



25 October 2023

(23-7173)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

Addendum

The following communication, dated 25 October 2023, is being circulated at the request of the delegation of Brazil.

Title: Draft resolution number 1136, 26 December 2022

Reason for Addendum:	
<input type="checkbox"/>	Comment period changed - date:
<input checked="" type="checkbox"/>	Notified measure adopted - date: 31 December 2026
<input type="checkbox"/>	Notified measure published - date:
<input type="checkbox"/>	Notified measure enters into force - date:
<input type="checkbox"/>	Text of final measure available from ¹ :
<input type="checkbox"/>	Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified:
<input type="checkbox"/>	Content or scope of notified measure changed and text available from ¹ : New deadline for comments (if applicable):
<input type="checkbox"/>	Interpretive guidance issued and text available from ¹ :
<input type="checkbox"/>	Other:

Description: Draft resolution 1136, 26 December 2022 - previously notified through G/TBT/N/BRA/1467 - which is regarded to a proposal to define the general guidelines for the pilot implementation of the optimized analysis procedure, based on risk criteria, to confirm the suitability of the documentation submitted to Anvisa for marketing authorization and post-marketing authorization changes to medicines., was adopted as Resolution 823, 19 October 2023.

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

http://antigo.anvisa.gov.br/documents/10181/6531732/RDC_823_2023_.pdf/097b9a99-6230-4f87-ba03-2c0738c4860f

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.