



NOTIFICATION

Addendum

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

Title: Draft resolution number 1108, 18 August 2022;

Reason for Addendum:	
<input type="checkbox"/>	Comment period changed - date:
<input checked="" type="checkbox"/>	Notified measure adopted - date: 1 April 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 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	Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified: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 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

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.