

**G / TBT / N / ARG / 251 / Add.2**

January 23 , 2019

( 19-0367 )

Page: 1/1

**Committee on Technical Barriers to Trade**

Original: Spanish

**NOTIFICATION***Addendum*

The following communication, dated January 22, 2019 , is distributed at the request of the delegation of Argentina .

Medicinal specialties for human use

It is reported that by Provision No. 513/2019 of the National Administration of Medicines, Food and Medical Technology proceeds to update the registration procedures in the Registry of Medicinal Specialties (REM) with Active Pharmaceutical Ingredients (IFA) of synthetic origin and semi-synthetic that do not require demonstration of Bioequivalence and / or Bioavailability in the terms of article 3 of Decree 150/92 (TO 1993).

The update seeks to comply with the principles of efficiency, economy, transparency and predictability in the technical and administrative evaluation of procedures.

## Reference Legislation:

Law No. 16,463

<http://servicios.infoleg.gob.ar/infolegInternet/anexos/20000-24999/20414/norma.htm>

Decree No. 150/1992

<http://servicios.infoleg.gob.ar/infolegInternet/anexos/5000-9999/8196/texact.htm>

OTC-OMC Focal Point of the Argentine Republic  
Directorate of Domestic Trade Policies and Competition  
Avda. Julio A. Roca 651 4th Floor Sector 23A  
(C1067ABB) Autonomous City of Buenos Aires  
Telephone: 54 11 4349 4067

E-mail: [focalotc@mecon.gob.ar](mailto:focalotc@mecon.gob.ar)

Text available:

[http://www.puntofocal.gov.ar/formularios/registro\\_arg09.php](http://www.puntofocal.gov.ar/formularios/registro_arg09.php)[https://members.wto.org/crnattachments/2019/TBT/ARG/19\\_0385\\_00\\_s.pdf](https://members.wto.org/crnattachments/2019/TBT/ARG/19_0385_00_s.pdf)