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22 December 2016

Ms Deborah Monk
Director, Ethics and Compliance
Medicines Australia
Deborah.Monk@medicinesaustralia.com.au

Dear Ms Monk

Re: A91436-A91440 Medicines Australia Ltd – Central Reporting System

Thank you for your correspondence on 16 November 2016 attaching a copy of Medicines Australia's third progress report (Report) prepared in accordance with condition 3(b) of the authorisation granted by the ACCC to Medicines Australia for its Code of Conduct (edition 18) on 24 April 2015 (Authorisation).

Broadly, condition C3 of the Australian Competition and Consumer Commission's (ACCC) authorisation requires that Medicines Australia must use reasonable endeavours to develop and implement a CRS which will allow the public to access information on payments and transfers of value from all member companies to healthcare professionals in a single location, via the internet. This condition also requires Medicines Australia to provide regular reports at least every six months identifying the steps taken each reporting period to develop and/or implement a CRS.

The ACCC notes that the Report provides a thorough description of the steps taken by Medicines Australia to develop a central reporting system (CRS). The ACCC also acknowledges the work undertaken by Medicines Australia during this time, including:

- the preparation and publication of baseline data for transparency reporting by member companies about reportable payments and transfers of value made to individual healthcare professionals between 1 October 2015 and 30 April 2016;
- the change from publication of information with healthcare professionals' consent to the reasonable expectation of publishing payment and transfer of value information from 1 October 2016;
- the completion of the Privacy Impact Assessment report (PIA report) in July 2016; and
- consultation with the Association of British Pharmaceutical Industry following the recent introduction of central reporting regarding reportable payments and transfers of value to individual healthcare professionals in the United Kingdom.

The Report refers to a number of matters raised in the PIA report, including:

- the need to ensure that the CRS database should contain and make public no more information than necessary to achieve the key aims of the CRS;
- alternative design options for validation of the data; and
- the need to minimise risks associated with the use of information contained in the CRS for unrelated secondary purposes.

In light of these matters, Medicines Australia has advised that its initial conceptual design of the CRS requires further review and amendment and that any differently designed CRS is likely to be more complex. Accordingly, Medicines Australia has advised that it will:

- in the coming months, reconsider the design, establishment cost and ongoing maintenance requirements for the CRS; and
- in 2017, engage in further consultation with healthcare professionals and potential users of the CRS.

As you are aware, in its decision to grant the Authorisation, the ACCC noted the importance of providing the public with a practical way to access individual transparency data. Accordingly, the ACCC took the view that developing and implementing a CRS should continue to be a matter of the highest priority for Medicines Australia and its members and noted:

- the ACCC's expectation that, subject to the identification of any unanticipated issues, the new CRS would be operational prior to Medicines Australia seeking reauthorisation of the Code; and
- the importance of Medicines Australia's progress in developing and implementing the CRS to the ACCC's consideration of such reauthorisation application.

It is clear from the Report that Medicines Australia has been working to develop and implement a CRS, including by obtaining the PIA report. I trust that Medicines Australia will continue to give the highest priority to the proposed CRS, including by addressing the issues referred to in the Report. This will be particularly important moving forward if a CRS is to be operational prior to Medicines Australia seeking reauthorisation before the Authorisation expires in 2020. For example, given that some six months has elapsed since Medicines Australia obtained the PIA report in July 2016, the ACCC would expect consultation on the PIA report and work on the design, establishment cost and ongoing maintenance requirements of a CRS to be undertaken as soon and as efficiently as possible.

We look forward to receiving your update on progress made in the next six monthly progress report to be provided in May 2017.

This letter has been placed on the ACCC's public register. If you wish to discuss any aspect of this matter, please contact Tess Macrae on (03) 9290 1835 (or at tess.macrae@accc.gov.au), or Darrell Channing on (02) 6243 4925 (or at darrell.channing@accc.gov.au).

Yours sincerely

David Jones
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