The LEPL State Regulations Agency for Medical Activities Road Map to 2020

Executive Summary

As part of its proactive approach to the continuing evolution of the pharmaceutical arena, the LEPL State Regulations Agency for Medical Activities has developed a strategy that will contribute to a better protection and promotion of public health, to improve the regulatory environment for medical products, and to help stimulate innovation, research and development in the Republic of Georgia.

Involving its partners and stakeholders in the consultation process on its strategy allowed the LEPL State Regulations Agency for Medical Activities to achieve a broad consensus on the best way forward for the Agency in view of the significant changes to its operating environment.

The resulting Road Map takes a realistic view of the challenges facing the Agency and the regulatory system as a whole, while offering viable proposals as to how those challenges can be met.

The ultimate objective of the Road Map exercise is to ensure that, building on the achievements, the LEPL State Regulations Agency for Medical Activities adequately prepares for the further success in the future.

THE CURRENT SITUATION

Registration of medicinal products

The LEPL State Regulations Agency for Medical Activities covers three main activities in relation to medicines regulation, i.e. scientific assessment, monitoring of authorised medicines and harmonisation of the technical requirements for the evaluation and supervision of medicines.

The registration process for medicinal products seems more like a validation procedure than an authorization procedure as it is conducted in the EU. The applications have to be made on paper in Georgian and with signature and company stamp. The administrative department has to use a general document management system that is not connected to their own digital systems. After the procedure is concluded all documents have to be archived. The documents have to stay archived forever.

The evaluation takes place in three stages, intake and coordination by the administrative part of the registration department, quality file by the quality assessors and clinical parts by the pharmacology assessors. In practice all boxes have to be ticked and – if necessary – new documents provided by the applicant. If the application meets the administrative criteria, the registration takes place. In the conclusion of the procedure, a internal hearing takes place. Applicants can at that time and at other moments ask any explication they want free of charge. During the evaluation, the

quality assessor may send a sample to a quality control, but this sample is provided by the applicant. There is also a limit to the frequency of analytical work being outsourced.

There are three types of applications for which the same procedure has to be followed: initial registration, variation and renewal (every five years). The number of applications is over 80 per week. The staff members work in shifts to cope with this large number and have to limit their scrutiny in order to meet the legal deadlines.

Special registration procedures

Next to the normal registration procedures, there are the special ones: parallel import and recognition regime. In both procedures it is not very clear who will be responsible for the recognition in terms of variations and Pharmacovigilance. A specific issue is that on the label the identity of the manufacturer needs to be mentioned, instead of the holder of the marketing authorisation.

Authorisation for pharmaceutical activity

These include authorisations for pharmacies as well as for manufacturing of medicinal products. The authorizations are being granted in case the right forms have been submitted. GMP is not required. This means that the authorizations are granted whenever the formal requirements are met, by no means guaranteeing the quality of the manufactured products.

Clinical trials

In the field of clinical research the agency seems to be functioning well. Clinical trials are conducted under (EU) GCP and medical-ethical committees in the hospitals perform well. The only problem is the relationship between the growing number of Georgian CROs and the regulatory staff supervising the area. It is therefore not clear if GCP standards are met in practice.

Pharmacovigilance

Pharmacovigilance currently is not really functioning in Georgia. Out of fear for claims many prescribers tend to be negative about communicating adverse events, leading to major underreporting. Due to the lack of harmonisation, with EU legislation Georgia is not able to play an active role in respect of maintaining the safe use of medicines.

Medical devices

Only dental products and In Vitro Diagnostics (“IVDs”) are regulated in Georgia. This means that the majority of medical devices are used without regulatory activity. The registration of dental products and IVDs takes place under a regime that resembles

the registration of medicinal products. It does not necessarily lead to more safety in healthcare. The current EU Regulatory System for human and veterinary medicines is a unique concept. It provides for a network between all EU Regulatory Authorities, coordinated by the LEPL State Regulations Agency for Medical Activities. One of the major inputs form the NCAs in this networking model is the provision of scientific resources at the level of the LEPL State Regulations Agency for Medical Activities.

Continuing organizational improvements

New legislation will provide for a series of changes in the field of medical products regulation with the particular aim of making effective and safe medical products faster available to patients and users of medicines and medical devices. The LEPL State Regulations Agency for Medical Activities organisation as a network is also strengthened with a reinforced coordinating role for the Agency. There could, however, be a pitfall to such decentralised structure, mainly related to the complexity of the system. In order to avoid the establishment of an insufficient system, clear roles and responsibilities need to be defined for all aspects of medicines regulation related to the GEO Regulatory System. A particular challenge in this respect will be a common approach at EU level towards transparency and communication. In addition, a culture of continual process improvement needs to develop, leading to efficient procedures and avoiding duplication, hence ensuring the best use of the available resources.

A challenging regulatory environment

Recent political, institutional, legislative and scientific developments in the Republic of Georgia, taking into account the Association Agreement with the EU signed in June 2014 will have a significant impact on the regulatory environment over the coming years.

Consequences for the LEPL State Regulations Agency for Medical Activities

These developments are to be seen as opportunities as well as challenges. The LEPL State Regulations Agency for Medical Activities will acquire new responsibilities with a greater focus on public health; the scientific components of the Agency's activity will become more important; its visibility and influence in both the EU and the international regulatory environment will grow at a faster rate.

Ultimately, the consequence of the changing environment, and the Agency's strategy for adapting to it, will be that the EU regulatory system is in a more secure position to become one of the foremost in the world, with the greatest benefit for the citizens of Europe.

The Road Map sets out a vision for the Agency, its objectives, and the specific actions it will implement to achieve those objectives.

Vision of the LEPL State Regulations Agency for Medical Activities

The key aspects of the Agency's vision for the coming years are to allow rapid access to safe and effective medicines, provide for adequately informed patients and users of medicines, encourage and facilitate innovation and research in Georgia, tackle

emerging public health challenges, prepare for developments in the pharmaceutical field, and reinforce the partnership between the LEPL State Regulations Agency for Medical Activities and the NRAs to establish a network.

The Agency will work to maintain and further strengthen its position as a regulatory authority which is public-health oriented, science-driven and transparent in the way it operates, and committed to applying good administrative practices.

Prerequisites for successful development

How these goals can could be achieved:

- Technical Assistance in the drafting of the Pharmaceutical law
- Technical Assistance in organizing the regulatory processes
- Internal and external investment in GMP standards

Partners for agency are:

- EU
- WHO Euro
- Others, like World Bank

Starting point must be Declaration of Interest or Memory of Understanding from Government/Ministry of Health of Georgia.

Relevant issues are: commitment to EU Association Agreement, compliance with WHO standards for National regulatory agencies/GRP.

Support at the level of agency staff is not effective. Support needs to be encompassed in national pharmaceutical policy and/or national policy on public health.

Organization of a task force of WHO country office and EU delegation to Georgia enforced with WHO Euro and European Commission representatives, to draw a sketch of national developments in Georgia. After commitment of all stakeholders: TAIEX programs and Twinning projects can be developed, as well as incidental Technical Assistance as required. A further strengthening of the Agency's networking model, building on the firm partnership which already exists between the EU Regulatory Authorities, will lead to the establishment of a network of excellence at EU level, and will be vital to the future success of the EU Regulatory System.

The Agency will have to put a robust quality assurance system in place to guarantee the overall quality and efficiency of its operations. This should result in a governance system level which assures quality and regulatory and scientific consistency of the evaluation processes.

Adequate workload and resource planning, including financial considerations, must be a priority if the LEPL State Regulations Agency for Medical Activities is to focus on making safe and effective medicinal products available to patients and users of medicines in the shortest possible timeframe.

The ultimate goals are:

- Legal framework organizes the activities optimally.

- Regulatory activity is efficient in respect of the protection of public health.
- GMP implemented and enforced.

In order to meet the key objectives it has set itself, the LEPL State Regulations Agency for Medical Activities has drafted an implementation plan that covers the following specific actions:

Revise the current procedural framework to establish the best possible environment for the provision of scientific advice; increase the level of scientific support provided by the LEPL State Regulations Agency for Medical Activities Secretariat to the Scientific Committees to improve the quality and regulatory and scientific consistency of their scientific assessment work;

Implement procedures foreseen by the new legislation which allow for more rapid access to medicines without compromising the safety of patients; implement special measures for innovative medicines, technologies and therapies, generic/non-prescription medicines and herbal medicines;

Explore options to enhance the continuous monitoring of medicinal products on the Georgian market, especially by applying a more proactive approach to pharmacovigilance;

Strengthen the coordination of good manufacturing and clinical practices;

Follow-up on initiatives to improve the Agency's transparency and communication, with special emphasis on the provision of useful, clear and comprehensive information to patients/users of medicines, and healthcare professionals;

Engage more fully in dialogue with health organizations, academia, learned societies and other stakeholders;

Strengthen the LEPL State Regulations Agency for Medical Activities' international collaboration with EU and non-EU Regulatory Authorities.

OBJECTIVES SET OUT IN THE ROAD MAP

The Road Map identifies the following as priority objectives that need to be achieved before the end of this decade.

Objective 1: Improving the regulatory system in the fields of medicine and medical devices.

1.1. Creation of a functioning legal framework for the regulation of medical products.

1.1.1. Draft separate legislation for medicinal products and medical devices, taking into account the EU legal frameworks as well as the WHO Good Regulatory Practices.

1.1.2. Allow input from the regulatory agency with regards to the necessary freedom to adopt practical implementation.

Objective 2: Strengthening the role of the "LEPL State Regulations Agency for Medical Activities" to regulate medicinal products and health technologies in the Georgia.

2.1 To strengthen institutional capacity by creating Pharmacovigilance Centre for Pharmacovigilance.

2.2 Transforming the Pharmaceutical Inspectorate in the GMP / GDP / GPP Inspectorate

ANNEX A Planning

Activity	2017 Q1	2017 Q2	2017 Q3	2017 Q4	2018 Q1	2018 Q2	2018 Q3	2018 Q4	2019 Q1	2019 Q2	2019 Q3	2019 Q4	2020 Q1	2020 Q2
1.1.1 Draft Legal Framework	X	X	X	X										
1.1.2 Practical implementation			X	X	X	X								
2.1 Establishing Pharmacovigilance Centre								X	X	X	X			
2.2 Establishing effective GxP inspectorate					X	X	X	X						