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From the President

28 April 2017

Reforms and Operations Section
Pharmacovigilance and Special Access Branch
Therapeutic Goods Administration
Po Box 100
Woden ACT 2606

Via Email: ReformsandOperations@health.gov.au

Dear Sir/Madam

Re: Strengthening monitoring of medicines in Australia

The Royal Australasian College of Physicians (RACP) welcomes this work to improve the post-market monitoring scheme for medicines and medical devices, and thanks the Therapeutic Goods Administration (TGA) for the opportunity to provide input into these important reforms.

The RACP acknowledges that the TGA has a very tight timeframe to determine and implement the recommendations of the Review of Medicines and Medical Devices Regulation, however, the short consultation period has not allowed us to consult with our membership as comprehensively as we would wish. We would like to reiterate our request that, where possible, we are provided with a longer timeframe sufficient to enable us to appropriately consult with our members. In instances where this is not possible, we would appreciate being provided with earlier notice of upcoming consultations, including their scope and associated timeframes.

Although we have not been able to undertake widespread consultation, we have collated some feedback from our members and provide this below for your consideration.

Adverse event reporting
The RACP supports the introduction of the Black Triangle Scheme and considers the criteria proposed to be sensible and feasible. To make this scheme even more effective and meaningful in the drug safety context, strong consideration should be given to the mandatory reporting of adverse events (AEs) by prescribing clinicians and pharmacists and by Drug and Therapeutics committees. This AE data must be held in a useable and useful format; one that enables specific searches and reports, and also one that enables patterns of safety issues or early signals to be brought to light. It is the use of this information that is of most importance.

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It will be vital that there is a comprehensive approach to educating health professionals and consumers on this new scheme and the importance of reporting adverse events. This education should be expected to take some time, and there must be the commitment to supporting this, including in resource constrained settings, until it achieves its intent otherwise the impact of the scheme will be lost.

That comprehensive approach needs to consider both the content and format of the educational resources, as well as how the education and information is to be provided, including the communication vehicles and opportunities that would be most effective. This is not a matter that we believe can be answered via a single question in a consultation paper. It will need to be fully worked through by experts in the areas of communications, education and health, as well as those who understand the needs of consumers and health professionals. This should also take account of the learning and clinical practice needs of trainee specialists, as well as those already registered. Is it also very likely that there are a number of initiatives that could be leveraged or built on, and these should be fully explored.

The RACP also welcomes the reform of the Product Information (PI). PIs should be updated as and when new data is available, so that they are based on the most up-to-date information and provide the correct advice and support to health professionals and consumers in their decision-making.

There is insufficient detail in the consultation paper regarding the actual changes that are proposed to enable us to further comment. However, the RACP urges the TGA to employ appropriate expertise and experience to inform this work, and ensure effective collaboration with both consumers and physicians – in particular drawing on the expertise of clinical pharmacologists – to ensure the changes are those that will be most effective.

Compliance

The RACP strongly supports the establishment of a more robust and rigorous pharmacovigilance inspection system; however there is insufficient detail provided regarding the proposed system to enable us to properly respond to the question posed.

Fundamental to the system is that it is comprehensive and timely, so that safety issues can be detected and responded to at the earliest possible time. It is important that penalties for non-compliance are sufficient to support them being effective. Two specific elements that the RACP supports being included are that sponsor companies can be required to provide safety data on the first 12 months of a medicine or medical devices use post its approval, and that the TGA is granted the authority to conduct random and targeted audits.

As to the Risk Management Plan (RMP) compliance monitoring, we did not have time to undertake consultation on this matter, but would be happy to follow-up on this if the TGA would like us to.

Data

The RACP strongly supports enhancing the TGA data analytics capabilities, and in particular calls for this reform to address the current inability to effectively link the disparate sources of health data. These reforms should ensure the ability to link data from the Pharmaceutical Benefits Scheme (PBS), Medicare Benefits Schedule (MBS), pathology and diagnostics data, as well as data from both public and private hospitals.

There is a significant opportunity with the Australian Digital Health Agency's work for the TGA to work strategically to both support and leverage the increased use of the electronic health record, to improve both the collection and use of health data in support of the Quality Use of Medicines. However, there is no mention of this within the consultation paper. If this is not being considered, we see this as a major lost opportunity.

We strongly support improvements being made to the Adverse Events Management System and the sharing of data between relevant international stakeholders, however there is insufficient detail in this paper for us to provide specific comments.

We would note however, that medicines used by children and adolescents need a particular focus due to the difficulty in obtaining clinical trial data on this population group, and also that there is a need for improved data on the impact on patients of switching between biosimilar medicines. This is an area where there is widespread acknowledgment that data is lacking, and where an improved pharmacovigilance system could be utilised to fill this gap with real-life data. Clinical trial data also omits study of patients who are elderly and have comorbidity, including obesity, a factor known to alter drug disposition, efficacy and toxicity. Provisional approval with close monitoring of these users with any new medicines is thus pivotal.

In summary, the RACP is very supportive of the proposed improvements to the existing monitoring of medicines in Australia, insofar as those details that have been provided. Their further detail and effective implementation will need to be fully informed and guided by relevant expertise and experience, including consumers, physicians and in particular clinical pharmacologists. The RACP would be pleased to provide further feedback on specific aspects of these reforms if that would support their effective and smooth implementation.

Should you require any further information regarding this matter, please contact Bella Wang, Policy Officer [redacted]

Yours faithfully

[redacted]

Dr Catherine Yelland PSM