NOTIFICATION

Addendum

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

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**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

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| **Reason for Addendum:** | |
| [ ] | Comment period changed - date: |
| [ ] | Notified measure adopted - date: |
| [ ] | Notified measure published - date: |
| [ ] | Notified measure enters into force - date: |
| [ ] | Text of final measure available from[[1]](#footnote-1): |
| [ ] | Notified measure withdrawn or revoked - date:  Relevant symbol if measure re-notified: |
| [X] | Content or scope of notified measure changed and text available from1:  <https://www.dof.gob.mx/nota_detalle.php?codigo=5653130&fecha=25/05/2022#gsc.tab=0>  New deadline for comments (if applicable): 4 July 2022 |
| [ ] | Interpretive guidance issued and text available from1: |
| [ ] | 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. 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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1. 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. [↑](#footnote-ref-1)