Ms Elizabeth Lee MLA

Chair

Standing Committee on Justice and Community Safety

ACT Legislative Assembly

London Circuit

CANBERRA ACT 2600

Dear Ms Lee

I am writing to provide advice in response to comments made in the Standing Committee on Justice and Community Safety (Legislative Scrutiny Role) Scrutiny Report 18 regarding the Medicines, Poisons and Therapeutic Goods Amendment Bill 2018 (the Bill).

I thank the Committee for its consideration of the Bill and provide the following comments in relation to the matters on which the Committee has requested a response.

Protecting patient privacy

The Committee has noted the explanatory statement to the Bill outlines practical steps that will be taken to limit the effect of the Amendment Bill’s interference with privacy and has asked how these measures will be enforced.

These measures include that relevant health professionals must use unique user names and passwords to access information on the Monitored Medicines Database (the database), and that users acknowledge a mandatory disclaimer before any health records can be accessed. ACT Health has also committed to update its relevant controlled medicine approval application forms to help ensure relevant health professionals and patients are reasonably aware of how their data is being collected and for what purpose.

ACT Health staff will also monitor appropriate access and use of database information and may take enforcement action where required. Enforcement action may include initiating prosecution under newly established offence provisions, or exercising existing administrative controls to ensure any response is appropriate and proportionate to any alleged breach of privacy.

As several of these additional privacy protection measures concern either administrative controls, or technical aspects of the database, it would not be appropriate to include these controls in the Bill. I am confident however that providing for these detailed privacy controls in the explanatory statement to the Bill demonstrates the Government’s ongoing commitment to protect privacy.

I note that the Committee has also raised concerns regarding arrangements with approved data source entities that are engaged by other jurisdictions to collect, store, access or deal with information on the database.

In accordance with general privacy principles under relevant ACT and Commonwealth law, the collection and use of personal information should only occur where necessary to support a stated function or activity. The Chief Health Officer’s authority to enter into an arrangement with an approved data source would be limited to those data sources that support a defined purpose of the database, and support a prescription monitoring initiative of a State or Commonwealth Government. Any database information shared outside the ACT would also require to have comparable legislative controls on the collection, access and use of database information. I note that other state Governments, including Victoria and New South Wales, have similar controls on the use and sharing of health records outside their jurisdiction. I am of the view that there are appropriate restrictions in place to ensure that information on the database is restricted to authorised uses.

Additional purpose for the database

The Committee has also raised concerns regarding the introduction of section 97C to the

*Medicines, Poisons and Therapeutic Goods Act 2008* (the Act), which will allow a regulation to prescribe additional purposes for the monitored medicines database. Concerns were raised regarding how these additional purposes may interact with other parts of the Act.

Other jurisdictions and the Federal Government have been working on the development of comparable databases to monitor the supply of certain medicines. This work is ongoing and may impact the way that the database operates in the ACT. It is considered critical to provide that additional database functions may be provided for by regulation to ensure the continued operation of database in the ACT and its integration with any other government sponsored public health initiative.

In noting that any proposed changes to regulation must be consistent with the purposes of the authorising Act, and that any change to subordinate legislation must consider its impacts on human rights and regulation impacts, and may be further examined by the Committee or subject to disallowance in the ACT Legislative Assembly, I am of the opinion there are adequate controls on inserting additional purposes to the database.

As the Committee has outlined, user access to the database by a person other than a relevant health professional can only be granted if the Chief Health Officer (CHO) considers it to be in the public interest to do so. This public interest requirement was purposefully included to ensure that any additional purposes are also in the public interest and that the right to privacy is protected to the greatest extent. It also ensures that the CHO can prevent access by those who make requests that may meet the purpose of the database but may cause privacy or other concerns.

Right to the presumption of innocence

The Committee noted that health professionals should be aware of the restrictions placed on access to information on the database and raised concerns about how steps listed in the explanatory statement will be enforced in the context of the right to the presumption of innocence.

As noted in the explanatory statement to the Bill, registered health professionals ought to be reasonably aware of their obligations to patient privacy due to the operation of the *Health Records (Privacy and Access) Act 1997*. Additionally, health practitioners are reminded of their obligations to protect sensitive health information, and that penalties may apply to the unauthorised access or use of health information before remote access to the database is granted. Acknowledgement of this disclaimer will be enforced by preventing the user from accessing the monitored medicines database until they acknowledge it. These measures, in addition to the application of strict liability for certain parts of the newly inserted offence provisions, are considered critical to protecting patient privacy.

Clause 14

The Committee has requested additional information concerning Clause 14 of the Bill. Clause 14 of the Bill seeks to update the regulatory framework to ensure the supply of monitored medicines during patient consultations are reported in the same fashion as monitored medicines supplied by a pharmacy. I note the Committee’s comments that clause 14 of the Bill has not been satisfactorily explained by the explanatory statement and will ensure that future explanatory statements prepared by ACT Health expressly address each clause of any amending legislation.

I trust that this information addresses the Committee’s comments.

Yours sincerely

Meegan Fitzharris MLA

Minister for Health and Wellbeing