

**Regional Statement by Rwanda on behalf of the WHO Africa Region on Item
13.5 (Substandard and Falsified Medical Products)**

78th Session of the World Health Assembly

Date and Time: May 23, 2025 – Afternoon Session (14.30 – 18.00).

Location : Palais des Nations- Room XX, Committee A

- Thank you, Madam Chair
- Excellencies,
- Ladies and Gentlemen,

1. Rwanda has the honour to deliver this statement on behalf of the WHO African Region on Agenda Item 13.5: Substandard and Falsified Medical Products.
2. We have noted with appreciation the Reports of the 12th and 13th Meetings of the Member States' Mechanism on Substandard and Falsified Medical Products as well as the Report on the evaluation of the Mechanism, which were considered by the Executive Board at its 156th Session held in January 2025.
3. The WHO Africa Region remains the region most affected by substandard and falsified medical products. Millions of people in Africa continue to die from preventable causes due to substandard and falsified medical products. Our region also has the highest prevalence of poor-quality medicines, with an estimated 18.7% prevalence of falsified and substandard medicines among low- and middle-income countries worldwide. Substandard and falsified medical products further exacerbate the problem of antimicrobial resistance which has now become a major threat to public health.
4. Against this backdrop, we see the work of the Mechanism as an important step towards ensuring access to safe medicines in Africa and globally.
5. In spite of many challenges, some positive developments are worth noting. 45 out of our 47 countries have appointed Substandard and Falsified medical products focal points with access to the WHO Global Surveillance and Monitoring System. This improved access has led to the publication of 39 alerts between 2020 and 2025. More countries have conducted post-market surveillance, trained regulatory staff, and piloted mobile reporting app.
6. We welcome the recommendations from the independent evaluation that was carried out between December 2023 and September 2024 to assess the Mechanism's relevance, effectiveness, efficiency, coherence, sustainability and equity considerations and we share the view that certain recommendations are straightforward and operational in nature and as such should be actioned without delay, while others especially on the possible revision of the format of the mechanism and improvement of external engagement, need more time for further consideration.
7. With a view of strengthening the Mechanism, we call for improved funding of the Mechanism, more support to national regulatory institutions, strengthening the regional representation in the membership of the Steering Committee, whilst also ensuring clearer obligations and more consistent participation from all Member States in the Member State mechanism. The development and implementation of national action plans on SFMP is equally important, including improving collaboration and information sharing.

8. We wish also to underscore the importance of adopting a multi-sector approach since the issue of substandard and falsified medical products goes beyond the Ministries of Health, and putting in place medical product traceability systems across many countries while ensuring their effective implementation.
9. In conclusion, Madam Chair, the Africa Group supports the proposed decision which is well aligned with the relevant decision of the Executive Board to submit the report of the fourteenth meeting of the Member State mechanism to the Seventy-ninth World Health Assembly through the Executive Board at its 158th Session.
10. I thank you.
