

2 August 2018

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Committee on Technical Barriers to Trade

Original: Spanish

NOTIFICATION

Addendum

The following communication, dated 2 August 2018, is being circulated at the request of the delegation of Colombia.

Decree No. 1782 establishing the requirements and procedure for pharmacological and pharmaceutical assessments of biological medicines during the sanitary registration process

The Republic of Colombia hereby advises that a draft Resolution establishing guidelines on the comparability of biological medicines has been prepared in accordance with Ministry of Health and Social Welfare Decree No. 1782 of 18 September 2014 establishing the requirements and procedure for pharmacological and pharmaceutical assessments of biological medicines during the sanitary registration process, notified on 10 October 2014 by the World Trade Organization in document G/TBT/N/COL/196/Add.1. A deadline for comments has been set at 2 November 2018.

Text available online at:

http://extranet.comunidadandina.org/SIRT/public/index.aspx

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http://www.sical.gov.co/reglamentos-tecnicos

Also available at:

https://members.wto.org/crnattachments/2018/TBT/COL/18 4155 00 s.pdf