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REPLIES TO QUESTIONNAIRE ON IMPORT LICENSING PROCEDURES

AUSTRALIA

Revision

The following revised notification[1] has been received from Australia in response to the Questionnaire on Import Licensing Procedures annexed to L/5640/Rev.8. It updates and replaces document L/5640/Add.13/Rev.5.

REPONSES AU QUESTIONNAIRE RELATIF AUX PROCEDURES EN MATIERE DE LICENCES D'IMPORTATION

AUSTRALIE

Révision

La délégation de l'Australie a fait parvenir au secrétariat la notification révisée[1] ci-après, en réponse au questionnaire relatif aux procédures en matière de licences d'importation annexé au document L/5640/Rev.8. Cette notification met à jour et remplace le document L/5640/Add.13/Rev.5.

RESPUESTAS AL CUESTIONARIO RELATIVO A LOS PROCEDIMIENTOS PARA EL TRAMITE DE LICENCIAS DE IMPORTACION

AUSTRALIA

Revisión

Se ha recibido de Australia la siguiente notificación revisada[1] en respuesta al cuestionario relativo a los procedimientos para el trámite de licencias de importación anexo al documento L/5640/Rev.8. Con ella queda actualizada y sustituida la información contenida en el documento L/5640/Add.13/Rev.5.

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[1] English only/Anglais seulement/En inglés solamente

REPLIES TO QUESTIONNAIRE ON IMPORT LICENSING PROCEDURES

The following notification for 1992 on import licensing procedures is submitted by Australia in response to the questionnaire annexed to L/5640. It comprises three sections with the relevant information on:

1. Customs (Import Licensing) Regulations covering industrial products (pages 3-5);

2. Customs (Prohibited Imports) Regulations - Regulations 5A to 5H and accompanying Eighth Schedule to the Regulations covering therapeutic substances and goods (pages 6-8); and

3. Customs (Prohibited Imports) Regulations - Regulations 5 and accompanying Fourth Schedule to the Regulations, covering narcotic drugs and certain psychotropic substances (pages 9-13).

1. CUSTOMS (IMPORT LICENSING) REGULATIONS COVERING INDUSTRIAL PRODUCTS

Outline of system and purpose of controls

1. The Customs (Import Licensing) Regulations provide that the importation of all goods into Australia is prohibited unless:

- The goods are exempted from the application of the Regulations, or

- A licence is issued under the Regulations.

In practice currently all goods are exempted from the Regulations.

The Minister for Industry, Technology and Commerce or the Minister for Small Business, Construction and Customs are responsible for the administration of the Regulations. Certain powers can be delegated under the Regulations including the power to issue licences.

Coverage of controls

2. Currently no goods are covered by import licensing controls.

3. Import licensing controls when in force are global.

4. No goods are currently subject to licensing.

5. Import licensing is a statutory requirement under the Customs (Import Licensing) Regulations. Decisions to apply licensing is at Ministerial level but generally follow Government decisions on particular products. Controls may be abolished without legislative approval but would only be so abolished by Government decision.

Procedures

6. I. Should goods become subject to licensing the usual procedures for advising of a change in assistance arrangements, including the imposition of licensing, involve a Ministerial press statement and, where appropriate, a Notice published in a Government Gazette available to the public. A detailed explanation of administrative details is then published in an Australian Customs Notice.

There are no goods currently subject to Australia's import licensing arrangements. If controls are in place, there is usually no limit to the quantity that can be imported and issue of licence is generally based on whether or not goods serving similar functions are produced or are capable of being produced in Australia in the normal course of business (See answer 7).

II.-XI. Not applicable.

7. Import licensing when in force is usually not subject to quantitative limits nor limitations as to the country of origin.

(a) An application for a licence may be made before the goods are ordered, however, licences must be issued before the goods actually arrive in Australia.

(b) A licence could be issued immediately on request provided the application meets the established criteria.

(c) There would be no limitations as to the period of the year when applications for licences could be accepted and/or importation could be made. However, licences would generally be valid for twelve months from the date of issue.

(d) Issue of licences would be made by the Australian Customs Service.

8. Applications for licences would only be refused on grounds of failure to meet specified criteria. Applicants would be advised of reasons for refusal of the granting of a licence. A number of avenues would be available for applicants to appeal against a decision to refuse the issue of a licence. Internal reviews would be held by the Australian Customs Service or, alternatively, some issues could be brought before the Administrative Appeals Tribunal or the Federal Court under the Administrative Decisions (Judicial Review) Act.

Eligibility of importers to apply for licence

9. There would be no restriction on who may apply for a licence. No registration fee would be payable. Names, addresses and entitlements of importers would be published six-monthly in a Government Gazette which is available to the public.

Documentational and other requirements for application for licence

10. Application forms would not be required for the issuance of a licence. However, applications would be in writing and provide the following details:

- Name and address of applicant;
- Intended port of importation;
- Tariff heading;
- Quantity and full description of goods including origin;
- Customs value of the goods (i.e. value for duty) where required.

11. To enable clearance of the goods, a Customs Entry (Goods Declaration), invoices and the licence would be required to be produced.

12. There would be no licensing fee nor administrative charge payable.

13. Not applicable.

Conditions of licensing

14. The period of validity of a licence would generally be twelve months, but could be extended by a request in writing.

15. No penalties would be applied where under-use of licences occurred.

16. Individual licences would not be transferable but licence entitlement could be transferred.

17. The Customs (Import Licensing) Regulations provide that a licence could be conditioned and that, when required, securities could be held against compliance with those conditions.

18. No.

19. Goods subject to import licensing would not be subject to any different or separate treatment in relation to the provision of foreign exchange.

2. CUSTOMS (PROHIBITED IMPORTS) REGULATIONS - REGULATIONS 5A TO 5H AND ACCOMPANYING EIGHTH SCHEDULE 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 previously applying under Regulations 5A to 5H of the Customs (Prohibited Imports) Regulations were repealed. The import licensing system previously operating under Regulation 5A(3) has ceased. Controls remaining in force under Regulations 5A to 5H prohibit the importation of substances specified in Regulation 5A(1), or goods included in the Eighth Schedule to the Regulations, except with permission of the Secretary of the Department of Health, Housing 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 the Eighth Schedule 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 the Eighth Schedule 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. The system cannot be abolished without legislative approval.

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 entirely within the Department of Health, Housing 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 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 regulations 5A(1)), applications should be made in writing, including the following information:

- Importer's name and address;
- Name and location of the manufacturers of the goods;
- Details of the goods (whether raw material or formulated product);
- Quantity and distribution (end-use).

(ii) For goods in the Eighth Schedule (Regulation 5H refer):

- Importer's name and address;
- Exporter's name and address;
- Full details of the product proposed for import;
- Information on proposed end-use;
- Supervising doctor's prescription, if applicable;
- Depending on the nature of the goods and the intended purposes, further documentation or evidence may be required for consideration.

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 familiarise 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 Australia 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.

3. CUSTOMS (PROHIBITED IMPORTS) REGULATIONS - REGULATION 5 AND ACCOMPANYING FOURTH SCHEDULE TO THE REGULATIONS, COVERING NARCOTIC DRUGS AND CERTAIN PSYCHOTROPIC SUBSTANCES

Outline of system

1. Import licensing is used to control the importation of narcotics and certain psychotropic substances and drug precursors into Australia.

These controls ensure that importation is restricted to quantities necessary to meet medical and scientific requirements and that Australia's international obligations and domestic regulations are observed.

Purposes and coverage of licensing

2. The licensing system covers all narcotic drugs, certain psychotropic substances and some drug precursors. These are listed in Schedule 4 of the Customs (Prohibited Imports) Regulations. It includes all of the drugs required to be controlled under the Single Convention on Narcotic Drugs, 1961, and the Convention on Psychotropic Substances, 1971, and the substances in Table 1 of the Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances.

3. The system applies to imports of controlled drugs from all countries.

4. The use of import licences and permits enables the Government to restrict and monitor the quantities of the controlled drugs imported. By monitoring imports, the origin, quality, quantity and end-use of drugs can be checked. Restricting imports to the level required for legitimate medical and scientific use is one means of protecting the public health and welfare of the population from over-supply, diversion and abuse of controlled drugs. The system is based on the requirements of the international treaties.

5. The Customs Act 1901: The Customs (Prohibited Imports) Regulations.

Licensing of importers is a statutory requirement under the above Regulations. The drugs subject to licensing control are determined by statutory rules. The system cannot be abolished without legislative approval.

Procedures

6. I. Imports of narcotics are limited through application of an estimate system administered by the International Narcotics Control Board (INCB). Importers are advised of the quotas allocated to them. Details of quotas are not published or made available to third parties because the information is regarded as commercial-in-confidence. Estimates of requirements and stocks of narcotics are forwarded to the INCB. The estimates for all parties to the international conventions are published in United Nations documents.

II. Quotas are allocated annually to each importer but are subject to review if the importer has used up his quota and requests additional allocation. Quotas can be transferred with the agreement of both parties.

III. Import permits are only issued to licensed importers. To be a domestic producer is not a requirement for an import licence. If an import permit is not issued within its period of validity (normally six months), the importer is contacted to see whether an extension is required or whether the permit should be cancelled. Unused allocations are not allocated to quotas for the succeeding year. The names of licensed importers would be made available on request to overseas governments. Further details (such as quota allocations) would not be made available because the information is regarded as commercial-in-confidence.

IV. Not applicable; individual determinations are made for licences and permits.

V. Maximum turn-around time for the issuing of permits is normally 10 working days. In urgent situations an import permit can be issued immediately. The processing of licence applications usually takes longer than permits; 10 working days would be a typical length of time.

VI. If an import licence is granted, the date of opening of the first import issued under that licence could be the same.

VII. Where the application for an import permit involves a drug for human use not approved in Australia, approval must first be obtained from the Therapeutic Goods Administration of the Department of Health, Housing and Community Services for the use or the sale of the drug in Australia before the importation can be proceeded with. Application for import licences and import permits is made to the licensing and permit issuing authority: Drugs Monitoring Section, Drugs of Dependence Branch, Department of Health, Housing and Community Services. Certain substances controlled under Regulation 5 may be subject to additional controls, e.g. Quarantine, Australian Radiation Laboratories. Intending importers of goods likely to be affected by these controls are advised to contact the permit issuing authority.

VIII. There is no restriction on the number of licences that can be issued but for narcotic drugs the amount that each licence holder is entitled to import is restricted by quota. Quota allocations are made within the context of the national estimate for each importer and based on need and past utilization. New importers of narcotic drugs can be accommodated to a limited extent by allocating quotas from an amount kept in reserve. Applications are examined simultaneously.

IX. Import permits are required for all substances covered by Regulation 5 irrespective of whether or not export permits are issued by the exporting countries unless an exemption has been made for a particular

formulation. Exemptions are made in accordance with the provisions of international drug conventions. For all narcotic drugs covered by the Single Convention on Narcotic Drugs 1961, except formulations in Schedule III of that Convention, and for those substances in Schedules 1 and 2 of the Convention on Psychotropic Substances 1971, export permits are always required and should only be issued after an import permit has been obtained.

X. Not applicable.

XI. Yes. When quantities are imported for the purposes of re-export and where such quantities exceed the domestic requirements.

7. (a) There is no specified time for an importer to apply for a licence in advance of an importation, but an import permit would not be issued unless the importer is licensed. Similarly, there is no specified time for a licensed importer to apply for an import permit in advance of an importation, but a consignment cannot be imported without a permit being first obtained.

(b) A licence would not normally be granted immediately because of the checking required.

(c) No.

(d) Yes; both import licences and import permits are issued by the Secretary, Australian Department of Health, Housing and Community Services.

8. An application for a licence would only be refused on the basis of inadequate security for storage or doubts about the suitability or bona-fides of the applicant. A licence or permit may be revoked if the licence holder fails to comply with the conditions of the licence or the permit. An application for a permit may be refused if the licensing authority considered the import to be excessive to national requirements. Where other permissions must be obtained for a permit (quarantine, radiation, therapeutic goods), a permit will not be issued until these permissions have been obtained. A person whose application for a licence or permit is revoked is informed in writing of the decision. The applicant may request the Minister for Health, Housing and Community Services to reconsider the initial decision. The applicant is informed in writing of the result of the reconsideration. Appeal against the Minister's decision can be made to the Administrative Appeals Tribunal.

Eligibility of importers to apply for licence

9. Anyone who needs to be in the possession of controlled substances for legitimate commercial, medical or scientific reasons is eligible to apply for an import licence. Licences are only granted to bona-fide enterprises who have adequate security for the storage of the substances and are

granted subject to compliance with certain other conditions with respect to the use, sale or distribution of the substances. Import permits are issued only to licensed importers. The applicant must have an authority under State or Territory law to be in possession of the drugs before a permit is granted. There is a registration fee. A list of licence holders is available from the issuing authority but is not published.

Documentational and other requirements for application for licence

10. Applicants for import licences are required to submit the following information in writing:

- Name of the organization or person;
- Address of the premises on which the controlled substance will be held;
- Copies of State or Territory licences relating to the storage, manufacture or distribution of the substances;
- Details of the persons who will have access to the controlled substances, including their positions and qualifications and whether they have any criminal records;
- Details of the security arrangements for the storage, distribution and handling of the substances.

An application for an import permit is made in writing and must state the following information:

- Name of the importer;
- Address of the consignment;
- Number and size of the packs;
- Name, form and strength of the controlled substance;
- Total amount of the controlled substance;
- Name of the exporter;
- Address of the exporter.

There are no application forms for licences or permits.

11. The import permit is the required document and in some instances the complementary overseas export permit.

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

13. Not applicable for a licence. Not required for a permit.

Conditions of licensing

14. Import licences are valid until the end of the calendar year following the year of application. Import permits are usually valid for six months, but the period can be varied to suit particular circumstances.

15. There is no penalty for non-use of a licence or permit. However, if a licence holder has not used his licence during the preceding year, he/she may be questioned on the need to retain the licence at the time of renewal.

16. Licences and permits are not transferable.

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, e.g. for re-export only, for veterinary use only.

Other procedural requirements

18. No.

19. Goods subject to import licensing are not subject to any different or separate treatment in relation to the provision of foreign exchange.