WORLD TRADE ORGANIZATION

G/LIC/N/2/TON/7

24 August 2021

(21-6388)

Committee on Import Licensing

AGREEMENT ON IMPORT LICENSING PROCEDURES

NOTIFICATION UNDER ARTICLE 5.1 TO 5.4 OF THE AGREEMENT[1]

TONGA

The following notification dated 16 August 2021, is being circulated at the request of the delegation of Tonga.

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1 THERAPEUTIC GOODS ACT [CAP.12.16]

	Category	Notification details
1	**Notifying Member**	**Tonga**
2	**Title of new legislation/ procedure**	Therapeutic Goods Act [CAP.12.16]
3	**Date of Publication**	11th July 2001
4	**Date of entry into force**	1st July 2010
5	**Website link/Official publication of the new regulation/procedure**	Therapeutic Goods Act (ago.gov.to)
6	**Have you attached a copy of the regulation (PDF) to the Secretariat**	[x] Yes. (*Please attach a copy of the regulation to the notification.*) [ ] No.
7	**Type of notification**	[x] (a) New licensing regulation/procedure[2]; (please answer question 8 to 14) [ ] (b) Changes to a regulation/procedure which has been previously notified in document; (*please answer question 15 and 16*)
8	**List of products subject to licensing**	Registered List: Class 1: Medicinal drugs available from licensed retail outlets; Class 2: Medicinal drugs available from registered pharmacy premises under the supervision of a registered pharmacist, divided into – Class 2A: Where advice of pharmacist at point of sale is not required; Class 2B: Where advice of pharmacist at point of sale is required; Class 3: Medicinal drugs available on prescription only and dispensed by a pharmacist or assistant pharmacist; Class 4: Medicinal drugs available on special prescription only and dispensed by a pharmacist or assistant pharmacist; Class 5: Narcotic drugs and psychotropic substances subject to special import controls; Class 6: Medicinal drugs available from veterinary practitioners for animal use.

[1] It is understood that the notifying Member has also completed its notification obligations under Article 1.4(a) and Article 8.2(b) regarding the relevant law/regulation/procedure notified for by filling this form in a full and complete manner.

[2] "New licensing regulation/procedure" is understood to refer to any newly introduced law, regulation or procedure, and those which are in force but being notified for the first time to the Committee.

	Category	Notification details
9	**Nature of licensing**	Automatic: [ ] Non-Automatic: [x]
10	**Administrative purpose/measure being implemented**	(a) ☐ Protect public morals; (b) ☒ Protect human, animal or plant life and health; protect environment; (c) ☐ Collect trade statistics or market surveillance; (d) ☐ Protection of patents, trademarks and copyrights, and the prevention of deceptive practices; (e) ☐ Pursue obligations under the UN Charter and other international treaties (*i.e. CITES, Basel Convention, Rotterdam Convention, UNSC Resolutions etc.)* (f) ☐ Quota (including TRQ) administration; (g) ☐ Regulate imports of arms, ammunition or fissionable materials and safeguard national security; (h) ☐ Other: _____ *(please specify)*
11	**Administrative body(ies) for submission of applications**	Ministry/authority and Department: Ministry of Health and Pharmaceutical Department Address: Drug Regulatory Authority, Pharmaceutical Department, Baron Road, Vaiola Motu'a, Nuku'alofa Website: http://www.health.gov.to/ Telephone: (+676) 24553/7400200 E-Mail: tongadrugregulatory@gmail.com
12	**Contact point for information on eligibility**	Ministry/authority and Department: Ministry of Health and Pharmaceutical Department Address: Drug Regulatory Authority, Pharmaceutical Department, Baron Road, Vaiola Motu'a, Nuku'alofa Website: http://www.health.gov.to/ Telephone: (+676) 24553/7400200 E-Mail: tongadrugregulatory@gmail.com
13	**Expected duration of licensing procedure**	Ongoing
14	**A summary of the notification in one of the WTO official languages**	This Act is to establish a system of regulation of therapeutic goods, to establish a national drugs and medical supplies committee, to regulate the import of quality, safety, efficacy, affordability, availability and use of registered therapeutic goods, including narcotic drugs and psychotropic substances and for ancillary purposes.
15	**In the case of 7(b), please indicate the type of new change(s)**	**(a)** ☐ **Termination** **(b)** ☐ **Suspension** **(c)** ☐ **Modification of specific details in existing procedures:** ☐ Product coverage; ☐ Administrative purpose; ☐ Automatic or Non-automatic; ☐ Duration of licensing; ☐ Change the nature of quantity/value restriction; ☐ Eligibility of applicants; ☐ Contact information on eligibility; ☐ Administrative body(ies) for submission of application; ☐ Documentation requirements (including application form); ☐ Period for Application; ☐ Administrative body(ies) to issue licence; ☐ Processing time for issuing licence; ☐ Licence fee/administrative charge; ☐ Deposit/advance payment and relevant conditions; ☐ Appeal regulations/procedures; ☐ Validity of licence;

	Category	Notification details
		☐ Other conditions of licence (extension, transferability, penalty of non-use etc.); ☐ Foreign exchange requirements; ☐ Other: _____ (please specify).
16	**Please elaborate the changes in detail (in one of the WTO official languages)**	

2 THERAPEUTIC GOODS REGULATIONS [CAP.12.16.01]

	Category	Notification details
1	**Notifying Member**	**Tonga**
2	**Title of new legislation/ procedure**	Therapeutic Goods Regulations [CAP.12.16.01]
3	**Date of Publication**	11 June 2011
4	**Date of entry into force**	16 June 2011
5	**Website link/Official publication of the new regulation/procedure**	Therapeutic Goods Regulations 2011 (ago.gov.to)
6	**Have you attached a copy of the regulation (PDF) to the Secretariat**	[ ] Yes. (*Please attach a copy of the regulation to the notification.*) [x] No.
7	**Type of notification**	[x] (a) New licensing regulation/procedure[3]; (please answer question 8 to 14) [ ] (b) Changes to a regulation/procedure which has been previously notified in document; (*please answer question 15 and 16*)
8	**List of products subject to licensing**	Registered List: Class 1: Medicinal drugs available from licensed retail outlets; Class 2: Medicinal drugs available from registered pharmacy premises under the supervision of a registered pharmacist, divided into – Class 2A: Where advice of pharmacist at point of sale is not required; Class 2B: Where advice of pharmacist at point of sale is required; Class 3: Medicinal drugs available on prescription only and dispensed by a pharmacist or assistant pharmacist; Class 4: Medicinal drugs available on special prescription only and dispensed by a pharmacist or assistant pharmacist; Class 5: Narcotic drugs and psychotropic substances subject to special import controls; Class 6: Medicinal drugs available from veterinary practitioners for animal use.
9	**Nature of licensing**	Automatic: [ ] Non-Automatic: [x]
10	**Administrative purpose/measure being implemented**	(a) ☐ Protect public morals; (b) ☒ Protect human, animal or plant life and health; protect environment; (c) ☐ Collect trade statistics or market surveillance; (d) ☐ Protection of patents, trademarks and copyrights, and the prevention of deceptive practices; (e) ☐ Pursue obligations under the UN Charter and other international treaties (*i.e. CITES, Basel Convention, Rotterdam Convention, UNSC Resolutions etc.)* (f) ☐ Quota (including TRQ) administration;

[3] "New licensing regulation/procedure" is understood to refer to any newly introduced law, regulation or procedure, and those which are in force but being notified for the first time to the Committee.

	Category	Notification details
		(g) ☐ Regulate imports of arms, ammunition or fissionable materials and safeguard national security; (h) ☐ Other: _____ *(please specify)*
11	**Administrative body(ies) for submission of applications**	Ministry/authority and Department: Ministry of Health and Pharmaceutical Department Address: Baron Road, Vaiola Motu'a, Ministry of Health, Nuku'alofa Website: http://www.health.gov.to/ Telephone: (+676) 24553/7400200 E-Mail: tongadrugregulatory@gmail.com
12	**Contact point for information on eligibility**	Ministry/authority and Department: Ministry of Health and Pharmaceutical Department Address: Baron Road, Vaiola Motu'a, Ministry of Health, Nuku'alofa Website: http://www.health.gov.to/ Telephone: (+676) 24553/7400200 E-Mail: tongadrugregulatory@gmail.com
13	**Expected duration of licensing procedure**	Ongoing
14	**A summary of the notification in one of the WTO official languages**	In exercise of the powers conferred by section 35 of the Therapeutic Goods Act 2001, the Minister of Health with the consent of Cabinet has made these Regulations.
15	**In the case of 7(b), please indicate the type of new change(s)**	**(a)** ☐ **Termination** **(b)** ☐ **Suspension** **(c)** ☐ **Modification of specific details in existing procedures:** ☐ Product coverage; ☐ Administrative purpose; ☐ Automatic or Non-automatic; ☐ Duration of licensing; ☐ Change the nature of quantity/value restriction; ☐ Eligibility of applicants; ☐ Contact information on eligibility; ☐ Administrative body(ies) for submission of application; ☐ Documentation requirements (including application form); ☐ Period for Application; ☐ Administrative body(ies) to issue licence; ☐ Processing time for issuing licence; ☐ Licence fee/administrative charge; ☐ Deposit/advance payment and relevant conditions; ☐ Appeal regulations/procedures; ☐ Validity of licence; ☐ Other conditions of licence (extension, transferability, penalty of non-use etc.); ☐ Foreign exchange requirements; ☐ Other: _____ (please specify).
16	**Please elaborate the changes in detail (in one of the WTO official languages)**	