



**NOTIFICATION**

*Addendum*

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

**Title:** Resolution – RDC number 461, 22 January 2021

<b>Reason for Addendum:</b>	
<input type="checkbox"/>	Comment period changed - date:
<input type="checkbox"/>	Notified measure adopted - date:
<input checked="" type="checkbox"/>	Notified measure published - date: 23 January 2021
<input checked="" type="checkbox"/>	Notified measure enters into force - date: 23 January 2021
<input checked="" type="checkbox"/>	Text of final measure available from <sup>1</sup> : <a href="http://antigo.anvisa.gov.br/documents/10181/2718376/RDC_461_2021_.pdf/e999c540-64cb-4bb3-9850-1829f7b365a5">http://antigo.anvisa.gov.br/documents/10181/2718376/RDC_461_2021_.pdf/e999c540-64cb-4bb3-9850-1829f7b365a5</a>
<input type="checkbox"/>	Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified:
<input checked="" type="checkbox"/>	Content or scope of notified measure changed New deadline for comments (if applicable):
<input type="checkbox"/>	Interpretive guidance issued and text available from:
<input type="checkbox"/>	Other:

**Description:**

The Resolution – RDC number 392, 26 May 2020 – previously notified through [G/TBT/N/BRA/1032](http://www.wto.org) – which establishes temporary and extraordinary criteria for the application of exceptionalities to specific technical requirements of the Good Manufacturing and Import Practice of Medicinal Products and Active Pharmaceutical Ingredients, due to the international public health emergency of the new coronavirus (Covid-19), was changed by the Resolution – RDC number 461, 22 January 2021.

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

[http://antigo.anvisa.gov.br/documents/10181/2718376/RDC\\_461\\_2021\\_.pdf/e999c540-64cb-4bb3-9850-1829f7b365a5](http://antigo.anvisa.gov.br/documents/10181/2718376/RDC_461_2021_.pdf/e999c540-64cb-4bb3-9850-1829f7b365a5)