

13 February 2020

Real Time Prescription Monitoring  
NSW Ministry of Health  
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Dear The Real Time Prescription Monitoring Project Team,

**Re: Consultation regarding Regulation to Support Real Time Prescription Monitoring**

We are writing in response to the Regulation to Support Real Time Prescription Monitoring (RTPM) consultation paper released in December 2020, which aims to support the use of RTPM via an amendment to the Poisons and Therapeutic Goods Regulation 2008.

Positive Life NSW (Positive Life) is the lead peer-based agency representing all people living with and affected by HIV in NSW. We provide leadership and advocacy in advancing the human rights and quality of life of all people living with HIV (PLHIV), and to change systems and practices that discriminate against PLHIV, our friends, family, and carers in NSW.

We acknowledge the importance of safe dispensing of prescription medicines. We also acknowledge that some prescription medicines can cause dependence and can become harmful. We in no way minimise the harm that comes from overuse or non-medical use of certain prescription medicines in some instances.

However, Positive Life would like to express a number of concerns that we have over the proposed regulations as outlined in the Regulation to support Real Time Prescription Monitoring (RTPM) Consultation Paper ('the Consultation Paper'), as outlined below:

Purpose

The Australian Government Department of Health, which has legislated the introduction of these regulations in each state and territory jurisdiction within Australia, specifies that one of the reasons RTPM is important, is because "Technology developments can help reduce misuse of medicines listed as controlled substances, while ensuring that patients who genuinely need these medicines are able to access them."<sup>1</sup>

Additionally, the Consultation Paper notes that the RTPM system "information will help your doctor and pharmacist to make safer clinical decisions and will also help them to identify circumstances where you may be receiving potentially harmful medicines beyond medical need" as well as stating that the harm aimed at being minimised is "some prescription medicines can cause dependence and can become harmful", with 2018 statistics of nationwide unintentional drug-induced deaths quoted.<sup>2</sup>

PLHIV genuinely and routinely need certain medications for co- and multi-morbidities that are common among PLHIV, including peripheral neuropathy and sleep disturbances. Many

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<sup>1</sup> Australia Government Department of Health, *National Real Time Prescription Monitoring (RTPM)*, 2021, Available online: <https://www.health.gov.au/initiatives-and-programs/national-real-time-prescription-monitoring-rtpm>

<sup>2</sup> NSW Government Department of Health, *Regulation to support Real Time Prescription Monitoring (RTPM) Consultation Paper*, 2020

people already have difficulty accessing pain management services and other healthcare services, particularly when experiencing multiple chronic health conditions.

Furthermore, the issue of dependence and harm minimisation through RTPM is more nuanced than simply individual people being prescribed certain amounts of medications over a certain period of time. These intersecting issues relate to things such as the cost of doctor appointments to access scripts; regional/rural location necessitating long and/or expensive travel time to prescribers (doctors) and dispensers (pharmacists); the cost, time, and mental load of managing multiple health conditions and medications, etc. Some people may prefer to receive six months' worth of medication per prescribing and dispensing encounter, due to all of these issues and potentially more. Moreover, an unintentional drug-induced death may occur with only one script prescribed and dispensed, depending on the conditions and the medicine.

If RTPM regulations are introduced in NSW without increased investment in pain management and other healthcare services and/or without adequate protections for PLHIV with chronic and complex health conditions, we are concerned that PLHIV will be at increased risk of harm if they are unable to access medications that work for them. This contradicts the intended outcome of RTPM regulations, in reducing harm to Australians who use the medicines included on the Monitored Medicines List. A comprehensive support network for good health needs to be met, which addresses the core issues attempting to be solved by RTPM with prescribers and dispensers, rather than a punitive and data-monitoring approach for health consumers.

#### Monitored Medicines List

We note that the list of monitored medicines is not the subject of this consultation, and that an "expert panel of medical advisors and researchers will determine which medicines should be included in the list of medicines to be monitored in RTPM (monitored medicines). This will be based on the latest international and local research."<sup>3</sup> However, we suggest that the consultation period of just before Christmas 2020 to mid-February 2021 is not sufficient time to conduct a comprehensive consultation period. We recommend that meaningful consultation be made with community representatives and health consumers, especially those with chronic and complex health conditions including PLHIV, be involved in the "expert panel" which decides on the medicines to be included in the monitored medicines list.

#### Training and Clinical Decisions of Prescribers and Dispensers

The implementation in Victoria of the SafeScript system is "accompanied by a range of initiatives to support and prepare patients and health professionals for the implementation of SafeScript. This includes:

- A public awareness campaign to inform the general public of SafeScript and to improve the understanding of the risks associated with some prescription medicines
- Training for prescribers and pharmacists, on how to more safely prescribe and dispense high-risk medications and respond to the needs of patients."<sup>4</sup>

The Consultation Paper states that training will be "made available" to doctors and pharmacists, however the "Details of the Amendment to the Poisons and Therapeutic Goods Regulation (2008)" section does not mention anything about training of prescribers and dispensers. Positive Life recommends a comprehensive training and support program be included in the regulations as a mandatory requirement of the rollout of the system.

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<sup>3</sup> NSW Government Department of Health, *Regulation to support Real Time Prescription Monitoring (RTPM) Consultation Paper, 2020*

<sup>4</sup> South Eastern Melbourne Primary Health Network, *SafeScript – real-time prescription monitoring*, Accessed 4 February 2021, Available online: <https://www.semphn.org.au/resources/alcohol-and-other-drugs/safescript-real-time-prescription-monitoring.html>

This compulsory training is pertinent considering the Consultation Paper states that the “RTPM will not instruct your doctor what to do or whether a medicine should or should not be prescribed for you. This clinical decision remains with them as they are best placed to determine whether the medicines prescribed to you remain the safest and best option for your health needs.”<sup>5</sup> Safeguards must be in place to avoid a situation of opposing clinical decisions, where, for instance, a dispenser attempts to withhold medications to a person, even though the prescriber has utilised the RTPM system and written a prescription based on their clinical decision.

Additionally, we are concerned that the RTPM system may cause prescribers to be overly cautious in the prescribing of medicines on the monitored medicines list and may abruptly cease prescribing a certain medication without adequate mental health or alcohol and other drugs (AOD) service linkage for the patient. Both the mental health and AOD sectors are considerably underfunded throughout NSW, particularly in regional, rural, and remote areas, and without sufficient additional funding to these services as well as comprehensive training and support for healthcare workers there is considerable risk that patients will become disengaged from all services and their healthcare needs not be met.

### Exemptions

The implementation in Victoria of the SafeScript system states that: “It will be mandatory to check SafeScript prior to writing or dispensing a prescription for a high-risk medicine from April 2020. There will be exceptions in some circumstances, including when treating patients in hospitals, prisons, police jails, aged care and palliative care.”<sup>6</sup>

The Consultation Paper: “Details of the Amendment to the Poisons and Therapeutic Goods Regulation (2008)” section, clause 8 states the Regulation will: “allow exemptions under certain circumstances, such as exempting particular types of prescribers in some settings, for example, palliative care where monitored medicines are routinely used for symptom relief.”<sup>7</sup> Positive Life recommends that the list of exemptions be expanded to encapsulate all exemption categories outlined in the Victorian SafeScript system, as well as exempting PLHIV from monitoring under the regulations. Exemptions must be non-identifiable upon dispensing, see further below re: Privacy Provisions.

### Privacy Provisions

The Consultation Paper outlines that the Regulations will ensure that adequate privacy protections will be implemented in the RTPM system. A number of protections are outlined in the Consultation Paper section entitled “How does RTPM keep my records secure?” However, these are not included, nor are any protections specified, in the Regulations section of the Consultation Paper. The only mention of data privacy and security in the proposed Regulations section is outlining who can view and use information contained in the database, and the penalties for unauthorised access, use, or disclosure of information in the database.

Positive Life is concerned that the implementation of the RTPM system may result in increased sharing of people’s personal health information without their consent. This is particularly prescient considering the amount of identifiable private health information that will be included in the database. The Consultation Paper states that: “The Commonwealth

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<sup>5</sup> NSW Government Department of Health, *Regulation to support Real Time Prescription Monitoring (RTPM) Consultation Paper*, 2020

<sup>6</sup> South Eastern Melbourne Primary Health Network, *SafeScript – real-time prescription monitoring*, Accessed 4 February 2021, Available online: <https://www.semphn.org.au/resources/alcohol-and-other-drugs/safescript-real-time-prescription-monitoring.html>

<sup>7</sup> NSW Government Department of Health, *Regulation to support Real Time Prescription Monitoring (RTPM) Consultation Paper*, 2020

has determined the minimum dataset required for accurate patient matching in RTPM and it includes the following: The patient's:

- a. full name, and
- b. date of birth, and
- c. gender, and
- d. Medicare number, if available, and
- e. Department of Veterans Affairs (DVA) number, if available, and
- f. Individual Healthcare Identifier assigned under the Healthcare Identifiers Act 2010 of the Commonwealth, if available.”<sup>8</sup>

Positive Life recommends a 2x2 coding system be incorporated into the RTPM database to protect individual data privacy. Additionally, Positive Life recommends stringent data protections be outlined in the Regulations, to be imbedded in the RTPM system as it is developed, operated, maintained, and reviewed.

### Monitoring and Evaluation

The Consultation Paper does not address the monitoring or evaluation of the RTPM system, the implementation process, the database operations, the prescriber and dispenser use, or the outcomes and impact on NSW-based individuals using these monitored medicines. Positive Life recommends a thorough monitoring and evaluation process be embedded in the Regulations, to assess the implementation and outcomes of the RTMP system against the intended purposes, with the initial evaluation to occur no later than 2 years after implementation, and then every five years after that.

### Conclusions

Positive Life would like to commend the Real Time Prescription Monitoring Project Team for their consultation process with the aim of making the government and community response to healthcare as strong and equitable as possible for all Australians including those of us living with HIV.

We would welcome the opportunity to meet to discuss our submission on the Regulation to Support Real Time Prescription Monitoring in further detail and contribute our more than 30 years of experience in representing people living with HIV in NSW. To arrange a meeting, please call Jane Costello on (02) 9206 2177 or email [janec@positivelife.org.au](mailto:janec@positivelife.org.au).

We look forward to hearing from you.

Sincerely,



Jane Costello  
**Chief Executive Officer**

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<sup>8</sup> NSW Government Department of Health, *Regulation to support Real Time Prescription Monitoring (RTPM) Consultation Paper, 2020*