

# **PREQUALIFIED VACCINES ANNUAL REPORT**

**Briefing on Vaccine Prequalification for  
manufacturers**

**Buenos Aires, Argentina, 24 October 2016**

- Prequalified Vaccine Annual Product Report (**PQVAR**) is a part of the **continued assessment** of the **acceptability** of vaccines that are purchased by the United Nations procurement agencies.
- It is one of the obligations of a manufacturer after prequalification is granted to a vaccine as per PQ procedure TRS 978 - Annex 6, Section 8
- PQVAR is used as a tool for risk based reassessment decision making for prequalified vaccines.

# Components

- A. VARIATIONS
- B. STABILITY TEST RESULTS
- C. PRODUCTION & DISTRIBUTION DATA
- D. REGULATORY INSPECTIONS
- E. POST PQ COMMITMENTS
- F. PERIODIC SAFETY UPDATE REPORT (PSUR)

# Deadline for submission of PQVAR

- 3 deadlines for submission : 31 January, 31 May and 30 September
- Submission of the **first annual report** should be the **first submission deadline one year after** the date of **prequalification**, with **subsequent** submissions **each year** on the **same date**
- **Examples:**
  1. **PQ date on 15 July 2014 :**
    - First PQVAR submission date : next deadline after the PQ date + 1 year (15 July 2014 + 1 = 15 July 2015) which is 30 Sep 2015
    - Next PQVARs after first PQVAR : 30 Sep 16, 30 Sep 17....
  2. **PQ date on 22 Oct 2014:**
    - First PQVAR submission date : next deadline after the PQ date + 1 year (22 Oct 2014 + 1 = 22 Oct 2015) which is 31 Jan 2016
    - Next PQVARs after first PQVAR : 31 Jan 2017, 31 Jan 2018 ...

# Introduction to the PQVAR module

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Type or paste the following link in address tab of your browser to reach the PQVAR module.

[https://extranet.who.int/gavi/PQ\\_MAFRep/Login.aspx](https://extranet.who.int/gavi/PQ_MAFRep/Login.aspx)

Login screen will appear

# Login Screen

Common Login Screen both for Manufacturer and WHO

Individual Account Login and Password.

The screenshot shows a web browser window with the URL [https://extranet.who.int/gavi/PQ\\_MAFRep/Login.aspx](https://extranet.who.int/gavi/PQ_MAFRep/Login.aspx). The page header includes the World Health Organization logo and the title "Module for PQVAR Submission, Screening and Evaluation". On the left, there is a sidebar with "Permissions" and "ADS Account" links. The main content area features a "Log in..." section with a dropdown menu set to "WHO HQ (WIMS Account)", a "User Name" field containing "chawlaa", a "Password" field with masked characters, and a "Log In" button. To the right of the login form, there is a section titled "About the database:" showing "32 Submitted Reports". Below the login form, there is a section titled "Access for Manufacturers..." with instructions for creating an ADS account, requesting access, and logging in. A dropdown menu is also visible, showing options for "System User (ADS Account)" and "WHO Staff (WIMS Account)".

Log in...

WHO HQ (WIMS Account)

User Name: chawlaa

Password: .....

Log In

Module for PQVAR Submission, Screening and Evaluation

This application is introduced to streamline the procedure for annual reporting for the prequalified vaccines, with respect to submission, screening and evaluation. This electronic system is subject to WHO oversight.

Access for Manufacturers...

1) Create an Application Directory Service (ADS) account:  
Use the link on the left toolbar "ADS Account" to create an account.

2) Request access using your ADS account:  
Log in using your newly created ADS account. From the system.

3) Log in:  
Once access is granted, you will receive a confirmation e-mail, and you will be able to use that same account to log in.

System User (ADS Account)

System User (ADS Account)

WHO Staff (WIMS Account)

Log In

About the database:  
\* 32 Submitted Reports

# Manufacturer Entry Screen

- Company can create new report or view existing report details
- Manufacturer only has access to its own reports.
- Information concerning other manufacturers' submissions is not visible.

World Health Organization  
Module for PQVAR Submission, Screening and Evaluation  
Serum Institute of India Limited, India

Annual Reports  
New Report  
Reports

Annual Reports:

Filter Reports:

Manufacturers: Serum Institute of India Limited, India

Vaccine: All

You can always display all the available data by selecting [All] for the search criteria and clicking the "Filter" button.

Vaccine	NRA	Cancelled	Submitted
<a href="#">Diphtheria-Tetanus-Pertussis (whole cell)-Hepatitis B: Diphtheria ,Tetanus,Pertussis and Hepatitis B Vaccine Adsorbed</a>	India: Central Drugs Standard Control Organization		30/09/2015 10:42
<a href="#">Meningococcal A Conjugate: MenAfriVac</a>	India: Central Drugs Standard Control Organization		30/09/2015 10:42
<a href="#">Diphtheria-Tetanus-Pertussis (whole cell)-Hepatitis B-Haemophilus influenzae type b: Diphtheria, Tetanus, Pertussis, Hepatitis B and Haemophilus influenzae type b Conjugate Vaccine Adsorbed</a>	India: Central Drugs Standard Control Organization		30/09/2015 10:32
<a href="#">Diphtheria-Tetanus-Pertussis (whole cell)-Haemophilus influenzae type b: Diphtheria, Tetanus, Pertussis and Haemophilus influenzae type b Conjugate Vaccine</a>	India: Central Drugs Standard Control Organization		30/09/2015 10:28
<a href="#">Measles and Rubella: Measles and Rubella Virus Vaccine Live</a>	India: Central Drugs Standard Control Organization		30/09/2015 08:16
<a href="#">Measles, Mumps and Rubella: Measles,Mumps and Rubella Vaccine,Live ,attenuated</a>	India: Central Drugs Standard Control Organization		30/09/2015 08:16
<a href="#">Rubella: Rubella Vaccine ,Live,attenuated</a>	India: Central Drugs Standard Control Organization		30/09/2015 08:16

# New Report



[Vaccine Annual Report Cover:](#)

[Save](#)

## Report Identification

**Manufacturer Reference:**

## Manufacturer Information

**Name:** Serum Institute of India Limited  
**Acronym:** SII

**Address:**  
*Street:* 212/2 Hadapsar  
*City:* Pune  
*State:*  
*ZIP:* 411028  
*Country:* India

**Telephone:** 0091 20 2699 3900  
**Facsimile:** 0091 20 2699 3921  
**e-mail:** ssj@seruminstitute.com

## Responsible Officer

**Officer Responsible:**

**Contact Information:**

*Position:* Executive Director  
*Department:* Quality Assurance & Regulatory Affairs  
*Telephone:* +91 202 699 3900/26602379  
*Facsimile:* +91 202 699 3945/3921  
*Mobile:* +(91 98) 230 22248  
*e-mail:* ssj@seruminstitute.com  
*Secondary e-mail:* ssj@vsnl.com  
*Comments:* Direct tel 91 20 2660 2378, Fax Direct 91 20 2699 3945

## NRA Contacts for the Country of Manufacturer

**NRA:**   
*National Regularity Authority*

**Principal Contact:**

## NRA Contacts for the Country of Manufacturer

**NRA:**

*National Regularity Authority*

**Principal Contact:**

**Contact Information:**

*Position:* Drugs Controller General India (DCGI)  
*Department:* Ministry of Health & Family Welfare  
*Telephone:* +91 11 232 36965  
*Facsimile:* +91 11 23236973  
*Mobile:*  
*e-mail:* dci@nic.in  
*Secondary e-mail:*  
*Comments:* NRA. As of 21 Feb 2012 for 3 months  
Also Secretary & Scientific Director Indian Pharmacopeia Commission

**VaccineType: Brand Name**

## Product

**Vaccine Details:**

*Vaccine Type:* BCG  
*Vaccine Type Remarks:*  
*Brand Name:* BCG Vaccine

*Prequalification Status:* Current  
*Prequalification Date:* 5/29/2003 12:00:00 AM  
*Prequalification Status Remarks:* y

*Bulk Supplier:*

## Additional information

**Manufacturer Remarks:**





# Vaccine Annual Report Fields

Cover page provide information and this information is read only except the additional information Column both for Manufacturer and WHO

<b>Recapitulation</b>	<b>Manufacturer:, Vaccine, NRA</b>
<b>Report Identification</b>	<b>Manufacturer Reference:, WHO Reference:</b>
<b>Manufacturer Information</b>	<b>Name, Address, Telephone, Facsimile, e-mail:</b>
<b>Responsible Officer</b>	<b>Officer Responsible, Contact Information</b>
<b>NRA Contacts for the Country of Manufacturer</b>	<b>NRA, Principal Contact, Contact Information</b>
<b>Vaccine Type: Brand Name Vaccine Details:</b>	<b>Vaccine Type, Vaccine Type Remarks, Brand Name, Prequalification Status, Current Prequalification Date, Prequalification Status Remarks and Bulk Supplier</b>
<b>Additional information</b>	<b>Manufacturer Remarks, WHO Remarks</b>

# New Report



## Annual Report Content:

[\[ Cover Page \]](#) [\[ Content \]](#) [\[ Attachments \]](#) [\[ Performance/Manufacturing Information \]](#)

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### Recapitulation

Manufacturer:

Vaccine:

NRA:

[Save](#)

	P	NA	Manufacturer Comments
<b>A. Variations Summary</b> - Not more than 1000 words	<input type="checkbox"/>	<input type="checkbox"/>	
<b>B. Stability Programs Test Results Summary</b> - Not more than 1000 words	<input type="checkbox"/>	<input type="checkbox"/>	
<b>C. Production and Distribution Summary</b> - Not more than 1000 words	<input type="checkbox"/>	<input type="checkbox"/>	
<b>D. Regulatory Inspections Summary</b> - Not more than 1000 words	<input type="checkbox"/>	<input type="checkbox"/>	
<b>E. Post PQ Commitments Summary</b> - Not more than 1000 words	<input type="checkbox"/>	<input type="checkbox"/>	
<b>F. Periodic Safety Update Report Summary</b> - Not more than 1000 words	<input type="checkbox"/>	<input type="checkbox"/>	

# Report Fields

- ✓ Variations
- ✓ Stability Programs Test Results
- ✓ Production and Distribution Summary
- ✓ Regulatory Inspections Summary
- ✓ Post PQ Commitments Summary
- ✓ Periodic Safety Update Report Summary

# New Report- Attachments



Annual Report Attachments:

[\[ Cover Page \]](#) [\[ Content \]](#) [\[ Attachments \]](#) [\[ Performance/Manufacturing Information \]](#)

Recapitulation

Manufacturer:

Vaccine:

NRA:

Upload

New Attachment

Name:

*Maximum file size = 12MB per attachment.*

File:

Choose File No file chosen



# Annual Report Monitoring

To Access the information

- Either select the vaccine or of manufacture and hit the filter button
- Or directly click on the vaccine name to access the information.

World Health Organization

Module for PQAR Submission, Screening and Evaluation

Annual Reports

Filter Reports:

Manufacturer: All

Vaccine: All

Filter

You can always display all the available data by selecting [All] for the search criteria and clicking the "Filter" button.

32 Report(s)

Vaccine	Manufacturer	NRA	Submitted	Screened	Clinically Evaluated	Evaluated	Information Required	Closed
<a href="#">Hepatitis B: Hepatitis B Vaccine (rDNA) (Adult)</a>	Serum Institute of India Limited, India	India: Central Drugs Standard Control Organization	20/02/2013 06:54	15/04/2013 15:23	11/06/2013 15:33	31/05/2013 10:34		04/07/2013 15:09
<a href="#">Hepatitis B: Hepatitis B Vaccine (rDNA) (Ped)</a>	Serum Institute of India Limited, India	India: Central Drugs Standard Control Organization	20/02/2013 07:06	15/04/2013 15:25	11/06/2013 15:54	31/05/2013 10:40		11/06/2013 15:55

# Annual Report Monitoring

<u>Vaccine</u>	<u>NRA</u>	<u>Cancelled</u>	<u>Submitted</u>	<u>Screened</u>	<u>Clinically Evaluated</u>	<u>Evaluated</u>	<u>Information Required</u>	<u>Closed</u>
<a href="#">Diphtheria-Tetanus-Pertussis (whole cell)-Hepatitis B: Diphtheria, Tetanus, Pertussis and Hepatitis B Vaccine Adsorbed</a>	India: Central Drugs Standard Control Organization		30/09/2014 13:22	08/12/2014 15:38	30/04/2015 17:00	30/04/2015 17:21	01/05/2015 11:05	04/05/201 10:15

# Vaccine Annual Report Evaluation

After Clicking the Content Tab Content Page opened

WHO Module for PQVAR Submission, Screening and Evaluation

Annual Reports

Reports

Recapitulation

Manufacturer:

Vaccine:

NRA:

\* Read Only \*

A. Variations Summary - Not more than 1000 words	P	NA	Manufacturer Comments	Screening Comments	Evaluation Comments
<p>Total no. of changes: 18 nos.</p> <p>Changes related to Drug substance (HBsAg): No change since the changes listed in last PQVAR submitted in October 2012 as a part of DTP+Hib+Hb vaccine.</p> <p>Changes related to Drug Product (Hepatitis B Vaccine</p>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		ampoules and Limit of PBS is changed from 0.25 EU/ml to 1 EU/ml for bacterial endotoxin test by KIA are relaxed. Rationale for	There have been several changes that needed to be assessed by WHO before implementation that were submitted to WHO. Some UN tender were
<p>B. Stability Programs Test Results Summary - Not more than 1000 words</p> <p>Ongoing stability data of Drug substance (HBsAg): 04 batches:</p> <p>The stability study of Lot No. 084-317, 084-318, 084-319 and 058K1086 is ongoing and are found to be stable up to 48, 48, 48 and 9 months respectively.</p>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		Sufficient information provided	Ok

# Common gaps and challenges 1/3

- No company reference number provided
- The focal point is not updated
- Submission not on time and offline
- Stability :
  - stability program not provided
  - lack of trend analysis for testing stability data
  - in case of a vaccine shelf life extension, the real time stability testing protocol should cover the new proposed shelf life.
- Distribution data format



# Common gaps and challenges 2/3

## ● Variations :

- table not provided or incomplete
- No reference to major variation (s) which must be submitted before any implementation
- Data not adequate
- Proof of acceptance of variation from responsible NRA not provided.

# Common gaps and challenges 3/3

- Status of PQ commitments not provided
- GMP inspection
  - brief outcomes not provided properly (only a list of inspections)
  - results such as satisfactory/not satisfactory/satisfactory with minor observations/recommendation etc... are expected
- PQVAR generated without QMS control.

# Performance and Monitoring for Risk Assessment for Requalification

Parameters:

*\* Filled by the manufacturer \**

No.	Parameter	Total annual production			
		No rejection	$\leq 0.2\%$	0.2 - 1 %	> 1% rejection
1.	% of lots rejected by manufacturer (Finished Product)	0	3	10	20

No.	Parameter	Annual target testing tested and failed		
		Compliance with specs.	No lot tested	Non-compliance with specs.
2.	WHO independent testing.	0	20	40

*\* Filled by the manufacturer \**

No.	Parameter	Number of annual variations			
		No variations	1 - 2 variations	3 - 4 variations	5 or more variations
3.	No. of variations (requiring pre-approval by NRA/HQ) in manufacturing, QC/QA or any other technical areas.	0	10	20	40

*\* Filled by the manufacturer \**

No.	Parameter	Number of annual interruptions		
		No interruptions	1 - 2 interruptions	3 or more interruptions
4.	Interruption to production	0	5	10

No.	Parameter	Total number of annual complaints received by WHO		
		No complaints	1 - 2 complaints	3 or more complaints
5.	Quality Complaints	0	20	40

# Performance and Monitoring for Risk Assessment for Requalification

No.	Parameter	Total number of unresolved/quality related AEFI		
		No AEFI	1 - 2 AEFI	3 or more AEFI
6.	Reported AEFI to WHO	0	20	40

\* Filled by the manufacturer \*

Filed by the manufacturer













No.	Parameter	Maturity level of QMS										
		First PQ date (Year)			PQed Products			WHO last satisfactory site audit (Year)			Warning letters/ Suspension/ Disqualification incidences	
		<= 1	<= 2	>= 3	<= 1	>= 2	>= 3	Major findings	Many minor findings	Satisfactory assessment (A few minor findings)	>= 1	0
7.	QMS	5	2	0	5	2	0	50	25	0	50	0

UN Agencies Supplied:

Total procurement by UN agencies for vaccine type *	<input type="text"/>	(Doses)
Doses supplied by mfg to UN agencies *	<input type="text"/>	(Doses)
No. of PQed vaccines C x (factor)	<input type="radio"/> <= 3 <input type="radio"/> 4 - 5 <input type="radio"/> >= 6	

\* Figures not older than 2 years are considered, and include UNICEF, PAHO, WHO-HQ procurement (the worst case in last two years).

Detection Factor:

No.	NRA (name - country)	Criteria											
		Functional for (years)			Signed agreements			Comm./responsiveness to/with WHO			Oversight of mgf.		
		 < 3	 3 - 5	 > 5	 N	 D	 Y	 L	 M	 E	 L	 M	 S
		25.0	10.0	2.5	25.0	10.0	2.5	25.0	10.0	2.5	25.0	10.0	2.5

# Risk based reassessment frequency

- Uses data from PQVAR
- Parameters:
  - Lots rejected, released.
  - Number (and type) of variations
  - Interruption of production (reasons)
  - Complaints/AEFIs
  - WHO experience: Number of years PQed, number of PQed products, last WHO satisfactory audit, suspensions/ warning letters
  - Volume of supply and number of other suppliers
  - NRAs: time of assessment as functional, agreements signed, responsiveness, oversight

# Summary

- Annual Reporting (PQVAR) is a post-PQ commitment by the manufacturer
- PQVAR is submitted on-line
- Evaluation managed by on-line module
- Data from PQVAR analysed to determine Risk Priority Number as a basis for Requalification.

● Thank You



World Health  
Organization