Progress Report: A Centralised Reporting System for Medicines Australia Member Companies’ Payments and Transfers of Value to Health Care Professionals

Background


A condition of the authorisation is that Medicines Australia must use reasonable endeavours to develop and implement a Central Reporting System which will allow the public to access information on payments and transfers of value from all companies to healthcare professionals in a single location, via the internet. This condition also requires Medicines Australia to provide regular six-monthly reports identifying the steps taken each reporting period to develop and/or implement a Central Reporting System.

This report summarises Medicines Australia’s work in the third six months following authorisation of Code Edition 18.

Centralised Database Working Group

The Centralised Database Working Group (CDWG), comprising personnel from Medicines Australia’s member companies, has continued investigating the feasibility of developing and implementing a central reporting system or database. The Working Group and the Board of Medicines Australia are aware that establishing a central reporting system is a significant project, with both short and long-term challenges that must be thoroughly assessed in order for it to be fit for purpose, legally compliant, financially viable, appropriately supported by member companies and acceptable to all stakeholders.

Since the second progress report in May 2016, the Working Group has undertaken work on the following issues.

Privacy Impact Assessment

Medicines Australia engaged an external organisation with expertise in Australia’s privacy laws to conduct a Privacy Impact Assessment (PIA) to ensure that a central reporting system could comply with Australia’s privacy laws and meet all legal obligations of Medicines Australia and its member companies. The final PIA Report was received by Medicines Australia in July 2016.

The PIA has identified a number of risks from a central reporting system and has recommended further work and consultation that should be undertaken.

For example, the PIA has recommended that Medicines Australia should identify the minimum elements of information about healthcare professionals that are necessary to

- uniquely identify a healthcare professional and ensure that the right information is associated with each individual;
- enable a member of the public to identify the right healthcare professional about whom they are seeking information; and
- administer the system, including handling any disputes or queries about the information and communicating with healthcare professionals.

Apart from the reportable information about payments and transfers of value, a central database should contain and make public no more information than is necessary to meet these purposes.
The PIA also has recommended investigating alternative design options for a central reporting system that would ensure that if the system requires data to be disclosed to a data validator, a data validator should only receive or have access to the information that is necessary to uniquely identify and validate the address information for a healthcare professional. A data validator should not receive information that is unnecessary for their role, such as payment and transfer of value information, and should be contractually required to only use the information they receive about healthcare professionals for the purposes for which they have received it.

The PIA has further identified risks associated with the potential use of any information published in a central reporting system for an unrelated secondary purpose and recommended how this risk could be minimised, such as by separating the function that would enable a search for an individual healthcare professional’s data from the function that would allow research and analysis of the entire data set.

These recommendations for managing risks, and others contained in the PIA, have identified that the initial conceptual design of the central reporting system requires further review and amendment to ensure the risks are managed and that healthcare professionals’ personal information is properly managed and appropriately protected. A different design for a central reporting system is likely to be more complex – for example to manage the risk of sharing unnecessary information with data validators whilst ensuring that the data about individual healthcare professionals is not changed or connected to a different healthcare professional – and therefore more costly to implement and to maintain.

The Central Database Working Group will reconsider the design, establishment cost and ongoing maintenance requirements for a central reporting system in the coming months.

Further consultation is needed with both healthcare professionals and potential users of a central reporting system in order to strike an appropriate balance between transparency objectives and minimising risks to both healthcare professionals, Medicines Australia and its members. The CDWG and Medicines Australia plans to commence this discussion and consultation in 2017.

First Transparency Reports

Considerable time and effort in the last six months has been given to preparing the information for the first reports of information about reportable payments and transfers of value to individual healthcare professionals. This constitutes the baseline data that would be included in a central reporting system. The first reports, relating to activities occurring between 1 October 2015 and 30 April 2016, were published on 31 August 2016. 35 member companies published their reports on their company websites. On average, nearly two out of three healthcare professionals agreed to have their information published. Where consent was not provided, payments and transfers of value were published in aggregate.

The publication of the first reports about payments and transfers of value to individual healthcare professionals has given Medicines Australia and the CDWG valuable insights into the scope and quantity of data that would be required to be managed within a central reporting system. In addition, member companies’ experience when validating the data with individual healthcare professionals before it was published has provided some very useful insights about the challenges of ensuring that the information recorded to identify an individual healthcare professional is accurate. This is a fundamental challenge for a central reporting system, if it is proposed that these data would be validated by the system instead of, or in addition to, member companies. This has highlighted the complexity of managing the data and the risk identified in the PIA that a central reporting system could publish inaccurate or incorrect information about a healthcare professional, which may require the conceptual design of a central reporting system to be revised.
It should be noted that one or more third parties downloaded, collated and re-published some of the information about payments and transfers of value to healthcare professionals following the release of the data by Medicines Australia members. However, these third parties might not have applied the same data management standards required of pharmaceutical companies that collect, validate and publish healthcare professionals’ personal information to ensure compliance with Australia’s privacy laws, as highlighted in the PIA.

The PIA had also identified the potential risk of third parties using the data for possibly unrelated purposes and has recommended that a central reporting system should be designed in a way that minimises these risks. This will need to be taken into account in reconsidering of the design of a central reporting system.

Considerable resources have also been required within companies and Medicines Australia to manage the change from publication of information with healthcare professionals’ consent to the reasonable expectation of publishing payment and transfer of value information. This change became effective for activities occurring from 1 October 2016.

Managing these activities associated with the first reports of payment and transfer of value information has been the priority for Medicines Australia during the last six months.

**Learning from other countries**

As previously reported, a senior manager from Medicines Australia met with the Association of the British Pharmaceutical Industry (ABPI) in May 2016 to gather further information about their progress in establishing the ABPI central database for payments and transfers of value. The first reports in the UK were published on 30 June 2016.

The ABPI database managers found that there were challenges in ensuring accuracy of the information when combining the data from more than 100 companies. For example, different companies may have had different identifying information for an individual healthcare professional, such as a difference in the name, practice address or title. These differences must be resolved before the data can be published, to ensure that the right information is attributed to each individual healthcare professional. This has highlighted further challenges to the complexity of a central reporting system that must be considered in its design and functionality.

The ABPI also found that up to one in ten healthcare professionals had made an enquiry about their data during the data validation period. It required considerable human resources to manage these enquiries. Medicines Australia does not currently have the capacity to manage these enquiries if a similar proportion of Australian healthcare professionals made an enquiry about their data. These resource requirements, in combination with the aforementioned challenges of ensuring data integrity would likely have significant cost implications, which may fall outside of the Association’s capacity to pay.

**Next steps**

The work of Medicines Australia and its members in the six months to November 2016 has demonstrated substantial progress on consideration of the development of a central reporting system whilst delivering transparent reporting of payments and transfers of value to healthcare professionals for activities between October 2015 and April 2016. Our further investigations and learning in regard to the design and management of a central reporting system, including the Privacy Impact Assessment, have identified a number of technical complexities and challenges with respect to managing privacy risks that Medicines Australia will consider in 2017. It is important to note that the considerable effort that has gone into understanding the finer details of this project has identified a far more complex project with greater cost implications and risks for Medicines Australia and its members than was initially
anticipated. Medicines Australia continues to explore solutions to these growing challenges. However, the solutions are less clear than was the case in our previous progress report.

When considering implementing a project of the scale, complexity and potential impact of a central reporting system for healthcare professionals’ payments and transfers of value it is important to have a clear view of the purpose for the system; whether the proposed solution is the best option to achieve that purpose having considered other options; the impacts on all relevant stakeholders including healthcare professionals, the expected users of the system and companies; and that the benefits of the system to the community sufficiently counterbalance any detriments to healthcare professionals and companies.

Medicines Australia will continue to consider these important objectives.

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