NOTIFICATION

Addendum

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

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Title:** Draft resolution 1188, 03 August 2023

|  |  |
| --- | --- |
| **Reason for Addendum:** | |
| [ ] | Comment period changed - date: |
| [X] | Notified measure adopted - date: 1 May 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| [ ] | Notified measure withdrawn or revoked - date:  Relevant symbol if measure re-notified: |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 1188, 03 August 2023 - previously notified through G/TBT/N/BRA/1493 - whichcontains provisions on health requirements for safety and efficacy for post-marketing registration alterations of synthetic and semi-synthetic drugs classified as new or innovative, was adopted as Resolution 851, 20 March 2024.

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

<http://antigo.anvisa.gov.br/documents/10181/6636520/RDC_851_2024_.pdf/46470423-d17a-4aef-8dbc-86af88eb65b9>

**\_\_\_\_\_\_\_\_\_\_**

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)