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Via email: MyHealthRecorddata@healthconsult.com.au

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Dear Sir/Madam

Medicines Australia welcomes the opportunity to provide comment on the Development of a Framework for Secondary Use of My Health Record (MHR) Data Public Consultation Paper.

Medicines Australia represents the research-based medicines industry in Australia, which brings new medicines, vaccines and health services to the Australian market. Our industry generates around \$3 billion in exports and invests over \$1 billion in research and development every year. To achieve this, our industry is highly reliant on a stable and predictable policy and intellectual property environment in Australia.

Medicines Australia generally supports the use of MHR data where it may help to provide better insights to government decision makers and policy makers, about the value of medicines and their place in the overall health care and health care delivery environment in Australia. Value can also be derived from such data by those working with and for health consumers, to ensure that continuous improvement in health and wellbeing outcomes can be fostered and achieved in Australia. That said, the successful implementation of the MHR and any uses of the data it contains, must be supported by the community at large if its potential is to be realised. We would therefore suggest that the Department give adequate and due consideration to ensuring that all Australians are provided with timely and accurate information about the MHR, what they can expect from it, where they can opt out; and also, some of the overall benefits to the health sector at large of the uses that can be derived from the data in the MHR. Privacy of course must be respected, and assurances provided to consumers that build their confidence in the MHR.

Our specific comments are contained in the Attachment to this letter. We would be happy to discuss or provide further comment on any aspect of our response and we appreciate learning of further developments as they are worked through from here. Thank you again for consulting with us

Yours sincerely



Milton Catelin
Chief Executive

ATTACHMENT

Introduction to listing of medicines in Australia on the PBS

We believe it is important to outline the context in which many of our members operate, in order to provide better understanding of our perspective on the possible secondary uses of MHR data.

In particular, current evaluation systems in Australia for the regulation and reimbursement of medicines rely on relatively complete data on safety, efficacy being provided at the time that a treatment comes to market and cost effectiveness being assessed before a medicine becomes available on the PBS. Whilst there have been reforms recently to begin addressing this (such as the Medicines and Medical Devices Review), there is an opportunity with secondary data use to link “real world” data to complement data available from clinical trials.

Whilst it is noted in the consultation paper that the intent of the My Health Record is not to determine remuneration or appropriate rebate claiming practices, there is an opportunity presented by the MHR to better understand the experience of patients, particularly those with certain medical conditions. In doing so, this may better inform public policy and ensure the appropriate use and uptake of new technologies. This use of real world evidence of patients’ interactions with the health system and use of medicines, may require a shift in perspective regarding how secondary data is provided by the government, and how relevant bodies view this data in reimbursement submissions.

Development of real world evidence need not be complex or expensive. By linking important datasets, government and researchers could have much easier access to the kind of evidence that would support the full value of medicines. Secondary access to My Health Record data will assist in supporting the accurate measurement of this value, for example, through data that demonstrated the number of hospitalisations avoided, the reductions in demand/need for other medical services, the number of patients remaining in employment and/or carers returning to paid employment.

Decisions about making medicines available in Australia are difficult and nuanced matters. The PBS data set could be described as “broad yet shallow” - almost 208 million PBS prescriptions were claimed in the 2015-16 financial year (Australian Government Department of Health, *Expenditure & Prescriptions report 2015-16*, www.pbs.gov.au), however the only information that can currently be ascertained with reasonable confidence is limited to the following:

- The date that a supply of an over co-payment drug is claimed by an approved pharmacy and;
- For drugs requiring prior approval, the date the approval was given.

Almost all other key information that could be derived from the current PBS data set must be determined with caveats and using assumptions. These include such things as:

- The date the patient actually began or ceased using a drug;
- Whether two drugs were used concomitantly, or whether one drug replaced the other;
- If a drug is listed on the PBS for multiple conditions, to which disease should the use of the drug be attributed?
- The stage or severity of disease before treatment;
- Co-morbid conditions that may impact on the current treatment;

- Where a medicine is observed to have been supplied at irregular intervals, whether or not this indicates use on an “as needed” basis, or indicates difficulty experienced by the consumer in keeping to the directed dosing schedule.

In addition, some very important information cannot be determined at all from the current PBS data set:

- If the patient ceased to be on a drug, whether this was due to treatment failure, drug intolerance or an adverse reaction;
- The benefit derived from using the drug, aside from the inference that some response must have been demonstrated for the PBS continuation criteria to be satisfied;
- Quality of Life (QoL) benefits of a drug.

Finally, for the most part, inferences about the characteristics of the patient population are limited to binary variables. For example:

- The glycosylated haemoglobin for a patient with diabetes must have been above 7% to qualify for PBS treatment – the actual HbA1c value is unknown;
- Patients with non-small cell lung cancer must have had stage 3b or stage 4 disease to meet the PBS restriction – the proportions of patients with the more and less advanced disease are unknown;
- A patient with relapsing-remitting multiple sclerosis (MS) must have had at least two prior episodes of neurological dysfunction in the preceding two years in order to receive PBS-subsidised treatment – how recent or numerous those attacks were, are unknown.

It is plausible that other outcomes or measures would be relevant in considering a new drug for listing, or monitoring the use of a currently-listed medicine. The My Health Record would provide both a richer PBS data set (a wider range of factors, including continuous variables), as well as the potential for cross referencing PBS data with MBS services, pathology results and other important elements.

The PBS subsidises around \$10 billion worth of medicines each year, with more new drugs recommended every year to be added to the Scheme. Decisions are based on the best information available at the time, but promising yet incomplete early-phase data may or may not be borne out by mature trial results. Sometimes no new trial data are likely to become available in a reasonable timeframe, and many Australian patients with severe diseases cannot wait.

The My Health Record may provide alternatives to waiting for more information - by removing uncertainties, verifying assumptions and mitigating risks that may otherwise lead to a delay in PBS listing:

- The effectiveness of a current drug in clinical practice could be reliably ascertained, meaning that the added benefit by the new drug can be appropriately evaluated;
- The actual utilisation of a new drug can be more accurately tracked and compared with the pre-listing predictions, meaning that future estimates can be honed;
- The performance of a new drug in practice can be confirmed with more precision than is currently possible, meaning that the value of the drug can be reliably confirmed.

These and many other approaches would become more feasible with the use of the My Health Record dataset. More innovative, effective medicines could be listed on the PBS with reduced delays – an outcome that all Australians would welcome.

Medicines Australia therefore supports Government's consideration of the secondary uses of the My Health Record dataset and looks forward to contributing further to the process.

The following aspects of pharmaceutical use in Australia could benefit from secondary use of My Health Record data:

- A more nuanced understanding of current drug utilisation trends to better inform PBAC submissions;
- Observational research, noting that the My Health Record data set could be a valuable supplement to registry data
- More confident monitoring of new drugs, both for routine purposes and for administering Risk Share Arrangement (RSA), Managed Entry Scheme (MES) and Pay for Performance (PfP) agreements and other agreements as identified.
- Pharmacovigilance
- Improve the efficiency of recruitment into clinical trials. This may be particularly relevant for rare diseases, where recruitment challenges can lead to failed trials
- Quality of life (QoL) in clinical trials

Before moving to the questions posed in the consultation paper, Medicines Australia notes the following recommendations from the 2015 Senate Committee Inquiry into the availability of new, innovative and specialist cancer drugs in Australia:

- More effective integration of existing cancer databases;
- Capturing data from off-label use of cancer medicines;
- Consideration of a national cancer registry.

Medicines Australia proposes that these important aims could be effectively advanced by the use of data from the My Health Record.

1. What secondary purposes, if any, should My Health Record data be used for?

There are a number of secondary purposes for My Health Record data that will promote public health and further research objectives. This data will be particularly important in helping to inform the development of new medicines for Australian patients. My Health Record data could be valuable before a medicine lists on the PBS in several ways:

- Linking prospective trial participants with recruiting trials;
- Helping to determine the cost effectiveness of a new drug by clarifying how patients with a disease are currently treated in Australia;
- Australian historical control data could help to quantify the additional benefits of new drugs or other interventions, especially where data are sparse or limited to single-arm trials. Such analyses could help determine the appropriateness of a new drug's PBS listing.

It should be noted that the My Health Record would not replace clinical trials as a means to research the effectiveness of a new drug. Rather, it would be considered an important supportive data source by which the real-world performance of the drug can be evaluated.

My Health Record data could also be highly useful once a drug is listed on the PBS in:

- Capturing complete information on how a new drug is used in practice;

- Elucidating the benefits of the drug to Australian patients in terms of response to treatment, quality of life and other patient-relevant measures;
- Providing reliable data on the use of a drug in practice to support commercial agreements with the Commonwealth, such as annual expenditure caps, managed entry schemes or pay-for-performance arrangements.

These uses of the data should be supported by a robust and well-resourced framework that maintains an appropriate governance process to ensure timely access to the data.

2. What secondary purposes should My Health Record data NOT be used for?

Medicines Australia supports the policy direction of the consultation document in that commercial purposes unrelated to public health are considered out of scope for use of My Health Record data. It would be important to ensure that a principles approach is taken in establishing the framework so as to ensure that the data is used for the public health purposes.

3. What types of organisations/individuals should be able to access My Health Record data for secondary purposes?

Medicines Australia notes the large range of stakeholders that could feasibly demonstrate a public health related need to access the My Health Record dataset. These could include pharmaceutical companies, health-related consultancies, patient- and clinician-focused groups, Universities and other research-oriented bodies, Commonwealth and State/Territory Health Departments and the PBAC and its related evaluation groups and subcommittees. Subject to appropriate controls and governance, Medicines Australia proposes that any such individual or organisation with a demonstrable health-related interest should be able to access the My Health Record dataset.

4. Should access to My Health Record data for secondary uses be restricted to Australian users only or could overseas users be allowed access?

Medicines Australia proposes that it would be equally appropriate for overseas individuals or organisations with a demonstrable health-related interest to have access to the My Health Record dataset as for parties in Australia. Access to identifiable patient-level data should only be accessible to overseas researchers where there is a demonstrated need for identifying data and the public health benefit outweighs the risks to patient privacy.

It is important to ensure that the community is consulted about those who may access data on the MHR, the terms and conditions and the criteria that will be applied

5. What principles, if any, should be included in the Framework to guide the release of data for secondary purposes from the My Health Record system?

Medicines Australia considers the protection of individual privacy to be the primary guiding principle in handling of My Health Record data. In that context, Medicines Australia proposes the following general principles:

- The community is aware of and understands the value inherent in the Framework;
- The data are requested to answer a legitimate health question;
- The data are handled sensitively, with adequate security on the part of the individual or organisation requesting the data;

- The data are used for the purpose for which they were requested;
- The data are not retained once the purpose for which they were requested is complete.

An important principle for the design and use of the My Health Record is the need to be able to accommodate the results of new tests and procedures as they become part of standard clinical practice.

Finally, where one or more patients have opted to suppress part or all of their My Health Record, the fact that some data are unavailable may affect the interpretation of the remaining data. Medicines Australia therefore proposes that, insofar as it does not compromise the privacy of individual patients, requesting parties be advised that some records were not included at the request of the patient

6. Which of the governance models should be adopted to oversee the secondary use of My Health Record data?

Medicines Australia notes that each of the proposed models has distinct advantages and therefore considers that a governance arrangement that harnesses as many of those advantages as possible would be appropriate. Medicines Australia does note that the use of a single committee, as with the AIHW, does carry the risk that the number of requests could overwhelm the capacity of a single body to consider and grant requests in a timely fashion. As delays in these matters could tangibly delay the availability of needed medicines, avoidance of such a situation would be important.

Medicines Australia proposes that the adopted model should provide appropriate levels of transparency into the reasoning and decision-making process of the responsible entity so that decisions not to release data can be understood by an external party. Additionally, Medicines Australia proposes that an appeals process would be appropriate to ensure procedural fairness for applicants. Regardless of the model that is used, the focus should be on timely access to data that minimises the financial impact on researchers. Some other Government data available to researchers have prohibitive fees to access. Whichever governance model is used should consider the accessibility of the data and not limiting use due to cost.

7. What principles, if any, should be adopted to enable organisations/researchers to request and gain approval for de-identified data from the My Health Record system to be provided for secondary purposes?

Medicines Australia notes that the general principles proposed in answer to question 5 (above) are relevant to de-identified data sets, as is ongoing stakeholder engagement.

It should also be noted that in assessing the effect of a medicine, in most cases it is neither necessary nor useful to know the identity of an individual patient. Therefore, in most cases it would be aggregate, de-identified data which would be required for pharmaceutical research.

Medicines Australia also notes that the matters for which My Health Record data may be required may be exceptionally urgent, therefore timeliness of reporting is also an important principle. The Department may like to consider providing regular updates to the public on issues such as the implementation progress and related matters.

8. What principles, if any, should be adopted to enable organisations/researchers to request and gain approval for identified data from the My Health Record system to be provided for secondary purposes?

In addition to the guiding principles for de-identified data, there are some situations where it may not be possible to de-identify data:

- Rare conditions – if a disease occurs in only a handful of patients, aggregating the data so as to avoid identifying the patient may not be possible. Medicines Australia proposes that in such situations, all alternatives to release the data (perturbation, suppression of unsafe cells) be explored as a preference to declining to release the data.
- Survival status – Medicines Australia notes that Section 9(3)(h) of the My Health Records Act 2012 defines “...the date of death, and the date of death accuracy indicator, of the individual,” as identifying information. In oncology and haematology, the ultimate goal of treatment is to prolong the life of the patient – monitoring patient survival to confirm the drug’s trial performance may be critical to achieving PBS listing. Medicines Australia therefore suggests further discussion of the implications of this definition in the Act for the future PBS listing of drugs for oncology and haematology. In making this suggestion, Medicines Australia also notes that:
 - The actual identity of the patient (name, address, date of birth) need not be known in making an assessment, therefore in this regard the data remain de-identified;
 - Notwithstanding the definition in the Act, it is the aggregate data (i.e. the proportion of patients alive at a certain time after starting treatment) that are the most influential. Therefore, it could be argued that, notwithstanding the definitions in the Act, such an aggregate data set could be considered to be de-identified.

Medicines Australia also notes and supports the statements in the consultation document regarding the pivotal importance of obtaining informed consent from affected individuals before release of identified data. If informed patients are able to opt into providing their identified data at any time (for example, at the point of enrolling in a clinical trial or commencing off-label use of a drug) this would make that patient’s wishes unequivocal. A seamless approach should be considered whereby a single point of consent is required for subsequent use of the data with an opt-out at any stage provision. This will assist in uses of the data in clinical trials and multiple research projects and reduce the burden on individuals and researchers of having to obtain consent for each use.

9. Should there be specific requirements if researchers/organisations make a request that needs the My Health Record data to be linked to another data set? If so, what should these requirements be?

Medicines Australia notes the potential value in linking the My Health Record dataset with other data sets, and supports the calls of contributors to the Senate Inquiry into the availability of new, innovative and specialist cancer medicines in Australia for more effective linkage of related data sets. The prime consideration would be the effective management of the risk that data linkage could (inadvertently or otherwise) re-identify the data set. Quality assurance would also be considered a key consideration – inadvertently

linking the wrong records would erode confidence in the quality and utility of the My Health Record dataset.

10. What processes should be used to ensure that data released for secondary purposes protects the privacy of the individual?

Medicines Australia notes that perturbing of data (adjusting individual data points without affecting the aggregate result) may not be practical in the context of rare diseases. Medicines Australia therefore counsels that multiple approaches to de-identification be considered, in consultation with the requesting party, prior to release. Medicines Australia also notes the reliance of the Expert Determination Method on the availability of suitably experienced individuals to handle requests – this dependence on individual experts could risk creating delays in the event of a large number of requests.

11. What precautions should be taken to reduce the risk of de-identified data from the My Health Record system being re-identified after release?

Medicines Australia is broadly supportive of prudent measures to mitigate the risk of re-identification of My Health Record data following release. A risk-balanced approach should be used that allows continued access whilst providing appropriate disincentives to re-identify individuals.

Medicines Australia supports appropriate punitive measures in the form of injunctions and civil penalties that are available for the Government to use in cases where re-identification occurs.

12. What arrangements should be considered for the preparation and release of My Health Record data and who should be responsible for undertaking and overseeing these arrangements?

Medicines Australia notes that although regular publications would be administratively more straightforward for the Commonwealth, frequently the data of interest may be within a specific disease and/or run over multiple years. The utility of virtual environments in which researchers can flexibly access the entirety of the My Health Record is considerable and game changing.

Medicines Australia also notes both the potential value of linking of MBS and PBS data in the same database, as well as the long-standing privacy provisions of the National Health Act 1953 and the associated rules issued by the Privacy Commissioner. Accordingly, it is unclear whether release of My Health Record data will be able to include PBS and MBS data – clarity on this point would be welcomed by numerous individuals and organisations in the research sector.

13. Whose responsibility should it be to make a quality statement about the My Health Record data and to ensure the data are of high quality?

The organisation responsible for the prudent management of the My Health Record dataset would be best placed to attest to the quality of the data.

14. What monitoring and assurance processes, if any, should be considered to ensure My Health Record data secondary users comply with the Framework?

Subject to the technical design of the My Health Record database and the reports generated, Medicines Australia notes that it is possible for reports to be designed in such a way as to become unusable after a specific period – such a mechanism would be more effective than the current requirement for the receiver of the data to manually destroy the data and to provide a statutory declaration to that effect.

15. What risk mitigation strategies should be included in the Framework?

Medicines Australia considers that the primary risks are to patient and healthcare provider privacy and to data accuracy. Balancing these concerns against reasonable and timely access will be the main challenge in effective risk management.

16. Should there be a public register which shows which organisations/researchers have requested data, the purpose, the status of their data request, what they have found by using the data and any publications that have resulted from using the data?

Medicines Australia recognises the value of such as register in terms of public accountability and therefore supports this suggestion, anticipating that relevant stakeholders would also need to be consulted on specific details.

17. Are the existing penalties under the My Health Record Act sufficient?

Medicines Australia considers that the existing penalties offer sufficient disincentive in the form of injunctions and civil penalties promote compliance with the provisions of the Act.

18. What policy changes, if any, need to be considered to support the release of de-identified data for secondary uses from the My Health Record system?

As above, Medicines Australia (along with other interested parties in the research sector) would welcome clarity around how the existing privacy provisions regarding linking of MBS and PBS data will affect releases of My Health Record data.