General Chapter Prospectus: Evaluating Screening Technologies for Assessing Medicine Quality

Type of Posting: General Announcement
Posting Date: 29–Dec–2017
Expert Committee: Council of Experts
Expert Panel: Review of Surveillance and Screening Technologies for the Quality Assurance of Medicines
Input Deadline: 28–Jan–2018

Suggested audience: Regulators, global health NGOs, procurement agencies, pharmaceutical industry, distributors and others working against substandard and falsified medicines

Estimated proposal PF: Pharmaceopial Forum 44(3) [May-Jun. 2018]

Background and objective(s): Various portable screening technologies have been developed to assess the quality and authenticity of medicines and thereby combat the growing global problem of substandard and falsified (SF) medicines. However, the capabilities and limitations of many screening technologies are not well characterized, particularly when used outside the laboratory, for example in supply chain testing, at the point of care or in low and middle income countries. This new General Chapter addresses the need for structured, effective approaches to performing a pragmatic review of a given technology. The information collected during the review will inform the selection and deployment of the technologies of interest, which in turn can help can prevent SF drugs from reaching vulnerable populations.

Description of scope and application: To be used by organizations evaluating and deploying screening technologies. General Chapter will enable the standardization of screening technology evaluations so that technologies, which have been evaluated by different organizations can be compared and used to inform decision making

Preliminary outline: Published as Stimuli article in PF 43(5)

Anticipated proposed design phase activities: Published as Stimuli article in PF 43(5)

Anticipated implementation timing: Routine

Other USP-NF, regulatory, or other sources of related information: none

Other information: none

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