World Health Organization

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In reply please refer to: RSS/RO-my

Your reference: RSS-I8-370-42

Mr Zaal Kapanadze
Head
Agency of Medical and Pharmaceutical Activities
Tbilisi
Géorgie

2 April 2020

Dear Mr Kapanadze,

WHO study visit to the Swiss Agency for Therapeutic Proucts (Swissmedic) from 15 to 18 June 2020 in Bern, Switzerland

In the context of WHO`s support to Member States in strengthening their regulatory systems, the Regulatory Systems Strengthening (RSS) Team of the Regulation and Safety (REG) Unit in collaboration with the Swiss Agency for Therapeutic Products (Swissmedic) is organizing a study visit to Swissmedic. The study visit is planned in Bern, from 15 to 18 June 2020. The draft terms of reference are attached.

WHO is encouraging study visits between national regulatory authorities (NRAs) in order to share good practices and experience. A study visit is a learning opportunity both for the visitor NRA and the host NRA. All participants are, therefore, encouraged to present and share the experiences of their country; disseminate to their peers the knowledge and information acquired during the visit upon their return; and establish professional contacts that would facilitate follow up activities and exchange of information.

The main objective of the study visit is to strengthen the capacity of the NRA of Georgia through experience and knowledge exchange in applying up-to-date methods and procedures for the day-to-day operations for the Quality Management System (QMS), Marketing Authorization and Registration (MA) and Vigilance (VL), in accordance with the WHO and other international standards and best practices. Participants will participate in a peer learning experience; and will be able to use the practical application of methods and procedures for the above-mentioned functions. More specifically, this exercise will lead to an increased capacity to interpret and apply the skills gained in their day-to-day activities in developing and implementing the good practices for the quality management system, registration and marketing authorization and vigilance function in their own NRA.

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cc: The WHO Representative and Head of Country Office, Georgia
EURO

We would therefore like to invite three representatives from your institution to participate in this study visit, which will be conducted in English. The representatives should be NRA officers, each responsible for quality management system, pharmacovigilance and marketing authorization activities. WHO will cover the participation costs of the representatives, including travel and per diem for the duration of the visit.

If you are in agreement with this proposal, we would greatly appreciate it if you could kindly let us know the details of the experts you wish to nominate by email to Dr Razieh Ostad Dehaghi, ostadalidehaghir@who.int (responsible officer) **by end of April 2020** in order for us to complete administrative formalities in a timely manner.

Yours sincerely,

Mr Hiiti Sillo
Officer in Charge
Regulation and Safety