

WORLD TRADE ORGANIZATION

G/TBT/N/ARG/251

18 June 2009

(09-2993)

Committee on Technical Barriers to Trade

Original: Spanish

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

1. Member to Agreement notifying: <u>ARGENTINA</u> If applicable, name of local government involved (Articles 3.2 and 7.2):
2. Agency responsible: <i>Administración Nacional de Medicamentos, Alimentos y Tecnología Médica</i> , ANMAT (National Drug, Food and Medical Technology Administration) Avda. de Mayo 869 (C1084AAD), Ciudad Autónoma de Buenos Aires Tel.: 54-11-4342-8684 Fax: 54-11-4340-0800, Ext. 1173 E-mail: direccion@anmat.gov.ar Name and address (including telephone and fax numbers, E-mail and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:
3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], other:
4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Medicinal preparations for human use.
5. Title, number of pages and language(s) of the notified document: " <i>Registro de Especialidades Medicinales (REM) - Nueva Inscripción</i> " (Register of Medicinal Preparations - Registration renewal) (1 page, in Spanish).
6. Description of content: Article 8 of Law No. 16.463 provides that authorizations for the preparation and sale of medicines may be cancelled: (a) at the request of the owner; (b) in the event of any change, alteration or failure to comply with the conditions of authorization; (c) upon expiry of the time period established in Article 7 (five years); or (d) when, as a result of scientific developments, the product no longer serves any useful therapeutic purpose. With regard to the cancellation of authorizations under Article 8(c) of the Law, which is the most frequent grounds for cancellation, ANMAT has duly established the information and documentation requirements for the renewal of entries in the Register of Medicinal Preparations, whilst maintaining the requirements concerning the product, its therapeutic validity and its safety parameters.

6.	Description of content: (cont'd)
ANMAT has deemed it necessary to review the regulations governing all products which are currently entered in the Register of Medicinal Preparations, and has established the following:	
<ul style="list-style-type: none"> - Laboratories that own medicinal preparations the registration certificates (authorizations) of which have ceased to be valid following the expiry of the time period provided for in Article 7 of the Law, and reiterated in Article 8(c) thereof, may apply to renew their registration within one hundred and eighty (180) calendar days as of 15 May 2009; - once this period has elapsed, if no request for registration renewal - or cancellation if appropriate - has been received, certificates which have ceased to be valid will be cancelled pursuant to the corresponding administrative decree. 	
7.	Objective and rationale, including the nature of urgent problems where applicable: A review of the regulations is required given the considerable number of certificates which are no longer valid and for which no application for either registration renewal or cancellation has been submitted. There is, therefore, a need to re-establish record-keeping principles, namely organization, standardization, consistency, accuracy and reliability, which are essential to the proper functioning of control activities.
8.	Relevant documents: Law (<i>Ley</i>) No. 16.463, Decrees (<i>Decretos</i>) Nos. 9763/64 and 150/92 (amended text of 1993), ANMAT Resolutions (<i>Disposiciones</i>) Nos. 818/98 and 2066/2009.
9.	Proposed date of adoption: } Proposed date of entry into force: } -
10.	Final date for comments: -
11.	Texts available from: National enquiry point [X] or address, telephone and fax numbers, E-mail and website addresses, if available, of other body: Punto Focal de la Republica Argentina Dirección Nacional de Comercio Interior Avda. Julio. A. Roca 651, Piso 4°, Sector 2 (C1067ABB) Ciudad Autónoma de Buenos Aires Tel.: 54 11 4349 4067 Fax: 54 11 4349 4072 E-mail: focalotc@mecon.gov.ar Text available at: http://www.puntofocal.gov.ar/notific_arg.htm