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Australian Digital Health Agency

DISCUSSION PAPER

Co-designing and publishing a Digital Medicines Program Blueprint

31 January 2019 Version 1.0

Approved for external consultation



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Responding to this discussion paper

Throughout this discussion paper, questions have been suggested to prompt feedback and input to the development of the Digital Medicines Program Blueprint.

Responses to the discussion paper, input to the blueprint, and any questions about the project can be sent to the Nous project team at ADHA.blueprint@nousgroup.com.au.

All submissions will be kept confidential within the project team, but if your submission includes information that may be sensitive, confidential, or should otherwise have limited circulation, please contact the Nous team before submitting.

If you would like to contribute to the blueprint through workshops or meetings, please email the Nous team.

About Nous Group

Nous Group is an independent consulting company, commissioned by the Australian Digital Health Agency to support development of the Digital Medicines Program Blueprint. Nous Group is an award-winning management consulting firm. We partner with leaders across the Australian healthcare system to shape world-class services, effective policy, and empowered communities.

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1 Executive summary

Australia's National Digital Health Strategy – Safe, Seamless and Secure establishes a vision to further evolve the digital transformation of healthcare. As part of the strategy, changes to how we access, share and manage information about medicines are needed to deliver benefits to patients and the health sector more broadly. The benefits of improving medicines safety are multiple – reduced harm, greater efficiency and better use of medicines, leading to better health outcomes.

Achieving these benefits will require changes to how health professionals work, how medicines are prescribed and supplied, and how consumers use medicines. New platforms and digital enablers will be required and will be delivered across industry and the public sector. Potentially, changes in regulation and legislative frameworks will be required. Implementation and change will need collaboration between states, Commonwealth, practitioners and other healthcare providers, pharmacy, hospitals, software industry and pharmaceutical manufacturers. Health consumers will need to be involved to help others understand impact, benefits and prioritisation of the changes. Ultimately, the benefits of improved medicines safety will also be shared.

The Australian Digital Health Agency is working with stakeholders across the digital industry and health sector to develop a Digital Medicines Program Blueprint (the blueprint), as outlined in the National Digital Health Strategy and its associated Framework for Action. The Medicines Safety strategic priority in the framework comprises nine action areas to support improved access to information about medicines, their use and the monitoring and minimisation of risk and harm from medicines. It is part of the Agency's operational response to the National Digital Health Strategy. As one of the nine actions, the blueprint will set out how the Agency will progress the remaining action areas as a coherent Medicines Safety Program over the next three years, to 2022. It will help the Agency to work effectively with all stakeholders towards a shared ambition for improved medicines safety.

The Agency acknowledges that future innovation in digital medicines and digital health more broadly will likely go beyond the current scope of the Framework for Action and will be achieved through health-sector and industry-led innovation and change.

The Agency recognises the blueprint will support improvements already underway across the health sector, involving the Agency, industry, government, and other stakeholders. Progress has already been achieved in how medicines and prescriptions information are managed, including e-prescribing and real-time prescription monitoring, medicines information management, and decision support tools in multiple settings.

This discussion paper is an initial invitation to contribute to the development of the Digital Medicines Program Blueprint.

Developing the Digital Medicines Program Blueprint will need input from a broad range of stakeholders. These perspectives include health consumers, practitioners, associations and peak bodies, the pharmaceutical and medical software industries, community and hospital pharmacists and government. These views are being sought initially through this public discussion document. Specifically, comment is invited on:

- context and related activities
- information that needs to be included in the blueprint
- the importance of different actions to improve medicines safety
- change pathways to achieve digital transformation in medicines safety
- the role of the Australian Digital Health Agency to enable these changes.

Question prompts are identified in this document. We welcome input beyond these specific questions. Further opportunities will be made available for stakeholders to contribute to development of the blueprint over the coming months, including through participation in workshops, written submissions, interviews, and round-table sessions. The Agency has appointed Nous Group to support delivery of the blueprint and the consultation process. Initial research and targeted consultation with stakeholders, including with the external reference group for the Medicines Safety Program, was completed as a precursor to the release of this discussion paper.

Following the initial consultation process, a draft blueprint will be released by the Agency for further consultation and feedback. The final blueprint is due to be delivered by the Agency in mid-2019.

2 Digital medicines safety is part of Australia's National Digital Health Strategy

Through the National Digital Health Strategy, Australia's governments have committed to ensuring that all consumers and their healthcare providers have access to comprehensive views of prescribed and dispensed medications. In addition, there will be digitally enabled paper-free options for medication management in Australia by 2022. People will be able to digitally request their medicines online, and all prescribers and pharmacists will have access to electronic prescribing and dispensing. This will increase convenience for consumers filling prescriptions and improve overall safety.¹

The National Digital Health Strategy will benefit Australians by²:

- preventing adverse drug events, reducing medical errors, improving vaccination rates and bettering care coordination and information to inform treatment decisions
- sustaining a more efficient health system, through less time searching for patient data, reduction of avoidable hospitalisations, and reduced duplication of pathology tests and X-rays which inconvenience patients and increase the cost of healthcare
- improving healthcare availability and patient experience by putting the patient at the centre of their healthcare, and keeping people out of hospital
- providing greater access to healthcare for people living in rural and remote areas of Australia
- protecting the national digital health infrastructure and securing the personal health information of Australians.

The National Digital Health Strategy sets out priorities that will deliver safe, seamless and secure health information

The aim of the National Digital Health Strategy is to ensure health information is available to patients and providers whenever and wherever it is needed by 2022. Seven priority outcomes are identified in the National Digital Health Strategy:

- 1 **My Health Record** – Key health information will be available whenever and wherever it is needed.
- 2 **Secure Messaging** – Health information will be exchanged securely.
- 3 **Interoperability and Data Quality** - Enable exchange of high quality data with a commonly understood meaning that can be used with confidence.
- 4 **Medicines Safety** – Better availability and access to prescriptions and medicines information.
- 5 **Digitally Enhanced Models of Care** – Digitally enabled models of care that improve accessibility, quality, safety and efficiency.
- 6 **Workforce and Education** – A workforce confidently using digital health technologies to deliver health and care.

¹ *Australia's National Digital Health Strategy: Framework For Action- how Australia will deliver the benefits of digitally enabled health and care.* Canberra: Commonwealth of Australia; July 2018. Available from <<https://conversation.digitalhealth.gov.au/framework-for-action>>

² *Australia's National Digital Health Strategy- safe, seamless and secure: evolving health and care to meet the needs of modern Australia.* Canberra: Commonwealth of Australia; July 2018. Available from <<https://conversation.digitalhealth.gov.au/australias-national-digital-health-strategy>>

7 Driving Innovation – A thriving digital health industry delivering world-class innovation.

The National Digital Health Strategy also outlines the case for why better availability and access to prescriptions and medicines information will reduce the incidence of medication errors and adverse drug events, minimise harm to patients and create significant cost savings.

The vision for improved digital medicines safety

To deliver better health outcomes through partnerships for the provision of readily accessible, relevant, useful, usable and up-to-date information, in context, to help consumers and their healthcare providers make decisions about medicines and to support organisational change at all levels.

In July 2018, the Australian Digital Health Agency released the Framework for Action, identifying 44 actions that will be delivered between 2018 and 2022, including the Medicines Safety strategic priority.

For example; capturing a patient's current medicines and allergy information in a structured, coded, standardised and shareable form will support improved sharing of accurate and complete information across care boundaries, support quality use of medicines, prevent avoidable injuries and deaths, reduce hospital admissions and give consumers the opportunity to take more control of their own health and care.

The Australian Digital Health Agency's Medicines Safety Program aims to establish a nationally coordinated digital medicines program to assist in implementing digital services and solutions that will increase the safety and quality of medicines use across health and care.

3 The Medicines Safety strategic priority has nine actions that will be delivered by 2022

In the Framework for Action, the Medicines Safety strategic priority identifies nine actions to deliver benefits to healthcare consumers, which includes the need to establish a Digital Medicines Program Blueprint to coordinate delivery across the other eight actions. Each action will impact a consumer’s experience of using medicine and their journey through different steps in the medicines management pathway³, and will involve potentially significant changes to the ways in which the health system functions compared to today.

Each action may involve different stakeholders; some initiatives will require working with major changes that are already underway (particularly for real-time prescription monitoring and e-prescribing), whereas others (such as the national medicines data service) are not yet initiated. Further details on the actions can be found in Section 6 of this discussion paper.

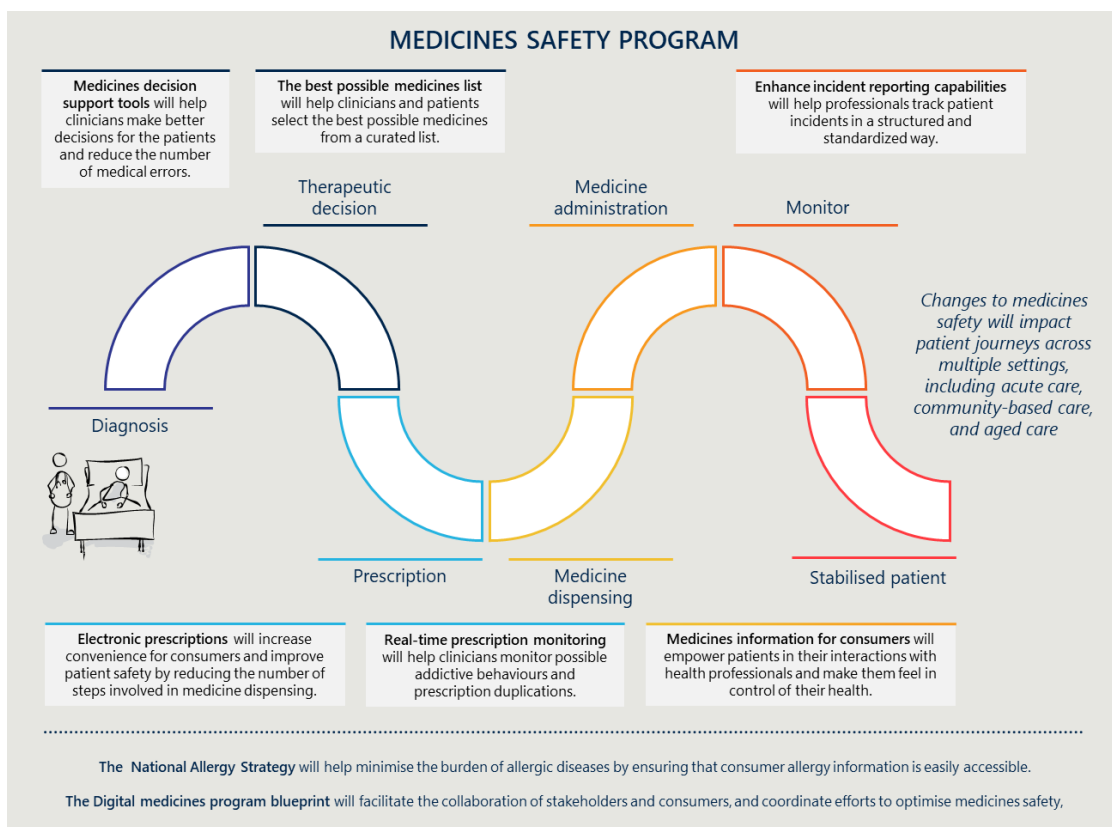


Figure 1. Overview of priority actions as they relate to the patient journey

Questions for consideration

What are the most important Actions and impacts across the patient journey?

Are there other digitally enhanced developments in addition to the eight Actions that are relevant to the patient journey?

³ Stowasser DA, Allinson YM, O’Leary KM. Understanding the medicines management pathway. J Pharm Pract Res 2004; 34: 293-6.

4 The blueprint will support and enable substantial work already underway across Australia

Changes to how medicines are prescribed, supplied and used effectively to benefit patients are being made today, and more changes are planned. This includes changes driven by governments - both State and Commonwealth - and changes that have arisen from innovative solutions to consumer needs within the technology industry and health sector. Some of these programs and projects, related to specific actions within the Medicines Safety strategic priority are highlighted below.

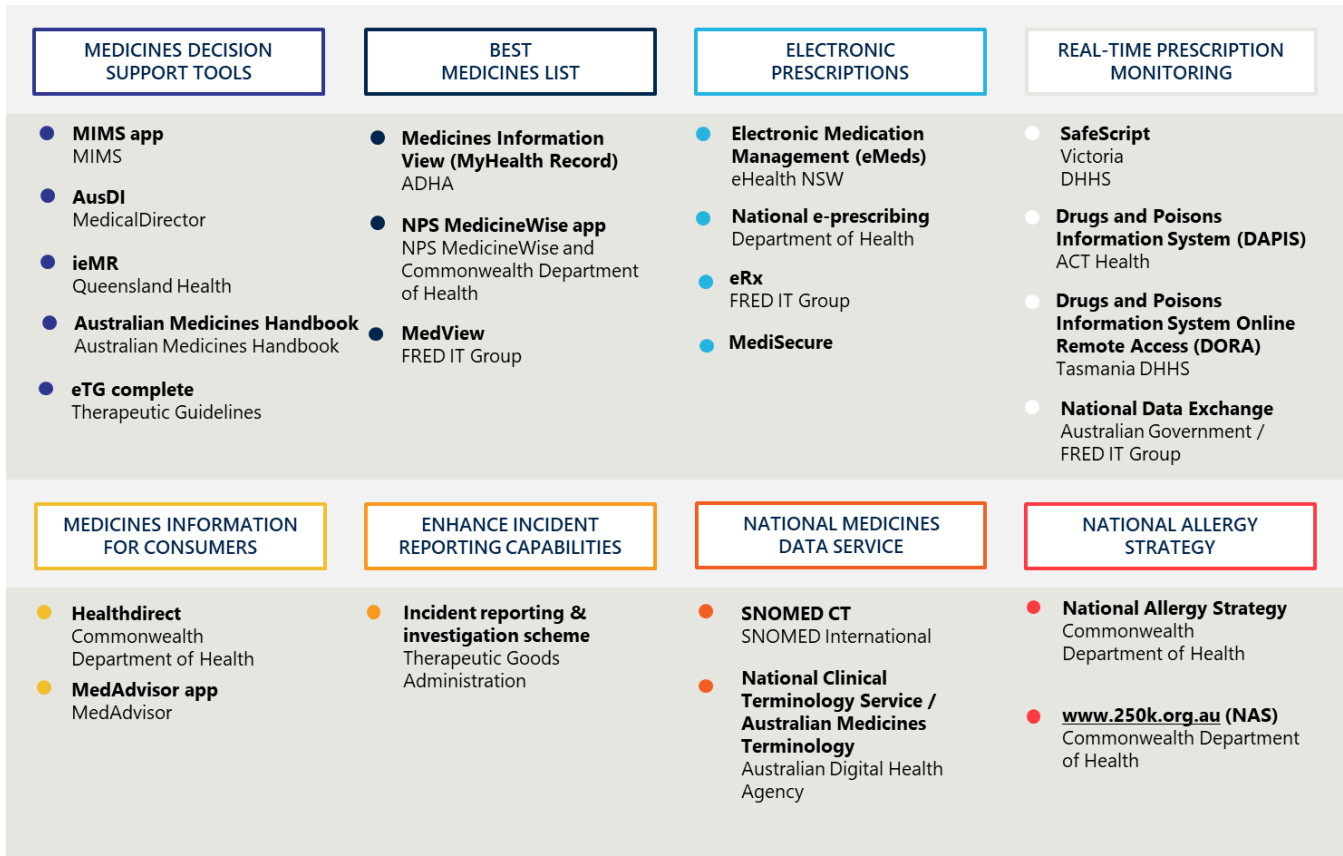


Figure 2. Examples of existing programs relating to medicines safety⁴

The blueprint will consider how current activities are linked to or included within actions, and what new activities will be needed to support other actions (such as the National Medicines Data Service). The blueprint will need to clearly identify related activities, key interfaces, and define how the Agency and other stakeholders will work together to deliver the Medicines Safety strategic priority benefits to consumers and others within the healthcare system. Delivery of the Agency's Medicines Safety Program will need to be continuously monitored in relation to the Australian healthcare landscape and help to ensure that efforts are coordinated and aligned to strategic priorities of the National Digital Health Strategy.

⁴ Example case studies from the Framework For Action

The vision for digital medicines safety involves the concerted efforts of all stakeholders

Digital health requires interdisciplinary and cross-sector collaboration. It depends as much on the expertise of technologists as it does on the expertise of clinicians. Equally, consumers, policymakers, industry experts and process engineers play vital roles in achieving digital medicines safety.

The blueprint provides an opportunity to define how stakeholders will contribute to the Medicines Safety strategic priority as identified in the Framework for Action, and what changes and initiatives will be required to deliver these actions. One of the key benefits of the blueprint will be defining how each of the actions will need to be delivered, and by whom. The Agency invites stakeholders to consider what roles they, and other stakeholders, including the Agency and its Medicines Safety Program, need to play in delivering the priority actions.

5 The blueprint will set out a planned program of actions within the Medicines Safety strategic priority area

The structure of the blueprint will identify the long-term goals to be achieved by the Agency’s Medicines Safety Program, collaborators and stakeholders and work backwards to map pre-conditions. The blueprint will provide a specific methodology for planning, participation and evaluation that clarifies how incremental progress contributes to the achievement of the long-term outcomes. It will also detail the necessary and sufficient conditions to achieving the long-term outcome – such as resourcing, governance, enabling factors, sequencing and interdependencies across actions.

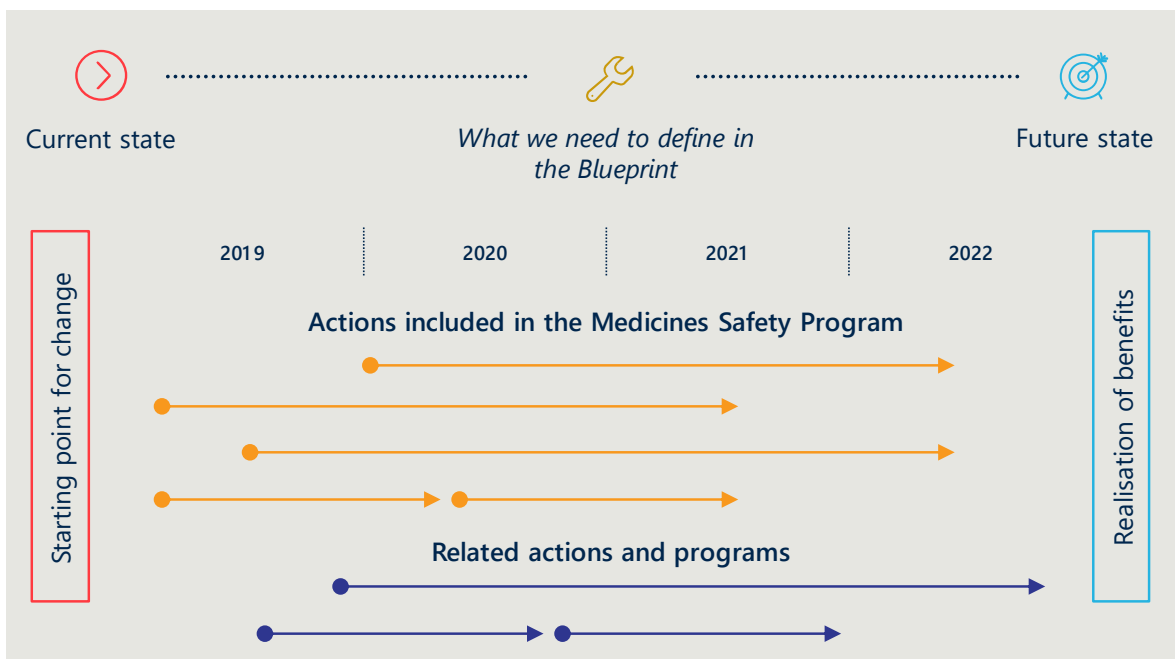











Figure 3: The blueprint will use the priority actions as building blocks to deliver the Medicines Safety strategic priority and help define the work plan for the Agency’s Medicines Safety Program.

The blueprint will support industry, government, consumers and clinicians in the delivery of digital medicines safety. There needs to be coordination and alignment of effort across Australia to maximise the positive impact of these changes on patients and consumers. While the blueprint is not intended to be a prescription of a future program of work, it will serve as a synthesis of diverse views, enable the initiation of future developments where needed and identify how interfaces with work already under way or other programs, will be managed.

The blueprint will identify, for each action:

	Success factors	What success looks like for each action
	Status	What has already been achieved
	Timeframe	When delivery needs to happen, considering dependencies and the benefits of the action
	Dependencies	What current and planned activities are pre-requisites or depend on delivery
	Responsibilities	Who will be responsible for delivery of the action, in terms of agencies, industry partners, and other stakeholders
	Risks	What are the key risks, challenges, and constraints that will need to be considered
	Benefits	What is the benefit, in terms of the health sector, patients and consumers, practitioners, or providers
	Related work	What other initiatives are related to the action, but are not pre-requisites or dependencies
	Work breakdown structure	What specific outcomes and deliverables might need to be produced under this action

Questions for consideration

- What does the blueprint need to include, both in terms of the priority actions and the Agency's Medicines Safety Program?

The blueprint will be a living document that is subject to regular reviews with stakeholders to ensure relevance and data accuracy. It is intended to be the primary workplan reference document related to the Agency's Medicines Safety Program, serving as a source of truth and the synthesis of a significant consultation process. The blueprint is vital to ensuring that all work relating to digital medicines safety is aligned, captured and made aware to stakeholders across the technology industry and the health sector. The document is especially beneficial to program managers and developers as it will enable the cross-pollination of expertise across Australia.

6 The blueprint will establish a shared understanding of each action

Questions for consideration for each of the actions

- What are the key success factors?
- What are the most important benefits?
- What are the related programs or projects which need to be further acknowledged and included in analysis and development of the blueprint?
- What are the key dependencies and related activities which need to be managed?
- Who needs to be involved in delivery and in what ways?

Each action will contribute towards delivering the overall benefits of the Medicines Safety strategic priority. The blueprint will set out the definition and planned high-level benefits for each action; detailed definitions and benefits realisation plans for each action will need to be developed and included as part of the Medicines Safety Program workplan.

Input is invited from stakeholders on the actions which are most relevant to them, as the Agency acknowledges that medicines safety and the priority actions has a broad impact across Australian health stakeholders.

A summary of the actions and highlights of related activities is presented below. These highlights are not intended to be comprehensive, but to prompt discussion and feedback on other initiatives which might be related to one or more of the actions. This could also include feedback on how innovation and change in digital health can be achieved more broadly, such as health-sector and industry-led changes outside of the Agency's plans and identified framework actions.

Further detail on the Framework for Action is available on the [Australian Digital Health Agency website](#).

6.1 Electronic prescriptions

The Australian Government will provide \$28.2 million over five years to support the national electronic prescribing system. The system will provide an option for prescribers and their patients to have a fully electronic prescription as an alternative to paper-based PBS prescriptions.

Target timeframes	Key benefits
2017/18-2018/19 Finalise legal framework and technology requirements	Greater convenience for consumers and increased capability to manage prescriptions for prescribers
2018/2020 Begin national rollout	

Examples:

eHealth NSW eMeds program

The eMeds program provides support for doctors, nurses and pharmacists to prescribe, order, check, reconcile, dispense and record the administration of medicines, will be expanded from 25 to 178 hospitals.

eRx (Fred IT Group)

The eRx platform allows the secure exchange of prescriptions between prescribers and dispensing pharmacists, using compatible software packages in practices and pharmacies. The system operates at scale, with up to 2.5 billion prescription events occurring across the platform since implementation.

6.2 Best possible medicines list

Delivered via the My Health Record system through an improved Available Medicines View, the best possible medicines list will be developed in a structured format that includes a pharmacy-curated medicines list and consumer-uploaded medicines (including over-the-counter medicines).

Target timeframes	Key benefits
<p>2017/18 Implementation of upload of medicines list</p> <p>2018/19 – 2021/22 Continuously improve maturity, consistency and quality of medicines information view</p>	<p>Improved coordination between settings of care, reducing risk of harm to patients and leading to better outcomes from medicines use</p>

Examples:

Medicines Information View

The Agency has developed the Medicines Information View in the My Health Record that collects patient medicines information from multiple sources (such as prescription and dispense records, shared health summaries and e-referral notes) into a single view, which can be sorted by date or alphabetically, showing the patient’s most recent (and up to two years’) prescription and dispense records and other Pharmaceutical Benefits Scheme claims information.

NPS MedicineWise

The MedicineWise App lets consumers build, edit and share a list of their medicines, set the dose and appointment alerts, view rich media content and record important health information.

MedView

Powered by eRx Script Exchange, MedView is the national cloud-based platform that gives health professionals a full picture of their patient’s medication history, as well as tools to manage their care.

6.3 National medicines data service

A national medicines data service that aligns medicines data to a standard code set will be established. The service will build on existing programs and infrastructure, enabling jurisdictions and health service organisations to maintain their own tailored medicines master data of all medicines suitable for use, or receive a managed service.

Target timeframes	Key benefits
<p>2018/19 Co-develop business case for national rollout.</p>	<p>Enhanced interoperability and compatibility between systems to facilitate the exchange of medicines information and the more effective development of systems across prescribers.</p>

Example:

National Clinical Terminology Service

The Agency is currently the Australian release centre for SNOMED-CT and manages the Australian Medicines Terminology, providing a standardised vocabulary for clinical and medicines information systems.

6.4 Medicines information for consumers

The medicines information for consumers is the provision of reader-friendly medicines information on the safe and effective use of medicines. The My Health Record system will provide targeted consumer medicines information (CMI), consumer entered over-the-counter medicines information, as well as information on recalls and warnings relevant to the consumer.

Target timeframes	Key benefits
2018/19 Co-produce national Digital Medicines Program Blueprint.	Improved access to information leading to better compliance, medicines self-management, and consumer engagement with their own medication.

Example:

Healthdirect

Healthdirect has developed a database, currently being used by Australians approximately 296,000 times per month, of over 7,000 medications to provide consumer-oriented information drawn from multiple sources. The database already supports advice on recalls, warnings for elderly patients is being enhanced with the addition of multi-platform electronic consumer medication information.

6.5 Medicine decision support tools

Clinical decision support systems at appropriate interactions will be developed to improve the quality of medicine management and safety of consumers. The systems will be supported by a minimum set of functional guidelines and conformance requirements that allow consistent and standardised collection and presentation of information.

Target timeframes	Key benefits
2018/19 Co-produce national digital medicines program blueprint.	Greater confidence in the conformance and quality of decision support tools, and agreement on how these tools should work within the Australian prescribing context.

Examples:

Innovative patient-specific drug compliance management programs

EBOS Group companies, Zest and MedAdvisor, are providing innovative patient-specific drug compliance management programs that will allow early appraisal of at-risk patients to be flagged before they enter the hospital system, while also helping manage patient program compliance after leaving hospital.

Enhanced models of medication management

MIMS is working with various partners to design and develop enhanced models of medication management and adherence to ensure patients are remotely monitored to improve their health outcomes, and to drive cost efficiencies within the healthcare ecosystems.

6.6 Enhance incident reporting capabilities

Development of digital solutions to enhance incident and adverse event reporting that is structured and standardised.

Target timeframes	Key benefits
2018/19 Co-produce business case for national rollout	Reducing time to report adverse events and incidents and giving pharmaceutical manufacturers greater insight into real-world use of their products.

6.7 National Allergy Strategy

The current National Allergy Strategy aims to improve the health and quality of life of Australians with allergic diseases and minimise the burden of allergic diseases by ensuring that consumer allergy information is easily accessible for healthcare providers in the My Health Record.

Target timeframes	Key benefits
2018/19 Co-produce national digital medicines program blueprint.	Reduced risk of avoidable harm events from medicines misadventure and improved use of most appropriate treatment option.

Examples:

National Allergy Strategy

The National Allergy Strategy has engaged with the Australian Digital Health Agency and the Australian Commission for Safety and Quality in Health Care to identify key issues in drug allergy management in terms of clinical education requirements and potential improvements to My Health Record to increase patient safety for drug allergy.

www.250K.org.au

A hub for the 250,000 young Australians living with severe allergies, www.250K.org.au provides age-appropriate information and resources to assist young people who are living with severe allergies, and help them feel more connected with other teens and young adults going through similar experiences, in a fun but informative way.

6.8 Real-time prescription monitoring

Real-time reporting will assist doctors and pharmacists to identify patients who are at risk of harm due to dependency, misuse or abuse of controlled drugs. National capability for real-time prescription monitoring will be established by building on existing programs and specifications, and utilising national infrastructure.

Target timeframes	Key benefits
2018/19 Implementation commenced; timelines and targets to be included in blueprint	Giving prescribers the tools they need to monitor and manage potentially harmful medicines use.

Example:

SafeScript

Victoria’s real-time prescription monitoring system, SafeScript, will provide health professionals with real-time alerting to their clinical desktop and access to their patients’ prescription histories for certain high-risk medicines to enable safer clinical decisions on whether to prescribe or dispense a medicine.

National Data Exchange

FredIT has been contracted to deliver the national data exchange (NDE) to underpin and support national real-time prescription monitoring. Delivery of the NDE is underway, with the core delivered for testing in late 2018.

7 The blueprint will define the governance structure for delivery of the Medicines Safety strategic priority

The Agency and its collaborators and stakeholders need to agree clear roles and accountabilities for both the priority actions and the Agency's role. For the Agency, a critical question is to define the role(s) that it needs to play in each of the actions and via its Medicines Safety Program and its other work streams. Specifically, in relation to the Medicines Safety Program, the Agency's strategy is to *enable* change and development across the sector by working closely with industry (including both the pharmaceutical and medical software sectors), government, peak bodies, healthcare providers and consumers.

Potential roles and models for the Agency and how it should be involved are set out below:

Enabler

The Agency will support and enable change through coordination, program management, and facilitation of interactions across industry and other stakeholders who will deliver projects that achieve each of the actions within the Medicines Safety strategic priority.

The Agency will work with State and Commonwealth governments and agencies to agree and harmonise regulation and enabling legislation where needed. Industry, including medical software and pharmaceutical manufacturers, would need to support and comply with agreed standards, which would be developed through consultative processes and would ensure the delivery of the medicines safety priority actions.

Change advisor

Significant change is required in technology, ways of practising, regulatory frameworks and enabling legislation. Fragmented regulatory environments, particularly for medicines supply in community settings, may hamper the effective national implementation of the priority actions. The Agency's role may be to advise on, monitor, and support implementation of change, focusing on enabling positive changes in practice and uptake of new ways of working with improved digital medicines safety enablers.

Technical expert

The Agency currently has significant technical expertise in specific domains, notably in managing release of SNOMED-CT and AMT through the National Clinical Terminology Service, and as the system operator of the My Health Record.

Program steward

Through consultations, the Agency has identified the need for a program steward to keep focused and maintain the scope of the Medicines Safety Program. This may involve creating standards (including but not limited to interoperability, privacy, secure messaging). The role would also involve creating the blueprint and other documents that support the fulfilment of the complete program. In addition, as program steward, the Agency will facilitate engagement across stakeholder groups to inform and shape the blueprint.

Delivery manager

The Agency would take carriage of coordinating and managing the delivery of work streams and actions, under agreed project and program management standards, with the expectation that industry partners and others would be responsible for implementation.

Questions for consideration

- In which roles can the Agency best leverage expertise to deliver the planned actions which contribute to the Medicines Safety strategic priority?
- In which roles can the Agency contribute the most value to deliver the Medicines Safety strategic priority?
- Should the Agency play different roles for some Actions?

8 Responding to this discussion paper

Throughout this discussion paper, questions have been suggested to prompt feedback and input to the development of the Medicines Safety Blueprint.

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Appendix A Links and additional resources

Australia's National Digital Health Strategy – Safe, Seamless and Secure

<https://conversation.digitalhealth.gov.au/australias-national-digital-health-strategy>

Framework for Action – How Australia Will Deliver the Benefits of Digitally Enabled Health and Care

<https://conversation.digitalhealth.gov.au/framework-for-action>