Programmatic Suitability for Prequalification

Briefing on Vaccine Prequalification for manufacturers

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Programmatic suitability and its assessment

- Vaccines produced in developed countries may not have taken into account programmatic challenges in developing countries.
- Examples:
  - Non auto-disable prefilled syringe presentations
  - Stability of components in the event of cold chain breakdown
- WHO PQT has always considered programmatic suitability but it was in 2012 that a written guidance (PSPQ) was developed and put in place

- Objectives of PSPQ
  - Judge the programmatic suitability against defined mandatory, critical and preferred characteristics
- Benefits of PSPQ
  - Give clear directions to vaccine industry before submission
  - Reduce decision making time

Submission screening and SC assessment

- Upon receipt, product summary files (PSFs) are screened for completeness and compliance with the required format and contents by the PQ secretariat.
- PSFs are also screened by the PQ Secretariat for compliance with programmatic suitability criteria,
  - if mandatory characteristics are not met the PSF is rejected.
  - if the PQ Secretariat identifies a deviation from the critical characteristics or finds a unique characteristic, the product will be referred to the PSPQ Standing Committee for independent review of the characteristic.

Who makes the final decision?

- The PSPQ SC makes a recommendation to the Director of the Essential Medicines and Health Products Department (EMP) considering programmatic risk from non compliance with a criterion and public health needs for a vaccine as to whether the product should be accepted for review for prequalification
- Decision-making rests with EMP

PSPQ Current status

- Revised document endorsed by Immunization Practices Advisory Committee (IPAC)11-12 June 2014 IPAC

The new PSPQ requirements came into effect on 1 January 2015.

Main changes:

(1) Antimicrobial preservatives and the definition of "inadequately preserved" vaccines;

(2) antigenic stability for 28 days;

(3) the management of vaccines that were pre-qualified prior to the PSPQ implementation (grandfathering);

(4) new mandatory and preferred characteristics and the transition to critical characteristics.

Mandatory characteristics

- Antimicrobial preservative is required in ready to use injectable vaccines containing more than two-doses.
- Thermostability: The vaccine or any component presented for prequalification should not require storage at less than -20°C.
- Dose volume for injectable vaccines for children 5 years and under should be not more than 1 ml
- vaccine presented for prequalification should not require an intravenous route of administration

Unique or innovative characteristic

- No guidance documents developed
- Examples: Nano-patches, nasal aerosols, micro-needle application
- Based on programme knowledge SC will judge the suitability of such vaccines for the developing market

Critical characteristics (1)

- The vaccine should fit into currently commonly used schedules of vaccination visits.
- Oral vaccines should be ready to use
- Thermostability: If the vaccine requires storage below +2°C during its shelf-life period, it should be stable at +2°C and +8°C for a minimum of 6 months
- Vaccine Vial Monitor (VVM): Proof of feasibility and intent to apply appropriate VVM if a tender requirement

Critical characteristics (2)

- Antimicrobial preservative is required in ready to use injectable vaccines containing two-doses or in vaccines requiring reconstitution that are not live-attenuated
- Dose volume of injectable vaccines can be delivered using available PQed auto-disable syringes
- Vaccines in pre-filled injection devices should have an auto-disable feature
- Packaging material can be disposed of appropriately in the field using standard procedures

Preferred characteristics

- A vaccine not complying to preferred characteristics are not reviewed by PSPQ SC before evaluation for pre-qualification
- They indicate what WHO and national immunization programmes would want in a best case scenario
- They provide a guide vaccine manufacturers during the development of the new vaccine formulations
- In time, a preferred characteristic may be reclassified as critical

Preferred characteristics (1)

- Antigenic stability following reconstitution
- Small packed volume
- Small, standardised dose volumes for oral vaccines
- Minimize number of doses that cannot be reused in subsequent sessions once the container is open
- ≤10 doses per vial in routine setting; ≥ 10 doses per vial in campaign setting

Preferred characteristics (2)

- Doses per secondary container reflect logistical needs
- Small, standardised dose volumes for oral vaccines
- Ready to use vaccines
- Multicomponent vaccine formats reduce potential for error
  - If components are packed in separate secondary containers, they should contain the same number of doses

Preferred characteristics (3)

- Increased thermostability
- No freeze sensitivity
- Packaging designed to minimise environmental impact
- Novel delivery devices that reduce risk of contamination
- Compact prefilled auto-disable injection system (eg. UniJect®)
- Labelling (TRS revision in preparation)
- Barcoding

http://www.who.int/immunization_standards/vaccine_quality/pspq2_v140512.pdf