Objective:
To use WHO ERP to review the potential risk/benefit for FPPs not yet WHO-prequalified or SRA-authorized, for the purpose of providing advise to help immediate procurement decisions.
Eligibility criteria and fundamental principles

• **Criteria 1 (products included in WHO PQ EOI)**
  - FPP manufacturing site GMP compliant as certified by WHO PQ, SRA or PIC/S inspectors.

• **Criteria 2 (products not included in WHO PQ EOI)**
  - The FPP manufacturing site GMP compliant as certified by WHO PQP, SRA,PIC/S inspectors (some cases NRAs)
  - Procurement recommendations based on ERP advise are valid for 12 months only, except for RH, where duration is 18 months (both with possibility for extension based on progresses made)
  - Pharmaceutical Product Questionnaire and supporting annexes used - not a full regulatory dossier.
  - The ERP session is a one-off review, however additional data may be requested if likely to improve the risk category.
General attributes for risk categorization

a. FPP manufacturing process and FPP specification
b. FPP stability data
c. Evidence of safety/efficacy
d. API source and API quality

Possible outcomes

- Risk categories 1 or 2 - "No objection" for procurement
- Risk categories 3* and 4 - “Objection" against procurement
- Request for additional data

*Risk category 3 can be considered only if there is no other option and the risks of not treating the disease is higher than the risk of using medicines not meeting all quality standards.
ERP for deworming tablets 1

- ERP reviews for Neglected Tropical Diseases, (NTD) started April 2010
- Covers:
  - Albendazole 400mg chewable tablets
  - Mebendazole 500mg chewable tablets
  - Praziquantel 600mg tablets
  - Diethylcarbamazine citrate (DEC) 100mg tablets
- Revised eligibility criteria that only require evidence of GMP compliance as inspected by WHO/SRA/PICs or NRAs
ERP for deworming tablets 2

• Does not require prior dossier submission to PQ/SRA
• There is specific advice on performance of dissolution studies to support safety/efficacy as an interim solution (instead of BE)
• Expectation that the supplier will conduct BE study and submit dossier for WHO PQ assessment
• In 2015, WHO & UNICEF signed an agreement that future procurements of these products will be guided by a review of WHO ERP in order to improve quality of these FPP
• Invitation for ERP for FPP and APIs is currently open and there is urgent need for these products;
• 2014 UNICEF procurement; Albendazole 400mg chewable – 75 million tabs, Mebendazole 500mg chewable – 60 million tabs
• Interested suppliers can contact WHO-NTD, Azadeh Baghaki at baghakia@who.int
ERP for Amoxicillin DT for childhood pneumonia

- Currently Amoxicillin DT is not in WHO PQ programme but it is one of the 13 UN Commodities for mothers and children.
- UNICEF published first EOI in 2013 with a view to identify gaps in quality of available products in market
- Revised eligibility criteria that only require evidence of GMP compliance as inspected by WHO/SRA/PICs or UNICEF
- Absence of BE study was identified as the main barrier – only 2 manufacturers had BE studies
- Suppliers were given time to undertake BE studies and in May 2015, the second ERP EOI was published
- Seven manufacturers have completed BE studies and their product dossiers are under review by WHO ERP
- Future UNICEF tenders for Amoxicillin DT will rely on the WHO ERP outcome
Annual orders for Amoxicillin DT through UNICEF have grown 13x since 2011
ERP for Reproductive Health products 1

- Adopted for reproductive health in 2011, Secretariat in UNFPA.

- EOI for submission published twice a year:
  - UNGM: https://www.ungm.org/Public/Notice/36144
  - UNFPA site: http://www.unfpa.org/resources/reproductive-health-medicines
  - WHO PQ site: http://apps.who.int/prequal/

- The ERP session is a one-off review, however additional data may be requested if likely to improve the risk category, only once.
ERP for Reproductive Health products 2

• RH is recognised as a difficult area: few dossier submissions to PQ, slow progress, few products WHO prequalified

• Peculiarities of RH ERP:

  • **GMP status:**
    - Evidence of GMP compliance is not limited to WHO PQP, SRA, PIC/S member inspectorates.

  • **Dossier submission status:**
    - Dossier has been submitted to PQP/SRA and accepted for assessment, or
    - Commitment to submit dossier to PQP/SRA within three months from the date of 1st ERP review.

  • **Duration of ERP positive opinions:**
    - Procurement recommendations based on ERP advise for RH medicines are valid for 18 months.
    - Possibility for extension based on progresses made.
    - Contact: Isabel Lucas-Manzano; manzano@unfpa.org or Seloi Mogatle; mogatle@unfpa.org