WHO workshop on post-market surveillance of in vitro diagnostics (IVDs) for testing providers and regulators in the WHO European region

Victoria Olimp Hotel, Minsk, Belarus
4 to 5 July 2018

Scope and Purpose

The deficiencies of regulatory oversight for in vitro diagnostics (IVDs), both for pre-market assessment and post-market activities, have widely been acknowledged as a shortcoming for assuring the safety, quality and performance of IVDs. Post-market information on IVDs empowers end-users to detect issues, and for national regulatory authorities to investigate, communicate and contain events that threaten public health security, and for authorities to take appropriate action.

Post-market surveillance for IVDs is:

- reactive post-market surveillance through reporting and evaluation of complaints, including adverse events and other incidents, and any required actions to correct and prevent recurrence; and
- proactive post-market surveillance through independent lot verification testing; evaluation of data from external quality assessment (EQA) schemes.

This workshop will focus on developing the skills of end-users (testing providers) and regulators to conduct post-market surveillance for IVDs. This will be achieved through step-by-step group work of each relevant topic, and a resulting draft plan of action to be discussed and implemented upon return to their country. Furthermore, the opportunity to understand reluctance or otherwise of complaint reporting and other post-market surveillance will be measured through a baseline survey that will be repeated in the future to measure the impact of WHO capacity building.

Objectives:

1. To build capacity for end-users and regulators on WHO guidance for post-market surveillance of IVDs.

Outcomes:

1. Draft plan of action for implementation of post-market surveillance of IVDs for each respective country.
2. Baseline survey of status of post-market surveillance measures for each respective country.

Target audience:

1. National authorities – national regulatory agencies, national reference laboratories, national HIV or viral hepatitis programme managers, managers of laboratories and other testing services, Ministry of Health and policy makers; and
2. Implementing partners.
3. Countries: Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Russian Federation, Turkmenistan, Ukraine, Uzbekistan, Republic of Moldova and Tajikistan.

Languages

The meeting will be held in Russian and English, with simultaneous translation.