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Harmonizing Quality Assurance Guidelines for Medicines Procurement – an IPC* Initiative

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What is the problem?

- Different quality standards applied by donor agencies (for example Global Fund, World Bank, USAID) can be confusing for procuring countries
- Inconsistency between product classes (those for which WHO offers Prequalification Programme and all others)
- Wrong signal to markets – if manufacturers are able to make money with low quality products
- Even if requirements on paper are similar, enforcement and verification may vary significantly between agencies
- Increasing sophistication of grey market and criminal actors in exploiting weaknesses of international procurement, contributing to the risk that bad quality drugs cause harm to patients

Examples

- Forged inspection certificates, analytical reports or COPPs
- Papers submitted do not match products delivered (origin, manufacturing site)
- COPP issued by “less than stringent” regulatory agency
- Analytical tests performed in labs with questionable qualification and independence
- Seller of “orphan” API provides analytical method (no public pharmacopeial monograph available) – this led to a case in which a country acquired counterfeit drugs for a public health campaign
- No documentation of bio-equivalence for different brands of the same INN

What does IPC want to do

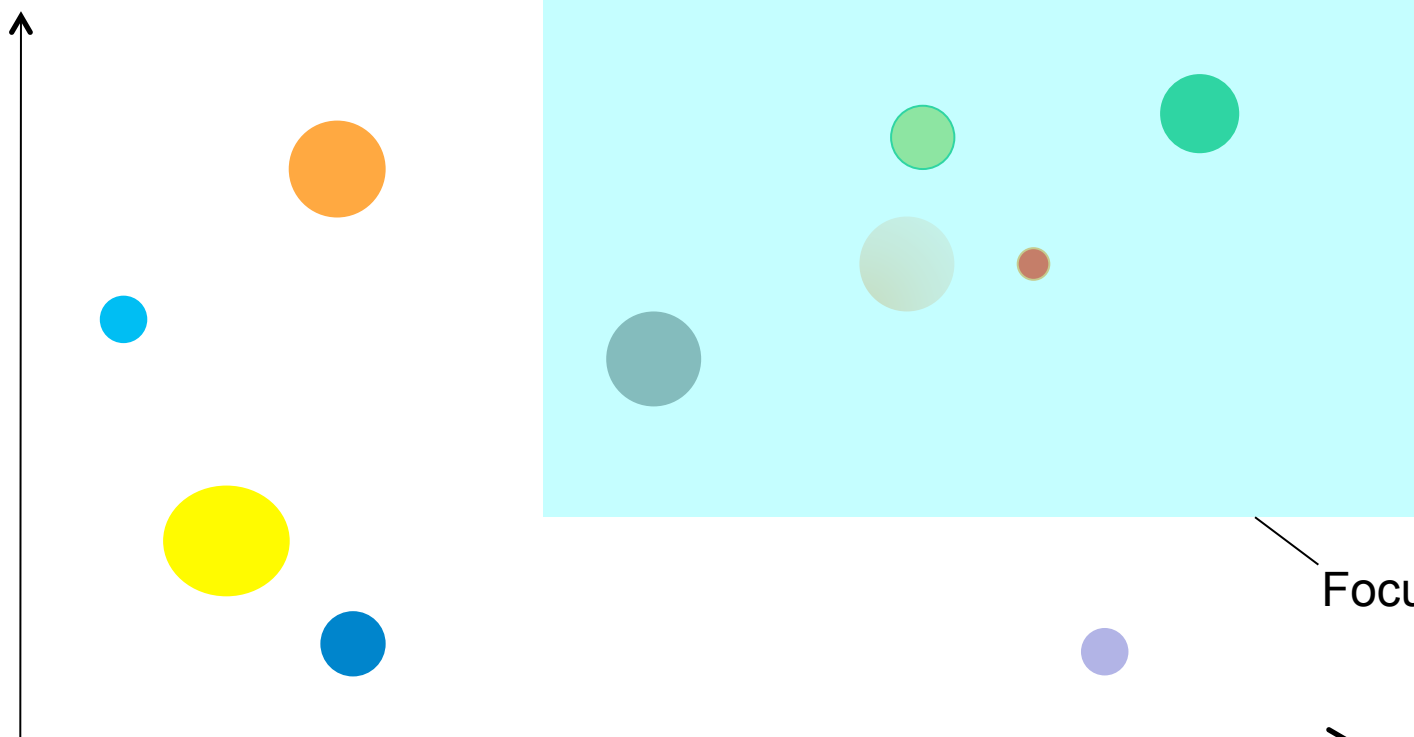
- Convene small project team to suggest harmonized approach to quality assurance in procurement of essential medicines
- Lay out a risk based approach with pragmatic guidance, considering market realities and existing capacity in countries and international agencies
- Core group (initially): World Bank, WHO, Global Fund
- Consultation with UNICEF, UNFPA, IDA Foundation, Missionpharma, SCMS, PFSCM and other interested partners
- Expected time to completion: one year (without adoption process required to turn the product of the work into official policy of participating agencies)

What are potential options?

- A global prequalification mechanism for all essential drugs?
.. unlikely
- A case-by-case review and risk-assessment similar to the Global Fund's Expert Review Panel?
.. possible, but not practical in a centralized fashion for all EMs
- A mechanism to prequalify procurement agencies?
.. possible
- Strengthening national regulatory agencies?
.. essential but will take time

Risk-Based Approach

Pharmacological



Focus area

Clinical

Potential Implications

- Conflicts with national procurement laws and procedures may need to be managed
- Temporary shortages or price increases in some market segments
- Clash with “buy national” policies possible
- Potential lack of competent players that would fulfill prequalification criteria; need for capacity building (with funding requirements)
- Dependency on external expertise for countries with low level of capacity
- Need for sharing of data and information, cross-national or regional collaboration (example AMRH)