NPS MedicineWise's extensive linkages into GP practices is an important strategic asset. Clinicians value NPS MedicineWise's products and each year welcome their educators into their practices or attend NPS MedicineWise workshops to improve their prescribing practices.

NPS MedicineWise's reputation as an organisation perceived as independent of government and the pharmaceutical industry in its operation and designs programs and resources for the Australian context is

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its strategic advantage. The RACGP's submission highlighted the importance of NPS MedicineWise independence and the quality of its work and value to GPs:

From the general practice perspective, NPS MedicineWise's greatest value is as a source of independent and trusted information about medicines and interventions. Its evidence appraisals and academic detailing are an important counterbalance to the marketing information provided by pharmaceutical and other industry interests.

Education modules delivered by NPS MedicineWise are high quality, and the fact that these are created independently of industry interests is highly valued by GPs (18).

One health professional reported using their services on a daily basis because their services were:

1. Written by Australians for Australian context;
2. Independent, non-biased information;
3. Important clinical updates in easy-to-read format (both print, digital and handheld devices);
4. Collaborative research work between different health professions;
5. Collation of global evidence and application to Australian health practice (47).

Nearly all stakeholders emphasised that while they may have specific criticisms of recent directions, there was almost universal support for the organisation's work.

Any new Grant Agreement should recognise that NPS MedicineWise's role is greater than a provider of education and encourage the organisation to take on a greater stewardship role.

7.20 Options likely to achieve savings to PBS & MBS

The identification and delivery of savings through QUM interventions contributes to the sustainability of the PBS and MBS and ensures equity of access, a key pillar of the NMP. It is therefore an important objective on the achievement of which NPS MedicineWise should report.

But as stakeholders noted, savings were a by-product of QUME programs, not their primary purpose. The impact of initiatives such as statutory price reductions in F1 and F2 and price disclosure, as well as therapeutic groups and reference pricing, were credited with containing PBS expenditure not NPS MedicineWise's interventions (17) (19).

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There are many QUM issues with the capacity to deliver saving as a by-product including:

- Identifying adverse events and minimising them through the use of MedicineInsight in post-market surveillance.
- Identifying the hierarchy of therapeutics and getting people to comply with the hierarchy as recommended by PBAC.
- Promoting cost effective treatment algorithms for therapeutic management of patients.

The consultation with the MBS Review Taskforce also highlighted the potential for NPS MedicineWise programs to deliver larger MBS savings than is current.

The identification of savings will require better interactions and flow of intelligence between NPS MedicineWise and the Department. This includes NPS MedicineWise taking responsibility for alerting the Department to issues and proactively recommending policy solutions as a genuine QUM partner. The interactions between NPS MedicineWise and the Department have become transactional. Any new Agreement must put in place mechanisms that support more relational interactions.

8 Part 3. Evaluation Methodology and Broader Outcomes

8.1 Evaluation Methods

Part Three of the Review examines the current NPS MedicineWise methodology for assessing the effectiveness of its programs and the model for the evaluation and reporting of savings and outcomes from its activities and seeks to identify options:

- for a methodology and model to evaluate savings to the PBS and MBS that is robust;
- to ensure that the methodology is as streamlined and efficient as possible, so that savings for all activities expected to result in savings can be evaluated and reported in a timely fashion after delivery;
- to identify, evaluate and report on savings not directly attributed to the PBS or MBS; and
- to identify and report on outcomes that result in improvements to the health of Australians but do not result in financial savings to the PBS and MBS.

The evaluation of NPS MedicineWise programs is the responsibility of the Health Insights and Evaluation team which consists of approximately 20 FTEs. The evaluation uses a framework which identifies three main types of evaluation, namely process, impact and outcome.

Process Evaluation

- Measures associated inputs and outputs
- Provides information about the implementation or delivery of a program, project or intervention once it is operational e.g. participation, reach, satisfaction and perceived value.

Impact Evaluation

- Measures the effectiveness of a program, project or intervention by assessing any short-term or intermediate change in relevant parameters e.g. awareness, knowledge, attitudes and beliefs, skill and behavior.

Outcome Evaluation

- Assesses whether the longer term goals of the organisation and its programs have been met e.g. savings to PBS and MBS or cost consequence analyses. Data are most often collected at the end of a program, or sometimes years later and compared with base-line data.

Table 9 lists the various methods used to evaluate the NPS MedicineWise programs.

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Table 9 - Methods Used in NPS MedicineWise Evaluations (36)

Method	Description
Health outcomes	Using the NSW 45 and Up Study to assess impact of NPS MedicineWise programs
Economic Evaluation	Cost-benefit analysis, making a comparative assessment of all the benefits as a consequence of the activity and all the costs to support the activity. Data from NPS MedicineWise systems on costs, MedicineInsight data and PBS data were used.
Time-series analysis	The main statistical method used to assess the impact of our interventions on Pharmaceutical Benefits Scheme (PBS) and Medical Benefits Schedule (MBS) expenditure, and changes in prescribing or referral behaviour in relation to medicines and medical tests.
Bayesian Structural Time-series analysis	The statistical method used to assess the impact on PBS and MBS expenditure and changes in prescribing or referral behaviour in relation to medicines and medical tests with a control group. The statistical inferences in the Bayesian analysis are conducted by introducing prior distributions to the unknown quantities to be estimated in the analysis.
Cross-sectional Survey	Used to identify trends within populations / areas of interest and assess changes in awareness, knowledge, and attitudes associated with interventions. Designs: cross-sectional and pre-experimental (e.g. pre– post, post + control group, retrospective pre-test). Modes: paper, online and telephone
Focus groups	Used to explore broad themes, experiences, beliefs and opinions about products or services. Face-to-face focus groups typically comprise 6–8 participants. Online focus groups can be conducted by Skype, with up to 10 participants able to log in remotely. Modes: face-to-face, online
Semi-structured Interview	Used to gain an understanding of customer attitudes, motivations and perceptions relevant to our products and services. It may serve to inform survey design or to explain quantitative data. Designs: in-depth, key informant, structured, semi-structured Modes: telephone, face-to-face, online, electronic communication

8.2 Annual Evaluation Reports

Each year NPS MedicineWise prepares an Annual Evaluation Report detailing the outcome of its activities. These reports include the results of specific programs as well as other activities undertaken. The public availability of the Annual Evaluation Reports is uncertain as only the executive summary is available on the NPS MedicineWise website. Consideration should be given to these Reports, together with the more

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detailed Economic Evaluations of programs and the Financial Impact Reports on MBS and PBS costings, being made publicly available.

8.3 Methodology to estimate savings to PBS and MBS

NPS MedicineWise is required under the QUME Grant Agreement to provide evidence that the programs listed in the Agreement contribute to savings to the PBS and MBS. Under the current Agreement, NPS MedicineWise must deliver a saving of \$280 million to the PBS and \$52 million to the MBS during the activity period of 1 July 2015 to 30 June 2019.

Program Selection

In the 2014/15, 2015/16 and 2016/17 annual financial impact reports, savings were attributed from eleven unique programs covering the time period from 2009 to 2017. A list of the programs selected for inclusion in the annual financial impact report, along with the savings amount for each of the 2016, 2017 and 2018 reports is included at Appendix H.

The specific programs identified by NPS MedicineWise in the current Agreement against which savings to the PBS are expected are:

- Opioid use in chronic pain
- CVD risk-guiding lipid management
- Balancing the risk and harms of antipsychotic therapy
- Achieving good anticoagulant practice
- Older, wiser, safe use of medicines in older people
- *Asthma; steps to control
- *High Blood pressure measurement
- *Proton pump inhibitors; too much of a good thing
- *Opioids and beyond in chronic pain
- *Judicious use of antidepressants and
- *Reducing antibiotic resistance (14)

**Programs used to calculate PBS savings over the 2016/17 financial year- Savings from the program "Type 2 diabetes-what's after metformin" was also included in the savings total but not mentioned in the contract.*

8.3.1 Interrupted Time-Series and Calculating Savings

The methodology used to calculate savings is an interrupted time series analysis. This established methodology is widely used in the examination of the impact of an intervention. Jandoc *et al* (2005) stated that:

interrupted time series analysis is the strongest and most commonly used quasi-experimental design to assess the impact of an intervention when a randomized trial is not feasible (48).

In simple terms the method uses data (e.g. prescription volume) obtained consecutively over time prior to the intervention to predict future trends in

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the absence of an intervention and compares the predicted outcome with the actual outcome observed after the intervention. Various confounding factors such as seasonality, autocorrelation and non-stationarity can be accommodated in the modelling. The trend lines before and after the intervention must be significantly different and indicate a 'break-point' identified by the segmented regression analysis. This break point must occur at or just after the introduction of the intervention.

Whilst this is the appropriate method to apply, the financial impact evaluations using time series analysis provided by NPS MedicineWise to the Review are not sufficiently detailed to validate the outcomes reported.

Greater transparency in the methods applied including technical appendices are needed. The graphical presentations do not include confidence intervals, making it difficult to determine whether an intervention was the actual cause of the claimed difference in the projected and actual prescription volumes.

Based on a review of a number of evaluation reports prepared by NPS MedicineWise, the accounting methods used by NPS MedicineWise to estimate savings to the PBS and MBS do not align with the approach used by the Australian Government in developing policy costings, and in particular the approach to estimating savings¹. During 2017-2018 the Australian National Audit Office undertook an audit of the Management of Commonwealth Leased Office Property Report 8. The report stated that:

where advice to Government includes savings estimates, entities should ensure that the estimates are supported by a suitable model or methodology, and the government is advised of any limitation (49).

As delivering savings to the PBS and MBS is one of NPS MedicineWise's objectives, the method used should be consistent with the Australian Government's approach to calculating savings. This would then enable the outcomes of NPS MedicineWise's activities to be integrated into the budget models used by the Department in setting policy costings and estimates variations for the PBS and MBS with the Department of Finance.

The development of a formal methodology for determining the financial impact (as opposed to just savings) would also provide greater clarity on the actual impact of NPS MedicineWise programs. It would enable any other effects, such as substitution of medicines to be identified as well as the impact that those effects have on the overall cost of the PBS and MBS.

¹ For a summary of the costing approaches used by the Australian Government, refer to Appendix I.

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Recommendation. A formal methodology for estimating savings to PBS and MBS should be developed by NPS MedicineWise and agreed with the Department and align with the Australian Government's approach to calculating savings.

8.3.1.1 Partial Reporting of Financial Impacts

The selective or partial reporting of a program's impact means that, for some initiatives it is not possible to determine whether some patients were transferred to alternative therapies or enrolled in other programs. Unfortunately, there is generally no mention of these possibilities and no attempt to examine the consequences other than the reduction in the prescription volumes for selected products in the financial impacts that NPS MedicineWise reports.

For example, these shortcomings were evident in the reporting of the PPI programs. The program involving high dose PPIs resulted in a decrease in higher dose strengths but no mention was made of whether there was a correspondingly higher uptake of lower dose options as would have been anticipated from the targeted messages. The PBS savings calculated did not take this into account and in view of the small price difference between the lower and higher strengths the net cost savings to the PBS would be considerably less than that claimed. Notwithstanding this, there would have likely been other benefits from the reduction in the number of persons prescribed the higher strength products. This highlights the limitations of heavily weighting the impact of programs on prescription cost savings.

8.3.2 *Independent Review of Evaluation Method*

NPS MedicineWise has commissioned a number of reviews over the past five years that considered its approach to evaluation and the broader economic and social benefits generated by their activities. Although each of the reviews referenced the savings generated by NPS MedicineWise and commented on the underpinning methodology for determining those savings, there was not a detailed evaluation of the use of the methodology in regard to any specific activity. The reports made available for this review were:

- Deloitte Access Economics, Financial and Health benefits realised from NPS MedicineWise, 27 February 2014
- Ernst and Young, Report on social and economic impact, 19 May 2017
- Viney, Jan and Wagner, Assessment of evaluation methods used by NPS MedicineWise, 8 October 2018

Whilst each of those reports looked at various aspects of the evaluations undertaken by NPS MedicineWise, each had some limitation in relation to

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the savings amounts calculated. The report by Deloitte Access Economics specifically excluded the assessment of the quantum of the savings and the reasonableness or otherwise of the data sources and included assumptions². The report by Ernst and Young (EY) noted the level of savings achieved and noted that no further assumptions needed to be applied by EY in measuring the savings outcomes³.

The report by Viney *et al* looked in-depth at a number of evaluations and noted strengths and limitations for the each evaluation reviewed. It did not address the reliability of the cost estimates developed and reported to the Department as part of its review.

In particular, the review undertaken by Viney *et al* in 2018 noted that NPS MedicineWise used a consistent and methodologically sound approach to estimating changes in medication utilisation and resultant savings⁴. However, that report also noted some limitations in the application of the methodology in assessing costs and benefits arising from NPS MedicineWise programs⁵. In addition, the scope of the review did not address the linkage between the conclusions in the detailed evaluation report and the amounts reported to the Department in the annual financial impact report of the impact of NPS MedicineWise activities.

The Viney *et al* (2018) Report made a number of recommendations in regard to the transparency of the analyses presented and suggested that the:

Evaluation reports be more comprehensive in detailing their limitations and discuss the impacts these limitations may have on the interpretation of the results (29).

Each of the independent review reports also took a broader view of benefits that NPS MedicineWise programs and activities deliver. Adopting a broader view of benefits provides a view across the health system of the overall consequences of NPS MedicineWise's activities. Whilst this approach provides useful information, it does not address the underlying reliability of the savings generated by NPS MedicineWise activities.

² Page 33, *Financial and health benefits realized from NPS MedicineWise*, Deloitte Access Economics, 27 February 2014

³ Page 1, *Report on social and economic benefit*, Ernst and Young, 19 May 2017

⁴ Page 4, *Assessment of evaluation methods used by NPS MedicineWise*, Viney, Jan and Wagner, 8 October 2018

⁵ for example, see page 14, Viney *et al* regarding the limitations applying to the costs of the program being estimated and the overall program resulting in increased costs across the PBS and MBS

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8.3.3 Economic Evaluations

Each year NPS MedicineWise is required to submit an Economic Evaluation of one program. In August 2018, a cost-benefit analysis of the program “Proton pump inhibitors: too much of a good thing? (2015)” was submitted. This evaluation is in addition to the financial impact evaluation discussed above. The total cost of the intervention was calculated as \$425,764 (adjusted and discounted) and the savings to the PBS through a reduction in high dose (PPIs) was estimated to be \$11,383,311 giving a benefit to cost ratio of 28:1. The report states that “*there was no evidence that the reduction in high strength PPIs increased the prescribing of low strength PPIs*” although no details are provided apart from a time series for monthly prescribing of low strength PPIs.

In the Annual Evaluation Report 2017 discussing the outcome of the PPI program launched in 2015, it is stated that “there was a significant reduction in community-based dispensing of high and low strength PPIs”. If there was such a reduction in the use of low dose PPIs, this would have also contributed to savings in this period (April 2015-July 2016) but no mention of this is made in this Report. In the period July 2016 to June 2017 there was a further reduction in high dose PPI prescriptions. It is interesting to note that in the financial report of the same program, it is stated that the PBS item codes used in the analysis were all high dose PPIs. In contrast to the Economic Evaluation of 2018, a Review in 2012-2013 of the PPI program (2009) reported a reduction of 571,960 for high dose PPIs and an increase of 258,476 prescriptions for the lower strength PPIs. The key messages for the 2009 and 2015 programs are similar.

It would have been preferable to expand the financial analysis to the entire range of PPIs (low and high dose) in order to investigate the substitution patterns. For example, an examination of how many concessional patients reduced their dose of PPIs or ceased therapy within the time period of analysis would be highly informative and give a clearer insight into PPI use in this cohort.

Another confounder in the interpretation from the analysis is the cumulative effects of multiple programs regarding the quality use of PPIs from the TGA, DVA's MATES program and Choosing Wisely initiatives. In the Economic Evaluation of August 2018 on this program, no mention is made of these other initiatives and full attribution to the cost saving is given to NPS MedicineWise's activities, primarily the PBS feedback. This adds further to the uncertainty around the Benefit to Cost ratio provided in the Economic Evaluation.

Recommendation. In the estimation of savings to MBS and PBS using time-series analysis, the issue of substitution must be taken into account. Savings claimed from reduction of one medicine could be offset by substitution to alternate therapies.

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8.4 Summary

While accepting the adoption of the use of an interrupted time-series approach as an appropriate methodology by which to assess the cost benefits of interventions, the Review acknowledges the need for greater transparency and documentation of the financial impact of NPS MedicineWise's programs. The limitations of the estimates of savings needs better identification including that of substitution where applicable. In view of the concerns expressed above, the Review believes there is uncertainty in regard to the magnitude of any net savings to the PBS and MBS systems.

Recommendation. A formal financial methodology and process should be agreed between the Department and NPS MedicineWise that addresses the following issues:

- The selection of programs/activities to include in the annual financial impact reports.
- The specifications of a costing methodology, that aligns with Australian Government policy costing guidance, particularly on the qualitative explanations to accompany the financial impact report.
- The selection of data sources and the documentation of the source and any limitations it might present.
- The use of assumptions and the requirement to provide clear and plain English explanations on the impact of those assumptions on the overall reliability of the financial impact.
- Guidance on when savings can be considered ongoing or whether they are temporary in nature.

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9 Conclusion

As the national organisation funded by the Commonwealth Government to implement the NSQUM, NPS MedicineWise's actions must embody the Strategy's five Principles which are:

- The primacy of consumers;
- Partnership;
- Consultative, collaborative, multidisciplinary activity;
- Support for existing activity; and
- Systems-based approaches.

The Review acknowledges the reduction in funding will require a response from NPS MedicineWise including its role in the ecosystem and the potential to leverage the Grants funds through partnerships that deliver QUM outcomes.

The Review's stakeholder consultations suggest that NPS MedicineWise had been withdrawing from its national QUM stewardship responsibilities: increasingly adopting a transactional rather than relational approach to its QUM programs; reducing collaboration and limiting the flow of information about its programs. This is resulting in a lack of co-ordination and duplication of effort. This response to the changing quality use of medicine landscape and the reduction in Commonwealth Grant funding is inconsistent with the role that NPS MedicineWise was originally established to fulfil.

This Review is an opportunity for NPS MedicineWise to assess its processes for delivering programs, consider structural changes and explore opportunities to leverage partnerships that increase efficiencies and reduce duplication.

An important question for NPS MedicineWise to consider is – do they want to be another player competing for QUM funding or demonstrate their expertise and national leadership capability by delivering their programs in a manner that creates environments consistent with the principles of the National QUM strategy?

The growing complexity of the QUM landscape reinforces the need for NPS MedicineWise to promote the five NSQUM principles in the identification, design and implementation of all programs funded through the Government-NPS MedicineWise Agreement arrangements.

NPS MedicineWise has been a government preferred provider for QUM activities because it is independent, has recognised expertise and a record of producing high quality evidence-based resources. To maintain this position it has to re-establish itself as the steward of QUM in Australia and adopt a more collaborative approach to working with stakeholders. This may result in NPS MedicineWise refocusing its efforts onto under-served

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QUM priorities such as promoting QUM for multi-morbid patients and exiting areas where other providers are competing commercially such as the provision of CPD.

The Government's investment in MedicineInsight is a strategic asset worthy of continued support. However, NPS MedicineWise's financial processes need to be able to transparently demonstrate that Grant funding is only used for the purpose for which it was given.

Furthermore, the method currently used by NPS MedicineWise to evaluate savings to the PBS and MBS needs to be transparently applied and reported in a manner consistent with the requirements of the Government's approach to calculate savings.

Any new Grant Agreement should recognise that NPS MedicineWise's role is greater than a provider of education, ensure that program selection is not dominated by the need to deliver PBS and MBS savings and encourage the organisation to take on a greater QUM stewardship role.

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11 Appendix

Appendix A - List of Submissions

No.	Organisation/Name	Date	Internal/ External
1	Ms Debra Kay, Representative NPS MedicineWise Consumer Advisory Committee (2011-2013) & NPS MedicineWise Board (2013-2018)	04-Jan-19	External
2	Professor Richard Day AM MD FRACP, Professor of Clinical Pharmacology, University of New South Wales, Medicine - St Vincent's Hospital	09-Jan-19	External
3	Australian Healthcare & Hospitals Association (AHHA)	21-Jan-19	External
4	Mr Frank Formby, Palliative care physician	11-Jan-19	External
5	Primary Care Taskforce, Department of Health	11-Jan-19	Internal
6	Optometry Australia	15-Jan-19	External
7	Dr Christine Walker, CEO - Chronic Illness Alliance	16-Jan-19	External
8	Office of Health Protection (OHP), Department of Health	18-Jan-19	Internal
9	Consumers Health Forum of Australia (CHF)	18-Jan-19	External
10	Zachary Zhiyong SUM, Pharmacist	20-Jan-19	External
11	Name Withheld	21-Jan-19	External
12	Primary Health Care Institute	21-Jan-19	External
13	Northern Territory PHN (NT PHN)	22-Jan-19	External
14	Monthly Index of Medical Specialities (MIMS) Australia	22-Jan-19	External
15	Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT)	22-Jan-19	External
16	Ms Jan Donovan, CHF Board member, member of DUSC, NPS MedicineWise Board member (1998-2007)	22-Jan-19	External
17	Capital Health Network - ACT PHN	23-Jan-19	External
18	Robert Wade, Member of the public	23-Jan-19	External
19	Painaustralia	23-Jan-19	External
20	Lung Foundation Australia	23-Jan-19	External
21	Mary Hemming AO, pharmacist and an epidemiologist, CEO of Therapeutic Guidelines (1996-2012)	23-Jan-19	External
22	Name Withheld	23-Jan-19	External
23	Australian Medical Association (AMA)	23-Jan-19	External
24	Health Products Regulation Group (HPRG), Department of Health	23-Jan-19	Internal
25	Editorial Executive Committee of Australian Prescriber	24-Jan-19	External
26	Victorian and Tasmanian PHN Alliance	24-Jan-19	External
27	Australian College of Nurse Practitioners (ACNP)	24-Jan-19	External
28	The Royal College of Pathologists of Australasia (RCPA)	24-Jan-19	External
29	Western Australian Primary Health Alliance (WAPHA) - Perth North, Perth South, Country WA PHN	24-Jan-19	External
30	Medicines Australia	24-Jan-19	External
31	NSW Therapeutic Advisory Group (NSW TAG)	24-Jan-19	External
32	Medical Defence Association of South Australia & Medical Insurance Australia Pty Ltd (MIGA)	24-Jan-19	External
33	Royal Australian & New Zealand College of Psychiatrists	24-Jan-19	External

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No.	Organisation/Name	Date	Internal/ External
34	Australian Primary Health Care Nurses Association (APNA)	24-Jan-19	External
35	The Pharmacy Guild of Australia	24-Jan-19	External
36	The Australian & New Zealand Society of Palliative Medicine (ANZSPM)	24-Jan-19	External
37	Pharmaceutical Society of Australia (PSA)	24-Jan-19	External
38	Dr David Liew, Consultant Rheumatologist and Clinical Pharmacologist - Austin Health	24-Jan-19	External
39	Australian College of Rural and Remote Medicine	25-Jan-19	External
40	Council of Australian Therapeutic Advisory Groups (CATAG)	25-Jan-19	External
41	Medical Oncology Group of Australia (MOGA)	25-Jan-19	External
42	Margaret Williamson, Epidemiologist	25-Jan-19	External
43	Hepatitis Australia	25-Jan-19	External
44	Mary Murray, Former Chair of the PHARM Working Party and Advisory Committee (1991-1995)	29-Jan-19	External
45	Professor Catherine Hill MBBS MD MSc FRACP, Director, Rheumatology Unit, The Queen Elizabeth Hospital	30-Jan-19	External
46	Dr Craig Boutlis, Infectious Diseases Physician	30-Jan-19	External
47	The Royal Australian College of General Practitioners (RACGP)	01-Feb-19	External
48	Australian Rheumatology Association (ARA)	01-Feb-19	External
49	Australian Commission on Safety and Quality in Health Care (ACSQHC)	04-Feb-19	External
50	Australian and New Zealand College of Anaesthetists (ANZCA)	05-Feb-19	External
51	The Society of Hospital Pharmacists of Australia (SHPA)	07-Feb-19	External
52	staff of Australian Medicines Handbook (AMH)	07-Feb-19	External
53	Department of Veterans' Affairs (DVA)	08-Feb-19	External
54	NPS MedicineWise	26-Feb-19	External

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Appendix B - List of Interviews

No.	Meetings	Location	Internal/ External
1	Mr Chris Bedford, Assistant Secretary - Primary Health Networks Branch, Department of Health	Canberra	Internal
2	Professor Libby Roughead, Director - Quality Use of Medicines and Pharmacy Research Centre, University of south Australia	Adelaide	External
3	Professor Debra Rowett - Drug and Therapeutics Information Service (DATIS) Adelaide External	Adelaide	External
4	Mr Steve Morris, CEO and staff of NPS MedicineWise	Sydney	NPS MedicineWise
5	Professor Andrew McLachlan AM, Chair of Safety and Quality Medicines Oversight Committee	Sydney	External
6	Mr Chris Leahy, Director - eHealth and Medication Safety, Australian Commission on Safety and Quality in Health Care (ACSQHC)	Sydney	External
7	Professor Andrew Wilson, Chair of PBAC. Sydney University	Sydney	External
8	Professor Robyn Ward, Executive Dean Faculty of Medicine and Health	Sydney	External
9	Ms Barbara Whitlock, Director - Data Development and Informatics Section, Health Economics and Research Division, Department of Health	Canberra	Internal
10	Ms Libby Kerr, Director and staff of Supply Programs Section - Technology Assessment and Access Division, Department of Health	Canberra	Internal
11	Ms Natasha Ploenges, Director - Pharmacy Policy & Stakeholder Engagement Section, Technology Assessment and Access Division, Department of Health	Canberra	Internal
12	Ms Monique Machutta, Director - Practice Support Section, Primary Health Networks Branch, Department of Health	Canberra	Internal
13	Professor Jennifer H Martin and P&A Executive - Royal Australasian College of Physicians	Sydney	External
14	Professor Richard Day AM MD FRACP, Professor of Clinical Pharmacology, University of New South Wales, Medicine - St Vincent's Hospital	Sydney	External
15	Professor Lyn March AM - Australian Rheumatology Association	Sydney	External
16	Associate Professor Winston Liauw, Board Member - NPS MedicineWise	Sydney	NPS MedicineWise
17	Dr Andrew Knight, Board Member - NPS MedicineWise	Sydney	NPS MedicineWise
18	Ms Leanne Wells, CEO, Ms Jo Root, Policy Manager, and Ms Leanne Kelly, Safety Policy Officer - Consumer Health Forum	Canberra	External
19	Mr Michael Frost - Primary Health Care & Veterans Group, Australian Institute of Health & Welfare	Canberra	External
20	Ms Rachel Meyer, Assistant Director and Mr Stephen Hall, Consultant - Primary Healthcare Reporting and Data Quality Section, Indigenous Health Division, Department of Health	Canberra	Internal
21	Name Withheld	Melbourne	External
22	Ms Toni Riley, Project Manager - National Return and Disposal of Unwanted Medicines	Melbourne	External
23	Mr Adam McLeod, CEO - Outcome Health	Melbourne	External
24	Adj. Professor Chris Carter, CEO and Ms Julie Bornikhof, Deputy CEO - North Western Melbourne PHN	Melbourne	External

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No.	Meetings	Location	Internal/ External
25	Ms Mary Hemming AO, CEO - Therapeutic Guidelines Ltd from 1997-2012	Melbourne	External
26	Mr Peter Turner, Chair of NPS MedicineWise Board	Melbourne	NPS MedicineWise
27	Mrs Susan Edwards, Consultant Clinical Pharmacist	Adelaide	External
28	Professor Nigel Stocks, Chair of NPS Data Governance Committee	Adelaide	External
29	Ms Simone Rossi, Managing Editor and staff of the Australian Medicines Handbook	Adelaide	External
30	Ms Jane Goode, Innovation & Design Officer - Adelaide PHN	Adelaide	External
31	Dr Chris Freeman, National President - Pharmaceutical Society of Australia	Brisbane	External
32	Ms Sue Scheinpflug, CEO and Ms Sharon Sweeney, General Manager of Primary Health - Brisbane South PHN	Brisbane	External
33	Ms Libby Dunstan, Deputy CEO and Amanda Queen, Primary Care Liason - Brisbane North PHN	Brisbane	External
34	Dr Stephen R Phillips, Inaugural Chair of NPS MedicineWise from 1998 - 2006	Brisbane	External
35	Ms Debbie Rigby, Board Member - NPS MedicineWise	Brisbane	NPS MedicineWise
36	Mr Andrew Simpson, Assistant Secretary - Medicare Review Unit, Department of Health	Canberra	Internal
37	Ms Carol Bennett, CEO - Painaustralia	Canberra	External
38	Health Products Regulation Group, Department of Health	Canberra	Internal
39	Dr Jo-Anne Manski-Nankervis, Senior Lecturer - Primary Care, Department of General Practice, Melbourne Medical School, Faculty of Medicine, University of Melbourne, Dentistry & Health Science	Teleconference	External

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Appendix C - Information Request to NPS MedicineWise

Review of the Delivery of QUME programs by NPS MedicineWise: Request for Documents and Information

Terms of Reference	#	Information Requested	Due Date
Governance, Transparency and Accountability	1	NPS MedicineWise's organisational structure including information on all its advisory structures and expertise including their connections with activities funded by the Commonwealth Government.	24-Jan-19
	2	A list of all Commonwealth Government funding that NPS MedicineWise receives for its activities listing the sources, amounts and purpose for each program/activity.	24-Jan-19
	3	A list of NPS MedicineWise Standard Operating Procedures including its Risk Management Framework.	24-Jan-19
	4	NPS MedicineWise processes for determining resource allocations including the allocation of funding to the six Department of Health funded activities and the attribution of staff time and other resources to each activity. For example, the formulae for attributing fixed costs.	1-Feb-19
	5	NPS MedicineWise's relationship with VentureWise including: a. VentureWise's use of and payments for MedicineInsight data; b. MedicineInsight's processes for accepting VentureWise requests for data; c. The allocation of Commonwealth funded NPS MedicineWise staff and resources to VentureWise activities.	1-Feb-19

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Terms of Reference	#	Information Requested	Due Date
	6	<p>NPS MedicineWise's relationship with MedicineInsight including:</p> <ul style="list-style-type: none"> a. the differences between MedicineInsight and alternative programs currently being used by primary health care providers eg Polar and PenCS; b. any fees or charges for access to MedicineInsight data levied and the organisations that purchase this information; c. information on the Independent Data Governance Committee. 	1-Feb-19
	7	<p>NPS MedicineWise's implementation of Choosing Wisely including:</p> <ul style="list-style-type: none"> a. The scope of NPS MedicineWise's Choosing Wisely activities; b. Commonwealth Government funding allocated to different Choosing Wisely activities; c. Arrangements with learned Collages in regard to the preparation and ownership of material. 	1-Feb-19
	8	<p>At least three illustrative case studies to explain NPS MedicineWise's program development processes covering topic selection, strategy development, implementation and evaluation.</p>	1-Feb-19
Efficiency and Effectiveness	9	<p>Information on the mechanisms NPS MedicineWise uses to measure the effectiveness of its programs including:</p> <ul style="list-style-type: none"> a. Annual budgets for each program; b. Program Logic Models; c. Monitoring and reporting requirements (frequency and nature); d. Performance Measures (KPIs) and how these are determined; d. Performance reports; f. It would also be useful to understand whether MedicineWise have any data/statistics on the proportion of evaluations that include a savings/economic/financial assessment. 	7-Jan-19

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Terms of Reference	#	Information Requested	Due Date
Savings Methodology	10	<p>The following documents/information to enable an assessment of the savings methodology used by NPS MedicineWise.</p> <ul style="list-style-type: none"> a. Policy or procedural documents describing the methodology for determining savings/economic/financial impact of programs/activities/measures; b. Policy or procedural documents describing evaluation methodologies (or extracts relevant to determine savings); c. Spreadsheet models used to determine savings/economic/financial impact; d. Any internal or external reviews or audits on savings generated by NPS MedicineWise; e. Examples of the savings/economic/financial methodology being applied in evaluations (for example the reviews assessed by Viney <i>et al</i>); f. Any working documents or explanations on how the total value of savings reported in the NPS MedicineWise Annual Report have been determined. 	7-Jan-19
Linkages with relevant stakeholders (QUM Ecosystem)	11	<p>An NPS MedicineWise map of all its interactions with stakeholders within the QUM ecosystem including interactions and financial transactions with the following:</p> <ul style="list-style-type: none"> a. Primary Health Networks; b. Pharmacy; c. Medical specialists; d. Health Consumer or Disease Specific Organisations; e. Private Health Insurers; f. State-based QUM activities including CATAG; g. Australian Commission on Safety and Quality in Health Care; h. NPS MedicineWise's relationship building activities including marketing, public affairs, promotions and conferences including budgets allocation for each. 	1-Feb-19

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Appendix D - List of NPS MedicineWise Members

1. Asthma Australia
2. Australian Association of Consultant Pharmacy (AAPC)
3. Australasian Medical Writers Association (AMWA)
4. Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT)
5. Australian and New Zealand College of Anaesthetists (ANZCA)
6. Australian College of Nursing (ACN)
7. Australian College of Nurse Practitioners (ACNP)
8. Australian College of Rural and Remote Medicine (ACRRM)
9. Australian Dental Association (ADA)
10. Australian Government Department of Health
11. Australian Government Department of Veterans' Affairs (DVA)
12. Australian Healthcare & Hospitals Association (AHHA)
13. Australian Medical Association (AMA)
14. Australian Nursing and Midwifery Federation (ANMF)
15. Australian Pensioners and Superannuants Federation
16. Australian Primary Health Care Nurses Association (APNA)
17. Australian Private Hospitals Association
18. Australian Self-Medication Industry (ASMI)
19. Carers Australia
20. Chronic Illness Alliance
21. Consumers' Health Forum of Australia (CHF)
22. Council on the Ageing (COTA)
23. Diabetes Australia
24. Federation of Ethnic Communities' Councils of Australia (FECCA)
25. Generic and Biosimilar Medicines Association
26. Health Education Australia Limited (HEAL)
27. Lung Foundation Australia
28. Medical Software Industry Association (MSIA)
29. Medicines Australia
30. National Aboriginal Community Controlled Health Organisation (NACCHO)
31. National Asthma Council of Australia
32. National Heart Foundation of Australia
33. NSW Therapeutic Advisory Group Inc. (NSW TAG)
34. Optometrists Association Australia
35. Palliative Care Australia
36. Pharmaceutical Society of Australia (PSA)
37. Pharmacy Guild of Australia
38. Royal Australasian College of Physicians (RACP)
39. Royal Australian College of General Practitioners (RACGP)
40. Royal Australian and New Zealand College of Psychiatrists (RANZCP)
41. Royal Australian and New Zealand College of Radiologists (RANZCR)
42. Royal College of Pathologists of Australasia (RCPA)

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43. Rural Doctors Association of Australia (RDAA)
44. Society of Hospital Pharmacists of Australia (SHPA)
45. Therapeutic Guidelines Ltd

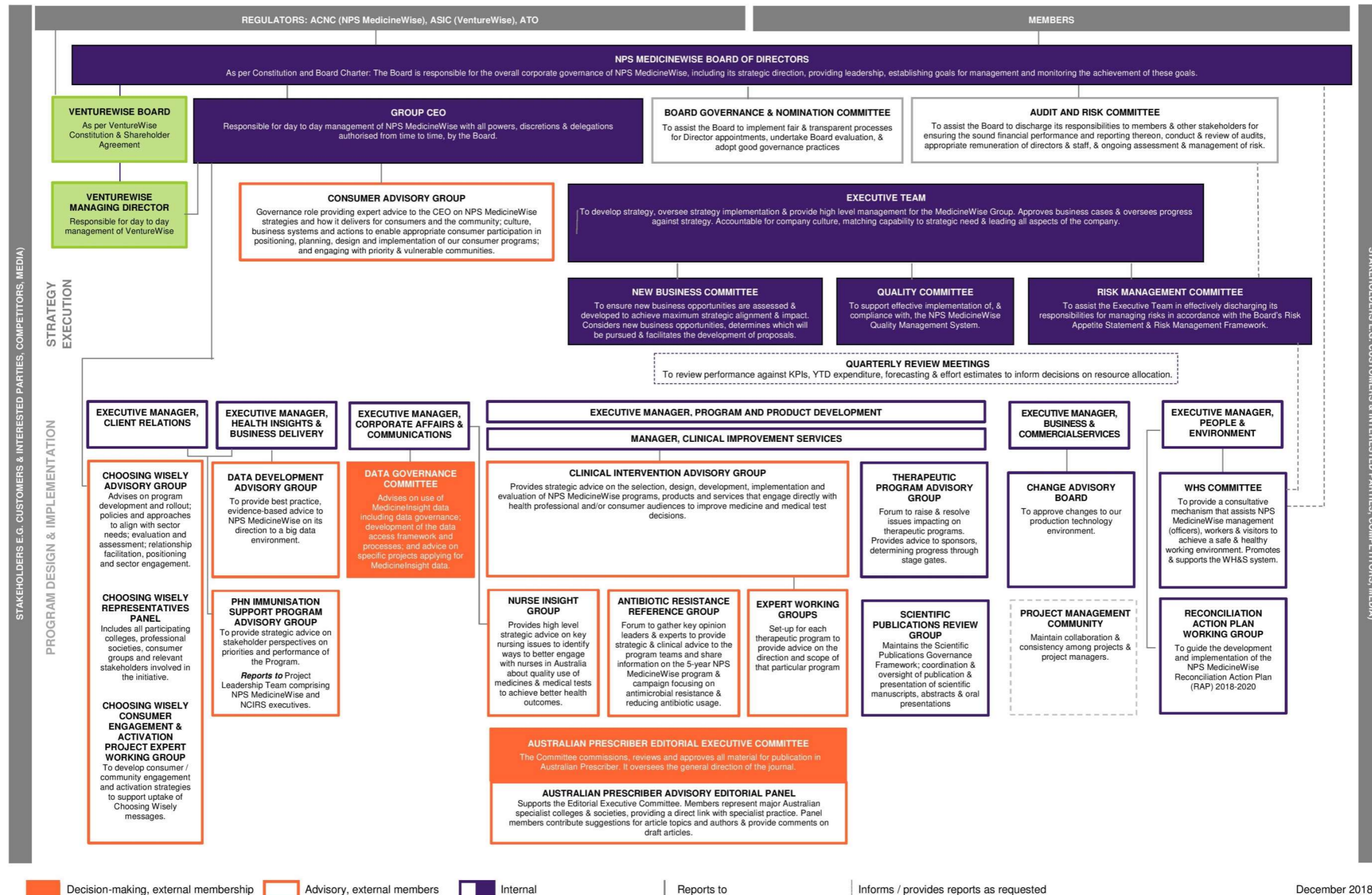
Honorary Members

1. Dr John Aloizos AM
2. Dr Stephen Phillips AM
3. Emeritus Professor Anthony Smith AM
4. Emeritus Professor Lloyd Sansom AO
5. Professor Andrea Mant
6. Ms Mary Hemming AO
7. Mr Gerard Stevens AM
8. Mr Tony Wade
9. Ms Jan Donovan
10. Ms Janne Graham AM
11. Professor Richard Day AM
12. Professor Gillian Shenfield AM
13. Mr Simon Appel OAM
14. Dr Susan Hunt
15. Professor Robert Moulds
16. Ms Jo Watson
17. Dr Geraldine Moses AM
18. Mr Mitchell Claes

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Appendix E - MedicineWise Group Governance (50)

MEDICINEWISE GROUP GOVERNANCE



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Appendix F - Clinical Intervention Advisory Group (CIAG) Membership

- Tim Usherwood (Chair) Professor General Practice, University of Sydney
- Meera Agar Professor Palliative Medicine, University of Technology Sydney
- Luke Bereznicki, Professor Pharmacy Practice, University of Tasmania
- Melissa Cromarty Team Leader, Practice Support and Development, Hunter New England and Central Coast PHN
- Kirsten McCaffery Professor Health Psychology, School of Public Health, University of Sydney
- Anthony Rodgers Professor Global Health Sciences, The George Institute
- Ian Scott Director, Department of Internal Medicine and Clinical Epidemiology, Princess Alexandra Hospital
- Mieke van Driel Professor General Practice, University of Queensland
- Rachelle Buchbinder Professor Clinical Epidemiology, Monash University
- Darlene Cox Executive Director, Health Care Consumers' Association ACT
- Debra Kay, Senior Consumer Representative, Consumers Health Forum of Australia (CHF), Chair, MBS Review Consumer Panel, Consumer Advocate, Health Consumers Alliance South Australia (HCA)

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Appendix G - Lists of all the projects supported by MedicineInsight Data

Projects via VentureWise Pty Ltd

Year	Funder	Project Title	Summary
2016	Gilead	Assessing the management of renal toxicity in primary care associated with Stribild™	This project uses MedicineInsight data to assess if Highly Specialised Drugs (s100) prescribers of human immunodeficiency virus (HIV) medicines are managing appropriately the renal toxicity risks associated with Stribild™. The use of MedicineInsight data will provide evidence of the utility of the data to support risk management plans and help to develop strategies to support safety of new pharmaceutical products.
2017	Sanofi Genzyme and BioMarin Pharmaceutic al Australia	Finding improved pathways to diagnosis of mucopolysaccharidoses (MPS) disorders	The objective of this project is to analyse MedicineInsight data to determine if there are any patterns in mucopolysaccharidoses (MPS) disorders cases that may facilitate an earlier diagnosis of these disorders. The MedicineInsight data analysis was used to provide a preliminary report identifying data potential and limitations for this purpose.
2017	AstraZeneca	Prevalence of hyperkalaemia in general practice using MedicineInsight data	This project uses MedicineInsight data to estimate the prevalence of hyperkalaemia in primary care. The outputs of this project will inform an evidence-based submission to the Pharmaceutical Benefits Advisory Committee (PBAC) by the funder who is also the sponsor for a new potassium-binding medicine for the treatment of hyperkalaemia in adults.
2017	Amgen	Osteoporosis feasibility assessment	This project uses MedicineInsight data to better understand the prevalence and management of osteoporosis in general practice. The outputs of the data analysis will be used to inform future education interventions and practice reports delivered independently by NPS MedicineWise.

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Year	Funder	Project Title	Summary
2017	Gilead	Hepatitis C educational and quality improvement program for general practice	<p>NPS MedicineWise is undertaking a project in general practice to support general practitioners (GP) in the diagnosis and management of patients with chronic hepatitis C infection. The project will focus on the appropriate use of medical tests and medicines, and a quality improvement program designed and developed as a result of the analysis from the MedicineInsight data will be delivered to about 100 general practices across Australia.</p> <p>Publication: Chidwick K, Kiss D, Gray R, Yoo J, Aufgang M, Zekry A. Insights into the management of chronic hepatitis C in primary care using MedicineInsight. Aust J Gen Pract 2018;47:639-45.</p>
2017	Gilead	Preventive cardio-metabolic health care in general practice for people living with HIV compared with the general population	<p>Human immunodeficiency virus (HIV) is an important health problem in Australia. People living with HIV have higher risks of developing cardiovascular disease. NPS MedicineWise is aiming to use MedicineInsight data to compare and identify gaps in the management of cardiovascular risk factors of people living with HIV. The results of the analysis will be used to develop an educational program for selected general practices treating people with HIV. Outcomes of the project will be made public on the NPS MedicineWise website.</p> <p>Publications (2 planned)</p>
2017	Medtronic	Study to describe the prevalence and characterisation of aortic stenosis in Australian general practice	<p>This project is examining MedicineInsight data to provide preliminary understanding of prevalence of aortic stenosis in primary care and specific population characteristics, including those used to guide clinical management.</p>

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2018	Boehringer Ingelheim	Diagnosed conditions for prescribing tiotropium	This project used MedicineInsight data to generate a report showing evidence on diagnosed conditions for prescribing tiotropium (a PBS-listed medicine). The report will be submitted by the funder, as the sponsor of the medicine, to the PBAC to provide evidence-based information about the medicine to support PBAC decision making.
2018	MTPConnect	Feasibility of MedicineInsight data to support clinical trials in Australian general practice	This project is testing the feasibility of using MedicineInsight data to setting up clinical trial sites in Australia and identifying potential patients to be recruited into clinical trials.
2018	Theramex	A pharmaco-epidemiological study of osteoporosis management in Australian general practice	The aim of this project is to determine the prevalence and patterns of osteoporosis treatment pathways and treatment-associated outcomes. The analysis of MedicineInsight is part of a broader project which will also recruit GPs with high numbers of cases of osteoporosis patients for interview on reasons for treatment pathways. Publications (1 planned)
2018	Emerge Health	Management of Crohn's disease in Australian general practice	This project used MedicineInsight data to generate a report on the prevalence and pharmaceutical treatment of Crohn's disease. The report will be submitted by the funder, as the sponsor of budesonide oral, a medicine used to treat Crohn's disease, to the PBAC to provide evidence-based information about the medicine to support PBAC decision making.
2018	Vifor	Iron deficiency and associated conditions in Australian general practice	MedicineInsight was studied to understand the diagnosis and management of iron deficiency, and characterisation of patients with iron deficiency. It is anticipated that the results of this study may form the basis for future research and potentially inform the development of educational interventions aimed at improving outcomes for patients.

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2018	Gilead	Evaluating the impact of the 2017 NPS MedicineWise educational quality improvement program to improve the management of chronic hepatitis C in general practice	The purpose of this study was to use MedicineInsight data to evaluate how an educational intervention, designed by NPS MedicineWise and delivered to general practices participating in the MedicineInsight program between October and December of 2017, impacted on the treatment and management of patients with CHC.
2018	Gilead	A cluster randomised controlled trial of a MedicineInsight educational quality improvement program to enhance the diagnosis and treatment of chronic hepatitis C in general practice (the EQUIP-HEPC trial)	The purpose of this study is to evaluate the effectiveness of the NPS MedicineWise educational intervention to enhance case finding, assessment and treatment of patients with CHC using MedicineInsight data. The results of this trial will help inform future initiatives in Australia as well as internationally to continue the treatment momentum to help eliminate CHC.

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Non-QUME projects

Year	Funder	Project Title	Summary
2016	Cancer Institute of NSW (CINSW)	Lung cancer management in primary care: Feasibility project	This program aimed to test the feasibility of using MedicineInsight data to gain insights into the primary care provided to patients diagnosed with lung cancer since the time of their first recorded diagnosis. The data analysis will assist the Cancer Institute New South Wales (CINSW) to better understand the impact of lung cancer on general practices and improve development and evaluation in this field, with primary health care.
2016	DOH	MedicineInsight report on general practice activity in Australia 2015-2016	This project uses MedicineInsight data to generate a report describing patient's management including number of encounters and prescriptions for common conditions such as type 2 diabetes mellitus, chronic obstructive pulmonary disease (COPD) and depression. The representative of MedicineInsight data is compared with other data sources such as Australian Medical Publishing Company, General Practice Workforce Statistics, Medical Benefits Schedule (MBS) statistics, among other national data sources.
2017	Australian Commission on Safety and Quality in Health Care	Antimicrobial Use and Resistance in Australia (AURA) - 2017 report	The Antimicrobial Use and Resistance in Australia (AURA) Surveillance System objective is to prevent and contain the risk of antimicrobial resistance for human health. This program reports on the use and appropriate prescription of antimicrobials in hospitals, aged care homes and the community. MedicineInsight data is used for the generation of the AURA 2017 report that will be made available on the Australian Commission on Safety and Quality in Health Care webpage.
2017	Australian Digital Health Agency	The impact of My Health Record use in primary care: Qualitative study	This project uses MedicineInsight data to explore the use of the My Health Record in relation to medication management, in particular by determining high users of the My Health Record in NSW and Victoria, to recruit GPs and consumers to conduct in-depth interviews. The outcome of this study will also help inform other studies focusing on the impact of My Health Record in primary care.

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Year	Funder	Project Title	Summary
2017	Australian Digital Health Agency	The impact of My Health Record use in primary care: Quantitative study	This project is a continuation of the qualitative study undertaken by NPS MedicineWise, to explore the use of the My Health Record in relation to whether having a My Health Record reduces duplication of tests and prescriptions for people concurrently attending multiple practices, and the measurement of the proportion of allergy and adverse drug reactions captured in the practice clinical information system and the My Health
2017	Department of Health	Identifying factors and subpopulations associated with high use and high cost of services in general practice. A feasibility study	This project uses MedicineInsight data to determine which demographic factors and comorbidities are associated with high service use and high service costs in the general practice setting. The outputs of the data analysis will generate a report that will be used by NPS MedicineWise and the Menzies Centre for Health Policy to develop a simulation model to identify the impact of interventions to reduce low value care.
2017	Department of Health	Health Care Homes evaluation	
2018	Department of Health	MedicineInsight report on general practice activity in Australia 2016-2017	This project uses MedicineInsight data to generate a report describing patient's management including number of encounters and prescriptions for common conditions such as type 2 diabetes mellitus, chronic obstructive pulmonary disease (COPD) and depression. The representative of MedicineInsight data is compared with other data sources such as Australian Medical Publishing Company, General Practice Workforce Statistics, MBS statistics, among other national data sources.

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2018	Australian Commission on Safety and Quality in Health Care	Antimicrobial Use and Resistance in Australia (AURA) - 2019 report	The Antimicrobial Use and Resistance in Australia (AURA) Surveillance System objective is to prevent and contain the risk of antimicrobial resistance for human health. This program reports on the use and appropriate prescription of antimicrobials in hospitals, aged care homes and the community. MedicineInsight data is used for the generation of the AURA 2019 report that will be made available on the Australian Commission of Safety and Quality in Health Care webpage.
2018	TGA (Therapeutic Good Administration)	A pharmaco-epidemiological study of Pregabalin in Australian general practice	This study describes the pharmaco-epidemiological profile of Pregabalin prescribing in Australian general practice. The results of this study are intended to guide the assessment of safe use of Pregabalin in general practice by the TGA.
2018/19	TGA (Therapeutic Good Administration)	A pharmaco-epidemiological study of Fentanyl and opiate prescribing in Australian general practice	This study describes the pharmaco-epidemiological profile of Fentanyl patches prescribing in Australian general practice. The results of this study are intended to guide the assessment of safe use of Fentanyl patches in general practice by the TGA.
2019	Department of Health	MedicineInsight report on general practice activity in Australia 2017-2018	This project uses MedicineInsight data to generate a report describing patient's management including number of encounters and prescriptions for common conditions such as type 2 diabetes mellitus, chronic obstructive pulmonary disease (COPD) and depression. The representative of MedicineInsight data is compared with other data sources such as Australian Medical Publishing Company, General Practice Workforce Statistics, MBS statistics, among other national data sources.

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Health Analytics Work – Practice Reports (non-QUME)

Year	Project Title	Summary
2017	HCV	VentureWise – Gilead
2017	HIV	VentureWise – Gilead
2018	Managing Type 2 diabetes and CVD	VentureWise
2018	HIV education	VentureWise – Gilead
2019	HCV education	VentureWise – Gilead
2019	Hunter New England Alliance – Diabetes	Contract with HNELHD

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Health analytics work – data extracts

Year	Number	Project Title	Summary
2017	1	Blood Pressure and CVD	George Institute (A Rogers)
	2	Influenza vaccine effectiveness	Adelaide University (N Stocks)
	3	Continuity primary care	Curtin University (R Moorin)
	4	Diabetes Type 2	University of Melbourne (J Manski-Nankervis)
	5	Evaluation Diabetes – Hunter NE	HNELHD (M Parsons)
	6	Hyperkalaemia	George Institute (M Jun)
	7	Infectious Diseases	University NSW (A Newall)
	8	Type 2 Diabetes	Sydney University (C Tam)
	9	End of Life	University NSW (M Cardona, Morell)
	10	Antibiotics	AURA report tables
	11	MTP Connect Clinical Trial Assist	VentureWise
2018	12	Quality in GP trial	Wollongong University (A Bonney)
	13	Heart Disease	La Trobe Uni (R Huxley)
	14	Influenza Surveillance	DHHSV (L Franklin)

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Year	Number	Project Title	Summary
	15	Thunderstorm Asthma	DHHSV (V Mulvenna)
	16	Pneumococcal 65	Adelaide University (O Frank)
	17	VPD	University NSW (R Menzies)
	18	Osteoarthritis in GP	University Melbourne (J Manksi-Nankervis)
	19	Indigenous CVD	University of Melbourne (L Burchill)
	20	Adverse events following immunisation	University NSW (Brahman)
	21	Pollen, asthma and rhinitis	University NSW (D Muscatello)
	22	Antibiotics	AURA report tables
	23	Vaccinations	AusVax
	24	My Health Record study	University Melbourne (J Manski-Nankervis)
	25	Health Care Homes evaluation	University NSW
	26	nib report and HNE expansion	VentureWise

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Appendix H - PBS Savings Claimed for the 2015-16, 2016-17 and 2017-18 financial years

Therapeutic area	Year implemented	Medicines analysed	2015-16	2016-17	2017-18
Antibiotic resistance (2004 -15, visiting and non-visiting programs) <i>Note: The 2017 and 2018 reports listed this as 'Reducing antibiotic resistance'</i>	Ongoing	Antibiotics for RTI and UTI	\$28.50m	\$20.30m	\$21.37m
Management options to maximise sleep (2009, visiting program)	2009	Benzodiazepines	\$0.50m		
Opioid use in chronic pain – use a planned approach (2010, visiting program) <i>Note: The 2017 and 2018 reports listed this as 'Chronic pain: opioids and beyond'</i>	2015	Opioid analgesics	\$1.82m	\$3.27m	\$10.45m
Cardiovascular risk – guiding lipid management (2011, visiting program)	2011	Statins Ezetimibe	\$11.77m \$5.98m	\$8.04m \$5.67m	
Balancing the benefits and harms of antipsychotic therapy (2011, visiting program)	2011	Antipsychotics	\$2.13m	\$2.05m	
Depression – challenges in primary care (2012, non-visiting program) <i>Note: The 2018 report listed this as Depression: Challenges in Primary Care (2012) and Re-examining the options</i>	2012	Antidepressants	\$15.33m	\$15.35m	\$7.55m
Exploring inhaled medicines use and asthma control (2014, visiting program)	2014	ICS/LABA combinations	\$9.18m	\$8.90m	\$10.46m
2017 Report – Blood Pressure: what's changing in how we measure, manage, monitor?	2015	Antihyperintensives		\$3.70m	\$2.71m

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Therapeutic area	Year implemented	Medicines analysed	2015-16	2016-17	2017-18
<i>Note: The 2018 Report listed this as Blood pressure: Measure, manage, monitor</i>					
2017 Report – Proton Pump Inhibitors: too much of a good thing?	2015	Proton Pump Inhibitors		\$6.37m	\$8.43m
2018 Report – Type 2 Diabetes: What's next after Metformin	2016	FDC Oral glucose-lowering agents			\$9.05m
		SGLT-2 inhibitors			\$1.60m
TOTAL REPORTED SAVINGS			\$75.21m	\$73.65m	\$71.62m

NB: A blank cell indicates that the program was not included in that years' report.

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Appendix I - The Australian Government's approach to calculating savings

The Commonwealth Government has a well defined approach to costing policy initiatives of government, including the estimation of savings. That approach is defined across a number of documents, some of which are not publicly available. However, the Department of Finance and the Parliamentary Budget Office have published guidance that provides a useful reference point in assessing the methodology applied by NPS in determining savings achieved for the PBS and MBS.

Department of Finance guidance

The Department of Finance has issued guidance in relation to how it will cost policy commitments under the Charter of Budget Honesty 1998. There are two main assumptions that are relevant for estimating savings:

- 1) Consistency and transparency in the use of assumptions;

Using the most recent data available and applying it consistently across the costing is a key factor in developing cost estimates. In addition, disclosing the nature of assumptions, and any significant caveats on the data is important.

- 2) The type of effect included in the costing

As a general rule, only direct behavioural effects are included in a costing and broader economic effects are not included. The guidance notes that this is usually due to the level of uncertainty attaching to those indirect effects.

Parliamentary Budget Office (PBO) guidance

The Parliamentary Budget Office has published a number of documents that outline key issues when developing policy costings for consideration by government. Factors affecting the quality of costings include:

- The quality of data available to undertaken the costing;
- The number and soundness of any assumptions made in the costing analysis;
- The volatility of the costing base; and
- The magnitude of the policy change.

The PBO guidance also provides information on the type of qualitative disclosures that should be made to ensure that there is transparency in the costing and that the level of uncertainty attaching to the particular costing is evident to the reader.

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Examination of costing activities by Australian National Audit Office

During 2017-18, the Australian National Audit Office (ANAO) undertook an audit of the Management of Commonwealth Leased Office Property, Report 8, 2018-2019. A key learning promulgated by the ANAO arising from that audit is that: "Where advice to government includes savings estimates, entities should ensure that the estimates are supported by a suitable model or methodology, and that government is advised of any limitation with the estimates as well as timeframes for receiving more robust advice."

Key elements identified in that Audit include:

- Identifying all relevant costs and benefits,
- Clear rationale for assumptions used,
- Verifying savings estimates if actuals become available

Further information on developing policy costings and savings is available from a number of sources including:

- Charter of Budget Honesty Policy Costing Guidelines, Department of Finance, 2018
- Information Paper 01/2017, Factors influencing the reliability of policy costings, Parliamentary Budget Office
- Information Paper 02/2017, What is a PBO Costing, Parliamentary Budget Office
- Information Paper 03/2017, Including broader economic effects in policy costings, Parliamentary Budget Office