Safety Notice 007/20

Illicit supply of counterfeit alprazolam

16 July 2020

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Director Regulation and Compliance Unit

Action required by:

- Chief Executives
- Directors of Clinical Governance
- Director Regulation and Compliance Unit

We recommend you also inform:

- Drug and Alcohol Directors and staff
- All Service Directors
- Mental Health Staff
- Emergency Department
- Intensive Care Unit
- Toxicology Units
- Ambulance
- All Toxicology Staff

Expert Reference Group

Content reviewed by:

- Centre for Alcohol and Other Drugs, NSW Ministry of Health
- Standing Panel on Toxicity Risk, NSW Ministry of Health
- Emergency Care Institute Director

Clinical Excellence Commission

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Internet Website: http://health.nsw.gov.au/sabs

Intranet Website: http://internal.health.nsw.gov.au/quality/sabs

Review date
January 2021

Background

A recent increase in poisonings involving alprazolam has been detected by the NSW Poisons Information Centre. There appears to be a growing market of counterfeit alprazolam and the unregistered 'designer' benzodiazepine 'etizolam' in Australia. The product is often sold as 'Xanax', with packaging and tablet appearance resembling legitimate pharmaceutical alprazolam 2mg tablets such as Australian brand 'Kalma' or international versions 'Xanax', 'Mylan' and 'Sandoz' alprazolam. The products have not infiltrated the pharmacy supply chain and to date, seem to be limited to illicit supply. TGA released the following alert on 29 June 2020:

https://www.tga.gov.au/alert/counterfeit-alprazolam-2mg-and-kalma-2-tablets

NSW Health issued a previous alert on 12 December 2019, regarding non-pharmaceutical grade (counterfeit) alprazolam tablets containing etizolam: https://www.health.nsw.gov.au/aod//public-drug-alerts/Pages/drug-warning-counterfeit-alprazolam.aspx

Substances detected to date in counterfeit alprazolam labelled products in Australia, alone or in combination, include: etizolam (most common), alprazolam, clonazepam, flubromazolam, flualprazolam, flubromazepam, barbitone, cyproheptadine, promethazine, doxepin, MMTMP (Irgacure 907), amantadine, 5-methoxy-N,N-dibutyltryptamine and lidocaine.

Notify NSW Ministry of Health of counterfeit and designer benzodiazepine cases

The Therapeutic Goods Administration (TGA) has requested that NSW Health provides information on future cases of exposure to counterfeit benzodiazepine products (e.g. alprazolam) and designer benzodiazepines (e.g. etizolam).

Suggested actions required by Local Health Districts/Networks

1. Instruct clinicians to be alert for increased circulating counterfeit alprazolam products and be vigilant during patient histories which report use of 'alprazolam'.

2. Instruct clinicians to report cases of suspected counterfeit and designer benzodiazepine patient presentations (not already referred to the NSW Poisons Information Centre) to the NSW Ministry of Health (email: MOH-PRISE@health.nsw.gov.au; fax: 02 9845 3597) who will forward to the TGA.

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Clinician actions

1. If the patient has significant signs such as CNS and respiratory depression, seizures, and/or ECG changes, consult your local toxicologist or the Poisons Information Centre on 13 11 26.
2. For patients who do not meet the above criteria, email case reports to the Centre for Alcohol and Other Drugs, NSW Ministry of Health, at MOH-PRISE@health.nsw.gov.au or fax to 02 9845 3597 with the following information:
    - Suspected substance
    - Age and gender of patient
    - Hospital/facility name
    - Ward/service (outpatient, ED, ICU)
    - Location of exposure (e.g. school, home, public area, licensed public venue etc.)
    - Source of product (e.g. street, school, Internet)
    - Photos of substance and packaging if available; or, description reported by patient (e.g. colour, shape, marking, strength, pack size)
    - Name, email and phone number of a key contact for follow up if needed
    - Has substance been handed over by patient that could be tested? (Y/N)

    Note that where consultation with the NSW Poisons Information Centre (PIC) occurs, the data collected by the PIC will be passed on to the NSW Ministry of Health.
3. Request a routine urine drug screen and store sample refrigerated.*
4. Store any product handed over by patient in a bag/container labelled “DO NOT USE – FOR ANALYSIS”. Record the quantity of each suspected counterfeit product in a separate page in the drug register as “suspected counterfeit product labelled as [insert description here]”. As alprazolam is a Schedule 8 medicine, lock the product in a drug of addiction safe, preferably in the hospital pharmacy.
5. After the NSW Ministry of Health has notified the TGA, the TGA will contact the hospital key contact with courier details to collect the sample(s) for analysis. The courier must sign a receipt for receiving the sample(s) and the TGA will return a delivery receipt when reporting results. The hospital must retain the receipts and an entry must be made in the hospital drug register for the supply of the product to the TGA.

The NSW Ministry of Health and the Poisons Information Centre will collate the de-identified NSW case information and pass on to the TGA.

De-identified results from TGA testing will be reported to NSW Ministry of Health, reporting clinician, pharmacy (if applicable) and NSW Poisons Information Centre via email.

*Urine drug screens and other testing

Most routine hospital urine drug screens detect benzodiazepines as a class only and not all can detect etizolam or other designer benzodiazepines. Individual benzodiazepines are only reported if samples are sent for confirmatory testing. A special request needs to be made for ‘etizolam’ or any other suspected designer benzodiazepine in the notes of usual pathology UDS request forms for a report on these substances.