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## Programmatic Suitability for Prequalification (PSPQ)

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# RATIONALE FOR STABLISHMENT OF PSPQ

- Vaccines produced in higher income countries made available to emerging countries

- Such vaccines show characteristics that while being acceptable for industrialized countries are not always suitable for emerging markets.

  Examples:

  - A pneumococcal vaccine filled in non-autodisable pre-filled syringes
  - A rotavirus vaccine with poor stability in case of cold chain break

## Objective 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 for vaccines that are not in compliance with PSPQ characteristics

# PROCESS OF REVIEWING THE CHARACTERISTICS OF CANDIDATE VACCINES

- PQ dossiers are screened for completeness and compliance with the required format and contents
- And also, for compliance with programmatic suitability criteria.
  - If mandatory characteristics are not met the dossier is rejected.
  - If the PQ assessor identifies a deviation from the critical characteristics or finds a unique characteristic, the product will be referred to the PSPQ Standing Committee (PSPQ SC) for independent review

# The PSPQ Standing Committee (SC)

- Is an independent advisory committee to the WHO PQ - experts on immunization programmes, regulatory and policy experience.
- Aligned to Immunization Practices Advisory Committee (IPAC).
- Review, discussion and recommendation-making.
- The maximum allowed time for review by the PSPQ Standing Committee is 90 days.

# Types of vaccine characteristics

| | |
|---|---|
| Mandatory | • Compliance is compulsory |
| Critical | • Compliance is compulsory<br>• Deviations in vaccine characteristics will be reviewed by the PSPQ SC |
| Preferred | • Not compulsory<br>• Reflect programmatic preferences |
| Unique & innovative | • There is no guidance document developed<br>• Will be referred to the PSPQ SC |

# Mandatory characteristics

- **Anti-microbial preservative** required in ready to use vaccines containing more that two-doses
- **Thermo-stability.** The vaccine or any component presented for PQ should not required storage at less than -20°C
- **Dose volume** should not be more that 1 ml/per dose for children > 5 years.
- Vaccine presented should not require an intravenous **route of administration**

# Critical characteristics (1)

- The vaccine should fit into currently commonly used schedules of **vaccination visits**.
- Oral vaccines should be ready to use
- **Thermo-stability/ storage**: Vaccines submitted for prequalification should not require storage below +2°C for longer than 6 months
- **Vaccine Vial Monitor (VVM)**: vaccine submitted should present data confirming that it has a thermostability profile to apply VVM.

# Critical characteristics (2)

- Packaging material that can be disposed of appropriately in the field using standard procedures
- Vaccines in pre-filled injection devices should have an auto-disable feature
- Vaccine dosed in standardized volumes (e.g. 1, 0.5, 0.25 ml)

# Preferred characteristics

- Antigenic stability after reconstitution
- Small packed volume
- Small and standardized dose volumes for oral vaccines
- Minimize number of doses that cannot be reused in subsequent sessions once the container is open
- Doses per primary container:
  ≤10 doses per vial in routine setting
  ≥10 doses per vial in campaign setting

# Unique or innovative characteristics

Examples:

- Nano-patches
- Nasal aerosols
- Micro-needle application

**“Assessing the programmatic suitability of vaccine candidates for WHO prequalification”**

https://www.who.int/publications/i/item/WHO-IVB-14.10

# THANK YOU