STATEMENT BY THE DELEGATION OF THE REPUBLIC OF INDONESIA ON THE AGENDA ITEM 10. SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS (DOCUMENT EB 148/12) AND AGENDA ITEM 11. STANDARDIZATION OF MEDICAL DEVICES NOMENCLATURE AT THE 148TH SESSION EXECUTIVE BOARD WHO MEETING VIRTUAL, 18-26 JANUARY 2021

Thank you Chair.

Indonesia would like to thank the Secretariat for developing the background document under this agenda item.

In this regard, Indonesia will deliver intervention for both agenda item 10 and 11 respectively.

On the agenda item 10,

Indonesia, as a member of the Steering Committee of the Member State Mechanism (MSM) on SFMP, fully supports the scope of activities of the MSM, which focuses on the capacity improvement of controlling SFMP and sharing related information between countries. It would be useful for developing a better policy and strategy for each Member State.

Indonesia values the importance of the quality reporting method to detect the SFMP. Therefore, Indonesia, with support of the WHO Secretariat, has piloted a mobile application in 2018 to report the SFMP among health-workers. The result of this pilot project will be published by WHO, of whom Indonesia would like to deliver its sincere appreciation, and will support this endeavour as the co-author of the publication.

Indonesia supports the MSM endeavours to address the distribution or supply of SFMP on the internet. Moreover, Indonesia also supports the plan to include medical devices, including in-vitro diagnostics, as one of the SFMP issues of concern.

Recognizing the concrete benefits of the Mechanism since its establishment, Indonesia calls for more participation from the Member States in this Mechanism to improve the global efforts in response to SFMP in ensuring better quality health care.

On the agenda item 11,

Indonesia applies a medical device nomenclature system in the form of license number arranged in a standard, systematic, and traceable manner. Each license number consists of the code of medical device risk classification; categories and sub-categories of the medical devices; and number, which is automatically generated by the system.

The medical device nomenclature system in Indonesia has been implemented and integrated with the procurement system through the online catalogue of medical devices and the reporting system for medical devices in health care facilities.
We recognise the importance of global harmonization and standardization of medical device nomenclature system. However, we also acknowledge that there are obstacles to realize this due to diverse systems among countries.

Therefore, we support the global standardization of medical devices nomenclature system that is based on scientific findings and international standard. In addition, the global standardization must consider the diverse regulatory systems and manufacturing conditions in all Member States, so that it can be applicable globally.

Thank you, Chair.