NOTIFICATION

Addendum

The following communication, dated 20 September 2024, is being circulated at the request of the delegation of Mexico.

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**Title**: *Proyecto de norma oficial mexicana PROY-NOM-059-SSA1-2015, buenas prácticas de fabricación de medicamentos* (Draft Mexican Official Standard PROY-NOM-059-SSA1-2015: Good manufacturing practices for medicinal products)

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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| [ ] | Notified measure withdrawn or revoked - date:Relevant symbol if measure re-notified: |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://dof.gob.mx/nota_detalle.php?codigo=5738508&fecha=06/09/2024#gsc.tab=0>Draft amendments to various points of Mexican Official Standard NOM-059-SSA1-2015: Good manufacturing practices for medicinal products, published on 5 February 2016.<https://members.wto.org/crnattachments/2024/TBT/MEX/modification/24_06142_00_s.pdf>New deadline for comments (if applicable): 60 days from notification |
| [ ] | Interpretive guidance issued and text available from1: |
| [ ] | Other: |

**Description**: Mexico hereby advises of the publication of the draft amendments to various points of Mexican Official Standard NOM-059-SSA1-2015: Good manufacturing practices for medicinal products, published on 5 February 2016, which establishes a reliance scheme to optimize the entry process for safe, effective and quality new treatment options for illnesses requiring advanced therapies (mainly biotechnological medicines) such as cancer and diabetes mellitus.

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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)