Role of strong regulatory systems in pharmaceutical sector growth

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Agenda

- Discuss role regulators play in advancing public health AND support pharma sector growth
- Review (at high level) key initiatives to advance regulatory systems across the continent
- Share a few ideas for discussion

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WHA Resolution 67.20 recognized the critical role regulators play in public health and local production

- Effective regulatory systems contribute to better public health outcomes,
- Regulators are an essential part of the health workforce,
- Inefficient regulatory systems themselves can be a barrier to access to safe, effective and quality medical products.
- Effective regulatory system can support expansion of local or regional production of quality medicines

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Across the product lifecycle good regulatory practice advances public health and helps strengthen the pharma sector

	Regulatory best practice	Business and health implications
Innovation	• Transparent and consistent rule making and processes • Consistent high quality bar based on international standards	• Fosters foreign and domestic investments • De-risks long-term investments in quality
Access	• Risk-based review pathways framed in public health need/ priority • Regulatory reliance	• Efficiency savings for both regulator and manufacturer • Timely access to medicines and market
Decision making and Usage	• Rewarding “built in” quality practices, with high up-front quality bar • Robust, risk-based quality/ pharmacovigilance systems	• Greater provider and public confidence to facilitate adoption/ uptake • Prevention of patient harm and mitigation against costly and confidence-eroding safety and quality events/ recalls

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Mexico's COFEPRIS provides a brief case study on the benefits of regulatory reform

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

Mexico's regulatory authority, COFEPRIS, implemented reform agenda beginning in March, 2011

- Cleared back log of ~4,500 products
- Instituted risk-based approach to regulatory filings
- Implemented reliance program

These reforms improved patient access and fostered pharmaceutical sector growth

- Increased use in generic drugs by 77% over 2 years, resulting in cumulative average annual savings of over $1.5BN
- Pharmaceutical industry growth of 13.2% between 2011 to 2014 (versus 1.8% between 2008 and 2010)
- Increase in exports by 21%

Optimized Medical Product Regulation in Mexico: A Win-Win for Public and Economic Health, Therapeutic Innovation and Regulatory Science, 2017

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African Medicines Regulatory Harmonization has made strides to strengthen regulation across Africa – with opportunities remaining

- Across 54 NMRAs in Africa full picture of maturity is not completely known, though in 2017 WHO estimate, vast majority have minimal or no capacity, though this picture is improving, marked by recent designations of Tanzania and Ghana FDAs as GBT level 3
- AU Model law represented major stride as underpinning for effective regulation; however, domestication still underway
- Establishment of Regional Centers of Excellence (RCOREs) in 2014 provides opportunity to advance workforce development across regulatory science areas
- Joint dossier review activities across RECs show promise, including:
  - Reduce marketing authorization timelines (30-40%) in East African Community (EAC) and the Southern African Development Community (SADC) member states
  - More than 100 products recommended for registration in the Zazibona Scheme in the SADC region, and 13 in the EAC region following joint assessments

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How regulators can advance to support to local pharmaceutical production *A few thoughts…*

Governance

- Domesticate AU Model Law
- Deploy understandable, adaptable guidelines for manufacturers based on international standards
- Publicly publish guidelines, procedures, NMRA decisions and reports
- Hold regular meetings and discussion forums with manufacturers and other stakeholders

Registration and Inspection

- Invest in clearing backlogs and implement risk-based review and inspection approaches
- Adopt international standards such as common technical document to facilitate convergence and predictability
- Waive registration fee (if possible) for medicines that are continuously in short supply.
- Implement reliance schemes

Harmonization

- Accelerate networking, regulatory reliance and mutual recognition to create larger potential markets and remove hurdles to market access, building on existing harmonization initiatives.
- Create common database of API and raw material sources accessible to African manufacturers

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