Agenda item: 13.3
Document Number: A76/7

Statement of I.R. IRAN on "Substandard and Falsified Medicine Products (SF)"

We do appreciate the DG and the secretariat for developing the document A76/7 with clear determination of prioritized actions and information about progress in each action area. It will certainly be helpful to prevent, detect and response to Substandard and Falsified medicine products.

In line with priority activity No. "C", the Islamic Republic of Iran has been using an electronic tool known "TTAC" (set for Tracing, Tracking and Authentication Control) as National Regulatory Tracing system (NRT). This e-tool helps end users to be sure about originality of medicine products **as well as** NRA be able to trace the identity of those products. Moreover, in line with priority activity No. "A", we have prepared basic documents to prevent, detect and response to SF medicines Furthermore, Post Marketing Quality Control (PMQC) process has been performing as a part of post marketing surveillance (PMS) based on WHO and domestic guidelines. The data are collected and archived in GMP Inspectorate Office (GIO) at Iran's FDA.

To achieve the objectives mentioned in the document, Director General needs to play a more supportive role for different countries by considering their development level and needs as those can be achieved only by effective engagement, communication with, and cooperation between all member states. Each member state owns capabilities in different aspects and it would be a great opportunity for the mechanism to benefit all these capabilities collectively to manage the SF problem in the world. Iran's FDA stands ready to work with all team leads of priority action areas and their groups.

Madam chair, thank you for this opportunity.

Iran's Food and Drug Administration
Ministry of Health and Medical Education
I.R. Iran.