SAHPRA
South African
Health Products
Regulatory Authority

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Reliance Update

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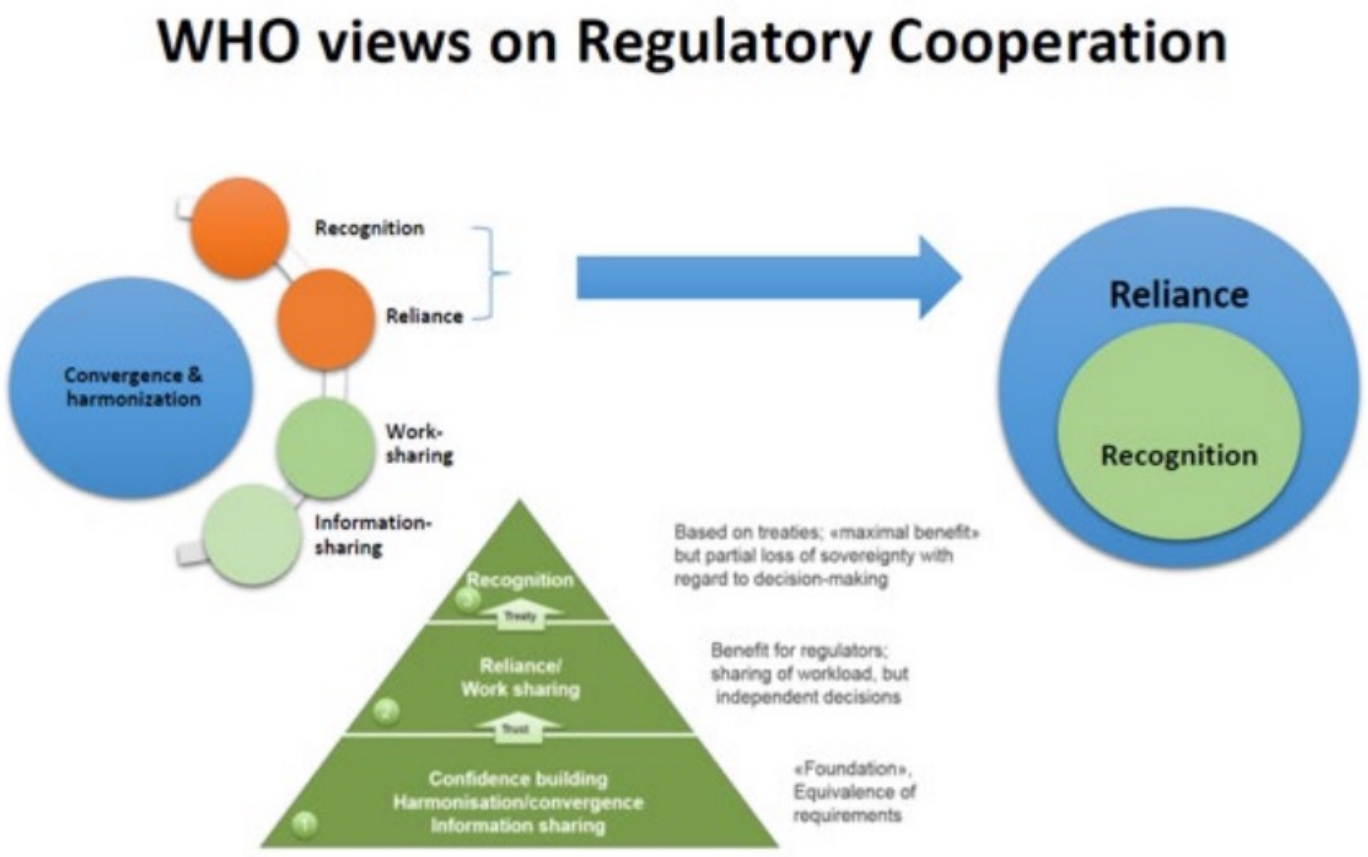
Regulatory Reliance - Summary



Source: WHO Presentation

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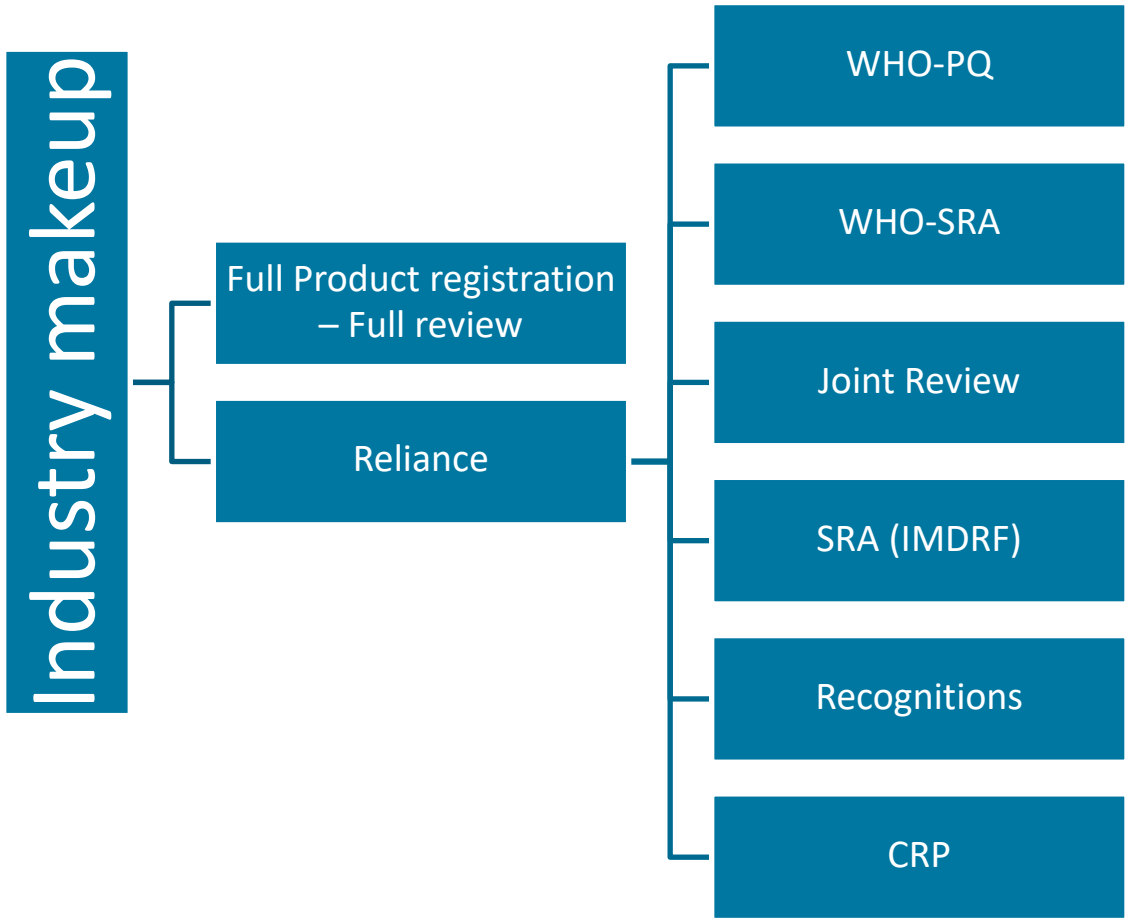
Registration pathways



Local Manufacturer

Distributors (Importers): SRA countries/WHO-PQ

Distributors (Importers): Non-SRA countries/Non WHO PQ

Local Manufacturer SRA countries/WHO-PQ

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Reliance Efforts

Information sharing and work sharing:

- Stakeholder engagement: NRA's (continental & International Level); industry; government institutions
- Technical information review and sharing e.g., TMDA, WHO-CRP, WHO – facilitated Reviews
- MDRC workshop
- BCG training with industry

Reliance

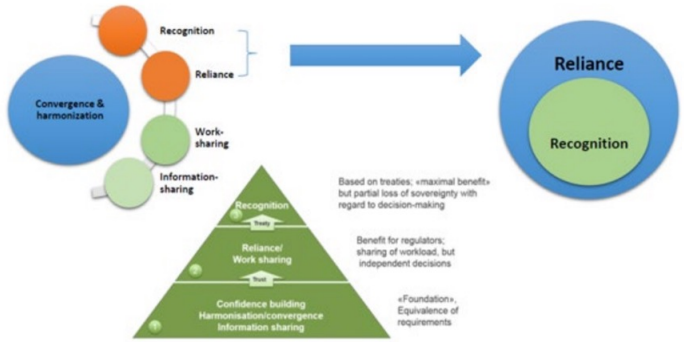
Currently = IMDRF founding members (6)

To add others (HSA, Swissmedic, MHRA)

Operationalization of Reliance:

- MoU with various NRA's (incl MD & IVDs)
- Continental and international level
- Information sharing
- Active participation in various continental and international platform (3 WG within IMDRF)
- CRP listed country

WHO views on Regulatory Cooperation



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Reliance opportunities

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Regulatory Authorities Relied upon

Regulatory authority	Guidance documents
TGA & UK MHRA	Adopted COVID 19 Antigen test kits specifications (Professional and self test); EUA Verification for all covid 19 test kits approved;
WHO	Adopted COVID 19 Antibody and molecular test kits specifications ; EUA Verification to WHO published list of IVDS Listed by IMDRF NRA
EU	Verification using EU Commission Common list of COVID-19 rapid antigen tests
US FDA , Health Canada , Brazil Anvisa	EUA Verification for all covid 19 test kits approved ;

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COVID 19 TEST KITS UPDATE- March 2020 to date

Status	Antigen Professional Test	Antigen Self test	Antibody test (Professional)	Molecular Test (Professional)
Received	178	38	242	165
Rejected	84	16	185	27
Approved	90	11	55	136

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RELIANCE HURDLES EXPERIENCED

1. Incomplete documentation
   - Incomplete and incorrect information in Product label/IFU
   - Technical dossier and IFU not matching in terms performance , stability
   - No technical dossier
   - No raw data
   - Emergency use authorization or registration in another jurisdiction is not provided.
   - Difference in Risk classification in country of origin
2. Difference in performance of imported test during performance evaluation
3. Access to verification databases of submitted EUA
4. Communication with other regulatory authorities was not easily available

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RELIANCE VICTORIES

- increase the quality of regulatory decisions
- reduce duplication of effort and, ultimately, promote timely access to safe, efficacious and quality-assured medical products.

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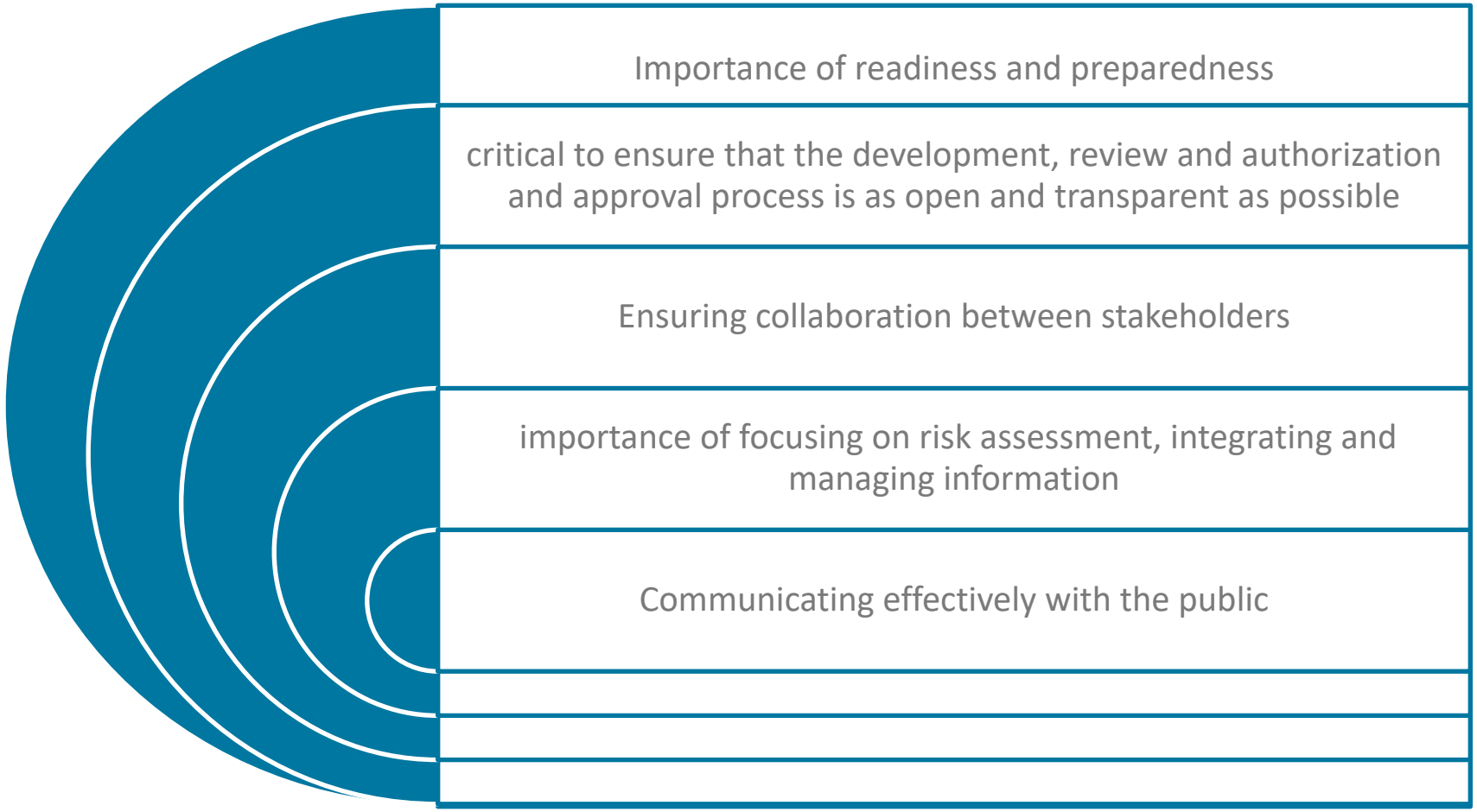
Lessons Learnt



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