IMDRF International Medical Device Regulators Forum

Update on WHO work

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World Health Organization

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What's new since March 2015

- Prequalification of IVDs:
  - Dossier, inspections, changes, PMS
- Ebola-related work
- Regulatory strengthening

Prequalification of IVDs

- Streamlined PQ since mid-2014:
  - Emerging Mx need guidance and assistance
  - QMS implementation is the most difficult part
  - Unmet needs, especially for HCV
- Capacity building mechanism to strengthen NRAs
  - Joint assessments
  - Collaborative procedure
  - NRA and manufacturers training
- Programme framework expansion to PoC/near to PoC HPV IVDs
- QA partnership with USG (USAID and CDC): common assessment mechanism informing UN, Pepfar and partner organizations' procurement

ToC / PQDx Product dossier

- PQDx in active implementation phase since 2010: submissions quality is increasing
- However, still urgent need for guidance
- PQDx developing 13 guidance documents
  - Reference documents
  - Stability studies
  - 3 Sample dossiers
  - IFU
  - Quality control principles

  Closest to publication for public comments

  - Excellent support to WHO PQ on development of these by regulators and from standards bodies

MDSAP / PQDx inspections alignment

Alignment with MDSAP	Status (August 2015)	
Inspection Cycle	Initial (stage 1 and 2) Surveillance (replaced by annual report) Special (follow up, changes / complaints) Re-inspection	√ No √ √
Inspection time calculation	MDSAP_AU-F0008.1 (unlocked version)	√
Grading of nonconformities	Level 1 – level 5 (separate for QMS and dossier) **Clarification required (escalation rules)**	√
List of nonconformities	Fully implemented	√
Inspection report	Available report template cannot be used Adapted activity based report implemented (reviewed evidence, trail, persons involved & evaluation / conclusion) **Training ongoing**	√

PQDx changes notification and assessment

- Current guidance on reporting of changes in place since June 2014
- Result has been variable compliance and significant work load for PQDx
- PQ currently revising guidance
  - Improve clarity to ensure consistency and transparency in decision making process
- Lack of substantive international guidance on this topic (changes/variations) makes it difficult for manufacturers
  - Need for international harmonization

PQDx post-market surveillance

- Launch of WHO guidance on post-market surveillance for in vitro diagnostics
  http://www.who.int/diagnostics_laboratory/postmarket/en/
- Continuation of WHO complaint handling procedure through standardized IVD complaint form
  - 7 new complaints in 2015
  - most of the complaints that we have received are for RoW regulatory versions but are of relevance to the stringently regulated products
- Expect to see improvement in vigilance reporting from Mx and end users

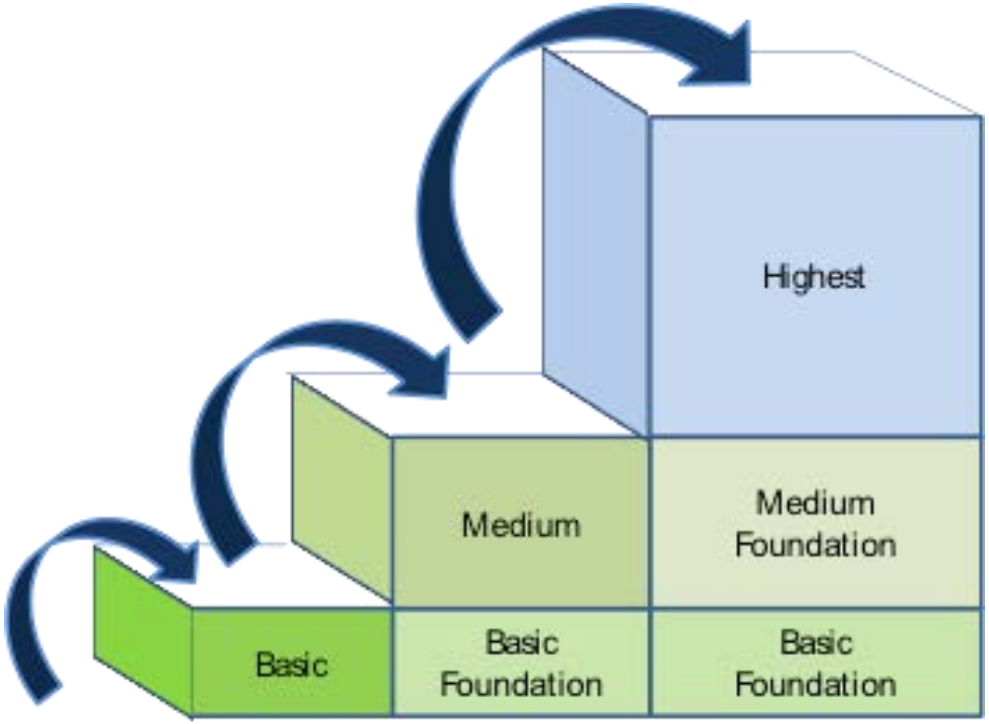
Ebola-related efforts

- The response to the Ebola outbreak is now heading into enhanced surveillance activities to identify all remaining cases
- WHO Emergency Use Assessment and Listing (EUAL) procedure for IVDs, medicines and vaccines finalised and published

http://www.who.int/medicines/news/public_consult_med_prods/en/

- EUAL assessment of IVDs:
  - 24 applications for IVDs; 4 products listed, one more shortly

Survey on regulation of medical devices: categories

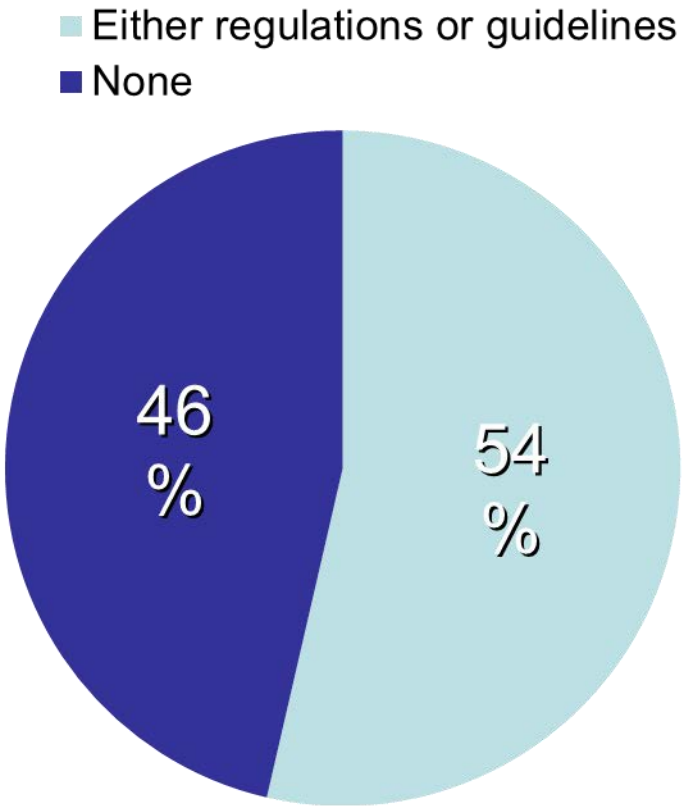


Market surveillance
Inspection/QMS
Enforcement
FSCA Monitoring

Reliance
Conformity assessment
Advertising
Clinical investigation controls

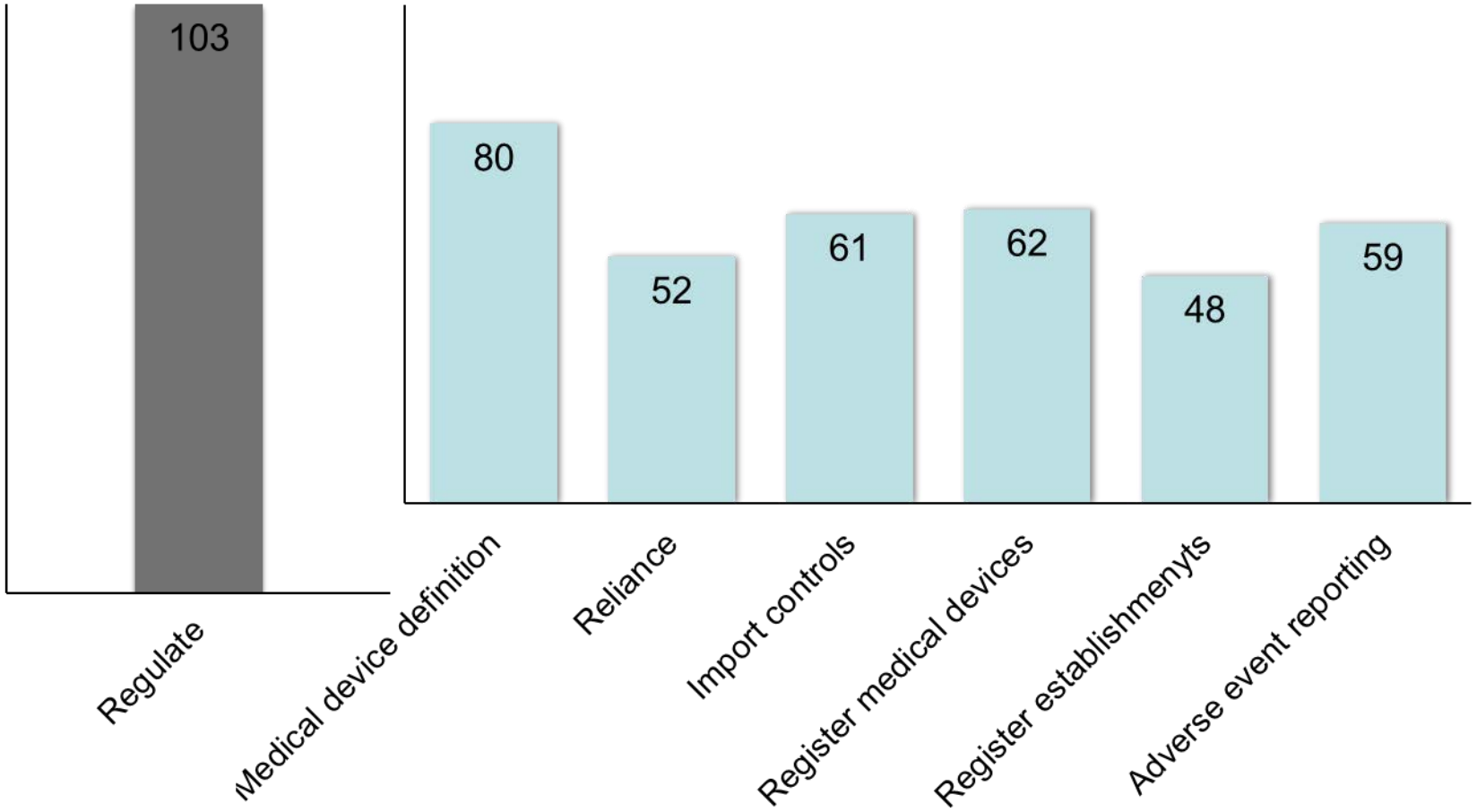
Legal Framework (regulation, guideline)
National Regulatory Authority (NRA)
Definition of a Medical Device
Registries of establishment and devices
Labelling
Risk Classification
Adverse Event Reporting
Import controls

Global trends: regulatory frameworks

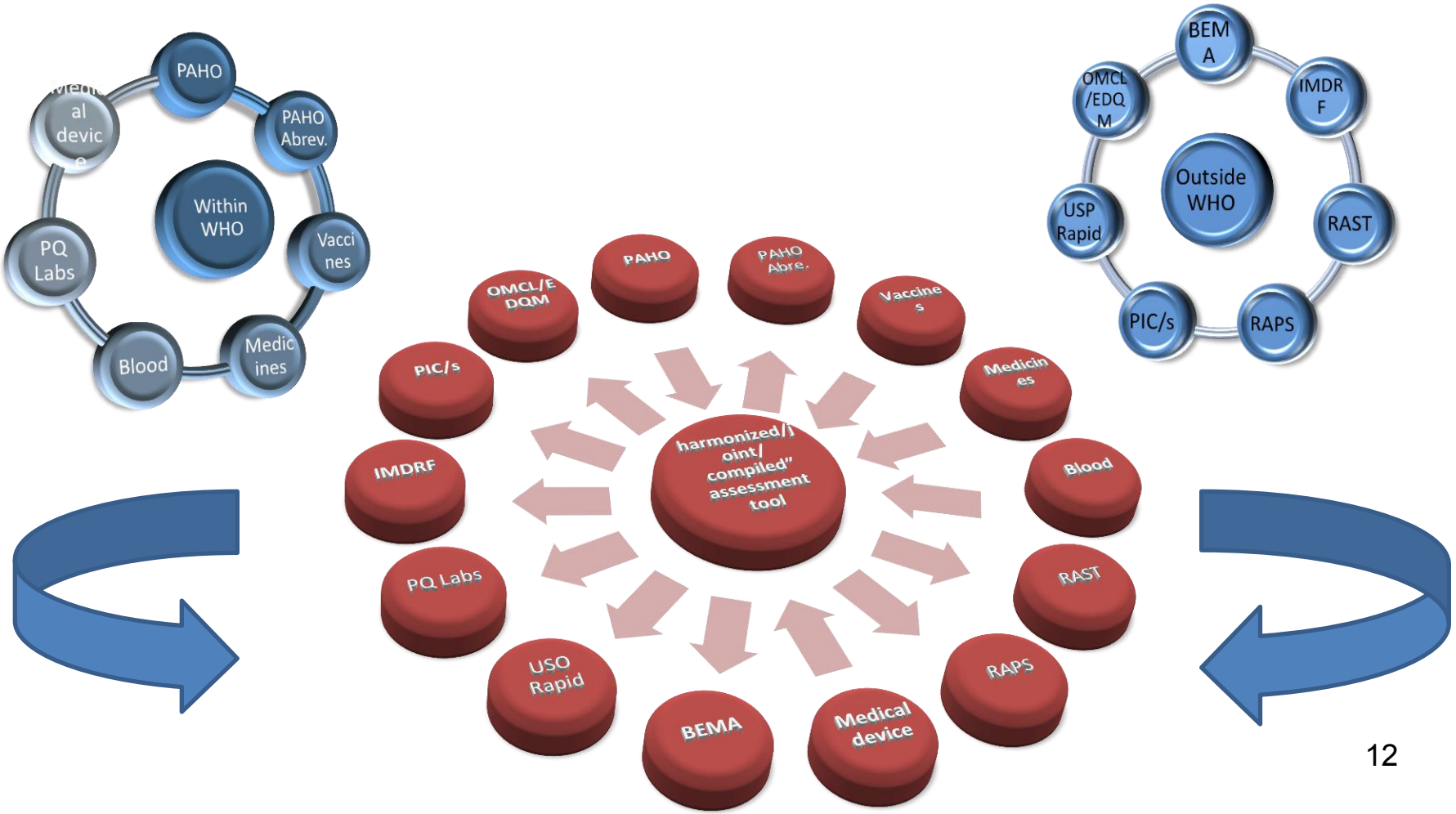


To the extent that regulations and guidelines are made available and accessible, comporting with principles of good regulatory practice, these data represent a global overview of medical device regulation, *not* implementation.

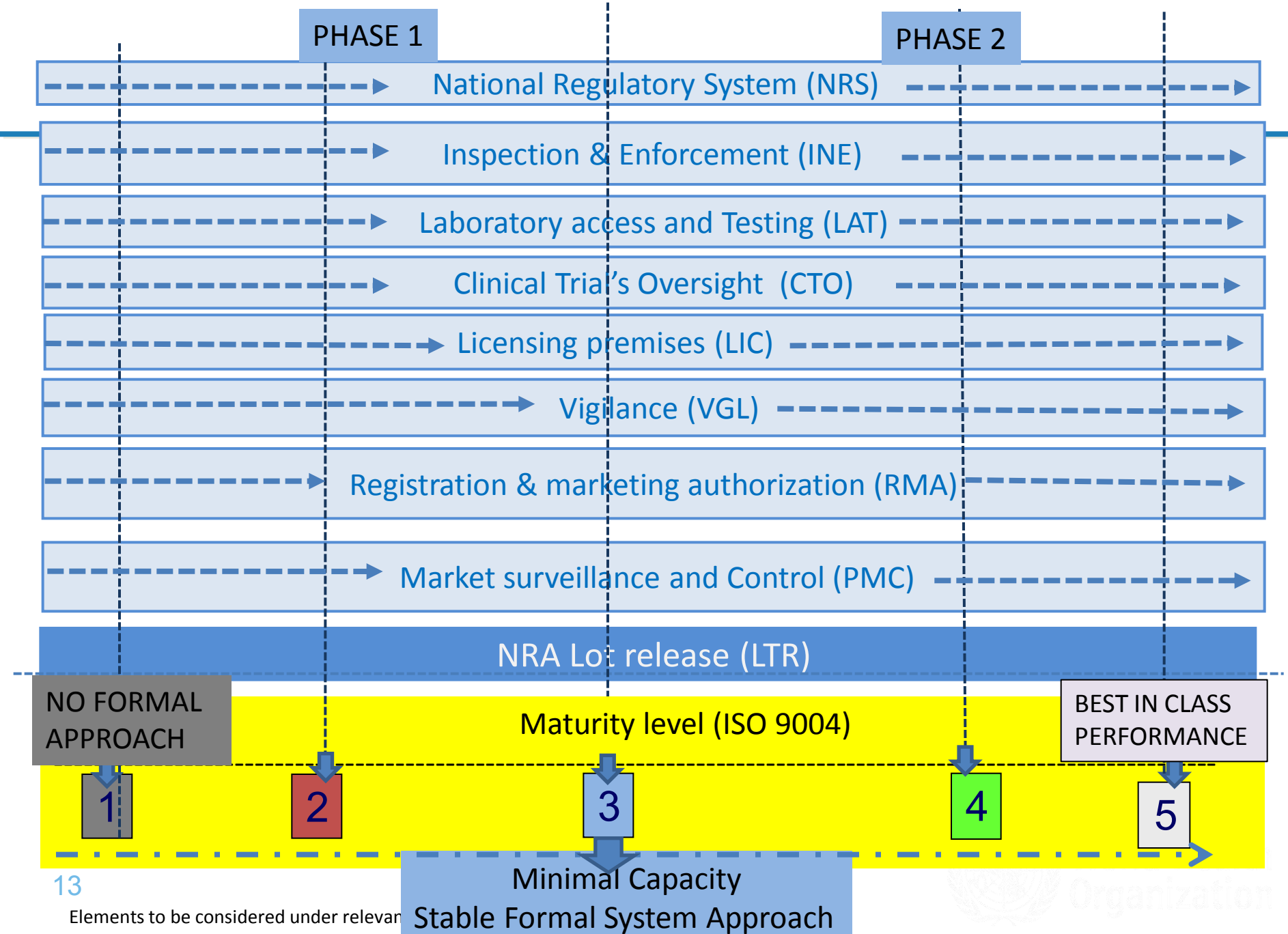
Global trends: regulatory frameworks



Global assessment tools: input for harmonized tool



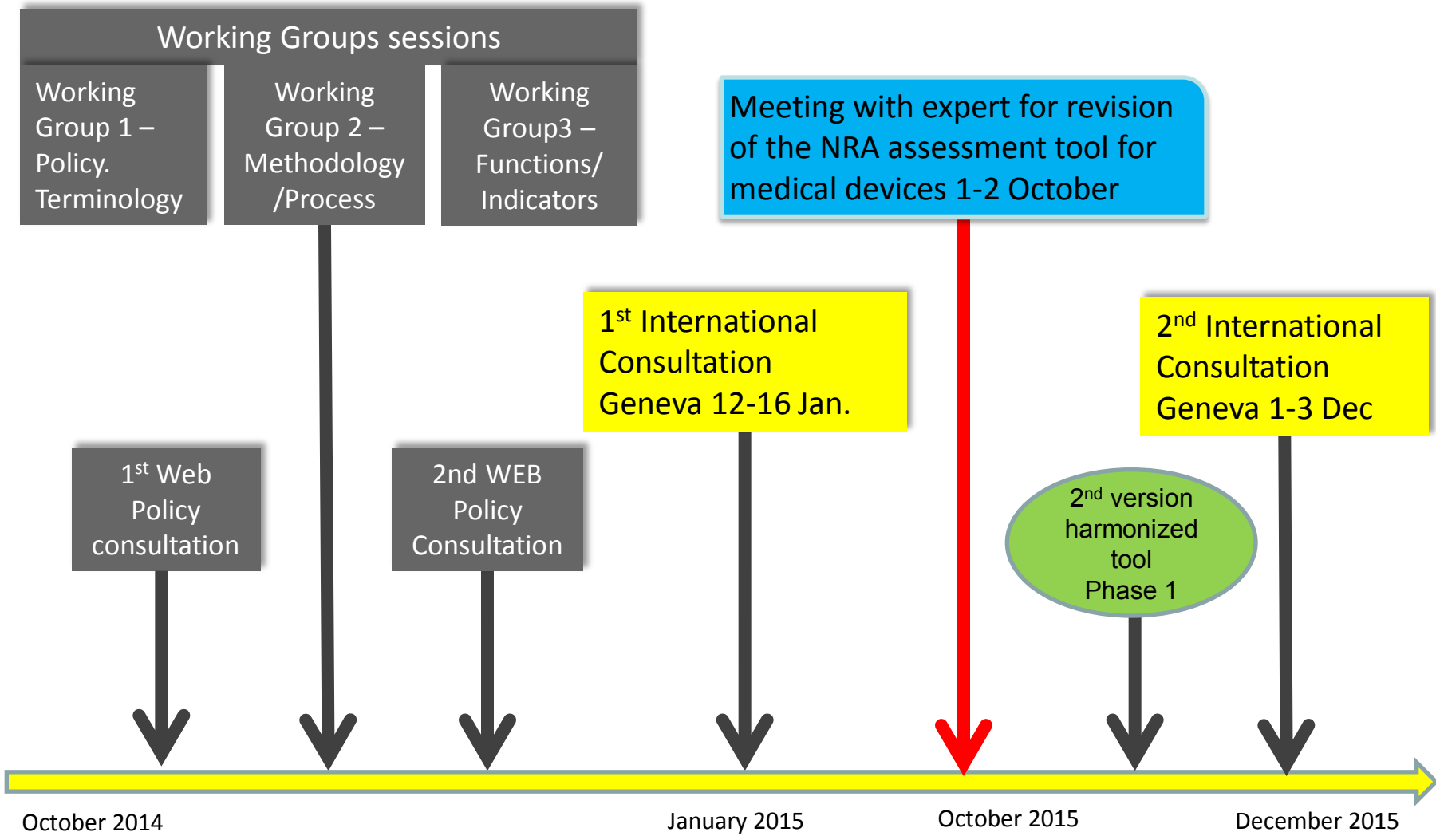
Harmonized tool : Phase 1 and 2



Elements to be considered under relevan

Planning for the WHO International Consultation on Regulatory Systems Strengthening (RSS), 2014-2015

Harmonization of medicines, IVDs, medical devices , blood , traditional medicines & vaccines tools



Thank you