Promoting the **QUALITY OF MEDICINES** Plus

PCT NTD Dashboard-Operations Manual



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About PQM+

The Promoting the Quality of Medicines Plus (PQM+) Program is a five-year cooperative agreement between USAID and USP to sustainably strengthen medical product quality assurance systems in lowand middle-income countries. The program works to improve medical product quality through crosssectoral and systems strengthening approaches and the application of international quality assurance standards across the pharmaceutical system. By sharing scientific expertise and providing technical support and leadership, PQM+ helps create resilient and robust local health systems that address diseases such as HIV/AIDS, tuberculosis, malaria, and neglected tropical diseases, as well as improve maternal, newborn, and child health.

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Definition of Terms, Acronyms, and Abbreviations

CSV	Comma-Separated Values/Coma Delimited Values
EML	Essential Medicines List
GUI	Graphical User Interface
INN	International Nonproprietary Name
PCT	Preventive Chemotherapy
LMIC	Low-middle Income country
NTD	Neglected Tropical Diseases
MRA	Medicines Regulatory Authority
NMRA	National Medicines Regulatory Authority
PQM	Promoting the Quality of Medicines program
PQM+	Promoting the Quality of Medicines Plus Program
PMS	Post Marketing Surveillance
PMQS	Post Marketing Quality Surveillance
QA	Quality Assurance
QC	Quality Control
RB-PMS	Risk-based Post-marketing Surveillance
USP	United State Pharmacopeia
WHO	World Health Organization

1. PCT NTD Dashboard Overview

Limited information and data available in public domain on source (country of origin, manufacturer, supplier, distributor), dosage forms and strengths, legal status, guality, availability, shortage, and price of preventive chemotherapy (PCT) NTD medicinal products for both APIs and FPPs, It will be useful to regulators, manufacturers, suppliers, procurement agencies and other organizations working to increase the supply of quality assured PCT NTD medicinal products if a data-base is available publicly in one location e.g. USP PQM+ website. To ensure this information is widely available and accessible freely to inform a harmonized procurement decision of involved stakeholders, the procurement agencies. PQM+ will develop a publicly available database repository to store and regularly update data. PQM+ will coordinate with WHO and other key stakeholders to ensure information collected and displayed is complementary. Through this database, a dashboard will be developed with graphic visualization of key data representations (see more details under Dashboard Section). Information will be disseminated periodically, as changes occur. In case of shortages of particular products, an email alert will be sent to the list of interested clients, those that subscribe to the site. The database will house important information on quality-assured products which include the WHO prequalified products; the Expert Review Panel (ERP) reviewed products (risk categories 1 and 2); those products that have been approved by SRAs and WHO Listed Authorities (WLA).

The main purpose of this database and dashboard is to assist MRAs, procurement agencies, manufacturers, suppliers, MRAs, relevant programs and initiatives (national and regional) that are interested in collecting necessary information and/or involved in the planning, forecasting of needs, procurement and supply of PCT NTD pharmaceutical products.

A few additional features and platform will be built in the dashboard, these may include: 1) Frequently asked questions and answered to clients on product's generic product manufacturing process, formulation, GMP, quality control, etc.; and 2) Clients may use this additional feature and platform to ask specific technical questions(s) on the above and will be receiving response(s) from PQM+ in a given time.

1.1. Users' Roles

Following are the PCT NTD Dashboard user roles:

1. General Public

This is a role that's available for general public and there is no requirement to get registered or obtain any login credentials. Open access is given to general public to search PCT NTD products as per given parameters.

2. Getting Started

2.1. Graphical User Interfaces (GUI)

2.1.1. Get Familiarized with Graphical User Interfaces

After entering the web address for *PCT NTD Dashboard* URL, (<u>https://ntd.pqmplustools.com/</u>) provided by PQM+, the following landing page will be displayed to user:



Image – 01 – Landing Page Interface

Following is an image of landing page which is further described as shown below.



Image – 1.1 – Details of Landing Page – Links indication

Following numbers show the related interfaces:

- 1. Logo of USAID PQM+, USP
- 2. NTD Dashboard Logo
- 3. Links to access NTD Dashboard



Image – 1.2 – Details of Landing Page – Access Links

- a. Free Subscription
- b. Login as subscribed user
- c. Public Access
- 4. Link to Terms of use, Privacy Policy, Disclaimer and Contact Us

Terms of Use | Privacy Policy | Disclaimer | Contact Us

- Image 1.3 Details of Landing Page Other Links
 - 5. Link to **Feedback** form



Image – 1.4– Details of Landing Page – Feedback Link

User will click on this link and following feedback form will be displayed:

Feedback	×
Thank you for visiting our NTD MID Dashboard, your feedback is important to us for improving the feature, functionality and the information it contains. Please respond to the following questions: What information do you find most useful?	,
What information would you recommend to be added in the dashboard?	
What features/ functionality need improvement?	4
We appreciate your feedback.	
Submit	

Image – 1.5 – Details of Landing Page – Feedback Form

User will fill out this form and this feedback form will go to NTD Dashboard Support team.

Contact Us form is also available for the NTD Dashboard visitors who can contact NTD Dashboard support team for any query. User will click on the **Contact** Us link and following form will be displayed to user to input the details:

Contact Us			×
* Name		* Email	
* Message Valid	ation code: Enter the code abo Can't read the image	ve here : ? click here to refresh.	Į.
Submit			

Image – 1.6 – Details of Landing Page – Contact Us Form

Free Subscription: Hover you mouse on this button and user can see the details of this feature before clicking on this button. Click on this **Free Subscription** button. The following instructions interface is displayed; subscriber needs to read the instructions carefully before proceeding to the subscription form:

×

Instructions for new registration

Instructions on how to request a new user account for NTD MID database Subscribers can request a NTD MID user account.

To obtain access to NTD MID database:

- 1. Click the "free subscription" button to access the form and complete all requested fields
- 2. Upon completion of your request, you will be notified via e-mail to the address provided in the form
- 3. For any questions or clarifications, please click the "contact us" button on the landing page

USP respects your privacy and takes seriously its responsibilities regarding the privacy and security of your information. Please refer to the bottom of the NTD MID homepage for detailed information on USP privacy policy.



Image – 02 – Free Subscription – Instructions Interface

After reading the instructions, click on the **Proceed** button to open the registration form as displayed below:

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	NTD	MID		
	Register a n	ew account		
* Category				
Select	~			
Pre-Qualification Ref. No.	ERP Ref. No.		SRA / WHO-ML3 Ref. No.	
* Country		Address		
Select Country	~			
* State / Province		* City		
Zip Code		≭ First Name		
Middle Name		* Last Name		
* Phone		* Additional Phone	8	
Fax No.		* Additional Email		
★ Email (will be used to login)				
Remarks				
Remarks				
				li
Validati	ion code:	vn		
	Enter the c	ode above here :		
	Can't read t	he image? click here to	refresh.	
I agree to the terms			Register	
I already have an account				
opyright © 2022 The U.S. Pharmacopeial Con	avention All rights rese	med Terms of Use 1	Privacy policy	

Image – 03 – New Subscription Form

Note: All fields indicated with (*) in this form are mandatory and subscriber must fill.

This subscription form will go to NTD Super Admin who will review the form and same will approve or disapprove the subscription. On approval, subscriber will get an email with login credentials for the NTD Dashboard.

If user has already subscribed and has valid login credentials from NTD Dashboard Super Admin, then user can click on **I already have an account** and login interface will be displayed as below:

Promoting the Quality of Medicines Plus (PQM+)
Sign In Email
Sign in I forgot my password Neglected Tropical Disease

Image – 04 – Login Interface

Input the valid user Id and password click on **Sign In** button. If user forgets his /her password then, user can use the **I forgot my password** link to reset the password by following the instructions as shown below:

	NTD MID	
	You forgot your password? Here you can easily retrieve a new password.	
	Email	
	Validation code: Enter the code above here : Carit read the image? click here to refresh.	
	Request new password	
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Image – 05– Login Interface – Reset Password

User has to input validation /security code, the **Validation Code** given at the bottom of the page. If this code is not visible enough to be read, user can click on the Refresh link to generate a new code. Click on **Reset New Password** button.

Note: Applicant must be verifiable or known WHO, UNICEF, USFDA or Manufacturer /Supplier. Otherwise, applicant must ensure USP has received an email from an authorized representative

(director level or above) of the respective organization designating applicant as the focal person to be granted access on behalf of the same organization.

After the user account is activated, the applicant user will get an email with auto-generated login credentials.

Enter Login credentials into the Login Interface #2 as indicated in earlier section.

3. General Public Core Functions/Features

Following are core functions/features for General Public role:

3.1. Search PCT NDT Product

General public user will open the main landing page of PCT NTD Dashboard and from there, user will click on the **Public Access** button as highlighted below:



Image – 05 – Landing page with Public Access Button highlighted

When user will click on the **Public Access** button, the searching page will be open as shown in the below image:

NTD		0
Q Database Se	earch	← Go Baok
		Last Updated On: 25-Jan-22
Click on the tabs below	w for summary information of NTD products or use S	Search fields for more details.
FPP Global Outlook	API Global Outlook Expression of Interest C	Other Resources Product Updates
Search Type		PCT NTD Products
Select	~	Select PCT NTD Products
		Submit
_		
_		
Copyright © 2022 The U.S	S. Pharmacopeial Convention. All rights reserved.	NTD Version 3.1.0-rc Powered By: USP PQM+ (usp.org)

Image – 06 – Searching page

User can search NTD products details by selecting the following types from the **Search Type** dropdown:

API

FPP

Procurement

Manufacturer

In addition to this, if user want to see a specific NTD product, user can select from the **PCT NTD Product** dropdown as shown below:

Search Type	PCT NTD Products	7
FPP V	Albendazole V	
Reference No.	Strength	Dosage Form
		Select Dosage Form *
CAS	IDMP	UNII
Select CAS *		Select UNII *
NDC	Applicant Name	Manufacturer Name
Select NDC *		
Drug Master File	API Source	Legal Status
		Select Legal Status *
Packaging	Storage Condition	

Image – 06.1 – Searching page - Parameters

Once user selects the **Search Type**, all other relevant parameters are displayed. These are other filtration parameters that can be used to further narrow-down the search against any search type as desired.

Once all required parameters are set, user will press the **Submit** button and relevant out data will be displayed just below the **Submit** button as shown below:

TD																			
Select						•	Select PC1	NTD Products					~						
																		Submit	Ī
																			0
Report C	Dutput																		ĺ
Сору	CSV Exc	el PDF Print	Column visi	ibility 👻													Search:		
S.# 1↓	Source ↑↓	Reference / Certificate / Application No.	Strength ↑↓	Dosage Form ↑↓	inn 14	CAS ↑↓	IDMP 11	UNII 14	NDC 1	BCS Classification ↑↓	ATC Code ↑↓	DDD 11	Applicant Name ↑J	Manufacturer Name ↑↓	Manufacturing Country î↓	Drug Master File î↓	API Source î∔	Legal Status ↑↓	
1.	WHO	NT005	400 mg	Tablet	Albendazole	54965- 21-8		F4216019LN				0.4 g	Cipla Ltd, Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai, Maharashtra, 400 013, India	Cipla Ltd	India	DMP	Cipla Ltd, Plot D-7 MIDC Industrial Area, Kurkumbh Village, Taluka- Daund, Pune District, Maharashtra, 413Å 802, India		
2.	Tanzania MDA (ML3)	TAN 07,314 P02X IND	400 mg	Tablets	Albendazole	54965- 21-8		F4216019LN				0.4 g	Indoco Remedies Limited	Indoco Remedies Limited	INDIA			Tanzania (WHO- WLA	

Image – 06.2 – Searching page – Result output

On top-left of the output /result table, following data features are available:



Image – 06.3 – Searching page – Result output

User can have the results in the following manner:

- 1. Export results in **PDF** format
- 2. Export results in **Excel** format
- 3. Export results in **CSV** format
- 4. **Copy** results in Clipboard
- 5. **Print** results on the attached printer

Note: User can also hide /unhide the visibility of columns in the result output table.

Furthermore, there are total 5 tabs on this interface as shown below where user can click and see the summary level information of each PCT NTD product:

NTD		
Q Database Sear	rch	← Go Back
-		
Click on the tabs below for	summary information of NTD products or use Search fields for n	Last Updated On: 25-Jan-22
î	PI Global Outlook Expression of Interest Other Resources	
TTTT GIODAT CULLOOK A		
Search Type		T NTD Products
Select	*	Select PCT NTD Products
		Submit
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Image – 06.3 – Searching page – More Searchable Tabs FPP Global Outlook of PCT NTD Products Tab

Column Visibility	ession of interest Other Resources Product Updates PCT NTD Product	PQ / ERP Approved	Products Approved (ML3, ML4, SRA or	Available Manufacturers	In Shortage	
•	Albendazole	8	WLA) 62	-		
	Mebendazole		45	3	No	
	Ivermectin	3		9	No	
	Praziquantel	8	32	2	No	
		4	14	8	No	
	Diethylcarbamazine	1	1	1	No	
	Tetracycline eye ointment	0	1	0	No	
	Azithromycin	27	224	32	No	
h Type		PCT NTD Products		~		-

Image – 06.4 – Searching page – FPP Global Outlook Summary View

Note: User can hover the mouse on each column of the table to view the description of each column as shown below:

k on the tabs below for summary information of	NTD products or use Search fields for more details.					Last Updated On: 31-E
PP Global Outlook API Global Outlook Exp	ression of Interest Other Resources Product Updates					
Column Visibility	PCT NTD Product	PQ / ERP Approved	Products Approved (ML3, ML4, SRA or WLA)	Available Manufacturers	In Shortage	
	Albendazole	a standardized evalu	products that went through uation and attained WHO us / Interim expert review	3	No	
Mebendazole		panel approved proc and categorized acc purpose	duct based on quality risk cordingly for procurement	9	No	
	Ivermectin	8	32	2	No	
	Praziquantel	4	14	8	No	
	Diethylcarbamazine	1	1	1	No	
	Tetracycline eye ointment	0	1	0	No	
	Azithromycin	27	224	32	No	
ch Type		PCT NTD Products				

Image – 06.5 – Searching page – FPP Global Outlook Summary View – Mouse-hover view

User can also set columns' visibility by hovering the mouse on **Column Visibility** and then by selecting /unselecting the column names as appropriate.

API Global Outlook of PCT NTD Products Tab

k on the tabs below for summary information of NTD products or u PP Global Outlook API Global Outlook Expression of Interest			Last Updated On: 25-Jt
	Available Manufacturers	API Approved	In Shortage
Albendazole	7	7	No
Mebendazole	7	8	No
lvermectin	7	7	No
Praziquantel	18	21	No
Diethylcarbamazine	0	0	No
Tetracycline eye ointment	0	0	No
Azithromycin	1	1	No
ch Type lect	PCT NTD Products Select PCT NTD Products	~ v	

Image – 06.6 – Searching page – API Global Outlook Summary View

Expression of Interest Tab

NTD	
Q Database Search	← Go Back
Click on the tabs below for summary information of NTD products or use Search fields for more details.	Last Updated On: 25-Jan-22
FPP Global Outlook API Global Outlook Expression of Interest Other Resources Product Updates	
▲ POM+ Expression of Interest	
▲ VHO Expression of Interest	
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Image – 06.7 – Expression of Interest

Other Resources Tab

NTD	
Q Database Search	← Go Back
Click on the table below for summary information of NTD products or use Bearch fields for more details.	Last Updated On: 31-Dec-2022
PPP Global Outlock API Global Outlock Expression of Interest Other Resources Introduct Lipbases	
WHO POLINLINS LIE DA Bootese Lat Lah WHO AND Populate 2011-2020	
Product Information Second EEPEN L Departed Secold Protect & Emission of NTDs NTDs NTDs NTDs NTDs NTDs NTDs NTDs	
UNCEE Supply Catalogue In: MD Medicines 0:855 Eligible Executiv Medicines List	
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Image – 06.8 – Other Resources

Product Updates Tab

NTD O
Q Database Search
Last Updated On: 25-Jan-22
Click on the tabs below for summary information of NTD products or use Search fields for more details.
FPP Global Outlook API Global Outlook Expression of Interest Other Resources Product Updates
Product Update
Copy CSV Excel PDF Print Column visibility*
S.# 1 Date of Update 1 Product Name 1 Product Update 1
1. 2021-11-10 Albendazole Something new has popped up here.
Showing 1 to 1 of 1 entries Previous 1 Next
Copyright © 2022 The U.S. Pharmacopeial Convention. All rights reserved. NTD Version 3.1.0-rc Powered By: USP POM+ (usp. org)

Image – 06.9 – Product Updates

NTD		0								
Search Type Select	PCT NTD Products Select PCT NTD Pr	oducts								
						Submit				
Report Output										
Reference		BCS	ATC	Manufacturer	Manufacturing					
S.# Î↓ No. Î↓ INN Î↓ CAS Î	↓ IDMP ↑↓ UNII	1↓ Classification 1↓	Code ↑↓ DDD ↑↓	Name ↑↓	Country ↑↓	APIMF Version No.				
1. WHOAPI-243 Praziquantel 55268- 74-1	6490C9U4	157	P02BA01 3	Solara Active Pharma Sciences Ltd	India	Solara/WHO/Praziquantel/OP/001/November 2018 & Solara/WHO/Praziquantel/RP/001/November 2018				
Showing 1 to 1 of 1 entries						Previous 1 Next				
Copyright © 2021 The U.S. Pharmacopeial Convention	All rights reserved.				NTD	Version 3.1.0-rc Powered By: USP PQM+ (usp.org)				

Image – 10 – Result Sorting and Filtering

In the above image, user can click on the name of each column to sort the records in ascending order based on that particular column. If user will click on the same column again, same column contents will be sorted out in descending order. Means column name is a toggle object for Ascending and Descending order of the table data.

Now if users want to display the data of the table based on data filtration, user can input the keyword under the column name of each column of the table as shown in the above image.

7. General Instructions

Please consider the following general instructions for the optimum utilization of the PCT NTD Dashboard:

- 1. For best look and feel of the PCT NTD Dashboard, please use the following latest web browsers:
 - a. Google Chrome
 - b. Microsoft Edge
 - c. Firefox Mozilla
 - d. Safari
 - e. Opera

8. Support

For any technical support related to **PCT NTD Dashboard** user can contact the under-signed: PQM+

Call:1-800-227-8772, +1-301-881-0666, or 00-800-4875-5555 Email: pqm@usp.org