

6.2 Member State mechanism on substandard and falsified medical products

We appreciate the Member State mechanism's decision in 2016 to remove the term "counterfeit" from the nomenclature to refer to quality-compromised medicines. However, we are disappointed by the fact that the Secretariat continues to use the terms "substandard" and "falsified" together and is providing figures on falsified medicines, based on unclear methodology. We call upon the Secretariat to provide clear evidence. "Substandard" and "falsified" are different issues and should not be conflated together.

We need to address the root causes that result in the circulation of these types of medicines in the market. Unmet demand, particularly due to the high price, works as an incentive for the circulation of quality-compromised medicines. Therefore, without facilitating access we cannot address the problem of falsified medicines effectively.

We would like to ask for caution regarding the Mechanism's work programme on medicines in transit. The regulatory authority of the respective countries should be the only one to intervene in this issue. Intervention during transit could be misused to pursue trade interests and could compromise access to medicine.

Furthermore, we take this opportunity to express concern at the participation of WHO in the Global Committee on Quality Assurance. Some actors who established the Global Committee had previously been involved with pursuing the agenda against "counterfeit" medicine – an agenda that has been favored by the big pharmaceutical companies. WHO's participation as an observer should be transparent and the Secretariat should publish all its interventions on the MSM website

Lastly, we call upon both the Secretariat and the MS that measures to safeguard the quality of medical products should not compromise access to medical products.