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A PHARMACEUTICAL AND CHEMICAL INDUSTRIES  
TRAINING AND AWARENESS PROGRAM

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THE CONTROL AND MONITORING  
OF  
DRUGS AND CHEMICALS  
TO PREVENT THEIR DIVERSION  
FOR ILLICIT USE

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## Acknowledgments

Development of this training package relied on consultation with senior personnel of State and Territory Health Departments, Law Enforcement Agencies, Industry Associations (PACIA, Medicines Australia and SIA), the Australian Customs Service, Poppy Advisory And Control Board and a number of chemical and pharmaceutical companies.

The assistance and valuable feedback provided by the many people who contributed in any way is gratefully acknowledged.

## Disclaimer

The information contained in this program is provided for training purposes and should **not** be regarded as the basis for development and implementation of all Company procedures with respect to the substances described. Information in this package is likely to be affected by changes to relevant Commonwealth, State and Territory legislation. Company officials should contact the relevant Commonwealth and State or Territory authorities directly to ascertain their legal responsibilities.

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THE CONTROL AND MONITORING OF  
DRUGS AND CHEMICALS TO PREVENT  
THEIR DIVERSION FOR ILLICIT USE

MODULE 1

Controlled Drugs and other Restricted  
Substances

An Introduction

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## MODULE ONE

### CONTENTS

Training Program Overview

Module Introduction Who Should Complete This Module?

List of acronyms used in this Training Package

Unit One	Australia's Responsibilities to the relevant UN Treaties
Unit Two	Definitions of important key terms
Unit Three	Rationale for controls on some drugs
Unit Four	Social, Medical and Industrial Relevance of Controlled Drugs
Unit Five	Classification and Scheduling of Controlled Drugs
Unit Six	Precursor Chemicals to Controlled drugs and other restricted substances or Items which can be used in the Manufacture of Illegal Drugs
Unit Seven Professional	Programs Coordinated by Relevant Agencies, Authorities or Groups

### Appendices

Appendix 1.	Tables I and II, "Substances Frequently Used in the illicit manufacture of Narcotic and Psychotropic Substances", United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988 with additional Substances as per 1993 amendment
Appendix 2	Categories of Precursors and Ancillary Materials from <i>The Code Of Practice for Supply Diversion into Illicit Drug Manufacture</i>

For the most current **lists of narcotic and psychotropic substances** subject to international controls refer URL <http://www.incb.org> (also known as the yellow list and the green list respectively).

## TRAINING PROGRAM OVERVIEW

This training program has been developed to assist employees in the pharmaceutical and chemical industries understand the various control and monitoring requirements of certain substances and how to minimise diversion of their products to the illicit drug market. Employees can play a vital role in preventing this diversion by implementing appropriate procedures in the course of their employment.

There are several levels of control which help prevent the diversion of controlled substances including

- Company procedures
- Industry policies and Codes of Practice
- State legislation and regulations
- Commonwealth Legislation
- International treaties and conventions

### **This training program will provide you with information about**

- the rationale behind the procedures
- what you as an employee are required to do and how you can do it
- what the possible consequences may be if you do or do not follow the correct procedures
- how you may obtain information and assistance regarding the correct procedures
- what to do if you are faced with someone who is behaving “suspiciously”

### **The information provided will be relevant to personnel involved with the following activities**

- manufacturing and production line
- laboratory and Quality Control
- sales
- warehousing

## **TRAINING PROGRAM OUTLINE**

This industry training program consists of the following modules

<b>MODULE 1</b>	Controlled Drugs and other Restricted substances- An Introduction
<b>MODULE 2</b>	Restricted Substances: Conventions, Regulations, Monitoring and Reporting
<b>MODULE 3</b>	The Recognition and Handling of Suspicious Activities
<b>MODULE 4</b>	Trainer's Guide

### **TRAINER'S GUIDE**

This guide contains information to assist company-based trainers conduct the relevant training at the workplace. The information provided is set out specific to each module. It is recommended that trainers themselves attend a "Trainer" course.

### **TRAINER COURSE**

"The Control and Monitoring of Drugs and Chemicals To Prevent Their Diversion For Illicit Use" may be accessed through the Therapeutic Goods Administration website at:

URL <http://www.health.gov.au/tga>

Contact details for relevant Industry Associations are printed on the next page:

## **Thereapeutic Goods Administration**

Treaties and Export Section  
Non-prescription Medicines Branch  
Canberra ACT 2601  
Ph (02) 6270 4334

<b>PACIA</b>	<b>Plastics and Chemicals Industries Association</b>
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Phone 03 9429 0670 Fax: 03 9429 0690

<b>Medicines Australia</b>
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Phone 02 9922 2699 Fax: 02 9959 4860

<b>SIA</b>	<b>Science Industry Australia</b>
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Phone: 02 9804 8051 Fax: 02 9804 8052

## **USE OF THE TRAINING MATERIALS**

This program is designed to be relevant and flexible. It is recommended that all relevant personnel complete the entire training package. Alternatively, the package can serve as a resource or reference to supplement existing training.

Specific industries or companies, large and small should utilise those sections which contain information relevant to the workplace activities and responsibilities of their employees.

Comments about this training are welcome and should be forwarded to:-

**The Manager  
Treaties and Export Section  
Therapeutic Goods Administration  
PO Box 100  
WODEN ACT 2606**

**Telephone TGA information line 1800 020 653 or Facsimile 02 6270 4336**

The TGA recognises that working with industry to promote a greater understanding of the regulatory requirements for handling restricted substances and raising awareness of the tactics used by the illegal drug trade is an important element in preventing the diversion of chemicals for illicit use. This training manual is intended to answer questions you may have concerning your responsibilities and provide you with guidance in complying with regulatory requirements.

## WHO SHOULD COMPLETE THIS MODULE?

Employees whose work at any time involves the following restricted substances, should be familiar with the information provided in this training module:

- **Narcotic dugs**
- **Psychotropic drugs**
- **Precursor chemicals to controlled substances**

The information presented in this module is primarily relevant to employees of **Chemical** and **Pharmaceutical** Companies. Employees who have workplace responsibility for any substances scheduled as *controlled drugs* must be familiar with Commonwealth and State monitoring and regulatory requirements. Information about those areas is presented in Module Two.

In addition, employees who at any time may be involved with the distribution of certain types of scientific equipment used for chemical or pharmaceutical purposes should be familiar with information provided in units 1,2, 3, 6 and 7.

**ACRONYMS USED IN THIS TRAINING PACKAGE**

<b>ECOSOC</b>	Economic and Social Council (of the United Nations)
<b>EUD</b>	End User Declaration
<b>EUS</b>	End User Statement
<b>GMP</b>	Good Management Practices
<b>HCS</b>	Health and Community Services (Tasmania)
<b>NDPSC</b>	National Drugs and Poisons Schedule Committee
<b>OHS</b>	Occupational Health and Safety
<b>PACIA</b>	Plastics and Chemicals Industries Association
<b>SAHC</b>	South Australian Health Commission
<b>SOP</b>	Standard Operating Procedure
<b>SIA</b>	Science Industry Australia
<b>SUSDP</b>	Standard for the Uniform Scheduling of Drugs and Poisons
<b>UN</b>	United Nations
<b>WHO</b>	World Health Organisation

## UNIT ONE

### **Australia's Responsibilities under the International Drug Treaties**

**This training supports three United Nations Conventions to which Australia is a signatory. They are:**

- “Single Convention on Narcotic Drugs, 1961”
- “Single Convention on Psychotropic Substances, 1971”
- “United Nations Convention against Illicit Traffic In Narcotics and Psychotropic Substances”, 1988

Essentially these conventions require signatories to develop and enact relevant legislation and set up the administration for the monitoring and control of drugs at risk of abuse or misuse which may lead to physical or psychological dependence (ie controlled drugs) and certain other specified substances.

**Australia's responsibilities in this regard include:**

- establishing procedures designed to prevent the flow of these substances to the illicit drug market both internationally and within Australia; and
- implementation of a monitoring system that provides accurate data on the domestic consumption and needs estimates of restricted substances.

**Australia aims to fulfil its responsibilities to these treaties through**

- Commonwealth legislation *Customs (Prohibited Imports) Regulations*  
*Customs (Prohibited Exports) Regulations*
- Commonwealth Monitoring movements Companies are required to report weekly, on *of controlled drugs* to the Department of Health and Ageing
- State Legislation State Acts of Parliament which regulate Drugs, Poisons and Controlled Substances
- State, Territory and Federal Law Enforcement Australian Federal Police and State law Enforcement Agencies become involved in cases where State or Federal laws are breached
- Other National and State programs National and State Drug Awareness Programs, Drug addiction Treatment Programs

Module Two of this Training Program provides further information about:

- the Conventions;
- how Australia complies with the Conventions;
- requirements placed on Pharmaceutical and Chemical Industries; and
- control and monitoring of the substances, for licit use, by relevant authorities.

### **PURPOSES OF MONITORING AND CONTROL**

**A key aim of the control and monitoring processes is to prevent diversion and the manufacturing and trafficking of illicit drugs and substances.**

Thus, Control and Monitoring aim to ensure that these substances are used appropriately for medical and scientific purposes.

## UNIT TWO

### Definitions of Important Terms

#### Drugs

Certain chemical substances can, to a lesser or greater extent, affect the way in which the body functions. Some are used to reduce pain, lower the severity of illness or affect the mental state. Chemicals used for medical purposes are often referred to as “drugs”. Even though they have no current medical use, some chemical substances are referred to as drugs, because they are known to affect the body.

Medically, some drugs can cause *addiction*. The taking of these drugs can become compulsive, and can also lead to *tolerance* and other health problems (physical and emotional).

Tolerance refers to a physiological condition in which a drug no longer has the same effect. The user needs more of the drug to get the same reaction.

#### Controlled drugs

For the purposes of the **Commonwealth** Reporting system, *Controlled drugs* are defined under respective **State/Territory Acts** and **Regulations**. Generally, the State/Territory legislation defines these substances through adopting or referring to **Schedule 8 of the Standard for the Uniform Scheduling of Drugs and Poisons** (which includes controlled drugs declared to be drugs of addiction or dangerous drugs). Regulations and Schedules to the primary legislation (ie the Acts) are subject to regular updates.

These substances are therefore *controlled* and *monitored* by relevant State and Commonwealth authorities. A person or Company may be charged and prosecuted by law enforcement agencies if legal requirements are breached.

A Company, whose business operations involve *controlled drugs*, is required to follow State and Commonwealth laws and regulations.

#### Licit, Illicit

The terms “*licit*” and “*illicit*” are used in conjunction with *drugs* or substances that are controlled or licensed.

Licit refers to the drugs that are permitted with a licence and Illicit refers to the drugs that are used unlawfully or forbidden. “Illicit traffic” under the relevant UN Convention (1971) is defined as the manufacture of or trafficking in listed substances contrary to the provision of this convention.

The illicit manufacture of amphetamines and other drugs, in Australia, is of concern. The chemical composition and therefore the physiological effects of illicit drugs are most often unknown and can lead to injury. Accessibility, lack of education or knowledge about the dangers and social peer-group pressures, have increased the likelihood of some Australian youth taking illicit drugs. A number of educational, training and law enforcement programs have been established in order to reduce the personal and social damage caused by illicit drugs (see Unit 7).

### **Restricted Substance**

In general, restricted substances are those subject to some type of regulatory control. This varies with respect to the type of chemical, its presentation and its intended use.

**The three types of restricted substances which relate to this training are:**

- **narcotic drugs;**
- **psychotropic drugs; and**
- **precursor chemicals to controlled substances.**

It should be noted that this list is not exhaustive, other types of substances are also regulated in Australia including anabolic steroids, antibiotics, abortifacients and human growth hormones.

The narcotic, psychotropic and some precursor substances are listed in schedules 4, 8 and 9 of the SUSDP (*Standard for the Uniform Scheduling of Drugs and Poisons*).

However there are some chemicals that may be used for the production of specific illicit drugs that are **not** scheduled as either narcotic or psychotropic substances. Nevertheless some *control* mechanisms have been introduced to reduce the likelihood of, or to prevent the diversion of these chemicals to the illicit production of drugs.

The **Code Of Practice**, (PACIA, SIA, in conjunction with the Government and Law Enforcement Agencies) is an important part of Industry's role in preventing this diversion. A "Code of Practice" has now been implemented in a number of Australian States. (See Appendix 2.) Unit 7 provides further details about the Code of Practice.

## **NARCOTIC DRUGS**

Medically, Narcotic drugs (narcotics) are used for their strong anaesthetic properties (for the relief of severe pain). They can induce stupor and insensibility. The term Narcotic is used particularly for morphine and other derivatives of opium but it is also applied to other drugs which depress brain function.

The use of narcotics can lead to *dependence* and *tolerance*.

Because of their powerful effects on the body and their addictive nature, Narcotics are ***controlled drugs*** and their use is restricted. Medical supervision is required to minimise the risk of serious side effects or possibly death due to overdose.

**For the purposes of this training, the *Single Convention on Narcotic Drugs, 1961*, identifies narcotics as those substances listed in Schedules I, II and IV of the Convention. Please see <http://www.incb.org> for a list of Narcotic drugs under International control.**

Currently in Australia some Narcotics are not available for medical purposes, because of their addictive properties and the availability of alternate substances. These substances are in Schedule 9 of the SU SDP and are only available for research and testing purposes (eg heroin).

## **PSYCHOTROPIC DRUGS**

Medically, these drugs can affect (or alter) a person's perceptions and mood. Generally anti-depressants, sedatives, stimulants and tranquillisers are referred to as psychotropic drugs. The ***Convention On Psychotropic Substances, 1971*** identifies "psychotropic substance" as any substance, natural or synthetic, or any natural material in Schedules I, II, III and IV of the Convention (see the "green list" on the website of the International Narcotics Control Board).

Examples are

- amphetamines
- cocaine
- ephedrine

While many psychotropic substances have a legitimate role in medical practice, some have no recognised therapeutic use and are therefore in Schedule 9 of the SU SDP and are only available for research and testing purposes (eg 'ecstasy' otherwise known as 5-methoxy- $\alpha$ -methyl-3,4-(methylenedioxy)phenethylamine or MDMA).

## **AMPHETAMINES**

The indiscriminate use of amphetamines has become a significant problem in Australia. Amphetamines were once considered safe to use for medicinal purposes, and they were commonly used to treat many problems such as depression, epilepsy, obesity and depression. Amphetamines are now found to be toxic (ie damaging to the body) and addictive. Tolerance to amphetamines develops rapidly and prolonged use may lead to dependence.

Effects of amphetamines are diverse, dependent upon the dose and the length of time they have been used. Examples include:

- feeling of increased self confidence
- impression of heightened alertness and increased capacity for concentration
- reduction of appetite which can lead to malnutrition
- raised blood pressure and increased breathing and heart rate
- blurred vision
- loss of coordination, possible seizures

The inappropriate use of amphetamines to inhibit sleep and stop fatigue is of significant concern, particularly when a person under the influence of these drugs is driving a motor vehicle or operating other machinery.

A combination of drugs, taken together can produce enhanced or more extensive effects on the body. The use of amphetamines together with alcohol can pose a significant risk. This combination can be fatal.

## DISCUSSION QUESTIONS

*Why are drugs important? Can the use of licit drugs cause problems?*

*What side effects can legally and illegally used drugs have?*

*Are there “substances” in your work place, over which you have some responsibility, that could be used for the manufacture of illicit drugs? If so which substances?*

*What procedures has your company developed to prevent the diversion of such substances?*

## UNIT THREE

### Rationale for Controlled substances and other Restricted Substances

#### SECTION 1            Social Consequences of Illicit Drugs

The illicit manufacture of amphetamines and similar drugs is of great concern in Australia. The Convention On Psychotropic Substances, 1971 defines the term “*Manufacture*” as:  
*all processes by which psychotropic substances may be obtained, and include refining as well as the transformation of psychotropic substances into other psychotropic substances. The term also includes the manufacture of preparations other than those available on prescription in pharmacies”.*

State laws allow prosecution for the illegal possession of various substances. The possession of these substances can, on its own, lead to prosecution by State Law Enforcement Agencies.

The three treaties noted in Unit One (and explained more fully in Module Two), were developed and accepted by participating Nations and signatories because they seek to protect people and societies from the harmful effects of illicit drugs and the use of drugs when **not** medically warranted.

Questions for consideration and discussion with your trainer or group members:

*Are there any benefits to the individual or our society from the use of illicit drugs?*

*Will a person be "better off" by NOT taking illicit drugs?*

*Is it likely that a person will be "worse off" in some way, by taking illicit drugs?*

*The treaties were written to protect society from the effects of the illicit drug trade. What are some of these effects?*

Consider and discuss briefly each of the following points.

*“Every person can do something to help prevent the manufacture of illicit drugs. The easiest thing to do is not take any illicit drugs!”*

*Personnel in chemical and pharmaceutical industries have a special role to play.*

## **Consequences for society if drugs and certain substances are not *Monitored* and *Controlled***

### **Health**

- Certain substances, important for medical or scientific purposes, may be harmful if used inappropriately.
- Diseases such as HIV, HEP B and HEP C are spread more easily by certain procedures used for the "self-administration" of some illicit drugs. The procedures represent a significant reduction in hygiene.
- Lethal effects of drugs, or combinations of drugs and alcohol, pose great risks to people "self administering" these substances.

### **Society**

#### Problems include

- Social problems, such as damage to relationships within the family or family break up and possible jail sentences
- Unwarranted violence
- Injury to innocent "bystanders"
- Otherwise innocent people who get caught up in the illicit trade, especially adolescents who may, because of their ignorance, be used for trafficking activities
- Drug addiction

### **Safety/Environment**

- Environmental effects of clandestine laboratories (see next section)

### **Cost**

- Resources are needed to assist addicts gain access to, for example, rehabilitation programs and other medical treatments
- Prosecution and detention of those charged with criminal activities

## SECTION 2                    Clandestine Laboratories

*Clandestine laboratories* is the term given to illegal laboratories set up for the manufacture of illicit substances. In these laboratories drugs such as amphetamines and "home bake" heroin (heroin produced from commercial precursor substances) are made.

### **These dangerous laboratories might be set up in**

- garages
- houses
- factories
- mobile structures such as caravans

The **licit** production of substances involves Good Manufacturing Practices (GMP), Occupational Health and Safety Practices (OHS) and other government controls to ensure worker and environmental safety and product quality requirements are met. No such controls are put into effect in the operation of clandestine laboratories. The production of the illicit substances is, in itself, a danger. Some of these illegal laboratories have been discovered because they have "blown up".

### **Clandestine laboratories present risks to the**

- police
- community
- manufacturer
- environment
- users of the illicit drugs

Chemicals used in a clandestine laboratory are frequently purchased or stolen from a **chemical or pharmaceutical supplier**. They are often very dangerous and may be stored in a nearby outdoor location. Damages to a container (for example a drum) can pose a hazard, via fumes or leakage into the surrounding soil and water-way.

**The chemicals can be**

- Toxic
- Flammable
- Corrosive
- Explosive

**The "manufacturer", who is acting illegally, within a clandestine laboratory could be a**

- Qualified chemist
- Person with some knowledge of chemistry
- Person with virtually no knowledge of chemistry who just follows a "recipe"

## DISCUSSION QUESTIONS

*What concerns would you have for anyone who lived close to a clandestine laboratory?*

*What risks are there when a person with little or no knowledge of chemistry, follows a "recipe" for the illicit manufacture of drugs?*

*How can personnel in chemical or pharmaceutical companies help prevent the illicit production of drugs?*

(See Module Three for information about the recognition and handling of suspicious activities.)

## UNIT FOUR

### **SOCIAL, MEDICAL AND INDUSTRIAL RELEVANCE OF “RESTRICTED SUBSTANCES”.**

This module has described some of the effects of licit and illicit drugs and the problems with illicit drug use has been highlighted. The importance of restricted substances (including licit medicines) in our society should not be overlooked. Lists under the following headings identify some of the benefits and uses of these substances.

#### **Medical**

- Minimise suffering
- Shorten convalescence
- Enable necessary surgical procedures that otherwise may not be possible
- Veterinary Medicine
- Dentistry

#### **Industrial**

- Agriculture (Plants and animals)
- Manufacture of other useful chemicals, pharmaceuticals, cleaning agents.
- Health care products
- Cosmetics
- Food additives

#### **Social**

- Medicines and pain relief reduce suffering and help people return to work or normal activities
- Stress relief, assist in the treatment of sleeping disorders
- Provision of employment within legal industries
- Export earnings

Anyone who has seen a close friend or loved-one dying from cancer quickly appreciates how morphine makes the final days of the ill person, bearable, because of the pain relief. Our society believes that a person should not be left to suffer excruciating pain when effective treatment can be provided.

Perhaps your company plays an important role in producing medically important chemicals or drugs. Your role may be crucial to ensuring that the company's valued “Good Corporate Citizenship” is in no way damaged as a result of "diversion" of drugs or other substances.

## UNIT FIVE

### CLASSIFICATION AND SCHEDULING OF RESTRICTED SUBSTANCES

During the 1970's systems were introduced in Australia to monitor the movement of licit drugs. These covered the areas of import, manufacture, export and final distribution (for example a hospital or pharmacy).

There are many different types of control systems and the classification can seem quite confusing.

#### STANDARD FOR THE UNIFORM SCHEDULING OF DRUGS AND POISONS (SUSDP)

The National Drugs and Poisons Schedule Committee (NDPSC), a statutory committee within the Therapeutic Goods Administration, is responsible for determining the appropriate scheduling for the classification of drugs and poisons that may pose a potential risk to public health and safety such as medicines, agricultural and veterinary chemicals, and household chemicals. Scheduling decisions made by the NDPSC are included in the SUSDP, which is given legal effect through adoption into State and Territory drugs, poisons and/or controlled substances legislation.

The NDPSC membership comprises of representatives from the Commonwealth, States and Territories, New Zealand, professionals, industry, consumers as well as relevant medical and scientific experts. The aim of the scheduling is to promote consistency with regards to "availability" (manufacture, possession and distribution) of substances and the uniform labelling and packaging requirements within Australia

#### **A number of factors are considered for the scheduling of substances, including**

- potential for abuse
- safety in use
- legitimate need for the substance
- the extent and patterns of use of the substance

Poisons for therapeutic use (medicines) are included in Schedules 2, 3, 4 and 8. Progression through schedules signifies increasingly strict controls.

Note, under the system, accurate records about scheduled substances must be kept and forwarded as required to the relevant State Health Department. Movements of Schedule 8 substances must be reported to the TGA (See Module Two). Any **recording of information cannot be changed**, without following stipulated procedures. (See Module Two for information about this.)

**STATE SCHEDULING:**

States and Territories have essentially adopted the system of Scheduling as described by the SUSDP. Acts of Parliament stipulate requirements for manufacture, wholesale and distribution of scheduled substances (see Module 2).

## UNIT SIX

### **PRECURSOR CHEMICALS TO CONTROLLED DRUGS AND OTHER RESTRICTED SUBSTANCES OR EQUIPMENT WHICH COULD BE USED IN THE MANUFACTURE OF ILLEGAL DRUGS.**

#### **PRECURSOR CHEMICALS**

This term refers to chemicals or substances that are used in the manufacture of other substances. They are used in products such as pharmaceuticals, plastics, cosmetics and dyes. Precursor chemicals have also been used for the manufacture of illicit drugs, in clandestine laboratories.

Precursor chemicals are the base materials for making specific drugs and they are therefore required to be controlled or monitored. Some precursors are in fact *scheduled* and controlled under State laws or they are monitored by Commonwealth procedures. If you have responsibility for such a substance you will be required to follow a Standard Operating Procedure (SOP), as described by your Company.

Please see appendix 1, Module 2 for an example of a SOP.

Appendix 1 of this module identifies 23 substances noted (by the 1988 UN Convention) as being commonly used for the illicit manufacture of drugs.

#### **OTHER SUBSTANCES USED IN THE ILLICIT PRODUCTION OF DRUGS**

To manufacture drugs, other chemicals known as essential chemicals are also needed. These chemicals are often used for a variety of legitimate purposes in many laboratories and industrial contexts.

A more extensive listing to the 23 substances noted above has been developed. Recommended procedures for the storage, sales monitoring and record keeping for chemicals, **and certain items of equipment**, which could be used in the illicit manufacturing of drugs, have been developed by PACIA and SIA working in conjunction with the Police. This information and set of recommended Industry procedures have been formalised as a "Code of Practice" which is being increasingly adopted by Australian States and relevant industries (see appendix 2).

The risk of thefts of these types of chemicals has increased, as they become more difficult to obtain through legitimate channels. The risks posed should be assessed and appropriate security arrangements put in place.

## **EQUIPMENT**

The monitoring of glassware and equipment sales by industry personnel has been helpful in providing police with leads to criminal activities. Certain pieces of equipment and glassware are commonly used in the production of drugs. The monitoring of these, in a manner described by the Code of Practice, or as determined by law enforcement agencies, has been useful in stopping their use in illicit practices.

QUESTIONS

*Do you know of any precursor or essential chemicals that are in your work place, which could be diverted to the manufacture of illicit drugs?*

*What procedures have been established in your work place for handling, and monitoring their distribution to prevent their diversion for illicit purposes?*

*What factors should be taken into account when considering the risk of theft of precursor substances?*

*What should you do if you suspect someone is diverting some substances that may be used to make illicit drugs? (See Module 3 for more information)*

*What may be the implications of failing to report diversion by a fellow employee?*

## UNIT SEVEN

### PROGRAMS COORDINATED BY RELEVANT AGENCIES/AUTHORITIES/PROFESSIONAL GROUPS

#### Drug Squad links

Each State and Territory of Australia has its own Police Force. Within each Police force there will be a section or sections specifically set up for investigating illicit drugs.

The Federal Police are involved with Commonwealth obligations and therefore play an important law enforcement role in cases of illegal import and export of materials. Such materials could include heroin and cocaine.

Should you require advice or assistance or you are able to convey information about illicit drugs, you should contact the relevant drug law enforcement agency or your local Police Station.

#### Frontline

This is a joint venture between the Australian Customs Service and industry groups that are involved with international trade and transport, and seeks to combat trafficking in illicit drugs. Their program aims to educate

- via on going training programs
- staff of Customs agencies
- personnel in transport companies and travel organisations in the recognition of suspicious activities in relationship to drugs

Under Frontline, Customs provides those organisations that sign a *Memorandum of Understanding* (MOU) with advice on improving company security to prevent the inadvertent assistance to the illicit drug trade. Other forms of assistance and advice are also offered.

Details of **Frontline contacts** are available on the internet at:  
<http://www.customs.gov.au/bizlink/goods/business>

## National Best Practice

The National Best Practice Guidelines for Environment Health and Safety were initially developed by the National Drug Strategy Committee.

These Guidelines were formed because of the concerns with the increased risk to both the community and law enforcement authorities of the increasing number of clandestine laboratories illicitly manufacturing psycho-stimulants, including amphetamines and its “designer” drug derivatives

Police practitioners and several consulting groups, such as the OHS delegates, and environmental groups have worked together to produce the guidelines of “Best Practice”. These are strategies which aim to protect the community and authorities from hazards associated with Clandestine Laboratories.

## Industry Code of Practice

Serious concern about illicit amphetamine manufacture has led to the development of an industry “Code of Practice for Supply Diversion into Illicit Drug Manufacture”. This has been established by PACIA and the SIA working with the Government and Law Enforcement Agencies. The Code of Practice is a combined effort by participating Industry Associations in cooperation with State Police Drug Squads, and the State Departments of Health. **Copies of the Code** may be downloaded from the PACIA website at <http://www.pacia.org.au>.

The Code of Practice establishes communication and liaison between the above groups. Most **importantly** links are intended to **protect** the **welfare** of the **employees** of the companies who are implementing the Code.

## The main aims of this initiative are to

1. Protect against the diversion of chemicals to the illicit production of drugs.
2. Establish cooperation between government and law enforcement agencies in the controlled delivery of chemicals destined for use in the illicit production of drugs, where this is expected to lead to the apprehension and conviction of criminals involved in such trade or production.
3. Educate and train staff and, where practical, end users of the precursor drug chemicals about the issues involved and the procedures which should be adopted.

The Code of Practice is based on the “know your customer” principle which emphasises the need to identify customers and understand normal transaction patterns. It is a requirement of the Code that any person purchasing a category I or II chemical (refer Appendix 2) supply an end-user declaration (see Appendix 3).

The Code of Practice is being used increasingly by

- Chemical Manufacturers
- Laboratory Suppliers
- Importers
- Distributors

The Code of Practice, established by the Plastics and Chemicals Industry Association (PACIA) and Science Industry Australia (SIA) and sponsored by Crime Agencies, NSW Police, identifies three “Categories” of substances for which certain procedures should be implemented or vigilance exercised. Chemicals and ancillary materials known to have been used in the illicit manufacture of drugs are listed.

See appendix 2 for the Categories of Precursor Chemicals and Ancillary Materials from the Code of Practice.

In addition to any State Legal requirements with respect to monitoring or reporting movements of some of the chemicals listed in the three Categories described the Code of Practice requires that the following procedures are carried out:

### **Category I Chemicals**

End User Declaration to be completed for each purchase. These chemicals may only be sold to “account customers” or customers who open an account. Supply of chemicals must be delayed by at least 24 hours. The following information for each transaction shall be maintained for at least two years and shall be made available to the appropriate government authorities upon request:

- Name and address of purchaser
- Name and quantity of chemical
- Date of supply
- Completed End User Declaration (EUD)

## **Category II**

EUD required to be completed when sold to non-account customers

## **Category III**

No official reporting is required unless considered warranted. Company personnel should be alert for indicators of suspicious orders or enquires.

**See Module Three for the Recognition and Handling of Suspicious Activities.**

Details of **State/Territory contacts** can be found at Appendix 6 of the Code of Practice.

**APPENDIX 1****Substances Frequently Used in the Illicit Manufacture of Narcotic and Psychotropic Substances”, *United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988* with additional Substances as per 1993 amendment****Table I**

Acetic anhydride  
N-acetylanthranilic acid  
Ephedrine  
Ergometrine  
Ergotamine  
Isosafrole  
Lysergic Acid  
3,4-methylenedioxy phenyl-2-propanone  
Norephedrine  
1-phenyl -2-propanone  
Piperonal (heliotropine)  
Potassium permanganate  
Pseudoephedrine  
Safrole

**TABLE II**

Acetone  
Anthranilic acid  
Ethyl ether  
Hydrochloric acid  
Methyl ethyl ketone  
Phenylacetic acid  
Piperidine  
Sulphuric acid  
Toluene

## **APPENDIX 2**

### **CATEGORIES OF CHEMICALS AND ANCILLARY MATERIALS FROM:**

#### **THE CODE OF PRACTICE**

**EDITION June 2002**

CODE OF PRACTICE FOR SUPPLY DIVERSION INTO ILLICIT DRUG  
MANUFACTURE

PLASTICS AND CHEMICALS INDUSTRIES ASSOCIATION (PACIA)

SCIENCE INDUSTRY AUSTRALIA (SIA).

**Category I**

For Sale to Account Customers Only - EUD\* Required

CHEMICAL NAME	ALTERNATIVE NAME
Acetic Anhydride	
Bromobenzene	Phenylbromide
Bromo safrole	
Boron tribromide	
1-Chlorophenyl-2-aminopropane	
L-Ephedrine (and salts)	
Ethyl Phenyl Acetate	Methylbenzyl Acetate, Benzene acetic acid
Gamma butyrolactone	GBL
Gamma hydroxybutyrate	GHB
Hydriodic Acid	Hydrogen Iodide
Hydrophosphorous acid	Phosphinic acid
Methcathinone	
3,4 -Methylenedioxyphenylpropan -2-one	
N-Methyl Ephedrine	
Methyl Phenylacetate	Benzeneacetic acid
N-Methylpseudoephedrine	
Norpseudoephedrine	
Phenylacetamide	
Phenylacetic acid, salts & esters	
Phenylacetonitrile	Benzyl Cyanide
Phenylacetyl chloride	
1-Phenyl-2-chloropropane	
1-Phenyl-2-nitropropene	
Phenylpropanolamine	
1-Phenyl-2-propanone oxime	
1-Phenyl-2-propanone	Benzyl Methyl Ketone Phenylacetone
1-Phenyl-2-propanol	
Phosphorous red / white	
Phosphorous acid	Phosphonic acid
Pseudoephedrine (and salts)	
Pyridine	

(\* End User Declaration )

**Category II**

EUD Only Required When Sold to Non-Account Customers

CHEMICAL NAME	ALTERNATIVE NAME
N-Acetylanthranilic Acid	Acetamidobenzoic Acid Ajacene
Allylbenzene	3-Phenyl-1-propene
Ammonium formate	
Anthranilic Acid	2- Aminobenzoic Acid
Benzaldehyde	
Benzyl chloride-chlorotoluene	
Benzyl bromide	
Calcium metal	
Chromate salts	
Chromium trioxide	
Dichromate salts	
Ergometrine	
Ergotamine	
N-Ethylphenedrine	
N-Ethylpseudoephedrine	
Formamide	
Hypophosphite salts	
Iodine (salts)	
Isosafrole	
Lithium metal	
Lysergic Acid	9,10-Didehydro-6-methyl-ergoline-8 Carboxylic Acid
Lysergic Acid	
Magnesium metal	
Methylamine (gas)	Aminomethane / Monomethylamine
Methylammonium salts	
N-Methylformamide	
Palladium (salts)	
Phenylalanine	
Piperidine	Hexahydropyridine Pentamethylene Imine
Piperonal	3,4-Methylenedioxy-benzaldehyde
Heliotropine	
Potassium metal	
Propionic Anhydride	
Raney nickel	
Safrole	
Sassafras oil	
Sodium metal	
Thionyl Chloride	
Thorium (salts)	

**APPLICABLE APPARATUS**

Gas cylinders: hydrogen sulfide gas, hydrogen chloride gas, hydrogen gas, ammonia gas, methylamine gas.

Glassware: Round bottom reaction flask (>500mL), condenser (joint size B19 or greater), splash heads and distillation heads.

Apparatus: Heating Mantles (>500mL), pill presses, rotary evaporators

### Category III

No Reporting Required. This list should be used as guide to alert staff that these products may be used in illicit drug manufacture.

CHEMICAL NAME	ALTERNATIVE NAME
Acetic Acid	
Acetone	
Acetonitrile	
Acetyl Chloride	
Chloroform	
Cyclohexanone	Sextone
Diethyl ether	Ethyl Ether, Ether
Formic acid	Hydrogen Carboxylic Acid
Hydrochloric acid	Muriatic Acid, Hydrogen Chloride
Lithium aluminium hydride	LAH, Lithium Alanate, Aluminium Lithium Hydride
Mercuric Chloride	Mercury (II) Chloride, Mercury Bichloride
Methyl ethyl ketone	MEK, 2-Butanone, Ethyl Methyl Ketone
Nitroethane	
Phosphorus pentachloride	
Phosphorus pentoxide	Phosphoric Oxide, Phosphoric Anhydride
Phosphorus trichloride	Phosphorous Chloride
Potassium cyanide	
Potassium permanganate	
Sodium acetate	
Sodium cyanide	
Sodium hydroxide	Caustic Soda
Sulphuric acid	
Tetrahydrofuran	
Toluene	Methyl Benzene, Methyl Phenyl Methane

**Applicable apparatus:** buchner funnels, buchner flasks, magnetic stirrer/hotplates, separating funnels, chemical balances, quickfit adapters.

**APPENDIX 3**

**Sample End User Declaration from The Code Of Practice (PACIA, SIA)**

The Chemical product(s) I wish to purchase is classified as a possible illicit drug precursor or auxiliary reagent. I understand that to be supplied this product a signed end-user declaration must be provided together with an order, on identifiable company stationery. (Please note that cash sale transactions are not acceptable for Category 1 Items).

<u>Catalogue No.</u>	<u>Product Name</u>	<u>Quantity</u>	<u>Pack Size</u>	<u>Order No.</u>
.....	.....	.....	.....	.....
.....	.....	.....	.....	.....

**Intended use:** Analytical , R & D , Other , Manufacturing , Resale ,

Please specify full details of assay, project, product customer etc: .....

**Purchaser Details and Declaration**

I, .....(Full Name) being .....(Position)

on behalf of \_\_\_\_\_(Company or Institution)

Address \_\_\_\_\_

Account No: \_\_\_\_\_ACN No:.....

hereby declare that the above chemical product(s)/ apparatus will not be used for the manufacture of illicit drugs.

Signature \_\_\_\_\_ Date\_\_\_\_\_

**Details of Collecting Agent's Identification**

, Current Passport No:..... Country of Issue .....

, Current Photograph Licence No:..... Expiry date .....

, Photo Identification Card Type.....

**End User Distributor / Supplier Details and Declaration**

I, \_\_\_\_\_(Full Name) being .....(Position)

on behalf of \_\_\_\_\_(Company or Institution)

Address \_\_\_\_\_

Account No: \_\_\_\_\_ACN No:.....

hereby declare that the above chemical product(s)/ apparatus will not be used for the manufacture of illicit drugs.

Signature \_\_\_\_\_ Date\_\_\_\_\_

# THE CONTROL AND MONITORING OF DRUGS AND CHEMICALS TO PREVENT THEIR DIVERSION FOR ILLICIT USE

## MODULE 2

### Restricted Substances

### Conventions, Regulations, Monitoring and Reporting

## CONTENTS

Unit One	Introduction
Unit Two	General Background to the United Nations and Relevance to Drug Control
Unit Three	United Nations Conventions and Drug Control Treaties
Unit Four	Control Responsibilities in Australia
Unit Five	Commonwealth Customs Regulations and Controls Importing Exporting State Regulations and Controls
Unit Six	Movement of Controlled Drugs in Australia
Unit Seven	Specific State or Territory Regulations and Controls, End User Declarations New South Wales Queensland South Australia Tasmania Victoria Western Australia Australian Capital Territory Northern Territory
Appendix 1	Sample Standard Operating Procedure
Appendix 2	SUSDP Schedules

## UNIT ONE

### INTRODUCTION

**This module will provide you with an understanding of**

- Australia's international obligations in handling "Restricted Substances" that is, certain **precursor chemicals** and **controlled drugs** (as defined in Module One)
- Commonwealth Laws, State Laws and Regulations which reflect those Laws
- Relevant Company Policies which reflect these Laws and Conventions

**With Respect to "Restricted Substances" you will examine**

- the lawful foundation or framework within which you are employed in your industry
- the lawful framework which binds the Company which employs you

Employees are required to follow rules and procedures in their work which reflect the requirements and expectations of the community. Very frequently, these rules and procedures are simply commonsense, but some may be an outcome of the Law which your Company, through you, **must** follow.

Australia has had laws governing **sale**, **manufacture** and **distribution** of restricted substances before and since Federation.

This module will provide information about:

- Recent UN Conventions and how Industry must play its part in supporting them;
- Commonwealth and State regulations, monitoring and reporting requirements.

**Discuss what is meant by each of the following terms**

***1. Controlled drug***

***2. Restricted substance***

***3. precursor chemical (to a controlled drug)***

(Definitions are provided in Module One, Unit 2)

## UNIT TWO

### GENERAL BACKGROUND TO THE UNITED NATIONS AND RELEVANCE TO DRUG CONTROL

#### The United Nations

Following cessation of all hostilities in 1945 the *United Nations (UN)* was officially born on 24 October 1945.

**Four main purposes of the *UN* are to**

- keep peace throughout the world
- develop friendly relations among nations
- work together to help the poor live better lives, to remove poverty, disease and illiteracy in the world, and to encourage respect for each other's rights and freedoms
- be a centre for helping nations achieve these goals

*(Which of these UN goals do you consider to be relevant to Drug Control globally? Why?)*

The United Nations is "*organised*", and its activities are coordinated through six main "*organs*".

Examine the Chart and identify the main "*organs*".

***Which "organ" do you believe might be involved with International drug control and movement?***

***(Where are the UN headquarters?)***



UNITED NATIONS

# The UNITED NATIONS system

P R I N C I P A L O R G A N S O F T H E U N I T E D N A T I O N S

## INTERNATIONAL COURT OF JUSTICE

Military Staff Committee  
Standing Committee and ad hoc bodies  
International Criminal Tribunal for the Former Yugoslavia  
International Criminal Tribunal for Rwanda  
UN Monitoring, Verification and Inspection Commission (Iraq)  
United Nations Compensation Commission  
Peacekeeping Operations and Missions

## SECURITY COUNCIL

Main committees  
Other sessional committees  
Standing committees  
and ad hoc bodies  
Other subsidiary organs

## GENERAL ASSEMBLY

**FUNCTIONAL COMMISSIONS**  
Commission for Social Development  
Commission on Human Rights  
Commission on Narcotic Drugs  
Commission on Crime Prevention  
and Criminal Justice  
Commission on Science and Technology  
for Development  
Commission on Sustainable Development  
Commission on the Status of Women  
Commission on Population and  
Development  
Statistical Commission  
**REGIONAL COMMISSIONS**  
Economic Commission for Africa (ECA)  
Economic Commission for Europe (ECE)  
Economic Commission for Latin America  
and the Caribbean (ECLAC)  
Economic and Social Commission for Asia  
and the Pacific (ESCAP)  
Economic and Social Commission  
for Western Asia (ESCWA)  
United Nations Forum on Forests  
Sessional and Standing Committees  
Expert, ad hoc and related bodies

## ECONOMIC AND SOCIAL COUNCIL

**SPECIALIZED AGENCIES\***  
ILO International Labour Organization  
FAO Food and Agriculture Organization  
of the United Nations  
UNESCO United Nations Educational, Scientific  
and Cultural Organization  
WHO World Health Organization  
**WORLD BANK GROUP**  
IBRD International Bank for Reconstruction  
and Development  
IDA International Development Association  
IFC International Finance Corporation  
MIGA Multilateral Investment Guarantee Agency  
ICSID International Centre for Settlement  
of Investment Disputes  
IMF International Monetary Fund  
ICAO International Civil Aviation Organization  
IMO International Maritime Organization  
ITU International Telecommunication Union  
UPU Universal Postal Union  
WMO World Meteorological Organization  
WIPO World Intellectual Property Organization  
IFAD International Fund for Agricultural Development  
UNIDO United Nations Industrial Development  
Organization

## TRUSTEESHIP COUNCIL

**OSG** Office of the Secretary-General  
**OIOS** Office of Internal Oversight Services  
**OLA** Office of Legal Affairs  
**DPA** Department of Political Affairs  
**DDA** Department for Disarmament Affairs  
**DPKO** Department of Peacekeeping Operations  
**OCHA** Office for the Coordination  
of Humanitarian Affairs  
**DESA** Department of Economic  
and Social Affairs  
**DGAACS** Department of General Assembly  
Affairs and Conference Services  
**DPI** Department of Public Information  
**DM** Department of Management  
**QIP** Office of the Iraq Programme  
**UNSECOORD** Office of the United Nations  
Security Coordinator  
**ODCCP** Office for Drug Control and Crime  
Prevention  
**UNOG** UN Office at Geneva  
**UNOV** UN Office at Vienna  
**UNON** UN Office at Nairobi

## SECRETARIAT

## PROGRAMMES AND FUNDS

**UNCTAD** United Nations Conference on  
Trade and Development  
**ITC** International Trade Centre  
(UNCTAD/WTO)  
**UNDCP** United Nations  
Drug Control Programme  
**UNEP** United Nations  
Environment Programme  
**UNHSP** United Nations Human  
Settlements Programme  
(UN-Habitat)  
**OTHER UN ENTITIES**  
**OHCHR** Office of the United  
Nations High  
Commissioner  
for Human Rights  
**UNOPS** United Nations Office  
for Project Services  
**UNU** United Nations  
University  
**UNSSC** United Nations  
System Staff College  
**UNDIR\*\***  
United Nations Institute  
for Disarmament Research  
**UNIRISD**  
United Nations Research Institute  
for Social Development  
**UNICRI** United Nations Interregional Crime  
and Justice Research Institute

## RELATED ORGANIZATIONS

**IAEA** International Atomic Energy Agency  
**WTO (trade)** World Trade Organization  
**WTO (tourism)** World Tourism Organization  
**CTBTO Preparatory Commission** for the Comprehen-  
sive Nuclear-test-Ban-Treaty Organization  
**OPCW** Organization for the Prohibition of  
Chemical Weapons

## RESEARCH AND TRAINING INSTITUTES

**INSTRAW** International Research  
and Training Institute  
for the Advancement of Women  
**UNICRI** United Nations Interregional Crime  
and Justice Research Institute

\* Autonomous organizations working with the United Nations and each other through the coordinat-  
ing machinery of the Economic and Social Council.  
\*\* Report only to the General Assembly.

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## The Economic and Social Council (ECOSOC)

Nine UN Programmes and Funds report to *ECOSOC*.

*Identify these programmes / funds from the chart provided on the next page.*

Examine the chart carefully.

*Can you identify further functions of the UN ?*

*Identify which programme might be concerned with international control of drugs.*

**Three (3) separate steps have been made by the UN to:**

- limit use of controlled substances to medical and scientific purposes through legitimate markets;

and to

- take action against illicit manufacture, diversion and trafficking.

The three relevant UN Conventions are described in Unit Three.

## UNIT THREE

### CONVENTIONS AND DRUG CONTROL TREATIES

#### A. *Single Convention on Narcotic Drugs 1961*

The *ECOSOC* (Economic and Social Council) convened a conference early in 1961 which was attended by Australia and 72 other countries. The following *UN* agencies participated:

- **FAO**
- **ICAO**
- **ILO**
- **WHO**

The parties which signed the Convention (including *our own* country) agreed to take appropriate legislative action to:

1. Carry out the Convention provisions within their country;
2. To cooperate with other countries in executing provisions of the convention;
3. Limit production, manufacture, export, import distribution, trade, use and possession of Narcotic Drugs *exclusively to scientific and medical purposes*.

**Signatories are required to furnish *estimates for use*, and then to furnish *statistical returns (based on calendar years)*, in order to ensure that execution of provision of the Convention is occurring.**

**Statistical returns** which are required annually, cover such areas as, imports, exports, production/manufacture, drug consumption, details of illicit drug seizure and disposal, and finally, **details of stock quantities held at 31 December each year**. The Therapeutic Goods Administration (TGA) is the competent reporting authority for the purposes of the Convention and relies on the co-operation of companies which handle these narcotic substances to provide accurate and timely reports to the International Narcotics Control Board.

Failure to provide this information may breach State/Territory legislation.

***Limits are placed on import, export, manufacture and storage with respect to a country's stated needs and estimates.***

The Convention also deals with *cultivation* of the opium poppy, coca bush and cannabis plant, with growers required to be licensed by government.

*Trade, manufacture and distribution* of narcotic drugs are controlled by a system of licences.

The Convention requires signatories to be accountable by implementing appropriate systems of *inspection and supervision*.

Finally, each country is required to establish *penal provisions* which must be implemented against individuals or groups, who contravene that country's laws established as a "flow-on" from the Convention.

The Convention details four groups of Narcotic Drugs which must be controlled and monitored by signatories. These groups are listed in Schedules I, II and IV of the 1961 Convention (see INCB website - Module One). Schedule III listed those drugs which are specifically exempted from these controls due to the way in which they are compounded.

## **B. Convention On Psychotropic Substances, 1971**

*ECOSOC* convened a further conference early 1971 which was attended by Australia and 70 other countries.

The *WHO* (World Health Organisation) was the specialised *UN* Agency represented at the Conference.

***What are psychotropic drugs?***

***Name some psychotropic drugs.***

The provisions of this Convention more or less parallel its predecessor of 1961, in recognising uses in science and medicine while being determined to combat abuse and illicit traffic. The Convention outlines similar rigorous measures which are necessary to restrict use of psychotropic substances to legitimate purposes.

Again, systems of estimates and statistical returns are required with respect to manufacture, import, export, usage, trade and distribution. Licences and penal provisions and inspection similarly apply.

Because different types of drugs are involved here, cultivation provisions are **not** relevant, but certainly medical prescriptions and record-keeping by retail pharmacists (who must also be licensed) is an important facet of the 1971 Convention.

This Convention appears to have tight import and export controls in that it has provisions for countries to comply with standard separate import and export authorisation forms which must accompany every consignment, with copies also being sent ahead to the importing or exporting country. There are also provisions made for countries to nominate that they wish to prohibit import of certain Schedule II, III and IV substances; exporting countries are then notified of these wishes.

As with Narcotic Drugs, the Psychotropics covered in this Convention, are classified into four groups as Schedules I to IV.

### **C. *UN Convention Against Illicit Traffic In Narcotic Drugs And Psychotropic Substances - 1988***

By 1988 the parties to this convention recognised

- rising trends in illicit production of narcotic drugs and psychotropic substances which pose a threat to health and welfare of humans with the potential to undermine economic, cultural and political fabric of society,
- an increasing tendency for children as illicit drug consumers, and even for illicit production and distribution,
- that links between organised crime and illicit traffic posed a threat to the stability of some member countries,
- that illicit traffic which generates large financial profit, allows transnational crime to penetrate, contaminate, and corrupt structures of government, business and society at all levels.

They therefore determined to

- deprive persons so engaged in illicit traffic of the proceeds of their activity thus eliminating their incentive,
- estimate root causes for demand (ie. abuse) and so eliminate the profits made,
- consider the necessary measures to monitor certain substances eg. precursor chemicals and solvents which are used to manufacture narcotic drugs and psychotropic substances,
- improve international cooperation, and coordinated action,
- reaffirm principles and reinforcement of the measures outlined in the Conventions of 1961 and 1971,
- strengthen legal and international enforcement means in criminal matters.

***Consider the deteriorating illicit drug scene between 1972 and 1988. Write down, for further discussion, as many reasons as you can deduce, possible factors in this deterioration.***

This Convention reflects the concern of participating Nations (including Australia) by introducing extra and tougher measures of recommended control.

**Some of these extra measures include**

- confiscation of property and proceeds
- extradition agreements, and legal proceedings against suspects
- mutually cooperative legal assistance between Nations
- cooperation between law enforcement agencies between Nations
- a tightening of measures taken by Commercial distributors/carriers
- suppression of illicit traffic by sea by measure of flag identification, and in cases of grave doubts, measures for boarding, searching and impounding vessels
- suppression of use of “mails” (eg: postal services)

**Especially relevant to you as an employee within the chemical or pharmaceutical industries are two Articles (or Sections) to this Convention.**

1. The first of these deals with substances (chemicals) which are often used in the illicit manufacture of narcotic drugs and psychotropic substances in clandestine laboratories.

*What name is given to such necessary chemicals in this context ?*

*What are clandestine laboratories ?*

(see module 1, if you require information)

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**The Convention recommends that for licit manufacture and distributions**

- all persons so engaged, be controlled
  - control under licence, the premises and establishment
  - licensees obtain a permit for conducting their operations of manufacture and/or distribution
  - product accumulation by manufactures and distributors, in excess of normal market demand conditions, should be prevented
2. The second Article deals with illicit trade in equipment (laboratory hardware) which could be used to manufacture illicit drugs of dependence.

Twenty-three (23) Chemicals are now listed as requiring Regulations, and these are grouped (classified) in two Tables (Table I and Table II). **See appendix 1 module 1**

**The three Conventions form a co-ordinated whole, including control of restricted substances through legitimate markets, together with the various aspects of action against illicit manufacture, diversion and trafficking.**

*What do you think are some of the considerations in deciding to place new substances under these UN Conventions?*

## UNIT FOUR

### CONTROL RESPONSIBILITY IN AUSTRALIA

In Australia the Therapeutic Goods Administration (as part of the Commonwealth Department of Health and Ageing) is responsible for implementing control measures for which it has obligations as a responsible member of the *UN* and as a responsible signatory to all three *UN* Conventions on Illicit Drugs. The States and Territories have responsibility for licensing formulators, distributors and wholesalers and for controlling availability within their borders, of drugs and chemicals covered by the Conventions.

There are essentially three levels of monitoring and controls:

#### 1. Commonwealth requirements.

The requirements of the Convention which relate specifically to the manufacture of narcotics are implemented through the *Narcotic Drugs Act 1967*. Under this Act, all manufacturers must hold a manufacturing licence and keep certain types of records to manufacture narcotic materials. Provisions relating to the trans-shipment of narcotic drugs through Australia are also set out in this Act.

The *Customs (Prohibited Exports) Regulations* and the *Customs (Prohibited Imports) Regulations* are two sets of Regulations which control (amongst other things) - EXPORT and IMPORT of drugs out of and into Australia respectively. Two Commonwealth Government Departments are charged with responsibility and implementation of this Legislation. They are:

- The Therapeutic Goods Administration as the permit issuing agency; and
- The Australian Customs Service as the border control authority.

#### 2. Various State and Territory Poison and Drugs legislative controls

(see Unit 7 of this Module)

#### 3. Voluntary monitoring and control

The voluntary "Code of Practice" is described in more detail in Unit 7 of Module 1.

*Over what areas, relevant to illicit drug control, does the Australian Government have legislative and Constitutional power?*

***What function can it control?***

It should be noted that many of the drugs and precursor chemicals covered by the *UN* Conventions, are dealt with by Australian law in this way. This is the way in which Australia meets its INTERNATIONAL OBLIGATIONS and responsibilities as a member of the *UN* and as a signatory to its three Conventions.

## UNIT FIVE

# COMMONWEALTH CUSTOMS REGULATIONS AND CONTROLS

### IMPORTING DRUGS INTO AUSTRALIA

Australia is not self-sufficient in chemicals, pharmaceuticals or drugs, and it thus relies on imports from overseas to a substantial degree in order to satisfy legitimate community demand for scientific research, and for care and treatment of people and animals in need of medical care.

In order to import therapeutic drugs or chemicals which are controlled under the *Customs (Prohibited Imports) Regulations*, a company or person must apply for a **licence** in writing to the Secretary of the **Department of Health and Ageing** (the Department). Information concerning the need to obtain a Permit to Import can be obtained from the Regulatory Affairs Officer of your company or directly from the **Therapeutic Goods Administration** (TGA) as part of the Department of Health and Ageing.

*What is meant by a Therapeutic drug or chemical?*

### **Licences**

A licence to import drugs is granted only if the:

- applicant is deemed to be “fit and proper”.
- applicant has supplied all the information which the Department requires (including a current copy of a State/Territory licence, where relevant) .
- that the agents which the applicant employs for business purposes carried out by the applicant, are also fit and proper persons.
- the applicant’s premises (for the duration of the licence) are secure and safe for that purpose.

*Who are the “agents” referred to here?*

*How might this provision be relevant to you?*

## INFORMATION WHICH MUST BE SUPPLIED BY AN APPLICANT FOR AN IMPORT LICENCE

- Name (applicant and/or organisation)
- Address of premises on which the controlled substance will be held
- Nature of the business (ie: manufacture, distribution)
- Classes of substance to be held (ie: narcotic drug, psychotropic substance, or precursor chemical)
- Details of persons who will have access to the controlled substance. This will include details of positions and qualifications.
- Details of any agents appointed by the applicant (shipping, customs, internal transport).
- Details of security arrangements for storage and subsequent distribution

### Other conditions to be met before a licence can be granted include:

- safety precautions if drugs are moved at any time;
- precautions which almost preclude loss or theft of any drug;
- disposal of drugs must be such that the Licence holder, ensures use of the drugs will be solely for scientific or medicinal purposes.
- The Licensee must keep a **record book** or **electronic record** which reveals
  - - name and quantity of each drug possessed, and full details of its source.
  - - when supply is made to another person, full details of quantity and address of the other person, are shown in the record.
- Full details of loss of drug quantities, when that drug is used in subsequent manufacture of another preparation. Details must even include loss by evaporation, or destruction in that process.
- The Licensee must, when required by the TGA produce the record, and any drug in possession of the Licence Holder.
- Requirement of weekly reporting and sending into the TGA, weekly returns which reconcile with details in the record.

- When requested by the TGA, a Licensee, must be able to supply within 14 days, details of orders for controlled substances already placed, or expected to be placed with the Licensee.

*How is this relevant to the UN Conventions?*

It can now readily be seen that where a Company imports controlled substances, very stringent requirements must be met before it is **licensed**.

## Permits

The Licensee must apply for permission to import if the goods are a restricted substance as described under the relevant Schedules to the Customs Regulations. Permission to import (by the authorised licence) is then given by the TGA provided the Licensee can still meet all the necessary requirements.

Each new import by a Licence Holder, requires a *new permit*. All permits must be obtained prior to arrival of the shipment.

Equally stringent conditions must be met, and full details of the intended import given, before permission to import will be given by the TGA. Applications to receive a permit (permission) must

- be in writing
- supply name, and address details of the Licence Holder
- name and address of the supplier in the country from which the export is to be made
- state the common name, and also the non-proprietary name of the drug
- state the proposed quantity of drug to be imported
- where the drug is a pharmaceutical product:
  - the form of the drug must be stated;
  - the strength of each active ingredient must be stated.
  - the AUST R number of the good in the Australian Register of Therapeutic Goods must be stated (where relevant)
- state the duration of the proposed importation
- state the number, and size of packs
- state the date of import
- give the mode of arrival from overseas, ie: whether by sea or air freight
- give details of name and address of the end user and the use of the end substance

When a permit is granted, it may well be required that conditions of

- possession
- safe custody
- storage
- transportation
- use
- disposal
- distribution

are met by the permit holder.

The importation of some substances which are not narcotics, psychotropics or precursors subject to the International Drug Treaties require only an import permit to be held (eg anabolic substances, abortifacients). More information on these substances is available on the TGA website at <http://www.health.gov.au/tga>.

***Why would some substances be subject to Australian import controls which are not under International control?***

When an imported drug is collected, the Collector must, in writing, certify the quantity imported, and the date of importation. Then, if for any reasons outside the control of the permit holder, any part of the specified drug could not be imported within the period specified in the permit, the holder of the permit, must apply in writing to the TGA for a time-variation.

When and/or if, a Licence and Permit holder fails to comply with these permit conditions, they could well be charged with an offence against the Customs Act of 1901.

***If this did occur to your employer, what possible consequences could result for the employer? For the employee?***

***Write down as many reasons as you can, why this should be so. If possible compare them with reasons given by fellow trainees.***

***In this regard, what are the responsibilities for the employer?***

***What responsibilities might the employees have?***

***If this did unfortunately occur, what could be the consequences for employer and employees, of their negligence?***

When and/or if, a Licence and Permit holder fails to comply with these Permit conditions, TGA could well revoke the Licence!

The copy of the permit which is certified by the Collector (**the triplicate**) must be returned to the TGA within 5 working days of the date of importation as the certified amount (rather than the requested amount) is included in reports to the International Narcotics Control Board.

*What processes does your company have in place to ensure that all triplicates are returned within 5 working days?*

If a triplicate is misplaced, a statutory declaration must be provided to this effect. Failure to provide triplicates or a statutory declaration is grounds for revoking a Company's import licence.

## **EXPORTING DRUGS FROM AUSTRALIA**

Australia is self-sufficient in some drugs and chemicals, is in a position to export some, and accordingly, does so.

*What advantages does this have for Australia?*

### **Licences (Export)**

A person or company can only export a drug from Australia, if they are a *licensed exporter*. Then, that licensed exporter can only export a drug with a *permit* being issued by the TGA, and within three months of that permit being issued. The drug must only be consigned to the country specified in the permit, and the exporter must be prepared to produce the permit if requested by the Customs.

Consignment of *Prohibited Exports* drug through the Post Office is prohibited unless authorised by TGA to do so. An applicant for a licence must put the application in writing to TGA. If granted, the person who is the recipient of a licence shall

- keep a book record of each controlled substance exported, showing date, quantity and full name and whereabouts of the importer
- keep the record books until such time that TGA approves their destruction
- be prepared to submit books for examination by an authorised officer at any reasonable time of the day

- submit weekly returns to the TGA, with respect to transactions referred to in the record book
- undertake all precautions for safe keeping, to prevent loss or theft of drugs in his/her possession

Licences are granted for a specified period only, and they may be revoked by TGA, if the above conditions are not met continuously over time.

## Permits (Export)

Permits are issued by TGA. Licensed applicants must submit requests in writing, and must specify the country of destination.

Each drug export requires a separate permit. Furthermore, each request for a permit must be accompanied by appropriate written Governmental approval for import by the importing country.

The TGA is mindful of the commercial need to minimise delays. Delivery times between distant States and Canberra need to be considered when forwarding applications. Note that ten working days are required for processing applications and dispatching permits. Faxing permit applications is acceptable and may assist the process.

***Referring to your knowledge of Australia's international obligations, show how this system of Licences and Permits, helps meet those obligations and responsibilities.***

Just as with import permits, so too may export permits be revoked if a holder fails to comply with any of the conditions of their issue.

***If this did occur, what consequences may result for***

- *the company?*
- *employees?*

## Export of Precursors - licensing and pre-export notifications

As from 1 September 2002, a new scheme will be in place to satisfy Australia's obligation under the 1988 Precursor Convention. This new scheme will affect exporters of potassium permanganate, acetic anhydride and substances in Table II to the Convention (See appendix 1 Module 1). Exporters of potassium permanganate and acetic anhydride will need to hold an

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export licence and to submit a pre-export notification within 5 working days of the intended date of export.

Similarly exporters of all Table II precursors will need to hold a licence if they are exporting more than 100 litres per consignment and to submit a pre-export notification if the destination country has made such a request. A list of all the countries which have asked for pre-export notification will be published in the Commonwealth gazette.

This process provides TGA with an opportunity to verify the exporter as a licence holder and to take necessary action to stop the shipment if it is determined that it may be diverted into illicit traffic. Verification must be co-ordinated with other overseas authorities and to facilitate the efforts of the TGA, exporters should submit the pre-export notification form as much ahead of the date of export as possible.

Further information is available on the TGA website.

**UNIT SIX****MOVEMENT OF CONTROLLED DRUGS IN AUSTRALIA**

In 1970, Australia introduced a system to monitor the movement of Schedule 8 (SU SDP) controlled drugs (including drugs of addiction and other dangerous drugs) from:

- the point of manufacture to export;
- the point of manufacture to “final” distribution sites viz. pharmacies, hospitals, clinics, and universities;
- import point to storage and thence to the above localities.

*What modes of transport are most likely used in these transfers?*

At present, in Australia there are more than 140 licensed Companies which must report such movements. The system enables interstate movement of drugs to be “tracked”, and these movements total many thousands each week. Quantities of drugs used legally for medical and scientific purposes, can, in this way, be estimated.

From the information provided in the weekly reports on drug movements, details of legal drug transactions are obtained. The information also helps in the estimate of stock balances held, and it assists in the preparation of import and export quotas.

*With reference to earlier sections of your Training, why is Australia obliged to prepare this information?*

The monitoring system also provides data on Australia’s consumption of controlled drugs which then helps in estimating our requirements, identifying usage trends, and all of this helps fulfil our obligations internationally.

*Again, what international obligations do we have?*

## REPORTING ON MOVEMENT OF CONTROLLED DRUGS BY INDUSTRY

Instructions to Companies on the actual mechanics of reporting, are very detailed indeed. This training will outline what are considered to be the important areas for Trainees to know.

### What types of Companies must Report Movements?

They are

- Importers
- Exporters
- Formulators
- Manufacturers
- Resellers
- and
- Wholesalers

*Explain what these types of Companies do? (with your explanations clearly revealing the functional difference between them).*

The TGA has prepared detailed reporting instructions for Companies which are involved in the movement of controlled (Schedule 8) drugs. Contact the Treaties and Monitoring Unit of TGA on 02 6270 4326 to obtain a monitoring information pack. These important details **must** be attended to diligently by senior personnel of the Companies involved.

### To whom are the Reports forwarded?

Weekly reports are to be transmitted electronically to: [tms@health.gov.au](mailto:tms@health.gov.au)

**Clearly then, Companies must implement a range of State and Commonwealth requirements which deal with the control and monitoring of drugs and certain other scheduled substances.**

**An employee may therefore be required to follow exactly, a set of instructions designed to ensure that the Company's obligations are met. Such instructions are commonly referred to as a Standard Operating Procedure (SOP). See appendix 1 for an example.**

**UNIT SEVEN**

**CONTROL RESPONSIBILITIES IN THE STATES**

## CONTROL RESPONSIBILITIES IN THE STATES WESTERN AUSTRALIA

In WA poisons are controlled under the Poisons Act 1964 and Poison Regulations 1965.

### A. Licences

**The Health Department of WA issues 4 different types of poisons licences.**

1. Licence to procure, manufacture and supply poisons by wholesale dealing.
2. Pharmaceutical chemists licence to sell poisons.
3. Licence to sell by retail poisons specified in Schedule 2 to the Poisons Act 1964.
4. Licence to sell by retail poisons specified in the Schedule 7 to the Poisons Act 1964.

Licences 1 covers wholesale manufacture and sales, licences 2 to 4 cover retail sales.

### B. Permits

*The Health Department of WA issues 5 different types of permits allowing the holder to purchase poisons specified on the permit for industrial, educational, advisory or research purposes, but not to re-sell or supply to others. The types of permits are:*

<b>6B</b>	Poisons Permit (Distribution of samples)
<b>7</b>	Poisons Permit (Industrial)
<b>8</b>	Poisons Permit (Educational, advisory or research)
<b>11AA</b>	Stockfeed Manufacturers Permits
<b>13</b>	Poisons Permit (Departmental and Hospital)

## **DISTRIBUTION**

If supplying Substances in Schedules 2, 3, 4, 7 and 8, there are restrictions to whom the Company may sell.

1. It may sell (distribute) to a Company or person who holds a current Licence or Permit relevant to that compound or Schedule.
2. It may distribute to an “*authorised person*” such as: medical practitioner; veterinarians; retail pharmacists and dentists. These people do not need a Permit because they are already “*authorised*” by the fact of their qualifications and professional registration under the Act.

*What State Permits/Licences does your Company hold?*

*Under the Act, what operations can it undertake with respect to Controlled Substances?*

## **TRANSPORTATION**

Obligations here require that any loss during transportation must be reported to the Police and the State Health Department. Trainees should report any perceived suspicious behaviour, or any loss, or anything out of order in this area, to a Company supervisor.

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## **STORAGE**

1. Schedule 8 substances must be in a vault or safe.
2. Schedule 4 substances must be located in a locked storage facility such as a cupboard, room or entire warehouse, depending on the quantity required for storage. Security systems like alarms must be in place to deter unauthorised entry, but which allows for Fire Brigade access.

## **RECORDS**

The State requires that Companies keep full records for two years except for records of Schedule 8 drug transactions that must be kept for 7 years, which, as required, can subsequently be audited.

## **MORE DETAILS ON LICENCES AND PERMITS** **WESTERN AUSTRALIA**

### **How are Licences and Permits Issued?**

- The person must apply in writing to the Commissioner of Health.
- The application must be accompanied by the prescribed fee.
- The applicant must establish personal qualities and credentials to justify licence and/or permit issue to them.
- A licence and/or permit issued under the Poisons Act relates only to the premises described in that licence and/or permit, and to no other premises.
- Before issue, the Health Department may check that the premises are suitable for the purposes stated, clean, hygienic and adequately equipped for manufacture, sale or supply of the Controlled Substances to which the licence or permit is relevant.

*If premises were changed, what would the Law require?*

### **What do the Appropriate Licences and Permits Authorise?**

In WA, details of what is authorised are described in the Licence/Permit document(s).

Of course, licences and permits cover all classes of pharmaceuticals and chemicals, but Trainees should note that these details are beyond the scope of this particular Training.

### **Duration**

Licences and Permits are valid for between one (1) and three (3) years from the 1 July and may be renewed on payment of a fee.

## Inspection

Before initial issue of Permits and/or Licences, an inspection of the premises may occur to ensure compliance, and further inspections will occur on a routine basis.

## Suspension or Cancellation

### Licences and/or Permits may be suspended or cancelled if

- there is lack of compliance by the Holder with the terms, conditions, limitations and restrictions of those Licences and/or Permits.
- the Holder, by subsequent behaviour or investigations reveals their lack of suitability to possess a Licence and/or Permit.
- the Holder has been convicted of an offence against the Poisons Act.
- the Holder ceases business operations at those premises outlined in the documents.

Where cancellation or suspension occurs, the actual original Licence and/or Permit documents must be surrendered to the Health Department.

*Taking the first three of the above circumstances, write down the relevance and responsibilities of Trainees, as employees, for each one separately.*

## **END USER DECLARATION**

NSW Regulations require that vendors of chemicals and pharmaceuticals should retain records of all transactions for a period of two years, and that Police and State Health Departments must have access to these. It now seems that most, if not all States have moved to, or are in the process of implementing, equivalent similar systems.

Industry itself, in many areas of Australia, has introduced, and is using, a system of proformae called ***END USER DECLARATIONS (EUD)***. (A sample is included for you to examine, please see appendix 2.)

***List the requirements of a purchaser in order to comply with an EUD.***

***Which SUSDP schedules are involved here?***

***What is a vendor?***

Industry associations are keen to see this system implemented by all members, and eventually, by all vendors of these substances, throughout all States and Territories.

An *EUD* must (where in use) be completed for every single transaction (purchase), even including account customers.

Trainees should note that *EUD*'s have no lawful status. This does not mean that they do not perform a very useful community function.

***Outline fully, all the useful functions carried out by an EUD system.***

**Trainees should also note that where in use**

1. your Company will not supply Controlled Substances, unless a fully completed *EUD* is supplied, and
2. even though *EUD*'s have no lawful status, where your Company is responsibly using them, you as an employee must comply fully and willingly where and if you are involved, as it will be "*Company Policy*", and therefore your willing compliance will be essential as part of your conditions of employment.

## **CONTROL RESPONSIBILITIES IN THE STATES** **SOUTH AUSTRALIA**

In South Australia, poisons and drugs are controlled by the *Controlled Substances Act 1984*. The Regulations incorporate, the poisons schedules of the *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSDP). All States have agreed to adopt these schedules, and thus there is generally uniformity throughout Australia.

*Why is this general uniformity of Scheduling very desirable?*

*Can you think of any previous lack of uniformity in other areas between States, which contrasts with this?*

*What detrimental effects has this had for Australia?*

*List some for discussion.*

The SUSDP also contains details on packaging and labelling, together with *Safety Directions, Warning and First Aid Statements* which are required to be printed on the label of the relevant chemicals. These have also been adopted by each State.

### **A. Licences**

In South Australia a system of licences operates. Licences are issued by the Department of Human Services (DHS).

1. Manufacturers Licence

- To manufacture, produce, pack and sell by wholesale certain schedules poisons

Manufacturing licences refer to substances in Schedules 2 to 8 inclusively.

2. Wholesale Licence

- To sell by wholesale dealing certain scheduled poisons

Wholesale licences refer to substances in Schedules 2 to 8 inclusively

In South Australia, a system of Licences also exists to obtain and use (ie: to purchase, possess and use) Controlled Substances, but certainly not to *re-sell* or to supply to others.

**Substances requiring a licence are classified in Schedules 4, 8 and some of 7.**

## B. Permits

A permit is issued at no cost, for legitimate research and training purposes for any Poison or Prohibited Substance. Applicants are required to stipulate precisely what the substance or substances will be used for. Currently in South Australia all permits expire on June 30.

## DISTRIBUTION

If supplying substances in Schedules 2, 3, 4, 8 and some of 7, there are restrictions to whom the Company may sell.

1. It may sell (distribute) to a Company or person who holds a current Licence or Permit relevant to that compound or Schedule.
2. It may distribute to an “*authorised person*” such as: medical practitioner; veterinarian; retail pharmacist and dentist. These persons do not need a Licence because they are already “*authorised*” by their qualifications and professional registration.

*What State Permits/Licences does your Company hold?*

*Under the Act, what operations can it undertake with respect to Controlled Substances?*

## TRANSPORTATION

Obligations here require that any loss during transportation must be reported to the Police and the Department of Human Services. Company employees should report any perceived suspicious behaviour, or any loss, or anything out of order in this area, to a Company supervisor.

## STORAGE

1. Controlled (Schedule 8) drugs must be stored in accordance with the “Code of Practice for the Storage and Transport of Drugs of Dependence”, with access limited to persons stipulated in the Licence.
2. Schedule 4 substances must be located in a locked storage facility such as a cupboard, room or entire warehouse, depending on the quantity required for storage. Security systems like alarms must be in place to deter unauthorised entry, but which allows for Fire Brigade access.

In South Australia, before a Licence for Schedule 8 compounds is issued, a Crime Prevention Report from the Police is necessary. The purpose of this requirement is to ensure security and prevent unauthorised access to Schedules 8 compounds.

## **RECORDS**

The State requires that Companies keep full records for two years which, as required, can be audited subsequently.

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## **MORE DETAILS ON LICENCES AND PERMITS** **SOUTH AUSTRALIA**

### **How are Licences and Permits Issued?**

- Written application must be forwarded to the Hazardous Substances Section of the Environmental Health Branch at the Department of Human Services.
- The application must be accompanied by the prescribed fee.
- The applicant must establish personal qualities and credentials to justify licence and/or permit issue to them.
- A licence and/or permit issued under the 1984 Act relates only to the premises described in that licence and/or permit, and to no other premises.
- Before issue, the Department of Human Services must be satisfied that the premises are suitable for the purposes stated, clean, hygienic and adequately equipped for manufacture, sale or supply of the Controlled Substances to which the licence or permit is relevant.

*If premises were changed, what would the Law require?*

### **What do the Appropriate Licences and Permits Authorise?**

- Manufacture, production, packaging and sale by wholesale, scheduled poisons.
- Sale or supply by wholesale of scheduled poisons.
- Manufacture and possession of scheduled poisons and prohibited substances (Schedule 9 substances) for research purposes.

Of course, licences and permits cover all classes of pharmaceuticals and chemicals, but trainees should note that these details are beyond the scope of this particular training.

## Duration

Licences expire annually and may be renewed annually for a fee.

## Inspection

Before initial issue of Permits and/or Licences, an inspection of the premises may occur to ensure compliance, and further inspections will occur on a routine basis.

## Suspension or Cancellation

**It is an offence to breach conditions of Licence or Permit allocation.**

Licences and/or Permits may be suspended or cancelled if:

- the holder obtained the Licence/Permit improperly.
- there is lack of compliance by the Holder with the terms, conditions, limitations and restrictions of those Licences and/or Permits in the opinion of the Department of Human Services.
- the Holder, by subsequent behaviour or investigations reveals their lack of suitability to possess a Licence and/or Permit.
- the Holder has been convicted of an offence against the Act of 1984.
- the Holder ceases business operations at those premises outlined in the documents.

Where cancellation or suspension occurs, the actual original Licence and/or Permit documents must be surrendered to the Department.

The person may appeal to the Supreme Court against the revocation.

*Taking the first three of the above circumstances, write down the relevance and responsibilities of Trainees, as employees, for each one separately.*

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## **END USER STATEMENT**

South Australian Regulations require that vendors of chemicals and pharmaceuticals should retain records of all transactions for a period of two years, and that Police and the DHS must have access to these. It now seems that most, if not all States have moved to, or are in the process of implementing, equivalent similar systems.

Industry itself, in many areas of Australia, has introduced, and is using, a system of proforma called ***END USER DECLARATIONS*** (EUD) (A sample is included for you to examine, see appendix 2.)

***List the requirements of a purchaser in order to comply with an EUD.***

***Which SUSDP schedules are involved here?***

***What is a vendor?***

Industry associations are keen to see this system implemented by all members, and eventually, by all vendors of these substances, throughout all States and Territories.

An *EUD* must (where in use) be completed for every single transaction (purchase), even including account customers.

Trainees should note that *EUD*'s have no lawful status. This does not mean that they do not perform a very useful community function.

***Outline fully, all the useful functions carried out by an EUD system***

Trainees should also note where :

1. your Company will not supply Controlled Substances, unless a fully completed *EUD* is supplied; and
2. even though *EUD*'s have no lawful status, where your Company is responsibly using them, you as an employee must comply fully and willingly where and if you are involved, as it will be "Company Policy", and therefore your willing compliance will be essential as part of your conditions of employment.

## **CONTROL RESPONSIBILITIES IN THE STATES** **VICTORIA**

In Victoria, poisons and Controlled Substances, are controlled by the *Drugs, Poisons and Controlled Substances Act 1981*, and Regulations 1995. The Act incorporates, via a Poisons Code, the poisons schedules of the *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSDP). All States have agreed to adopt these schedules, and thus there is generally uniformity throughout Australia.

*Why is this general uniformity of Scheduling very desirable?*

*Can you think of any previous lack of uniformity in other areas between States, which contrasts with this?*

*What detrimental effects has this had for Australia?*

*List some for discussion.*

The SUSDP schedules also contain details on packaging and labelling, together with *Safety Directions, Warning and First Aid Statements* which are required to be printed on the label of the relevant chemicals. These have also been adopted by each State.

### **A. Licences**

In Victoria a system of licences operates. Licences are issued by the Department of Human Services.

#### **1. Licences to Manufacture**

Two types (classes) of Licences exist. They are:

- 1.1 Manufacture and sell or supply by wholesale Schedule 8 or 9 poisons
- 1.2 Manufacture and sell or supply by wholesale Scheduled poisons (other than Schedule 8 or 9 poisons)

#### **2. Licence to sell by Wholesale**

Two classes of Licences exist. They are:

- 2.1 Sell or supply by wholesale Schedule 8 or 9 poisons
- 2.2 Sell or supply by wholesale Scheduled poisons (other than Schedule 8 or 9 poisons)

## **B. Permits**

In Victoria, a system of Permits also exist to obtain and use (ie: to purchase) Controlled Substances, but certainly not to *re-sell* or to supply others.

Substances thus requiring a permit are classified in Schedules 2, 3 4, 8 and some of 7.

**Note:** If, after purchase (with a Permit), that item is converted to another scheduled compound, then a Licence is required.

## **DISTRIBUTION**

If supplying Substances in Schedules 2, 3, 4, 8 and some of 7, there are restrictions to whom the Company may sell. A Company may

1. sell (distribute) to a Company or person who holds a current Licence or Permit relevant to that compound or Schedule.
2. distribute to an “*authorised person*” such as: medical practitioner; veterinarian; retail pharmacist and dentist. These people do not need a Permit because they are already “*authorised*” through their qualifications and professional registration under the Act.

*What State Permits/Licences does your Company hold?*

*Under the Act, what operations can it undertake with respect to Controlled Substances?*

## **TRANSPORTATION**

Obligations here require that any loss during transportation must be reported to the Police and the State Health Department. Employees should report any perceived suspicious behaviour, or any loss, or anything out of order in this area, to a Company supervisor.

## **STORAGE**

In Victoria, before a Licence for Schedule 8 and some other higher risk drugs in Schedule 4 is issued, a security report from a security consultant approved by the Drugs and Poisons Unit is required. The report must cover suitability of the storage facility, the alarm system used, procedures used to prevent unauthorised access to the facility and the premises in general.

## **RECORDS**

The State requires that Companies keep full records for three years which, as required, can subsequently be audited.

### **How are Licences and Permits Issued?**

- The person making the application must apply in writing to the Secretary of the Department of Human Services.
- The application must be accompanied by the prescribed fee.
- The applicant must establish personal qualities and credentials to justify licence and/or permit issue to them.
- A licence and/or permit issued under the 1981 Act relates only to the premises described in that licence and/or permit, and to no other premises.

#### *If premises were changed, what would the Law require?*

Before issue, the Department of Human Services must be satisfied that the premises are suitable for the purposes stated, clean, hygienic and adequately equipped for manufacture, sale or supply of the Controlled Substances to which the licence or permit is relevant.

### **What do the Appropriate Licences and Permits Authorise?**

- Manufacture and sale or supply of Schedule 8 or 9 poisons.
- Manufacture and sale or supply of other Scheduled compounds.
- Sale or supply by wholesale of Schedule 8 or 9 poisons.
- Sale or supply by wholesale of other Scheduled compounds.

Of course, licences and permits cover all classes of pharmaceuticals and chemicals, but Trainees should note that these details are beyond the scope of this particular Training.

## Duration

Licences and Permits are valid for 12 months from the date of issue, and may be renewed on payment of a fee.

## Inspection

Before initial issue of Permits and/or Licences, an inspection of the premises must occur to ensure compliance, and further inspections will occur on a routine basis.

## Suspension or Cancellation

### **Licences and/or Permits may be suspended or cancelled if:**

- there is lack of compliance by the Holder with the terms, conditions, limitations and restrictions of those Licences and/or Permits;
- the Holder, by subsequent behaviour or investigations reveals their lack of suitability to possess a Licence and/or Permit;
- the Holder has been convicted of an offence against the Act of 1981;
- the Holder ceases business operations at those premises outlined in the documents;
- Where cancellation or suspension occurs, the actual original Licence and/or Permit documents must be surrendered to the Department.

*Taking the first three of the above circumstances, write down the relevance and responsibilities of Trainees, as employees, for each one separately.*

## **END USER DECLARATION**

Victorian Regulations require that vendors of chemicals and pharmaceuticals should retain records of all transactions for a period of three years, and that Police and authorised officers of the Departments must have access to these. It now seems that most, if not all States have moved to, or are in the process of implementing, equivalent similar systems.

Industry itself, in many areas of Australia, has introduced, and is using, a system of proformae called **END USER DECLARATIONS (EUD)**. (A sample is included for you to examine. Please see appendix 2.)

*List the requirements of a purchaser in order to comply with an EUD.*

*Which SUSDP schedules are involved here?*

*What is a vendor?*

Industry associations are keen to see this system implemented by all members, and eventually, by all vendors of these substances, throughout all States and Territories.

An *EUD* must (where in use) be completed for every single transaction (purchase), even including account customers.

Trainees should note that *EUD*'s have no lawful status. This does not mean that they do not perform a very useful community function.

*Outline fully, all the useful functions carried out by an EUD system*

**Trainees should also note that where in use**

1. your Company should not supply Controlled Substances, unless a fully completed *EUD* is supplied, and
2. even though *EUD*'s have no lawful status, where your Company is responsibly using them, you as an employee must comply fully and willingly where and if you are involved, as it will be "*Company Policy*", and therefore your willing compliance will be essential as part of your conditions of employment.

## **CONTROL RESPONSIBILITIES IN THE AUSTRALIAN CAPITAL TERRITORY**

In the ACT medical and non medical poisons are controlled by the *Poisons Act 1933*, *Regulations, Poisons and Drugs Act 1978* and *Regulations and the Drugs of Dependence Act 1989* and Regulations.

Provisions in the *Poisons and Drugs ACT 1978* adopt by reference Schedules 1 to 8 of the Standard for the Uniform Scheduling of Drugs and Poisons, “as amended from time to time, and as modified by the Minister by instrument for the purposes of this Act”. The provisions became effective on 31 March 1993.

Modification of the schedules by disallowable instrument has been employed once only. The amphetamine precursors (1-chloro-phenyl-2-aminopropane, phenylacetic acid, 1-phenyl-2-chloropropane, 1-phenyl-2-nitropropene, 1-phenyl-2-propanol, 1-phenyl-2-propanone, 1-phenyl-2-propanone oxime) were listed in schedule 7 by disallowable instrument on 20 October 1993. The instrument gave effect to the recommendations of the National Working Party on Amphetamine Control that sales of the precursors be recorded.

*Why is general uniformity of Scheduling, by States and Territories very desirable?*

*Can you think of any previous lack of uniformity in other areas between States, which contrasts with this?*

*What detrimental effects has this had for Australia?*

*List some for discussion.*

The SUSDP schedules also contain details on packaging and labelling, together with *Safety Directions, Warning and First Aid Statements* which are required to be printed on the label of the relevant chemicals. These have also been adopted by each State.

### **A. Licences**

In the ACT a system of licences operates. Licences are issued by the Department of Health and Community Care.

1. Licences to Manufacture

Two types (classes) of Licences exist. They are

1.1 Manufacture of Schedule 8 Drugs and Poisons

1.2 Manufacture of Schedule 7 Poisons

**These manufacturing licences refer to substances in Schedules 8 and 7 only.**

2. Licence to sell by Wholesale  
Again, two classes of Licences exist. They are:
  - 2.1 Sale of Schedule 8 Drugs and Poisons
  - 2.2 Sale of other Scheduled Drugs and Poisons

## B. Permits

In the ACT, a system of Authorisations also exist to obtain and use (ie: to purchase) Poisons and drugs of dependence, but certainly not to *re-sell* or to supply others.

Substances thus requiring a permit are classified in Schedules 7 and 8.

**Note:** If, after purchase (with a Permit), a substance is converted to another scheduled compound, then a Licence is required.

## DISTRIBUTION

If supplying Substances in Schedules 2, 3, 4, 8 and some of 7, there are restrictions to whom the Company may sell.

1. It may sell (distribute) to a Company or person who holds a current Licence or Permit relevant to that compound or Schedule.
2. It may distribute to an “*authorised person*” such as: medical practitioner; veterinarian; retail pharmacist and dentist. These persons do not need a Permit because they are already “*authorised*” by their qualifications and professional registration under the Act.

*What State Permits/Licences does your Company hold?*

*Under the Act, what operations can it undertake with respect to Controlled Substances?*

## TRANSPORTATION

Obligations here require that any loss during transportation must be reported to the Police and the State Health Department. Company employees should report any perceived suspicious behaviour, or any loss, or anything out of order in this area, to a Company supervisor.

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## STORAGE

1. Schedule 8 substances must be stored in a vault or safe.
2. Schedule 4 substances must be located in a locked storage facility such as a cupboard, room or entire warehouse, depending on the quantity required for storage. Security systems like alarms must be in place to deter unauthorised entry, but which allows for Fire Brigade access.

In the ACT, before a Licence for Schedule 8 and some Schedule 4 compounds is issued, a Crime Prevention Report from the Police is necessary. This requirement's aim is to ensure security and prevent unauthorised access to Schedules 4 and 8 compounds.

## RECORDS

Companies are required to keep full records for three years, which can be audited as required.

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## **MORE DETAILS ON LICENCES AND PERMITS** **AUSTRALIAN CAPITAL TERRITORY**

### **How are Licences and Permits Issued?**

- The person must apply in writing to the Chief Medical Officer.
- The application must be accompanied by the prescribed fee.
- The applicant must establish personal qualities and credentials to justify licence and/or permit issue to them.
- A licence and/or permit issued under the Act relates only to the premises described in that licence and/or permit, and to no other premises.
- Before issue, HCC must be satisfied that the premises are suitable for the purposes stated, clean, hygienic and adequately equipped for manufacture, sale or supply of the Controlled Substances to which the licence or permit is relevant.

*If premises were changed, what would the Law require?*

### **What do the Appropriate Licences and Permits Authorise?**

- Manufacture of Schedule 8 substances.
- Manufacture of other Schedule 7 substances.
- Sale or supply by wholesale of Schedule 8 substances.
- Sale or supply by wholesale of other Scheduled substances.

Of course, licences and permits cover all classes of pharmaceuticals and chemicals, but Trainees should note that these details are beyond the scope of this particular Training.

### **Duration**

Licences and Permits are valid for 12 months from the date of issue, and may be renewed on payment of a fee.

### **Inspection**

Before initial issue of Permits and/or Licences, an inspection of the premises must occur to ensure compliance, and further inspections will occur on a routine basis.

## **Suspension or Cancellation**

Licences and/or Permits may be suspended or cancelled if

- there is lack of compliance by the Holder with the terms, conditions, limitations and restrictions of those Licences and/or Permits.
- the Holder, by subsequent behaviour or investigations reveals their lack of suitability to possess a Licence and/or Permit.
- the Holder has been convicted of an offence against the Act.
- the Holder ceases business operations at those premises outlined in the documents.
- where cancellation or suspension occurs, the actual original Licence and/or Permit documents must be surrendered to Department of Health and Community Care.

*Taking the first three of the above circumstances, write down the relevance and responsibilities of Trainees, as employees, for each one separately.*

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## **END USER DECLARATION**

ACT Regulations require that vendors of chemicals and pharmaceuticals should retain records of all transactions for a period of two years, and that Police and State Health Departments must have access to these. It now seems that most, if not all States have moved to, or are in the process of implementing, equivalent similar systems.

Industry itself, in many areas of Australia, has introduced, and is using, a system of proforma called **END USER DECLARATIONS (EUD)**. (A sample is included for you to examine, see appendix 2.)

*List the requirements of a purchaser in order to comply with an EUD.*

*Which SUSDP schedules are involved here?*

*What is a vendor?*

Industry associations are keen to see this system implemented by all members, and eventually, by all vendors of these substances, throughout all States and Territories.

An *EUD* must (where in use) be completed for every single transaction (purchase), even including account customers.

Trainees should note that *EUD*'s have no lawful status. This does not mean that they do not perform a very useful community function.

*Outline fully, all the useful functions carried out by an EUD system*

Trainees should also note that where in use

1. your Company should not supply Controlled Substances, unless a fully completed *EUD* is supplied, and
2. even though *EUD*'s have no lawful status, where your Company is responsibly using them, you as an employee must comply fully and willingly where and if you are involved, as it will be "*Company Policy*", and therefore your willing compliance will be essential as part of your conditions of employment.

## **CONTROL RESPONSIBILITIES IN THE STATES** **QUEENSLAND**

In Queensland, drugs, poisons and controlled substances are controlled by the *Health (Drugs and Poisons) Regulation 1996*, made under the Queensland Health Act 1937. The Health (Drugs and Poisons) Regulation 1996 has adopted by reference, certain parts of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP), including the poisons schedules. This adoption of the SUSDP was made with a view to national uniformity throughout Australia.

Other parts of the SUSDP which have been adopted into Queensland's Regulation include those sections on the labelling and packaging of drugs and poisons. This includes first aid directions, and warning and safety direction statements required to be included on the label of relevant poisons for sale.

### **A. Licences**

In Queensland a number of different licences are issued by the Queensland Department of Health under the provisions of the *Health (Drugs and Poisons) Regulation 1996*. These licences are for the manufacture and wholesaling of restricted drugs and dangerous drugs, and for the manufacture, wholesale and retails of poisons.

#### **1. Licences to Manufacture**

Three different licences exist. They are:

- 1.1 Licence to Manufacture Restricted Drugs (Schedule 4; Schedules 1, 2, 3 and 7 may also be manufactured under this licence).
- 1.2 Licence to Manufacture Dangerous Drugs (Schedule 8 only)
- 1.3 Licence to Manufacture and/or Sell by Wholesale Poisons (Schedules 1, 2, 3 and 7 only).

A person holding a licence to manufacture a restricted drug, dangerous drug or a poison is also deemed to be licensed to sell that restricted drug, dangerous drug or poison by wholesale.

A licence is not required for the manufacture of Schedule 5 or 6 poisons.

#### **2. Licences to Sell by Wholesale**

Three different licences exist. They are:

- 2.1 Licence to Sell Restricted Drugs by Wholesale (Schedule 4; Schedules 1, 2, 3 and 7 may also be sold by wholesale under this licence)
- 2.2 Licence to Sell Dangerous Drugs by Wholesale (Schedule 8 only)
- 2.3 Licence to manufacture and/or Sell by Wholesale Poisons (as in 1.3 above)

A Licence is not required to wholesale Schedule 5 and 6 poisons.

### **3. Wholesale Representative's Authority**

Allows wholesale representatives employed by licensed manufacturers or wholesale sellers of restricted drugs to supply as samples Schedule 4 drugs to medical practitioners, veterinarian surgeons and dentists.

## **B. Permits**

In Queensland there are two types of permits issued under the provisions of the *Health (Drugs and Poisons) Regulation 1996*. These are:

1. Cyanide Permit
2. Strychnine Permit

These permits are required by any person who wishes to obtain, be in possession of or use any substance containing cyanide or strychnine respectively. The permits do not allow the holder to supply or sell cyanide or strychnine to other people. Stringent conditions are attached to each permit issued.

## **C. Authorities and Approvals**

The *Health (Drugs and Poisons) Regulation 1996* of Queensland allows for the Chief Executive of the Department of Health to issue authorities and approvals to persons for restricted drugs, dangerous drugs, controlled drugs and poisons and certain other poisons.

Authorities and approvals are issued by the Department, subject to stringent conditions and are generally specific to particular drug(s), or poison(s).

## **DISTRIBUTION**

In supplying drugs or poisons specified in Schedules 2, 3, 4, 7 and 8, there are restrictions as to whom a licensed person may sell these substances to.

1. A licensee may sell or supply to another person who is also licensed to manufacture or sell that particular schedule(s) of drug or poison.
2. A licensee may also sell or supply to 'authorised persons' including but not limited to medical practitioners, pharmacists, dentists and veterinary surgeons. The authority of these 'authorised persons' is only to the extent necessary for the conduct of their respective professions.
3. Holders of a Wholesale Representative's Authority may supply Schedule 4 drug samples to medical practitioners, veterinary surgeons and dentists only.

## **TRANSPORTATION**

Delivery of a dangerous drug to an authorised person may be made by registered post or by a carrier or transport service where by signed or officially receipted documentary proof of consignment and delivery is obtained.

Dangerous drugs delivered in the above manner must be delivered or forwarded separately from any other goods and must be in a securely closed package addressed to the authorised person.

Restricted drugs may be delivered to an authorised person by personal delivery or by forwarding such restricted drug by post or by a carrier or transport service.

If delivered in the above manner, a restricted drug must be contained in a securely closed package addressed to the authorised person.

## **STORAGE**

1. All Schedule 8 drugs and controlled drugs and poisons must be stored in a receptacle approved in writing for that purpose by the Chief Executive or in a secure place to the satisfaction of the Chief Executive. The approved receptacle generally includes safes, cabinets and vaults which have been approved by the Chief Executive.
2. Schedule 4 drugs must be kept in a dispensary, storeroom or other portion of a premises which is partitioned off or similarly separated from any portion of the premises which the public is permitted to enter. Storage may also be in a cupboard or drawer so situated in the premises as to be inaccessible to the public.
3. Poisons in Schedules 2, 3 and 7 for wholesale sale must be stored in a manner so as inaccessible to the general public.

Where dangerous drugs, restricted drugs or poisons are stored by a licensed manufacturer or wholesaler, such drugs or poisons must only be stored at the premises specified in the licence.

## **RECORDS**

Records are required to be kept for the manufacture or wholesale sale of dangerous drugs, restricted drugs and poisons. The following details must be kept:

1. A person licensed to manufacture or sell by wholesale dangerous drugs must keep a 'Drugs Register' at the premises specified in the licence in which must be recorded details of each and every transaction in dangerous drugs. Such register must be retained for a period of not less than two years from the date of the last transaction.
2. A person licensed to manufacture or sell by wholesale restricted drugs must issue to the purchaser or the person supplied, an invoice containing details of each transaction. A record of every invoice and the details contained therein must be retained for a period of not less than two years from the date of the invoice.

3. A person licensed to manufacture and/or sell by wholesale poisons specified in Schedules 2, 3 and 7 must issue to the person supplied, an invoice containing details of the transaction. A faithful record of every invoice must be retained at the licensed person's place of business for a period of not less than two years.

## **MORE DETAILS ON LICENCES AND PERMITS** **QUEENSLAND**

### **How are Licences and Permits Issued?**

- The person must make written application on the prescribed form to the Chief Executive, Department of Health.
- The application must be accompanied by the prescribed fee. Note there is currently no fee required for a permit for cyanide or strychnine.
- The applicant must be a fit and proper person to hold the licence or permit.
- The application must be bona-fide.
- The applicant must be familiar with the provisions of the *Health (Drugs and Poisons) Regulation 1996* as they apply to the particular type of licence or permit.
- The licence issued relates only to the premises specified in the licence. A licence is issued in respect of one premises only.

### **What do the Appropriate Licences, Permits and Authorities and Approvals Authorise?**

- Licence to Manufacture Restricted Drugs - manufacture of Schedule 4 drugs; wholesale sale of Schedule 4 drugs; manufacture and/or sale of Schedule 2, 3 and 7 poisons.
- Licence to Sell Restricted Drugs by Wholesale - wholesale of Schedule 4 drugs; manufacture and/or wholesale of Schedule 2, 3 and 7 poisons.
- Licence to Manufacture Dangerous Drugs - manufacture of Schedule 8 drugs; wholesale sale of Schedule 8 drugs.
- Licence to Sell Dangerous Drugs by Wholesale - wholesale sale of Schedule 8 drugs.
- Licence to Manufacture and/or Sell by Wholesale Poisons - manufacture and/or wholesale sale of Schedule 2, 3 and 7 poisons.
- Cyanide Permit - obtain, be in possession of and use cyanide or compounds containing cyanide.
- Strychnine Permit - obtain, be in possession of and use strychnine.
- Wholesale Representative's Authority - supply of Schedule 4 drug samples to medical practitioners, veterinary surgeons and dentists.
- Authorities and Approvals are specific to particular drugs or poisons. Authorities and Approvals may be for the possession, prescribing, dispensing, purchase, sale, obtaining,

lending, giving away, supplying or use of the particular drugs or poisons and is at the discretion of the Chief Executive.

## **Duration**

All licences and Wholesale Representative's Authorities issued by the Department are valid for a period of one year from the date of issue.

Wholesale Representative's Authorities are not renewable. A new application must be made on expiry of the authority.

Cyanide and Strychnine permits are issued for up to a maximum of two years. Permits are not renewable. A new application must be made on expiry.

Authorities and Approvals are issued over variable time periods dependant upon circumstances specific to the Authority or Approval. Generally a maximum period of two years applies.

## **Inspection/Assessment**

Prior to the issue of any licence inspection of the premises and assessment of the applicant is made by officers of Queensland Health.

Where a licensee changes location of the premises specified in the licence, inspection of the new premises must be made prior to licensing of the new premises.

On application for a licence to manufacture restricted drugs or a licence to manufacture dangerous drugs, the person nominated in the application to personally supervise the manufacture of the drugs must be assessed under specific qualification and experience criteria.

## **Suspension or Cancellation**

Licences or permits may be cancelled or suspended if:

- the licensee has been convicted or an offence against the provisions of the Act or Regulation
- the licensee is deemed by the Chief Executive to be unfit to hold such a licence
- the licensee's premises are deemed by the Chief Executive to be unfit for the purpose for which such licence was granted.

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- **END USER DECLARATION**

Queensland Regulations require that vendors of chemicals and pharmaceuticals should retain records of all transactions for a period of two years, and that Police and State Health Departments must have access to these. It now seems that most, if not all States have moved to, or are in the process of implementing, equivalent similar systems.

Industry itself, in many areas of Australia, has introduced, and is using, a system of proformae called **END USER DECLARATIONS (EUD)** (A sample is included for you to examine, see appendix 2.)

*List the requirements of a purchaser in order to comply with an EUD.*

*Which SUSDP schedules are involved here?*

*What is a vendor?*

Industry associations are keen to see this system implemented by all members, and eventually, by all vendors of these substances, throughout all States and Territories.

An *EUD* must (where in use) be completed for every single transaction (purchase), even including account customers.

Trainees should note that *EUD*'s have no lawful status. This does not mean that they do not perform a very useful community function.

*Outline fully, all the useful functions carried out by an EUD system*

Trainees should also note that where in use

1. your Company will not supply Controlled Substances, unless a fully completed *EUD* is supplied, and
2. even though *EUD*'s have no lawful status, where your Company is responsibly using them, you as an employee must comply fully and willingly where and if you are involved, as it will be "*Company Policy*", and therefore your willing compliance will be essential as part of your conditions of employment.

## **CONTROL RESPONSIBILITIES IN THE STATES** **NEW SOUTH WALES**

In New South Wales, poisons, restricted substances (S4) and controlled drugs (S8), are controlled by the *Poisons and Therapeutic Goods Act 1966*, *Poisons and Therapeutic Goods Regulation 1994* and the *Drug Misuse and Trafficking Act 1985*. The Poisons and Therapeutic Goods Act provides for the Poisons list which, with some exceptions adopts poisons schedules 1 to 8 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). All States have agreed to adopt these schedules, and thus there is uniformity throughout Australia.

*Why is this general uniformity of Scheduling very desirable?*

*Can you think of any previous lack of uniformity in other areas between States, which contrasts with this?*

*What detrimental effects has this had for Australia?*

*List some for discussion.*

The SUSDP also contains details on packaging and labelling, together with *Safety Directions*, *Warning and First Aid Statements* which are required to be printed on the label of the relevant chemicals. These have also been adopted by each State.

### **Licences and Authorities**

In New South Wales a system of Licences operates for wholesaling therapeutic goods, including Schedule 8 substances, and Authorities are issued for manufacturing and wholesaling veterinary substances. Licences and authorities are issued by the Pharmaceutical Services Branch of the Department of Health.

Additionally, Licences are issued for the Manufacture of Schedule 8 substances.

All other licensing of manufacturers is handled by the Commonwealth.

#### Licence to sell by Wholesale

Two classes of Licences exist. They are

- Sale of Schedule 8 substances
- Sale of Schedule 2 and/or 3 or 4 substances

Authorities are also issued for persons who are not licensed or otherwise authorised, to obtain and use certain substances including substances in Schedule 7.

## DISTRIBUTION

If supplying Substances in Schedules 2, 3, 4, 8 and some of 7, there are restrictions to whom the Company may supply.

1. It may supply to a Company or person who holds a current Licence or Authority relevant to that compound or Schedule.
2. It may distribute to an “*authorised person*” such as: medical practitioner; veterinarian; retail pharmacist and dentist. These persons do not need a Licence because they are already “*authorised*” by their qualifications and professional registration under the Act.

*What State Licences/Authorities does your Company hold?*

*Under the Act, what operations can it undertake with respect to Controlled Substances?*

## TRANSPORTATION

Obligations here require that any loss during transportation must be reported to the Police and the State Health Department. Company employees should report any perceived suspicious behaviour, or any loss, or anything out of order in this area, to a Company supervisor.

## STORAGE

1. Schedule 8 substances must be in a vault or safe.
2. Schedule 4 substances must be located in a locked storage facility such as a cupboard, room or entire warehouse, depending on the quantity required for storage. Security systems like alarms must be in place to deter unauthorised entry, but which allows for Fire Brigade access.

In New South Wales, before a licence is issued, the security and suitability of the premises are inspected by the Pharmaceutical Services Branch of the New South Wales Health Department.

## RECORDS

New South Wales requires that Companies keep full records for two years which, as required, can be audited subsequently.

## **MORE DETAILS ON LICENCES AND AUTHORITIES** **NEW SOUTH WALES**

### **How are Licences and Authorities Issued?**

- The person must apply in writing to the Chief Pharmacist of the Pharmaceutical Services Branch of the State Department of Health.
- The application must be accompanied by the prescribed fee.
- The applicant must establish a bona fide need for the authority licence and/or authority.
- A licence and/or authority issued, relates only to the premises described in that licence and/or authority, and to no other premises.
- Before issue, the Department of Health must be satisfied that the premises are suitable for the purposes stated, clean, hygienic and adequately equipped for manufacture, sale or supply of the Controlled Substances to which the licence or authority is relevant.

*If premises were changed, what would the Law require?*

### **What do the Appropriate Licences and Authorities Permit?**

- Manufacture of Schedule 8 compounds.
- Supply by wholesale of Schedule 8 compounds.
- Supply by wholesale of other Scheduled compounds.
- Supply by retail (in specified circumstances) of Schedule 2 substances.

Of course, licences and authorities cover all classes of pharmaceuticals and chemicals, but Trainees should note that these details are beyond the scope of this particular Training.

### **Duration**

Licences to supply by wholesale are valid until 30 September in the year following the date on which they were issued, and may be renewed on payment of a fee for a further 12 months. Authorities are usually open-ended and there is no charge for their issue.

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## Inspection

Before initial issue of Authorities and/or Licences, an inspection of the premises must occur to ensure compliance, and further inspections will occur.

## Suspension or Cancellation

Licences and/or Authorities may be suspended or cancelled if:

- there is lack of compliance by the Holder with the terms, conditions, limitations and restrictions of those Licences and/or Authorities;
- the Holder, by subsequent behaviour or investigations reveals their lack of suitability to possess a Licence and/or an Authority;
- the Holder has been convicted of an offence against the Act or the Regulation;
- the Holder ceases business operations at those premises outlined in the documents;
- Annual fees not paid.

Where cancellation or suspension occurs, the actual original Licence and/or Authority documents must be surrendered.

*Taking the first three of the above circumstances, write down the relevance and responsibilities of Trainees, as employees, for each one separately.*

## **END USER DECLARATION**

New South Wales Regulations require that vendors of chemicals and pharmaceuticals should retain records of all transactions for a period of two years, and that Police and State Health Departments must have access to these. It now seems that most, if not all States have moved to, or are in the process of implementing, equivalent similar systems.

Industry itself, in many areas of Australia, has introduced, and is using, a system of proformae called **END USER DECLARATIONS (EUD)** (A sample is included for you to examine, see appendix 2.)

*List the requirements of a purchaser in order to comply with an EUD.*

*Which SUSDP schedules are involved here?*

*What is a vendor?*

Industry associations are keen to see this system implemented by all members, and eventually, by all vendors of these substances, throughout all States and Territories.

An *EUD* must (where in use) be completed for every single transaction (purchase), even including account customers.

Trainees should note that *EUD*'s have no lawful status. This does not mean that they do not perform a very useful community function.

*Outline fully, all the useful functions carried out by an EUD system.*

Trainees should also note that where in use

1. your Company should not supply Controlled Substances, unless a fully completed *EUD* is supplied, and
2. even though *EUD*'s have no lawful status, where your Company is responsibly using them, you as an employee must comply fully and willingly where and if you are involved, as it will be "*Company Policy*", and therefore your willing compliance will be essential as part of your conditions of employment.

## **CONTROL RESPONSIBILITIES IN THE STATES** **TASMANIA**

In Tasmania access to drugs and poisons is controlled under the *Poisons Act 1971* and Regulations 1975. The Act incorporates a system for scheduling or classifying substances for the purposes of controlling access and it is based on the model poisons schedules of the *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSDP). All States have agreed to adopt these schedules (with rare variations) and thus there is near complete uniformity throughout Australia.

*Why is this general uniformity of Scheduling very desirable?*

*Can you think of any previous lack of uniformity in other areas between States, which contrasts with this?*

*What detrimental effects has this had for Australia?*

*List some for discussion.*

The SUSDP also contains details on packaging and labelling, together with *Safety Directions*, *Warning and First Aid Statements* which are required to be printed on the label of the relevant chemicals. These have also been adopted by each State.

### **A. Licences**

In Tasmania a system of licences operates which the Department of Health and Human Services issue.

#### **1. Licences to Manufacture**

Two types (classes) of licences exist. They are

- 1.1 Manufacture of schedule 8 substances
- 1.2 Manufacture of other scheduled substances

The latter manufacturing licences refer to substances in Schedules 2, 3, 4 or 7.

#### **2. Licence to sell by Wholesale**

Again, two classes of licences exist. They are

- 2.1 Sale of schedule 8 substances
- 2.2 Sale of other scheduled substances included in schedules 2,3,4 or 7.

## **B. Permits**

In Tasmania a system of permits also exist to allow a person to obtain (ie purchase), possess and use Controlled Substances. These permits generally do not allow the permit holder to supply the substance to another person unless the permit specifically authorises sale or supply (eg a licensed wholesaler or retailer of a particular substance or class of substances).

Substances thus requiring a permit are classified in Schedules 2, 3 4, 8 and some of 7.

**Note:** If, after purchase (with a Permit), that item is converted to another scheduled compound, then a Licence is required.

## **DISTRIBUTION**

If supplying Substances in Schedules 2, 3, 4, 8 and some of 7, there are restrictions to whom the Company may sell.

1. It may sell (distribute) to a Company or person who holds a current Licence or Permit relevant to that compound or Schedule.
2. It may distribute to an “*authorised person*” such as a named medical practitioner; veterinarian; retail pharmacist or dentist. These people do not need a Permit because they are already “*authorised*” by the fact of their qualifications and professional registration under the Act.

*What State Permits/Licences does your Company hold?*

*Under the Act, what operations can it undertake with respect to Scheduled Substances?*

## **TRANSPORTATION**

Obligations here required that any loss during transportation must be reported to the Police and the State Department of health and Human Services. Trainees should report any perceived suspicious behaviour, or any loss, or anything out of order in this area, to a Company supervisor.

## **STORAGE**

1. Schedule 8 substances must be kept in a vault or safe approved by the Department of Health and Human Services. Special security requirements apply for large quantities.
2. Schedule 4 substances must be located in a locked storage facility such as a cupboard, room or entire warehouse, depending on the quantity required for storage. Security systems like alarms must be in place to deter unauthorised entry, but which allows for Fire Brigade access. This applies to Schedule 8 too.

In Tasmania, before a Licence for Schedule 8 and some Schedule 4 substances is issued, a Crime Prevention Report from the Police is necessary. The aim of this requirement is to ensure security and prevent unauthorised access to Schedules 4 and 8 compounds.

## **RECORDS**

The State requires that Companies keep full records for two years which, as required, can subsequently be audited.

## **MORE DETAILS ON LICENCES AND PERMITS** **TASMANIA**

### **How are Licences and Permits Issued?**

- The person must apply in writing to the Secretary of the State Department of Health and Human Services (DHHS).
- The application must be accompanied by the prescribed fee.
- The applicant must establish personal qualities and credentials to justify licence and/or permit issue to them.
- A licence and/or permit issued under the 1971 Act relates only to the premises described in that licence and/or permit, and to no other premises.
- Before issue, HCS must be satisfied that the premises are suitable for the purposes stated, clean, hygienic and adequately equipped for manufacture, sale or supply of the Controlled Substances to which the licence or permit is relevant.

*If premises were changed, what would the Law require?*

### **What do the Appropriate Licences and Permits Authorise?**

- Manufacture of Schedule 8 substances
- Manufacture of other Scheduled substances
- Sale or supply by wholesale of Schedule 8 substances
- Sale or supply by wholesale of other Scheduled substances

Of course, licences and permits may cover any classes of pharmaceuticals and chemicals, but Trainees should note that these details are beyond the scope of this particular Training.

## **Duration**

Licences and Permits are valid for 12 months from the date of issue, and may be renewed on payment of a fee.

## **Inspection**

Before initial issue of Permits and/or Licences, an inspection of the premises must occur to ensure compliance, and further inspections will occur on a routine basis.

## Suspension or Cancellation

### Licences and/or Permits may be suspended or cancelled if

- there is lack of compliance by the Holder with the terms, conditions, limitations and restrictions of those Licences and/or Permits.
- the Holder, by subsequent behaviour or investigations reveals their lack of suitability to possess a Licence and/or Permit.
- the Holder has been convicted of an offence against the Act of 1971.
- the Holder ceases business operations at those premises outlined in the documents.

Where cancellation or suspension occurs, the actual original Licence and/or Permit documents must be surrendered to DHHS.

*Taking the first three of the above circumstances, write down the relevance and responsibilities of Trainees, as employees, for each one separately.*

## State Health Department Contact

The contact in Tasmania is:

Chief Pharmacist  
Pharmaceutical Services Branch  
Department of Community and Health Services  
GPO Box 125B  
HOBART TAS 7001

## **END USER DECLARATION**

Tasmanian Regulations require that wholesalers of chemicals and pharmaceuticals should retain records of all transactions for a period of two years, and that Police and State Health Departments Poisons Inspectors must have access to these. It now seems that most, if not all States have moved to, or are in the process of implementing, equivalent similar systems.

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*Outline fully, all the useful functions carried out by an EUD system*

**Trainees should also note that where in use :**

1. your Company will not supply Controlled Substances, unless a fully completed *EUD* is supplied, and
2. even though *EUD*'s have no lawful status, where your Company is responsibly using them, you as an employee must comply fully and willingly where and if you are involved, as it will be "*Company Policy*", and therefore your willing compliance will be essential as part of your conditions of employment.

## **CONTROL RESPONSIBILITIES IN THE NORTHERN TERRITORY**

In the Northern Territory scheduled substances are controlled by the *Poisons and Dangerous Drugs Act*, and *Regulations 1983*. The Act adopts the poisons schedules of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

The contact office is Poisons Control, Department of Health and Community Services, telephone (08) 8922 7341 or facsimile (08) 8922 7200.

### **A. Licences**

In the Northern Territory retailers of scheduled poisons are required to be licenced if they deal in poisons in Schedules 2, 6 or 7. It is intended to remove the requirement for licencing of Schedule 6 retailers in the near future.

Applicants must complete a prescribed application form. Persons wishing to retail Schedule 7 poisons require Agsafe accreditation for premises and personnel.

### **B. Registration of premises**

Premises used for wholesaling or manufacturing Poisons must be registered.

Wholesalers of scheduled substances for human use must comply with the Australian Code of Good Wholesaling Practice for Therapeutic Goods for Human Use.

Samples of scheduled substances to medical practitioners etc must be obtained from a registered wholesaler. Sales representatives are not authorised to possess/provide samples unless an order is placed by the medical practitioner to a registered wholesaler.

### **C. Authorisations**

A system of Authorisations under various sections of the *Act* exists allowing individuals to purchase, possess and use S4, S7 and S8 substances.

## **DISTRIBUTION**

Scheduled Substances in Schedules 2, 3, 4, 7 or 8 may only be supplied to persons or businesses authorised under the *Poisons & Dangerous Drugs Act*.

1. A business or person who holds a current Licence, Registration or Authorisation relevant to that substance or Schedule.
2. Medical practitioners; veterinarians; pharmacists and dentists are deemed to be authorised under *the Act*.

## STORAGE

1. Schedule 8 substances must be kept (except when in actual use) in a locked room, safe, cupboard or container of a type approved by the Chief Health Officer. Pharmacists are required to keep Schedule 8 in a safe.
2. Schedule 4 and Schedule 7 substances must be stored so as to prevent unauthorised access ie located in a locked storage facility such as a cupboard, room or entire warehouse, depending on the quantity required for storage.

## RECORDS

The *Poisons and Dangerous Drugs Act* requires that records must be kept for two years. These records must be available for audit by a Poisons Inspector.

## How are Licences, Registrations and Authorisations Issued?

- the person must apply in writing to the Chief Poisons Inspector, Poisons Control, Department of Health and Community Services.
- The application must be accompanied by the prescribed fee.
- The applicant must establish credentials to justify issue of the Licence, Registration or Authorisation.
- A Licence, Registration or permit issued under the *Act* relates only to the premises described in the authorisation document.
- The applicant must provide evidence that the premises are suitable for the purposes stated, and that storage and record keeping comply with the *Act*.

## Duration

Licences, Registrations and Authorisations are valid for varying periods from the date of issue, but for no more than two years from issue.

## Inspection

Inspections of premises are carried out on a risk management basis both before issue of a Licence, Registration or Authorisation, and after issue of such.

## **Suspension or Cancellation**

### **Licences, Registrations and Authorisations may be suspended or cancelled if**

- there is lack of compliance by the holder with the *Poisons and Dangerous Drugs Act* or conditions of the licence, registration or authorisation.
- the holder has been convicted of an offence against the *Poisons and Dangerous Drugs Act*.
- the holder ceases business operations at those premises outlined in the documents.
- Where cancellation or suspension occurs, the actual original Licence, Registration or Authorisation documents must be surrendered.

## Appendix 1

### Sample Standard Operating Procedure

### Packing of Schedule 8 (Narcotic) Material

#### Aim

This SOP details the procedures to be followed when packing Schedule 8 materials.

#### A. General procedure

The standard procedures and methods of the production system are to be employed except for the following points which relate specifically to narcotics.

#### B. Approved personnel

1. Only personnel listed on the Narcotic Supervisor's approved list (and persons with Grade 3 Operator experience) are permitted to be engaged in the packing of narcotics.
2. The Finishing Department Supervisor will select personnel from the approved list for the packing of any Schedule 8 materials.
3. For packing runs requiring large crews, persons with Grade 3 Operator experience may be selected by the Finishing Department Supervisor.

#### C. Issue and receipt of Schedule 8 materials

1. On receipt of the packaging work order from the Finishing Department, the Narcotics Supervisor will issue the necessary material from the Narcotics Store.
2. The leading hand and Narcotics Supervisor will check weigh the material using the digital electronic scales in the Dispensary, Packing or Liquid Manufacturing Departments.
3. The gross weight is to be accurately recorded on the Production Documents and the container.
4. The Narcotics Supervisor is to escort the material to the appropriate filling line in the Finishing Department.
5. All bulk containers and their covers are to be retained so the tare weights can be checked at the end of the run.
6. The Leading Hand and the Narcotics Supervisor will then sign the Production Documents in the appropriate place.

**D. Production planning**

1. Only one Schedule 8 packaging work order is to be issued at one time.
2. Normally the bulk material will be issued, the job completed, and the finished goods stored in the Narcotics Store entirely within the one morning or afternoon in the case of liquids.
3. Except for the Schedule 8 material itself, items pertaining to the job may be assembled beforehand and stored in the locked Line 1 area.

**E. Packing area and access**

1. All Schedule 8 materials are to be packed on Line 1.
2. The Leading Hand in charge of the job is to restrict access to all unauthorised personnel while Schedule 8 material is in the room.
3. If a Machine Setter, Floorman or QA Inspector is required to enter while the Schedule 8 material is in the room, the Leading Hand will personally supervise through-out the required operations.
4. With the above exceptions, the only personnel who may enter the room during the run are: a. one of the Narcotics Supervisors, b. the quality Assurance Manager, c. A Senior Company Executive or authorised Poisons Inspector provided they are accompanied by the Finishing Department Supervisor or his deputy, or one of the Narcotics Supervisors.
5. Two of the doors of the Packing Room will be locked at all times during the run.
6. The third door will be closed, but not locked, during the run.
7. The leading Hand will lock the third door, take charge of the keys and check all locks whenever the packing team vacates the room while Schedule 8 material is inside.
8. In this case, immediately upon leaving the locked room, the Leading Hand will notify the Finishing Room Supervisor or Deputy, who will examine the locks.

**F. Packing procedure and reconciliation**

1. All items of packaging material are to be re-counted and recorded before commencing the run.
2. All items of packaging material are to be counted, recorded and reconciled after the run.
3. None of the materials to be packed, the packaging materials rubbish or equipment is to be removed from the room during the run.
4. For the filling of liquid products, use the Filamatic machine set to dispense the correct target fill.
5. The digital electronic balance graduated to display 0.19 intervals is to be used for checking the fill.
6. Check the accuracy of the balance with suitable standard weights (1 gram and 200 grams) before the run.
7. Keep material and empty bottles near the filler; keep the caps and labels in front of the second operator.
8. The Leading Hand will carry out the weight control checks and report the results, as per regular operations on liquid filling lines.
9. Any spilt, broken or damaged material will be collected as best as possible.
10. The Leading Hand is to estimate the amount of material involved and notify the Narcotics Supervisor who will carry out a reconciliation and decide on the appropriate action.
11. Damaged packaging material will be retained until the Leading Hand and the Narcotics Supervisor have completed their reconciliation.
12. At the end of the packing run, the Narcotics Supervisor will check weigh the empty bulk containers, closures, etc. on suitable digital scales in the Dispensary, Packing or Liquid Manufacturing Departments.
13. The Laboratory samples will consist of the first bottle filled and labelled, and the last bottle, which may contain less than the standard fill.
14. The amount of bulk material actually used for the job is to be calculated and checked against the quantity originally issued.
15. The nett production and laboratory samples will be recorded separately on the Work Order.
16. The Leading Hand and the Narcotics Supervisor will jointly check the reconciliation of production.

END OF PROCEDURE

**APPENDIX TWO****Standard for the Uniform Scheduling of Drugs and Poisons - SCHEDULES****CLASSIFICATION**

Poisons are classified according to the Schedules in which they are included, as follows:

- Schedule 1** blank.
- Schedule 2** **Pharmacy Medicines** – Substances, the safe use of which may require advice from a pharmacist and which should be available from a pharmacy or, where a pharmacy service is not available from a licensed person.
- Schedule 3** **Pharmacist Only Medicine** – Substances, the safe use of which requires professional advice, but which should be available to the public from a pharmacist without prescription.
- Schedule 4** **Prescription only Medicine, or Prescription Animal Remedy** – Substances, the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe and should be available from a pharmacist on prescription.
- Schedule 5** **Caution** – Substances with a low potential for causing harm, the extent of which can be reduced through the use of appropriate packaging with simple warnings and safety directions on the label.
- Schedule 6** **Poison** – Substances with a moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label.
- Schedule 7** **Dangerous Poison** – Substances with a high potential for causing harm at low exposure and which require special precautions during manufacture, handling, storage or use. These poisons should be available only to specialised or authorised users who have the skills necessary to handle them safely. Special regulations restricting their availability, possession, storage or use may apply.
- Schedule 8** **Controlled Drug** – Substances which should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence.
- Schedule 9** **Prohibited Substance** – Substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities.

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**Preparations containing poisons listed in two or more schedules.**

If a preparation contains two or more poisons, the provisions relating to each of the Schedules in which those poisons are included apply.

Where it is not possible to comply both with a provision relating to one of those Schedules and with a provision relating to another of those Schedules, the provision of the more restrictive Schedule applies, unless a contrary intention is indicated in the Schedules or relevant legislation.

The Schedules listed in order of greatest to least restriction are 8, 4, 7, 3, 2, 6, 5.

THE CONTROL AND MONITORING OF  
DRUGS AND CHEMICALS TO PREVENT  
THEIR DIVERSION FOR ILLICIT USE

MODULE 3

The Recognition and Handling of  
Suspicious Activities

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## INTRODUCTION

In the course of their employment, employees (Trainees) must realise that some forms or patterns of human behaviour by either known or unknown persons, may indicate a potential for illegal redirection of precursor chemicals to drugs of dependence, or even to actual drugs of dependence themselves.

It is therefore important that employees, in order to minimise the risk of illegal redirection occurring, follow all legal requirements and Company policy, in pursuing their duties. Commonwealth and State Laws must be complied with by your Company, which then formulates its own policies and procedures, which in turn reflect those legal requirements of Commonwealth and State. Your Company provides chemicals, pharmaceuticals or equipment for legitimate use to reduce human and animal suffering.

*Write down for discussion, other legitimate uses for chemicals, pharmaceuticals and laboratory apparatus.*

**When redirected illegally, human suffering occurs because of**

- reduced availability to those in legitimate need, and
- addiction and the consequential social problems thus caused.

*Write down for discussion, beginning with the above list, other consequences for the general community caused by illegal redirection.*

Employees by vigilance, use of common sense, and practised recognition, can help prevent illegal redirection by knowing that some forms of human behaviour, might reveal the potential for illegal dispersion of controlled substances.

## SUSPICIOUS BEHAVIOUR AND SUSPICIOUS ACTIVITIES

Suspicious behaviour and suspicious activity by an individual, or groups, could be defined as behaviour or activity which you may perceive to be:

- not conforming to requirements of the Law.
- not conforming to Company Policy.
- inconsistent with “normal” or mostly “normal” patterns of behaviour in a particular situation.

*Can you add to these three above? If so write them down, and share your ideas with fellow trainees.*

## THE IMPORTANCE OF RECOGNISING SUSPICIOUS ACTIVITY AND BEHAVIOUR

Unless suspicious, irregular behaviour and/or activities are recognised, then it becomes more difficult subsequently, for correction and apprehension to occur.

Recognition then, should be seen by employees as the first and most important step in preventing illegal redirection. The importance then in recognition, is that it helps minimise diversion, and therefore that in turn helps minimise the consequences.

Return to the questions posed in the “Introduction”.

*In the context of your work environment write down in tabular form all the legitimate uses for pharmaceuticals, chemicals and laboratory apparatus which you and your group have been able to devise. Now against each of these, write down a consequence of illegal redirection with respect to that use?*

*example:*

<u>Legitimate Use</u>	<u>Consequences of Diversion for Illicit Use</u>
Relief of human pain (Morphine)	<ul style="list-style-type: none"> <li>• increased suffering of post-operative patients</li> <li>• increased suffering of those with terminal illness</li> <li>• increased suffering of road accident victims</li> <li>• risk of <i>addiction</i> and <i>tolerance</i> in the person taking the drug illicitly</li> <li>• risk of death or serious injury due to overdose by illicit use</li> </ul>

Review your complete list. This will give you a real insight into why informed, sensitive, and sensible recognition is important for the community in which we are all participants.

## (INDICATORS) IDENTIFICATION OF SUSPICIOUS BEHAVIOUR

Your Trainer (Supervisor) will possibly introduce you to some plays where the scripts consider this issue. There are five situations

1. The Delivery
2. A new Customer
3. Later Identification (of a suspicious customer)
4. The Telephone Inquiry
5. The Sales Representative and The Samples

*Consider each in turn as designated by your trainer.*

*Compile your own, and hence compile a group list of “indicators”.*

## WHAT SHOULD OCCUR FOLLOWING RECOGNITION?

As revealed earlier in this module, employees (trainees) play their major role in alertness, and sensitivity in the recognition of suspicious behaviour and activity.

A key question is: *“Who actually handles the matter once recognition has occurred?”*

Your Company will have procedures in place. You should refer to any Standard Operating Procedures (SOP) your Company may have concerning suspicious behaviour. In most cases the pattern of handling will be

1. Reporting your concern to a superior or supervisor promptly and quietly.
2. Your superior or supervisor will then see that the Police are informed.

In most, if not all cases, your Company probably will not require more from you than commonsense, alertness and sensitivity, then reporting suspicious behaviour to a superior or supervisor quietly and unobtrusively. If you deviate from this then undesirable consequences could result such as:

- warning and alerting the offender who escapes detection and later apprehension.
- in extreme cases, placing yourself in possible physical danger.

## WHAT ARE THE CONSEQUENCES FOR VARIOUS GROUPS, IF SUSPICIOUS BEHAVIOUR RECOGNITION AND HANDLING IS NOT UNDERTAKEN?

### A. Possible consequences for the person who is behaving suspiciously

1. Monetary gain.  
*(Trainees should realise that this point eludes to the insidious undertones of human behaviour with respect to the illicit drug trade.)*
2. Apprehension and punitive action by the Law.
3. In the case of some drugs, severe injury or even death.

### B. Possible consequences for the industry

1. Decrease in public esteem, credibility
2. Lower profitability.
3. Loss of Import/Export Capacity

*(How could this occur?)*

### C. What are the consequences for the Company?

1. Decrease in public esteem, credibility
2. Possible lower profitability.
3. Poorer returns to shareholders.
4. Possible loss, suspension of permits and licences (State and/or Commonwealth)

*(How could this be so?)*

### D. Possible consequences for the Employee

Consequences for the employee (Trainee) are directly affected by consequences which affect the Company.

*Consider C (2, 3, 4 above), how could these affect an employee?*

## **ASSISTANCE - From Whom ?**

As explained earlier, employees who, because of experience, training, alertness and sensitivity detect behaviour which they believe constitutes suspicious conduct, should:

- report to a senior colleague or supervisor who is a clearly identified person within your Company.
- Then, that appointed person has the authority to seek
- Police assistance. The Police are trained to take over at this point, you are not. If Police in your State seek it, they may also call in the Federal Police. Customs could even be involved, depending on the Controlled Substance in question and the circumstances.

**Your Company possibly belongs to a group called an Industry Association. Such examples include:**

- Pharmaceutical Companies – Medicines Australia
- Chemical Companies - PACIA
- Science Industry Australia (SIA)

### ***What are Medicines Australia and PACIA?***

These Associations are sources of professional support and advice for member companies.

Contacts for these Associations are listed in the “Outline” for this training program.

State contacts for law enforcement agencies are listed in Appendix 6 to the *Code of Practice for Supply Diversion into Illicit Drug Manufacture*.

## WHICH PEOPLE OR GROUPS COULD POSSIBLY DISPLAY SUSPICIOUS BEHAVIOUR?

This training program re-iterates that informed alertness is a key quality required of employees.

Two groups of people have been found to be potential sources of illegal leakage of Controlled Substances into the Illicit drug market. There are:

**Company Personnel**  
and

**Known Customers**

as well as

**Outside persons of unknown authenticity.**

In the cases of Company personnel and customers, you must remember your training, and still report to a supervisor or trusted senior colleague, even though the situation may well be very awkward. Responsibility to your Company, your family and yourself must always override one's perception of colleague loyalty in those situations where indicators of suspicious behaviour exist, and your Company recognise them.

THE CONTROL AND MONITORING OF  
DRUGS AND CHEMICALS TO PREVENT  
THEIR DIVERSION FOR ILLICIT USE

Trainers Guide

## TRAINER'S GUIDE

### CONTENTS

#### General Statement on The Use of The Three Training Modules

#### Trainer Guide Notes

#### Module One

#### Trainer Guide Notes

#### Module Two

General Outline of Module Two  
Learning Outcomes

#### Trainer Guide Notes

#### Module Three

General Outline of Module Three  
Learning Outcomes  
Five Plays (Demonstrating Suspicious Behaviour)  
Discussion Questions and Suggested Answers  
List of Indicators of Suspicious Behaviour

## GENERAL STATEMENT ON THE USE OF THE THREE TRAINING MODULES.

Many Companies provide “in-house” training for their personnel. This Program has been designed to supplement that training with relevant information regarding narcotic and psychotropic drugs and precursor chemicals to controlled drugs.

This training package can be used

- for the training of Company personnel
- in its entirety
- as a resource to supplement and complement existing training programs in companies
- as a reference guide

Modules 1 and 2 have been presented as individual units. This will facilitate the process of selecting those components most relevant to the individual Company needs.

The training program should be kept as a resource for future reference purposes.

Whilst great care has been taken in the development of Modules, Company employees should seek expert advice from the relevant Commonwealth, and State/Territory authorities to ensure that their procedures meet legal requirements. The information provided in this training should **not** be regarded as **the basis** upon which Companies conduct all their operations with respect to “Controlled Substances” but should form an integral part of the Good Management Practices of the organisation. Regulations and other legal requirements regularly change. You should ensure that your Company has a process for checking compliance with legislation on a regular basis. This may be a part of your Company’s Quality Assurance. Nevertheless should procedures in your Company depart radically from the descriptions in this training package, it is recommended that you contact the relevant authorities without delay to ascertain whether, and which changes should be put into effect.

## ROLE OF THE TRAINER

This guide should assist you to present the training material in a manner which supports adult learning. To be an effective trainer use the program as fully as possible and develop group discussion, encouraging everyone to participate.

Before acting in the role of trainer, you should be familiar with the training program and the requirements of your Company personnel. To ensure that your presentation is up-to-date do not hesitate to contact Commonwealth and State Government personnel, or the Industry Associations noted in this training package.

**The main aim of the trainer is to create a productive learning environment in which the trainee can participate, contribute and learn.**

Other roles include:

- assessing which components of the training are relevant to the particular needs of company personnel
- devising learning strategies, appropriate to the particular trainee

## TRAINING

For new trainers the following general points should be helpful.

- Make sure you understand the purpose and outcomes of the modules. Nevertheless questions could well arise for which you may not have an immediate answer. Simply indicate this to the trainees and that you will endeavour to provide such a response in due course.
- Design group activities - the more involved trainees are with the learning process the more fruitful the learning outcomes of the activity/ies will be.
- Prepare local or Company specific examples relating to the learning.
- Ascertain whether your trainees have any difficulties which may affect their learning such as language barriers/hearing defects.
- Towards the end of each session, facilitate the group to summarise the main points.
- Use examples of drug related problems in society, from newspaper or magazine articles.
- At the beginning of a new session, revise using questions, or main points, from the previous session.
- Introduce sessions with relevant, topical and stimulating questions which generate interest.

## LEARNING OUTCOMES

For Trainers, Learning Outcomes for each Module are presented in this guide. These may serve to

- function as a set of aims for the Module.
- form a basis on which the trainees could be assessed as having satisfactorily completed this piece of learning.

## **TRAINER GUIDE NOTES FOR MODULE 1**

This Guide contains the following

- Outline of the Module
- Learning Outcomes

## OUTLINE OF MODULE ONE

This Module provides a comprehensive overview of restricted substances, and why controls are in place. It asks trainees (as employees of relevant chemical and pharmaceutical companies) to consider their own knowledge about these matters, their responsibilities and finally what they can do to help prevent the diversion of chemicals to the illicit drug market.

The Module has been divided into units so that selection of the most appropriate components can be made to suit local circumstances (availability of time, relevance for personnel). However as far as practicable the module should be completed in its entirety and in the sequence presented.

Division into units should also improve flexibility of delivery. A number of training sessions can be conducted over a period of time without an otherwise severe loss of continuity.

In this Module “Discussion Questions” are placed at the end of specific sections of information. It is recommended that, as far as practicable, these be discussed before proceeding to subsequent sections.

### UNIT ONE

#### **Introduction and Australia’s Responsibility to The UN conventions**

The main aim of unit one is to introduce the three UN Conventions

- ie. “Single Convention on Narcotic Drugs, 1961”
- “Single Convention on Psychotropic Substances, 1971”
- “United Nations Convention against Illicit Traffic In Narcotics and Psychotropic Substances” 1988.

and Australia’s response, such as relevant legislation, monitoring and control procedures and the authorities responsible for them.

### UNIT TWO

#### **Definitions of Important Key Terms**

This unit contains explanations of some background information and terminology so that the relevant legislation, monitoring and control details can be more easily understood.

## **UNIT THREE**

### **Rationale for special monitoring of controlled drugs**

Section one considers the Social Consequences of Illicit Drugs and the consequence if these drugs are not monitored.

The three main areas of interest are

- health
- society
- environment

The terms “Manufacture” and “illegal possession” are important and the trainees should discuss these terms, so that they understand the full ramifications for themselves and the Company.

Section two reviews clandestine laboratories and the risks they pose for society.

## **UNIT FOUR**

### **Social, Medical and Industrial Relevance of “restricted substances” and controlled drugs**

The main emphasis here is to consider licit uses of drugs and restricted substances in society.

## **UNIT FIVE**

### **Classification and scheduling of restricted substances**

The areas covered are

- introduction to the SUSDP (Standard for the Uniform Scheduling of Drugs and Poisons) (Appendix three of Module Two contains the schedules)
- the functions of the SUSDP

A practical exercise for the trainees could be to determine the SUSDP Schedule Number of some substances (possibly those with which they are directly involved in their particular work situation, if this information is not confidential).

## UNIT SIX

### **Precursor Chemicals to Controlled Drugs and other substances or items which can be used in the manufacture of illegal drugs**

Unit six considers procedures in the work place designed to prevent the diversion of precursor substances and essential chemicals. Assist relevant trainees to identify chemicals and glassware (supplied by your Company) that could be used in the manufacture of illegal drugs. Then identify the procedures that are already set in place, to help prevent the diversion of these chemicals. Explain or discuss why specific procedures are used.

Factors which can influence the risk of theft of chemicals include:

- The quantity carried in stock
- The location of the building
- The type of building
- Existing security arrangements (eg alarm systems)
- Public access
- Employee supervision

## UNIT SEVEN

### **Programs coordinated by relevant Agencies, Authorities, Professional groups**

Unit seven reviews several of the organisations working to help prevent illicit drug production. The roles of the individual organisations can be clarified by preparing a table which depicts the functional differences between the groups.

Example:

<b>Name of Program</b>	<b>Organisations involved in program</b>	<b>Task of Program</b>	<b>Contact Person and Number</b>
Frontline			
National Best Practice			
Drug Squad Programs (State based)			
Code of Practice			

Some agencies may be able to offer assistance which compliments your training program.  
For example

- Frontline - has a training video (which you may be able to borrow)
- Drug squads have a liaison role with Companies and may offer their time to help with training
- Industry Associations, for example “The Code of Practice” (Plastics And Chemicals Industry Association, and the Science Industry Australia)
- National Best Practice brochure

## LEARNING OUTCOMES FOR MODULE ONE

**At the satisfactory completion of this module, the trainee should be able to**

1. Provide a concise explanation, supplemented with appropriate examples of each of the following terms
  - controlled substance
  - narcotic drug
  - psychotropic drug
  - precursor chemicals to controlled substances
  - “essential chemicals” for the production of controlled substances
  - amphetamines
  - licit/illicit
2. Explain why specified chemical substances are, of necessity, controlled in Australia.
3. State some of the undesirable serious social and legal consequences which can result from a lack of adequate supervision of controlled substances.
4. Identify those substances, handled by the trainee or the company in which he/she works, which require special precautions with respect to monitoring and control.
5. Identify key personnel within the Company and from State or Commonwealth Government authorities from whom assistance can be sought with respect to “restricted substances” in their work responsibilities.
6. Describe the role they play which ensures that legislative requirements and Company requirements are met with respect to prevention of the diversion of restricted substances to the illicit drug market.

7. State the location of the Company's protocols for the correct handling, monitoring and control of scheduled substances.
8. Clearly describe the importance of "their particular role" in preventing the diversion of chemicals.
9. State which substances in the workplace require monitoring.

## **TRAINER GUIDE NOTES FOR MODULE 2**

This Guide contains the following

- A General Outline of the Module
- The desired Learning Outcomes for trainees

## A General Overview of Module 2

(See “Introduction” of Module 2.)

As the module deals with the three *UN* Conventions of 1961, 1977 and 1988, it commences with a brief history of the United Nations, then its structure of main organs, organs and specialised agencies. It is recommended that you do use the chart, or a similar overhead transparency in covering this introductory section. Relevant details on the three *UN* Conventions are then written, followed by a consideration of Australian Law governing import and export of controlled drugs and chemicals. Australia’s laws, for the purposes of training, are treated as outcomes of our international commitments. Then follows a consideration of State (Territory) Law with respect to these substances. The unit is completed with information about control at the local level where End User Documents may be required by Industry and/or some States by Law.

The Module follows a logical sequence from the International, to National, to State, and finally to the Industry level itself. The Module has been broken down into more or less self-contained units because, in some workplace settings, a few units may be considered by trainers as irrelevant in their particular context.

### Suggested Methodology of Delivery

The Module has been written so that information is interspersed with questions written in bold italic type. These questions are designed for group discussion, or discussion after written answers have been attempted, and at times simply for written responses.

Although the Module is largely concerned with factual material, Trainers are strongly urged to adopt an “**enquiry approach**” with their trainees.

### Revision Questions about Drugs

The discussion questions about drugs -

The Introduction

- Controlled drugs
- Restricted substances
- precursor chemicals

and

*UN* Conventions

- narcotic drugs
- psychotropic drugs

are so placed as to revise material covered in Module 1. If some trainees have not attempted Module 1, then the trainer must ensure that trainees have a firm grasp of these concepts and terms before proceeding further with **this** Module.

## The *UN* Conventions

Those of 1961 and 1971 are fairly straightforward and are therefore dealt with briefly in the Module itself. However, more time is spent on the 1988 Convention because in the intervening seventeen years, there was increasing illicit **production** of narcotic and psychotropic drugs. It is recommended that trainees be encouraged to think carefully for themselves, about some of the possible causes of this deterioration in the illicit drug scene during this time.

The basic concepts that determine inclusion of drugs and chemicals in these Conventions are:

- the substances have, in general, legitimate scientific or medicinal use that must be protected;
- the abuse of certain substances gives rise to public health, social and economic consequences;
- vigorous measures are necessary to restrict their use to legitimate purposes; and
- to be effective such measures require co-ordinated and universal action at the international level.

## Control - Australia

Again, as with earlier questions about types of drugs, a knowledge about Poisons/SUSDP Schedules is assumed. If Module 1 has not been attempted by trainees, then the trainer should refer to Module 1 and ensure that the background and significance of these Schedules is covered before proceeding with Module 2.

This section of the training **in particular**, is treated as an outcome of Australia's obligations as a responsible signatory of *UN* Conventions, especially the 1988 Convention. It is strongly recommended that you facilitate learning in such a way that the system of Licences and Permits (both for Import and Export), and all the conditions imposed therein, are seen as logical legal outcomes of the Conventions.

Also, this section of training is treated in such a way that trainees:

- (i) should realise the significance and rationale of the Laws under whose contextual framework they are employed in industry.
- (ii) should be aware of their responsibilities as trusted employees.
- (iii) grasp the full significance of possible consequences for their Company and themselves as Company employees, should negligence occur in the workplace resulting in loss of Permits and Licences.

### NOTE:

**These points are made again later in the Module where State Laws are considered. In most cases, a system of State Licences and Permits controls sale, manufacture, distribution, storage and handling of drugs, poisons and controlled substances, laboratory hardware and some therapeutic devices. Again, as in Commonwealth control (above), the same sorts of issues are tackled, and the same sorts of questions are posed in order to reinforce these points.**

The section on Australia concludes with a brief look at Drug Movement, and the set questions outline the focus which is recommended.

## States

- (i) As there is some variation between State and Territory legislation in their requirements for Chemical, Pharmaceutical and Laboratory hardware suppliers, a separate Module section has been written for each State. (The writers are grateful for the help and advice from Senior personnel in the various State and Territory Health Departments.)
- (ii) There is a great deal in common such as the adoption of SUSDP Schedules and associated recommendations.
- (iii) Most have a system of Licences and Permits as referred to above. Although not identical, their systems have much in common.
- (iv) There is variation in the local method of classification and treatment of non-scheduled precursor chemicals. This area is quite complex, and no attempt has been made to clarify it in Module 2 or in this Guide. It is recommended to Trainers that should they decide to tackle this area in their work with trainees, then further personal research should be undertaken, and expert advice sought at the State level.

## End User Declarations

(In South Australia, these are called End User Statements)

Industry Associations presently encourage use of these documents. In some States, the system is not enshrined in State Law. In others, such as New South Wales and South Australia, it appears to be so.

Trainers may wish to have trainees attempt to complete an EUD (EUS).

## Learning Outcomes

As already indicated, Learning Outcomes (which accompany this Guide) may serve to

- function as a set of aims for the Module.
- form a basis on which Module 2 trainees could be assessed as having satisfactorily completed this piece of learning.

## LEARNING OUTCOMES FOR MODULE 2

At the satisfactory completion of this Module, the trainee should be able to

1. State some key functions of the United Nations with respect to World Health.
2. Describe in clear detail, Australia's obligations under the UN Single Convention on Narcotic Drugs, 1961, especially with respect to their Company and their role within the Company.
3. Describe in clear detail, Australia's obligations under the UN Convention on Psychotropic Substances, 1971, especially with respect to their Company, and their role within the Company.
4. Describe in clear detail, Australia's obligations under the UN 1988 Convention against illicit traffic in Narcotic Drugs and Psychotropic Substances, particularly with respect to Articles 12 and 13, especially with respect to their Company, and their role within the Company.
5. Describe in summary, *Commonwealth Customs (Prohibited Imports) Regulations*, particularly as they apply to Schedule 4 Drugs and Chemicals.
6. Describe in summary, *Commonwealth Customs (Prohibited Exports) Regulations*, particularly as they apply to Schedule 8 Drugs and Chemicals.
7. Clearly explain and link Australia's Prohibited Import and Export Regulations to its requirements and obligations under the three *UN* Conventions.
8. Clearly explain the responsibilities of employer and employee in meeting the requirements of holders of Licences and Permits for both Import and Export. Possible consequences for employee and employer of breaches of these responsibilities must also be able to be clearly stated.
9. Provide a general explanation about the reporting requirements within Australia for movements of controlled drugs.

10. Describe the requirements which must be met before any of the following transactions can be effected by an authorised company:
  - (i) issue of any restricted substance to a customer;
  - (ii) physical transfer of any restricted substance, within a company or between companies.
11. Explain the purpose of an “End User Declaration” document.
12. Describe briefly, how a particular company can be audited to ensure that control measures have been appropriately completed.
13. Describe briefly, possible consequences for a company or personnel, if quantities of controlled substances cannot be accounted for as required by relevant authorities.
14. Suggest an appropriate course of action for a company or personnel, when a controlled substance has been dispatched and not reached its legal destination.
15. Within the relevant State, write down:
  - (i) the types of Licences and Permits which exist;
  - (ii) the rights and responsibilities given by Permits and Licences with respect to such areas as Sales, Manufacture, Distribution, Transport, Storage and Record-keeping.

## **TRAINER GUIDE NOTES FOR MODULE 3**

This Guide contains the following

- A General Outline of Module Three
- The desired Learning Outcomes for trainees
- Four plays, Discussion Questions and Suggested Answers
- A list of Indicators of Suspicious Behaviour

## **A GENERAL OUTLINE OF MODULE THREE**

Module 1 included a Section which looked at the Code of Practice, developed by Industry Associations. Module 3 takes one particular part of that Code, and develops it more fully. In essence, it deals with the Recognition and Handling of Suspicious Activities and Behaviour.

Module 3 is written for Company employees who presently, or who may in the future, handle restricted substances, and who also interface with members of the general public.

### **A. The List of Indicators of Suspicious Behaviour**

It is strongly recommended that you do not give this list to your trainees until the relevant part of the Module has been completed. Module 3 has been written so that gradually, under your guidance, and with your teaching skills, trainees will build up a comprehensive list themselves. This will occur through use of discussion questions written throughout the Module, and by use of the Plays. Some groups of trainees may even develop indicators which are not listed. It is recommended that when all avenues for development have been exhausted, that Trainers may then divulge the remaining indicators to trainees.

### **B. Consequences for the Various Groups**

In the consideration of Section C(4) of Module 3, trainees really need to have completed Module 2 for this area to be revised and developed. If Module 2 (Units 5 and 7) has not been completed, then C(4) should be deleted, or treatment of it delayed, until a more suitable occasion arises.

### **C. The Plays**

How the Trainer uses these plays, may vary from one situation to another, and according to the time and resources to which the Trainer has access, such as the number of trainees.

The plays could be

- (i) in the very simplest situation, just read out by trainees in the group.
- (ii) used for role play situations within the group of trainees.
- (iii) acted by Company employees where the situation of resources allows this. They could even be acted by personnel brought in from elsewhere by Trainers.

Whatever the methodology employed, a function of these plays is to illustrate, and to help trainees recognise through their use, **some** of the indicators of suspicious orders and behaviours which are known to exist. Another function of the plays is to generate interest. It is therefore essential for Trainers, in their preparation of the plays, to bear this in mind.

In using the Plays, trainers should also bear in mind, the local situation of their trainees. That is:

- the type of Company (Chemical, Pharmaceutical, Hardware Suppliers);
- the types of relevant precursor chemicals supplied to the Customers;
- the types of pharmaceuticals supplied to the Community.

The order in which the Plays are treated is not important, and this can be varied according to circumstances such as Company priorities and Trainer preference. Also, trainers may wish to use one or two plays in detail, and omit the others. Indeed, if this strategy was deemed desirable in generating the interest outcome in trainees, it would be quite satisfactory and desirable to do so.

## D. The Outcomes of Recognition

So far, A, B, and C of this Guide have been concerned with **Recognition** of Suspicious Behaviour and Orders, the remainder of Module 3 considers **what must actually be done** by employees when suspicions are aroused.

Although the Module is very straightforward from this point until its completion, Trainers should realise that this area must be dealt with both *sensitively and discreetly*. Consequently, the Module is very brief at this point, and very few discussion questions are (quite deliberately) written for trainees. This will give Trainers maximum opportunity to develop this area themselves, using their skills of discretion and sensitivity, and taking fully into account, the local situation.

## LEARNING OUTCOMES

As already indicated Learning Outcomes for Module 3, may in fact serve to

- function as a set of aims for the Module
- form a basis on which the Module 3 trainees could be assessed as having satisfactorily completed this piece of learning

## LEARNING OUTCOMES FOR MODULE 3

**At the satisfactory completion of this module, the trainee should be able to**

1. State the responsibilities of an employee who deals directly with customers for distribution or sale of controlled substances.
2. Nominate what they do, and to whom they report, their suspicions.
3. Describe how suspected events can be conveyed to the relevant authority in the most effective manner.
4. Describe how prompt employee response to potentially illegal behaviour, can minimise illegal redirection.
5. Describe in detail, the various typical indicators of suspicious behaviour which might indicate the potential for future illegal redirection of chemicals and or pharmaceuticals.
6. Define suspicious behaviour/activity, and identify the key groups of personnel who could display suspicious behaviour.
7. State relevant company policy with respect to dealing with suspicious behaviour/activity.

## THE TELEPHONE ENQUIRY

**Setting:** A suburban branch of a large chemical distribution company. The internal sales staffer, Gina, has been with the company for several years and is quickly suspicious of “B”.

**Gina:** Barret Chemicals, can I help you?

**B:** Yes I wanted to place an order for some Phenylacetic Acid.

**Gina:** Do you have an account with us sir?

**B:** No. Is that necessary?

**Gina:** For that particular chemical yes.

**B:** And that would be the case everywhere else?

**Gina:** Yes pretty much so. You would realise of course that it's a Category 1 chemical.

**B:** How do you mean?

**Gina:** Well sir we can't take an order from you unless you have an account with us.

**B:** Oh well that's fine. I'll open an account then. You do stock Phenylacetic Acid then?

**Gina:** Well we wouldn't have it on our shelves right now. I'd have to check on the computer for you. If we do have to get it in for you there would probably be about a week's delay before we could deliver. How much were you wanting to order?

**B:** We need 15 kilos. What is it a kilo?

**Gina:** Well you're looking at 500 dollars per kilo so that would be 7,500.

**B:** Fine. Does it always take that long to get in? I mean we need it pretty quickly. Can't you speed it up a bit?

- Gina:** I'm afraid not. As I said I'm not even 100% sure of its availability. But I can check with the warehouse fairly quickly on that if you want me to.
- B:** Yes please. When could I know if it's available?
- Gina:** I could ring you back in 15 minutes if that suits you.
- B:** It would probably be a lot easier if I rang you back in 15. I'm in and out so you probably wouldn't catch me.
- Gina:** Well I'm going to need some kind of contact if you want me to let you know about availability.
- B:** I see. Well I'll give you my mobile number.  
It's 018 333 3333.
- Gina:** And what was your name sir?
- B:** Andrew Parsons. But like I said I'll ring you back in about 15 minutes.
- Gina:** Well I'll be taking my break soon so I'll leave the details with Jenny Bishop. She's internal sales and can give you some more details about opening an account. If I'm not around you can speak to her. Do you want her direct number?
- B:** Yeah! that'd be good.
- Gina:** It's 123 45678 (By prior arrangement this number could in fact be a Direct number to -a Company supervisor; Authority personnel or to the Drug Squad)
- B:** Thanks very much.
- Gina:** You're welcome.

**“THE TELEPHONE ENQUIRY”****FOR DISCUSSION**

1. What procedural differences are there when dealing with *Category 1, Category 2 and Category 3 drugs?*  
*Category 1: For sale to account customers only, EUD required.*  
*Category 2: EUD only required when sold to non-account customers.*  
*Category 3: No reporting required. The list is to be used as a guide to alert staff that these products may be used in the manufacture of illicit drugs.*  
*Information taken from the Code Of Practice.*
2. What is it about “**B**’s” enquiry that would arouse suspicion?  
*Orders a **Category 1 drug** without knowing the procedure associated with such a request.*  
*Is a new customer.*  
*Is more concerned with availability than cost.*  
*Doesn’t question the high price quoted.*  
*Is hesitant to give a phone number.*  
*Leaves a mobile phone number*
3. What other information could **Gina** have tried to extract from “**B**” which would help to identify them or their company?  
*Company name*  
*Address (home or business) or suburb/area*  
*Purpose for purchase*

4. How would you phrase these further questions without arousing “B’s” suspicions?

*I’ll need your Company name to leave with Jenny.*

*I’ll need to include the cost of delivery. Where will we be delivering?*

*I’ll need some details if you want to open an account to place the order.*

5. Who should **Gina** contact within her company if she was suspicious of such an enquiry?

*This will most likely be the person’s immediate superior however there may be more than one person who should/could be informed.*

## THE DELIVERY

**Setting:** Ausco Pharmaceuticals is a large manufacturer of a range of drugs from cough medicine to Schedule 8 drugs. The head storeman, Tim, knows he is to expect delivery of 50 kilos of Pseudoephedrine between 2pm and 4pm that day. The delivery truck arrives and the following occurs.

**Tim:** You're finally here. We were just about to ring Sydney to let them know you were late.

**Driver:** No worries mate. You know what the traffic's like this time on a Friday. I got stuck on the South Eastern for 1/2 an hour. So where do you want it?

**Tim:** Just back the truck in here a bit and you'll be fine.

**Driver:** I need Luke Jones to take receipt of this before I do anything. Is he around?

**Tim:** Nah, I think he's on a break.

**Driver:** Well I can't hang around. Do you want to sign for him and fix it up later?

**Tim:** Wouldn't be worth my job sport. Just wait a minute and I'll get him paged.

**Driver:** Well can I start unloading?

**Tim:** Don't touch anything. We haven't taken receipt of the order yet so you're still responsible.

**Driver:** O.K.  
(Tim goes to the phone, pages Luke, picks up the accounts book and returns to the driver. In a couple of minutes Luke appears.)

**Luke:** Sorry. I just stepped out for a minute. Now, you want a signature?

**Driver:** You're the nominated receiver?  
(Checks the docket) Luke Jones?

**Luke:** That's right.  
(Luke signs for delivery and the account form is completed. The stock is unloaded from the truck. Once the stock is on the warehouse floor a page comes over the loud speaker for Luke Jones to take a 'phone call in the office.)

**Luke:** Damn..... it'll have to wait.

**Tim:** I can secure it for you if you give me the keys. We've signed for it now.

**Luke:** No, we'll do it together. These keys are glued to my side mate.

**Tim:** Whatever!  
(As they place the stock into the vault Luke notices one box seems to have been slightly damaged.)

**Luke:** Did you notice this when you took it off the truck? It doesn't look like much but let's check for sure. I'll get it sampled straight away.

**Tim:** Do you want me to ring through?

**Luke:** No, let's both get this finished and I'll lock it up. Then I'll get someone down this afternoon.

**Tim:** Geez, no one's going to want to come down now, on a Friday afternoon.

**Luke:** Too bad. This can't wait.

**“THE DELIVERY”**  
**FOR DISCUSSION**

1. What irregularities or breaches of security are suggested (but not acted upon) in the script?

*The stock being signed for by anyone other than the nominated receiver.*

*Unloading before responsibility is clearly passed on to the firm taking delivery.*

*The stock being handled in the absence of the nominated receiver.*

*The keys to the vault being passed to someone without authority to have them.*

*Disturbed packaging.*

2. At what points in the script could the stock have been interfered with if correct procedure were not followed?

*If the stock were unloaded before Ausco had taken official delivery.*

*If the nominated receiver were not in attendance throughout the delivery and storage.*

3. Who should **Luke** contact in relation to his concerns?

*This will most likely be the person's immediate superior however there may be more than one person who should/could be contacted.*

4. Why should **Luke** act on his concerns so quickly?

*So the truck driver and anyone else involved in the handling of the order can be located immediately.*

*To allow police time to begin enquiries before the weekend.*

5. What might be the consequences if **Luke** were content to leave the problem until next week?

*Any guilty party might have time to disappear*

*The weekend would be too long to leave before beginning investigations*

*Memories can become blurred the longer the period of time*

*His lack of action could be seen as suspect by both his employer and the police.*

## IDENTIFICATION

**Setting:** “Scientific and Industrial” is a chemical and equipment distributor. Some sales of equipment is done over the counter as the following scene shows. The sales person Neil becomes suspicious of the customer Mick.

**The Scene:**

Mick walks into the sales area. He is a little shorter than the top of the window frames in the office. He is wearing grey trousers and a blue shirt. His hair is pulled back in a neat pony tail and he is unshaven and slightly balding.

**Neil:** Can I help you there?

**Mick:** Yes, I want to buy some equipment.  
(He takes out a list from his pocket)

I need ahhh.....a condenser, half a dozen 500 ml. conical flasks, a 500 ml. vacuum flask, a buchner funnel, a separating funnel and a heating mantle.

You carry that sort of stuff don't you?

**Neil:** Yeah! we do. Who are you with?

**Mick:** Oh! just a small company. You wouldn't know them.  
So do you have that stuff in stock or what?

**Neil:** Here, give me the list and I'll just check over it and see what we've got .  
(Neil takes the list and reads it. He hangs onto the list and at this stage he feels suspicious of Mick)

**Neil:** That shouldn't be a problem. I'll just check out the back. Can you wait a minute?

**Mick:** Yeah! sure.

(Neil goes out the back and at this point either switches on the video camera in the shop or collects his thoughts and decides to make as useful observations about Mick as possible without arousing his suspicions.)

**Neil:** We can help you with almost everything except the condenser. I know we're getting some in a couple of days so I'll ring you when they arrive if you like. It should only take one or two days. Have you got a number I can contact you on?

**Mick:** Um.....yeah! it's 222 2222. What about the other stuff?

**Neil:** Yep, I can get that for you now if you want.  
How do you want to pay for it?

**Mick:** What does it come to?

**Neil:** Ah! let's see.  
(Grabs a calculator)

That's \$540.

**Mick:** I'll pay by cash.

**Neil:** Right, well I'll just get it for you. You're sure this'll all fit in your car?  
It's mostly glassware you don't want to break any of it.  
You don't want us to arrange delivery?

**Mick:** No. it's O.K. I'm in the van. Heaps of room.

(Mick collects the equipment from out the back and places it on the counter.)

**Neil:** That's \$540 thanks.

(Mick pulls out his wallet to get the cash. As he does so Neil catches a glimpse of his license.)

**Neil:** I'll give you a hand carrying it out to the car.

**Mick:** Nah! I'll be right.

**Neil:** Well, I'll grab the door for you.

(As Mick loads the equipment into the car he covers it all with a large grey blanket. Neil notes the car registration.)

**Mick:** You should hear from me in a couple days about the condenser.

**Neil:** No worries.

**“IDENTIFICATION”**  
**FOR DISCUSSION**

1.           What physical details might Neil be able to recall of Mick’s appearance?  
*Height (against height of window frame)*  
*Weight*  
*Hair colour and style*  
*Facial hair*  
*Clothes*  
*Distinguishing features*
  
2.           What kind of questions would have been appropriate to ask of Mick in relation to this sale?  
*Intention for use*  
*Name of company*  
*Company identification*
  
3.           In such dealings what details about a customer can be quickly and easily observed without arousing their suspicion?  
*how they speak*  
*product knowledge*  
*familiarity with business procedure*  
*peculiarities of vehicle*

## WALK-IN CUSTOMER

**Setting:** Biltcorp is a chemical distribution company with sites around Australia. They service mainly the aviation, cosmetic, photographic and mining industries.

### The scene

A potential customer drives up in a car without a company logo and speaks to a sales staff member, Theo, hoping to place an order.

**Theo:** Can I help you there?

**Greg:** Yes mate, I'm Greg Ricci from Fleur Cosmetics. Here's my card.  
(Hands over a business card)

Fleur Cosmetics Inc.  
Greg Ricci  
Product Manager  
Melbourne Office  
15 Chute St  
Hawthorn

Mobile: 018 22 3456

**Greg:** I wanted to place an order with you for some stock.

**Theo:** Right, do you have an account with us?

**Greg:** No, I'll probably need to open one at a later stage. I only need some acetone and sulphuric acid at the moment.

Do you have the acetone and sulphuric acid in stock now?

**Theo:** Shouldn't be a problem. We usually always have some in the warehouse. We'd prefer to wait until you're doing some regular business with us before we'd open an account for you. We'd want some trade references, that sort of thing.

**Greg:** Yeah! of course.

**Theo:** How much were you looking at ordering?

**Greg:** Let's say 60 litres of each.

**Theo:** And you'll pay for that by bank cheque?

**Greg:** What would it come to?

**Theo:** I can tell you exactly ahhhh.....(working it out)..... \$1200

**Greg:** Not a problem. I'll pay by cash. We can collect that today?

**Theo:** No mate you'll have to wait a couple of days at least while we process the order and stores puts it through.

Where do we deliver?

**Greg:** Oh! we usually collect it ourselves when you tell us its ready.

**Theo:** No, we'll have to get it to you. Do we deliver to the Hawthorn address on your card?

**Greg:** No, I'd prefer you don't do that. That wouldn't suit at the moment. I'll give you another address to deliver it to, or I'm quite happy to get our own courier to collect if you can have it ready by tomorrow. Save you a bit of effort.

**Theo:** Why don't you take a seat and I'll arrange things.

**“WALK-IN CUSTOMER”****FOR DISCUSSION**

1. What forms of company identification might you expect a legitimate customer to have?

*Company order book*

*Company letterheads*

*Company logo on car*

*Professional business card*

2. Which of Greg's requests might arouse your suspicions?

*Offer to pay by cash*

*Immediate collection*

*Collection by the company ordering*

3. What details might be required to open a new account?

*Initial business on C.O.D basis*

*Reputable trade references (names 'phone numbers)*

*Banking details*

4. Although the chemicals Greg names are Category 3 chemicals and do not require reporting you may feel uncertain of the legitimacy of Greg's order.

What further questions could you ask of Greg which would help identify his intentions?

*Type of products to be manufactured*

*Quantity of product to be manufactured*

*Names of other business associates*

5. If you were suspicious of Greg who would you contact in your company?

*This will most likely be the person's immediate superior however there may be more than one person who should/could be contacted.*

6. When would you speak to someone in your company if you had concerns?

*Immediately.*

## THE SALES REPRESENTATIVE AND THE SAMPLES

**Setting:** A warehouse person (Kevin) at a large pharmaceutical manufacturing company notices that one of the sales representatives (Emily) is requesting extra samples of a particular type of drug to supply to doctors. The representative in question is requesting and distributing much more than the other reps. The storeman becomes suspicious but is unsure of what to do or who to tell. He knows that he is allocating an unusually large amount of drug to the rep to fulfil her requests for samples, and he has also seen her “borrowing” samples from the other reps. The representative tends to become annoyed when the supply of samples is delayed. Kevin decides to talk to his superior, Alan.

**Kevin:** Hey! Alan, do all the reps usually get the same amount of samples?

**Alan:** Yeah! they are usually allocated the same amount but they can request more if they want to supply some to doctors who have made a specific request.

**Kevin:** Well, how do we know if they really are supplying the samples to doctors?

**Alan:** The doctors sign a sample request or supply form. It should have the doctor's name and address and signature and also the name, strength and quantity of tablets supplied. The reps have to submit a reconciliation sheet of samples received and supplied each week.

**Kevin:** Does any one ever check on the doctors to verify that they actually received what is on the sample request form? Does any one ever check the reconciliation forms?

**Alan:** I'm not sure. I think that is up to the rep's manager. Why the sudden interest in what the reps are doing? Haven't you got enough to do already?

**Kevin:** I just wondered. I seem to be putting a lot more samples in some reps' cupboards than in others.

**Alan:** Well maybe some reps work harder than others. It is not our problem.

**Kevin:** I was just wondering. Who knows what they do with all these samples? Emily seems to be giving away a lot more samples than anyone else. Maybe we should check it out.

**Alan:** OK! It's probably nothing to worry about but I could speak to her manager if you think there is a problem.

**Kevin:** Yeah! I think maybe you should.

Alan goes to speak to Emily's manager, Cathy. Cathy is reluctant at first to believe that there is any problem. She insists that she trusts all her reps and that it might be difficult to check with Emily's doctors to verify that they have actually received the samples as listed on the sample request forms. When Cathy does contact a number of the doctors they have difficulty remembering the drugs they may have signed for and they certainly have trouble remembering the quantities. However, a few say they received one or two samples even though Emily's request forms list them as receiving three or four.

Cathy is now faced with a dilemma:

Does she continue to accept Emily's reconciliation forms as being honest and accurate? Is she in a position to accuse Emily of dishonesty on the somewhat shaky evidence provided by a few doctors? Is Emily being dishonest or merely careless in her recording of sample distribution? It is possible that Emily is recording that she has supplied a doctor with four samples whilst only giving him two (for which he has signed) and keeping the others for an illegal purpose. It is possible that a busy doctor may just sign the form without writing down the quantities received. Cathy and Emily have a friendly working relationship which would be severely damaged by an unfounded accusation. Cathy is also aware of the implications of dismissing someone unfairly. It is time to call in the Human Resources personnel.

**“THE SALES REPRESENTATIVE AND THE SAMPLES”****FOR DISCUSSION**

- What procedures are in place to control the lawful distribution of samples?
- What procedures are in place to control and account for the movement of drugs and chemicals within a company? (Good Management Practices; Standard Operating Procedures).
- Are these procedures governed by company policies or government regulations or both?
- Is there a routine verification procedure to ensure the accuracy of documentation and procedures? (ie. does any one actually check the reconciliation forms?)
- Whose responsibility is it to report suspicious behaviour? Remember, Alan initially said “it’s not our problem”.
- Do you think that employees may be reluctant to report suspicious behaviour on the part of a fellow employee?
- What has to be done to turn suspicion into evidence before making an accusation against an employee?
- What are the implications for a company in accusing or dismissing someone (possibly unfairly)?
- How does a company reconcile good relations with its employees with the need to check on them?
- Which areas of a company may be susceptible to illicit diversion of drugs and chemicals (eg. manufacturing, quality control, warehouse, sales)?
- Are the controls the same for all States in Australia?
- Are some drugs more likely than others to be an attractive proposition for illicit diversion?

## SOME INDICATORS OF SUSPICIOUS ORDERS OR ENQUIRIES

### **INDICATORS WHICH CAN BE USED BY INDUSTRY PERSONNEL TO IDENTIFY SUSPECT CUSTOMERS OR CHEMICAL SHIPMENTS**

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- A new customer or unfamiliar representative of an established customer who deviates from previous ordering methods.
- A “walk-in” customer (personal appearance).
- An offer to pay an excessive price for certain chemicals or for rapid delivery.
- Cash payments, even for large purchases.
- Requests to have the merchandise delivered in non-commercial or unmarked packing.
- Purchases in small containers even when industrial use is claimed.
- Irregular ordering patterns.
- Unusual quantities ordered.
- Orders or purchases by persons or companies with no obvious need for these chemicals.
- Indications of intended use that is inconsistent with the chemical ordered.
- Merchandise that is collected with the purchaser’s own vehicle.
- Request for delivery by air freight.
- Delivery to a post office box or other incomplete address.
- Failure or unwillingness to supply a telephone number or an address.
- Lack of business acumen.
- Absence of standard business stationery.
- Reluctance to supply a written order.
- Orders for more than one precursor chemical.
- Orders to universities or well-known companies where the normal arrangements for ordering are used but delivery is requested to a specific individual.
- Orders to companies which are not known and cannot readily be traced in trade directories.
- Orders for chemicals with delivery instructions where the cost of delivery or routing exceeds the cost of the merchandise.
- An established customer who deviates from previous orders or ordering methods.
- A customer who has difficulty in pronouncing chemical names, titles of equipment, etc.
- A customer who is vague about the company address, telephone number and reason for desiring a listed chemical.

- A customer who prefers to pay by cashiers cheque, postal money order, etc.
- A customer who is not a member of a trade, professional, or business association.
- A customer who furnishes false or suspicious addresses, telephone numbers, references etc.
- A customer whose communication either by telephone, mail or other means is not conducted or prepared in a professional manner.
- A customer who requests other unusual methods or routes of shipment, or who provides unusual shipping, labelling or packing instructions.
- A customer who purchases unusual quantities or combinations of chemicals or glassware in contrast with customary practice and usage.
- Use of a freight forwarder as ultimate consignee.
- Use of intermediate consignee(s) whose location or business are incompatible with the end-user's nature of business.
- Evasive responses to any questions, or responses that indicate a lack of basic knowledge of the industry, or inability to supply information on whether listed chemicals are for domestic use or export.