Post-prequalification activities
- clinical

Briefing on Vaccine Prequalification for manufacturers
DCVMN meeting, Kunming, China, 13 March 2016
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Annual Reporting for clinical
Prequalified Vaccine Annual Report (PQVAR)

Variations

- Summary of changes/variations (minor)

  Those requiring "approval before implementation" are assessed separately

Implementation of post-prequalification commitments

- Results/update of ongoing/planned clinical trials/observational studies
- Post-marketing surveillance commitments

Periodic Safety Update Report (PSUR)

Reassessments

Evaluation of the updated Product Summary File (PSF)

- Ideally only sections indicated as changed will be evaluated…

PSURs and Vaccine Prequalification

PSURs can be received by WHO Vaccine PQ Secretariat in two situations:

- Before prequalification

- In case of new applications for PQ of vaccines already marketed for more than a year

- After prequalification

- PSURs should be submitted annually as part of the Prequalification Vaccine Annual Review (PQVAR) documentation

PSUR format

- **No specific format required**
  - The format required by the National Regulatory Authority (NRA) of reference is accepted by WHO
- **Content is what matters**
- **ICH format is accepted**

PSUR evaluators

- **WHO staff member and /or**
- **External expert(s) contracted by WHO**
  - **Two for the clinical evaluation of a new application of a vaccine for PQ**
    - PSUR evaluation is just one component
  - **Usually one in case of annual review of novel vaccines**
    - PSUR evaluation is the sole purpose
  - **External experts have to**
    - sign a Confidentiality Agreement
    - fill in and sign a Declaration of Interests

Evaluation of the PSUR - 1

1. Background information on the vaccine product

1.1 Composition of the vaccine

1.2 Recommended schedules and routes of administration

1.3 Marketing authorization status

Evaluation of the PSUR - 2

2. Presentation of PSUR(s)

- 2.1 General information
- 2.2 Serious unlisted adverse events
- 2.3 Non-serious unlisted reported adverse events
- 2.4 Serious and non-serious listed events
- 2.5 Medically unconfirmed cases
- 2.6 Clustering
- 2.7 Other safety information

3. Overall safety evaluation, conclusions and recommendations

Additional considerations - 1

- **All dosage forms, formulations and indications for a given vaccine should be covered in one PSUR**

- **Within a single PSUR separate presentations of data may be appropriate for different**
  - dosage forms
  - indications
  - populations (e.g. children vs. adults)
  - schedules (e.g. age at administration, booster dose)
  - and routes of administration

Additional considerations - 2

- **For combination vaccines a separate PSUR is required even when its individual components, alone or in combination, are marketed individually**
  - e.g. measles-mumps-rubella vaccine, measles-rubella vaccine, measles vaccine etc…produced by the same manufacturer

Thank you