MSF Statement
Agenda Item 13.3 - Substandard and falsified medical products
76th World Health Assembly – May 2023

Speaker: Nathalie Ernoult

MSF witnesses the issue of substandard medical products. While more data on the problem are needed, its root cause is well known: regulatory systems in producing and importing countries.

Key manufacturing countries, particularly low- and middle-income, should participate in the WHO regulatory systems strengthening programme to establish their maturity level (ML) for medicines and vaccines, working towards becoming WHO-listed authorities (WLAs).

Importing countries can rely on WHO Prequalification (PQ). For medical products outside PQ scope, ML1/2 countries should consider relying on authorities becoming WLAs.

The links among the Member State Mechanism, WHO Global Surveillance and Monitoring System, Regulatory Systems Strengthening / Global Benchmarking Tool, and PQ are unclear; they should be integrated to ensure a significant decrease in substandard medical products.