Australian Government
Department of Health

Deputy Secretary

Mr Patrick O'Connor
[redacted]

Dear Mr O'Connor

Your letter and report, 'Prescribed Deaths – Life in the Killing Zone'

Thank you for your correspondence dated 7 July 2020 and the attached report. I note the significant investment of time and effort that has gone into writing the report.

I am responding on the regulatory issues you have raised relevant to the Therapeutic Goods Administration (TGA), which is part of the Department of Health. Although I acknowledge that you have also raised important and related clinical practice matters such as informed consent, the regulation of the health profession is the responsibility of the Medical Board of Australia.

In your letter and report, you express specific concerns about the content of Consumer Medicines Information (CMI) documents for a number of medicines, relative to the content of their corresponding Australian Product Information (PI).

Pharmaceutical companies have the responsibility to write and maintain their CMI; TGA does not have a role approving CMIs. As you identify in your report, the CMI is required by the *Therapeutic Goods Regulations 1990* to be consistent with the PI. However, I should clarify that they are not required to contain exactly the same content. This is chiefly because, although both are publically available, the information contained in the PI is targeted at health professionals whereas the CMI is predominantly for patients and their carers.

The Regulations also require that the CMI is written in language that will be easily understood by patients and therefore the content is often less technical than that found in the PI. For example, a CMI often describes more easily understood symptoms in lieu of the precise medical terminology for individual side effects. Similarly, it usually advises the importance of having further discussions with the prescribing doctor or the dispensing pharmacist, particularly if the consumer has any concerns or questions about using the medicine.

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For example, in a situation such as you have described on page 109 of your report, where there is a specific neonatal or foetal risk included in the PI, it would be considered consistent for the CMI to instead advise the patient to speak with their doctor if they are pregnant, planning to become pregnant or breastfeeding. This is because the inclusion of additional technical details would require a high degree of medical literacy (which sadly is comparatively low in Australia) and could have the potential to confuse and delay action by patients.

While PI and CMI are important tools to assist prescribers and consumers to be aware of potential risks, they are not intended to be a substitute for individualised health professional advice or informed consent, which are clinical practice matters. Prescribing decisions may also be informed by clinical guidelines and other resources published by clinical colleges.

You may be aware that the TGA has recently undertaken a project to further reduce complexity and improve readability of CMIs. This has resulted in the development of a new format that based on extensive consumer testing provides more accessible safety and other information for consumers. This new format will be implemented for all new medicines that require a CMI from the start of next year and adopted other medicines within a set transition period. Pharmaceutical companies can elect to adopt the new format sooner and some have already indicated their intention to do so.

While our regulatory remit is limited to medicines and other therapeutic goods, the TGA does work to improve awareness of potential safety issues to influence prescriber behaviour. For example, the opioid reforms that you have mentioned have the overall aim to reduce harmful and hazardous use of these products while maintaining appropriate use. This is resulting in stronger warnings in the PI and CMI of these products in addition to a number of other changes that have been informed by an advisory group of clinical experts and consumer representatives.

We are undertaking a range of other activities in conjunction with various clinical groups to support the opioid reforms and provide health professionals with the tools and resources to apply them in practice. There will also be a range of resources for consumers to empower them to make informed choices about their treatment.

While responding to opioid issues is currently a priority, the TGA also continues to monitor and respond to issues concerning other medicine classes, including antidepressants, benzodiazepines and gabapentinoids.

Your letter directed us to the recommendations made in your report. I am unable to comment on many of the recommendations that require specific Government action like a Royal Commission, or a new healthcare safety regulator, as a decision on these would be for the Parliament to make.

In relation to your recommendations in section 4.2 of the last chapter of your report, the TGA applies scientific and clinical expertise to decision-making to ensure that the benefits of a medicine outweigh its risks across the lifecycle of a medicine for its intended population. While there may be variation in some processes, TGA standards are aligned with those employed by other medicines regulators including

the FDA and the EMA, and we collaborate and communicate very regularly with these organisations. I can reassure you that the TGA continually monitors and responds to medicine safety issues as they arise.

Thank you for your interest in medicines safety.

Yours sincerely

Adj. Professor John Skerritt
Health Products Regulation Group

23 July 2020