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**Senate Community Affairs References Committee – Inquiry into the My Health Record system**

Medicines Australia welcomes the opportunity to provide a submission to the Senate inquiry into the My Health Record system (the system).

Medicines Australia represents the discovery-driven pharmaceutical industry in Australia. Our member companies invent, manufacture and supply innovative medicines and vaccines to the Australian community. Those medicines keep Australians out of hospitals, prevent disease and play a pivotal role in ensuring a productive and healthy community.

Medicines Australia recognises the value that the My Health Record system can contribute to the Australian healthcare system and to the health outcomes of Australians. There are a number of opportunities that a robust My Health Record dataset can provide, including:

- The quality and efficiency of healthcare can be improved by enabling health professionals to access health information at the right time, enabling fully-informed treatment decisions to be made safely and in a timely manner.
- The data capability of the system can contribute to the accuracy of adverse event reporting.
- Driving future medical innovation and health research tailored to Australian patient needs by ensuring appropriate access to quality data.
- Access to population health data can enable the development of targeted health policies, allowing for the efficient and effective use of government resources.

Further restrictions on the availability and use of the data will limit this potential and miss key opportunities for better patient health outcomes, as well as contributions to innovative medical and health research.

A number of concerns have been raised recently over the integrity of use of My Health Record data. Despite these concerns, Medicines Australia believes that the current systems, processes and procedures that have been publicly shared by the Australian Digital Health Agency (ADHA) provide a robust framework for the collection and use of health records. Further education and communication of the health benefits and security provisions will assist in addressing any community concerns. Medicines Australia supports the implementation of the opt-out approach to the My Health Record system providing there is a well-resourced and robust governance system that promotes better health outcomes for patients as well as achieving broader public health gains.

## The expected benefits of the My Health Record system

- **Improved quality and efficiency of health care** - The My Health Record system will provide any healthcare professional involved in treating a patient with timely and transparent access to comprehensive health records. This can lead to improved health care due to more comprehensive understandings of clinical decision making. The pharmaceutical industry invests in significant valuable education of healthcare professionals regarding the appropriate use, benefits and risks of their products. Despite this, it is estimated that in Australia there are approximately 230,000 medication related hospital admissions annually, resulting in an annual cost of \$1.2 billion<sup>1</sup>. Medication errors may be due to inadequate awareness of a patient's medical history by the healthcare professional and may result in the prescribing of an inappropriate medication with respect to interactions (drug-drug or drug-disease), dose, contraindications or allergies. In this regard, the availability of a central repository of medical information is likely to reduce the incidence of medication errors, and subsequently save the lives of patients wherever they find themselves across the country, by allowing practitioners to make fully informed treatment decisions and better coordinate patient care. This will have the dual benefit of better patient outcomes for individuals and better utilisation of healthcare expenditure by reducing unnecessary hospital admissions.
- **Enhanced pharmacovigilance** - With appropriate patient privacy ensured, aggregated or de-identified medical information in a central repository should also assist in post-market surveillance for safety, quality and effectiveness and better allow the identification of adverse events, thereby strengthening Australia's pharmacovigilance system. This can be particularly beneficial with the increased uptake of biosimilar medicines, especially those dispensed from retail pharmacies. Alignment of education initiatives with the TGA will further help ensure adverse event reporters are aware of the system's contribution to improving Australia's pharmacovigilance system. Highlighting this important association in public communications will further demonstrate the value for the system to contribute to the safe use of medicines.
- **Research and development** – The My Health Record system will enable industry to utilise de-identified data to evaluate the impact of treatments across the health system, potentially leading to new innovative discoveries in medicine and more focused research. With patient consent, the system could be used to improve and streamline clinical trials. For example; data captured in the system can fill evidence gaps that are not available from clinical trials (such as in rare diseases). It could also reduce the time and cost for regulatory and reimbursement decisions and be used to monitor outcomes associated with the uptake of new treatments.
- **Health Policy** – The system has the potential to transform the future efficiency and quality of healthcare delivery in Australia. As previously mentioned, access to more detailed data about the population's health status can enable the development of more targeted health policies, thus providing more efficient utilisation of healthcare in Australia and reducing unnecessary expenditure.

## **The decision to shift from opt-in to opt-out**

Moving from an opt-in to opt-out system reduces the red tape burden on Australians to nominate being part of My Health Record system, whilst still supporting and maintaining patient choice. An opt-in system will limit the benefits of the system, as opt-in consent may lead to bias in participant characteristics and lower participation rates. As a system designed to improve the health of Australians, Medicines Australia supports the move to opt-out.

### **Privacy and security, including concerns regarding:**

- i. the vulnerability of the system to unauthorised access,**
- ii. the arrangements for third party access by law enforcement, government agencies, researchers and commercial interests, and**
- iii. arrangements to exclude third party access arrangements to include any other party, including health or life insurers.**

Medicines Australia supports the current approach taken by the ADHA and believes that with a more comprehensive capture of medicines data the system will create further benefits for patients and physicians. However, security of patient information is paramount for the system to fully achieve its potential and intended purpose.

Whilst there are always concerns around the security of data held by Government systems, the ADHA has outlined the best practice security provisions for storage of health records. The secondary use of My Health Record data is important to ensure that further health innovation and research is undertaken. With appropriate governance arrangements in place, the use of deidentification algorithms and confidentiality agreements could be used to ensure that data is used for appropriate research purposes. A balanced approach should be taken that ensures useable data is captured and maintained within the system, whilst ensuring privacy and security integrity is upheld. Otherwise, there is a risk of creating restrictions and limiting the use of data to an extent that the benefits of having the system are no longer achieved.

### **Measures that are necessary to address community privacy concerns in the My Health Record system**

Medicines Australia believes that there is a need for further education and awareness of the health benefits of capturing data in the My Health Record system, and how it allows health professionals to make more informed decisions for their patients.

There is a role for the ADHA to undertake further community consultation to ensure that there is a level of comfort with the high level of security processes and infrastructure in place. This communication could further outline the criminal penalties that are applicable for breaches. Further communication on the current security protocols may assist with alleviating fears of inappropriate use of My Health Record data, as there is a risk that further privacy restrictions on the data that is contained within the system will limit the potential health benefits.

## Other matters

- Consumers should be entitled to edit incorrect elements of their records and remove their record entirely if they wish to do so. Such empowerment could lead to increased consumer confidence in the system.
- The benefits of the My Health Record system will only be realised when information is used by health professionals as part of the decision-making process, i.e. when treating a patient. However, there is no mandate at present for clinical providers to access, review or upload information to the record, therefore there is the concerning potential for the system to not contain all the relevant information.

In summary, Medicines Australia supports the implementation of the My Health Record system. The secondary use of data from the system will ensure Australia maintains its status as a global leader in providing quality healthcare and in medical innovation. We welcome opportunities in the future to collaborate with government, academia, and the public to ensure that the benefits of the My Health Record system are fully realised, and the views of all relevant stakeholders are taken into account.

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Yours sincerely,



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## References

1. Roughead EE, Semple SJ, Rosenfeld E. The extent of medication errors and adverse drug reactions throughout the patient journey in acute care in Australia. *International Journal of Evidence-Based Healthcare*. 2016; 14(3).