SAFEMed

Safe, Affordable, and Effective Medicines for Ukrainians

Terms of Reference

Technical assistance for development of strategy on bioequivalence of medicines

WP Y1 Activity 1.2.1.[1] Review current Ukrainian and European Union legislation on bioequivaleance in collaboration with the Ministry of Health

Background

The Ministry of Health (MoH) wants to improve access to quality, generic medicines by improving regulations and requirements on bioequivalence in accordance with principles of good clinical practice. Proven therapeutic equivalence and effectiveness of generic pharmaceuticals is very important to successfully implementing the Government's procurement policy of obtaining medicines found on the essential medicines list. These generic medicines are listed by their international nonproprietary names and active pharmaceutical ingredients (APIs).

Requirements for bioequivalence of medicines and APIs were harmonized with the European Committee directives. In addition, state standards and requirements for medicines and API registration procedures were established in accordance with the Law of Ukraine "On medicines", CMU Resolution No. 411 of March 2004, MoH order No. 426 of August 26, 2005. However, this legislation was only partially implemented.

Purpose

The purpose of this assignment is to support the MoH and provide international expertise to develop a strategy on improving regulations on the bioequivalence of generic medicines in line with European Union (EU) practices.

Scope of work

The consultant, in collaboration with SAFEMed's legal firm, will be expected to:

1. Review current Ukrainian and EU legislation on bioequivalence of generic medicines
2. Design several options for gradual implementation of international requirements for generic medicines, including their costs, and discuss them with the MoH and key stakeholders
3. Draft a strategy for generic medicines bioequivalence implementation and a road map for implementation
4. Assist SAFEMed in defining the next steps in support of the MoH and plan activities for the next year

[1] SAFEMed WP Y1 updated on June 1, 2018

Deliverables

- Draft of a strategy to improve bioequivalence of generic medicines, which will include, among other things, a review of the current situation, discussion of several options and estimated costs for Ukraine, and a road map for implementation *by August 30, 2018*
- Trip report - *within 7 days after visit*

Duration

Total number of working days: 30
From June (upon contracting) to the end of September 2018

Consultant's inputs

It is expected that the consultant will spend time as follows:

- One 5-day visit to Ukraine (August–September 2018)
- 25 working days at home (20 days to draft the strategy, 5 days to finalize it after discussion with client and key stakeholders and comments)

Qualification requirements

Proven significant experience, deep knowledge of EU regulations, and experience with bioequivalence in European countries

Application due date and submission

Applications should be submitted by July 9, 2018 (COB EEST), to this email address: ua-safemed@msh.org.

Acronyms

API	active pharmaceutical ingredients
CMU	Cabinet of Ministers of Ukraine
EU	European Union
MoH	Ministry of Health
SAFEMed	Safe, Affordable, Effective Medicines for Ukrainians (Project)