



17 May 2022

(22-3818)

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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**

REPUBLIC OF MOLDOVA: LAW AMENDING AND SUPPLEMENTING  
CERTAIN LEGISLATIVE ACTS NO. 24 OF 23.02.2018

<b>Notifying Member</b>	REPUBLIC OF MOLDOVA
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**Details of the notified legal text**

<b>Title</b>	Law Amending and Supplementing Certain Legislative Acts No. 24 of 23.02.2018
<b>Subject matter</b>	Undisclosed information
<b>Nature of notification</b>	<input type="checkbox"/> Main dedicated intellectual property law or regulation <input checked="" type="checkbox"/> Other law or regulation
<b>Link to legal text*</b>	<a href="https://ip-documents.info/2022/IP/MDA/22_3452_00_e.pdf">https://ip-documents.info/2022/IP/MDA/22_3452_00_e.pdf</a>
<b>Notification status</b>	<input checked="" type="checkbox"/> First notification <input type="checkbox"/> Amendment or revision to notified legal text <input type="checkbox"/> Replacement or consolidation of notified legal text(s)
<b>Previous notification(s) referred to</b>	Not applicable
<b>Brief description of the notified legal text</b>	
<p>The notification is related to the amendments made to the Law No. 1456/1993 (see "Other information" below) on Pharmaceutical Activity introducing IP related measures relating to medicinal products for human use, namely for holders of an original medicinal product for which marketing authorization is requested which shall benefit from a 5-year period of data protection for preclinical and clinical trials from the date of authorization and an additional 2-year period of marketing protection for the medicinal product concerned.</p> <p>The 2-year period of market protection may be extended to a maximum of 3 years if, during the data protection period for tests and trials, the marketing authorization holder obtains an authorization for one or more new therapeutic indications thereof which, following a scientific evaluation prior to the authorization of the medicinal product, are considered to bring significant clinical benefits in comparison with existing therapies provided that significant preclinical tests and clinical trials are carried out and presented with regard to the new indication/new indications.</p>	
<b>Language(s) of notified legal text</b>	English
<b>Entry into force</b>	16 March 2018

<b>Other date</b>	
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**Notification details**

<b>Submission date of notification</b>	16 May 2022
<b>Other information</b>	<p>Text in Romanian -  <a href="https://www.legis.md/cautare/getResults?doc_id=105763&amp;lang=ro">https://www.legis.md/cautare/getResults?doc_id=105763&amp;lang=ro</a></p> <p>Law on pharmaceutical activity No. 1456 of 25.05.1993</p> <p><a href="https://www.legis.md/cautare/getResults?doc_id=128121&amp;lang=ro">https://www.legis.md/cautare/getResults?doc_id=128121&amp;lang=ro</a>  <i>(Romanian)</i></p> <p><a href="https://www.legis.md/cautare/getResults?doc_id=128121&amp;lang=ru">https://www.legis.md/cautare/getResults?doc_id=128121&amp;lang=ru</a>  <i>(Russian)</i></p> <p>Law on medicinal products No. 1409 of 17.12.1997</p> <p><a href="https://www.legis.md/cautare/getResults?doc_id=115116&amp;lang=ro">https://www.legis.md/cautare/getResults?doc_id=115116&amp;lang=ro</a>  <i>(Romanian)</i></p> <p><a href="https://www.legis.md/cautare/getResults?doc_id=115116&amp;lang=ru">https://www.legis.md/cautare/getResults?doc_id=115116&amp;lang=ru</a>  <i>(Russian)</i></p>
<b>Agency or authority responsible</b>	<p>STATE AGENCY ON INTELLECTUAL PROPERTY OF THE REPUBLIC OF MOLDOVA (AGEPI)</p> <p>24/1 Andrei Doga st.  MD-2024  Chisinau  Republic of Moldova</p> <p>Telephone: (+373) 22400583  Call-centre: (+373) 22400500  Fax: (+373) 22440119  Email: <a href="mailto:office@agepi.gov.md">office@agepi.gov.md</a>  Website: <a href="http://www.agepi.gov.md">www.agepi.gov.md</a></p>

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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.