Therapeutic Goods (Victoria) Bill

EXPLANATORY MEMORANDUM

Outline

The aim of the Bill is to set up model legislation to complement the Commonwealth's regulation of the quality, safety and efficacy of therapeutic goods manufactured for supply and use in Australia.

The Bill also establishes a licensing system for Victorian wholesale suppliers of therapeutic goods and creates certain offences.

Clause Notes

PART 1—PRELIMINARY

Clause 1 sets out the purpose of the Bill.

Clause 2 is the commencement provision.

Clause 3 defines a number of important terms used throughout the Bill. The more significant ones are:

"therapeutic goods" includes goods that are represented in any way to be, or likely to be taken to be for therapeutic use, for use as an ingredient or component in the manufacture of therapeutic goods or for use as a container or part of a container for therapeutic goods. They also include goods declared to be therapeutic goods under an order under section 7 of the Commonwealth Act.

"therapeutic use" is broadly defined and includes use in the diagnosis of disease, ailments or injuries as well as in their prevention or treatment. It also specifically extends to use in connection with contraception and testing for pregnancy.

"Register" refers to the Australian Register of Therapeutic Goods maintained under section 17 of the Commonwealth Therapeutic Goods Act 1989. ("the Commonwealth Act").

"Secretary" means the Secretary to the Commonwealth Department of Human Services and Health.

- **"sponsor"** in relation to therapeutic goods refers to a person who, in Victoria, manufactures the goods, or arranges for another person to manufacture the goods, for supply (whether in Victoria or not).

"supply" includes provision of goods whether free or otherwise in a wide range of stated circumstances.

a **"standard"** for therapeutic goods is constituted by an applicable monograph in the British Pharmacopoeia or British Pharmacopoeia (Veterinary) unless another standard for those goods has been specifically determined under section 10 of the Commonwealth Act.

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an **"authorised person"** may be a person authorised by the Chief General Manager, an authorised person within the meaning of paragraph (*a*) of the definition of "authorised person" in the Commonwealth Act or a member of the State or federal police.

Clause 4 provides that words and expressions used in the Commonwealth Act and this Bill have the same meanings in the Bill as in the Commonwealth Act unless the context indicates otherwise.

Clause 5 provides that—

goods are to be taken to be for human use if they are not labelled or otherwise represented to be solely for use in animals;

a list of authorised persons be published in the Victoria Government Gazette at least once a year. The principal roles of an authorised person will be to inspect the manufacture of therapeutic goods and to monitor compliance with the Bill;

provisions of this Bill do not negate, and are not negated by, provisions under other Acts that deal with therapeutic goods.

Circumstances in which the presentation of therapeutic goods is unacceptable from the point of view of being misleading or confusing as to the content or proper use of the goods are defined in this clause. Unacceptable presentation is a reason for refusing to register or list goods on the Register.

Clause 6 recognises the divisibility of the Crown and provides that the Bill will bind the Crown not only in right of Victoria, but also, so far as the legislative power of the Parliament permits, the Crown in all its other capacities.

Clause 7 provides that the Chief General Manager may authorise certain persons to exercise powers under specified sections of the Bill.

Clause 8 (1) allows the Secretary to approve the supply of goods (which are neither in the Register nor exempt from the Register), for use in the treatment of particular persons (this is commonly known as "individual patient use") or for experimental purposes in humans (clinical trials). Conditions may be applied to such approvals.

Sub-clause (2) provides that conditions on approvals granted under sub-clause (1) may relate to the charges that can be made for goods used in those circumstances. This clause provides a safeguard against special use approvals being used as a route to defacto marketing of goods and the normal evaluation process being evaded.

Sub-clause (3) describes the required method and form of applications for the special approvals provided for in sub-clause (1), and requires payment of an evaluation fee in the case of applications for clinical trial approvals.

Sub-clause (4) requires the Secretary to notify an applicant of the decision within 28 days of its making.

Clause 9 gives the Minister power to exempt any person, or goods, from provisions of the Bill as specified in an Order to be published in the Victoria Government Gazette.

Clause 10 introduces "kits" as a class of "grouped therapeutic goods".

Clause 11 allows the Secretary to require information about particular goods to be provided by the supplier.

PART 2—STANDARDS

Clause 12 provides that unless the Secretary consents in writing it is an offence to supply therapeutic goods for use in Victoria which do not conform to an applicable standard Penalty: 240 penalty units. (1 penalty unit equals $100).

It also provides for gazettal of decisions made by the Secretary granting consent, and for applicants to be given the reasons for a decision where consent is refused.

Clause 13 states that the Secretary may place conditions on a consent under clause 12, and it is an offence not to comply with the conditions. Penalty: 120 penalty units.

PART 3—AUSTRALIAN REGISTER OF THERAPEUTIC GOODS

Division 1—Preliminary

This part applies to therapeutic goods for use in humans.

Clause 14 makes it an offence for a person to supply goods in Victoria for use in humans unless the goods are registered or listed in that person's name, or the goods are exempt, or are the subject of an approval under section 19 of the Commonwealth Act or an approval or authority under clause 8 of this Bill. Penalty: 240 penalty units.

It also requires registered goods or listed goods to have their registration number or listing number on their label in the manner prescribed by the Commonwealth Act. Penalties of 60 penalty units are imposed for failing to comply.

Clause 15 makes it an offence to knowingly or recklessly supply therapeutic goods (other than listable devices) unless the goods are registered, listed, exempt, or the subject of an approval or authority under section 19 of the Commonwealth Act or an approval or authority under clause 8 of this Bill, and provides a penalty of 120 penalty units.

The reason for excluding supply of unlisted devices from this offence provision is that listed devices will not carry a list number on their labels. The status of other therapeutic goods will be recognisable from their labelling and from published lists of classes of products to which exemptions apply.

Clause 16 prohibits hawking of therapeutic goods without the written consent of the Chief General Manager. There are certain exemptions for samples supplied to particular classes of professionals.

Clause 17 prohibits the installation of a vending machine for the supply of therapeutic goods and the supply of such goods from a vending machine without written consent of the Chief General Manager.

Clause 18 creates a number of general offences and penalties relating to the registration and listing of goods. These are:

to place a false registration number or listing number on the label of goods deliberately;

in connection with an application under this Part, making a statement that is, to the applicant's knowledge, false or misleading;

breaching a condition of the registration or listing of goods;

deliberately misrepresenting the status of the goods in relation to the Register;

if a person is a sponsor of therapeutic goods included in the Register, advertising the goods for an indication other than those accepted for their inclusion in the Register;

making a claim that the supply can be arranged of therapeutic goods that are neither registered nor listed;

breaching a condition (if any) of an exemption under clause 9 or under section 18 (1) of the Commonwealth Act or an approval under section 19 of that Act;

using unregistered or unlisted therapeutic goods for experimental purposes in humans except in accordance with an approval under clause 8 or under section 19 of the Commonwealth Act.

The penalty for any of these offences is 60 penalty units.

Clause 19 creates the offence of making a false statement knowingly or recklessly in an application for registration of therapeutic goods. Penalty: 400 penalty units.

Division 2—Registration and Listing

Clause 20 establishes the procedure for making an application for the registration or listing of therapeutic goods, and the required form of the application.

Clause 21 requires the Secretary to notify the applicant of the fee, (which is determined in accordance with the Commonwealth regulations), for evaluating goods for registration. If the evaluation fee is not paid within two months of when the applicant was notified, the application lapses.

Clause 22 states that the evaluation fee is due for payment on the day the applicant is notified of the amount, unless it is payable by instalments under clause 23 or the amount is reduced under clause 25.

Clause 23 states that if the Commonwealth regulations provide for payment by instalments of evaluation fees, such fees may be paid by instalments under this Bill.

Clause 24 empowers the Commonwealth to recover unpaid evaluation fees.

Clause 25 states that where an evaluation is not completed within the prescribed period the evaluation fee is reduced to three-quarters of the fee that would otherwise be applicable.

Clause 26 gives the applicant a discretion to treat the application as having been refused if the evaluation is not completed with the prescribed period. The applicant may give the Secretary written notice of his or her intention to treat the application as having been refused at any time before the evaluation is completed.

Clause 27 sets out the matters which must be considered in the evaluation of goods for registration. The Secretary must notify the applicant of the decision on the evaluation of goods within 28 days of making the decision and give reasons if registration is refused. Registration is to commence on the date specified on the certificate.

Clause 28 describes the grounds on which listing of therapeutic goods may be refused. When an application for listing is made, the Secretary is to notify the applicant within 28 days of making a decision and, in the case of a refusal to include the goods in the list, of the reasons for the decision. If listing is approved, listing commences on the day specified on a certificate of listing which is issued to the applicant.

Clause 29 provides that a unique registration or listing number is assigned to goods which are entered in the Register.

Clause 30 provides that the Secretary may impose conditions on the registration or listing of goods relating to such aspects as the manufacture of the goods, their custody, use, supply, disposal or destruction, the keeping of records, or matters relating to the standards applicable to the goods.

The Secretary is required to give at least 28 days notice to the sponsor of goods on the Register of any proposed addition or change to conditions applicable to the registration or listing of goods. The purpose of this clause is to give the sponsor time to make submissions about the proposed action except where urgent action is necessary to prevent an imminent risk of death, serious illness or serious injury.

A general condition of registration or listing of goods is that authorised persons must be allowed to enter and inspect premises at which the sponsor deals with the goods, to examine therapeutic goods and related record documents on the premises, and to take samples of the goods. This clause should be contrasted with clauses 57 to 61 which require monitoring and offence warrants to be obtained to enter other premises where it is thought goods are being manufactured or supplied in contravention of the Act.

Clause 31 Once goods are entered in the Register, they remain registered or listed goods until action is taken to cancel their registration or listing.

Clause 32 obliges a person in relation to whom therapeutic goods are registered to give written information to the Secretary as soon as the person is aware of adverse effects of registered therapeutic goods. An offence under this provision is an indictable offence, with a maximum penalty of 400 penalty units.

Clause 33 provides for the Secretary to give an applicant whose application has been withdrawn or lapsed written notice requiring notification of adverse effects of therapeutic goods. The Secretary may give such a notice within 14 days after the application is withdrawn or lapses. The applicant must comply with the notice requirements within 30 days. Failure to comply with notice requirements or knowingly or recklessly giving false or misleading information are indictable offences under this clause, with a maximum penalty of 400 penalty units.

Clause 34 states the grounds on which registration or listing of goods may be cancelled by the Secretary.

When cancellation is proposed for any of the reasons stated, the sponsor of the goods must be given prior notice and a reasonable opportunity to make submissions in relation to the proposed action. In these cases the Secretary must not make a final decision about cancellation without taking the sponsor's submission into account. Cancellations made under sub-clause (1), which include cancellations made in more urgent circumstances, are effective immediately. In other cases, the date of effect is to be specified in the notice of cancellation. The Secretary may also require the sponsor of goods whose registration or

listing has been cancelled to inform the public or specified sections of the public of the cancellation, or to take steps to recover any of the goods that have been distributed. The Secretary is to publish a notice of cancellation in the Commonwealth Gazette as soon as practicable after cancellation. It is an offence to knowingly or recklessly refuse or fail to comply with requirement under sub-clause (6). Penalty: 60 penalty units.

Division 3—General

Clause 35 provides that the Secretary may require an applicant for registration or listing, or the person in whose name goods are registered or listed, to provide specified types of information about the goods concerned.

This information may facilitate assessment of applications or subsequent review of products in the Register. Penalties apply for failure to comply with a notice under this clause or for knowingly or recklessly providing false or misleading information.

Clause 36 provides that the person in whose name the goods have been registered or listed may obtain a copy of the entry relating to his or her goods on request. The reason for the Register not being publicly accessible is that entries will contain information that is confidential to a particular product's sponsor. Section 61 (6) of the Commonwealth Act provides for the release of certain non-confidential parts of Register information. Such release is subject to the Freedom of Information Act 1982 (Commonwealth).

This clause also provides for amendments to be made to incomplete or incorrect entries on the Register.

Clause 37 requires the Secretary to publish a list of the therapeutic goods included on the register at least every 12 months.

PART 4—MANUFACTURING OF THERAPEUTIC GOODS

This part applies to goods which are for therapeutic use in humans.

Clause 38 Sub-clause (1) makes it an offence for a person to carry out any step in the manufacture of therapeutic goods which are for use in humans unless the person is licensed to do so, or the person or the goods are exempt. Penalty: 240 penalty units.

Sub-clause (2) requires a licence holder to comply with conditions to which the licence is subject. Conditions of licences are set out in clause 42 of the Bill. The penalty for an offence under this sub-clause is 120 penalty units.

Sub-clause (3) makes it an offence for a person knowingly to give false or misleading information in connection with an application for a licence to manufacture therapeutic goods. The penalty is 60 penalty units.

Clause 39 describes the form of, and the procedure for lodging, an application for a manufacturing licence.

The Secretary may request an applicant for a licence to supply further information and to allow authorised persons to inspect manufacturing premises and aspects of the manufacturing processes which will be used to manufacture the goods concerned.

Clause 40 (1) requires the Secretary to grant a licence except for the reasons stated in the sub-clause. A major reason is lack of compliance with the manufacturing principles.

Sub-clause (2) allows the Secretary to grant a licence under circumstances where a licence would not normally be granted. For example, although an applicant may have been refused a licence for a reason in subsection (1) (*f*), the person may have subsequently obtained appropriate staff or facilities so that the Secretary is satisfied that the licence can be issued or re-issued as the case may be.

The clause also provides that the applicant must be advised of whether or not the application has been successful and given reasons if the licence is refused. Particulars of the decision to approve a licence are to be published in the Commonwealth Gazette.

Clause 41 sets the effective commencing date of a licence. A licence is perpetual unless it is suspended or revoked under clause 43.

Clause 42 Sub-clause (1) permits the Secretary to place conditions on the granting of a manufacturing licence. Conditions may include restrictions as to the classes of goods that the manufacturer can manufacture.

Sub-clause (2) provides that the Secretary may change, add to or remove the conditions applicable to a licence. The licence holder must be given at least 28 days to comply with the changed conditions unless urgent action is necessary.

Sub-clause (4) is a similar provision to clause 30 (6) of the Bill and makes it an additional condition of the licence that the licence holder must ensure that manufactured goods comply with relevant standards and also allow an authorised person to inspect the licensed premises and take samples.

Clause 43 provides for the revoking or suspending of a licence by the Secretary on the grounds specified in sub-clause (1). Sub-clauses (2) and (3) define those situations in which the Secretary must advise the licence holder of the intended revocation or suspension of the licence and allow a reasonable time for a submission to be made by the licence holder and considered before a decision is made. Decisions to suspend or cancel licences must be published in the Commonwealth Gazette.

Clause 44 permits details of licensed manufacturers to be published by the Secretary from time to time. Details which may be published include a list of persons licensed to manufacture therapeutic goods, the types of goods each manufactures and the addresses of premises to which the licence relates. In view of the frequent use of subcontract manufacturers in the Therapeutic Goods Industry, it is desirable that the status of manufacturers is made generally available.

PART 5—LICENCES TO SUPPLY BY WHOLESALE

Clause 45 defines the phrase "supply by wholesale" and sets out the application of this Part.

Clause 46 (1) makes it an offence for a person in Victoria to supply by wholesale therapeutic goods for use in humans unless the person is licensed to do so or the person or the goods are exempt. Penalty: 100 penalty units.

Sub-clause (2) requires a licence holder to comply with conditions to which the licence is subject. Conditions of licence are set out in clause 51 of the Bill. The penalty for an offence under this sub-clause is 100 penalty units.

Sub-clause (3) makes it an offence for a person knowingly to give false or misleading information in connection with an application for a licence to supply by wholesale therapeutic goods for use in humans. The penalty is 60 penalty units.

Sub-clause (4) provides that only persons supplying prescribed therapeutic devices by wholesale will require a licence.

Clause 47 describes the form of, and the procedure for lodging, an application for a licence to supply therapeutic goods by wholesale.

The Chief General Manager may request an applicant for a licence to supply further information and to allow authorised persons to inspect the premises and process proposed to be used by the applicant in the supply of goods by wholesale.

Clause 48 requires the Chief General Manager to grant a licence except for reasons stated. This clause also provides that the applicant must be advised of whether or not the application has been successful and given reasons if the licence is refused.

Clause 49 sets the effective commencing date of a licence. A licence remains in force for 12 months.

Clause 50 provides for an annual renewal of a licence to supply by wholesale.

Clause 51 (1) permits the Chief General Manager to place conditions on the granting of a licence to supply by wholesale.

Sub-clause (2) provides that the Chief General Manager may change, add to or remove the conditions applicable to a licence. The licence holder must be given at least 28 days to comply with the changed conditions unless urgent action is necessary.

Sub-clause (4) is a similar provision to clause 30 (6) of the Bill and makes it an additional condition of the licence that the licence holder must ensure that the goods comply with relevant standards and also allow an authorised person to inspect the licensed premises and take samples.

Clause 52 provides for the revoking or suspending of a licence by the Chief General Manager on the grounds specified in sub-clause (1). Sub-clauses (2) and (3) define those situations in which the Chief General Manager must advise the licence holder of the intended revocation or suspension of the licence and allow a reasonable time for a submission to be made by the licence holder and considered before a decision is made. Decisions to suspend or cancel licences must be published in the Victoria Government Gazette.

Clause 53 permits details of licensed suppliers by wholesale to be published by the Chief General Manager from time to time.

PART 6—PAYMENT OF CHARGES

Clause 54 states those persons responsible for paying an annual charge in respect of the registration or listing or therapeutic goods, and on the licensing of manufacturers of therapeutic goods.

Clause 55 provides that when goods become registered or listed the first payment is due at the time of the goods' entry into the register. Similarly, when manufacturers become licensed, the charge is payable on the date the licence commences.

Subsequent payments will fall due on the anniversary of the first payment or on another date in the financial year which may be set by the Secretary during the first 12 month period. The allowance for an alternative date is included so that administrative arrangements can be varied if necessary to facilitate efficient processing of payments by distributing the due dates throughout the year.

It may also be convenient to sponsor companies to have payments for all their products fall due on a particular day rather than on the anniversaries of their entry into the Register. A general provision is therefore included in sub-clause (4) for the date of payment for annual charges to be varied by agreement between the Secretary and the person responsible for the payments.

Clause 56 empowers the Commonwealth to recover unpaid charges.

PART 7—MISCELLANEOUS

Clauses 57 to 61 of this Part allow authorised persons to enter premises in circumstances other than those under which entry to premises is a condition attaching to the registration or listing of therapeutic goods (clause 30 (6)), or a condition precedent to the issue of a manufacturing licence under clause 42 (4).

Clause 57 provides that an authorised person (as defined in clause 3 of the Bill) may enter premises, and exercise specified powers, in the course of investigating whether the requirements of the Bill are being complied with. This function may be carried out either with the consent of the occupier of the premises or under a monitoring warrant issued for this purpose under clause 60.

Clause 58 outlines the powers of entry and seizure exercisable by an authorised person who has reason to suspect that there is evidence of an offence against the Bill on particular premises. Evidence of the commission of an offence may be seized in accordance with procedures outlined in this clause.

Entry to the premises may be effected either with the consent of the occupier of the premises or under an offence-related warrant (clause 58 and clause 61 refer).

Clause 59 (1) sets out the general powers of an authorised person who enters premises to monitor compliance with the Bill under clauses 57 and 58.

Sub-clause (3) makes it an offence for a person on the premises to refuse or fail to answer an authorised person's questions or provide requested record documents as required under sub-clause (1) (*e*). Penalty: 30 penalty units.

Sub-clause (4) accepts that it is a reasonable excuse for a person to refuse or fail to answer a question or produce a document if by doing so the person would be likely to incriminate himself or herself.

Clause 60 describes the procedure for obtaining a monitoring warrant. The varying steps in the procedure and the provisions of the Bill to which they relate are as follows:

Sub-clause (1) applications may be made to a magistrate.

Sub-clause (2) the magistrate must be satisfied by information on oath, that it is reasonably necessary for the authorised person to have access to particular premises.

Sub-clause (3) the magistrate must be given any further information required concerning the grounds for issue of a warrant.

Sub-clause (4) the warrant must authorise the authorised person to exercise the powers in clause 59 (1), the times at which entry is authorised, the day (up to 6 months after its issue) when the warrant ceases to have effect, and the purpose for which it is issued.

Clause 61 sets out the requirements for issue of an offence related warrant. Offence warrants may be issued by a magistrate who must be satisfied, by information on oath, that there are reasonable grounds for suspecting that evidence of an offence may be on particular premises. Any further information required by the magistrate must be provided before the warrant is issued. The warrant must state the name of the authorised person, the powers that may be exercised, the times when entry may be made, the day (up to one week from issue) when the warrant ceases to have effect, and the purpose for which it is issued.

Clause 62 provides for the issue of identity cards to officers who are authorised by the Chief General Manager under clause 3 of the Bill. The identity card, which will incorporate a recent photograph of the person authorised by the Chief General Manager, must be produced on request when entry to premises is made otherwise than under a warrant.

A person who ceases to be authorised is required to return the identity card. The penalty for not doing so is 1 penalty unit.

Clause 63 provides that offences under clauses 19, 32 and 33 are indictable offences and that a prosecution for such an offence may be commenced within 3 years after commission of the offence. The court may order that the therapeutic goods be forfeited to the State.

Clause 64 provides for a certificate signed by the Chief General Manager to be prima facie evidence of the facts stated in the certificate in any legal proceeding under the Bill.

Clause 65 provides for a certificate signed by the Secretary to be prima facie evidence of the facts stated in the certificate in any legal proceedings under the Bill.

Clause 66 relates to circumstances where it becomes necessary in proceedings for offences against the Bill, to establish the state of mind of a body corporate in relation to particular conduct. In such circumstances it will be sufficient to show that if a director, servant or agent of the body corporate had the requisite state of mind and engaged in the relevant conduct, that the body corporate engaged in the conduct.

Under this clause, it is a defence for the body corporate to establish that it took reasonable precautions to avoid the conduct in question.

Similarly, if the servant or agent of a person (other than a body corporate) is found to have state of mind or engaged in conduct connected with an offence, then the state of mind and the conduct is taken to have been proved against the person.

Clause 67 provides that all courts are to take judicial notice of the British Pharmacopoeia and the British Pharmacopoeia (Veterinary).

Clause 68 provides authority for the Secretary to delegate his or her powers under the Bill other than the power of delegation to those persons to whom the Secretary may delegate powers under section 57 of the Commonwealth Act.

Clause 69 prevents a person from being punished for the same offence under both the Commonwealth Act and this Bill.

Clause 70 provides for the Commonwealth Administrative Appeals Tribunal to review certain decisions made under the Bill. A decision under this clause has the same meaning as in the Administrative Appeals Tribunal Act 1975 of the Commonwealth.

Clause 71 provides for a review of decisions made by the Chief General Manager under Part 5 to the Administrative Appeals Tribunal of Victoria.

Clause 72 provides that the Governor in Council may make regulations which are not inconsistent with the Bill.

PART 8—CONSEQUENTIAL AMENDMENTS AND TRANSITIONAL PROVISIONS

Clause 73 makes various consequential amendments to the **Health Act 1958** including the repeal of Divisions 3 and 3B of Part XIV.

Clause 74 makes a consequential amendment to the definition of "drug" in the **Food Act 1984.**

Clauses 75 and 76 contain transitional arrangements for Parts 4 and 5.

Clause 77 The transitional arrangements set out in this clause are to apply to goods which are already legally available in Victoria at the time of the commencement of the Bill.

Sub-clause (2) provides that provided the sponsor of goods referred to in sub-clause (1) has not, to the Secretary's knowledge, imported the goods in contravention of the regulations to the **Customs Act 1901**, and has not been convicted of an offence against Commonwealth or State or Territory law in respect of those goods during the previous 2 years, the sponsor will not be held to be liable for the offence of manufacturing or supplying unregistered or unlisted goods, and of not having the registration number on their label, in the first 3 months after this clause of the Bill comes into operation.

If the sponsor of established goods applies within 3 months of the commencement of this clause of the Bill to have the goods registered or listed under the new system, he or she may continue to supply the goods for 6 months (or a longer specified period) without being liable for an offence under clause 14 (1), and is not required to have the registration number on the label of the goods until 12 months (or a longer specified period) after that commencement. This allows time for the applications to be made and processed, and then gives the sponsor extra time to make necessary adjustments to the product labels to include the new registration number.

Sub-clause (5) provides that a sponsor of established goods who applies to have the goods registered or listed in accordance with sub-clause (3) will not be required to pay an application fee.

Established goods will be registered without an evaluation being carried out, so no evaluation fee is payable at that time. However, if the goods are evaluated at a later stage as part of a review of their registration a fee will be payable for that evaluation.

By Authority L. V. North, Government Printer Melbourne