INTRODUCTION

The Pharmaceutical Services Unit is part of the Legal and Regulatory Services Branch of the NSW Ministry of Health. The Unit is responsible for the administration of the Poisons and Therapeutic Goods Act 1966 (NSW) and the Poisons and Therapeutic Goods Regulation 2008 (NSW), and the development of policies and guidelines to complement the legislation.

The objectives of the Unit are:

- to promote the health, safety and welfare of the public through the appropriate use of medicines, other therapeutic goods and poisons,
- to minimise the risk of harm to the public arising in the course of the prescription, manufacture, sale, supply, storage, handling, use and disposal of medicines, therapeutic goods and poisons, and
- to minimise the risk of medicines, therapeutic goods and poisons being diverted for unlawful purposes in the course of their prescription, manufacture, sale, supply, storage, handling, use and disposal.

This policy sets out the Unit’s overall approach to compliance and enforcement that facilitates the effective achievement of the Unit’s objectives.

RISK-BASED APPROACH

A risk-based approach is applied to its regulatory functional decisions to enable resources to be targeted to the areas where they are most needed and that will prove to be the most effective.

Risk is measured in terms of the likelihood of an event occurring and the risk of harm to individuals and the community. More detail is provided in the risk-matrix in Figure 1.

An example of an event with low risk is the failure of a pharmacist to personally handle the sale of a Schedule 3 salbutamol asthma inhalant to a customer in breach of the Poisons and Therapeutic Goods Regulation. The risks associated with such a breach are considered minor because the proper use of these inhalers is generally initiated under medical supervision and the great majority of supplies by pharmacists are repeat supplies where a pharmacist’s advice is not required.

On the other hand, the prescribing of high-dose Schedule 8 opioid drugs to drug dependent persons without authority in breach of Section 28 of the Poisons and Therapeutic Goods Act would be considered an event with high risk. This is because the likelihood of abuse/misuse is at a high level and the consequences of such misuse can be severe and potentially life threatening.

Actions taken by the Unit in response to non-compliance will depend on the likely risk associated with the non-compliance.
RESPONSE TO NON-COMPLIANCE

A graduated and proportionate approach is applied to the application of enforcement tools. A range of tools are available when taking action on a compliance matter, and in some circumstances multiple tools may be used at the same time.

Authorised Inspectors

The Poisons and Therapeutic Goods legislation provides for the authorisation of inspectors to exercise a variety of powers, including powers of entry, search and seizure of records and goods.

Encouragement/Guidance

To facilitate compliance, guidance is provided to stakeholders, and interacts with stakeholders in a way that fosters understanding of the requirements and importance of compliance.

Advisory Letters

Advisory letters are issued to confirm verbal advice given by Ministry officers regarding insignificant or minor non-compliance with legislation.

Show Cause Letters

Show cause letters are issued in accordance with statutory provisions of legislation when there is an intention to suspend or cancel a licence or authority.

Cautions/Warnings

Cautions or warning letters are issued to confirm verbal advice given regarding minor to moderate non-compliance with legislation, particularly where there is no previous history of non-compliance.

Restrictions/Cancellations

Restrictions or cancellation action is undertaken when there is evidence of major or extreme consequences to protect the health of individuals or the public generally.
Referrals

Referrals to other co-regulatory agencies, such as health professional councils or the Health Care Complaints Commission, typically occur in circumstances where a health professional has engaged in professional misconduct. In some circumstances a matter may be referred to the police for investigation as a criminal matter.

Prosecutions

Prosecution may be initiated for more serious breaches, but usually only when a more appropriate enforcement option is not available. Further information can be found in the Ministry of Health document PD 2014_021 Prosecution Policy and Guidelines.

OTHER AGENCIES

Pharmaceutical Services Unit may liaise and interact with numerous agencies with respect to compliance and enforcement matters. The agencies the Unit most frequently engages with are the health professional councils (e.g. Medical Council of New South Wales, Nursing and Midwifery Council of New South Wales, Pharmacy Council of New South Wales), the Health Care Complaints Commission, the Commonwealth Therapeutic Goods Administration, and the NSW Police Force.

For further information or clarification of this document, contact the Duty Pharmaceutical Officer, Pharmaceutical Services during office hours on (02) 9391 9944.