NOTIFICATION

Addendum

The following communication, dated 27 March 2024, is being circulated at the request of the delegation of Brazil.

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**Title:** Draft resolution number 1108, 18 August 2022;

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| **Reason for Addendum:** |
| [ ] | Comment period changed - date:  |
| [X] | Notified measure adopted - date: 1 April 2024 |
| [ ] | 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| [ ] | Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified:  |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:  |
| [ ] | Other:  |

**Description:** Draft resolution number 1108, 18 August 2022 - previously notified through G/TBT/N/BRA/1442 - which is regarded to a proposal for a Normative Instruction that establishes the modalities and criteria applied for the optimized analysis procedure, in which the evaluations conducted by the Equivalent Foreign Regulatory Authority (EFRA) are used to analyze the market authorization and post-market authorization petitions of medicines and biological products, and a letter of adequacy of active pharmaceutical ingredient (CADIFA), in national territory, was adopted as Normative Instruction 289, 20 March 2024.

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

<http://antigo.anvisa.gov.br/documents/10181/6354042/IN_289_2024_.pdf/ec565fb0-e17e-4e0a-a8c0-a88935fb6cca>

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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)