Briefing on Vaccine Prequalification for DCVMN manufacturers

Webinar : day 2

24 April 2014

Overview of the Suitability of Product Characteristics for Prequalification

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World Health Organization

RATIONALE FOR ESTABLISHMENT OF PSPQ

In the past WHO was prequalifying almost exclusively vaccines that have been in the market for many years

- More recently, vaccines developed originally for industrialized countries were made available to emerging economies

Such vaccines showed characteristics that while being acceptable for industrialized countries were not really suitable for developing markets

- Examples were a pneumococcal vaccine filled in non-auto-disable pre-filled syringes and a rotavirus vaccine with poor stability in case of cold chain break

Programmatic suitability review before PSPQ

- Based on precedent and existing policies
- Consultation with programme components in WHO and in countries and with UN procuring agencies and GAVI
- Decision made on a case-by-case basis
- Timeframe for decision making highly variable

The emergence of unique vaccine presentations has driven the need to define the characteristics that determine programmatic suitability and to formally structure the process for assessing compliance with these characteristics

Objectives of PSPQ

- Define the components of programmatic feasibility better
- Clearly state suitable characteristics
- Judge the programmatic suitability against the mandatory, critical and preferred characteristics
- Maintain "human judgement" in all cases

Benefits of PSPQ

- Clear procedure and decision making criteria to work with
- Clear directions to vaccine industry
- Shorter decision track for complicated presentations (viz. recent complicated presentations were held up in pre-qualification *inter alia* on programmatic grounds for more than 18 months)

Purpose of PSP

Suitability of individual products

- To provide transparency and objectivity to the WHO PQ Secretariat and the Directors of Immunization vaccines and Biologicals (IVB) and Essential Medicines and Health Products decisions of what is a programmatically suitable vaccine:
  - by defining the characteristics that determine programmatic suitability, and
  - by defining the process for assessing compliance with these characteristics.
- To indicate vaccine characteristic prefe
  industry and other vaccine developm

"Market shaping"

Process for review of candidate vaccine characteristics

- Upon receipt, product summary files (PSFs) are currently 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.

Process for screening to determine programmatic suitability of the vaccine

- Application letter received from the manufacturer
- PQ Secretariat review: compliance with PQ priorities. (accept/reject)
- Acceptance of the application,
  Product summary file requested from the manufacturer
- Product summary file received from the manufacturer
- PQ Secretariat assessment of programmatic suitability characteristics
- If critical characteristic not met or innovative characteristic identified vaccine referred to the PSPQ Standing Committee
- Acceptance or rejection of the PSF for evaluation based on SC recommendation

What is the Programmatic Suitability for Prequalification (PSPQ) Standing Committee

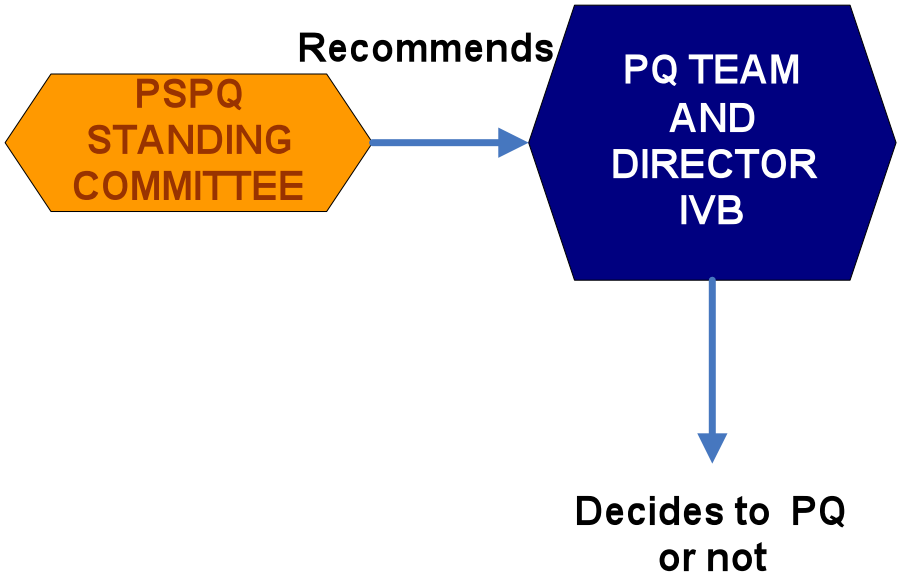
- It is an independent advisory committee to the WHO Prequalification (PQ) Secretariat made up of experts with immunization program, regulatory and policy experience.
- It is aligned to IPAC as one of the IPAC Standing Committees
- During their review, discussion and recommendation-making, the PSPQ Standing Committee may engage in confidential discussion with manufacturers and additional technical experts. They may also recommend validation by research of the acceptability of non-compliant characteristics.
- The maximum allowed time for review by the PSPQ Standing Committee is 3 months.

PSPQ characteristic categories

Type of characteristic	Compliance	Deviation
Mandatory	Prequalification evaluation proceeds.	Rejection of application for prequalification evaluation.
Critical	Prequalification evaluation proceeds.	Referral to the PSPQ Standing Committee for review, discussion and recommendation. After consideration of the PSPQ Standing Committee advice, the vaccine may be accepted or rejected for prequalification evaluation.
Unique and innovative	Referral to the PSPQ Standing Committee for review, discussion and recommendation. After consideration of the PSPQ Standing Committee advice, the vaccine may be accepted or rejected for prequalification evaluation.	
Preferred	Prequalification evaluation proceeds.	

Who makes the final decision?

- **PQ decision-making**
  - **These rules give guidance, the decision to pre-qualify or not lies entirely with the PQ team and EMP/IVB directors**
- **Maintain "human judgement" in cases that require closer scrutiny for reasons of public health need**



Mandatory characteristics

Antimicrobial preservati

MANDATORY

Anti-microbial preservative	Only vaccines that: •are in ready to use (no reconstitution) presentation. and •are in multi-dose containers of more than 2 doses per vial	The vaccine presented for prequalification should be adequately preserved. (WHO/EPI)

Why? Because if the vial is going to be used in subsequent : sessions there may be a risk of contamination: apply (MDVP) multidose vial policy

Implications of MDVP implementation

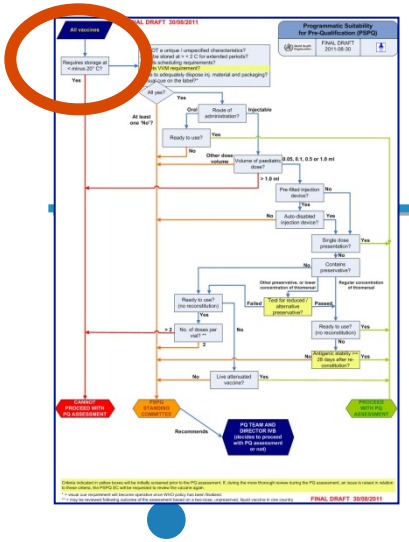
- **Performance: reduced missed opportunities & contributed to improve coverage.**
- **Management: implementation has greatly reduced vaccine wastage.**
- **Quality & Safety: from 2000 up to date, no report was received on adverse events due to implementation of the policy.**

MDVP: tension between three aspects

Wastage

Safety

Price



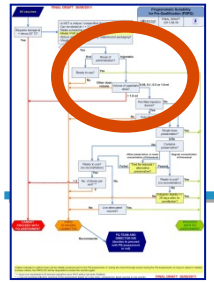
Thermostability

MANDATORY

Applies to all vaccines

The vaccine or any component presented for prequalification should not require storage at less than -20°C (WHO EPI).

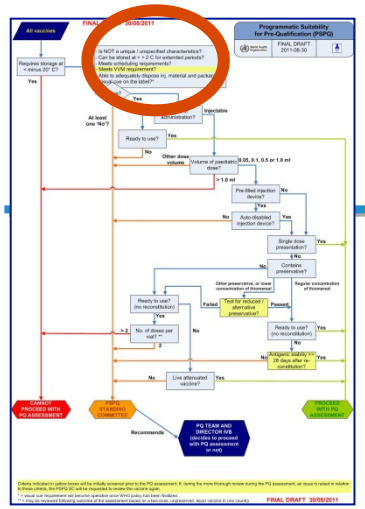
- **Why?**
  - **National programmes will be unable to maintain a cold chain that requires extended deep freezing storage, even at national levels.**



Dose volume

MANDATORY

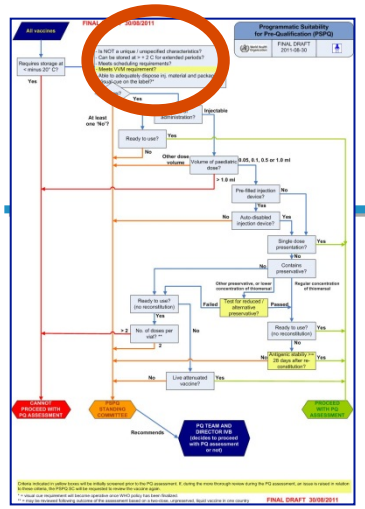
- Applied to injectable vaccines for use in children < 5 yrs
- The vaccine presented for prequalification should not be more than 1ml per dose for the paediatric indication (WHO EPI).
- Why?
  - Large volume injections are too painful
  - Formulations can be concentrated to be appropriate volume for small children use



Unique or unspecified characteristic

Applies to all vaccines

- By definition there is no guidance regarding vaccine candidates with characteristics or characteristic values not otherwise specified as ‘mandatory’ or ‘critical’. Because of this, vaccine candidates with unique and innovative programmatic suitability characteristics will be referred to the PSPQ Standing Committee for review, discussion and recommendation.

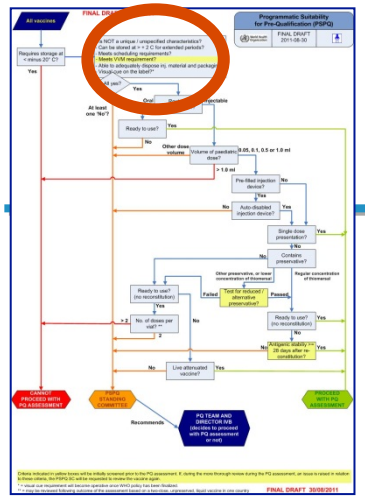


Unique or unspecified characteristic

Why?

- Catch-all for unusual presentations
- Examples: Nano-patches, nasal aerosols, micro-needle application, etc
- PSPQSC will have to – based on programme knowledge – judge the suitability of such vaccines for the developing market

Critical characteristics

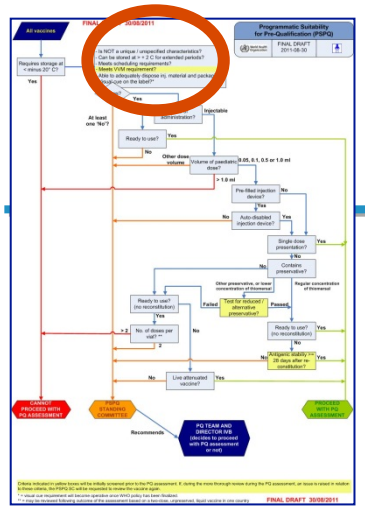


Thermostability / storage

Applies to all vaccines

- **The vaccine presented for prequalification should not require storage below +2°C for longer than 6 months (WHO/IVB/06.10)**

- **Why?**
  - **Moving away from negative cold storage space, simplifying the cold chain**
  - **OPV only vaccine that requires negative storage**



Scheduling requirement

Applies to all vaccines

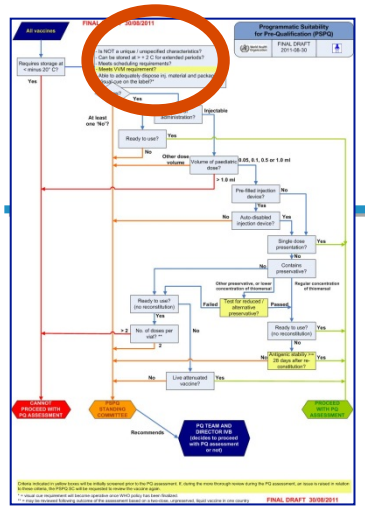
- **The following are deemed to meet this characteristic and do not require further review by the PSPQ Standing Committee:**
- **If the proposed vaccine is meant for use in children under five, it should be recommended to be given at one or more of the following regular immunization visits:**
  - **within 24 hours after birth;**
  - **at not more than three visits, 4 to 8 weeks apart, with the first visit at or after 6 weeks of age and the third visit at or before 6 months of age;**
  - **at not more than one visit between 9 and 12 months of age;**
  - **at not more than one visit between 18 and 24 months of age;**
  - **at not more than one visit in the fifth year of life.**

Scheduling requirement

- If the proposed vaccine is designed to be given to adolescents aged 9 to 1[illegible] than four [illegible] immuniz[illegible]
- If t[illegible] desig[illegible] (pan[illegible]
- If [illegible] is the[illegible]
- If th[illegible] proposed vaccine requi[illegible] more than one dose to be administered within a two week period.
- If the vaccine does not fit into one of the above criteria, it must be reviewed by the PSPQ Standing Committee. (WHO EPI).

Intent:

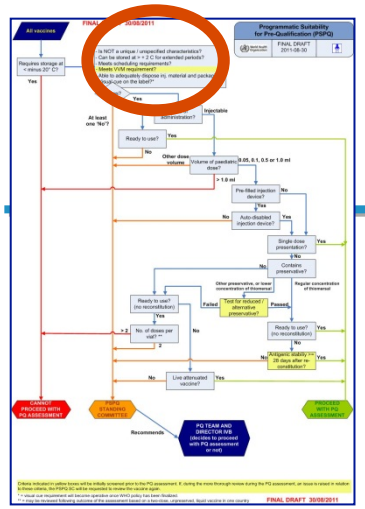
Refer to PSPQ SC any vaccine that requires the programme to expand the scheduled vaccination visits…



Scheduling requirement

Why?

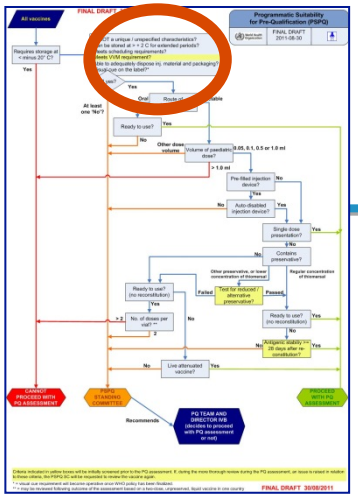
- In the under five age group, guide towards existing scheduled visits
- In adolescents, guide towards four doses
- Exclude vaccines used exclusively in reactive campaigns (eg pandemic flu, emergencies, etc)
- Excludes post-exposure vaccines



Vaccine Vial Monitor

Applies to all vaccines

- **Proof of feasibility and intent to apply a VVM to the proposed vaccine, as defined below:**
- **The vaccine presented for prequalification presents data confirming that it has a thermostability profile that will enable it to be matched to a current WHO approved VVM type (VVM2, VVM7, VVM14 or VVM30) or a future VVM type approved by WHO (WHO/V&B/99.18, WHO/IVB/07.04).**
- **Signed declaration, as part of the cover letter submitted along with the file for prequalification confirming that the manufacturer will apply a VVM to the vaccine and has the technical capacity to do so, if requested to do by the purchasing specifications.**

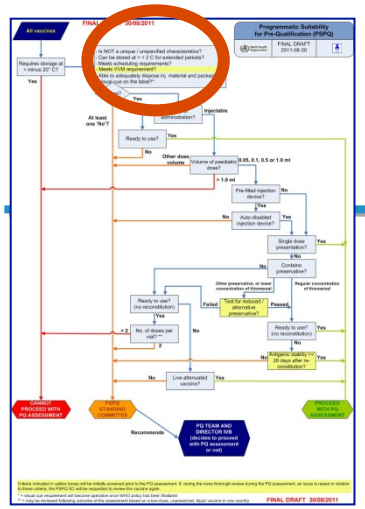


VVM

Why?

- Measurement of time and temperature accumulated excursions for the specific vial where the VVM is attached
- VVM has become a key monitoring tool for vaccines in developing countries
- Increasing importance with new costlier vaccines
- Additional use in out-of-cold-chain use and campaigns

- **VVM criteria can be referred back to PSPQ SC during pre-qualification itself**

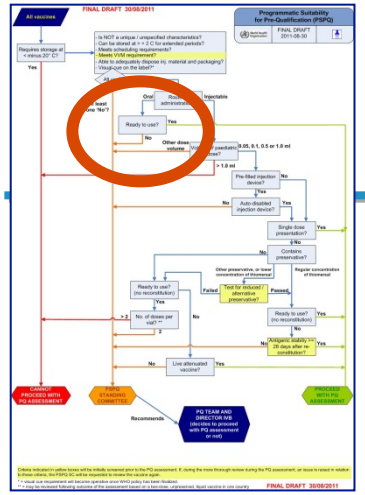


Materials, primary and secondary packaging and injection material

Applied to all vaccines

- **The vaccine presented for prequalification should be packaged in materials that can be disposed of appropriately in the field using standard procedures (e.g., pit burning and burying, low temp incinerations. etc.) (WHO EPI).**

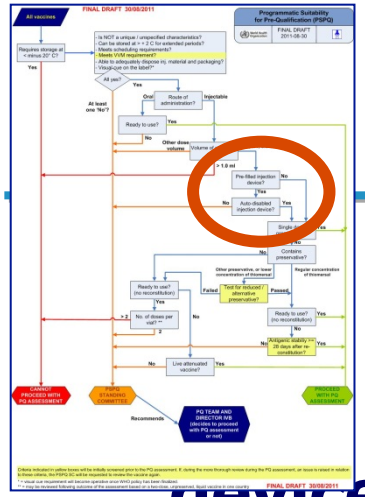
- **Why?**
  - **Environmental concerns**
  - **Ability to dispose of vials / syringes safely**



Process of preparation for administration

Applies to all oral vaccines

- **The vaccine presented for prequalification should be packaged in a single component/ready to use format (WHO EPI).**
- **Why?**
  - **To move towards oral vaccines that are easier to use.**
  - **To avoid confusion and delay with vaccines requiring reconstitution**



Pre-filled injection devices

Applied only to vax. in pre-filled injection devices

- **The vaccine presented for prequalification in a prefilled injection device should include an auto-disable (AD) feature (WHO/V&B/99.25).**
- **Why?**
  - **To prevent re-use of pre-filled injection devices, they should automatically become disabled after being used once**

Background: MDVP interpretation

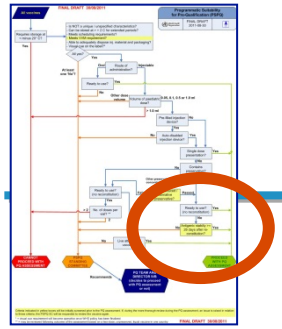
- **Based on the previous MDVP, and the health worker's interpretation of it:**
- **Fully liquid vaccines assumed as being preserved and stable → able to be kept after opening**
  - **Availability of unpreserved multi-dose liquid vaccines among newer formulations presents a potential safety risk, as health workers assuming (wrongly) that these multi-dose liquid vaccines can be kept are in fact endangering their patients.**
- **Reconstituted vaccines are assumed to be unpreserved and/or unstable → discard at end of session**
  - **Availability of preserved and stable reconstituted vaccines present an unnecessary wastage, as health workers assume (wrongly) that these vaccines have to be discarded, when in fact they can be safely stored and given in subsequent sessions.**

What do preservatives allow us to do?

- **Put vaccines in multidose vials…**
  - **Less cold storage space (incl vaccine carriers / transport) – less logistics**
  - **Keep opened vials safely for subsequent sessions – less wastage**
  - **Allow for multiple puncture of septum – ease of use**
- **…while remaining safe**
  - **Reduced risk of pathogen growth in vaccine**

When is it OK not to have preservatives?

- Campaign use multidose ▸ no waste
  - Drawback – not useful to the routine programme
- Cheap vaccines ▸ don't mind waste
  - Drawback – Potent vaccine discarded
- Single dose vials / pre-filled devices ▸ no waste
  - Drawback: Increased cold chain space & logistics
- (Low multi-dose) ▸ perceived low risk
  - Drawback: "Playing with fire… one mistake…"



Antigenic stability after reconstitution

- Injectable vaccines in multidose vials, adequately preserved, requiring reconstitution
- The components of the vaccine must show antigenic stability for 28 days after reconstitution.
- Why?
  - This type of vaccine would be ideally included in the future MDVP if antigenic stability is proven
  - If antigenic stability after reconstitution cannot be proven, then vaccine has to be discarded at the end of the session

- Antigenic stability after reconstitution criteria can be referred back to PSPQ SC during pre-qualification itself

Vaccine characteristics that are preferred (but do not affect PQ)

- **Preferred**
  - Are intended to indicate what WHO and national immunization programmes would want in a best case scenario and expect in the future
  - Are meant to guide vaccine manufacturers during the development of the new vaccine formulations
  - A vaccine not complying to preferred characteristics would not be prevented to be further reviewed for pre-qualification
  - However with time, a preferred characteristic may in future revisions be deemed to become critical

Table 4: Preferred vaccine characteristics and characteristic values

Characteristic	Applies to...	Value
Maximum packed volume	All vaccines	A smaller packed volume is preferred. Where appropriate, components should be packed/shipped together, e.g. for ready-to-use presentations: pre-filled AD syringe with needle, etc.Packaging devices should be considered, to assure components are shipped together, e.g. vial clip. (WHO EPI, VPPAG gPPP: maximum packed volume; see Guidelines on the international packaging and shipping of vaccines11 .
Dose volume	Oral vaccines	Smaller volumes and standardized volumes are preferred (WHO EPI).
Doses per primary container, non-campaign setting	All vaccines	Vials with ≤10 doses per vial are preferred (WHO EPI, VPPAG gPPP: optimal number of doses per primary container, work programme).
Doses per primary container, campaign setting	All vaccines	Vials with ≥ 10 doses per vial are preferred (WHO EPI).
Doses per secondary container	All vaccines	Should reflect logistics schedule and needs in order to minimize stock accumulation at the peripheral level (WHO EPI).
Process of preparation for administration	All vaccines	Single component/ready to use (e.g. liquid) formats are preferred (WHO EPI). For multi-component vaccines, vaccines with a short and simple preparation process are preferred (WHO EPI).
Thermo stability / storage	All vaccines	Vaccines and diluents that can be stored for extended periods at temperatures above +8°C are preferred (TLAC).
Freeze sensitivity	All vaccines	Vaccines that are not damaged by freezing temperatures (<0°C) are preferred (TLAC).
Materials, primary and secondary packaging and injection material	All vaccines	Materials that minimize environmental impact are preferred (VPPAG gPPP: materials).
Secondary packaging, diluents and vaccines	Vaccines requiring reconstitution	Diluents and vaccines should have the same number of doses per secondary container.

Post-Prequalification monitoring activities

Briefing on Vaccine Prequalification for DCVMN manufacturers

Webinar 24 April 2014

World Health Organization

Outline of presentation

- Prequalified vaccines annual report (PQVAR)
- Variations
- Reassessment
- Targeted testing program
- Monitoring of vaccine quality and cold chain complaints
- Monitoring of Adverse Events following immunization (AEFI)

Prequalified Vaccine Annual Reports (PQVAR)

Annual submission of:

- **A summary of changes/variations to the product(s) that have been implemented since the previous annual report along with copy of NRA approval**
- **Testing results from the ongoing stability programme**
- **Production and distribution data.**
- **GMP inspections performed since the previous annual report.**
- **A summary update on implementation of post-PQ commitments**
- **Periodic Safety Update Report (electronic data only).**

Variations (1)

- Variations that may impact on the quality, safety and efficacy of the vaccine should be approved by the NRA and reviewed by WHO before implementation.
- Supply through the UN system only after confirmation by WHO
- UN procuring agencies will be informed by WHO (eg labels, inserts, additional presentations)
- WHO webpage may be updated

Variations (2)

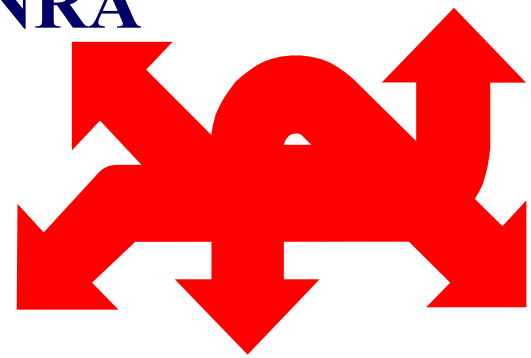
Manufacturer should submit:

- **Justification of the variation**
- **Documentation supporting the variation**
- **Timelines for implementation**
- **Approval by the National Regulatory Authority**

Additional information may be requested by WHO

REASSESSMENT EVALUATION PRINCIPLES

Reliance on NRA



Update information on production and QC

Verification of GMP compliance (site visit)

Targeted testing results plus specific testing if required

Monitoring field performance

Reassessment Process

- Review of updated PSF
- Targeted testing or specific testing of lots
- Monitoring for failure to meet specifications
- Consultation meeting with NRA
- Site visit to manufacturer jointly with NRA

Targeted testing program (1)

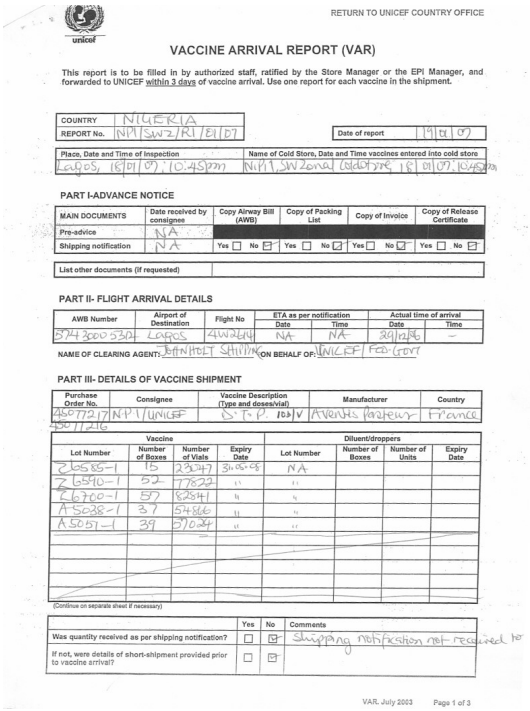
- Independent testing of vaccine lots supplied to UN at least once a year.
- Three to five lots (50-150 samples) selected by WHO from a list of products supplied to UN agencies will be requested from the manufacturer.
- The manufacturer will provide lot summary protocols and the NRA/NCL release certificate as appropriate, Manufacturers should commit to keep adequate number of retention samples for this testing program.

Targeted testing program (2)

- Manufacturers will, in any case be contacted for follow-up actions in case of failure to meet specifications.

- In the event of failure to meet the established criteria WHO will investigate the problem and provide the UN agency with written information, copied to the manufacturer and the NRA, on the actions that need to be taken.

Vaccine quality and cold chain complaints



RETURN TO UNICEF COUNTRY OFFICE

VACCINE ARRIVAL REPORT (VAR)

This report is to be filled in by authorized staff, ratified by the Store Manager or the EPI Manager, and forwarded to UNICEF within 3 days of vaccine arrival. Use one report for each vaccine in the shipment.

COUNTRY	NIGERIA
REPORT No.	NPI/SW2/RI/E1/07
Date of report	19/01/07

Place, Date and Time of Inspection	Name of Cold Store, Date and Time vaccines entered into cold store
Lagos, 18/01/07, 10.45pm	NPI, SW Zonal Cold Store, 18/01/07, 10.45pm

PART I-ADVANCE NOTICE

MAIN DOCUMENTS	Date received by consignee	Copy Airway Bill (AWB)	Copy of Packing List	Copy of Invoice	Copy of Release Certificate
Pre-advice	NA				
Shipping notification	NA	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
List other documents (if requested)					

PART II- FLIGHT ARRIVAL DETAILS

AWB Number	Airport of Destination	Flight No	ETA as per notification		Actual time of arrival	
			Date	Time	Date	Time
57430005304	LAGOS	4W2644	NA	NA	20/1/06	-

NAME OF CLEARING AGENTS: BENHOLT SHIPPING ON BEHALF OF: UNICEF/FED GOVT

PART III- DETAILS OF VACCINE SHIPMENT

Purchase Order No.	Consignee	Vaccine Description (Type and doses/vial)	Manufacturer	Country
450772/7 450771216	NPI/UNICEF	D.T.P. 10D/V	Aventis Pasteur	France

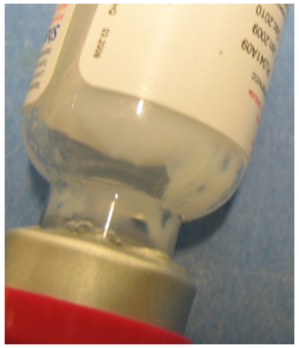
Vaccine				Diluent/droppers			
Lot Number	Number of Boxes	Number of Vials	Expiry Date	Lot Number	Number of Boxes	Number of Units	Expiry Date
Z1055-1	15	23347	31.05.05	NA			
Z6590-1	52	77822	"	"			
Z6700-1	57	85341	"	"			
A5038-1	37	54866	"	"			
A5051-1	39	57024	"	"			

(Continue on separate sheet if necessary)

	Yes	No	Comments
Was quantity received as per shipping notification?	☐	☑	Shipping notification not received by
If not, were details of short-shipment provided prior to vaccine arrival?	☐	☐	

VAR. July 2003 Page 1 of 3

Storage of the vaccine



OOS testing results:

Manufacturer NCLs

Shipping Manufacturing

Reports of AEFI

- **Increased reactogenicity**
  - **License and PQ withdrawal**
- **Coincidental/non related**
- **Programmatic**
  - **Vaccine handling procedures**

    Change of the inserts, training material and mock up samples
  - **Other programmatic reasons → Training needs**

Other issues of concern

Porcine circuviruses detected in 2 rotaviruses vaccines

Suspension of the supply

Addressing programmatic issues: VVM and cold chain

Addressing quality of PQ vaccines produced by manufacturers recalling other non PQ vaccines

4 Strategic Priorities

Secure the supply base for priority vaccines for developing countries

Facilitate access to quality products for developing countries

Improve efficiency of the prequalification procedure

Expand portfolio according to needs and options for introduction

Supply Security

Monitor closely the performance of prequalified vaccines including FU audits and conducting production capacity assessments

Actively seek for additional sources for priority vaccines

Secure the supply base for priority vaccines for developing countries

Establish risk mitigation strategies in case of failure of NRA

Access

Facilitate access to quality products for developing countries

Single standard of quality (WHO recommended requirements)

Consolidated investigation, reporting and communication in response to quality or safety concerns

Implementation of an expedited/ facilitated registration procedure for prequalified vaccines in receiving countries

Mechanisms to minimize wastage of vaccines, facilitate outreach (VVMs, MDVP, CTC)

Contribution development of Controlled Temperature Chain
Project Optimize: PATH/WHO

Mali, polio campaign, Photos: WHO/Olivier Ronveaux

National cold room during the campaign

Nicaragua, rotavirus delivery, Photo: Gates Foundation

Transport to health centre

e 53

World Health Organization

Allow specific vaccines to be kept and administered at ambient temperatures, up to 40ºC

For one, limited period of time immediately preceding administration

For vaccines meeting a number of stability conditions

Current focus: *vaccines administered during campaigns and special strategies: eg Meningo conjugate A, Yellow Fever, Pneumo, Hepatitis B, Rota, Cholera*

Manufacturers

Studies to enable on label use of vaccines under CTC and regulatory submissions

Regulators

Regulatory pathways

Review data for licensing under CTC

WHO

CTC Guidelines(Norms)

Work w/regulators to define Regulatory Pathways and prequalification (vPQ)

Field studies to show programmatic challenges , opportunities and impact of CTC (EPI-IVB)

Post-prequalification activities
- clinical

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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

Expedited procedure

Briefing on Vaccine Prequalification for DCVMN manufacturers

Webinar 24 April 2014

World Health Organization

4 Strategic Priorities

Secure the supply base for priority vaccines for developing countries

Facilitate access to quality products for developing countries

Improve efficiency of the prequalification procedure

Expand portfolio according to needs and options for introduction

Access

Facilitate access to quality products for developing countries

Single standard of quality (WHO recommended requirements)

Consolidated investigation, reporting and communication in response to quality or safety concerns

Implementation of an expedited/ facilitated registration procedure for prequalified vaccines in receiving countries

Mechanisms to minimize wastage of vaccines, facilitate outreach (VVMs, MDVP, CTC)

Expedited procedure for registration of WHO prequalified vaccines

Objective

Assist countries to adopt a facilitated, expedited procedure for the national registration of prequalified vaccines.

Who can benefit

- Countries procuring through UN agencies

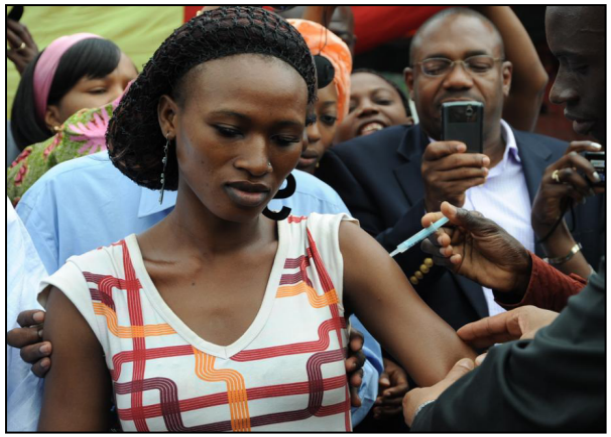
  and/or

- Countries procuring directly but requiring WHO prequalification as a tender condition

where the national regulations include provisions to shorten the normal regulatory approval process.

Implementation of Procedure for expedited review of imported prequalified vaccines for use in national immunization programmes (WHO/IVB/07.08)

Firstly used for registration of MenAfriVac in 26 countries of the belt



Polio end-game strategy

The Strategic Advisory Group of Experts on Immunization (SAGE), recommended in 2012 the withdrawal of the type 2 component of oral polio vaccine (OPV) from routine immunization programmes in all countries, facilitated by the introduction of at least one dose of IPV

Weekly epidemiological record wer 8901

Registration of IPV and bOPV in all countries

Expedited procedure

Standard procedure

Procedure for expedited review of imported prequalified vaccines for use in national immunization programmes (WHO/IVB/07.08

National Regulation and PQ

Documents
Forms 1a, 1b
PQ letter
List of countries

Samples (labels& inserts)
LSP, NRA release certificates

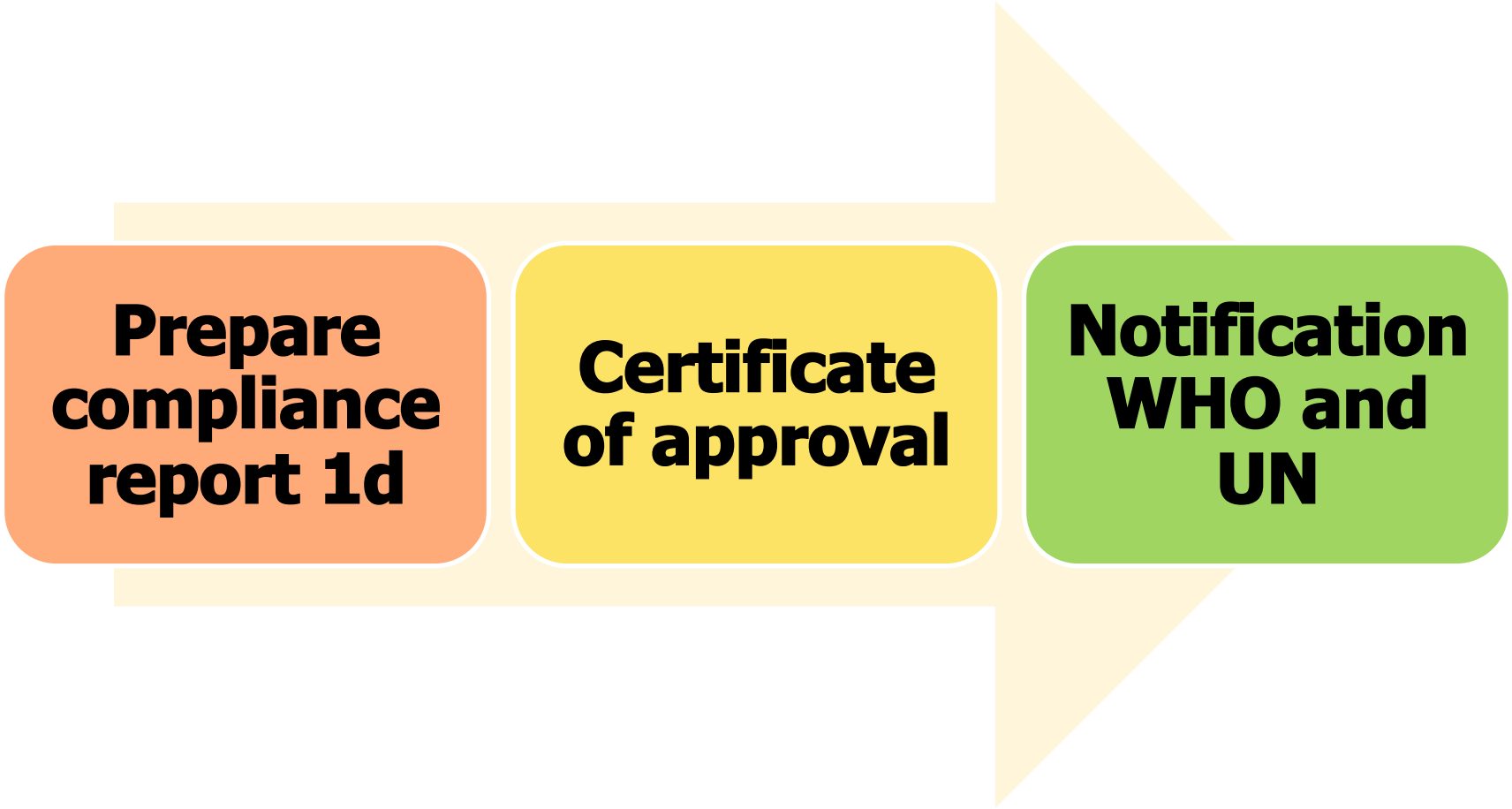
Acceptance of the application

Review docs

Visual inspection of samples (VVM)

Review labels& inserts
Review compliance specs LSP,

Procedure for expedited review of imported prequalified vaccines for use in national immunization programmes (WHO/IVB/07.08



Expedited procedure

Meningitis vaccines

Two workshops

26 member states (43 participants)

Other vaccines

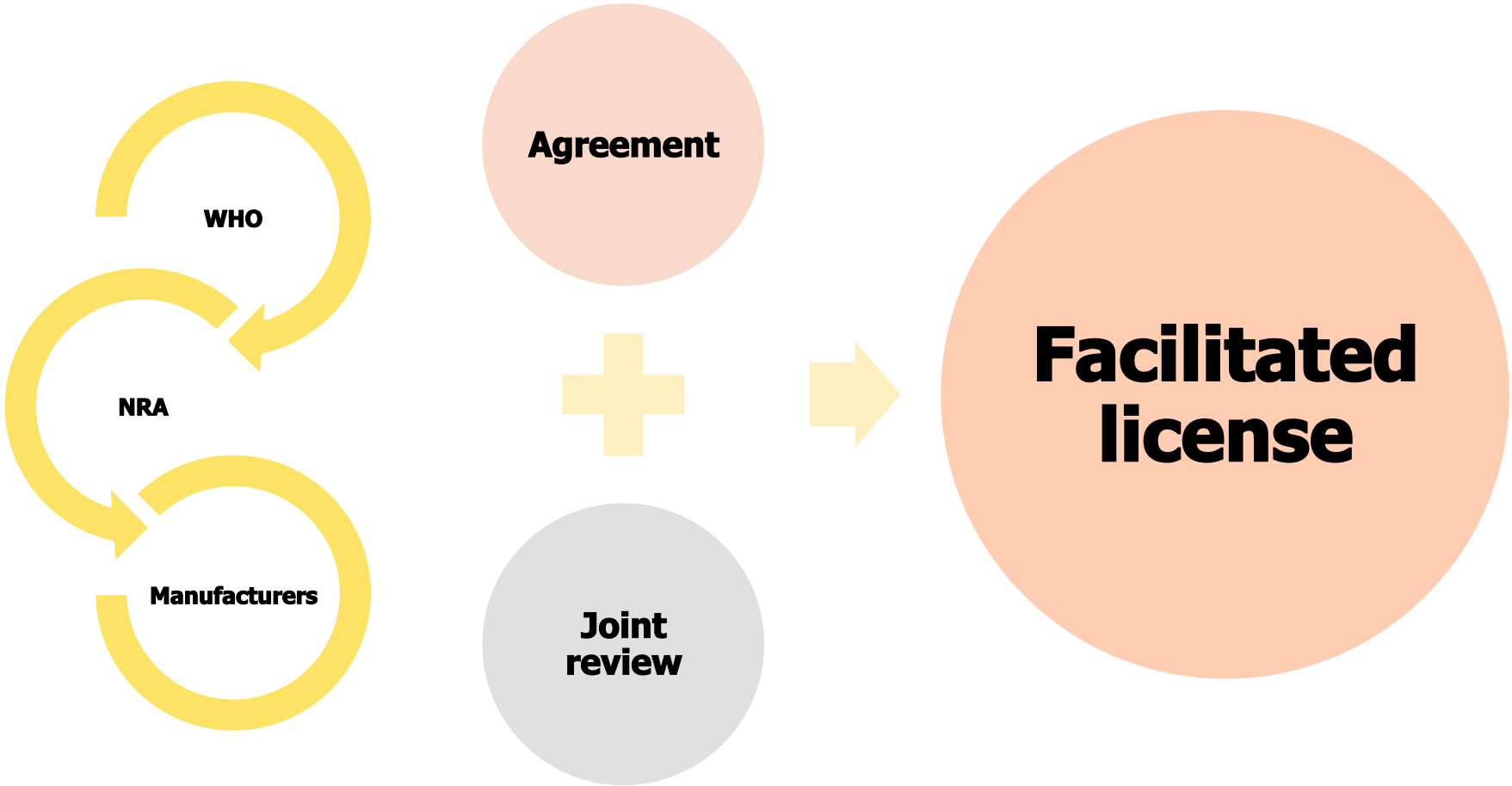
Four workshops (50 participants AFRO, EMRO and WPRO)

registrations applications for polio, pneumo and other vaccines

Internet based tool developed and hosted on WHO server for online submission, processing and monitoring of registration applications. 2 applications completed

One to one follow up for implementation

Revision of procedure




Vaccination
for health protection


Thank you

Contacts and References

- The PQT can have one-to-one discussions with manufacturers:
  - Prior to submission
  - During the evaluation process
  - Following prequalification

Your webinar presenters:

- Carmen Rodriguez rodriguezhernandezc@who.int
- Drew Meek meekd@who.int
- Olivier Lapujade lapujadeo@who.int

Vaccine Prequalification Website

- http://www.who.int/immunization_standards/vaccine_quality/pq_system/en/


"That's all Folks!"