NOTIFICATION

Addendum

The following communication, dated 18 September 2020, is being circulated at the request of the delegation of Brazil.

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**Title:** Post-market authorization alterations of biological products

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| **Reason for Addendum:** | |
| [  ] | Comment period changed - date: |
| [X] | Notified measure adopted - date: 20 August 2020 |
| [  ] | Notified measure published - date: |
| [  ] | Notified measure enters into force - date: |
| [  ] | Text of final measure available from[[1]](#footnote-1): |
| [  ] | Notified measure withdrawn or revoked - date:  Relevant symbol if measure re-notified: |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 from1: |
| [X] | Other: <http://portal.anvisa.gov.br/documents/10181/4247824/RDC_413_2020_.pdf/8f16d69f-a8ba-43d0-9a99-732da1583bac> |

**Description:** The Draft Resolution number 687, 12 August 2019 – previously notified through [G/TBT/N/BRA/901](https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?MetaCollection=WTO&SymbolList=%22G%2fTBT%2fN%2fBRA%2f901%22+OR+%22G%2fTBT%2fN%2fBRA%2f901%2f*%22&Serial=&IssuingDateFrom=&IssuingDateTo=&CATTITLE=&ConcernedCountryList=&OtherCountryList=&SubjectList=&TypeList=&FullTextHash=371857150&ProductList=&BodyList=&OrganizationList=&ArticleList=&Contents=&CollectionList=&RestrictionTypeName=&PostingDateFrom=&PostingDateTo=&DerestrictionDateFrom=&DerestrictionDateTo=&ReferenceList=&Language=ENGLISH&SearchPage=FE_S_S001&ActiveTabIndex=0&languageUIChanged=true) – which proposes an initiative for the revision of the Resolution – RDC number 49, 20 September 2011, which establishes post-market authorization alterations of biological products, was adopted as Resolution – RDC number 413, 20 August 2020.

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1. This information can be provided by including a website address, a pdf attachment, or other information on where the text of the final measure and/or interpretive guidance can be obtained. [↑](#footnote-ref-1)