IN THE CORONERS COURT
OF VICTORIA
AT MELBOURNE

Court Reference: COR 2012 002601

FINDING INTO DEATH WITHOUT INQUEST

Form 38 Rule 60(2)
Section 67 of the ***Coroners Act 2008***

I, K. M. W. PARKINSON, Coroner having investigated the death of CHRISTINA MIFSUD without holding an inquest:

find that the identity of the deceased was CHRISTINA MIFSUD
born on 6 February 1966
and the death occurred on 4 July 2012
at Frankston, Victoria

from:

1a. COMBINED DRUG TOXICITY

Pursuant to Section 67(2) of the *Coroners Act 2008*, I make these findings with respect to the following circumstances:

1. Ms Mifsud was born on 6 February 1966 and she was 45 years old at the time of her death. Ms Mifsud resided in Frankston, Victoria with her partner, Mr Wayne Bult. Ms Mifsud had recently moved to Frankston from Altona following the death of her father, so that she could be closer to her ill mother.

2. A brief prepared by Victoria Police for the Coroner includes statements obtained from Ms Mifsud's partner, her sister, her clinician and from investigating officers. I have drawn on all of this material as to the factual matters in this finding.

3. Ms Mifsud had a history of substance abuse, including alcohol, illicit drugs and prescription medication and she was being treated for depression. Prior to her death, Ms Mifsud was

observed by Mr Bult and her family to be affected by her father's death and her mother's illness however she did not provide any indication of wanting to take her own life.

4. Mr Bult was on the methadone program and attended a local pharmacy in Foot Street, Frankston where he would collect a "take home pack" which consisted of five separate 75ml daily doses of methadone.

5. Methadone is a prescribed drug pursuant to Schedule 8 of the *Drugs, Poisons and Controlled Substances Act 2006*. The supply of methadone is regulated under the *Drugs, Poisons and Controlled Substances Act 1981* and *Regulations 2006*. Medical Practitioners and Pharmacists prescribing or dispensing pharmacotherapy (methadone and buprenorphine) require approval from the Drugs and Poisons Reference Group (DPRG) of the Department of Health (Cwlth). The prescribing and dispensing of methadone is regulated by that Act and there are professional practice guidelines issued by professional bodies and by the health or community services departments of both the State and Commonwealth.

6. Methadone is usually dispensed by the pharmacist to the patient at the pharmacy where it is ingested under the supervision of the pharmacist. This enables supervision of consumption as well as ensuring no adverse reaction or combination with other substances. A practice known as take away doses exists by which a stable patient may be allowed to take home doses a limited number of days per week, often weekends. This measure is largely for the convenience of the patient.

7. At around 9 a.m. on Thursday 28 June 2012, Mr Bult attended his local pharmacy and was administered his daily dose of methadone. He also collected his "take home pack" of methadone, which had been prescribed to last him until Tuesday 3 July 2012 (inclusive). Upon returning home, Mr Bult stored the takeaway methadone in a plastic bag and kept it in the spare room.

8. On Monday 2 July 2012, Mr Bult went to his general practitioner in the city to collect his prescription medication. Mr Bult also visited his drop in centre and a pharmacy, before travelling back home. While he was in the city, he spoke to Ms Mifsud on the phone and has reported that she was crying and was worried about her mother, following the death of Ms Mifsud's father. Mr Bult returned home around 4 p.m. and spent some time with Ms Mifsud.

9. On Tuesday 3 July 2012, Mr Bult discovered that he did not have any remaining doses of methadone in his "take home pack". At around 10 a.m., he proceeded to attend his local pharmacy to obtain his usual "take home pack" however he was informed by the pharmacist that he should have one remaining dose from the takeaway doses he was given the previous week, which would include the dose for the present day. Mr Bult returned home and did not discuss this matter with Ms Mifsud.

10. Later that evening, Mr Bult was watching TV in the lounge room while Ms Mifsud slept on the couch, where she had been sleeping since around midday. At around 1 a.m. on Wednesday 4 July 2013, Mr Bult proceeded to his bedroom and left Ms Mifsud on the couch, having observed that she was snoring.

11. At around 7 a.m., Mr Bult woke and observed Ms Mifsud still lying on the couch. He also observed fluid coming out of her mouth and proceeded to wipe it away with a towel. Mr Bult then rolled Ms Mifsud onto her side, as she had been lying on her back, however when he rolled her he observed her to be limp. Mr Bult attempted to elicit a response from Ms Mifsud however she remained unresponsive. Mr Bult phoned emergency services who arrived shortly after however paramedics were unable to revive Ms Mifsud.

12. Police attended the scene and located empty and partially used packets of medication prescribed to Mr Bult and Ms Mifsud, including medication that Mr Bult had collected during his recent visit to the pharmacy.

13. An examination and report was undertaken by Dr Michael Burke, Senior Forensic Pathologist at the Victorian Institute of Forensic Medicine. Dr Burke reported that the cause of death was 1(a) Combined Drug Toxicity. There was no evidence of any injury that would have contributed or led to death.

14. Toxicological analysis identified methadone (0.4 mg/L), diazepam (0.4 mg/L) and its metabolite, nordiazepam (0.1 mg/L), the anti-depressant paroxetine (0.1 mg/L), 7-aminonitrazepam (0.5 mg/L) and delta9-tetrahydrocannabinol (120 ng/mg) in blood.

15. I am satisfied having considered all of the evidence before me that no further investigation is required. I am satisfied that there were no suspicious circumstances surrounding Ms Mifsud's death.

16. I find that Ms Christina Mifsud died on 4 July 2012 and that the cause of her death was Combined Drug Toxicity.

COMMENTS

Pursuant to section 67(3) of the *Coroners Act 2008*, I make the following comments connected with the death:

17. Ms Mifsud died as a result of combined drug toxicity, including methadone toxicity. An issue arises in this case as to the appropriateness of the storage of methadone at Ms Mifsud's premises and the supervision by any authority of the safety of storage. The ready availability of Mr Bult's methadone in this case has contributed to Ms Mifsud's death.

18. Methadone is a prescribed drug pursuant to Schedule 8, of the *Drugs, Poisons and Controlled Substances Act 2006*. The supply of methadone is regulated under the *Drugs, Poisons and Controlled Substances Act 1981* and *Regulations 2006*. Medical Practitioners and Pharmacists prescribing or dispensing pharmacotherapies (methadone and buprenorphine) require approval from the Drugs and Poisons Group (DPRG) of the Department of Health (DH).

19. Whilst there is no prohibition upon an authorised prescriber directing take away dosage, regulatory authority guidelines provide criteria as to the circumstances in which take away dosage is appropriate. These include the following guidelines issued by the Department of Health and Department of Human Services (Victoria) and by the National Pharmacy Board of Australia:

    - Policy for Maintenance Pharmacotherapy for Opioid Dependence (2013);

    - National Clinical Guidelines and Procedures for the Use of Methadone in the Maintenance Treatment of Opioid Dependence (2003); and

    - National Clinical Guidelines and Procedures for the Use of Buprenorphine in the Treatment of Opioid Dependence (2003).

20. These guidelines are an attempt to insure against a number of concerns, including the very circumstance which has arisen in this case, that persons other than those for whom the medication is prescribed may be able to access the drug.

21. Whilst there is a presumption in the legislation and the regulatory mechanisms that the provision of methadone for take away doses comes with a level of supervision of the patient and that there are satisfactory arrangements for secure storage, it appears to me that there is little effective supervision of the manner in which takeaway doses of methadone are stored.

22. Although the guidelines suggest that advice should be provided to the patient regarding secure, safe storage of their methadone, the guidelines do not specifically identify who is responsible for the oversight of matters such as safe storage or what steps are required to be taken to ensure safety prior to take away doses being allowed. To leave the decision-making and storage arrangements solely in the hands of the addicted person seems to be an approach which is fraught with risk, given the unreliability often associated with persons suffering with substance addiction.

23. Among the 124 deaths from acute drug toxicity investigated by Victorian coroners in 2010 and 2011, methadone source has been confirmed in 68 of these deaths. Of these 68 deaths, 21 deaths occurred in circumstances where methadone was dispensed as a takeaway dose to another person for opioid replacement therapy, then diverted to the deceased.[1]

24. That lack of supervision and lack of regulation of the storage arrangements is in my view an extremely dangerous practice which has the potential to result in the death of persons other than the patient. In this case I am satisfied that the lack of supervision of these matters contributed to the death.

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[1] Memorandum from Coroners Prevention Unit dated 11 February 2013.

RECOMMENDATIONS

Pursuant to section 72(2) of the *Coroners Act 2008*, I make the following recommendations connected with the death:

25. That regulatory authorities establish a clear mechanism of supervision of the safety arrangements for storage of take away dosage of methadone.

26. That there be a prohibition upon take away methadone dosage unless a responsible regulatory authority is satisfied that safe storage arrangements are in place in the premises in which the drug is to be stored.

I direct that a copy of this finding be provided to the following:

The family of Ms Christina Mifsud;
The Investigating Member;
The Minister for Health (Victoria);
The Minister for Community Services of Victoria;
The Health Practitioner's Board Australia;
The National Pharmacy Board of Australia; and
Interested parties.

Signature:

K. M. W. PARKINSON
CORONER
Date: 1 October 2013