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Date: 01 November 2017

Dr David Sergeenko  
Minister of Labour, Health and Social Affairs  
Ministry of Labour, Health and Social Affairs  
144, Ak. Tsereteli Ave.  
Tbilisi 0119  
Georgia

Dear Sir,

Thank you for your letter dated 11 October 2017 regarding collaboration with WHO on further strengthening the health system in Georgia with a specific focus on the regulation of pharmaceuticals.

Public confidence in the quality and safety of medical products translates into confidence in national health services and confidence in the government's commitment to protect its people.

I am therefore pleased to know of your plans for following up on the work collaboration started in 2014 and your intention to expand your regulatory strengthening work towards implementation of Good Regulatory Practices. In 2014 and as part of the Pandemic Influenza Preparedness (PIP) framework and Partnership Contribution (PC) context, WHO provided technical assistance to Georgia – as a priority country in the WHO European region to build regulatory capacity for influenza products including vaccines, antivirals and diagnostics and to accelerate national approval of these commodities in case of influenza pandemic, addressing the gaps in regulatory systems as well as marketing authorization and pharmacovigilance functions. The major responsibility of a National Regulatory Agency is to safeguard public health in an expedient manner under both normal and public health emergency situations by ensuring the quality, safety and efficacy of medical products available in the national market. I attach the draft LEPL State Regulations Agency for Medical Activities Road Map to 2020 that our VPI programme shared with you in December 2016. Follow up to this plan for how to implement international guidance in Georgia is important.

Our view is that it may be useful to plan for a follow up workshop and assessment of the national medicines regulatory systems, see [http://www.who.int/medicines/areas/quality\\_safety/regulation\\_legislation/assessment/en/](http://www.who.int/medicines/areas/quality_safety/regulation_legislation/assessment/en/). This will include an NRA assessment, the inspection of cGMP work, as suggested by you, and provide you with an overall plan for further strengthening the pharmaceutical regulation in Georgia. This approach will provide a good overview of priority actions to be planned and rolled out over a period of time.

Considering the extensive and broad nature of the proposed work, I would like to request you to include this in the Bilateral Collaborative Agreement, which will help us mobilize both the human and financial resources required.

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I understand from your letter the urgency of this support and we will try our utmost best for the first visit to take place in the first half of 2018. Please do not hesitate to contact Dr Hans Kluge, Director of the Health Systems and Public Health Division (email: [klugeh@who.int](mailto:klugeh@who.int)), who then will provide the technical details to advance this work.

I look forward to hearing from you on the approach outlined above and whether this is a suitable way for us to support your efforts in strengthening regulation of pharmaceuticals in Georgia.

Yours very truly,



Dr Zsuzsanna Jakab  
Regional Director

**Copy for information to:**

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Dr Sofiko Belkania, Head, Executive Department, Ministry of Labour, Health and Social Affairs, 144, Ak. Tsereteli Ave., Tbilisi 0119, Georgia

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