



27 October 2023

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**Council for Trade-Related Aspects of  
Intellectual Property Rights**

Original: English

**NOTIFICATION OF LAWS AND REGULATIONS  
UNDER ARTICLE 63.2 OF THE TRIPS AGREEMENT**

THE SEPARATE CUSTOMS TERRITORY OF TAIWAN, PENGHU, KINMEN AND MATSU:  
REGULATIONS GOVERNING THE DETERMINATION OF PATENT TERM EXTENSION

<b>Notifying Member</b>	<b>THE SEPARATE CUSTOMS TERRITORY OF TAIWAN, PENGHU, KINMEN AND MATSU</b>
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**Details of the notified legal text**

<b>Title</b>	Regulations Governing the Determination of Patent Term Extension
<b>Subject matter</b>	Patents (including plant variety protection)
<b>Nature of notification</b>	<input checked="" type="checkbox"/> Main dedicated intellectual property law or regulation <input type="checkbox"/> Other law or regulation
<b>Link to legal text*</b>	<a href="https://ip-documents.info/2023/IP/TPKM/23_12963_00_x.pdf">https://ip-documents.info/2023/IP/TPKM/23_12963_00_x.pdf</a> <a href="https://ip-documents.info/2023/IP/TPKM/23_12963_00_e.pdf">https://ip-documents.info/2023/IP/TPKM/23_12963_00_e.pdf</a>
<b>Notification status</b>	<input type="checkbox"/> First notification <input type="checkbox"/> Amendment or revision to notified legal text <input checked="" type="checkbox"/> Replacement or consolidation of notified legal text(s)
<b>Previous notification(s) referred to</b>	<a href="#">IP/N/1/TPKM/P/11</a>
<b>Brief description of the notified legal text</b>	
<p>To streamline administrative procedures, Articles 4 and 10 of the Regulations Governing the Determination of Patent Term Extension were amended and entered into force on 1 July 2023.</p> <p>The main point of the amendments is outlined as follows: The Specific Patent Agency, namely the Intellectual Property Office (TIPO), may utilize documents submitted by applicants pertaining to the period of domestic and/or foreign clinical trials conducted for pharmaceutical approvals, as confirmed by the "the central competent authority in charge of the business" (the Ministry of Health and Welfare, in the case of pharmaceuticals), as a basis for determination of eligibility for extension of patent term. TIPO is no longer required to forward the applicants' submitted documents to the Ministry of Health and Welfare for further confirmation.</p>	
<b>Language(s) of notified legal text</b>	English, Chinese
<b>Entry into force</b>	1 July 2023
<b>Other date</b>	Adoption: 28 June 2023

**Notification details**

<b>Submission date of notification</b>	4 September 2023
<b>Other information</b>	
<b>Agency or authority responsible</b>	Please refer to the website of the Intellectual Property Office (TIPO) of the Ministry of Economic Affairs to get more information about Regulations Governing the Determination of Patent Term Extension.  Website: <a href="http://www.tipo.gov.tw">http://www.tipo.gov.tw</a> Contact email address: <a href="mailto:ipogp@tipo.gov.tw">ipogp@tipo.gov.tw</a>

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\* Links are provided to texts of laws and regulations notified under the TRIPS Agreement in the form supplied by the Member concerned; the WTO Secretariat does not endorse or revise their content.