



**NOTIFICATION**

*Addendum*

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

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

<b>Reason for Addendum:</b>	
<input type="checkbox"/>	Comment period changed - date:
<input checked="" type="checkbox"/>	Notified measure adopted - date: 1 May 2024
<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 <sup>1</sup> :
<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	Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified: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 <sup>1</sup> : New deadline for comments (if applicable):
<input type="checkbox"/>	Interpretive guidance issued and text available from <sup>1</sup> :
<input type="checkbox"/>	Other:

**Description:** Draft resolution 1188, 03 August 2023 - previously notified through G/TBT/N/BRA/1493 - which contains 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](http://antigo.anvisa.gov.br/documents/10181/6636520/RDC_851_2024_.pdf/46470423-d17a-4aef-8dbc-86af88eb65b9)

<sup>1</sup> 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.