World Health Organization

REGIONAL OFFICE FOR Africa

AFRICAN UNION

NEPAD
TRANSFORMING AFRICA

Regulation Of Medical Devices & IVDs in Africa- New Horizon

Plenary 4:Regulatory landscapes in Africa

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Presentation Outline

- ✓ Introduction/Background
- ✓ Leadership
- ✓ Membership
- ✓ Mandate for MD regulation
- ✓ Medical devices regulation through product life cycle
- ✓ Progress
- ✓ Future plans
- ✓ Summary

Background

- PAHWP is a Continental Technical Working Group for Medical Devices and Diagnostics including In vitro diagnostics under the AMRH Program.
- Formed by regulators in Africa aiming at improving access to Medical Devices &IVDs that are safe, of Acceptable quality and performance in accordance with the internationally recognized guidance documents and standards.
- PAHWP was formed in 2012, focusing on awareness and advocacy activities.
- PAHWP new leadership unveiled in Rwanda December 2018 during the 5th AMRC meeting

Leadership

December 2018 AMRC in Rwanda, nominations were done by member states and the following were chosen to lead the party for a three year term:

- Chairperson – Mrs Andrea Julsing Keyter (South Africa Health Products Regulatory Authority)(SADC REC)
- Vice Chair- Mrs Paulyne Wairimu (Kenya, Pharmacy and Poisons Board) (EAC REC)
- Secretary (Burkina Faso, and Mali Representatives, to represent the Anglophone and Francophone speaking countries). (ECOWAS REC)

Member Countries to the PAHWP

- Current members: 19

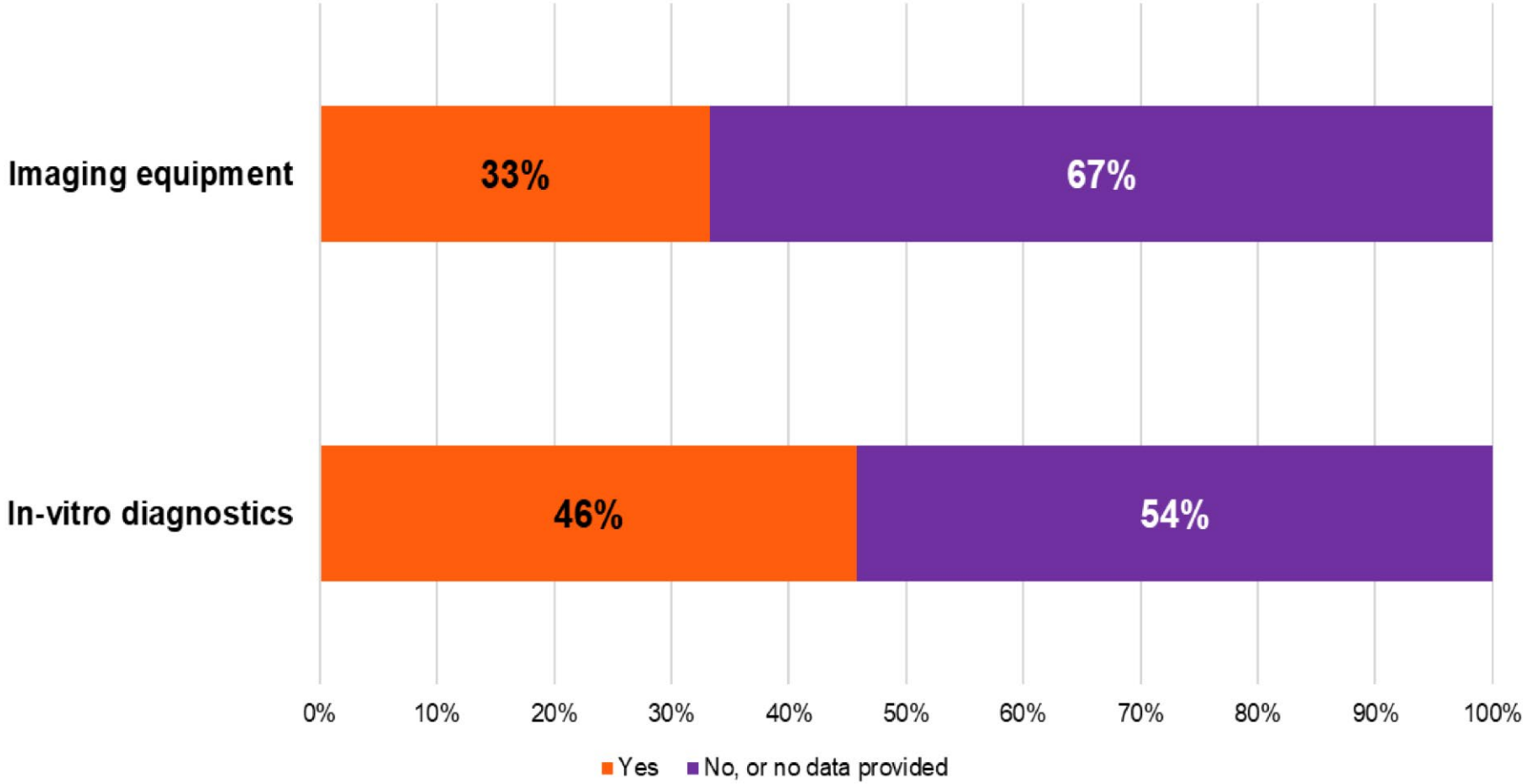
- Names: Burkina Faso, Burundi, Ethiopia, Ghana, Kenya, Malawi, Mozambique, Nigeria, Rwanda, Senegal, Sierra Leone, South Africa, Uganda, Tanzania, Togo, Zambia, Zanzibar, Zimbabwe and Eritrea.

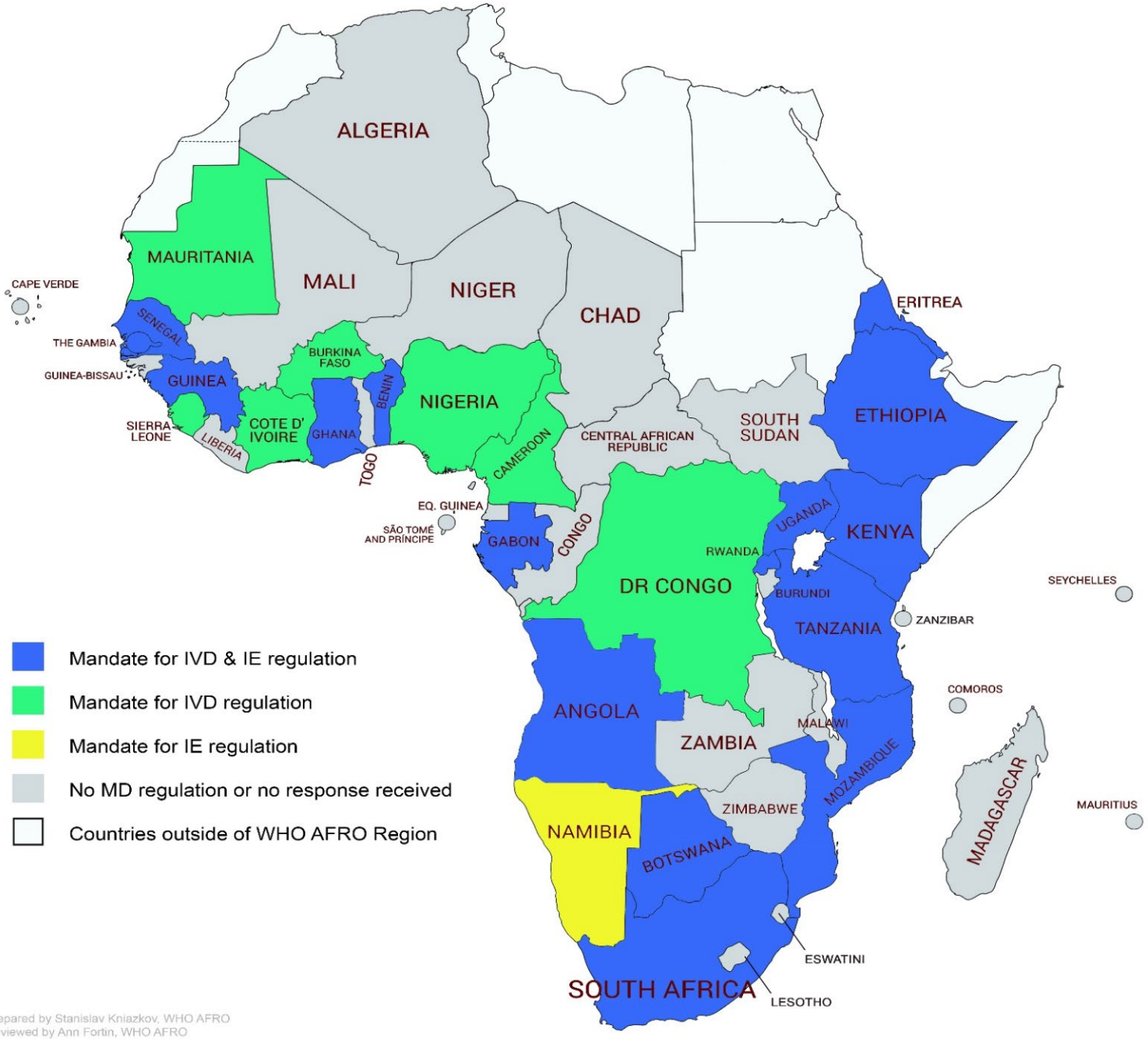
PAN AFRICAN HARMONIZATION WORKING PARTY MEMBER AND NON MEMBER COUNTRIES

Key

- Members
- Non Members

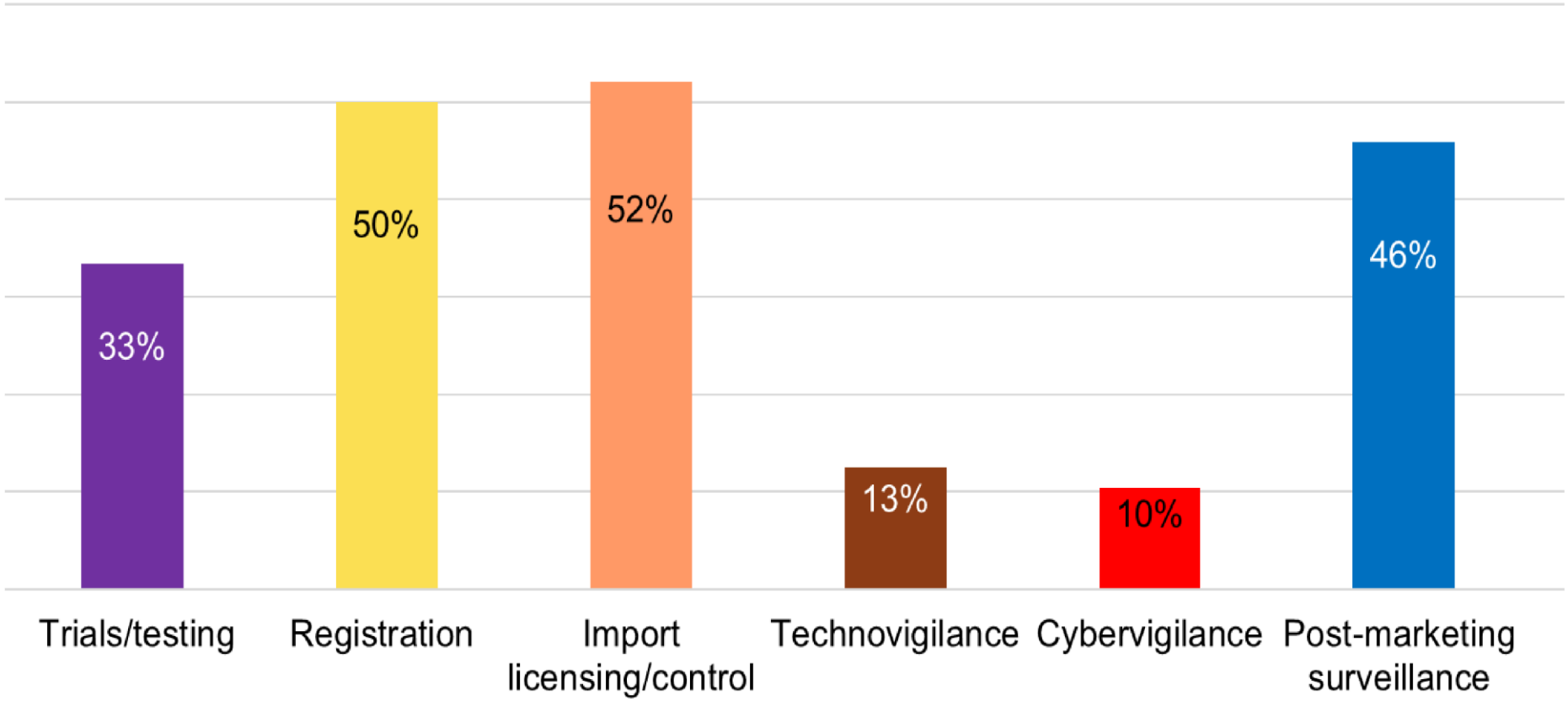
Mandate for MD regulation





Prepared by Stanislav Kniazkov, WHO AFRO
Reviewed by Ann Fortin, WHO AFRO

Medical Device Regulation through Product Life-Cycle



Adapted from State of Health in the African Region: analysis of the status of health, health services and health systems in the context of Sustainable development. Brazzaville: WHO Regional Office for Africa, 2018

Key Highlight on Progress made

- ✓ Development of draft Model Terms of Reference based on AMRH Model Continental TORs
- ✓ Development of draft strategic document and Work plan for 2019/20
- ✓ 2 Teleconferences via WebEx held between the party leadership and secretariat (WHO/ AUDA-NEPAD), 2 WebEx tele-con with member states
- ✓ Recruitment of new membership (Eritrea, Gambia, Namibia)
- ✓ Updating of the website and email communication to members
- ✓ PAHWP Med-net Platform for networking, work sharing, learning (materials and between experts) and regular updates.
- ✓ Compilation of a list of contact points and responsible institutions for the products.

Future Outlook

- Sustainability of the CTWG with strained resources presents an immediate challenge
- Inviting partners to support the CTWG, especially for those in areas of Diagnostics, other Medical Devices
- The Vast scope of Medical devices indicative of the work load
- Collaborative efforts with harmonization initiatives for a common purpose
- Collaborate with other cTWGs in cross cutting areas of regulation

Conclusion

- **STATE OF AFFAIRS**
- **Made strides in the regulation of MD &IVDs**
- **Fragmentation**
- **Countries at different stages of implementation**
- **Loose ends**

RECOMMENDATIONS

- **Leverage on existing opportunities**
- **Partners to provide resources(financial and technical) for development of technical documents and work of cTWG.**
- **Support establishment of RCOREs, as a sustainable means for Capacity building**

Acknowledgement

- WHO HQ, WHO AFRO
- AUDA-NEPAD
- MEMBER STATES
- PARTNERS

Thank you for your attention!

Asante