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# **Therapeutic Good Administration Australia [TGA]**

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## HISTORY-

The Evolution of Therapeutic goods Administration in Australia can be broadly segmented into following periods.

**1)The period until 1938** -During this period there was an increasing number of medicines appearing in an unregulated market, with many products regarded as 'quack' medicine.

**2)1939-1961:NHMRC** developing a more uniform national approach to labeling and standards need for independent laboratory testing. The government moved to regulate the standards for medicines for good quality. The National Biological Standards Laboratory was established to independently test medicines on the Australian market and regulate their manufacture.

**3)1962-1988:** Pre-market assessment of quality, safety and efficacy evolved and finally was integrated into National system of integration of therapeutic good regulation and establishment of TGA.

**4)1989-2007:**The national system TGA continued to mature into an internationally harmonized regulatory system with increasing globalization.

## INTRODUCTION OF TGA:

- The Therapeutic Goods Administration (TGA) is a unit of the Australian Government Department of Health and Ageing.
- The TGA monitoring activities to ensure therapeutic goods available in Australia are of an acceptable standard.
- The Australian community expects that medicines and medical devices in the marketplace are safe and of high quality, and of a standard at least equal to that of comparable countries.
- The regulatory framework within which the TGA operates is based on a risk management approach. It is designed to ensure public health and safety.
- It is beneficial for both consumers and industry
- In undertaking its responsibility, the TGA has developed a constructive partnership with industry at the same time freeing industry from any unnecessary regulatory burden and minimizing the cost of medicines.

## TGA STRUCTRE-

- The TGA Regulatory offices are grouped into –
  1. Market Authorisation Group
  2. Monitoring and Compliance Group
  3. Regulatory Support Group
- **TGA Executive**
- The TGA Executive has overall responsibility for the management of the TGA's regulatory activities.

### **1. Market Authorization Group**

- The Market Authorization Group is responsible for the evaluation and authorization of therapeutic goods to ensure they meet appropriate standards of quality, safety and efficacy.



## **2. Monitoring and Compliance Group-**

- The Monitoring and Compliance Group is responsible for monitoring of therapeutic goods on the Australian market to ensure that they comply with required standards of quality, safety, efficacy .

## **3. Regulatory Support Group**

- The Regulatory Support Group provides the business systems and support services that help the TGA to undertake its regulatory responsibilities.
- **Office of Regulatory Integrity**
- The Office of Regulatory Integrity functions as an internal auditor of regulatory activity and advises the TGA Executive on the appropriate operations.

# Therapeutic Goods Act 1989

- Therapeutic Goods Act 1989, is to provide a national framework for the regulation of therapeutic goods in Australia to ensure the  
Quality, Safety and Efficacy of medicines  
Ensure the quality, safety and performance of medical devices.
- The Act is a Commonwealth Act that provides a uniform national system of controls over therapeutic goods.
- facilitating trade between the States/Territories and benefiting for both consumers and industry.
- Essentially therapeutic goods must be entered on the Australian Register of Therapeutic Goods (ARTG) before they can be supplied in Australia.
- The ARTG is a computer database of information about therapeutic goods for human use approved for supply in, or exported from Australia.

- It also details the requirements for listing or registering medicines in the Australian Register of Therapeutic Goods.
- The act sets out the legal requirement for the import , export, and supply of medicines in Australia.
- The Therapeutic Goods Act sets out requirements for manufacturing, advertising and labeling of medicines in Australia.
- It also establishes controls relating to the advertising of therapeutic goods which aim to minimize the risk of misuse of such products arising out of, for example, misrepresentation or misunderstanding about the uses of the goods.
- It offers the advantage for consumers and healthcare professionals to be able to have confidence in the standard of ready-made proprietary therapeutic goods which they use or prescribe.



## Does the Act apply to your product?

You will need to comply with the Act if your product is a 'therapeutic good'. 'Therapeutic goods' may be:

- Medicines, or
- Medical devices
- Some products will be classified as a medicine or as a food or cosmetic depending on how that particular product fits with the criteria set out in the Act.

## What are 'therapeutic goods'?

A 'therapeutic good' is broadly defined as a good which is represented in any way to be, or is likely to be taken to be, for therapeutic use under section 7 of the Act.

- Therapeutic good is a product for use in humans that is used in, or in connection with:-
- Preventing, diagnosing, curing a disease, defect or injury OR
- Influencing, inhibiting or modifying a physiological process OR
- Testing the susceptibility of persons to a disease OR
- Influencing, controlling or preventing conception OR
- Testing for pregnancy

## Is it a medicine or food?

- Products for oral consumption are regulated as either foods or therapeutic goods
- Products which may fit within the definition of either a food or a medicine are referred to a joint TGA/Food Standards Australia committee which recommends whether the goods should be regulated as a therapeutic good or as food
- A product's principal use is of primary consideration when determining whether it is a food or a medicine
- The presentation of a product can help to determine whether it will be treated as a food or a medicine. For example, a clove of garlic is a food. However, if it is concentrated and marketed in capsule form with claims that it can be used to relieve cold and 'flu symptoms it will be treated as a medicine

## Is it a medicine or a cosmetic?

- One of the main factors in determining whether a product is a cosmetic or a medicine is the claims made about the product.
- For example, moisturizers which contain a sun screening agent as a secondary component and have a stated therapeutic purpose (e.g. 'helps protect skin from the damaging effects of UV radiation') are medicine
- Note that the Trade Practices Act 1974 also operates in this area and influences what may or may not be claimed.
- The Cosmetic Claims Guidelines provides further guidance on the difference between cosmetic and therapeutic claims



# Regulation of Medicines

- The Therapeutic Goods Administration overall control the of supply of medicines in Australia is exercised through following main processes:
- 1. Pre-market evaluation and approval of medicines intended for supply in Australia
- 2. Licensing of manufacturers in accordance with international standards under Good Manufacturing Practice
- 3. Post-market monitoring, through sampling, adverse event reporting, surveillance activities, and response to public inquiries
- 4. maintenance and monitoring of the systems for registering and listing of medicines

## Pre-Market Assessment-

- Drugs are required to undergo an assessment before it can be listed or registered.
- Number of factors are taken into consideration including:
- The toxicity of the ingredients.
- The dosage form of the medicine
- whether the medicine is indicated for a serious form of a disease, or disorder, or for the treatment, cure, prevention of a disease or disorder
- whether the drug is likely to result in significant side effects, including interactions with other medicines; and
- The degree of control over a medicine is directly related to the risk level of that medicine. Therefore, registered medicines are required to undergo a more rigorous assessment than listed medicines

- **Manufacturing Requirements-** Australian manufacturers of medicines must be licensed under the Therapeutic Goods Act 1989. Their manufacturing processes must comply with principles of Good Manufacturing Practice. The aim of licensing is to protect public health by ensuring that medicines meet definable standards of quality assurance and are manufactured in conditions which are clean and free of contaminants.
- **Licensing of Manufacturers**

Applications for a manufacturing license are assessed through an inspection of the manufacturing premises. Auditors from the TGA conduct audits of manufacturing premises and a license is issued only after all the requirements have been met. Audits are conducted before a license is issued, And at regular intervals after the license has been granted generally every 15 to 24 months.

## Post-Market Vigilance-

In Australia, post-market vigilance activities include the following:

- Conducting laboratory testing of products on the market and if necessary, conducting recalls of deficient medicines.
- According to the TGA, these activities are conducted regularly and in response to problem reports received.
- **Adverse Drug Event Reporting-** The Adverse Drug Reactions Advisory Committee(ADRAC) is responsible for monitoring drug safety in the post-marketing phase.
- This involves checking the report of adverse reaction of the drug, investigating problems by the Therapeutic Goods Administration and relevant committees to ensure that medicines are of an acceptable standard.



- Making the decision as to whether further information such as clinical or laboratory testing results are required.
- The reports are then entered into a database and reviewed by the ADRAC which would provide advice on the appropriate responses to adverse reactions such as a recall of deficient medicines to the relevant authorities e.g. Australian Drug Evaluation Committee for pharmaceutical products, Medicines Evaluation Committee for over-the-counter medicines, Office of Complementary Medicines of the T G A for complementary medicines, etc.
- **Recall of Medicines-**
- A recall is a permanent removal of deficient medicines from the market. Most recalls are conducted on a voluntary basis. However, the recall procedures are carried by Therapeutic Goods Act 1989 and the Trade Practices Act 1974.

- There are four levels of recall: wholesale, hospital, retail and consumer.
- A wholesale level refers to a recall from state purchasing authorities.
- A hospital level recall includes a whole sale level recall and recalls from nursing homes, hospital pharmacies, etc.
- A retail level recall includes a wholesale level recall, a hospital level recall and recalls from retail pharmacists, medical practitioners, retail outlets, etc.
- A consumer level recall includes a whole sale level recall, a hospital level recall, a retail level recall and recalls from patients and other consumers.

## REGULATION OF MEDICINE IN AUSTRALIA

In Australia, medicines can be classified as

- 1) Registered medicines or
- 2) Listed medicines, depending on their ingredients and claims made.

Registered medicines can be further classified as-

- 1) Non-prescription (low risk) registered medicines and as
- 2) Prescription (high risk) registered medicines.

All medicines which are for export only are considered as listed medicines.

- Registered medicines are of higher risk than listed medicines, therefore, the degree of control imposed on registered medicines is higher than that of listed medicines;
- Registered medicines are evaluated for safety, quality and efficacy while listed medicines are evaluated for safety and quality only.

**THERAPEUTIC GOODS**

**MEDICINES**

**MEDICAL DEVICE**

**REGISTERED MEDICINES**

**LISTED MEDICINES**

**NON-PRSCRIPTION  
MEDICINES**

**PRSCRIPTION  
MEDICINES**

**COMPLEMENTARY  
MEDICINES**

**OTC MEDICINES  
(Non Complementary Medicines)**

**LISTED NON-PRSCRIPTION  
MEDICINES**



- **Austrelian Register for Therapeutic Good**
- The Australian Register of Therapeutic Goods is a database of information about therapeutic goods which are approved for supply in or export from Australia.
- Registered medicines in the Australian Register of Therapeutic Goods are of higher risk than listed medicines.
- Therefore the level of assessment and the degree of regulation which registered medicines undergo are also more rigorous and detailed.
- The sponsors of registered medicines are required to provide comprehensive safety, quality and efficacy data.
- sponsors of listed medicines are required to provide data on safety and quality only.
- Diagram shows the risk relationship between the various types of medicines registered or listed in the ARTG.

## **Low Risk**

Evaluated for safety  
and quality

## **High Risk**

Evaluated for safety,  
quality and efficacy

**Listed  
Non-Prescription  
Medicines**

**Registered  
Non-Prescription  
Medicines**

**Complementary  
Medicines**

(may be registered or listed, depending  
on ingredients and claims made)

**Registered  
Prescription  
Medicines**

## Listed Medicines (low-risk)-

- A listed medicine is one that contains chemical, biological, or herbal ingredients that are well-known and considered safe to the user such ingredients usually have a long history of use.
- They are considered as low-risk, their ingredients appear in the TGA's approved list of substances.
- Listed medicines do not contain substances which are scheduled in the Standard for Uniform Scheduling of Drugs and Poisons.
- The therapeutic claim of medicine relates to health maintenance, health enhancement, or non-serious, self-limiting conditions.
- Listed medicines are assessed by the TGA for quality and safety but not efficacy. This means that the TGA has not evaluated them individually to see if they work.

- Listed medicines are low risk medicines and they may only contain ingredients which are listed in the Australian Register of Therapeutic Goods.
- For the evaluation process, sponsors are allowed to self-assess the products, i.e. the products are assessed by sponsors against standards defined by the Therapeutic Goods Administration.
- The assessment is then subject to a simple 'eligibility review' by the Therapeutic Goods Administration for compliance with certain basic safety and quality parameters.
- If the assessment passes the 'eligibility review', the sponsor receives a confirmation letter from the Therapeutic Goods Administration and the medicine can be listed in the Australian Register of Therapeutic Goods



Sponcer applied to TGA for listing (self- assetment ) the product

The application and declaration lodge via electronic lodgement facility or via paper application form

Application and fee forward to business management unit of TGA

Application form forward to ARTG section of TGA

ACCEPTED

Application  
Decision by TGA

REJECTED

Certiifacte of listing issue to sponcer which include AUSTL NO.

Reasons for rejection are sent to the sponsor

If the application pass the eligibility check the sponcer receive the conformation letter and product listed in ARTG

Decision can be appealed or sponsor can reapply

## REGISTERED MEDICINE

- Registered medicines can be high risk products or low risk products.
- They can be classified either as non-prescription (low risk) registered medicines or as prescription (high risk) registered medicines.
- Medicines having a higher level of risk must be registered (not listed).
- The degree of assessment and regulation they undergo is rigorous and detailed, with sponsors being required to provide comprehensive safety, quality and efficacy data.
- All registered medicines must display an AUST R number on the label as proof of registration are evaluated as either 'high risk' or 'low risk' registered

- In assessing the level of 'risk', factors such as the strength of a product, side effects, potential harm through prolonged use, toxicity, and the seriousness of the medical condition for which the product is intended to be used are taken into account.

*Non-Prescription (Low Risk) Registered Medicines:*

- The purchase of non-prescription (low risk) registered medicines does not require a doctor's prescription. Examples of non-prescription (low risk) registered medicines are over-the-counter medicines such as analgesics, cough/cold preparations.

*Prescription (High Risk) Registered Medicines:*

- Prescription (high risk) registered medicines are available on prescription only.
- Examples all injectables such as insulin for diabetics

**Sponcer lodge application for Evolution by TGA. The sponcer may ask to submit additional information for evolution.**



**The application is forward to the business management unit of TGA . The sponcer receive the TGAID NO.**



**Evolution send to the Austrelian Drug Evolution comeety (ADEC)**



**Drug Safty Evaluation comeety to make recomondation to reject or approve submssion**



**ACCEPTED**

**Application  
Decision by TGA**

**REJECTED**

**A prscription medicine is  
registered on the ARTG**

**Reasons for rejection  
are sent to the sponsor**

**Product information sent to sponsor for verification.  
Upon confirmation certificate of registration is issue.**

**Decision can be appealed  
or sponsor can reapply.**



# Therapeutic Claims

- Both registered and listed medicines can carry therapeutic claims. There are three levels of therapeutic claims - high, medium and general.
- High level claims are the strongest claims such as treating, curing, managing or preventing a disease or disorder, or treating vitamin or mineral deficiency diseases.
- Medium level claims are lesser claims such as health enhancement claim
- General level claims are the broadest claims such as health maintenance claims
- Registered medicines are allowed to carry all three levels of therapeutic claims. Listed medicines are allowed to carry medium or general levels of therapeutic claims

## Complementary medicines

- Complementary medicines also known as 'traditional' or 'alternative' medicines Complementary medicines are low risk medicines which include herbal medicines, vitamins, nutritional supplements, aromatherapy ,homoeopathic and naturopathic products.
- Complementary medicines may be either listed or registered, depending on their ingredients and the claims made.
- The Therapeutic Goods Act 1989 requires that complementary medicines which are imported or manufactured for supply in Australia must be included in the Australian Register of Therapeutic Goods (ARTG).
- Sponsors of low risk products which carry general or medium levels claims are required to apply for the listing of the products in the Australian Register of Therapeutic Goods.

- However, if the sponsors wish to make claims about the *efficacy* of the low risk products, they must apply for the registration (not listing) of the products in the ARTG.
- Registered products are evaluated for safety, quality and efficacy before they are made available for supply in Australia.
- All complementary medicines supplied in Australia are required to comply with the Code of GMP. The Code of GMP describes the principles and practices that are necessary to follow in order to provide assurance that each complementary medicine product is safe and reliable. Most complementary medicines are widely available through direct marketing, health food stores and supermarkets.

## REGISTRATION OF COMPLEMENTARY MEDICINES

Sponsor lodge complementary application to the chemical & non prescription branch of TGA

The application is forward to the business management unit of TGA . The sponsor receive the TGAID NO.

The application is forward to the office of complementary medicine of TGA . The Office of Complementary Medicine prepare an evaluation report.

The evaluation report send to the complementary medicine evaluation committee for advice.

YES

NO

TGA decision

A provisional entry for complementary medicine is entered on ARTG

Reasons for rejection are sent to the sponsor

A provisional record and AUSTR no. is sent to sponsor for verification, upon confirmation product registered

Decision can be appealed / Reapply



**sponcer lodge complementary application to the chemical & non prescription branch of TGA**

**The application is forward to the business management unit of TGA . The sponcer receive the TGAID NO.**

**The application is forward to the office OTC medicine of TGA for the preperation of evaluation report.**

**The evolution report send to the medicine evolution commity for advice.**

**YES**

**NO**

**TGA decision**

**A provisional entry of OTC medicine is entered on ARTG**

**Reasons for rejection are sent to the sponsor**

**A provisional record and AUSTR no. is sent to sponsor for verification, upon confirmation product registered**

**Decision can be appealed/ Reapply**







## Buying medicines - What's on the label for me?

- Labelling is part of the national system of regulating medicines. Most of these products must be included in the Australian Register of Therapeutic Goods. Labeling of medicines is governed under the Therapeutic Goods Act 1989
- Apart from the general information such as name, quantity, and dosage of medicines, etc., which must be included in the labels, all medicines are required to carry either the "Aust R" or "Aust L" labels which indicate whether or not the efficacy of the products have been evaluated.

## What do the Aust R and Aust L numbers mean?

- **AUST R** medicines are assessed for **safety, quality and effectiveness**. They include all prescription only medicines and many over-the-counter products such as those for pain relief, coughs and colds and antiseptic creams.
- Prescription only medicines do not display their purpose on the label as the decision for using them lies with a doctor
- **AUST L** medicines are much lower risk self-medication products. They are used for minor health problems and are reviewed for safety and quality. They include sunscreens over and many vitamin, mineral, herbal and homoeopathic products.

## Always read the labels on medicines

-  – Check to see if there is an AUST R or AUST L number
-  – Unless it has been prescribed by a doctor, check the medicine's uses to make sure they are suitable for your needs.
-  – Read carefully all directions and warnings, and always follow them.
-  – Check the storage conditions including the recommended temperature.
-  – Check the expiry date. When the date is reached, safely dispose of any remaining medicine.
-  – See if the batch number and supplier's name and address are visible.



- A label is written, printed or graphic matter on or attached to a container to identify its contents and inform the consumer about its qualities, uses and hazards
- **Contrast and colours**
- As some people have poor sight or colour blindness and the label may have to be read under poorly lighted conditions, particular attention should be given to colour contrast.
- **Letter height**
- Approval will not be given for the use of letters less than 1mm.
- Language Labels must be written in English
- **Signal Words**
- The SUSDP requires specific signal words to be placed at the top of the main (front) label of drugs and poisons.



These signal words indicate either the restriction applying to the drug or poison or the relative danger of the product.

**Schedule**

**Signal Words**

2

-PHARMACY MEDICINE

3

-PHARMACIST ONLY MEDICINE

4

- PRESCRIPTION ONLY MEDICINE

5

- CAUTION

6

- POISON

7

- DANGEROUS POISON

8

- CONTROLLED DRUG

# Standard for the Uniform Scheduling of Drugs and Poisons(SUSDP)

Scheduling is a national classification system that controls how medicines and chemicals are made available to the public. Medicines and chemicals are classified into Schedules according to the level of regulatory control over the medicine or chemical, required to protect public health and safety. The Schedules are-

- Schedule 1 Not currently in use
- Schedule 2 Pharmacy Medicine
- Schedule 3 Pharmacist Only Medicine
- Schedule 4 Prescription Only Medicine
- Schedule 5 Caution
- Schedule 6 Poison

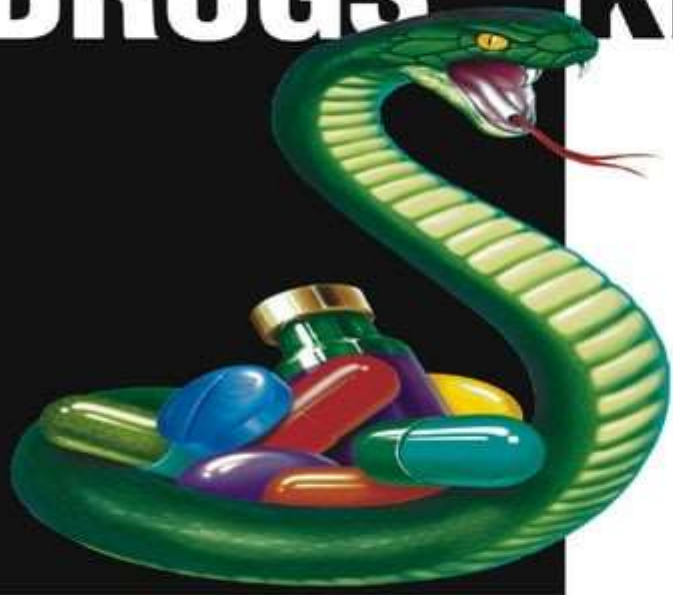
- Schedule 7 Dangerous Poison
- Schedule 8 Controlled Drug
- Schedule 9 Prohibited Substance
  
- The Schedules are published in the *Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP)* .
- The SUSDP lists all the substances, their classifications, labeling and packaging requirements. The classification takes into account a substance's toxicity profile, pattern of use, indications, product formulation and dosage, potential for abuse and need for access.
- The table below shows some examples:

SCHEDULE	DISCRIPTION	EXAMPLE
2(S2) Pharmacy medicine	Non-prescription medicine sold in pharmacies. Pharmacist advice require for safe use.	Daily use of 1200 mg or less of ibuprofen in preparation for oral use.
3(S3) Pharmacist only medicine	Non-prescription medicine for supply by pharmacist only.	Aerosol inhaler contain 100 mcg salbutamol
4(S4) Prescription only medicine	prescription only medicine for supply by pharmacist only.	vaccines
5(S5) Caution	Substance with low potential cause harm. appropriated labeling and packaging can reduce the extent of harm	Turpentine oil in preparation mainly contain more than 75% turpentine oil.
6(S6) Poison	Substance with moderate potential to cause harm, the use of distinctive packaging with strong warning and safety on label can reduce extent of harm	Sulphuric acid except in fire extinguisher or preparation containing 0.5% or less of Sulphuric acid.



SCHEDULE	DISCRIPTION	EXAMPLE
7(S7) Dangerous poison	Substance with high potential to cause harm, at low expose and require special precaution during manufacturing, handling for use.	Cyanides except ferricynide, ferrocyanide or if specified in other schedule
8(S8) Controlled drug	Sub. Which require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical and physiological dependence.	Methadone, morphine
9(S9) Prohibited sub.	Sub. Which may abuse or misuse, the illegal possession, use, sale should be prohibited by law.	Heroin, coca leaf

# COUNTERFEIT DRUGS KILL!



**Counterfeits have harmful effects on patients' health and can kill**

**Counterfeits frustrate efforts to deal with high burdens of disease**

**Counterfeits undermine health care systems**

**Increased international collaboration is essential to defeat counterfeiting**

**Combating counterfeiters requires acting at the same time on legislation, regulations, enforcement, technology and communication strategies**

- Counterfeit medicines or medical devices are often packaged or marketed to mimic a genuine item. Products are considered counterfeit if the labeling, presentation, advertising, formulation or source of the goods is false. Counterfeiting can apply to both branded (originator) and generic products.
- The TGA, with cooperation from State and Territory Governments, closely monitors the supply chain in Australia to prevent counterfeit medicines or medical devices from entering the market.
- Consumers can also suffer harm from leaving a serious medical condition untreated or inappropriately treated.
- All therapeutic goods are potential targets for counterfeiters.

- Examples of counterfeit medical products can range from widely used medicines such as paracetamol, through to limited use medicines such as cancer and heart medicine. Medical devices, such as contact lenses, condoms, blood glucose test strips and surgical mesh are also subject to counterfeiting.
- Counterfeit products detected in Australia are generally lifestyle medicines – such as weight loss, hair loss and erectile dysfunction medicines.
- Most of the counterfeit products that enter the country are imported mistakenly in small quantities for personal use by individuals making a purchase via the Internet, or by travellers who made the purchase while travelling overseas.
- To avoid purchasing counterfeit products, consumers should exercise caution when buying medicines on the Internet



- The Internet can offer consumers a convenient way to access therapeutic goods, but online purchases of medicines or devices should be approached with caution.
- **Do not order medicines, including dietary supplements and herbal preparations, over the Internet unless you know exactly what is in the preparation and have checked the legal requirements for importation and use in Australia.**
- Consumers are again advised to exercise extreme caution about purchasing medicines from unknown internet sites. Products purchased in this way may not meet the same standards of quality, safety and efficacy as those approved by the TGA for supply in Australia, and may contain undisclosed and potentially harmful ingredients.
- The Therapeutic Goods Administration (TGA) is aware that some Australian consumers have purchased the product ***SATURO capsules*** over the internet. The label of this product claims the ingredients to be 100% herbal in origin.

- However, analysis undertaken by the TGA Laboratories in Australia has confirmed the presence of therapeutic quantities of Sildenafil in these capsules. Sildenafil is the active ingredient in the approved Pfizer Australia Pty Ltd product Viagra.
- Consumers are advised that Sildenafil is a **prescription-only medicine** in Australia, and may be harmful if taken without the supervision of a medical professional, particularly in patients with history of cardiovascular disease.
- **SATURO capsules** have not been assessed by the TGA for quality, safety or efficacy as required under Australian legislation, and the place of manufacture is not approved by the TGA. In Australia, commercial supply of **SATURO capsules** is illegal.

