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THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

HOUSE OF REPRESENTATIVES

THERAPEUTIC GOODS AMENDMENT BILL 1995

EXPLANATORY MEMORANDUM

(Circulated by authority of the Minister for Family Services,
Senator the Hon Rosemary A. Crowley)

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THERAPEUTIC GOODS AMENDMENT BILL 1995

GENERAL OUTLINE

This Bill proposes amendments to the *Therapeutic Goods Act 1989.*

The effect of the changes made will be to:

(a) clarify the distinction between "food" and "therapeutic goods" to minimise confusion about what is regulated under the Act;

(b) enable the Secretary, the National Manager of the Therapeutic Goods Administration or the Director of the Drug Safety and Evaluation Section of that Administration to temporarily approve the supply of unevaluated drugs for use in Australia in limited circumstances. This covers situations where there is a shortage of a registered drug in the Australian market, or where a registered drug ceases to be available and there is no other equivalent registered product, in which case the unevaluated substitute may be temporarily approved for general marketing, providing an application to market that product in Australia has been lodged, or alternatively the product has been approved for general marketing in a country specified by the Secretary in a disallowable instrument. Where a new drug not available in Australia is required for use in the interests of the public, the designated persons described above may give temporary approval for its supply here if the sponsor of the new drug has lodged an application to register the drug in Australia;

(c) establish a new procedure for listing on the Australian Register of Therapeutic Goods drugs that are supplied for use in Australia. These are simple over-the-counter drugs including herbal and vitamin preparations suitable for self treatment of minor medical conditions. The new procedure will require the Secretary to give marketing approval for such drugs where the sponsor of those products certifies a list of matters that relate to the safety and quality of the goods, and the sponsor is able to meet certain conditions relating to the acceptability of manufacturing processes involved in the production of an imported drug product. In the event that sponsors wrongly certify any of the matters required to be certified, the Register listing will be cancelled, with the product subsequently being able to be removed from the market;

(d) to require sponsors of goods that have been unlawfully supplied to inform the public that it was wrongly supplied and/or require the sponsor to take steps to recover any of the goods that have already been distributed;

(e) establish a new Therapeutic Goods Administration Reserve to replace the Therapeutic Goods Administration Trust Account that will be abolished by the *Audit (Transitional and Miscellaneous) Amendment Act 1995*. Trust Accounts are to be replaced with a Reserved Money Fund that is to form part of the new financial arrangements to be established under legislation that will replace the present *Audit Act 1901*;

(f) clarify the offences provisions under the Act and introduce new offences that correspond to the temporary supply of unevaluated drugs and the accelerated listing procedure for listable drugs supplied in Australia. Changes have been made to terminology used in describing penalties or offences to bring these in line with recent Commonwealth legislation;

(g) streamline and update the search and seizure powers and provisions relating to warrants to bring it in line with recent Commonwealth policy following recommendations made by the Gibbs Review and as provided for under the *Crimes (Search Warrants and Powers of Arrest) Amendment Act 1994*;

(h) amend the procedures for reviewing decisions relating to the registration of therapeutic goods in the Australian Register of Therapeutic Goods. The amendment will ensure that any new technical or scientific data lodged by an applicant during review will first be subjected to expert evaluation before a decision on general marketing, based on merit, is made by the Administrative Appeals Tribunal.

FINANCIAL IMPACT STATEMENT

The amendments to the *Therapeutic Goods Act 1989* will have no significant financial impact.

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NOTES ON CLAUSES

Clause 1 - Short title

This is a formal provision that specifies the short title of the Act as the *Therapeutic Goods Amendment Act 1995*.

Clause 2 - Commencement

This clause provides that, with the exception of the matters dealt with in subclause (2), the provisions of the Act will commence on the day on which it receives Royal Assent, with the remainder taking effect as outlined in subclause (2).

Clause 3 - Schedules

This is a formal provision that specifies that the Acts and other items in the Schedule are amended or have effect as set out in the Schedule.

THE SCHEDULE

Item 1 - Subsection 3(1) (paragraph (b) of the definition of "authorised person")

This is a consequential amendment that inserts the correct reference to the relevant Part of the *Therapeutic Goods Act 1989* ("the Act") under which a member of the Australian Federal Police may exercise search and related powers to secure compliance with the Act. The relevant Part is now Part 5A, rather that Part 6.

Item 2 - Subsection 3(1) inserts a definition for "food". The definition of "therapeutic goods" excludes "food". "Food" will refer to goods, including additives or goods approved for use or standardised under the Food Standards Code, taken orally that have a principal use, in the form in which they are presented, as something that provides nutrition or hydration, or that is taken to satisfy hunger or thirst or a desire for taste, flavour or texture, and for which there is no dosage regimen, except where the dosage is a requirement under the Food Standards Code or where it is permitted under that Code.

The reference to "prescribed dose" and "frequency of administration" are terms used in a pharmaceutical sense, and are not intended to encompass serving suggestions applied to or normally associated with food and beverages.

Item 3 - Section 3 adds two new subsections that give instructions on the interpretation of the Act.

New subsection 3(7) provides that where in the Act there is any reference to "an offence against this Act", the phrase is intended to also include a reference to offences against any regulations made pursuant to the Act. In addition, the offences of aiding, abetting and inciting the commission of offences will also be included with each of the offences under both the Act or Regulations.

New subsection 3(8) states that the penalties applying to each section or subsection, as the case may be, represents the maximum penalty that may be applied against the offender. The penalty represents the penalty applicable to individuals. For corporate offenders, the amount is multiplied five times.

Items 4, 5, 6 and 7 - Subsections 8(2), 8(3), 14(1), 14(3) and 15(2) replace the present description of penalties, expressed in currency, with equivalent "penalty units" consistent with terminology used in other Commonwealth legislation. Each penalty unit is equivalent to $100. The penalties have not been changed, merely the way in which they are now described. In subsection 8(3) the adverb "knowingly" is replaced with "intentionally", consistent with terminology used for offences in other Commonwealth legislation.

Item 8 - Subsection 19(1) does not make any change other than to make it clear that the reference to "goods included in the Register" means registered or listed goods.

Item 9 inserts new **Section 19A**. The section sets out the circumstances under which the Secretary may grant temporary approval for an unapproved drug to be marketed to the general public, as distinct from the supply of unapproved drugs to individual patients permitted under section 19 of the Act. The circumstances are confined to the following situations.

New subsection 19A(1) provides that, where there is a shortage within Australia of particular registered drugs, or such drugs are no longer available, and there is an unregistered substitute for those drugs for which an application for general marketing has been lodged under part 3 of the Act or, alternatively, where there is no such application but the same substitute drugs have been approved for general marketing within another country specified in a disallowable Determination made by the Secretary, then the Secretary may approve the temporary marketing of the substitute drugs. Where there is no substitute registered drug on the Australian market, an unregistered drug may still be granted temporary approval where an application to register that drug has been lodged under section 23 of the Act. The Secretary may only give an approval under this provision in respect of drugs specified in Schedule 10 of the Therapeutic Goods Regulations, which are, in the main, new chemical entities or prescription drugs, or in respect of drugs specified by the Secretary in a disallowable Determination.

In making decisions under new section 19A, the Secretary must only consider the public interest in permitting unregistered drugs to be made available on a temporary basis, and not the commercial interests of the applicant seeking to market the drugs. When an approval is given under this section, the Secretary may impose conditions, and may set a time limit for the approval.

New subsections 19A(7) and (8) provide that the approval lapses where the time limit, if any, specified in the approval expires, or a decision is made on whether the drug may be registered, or any of the prerequisites giving rise to the temporary approval no longer exists or a condition of the approval has been breached. New subsection 19A(9) provides that where an approval lapses, this does not preclude the same drug being granted a fresh approval for temporary marketing where the conditions under section 19A can be met.

Item 10: Subsections 20(1) and (2).

Offences under subsection 20(1) of the Act apply only to sponsors. Sponsors can be broadly described as principal importers, exporters and manufacturers, and the definition of "sponsor" does not extend to include those who act on behalf of the principals, except where the principals operate offshore. Currently, in proceedings under this provision, to establish that a person is a sponsor the Crown is required to show, among other things, that there is no agency arrangement. However it is not possible to establish something that does not exist and a fact that is within the knowledge of the sponsor.

The effect of the changes made by Item 10 will be to require a "sponsor" in such a situation to establish that there was an agency arrangement, and that therefore the person did not act as a principal in unlawfully importing, exporting or manufacturing therapeutic goods.

The principal/agent relationship, particularly in cases not involving major corporations, can only be ascertained conclusively through confidential commercial arrangements known only to the parties concerned, to which the Commonwealth is not privy and often precluded from discovery for the purposes of establishing who committed an offence under section 20. Until the identity of the sponsor can be established, it is not possible to lay charges under section 20 of the Act so as to effectively preclude the exportation, importation, supply and use within Australia of unapproved therapeutic goods, including counterfeit drugs.

No change has been made to the nature of the offences under section 20, which apply only to "sponsors", as defined in subsection 3(1) of the Act.

Item 11 - Section 21

This amendment merely replaces the adverb "knowingly" with "intentionally" and redescribes the penalty by reference to penalty units, rather than currency. The penalty has not been altered.

Item 12 - Paragraph 21(b)

This is a consequential amendment, to accommodate new section 19A. The exceptions to the offence set out under section 21, relating to the wholesale supply of therapeutic goods that have not been registered or listed in the Register, have been extended to include goods that have been temporarily approved for marketing under new section 19A. It will not be an offence for wholesalers to supply such drugs.

Item 13 - Subsections 22(1), (2), (3), (4), (5), (6),and (7)

To accord with the practice adopted in other Commonwealth legislation in placing penalty provisions at the end of each subsection rather than at the end of a section that is divided into subsections, the existing penalty has been repeated for each of the offences set out under section 22 of the Act. Also, in these subsections the adverb "knowingly" has been replaced with "intentionally" to accord with terminology used in other Commonwealth legislation in connection with offences.

Item 14 - Paragraph 22(4)(c)

A new offence has also been included in subsection 22(4) to provide that it will be an offence for a person to represent that goods have been approved for supply under sections 19 and 19A when in fact they have not. This offence is in line with the present offence in paragraph 22(4)(b) relating to the unlawful supply of therapeutic goods by misrepresenting that such goods were not required to be approved for marketing when in fact they were.

Items 15, 16 and 17 - Subsections 22(7), 22(7A) and 22(8)

Subsections 22(7) and 22(8) are consequential amendments to accommodate new section 19A. At present, where an approval is granted for the import, export or supply of therapeutic goods that have not been evaluated or assessed under Part 3 of the Act, conditions for the supply of such products may be imposed. The effect of these two subsections is to make it clear that it is an offence not to comply with these conditions, whether they have been imposed pursuant to section 19 or new section 19A. Subsection 22(7A) replaces the currency description of the penalty with its equivalent "penalty units".

Item 18 - Section 22A replaces the adverb "knowingly" with "intentionally", and redescribes the existing penalty by reference to "penalty units".

Item 19 - Paragraph 26(1)(ba) makes it clear that listable drugs that are processed under new section 26A for the purposes of determining whether they may be included in the Register cannot be processed under this section.

Item 20 - Paragraph 26(1)(j)

This Item corrects an anomaly in paragraph 26(1)(j) of the Act, relating to the requirements for listing goods in the Register. Under this paragraph the Secretary may still list a product in the Australian Register of Therapeutic Goods even if it would not be approved for supply within Australia, providing the product was manufactured for export

only. However, before the Secretary decides whether or not to list goods intended solely for export, he may require "confirmation" that the relevant authority of the country to which the export-only product is destined has indicated its willingness to accept the goods.

At present, paragraph 26(1)(j) is confined to goods that "have been manufactured in Australia", and does not extend to include goods imported into Australia that are destined for re-export. Many companies use Australia as the distribution point for therapeutic goods not manufactured in this country but intended for supply in overseas markets in this region. The proposed amendment to paragraph 26(1)(j) is intended to ensure that before such goods are listed in the Register, the criteria for listing goods under paragraph 26(1)(j) currently applying to goods manufactured in Australia solely for export, will apply equally to goods imported into Australia solely for export.

Item 21 inserts new **section 26A**. This new clause establishes a new procedure for listing certain drugs. The new procedure applies only to "listable drugs", these mainly being simple over-the counter drugs and herbal or vitamin preparations that are described in Schedule 4 of the Therapeutic Goods Regulations. Where such listable drugs are supplied for use in Australia, then the procedure set out in section 26A applies. Listable drugs that are exported from Australia must still be processed under section 26 of the Act, along with listable therapeutic devices.

The new procedure permits an accelerated listing process under which marketing approval must be given to sponsors of listable drugs supplied for use in Australia provided that the conditions stipulated in section 26A have been met and the applicant certifies certain matters relating to the product for which marketing approval is being sought and lodges documentation and data, in accordance with the requirements of a section 23 application, to support the matters certified. Thus the applicant must certify, among other things, that the goods come within the category of listable therapeutic goods, that the goods are safe for the purposes for which they will be used, that the presentation of the goods is acceptable for the purposes of the Act, that the goods comply with any applicable standard as well as the advertising restrictions or requirements prescribed by the Therapeutic Goods Regulations and the drugs do not contain goods that are prohibited imports for the purposes of the Customs (Prohibited Imports) Regulations. The matters required to be certified by the applicant are set out under new subsection 26A(2).

New subsection 26A(3) provides that where any step in the manufacture of the listable drug occurred overseas, the Secretary must have certified prior to an application being made to list drugs under this section, that each step of manufacture that occurred overseas meets acceptable manufacturing and quality control procedures. To establish this, new subsection 26A(4) provides that consideration may be given to, among other things, whether the applicant can produce acceptable evidence to establish that the relevant overseas regulatory authority considered the manufacturing processes to be of an acceptable standard, and whether the applicant has agreed to provide, where the Secretary considers this to be necessary, funds for carrying out an audit of the overseas manufacturing procedures together with evidence that the overseas manufacturer has agreed to such an inspection.

Where the applicant is able to certify all the matters required to be certified under new section 26A and has met all the conditions contained in this section, the Secretary must list the product in the Register. Where the Secretary should subsequently establish that information certified by the applicant is incorrect, then under new paragraph 30(1)(e) of the Act this will be one of the grounds upon which the goods may be removed from the Register, and the applicant precluded from continuing to market the goods within Australia.

New subsections 26A(5),(6) and (7) provide that where certain goods or ingredients have been exempted under Part 4 of the Act from the requirement to comply with acceptable manufacturing standards, then the applicant seeking the listing of those goods or ingredients under s.26A need not certify that those goods have complied with manufacturing requirements.

New subsections 26A(8) and (9) provide that, within 28 days of making a decision whether or not to list the applicant's products under section 26A of the Act, the Secretary must notify the applicant of his or her decision and where a decision to refuse listing is made, the Secretary is to give reasons for the refusal. As soon as practicable after a notification that goods have been accepted for listing, the Secretary must give the applicant a certificate of listing of the goods, and the listing of the goods commences from the day specified in that certificate.

Items 22 and 23 - Subsections 29A(1) and 29B(3) substitute the currency value of the penalty with equivalent "penalty units".

Items 24 and 29 - Subsections 29B(4) and 30(7) replace the adverb "knowingly" with "intentionally" in line with the same change made to other offences provisions in this amending Act. Again, the currency value of penalties under both provisions have been replaced with equivalent "penalty units".

Items 25 and 26 - Paragraphs 30(1)(e) and **30(2)(ba)** inserts a new circumstance under which the Secretary may remove particular therapeutic goods from the Australian Register of Therapeutic Goods to preclude further marketing of those goods. The new circumstance is where, under the accelerated listing procedure established under new section 26A of the Act, it appears to the Secretary that any of the matters certified by the applicant under that provision is incorrect.

If the falsely certified matter relates to whether or not:

- the goods were eligible for listing;
- the manufacture of the goods was carried out by a licensed manufacturer;
- the goods contain prohibited imports; or

if the sponsor failed to obtain a certificate from the Secretary certifying that the manufacture of any imported drug or ingredient was acceptable, then the goods may be delisted immediately. As the listing of therapeutic goods under section 26A is based almost entirely upon the statements and assertions made by the applicant, it is appropriate that if any of the facts relating to safety required to be certified by the sponsor proves to

be untrue a mechanism exists to immediately remove the product from the market. In all other cases of false certifications, the sponsor of the listed goods will have the opportunity to explain these before any decision is made to delist the sponsor's product.

Items 27 and 28 - Paragraph 30(6)(a) and Subparagraph 30(6)(a)(i) make it clear that, where goods have been removed from the Register, the Secretary has the option of requiring the sponsor of the cancelled goods to either make this cancellation known to the public or a specified class of persons, or take steps to recall the cancelled products, or undertake both actions.

Item 30 inserts new **section 30A**. This section closes a gap in the Act. At present, where therapeutic goods have been removed from the Register under section 30 of the Act the Secretary may take action to have the cancelled goods recovered to prevent their further supply. However, where unapproved therapeutic goods are unlawfully marketed there is no equivalent power for the Secretary to have those products removed from the market place. New subsection 30A(2) provides the Secretary with the power to require sponsors to take steps to recover their unlawfully supplied goods, and/or require them to inform the public (or a particular group of persons) that the goods were unlawfully marketed. Where the Secretary takes such action, subsection 30A(3) requires him or her to publish in the Commonwealth Gazette details of the action taken. Failure to comply with the Secretary's powers under this section incurs a maximum penalty of $6,000, or $30,000 for a corporation.

Items 31 and 32 - Subsections 31(4) and (5) The currency value of the existing penalties under both subsections have been replaced with their equivalent "penalty units", and in subsection 31(5) the word "knowingly" has been replaced with "intentionally" in line with current legal terminology.

Items 33 and 34 - Subsection 32(1) and Subsection 32(2). Subsection 32(1) presently enables a person in relation to whom therapeutic goods have been included in the Register to request a copy of the entry relating to those goods. The amendments effected through subsections 32(1) and (2) clarify that the copy that may be supplied to the person is a copy of the entry contained in the computer database of the Register, rather than any other part of the Register. The computer database contains the essential information concerning the goods and the person in relation to whom those goods are registered or listed.

Item 35 - Subsection 32(2A) makes it clear that the "person" referred to under that provision is the person referred to in subsection 32(1).

Items 36 and 37 - Subsections 35(1) and (2) effect changes to replace the word "knowingly" with "intentionally" in line with current legal terminology and the currency value of the existing penalties under both subsections have been replaced with their equivalent "penalty units".

Item 38 - Subsection 35(3) translates the currency value of the penalty to its equivalent "penalty units".

Item 39 - New **Section 45** creates a Therapeutic Goods Administration Reserve, which will replace the present Therapeutic Goods Administration Trust Account. This will coincide with proposed changes to be effected by the new legislation package that will replace the *Audit Act 1901*, under which many Commonwealth trust accounts have been established.

New section 45 also allows the annual appropriation of funds from the Consolidated Revenue Fund to the Therapeutic Goods Administration Reserve. These funds represent any monies appropriated by Parliament for the purposes of the Reserve together with fees and charges collected by the Therapeutic Goods Administration ("the TGA"). These include statutory fees and charges payable to the TGA under the *Therapeutic Goods Act 1989* and the *Therapeutic Goods (Charges) Act 1989*. Also included are amounts equal to debts owing to the TGA, donations to TGA for the furtherance of a purpose of the Reserve, amounts equal to money received for services performed or to be performed by the TGA or for monies received in relation to dealings with, including the sale or lease of, TGA property paid for out of the TGA Reserve, and interest earned from TGA's investment of money from the TGA Reserve. The purposes of the TGA Reserve are to further the objects of the Act, including matters incidental to the furtherance of those objects, and to enable the Commonwealth to participate in the international harmonisation of the regulatory controls on therapeutic goods and related activities. New subsection 45(3) provides for the transfer of monies standing to the credit of the TGA Trust Account to the new Reserve set up under this section.

Item 40 inserts a new heading: "Part 5A - ENTRY, SEARCHES AND WARRANTS" into the Act.

Item 41 Repeals sections 46 and 47, and replaces them with comparable provisions, along with other provisions described below. The new sections inserted by **Item 41** are **sections 45A, 46, 46A, 46B and 47.**

Section 45A inserts new definitions, which are self explanatory, for the purposes of interpreting new Part 5A of the Act, which deals with search and seizure powers and prosecution matters.

Section 46 has been replaced with an equivalent provision, however the revised section 46 makes it clear that searches to monitor compliance with the Act precludes an authorised officer from seizing anything in the course of undertaking a search. Unless the authorised person produces his or her identity card for inspection by the occupier of the premises where the occupier has requested such production, the authorised person may not enter premises nor exercise any of the powers described in section 48 of the Act.

New section 46A draws together the powers of an authorised person to enter the premises of licensed manufacturers and sponsors of registered or listed goods for the purpose of monitoring compliance with the Act. Subsections 28(5) and 40(4) of the Act respectively impose a condition upon every sponsor of registered/listed therapeutic goods or every licensed manufacturer to permit an authorised person to enter their premises and exercise powers for the purposes of monitoring compliance with the Act.

Under subsection 46A(1), the powers an authorised person may exercise include searching premises or any thing in those premises, inspecting, examining and conducting tests concerning any thing on the premises that relates to therapeutic goods, taking samples for testing, taking photographs of or making other records of the premises or any thing on the premises, inspecting documentation or records on the premises and taking or making copies of such documentation or records. These powers may not be exercised in relation to premises used solely for residential purposes unless with the consent of the occupier. In addition, subsection 46A(3) provides that unless an authorised person produces his or her identity card when asked to do so by the occupier of premises, the authorised person cannot exercise any of the powers listed under subsection 46A(1).

To achieve consistency, the powers of an authorised person to enter premises and exercise powers described in subsection 46A(1) will be extended to include premises occupied by persons to whom permission to supply unapproved therapeutic goods have been granted under sections 19 and new 19A (subsection 46A(4)). This will enable the proper monitoring of persons who have been granted approval for the conditional supply of therapeutic goods that have not been evaluated or scrutinised by the Therapeutic Goods Administration but that have been permitted to be supplied under special circumstances.

Section 46B enables an authorised person to enter premises and exercise powers under this provision without a warrant where he or she has reasonable grounds for believing that there is something in those premises that contravenes the Act and that it would be necessary in the interests of public health for the authorised person to search for and seize the thing to avoid an imminent risk of death, serious illness or serious injury. Unless an authorised person produces his or her identity card when asked to do so by the occupier of premises, the authorised person cannot exercise any of the powers listed under subsection 46B(1).

Section 47 replaces the existing section 47 to clarify the powers of the authorised person who enters and conducts searches of premises to obtain evidence of a commission of an offence, and the circumstances under which those powers may be exercised. These powers have been brought into line with present criminal law provisions as set out in the *Crimes (Search Warrants and Powers of Arrest) Act 1994.*

For the purposes of securing particular relevant evidence, subsection 47(1) enables an authorised person to enter any premises where he or she has reasonable grounds for believing that the premises might contain that evidence, or that thing, that could establish whether or not an offence may have been committed against the Act or Regulations. Subsections 47(2) and (3) provide that an authorised person may only enter premises with the permission of the occupier of those premises, or under a warrant issued in accordance with section 50 of the Act. Providing a lawful entry has been made, the authorised person may seize the particular evidence he or she believed was on the premises and subsequently found, and exercise the powers listed under section 48(1) of the Act.

If, in the course of searching premises for a particular thing, something else is found that the authorised person reasonably believes would be relevant to an offence against the Act, that other evidence or thing may also be seized if the authorised person reasonably believes that a failure to do so may result in the loss, destruction or concealment of that evidence or else the thing could be used for the commission, continuation or repetition of a commission of an offence against the Act.

Item 42 - Subsections 48(1) and (2) replace existing subsections 48(1) and (2) by updating the search and seizure powers to bring it in line with comparable provisions in other recent Commonwealth legislation. The powers relate to and include the search of premises and things found on premises, the inspection, examination and testing of things on premises relating to therapeutic goods, the taking of photographs, or other forms of recordings, of premises and things, inspection and copying of records and any other documentation and other powers.

Item 43 - Subsection 48(3) translates the currency value of the penalty to its equivalent "penalty units".

Item 44 inserts new **Sections 48A, 48B, 48C, 48D, 48E, 48F, 48G, 48H & 48J.**

Section 48A provides that if a warrant in relation to premises is being executed, a copy of the warrant must be made available to the occupier of the premises. The authorised person responsible for the execution of the warrant must identify himself or herself. In order to prevent forgery or other wrongful use of the warrant copy, subsection 48A(3) provides that the copy need not include the signature of the Magistrate who issued the warrant.

Section 48B provides that before any authorised person enters premises under a search warrant he or she must announce that he or she is authorised to enter and give any person at the premises an opportunity to allow entry to the premises, unless there are reasonable grounds to believe that immediate entry to the premises is required to ensure the safety of a person or that the effective execution of the search warrant is not frustrated.

Subsection 48C(1) provides that the authorised person may operate equipment at the premises to see whether the evidential material is accessible or he or she believes that the equipment may be operated without damaging it. Subsection 48C(2) provides that, if evidential material is accessible, the authorised person may seize the equipment or any disk, tape or other associated device, or operate the equipment to obtain a print out and seize documents produced, or copy the records to another storage device and remove it from the premises.

Subsection 48C(3) is intended to encourage the seizure of printouts or duplicate discs wherever possible. It provides that an authorised person may seize equipment under subsection (2) only if it is not practicable to put the material into documentary form or copy them to a storage device or if possession by the occupier of the equipment could constitute an offence. Where original material is seized, section 48E requires the authorised person to provide a copy of the thing or information to the occupier unless its possession constitutes an offence.

Subsection 48C(4) provides that the authorised person may secure the equipment by locking it up or guarding it if he or she believes on reasonable grounds that the evidential material may be accessible by operating the equipment at the premises but expert assistance is needed to operate the equipment and the evidential material may be destroyed or otherwise interfered with if the equipment is not secured in the meantime. This is necessary to ensure that where the equipment is more sophisticated than expected and cannot be accessed or moved, then the opportunity to obtain expert assistance and to preserve evidential material is not lost. Material accessible on a computer can of course be removed with a swift keystroke from an operator. It is possible to preprogram the equipment to erase the evidence in this way.

Subsection 48C(5) requires the giving of notice to the occupier in cases where equipment may be secured for a period not exceeding 24 hours.

Subsection 48C(6) allows the equipment to be secured for either 24 hours or such lesser period when expert assistance is obtained to operate the equipment for the purposes of this Part.

Subsection 48C(7) allows an authorised person to apply to a magistrate for an extension of the time needed for securing the equipment if he or she believes on reasonable grounds that the expert assistance will not be available within the 24 hour period. The application must satisfy the criteria in subsection 48C(4). The occupier must be given notice under subsection 48C(8) and has a right to be heard in relation to the application.

Section 48D provides that if damage is caused to equipment as a result of it being operated as mentioned in s.48C and the damage resulted from insufficient care being exercised either in selecting the person to operate the equipment or by the person operating it, compensation is payable to the owner.

Compensation is payable out of a special Appropriation by the Parliament not from the Therapeutic Goods Administration Reserve. In determining the amount payable, regard is to be had to whether the occupier had provided any warning or guidance to the operation of the equipment. This is to minimise compensation in cases where there has been a deliberate programming of software to destroy or cause damage if not accessed in a particular manner or where the occupier failed to mitigate damage by providing warning or guidance.

Subsection 48E requires an authorised person, on request, to give a copy of a thing or information seized that can be readily copied. This does not apply if no original material was seized under paragraphs 48C(2)(b) or (c) or if possession of the thing seized could constitute an offence.

Section 48F provides that occupiers or their representatives may choose to observe the searching of the premises providing they do not impede the conduct of the search in any way. The right to search does not preclude authorised persons from searching 2 or more areas of the premises at the same time.

Section 48G provides that receipts are to be issued to occupiers for things seized. Under this provision it will be possible for the items to be listed on the same receipt. It is not envisaged that authorised persons would be required to identify absolutely every item individually where those items can be adequately identified by a class description.

Section 48H prescribes when things seized under Part 5A of the Act must be returned. Unless a court has ordered otherwise, the seized thing must be returned where the reason for its seizure no longer exists, where it is forfeited or forfeitable to the Commonwealth, or where it will not be used as evidence or after 90 days have expired from the day it was seized, unless proceedings in which the seized thing will be used have been brought against an offender within the 90 day limit and the proceedings have not finished, or an extension of time for the retention of the seized thing has been granted by a Magistrate, or the authorised person is otherwise entitled to keep the thing beyond 90 days or to destroy or dispose of it pursuant to some law or court order. Where the seized thing is returned, it may be returned on such terms and conditions as the Secretary sees fit.

Section 48J prescribes how an authorised person may apply to a Magistrate to retain a seized thing or evidence beyond the 90 day retention period permitted under section 48H of the Act. Subsection 48J(2) provides that if the Magistrate is satisfied that it is necessary for an extension of time to be granted to enable the authorised person to investigate whether or not an offence has been committed against the Act or to enable the evidence to be secured for the purposes of a prosecution, the Magistrate may grant an extension for such period as is specified in an order. Before making an application under this section, an authorised person must take reasonable steps to establish who has an interest in the retention of the seized goods and, if practicable, notify such persons.

Item 45 - Subsection 49(2) is amended to enable a Magistrate to issue a warrant under section 49 that permits more than one authorised person to enter the same premises for the purposes of establishing whether the Act and Regulations have been complied with.

Item 46 - Paragraph 49(4)(a) is amended to reflect the change made to subsection 49(2) of the Act, to refer to more than one authorised person permitted to enter premises to establish compliance with the Act.

Item 47 - Subsection 50(2) redescribes evidence with the description "evidential material", as defined in section 45A.

Items 48 and 49 - Paragraph 50(4)(a) has been amended to make it quite clear that a Magistrate can issue a warrant under this section that permits more than one authorised person to enter the same premises for the purpose of obtaining evidence or a thing relating to a commission of an offence against the Act or Regulations. Consequently, **paragraph 50(4)(b)** has been amended to reflect this amendment - **ITEM 49.**

Items 50 and 51 - Subparagraphs 50(4)(b)(ii) & (iii) are further consequential amendments, the first to make correct references to those provisions that contain the powers that may be exercised by authorised persons, the second to replace the reference to "evidence" with "thing", consistent with terminology used in amended section 47.

Items 52, 53 and 54 - the changes made to **subparagraph 51(5)(a)(ii) & paragraph 51(5)(b) & subsection 51(6)** merely clarify that the references to "persons" in those provisions refer to "authorised persons" as defined in section 3(1) of the Act.

Item 55 inserts new **Section 51B**. Section 51B creates an offence of knowingly making a false or misleading statement in an application for a warrant under this Part. The maximum penalty for this offence is imprisonment for 2 years. The section also creates offences arising from the preparation, and execution, of a form of warrant obtained by telephone under section 51. It is an offence for a person to name a person in a form of warrant as the Magistrate unless that Magistrate issued the warrant, or to knowingly state in a warrant something materially different from that authorised by the Magistrate. It is also an offence to purport to execute an unauthorised or false form of warrant or to give an issuing officer a form of warrant that is not the form that the person purported to execute. Offences under this section are punishable by imprisonment for up to 2 years.

Item 56 - Subsection 52(2) has been omitted because its contents have been moved to amended sections 46, 46A and 47 which contain the powers for entry and search. The provision requires an authorised person entering premises for the purposes of conducting searches or obtaining evidence to produce his or her identity card for inspection where requested to do so by the occupant of the premises.

Item 57 - Subsection 52(3) substitutes the description of the penalty, expressed in currency, with its equivalent "penalty units".

Item 58 inserts a new heading **"PART 6 - MISCELLANEOUS"**.

Item 59 - Subsections 54(1) & (2) has the effect of changing all the indictable offences under the Act and regulations into summary offences, except those offences described under sections 22A, 29A and 29B. These relate to the serious offences of sponsors failing to notify the Secretary of adverse effects of therapeutic goods where this is known to the sponsor of the goods, and of making false or misleading statements of a material nature when applying to register therapeutic goods.

Item 60 - Subsection 54(3) removes a qualifier in that provision which presently prevents goods the subject of a successful prosecution from being forfeited, where the prosecution was for an indictable offence. This amendment will enable therapeutic goods to be forfeited to the Commonwealth where they are subject of a successful prosecution in relation to either a summary or an indictable offence under the Act, not just the former.

Items 61 and 62 - Subsection 54(6), which prescribes a two year time limit for commencing prosecution for indictable offences, is repealed and replaced with a new **Section 54A** which provides that a prosecution for any offence against the Act must be commenced within three years after the commission of the offence.

Item 63 - omits **Subsection 55(9)** because its contents have been moved to new subsection 3(7), described above.

Item 64 inserts new **Section 56A**. This section permits the Secretary, or a person authorised to do so by the Secretary, to issue certificates containing statements of certain facts and, unless rebutted by the defendant, the facts contained in those certificates will be prima facie evidence of those matters for the purposes of proceedings brought under the Act in respect of the commission of offences against the Act or Regulations. The facts that may be asserted in the certificates are confined to those listed under paragraphs 56A(1)(a) to (l) inclusive.

The matters covered by paragraphs 56A(1)(a) to (l) relate to the making of certain statutory instruments under the Act or Regulations, or are facts that are published in the Government Gazette or are recorded in or can be ascertained from records maintained by the TGA including the Australian Register of Therapeutic Goods, which the Secretary is required to maintain pursuant to section 17 of the Act. These facts are that at a particular time or over a particular period:

* Particular therapeutic goods were not exempted from the requirement to be included in the Register;
* The Secretary did not give his or her approval under section 19 or section 19A of the Act to permit a person to supply particular unapproved therapeutic goods;
* Particular therapeutic goods were not registered or listed in the Australian Register of Therapeutic Goods;
* The inclusion of registered or listed goods in the Register were included subject to conditions, which include those described in the certificate;
* The listing or registration of particular goods was cancelled;
* No declaration under section 7 was made by the Secretary declaring that particular goods are, or are not, therapeutic goods;
* A person was a holder of a manufacturing licence issued under Part 4 of the Act;
* The conditions applying to a particular manufacturing licence;
* No exemption was effected under section 34(1) of the Act to exempt particular goods or a class of goods from the requirement to be manufactured under licence;
* No other exemption applies or applied to exempt a particular manufacturer from the requirement to obtain a relevant licence in accordance with Part 4 of the Act.

Under subsection 56A(2),a certificate may certify more than one of the matters listed in paragraphs 56A(1)(a) to (l) inclusive.

New subsection 56A(4) provides that where proceedings are brought under section 14 of the Act against a person that has exported from, imported into or supplied for use in Australia therapeutic goods, being goods that do not comply with relevant standards, the Secretary may issue a certificate to the effect that he or she has not consented, or has consented, to the exportation, importation or supply of the goods that are the subject of those proceedings. The certificate is prima facie evidence of those matters.

New subsection 56A(5) provides that where a proceeding for an offence against the Act or Regulations is brought, a document purporting to be a certificate issued under section 56A is to be taken to be such a certificate unless proven otherwise.

Items 65 and 67 - Subsections 57(1) and 57(7) provide for an additional qualifier to the general power of the Secretary to delegate his powers to any officer in the Department. This qualifier, set out in subsection 57(8), applies to the exercise of powers under new section 19A to grant temporary approval for the general marketing of certain registrable drugs (being those included in Schedule 10 of the Therapeutic Goods Regulations or such drugs as may be included in a disallowable Determination made by the Secretary) that have not been evaluated and registered. This power may only be delegated to the National Manager of the Therapeutic Goods Administration or the Director of Drug Safety and Evaluation Branch, or both.

Item 66 - Paragraph 57(4)(b) replaces the incorrect word "aurthorised" with the correct "authorised".

Items 68, 69 and 70 - Subsections 60(1), (3) & (4) include consequential amendments that make reference to the changes made by new section 60A described below, relating to appeals by applicants of decisions made under section 25 of the Act in respect of the registration of therapeutic goods.

Item 71 - new **Section 60A** applies to appeals made against decisions of the Secretary under section 25 of the Act. These concern decisions to register or not register therapeutic goods in the Australian Register of Therapeutic Goods.

New section 60A qualifies the way in which appeals against decisions made under section 25 of the Act are to be dealt with. Under section 25 registrable therapeutic goods must undergo rigorous scrutiny for the purposes of establishing whether they may be approved for general marketing. The decision to approve rests with the Secretary, following a long process of evaluation involving expert advice drawn from numerous disciplines including a specialist committee set up under the Therapeutic Goods Regulations to make recommendations concerning this matter.

New section 60A applies to circumstances where the Secretary makes a decision under section 25 and an aggrieved party affected by the decision lodges an appeal, together with new information to support that appeal, with the Minister under section 60 of the Act. The Minister must, for the purposes of review, either take into account any new material lodged by the applicant for review where the Minister or his delegate is capable of processing that material, or else remit the matter to a person who has been delegated powers to make decisions under section 25 of the Act, so that the new information may be properly evaluated by relevant experts. "New material", in relation to the product the subject of a review, refers to relevant information that came into existence before a decision was made under section 25 of the Act and that had not been evaluated under that section by the Secretary. Where new material is presented before the Administrative Appeals Tribunal ("the Tribunal") on appeal from the Minister's decision under this section, the Tribunal is precluded from considering any new material unless this was taken into account by the Minister under subsection 60A(2). Where the Tribunal is precluded from considering the new material, it may remit the new material to a person who has been delegated powers to make decisions under section 25 of the Act.

Where the Minister or the Tribunal remits to a person who has been delegated powers to make decisions under section 25 of the Act new material for reconsideration, the delegate must make a decision pursuant to that provision as though the applicant had made a fresh application, providing the applicant has paid the appropriate evaluation fees that an applicant under section 24 of the Act would have been required to pay. The decision of a delegate under this section is reviewable under sections 60 and 60A of the Act.

The effect of this amendment is to encourage sponsors applying for general marketing of therapeutic goods to lodge all relevant material with the Secretary so that the vigorous evaluation process employed in processing the product may be conducted properly in respect of all material sought to be relied upon by the applicant, and that when review of a decision is undertaken by the Administrative Appeals Tribunal any technical and scientific data not previously evaluated by the Secretary would first undergo proper evaluation before the matter is considered by the Tribunal and a decision on merits is made.

Item 72 - Paragraph 63(2)(j) substitutes the currency description of the penalty with its equivalent "penalty units".

Item 73 - Savings provision ensures that Regulations already made in respect of the previous paragraph 20(2)(d) before its replacement under **Item 10** with equivalent paragraph 20(2)(a) will continue to operate as though it were made under new paragraph 20(2)(a).