

Dr. Uliana Suprun

Acting Minister of Health of Ukraine

Ilyk Roman Romanovych

Deputy Minister of Health of Ukraine

Hrushevskoho Street, 7

Kyiv, 01601

31 July, 2017

Dear Dr. Suprun

Dear Mr. Ilyk,

We avail ourselves of this opportunity to thank you for a productive meeting and a constructive dialogue on the reform of the medicinal products registration authority in Ukraine.

The Consortium of Consultants has already begun its work on the preparation of an Institutional capacity building Plan in the sphere of medicinal products registration (or Roadmap).

With this letter, we would like to summarize the key theses of the meeting, which reflect the position of the Ministry of Health, and which create the basis of further work of the Consortium of Consultants:

Form of the new registration body

The new registration body should be created in the form of a central governmental body with a special status ("CGB with a special status"). This option is considered as optimal, since it provides a significant level of discretion in terms of funding, subordination, structure, appointment procedure of leadership, status of employees and payment of their labor.

The features of a new CGB with a special status should be determined by law.

Interaction and coordination with other state bodies

In order to ensure a proper management and balance in the circulation system of medicinal products, a new registration body and the CGB in the field of quality control of medicinal products should be subordinated directly to the Ministry of Health. The latter will require changes in the status of the CGB in the field of quality control of medicinal products.

Financing

The Ministry supports the idea that a certain percentage of the applicants' paid registration fees to the budget should be returned from the state budget in order to finance a new registration body.

This idea should be discussed with the representatives of the Ministry of Finance of Ukraine and the Ministry of Economic Development and Trade of Ukraine.

Status and remuneration of employees of the new registration body

The leadership of the newly created body (including the heads of departments) will have a status of civil servants (with a foreseeable increase in the level of wages at the level of a special law). Experts will not have a status of civil servants, but they will be subject to a range of additional rigorous and detailed law-level requirements.

Requirements should relate, in particular, to the prevention of conflict of interest (with a detailed definition of situations that can be considered as a conflict of interest), secondary employment and preventing corruption (in particular, the possible obligation to declare income of experts).

Allocation of responsibilities

The functions of registration of medicinal products and of production licensing, GMP certification and quality control should be allocated between the two bodies. In this case, effective interaction and coordination between the authorities should be ensured, in particular, due to changes in the part of their subordination to the Ministry of Health of Ukraine.

In accordance with the agreements reached in the framework of the meeting, we will be grateful for the information on specialists of the Ministry of Economic Development and Trade of Ukraine, the Ministry of Finance and the Secretariat of the Cabinet of Ministers of Ukraine, with which the Consortium of Experts will be able to discuss certain aspects of the recommended changes.

Kind regards,

Florence Bachelard-Bakal

Senior Banker

Regional Head of the Industry and Services Department of EBRD