



9 November 2022

(22-8370)

Page: 1/4

Committee on Import Licensing

Original: English

**AGREEMENT ON IMPORT LICENSING PROCEDURES**

NOTIFICATION UNDER ARTICLE 5.1 TO 5.4 OF THE AGREEMENT<sup>1</sup>

MACAO, CHINA

The following notification, dated 24 October 2022, is being circulated at the request of the delegation of Macao, China.

	Category	Notification details
1	<b>Notifying Member</b>	Macao, China
2	<b>Title of new legislation/procedure</b>	<ol style="list-style-type: none"> <li>1. Law on Pharmaceutical Activity in the Field of Traditional Chinese Medicines and the Registration of Proprietary Chinese Medicines (Law No. 11/2021)</li> <li>2. Enforcement Rules for the Law on Pharmaceutical Activity in the Field of Traditional Chinese Medicines and the Registration of Proprietary Chinese Medicines (Administrative Regulation No. 46/2021)</li> <li>3. List of Chinese Medicinal Materials Adopted in the Macao SAR (Secretary for Social Affairs and Culture's Decision No. 95/2021)</li> </ol>
3	<b>Date of Publication</b>	<ol style="list-style-type: none"> <li>1. 26 July 2021</li> <li>2. 6 December 2021</li> <li>3. 28 December 2021</li> </ol>
4	<b>Date of entry into force</b>	1 January 2022
5	<b>Website link/Official publication of the new regulation/procedure</b>	<ol style="list-style-type: none"> <li>1. <a href="https://images.io.gov.mo/bo/i/2021/30/lei-11-2021.pdf">https://images.io.gov.mo/bo/i/2021/30/lei-11-2021.pdf</a></li> <li>2. <a href="https://images.io.gov.mo/bo/i/2021/49/reg-46-2021.pdf">https://images.io.gov.mo/bo/i/2021/49/reg-46-2021.pdf</a></li> <li>3. <a href="https://images.io.gov.mo/bo/i/2021/52/despsasc-95-2021.pdf">https://images.io.gov.mo/bo/i/2021/52/despsasc-95-2021.pdf</a></li> </ol>
6	<b>Have you attached a copy of the regulation (PDF) to the Secretariat</b>	<p><input checked="" type="checkbox"/> Yes. (Please attach a copy of the regulation to the notification.)</p> <p><input type="checkbox"/> No.</p>
7	<b>Type of notification</b>	<p><input checked="" type="checkbox"/> (a) New licensing regulation/procedure<sup>2</sup>; (please answer question 8 to 14)</p> <p><input type="checkbox"/> (b) Changes to a regulation/procedure which has been previously notified in document: _____; (please answer question 15 and 16)</p>
8	<b>List of products subject to licensing</b>	<p>Please provide the HS codes and detailed descriptions of the products. In case of a long list, please attach the list as an Annex in MS WORD document.</p> <p><b>Please refer to the Annex</b></p>
9	<b>Nature of licensing</b>	<p>Automatic: <input type="checkbox"/></p> <p>Non-Automatic: <input checked="" type="checkbox"/></p>
10		(a) <input type="checkbox"/> Protect public morals;

<sup>1</sup> 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.

<sup>2</sup> "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
	<b>Administrative purpose/measure being implemented</b>	(b) <input checked="" type="checkbox"/> Protect human, animal or plant life and health; protect environment; (c) <input type="checkbox"/> Collect trade statistics or market surveillance; (d) <input type="checkbox"/> Protection of patents, trademarks and copyrights, and the prevention of deceptive practices; (e) <input type="checkbox"/> Pursue obligations under the UN Charter and other international treaties ( <i>i.e. CITES, Basel Convention, Rotterdam Convention, UNSC Resolutions etc.</i> ) (f) <input type="checkbox"/> Quota (including TRQ) administration; (g) <input type="checkbox"/> Regulate imports of arms, ammunition or fissionable materials and safeguard national security; (h) <input type="checkbox"/> Other: _____ ( <i>please specify</i> )
11	<b>Administrative body(ies) for submission of applications</b>	Pharmaceutical Administration Bureau Address: Avenida Sidónio Pais, No. 51, Edif. "China Plaza", 1-4.º andar, Macau Website: <a href="http://www.isaf.gov.mo/">http://www.isaf.gov.mo/</a> Telephone: (853) 28524708 E-Mail: <a href="mailto:info@isaf.gov.mo">info@isaf.gov.mo</a>
12	<b>Contact point for information on eligibility</b>	Pharmaceutical Administration Bureau Department of Registration Address: Avenida Sidónio Pais, n.º 51, Edif. "China Plaza", 1-4.º andar, Macau Website: <a href="http://www.isaf.gov.mo/">http://www.isaf.gov.mo/</a> Telephone: (853) 85983514 Email: <a href="mailto:dr@isaf.gov.mo">dr@isaf.gov.mo</a>
13	<b>Expected duration of licensing procedure</b>	Ongoing
14	<b>A summary of the notification in one of the WTO official languages</b>	1. Law No. 11/2021 stipulates that unless exempted by law, the import, export and wholesale activities of proprietary Chinese medicines, toxic Chinese medicinal materials or general Chinese medicinal materials included in the "List of Chinese Medicinal Materials Adopted in the Macao SAR", and their prepared portions or extracts shall be subject to licensing. It also stipulates that all proprietary Chinese medicines must first be registered with the Pharmaceutical Administration Bureau before they can be circulated in the Macao SAR. 2. Administrative Regulation No. 46/2021 sets out the application requirements for import, export and wholesale licenses of traditional Chinese medicines and the labelling requirements of proprietary Chinese medicines. 3. Secretary for Social Affairs and Culture's Decision No. 95/2021 approves the list of Chinese medicinal materials adopted in the Macao SAR.
15	<b>In the case of 7(b), please indicate the type of new change(s)</b>	(a) <input type="checkbox"/> <b>Termination</b> (b) <input type="checkbox"/> <b>Suspension</b> (c) <input type="checkbox"/> <b>Modification of specific details in existing procedures:</b> <input type="checkbox"/> Product coverage; <input type="checkbox"/> Administrative purpose; <input type="checkbox"/> Automatic or Non-automatic; <input type="checkbox"/> Duration of licensing; <input type="checkbox"/> Change the nature of quantity/value restriction; <input type="checkbox"/> Eligibility of applicants; <input type="checkbox"/> Contact information on eligibility; <input type="checkbox"/> Administrative body(ies) for submission of application; <input type="checkbox"/> Documentation requirements (including application form); <input type="checkbox"/> Period for Application; <input type="checkbox"/> Administrative body(ies) to issue licence; <input type="checkbox"/> Processing time for issuing licence; <input type="checkbox"/> Licence fee/administrative charge;

---

	<b>Category</b>	<b>Notification details</b>
		<input type="checkbox"/> Deposit/advance payment and relevant conditions; <input type="checkbox"/> Appeal regulations/procedures; <input type="checkbox"/> Validity of licence; <input type="checkbox"/> Other conditions of licence (extension, transferability, penalty of non-use etc.); <input type="checkbox"/> Foreign exchange requirements; <input type="checkbox"/> Other: _____ (please specify).
<b>16</b>	<b>Please elaborate the changes in detail (in one of the WTO official languages)</b>	

---

**ANNEX****CHANGES TO THE LIST OF PRODUCTS SUBJECT TO LICENSING BY PHARMACEUTICAL  
ADMINISTRATION BUREAU**

Product	HS Code
General Chinese medicinal materials, prepared portions or extracts	0305.59.40, 0305.59.50, 0507.90.12, 0507.90.92, 0508.00.12, 0508.00.92, 0510.00.20, 1211.90.70, 1301.90.20, 1302.19.20, 1515.90.20, 1521.10.20, 2530.90.30, 3001.90.20, 3003.90.40, 3004.90.50, 3503.00.20, ex. 0814.00.00, ex. 0908.31.00, ex. 0908.32.00, ex.1211.50.00, ex. 1702.60.00, ex. 2501.00.90, ex. 2507.00.00, ex. 2513.10.00, ex. 2515.11.00, ex. 2520.10.90, ex. 2520.20.90, ex. 2524.90.91, ex. 2525.10.00, ex. 2525.20.00, ex. 2526.10.20, ex. 2526.20.20, ex. 2528.00.20, ex. 2530.10.00, ex. 2601.11.00, ex. 2601.12.00, ex. 2603.00.00, ex. 2802.00.00, ex. 2824.10.00, ex. 2833.19.00, ex. 2833.25.00, ex. 2833.29.00, ex. 2833.30.00, ex. 2836.99.90, ex. 2906.19.00, ex. 2914.29.10, ex. 3806.10.00, ex. 7101.10.00, ex. 7101.21.00, ex. 7101.22.00, ex. 7204.49.90
Toxic Chinese medicinal materials, prepared portions or extracts	0507.90.11, 0507.90.91, 0508.00.11, 0508.00.91, 0510.00.10, 1211.90.60, 1301.90.10, 1302.19.10, 1515.90.10, 1521.10.10, 2530.90.20, 3001.90.10, 3003.90.30, 3004.90.40, 3503.00.10, ex. 2617.90.10, ex. 2805.40.00, ex. 2811.29.20, ex. 2852.10.10, ex. 2852.10.20, ex. 2852.10.50, ex. 2852.90.00

Remarks: "ex." refers to products that matched the product descriptions