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REPLIES TO THE 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.5. It updates and replaces document L/5640/Add.13/Rev.3.

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.5. Cette notification met à jour et remplace le document L/5640/Add.13/Rev.3.

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.5. Con ella queda actualizada y sustituida la información contenida en el documento L/5640/Add.13/Rev.3.

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

AUSTRALIA

REPLIES TO QUESTIONNAIRE ON

IMPORT LICENSING PROCEDURES

The following notification for 1988/89 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 3-7);**

2. **Customs (Prohibited Imports) Regulations - Regulations 5 and accompanying Fourth Schedules to the Regulations, covering narcotic drugs and certain psychotropic substances (pages 8-15); and**

3. **Customs (Prohibited Imports) Regulations - Regulations 5A to 5H and accompanying Eighth Schedule to the Regulations covering therapeutic substances and goods (pages 16-19).**

The present document replaces the data previously made available to contracting parties in document L/5640/Add.13/Rev.3.

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 all goods other than a limited range of secondhand, used or disposals material handling machinery and parts thereof (see Answer 2) are exempted from the Regulations.

The Minister for Science, Customs and Small Business is responsible for the administration of the Regulations. Certain powers can be and have been delegated under the Regulations including the power to issue licences.

Coverage of Controls

2. Goods covered by import licensing controls are used, secondhand or disposals material handling equipment (e.g. cranes, forklift trucks) and parts thereof, but not including goods classified under 8604 in Schedule 3.

3. Import licensing controls are global.

4. The import licensing regulations only apply to the secondhand goods referred to in answer 2 above as other measures were considered to be ineffective in protecting local industry due to the low prices at which large quantities of secondhand equipment are available overseas.

5. Import licensing is a statutory requirement under the Customs (Import Licensing) Regulations.

- Decision to apply licensing is at Ministerial level but generally follows Government decision on particular products.

- The controls may be abolished without legislative approval but would only be so abolished by Government decision.

- The Government has announced that these controls are to be removed at a date to be determined by the Minister for Industry, Technology and Commerce following discussions with Australian State Governments concerning appropriate means of ensuring imported goods comply with appropriate safety regulations.

Procedures

6.(a) 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 (ACN).

The only goods currently subject to Australia's import licensing arrangements are certain used, secondhand or disposals machinery and equipment. There is no limit to the quantity that can be imported and issue of licence is based on whether goods serving similar functions are produced or are capable of being produced in Australia in the normal course of business (See Answer 7).

6.(b) - 6.(k) Not applicable.

7. Import licensing is 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 are imported.

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

(c) There are no limitations as to the period of the year when applications for licences will be accepted and/or importation may be made. However, licences are generally valid for 12 months from the date of issue.

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

8. Applications for licences are only refused on grounds of failure to meet specified criteria.

. Applicants are advised of reasons for refusal of the granting of a licence.

A number of avenues are available for applicants to appeal against a decision to refuse the issue of a licence. Internal reviews may be held by the Australian Customs Service or, alternatively, some issues may 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 is no restriction on who may apply for a licence.

- No registration fee is payable.

- Names, addresses and entitlements of importers are published six-monthly in a Government Gazette which is available to the public.

Documentational and Other Requirements for Applications for Licences

10. Application forms are not required for issue of a licence. However, applications should 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 are required to be produced.

12. There is no licensing fee nor administrative charge payable.

13. Not applicable.

Conditions of Licensing

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

15. No penalties apply where underuse of licences occurs.

16. Individual licences are not transferable but licence entitlement may be transferred.

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

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.

2. 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 into Australia. The system is a two-tiered structure in which an importer must first be licensed and then an import permit must be obtained for every importation of the controlled drugs.

- In special circumstances, an importer may be licensed for a single importation if certain conditions are satisfied. This enables a university or other institution to import drugs for a specified purpose, although they do not normally hold an import licence. In such cases an import permit is issued and endorsed to constitute a licence for that consignment.

- 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.

Purpose and Coverage of the Licensing

2. The licensing system covers all narcotic drugs and certain psychotropic substances. These are listed in the Fourth Schedule of the Customs (Prohibited Imports) Regulations[1]. 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. In addition, a number of

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[1] A copy of this document is available for consultation in the GATT Secretariat (Centre William Rappard, Office No. 3063).

cther drugs not covered by the Conventions are similarly controlled in Australia.

3. The system applies to imports of controlled drugs from all countries. Narcotics are imported only from countries which are Parties to the Single Convention on Narcotic Drugs, 1961.

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(a). Allocations of quotas for narcotics are not published. Each year licensed importers are invited to nominate their annual requirements. The quota allocated is based on the quantities imported by each holder of a quota in previous years and the expected medical demand. Importers are advised of the quotas allocated to them. A new licensed

importer may be granted a quota if it is appropriate to the existing circumstances. Details of quotas are not made available to export countries. Estimates of narcotic consumption and stocks are forwarded to the International Narcotics Control Board (INCB). Similar estimates are forwarded for all drugs listed in Schedule 2, Convention on Psychotropic Substances. Estimates from all parties to the international conventions are published in United Nations documents.

(b) Quotas are determined annually. Quantities imported are reviewed with every application for an import permit. Additional quotas may be issued if the quota holder can demonstrate that the original quota is insufficient.

(c) Import permits are only issued to licensed importers. To be a domestic producer is not a requirement for a licence. If an import permit is not used within the specified time, it lapses. Unused allocations are not added to quotas for succeeding periods. The names of licensed importers would be disclosed on request, but quota allocations being information of a commercial or confidential nature would not.

(d) Not applicable; individual determinations are made for licences and permits.

(e) In urgent situations an import permit can be issued immediately. (This can also constitute a licence in special circumstances - see question 1 above.) Applications for import licenses and import permits are reviewed as they are received. An import permit is usually issued within five to ten days.

(f) If an import licence is granted, the date of opening of the first import permit issued under that licence could be the same.

(g)(i) When an application for an import permit involves the importation of a new drug or new formulation etc. approval must first be obtained from the Australian Drug Evaluation Committee. The applicant must apply initially to the Drug Evaluation Branch of the Australian Department of Community Services and Health and have the product approved for distribution in Australia.

(ii) All applications for import licences and import permits for controlled drugs or substances which have, or are exempt from the need for, general marketing approval, are forwarded to the Drug Dependence Branch, Australian Department of Community Services and Health.

(iii) Certain categories of controlled drugs or substances may be subject to additional control e.g. Quarantine, Australian Radiation Laboratories, Therapeutic Goods Act, etc. Intending importers of goods likely to be affected by these controls are advised to request additional information from the Australian Department of Community Services and Health.

(h) Licences are issued on the basis of normal trade requirements. Applicants are approved if they meet specified conditions including previous history in the market, security provisions, record keeping, State approval, etc. Import permits are issued to licensed importers as required, within quota limits, based on medical and scientific needs. Quotas for narcotics and certain psychotropic substances are set within national estimates submitted to the INCB. The system is flexible enough to allow part of individual quotas to be transferred from one licensee to another and for new licence holders to enter the market.

(i) Narcotics covered by an import permit must also be covered by an export permit issued by the appropriate authority in the exporting country. It is a provision of the Single Convention on Narcotic Drugs, 1961, that an export permit is only issued after an import permit is issued. In addition, export permits are also required from exporting countries for drugs covered by the Convention on Psychotropic Substances and certain other specified drugs. (These are listed in the Fourth Schedule of the Customs (Prohibited Imports) Regulations.)

(j) Not applicable.

(k) 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.

(b) A licence could be issued immediately, but this would not be the usual practice. An import permit can be issued immediately to a licensed importer on request.

(c) No.

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

8. An import licence is issued subject to certain conditions - see question 10 below. Prior to being issued with a licence applicants must demonstrate that they can comply with these conditions. Reasons for refusal would be given to an applicant. Applicants may appeal against a refusal to issue a licence or against a decision to revoke a licence. Import permits for narcotics may be refused if there is insufficient quota balance, security measures are inadequate or if any of the required conditions are not satisfied. Import permits for other controlled drugs may be refused if the importation is excessive to normal requirements, or if any of the required conditions are not satisfied.

New drugs or formulations must be approved before a permit can be issued.

There is no provision to appeal against a decision not to issue or to revoke an import permit.

Eligibility of Importers to Apply for Licence

9. Yes. Import licences are granted by the Secretary of the Australian Department of Community Services and Health subject to certain conditions and subject to applicants meeting specified criteria.

Import permits are only issued to licensed importers except in special circumstances - see question 1 above. A list of licensed importers is available. There is no registration fee.

Documentational and other Requirements for application for Licence

10. An application for a licence must be made in writing to the Minister for Community Services and Health and include

information as required. An application for an import permit is made in writing and must include the following:

- Name of importer;
- Address for consignment;
- Number and size of packs;
- Name, pharmaceutical form and strength of drugs;
- Name (International Non-proprietary Name (INN) if any);
- Controlled drug content (grams);
- Name of exporter;
- Address of exporter.

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 for a finite period usually five years.

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 is not operated on for a period of approximately three years the licence may be revoked.

16. Licences and permits are not transferable.

17. Licences are issued subject to the holder's meeting certain conditions.

Import permits may be endorsed for specific purposes, e.g. for veterinary use only, for re-export only, etc.

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.

3. CUSTOMS (PROHIBITED IMPORTS) REGULATIONS - REGULATIONS 5A TO 5H AND ACCOMPANYING EIGHTH SCHEDULE TO THE REGULATIONS COVERING THERAPEUTIC SUBSTANCES AND GOODS.

Outline of System

1. The control of the importation of therapeutic substances into Australia is exercised through:

(i) The issue of a 2 year licence which enables the licensee to import specified non-biological therapeutic substances without further reference to the Department of Community Services and Health. Where a therapeutic substance has become a designated therapeutic substance by virtue of the fact that it has either not been imported previously, or it was not imported during the previous 2 year licence period, then the importer must give 28 days written notice of intention to import such a substance to the Australian Department of Community Services and Health.

(ii) The issue of permits which may be valid for up to two years or may be issued for one specified consignment only. Permits are issued in respect of all therapeutic substances which are of a biological origin.

As a general rule licences are issued to those importers which import a wide range of therapeutic substances while permits are issued to the smaller commercial importer, and for all substances of biological origin.

Purposes and Coverage of the Licensing

2. The licensing system covers therapeutic substances which are defined as substances, including a mixture or compound of substances, that has a therapeutic use and includes a surgical ligature, suture or dressing, but does not include a vaccine

prepared from microscopic organisms from the body of a person or animal for use in the treatment of that person or animal only.

3. The system applies to the importation of therapeutic substances from all countries.

4. The use of import licences and permits ensures that those therapeutic substances being imported are of an acceptable standard in regard to quality and are safe and efficacious for the purpose for which they are to be used.

A proposal to replace the system of import licences and permits with a system of control over distribution by means of a national registration scheme for therapeutic substances is expected to be considered by the Australian Parliament during the latter part of 1989.

5. The Customs (Prohibited Imports) Regulations made under the Customs Act.

- The issue of licenses and permits is a statutory requirement under the above Regulations.

- All therapeutic substances as defined in the Regulations are subject to import control.

- The system cannot be abolished without legislative approval.

Procedures

6. Not applicable.

7(a). Where a substance is a designated therapeutic substance (see 1) then 28 days notice of intention to import must be given. In certain circumstances permission can be given

for the importation of therapeutic substances which have inadvertently arrived at a port of entry.

(b) It is not usual to issue a licence immediately. However, permits can be issued immediately.

(c) No.

(d) Yes, licences and permits are issued by the Secretary, Department of Community Services and Health.

8. In circumstances where permission to import a therapeutic substance has been refused, or where an application for a licence has been refused or where such a licence has been revoked the reasons for the refusal or revocation are notified to the importer in writing.

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. An application to import a finished therapeutic substance should be made in writing, and should include a completed National Register of Therapeutic Goods form 1145 for each therapeutic substance together with a Certificate of Pharmaceutical Product issued by the national regulatory authorities of the country of manufacture.

Depending upon the nature and proposed indications of the therapeutic substance, information in accordance with the NDF4 Guidelines may be required.

Application forms and Guidelines are available from the Australian Department of Community Services and Health.

In all instances the name and address of the importer and exporter must be given in addition to full details concerning the therapeutic substance to be imported. In the case of the importation of raw materials for use in manufacture of therapeutic substances, certificates of analysis may be required to show compliance with official standards or approved specifications.

11. A licence or an import permit.

12. There is no charge.

13. No.

Conditions of Licensing

14. A licence and some permits are valid for a finite period of two years. The validity of the licence or permits may be extended on the basis of an application from the importer.

15. No.

16. No.

17. The Secretary may impose such conditions as are considered necessary regarding the custody, use, disposal or distribution of therapeutic substances imported into Australia.

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.

Department of Community Services and Health

National Register of Therapeutic Goods

Information required on Therapeutic Goods that consist of a substance and are ready for use *(Therapeutic Goods Act 1966)*

Note: • ***Please provide a separate form for each dosage form and each strength of the same dosage form except where they are a composite pack and are distributed as the one product, e.g. injection set, oral contraceptive tablets. A separate form is not required for each pack size.***

• ***Read accompanying letter before completing.***

• ***Please type or print, do not use pencil.***

Australian sponsor *(The firm which is responsible for the product in Australia [Required for first H1312 form only])*

Sponsor's street address

Postcode

Product number

:P. 0 *(Office use only—do not fill in)*

Date notified *(Give year and month, e.g:* 1 9 8 4 0 2)

:P2. 1 9

Status *(Insert appropriate code)*

GM = General marketing
LM = Limited marketing. Follow this code by nature of limitation, e.g. hospitals only.
CI = Clinical investigation
OT = Other

:P3.

Proprietary (Trade) name *(Include any suffix or prefix)*

If no proprietary name, place cross in box

:P4.

:P4.

:P4.

Dosage form *(e.g: injection, ear drops, lotion. Where product consists of units containing substances differing in strength or kind, e.g: injection set, write 'Composite pack' after appropriate dosage form)*

:P5.

:P5.

Route(s) of administration *(e.g. Oral, I.M., I.V. infusion. List each route on a separate line. If insufficient space, leave blank and attach sheet giving information)*

:P6.

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Active substance(s) and nominal quantity(ies) per usual dosage unit or proportion

- *List each substance on a separate line. If insufficient space, attach sheet giving additional information.*
- *Use Australian Approved Name. If none, use other non-proprietary name. If no non-proprietary name, give chemical or biological description.*
- *Do not include overages.*
- *Where product is a composite pack and some of the substances are common to different units of the pack, substances may be listed in tabular form, e.g.*

P7.		Fawn	White	Ochre	Inert	
P7.		Tablet	Tablet	Tablet	Tablet	
P7.	levonorgestrel	50	75	125	NIL	micrograms
P7.	ethinyloestradiol	30	40	30	NIL	micrograms

- *Where product is a composite pack and few or no substances are common, list substances separately under separate headings*

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Excipients *(Substance other than active substance)*

- ***Do not list quantity or proportion.***
- ***List each excipient, including substances in coatings or cores, on a separate line. If insufficient space, attach sheet giving additional information.***
- ***Use Australian Approved Name, etc. as per Active Substances Section.***
- ***Record colourings, including those of capsule shells, beginning with Colour Index Number.***
- ***Where product is a composite pack, excipients may be listed in the same format as that used for active substances.***

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Australian sponsor *(The firm which is responsible for the product in Australia)*
[Office use only] (Office use only)

:P9. ☐☐☐

:P10. .....

Overseas/local manufacture *(Manufacture includes labelling and/or packaging. Insert appropriate code)*

:P11. ☐

A = Fully imported
B = Fully manufactured locally
C = Part manufactured locally
D = Fully imported and Fully manufactured locally
E = Fully imported and Part manufactured locally
F = Fully manufactured locally and Part manufactured locally
G = Fully imported and Fully manufactured locally and Part manufactured locally

Overseas manufacturer *(Also complete if only part manufactured overseas. If more than one overseas manufacturer, attach sheet giving additional information)*
(Office use only)

:P12. ☐☐☐☐

Overseas manufacturer's address

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Poisons schedules *(Give schedule number only. If not scheduled insert 'N'. If not supplied insert 'X')*

A.C.T	N.S.W	N.T	Q.L.D	S.A	TAS.	VIC.	W.A
P13. ☐	:P14. ☐	:P15. ☐	:P16. ☐	:P17. ☐	:P18. ☐	:P19. ☐	:P20. ☐

Therapeutic categories
(Office use only—do not fill in)

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Indications

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Visual identification *[eg Visual description including colour, shape, size, markings etc. (Use standard terminology as per letter)]*

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Product labels, other explanatory material accompanying the goods and packaging
(if packaging bears labelling or information on indications)

- *If no information on indications is on or accompanies the goods, attach promotional material.*
- *Attach two samples or copies of each.*
- *Insert cross in appropriate boxes.* Container label ☐ Primay pack label ☐ Package insert ☐ Other ☐