



news

The official newsletter of the Therapeutic Goods Administration

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## TGAL'S TESTING PROGRAM FOR HERBAL MEDICINES

IN the interests of public safety the TGA Laboratories regularly test herbal medicines. A recent survey of nine of the eleven products containing the herb *Stephania tetrandra* listed on the Australian Register of Therapeutic Goods revealed the presence of aristolochic acid in analysis of four of the products. A consumer level recall of the affected batches has been carried out. The presence of aristolochic acid is evidence that the *Stephania* has been contaminated or substituted with an *Aristolochia* species (possibly *Aristolochia fangchi*). Confusion between *Stephania* and *Aristolochia* can arise from superficial similarities in the appearance of the dried root materials and from similarities in their Chinese names and characters. Several countries have banned the use of both herbs because of serious adverse reactions linked to the presence of *Aristolochia fangchi*.

A survey is in progress of medicines listed as containing the herb *Scutellaria lateriflora*. To date TGAL has found that the majority of the products and raw herbal materials tested did not contain this herb. TGAL is working with the Nutritional Foods Association of Australia (NFAA) to identify the alternative herbs used and this process is complicated by the presence of mixtures of herbs in the products. The herbals testing unit (Chemistry Section), has developed methods to detect *Scutellaria lateriflora*, that will assist manufacturers of herbal medicines to test for the correct identity of bulk native herb



Dried *Stephania tetrandra* Root



Dried *Aristolochia fangchi* Root

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and herbal extract deliveries. This work will be published in the near future and will result in a general correction to the established literature on *S. lateriflora*.

Batches of Chinese herbal liniments were recalled recently when found by TGAL to contain chemical additives instead of the natural oils represented on the label.

Manufacturers of herbal medicines should note that it is their responsibility to ensure that the correct species of herb has been used in the product. Medicines which do not contain the herb as labelled and listed on the ARTG may be subject to recall action. In view of the errors found in some of the published literature and the recent failures of herbal medicines reported by TGA, manufacturers are well advised to take stock of their acceptance criteria and validate their methods of analysis, preferably using a specimen of the herb authenticated by a

reputable herbarium. The methods of analysis also should be able to distinguish the particular species of herb used.



*Scutellaria lateriflora* plant



Thin Layer Chromatogram of herbal extracts

All correspondence to TGA News  
PO Box 100 Woden ACT 2606  
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## TASKFORCE ESTABLISHED

In recognition of the delays being experienced by sponsors, the National Manager has established a **Task Force** to tackle the backlog of applications for the listing of medical devices in the ARTG. The Task Force of eight people (led by Michael Johnston and Helen Kosmas) will process **all applications received prior to 19 October 1997** and will also focus on codifying the decision making process to support the development of an Electronic Listing Facility (ELF) for medical devices.

**Applications received after 19 October** will be processed by the staff of the **Medical Devices Section**, who will be assisted by staff from the Task Force once the backlog has been removed. The dedication of these resources acknowledges the difficulties which have been experienced in achieving the agreed turn around time of 30 days for the processing of applications for listing of medical devices and the commitment of the TGA to ensuring timely access to safe and effective medical devices.



*Task Force members, from left: Linda Punyer, Jennifer Elijah, Helen Kosmas, Denise Sofoulis, Mike Johnston, Kelwant Dillon, Glenn Street*

## NEW HOME FOR THE NRL

The closure of the Fairfield Hospital on 30 June 1996 has necessitated the relocation of the National Serology Reference Laboratory (NRL, formerly known as the National HIV Reference Laboratory). Following an Australia wide tender process the St Vincent's Institute of Medical Research (SMVIR) has been chosen to host the NRL.

The selection of St Vincent's Institute of Medical Research will allow the NRL to continue its important role in providing quality HIV testing. This will mean that Australia and the Asia-Pacific region will have access to the best quality tests available to diagnose and combat the spread of serious viral diseases.

The Laboratory's role was expanded in 1995 to include Hepatitis C tests (HCV) to ensure the safety of blood and blood products, as well as tests used to monitor the effectiveness of drug treatment for these diseases.

The continued location of the National Serology Reference Laboratory in Melbourne will also allow it to develop an important working relationship with the Australian Red Cross Blood Service, which has recently established a national office in Victoria.

The NRL supports the Therapeutic Goods Administration (TGA) in the evaluation of HIV and HCV diagnostic tests prior to inclusion in the Australian Register of Therapeutic Goods (ARTG). The NRL also monitors post market performance of registered kits in Australia and coordinates a national laboratory quality assurance program.

The overall management of the Commonwealth contract with the host institution was transferred to the TGA from the Public Health Division in 1996.

## WARNING FOR IMPORTED MAIL ORDER THERAPEUTIC GOODS

A number of overseas companies are now advertising catalogue lines of health care products that include therapeutic goods in international journals and on the Internet. There is concern that these companies may be encouraging the importation and illegal use of unlisted or unregistered therapeutic goods in Australia. The people who import these goods and use them on people other than themselves or their immediate family, are in breach of the Therapeutic Goods Act 1989.

TGA has discussed the situation with overseas mail order companies and agreed it is important to provide guidance to customers on the legal issues that need to be considered when purchasing goods.

The TGA recommends that entities operating outside Australia advertising direct mail therapeutic goods should include the following warning statement:

**THE SAFETY, EFFICACY OR QUALITY OF THESE PRODUCTS HAVE NOT BEEN ESTABLISHED BY THE THERAPEUTIC GOODS ADMINISTRATION.**

**SUPPLY OF THESE PRODUCTS BY THE IMPORTER TO PERSONS OUTSIDE THE IMPORTER'S IMMEDIATE FAMILY IS ILLEGAL.**

**USE OF THE PRODUCTS IS UNDERTAKEN AT YOUR OWN RISK.**

The warning should appear clearly in all promotional information and product information.

Publishers within Australia should note that under Regulation 6 (1) of the Therapeutic Goods Regulations, it is an offence for a person to publish an advertisement about goods for therapeutic use that are not listed or registered with the Therapeutic Goods Administration.

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## REGULATION OF STERILANTS AND DISINFECTANTS

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The development and implementation of the regulatory framework for sterilants and disinfectants has proven a complex task and has required extensive stakeholder consultation to achieve a satisfactory outcome.

### GMP Licensing Requirements

At a meeting on 4 September 1996 between industry representatives and TGA it was agreed that:

- GMP and licensing will apply to manufacturers of sterilant and instrument grade disinfectants **only**, and not to manufacturers of hospital grade disinfectants (the Therapeutic Goods Regulations are currently being amended to give effect to this decision).
- Manufacturers will be able to select EN46001, EN46002, ISO13485 or ISO13488 as the standard against which their manufacturing operations will be assessed by TGA for the purpose of obtaining a licence (this choice of standards is consistent with the approach in Europe).
- Applications for a licence to manufacture sterilants or instrument grade disinfectants must be lodged with TGA by 1 January 1998. A company lodging a licence application by this date may continue to manufacture until TGA makes a determination on the licence application (failure to lodge a licence application by the due date will result in a manufacturer being in breach of the Therapeutic Goods Act if it were to continue manufacture and supply).
- From 1 January 1998 to 1 January 1999, the manufacturer may nominate the date of the TGA audit. If a TGA audit has not taken place by 1 January 1999, TGA will specify an audit date.
- Manufacturers will be permitted 24 months, from 1 January 1998, to achieve compliance with the selected manufacturing standard, provided reasonable improvement is observed at each successive audit.
- A TGA licence will be issued when the manufacturer demonstrates compliance with all the elements of the relevant standard. A quality systems certificate will also be issued if requested.
- Therapeutic Goods Orders (TGOs) No.54 and No.54A will apply to the initial development studies, such as microbial efficacy, toxicity, compatibility, stability, labelling, etc. These studies should be undertaken prior to the GMP audits. Copies of these TGO's can be obtained from the TGA Publications

Office (02 6232-8610).

- \* Sponsors of Overseas manufacturers of these products must provide, as part of the registration application, evidence that the overseas manufacturing site complies with an equivalent level of GMP.

### Industry seminars

Seminars hosted jointly by the Proprietary Medicines Association of Australia (PMAA) and the Australian Chemical Specialties Manufacturers Association (ACSMA) targeting suppliers of hospital and household grade disinfectants were held in late June in Sydney and Melbourne. A seminar held late in 1996 targeted sponsors of the higher risk sterilants and instrument grade disinfectants.

Industry organisations have emphasised there is a need for TGA and the industry to continue the education program for both industry and healthcare professionals. As it currently is being suggested that hospital grade disinfectants are satisfactory for use on instruments, this would include dental and medical practitioners .

### Applications and evaluations

At the closing date of 30 June 1997, approximately 80 applications for registration and 40 applications for listable products had been received. Evaluations for microbial efficacy, chemistry, toxicity and materials compatibility have commenced and additional scientific staff have been contracted to help undertake the task.

In general, the data supplied in support of the applications have been inadequate. The most common deficiency is the failure to provide adequate data to support the claims for the products, such as insufficient data on sporicidal activity, chemical stability, compatibility of materials, or risk analysis.

### Timeframes

All sponsors are reminded that to support applications for listing on the ARTG for registrable disinfectants (that is instrument grade, hospital grade with specific claims) or household/commercial disinfectants with specific claims, should have been lodged with the TGA by **30 November 1997**.

Sponsors who are unable to meet this deadline, should contact the Medical Devices Section of the TGA to discuss the timetable for lodgement of applications for particular products (Please quote the relevant TGA IN)

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## US FDA INTRODUCES LATEX LABELLING REQUIREMENTS

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In response to reports of allergic reactions to some medical devices, the United States Food and Drug Administration (FDA) is requiring all medical devices which contain natural rubber latex to be amended to

include a statement on the label which states, "Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions". Medical device packaging that contains latex will be required to carry a similar statement on the label. Products and packaging containing dry natural rubber will have to be identified as containing dry natural rubber.

The new requirements, published on 30 September 1997 in the Federal Register as a Final Regulation, will enable people who are allergic to latex to easily identify medical devices that contain latex.

Over the past decade, FDA has received more than 1,700 reports of severe allergic reactions, including 16 deaths, related to medical devices containing latex. The deaths were caused by a reaction to latex cuffs used on the tip of barium enema catheters which have been recalled from the market. The product supplied currently includes a silicone cuff.

Allergic reactions have been reported to a wide range of medical devices that contain latex, including latex surgical gloves, adhesive bandages, intravenous catheters, and anaesthesia equipment. FDA sponsored an international conference on latex sensitivity in 1992 to determine the cause and extent of the problem and explore ways to address it.

While the risk of an allergic reaction to latex for the general public is estimated to be less than 1 percent - health care workers and patients with conditions involving multiple surgical procedures are at greater risk due to frequent exposure.

FDA is also requiring that all "hypoallergenic" claims on medical devices be removed because of the potential to mislead people sensitive to latex. Such claims are currently found on many medical devices that contain reduced levels of latex protein. However, these products may still cause allergic reactions in people who are latex sensitive. While manufacturers may not use the term "hypoallergenic" the labelling may include a claim reduced incidence of sensitivity.

Manufacturers have one year - until September 30, 1998 to comply with the new law. The regulation does not apply to latex containing medical devices that do not come in contact with people.

## PROPOSED NEW STANDARDS FOR CONDOMS

The Therapeutic Goods Order (TGO) 39, which was gazetted on 30 May 1991, specifies the mandatory standards for rubber condoms based on ISO 4074:1990 - Rubber Condoms. Since 1991 nearly all of the parts of ISO 4074 have been revised.

The TGA recommended to the 20 November 1997 meeting of the Therapeutic Goods Committee (TGC) to adopt new mandatory requirements for rubber condoms based on the amended international standards.

The following table indicates the parts of ISO 4074 that are referenced in TGO 39 and the publication date of the revisions to be adopted by reference in a new TGO.

ISO 4074, 'Rubber Condoms' Part name	TGO 39 referenced part	Revised proposed in TGO
Part 1: Requirements	1990	1996
Part 2: Determination of length	1980	1994
Part 3: Determination of width	1980	1994
Part 4: Determination of colour fastness	1980	None
Part 5: Testing for holes	1984	1996
Part 6: Determination of bursting volume and pressure	1984	1996
Part 7: Oven conditioning	1986	1996
Part 9: Determination of tensile properties	1980	None
Part 10: Packaging and labelling Condoms in consumer packages	1990	1990

The effect of these changes is to align the requirements for leakage, and bursting volume and pressure, with international requirements. Requirements that did not relate to the safety of condoms, namely colourfastness and tensile strength, have been deleted from the revised standards. Technical details of the changes are set out below.

- The requirements, inspection level and AQL (acceptable quality level) for dimensions.
- The requirements and AQL for bursting volume and pressure have been modified. The minimum burst pressure has been increased from 0.9 kPa to 1.0 kPa. There is a slight (approximately 4%) increase in the minimum burst volume requirement. The AQL is modified to allow 1.0% defectives (previously 1.5%).
- The requirements and AQL for oven treated condoms are now the same as for untreated condoms. The inspection level is reduced to S-4. The ageing period has been increased from 48 hours to 168 hours.
- The requirements, inspection level and AQL for freedom from holes have been modified. The rolling technique previously unique to TGO 39 is now incorporated in ISO 4074. The inspection level remains at G-1, but the minimum sample size is 315 (previously 125). The AQL is modified to allow 0.25% defectives (previously 0.4%)
- The requirement for colourfastness has been deleted.
- The requirement for tensile properties has been deleted.
- The requirements and inspection level for packaging and labelling are unchanged. The AQL is modified to allow 4.0% defectives (previously 1.0%)

Sponsors of rubber condoms in Australia should check that their supplying manufacturers are aware of the requirements specified in the new international standard and determine whether their products are able to comply. Comments on the proposal are welcome and should be directed to Peter Wallner on (02) 6232 8711.

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## HARMONISATION WITH THE EUROPEAN UNION

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### What is it all about?

The Therapeutic Goods Administration (TGA) and the Government are committed to harmonising the Australian requirements for the regulation of medical devices with those of the European Union (EU).

### What is the TGA doing?

The TGA has established a team dedicated to the development of Regulation Impact Statement (RIS) exploring various options to harmonise the Australian requirements for the regulation of medical devices with that of the EU. This comprises an analysis of the costs and benefits for stakeholders for each option. A survey of sponsors in 1996 provided an assessment of the overall reaction to the proposal. An implementation strategy and a new structure of fees and charges, reflecting the proposed options, are now being developed. Following further consultation with device sponsors, industry associations and consumer groups, the draft fees and charges will be submitted together with the RIS for consideration by the government.

After enactment of the legislation and introduction of the preferred option for a new regulatory system for medical devices, the TGA will provide guidelines and conduct information sessions to assist the industry.

### When would the changes take effect?

It is anticipated that the new legislation will be considered by Parliament during the 1998 Spring sitting.

### Like to be involved?

TGA would like to hear from those who could assist by providing the industry perspective in assessing the impact of the various options to be examined in the RIS. Please contact Shane Clarke on Email: shane.clarke@health.gov.au or Ph: (02) 6232 8576 or Fax: (02) 6232 8687.

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## AUDITING WORKSHOP

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The TGA collaborated with the UK Medical Devices Agency to hold a four day workshop on "Auditing Sterile Device Manufacturers". The workshop provided a detailed insight into the harmonised standards for sterilisation adopted under the European Medical Device

Directive. Twenty six delegates attended the course including staff from TGA, the device industry and hospital sterilisation units, with two overseas delegates from the Singapore Ministry of Health and TUV in Japan.

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## MUTUAL RECOGNITION AGREEMENT WITH EUROPE

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It is anticipated that the Mutual Recognition Agreement (MRA) on Standards and Conformity Assessment negotiated between Australia and the European Union will be signed in February 1998.

The delay from the previously advised date of November 1997 relates to consideration of a request by the EU for an amendment to the deaccreditation procedures for determining the competence of Conformity Assessment Bodies.

The Department of Industry, Science and Technology, the National Association of Testing Authorities, Australia (NATA) and the Council of the Joint Accreditation System of Australia and New Zealand (JAS-ANZ) will hold discussions in November with the EC regarding the proposed changes.

Implementation of the MRA is scheduled to occur one month after signing.

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## DEVICE LABELLING

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While device manufacturers appear to be enthusiastically taking up the use of labelling symbols, it would appear more needs to be done by manufacturers or sponsors to educate Australian customers and users as to the meaning of the symbols. TGA has received many calls from health care workers seeking an explanation of the various symbols and in relation to the mandatory labelling requirements of TGO 37. Of particular concern are reports that the European Standard EN980 symbol for 'Do Not Reuse' is being used as the exclusive means of communicating that a medical device is intended for single use.

While TGO 37 is under review, the use of the EN980 symbol for 'Do Not Reuse' as the sole means of indicating that the product is intended for single use does not presently comply. Words such as "do not reuse", "single use" or "use only once" should also appear on the product label or on the information provided within the packaging. It is preferable that the explanatory words are printed near the appropriate symbol as this will expedite the education of users.

Sponsors should also be aware that changes to labelling made after products are entered on the ARTG are required to be notified or approved by the TGA. Attention is drawn to part VA of the Trade Practices Act which requires that goods are supplied free from defects and that they provide a level of safety that persons are

generally entitled to expect. This requirement extends to the provision of adequate instructions and warnings and suppliers of any goods should not rely exclusively on symbols to convey important safety information when

there is widespread ignorance of the meaning of these symbols.

To assist in the education of users the following symbols from EN980 are reproduced.

	<p>'SERIAL NUMBER'</p>
	<p>'CATALOGUE NUMBER'</p>
	<p>'BATCH CODE'</p>
	<p>'DO NOT REUSE'</p>
	<p>'STERILIZATION BY IRRADIATION'</p>
	<p>'SEE INSTRUCTIONS FOR USE'</p>
	<p>'STERILIZATION BY STEAM OR DRY HEAT'</p>
	<p>'USE BY'</p>
	<p>'STERILE'</p>
	<p>'STERILIZATION BY ETHYLENE OXIDE'</p>

## DISPLAY OF UNAUTHORISED GOODS

Schedule 5 of the Therapeutic Goods Regulations exempts certain goods from registration or listing in the ARTG. Item 3 specifically exempts;

“samples of therapeutic goods imported, exported, manufactured, or supplied for:

- a) submission to a regulatory authority; or
- b) subjection to developmental or quality control procedures; or
- c) examination, demonstration or display; or
- d) subjection to analysis or laboratory testing;

but not for supply for therapeutic use in humans”

This means sponsors may import and display therapeutic goods at conferences, trade fairs and other events prior to the entry of these goods on the ARTG, provided certain conditions are met. In the past, TGA issued conditional written authorisations to display unauthorised therapeutic devices for specific products and

events. This practice has been discontinued.

However sponsors displaying unauthorised devices **must** ensure these goods are displayed in a manner that makes it clear the devices are currently unauthorised and not available for supply. This means the display must include a clearly legible sign stating the goods are not entered on the Australian Register of Therapeutic Goods [ARTG] and their safety, quality and efficacy has not been established by the Therapeutic Goods Administration [TGA]. Any promotional material about these products distributed at the meeting should include a similar statement. There are additional trade display guidelines for unregistered drugs. These are included in the Australian Pharmaceutical Manufacturers Association (APMA) Code of Conduct.

The sponsor may hold these devices under the direct control for up to 12 months but must maintain records relating to the source and supply of the devices and provide this information to TGA if requested. The products must be destroyed or returned to the consignor of the devices within 1 month of the end of that period, unless the goods have been approved for entry onto the ARTG.

## DRUG SAFETY AND EVALUATION

### CERTIFIED PRODUCT DETAILS (CPD)

Most sponsors would be familiar with the CPD document and its content. The requirement for the preparation and submission of CPDs was first introduced as a firm TGA policy in 1990 after consultation with industry. The primary aim of requiring a CPD is to ensure that there is a single document which provides details of the finished product specifications (ie test parameters, limits and test methods) agreed between the sponsor and the TGA for registered drug products. The document is particularly useful for the TGA Laboratories (TGAL) for sample testing purposes. The CPD also includes additional information on the product, including formulation, pack sizes and shelf-life/storage conditions.

The following guidance is provided to assist sponsors in deciding at which point in the evaluation process and/or under what circumstances a CPD should be prepared and submitted.

1. **DO** submit a CPD incorporating the final agreed finished product specifications, including test methods, following the conclusion of the evaluation of the chemical and pharmaceutical (Part II) data in a Category 1 application. It is preferred that submission of the CPD be upon request by the TGA. Alternatively, submission may be at the sponsor's initiative if it is confident that all Part II matters have been resolved. In either case, it is in the sponsor's interest to provide the document in a

timely manner for checking by the evaluation section so that it is available for use by TGAL if sample testing is required.

2. A CPD will be requested of a sponsor upon approval of any Category 3 application which involved changes to certain elements of the finished product specifications, eg. changes to test parameters, limits or test methods. A one month timeframe is generally appropriate when such a request is made.

3. **DO** submit a CPD incorporating the relevant change(s) made to a product when notifying the TGA of a self-assessable change if it is a requirement in the self-assessment guidelines (Appendix 8 of the AGRD Vol 1, 2nd edition). Such changes again would relate in some way to product specifications.

4. It is generally **NOT** advisable to submit a CPD with the Part II data supporting a Category 3 application because experience has shown that the contents of the document often require further revision during the evaluation process and new editions are then generally required.

It is preferred that the document is submitted when requested by the TGA (see point 2).

5. **DO NOT** submit a CPD following changes to product details such as formulation, shelf-life/storage conditions, pack sizes or container type for a product **even though** such information is in the CPD document. This

is because such information is generally not critical for laboratory testing purposes. Additionally, since these aspects of the Part II data of a product do undergo variations rather frequently, it is undesirable and an unnecessary use of resources to constantly update the CPD due to such variations. Details of any changes of these types are in any case clearly reflected either in a specific TGA approval letter or in the sponsor's notification form if the change is self-assessable.

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## ORPHAN DRUG PROGRAM

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Orphan drug products are drugs, vaccines or *in vivo* diagnostic agents which physicians use to treat, prevent or diagnose rare diseases. Usually the drugs are not commercially viable. Pharmaceutical companies often do not develop and market such products because the financial return is small compared with the costs of development and marketing. When a drug has no sponsor for this reason, it is known as an "orphan" drug. The lack of such drugs may deprive patients with rare diseases of diagnosis and treatment but these patients have rights to drugs of the same quality, efficacy and safety as patients with common illnesses. The TGA intends the Orphan Drug Program to overcome this problem and has based its Program on that of the Food and Drug Administration of the USA.

The Australian Program encourages sponsors to market orphan drugs in Australia by reducing costs through waiving fees and by providing exclusive approval. The TGA will waive fees for the application for orphan drug designation, the application for registration and for the initial evaluation of data. A further commercial advantage is an expected shorter approval time than the statutory 255 working days for the usual Category 1 applications. Annual fees will still apply but may be reduced on the basis of low volume of usage and low value.

**Designation of a drug product as an orphan drug:** The first step in registering an orphan drug product is for the sponsor to apply to the Drug Safety and Evaluation Branch of the TGA for orphan drug designation. Orphan status is determined by the indication so that a drug is not designated an orphan except by reference to a specific indication.

Two requirements are to be met. The first is that the prevalence of the disease or disorder to be treated should be equal to or less than 2,000 affected individuals, or, if the drug is a vaccine or *in vivo* diagnostic agent, the persons to whom the drug will be administered in Australia are fewer than 2,000 per year at the time the request is made. The second requirement is when the prevalence of a disease or disorder is greater than 2,000 individuals but the sponsor can show the marketing of the drug would not be financially viable. The information needed to support this claim is the same as that required by the FDA.

If orphan status is given, the TGA will advise the sponsor and publish the drug's designated orphan status, with the dose form, indication and name of the sponsor in the Australian Government Gazette. The designation of an orphan drug is not an exclusive process and the TGA may designate more than one drug as orphan drugs for the same indication.

**Registration of a designated orphan drug product:** The second step is for the sponsor to apply to register the designated drug on the Australian Register of Therapeutic Goods (ARTG). The TGA will not approve registration of a drug product containing the same drug for the same indication as a product which is already registered for a rare disease or condition, unless it is shown to be clinically superior to the registered product. The definition of clinical superiority is that of the FDA for this purpose. Biologicals are a special case because criteria for the "sameness" of two biologicals are complex.

Under certain conditions, such as the inability of a sponsor to supply the orphan drug product in adequate quantity, the TGA may approve another product with the same active ingredient for registration for the same indication.

**Processing and Evaluation Times:** Initial applications to register a drug or to extend the indication for a registered drug will be Category 1 with a legal time frame for completion of 255 days. However the TGA expects the applications to be completed well before this date, especially when FDA designation and evaluation reports are available. It is not possible to estimate this time at present, but a review of the program, planned twelve months after its start, will indicate a reasonable time to completion. Category 3 application will incur full fees and be completed in the existing time frame of 45 days as for non-orphan Category 3 applications.

**Referral to the ADEC:** Applications for either designation or registration that are refused by the TGA, will be referred to the ADEC for advice and comment.

**Special Cases:** The TGA recommends that the following classes of products be discussed as soon as possible with the Orphan Drug Unit of the Drug Safety and Evaluation Branch because special circumstances may apply to their registration and use in Australia: products from blood and plasma; recombinant products; vaccines; products from human tissue regulated as drugs; products classed as those for gene therapy; and products for use in children.

**Information:** The TGA intends to publish its full policy in booklet form. More information can be obtained by contacting the Head of the Orphan Drug Unit, Dr Brian L Hillcoat, phone 02 6232 8113, fax 02 6232 8140, e-mail [brian.hillcoat@health.gov.au](mailto:brian.hillcoat@health.gov.au).

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## EUROPEAN UNION GUIDELINES

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In the August 1997 edition of TGA News we included a list of EU Guidelines agreed for adoption in Australia. Copies of these guidelines are available from

Hunter Publications  
PO Box 404  
Abbotsford  
Vic 3167

ph (03) 9417 5361  
fax (03) 9419 7154

## TGA LABORATORIES

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### TGAL'S PERIPATETIC MICROBIOLOGIST

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*Vivienne Christ and Terry Slater, National Manager TGA*

Chief Microbiologist, Ms Vivienne Christ was invited to present an overview of the TGA's approach to disinfectant and sterilant regulation during a panel discussion at a symposium on sporicides at the Association of Analytical Chemists (AOAC) annual meeting held in San Diego, California, September 1997. The forum provided an excellent opportunity for open discussion on this topical issue between industry, US EPA and FDA, and international representatives. Technical presentations on current developments and future directions for sporicidal testing preceded the panel discussion. Since the TGA has adopted the AOAC Sporicidal test as our preferred test for registration of high-level disinfectants and sterilants, it is essential that we be aware of any proposed changes to test methodology. This enables us to assist Australian industry and contract testing laboratories and facilitates TGA's participation in international collaborative studies .

Next was a visit to Stockholm, Sweden where Ms Christ was the official delegate of Standards Australia at the annual meeting of the International Standards Organization, Technical Committee 198 (ISO/TC 198) -

*Sterilization of healthcare products.* Australia is a full participating member of this committee. This is important in view of the role of ISO and EN standards for meeting the essential requirements under the European Medical Device Directive (MDD), and their adoption by pharmaceutical manufacturers, where relevant. At the meeting, a number of standards were finalised for voting as final ISO standards, and progress was made on drafts of others. Work also commenced on new standards for labelling and reprocessing of reusable medical devices, and for the performance of washer-disinfectors, which are relevant to the TGA and the Australian industry.

The President of the International Association for Pharmaceutical Science and Technology (PDA), Dr Edmund M. Fry recently extended an invitation to Ms Christ to present the Korczynski Lecture at the PDA 1997 Annual Meeting, Courses and Exhibition, "Meeting the Challenges of Change". This invitation was in recognition of Ms Christ and the work of the Microbiology Section, particularly in relation to the harmonisation of the sterility test. The meeting was held in Philadelphia, from November 10-12, 1997. The lecture and the associated travel grant is named in honour of PDA past president, Michael S. Korczynski, who was instrumental in advancing PDA international activities. Ms Christ has been asked to present TGA's and her own views on global harmonisation of a number of microbiological issues, which will include the sterility test, preservative efficacy testing, and microbial limits for non-sterile products.

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### DETECTION METHODS FOR GLYCOLS FOLLOWING SEPARATION BY THIN LAYER CHROMATOGRAPHY

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Following the 1996 outbreak of diethylene glycol (DEG) poisonings in Haiti where many children died, the WHO and the FDA set a 0.1% DEG limit for pharmaceutical raw materials and glycerin based elixirs. A TLC method for separation of glycols was developed by the FDA but WHO also required a cheap detection method that could be easily performed in the field. In response, Robert Prestridge and Kirsten Sharp from the Chemistry Section TGAL have developed a quick, robust and inexpensive method of detecting glycols in the Standard TLC test.

The method relies on the oxidation of glycols by potassium permanganate. It satisfies sensitivity requirements since it allows detection of 1µg or less of glycols equivalent to 0.01%. The work is soon to be published on behalf of WHO in the Journal of the Association of Official Analytical Chemists in collaboration with Dr Allen S. Kenyon's laboratory, Division of Drug Analysis, FDA.

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## CHANGES TO STRUCTURE OF TGA LABORATORIES BRANCH

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Dr Gary Grohmann has been appointed to head the Immunobiology section and took up his position in November. Gary has over 20 years experience in medical and environmental virology with a strong interest in public health virology, molecular diagnostics, viral immunology, prion diseases and viral vaccines and safety. After his university studies (BSc hons., UNSW and PhD, Sydney) he spent 14 years in clinical hospital virology, research for two years at the Center for Disease Control, Atlanta, Georgia, USA and four years at Sydney Water. He has spent the last 18 months as a private consultant in virology and holds adjunct academic appointments in the Department of Veterinary Anatomy and Pathology, University of Sydney and in the School of Microbiology and Immunology, University of NSW.

Following the retirement of Mr Russell Beckett and Mrs Jan Finn, the Animal Services section ceased to exist as a separate unit and its functions have been incorporated into the framework of the Immunobiology section. The Laboratory workshop has been relocated and refitted and is now administered by the Biomaterials and Engineering section.

Dr Clive Morris (02 6232 8532) has been appointed as section head of Molecular Biology. Clive came to the TGA in 1994 from the then National Food Authority (NFA, now Australia and New Zealand Food Authority). After graduating from the University of Queensland (BSc Hons, PhD), Clive spent several years doing medical research in both the UK and Australia before joining the NFA in late 1992. His scientific expertise lies in the areas of protein chemistry, molecular biology and cell biology.

The TGA Laboratories Executive Unit has been restructured. Dr Margaret Smith (telephone 02 6232 8448, fax 02 6232 8442) is the contact for laboratory matters and Dr Garry Hopkins (telephone 02 6232 8440, fax 02 6232 8442) has been appointed to liaise with outside organisations.

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## QUALITY OF VACCINES WORKSHOP

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A Workshop on the Role of National Control Authorities in Ensuring the Quality of Vaccines was held at the World Health Organization Western Pacific Regional

Office, Manila, Philippines, on 25 - 29 August 1997. The NCAs of Australia, Japan, Korea, China, Vietnam, Philippines, Singapore, Malaysia participated, together with Dr Julie Milstein from the Global Programme for Vaccines & Immunisation, WHO, Geneva, and WHO Western Pacific Regional Office staff who provided the Secretariat. Observers from the International Vaccines Institute, the United Nations Children's Fund (UNICEF), the Philippine-Australia National Drug Policy Co-operation Project, and the Department of Health, Philippines also participated.

The objectives of the workshop were to review the operation, responsibilities, structure and legislative basis of National Control Authorities (NCAs) with respect to vaccine quality, to discuss the relationship between NCAs and manufacturers, to define the responsibility of the National Control Laboratory and its relationship with the NCA, and to establish a system for information exchange and collaboration between NCAs in the Region.

Chris Rolls (TGAL) and Dr. Greg Smith (GMP Audit and Licensing Section) were involved in preparing the workshop content and presenting and facilitating many of the sessions. Dr. Smith, as the rapporteur, prepared the report for ratification by the WHO Secretariat.

Workshop outcomes included recognition of TGA's excellence in this field, the facilitation of communications between participants, and the identification of further assistance that TGA can provide to neighbouring countries through WHO. TGA will continue to provide training for countries with well developed regulatory systems for pharmaceuticals who need assistance to develop expertise in the regulation of vaccines. In addition TGA, in response to requests from WHO, may provide more intensive assistance to countries with less developed regulatory systems, including review of the operation, responsibilities, structure, and legislative basis of their National Control Authority. WHO will co-ordinate further activities arising from the workshop.



*Workshop on the Role of National Control Authorities in Ensuring the Quality of Vaccines 25-29 August 1997 Manila, Philippines*

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## EUROPEAN COMMISSION DECISION 97/534/EC: TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY RISK MATERIAL OF ANIMAL ORIGIN USED IN MANUFACTURE OF PRODUCTS EXPORTED TO THE EU.

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As of 1 January 1998, companies exporting medical, pharmaceutical or cosmetic products to the European Community may be required to supply a declaration that the products (or their starting materials or intermediate products) do not contain and are not derived from animal materials at risk of transmitting spongiform encephalopathies. Such declarations will have to be issued by a Competent Authority in the country of production, but will be required only upon request from the importing country. The specific risk materials defined in the Commission Decision 97/534/EC are the skull, including the brain and eyes, tonsils and spinal cord of bovine, ovine and caprine animals and the spleen of ovine and caprine animals.

TGA has discussed this matter with the Australian Quarantine Inspection Service (AQIS) and derogation from the above EC Decision is being sought, based on Australia's status as a country free from transmissible spongiform encephalopathies affecting animals. A decision is expected from the European Commission by the end of December. At that time there will be a further meeting of TGAL and AQIS to determine procedures for companies who may be requested by European authorities to supply a declaration in relation to the above Decision. In the meanwhile, all enquiries should be directed to:

Dr P. Vitlovich  
Food Policy Branch  
Australian Quarantine and Inspection Service  
Department of Primary Industries and Energy  
PO Box 858, Canberra ACT 2601

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## AUSTRALIAN INFLUENZA VACCINE FOR THE 1998 WINTER

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The composition of Australian Influenza Vaccine for the 1998 winter season was agreed at the meeting of the Australian Influenza Vaccine Committee (AIVC) held on 10 October 1997. Influenza surveillance data was reviewed for New Zealand (Dr David Featherstone), South Africa (Professor Barry Schoub and Dr Terry Besselaar) and Australia (Mrs Margaret Curran). Mr Alan Hampson presented a detailed analysis of WHO's surveillance data. As a result, changes will be made to the A components of the formulation of last year's vaccine.

Influenza vaccines for the 1998 season will contain the following:

- .A (H1N1):                   an A/Bayern/7/95 (H1N1) -Like strain  
  -NIB 39, a reassortant of  
  A/Johannesburg/82/96 is suitable.
- .A (H3N2):                   an A/Sydney/5/97 (H3N2) -Like strain  
  -Reassortants of A/Sydney/5/97  
  and its equivalent  
  A/Auckland/20/97 are suitable.
- .B:                               a B/Beijing/184/93 -Like strain  
  -B/Harbin/7/94 is suitable.

### ENFORCEMENT NEWS

#### Recent Prosecutions

Recent prosecutions by the Surveillance Unit have resulted in the convictions of:

- + a Melbourne man in relation to the manufacture and export of dental lignocaine, an **injectable anaesthetic**;
- + a Sydney man in relation to the import of **traditional Chinese medicines**;
- + a Brisbane company in relation to the import of **non-prescription drug products**; and
- + a Sydney company in relation to the import and supply of **herbal ecstasy tablets**.



*Part of a shipment of unapproved injectable lignocaine, destined for export to the Philippines, seized by TGA investigators in Melbourne*



*One of 212 cartons seized by TGA investigators in Sydney. These cartons of household goods were used to smuggle a large quantity of unapproved prescription and non-prescription drugs into Australia. The drugs also included a number of prohibited imports.*

#### “Export Only” Listings and Duty Free Stores

Products that are included in the Register (ARTG) as

“export only” listings are approved for export from Australia only. These products are not approved for supply in Australia and any such supply may constitute a criminal offence.

Supply of these products, by a sponsor or manufacturer, to a duty free store in Australia; or by a duty free store to customers in Australia, constitutes a supply in Australia of those goods. In these circumstances the goods have not been exported and the suppliers may be liable in relation to the unlawful supply of the goods in Australia.

#### Industry Fraud

Australia’s therapeutic goods industry enjoys a deserved reputation for the high quality of the product it produces and for the ethical standards under which it operates. As a general principal, the industry complies with the legislation and provides considerable cooperation to TGA investigations.

Fraudulent industry practices, such as substituting ingredients, switching labels to hide ingredients or extend expiry dates, and the production of documentation that misrepresents product ingredient, strength and dosage size have been detected during Surveillance Unit investigations.

The purpose of such schemes have generally been to enable unlawful product to be placed in the lawful market and are usually profit motivated. The damage such schemes can have on the reputation of the industry, particularly in Australia’s pharmaceutical export markets, can be considerable.

The Surveillance Unit greatly appreciates the support of sponsors and manufacturers in combating fraudulent practices that have the potential to undermine the integrity of the industry.

#### Australian Seahorses protected

Federal Environment Minister, Robert Hill has announced that from 1 January 1998, exports of all species of syngnathids (seahorses, seadragons and pipefishes) found in Australian waters will be stringently controlled.

“Half of the world’s 220 known species of syngnathids occur in Australian waters and there is strong demand for their use in traditional Asian medicines,” Senator Hill said.

“Populations of seahorses, seadragons and pipefishes have declined dramatically in many parts of the world through uncontrolled and excessive trade. The decision to protect these species is a precautionary measure by Australia, which acknowledges the worldwide concern over the exploitation of syngnathids,” Senator Hill said.

There are currently no therapeutic goods included in the ARTG that contain any of these species. Sponsors are advised however, that should they wish to export any

product in the future containing this material, in addition to TGA requirements, a permit will also be required from Environment Australia under the provisions of the *Wildlife Protection (Regulation of Exports and Imports) act, 1982*.

Environment Australia can be contacted on (02) 6250 0751 in relation to permits.



*A traditional Chinese medicine product seized by TGA investigators that contains 10% seahorse (hippocampus). This product was part of a large shipment of illegally imported drug products and also contains seven other internationally protected species as ingredients.*

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## CUSTOMER SERVICE CHARTER

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This issue of *TGA News* includes a copy of the draft TGA Customer Service Charter which is designed to promote greater transparency and client-focus in TGA operations.

TGA has always prided itself on providing professional service of a high level. This Charter helps explain to customers and staff alike what to expect of TGA and the responsibilities of clients to help ensure a world class service.

When the Charter is finalised it will be circulated widely and evaluated over the next twelve months. Any feedback on this draft Charter is most welcome. Please direct any comments to:

TGA Customer Service Charter  
GPO Box 100  
Woden ACT 2606

or phone Jonathan Benyei on (02) 6232 8231.

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## THE ROLE OF TGA LIBRARY IN LITERATURE-BASED SUBMISSIONS

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Information specialists from TGA Library have recently been involved in the development of new options for Literature Based Submissions (LBSs). The key change is the introduction of the Presubmission Meeting. This meeting provides an opportunity for TGA and industry

to come to agreement on various aspects of a specific submission, including the design of an effective literature search.

The Presubmission Meeting and other aspects of the LBS process are outlined in a draft update *points to consider* document (*Literature Based Submissions - Points to Consider*, update draft 4, 22/9/97) which has recently been distributed to industry through the Australian Pharmaceutical Manufacturers Association.

### The current role of TGA Library staff

TGA Library information specialists have a key role in advising Delegates from TGA's Drug Safety and Evaluation Branch (DSEB) on the adequacy of literature searches provided to TGA in support of Literature Based Submissions.

On the advice of the relevant Delegate in DSEB, TGA Library staff review the literature search provided in support of a LBS. This review is to investigate whether the relevant literature has been identified for the purposes of the submission. It involves a perusal of all aspects of the search conducted to support the LBS, including the selection of databases and the design of the search strategy used in identifying literature.

Library information specialists perform these tasks with advice from the Delegate on the relevant issues to be pursued with regard to the quality, safety and efficacy of the drug in question for the indication identified in the submission.

The information specialist performing the LBS investigation writes a report to the Delegate covering the nature and adequacy of the literature search. The delegate uses this report in coming to a decision on the submission.

### The Presubmission Meeting option

The Presubmission Meeting is a new option which is expected to assist in the compilation of a LBS.

Sponsors should submit their draft literature search well before the Presubmission Meeting. This will allow TGA Library information specialists to investigate relevant databases, indexing, strategies and other issues related to the product under evaluation prior to the Presubmission Meeting.

At the Presubmission Meeting, it is envisaged that a TGA Library information specialist will assist the Delegate and sponsor to come to an agreement on a literature search which is acceptable to TGA. For this to occur, the sponsor should come prepared to discuss the literature search and bring the strategist involved in the design of the search to the meeting.

Given an agreement on the literature search, providing this search is carried out as agreed and within reasonable time limits, the sponsor can be confident that the expenditure of further time and energy on the submission will not be lost through rejection of the literature search.

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## STRATEGIC INFORMATION PLANNING PROJECT — INFORMATION SYSTEMS TO IMPROVE TGA PERFORMANCE AND CLIENT ACCESS

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In the six years since TGA was established, we have come a long way in the use of Information Technology (IT). In the early years, the TGA had to develop IT systems quickly in order to meet the immediate information needs of the time. Generally this meant delaying the development of communication links between the various systems and the management information reporting capability. While these systems have served us well and enhancements have been made over the years, it is time to reassess whether they are adequate in today's environment.

Advances in technology and new business methods demand that we look closely at the way we do business. The Strategic Information Planning Project (SIPP) has been established to look particularly at the way we manage information and use technology to support our business practices. This includes looking at ways to increase the use and effectiveness of electronic transmission of data between the TGA and its various clients and stakeholders.

The SIPP project began in August. Phase 1 of the project — the mapping of our current environment, involved documenting the flow of information within the TGA and identifying all formal and informal internal electronic and paper information systems. This phase of the project is complete.

Phase 2 — identification of strategic information requirements, has begun. As part of the consultation process we have sought the views of industry representatives in the Australian Pharmaceutical Manufacturers Association (APMA), the Proprietary Medicines Association of Australia (PMAA), the Medical Industry Association of Australia (MIAA), the Nutritional Foods Association of Australia (NFAA) and the Cosmetic Toiletry and Fragrance Association of Australia (CTFAA) on ways we can improve sponsor access to information.

The project team would like to acknowledge the cooperation and positive contributions made by both the staff of the TGA and the industry representatives with whom we have spoken to date. As the project continues, this wider consultation will continue and we will keep you informed of progress by regular bulletins in future editions of the TGA News.

If you would like to discuss any aspect of this project, please contact the Project Manager, Dr Drew Meek on (02) 6232 8789.

## COMMENTS INVITED ON DECLARING GOODS TO BE THERAPEUTIC GOODS

A review of the definition of "foods" in the Therapeutic Goods Act 1989, is underway through the External Reference Panel on Therapeutic Goods/Foods Interface Matters (ERPIM). ERPIM is an advisory panel to provide advice on interface matters to TGA and the Australia New Zealand Food Authority (ANZFA). It consists of representatives from TGA, ANZFA, State, Territory and New Zealand health authorities, the Australian Quarantine Inspection Service, industry and consumers. In the meantime ERPIM is proposing three products be declared to be therapeutic goods and seeks public comment on the proposal.

This activity is in direct response to the recommendations of the 1996 Review of the Therapeutic Goods Administration. The objective is to streamline decisions about whether a product is a 'food' or a medicinal product which will provide greater certainty for industry and regulators. It addresses the problems of the protracted decision making process on a product by product basis that industry has, at times in the past, experienced.

Section 7 of the *Therapeutic Goods Act, 1989* provides for the Secretary to make a declaration on the status of a good if the Secretary is satisfied that the particular good or classes of good is, or is not, a therapeutic good. Declarations are published in the *Commonwealth Gazette*.

### Process for managing a proposal for section 7 declarations

- 1 A proposal to make a section 7 declaration may originate from the External Reference Panel on Therapeutic Goods/Foods Interface Matters (ERPIM), industry, ANZFA or TGA.
- 2 The proposal will be managed by the Complementary Medicines Section of TGA.
- 3 Notice that the proposal is being considered will be published in appropriate newsletters of TGA and ANZFA and circulated to industry associations and other stakeholder bodies inviting comment on it.
- 4 The proposal would be put to the Complementary Medicines Evaluation Committee and the TGA would consider its recommendations.
- 5 The Secretary may then make a decision with respect to the proposal.
- 6 If the Secretary makes a declaration, it will be published in the *Commonwealth Gazette*, to take effect on the date of publication.
- 7 Gazette notices and the reasons for the declarations will be more widely published for industry and stakeholder information (as above).

ERPIM has recommended that TGA prepare section 7 declarations that the following goods be therapeutic goods in accordance with the above process:

- 1 Goods for oral use labelled or promoted as being a source of fibre and supplied in capsule, tablet or pill form.
- 2 Goods for oral use:
  - (a) containing isolated selenium; or
  - (b) labelled or promoted as containing selenium; other than where standardised in the *Food Standards Code*.
- 3 Goods for oral use:
  - (a) containing isolated shark cartilage; or
  - (b) labelled or promoted as containing shark cartilage; other than where standardised in the *Food Standards Code*.

Comments on the above proposals are welcome and further consultation details can be obtained from Ms Pat Brown, Complementary Medicines Section, TGA, PO Box 100, Woden ACT 2606, tel 02 6232 8465, fax 02 6232 8428. The **deadline** for comments on these three proposals is **Friday 6 February 1998**.

## PRIOR INFORMED CONSENT - UPDATE

The fourth Intergovernmental Negotiating Committee on Prior Informed Consent met in Rome in October 1997. The Australian delegation included representatives of the Departments of: Foreign Affairs and Trade, Health and Family Services, Primary Industry and Energy, and Environment, Sport and Territories. The Prior Informed Consent Procedure is an international programme which requires countries which take national action to ban or severely restrict a chemical on health or environmental grounds, to notify this action on a product by product basis. This information on the action taken, and the reasons for the action, are supplied to a Secretariat which is jointly run by the United Nations Environment Programme (UNEP) and the Food and Agriculture Organisation (FAO). When notifications have been received, and the evidence of the health or environmental concerns has been considered, the chemical may be placed on an international list. Countries then have the opportunity to notify whether they wish to continue to receive the chemical or not. International negotiations are continuing to change the voluntary procedure to a legally binding process.

Discussions progressed in the fourth meeting. There was agreement on the need for an export notification system for chemicals which are banned or severely restricted in the country of export, although no agreement on the form or frequency of export notification could be reached. Progress was made on determining the criteria for listing a chemical on the international list. There was significant discussion on what information should be considered confidential, and Australia expressed

concern over a requirement to protect proprietary rights. In general, positions were more clearly defined at the fourth meeting, and countries are aware of the areas which will require compromises at the next meeting.

Importantly, there was no discussion of the current proposal for the exemption of all pharmaceuticals (given their control under other international instruments). However, this will not be finally negotiated until the fifth meeting, to be held in Brussels in either January or February next year.

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## C&NPD BRANCH PUBLICATIONS

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### *Handbook of First Aid Instructions and Safety Directions for Agricultural and Veterinary Chemicals (Including Pesticides)*

First Edition (November 1996)

The Handbook of First Aid Instructions and Safety Directions for Agricultural and veterinary Chemicals (including Pesticides) is now available. It contains details of first aid instructions and safety directions recommended to the National Registration Authority for Agricultural and Veterinary Chemicals (NRA) by the Therapeutic Goods Administration (TGA) for inclusion on the labels of agricultural and veterinary chemicals.

This information was previously published as Appendixes E and H to the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). It includes all entries previously included in the SUSDP, together with subsequent amendments established by the Department of Health and Family Services, TGA and Worksafe Australia up to the date of the publication.

This guide has been specifically prepared to assist manufacturers and packers of agricultural and veterinary

chemicals and pesticides to draft first aid and safety directions for labels for these products.

AGPS Cat. No. 96 0779x \$40.00

### *Handbook of First Aid Instructions and Safety Directions for Agricultural and Veterinary Chemicals (Including Pesticides)*

Amendment No 1 to First Edition (July 1997)

AGPS Cat. No. 97 02903 \$15.00

### *ADI List*

#### *Acceptable daily intakes for agricultural and veterinary chemicals*

April 1997

The ADI List is now available. It sets out the acceptable daily intakes (ADI's) for agricultural and veterinary chemicals used on food producing crops or animals. It includes figures which were recommended by the former Pesticides and Agricultural Chemicals Standing Committee (PACSC) of the National Health and Medical Research Council (NHMRC) until November 1992.

The responsibility for setting ADI's transferred to the Therapeutic Goods Administration (TGA) of the Commonwealth Department of Health and Family Services on 12 March 1994. ADI's established by TGA are included in this document.

The ADI List is an essential reference for companies marketing agricultural and veterinary chemicals, for regulatory agencies and for those with an interest in levels of agvet chemicals allowed in foods.

AGPS Cat. No. 96 09679 \$10.00

All of these publications are available from Government Info Shops (ph 132 447, URL <http://www.agps.gov.au>)

**THE HON. TRISH WORTH**

**Parliamentary Secretary to the Minister for  
Health and Family Services  
Member for Adelaide**

**29 October 1997**

### **NEW COMMITTEE TO ADVISE ON COMPLEMENTARY MEDICINES**

The Parliamentary Secretary for Health and Family Services, the Hon Trish Worth MP today announced the establishment of the Complementary Medicines Evaluation Committee.

"The establishment of this Committee recognises the increasingly important role which complementary medicines are playing in the health care choices of the Australian community," Ms Worth said.

"It is important that the community have confidence in the safety of the products they are using.

"The Committee will provide the Therapeutic Goods Administration (TGA) and myself with expert scientific and technical advice on the safety of complementary medicines," she said.

There are approximately 15,000 complementary medicinal products already approved for supply in Australia and new products are constantly being developed.

"This is a growing industry and we want the Australian community to have access to complementary medicinal products where there are no safety concerns.

"The Government believes that the level of regulation should be appropriate to the assessed risk to public health and safety. The Committee will have an important role to play in helping us achieve this.

"The Committee members have a wide range of expertise and experience which reflects the diversity of products classified as complementary medicines. Members will provide practical advice which recognises the philosophies of complementary products while ensuring that the required standards of safety, quality and efficacy are met.

"The membership includes experts in nutrition, complementary and traditional medicine, orthodox medicine, toxicology and chemistry as well as people with experience in consumer issues and the regulation of foods and drugs," Ms Worth said.

The Committee will be chaired by Professor David Roberts who is Foundation Professor of Nutrition and Dietetics at the University of Newcastle. The names of the other members will be announced shortly.

The Committee is expected to hold its first meeting before the end of the year.

Media Contact: Karen Halbert, Trish Worth's office - (02) 6277 4927 or 0412 119 389

## **STOP PRESS**

### **The First Meeting of CMEC**

The Complementary Medicines Evaluation Committee (CMEC) will hold its inaugural meeting on 16 and 17 December 1997. The meeting will be chaired by Professor David Roberts, Foundation Professor of Nutrition and Dietetics at the University of Newcastle.

The CMEC will provide the TGA with expert scientific advice on the safety of complementary medicines. It will review currently registered substances and products and assess new substances and products.

The safety of royal jelly and ginger (*Zingiber officinale*) are being considered at the first meeting.

The CMEC will also discuss any necessary amendments to the *Therapeutic Goods Regulations* and related administrative arrangements to support the Committee work.

Outcomes will be published in the next issue of *TGA News*.

### **WORTH A QUICK LOOK...**

Draft Customer Service Charter

TGA Internet Site

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

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### Introducing Trish Worth

By now, you will be familiar with the former nurse and midwife - Trish Worth - now the Parliamentary Secretary to the Minister for Health and Family Services.

Ms Worth, the Member for Adelaide, joins two doctors - Health and Family Services Minister Dr Michael Wooldridge, and health spokesman in the Senate, Senator John Herron - to make up the Government's health team.

Patricia Mary Worth was born on 21 April 1946 in Riverton, South Australia. Ms Worth was educated at Riverton High School and Cabra College, and completed her education at Calvary Hospital in Adelaide, where she became a registered nurse and midwife.

In 1967, at the age of 21, she became the Nurse of the Year and State Gold Medallist.

After moving up through various senior nursing positions covering the full range of hospital care, Ms Worth took up the private sector role of Patient Services Manager, Pathology, in 1989 - a position she held for the next four years.

It was at that stage that her career took an interesting turn. In 1993 she won the seat of Adelaide, and in the elections of 1996 retained the seat.

In 1996, Ms Worth became the first female Government Whip in the House of Representatives - a position in



which she remained until being appointed to her present position as Parliamentary Secretary.

She believes her background has placed her in a good position to see the broader health picture and also to understand the issues from the perspectives of both providers and consumers.

"My nursing background and the position of Patient Services Manager in a large private pathology company has provided me with a clear understanding of the issues affecting the broader health arena - from the needs of GPs and their patients in rural and remote areas to the highly specialised requirements of the services provided in the city," Ms Worth said.

Ms Worth has also served on a range of parliamentary committees, and was Chair of the Health, Family Services and Veterans' Affairs Committee for 14 months - a position from which she resigned to make time for her new responsibilities as Parliamentary Secretary. This work, she says, has provided her with exposure to different policy areas - and that will be valuable in her new role.

As Parliamentary Secretary to the Minister for Health and Family Services, she has specific responsibility for a range of areas, including: the Therapeutic Goods Administration (TGA); the Australia New Zealand Food Authority (ANZA); Hearing Services Program; the Pharmaceutical Benefits Scheme (PBS); and Health Services Australia.

Of her future ambitions, Ms Worth will say only "my aim is to see that the best possible decisions are made in an area that greatly affects the life of every Australian."

The TGA's Mission Statement: "To ensure the safety, quality and efficacy of therapeutic goods available in Australia at a standard equal to that of comparable countries, and to ensure that premarket assessment of therapeutic goods is conducted within a reasonable time."

**TGA**

**Therapeutic Goods  
Administration**

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