NOTIFICATION

Addendum

The following communication, dated 24 March 2023, is being circulated at the request of the delegation of Brazil.

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**Title:** Resolution - RDC number 750, 06 September 2022

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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| [ ] | Notified measure withdrawn or revoked - date:  Relevant symbol if measure re-notified: |
| [ ] | Content or scope of notified measure changed and text available from1:  New deadline for comments (if applicable): |
| [ ] | Interpretive guidance issued and text available from1: |
| [X] | Other:  The notified mesure had its validity period extended until 31 March 2024.  <http://antigo.anvisa.gov.br/documents/10181/6485985/RDC_781_2023_.pdf/f641a5f9-54b0-43b0-b1b0-3466e15209c8> |

**Description:** Resolution - RDC number 750, 06 September 2022 - previously notified through G/TBT/N/BRA/1444 -, which establishes a temporary optimized analysis procedure, in which the analyzes conducted by an Equivalent Foreign Regulatory Authority are used for the verified analysis of the market authorization and post-market authorization petitions of medicines, biological products and their inputs, and the letter of adequacy of the pharmaceutical ingredient dossier active, had its validity period extended until 31 March 2024 by Resolution- RDC number 781, 16 March 2023.

The final text is available only in Portuguese and can be downloaded at:

<http://antigo.anvisa.gov.br/documents/10181/6485985/RDC_781_2023_.pdf/f641a5f9-54b0-43b0-b1b0-3466e15209c8>

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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)