NOTIFICATION

Addendum

The following communication, dated 7 October 2021, is being circulated at the request of the delegation of the Philippines.

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**Title:** Revised Postmarketing Surveillance Requirements for New Drugs under Monitored Release

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| **Reason for Addendum:** |
| [  ] | Comment period changed - date:  |
| [  ] | Notified measure adopted - date:  |
| [X] | Notified measure published - date: 30 September 2021; Published in The Manila Times, page A2 |
| [X] | Notified measure enters into force - date: 15 October 2021 |
| [X] | Text of final measure available from[[1]](#footnote-1): <https://www.fda.gov.ph/wp-content/uploads/2021/09/FDA-Circular-No.2021-020.pdf> |
| [  ] | Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified:  |
| [  ] | Content or scope of notified measure changed and text available from1: New deadline for comments (if applicable):  |
| [  ] | Interpretive guidance issued and text available from1:  |
| [  ] | Other:  |

**Description:** The FDA Circular 2021-020 Revised Post-marketing Surveillance Requirements for New Drugs under Monitored Release was signed on 21 September 2021, published in The Manila Times on 30 September 2021 and shall take effect on 15 October 2021.

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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/modified measure and/or interpretive guidance can be obtained. [↑](#footnote-ref-1)