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Committee on Technical Barriers to Trade

Original: Spanish

NOTIFICATION*Addendum*

The following communication, dated December 18, 2018 , is distributed at the request of the delegation of Argentina .

Medicinal specialties for human use

It is reported that by Provision No. 2089/2018 of the National Administration of Drugs, Food and Medical Technology is proceeded to update the registration procedures in the Registry of Medicinal Specialties (REM), in the terms of articles 3 and 4 of Decree 150/92 (TO 1993) establishing the ANMAT Provision No. 5755/1996.

For its effects, Article 8 ° ANMAT Provision No. 5755/1996 is repealed.

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>
- Provision 5755/1996
<http://servicios.infoleg.gob.ar/infolegInternet/anexos/40000-44999/41808/norma.htm>

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Text available:

http://www.puntofocal.gov.ar/formularios/notific_arg.php

<http://www.puntofocal.gob.ar/>

https://members.wto.org/crnattachments/2018/TBT/ARG/18_6485_00_s.pdf