



Quality Assurance for Medicines and Medical Supplies in Humanitarian Aid

**Annual Conference of Humanitarian Aid
Partners of the European Commission**

Brussels, 13-14 December 2006



CONTEXT :

- QA was a working group topic at partners' conference in 2005.
- DG ECHO's partners → € 40 to 90 Million/year for medicines and medical supplies
- Review carried out by external consultants in 2006.
- Why a review ?
 - Myriad of new manufacturers on the market
 - Problem of counterfeit medicines and medical supplies
- How ? : Online survey: 60 partners consulted of which 23 responded (38%)



Quality Assurance for Medicines and Medical Supplies in H. Aid

ONLINE SURVEY RESULTS :

- Most partners use the EML of WHO but only 52% assess the needs and 70% use emergency kits
- 87% selected their medicine sources but only 22% include manufacturing assessment in the pre-qualification
- 52% have a logistician in charge of procurement of drugs and 26% have pharmacist
- 74% use HPCs for procurement (mainly IDA/UNICEF)
- 56% follow any standard for purchase of medical devices
- 87% train local health workers in rational prescription of drugs
- 35% have mechanisms to report adverse effects of medicines
- 48% accept donated medicines but only 35% apply WHO guidelines for drug donations
- 70% have disposal policy for sub-standard medicines but only 48% in line with the WHO recommendations



MAIN PROBLEMS :

- Sometimes difficult emergency circumstances.
- Clear QA risks involved when :
 - partners set up their own tendering for medicines;
 - partners select not pre-qualified providers.
- When price is the determinant rather than price/quality ratio.
- Financial and technical capabilities of partner NGOs to carry out pre-qualifications.



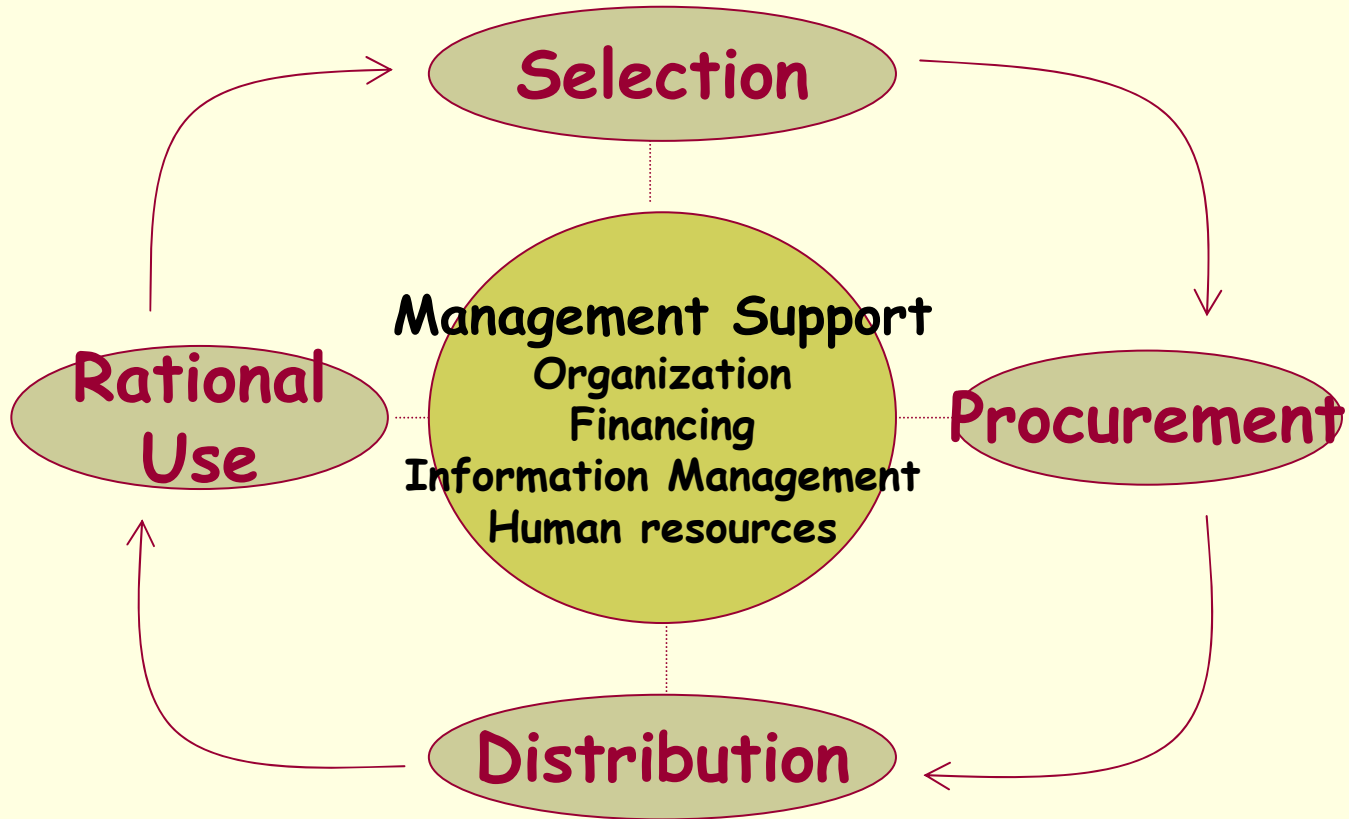
MAIN PROBLEMS (end) :

- Sub-standard drugs as :
 - Storage and climatic conditions can lead to instability.
 - Raw materials for drugs of poor quality.
 - Expiration of drugs.
 - Wrong product / insufficient dosage / absence of active product.
- Leading to :
 - Treatment failure, adverse reactions, drug resistance, increased morbidity and mortality, intoxication,
 - Waste of resources
 - Damage confidence in health system, damage public trust and investment in pharmaceutical industry



Quality Assurance for Medicines and Medical Supplies in H. Aid

THE DRUG MANAGEMENT CYCLE :



Policy and Legal Framework



Key during the procurement phase is the

PRE-QUALIFICATION PROCESS :

- Product related assessment.
- Manufacturer related assessment.
- Also site specific.
- RE- qualification and monitoring.



PRE-QUALIFICATION PROCESS :

What already exists :

- WHO pre-qualification scheme for ARVs, TB and malaria drugs.
- WHO already has a Model Quality Assurance System for Procurement Agencies (MQAS).
- Whole range of pre-qualification activities ongoing but :
 - differences were found in the way HPCs carry out the pre-qualification of manufacturers
 - Duplication
 - lack of information sharing
- Interagency Pharmaceutical coordination group (WHO, UNICEF, ICRC and MSF)



A POSSIBLE SOLUTION - THE HPCs :

Humanitarian Procurement Centres :

- Non-profit making, autonomous structures, specialised in technical and commercial management of supplies for implementation of humanitarian operations.
- Provide technical assistance to Humanitarian organisations (pre-established stocks, purchasing and logistics capacities).
- 10 HPCs recognised on a preliminary basis by ECHO.



A POSSIBLE SOLUTION - THE HPCs (end):

- Shifting pre-qualification burden, expertise and costs to HPC.
- Single bid procedure possible and overheads can be charged on funds used to purchase drugs.
- Non-HPC providers still an alternative option.
- Partner NGOs are still liable :
 - For the quality and specifications of selected products;
 - For preserving the quality of the products they receive from HPCs or other providers;
 - For reporting incidents of irregularities.



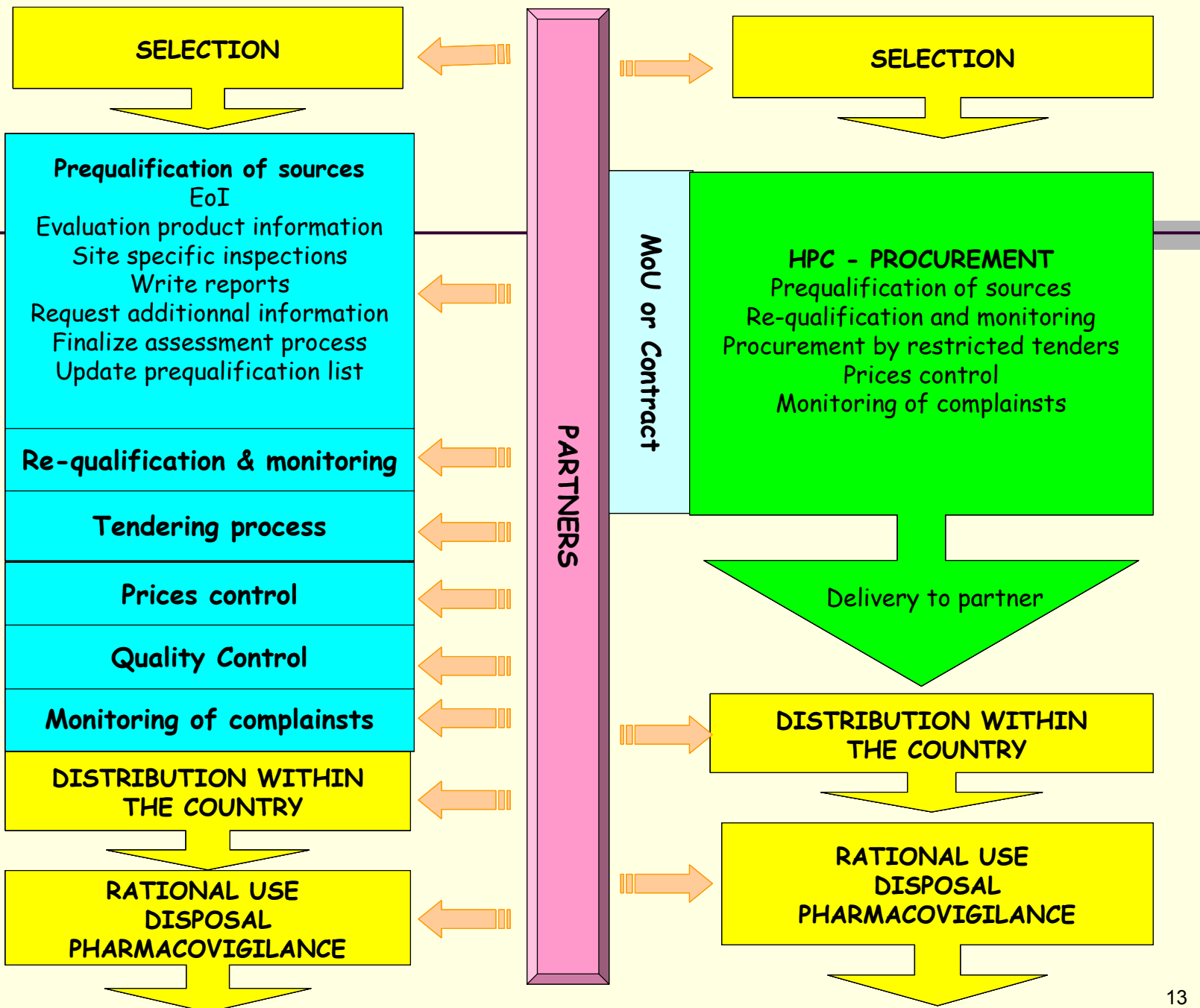
PROCUREMENT THROUGH HPCs :

- Is Safer:
 - good storage,
 - assured quality,
 - best price (economies of scale).
- Is Easier: no tenders, available stocks.
- Contract or MoU between HPC and partner.
- WHO pre-qualified list should be respected.



PROCUREMENT ALTERNATIVES :

- Product-supplier pair should be pre-qualified.
- The pre-qualification should be manufacturing site specific.
- Restricted tenders sent to at least 3 selected suppliers.
- Local procurement from national authorized suppliers, but no guarantee.
- WHO pre-qualified list should be respected as much as possible.



Quality Assurance Of Medicine For the patient



RECOMMENDATIONS FOR PARTNERS :

1. WHO standards for pharmaceutical products + national guidelines
2. Determine SOPs for drug management cycle
3. Recruit needed expertise (pharmacist)
4. Share results of suppliers selection in field
5. Support government health facilities staff on management cycle of medicines
6. Consider local purchase if standards are met
7. Strengthen local manufacturers, wholesalers and distributors in cooperation with WHO
8. Consider systems for pharmaco-vigilance
9. Use guidelines for pharmacological waste management and management of donations



RECOMMENDATIONS FOR HPCs :

1. Follow WHO pre- and re-qualification guidelines
2. Launch regular Expression of Interest
3. Cooperation and specialisation between HPCs
4. Sign MoUs with partners to clarify responsibilities
5. Follow up system with clients for additional training and technical back-up
6. Hire pharmacist (a must!)



"HOW ECHO CAN HELP" :

1. Support HPCs in pre and re-qualification tasks
2. Encourage joint action and information sharing for pre-qualification
3. Support partners in efforts to develop good SOPs for drug management cycle
4. Endorse as reference guidelines WHO documents
5. Support partners to install waste management systems



Quality Assurance for Medicines and Medical Supplies in H. Aid

**THANK YOU FOR YOUR
ATTENTION**