Aligning WHO Normative and Prequalification Processes

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Aligning WHO's normative and prequalification processes

Objective:

- To facilitate timely access to health products (medicines, vaccines, medical devices including diagnostics, vector control products and other health products) to maximize public health impact

Scope:

- All health products that:
  - are eligible for prequalification; and
  - require a new or extended recommendation from the relevant technical department; and
  - require a new dossier assessment for prequalification by RPQ.
- Normative processes include all technical WHO guidance, recommendations etc. on product use
- Prequalification processes include PQ listing Emergency Use Listing (EUL)

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Guiding principles:

1. WHO procedures are clear, streamlined, timely and quality assured

2. Independence of the processes to be upheld

3. Coherent and coordinated organizational positions on medical products

4. Build on the experience with SAGE Immunization and therapeutics during COVID-19 pandemic.

Summary of the proposed process:

1. Parallel processes and not sequential.
2. Formal trigger memo for the start of the parallel processes between Technical Department (TD)and Prequalification (PQ).
3. Regular coordination and communication along the way.
4. Decision on publication of the WHO Guidelines and PQ Listing not more than 12 months from receipt of a specified complete dossier/data package from the manufacturer. “Stop clock” in case more information is requested.
5. Coordinated external communication of outcome between guidelines and PQ

We need your feedback

- Please submit your inputs and comments by end of the year.
- Please use the following generic mailbox: NSP-PQTconsultations@who.int