PREQUALIFIED VACCINES ANNUAL REPORT

Briefing on Vaccine Prequalification for manufacturers

Buenos Aires, Argentina, 24 October 2016

World Health Organization

- 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

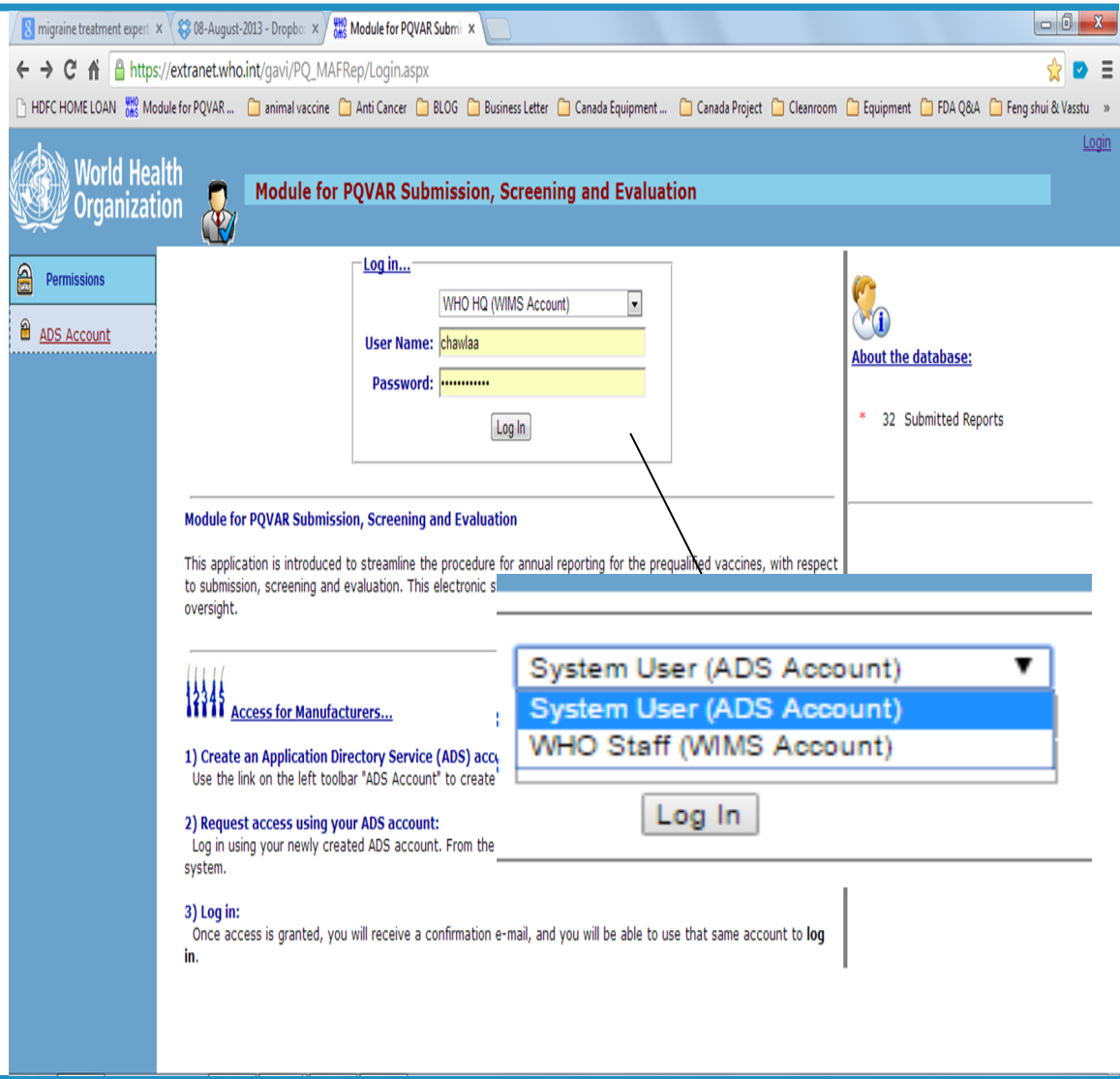
Type or paste the following link in address tab of your browser to reach the PQVAR module.

https://extranet.who.int/gavi/PQ_MAFRep/Login.aspx

Login screen will appear

Login Screen

- Common Login Screen both for Manufacturer and WHO
- Individual Account Login and Password.
- .



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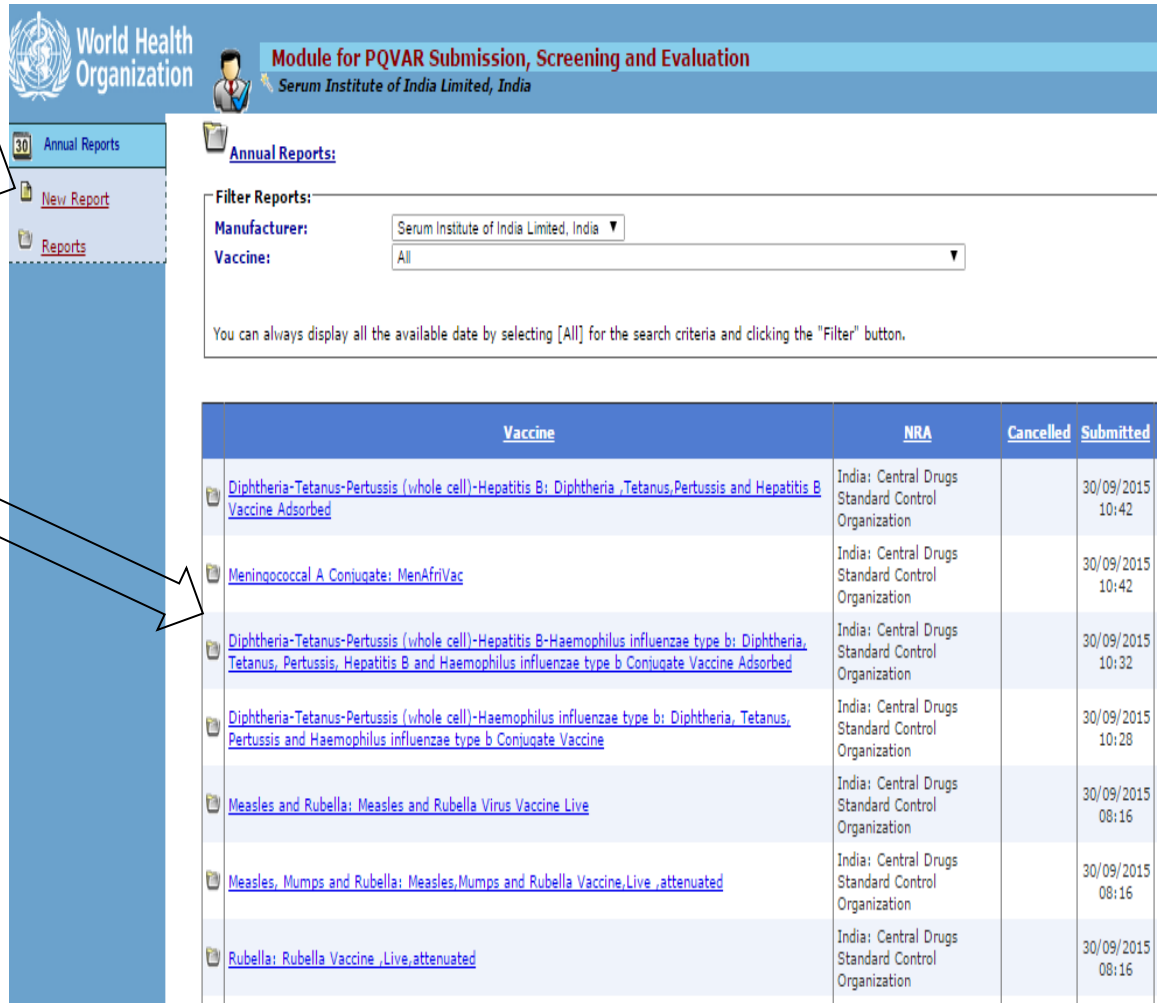
Manufacturer Entry Screen

- 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.



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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: Jadhav, Dr Suresh S.

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: India: Central Drugs Standard Control Organization
National Regularity Authority
Principal Contact: Singh, Dr Gynandra Nath

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National Regularity Authority
Principal Contact: Singh, Dr Gynandra Nath
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 Pharmacopea Commission

VaccineType: Brand Name BCG: BCG Vaccine

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:

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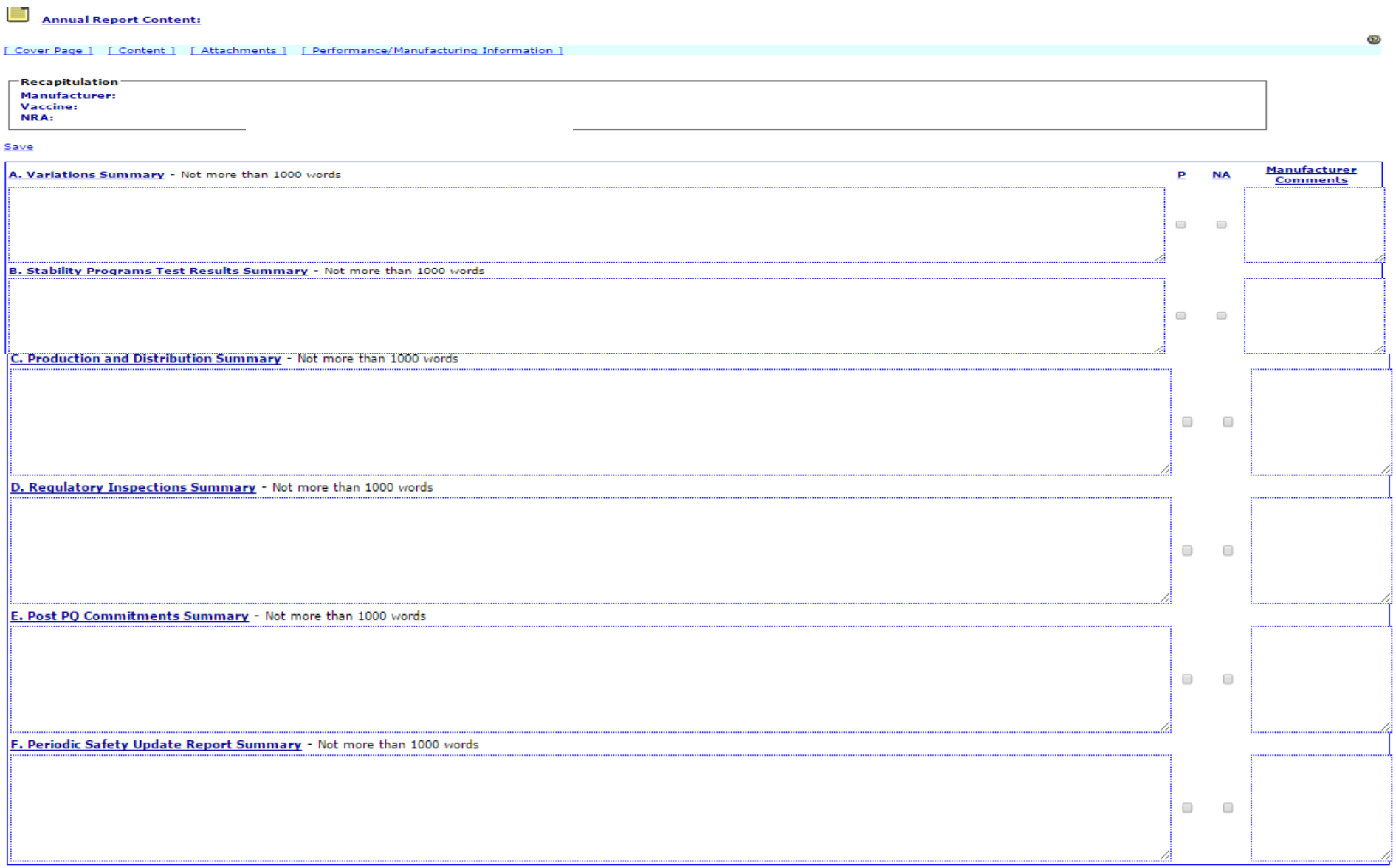
Vaccine Annual Report Fields

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

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

New Report



Organization

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

Maximum file size = 12MB per attachment.

Name:

File: Choose File No file chosen

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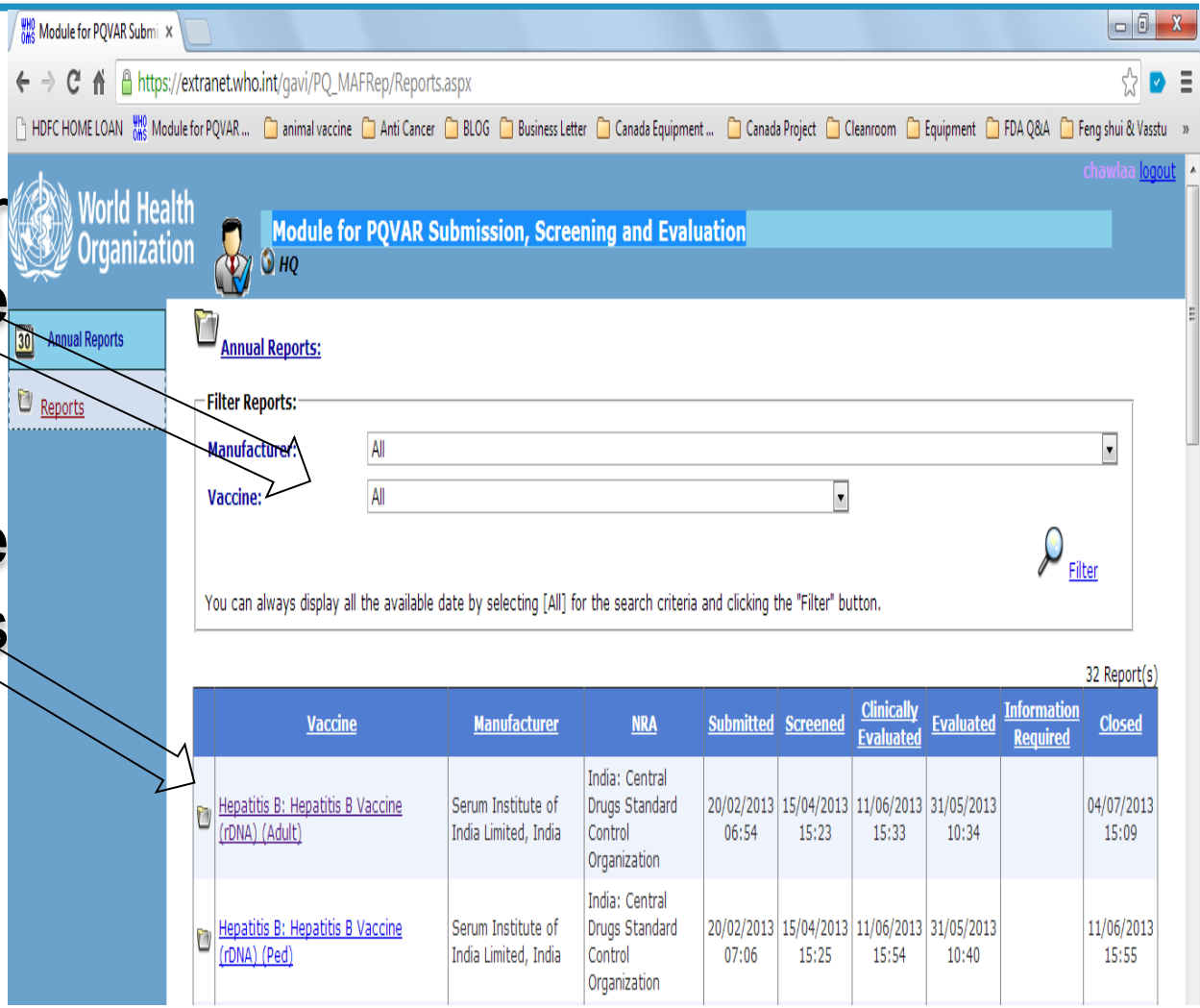
Annual Report Monitoring

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.



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Annual Report Monitoring

	Vaccine	NRA	Cancelled	Submitted	Screened	Clinically Evaluated	Evaluated	Information Required	Closed
	Diphtheria-Tetanus-Pertussis (whole cell)-Hepatitis B: Diphtheria ,Tetanus,Pertussis and Hepatitis B Vaccine Adsorbed	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

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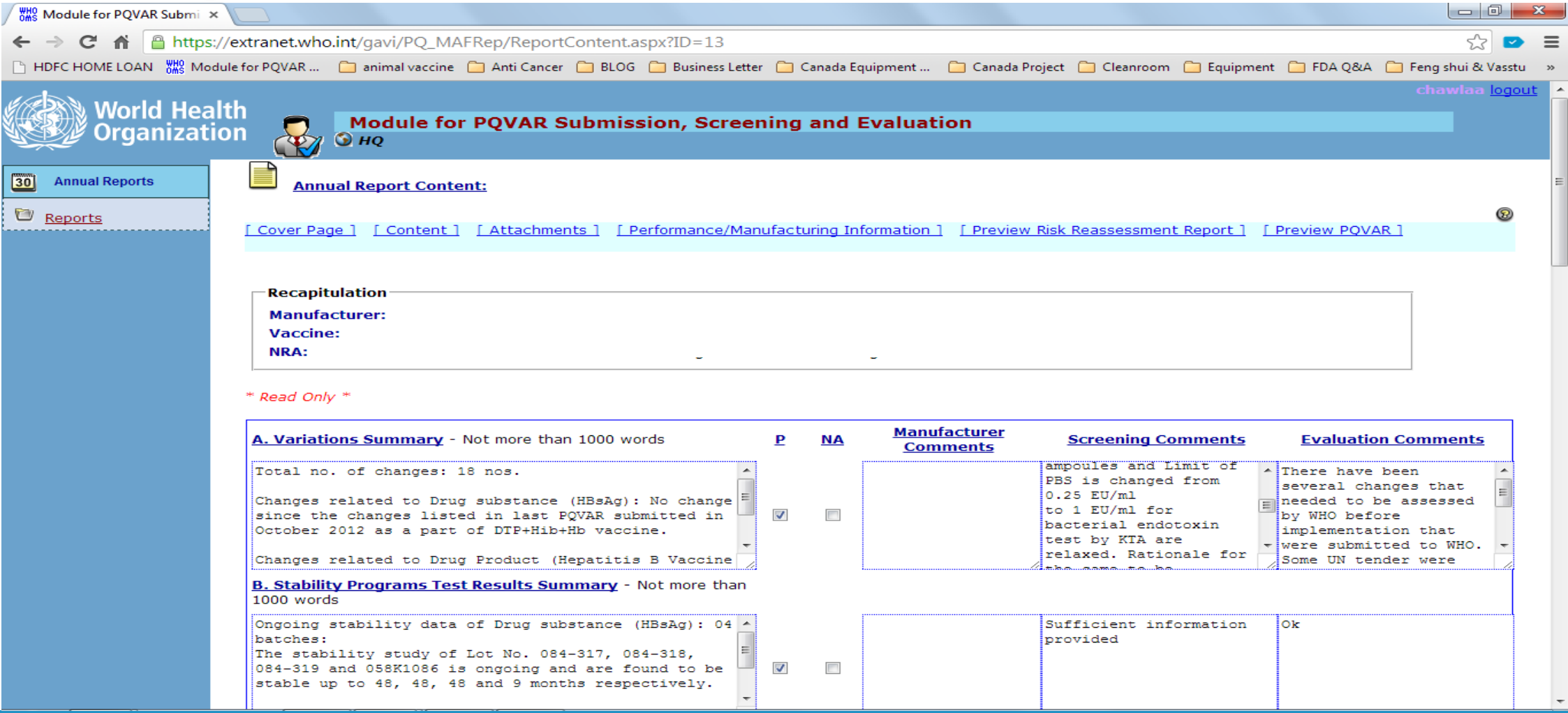
Vaccine Annual Report Evaluation

After Clicking the Content Tab Content Page opened



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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	○ <= 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 **

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 *	(Doses)
Doses supplied by mfg to UN agencies *	(Doses) ** Filled by the manufacturer **
No. of PQed vaccines C x (factor)	○ <= 3 ○ 4 - 5 ○ >= 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

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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

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