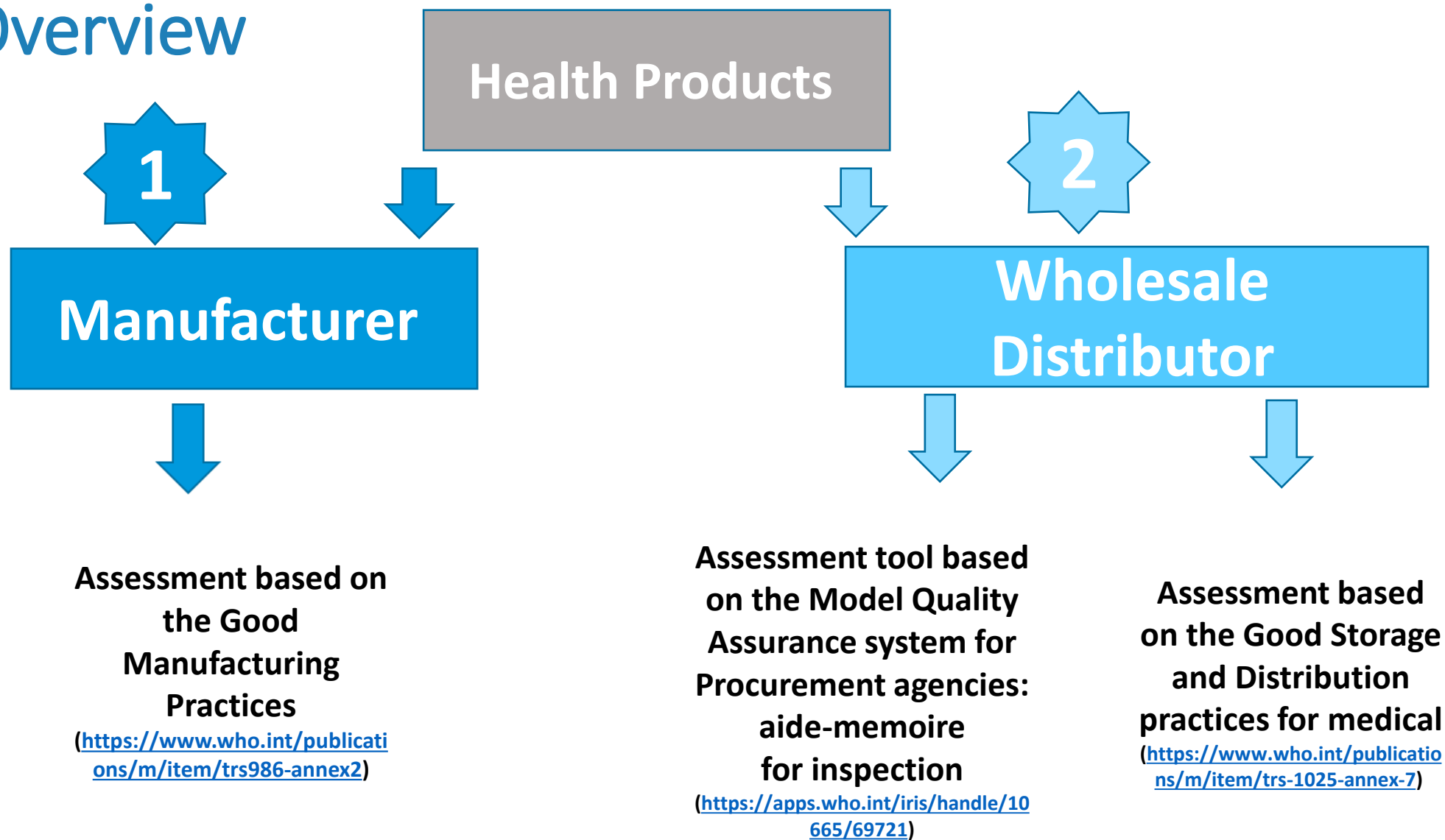


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# **Quality Assurance in Procurement of medicines: the different assessment types**

May 2023

# Overview



# WHO PQ program

M

Medicines

## Prequalified Medicinal Products



**Reference Number: HA516**

Date of prequalification: 23 May 2013

Basis of listing: Prequalified by WHO

Status: Active

INN: Tenofovir disoproxil fumarate

Therapeutic area: HIV/AIDS

Dosage form & strength: Tablet, Film-coated 300mg

Storage condition: Do not store above 30°C, protect from moisture

Shelf life (months): 24

Packaging: Bottle HDPE: 30x1

### Applicant:

Macleods Pharmaceuticals Ltd, 304 Atlanta Arcade, Marol Church Road, Andheri (East), Mumbai, 400 059, India

### FPP Manufacturing Site:

Macleods Pharmaceuticals Ltd, Unit 2, Plot No 25-27, Survey No 366, Premier Industrial Estate, Kachigam, Daman, 396 210, India  
Macleods Pharmaceuticals Ltd, Block No. N2, Village Theda, P.O. Lodhi Majra, Tehsil Baddi, District Solan, Himachal Pradesh, 174 101, India

### FPP WHO Public Inspection Reports:

**M** **Macleods Pharmaceuticals Ltd (Unit 2)**  
- Desk Review - (22 October 2018),  
Shanti Nagar, India

**M** **Macleods (N2 (Unit VI) - Desk Review -**  
(27 August 2018),  
Village Theda Baddi, India

### API Manufacturing Site:

(Tenofovir disoproxil fumarate) Acebright (India) Pharma Pvt Ltd, 77D & 116/117 KIADB Industrial Area, Jigani, Bangalore, Karnataka, 560 105, India  
(Tenofovir disoproxil fumarate) Hetero Labs Ltd, Unit 1, Survey No 10 IDA, Gaddapothoram Village, Kazipally, Jinnaram (M), Sangareddy District, Telangana, 502110, India  
(Tenofovir disoproxil fumarate) Hetero Labs Ltd, Unit 9, Plot 2 Hetero Infrastructure Ltd - SEZ, N Narasapuram Village, Nakkapalli Mandal, Visakhapatnam District, Andhra Pradesh, 531 081, India  
(Tenofovir disoproxil fumarate) Laurus Labs Ltd, Plot No 21, Jawaharlal Nehru Pharma City, Parawada, Visakhapatnam District, Andhra

- Tenofovir 300 mg tablets
- PQ website indicates the manufacturers and the manufacturing sites that were audited with positive outcome.
- PQ website lists 6 different manufacturers & sites among which products can be chosen
- Other manufacturers/sites outside of the PQ program exist, but what are the risks?

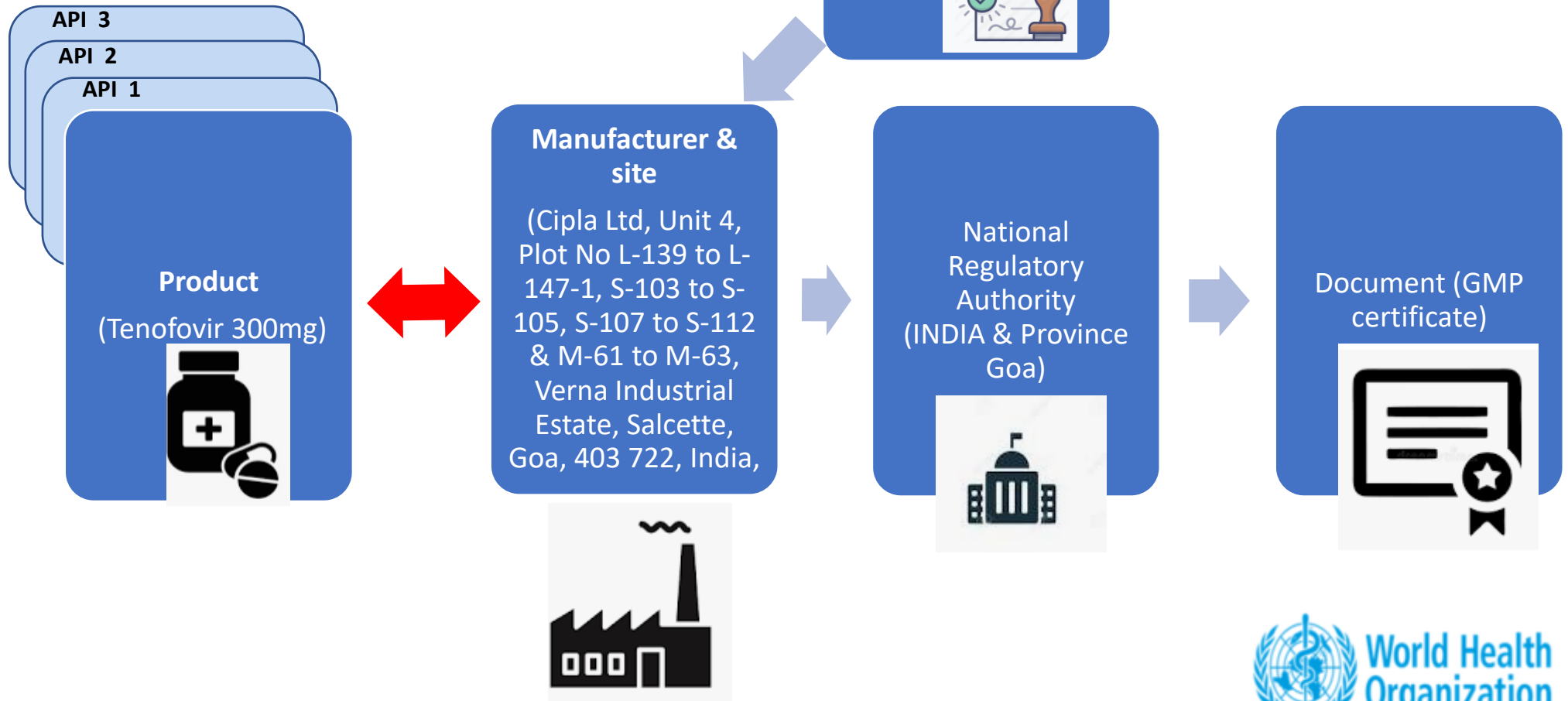
<https://extranet.who.int/pqweb/medicines/prequalified-lists>



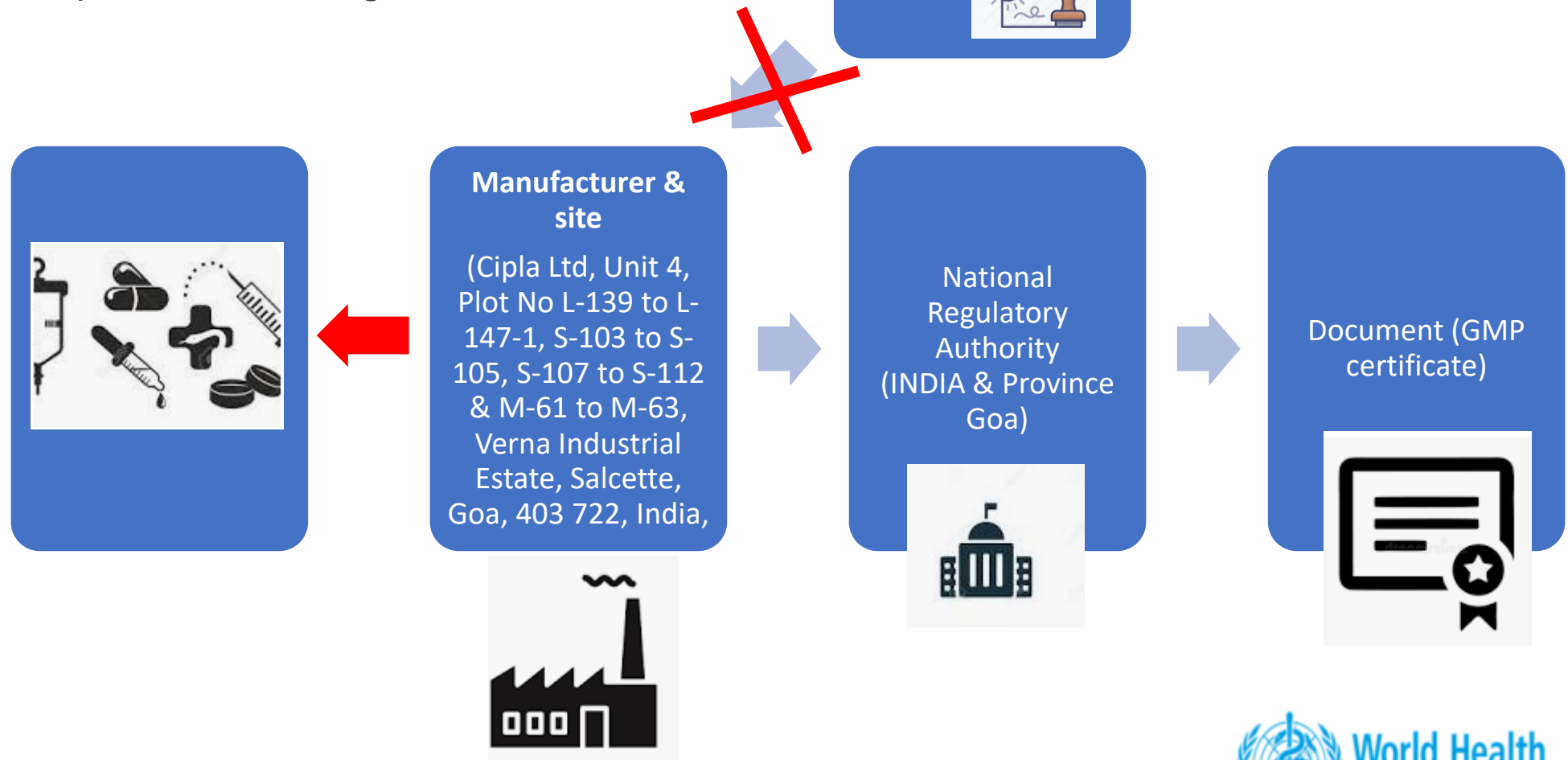
1

# WHO PQ assessment

<https://extranet.who.int/pqweb/medicines/prequalified-lists>

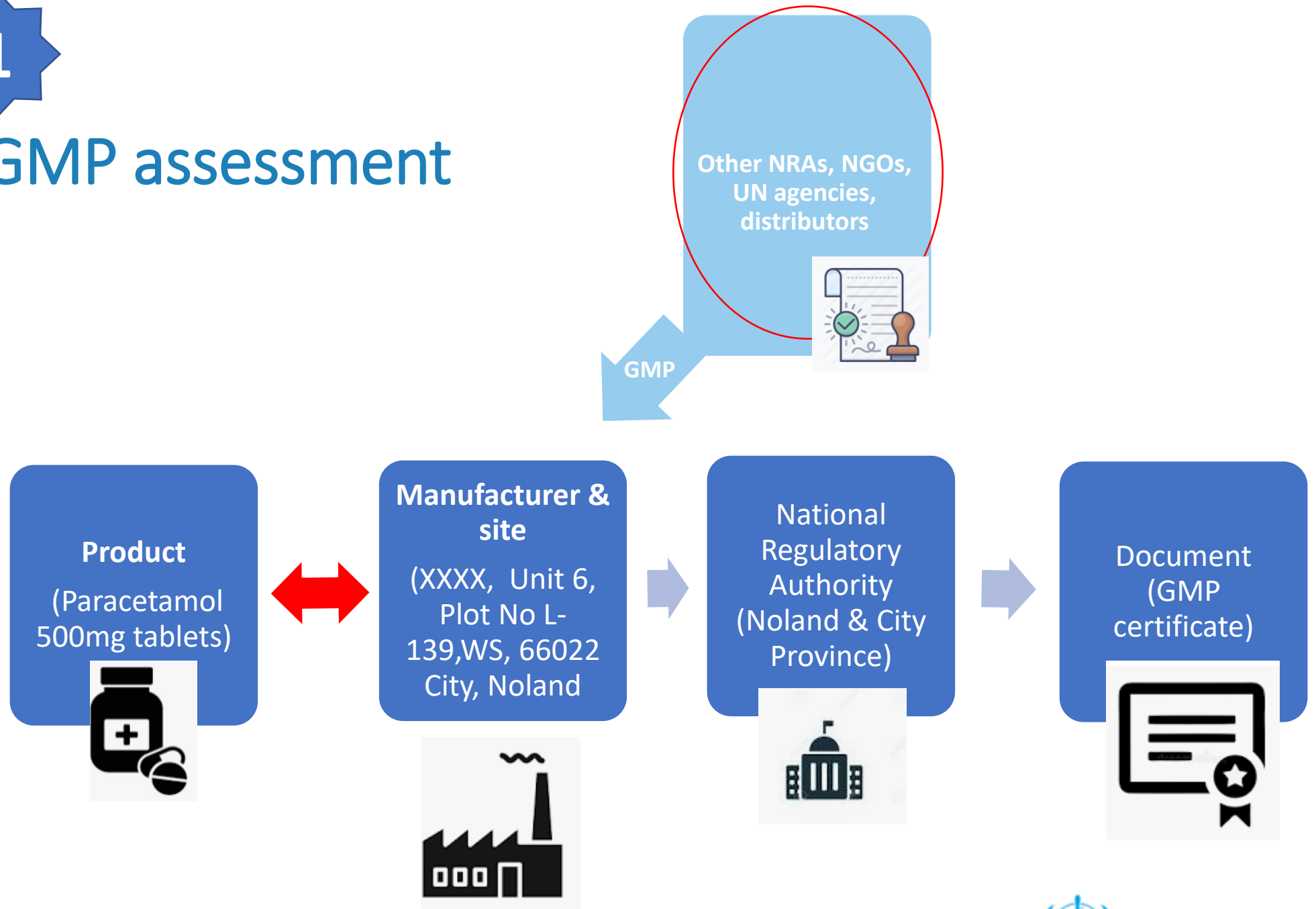


- Approved by WHO PQ is always a “pair” product/manufacturing site
- A product is linked with a manufacturing site + a workshop/Plot + production /filling line



1

# GMP assessment



## Stringent Regulatory Authorities (SRAs)

- A member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), being the European Commission, the US Food and Drug Administration and the Ministry of Health, Labour and Welfare of Japan also represented by the Pharmaceuticals and Medical Devices Agency (as before 23 October 2015); or
- an ICH observer, being the European Free Trade Association, as represented by Swissmedic, and Health Canada (as before 23 October 2015); or
- a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement, including Australia, Iceland, Liechtenstein and Norway (as before 23 October 2015)."

<https://www.who.int/initiatives/who-listed-authority-reg-authorities/SRAs>

## PICS countries

PIC/S (Pharmaceutical Inspection Co-operation Scheme) aims at harmonizing inspection procedures worldwide by developing common standards in the field of **GMP** and by providing training opportunities to inspectors.

### Members

#### LIST OF PIC/S PARTICIPATING AUTHORITIES



<https://picscheme.org/en/members>

### List of Stringent Regulatory Authorities (SRAs)



14 JUNE 2017  
TRS 1003 - 51st  
report of the  
WHO Expert  
Committee on  
Specifications  
for  
Pharmaceutical...

WHO Technical Report  
Series 1003

Download

Read More

# WHO Listed Authorities

## Maturity Level 1,2,3

- Based on the [Global Benchmarking Tool](#) (GBT) and [Manual](#) for benchmarking of the national regulatory system of medical products and formulation of institutional development plans.
- The WHO GBT
  - replaces all tools previously used by WHO, representing the first truly ‘global’ tool for benchmarking regulatory systems
  - is designed to evaluate the overarching regulatory framework and the component regulatory functions
  - Foundation for evaluating and publicly designating WHO Listed Authorities (WLAs)



[Home](#) / [Publications](#) / [Overview](#) / List of National Regulatory Authorities (NRAs) operating at maturity level 3 (ML3) and maturity level 4 (ML4)

## List of National Regulatory Authorities (NRAs) operating at maturity level 3 (ML3) and maturity level 4 (ML4)

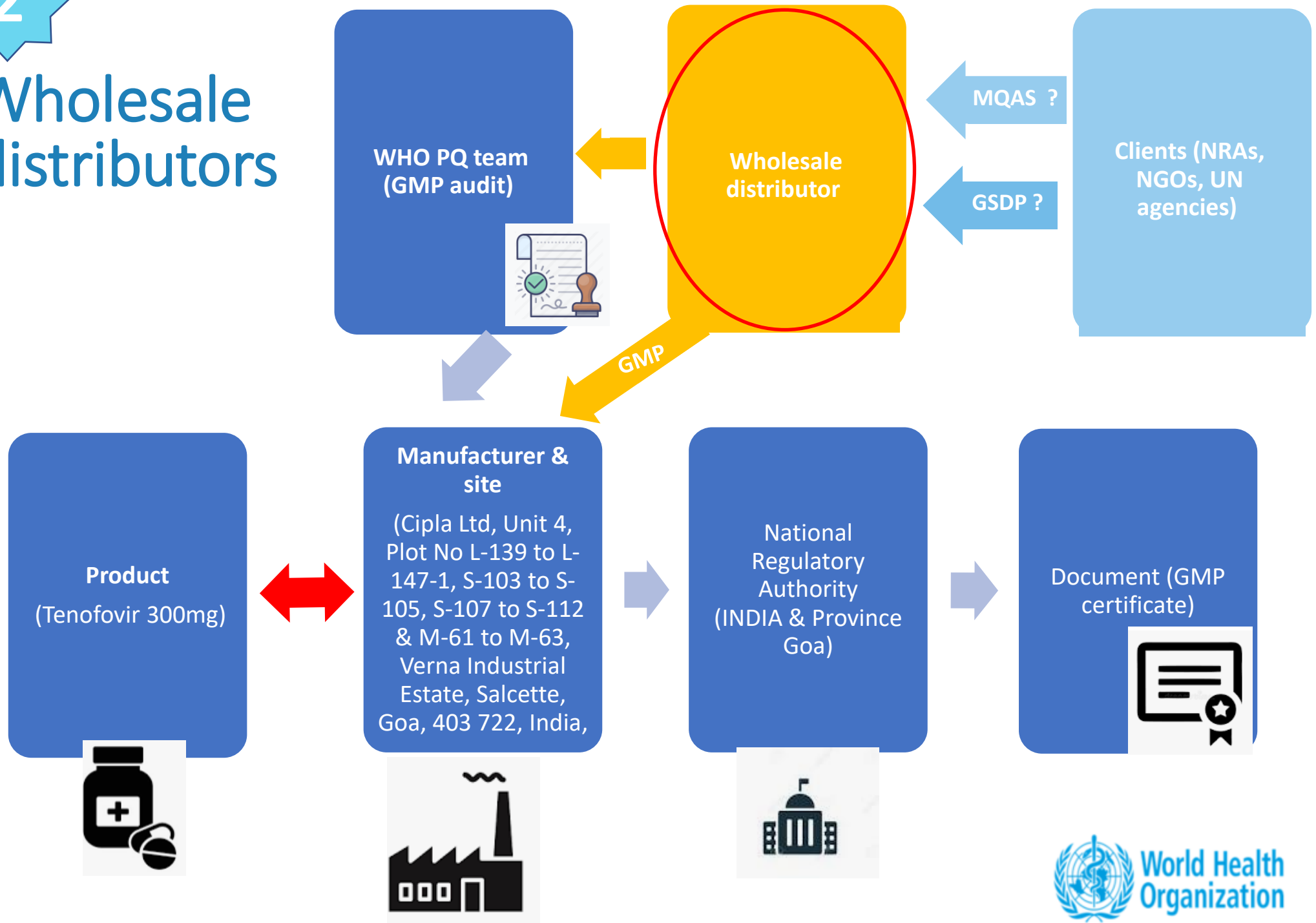


<https://www.who.int/initiatives/who-listed-authority-reg-authorities>



2

## Wholesale distributors



## The model quality assurance system for procurement agencies

The assessment tool is based on the six modules in the MQAS:

Module I	General requirements for procurement agencies
Module II	Prequalification
Module III	Purchasing
Module IV	Receiving and storage
Module V	Distribution
Module VI	Reassessment

## The Good storage and distribution practices for medical

### Annex 7

#### Good storage and distribution practices for medical products

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# Useful resources

## Procurement and procurement agencies

Assessment tool based on the model quality assurance system for procurement agencies: aide-memoire for inspection (2014)

WHO Technical Report Series, No. 986, Annex 4, 2014

Guide to good storage practices for pharmaceuticals (2003)

WHO Technical Report Series, No. 908, Annex 9, 2003

Guidelines for the preparation of a procurement agency information file (2003)

WHO Technical Report Series, No. 917, Annex 7, 2003

Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products (2011)

WHO Technical Report Series, No. 961, Annex 9, 2011

Model quality assurance system for procurement agencies (2014)

WHO Technical Report Series, No. 986, Annex 3, 2014

Outil d'évaluation des AA fondé sur le Système modèle d'assurance de la qualité pour AA : aide-mémoire pour les inspections (2014)

OMS Série de Rapports techniques, N° 986, Annexe 4, 2014

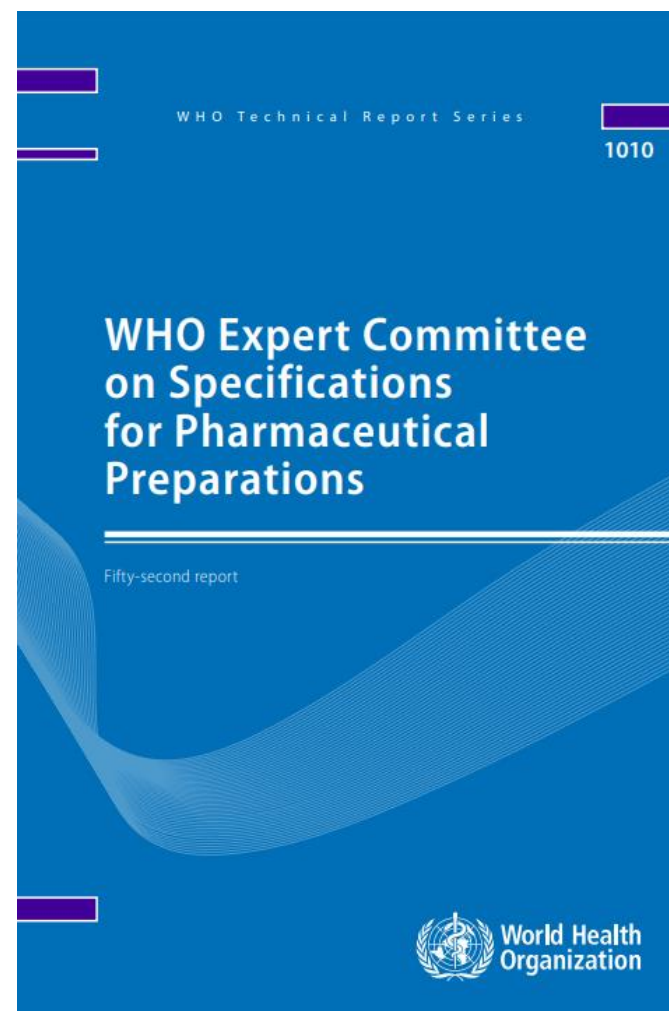
Procedure for assessing the acceptability, in principle, of procurement agencies for use by UN agencies (2003)

WHO Technical Report Series, No. 917, Annex 6, 2003

Système modèle d'assurance de la qualité pour agences d'approvisionnement (2014)

OMS Série de Rapports techniques, N° 986, Annexe 3, 2014

<https://www.who.int/medicines/publications/pharmprep/en/>



<https://extranet.who.int/prequal/content/WHOguidance-documents>



A large, dense group of children of various ethnicities, mostly of South Asian descent, are smiling and looking towards the camera. They are wearing colorful clothing, including blue, orange, and patterned shirts. The children are of different ages, from young boys to teenagers.

Merci  
Thank you



**World Health  
Organization**

[www.who.int](http://www.who.int)