Medicines Australia

Australian Government
Department of the Prime Minister and Cabinet
Office of the National Data Commissioner
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RE: Data Sharing and Release Legislative Reforms Discussion Paper

Medicines Australia welcomes the opportunity to provide a submission to the Australian Government consultation on Data Sharing and Release – Legislative Reforms.

Medicines Australia is the peak industry body representing the innovative research-based medicines industry in Australia. Our members are innovative companies that research, develop, manufacture and supply new medicines, therapies and vaccines to the Australian market. Those medicines keep Australians out of hospitals, prevent disease and play a pivotal role in ensuring a productive and healthy community. Our members are proud of the contribution they make to the health and well-being of everyday Australians, as well as to the local economy.

Medicines Australia is supportive of the Australian Government's initiative to develop a new legislative framework with the aim to streamline and modernise how the Government shares data, and importantly how data sharing can support policy, services and research. Big data offers many potential possibilities that will positively impact the Australian health sector, including medicines and emerging therapeutics, but this relies on the coordination of state and national databases, improved collection and collation of individuals' health data and improved legislation that will facilitate the safe sharing, and access to, health data.

With respect to the creation of an efficient and fit for purpose medical research and healthcare environment, data sharing has many benefits for the innovative medicines industry, Australian consumers and the Government, including:

- Informing the development of future health policies – for example, access to population health data can enable the development of targeted health policies, thus allowing for the efficient and effective use of resources

- Driving medical innovation and health research that is tailored to specific patient requirements

- Enhancing pharmacovigilance processes, thus contributing to the accuracy of adverse event reporting

- Ensuring that quality use of medicines principles are upheld – for example, by enabling healthcare professionals to access comprehensive health information on an individual when required, enabling fully informed treatment decisions to be made in a safe and timely manner

- Access to deidentified Pharmaceutical Benefits Scheme (PBS) claims data can assist with clinical trial feasibility, regulatory and reimbursement submissions and company demand planning and forecasting, thereby ensuring the elimination of unnecessary costs (e.g. from failure of a clinical trial or multiple resubmissions to the Pharmaceutical Benefits Advisory Committee [PBAC]) whilst also enabling the development of innovative medicines that are targeted to patient areas of need

For more a more detailed discussion on these issues, please see Appendix 1 below. Medicines Australia welcomes the opportunity to discuss and collaborate with the Australian Government and other stakeholders on this important issue. Please feel free to contact Betsy Anderson-Smith on banderson-smith@medaus.com.au if you would like to further discuss our submission.

Yours sincerely,

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APPENDIX 1

Access to innovative medicines, a sustainable PBS, and a viable medicines industry – Medicines Australia Strategic Agreement with the Australian Government

As previously stated, Medicines Australia supports the sharing of health data where it may help to provide better insights to Government decision makers and policy makers, regarding the value of medicines and their place in the overall health care and health care delivery environment in Australia. The value of medicines can also be derived from the sharing of data by healthcare professionals and consumers, to ensure that continuous improvement in health and wellbeing outcomes can be achieved.

Medicines Australia supports patients having access to the latest innovative medicines, when they need them, and at a cost they can afford. Many medicines are subsidised by the Australian Government on the PBS, which ensures that patients can access the medicines they need. It is therefore imperative that the sustainability of the PBS and the innovative medicines sector in Australia is upheld. In 2017, Medicines Australia entered into a five-year Strategic Agreement with the Australian Government that will deliver significant savings to Australian taxpayers, ensure patients have faster access to innovative medicines and foster an environment of business certainty for our members.

The Strategic Agreement is underpinned by the following principles:

- Stewardship of the health system, particularly the PBS, and a shared responsibility for its ongoing sustainability.
- Partnership in the delivery of the National Medicines Policy.
- Stability and certainty for the investment in innovative medicines, including recognition of the role that a predictable and stable PBS plays in encouraging investment.
- Transparency and efficiency of processes for listing medicines on the PBS.
- Integrity of Australia's world class health system, including patient safety and high value clinical care.

The Strategic Agreement also recognises that in order to enable monitoring of the sustainability of the innovative medicines sector in Australia, there is a need for the Government to enable Medicines Australia to access relevant information directly from the Department of Health's enterprise data warehouse, once available for use by parties external to the Government (as per the Strategic Agreement Clause 11.4: Access to PBS data)[1].

Medicines Australia believes that access to the enterprise data warehouse will assist industry, the Government and ultimately Australian consumers by:

- Improving medicines safety and adverse event reporting practices
- Enhancing the development of targeted health policies
- Inciting future medical innovation
- Providing reliable data on the use of a drug in practice to support commercial agreements with the Government
- Allowing a more nuanced understanding of drug utilisation trends to allow informed PBAC submissions
- Improving the efficiency of clinical trial recruitment, particularly important for rare diseases where lack of participants can lead to failed trials
- Allowing determination of the cost effectiveness of a new drug by clarifying how patients are currently treated with a specific disease

- By accessing historical control data, allowing quantification of the additional benefits of new drugs or other interventions to help determine the appropriateness of a new drug's PBS listing

Quality and efficiency in health care

In order for healthcare professionals to undertake informed clinical decision making, they require timely and transparent access to comprehensive health records. 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[2]. 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 medical information is likely to reduce the incidence of medication errors, and subsequently save the lives of patients. This will have the dual benefit of better patient outcomes for individuals and better utilisation of healthcare expenditure by reducing unnecessary hospital admissions.

Pharmacovigilance

Access to deidentified medical information data will strengthen Australia's pharmacovigilance system by assisting in post market surveillance for safety, quality and effectiveness of medicines and therapies. This can be particularly important with regards to the increased uptake of biosimilar medicines, as an effective system of pharmacovigilance relies upon the ability to distinguish every biologic medicine, through unique identification systems. In doing so, this will build clinical confidence in biological medicines, ensuring the safe and appropriate uptake of biosimilars, delivering savings and creating headroom to fund innovative medical therapies.

Medical Research

Data sharing will enable industry to utilise deidentified data to evaluate the impact of treatments across the health system, which can lead to innovative discoveries in medicines and better targeted research. Access to health data could also be used to streamline and improve the governance of clinical trials: for example; by filling evidence gaps that are not available from clinical trials (such as in rare diseases).

Health policy - regulation and reimbursement

Industry access to health data can benefit the Australian public via access to innovative medicines and flow on economic benefits. Indeed, there are strategic benefits at a national level in making data available, as global medicines companies seek to work in environments where the 'real world data ecosystem' enables companies to do cost effective research on medicines use beyond traditional clinical trials; thus bringing investment into the sector. Similarly, the coordinated access and sharing of de-identified real world evidence data will assist physicians to make clinical decision-making. The current PBS 10% licence model is an exemplar where private innovative companies such as Medicines Australia member company Prospection have built scalable digital health solutions that provide industry with important, timely, patient level data.

Access to PBS data can reduce the cost to government and industry (and subsequently taxpayers) for regulatory and reimbursement decisions and assist companies with demand planning and forecasting. For

example, by having access to data that gives better estimates of patient numbers in a PBAC submission, this allows better pricing and planning from companies.
The flow on benefits include access to new innovative medicines (public good); and economic benefits via highly skilled jobs and economic growth.

There appear to be a multitude of benefits regarding the utilisation of health data to inform future demand planning and forecasting, including:

- Ongoing access to medicines and avoidance of shortages
- The likelihood of success of a clinical trial
- Analysing a medicine's commercial viability prior to market access, as this will ensure both the elimination of unnecessary costs (e.g. from failure of a clinical trial or multiple resubmissions to PBAC) and the development of innovative medicines targeted to areas of patient need.

By providing better estimates of patient level data, the Government and the medicines company can both benefit in pricing and PBAC submission negotiations. In a hypothetical case, where a drug is a third line oncology product, longitudinal patient level data is important to ensure accurate estimates of the current and future patients at third line. For example, if there is an overall estimate of 15,000 patients being treated for an oncology type, there is still a need to get estimates for third line patients (as that may be aligned to the clinical trial/submission). In this case, there may be only 3000 patients at third line, and this can only be estimated through longitudinal claims data, which is representative at a national level.

REFERENCES

1. Medicines Australia Limited and the Commonwealth of Australia Strategic Agreement. Available from: https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2017/05/09-May-2017-Strategic-Agreement-with-Commonwealth-Signed.pdf

2. 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).