



31 May 2022

(22-4116)

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Committee on Technical Barriers to Trade

Original: Spanish

## NOTIFICATION

### Addendum

The following communication, dated 30 May 2022, is being circulated at the request of the delegation of Mexico.

**Title:** Draft Mexican Official Standard PROY-NOM-177-SSA1-2013 establishing tests and procedures to demonstrate that a medicine is interchangeable and a biotechnological medicine biocomparable, and the requirements to be met by authorized third parties, research centres and hospitals that conduct such tests

Reason for Addendum:	
<input type="checkbox"/>	Comment period changed - date:
<input type="checkbox"/>	Notified measure adopted - date:
<input type="checkbox"/>	Notified measure published - date:
<input type="checkbox"/>	Notified measure enters into force - date:
<input type="checkbox"/>	Text of final measure available from <sup>1</sup> :
<input type="checkbox"/>	Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified:
<input checked="" type="checkbox"/>	Content or scope of notified measure changed and text available from <sup>1</sup> : <a href="https://www.dof.gob.mx/nota_detalle.php?codigo=5653130&amp;fecha=25/05/2022#gsc.tab=0">https://www.dof.gob.mx/nota_detalle.php?codigo=5653130&amp;fecha=25/05/2022#gsc.tab=0</a> New deadline for comments (if applicable): 4 July 2022
<input type="checkbox"/>	Interpretive guidance issued and text available from <sup>1</sup> :
<input type="checkbox"/>	Other:

**Description: Amendments** have been made to points 2.1, 2.2, 6.1.2, 11.3.5, 11.8.3.1 and 11.8.3.2 and points 6.1.3, 6.1.3.1, 6.1.3.2, 12.2, 12.3, 12.4, 12.5, 12.6, 12.7, 12.8, 12.9, 12.10 and 12.11 have been **added** to Mexican Official Standard NOM-177-SSA1-2013 establishing tests and procedures to demonstrate that a medicine is interchangeable. Requirements to be met by authorized third parties that conduct interchangeability tests. Biocomparability study requirements.

<sup>1</sup> This information can be provided by including a website address, a PDF attachment, or other information on where the text of the final measure/change to the measure/interpretative guidance can be obtained.

Requirements to be met by authorized third parties, research centres and hospitals that conduct biocomparability tests, published in the Official Journal on 20 September 2013.

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