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REPLIES TO QUESTIONNAIRE ON IMPORT LICENSING PROCEDURES

AUSTRALIA

Revision

The following notification has been received from Australia in response to the Questionnaire on Import Licensing Procedures annexed to L/5640/Rev.10. It updates and replaces document L/5640/Add.13/Rev.7.

The following notification for January to June 1994 on import licensing procedures comprises two sections with the relevant information on:

I. Customs (Prohibited Imports) Regulations - Regulations 5A to 5H and Schedule 8 to the Regulations covering therapeutic substances and goods (pages 1-3); and

II. Customs (Prohibited Imports) Regulations - Regulation 5 and Schedule 4 to the Regulations, covering narcotic drugs, psychotropic substances and related chemicals (pages 3-7).

I. Customs (Prohibited Imports) Regulations - Regulations 5A to 5H and Schedule 8 to the Regulations Covering Therapeutic Substances and Goods

Outline of System

1. Following the introduction in February 1991 of a new Australian Registration system for therapeutic goods for human use under the provisions of the Therapeutic Goods Act, 1989, most of the barrier controls remaining in force under Regulations 5A to 5H prohibit the importation of substances specified in Regulation 5A(1), or goods included in Schedule 8 to the Regulations, except with permission of the Secretary of the Department of Health, Housing, Local Government and Community Services.

Purposes and Coverage of Licensing

2. The therapeutic substances/goods covered are:

(i) substances named in Regulation 5A(1). Currently only antibiotic substances are so specified. An exemption applies in the case of antibiotics carried by a passenger on

a ship or aircraft where the antibiotics are for the sole use of the passenger or the passenger's relative;

(ii) goods to which Regulation 5H refers, that is, goods which are listed in Schedule 8 to the Regulations.

3. The regulations apply to the importation of therapeutic goods from all countries.

4. The importation of antibiotics is regulated as a public health measure to provide information on antibiotic distribution and consumption in Australia. Goods included in Schedule 8 to the regulations are those known to be associated with particular hazards or concerns which warrant restriction or prohibition of their use. The monetary value of the goods is not a criterion for control.

5. The control on importation of the specified goods is a statutory requirement under the Customs (Prohibited Imports) Regulations made under the Customs Act, 1901.

Procedures

6. Not applicable.

7. (a) Applications should be made in advance of the arrival of the goods. In certain circumstances, import permission can be given for goods which have inadvertently arrived at the point of entry.

(b) Permits may be issued immediately if a genuine emergency exists.

(c) No.

(d) Applications for import permissions required by Regulations 5A to 5H are processed and issued within the Department of Health, Housing, Local Government and Community Services. [Note: separate import authorization may be required from other regulatory agencies under different legislation, such as quarantine laws applying to importation of materials of biological origin.]

8. If permission for importation is refused, the reasons are notified to the applicant in writing. An appeal to the Minister for Health may be made within 90 days of the decision being notified. In the case of the applicant being dissatisfied with the Minister's finding, application may be made to the Administrative Appeals Tribunal for the review of the decision.

Eligibility of Importers to Apply for Licence

9. (a) Not applicable.

(b) Yes, provided they are domiciled in Australia.

Documentational and Other Requirements for Application for Licence

10. (i) For antibiotic imports (under Regulation 5A(1)), applications should be made in writing, including the following information:

- importer's name and address;
- name and location of the manufacture of the goods;

- details of the goods (whether raw material or formulated product);
- quantity and distribution (end-use).

(ii) For goods in Schedule 8 (Regulation 5H refers):

- importer's name and address;
- exporter's name and address;
- full details of the product proposed for import;
- supervising doctor's prescription, if applicable;
- depending on the nature of the goods and the intended purposes, further documentation or evidence may be required.

11. Import authorization is usually issued in the form of a permit (Form T26), but may be by letter of authority.

12. No.

13. No.

Conditions of Licensing

14. Permits may apply to one consignment only, or remain valid for successive consignments within a stated period (usually two years maximum).

15. No.

16. No.

17. Conditions may be applied regarding the custody, use, disposal or distribution of the imported goods.

Other Procedural Requirements

18. Importers of therapeutic goods should familiarize themselves with the requirements of the Therapeutic Goods Act, 1989, in relation to the importation of therapeutic goods for supply in Australia; for example, requirements for entry of goods in the Australian Register of Therapeutic Goods prior to supply, requirements for compliance with standards and advertising regulations and with Codes of Good Manufacturing Practice.

19. Goods requiring import permission under Regulations 5A to 5H are not subject to any different or separate treatment in relation to the provision of foreign exchange.

II. Customs (Prohibited Imports) Regulations - Regulation 5 and Schedule 4 to the Regulations, Covering Narcotic Drugs, Psychotropic Substances and Related Chemicals

Outline of System

1. Licences and permits are issued to control the import of specified narcotic drugs, psychotropic substances and related chemicals. This system fulfils part of Australia's obligation under three United

Nations conventions in relation to restricting the supply of controlled substances to that necessary to meet medical and scientific need and preventing diversion to the illicit drug market.

Purposes and Coverage of Licensing

2. The licensing system covers persons involved in international trade of those substances listed in Schedule 4 of the Customs (Prohibited Imports) Regulations, their derivatives, precursors and related substances. These include the drugs and chemicals required to be controlled under the Single Convention on Narcotic Drugs, 1961, the Convention on Psychotropic Substances, 1971, and Table I of the Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.

3. The system applies to importers of controlled substances from all countries.

4. The use of import licences and permits enables the Government to restrict and monitor the quantities of controlled substances imported. This is intended to prevent the over-supply and diversion of controlled substances and is one strategy adopted to address drug misuse. The system is based on the requirements of the international treaties.

5. The Customs Act, 1901, together with the Customs (Prohibited Imports) Regulations. The Regulations require the licensing of importers. The drugs subject to licensing control are determined by statutory rules. The system cannot be abolished without legislative approval.

Procedures

6. I. National import limits for substances controlled by the Single Convention are set by an estimates system administered by the International Narcotics Control Board (INCB). The INCB publishes the estimates (import limits) for all parties to the conventions. Allocation of limits for imports from particular countries is not applicable. Individual importers are allocated a quota, within Australia's estimate, for each substance, and are advised of their quotas. These quotas are regarded as commercial-in-confidence and are not published or made available to third parties.

II. Quotas are allocated annually to each licensed importer based on previous requirements and stock levels. Some of the estimate is not allocated in initial quotas so that individual allocations may be increased where justified and to make provision for new importers.

III. Whether applicants are domestic producers is not relevant to their application for an import licence. Import permits are required for each shipment and are only issued to licensed importers. Quotas are maximums rather than targets and therefore it is not necessary for permits to be issued for the entire amount, nor is unused allocation accumulated. A list of licensed importers is available to governments on request. Quota information is not available.

IV. Applications for licences are accepted at any time. Quotas are assigned and reviewed as INCB estimates are set.

V. Licence applications may take six to eight weeks to process because of the stringent checks made on the personnel involved and on the security arrangements in place. Licences are issued annually. Permits generally take 10 working days to process. Where the importer is already licensed, a permit may be issued on the day of application. Almost all permits are issued within 10 working days of the application.

VI. An import permit may be issued immediately following the grant of a licence. Import could then proceed.

VII. Licences and permits are administered by the Treaties and Monitoring Section, Drugs of Dependence Branch, Department of Human Services and Health. Generally, no other authority is required. However, additional controls are imposed on some substances (for example, if the drug is not approved in Australia, quarantine restrictions, etc.) and the appropriate procedures for these controls must also be completed.

VIII. There is no limit on the number of licences and permits to be issued. However, where relevant, the total imports cannot exceed the INCB administered estimate. Licence renewals are examined simultaneously. New licence applications are examined upon receipt.

IX. Import permits are required for all shipments of controlled substances regardless of whether an export permit is also required. In fact, for many of the controlled substances, the conventions require that the export permit can only be issued after an import permit has been sighted.

X. As required by the Single Convention on Narcotic Drugs and the Convention on Psychotropic Substances, copies of all import and export permits are forwarded to the competent authority of the importing or exporting country.

XI. Yes, when an import would result in Australia exceeding the INCB estimate and the import is for the purpose of re-export.

7. (a) There is no minimum advance notice required for a licence or permit application. However, stringent checks of applicants for licences are undertaken in order to issue a licence. Permits will only be issued to a licensed importer. Goods arriving at the port without a permit cannot be imported and retrospective permits cannot be issued.

(b) A licence would not normally be granted immediately as some conditions must be fulfilled. Checking of applicants' suitability to hold a licence generally takes some time and therefore licences cannot generally be issued immediately upon request.

(c) No.

(d) Import licences and import permits are both issued by the Department of Health, Housing, Local Government and Community Services. When considering licence applications, other authorities may be contacted by the Department to verify application details (for example, criminal records). The applicant does not need to approach these authorities.

8. An application may be refused if the criteria are not met. These criteria require the importer to be a "fit and proper person" and maintain adequate security for storage. An application for a permit may be refused if the import would be excessive to national requirements. In addition, if other permissions are required (for example, quarantine, State licences), the permit will only be issued after these permissions have been obtained. A licence or permit may be revoked if the licence holder fails to comply with the conditions of the licence (for example, ensuring the safe storage and transport of the controlled substance and record keeping).

The affected person is notified in writing of any refusal or revocation. The person may appeal to the Minister of Health and subsequently to the Administrative Appeals Tribunal.

Eligibility of Importers to Apply for Licence

9. Any person who requires controlled substances for a legitimate commercial, medical or scientific purpose may apply for a licence. Providing the applicant has suitable security arrangements and is considered "fit and proper" to hold a licence, a licence is granted subject to conditions concerning use, sale and distribution of the substances. Import permits are only issued to licence holders. In addition, the applicant must have an authority under State or Territory law to be in possession of the substance before a permit will be issued. A list of licensed importers is available to other governments from the Department of Human Services and Health.

Documentational and Other Requirements for Application for Licence

10. Applications for licences and permits must be submitted on either an Application for a Licence to Import Controlled Substances or Application for a Permit to Import Controlled Substances respectively.

For a licence application, the following information must be supplied:

- name of the applicant (person or organization);
- address of the premises on which the controlled substance will be held;
- nature of the business (e.g., pharmaceutical manufacture, chemical distribution, etc.);
- classes of controlled substances to be held (e.g., narcotic drugs, psychotropic substances, precursor chemicals, laboratory standards, etc.);
- details of licences held relating to the storage, manufacture or distribution of the substances;
- details of all persons who will have access to the controlled substances, including their positions and qualifications and specific background information to enable a security check;
- details of the security arrangements for the storage, distribution and handling of the substances;
- details relating to the applicants appointment of an agent (e.g. shipping, agent, customs agent, etc.).

For a permit application, the following information must be supplied:

- importer's name and address;
- overseas exporter's name and address;
- product description (name, form and strength);
- number and size of the packs;
- proposed date of import;
- mode of transport (e.g., airfreight, seafreight, etc.);
- where necessary, the name of the end-user and the use of the end-substance.

11. The import permit is the required document and, for some substances, the complementary overseas export permit.

12. There is no charge for a licence or permit.

13. No.

Conditions of Licensing

14. Import licences are valid until the end of the calendar year (year of application if applied before September or following year). Import permits are usually valid for six months, but may be amended if necessary.

15. No. However, if a licence holder has not used the licence during the year and applies for a renewal, the applicant may need to justify retention of the licence.

16. Licences and permits are not transferable. However, quotas may be transferred between importers with the agreement of both parties.

17. For licences, conditions apply to the keeping of records and the reporting of movements. For permits, specific conditions may be endorsed on the permit, for example, for re-export only or for veterinary use only.

Other Procedural Requirements

18. No.

19. Controlled drugs subject to import licensing are not subject to any different treatment in relation to the provision of foreign exchange.