



NOTIFICATION

Addendum

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

Title: Draft resolution number 1136, 26 December 2022

Reason for Addendum:	
<input checked="" type="checkbox"/>	Comment period changed - date: 5 May 2023; Extends the comment period for 60 days. The extension text is available only in Portuguese and can be downloaded at: https://www.in.gov.br/en/web/dou/-/despacho-n-27-de-06-de-marco-de-2023-468130483
<input type="checkbox"/>	Notified measure adopted - date:
<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	Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified: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: The Draft resolution number 1136, 26 December 2022, previously notified through G/TBT/N/BRA/1467 - which regards 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, had its period for comments extended for 60 days by Order number 27, from 06 March 2023.

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

<https://www.in.gov.br/en/web/dou/-/despacho-n-27-de-06-de-marco-de-2023-468130483>

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.