Committee on Technical Barriers to Trade

Original:

NOTIFICATION

Addendum

The following communication, dated January 4th, 2021, is being circulated at the request of the delegation of Brazil.

Title: Documentation for the protocol of radiopharmaceutical register process

Reason for Addendum:	
[]	Comment period changed - date:
[ ]	Notified measure adopted - date:
[X]	Notified measure published - date: 23 December 2020
[X]	Notified measure enters into force - date: 1 February 2021
[X]	Text of final measure available from[1]: http://antigo.anvisa.gov.br/documents/10181/3633045/IN_80_2020_.pdf/e1514ef7-c00d-485b-8c97-0cba2714df97
[]	Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified:
[]	Content or scope of notified measure changed New deadline for comments (if applicable):
[]	Interpretive guidance issued and text available from:
[]	Other:

Description:

The Draft Resolution number 704, 23 August 2019 – previously notified through G/TBT/N/BRA/909 – which is a complement for the revision of the Resolution – RDC number 64, 18 December 2009, which establishes the market authorization for radiopharmaceuticals, and proposes the documenting necessary for the protocol of market authorization for radiopharmaceuticals, was adopted as Normative Instruction number 80, 16 December 2020.

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

http://antigo.anvisa.gov.br/documents/10181/3633045/IN_80_2020_.pdf/e1514ef7-c00d-485b-8c97-0cba2714df97