



Department of Health

Secretary



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07 DEC 2012

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Mr Jeff Dart
Coroner's Registrar
Coroners Court of Victoria
Level 11, 222 Exhibition Street
MELBOURNE VIC 3000

Dear Mr Dart

Court Reference: COR 2007 000549 Robert Anderson

I am writing in response to your letter dated 12 September 2012 in relation to Coroner Paresa Spanos' recommendations, to the Department of Health (the department), made on the above case.

As with previous responses to recent coronial findings, I once again acknowledge the serious issues that Mr Anderson's death bring to light in relation to the growing problem of misuse of prescription medicines. The department continues its work on the policy response to this; both through our leading of the National Pharmaceutical Drug Misuse Framework for Action and the Whole of Victorian Government Alcohol and Other Drug strategy.

The department's response to the three Coroner's recommendations which are directed to the department is as follows:

Recommendation 2:

That the Department of Health consider enhancement of the Schedule 8 permit scheme so as to audit permit compliance more comprehensively, ensuring at a minimum, that Schedule 8 drugs are being prescribed in strict accordance with the permit and not otherwise.

The department's response:

The department is already auditing permit compliance as thoroughly as the current manual system allows. The department issues permits for Schedule 8 poisons to prescribers which specify the period and quantity that a Schedule 8 poison may be prescribed. Compliance is monitored through manual prescription monitoring activities, with the intent of identifying medical practitioners who prescribe prescription medications in contravention of the *Drugs*,



Poisons and Controlled Substances Act 1981 and its associated Regulations. This does include prescribers who have failed to obtain Schedule 8 permits or who prescribe in excess of the limits of permits that have been issued.

The department carries out these activities with the resources it has available. This requires a risk-management approach following the assessment of information that is available to the department. Information may come through notifications by health practitioners or be obtained by departmental officers during prescription-monitoring, auditing and investigative activities. These sources include: complaints or reports from members of the public or other health practitioners, departmental officers obtaining dispensing records, from visits to pharmacies, monitoring and reviewing the records of supply of licensed suppliers, and reviewing data relating to transactions in Schedule 8 poisons provided by other regulatory agencies.

Further enhancement of compliance monitoring activities may involve the availability of information collected from a real-time prescription monitoring system, of the type that is currently being developed by the Australian Government through its Electronic Recording and Reporting of Controlled Drugs initiative. The department is engaging a vendor to assess the options available for a real-time prescription monitoring system in Victoria. While the department is undertaking this process, a decision cannot be made at this stage on its implementation.

Recommendation 3:

That the Department of Health considers enhancement of the Schedule 8 permit scheme so as to require all prescriptions to be dispensed only if accompanied by a copy of the relevant Schedule 8 permit, and only if prescribed in strict accordance with the permit as to strength of preparation, dose and dosing frequency, and route of administration.

The department's response:

It is not the role of the department to regulate the clinical judgment of health practitioners. A Schedule 8 permit is not an endorsement of any particular treatment, but rather a regulatory mechanism to prevent concurrent prescribing by more than one practitioner.

The Drugs, Poisons and Controlled Substances Regulations 2006 require a medical practitioner to take all reasonable steps to ensure that a therapeutic need exists before prescribing a Schedule 8 poison. The professional responsibility of ensuring that the prescribed medication and the prescribed dosage are safe and appropriate rests with the prescriber and the dispensing pharmacist, and are outside the remit of drugs and poisons legislation.

The legislation does not require pharmacists to confirm whether a permit exists when dispensing a prescription for Schedule 8 poison. The onus of responsibility rests with the prescriber to ensure a permit has been obtained in circumstances where it is necessary to apply for a permit. However, the legislation does place certain requirements upon pharmacists when dispensing prescriptions, including the obligation to confirm the bona fides of a prescription by verifying the handwriting of the prescriber. Also, a pharmacist must notify the department when called upon to dispense any prescription medication in greater quantities or more frequently than appears to be reasonably necessary.

Separately, pharmacists have professional obligations to practise in accordance with professional guidelines set out by Pharmacy Board of Australia (PBA). The PBA's "*Guidelines for dispensing of medicines*" require a pharmacist to take reasonable steps to ensure that the dispensing of a prescription for a medicine is consistent with the safety of the patient.

Medical practitioners and pharmacists have separate legal and professional obligations which they must adhere to in their respective practices. It is not appropriate to mandate that pharmacists police prescribers to ensure prescriptions are written in accordance with the specifications of a Schedule 8 permit.

Recommendation 4:

That the Department of Health initiate a dialogue with its Commonwealth counterparts about the feasibility of reconciliation of information from the Schedule 8 permit scheme on the one hand and the Medicare/PBS phone approval hotline, on the other.

The department's response:

The department is of the view that this recommendation is neither workable nor of benefit.

It is important to highlight the fundamentally different purposes of the Pharmaceutical Benefits Scheme (PBS) and Victorian drugs and poisons legislation.

The PBS was established solely as a mechanism for the Commonwealth to subsidise the cost of selected pharmaceutical medicines to consumers. The PBS is not intended to mandate legislative controls over who has access to drugs. While the Commonwealth may demand certain information in relation to the supply of medicines, this is for the purpose of and limited to administering payments for medicines listed in the Schedule of Pharmaceutical Benefits.

Controls over access to drugs are mandated by state and territories through drugs and poisons legislation. This is in place to ensure that substances captured are subject to adequate controls so that the community can benefit from access to those substances without suffering the harms that unfettered access might result in. An example of these controls is the requirement for permits to prescribe Schedule 8 poisons.

The Medicare Australia hotline exists only for telephone approval for payment purposes of PBS Authority prescriptions. It is staffed by administrative personnel whose only responsibility is to determine whether Medicare Australia will subsidise the cost of the medication. The phone operators are not trained or qualified to provide any information beyond PBS requirements for payment.

It should also be noted that not all Schedule 8 poisons on the market attract a PBS subsidy.

By contrast, permit requirements are applicable to all Schedule 8 poisons regardless of whether Medicare Australia subsidises the cost. Permit applications are assessed by suitably qualified officers (mainly pharmacists) in accordance with policies that make reference to established clinical guidelines for safe and appropriate prescribing.

Given the fundamentally different roles and objectives under which they were established, it is not a question of whether information from the PBS and the Schedule 8 permit system can be reconciled, as the two are wholly different matters.

If you require further information, please contact Mr Matthew McCrone, Chief Officer, Drugs and Poisons Regulation on 9096 5066 or email matthew.mccrone@health.vic.gov.au.

Yours sincerely



Dr Pradeep Philip
Secretary