Therapeutic Goods Regulations (Amendment) 1995 No. 208

EXPLANATORY STATEMENT

STATUTORY RULES 1995 No. 208

Issued by Authority of the Minister for Family Services

Therapeutic Goods Act 2969

Therapeutic Goods Regulations (Amendment)

The Therapeutic Goods Act 1989 (the Act) has for its objective the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods that are used In Australia or exported from Australia.

Sections 17, 18, 26, 34 and 63 of the Act enable the GovernorGeneral to make regulations prescribing, among other things, matters necessary or convenient to be prescribed for carrying out or giving effect to the Act. These include:

Paragraphs 17(4)(a) and 17(4) (b) and Subsections 18(1) and 18(3)

* prescribing the classes of therapeutic goods which are to be included in each part of the Australian Register of Therapeutic Goods (the Register), transferred from one part to the other, exempted from inclusion or included by revocation of an exemption;

Paragraph 26(1)(g)

* prescribing what devices are required to meet manufacturing and quality control procedures used in the manufacture of these goods where they are imported into Australia;

Subsections 34(1) and 34(3)

* prescribing the classes of therapeutic goods exempt from being manufactured by a licensed manufacturer and revoking such exemptions; and

Paragraph 63 (2) (c)

prescribing requirements for the advertising of therapeutic goods.

Accordingly, the regulations seek to:

(a) align Australia's statutory definitions for a number of therapeutic devices with those adopted by the European Union, to foster the harmonisation exercise between Australia and the European Union which should facilitate evaluation and marketing approval of common therapeutic goods marketed in both jurisdictions, and facilitate the export from Australia of such goods to the European Union;

(b) amend the functions and the composition of the current Therapeutic Goods committee act up under regulation 34 of the Regulations;

(c) introduce or increase the level of regulation of certain therapeutic goods in line with developments in other countries, or In response to a reconsideration of the level of health risk posed by these goods and the degree of control needed. These goods include: antiseptics and disinfectants used either to clean or sterilise surfaces or devices, such as re-usable medical devices; disinfectants with claims that they can kill certain microbes or bacteria associated with

transmissible or infectious diseases; HIV and hepatitis C test kits; blood collection tubes; goods containing ingredients of human or animal origin; non-powered endoscopes and endoscopic accessories; and certain active implantable devices, These goods will either be required to be included in the Register before they are marketed, or where they are already required to be included in the Register, they will require more stringent evaluation before the goods may continue to be marketed;

(d) clarify the operation of the Act to include a further example of what would constitute an "unacceptable presentation" of therapeutic goods. This includes the presentation of drugs In novelty dosage forms for children, where they could be mistaken for confectionery or toys. Also, the status of Ascorbyl palmitate as a "listable" product is to be clarified. Ascarbyl palmitate will continue to be listable where that drug product, or a drug product containing that ingredient, has a recommended daily total dose of a certain level of Ascorbyl palmitate;

(e) implement the recommendation of the Jenkins Report to extend the current requirement for sponsors of mainly prescription drugs to those sponsors of mainly prescription drugs to sponsors of drugs that are listed In Schedule 3 of the Poisons Schedule;

(f) exempt certain imported therapeutic goods from the requirement to be included in the Register where they have been imported into Australia for supply to Individual patients under the Special Access Scheme in accordance with subsection 19(1) of the Act, or imported for clinical trial purposes. The exemption Is subject to conditions specified in Schedule SA of the Regulations;

(g) revise the wording of some items in various schedules to clarify their meaning, particularly in respect of technical descriptions, and correct inaccurate references within and between schedules.

Further details of the amendments are set out in the Attachment.

There are five commencement dates in the Regulations. 4 July 1995 is the commencement date for all the amendments except for those that relate to the regulation of antiseptics and disinfectants, Ascorbyl palmitate, hepatitis C and HIV test kits and provisions amending the functions and composition of the Therapeutic Goods committee.

To provide industry with further time to comply with new regulatory requirements introduced by the amending Regulations for antiseptics and disinfectants, sponsors of those products will have until 1 January 1996 to obtain marketing approval for their goods before they may supply, or continue to supply, their products In Australia. Manufacturers of antiseptics and disinfectants will have a further year, until 1 January 1997, to upgrade their manufacturing processes and facilities to comply with manufacturing standards that will apply to the manufacture of certain classes of instrument grade, household grade and hospital grade disinfectants and antiseptics. Sponsors of Ascorbyl palmitate, hepatitis C and HIV test kits will have until 1 October 1995 to apply for registration of their products where these will no longer meet the criteria of a listable drug. Likewise, changes to the functions and membership of the Therapeutic Goods Committee will commence on 1 October 1995.

Further details of the amending Regulations are set out in the Attachment.

The Regulations, with four exceptional commence on 4 July 1995.

ATTACHMENT

Regulation 1: sets out the five commencement dates for the Regulations. These are:

(a) subregulation 1.1 - provides that, apart from the changes identified in this subregulation relating to disinfectants, the Therapeutic Goods Committee, Ascorbyl palmitate and hepatitis C and HIV test kits, the amendments contained in these amending Regulations are to commence on 4 July 1995;

(b) subregulation 1.2 - 1 October 1995 will be the commencement date for the changes relating to hepatitis C and HIV test kits. From that date, sponsors of those goods will be required to register these products In the Register. 1 October 1995 will also be the commencement date for changes relating to the composition and functions of the Therapeutic Goods Committee;

(c) subregulation 1.3 - 1 January 1996 will be the commencement date for the changes relating to certain classes of antiseptics and disinfectants. These provisions will require a range of antiseptics and disinfectants to be included in the Australian Register of Therapeutic Goods (the Register) before they may be supplied, or continue to be supplied, in Australia. At present, these products have been exempted from the requirement to be included in the Register. *Inclusion* in the Register signifies that, unless the goods are "grandfathered" products, they have undergone some form of assessment and scrutiny before their supply In Australia;

(d) subregulation 1.4 - 1 October 1996 will be the start date for the changes relating to the regulation of Ascorbyl palmitate. This will provide manufacturers of these products bearing a daily dose recommendation exceeding the stipulated level until 1 October 1996 to apply for registration of their product, or remove it from the market or modify the dosage required;

(e) subregulation 1.5 - 1 January 1997 will be the commencement date for the changes that introduce manufacturing controls over certain classes of antiseptics and disinfectants. industry will have a further year, after including their goods in the Register, within which to upgrade their manufacturing processes and facilities to a level that meets acceptable manufacturing standards.

Regulation 2 provides that the Therapeutic Goods Regulations are to be amended as set out in the amending Regulations.

Regulation 3 Inserts a number of definitions. Definitions for:

- "active implantable therapeutic device" and "active therapeutic device" have been taken directly from the definitions used by the European Union;

- "antiseptic", "disinfectant", "critical medical device", "fungicide", "high level disinfectant", "hospital grade disinfectant", "household disinfectant", "instrument grade disinfectant", "non critical medical device", "semi critical medical device", "sporicide", "sterilant", "tuberculocide" and "virucide" have been adapted from definitions used in the United States of America In the context of regulation of antiseptics and disinfectants.

Regulation 4 inserts a new regulation 6A to clarify that, for the purposes of what constitutes "unacceptable presentation,' under the Act, the presentation of therapeutic goods in a form likely to result in their being mistaken for, or confused with, confectionery or toys will be unacceptable,

Regulation 5 implements Recommendation 42 of the Report of the House of Representatives standing committee on Community Affairs (the Jenkins Report). This was a recommendation that drug; falling within Schedule 3 of the Poisons Standard, approved for marketing on or after 4 January 1994, should be accompanied by Consumer Product information ("CPI") when supplied to consumers. This date will now be 1 July 1995. Sponsors of drugs already being supplied will be required to produce CPIs for their products by the year 2004, or earlier if they should lodge an application to amend entries for such products already included In the Register. The kind of

information required to be included in the CPI is essentially similar to that currently required for prescription or similar drugs, as listed in Schedule 10 of the Regulations.

Regulation 6 amends the functions and composition of the Therapeutic Goods Committee act up under regulation 34 of the Regulations. The additional function to be assumed by the Committee will be to advise the Minister on the likely impact, on domestic and international trade, of any adoption of a particular standard for therapeutic goods. The new composition of the Committee will include representatives nominated by major Industry associations, and a representative nominated by a major consumer group.

Regulation 7 includes an amendment required to reflect a name change to one of the organisations listed in Schedule 1 of the Regulations. Schedule 1 lists all those organisations to which unrestricted advertising material, of a kind described in Part 2 of the Regulations, may be directed.

Regulation 8 lists new prohibited representations that may not be made in respect of antiseptics and disinfectants.

Subregulation 8.1 adds to the list of prohibited representations set out under Item 6. The prohibited representations are intended to minimise any confusion that may arise over what the products can achieve, and are designed to prevent any claims being made about their effect against viruses and certain bacteria such as Mycobacterium tuberculosis, unless these claims have been approved in writing by the Secretary. Also, no claims can be made about the disinfecting of inaccessible parts of drains.

Subregulation 8.2 introduces a new Item 6A into Schedule 2, to preclude any representations being made that anaesthetic or respiratory apparatus or surgical instruments can be stored In instrument-grade disinfectants after they have been disinfected.

Regulation 9 adds 4 new classes of therapeutic goods that will require registration in the Register. They are:

Item 4: active implantable medical devices other then those of a kind that were approved for marketing in Australia as at 3 July 1995, being auditory nerve stimulators, bone growth stimulators, incontinence control stimulators, peripheral nerve stimulators and spinal chord stimulators;

Item 5: instrument grade disinfectants claimed to be sterilants, fungicides, sporicides, tuberculocides or virucides intended for use on critical or semi critical medical devices;

Item. 6: hospital grade or household grade disinfectants that are claimed to be sterilents, fungicidee, sporicides, tuberculocides or virucides; and

Item 7: diagnostic goods for in vitro use that are goods for use in the diagnosis of Human Immunodeliciency Virus or hepatitis C virus.

The effect of this regulation will be that the high risk nervous system stimulators and other powered implantable devices intended to be covered by item 4 above, along with the other items listed by this regulation, will be required to be evaluated for safety, efficacy and quality before being approved for marketing.

Regulation 10 makes amendments to Schedule 4 of the Regulations. The amendments include consequential amendments associated with changes made to other Schedules of the Regulation, a correction of a typographical error and the inclusion of new products under this Schedule, signifying that these goods will require listing in the Register before they may be supplied.

Subregulations 10.1 and 10.2 are consequential amendments that include a new reference to Item 4 included in Schedule 3, and that refer to the new list of herbal substances included in Part 4 of Schedule 4 under Subregulation 10.8.

Subregulation 10.3 amends item 7 (listable sunscreens) by making more specific which sunscreens are required to be listed. Sunscreen preparations eligible for listing are those that are for dermal application with a Sun Protection Factor ("SPF") of 4 or greater, where the claimed SPF has been established by testing according to the method described in Standard AS/NZS 2604:1993 (as in force from time to time), and where the performance statements and markings on the label of the sunscreens comply with that standard. Sunscreens with an SPY of below 4 will still be required to be listed in the Register if they contain ingredients of human or animal origin. Subregulation 10.4 corrects a typographical error.

Subregulations 10.5 and 10.6 add new items that will be required to be listed In the Register before they may either be supplied or continue to be supplied. These are:

- non-powered endoscopes and endoscopic accessories; and

- hospital grade disinfectants recommended by their manufacturers to be used only on non critical surfaces, where no claims are made that the goods are sterilants, fungicides, sporicides, tuberculocides or virucide.

Subregulation 10.7 clarifies that "Ascorbyl palmitate" in oral preparations qualities for listing in the Register if the maximum daily dosage for that particular substance, whether it is supplied an its own or mixed with other ingredients, is not more than 100mg. Where the dose Is greater then this, the product is required to be registered in the Register.

Subregulation 10.8 has the effect of replacing Part 4 of Schedule 4 with a new list of herbal substances that must not be included in drugs that qualify for listing in the Register. Drugs incorporating these substances require registration in the Register. The new list updates the existing list in Schedule 4 and reflects the recommendations of the Traditional Medicines Evaluation Committee. The additional herbal substances that have been listed are deemed unsuitable !or Inclusion in listed or listable goods because they have raised some public health concerns.

Regulation 11 makes a number of changes to Schedule 5 of the Regulations. This schedule contains a list of goods that are exempted from the requirement to be Included In the Register before they may be marketed.

Subregulation 11.1 is a consequential amendment, made to reflect the fact the goods now described in Item 7(b)(1v), being diagnostic goods for in vitro use in the diagnosis of HIV infection or hepatitis C virus, are now required to be registered. The amendment removes the registration exemption for diagnostic goods used for the diagnosis of hepatitis C virus.

Subregulation 11.2 is another consequential amendment. The wording of the exclusion to the exemption, which is a reference to endoscopes and endoscopic accessories, has been amended to reflect the description of those goods inserted by subregulation 10.5.

Subregulation 11.3 substitutes the word "equipment" with "devices" In Item 7(g). The word "equipment" has caused confusion with industry as some sponsors believe "equipment" denotes complex apparatus. However, simple devices such as straps that hold other devices in place are intended to be covered by this item. The purpose of this amendment is to remove that confusion.

Subregulation 11.4 removes the current exemption for certain blood collection containers to be Included in the Register. These products will be required to be listed In the Register.

Subregulation 11.5 amends the exemption from registration/listing for homoeopathic preparations so that the exemption does not extend to include products that contain ingredients of human origin or specific animal origin. The animal parts described under this provision are those in Categories 1 (High Infectivity) and Category 2 (Medium Infectivity) of the "European guidelines for minimising the risk of transmission of agents causing Spongiform Encephalopathies via medicinal products".

Subregulation 11.6 clarifies the meaning of "medicated insect repellents". The term refers to Insect repellents that contain an antiseptic as a secondary active ingredient. The types of repellents intended to be exempted from the . requirement to be included in the Register are goods whose primary function is as an Insect repellent, but which may contain an antiseptic as added protection against sepals of a bite if the repellent fails.

Subregulation 11.7 is a consequential amendment, to reflect the changes made to Schedules 3 and 4 that will require certain disinfectants to be included in the Register, from 1 January 1996, before they may be supplied in Australia.

Subregulation 11.8 is a consequential amendment that mirrors the changes made to Item 7 of Schedule 4, which describes what sunscreens are listable. Sunscreens with a SPF factor below 4 are exempted from the requirement to be included In the Register, unless they contain ingredients of human or animal origin of a kind described In item 8(a) of Schedule 5, as amended by Subregulation 11.5.

The effect of Subregulation 12,1 is to amend Item 1 and insert new item 1A in Schedule 5A to enable an Importer to import unapproved therapeutic goods (other than prohibited imports) In circumstances where the Importer Intends to apply for an approval to supply the goods to individual patients in Australia under the Special Access Scheme, pursuant to subsection 19(1) of the Act, or to apply for permission to use the products for clinical trials. The conditions under which this exemption is to operate are essentially similar to those that currently apply. New conditions relating to the disposal of the goods are included where anticipated approval for the supply of the goods in Australia, in accordance with the terms of the exemption, is refused.

Subregulation 12.2 removes a requirement on manufacturers of certain device kite to separately include In the Register each and every therapeutic device, or part thereof, included in their kits before they may market their kite in Australia. The conditions for this exemption include a condition that none of the devices within the kits are separately marketed in their own right, or separately imported or exported other than as part of the kit that is supplied in Australia. Where component may be manufactured by a different person other than the kit manufacturer, then the kit manufacturer must be covered by an appropriate manufacturer's license issued under Part 4 of the Act.

Regulation 13 lists two additional classes of therapeutic goods under Schedule 6 of the Regulations. The effect of the amendments Is that certain hospital grade disinfectants and hepatitis C test kits will be required to comply with manufacturing standards where they have been manufactured overseas and imported into Australia.

Subregulation 14.1 adds hepatitis C test kits to the list of locally made goods required to meet manufacturing standards.

Subregulation 14.2 is another consequential amendment required to reflect the change in description of blood collection tubes, as set out under Schedule 4 of the Regulations. The blood collection tubes as described under Item 5(b), which are required to be included in the Register, must also meet manufacturing standards under Part 4 of the Act to ensure that the quality of the product will be acceptable.

Subregulation 14.3 is a consequential amendment to reflect the changes made to subregulation 11.6.

Subregulations 14.4 Introduces an amendment that will require certain classes of hospital grade disinfectants (to be regulated under Part 3 of the Act from 1 January 1996) manufactured in Australia to comply with manufacturing standards. To give manufacturers more time to upgrade their manufacturing processes and facilities in order to meet manufacturing principles, manufacturers of these products will have until 1 January 1997 to comply with manufacturing standards.

Subregulations 15.1 and 16.1 amend the reference to the name of the Branch responsible for evaluating drugs listed in Schedule 10 of the Regulations. The new name of the Branch is "Drug Safety and Evaluation Branch".

Subregulation 16.2 provides that barium sulphate preparations for radiological use will not be evaluated by the Drug Safety and Evaluation Branch, an this product Is more appropriately evaluated by the Compliance Branch of the Therapeutic Goods Administration.

Subregulation 17.1 amends the definition of "common name" to refer to a document published by the Therapeutic Goods Administration, rather then the world Health Organisation. The "common name" for drugs and herbal substances will be those listed under the Australian Approved Names. Adherence to the terms used under this document in dealings between Industry and the Therapeutic Goods Administration is intended to achieve consistency In approach in the correct identification of various drugs and herbal substances for the purposes of the Act and Regulations.

Subregulation 18.1 sets out what information must be included in Approved Patient Information that will be required to accompany drugs included in Schedule 3 of the Poisons Standard when these are supplied to consumers. This requirement applies to the Schedule 3 drugs that are approved for marketing on or after 1 July 1995.

Regulation 19 sets out the transitional provisions that are to apply to the amendments effected in respect of blood collection tubes, endoscopes and endoscopic accessories, sunscreens and homoeopathic preparations containing Ingredients of human or animal origin.