

Quality of Reproductive Health Medicines Programme (QuRHM) MDA briefing

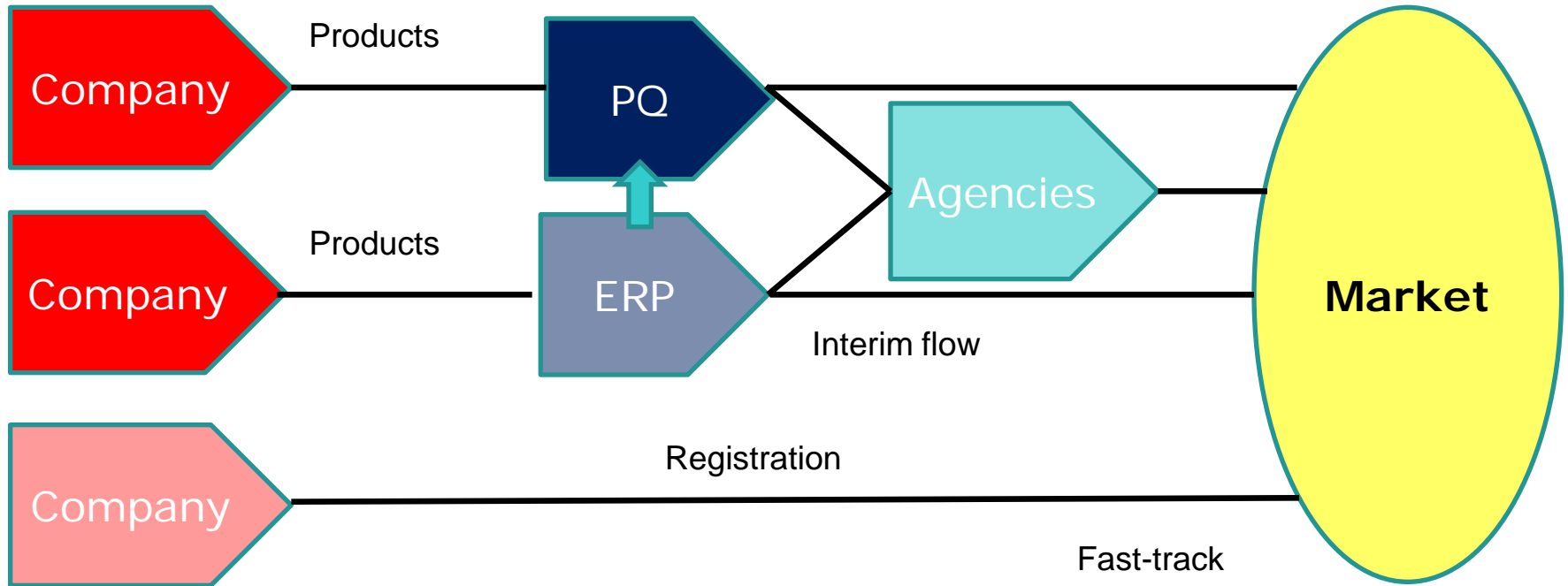
Paris, France, October 2012



Definition

The QuRHM programme is an intervention designed to shape the future market for RH medicines.

Programme outcomes



Output 1 – availability of quality assured RH medicines

Focus on manufacturers – supporting WHO-PQ programme –
to increase number of PQd products

- Studies to identify and assess contraceptive, other RH medicine and API manufacturers completed.
 - 9 API and 23 FPP manufacturers are in the QuRHM programme, covering full range of RH medicines, except magnesium sulphate.
- Two (2) generic Combined Oral Contraceptives (COCs) have been prequalified by WHO, 3 COCs and 2 emergency contraceptive pills (ECPs), 1 implant, 1 once-a-month contraceptive, 1 misoprostol and 2 oxytocins are currently under assessment.
- Four (4) API dossiers are under assessment by WHO and a further 6 are being prepared for submission.
- Collection of data and consultation with companies has been undertaken for a “Business case for manufacturers”.

Output 2 – Harmonize policies and approaches

Focus on procurers – international – **harmonization of international QA approaches**

- UNFPA's revised procurement policy was published and disseminated to procurers.
- The first QuRHM procurement workshop was held in April 2012.
- The ERP/RHM mechanism has been established and the latest invitation to participate was published on 13 April 2012.
 - Thirty three product dossiers were submitted to the June 2012 ERP, 22 screened for review by WHO.
 - Of these, 10 products, 6 COCs, 2 ECPs, 1 progestogen-only pill (POP) and 1 misoprostol have been categorized for time-limited purchase (categories 1&2); 1 ECP and 1 POP (category 3, requiring bioequivalence).
 - One DMPA product is still under review.



Emerging issues 1 and 2

1. What does the optimal manufacturing environment look like?
 - a) How many products per method do we need to establish a competitive QA market?
 - b) How many companies - scope of future QuRHM support?
2. The transition pathway from existing to new supplier base for international procurers.
 - a) Range of products to meet programme needs
 - b) Existing supplier base and contracts
 - c) Pricing
 - d) Donor requirements
 - e) SMOs - branding
3. Ensuring availability at country level
 - a) Registration in countries

Stakeholder requirements 1 and 2

Manufacturing Environment



Availability QA – country level ?



Procurement Transition



- Data on markets – international and national, size, type, segmentation,
 - Pricing guides,
 - access mechanisms,
 - Regulatory = expansion of registrations
 - investments required
 - cost/time
 - Evidence of ROI
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- Data on manufacturers – status QA, timelines, products, pricing, capacities,
 - Product registration status/plans
 - Product range meeting programme requirements – mix (brand options)
 - Consistency – donor requirements
 - Quality assured products
 - Competition
 - Assessment of impact

Output 3

Output 3 – Adoption of international QA policies and practices in selected countries - strengthening procurement and regulatory criteria and capacities.

Focus on countries – in four pilot countries

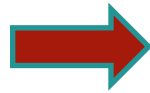
- The pilot four countries for situational analyses have been selected and the TOR for the activity completed.



- To inform the strategic approach to countries
- Provide data to support stakeholder requirements under Outputs 1 and 2

Key focus – country stakeholder requirements

Countries



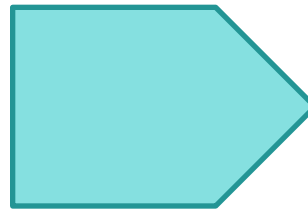
- Situational analyses
 - Strategic framework
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- Engagement on quality, provision of information
 - Advocacy around programme benefits,
 - Participative strategic plan development
 - Consistent with country goals
 - Risks and benefits
 - Support
- Country buy-in and leadership**

Output 4

- **Output 4 - Raise awareness of the QuRHM programme and related quality issues.**

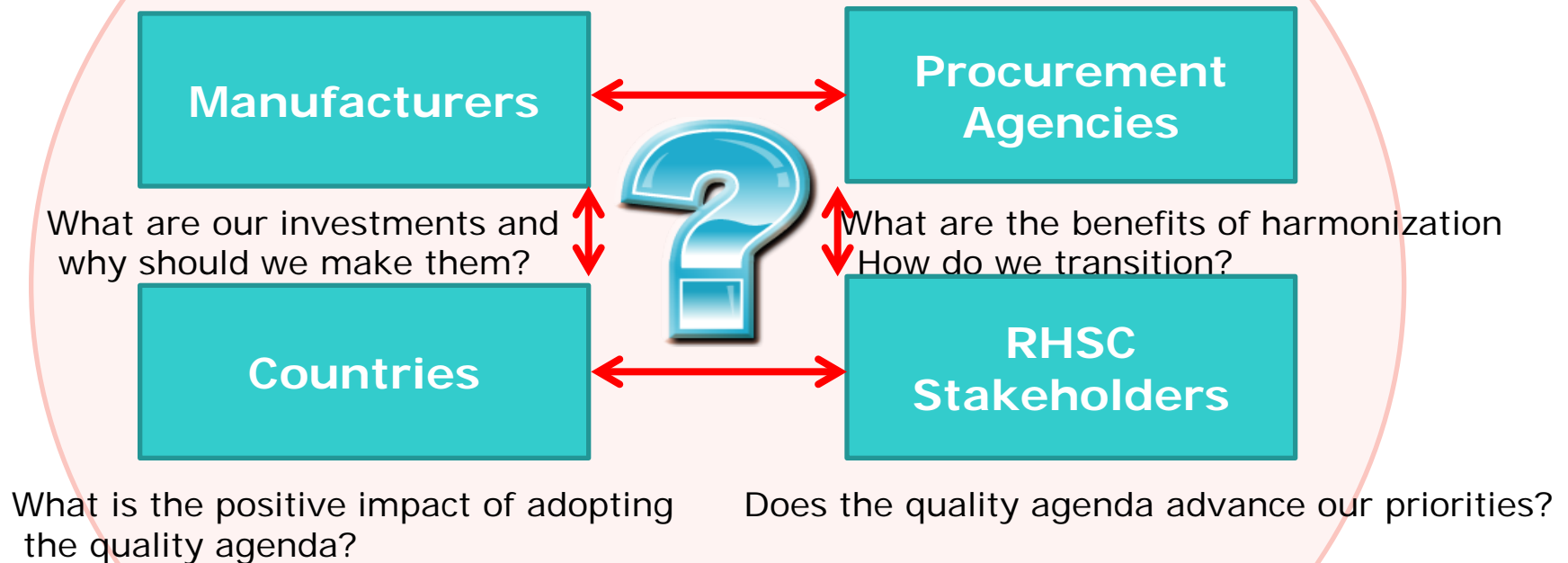
Focus on stakeholders – Advocacy/communication to build the business case for quality.

RHSC



Countries

Business case for quality





Challenges – market shaping

1. **Engagement of countries**, expansion in scope of **advocacy and communications** activities – beyond the pilot countries.
2. **Mapping** of existing country **product availability** and more QA product **registrations**.
3. **Forecasting** of global **volume** requirements and methods.
4. **Business case** for **all stakeholders** not only manufacturers.
5. **Closer** coordinated community **interaction** and engagement with **industry**.
6. **Scope** of **participating companies** v market needs and timelines.



Thank - you