



Statement to the 74th Session of the World Health Assembly, 24 May to 1 June 2021
on agenda item 13.7 Standardization of medical devices nomenclature

PHM commends the WHO for the report. An international classification, coding, and nomenclature for medical devices is a positive step in the right direction. However, a WHO-led nomenclature system derived from a public health perspective is required instead of the proposed use of an industry classification.

The prioritization and standardization of essential medical devices is the role of regulatory agencies and should not be determined by the medical device industry. The WHO must maintain control on the international standardization, prioritization, and regulation of medical devices. It is of great importance to have an essential devices list.

A single nomenclature system is crucial from a public health as well as from an economic perspective. Standardization of medical devices' nomenclature helps regulate product quality, efficacy, safety, and price, which benefit patients rather than prioritising profit.

Access to medical devices is a critical concern for low and middle-income countries. Lack of medical devices negatively impacts the quality of care, timely and adequate diagnosis, and leads to loss of life. In the context of localized medical device production, a nomenclature system helps reduce the entry barriers and facilitates competition for more companies to have market access which results in price reduction instead of market monopoly.

Lastly, we reiterate the urgent need to scale up and strengthen manufacturing, especially in developing countries, which requires technology transfer and addressing Intellectual Property, trade and sales issues. More focus should also be given to medical device dumping in the global south and how to address substandard and falsified medical devices.