Therapeutic Goods (Western Australia) Bill 2000

Explanatory Memorandum

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on behalf of

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THERAPEUTIC GOODS (WESTERN AUSTRALIA) BILL 2000

LONG TITLE

The Therapeutic Goods (Western Australia) Bill 2000 ("the Bill") is a Bill for:

> "An act to promote and facilitate the development of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods, and for that purpose to make provision in Western Australia for the implementation of controls forming part of such a system complementary, and additional, to the provision made by the *Therapeutic Goods Act 1989* of the Commonwealth."

BACKGROUND AND PURPOSE

The purpose of the Bill is to facilitate the development of a comprehensive national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods by implementing a State-based system which will complement the Commonwealth Act and allow for the implementation of controls specifically required by Western Australia.

The Commonwealth Act provides for the following main controls over therapeutic goods:

- a system for the licensing of manufacturers of therapeutic goods;
- a requirement that all therapeutic goods be included in the Australian Register of Therapeutic Goods which is maintained by the Commonwealth's Therapeutic Goods Administration; and
- requirements that standards be met in relation to such things as quality, labelling, packaging and advertising of therapeutic goods.

Due to constitutional limitations, the Commonwealth's controls do not extend to persons other than corporations (ie 'natural' persons) who operate only within an individual State or Territory. Agreement was therefore reached that all States and Territories would introduce complementary legislation to extend the system of controls put in place by the Commonwealth Act to persons in their respective States and Territories who were not otherwise covered by the Commonwealth Act.

The Bill has used the approach adopted by Victoria in their Therapeutic Goods (Victoria) Act 1994 whereby the scheme of controls created by the Commonwealth Act is replicated in "mirror" legislation which is enacted by the State Parliament. This approach was adopted in preference to the approach which was taken in New South Wales of making the Commonwealth provisions directly applicable to Western Australia.

Under the Commonwealth Act and the Bill, the term "therapeutic goods" is given a broad meaning. It encompasses any product or device which is used therapeutically, or which is represented to be, or intended for, therapeutic use. Items covered by the term range from high technology medical equipment (such as medical imaging equipment) through to simple surgical dressings, over-the-counter pharmaceutical products and complementary medicines.

A consistent and comprehensive approach to the regulation of therapeutic goods therefore requires that complementary State and Territory legislation be enacted to apply national consistent controls to all therapeutic goods.

OVERVIEW OF MAIN PROVISIONS

The Bill applies the following main controls in relation to therapeutic goods which are manufactured or supplied by individuals and unincorporated bodies in Western Australia.

- Regulate manufacture by requiring any person who carries out a step in the manufacture of a therapeutic good to be licensed by the Therapeutic Goods Administration. The Bill will make it an offence for therapeutic goods to be manufactured other than under the authority of a licence issued by the TGA under Part 4 of the Bill (clause 48 refers);
- Require the goods to be registered or listed[1] on the Australian Register of Therapeutic Goods (ARTG) following assessment by the TGA, and make it an offence for therapeutic goods which are not registered or listed (or which are not otherwise exempted or approved under the Commonwealth Act or WA Bill) to be manufactured or supplied in Western Australia (clauses 15 and 16 of the Bill refer);
- Require conformity with standards specified under the Commonwealth Act (Part 2 of the Bill refers); and
- Require wholesale suppliers of therapeutic goods to comply with a "Wholesaling Code of Practice" published by the Commonwealth Government (Part 5 of the Bill refers). Wholesale suppliers of pharmaceutical products which are "poisons" are already required to comply with this Code under the Poisons Act 1964 (WA).

Part 7 of the Bill provides enforcement powers (including powers of entry under warrant, inspection, search and seizure) for persons who are authorised under the Bill by the Commissioner of Health, persons authorised under the Commonwealth Act, and members of the Western Australian Police Service and Australian Federal Police.

In addition, a number of controls in relation to therapeutic goods which are currently found in unproclaimed sections of the Health Act 1911 (WA) have been included in the Bill.

These are:

- Prohibition on hawking (ie mail order or door-to-door selling) of therapeutic goods except where authorised by the Commissioner of Health (clause 17);
- Prohibition on the supply of therapeutic goods by automatic machine, subject to regulations made under the Bill (clause 18);
- Prohibition on the supply of therapeutic goods after the expiry date, except as authorised by the Commissioner of Health (clause 20);
- Prohibition on the use of certain therapeutic devices, except as authorised by the Commissioner of Health (clause 21).

The Bill's transitional provisions provide that Western Australian manufacturers and suppliers (referred to as "sponsors" in the Bill) of therapeutic goods already on the market who do not already operate under a licence or whose products are not already registered or listed on the ARTG under the Commonwealth Act will have 4 months following commencement of the

[1] Registered products are generally those which are used in the treatment of more serious conditions or which require special care in their use (eg prescription medicines, pharmaceutical products). These products are assessed for safety, quality and efficacy. Listed products are assessed for safety and quality, but not for efficacy.

Bill to make application to obtain a manufacturer's licence under Part 4 of the Bill or to have their products registered or listed on the ARTG under Part 3 of the Bill, as the case may be.

The Bill's transitional provisions also provide that the application fees which would ordinarily be payable under the Bill to the TGA at the time that an application to register or list therapeutic goods is submitted to register or list a new therapeutic good will not be payable by the sponsors of existing therapeutic goods who make application during that 4 month period.

However, the Bill's transitional provisions provide that an evaluation fee will be payable if the TGA registers any such goods without evaluation, and later decides to conduct an evaluation to determine whether they should continue to be included in the ARTG.

CONCLUSION

The provisions of the Bill have been the subject of consultation with industry, industry associations, the Health Consumers' Council, Pharmaceutical Society, and Commonwealth, State and Territory governments. A formal public consultation process was completed in March 2000. The Bill has general support from all groups.

Notes on individual clauses in the Bill are also attached.

CLAUSE NOTES

PART 1 - PRELIMINARY

Clause 1 Provides for the mode of citation of the proposed *Act*.

Clause 2 Provides for the proposed *Act* to commence on a day to be fixed by proclamation.

Clause 3 Sets out the objects of the Bill.

Clause 4 (1) Defines various terms used in the Bill, including:

"therapeutic goods" which is defined to mean goods that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be for: (a) therapeutic use; (b) use as an ingredient or component in the manufacture of therapeutic goods; or (c) for use as a container or part of a container for either;

and to include goods which may be specifically declared to be therapeutic goods under the Commonwealth Act, but not include goods declared not to be therapeutic goods under the Commonwealth Act or the Bill, or foods.

"therapeutic use" which is defined to mean a use in or in connection with: (a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals; (b) influencing, inhibiting or modifying a physiological process in persons or animals; (c) testing the susceptibility of persons or animals to a disease or ailment; (d) influencing, controlling or preventing conception in persons; (e) testing for pregnancy in persons; or (f) the replacement or modification of parts of the anatomy in persons or animals.

"sponsor" which is defined to mean a person who, in WA, manufactures therapeutic goods, or arranges for another person to do so, for supply (whether in WA or elsewhere).

"manufacture" which is defined to mean to produce therapeutic goods or to engage in a process of producing such goods or bringing them to their final state, and to specifically include engaging in the processing, assembling, packaging, labelling, storage, sterilising, testing or releasing for supply of such goods or a component or ingredient of the goods as part of such a process.

"Register" which is defined to mean the Australian Register of Therapeutic Goods maintained under the Commonwealth Act.

"Secretary" which is defined to mean the Secretary to the Commonwealth Department of Aged Care. In practice, delegated powers are exercised by the Commonwealth Therapeutic Goods Administration.

"sponsor" which is defined to mean a person who, in Western Australia, manufactures (or arranges for the manufacture of) therapeutic goods for supply, but does not include any person who does those things on behalf of another person who is a resident of, or carrying on business in, Western Australia.

"therapeutic device" which is defined to mean therapeutic goods which consist of an instrument, apparatus, appliance, material or other article which does not achieve its principal intended action by pharmacological, chemical or immunological means (subject to any declaration under the Commonwealth Act that goods which would otherwise fall within the definition are not therapeutic devices).

"authorised person" which is defined to mean a person authorised by the Commissioner, a person authorised under a corresponding provision of the Commonwealth Act and in relation to Part 7 of the Bill (Entry, searches and warrants) a member of the Wa Police Force or the Australian Federal Police.

"Commonwealth Act" which is defined to mean the *Therapeutic Goods Act 1989* (Cth).

Clause 4 (2) Provides for the circumstances in which therapeutic goods are to be taken for the purposes of the Bill to be for use in animals and to be for use in humans.

Clause 4 (3) Specifies the circumstances generally in which the presentation of therapeutic goods is to be taken to be unacceptable (ie where that presentation is capable of being misleading or confusing as to the content or proper use of the goods), sets out particular cases in which such presentation is to be regarded as unacceptable (eg. falsely states presence of ingredients, fails to declare presence of therapeutically active ingredient, may lead to unsafe use etc) and includes within the scope of the subclause any further particular cases which may be prescribed under the regulations.

Note: Whether the presentation of therapeutic goods is acceptable is a factor relevant to the decision to register or list therapeutic goods in the Register.

Clause 4 (4) Provides for terms in the Bill to have the same meaning as they have in the Commonwealth Act, except where another meaning is specified or clearly intended.

Clause 4 (5) Confirms that notes in the Bill are only intended to assistance understanding and do not form part of the Bill (see for example the note at the foot of clause 30 (1) of the Bill).

Clause 5 Provides for the Bill to bind the Crown, but not to expose the Crown to liability for prosecution under the Bill.

Clause 6 Confirms that the Bill does not derogate from any existing, or future, State legislation which may apply to goods which are therapeutic goods under the Bill (eg. *Poisons Act*) unless specifically provided in that other legislation.

Clause 7 Provides for the certain persons to be authorised persons for the purposes of the Bill, namely: (a) any person authorised by the Commissioner of Health; and (b) any person who is an authorised person under the Commonwealth Act in relation to any provision of the Bill which corresponds to a provision of the Commonwealth Act in relation to which the person is an authorised person.

Note: The Bill provides for authorised persons to exercise various powers (eg. conduct searches etc to monitor compliance with the Bill).

Clause 8 (1)-(4) Allows the Secretary to grant an approval to a person (subject to any conditions which may be imposed) to supply therapeutic goods although they are neither exempt or included in the Register: (a) for use in the treatment of another person; or (b) for use for experimental purposes.

Note: The provision allows for special approvals to be given in relation to the treatment of particular persons or for clinical trials.

Clause 8 (5)-(7) Allows the Secretary to authorise a medical practitioner to supply therapeutic goods specified in the authority to a particular class of recipients, where that medical practitioner is within a class of of medical practitioners prescribed under the Commonwealth Act and the class of recipients is one in relation to which an equivalent authority could be given under the Commonwealth Act.

Clause 8 (8) Provides for the State and Commonwealth to be immune from action for an loss, damage or injury suffered as a result of the use of therapeutic goods in relation to which an approval or authority was given under the clause.

Clause 9 Allows the Minister to exempt persons or goods (or classes of persons or goods) from all or any specified provisions of the Bill, or declare that goods are exempt for the purposes of a specified provision of the Bill when used, advertised, or presented for supply in a specified way.

An order is made by publishing it in the *Gazette* and may be made subject to specified conditions.

Clause 10 Provides for the circumstances in which a package and therapeutic goods are to be regarded for the purposes of the Bill as a kit.

Note: The Secretary is able to determine that a group of kits be treated for the purposes of the Bill as grouped therapeutic goods in relation to inclusion in the Register, so that only one registration or listing number need be assigned.

Clause 11 Allows the Secretary to require a person who has supplied in WA therapeutic goods (or goods which may be declared under the Commonwealth Act to not be therapeutic goods) to give relevant information about the goods, and makes it an offence to fail to comply with that requirement or provide false or misleading information in response to the requirement.

PART 2 - STANDARDS

Clause 12 Provides that goods may not be supplied for use in Western Australia unless the goods conform with any standard applicable to the goods (except with the consent in writing of the Secretary).

Note: The applicable standards are: (a) those established under the Commonwealth Act; or (b) where no such standard has been established, but the goods are the subject of a monograph in the British Pharmacopoeia or British Pharmacopoeia (Veterinary), the statements in the monograph.

The Secretary is required to publish details of any consent given under the clause in the Commonwealth Gazette, and to give any applicant written notice of any consent refused under the clause and the reasons for that decision.

Clause 13 (1) Allows any consent which may be given under clause 12 to be made subject to conditions or to be limited to particular goods or classes of goods.

Clause 13 (2) Creates an offence where a person breaches any condition to which a consent under clause 12 is made subject.

PART 3 – AUSTRALIAN REGISTER OF THERAPEUTIC GOODS

Division 1 - Preliminary

Clause 14 Allows the Secretary to determine that a group of therapeutic goods, therapeutic devices or kits be treated as grouped therapeutic goods for the purposes of the Bill (ie dealt with as a group for the purposes of the Bill rather than as separate and distinct therapeutic goods).

Determinations are made by order published in the Commonwealth *Gazette*.

Clause 15 (1) Creates an offence where a person manufactures or supplies in Western Australia therapeutic goods for use in humans which are not either registered or listed in the Register in relation to that person, exempt, or the subject of an approval or authority under the Commonwealth Act or the Bill.

Clause 15 (2) Creates a defence to any prosecution for contravening cl. 15 (1) where the person was not a sponsor of the goods.

Note: This has the effect of limiting the scope of cl. 15 (1) to the activities of the sponsors of the relevant goods.

Clause 15 (3) Creates an offence where a person in relation to whom therapeutic goods are registered or listed supplies the goods without the registration or listing number (as the case may be) being set out on the label of the goods.

Note: Therapeutic devices which are listed goods are not included within the scope of this prohibition.

Clause 16 Creates an offence where a person (other than a sponsor) supplies in Western Australia therapeutic goods for use in humans to another person when the goods are not either registered or listed in the Register, exempt, or the subject of an approval or authority under the Commonwealth Act or the Bill.

Note1: A lower maximum penalty is provided for this offence than for the equivalent offence under cl. 15 (1) committed by the sponsor of goods.

Note2: Therapeutic devices which are only required to be listed are not included within the scope of this prohibition.

Clause 17 Creates an offence of supplying unsolicited therapeutic goods in a street, by mail, or from house to house (ie 'hawking' therapeutic goods) except where this is done with the written approval of the Commissioner of Health or in accordance with the regulations.

Allows for the regulations to prescribe that particular classes of persons may 'hawk' therapeutic goods to other classes of persons (eg. licenced manufacturer to health professionals).

Clause 18 Creates offences of installing an automatic machine for the supply of therapeutic goods, permitting the installation of such a machine (where an occupier of premises) or the placing in the machine of therapeutic goods (where the person in control of such a machine), and supplying therapeutic goods by means of such a machine.

In each case, the offences are made subject to the regulations.

Clause 19 (1) Creates an offence of setting out, or causing to be set out, a registration or listing number on a container, package or label for therapeutic goods which is not the number for those goods (which is known to not be that number or which ought reasonably to have been known to not be that number).

Clause 19 (2) Creates an offence of making a false and misleading statement in connection with an application for listing of therapeutic goods (which is known to be false and misleading, or ought reasonably to have been known to be false and misleading).

Clause 19 (3) Creates an offence of breaching any condition of the registration or listing of therapeutic goods.

Clause 19 (4) Creates offences of representing that therapeutic goods are in the Register, exempt, included in a particular part of the Register, or the subject of an approval or authority under the Commonwealth Act or the Bill, when that is not the case (and is known by that person or ought reasonably to have been known by that person).

Clause 19 (5) Creates an offence of advertising therapeutic goods for an indication which is not one which has been accepted in relation to the inclusion of the goods in the Register (and is known to not have beem accepted or ought reasonably to have been known to not have been accepted).

Clause 19 (6) Creates an offence of claiming to be able to arrange the supply of therapeutic goods (other than exempt goods) which are not registered or listed.

Clause 19 (7)-(9) Creates offences of failing to comply with any conditions etc to which an exemption, authority or approval relates.

Clause 20 Creates the offence of supplying therapeutic goods for use in humans after the relevant expiry date.

Note: An offence is not committed where this is done with the written authorisation of the Commissioner.

Clause 21 Creates the offence of using certain prescribed therapeutic devices except in accordance with an authorisation given by the Commissioner in accordance with the regulations.

Clause 22 Creates an offence of making a false and misleading statement in connection with an application for registration of therapeutic goods (which is known to be false and misleading, or ought reasonably to have been known to be false and misleading).

Note: A higher maximum penalty is provided for this offence than for the equivalent offence under cl. 19 (2) committed in relation to an application for the listing of therapeutic goods.

Division 2 – Registration and listing

Clause 23 Provides generally for the procedure to be followed in making an application for the registration or listing of therapeutic goods (ie. use of approved form, payment of prescribed fee, place to deliver to, accompanying information and samples which may be required).

Clause 24 (1) Provides for an applicant for registration to be notified by the Secretary of the evaluation fee applicable to the application (an amount equal to that which would be payable for an equivalent application under the Commonwealth Act).

Clause 24 (2) Provides for the circumstances in which an application for registration will be taken to have lapsed (ie. evaluation fee remains unpaid after 2 months from when it was due and payable, inaccurate or misleading information provided by applicant, failure by applicant to comply with requirement for information made by Secretary in accordance with the Bill).

Clause 25 Provides for an evaluation fee notified in accordance with cl. 24 (1) to be due and payable on the date of notification.

Clause 26 Provides for payment of an evaluation fee by instalments under the Bill where this could be done under the Commonwealth Act in relation to an evaluation fee due and payable under that Act.

Clause 27 Provides for an evaluation fee under the Bill to be recoverable by the Commonwealth as a debt.

Clause 28 Applies to therapeutic goods in relation to which an evaluation period has been prescribed under the Commonwealth Act.

Provides that in relation to such therapeutic goods, only ¾ of the evaluation fee is payable before the completion of the evaluation, and that the balance is only payable if the evaluation is completed within the prescribed period.

Clause 29 Allows an applicant, at any time after a prescribed evaluation period has expired and before the evaluation is completed, to give notice to the Secretary that of a wish to treat the application as having been refused.

Where such a notice has been given, the Bill has effect as if there had been a refusal to register the goods.

Clause 30 (1) – (8) Provides for the matters to which the Secretary is to have regard in evaluating therapeutic goods for registration.

Note: The matters to which the Secretary is to have regard under the Bill are equivalent to those which would be considered by the Secretary in relation to an application under the Commonwealth Act.

Clause 30 (9) – (10) Provides for the applicant to be notified in writing of the decision on an evaluation (and the reasons for any decision not to register the goods).

Provides for the issuing of a certificate of registration and the inclusion the goods in the Register, if the decision is to register the goods.

Provides for registration to commence on the day specified in the certificate of registration.

Clause 30 (11) Protects the Commonwealth and the State from any legal action based on the failure to evaluate goods for registration within a prescribed evaluation period.

Clause 31 (1) – (3) Prevents the Secretary, in evaluating therapeutic goods for registration, from using information about other therapeutic goods that is "protected information" (ie information obtained as the result of another application under the Commonwealth Act or the Bill which is about an "active component" of those goods, is not available to the public and where 5 years have not passed since registration, and the person in relation to whom the goods are registered has not given permission for the Secretary to use the information).

An "active component" is defined as a substance that is primarily responsible for the effect identifying the goods as therapeutic goods.

Clause 31 (4) Protects the Commonwealth and the State from any legal action based on the use of "protected information" contrary to cl. 31 (1).

Clause 32 Provides for therapeutic devices in relation to which a conformity assessment certificate is provided (which relates to matters which would otherwise require evaluation) to be registered except where the Secretary considers that the device may compromise the health or safety of users.

Note: Conformity assessment certificates are issued by approved bodies in accordance with a Mutual Recognition Agreement between Australia and the European Community.

Clause 33 Prevents the Secretary from refusing to list goods (upon an application for listing) except where the Secretary is satisfied as to one of the specified matters (ie goods not eligible for listing, not safe, presentation unacceptable, step in manufacture outside Australia not in accordance with acceptable manufacturing and quality control procedures, manufactured contrary to requirements of Commonwealth Act, do not comply with prescribed quality or safety criteria, contain prohibited imports).

Note: The matters which entitle the Secretary to refuse to list goods are equivalent to those which would give such an entitlement in relation to an application to list goods under the Commonwealth Act.

Provides for the applicant to be notified in writing of the decision on listing (and the reasons for any decision not to list the goods).

Provides for the issuing of a certificate of listing if the decision is to list the goods, and for listing to commence on the day specified in the certificate.

Clause 34 Provides for therapeutic devices in relation to which a conformity assessment certificate is provided (which relates to matters which would otherwise require evaluation) to be listed except where the Secretary considers that the device may compromise the health or safety of users.

Note: Conformity assessment certificates are issued by approved bodies in accordance with a Mutual Recognition Agreement between Australia and the European Community.

Clause 35 Prevents the Secretary from refusing to list certain goods where an applicant has certified as to specified matters (eligibility, safety, acceptable presentation, conformity with standards and advertising requirements, manufactured in accordance with relevant licence, compliance with quality or safety criteria, no substance which is a prohibited import) and the Secretary has certified prior to the application that the manufacturing and quality control procedures used in any overseas step in the manufacture is acceptable.

Provides for the applicant to be notified in writing of the decision on listing (and the reasons for any decision not to list the goods).

Provides for the issuing of a certificate of listing if the decision is to list the goods, and for listing to commence on the day specified in the certificate.

Clause 36 Provides for the Secretary to assign a unique registration or listing number (as the case may be) to therapeutic goods (or in the case of grouped therapeutic goods to the group) when the goods are included in the Register in accordance with the Bill.

Note: This is the number which a person in relation to whom therapeutic goods are registered must ensure is set out on the label of the goods: see cl. 15 (3).

Clause 37 Allows the Secretary to impose conditions on the registration or listing of goods and (by notice in writing) to impose new conditions or vary or remove existing conditons.

Provides that in addition to any other conditions which may be imposed by the Secretary, any registration or listing is subject to conditions that the person in relation to whom the goods are registered or listed will permit access to premises, inspection by, and provide documents to, authorised persons.

Provides that where a claim in relation to goods is included in the Register, that the listing of the goods is subject to conditions that the sponsor has information or evidence to support the claim, retains that information or evidence and provides it to the Secretary on request.

Clause 38 Provides that goods remain included in the Register unless the registration or listing is cancelled in accordance with the Bill.

Clause 39 Requires a person in relation to whom goods are registered to provide written notification to the Secretary if the person becomes aware of information that:

contradicts information previously furnished to the Secretary or indicates that the use of the goods in accordance with the recommendations for their use may have an unintended harmful effect or may not be as effective as suggested by the application for registration or any information previously furnished to the Secretary.

Clause 40 Allows the Secretary to require an applicant whose application has lapsed or been withdrawn to (within 14 days of the lapse or withdrawal) to inform the Secretary whether the applicant is aware of information of the type referred to in cl. 39 (see above) and if so to give that information to the Secretary.

Where such a requirement is made, it must be complied with within 30 days, and it is an offence to provide false or misleading information information in response (which is known by the person to be false or misleading or which the person ought reasonably to know is false or misleading).

Clause 41 (1) – (4) Provides for the circumstances in which the Secretary may cancel the registration or listing of goods, and the procedures which apply before such a step may be taken by the Secretary where certain grounds for cancellation are relied upon by the Secretary.

Clause 41 (5) Requires the Secretary to cancel the registration of goods where it becomes apparent that "protected information" was used in evaluating the goods.

Clause 41 (6) Provides for when a cancellation takes effect.

Clause 41 (7) – (8) Allows the Secretary (where a registration or listing has been cancelled) to require the person in relation to whom the goods were registered or listed to inform the public (or a class of persons) of the cancellation and/or take steps to recover any goods which have been distributed, and creates an offence where such a requirement is not complied with.

Clause 42 Allows the Secretary to require the sponsor of goods which have been supplied in contravention of the Bill (ie which are not registered, listed, exempt etc) to inform the public (or a class of persons) of this and/or take steps to recover any goods which have been distributed, and creates an offence where such a requirement is not complied with.

Clause 43 Allows the Secretary to require the sponsor of goods, a batch of which have been supplied but do not conform to an applicable standard to inform the public (or a class of persons) of this and/or take steps to recover any goods which have been distributed, and creates an offence where such a requirement is not complied with.

Division 3 – General

Clause 44 Allows the Secretary (by writtten notice) to require applicants for registration or listing of therapeutic goods, or persons in relation to whom goods are registerd or listed, to give to the Secretary (within a reasonable time as specified in the notice) information or documents relating to any of the specified matters (ie formulation, composition, design specifications, quality, method and place of manufacture and standards applied, presentation, safety and efficacy, conformity with advertising requirements, regulatory history in any other country, any other prescribed matter).

Creates offences of failing to comply with such a requirement and providing false or misleading information in response to such a requirement.

Clause 45 Allows the Commissioner of Health (by written notice) to require a person who manufactures or supplies in, or imports into, Western Australia therapeutic goods (or another specified person) to provide information about the goods.

Creates offences of failing to comply with such a requirement and providing false or misleading information in response to such a requirement.

Clause 46 Allows persons in relation to whom goods are registered or listed to obtain copies of the relevant entries in the Register.

Allows the Secretary to vary entries in the Register if they are incomplete or incorrect.

Requires the Secretary to accede to a request from a person in relation to whom goods are registered or listed to vary "product information" in the Register if the only effect of that variation would be to reduce the class of persons for whom the goods are suitable or add a warning or precaution. "Product information" is information which relates to the safe and effective use of the goods.

Allows the Secretary to vary an entry in accordance with a request from the person in relation to whom the goods are registered or listed (although the request does not relate to the entry being incomplete or incorrect) if the variation does not indicate any reduction in quality, safety or efficacy.

Clause 47 Requires the Secretary to publish a list of goods included in the Register at least once every 12 months.

PART 4 – MANUFACTURING OF THERAPEUTIC GOODS

Clause 48 (1) Creates an offence where a person carries out any step in the manufacture of therapeutic goods (other than exempt goods) for supply for use in humans without being the holder of a licence under the Part 4 Bill or the Commonwealth Act which authorises that action (unless the person is an exempt person in relation to the manufacture of the goods).

Clause 48 (2) Creates an offence of breaching any condition of a licence to manufacture.

Clause 48 (3) Creates an offence of making a false and misleading statement in connection with an application for a licence to manufacture (which is known to be false and misleading, or ought reasonably to have been known to be false and misleading).

Clause 49 Provides for the procedure to be followed in making an application for a licence to manufacture (ie. use of approved form, information to be provided, place to deliver to, payment of prescribed fee).

Allows the Secretary to require the provision of further information concerning an application and/or that an authorised person be permitted to inspect the premises, equipment, processes and facilities to be used to manufacture the goods.

Clause 50 Requires the Secretary to grant a licence to manufacture (where the requisite fees have been paid and any requirements under cl. 49 (2) have been complied with) except in the specified circumstances (ie person unable to comply with manufacturing principles, premises not satisfactory, previous licence revoked, conviction for offence relating to therapeutic goods, failure to observe manufacturing principles).

Allows the Secretary to grant a licence to manufacture notwithstanding existence of disqualifying factor if special circumstances make it appropriate.

Provides for the applicant to be notified in writing of the decision on the application (and the reasons for any decision not to grant a licence).

Clause 51 Provides for the commencement and duration of a licence to manufacture.

Clause 52 Allows the Secretary to impose conditions on the grant of a licence to manufacture and (by notice in writing) to impose new conditions or vary or remove existing conditons.

Provides that in addition to any other conditions which may be imposed by the Secretary, any licence is subject to conditions that the holder will: ensure that the goods conform to any applicable standards and will permit access to premises, and inspection by, an authorised persons and answer questions relating to procedures and produce documents and batch samples.

Clause 53 Provides for the circumstances in which the Secretary may revoke or suspend for a specified period a licence to manufacture, and the procedures which apply before such a step may be taken by the Secretary.

Clause 54 Allows the Secretary to publish a list of licence holders and relevant details relating to the licences.

PART 5 – WHOLESALERS TO COMPLY WITH CODE OF PRACTICE

Clause 55 Creates an offence where a person who supplies therapeutic goods by wholesale fails to ensure that the *Code of Good Wholesaling Practice for Therapeutic Goods for Human Use* is complied with.

Note: Supply by wholesale includes supply for the purposes of resale or supply in wholesale quantities to public institutions or for use in connection with a profession, business, trade or industry.

PART 6 – PAYMENT OF CHARGES

Clause 56 Provides for the person who is liable to pay annual registration, listing and licensing charges (ie person in relation to whom goods are registered/listed and licence holder as the case may be).

Clause 57 (1) – (3) Provides for the dates on which annual charges are payable. In general, this will be on the date of commencement of registration/listing or a licence and on each anniversary of that commencement.

Clause 57 (4) Allows the Secretary, by agreement with the person liable, to vary the day on which any charges would otherwise be payable.

Clause 58 Provides for annual charges to be recoverable by the Commonwealth as a debt.

PART 7 – ENTRY, SEARCHES AND WARRANTS

Clause 59 Defines terms for the purposes of Part 7 of the Bill, including:

"evidential material" which is defined to mean any thing with respect to which an offence has been committed, or in relation to which there are reasonable grounds for suspecting: the commission of an offence, or that it will afford evidence of an offence or is to be used to commit an offence.

Clause 60 Allows an authorised person to enter premises (either with the consent of the occupier or a warrant issued under the Bill) for the purpose of monitoring compliance with the Bill and (upon producing an identity card if required by the occupier) to exercise any of the powers in cl. 64 (1) (ie search, inspect, examine, take measurements, conduct tests, take photographs, video recordings, ask questions, require production of documents etc).

Clause 61 Allows an authorised person to enter particular premises (ie premises of a person who has been granted a relevant approval or authority or in relation to whom goods are registered or listed; premises which have been made the subject of a condition of registration/listing requiring access to be given; premises in relation to which a licence to manufacture has been granted) and (upon producing an identity card if required by the occupier) to exercise various powers (ie search, inspect, examine, take measurements, conduct tests, take photographs, video recordings, inspect records).

Note: The power may only be exercised to the extent that it is reasonably necessary for the purpose of monitoring compliance, and may not be exercised in relation to premises that are a residence without the consent of the occupier (unless the residence is used for commercial purposes in relation to therapeutic goods).

Clause 62 Allows an authorised person to enter any premises and search for and seize any thing (upon producing an identity card if required by the occupier) if the authorised person has reasonable grounds for suspecting that there is such a thing on the premises in respect of which there has been non-compliance with the Bill and that it is necessary in the interests of public health to take that action to avoid an imminent risk of death, serious illness or serious injury.

Clause 63 Allows an authorised person to enter any premises (either with the consent of the occupier or a warrant issued under the Bill) if the authorised person has reasonable grounds for suspecting that there may be evidential material on the premises and (upon producing an identity card if required by the occupier) to exercise any of the powers in cl. 64 (1) (ie search, inspect, examine, take measurements, conduct tests, take photographs, video recordings, ask questions, require production of documents etc) and to seize the evidential material suspected of being on the premises if it is found.

Note: If a search is made pursuant to a warrant, and other evidential material (not the subject of the warrant) is discovered, it may be seized pursuant to the warrant if this is considered necessary to prevent its concealment, loss or destruction, or use to commit an offence against the Bill.

Clause 64 (1) Sets out the general powers an authorised person is entitled to exercise when acting under cl. 60 or cl. 63, which include the power to:

(a) search the premises and any thing on the premises;

(b) inspect, examine, take measurements of, conduct tests concerning any thing on the premises that relates to therapeutic goods;

(c) take photographs, video recordings, make sketches in relation to the premises or things on the premises;

(d) require the occupier (in the case of presence on the premises pursuant to consent) to answer questions and produce documents or any person to do these things (in the case of presence on the premises pursuant to a warrant);

(e) inspect and take extracts from documents on the premises.

Clause 64 (2) Creates an offence where a person fails, without reasonable excuse, to answer questions or produce documents pursuant to a requirement under cl. 64 (1).

Clause 64 (3) Provides that the potential for self-incrimination will be a reasonable excuse for the purposes of the offence created by cl. 64 (2).

Clause 65 Requires an authorised person must identify himself or herself to an occupier (or representative) when executing a warrant and make the warrant available to that person.

Clause 66 Requires an authorised person to give any person at premises the opportunity to consent to his or her entry before doing so pursuant to a warrant (unless the authorised person believes on reasonable grounds that immediate entry is required to ensure the safety of any person or the effectiveness of the action).

Clause 67 Allows an authorised person to operate electronic equipment on premises for the purpose of discovering whether evidential material can be accessed by that means, and if so to take various further steps depending on the circumstances (eg. seize equipment, operate it to put evidential material in documentary form, transfer the material to disk or other storage device, secure the equipment so that it can be operated later by an expert to extract the evidential material if it is considered that the material might otherwise be destroyed, altered or otherwise interfered with).

Note1: The step of seizing equipment cannot be taken unless possession of the equipment could constitute an offence or one of the other steps (ie convert to documentary form or transfer to disk etc) is not practicable.

Note2: If equipment is secured by the authorised person so that it can be later operated by an expert there is a time limit of 24 hours which applies (unless that period is extended by a Magistrate upon an application made with notice to the occupier and which allows the occupier an opportunity to be heard).

Clause 68 Provides for compensation to be payable to the owner where electronic equipment is damaged as a result of insufficient care being exercised when powers are being exercised under cl. 67.

Clause 69 Requires an authorised person (upon request) to provide to any occupier (or representative) a copy of any seized document or other thing which can be readily copied (unless possession of it could constitute an offence, or where the seized document or thing is itself a copy – eg. document or disk - made by operating electronic equipment pursuant to cl. 67).

Clause 70 Provides that an occupier (or representative) is entitled to be present during the conduct of a search (unless they impede that search).

Clause 71 Requires receipts to be provided for anything which is seized under the Bill.

Clause 72 Sets out the procedure which applies in relation to the return of things seized under the Bill. Generally, a limit of 90 days applies subject to a court order or the need to retain the thing for the purposes of pending court proceedings.

Allows for the conditional return of anything seized under the Bill.

Clause 73 Allows for the ordinarily applicable 90 day limit on the retention of seized things to be extended by a Magistrate if necessary for the purposes of an investigation or prosecution.

Requires reasonable steps to be taken to notify persons who may have an interest in any application to extend the 90 day limit.

Clauses 74 - 75 Set out the procedure which applies where an authorised person wishes to obtain a warrant to search premises for the purposes of the Bill.

A 'monitoring warrant' may be issued where a justice is satisfied that it is reasonably necessary to grant access to premises for the purpose of finding out whether the requirements of the Bill are being complied with.

An 'offence related warrant' may be issued where a justice is satisfied that there are reasonable grounds for suspecting that there is, or may be, evidential material on premises.

In either case, the grounds for the warrant must be established by information on oath, and the authorised person must provide the justice with such further information as may be required by the justice as to the grounds for the issue of the warrant.

Provides for the form in which any warrant should be issued.

Clause 76 Allows for an 'offence related warrant' to be applied for, and granted, by telephone (by a magistrate) in an urgent case.

Provides for the procedure which applies in such a case (ie authorised person completes a form of warrant in the terms granted and sends a copy with the information on which it was based to the magistrate).

Clause 77 Creates offences of making a false or misleading statement in an application for a warrant under the Bill or making the specified misrepresentations as to the existence or form of a warrant.

PART 8 - MISCELLANEOUS

Clause 78 Provides for persons authorised by the Commissioner as "authorised persons" for the purposes of the Bill to be issued with photographic identity cards.

Clause 79 Provides for more serious offences created by the Bill to be prosecuted as indictable offences (ie false or misleading statement in application for registration;

failure to notify adverse effects; false or misleading statement in response to requirement to notify about adverse effects).

Allows indictable offences to be tried summarily where considered appropriate by the court (and subject to prosecution and defence consent).

Allows a court to order the forfeiture to the State of therapeutic goods which relate to an offence under the Bill of which a person has been convicted.

Clause 80 Provides for a limitation period of 3 years for any prosecution under the Bill.

Clause 81 - 83 Provide for the facilitation of proof of various technical matters, for the purpose of proceedings under the Bill, by means of certificates issued by the Commissioner or Secretary.

Note: The certified matters are in each case to be taken to be proved, in the absence of evidence to the contrary.

Clause 84 Provides for a body corporate to be potentially liable for conduct engaged in on its behalf by directors, employees or agent acting within the scope of their respective authority (and for that person's state of mind to be the body corporate's state of mind where applicable) unless the body corporate took reasonable precautions and exercised due diligence to avoid the conduct.

Provides for a person other than a body corporate to be potentially liable for conduct engaged in on the person's behalf by a servant or agent acting within the scope of their respective authority (and for the servant or agent's state of mind to be that of the person) unless the person took reasonable precautions and exercised due diligence to avoid the conduct.

Clause 85 Facilitates 'proof' of any standard which may apply under the Bill by virtue of the British Pharmacopeias by requiring that courts take judicial notice of the contents of those texts (ie formal proof not required, court can inform itself of the contents of texts by any means considered appropriate).

Clauses 86 – 87 Allow for the Secretary and the Commissioner to delegate functions given to those persons under the Bill.

Clause 88 Provides that a person is not liable to be punished for an offence under the Bill if the person has already been punished for the same act or omission under the Commonwealth Act.

Clause 89 Allows a person to apply to the Commonwealth Administrative Appeals Tribunal for a review of a decision of the Secretary under the Bill.

Clause 90 Allows for regulations to be made for the purposes of the Bill.

PART 9 – CONSEQUENTIAL AMENDMENTS AND TRANSITIONAL PROVISIONS

Clause 91 - 93 Provide for consequential amendments and repeals.

Clause 94 Sets out the transitional arrangements for Part 4 of the Bill.

Provides for a period of 4 months from the commencement of the Bill during which a person already manufacturing goods will not be liable under cl. 48 (1) of the Bill (which prohibits manufacturing without a licence) and that where an application for a licence is made by such a person during that period of 4 months then cl. 48 (1) will not apply until the application is determined.

Clause 95 Sets out the transitional arrangements for Part 5 of the Bill.

Provides for a period of 4 months from the commencement of the Bill during which a sponsor already supplying goods in Western Australia for use in humans will not be liable under cl.15 (1) of the Bill (which prohibits supply of goods which are not registered or listed) or cl. 15 (3) of the Bill (which prohibits the supply of registered/listed goods without registration/listing numbers) and that where an application for registration or listing is made by a sponsor during that period of 4 months then cl. 15 (1) will not apply for a period of 6 months from commencement and cl. 15 (3) will not apply for a period of 12 months from commencement (or in each case such longer period as may be specified by the Secretary.

Allows the Secretary, in any case where goods have been registered upon an application under the transitional arrangements without evaluation, to give notice to the person in relation to whom the goods are registered that they are to be evaluated to determine whether they should continue to be registered.

Provides that no application fee is payable where an application is made under the transitional arrangements, and that no evaluation fee is payable in the case of an application for registration except in any case where goods have been registered without evaluation and then later evaluated to determine whether they should continue to be registered.