1993

THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

HOUSE OF REPRESENTATIVES

HEALTH AND COMMUNITY SERVICES LEGISLATION AMENDMENT BILL (NO. 2) 1993

EXPLANATORY MEMORANDUM

(Circulated by the authority of the Minister for Housing, Local Government and Community Services the Hon Brian Howe, MP)

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HEALTH AND COMMUNITY SERVICES LEGISLATION AMENDMENT BILL (NO. 2) 1993

GENERAL OUTLINE

Part 2 of the Bill amends the Disability Services Act 1986. One amendment provides protection against defamation actions for statements of the Minister, or reports of those statements, regarding breaches by funded organisations of prescribed standards under the Act. The other amendment enables the Commonwealth to include a new condition in agreements with grant transferees under section 16 of the Disability Services Act 1986.

Part 3 of the Bill addresses unintended consequences of existing provisions regarding the provision of pathology services in the Health Insurance Act 1973.

Part 4 of the Bill amends the Hearing Services Act 1991. One amendment extends the existing definition of "eligible persons" to include holders of 'Dependant Treatment Entitlement Cards' to ensure the provision of Commonwealth hearing concessions to war widows. Another amendment extends the definition of "protected symbols" to include the official symbol of Australian Hearing Services.

Part 5 of the Bill validates previous non-approved pharmacy relocations of approved pharmacists from their original approved premises prior to the commencement of the pharmacy restructuring scheme, and cancels the right of the Commonwealth to recover amounts paid in respect of the supply of "pharmaceutical benefits" from the premises to which they had relocated.

Part 6 of the Bill amends the National Health and Medical Research Council Act 1992. Subsection 36(6) of the Act provides, amongst other things, that, before appointing members of the Australian Health Ethics Committee who have expertise in philosophy, or experience in medical research or social science research, the Minister must seek nominations from such learned academics as are prescribed for the purpose. The intention of the Senate was that the nominations be sought from learned academies not learned academics. This Part amends paragraph 36(6)(b) of the Principal Act to give effect to the Senate's intention.

Part 7 of the Bill repeals subsection 25(2) and section 38 of the Nursing Homes and Hostels Legislation Amendment Act 1986. Neither provision was ever proclaimed as they became redundant when responsibility for the regulation of government nursing homes was transferred from the Nursing Homes Assistance Act 1974 to the National Health Act 1953.

Part 8 of the bill amends the Therapeutic Goods Act 1989 to:

(a) accommodate proposed complementary State and Territory legislation that is to be enacted to implement a uniform national system of controls for therapeutic goods;

(b) include provisions that will give effect to Australia's obligations under the Convention for the Mutual Recognition of Inspections in respect of the Manufacture of Pharmaceutical Products;

(c) remove any uncertainty concerning how therapeutic goods that are packaged together in kit form, as a convenience to the user, are to be included in the Australian Register of Therapeutic Goods (ARTG);

(d) facilitate current procedures for undertaking investigations of suspected breaches of the Act;

(e) clarify that an assessment of the standard of manufacture of goods which are to be included in the ARTG will only be necessary where such goods are also required to be manufactured under licence in Australia;

(f) clarify that the Commonwealth cannot be held responsible for the quality, safety or efficacy of those goods included in the ARTG under the transitional provisions that operated in respect of goods that were on the market at the time the Act commenced ("grandfathered" goods);

(g) improve administrative efficiency in the handling of applications for export certification by providing for the charging of an application fee for an export certificate instead of a fee for the issue of a certificate;

(h) in line with Professor Baume's Recommendation 81 in his Report on the Future of Drug Evaluation in Australia, provide that appropriate regulations may be made to enable certain deliberations and decisions of the Australian Drug Evaluation Committee to be made public;

(i) provide a penalty for a failure to comply with existing requirements for the lodgement and supply of adequate and accurate information concerning goods intended for supply or supplied for use in humans; and

(j) correct anomalies appearing in some provisions of the Principal Act.

FINANCIAL IMPACT STATEMENT

Part 2 of the Bill

There are no direct financial implications from the amendments.

Parts 3, 4, 5, 6 and 7 - no impact.

Part 8 of the Bill

There will be no additional call upon the budget as a result of these changes.

There will some impact on industry, where sponsors have grouped listings of therapeutic goods. This will particularly apply in the devices industry. The change causing this impact is in clause 37. This change has been extensively discussed with the devices industry association, as part of discussions on the overall level of revenue raising required by the Therapeutic Goods Administration. The devices industry has agreed to the changes. There is a minimal impact on the therapeutic drugs industry, as there is a negligible incidence of grouping of drug products.

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NOTES ON CLAUSES

PART 1 - PRELIMINARY

Clause 1 - Short title

This is a formal provision that specifies the short title of the Act as the Health and Community Services Legislation Amendment Act (No. 2) 1993.

Clause 2 - Commencement

This clause provides that, with the exception of the matters dealt with in subclauses (2), (3) and (4) the provisions of the Act will commence on the day on which it receives Royal Assent.

PART 2 - AMENDMENTS OF THE DISABILITY SERVICES ACT 1986

Clause 3 - Principal Act

This clause is a formal provision that specifies the Disability Services Act 1986 as the Principal Act referred to in this Part of the Bill.

Clause 4 - Information about Minister's declaration may be made available to the public

This clause amends section 14J of the Principal Act by stating that a defamation action will not lie against the Minister for making a statement under the section relating to funded services' breaches of standards, nor against any person making a fair report on or summary of such statements.

Clause 5 - Agreements may be entered into with transferees of land, etc.

This clause amends section 16 of the Principal Act to enable the Minister to enter into agreements with transferees to which land, buildings and equipment are transferred from Commonwealth grantees, on the same terms and conditions as the grantees. The amendment enables the Commonwealth to require a transferee to repay the grant.

PART 3 - AMENDMENTS OF THE HEALTH INSURANCE ACT 1973

Clause 6 - Principal Act

This clause is a formal provision that specifies the Health Insurance Act 1973 as the Principal Act referred to in this Part of the Bill.

Clause 7 - Medicare benefits in relation to pathology services

This clause amends section 16A of the Principal Act which sets out the requirements to be met before medicare benefits are payable for a pathology service, such as paragraph 16A(2)(c) which requires the proprietor of the laboratory where a service is rendered to be an approved pathology authority.

The clause substitutes a new paragraph 16A(2)(c), whose meaning is reinforced by a new paragraph 16A(2)(ca), to ensure that control over a pathology laboratory which renders a pathology service for which medicare benefits are payable, is restricted to one approved pathology authority. It also makes minor consequential changes to other provisions in section 16A.

Clause 8 - Request forms and confirmation forms

This clause amends section 23DK of the Principal Act by adding new subsections 23DK(1A) and 23DK(2A) to extend the requirement which presently attaches to approved pathology practitioners, to retain for a period of 18 months request forms for pathology services, to approved pathology authorities.

Clause 9 - Restricted meaning of approved pathology authority

This clause amends section 23DNAA of the Principal Act by omitting the existing paragraph (b) and substituting new paragraphs (b) and (c) to ensure that approved pathology authorities which are partly, as well as wholly, owned by a State, a Territory or a public authority are excluded from the definition.

Clause 10 - Determination of circumstances in which additional licensed collection centres may operate

This clause amends section 23DNC of the Principal Act by inserting new subsections (3A), (3B) and (3C) to allow the Minister to review a determination made under subsection 23DNC(1) concerning the grant of additional licences for collection centres, after it has been in force for a period of 12 months, and either to allow it to continue in force or to cancel it. The Minister must inform the approved pathology authority in writing of the decision.

Clause 11 - Partial refund of licence fee on cancellation of certain licences

This clause amends section 23DNI of the Principal Act by substituting a new subsection (3) that makes a minor alteration to the formula used to calculate the refund of fees on certain cancelled collection centre licences.

Clause 12 - Review of decisions

This clause amends section 23DO of the Principal Act by adding new subsections (2DA) and (2DB) to extend a right of review of a decision to persons aggrieved by a decision to cancel an additional licence, open to the Minister under the new subsection 23DNC(3C) of the Principal Act proposed in clause 10 of the Bill.

Clause 13 - Offences in relation to request forms and confirmation forms

This clause makes an amendment to section 23DP of the Principal Act, consequential on the amendment to section 23DK of the Principal Act contained in clause 8 of the Bill, by inserting new subsection (1A) to apply the same penalties that currently apply to approved pathology practitioners for offences regarding the retention of request forms, to approved pathology authorities.

PART 4 - AMENDMENTS OF THE HEARING SERVICES ACT 1991

Clause 14 - Principal Act

This clause is a formal provision that specifies the Hearing Services Act 1991 as the Principal Act referred to in this Part of the Bill.

Clause 15 - Eligible persons

This clause amends subsection 5(1) of the Principal Act by substituting new paragraphs (1)(a) and (1)(ab) for the existing paragraph 5(1)(a). The amendment has the effect of including within the definition of 'eligible persons', persons who hold a Dependant Treatment Entitlement Card (issued by the Department of Veterans' Affairs to war widows amongst others) to be eligible for hearing services provided by Australian Hearing Services.

Clause 16 - Person not to use protected names or protected symbols

This clause amends section 66 of the Principal Act to extend the protection provided by that section to the official symbol of Australian Hearing Services.

Clause 17 - Addition of Schedule

This clause amends the Principal Act by adding at the end of the Principal Act a Schedule that defines the official symbol of Australian Hearing Services.

PART 5 - AMENDMENTS OF THE NATIONAL HEALTH ACT 1953

Clause 18 - Principal Act

This clause is a formal provision that specifies the National Health Act 1953 as the Principal Act referred to in this Part of the Bill.

Clause 19 - Benefit payable for up to 2 days prior to admission

This clause amends the Principal Act by omitting section 46AB and inserting it immediately after section 46A.

Clause 20 - Approved pharmacists

Subclause 20(1) adds new subsections (5A), (5B) and (5C) to section 90 of the Principal Act. Subsection (5A) provides for approval to be deemed to have been given to a pharmacist to supply pharmaceutical benefits from premises to which he or she may have relocated, without having sought approval for the relocation at the time of relocation, provided that the relocation took place before the introduction of the pharmacy restructuring provisions contained in Divisions 4B and 4C of Part VII of the Principal Act (i.e. 18 December 1990).

Subsection (5B) provides that in paragraph (5A)(b) the reference to supplying pharmaceutical benefits includes supplies of drugs or medicinal preparations made from unapproved premises, but for which payment had been made as if they had been supplies of pharmaceutical benefits.

Subsection (5C) provides that new subsection (5A) does not apply if the approval of the pharmacist who relocated is no longer in force or if the pharmacist is not permitted to carry on business at the new premises under State or Territory law.

Subclause 20(2) cancels the right of the Commonwealth to recover past payments purportedly made under Part VII of the Principal Act for "pharmaceutical benefits" supplied from unapproved premises to those pharmacists whose relocations will now be taken to have been approved by virtue of new subsection 90(5A).

Clause 21 - Cancellation by Secretary of approval of pharmacists etc.

A new subsection (4A) is added to section 98 of the Principal Act which will have the effect that where approval of a pharmacist is deemed to have been given in respect of new premises in accordance with the proposed amendment outlined in clause 20 above, the approval of earlier premises is taken to have been cancelled.

PART 6 - AMENDMENTS OF THE NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL ACT 1992

Clause 22 - Principal Act

This clause is a formal provision that specifies the National Health and Medical Research Council Act 1992 as the Principal Act referred to in this Part of the Bill.

Clause 23 - Constitution of and appointment of the Australian Health Ethics Committee

This clause amends section 36 of the Principal Act by omitting from paragraph (6)(b) the word "academics" and substituting "academies".

PART 7 - AMENDMENTS OF THE NURSING HOMES AND HOSTELS LEGISLATION AMENDMENT ACT 1986

Clause 24 - Principal Act

This clause is a formal provision that specifies the Nursing Homes and Hostels Legislation Amendment Act 1986 as the Principal Act referred to in this Part of the Bill.

Clause 25 - Commencement

This clause omits subsection 25(2) and section 38 from the commencement provision in the Principal Act, and is a consequential amendment to the amendments proposed in clauses 27 and 28 below.

Clauses 26 - Interpretation

This clause omits subsection (2) from section 25 of the Principal Act.

Clause 27 - Repeal of section 38

This clause repeals section 38 of the Principal Act.

PART 8 - AMENDMENTS OF THE THERAPEUTIC GOODS ACT 1989

Clause 28 - Principal Act

This clause is a formal provision that specifies the Therapeutic Goods Act 1989 as the Principal Act referred to in this Part of the Bill.

Clause 29 - Interpretation

Paragraph 29(a) adds to the definition in subsection 3(1) of the Principal Act of "grouped therapeutic goods" to include "gazetted kits group". This is necessary because of the introduction of "kits" as a new class of "grouped therapeutic goods", referred to in clause 34.

Paragraph 29(b) changes the description of one of the acts of manufacture, that of "releasing for sale", with the description "releasing for supply". The word "supply" has a broader meaning defined elsewhere in the same subsection, and more accurately reflects the intended coverage of the Principal Act.

Paragraphs 29(c) and (d) change the definition in subsection (1) of the Principal Act of "manufacturing premises" so that sites other than buildings may also be licensed for the purposes of Part 4 of the Principal Act.

Paragraph 29(e) is a consequential amendment. The amendment corresponds to the amendment made by clause 33 of this Bill.

Paragraph 29(f) amends the definition of "authorised person" in subsections 3(1) of the Principal Act by making members of the Australian Federal Police "authorised persons" for the purposes of Part 6 of the Principal Act, and Paragraph 29(j) amends subsection 3(3) of the Principal Act by providing that the Secretary need not publish a list of "authorised persons" who are members of the Australian Federal Police.

Paragraph 29(g) inserts a definition for "gazetted kits group", which will be a new class of grouped therapeutic goods that may be declared pursuant to new subsection 16(3A) of the Principal Act.

Paragraph 29(h) adds to subsection 3(1) of the Principal Act definitions for the phrases "corresponding State law" and "State law". These phrases refer to complementary State and Territory therapeutic goods legislation that is to be enacted by each State and Territory to establish, in conjunction with the Principal Act, a uniform system of regulation over therapeutic goods throughout Australia.

To qualify as a "Corresponding State law", a State or Territory complementary legislation must include regulatory requirements that correspond with the Principal Act and Therapeutic Goods Regulations, as amended from time to time, and must also be identified as a "corresponding State law" under the Therapeutic Goods Regulations. This amendment, and the associated clauses that use this new definition, will commence from a date to be proclaimed (subclause 2(3) refers). Proclamation will coincide with the enactment of the first acceptable corresponding State law.

Subclause 29(i) adds to subsection 3(1) of the Principal Act the new definition of the phrase "Mutual Recognition Convention". This definition is used in clauses 37, 38, 47 and 50, which make provisions for implementing Australia's commitment to the Convention for the Mutual Recognition of Inspections in respect of the Manufacture of Pharmaceutical Products. This definition, and the associated clauses that use this definition, will commence from a date to be fixed by proclamation (subclause 2(4) refers). The proclamation will be made soon, as the necessary arrangements for Australia to meet its obligations under this convention are substantially in place.

Clause 30 - Object of the Act

This clause repeals the existing object of the Act contained in section 4 of the Principal Act, and replaces it with an expanded statement in a new section 4 that accommodates the concept of complementary State/Territory therapeutic goods legislation which will mirror the requirements of the Principal Act, so that a national uniform system of controls over all therapeutic goods supplied in Australia may be established.

This clause, together with all other clauses dealing with the complementary State laws, will commence on a date to be fixed by Proclamation. A specific date has not been set, as the commencement date must coincide with the enactment of a complementary State law. The Commonwealth must be prepared for the coming of that complementary State law, but cannot predict when it will come into operation.

Clauses 31 and 32 - Operation of Act

Clauses 31 and 32 amend section 6 of the Principal Act and introduce new sections 6A, 6B and 6C. These provisions will enable the Secretary, with the written approval of the Minister, to exercise powers under proposed State and Territory complementary legislation to be enacted, where such legislation provides for State or Territory powers to be conferred upon the Secretary. The effect of new paragraph 6A(2)(a) is to enable the person from time to time acting in the Secretary's position to continue to perform functions and exercise powers under State or Territory legislation as approved by the Minister in accordance with new subsection 6A(1). Under new paragraph 6A(2)(b), the Secretary may delegate such functions and powers under section 57 of the Principal Act.

New subsection 6A(3) provides that therapeutic goods required to be registered or listed under a corresponding State law are to be included in the Commonwealth's Australian Register of Therapeutic Goods (ARTG) created under the Principal Act, where such inclusion is authorised under a corresponding State law.

New subsection 6A(4) allows the Secretary to cancel an entry in the ARTG made pursuant to a corresponding State law, if the complementary State law expressly authorises or requires the Secretary to do so in accordance with that law.

New subsection 6A(5) ensures that any inclusion of goods in the ARTG as a result of an action under subsection 6A(3) does not subject any person to any liability under the Principal Act, except Part 5 of the Principal Act.

New subsection 6A(6) allows the Secretary to make notations in the ARTG that identify entries in the ARTG made through powers conferred under a corresponding State law, to distinguish it from an entry in the ARTG made by the Secretary exercising his or her powers under the Commonwealth's Principal Act.

New subsection 6A(7) allows for the simultaneous inclusion in the ARTG of the same goods, in respect of the same sponsor, under both the Principal Act as well as under a corresponding State law. This is to accommodate the situation where coverage of therapeutic goods may move from the jurisdiction of a corresponding State law to the Principal Act (and visa versa). This may occur as a result of a change in the circumstances of the sponsor of the therapeutic goods. An example would be a sponsor's changed or changing business activities.

New subsection 6A(8) clarifies that references to the inclusion of therapeutic goods in the ARTG are references to the inclusion of the goods either as registered or listed goods.

New section 6B provides that where the Secretary or the Secretary's delegate makes a decision in the course of performing a function or exercising a power pursuant to a corresponding State law, a review of that decision by the federal Administrative Appeals Tribunal is to be possible if the corresponding State law allows for this and the decision is declared in the Therapeutic Goods Regulations to be a reviewable decision for the purposes of this provision.

New Section 6C to the Principal Act provides a mechanism for the Commonwealth to receive fees in respect of work performed as a result of powers conferred by corresponding State laws. The practical effect is that the Commonwealth will be able to collect fees for performing functions and exercising powers on behalf of the States and Territories under their corresponding State laws. The fees to be collected will be commensurate with the existing fees charged for the same activities currently performed under the Principal Act.

Clause 33 - Declaration that goods are/are not therapeutic goods

Clause 33 amends section 7 of the Principal Act to correct an anomaly regarding one of the criteria by which the Secretary may declare goods to be, or not to be, "therapeutic goods". The present criteria are, among other things, that where goods are labelled in a certain way, they may then be declared not to be therapeutic goods. The word "labelled" is to be replaced by "advertised or presented", to prevent sponsors from avoiding regulation by merely labelling their goods in a certain manner, but continuing to advertise their products in such a way as to undermine the basis upon which a declaration was initially made that declared the goods not to be therapeutic goods. Paragraph 33(2)(a) has the effect of preserving all current Orders made under section 7 of the Principal Act, and paragraph 33(2)(b) has the effect of importing this amendment into existing section 7 Orders, so that any reference to the way goods must be labelled in those Orders is to be read as a reference to the way they are advertised or presented for supply.

Clause 34 - Authorised Persons and Kits

Clause 34 inserts two new sections into the Principal Act.

New section 7A relates to the amended definition of "authorised person" in paragraph 29(f) above. The amendment expressly empowers the Secretary to authorise "authorised persons", who may include certain officers having functions relating to law enforcement.

New section 7B provides a definition for 'kit' and confirms that the provisions of the Principal Act are to apply to the manufacture, quality and supply of kits as well as to the individual goods included in a kit. Kits amount to two or more items packed together, where the individual items include separate therapeutic goods for the purposes of the provisions of the Principal Act, but are supplied to the consumer as a single packaged product. The distinction is drawn between kits and "composite packs" where the individual items in a composite pack cannot or are not intended to be used separately or on their own, but as part of a single treatment, or single course of treatment.

Because composite packs are intended for a single treatment or single course of treatment, the components are combined before administration, or are used in a defined sequence. This is not the case with therapeutic goods included in a kit.

Examples where this provision will simplify listing requirements in the Australian Register of Therapeutic Goods include the marketing of "Doctors' bag" kits, and kits of devices for use in operating theatres.

Clause 35 - Therapeutic goods and gazetted groups

Clause 35 will enable kits to be grouped under a single listing number in the Australian Register of Therapeutic Goods ("ARTG") in the same way that individual therapeutic goods may be grouped. The effect of "grouping" goods is that all goods included in the same group may be allocated the same ARTG number, and sponsors of each group of goods are only liable for a single set of annual registration or listing charges for all the goods contained in each group of goods.

Clause 36 - Applications generally

This clause ensures that each separate product included in "grouped therapeutic goods" attracts a separate application fee, consistent with the treatment of all other applications under section 23 of the Principal Act. The amendment does not change the provision allowing only one annual charge to be made for all goods included in each group of "grouped therapeutic goods". This amendment will only affect application received by the Therapeutic Goods Administration on or after the day the amendment comes into operation.

Clause 37 - Evaluation of therapeutic goods

Paragraph 37(a) inserts new subsections 25(2B), (2C), and (2D). New subsections 25(2B) and (2C) will clarify that where an application is made, pursuant to section 23 of the Principal Act, to register goods manufactured in Australia in the ARTG, compliance with any manufacturing requirements applying under Part 4 of the Principal Act will be disregarded for the purposes of section 25 where those goods have been exempted from the need to comply with such requirements under that Part.

New subsection 25(2D) extends the same principles applying to locally manufactured therapeutic goods under new subsections 25(2B) and (2C) to goods manufactured overseas.

Paragraph 37(b) inserts new subsections 25(2E), (2F) and (2G). These new subsections recognise Australia's commitment to the Mutual Recognition Convention. The effect of these amendments is to allow the Secretary to have regard to information obtained in accordance with that treaty when assessing compliance with manufacturing practices.

Paragraphs 37(c) and (d) amend section 25 of the Principal Act by replacing paragraph (3)(b) and omitting paragraph (4) so that the procedural steps necessary to effect registration are minimised, through the deletion of the step requiring the sponsor to confirm the details of the information to be held in the ARTG prior to the issue of a Certificate of Registration.

Clause 38 - Listing of therapeutic goods

The changes introduced by this clause closely reflect the changes made by clause 37. This clause deals with listed goods, whereas clause 37 deals with registered goods.

Paragraph 38(a) inserts new subsections 26(2A), (2B) and (2C). New subsections 26(2A) and (2B) will clarify that where an application is made, pursuant to section 23 of the Principal Act, to list goods manufactured in Australia in the ARTG, compliance with any manufacturing requirements applying under Part 4 of the Principal Act will be disregarded for the purposes of section 26 where those goods have been exempted from the need to comply with such requirements under that Part.

New subsection 26(2C) extends the same principles applying to locally manufactured therapeutic goods under new subsections 26(2A) and (2B) to goods manufactured overseas.

Paragraph 38(b) inserts new subsections 26(2D), (2E) and (2F). These new subsections recognise Australia's commitment to the Mutual Recognition Convention. The effect of these amendments is to allow the Secretary to have regard to information obtained in accordance with that treaty when assessing compliance with manufacturing practices.

Paragraph 38(c) corrects an anomaly in the Principal Act. This amendment corrects an expression by substituting the words "include the goods in the list" in subsection 26(3) of the Principal Act with the words "to list the goods", consistent with terminology used throughout the Principal Act.

Paragraph 38(d) merely simplifies the language used in subsection 26(4) of the Principal Act.

Clause 39 - Conditions of registration or listing

Clause 39 amends section 28 of the Principal Act by omitting subsection (6), made obsolete by the amendment to paragraph 63(h) of the Principal Act effected by clause 51 of the Bill.

Clause 40 - Secretary may require information

Clause 40 amends section 31 of the Principal Act so that a failure by a sponsor to respond to a request for information about goods which have been registered or listed in the ARTG will be an offence, as also will be the provision, knowingly or recklessly, of false or misleading information, in response to such requests.

A penalty of 60 penalty units will apply to each offence.

Clause 41 - Inspection and variation of entries in the Register

Clause 41 amends section 32 of the Principal Act to correct an anomaly in the provisions of that section, to enable the Secretary to approve requests to vary product information (the published information about the uses of therapeutic goods) other than product information of a kind described in subsection 32(4)(b) of the Principal Act.

This amendment also omits subsection 32(2) of the Principal Act, as it is now superfluous as a result of the amendment in clause 51 to section 63 of the Principal Act.

Clauses 42, 43, 44 and 45 - Use of term "manufacturing premises"

These clauses change the terminology in various sections of the Principal Act, so that the term "manufacturing premises" is used consistently throughout Part 4 of the Principal Act.

The effect of replacing "premises" with "manufacturing premises" is to provide for a more effective enforcement of the licence and inspection provisions in respect of manufacturing activities. The amendment corrects an error in relation to the type of premises for which an application for a manufacturing licence may be made and for which a licence to manufacture should be issued. Licences should in fact be issued in respect of "manufacturing premises", rather than "premises". Manufacturing premises, as defined in subsection 3(1) of the Principal Act, are premises where the same persons have control of the management of the production of therapeutic goods and the procedures for quality control.

Clause 46 - Entry and search of premises - evidence of offences

Clause 46 will enable an authorised person to apply to a Magistrate to extend the period of time during which evidence seized to prove an offence against the Principal Act may be held. The Magistrate may extend the period during which evidence may be kept where the Magistrate is satisfied that this will be necessary to provide the authorised person with a reasonable opportunity of completing an investigation of an offence under the Principal Act. Extensions may not extend beyond a 2 year period, and an extension must be granted either before the 60 day period or a previously extended period has expired.

Clause 47 - Searches at request of manufacturer

Clause 47 inserts a new section 51A in to the Principal Act, which allows the Secretary to respond to a request for an inspection made in accordance with the provisions of the Mutual Recognition Convention. This amendments reflects Australia's commitment to that Convention.

Clause 48 - Offences

Clause 48 amends section 54 of the Principal Act to enable a prosecution for an indictable offence to commence anytime up to two years after the commission of the offence, rather than the one year allowed under section 15 of the Crimes Act 1914. This will ensure that there will be sufficient time for the Therapeutic Goods Administration to thoroughly conduct investigations and mount a proper case against offenders under the Principal Act.

Clause 49 - Export Certifications

Clause 49 amends section 58 of the Principal Act to replace the requirement for a fee to be paid in respect of the issue of an export certificate with a requirement for an application fee to be paid instead. Subclause 49(2) clarifies that the new arrangement will only apply to new applications made after the amendment comes into effect.

Clause 50 - Release of Information

Paragraph 50(1)(a) amends section 61 of the Principal Act to enable Regulations to be made for the release of information about therapeutic goods for which an application for inclusion in the Australian Register of Therapeutic Goods has been made. This provision will enable decisions of the Australian Drug Evaluation Committee to be gazetted, in line with Professor Peter Baume's Recommendation 81 contained in his "Report on the Future of Drug Evaluation in Australia", which was adopted by the Government as a package in July 1991.

Paragraph 50(1)(b) amends the references to how fees may be calculated, to accord with changes made to provisions relating to the charging of fees for retrieving and providing information under the Freedom of Information Act 1982.

Paragraph 50(1)(c) simplifies the language used in subsection 61(8C) of the Principal Act. This simplification is made possible by the amendment in clause 51.

Paragraph 50(d) ensures that Australia's commitment to the Mutual Recognition Convention is reflected in the release of information provisions of section 61 of the Principal Act. Particular information cannot be released by the Secretary if such a release would breach that Convention.

Subclause 50(2) has the effect of importing the amendments made by paragraph 50(1)(b) of the Bill into any Regulations that were made under subsection 61(8A) of the Principal Act and that are in force when this amendment comes into effect.

Clause 51 - Regulations

Paragraph 51(1)(a) removes the reference to "prescribe fees" in paragraph 63(2)(g) of the Principal Act as this will now be covered by new paragraph 63(2)(h) of the Principal Act, as amended.

Paragraph 51(1)(b) clarifies the powers of the Governor-General to make regulations relating to any activity conducted by the Secretary under the Principal Act and the regulations to that Act.

Subclause 51(2) has the effect of preserving any current regulations made pursuant to paragraph 63(2)(h) of the Principal Act before its replacement by new paragraph 63(2)(h).

Clause 52 - Transitional arrangements for goods required to be registered or listed

Paragraphs 52(a) and (b) clarify the operation of section 66 of the Principal Act.

New subsection 66(3A) clarifies that where, pursuant to section 66 of the Principal Act, goods have been registered in the ARTG without having been evaluated, the Secretary may, if the Secretary believes this is appropriate, notify a sponsor of such goods that the Secretary intends to conduct an evaluation of those goods to establish if they should remain in the ARTG.

New subsection 66(4A) clarifies that where an evaluation is conducted in respect of registered goods included in the ARTG as part of the "grandfathering" exercise under section 66 of the Principal Act, the requirements under section 25 of the Principal Act, including the requirement concerning payment of an evaluation fee referred to in section 24 of that Act, are to apply to the evaluation of such goods. In addition, sections 24A, 24B and 24C, dealing with payment of appropriate evaluation fees by sponsors, will apply to the sponsors of the "grandfathered" goods. However, section 24D, which allows for payment of reduced evaluation fees, and section 24E, permitting direct appeal to the Administrative Appeals Tribunal, will not apply to the evaluation of "grandfathered" goods as these provisions are intended to apply only to new applications lodged after the "grandfathering period" to register drugs identified in Schedule 10 of the Therapeutic Goods Regulations.

New subsection 66(4B) allows the Secretary to issue a written notice to the sponsor of a listed product that was "grandfathered" without an assessment, stating that the Secretary intends to determine whether the goods should continue to be listed.

New subsection 66(4C) provides that if a notice is issued under subsection 66(4B), then section 26 applies to the sponsor of that good. This means that the Secretary will then treat the sponsor as an applicant for listing of the good under section 26.

Paragraph 52(c) clarifies that no assurance of quality, safety or efficacy is given in respect of goods that were included in the ARTG under the transitional provisions of section 66, being goods that were supplied at the time of commencement of the Principal Act. Therefore, new subsection 66(6) provides that no liability will attach to the Commonwealth, Secretary or delegate for loss, damage or injury caused by or arising from the use of such goods.