World Health Organization

WHO Prequalification of medical products and health technologies

Ensuring the Quality of Priority Medicines –

Workshop for National Medicines Regulatory Authorities and Manufacturers of Anti-Tuberculosis and Neglected Tropical Disease Products

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Protecting and promoting public health

World Health Organization

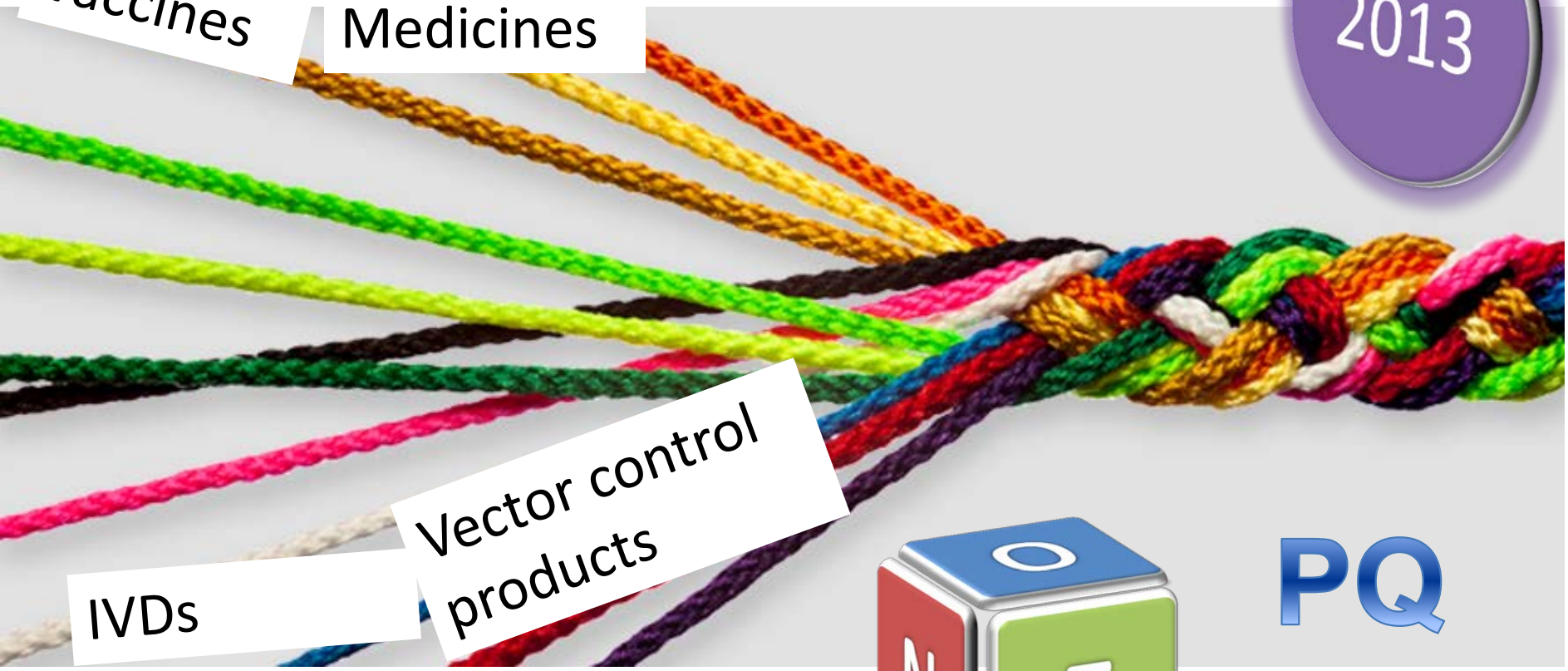
WHO PREQUALIFICATION TEAM

WHO Prequalification

Was created in response to procurement agencies and WHO Member States needs to ensure that products supplied through these agencies are consistently safe and effective under conditions of use in resource limited countries

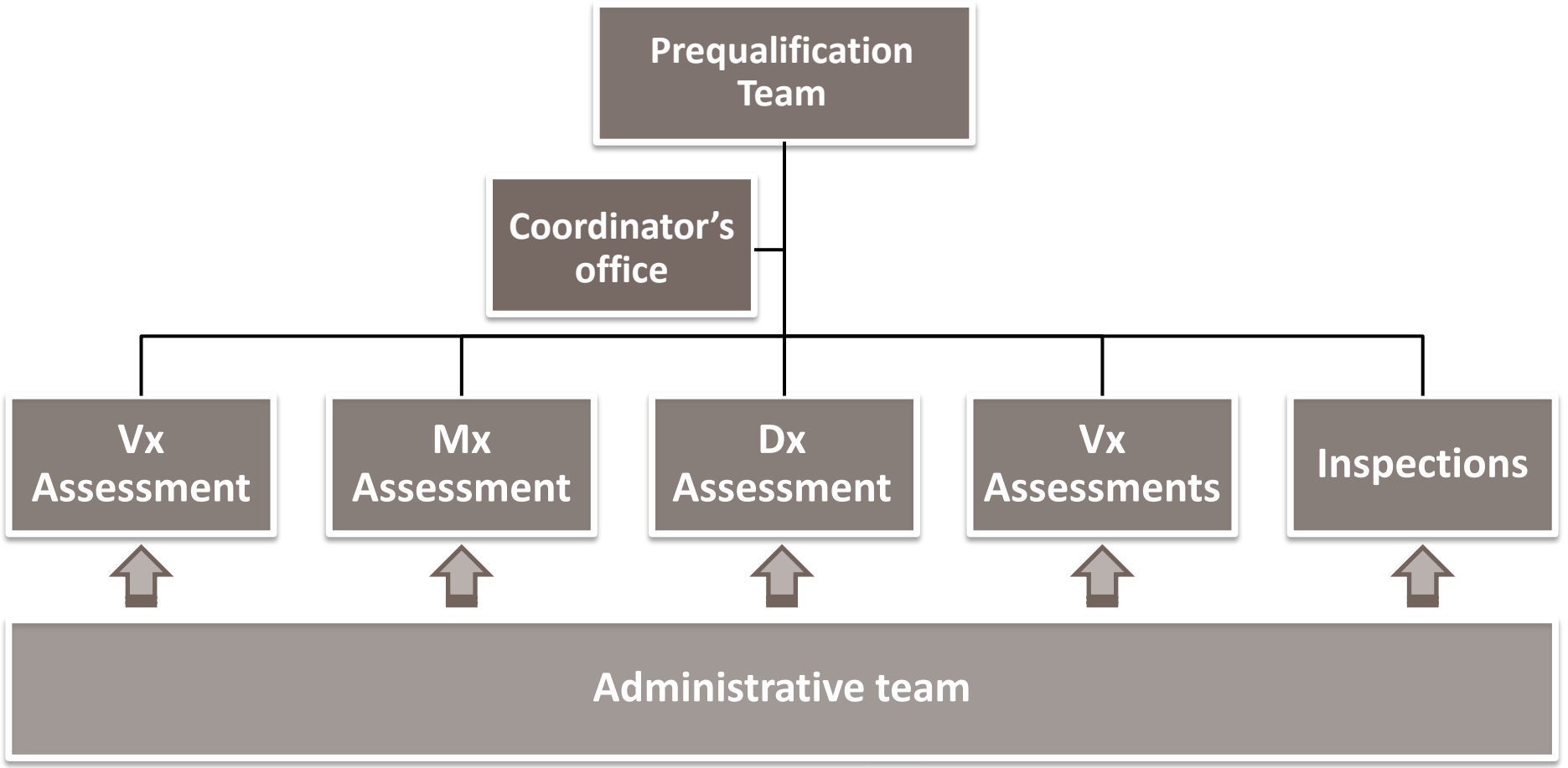
WHO Prequalification

In vitro Diagnostics
2010
HIV test kit evaluation
1988

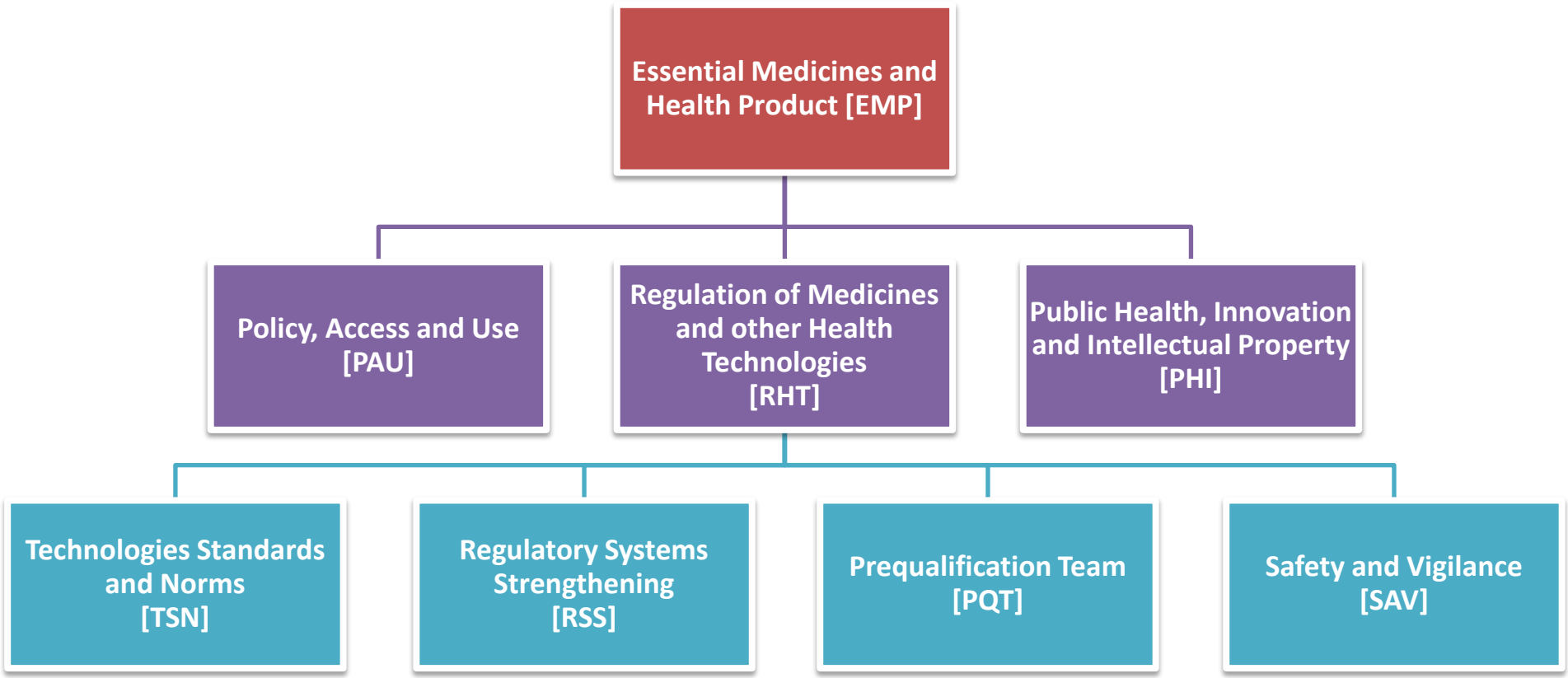


PQ Team

Structure of the Prequalification Team



Structure of Department of Essential Medicines & Health Products



5th Invitation to Manufacturers of Medicinal Products for Treatment of Neglected Tropical Diseases, to Submit an Expression of Interest (EOI) for Product Evaluation to the WHO Prequalification Team: medicines

To support national and global efforts to increase access to and the affordability of care and treatment of neglected tropical diseases, WHO invites manufacturers of selected pharmaceutical products to submit Expressions of Interest (EOI) for product evaluation.

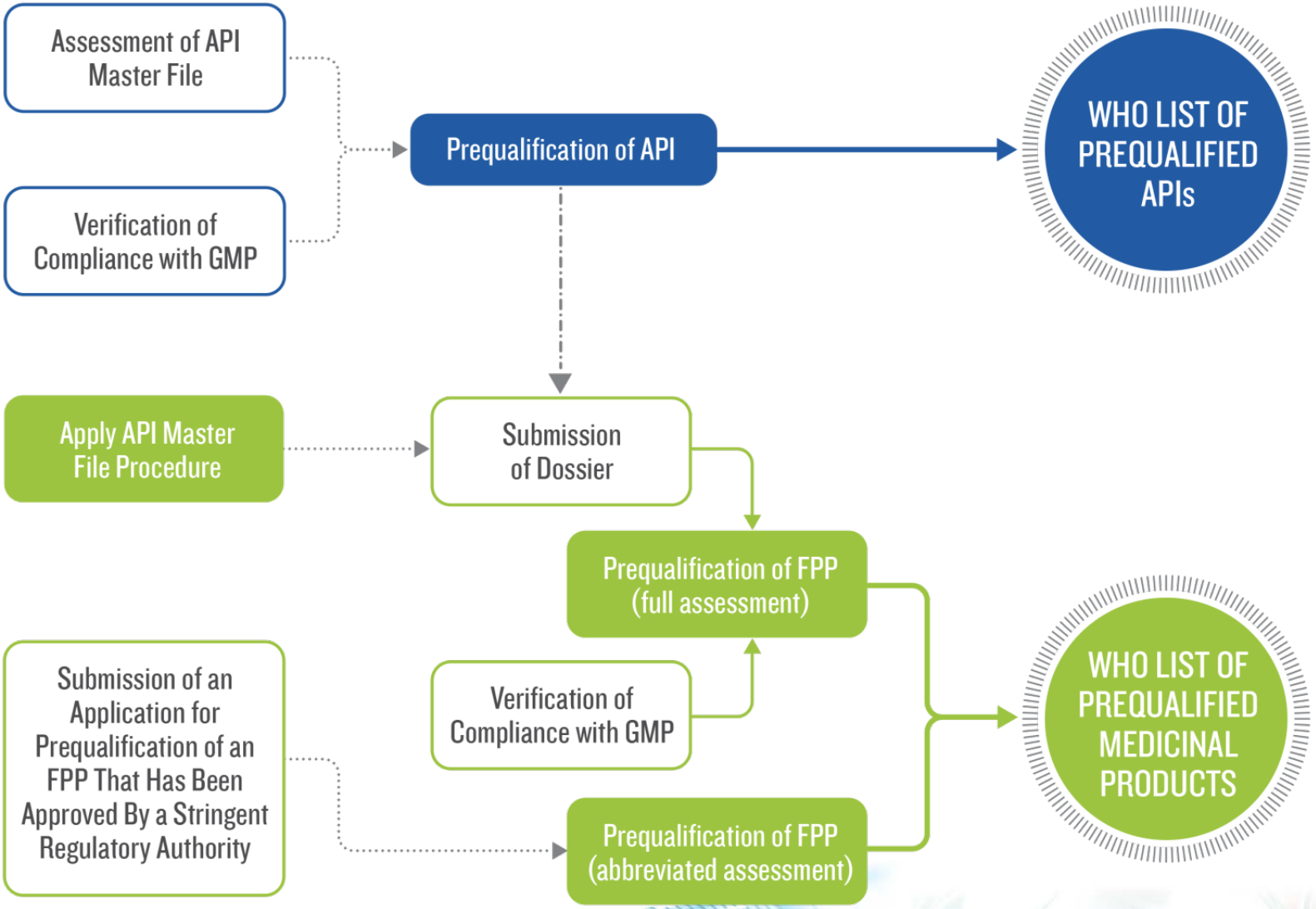
14th Invitation

to Manufacturers of Antituberculosis Medicines

to Submit an Expression of Interest (EOI) for Product Evaluation to the WHO Prequalification Team: medicines

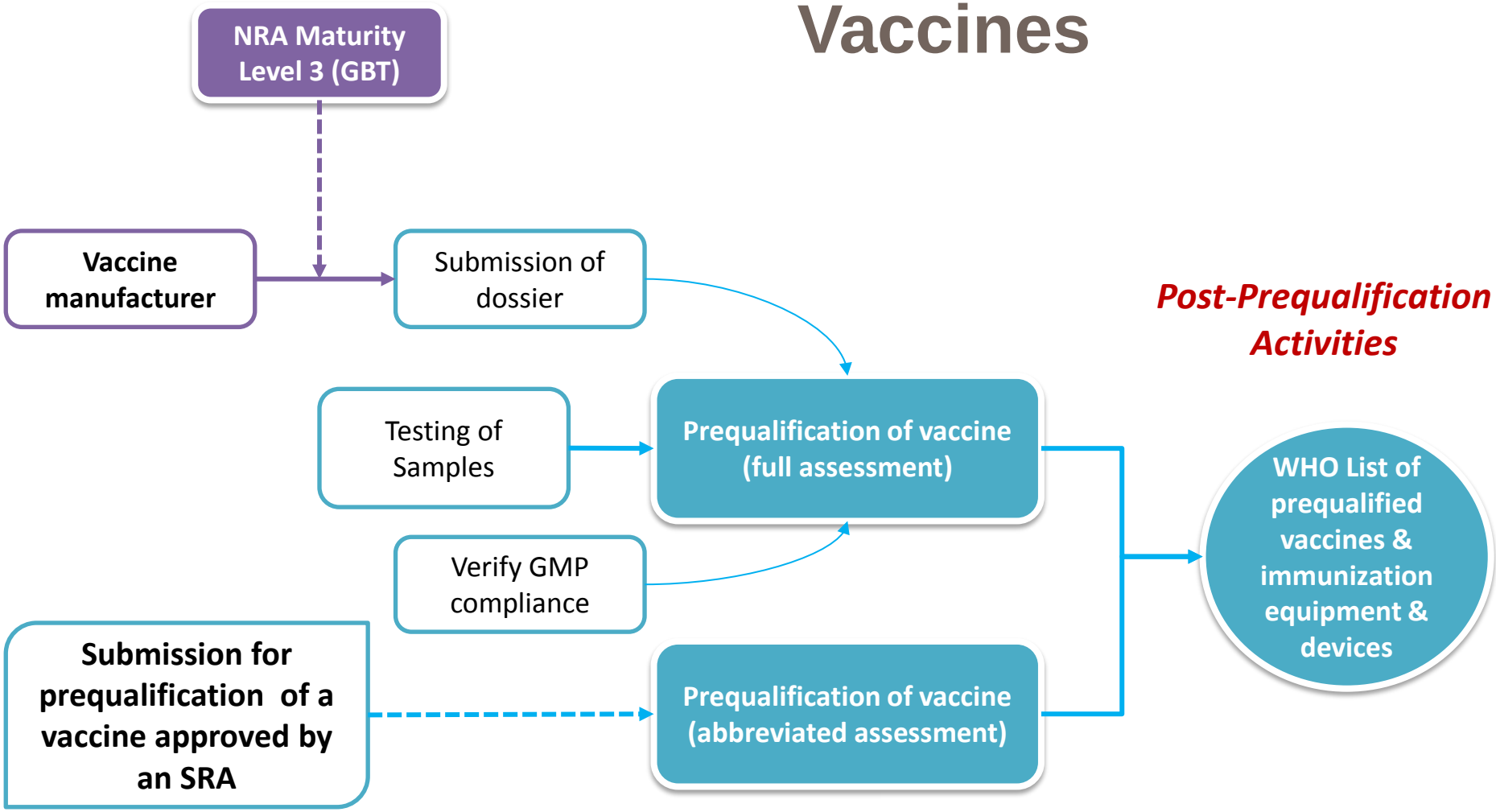
To support national and global efforts to increase access to and the affordability of care and treatment of tuberculosis, WHO, together with UNICEF, UNAIDS and UNITAID, invites manufacturers of selected pharmaceutical products to submit Expressions of Interest (EOIs) for product evaluation.

PQ Process Overview: Medicines



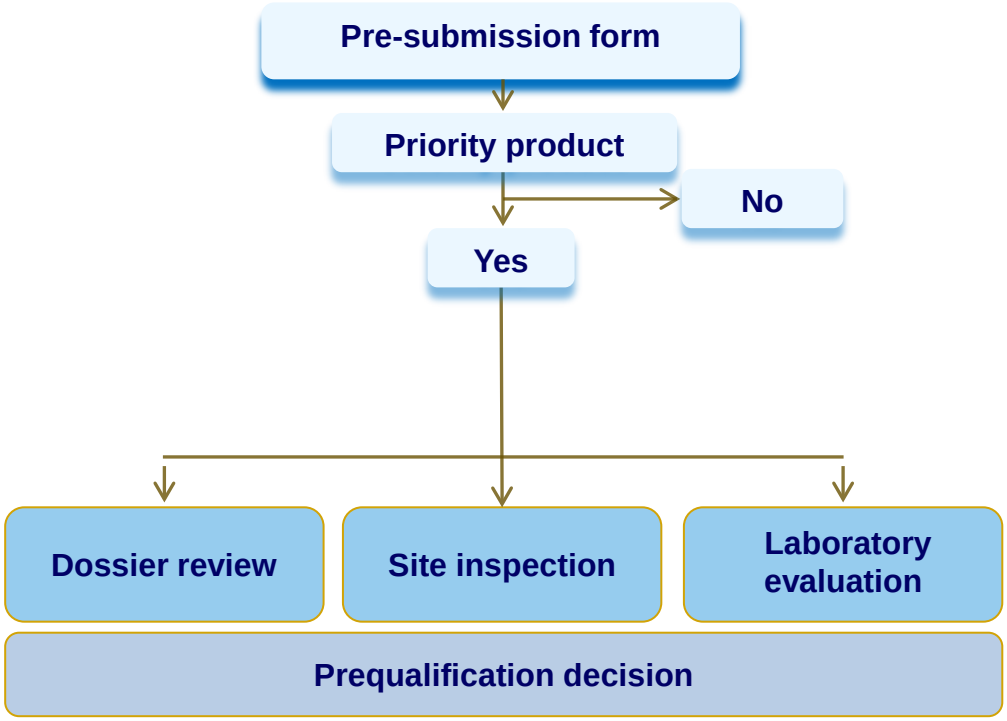
Post-Prequalification Activities

PQ process overview: Vaccines

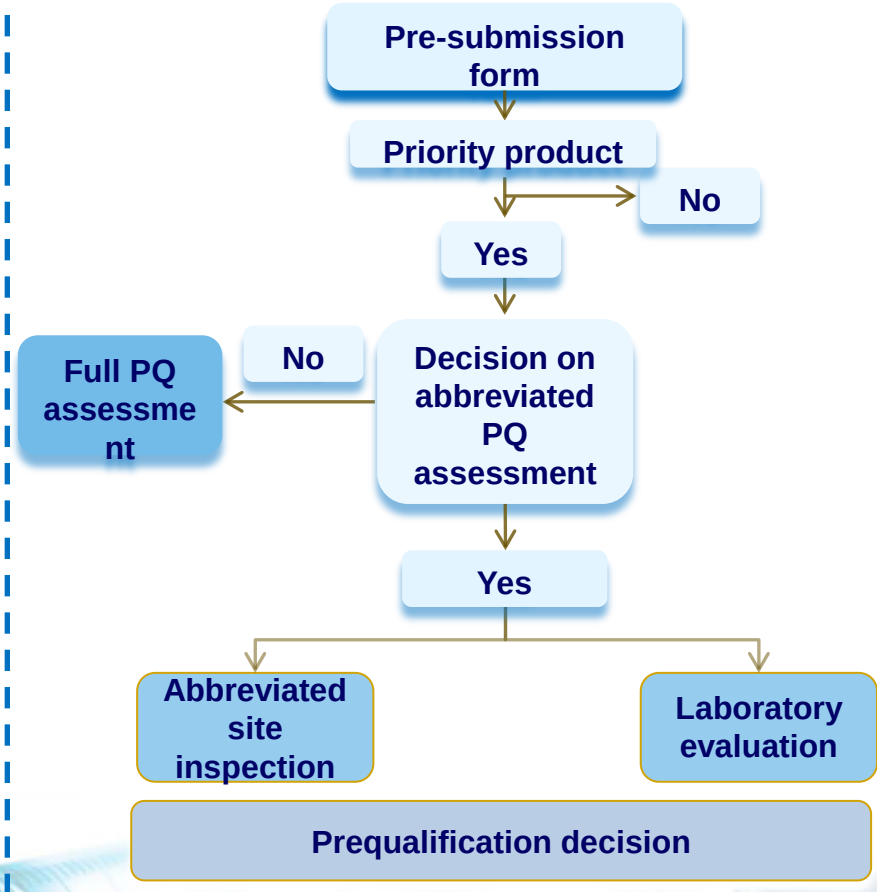


PQ process overview: IVDs

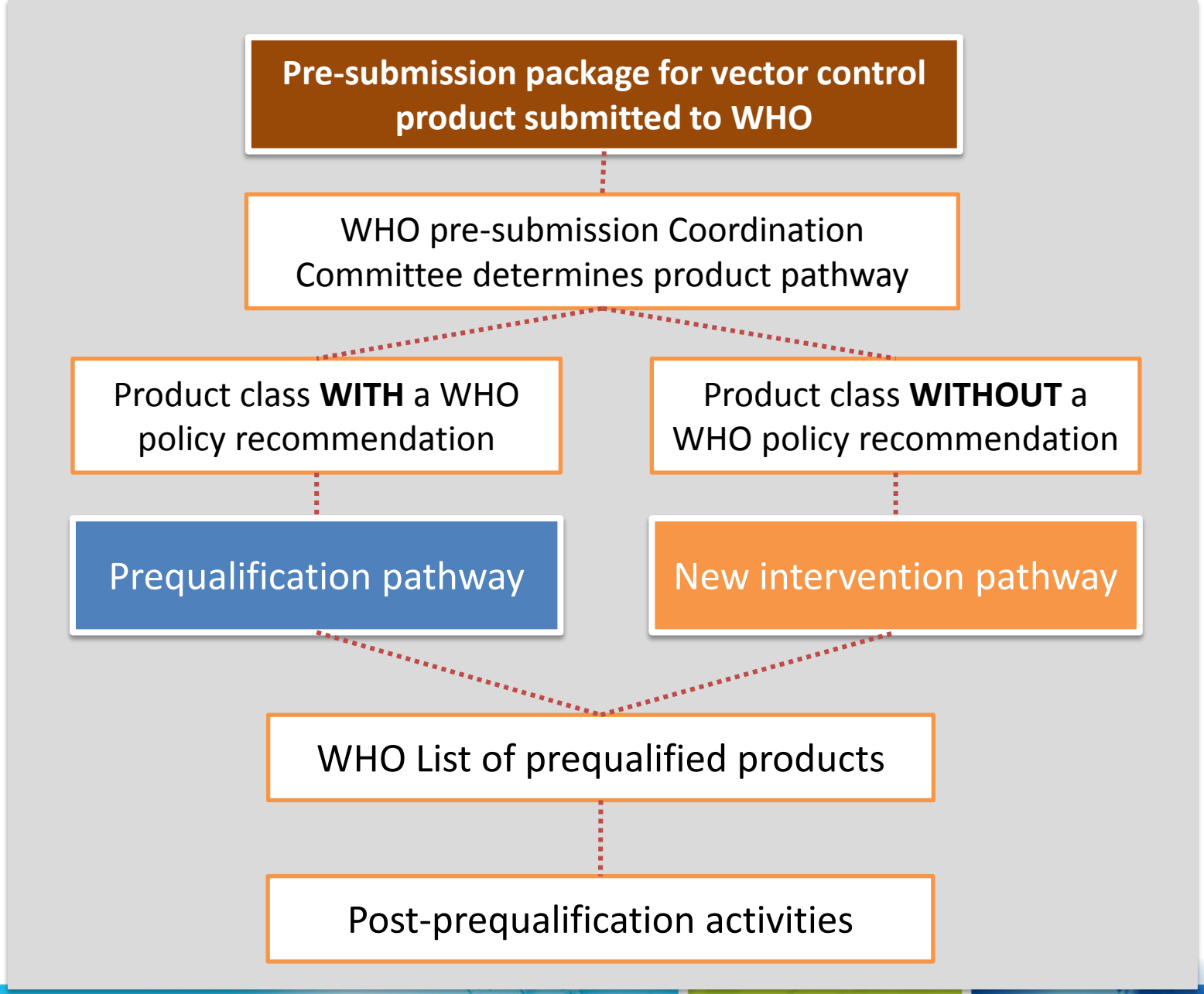
Full prequalification assessment



Abbreviated prequalification assessment

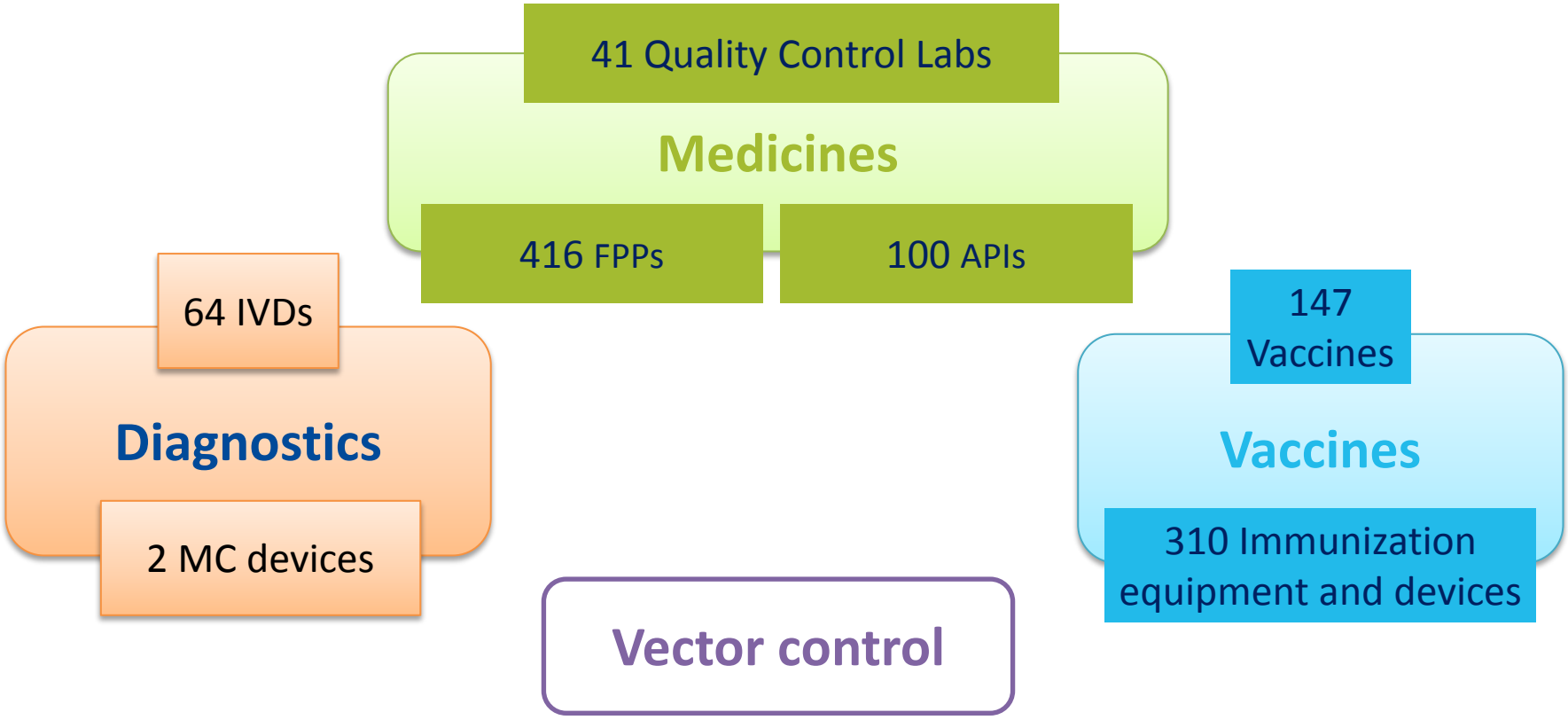


PQ process overview: Vector control products



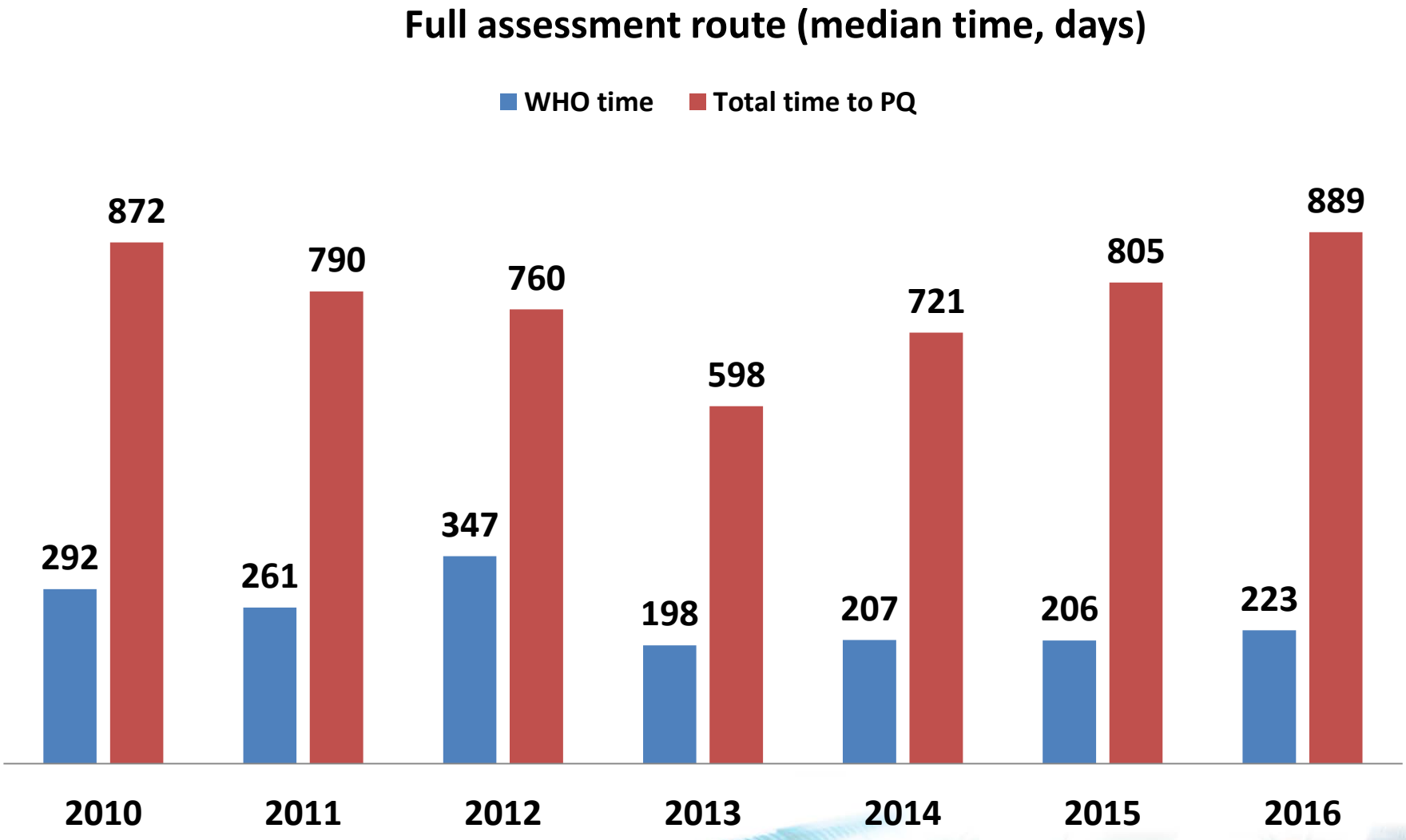
Prequalification by numbers:

At the close of 2016, the list of prequalified products* included:



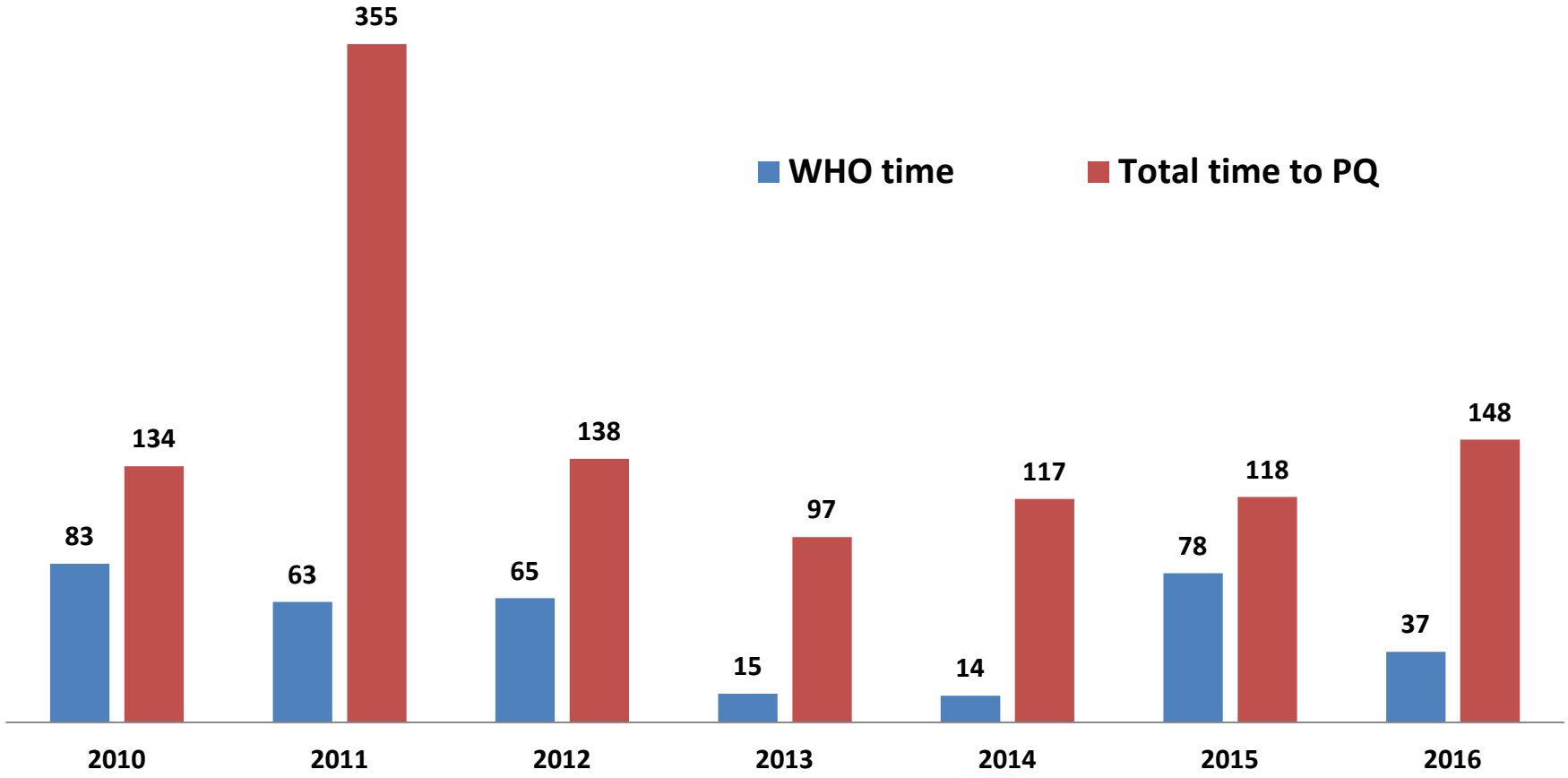
* Numbers are not the cumulative PQed products since their inceptions

Time to prequalification (FPPs)



Time to prequalification FPPs

→ **SRA route (median time, days)**



Prequalified NTD products

WHO Ref Number	INN	Applicant	Dosage form	Year
NT001 (a)	Diethylcarbamazine (citrate)	Sanofi-Aventis, France	Tablet 100mg	2016
NT002	Diethylcarbamazine (citrate)	Eisai Co Ltd, Japan	Tablet 100mg	2013
NT003	Praziquantel	Cipla Ltd, India	Tablet 600mg	2015

The aim of this 5th EOI is to ensure the availability of quality assured albendazole, diethylcarbamazine, ivermectin, mebendazole, praziquantel, miltefosine, sodium stibogluconate, paromomycin and azithromycin for the treatment of lymphatic filariasis (albendazole, diethylcarbamazine or ivermectin), onchocerciasis (iv… transmitted helminthiasis (STH) (albendazole, mebendazole or iverm…ctin), schistosomia… cutaneous leishmaniasis (miltefosine, sodium stibogluconate), viscer… stibogluconate and paromomycin sulfate) and yaws (azithromycin). … dosage forms and strengths listed in this document have been identified … Department for effective treatment of patients suffering from these dise… either in the WHO Model List of Essential Medicines 19th list, April 20… series.

3 prequalified NTD medicines¦ 9 products in EOI

96 Prequalified TB products

1. Isoniazid/Pyrazinamide/Rifampicin
2. Kanamycin (sulfate)
3. Linezolid
4. Para-aminosalicylate (sodium)
5. Protionamide
6. Rifapentine
7. Streptomycin (sulfate) - Sterile

Less than 3 prequalified products

1. Isoniazid / Rifapentine,
2. Ethambutol hydrochloride tablet 100 mg (scored, dispersible); 50 mg (dispersible)
3. Isoniazid tablet 100 mg (scored, dispersible); 50 mg (dispersible)
4. Cycloserine capsule 125 mg
5. Levofloxacin tablet 100 mg (dispersible)
6. Moxifloxacin tablet 100 mg (dispersible)
7. Linezolid tablet 150 mg (dispersible)

PQT – revised fee model- background

- PQT fees: **1999** (vaccines); **2008** (IVDs); **2013** (medicines & APIs)
- January **2017**; Revised fee model for vaccines, medicines and APIs.
- A revised fee model will be introduced for diagnostics in **2018.**
- The model includes screening, application/evaluation fee, inspection fee and annual fee.

PQT – revised fee model- Criteria

- The fees are structured in consideration of the following:
  - type of product: API, FPP or Vaccine
  - Product complexity (vaccines only): Simple/Traditional or Combinations/Novel
  - assessment procedure: Screening (vaccines only); Abridged or full assessment of new application; Assessment of major variations (medicines only)
  - Inspections (vaccines only)
  - PQ enabled sales (vaccines only)
- Annual fee: Fixed for medicines and APIs , Tiers based for vaccines

PQT – revised fee model- determination of Tier

- There is one Tier per company and NOT per vaccine
- The Tier is based on:
- prequalification-enabled vaccine sales (sales to UN agencies and GAVI, only).
  - prequalification-enabled vaccine sales (sales to UN agencies and GAVI, only).
  - average annual PQ-enabled sales of all prequalified vaccines from that manufacturer over the last three completed calendar years.

Tier	Average annual PQ-enabled Sales over the last completed three-year period. (US$)
1	US$0 to US$1 million
2	>US$1 million to US$20 million
3	>US$20 million to US$300 million
4	>US$300 million

Table 1: Fees for FPP and API prequalification applications (effective 1 January 2017)

	Single Registration Fee Per Product	Annual Fee Per Product	Post-PQ Changes
	Application Fee	Annual Fee	Major variation
FPP – Full assessment	$25,000	$20,000	$3,000
FPP – Abridged assessment[1]	$6,000	$5,000	NA
API	$20,000	$8,000	$3,000

[1] Refer to SRA-Approved Multisource (Generic) or Innovator FPPs procedure - https://extranet.who.int/prequal/content/abbreviated-assessment-multisource-generic-or-innovator-product-0

Table 2: Fees for Vaccine prequalification applications (effective 1 January 2017)

	Single Registration Fee Per Product			Annual Fee Per Product				Site Audit
	Application Screening Fee	Abridged assessment procedure[2]	Full assessment procedure	Tier 1	Tier 2	Tier 3	Tier 4	Site Audit Fee
Simple / Traditional Vaccines	$2,500	$25,000	$100,000	$4,800	$19,200	$41,500	$140,000	$30,000
Combinations or Novel Vaccines	$5,000	$66,500	$232,750	$8,400	$33,600	$72,500	$250,000	$30,000

[2] Refer to Streamlined Process. TRS 978 annex 6, http://www.who.int/entity/immunization_standards/vaccine_quality/TRS_978_61st_report_Annex_6_PQ_vaccine_procedure.pdf?ua=1

PQT – revised fee model - **Waivers**

- Waivers:
  - Applicants of products that generate only small profits, who may be discouraged from applying or maintaining their products on the list should contact the PQT. This will be discussed and a way forward reached on a case by case basis
  - A deferment, reduction or waiver to the annual fee may be granted if the applicant presents evidence that there has not been any sales in the previous year and the current year up to the date of invoicing – 01 September.

PQT has a value for manufacturers