Dedicated to public health

TETANUS CONTAINING VACCINE AND EXPERIENCE OF WHO-PQ AND NEW REGISTRATION IN OVERSEAS COUNTRIES

DCVMN-Medigen Workshop from 6-10 March 2017, Taipei

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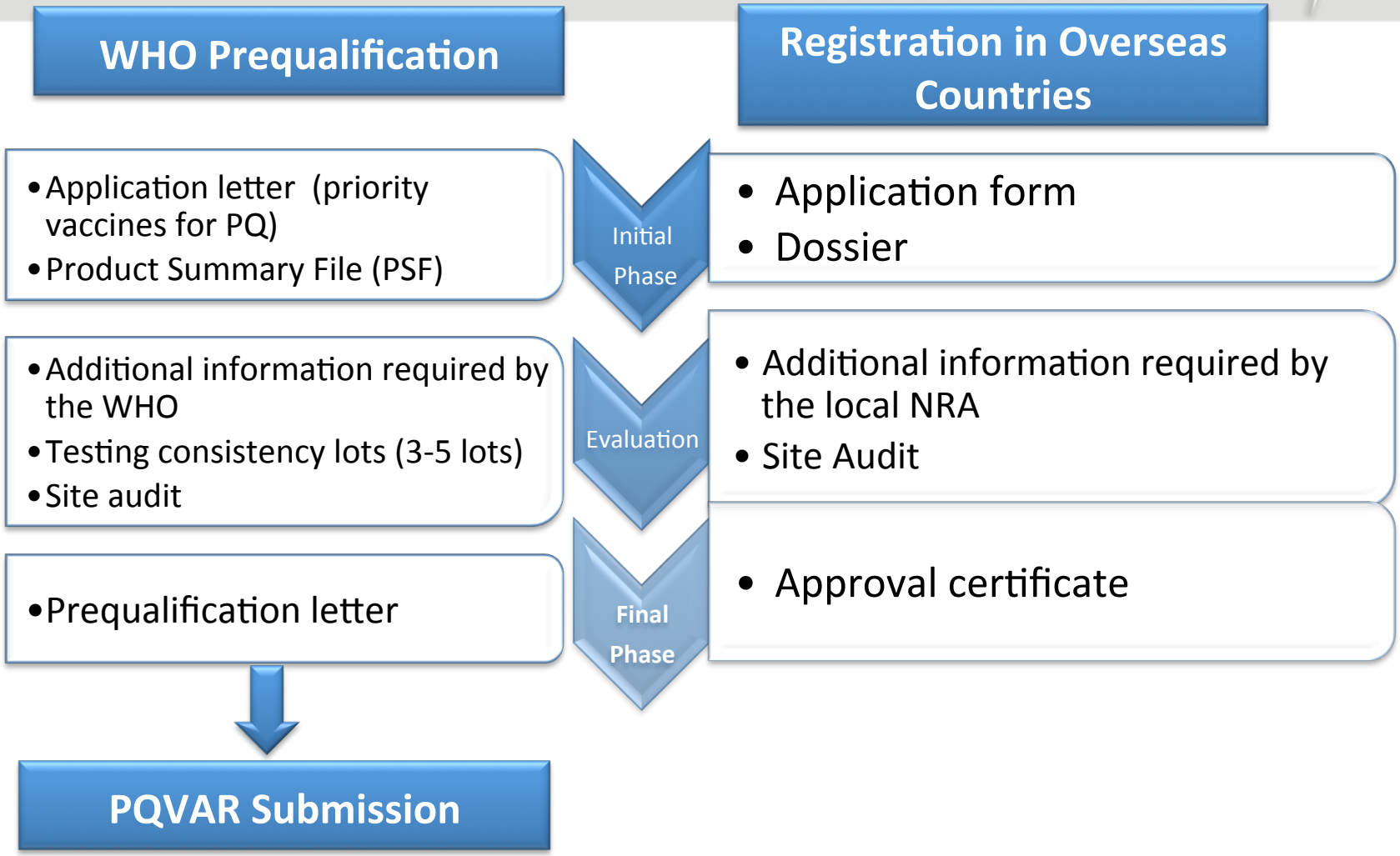
BACKGROUND

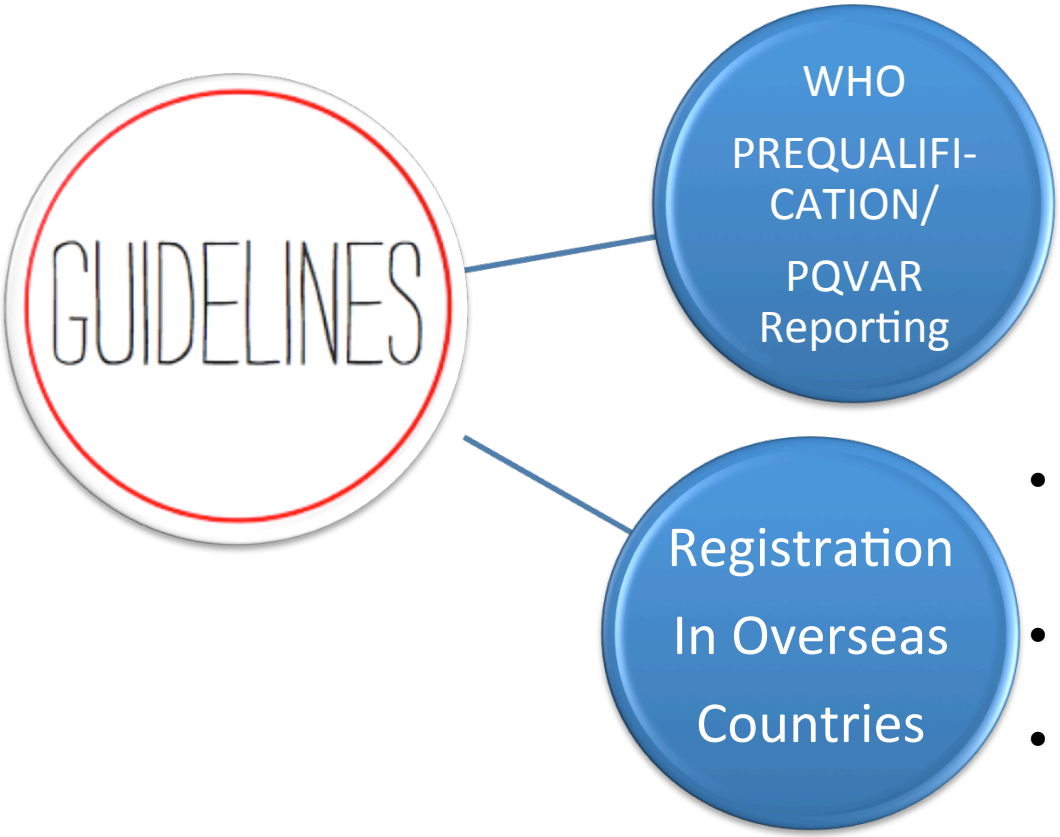
- WHO has recommended all its country members to use only vaccine that have met the WHO's requirements for immunization program.
- Requirements of registration in several countries that the only WHO-PQ products can be registered.
- All products (vaccines) supplied to UN Agencies should meet WHO Pre-qualification

TETANUS CONTAINING VACCINES

- **Tetanus containing vaccines of Bio Farma products that have obtained the PQ-WHO are as follows:**
  - **1999 : DT, TT vaccine**
  - **2001 : DTP vaccine**
  - **2004 : DTP-HB vaccine**
  - **2011 : Td vaccine**
  - **2014 : Pentabio vaccine (DTP-HB-Hib)**

Process flow outline





- **WHO TRS 978 Annex 6**
- **Procedure for assessing the acceptability, in principle, of vaccines for purchase by United Nations agencies, Feb 2012**

- **International Conference on Harmonisation Common Technical Document (ICH-CTD)**
- **ASEAN-Common Technical Document (ACTD)**
- **Specific format applied in local countries**

Auditee's response when conducted WHO site visit for PQ

- Required documents should be given as soon as possible
- Provide complete information
- At the end of audit should be asked whether there are critical finding
- Asked for time to clarify the findings, before starting on the next day audit

Auditee's prepared for clarification

do a comprehensive internal meetings

Discuss all findings, grouped according to the rules

- Correction → immediately repaired, prepare supporting data (documents, photos, etc.)
- Corrective action → create the most appropriate improvement plan, create a timeline

provide corrections and corrective action when clarification

Quality, Safety and Efficacy

- To ensuring the quality, efficacy and safety of the vaccines used in the program should be:

  - Meet WHO requirements
  - Production according to cGMP, GCP, GLP

WHO requirements

- Recommendations to assure the quality, safety and efficacy of tetanus vaccines (adsorbed). In:

  WHO Expert Committee on Biological Standardization. Sixty-third report

  Geneva, World Health Organization, 2014

  (WHO Technical Report Series, No. 980), Annex 5.

- Requirements for diphtheria, tetanus, pertussis and combined vaccines (revised 1989). In:

  WHO Expert Committee on Biological Standardization. Fortieth report

  Geneva, World Health Organization, 1990

  (WHO Technical Report Series, No. 800), Annex 2.

Important issues for ensuring the quality of DT-based combined vaccines

- The development of optimal formulations (including the choice of compatible adjuvants) and formulation conditions that lead to vaccines of adequate immunogenicity, acceptable reactogenicity, and stability, and that are appropriate for the intended use;

- The applicability of testing methods originally established for monocomponent vaccines;

- The suitability of using monocomponent reference materials in evaluating combined vaccines;

- The corresponding release and stability criteria.

WHO Requirements

For Safety and Efficacy refer to:

WHO guidelines on nonclinical evaluation of vaccines. In:

WHO Expert Committee on Biological Standardization. Fifty-fourth report Geneva, World Health Organization, 2005

(WHO Technical Report Series, No. 927), Annex 1.

WHO Guidelines on clinical evaluation of vaccines: In:

WHO Expert Committee on Biological Standardization. Fifty-second report Geneva, World Health Organization, 2004

(WHO Technical Report Series, No. 924), Annex 1.

Protectivity

No	Products	Number of Subjects	Protectivity (%)		
1.	DTP	160 (age 6 - 10 weeks)	D : 97.4	T : 100	P : 82.1
		83 (age 2 months)	D : 83.56	T : 100	
		160(age 2, 3 and 4 months)	D : 80	T : 100	
2.	TT	150 (age 10 – 18 years)	T : 100		
		56 (Pregnant Women)	T : 100		
3.	Td	150 (age 10 – 18 years)	D : 99.3	T : 100	

Distribution our products

- TT vaccine

No.	Year	Adsorbed TT Vaccine 10 ds (Doses)		
		Domestic	Export	
			Non Unicef	Unicef
1.	2015	14.062.310	3.907.000 ➔ (Malaysia) 140.000 ➔ (France) 750.600 ➔ (Egypt) 90.100 ➔ (Swaziland) 150.500 ➔ (Thailand) 100 ➔ (Oman) 300 ➔ (Saudi Arabia) 200 ➔ (Mozambique) 300 ➔ (Namibia) 1.000 ➔ (Iraq) 200 ➔ (Botswana)	11.813.000

Distribution our products

- Td vaccine

No.	Tahun	Adsorbed Td vaccine 10 ds (Doses)		
		Domestic	Export	
			Non Unicef	Unicef
1	2015	14.544.583	14.710.000 ➔ (Thailand) 200.000 ➔ (Kathmandu) 300 ➔ (Arabio) 1.000 ➔ (Iraq) 600 ➔ (Egypt) 30 ➔ (Nigeria) 100 ➔ (Oman) 100 ➔ (Philippine)	14.912.130

Distribution our products

- DTP vaccine

No.	Year	Adsorbed DTP Vaccine 10 ds (Doses)		
		Domestic	Export	
			Non Unicef	Unicef
1.	2015	3.650	701.500 ➔ (Thailand) 500.000 ➔ (Iran) 100.000 ➔ (Jamaica) 113.000 ➔ (Panama) 400.000 ➔ (Honduras) 7.700 ➔ (Bahamas) 3.500 ➔ (Barbados) 200.000 ➔ (Rep. Dominica) 9.500 ➔ (Trinidad) 4.161.200 ➔ (Mexico) 387.000 ➔ (Nicaragua) 250.000 ➔ (Columbia) 17.500 ➔ (Guyana) 60.000 ➔ (Uruguay) 1.500 ➔ (Antigua) 107.600 ➔ (Ecuador) 88.000 ➔ (Guatemala)	3.592.000

AEFI & PTC

In 2015

- No AEFI & PTC reported for TT and DTP Vaccines
- There is 1 AEFI reported for Td vaccine with classification : Coincidental unrelated


Thank You!