EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Single Market for Goods
Prevention of Technical Barriers

Brussels,
LK/nv – entr.c.3(2013)3435346

E-MAIL

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Number of pages:	1 + 2		

Subject: **G/TBT/N/COL/176 – DRAFT MINISTRY OF HEALTH AND SOCIAL WELFARE DECREE "REGULATING THE PROCEDURE TO ASSESS THE QUALITY, SAFETY AND EFFICACY OF BIOLOGICAL MEDICINES FOR SANITARY REGISTRATION PURPOSES, AND ADOPTING OTHER PROVISIONS" – EU COMMENTS**

Message:

Dear Sir or Madam

Please find attached the comments from the European Union on the above-mentioned notification.

Could you please acknowledge receipt of this e-mail? Thank you.

Yours faithfully

Giuseppe Casella
Head of Unit

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COMMENTS FROM THE EUROPEAN UNION CONCERNING
NOTIFICATION
G/TBT/N/COL/196

DRAFT MINISTRY OF HEALTH AND SOCIAL WELFARE DECREE "REGULATING THE PROCEDURE TO ASSESS THE QUALITY, SAFETY AND EFFICACY OF BIOLOGICAL MEDICINES FOR SANITARY REGISTRATION PURPOSES, AND ADOPTING OTHER PROVISIONS"

The European Union (EU) would like to thank the Colombian authorities for notifying Draft Ministry of Health and Social Welfare Decree "Regulating the procedure to assess the quality, safety and efficacy of biological medicines for sanitary registration purposes, and adopting other provisions" on 19 July 2013 and the possibility to comment upon it.

The EU would like to raise the following questions in relation to this notification.

The EU noted that, in the notified draft, Colombia intends to establish 3 pathways for submission of information on biological medicinal products for pharmacological evaluation.

Article 7 is establishing an abbreviated pathway for biological medicinal products to enter the Colombian market using data of authorities from other countries or regions to document the quality, safety and efficacy of the active substance. The EU considers that the wording of Article 7 is quite general. Therefore, the EU considers that at this stage it is difficult to ascertain the consequences of the proposed abbreviated pathway.

The EU would like to receive further details on the biological medicines intended for the abbreviated pathway and how it will be implemented in practice. In particular, it would appreciate to receive confirmation that this pathway will only apply to biological products that are authorised by the countries or regions from which information on the quality, safety and efficacy is collected. With the view to ensure the quality, safety and efficacy of the products authorised under this pathway and the adequacy of the collected information, the EU also invites the Colombian authorities to consider to apply this pathway to whole products instead of active substances.

The EU also notes that a number of guidelines are to be drafted according to Article 25 of the notified draft by the Ministry of Health and Social Welfare of Colombia. The EU welcomes the fact that these guidelines will be developed by taking into account international standards and without generating unnecessary barriers for the access to the market. The EU would ask the Colombian authorities to provide further details regarding the transparency of process of elaboration of these guidelines and the opportunities for other competent authorities or stakeholders to contribute to this process through public consultations.

Furthermore, the EU would like to ask the Colombian authorities whether they intend to notify under the TBT Agreement the guidelines relevant to the abbreviated pathway as defined in Article 25 of the notified draft.

The EU would like to thank the Colombian authorities in advance for taking the comments into account and looks forward to receiving a reply to these comments.

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