



**EUROPEAN COMMISSION**  
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Principal Adviser with special interest in Public Health

Luxembourg,  
DDG1.PA02/IDLMD (2011)

Dear Ms Zavidova,

**Subject: Mutual recognition between the EU and Russia**

Thank you for your email of 14 March 2011 to Commissioner Dalli regarding mutual recognition of clinical trials between European Union and Russian Federation.

There are no mutual recognition agreements on clinical trials. The European Union accepts the clinical trials performed in accordance with Good Clinical Practices.

The European Commission is aware of the new Law on Circulation of Medicines which came into force on 1<sup>st</sup> September 2010.

We have been in contact with the Russian Federation Ministry of Health and Social Policy regarding pharmaceuticals, including the topic of clinical trials.

The Terms of Reference for a Dialogue on Public Health were signed between the General Directorate for Health and Consumers and the Ministry of Health and Social Policy of the Russian Federation in 2009. Under this Dialogue a subgroup on Pharmaceuticals has been established.

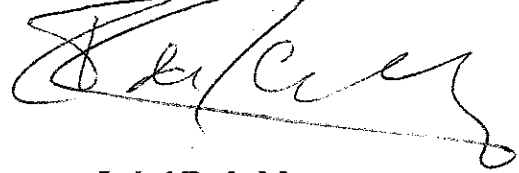
The European Commission is studying the Russian legislation and checking the equivalence with the European legislation on clinical trials. Both parties are interested in finalising this comparison as soon as possible.

Mrs Svetlana Zavidova  
Executive Director  
Association of Clinical Trials Organizations  
4, Malaya Dmitrovka Str., App. 5

127006 Moscow  
Russian Federation

Thanking you for your interest in our work for the well being of the European patients and the development of safe and affordable medicines.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Isabel De la Mata', written over a horizontal line.

Isabel De la Mata

Copy: CAB DALLI CAD, Mr. N Behrndt, Cabinet Dalli  
P. Brunko, DG SANCO C8  
A. Volpato (EEAS Moscow)