Exhibits compendium

Impact assessment of WHO Prequalification and systems supporting activities

March 2023

World Health Organization

Context and purpose

This document provides a compendium of exhibits used in the 2018 – 2022 Impact Assesment Report.

Exhibit 1: Comparison of the 2018 impact assessment and the 2022 one

			Impact assessment of PQ and its supporting activities (2019)	Impact assessment of RPQ (2023)	
Number of impact metrics analyzed			19	39	Twice more metrics than in 2019
Number of Stakeholders interviewed	WHO staff		8	27	WHO regional advisors and WHO Directors (of Diseases programmes) have been interviewed
	External stakeholders	NRAs	10	9	
		Manufacturers	15	18	
		Donors / Procurers	16	14	
		Others[1]	0	3	
	TOTAL		49	71	+ 22 stakeholders interviewed vs 2019
Survey targeting NRAs			✗	✓	38 NRAs provided some input

1. Including CSOs, Industry Associations

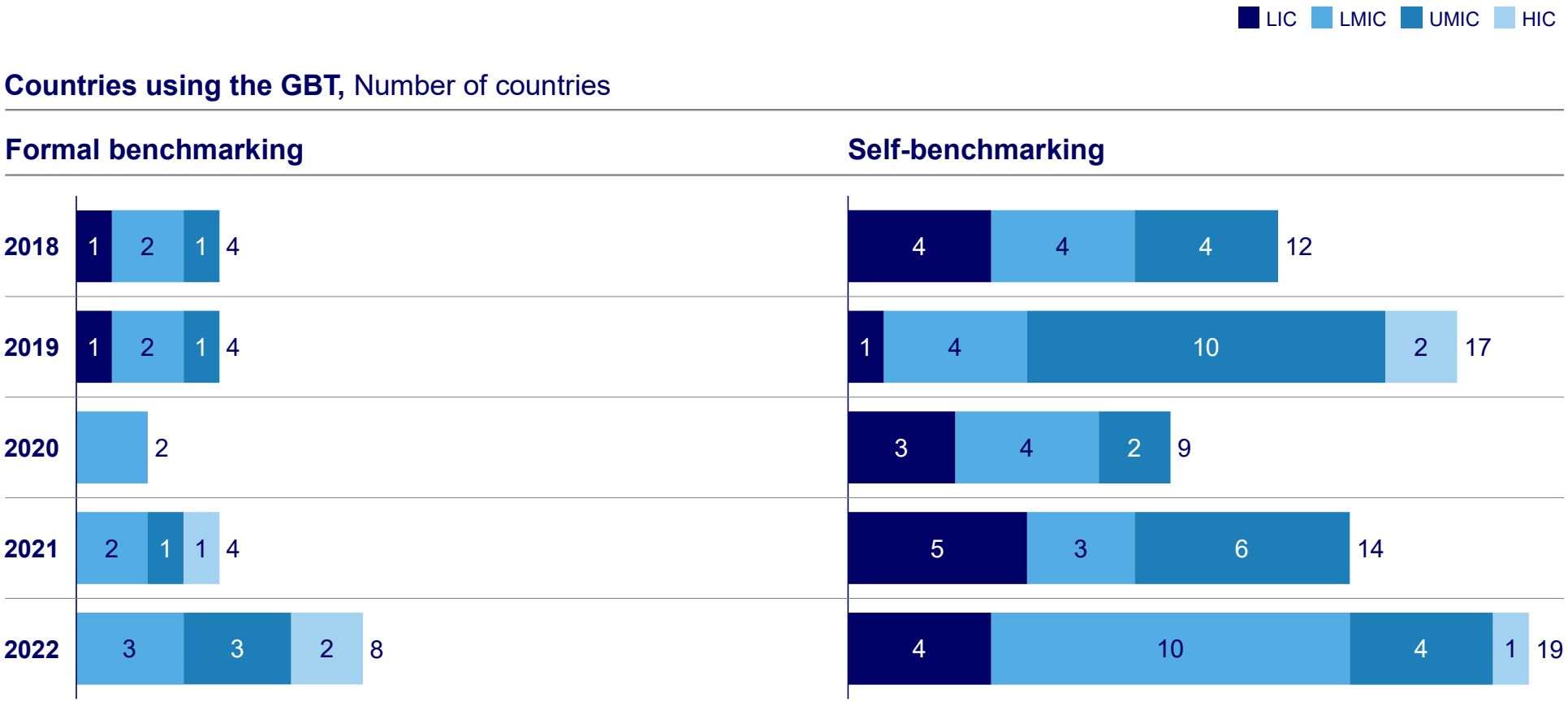
Contents

World Health Organization

Exhibit 3: Key metrics covered and the methodology for the assessment under Theme 1

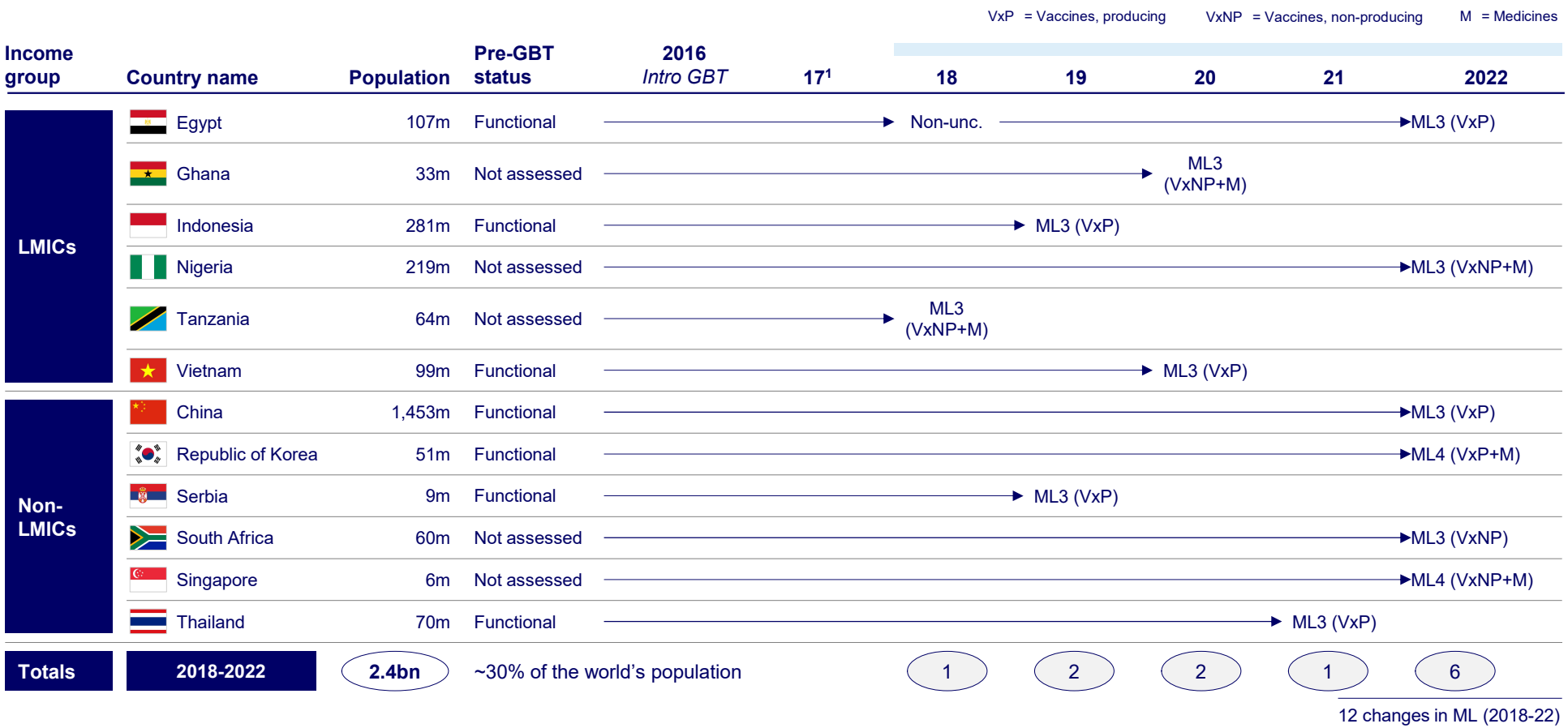
Topics	No.	Metric	Metric type
Strengthening regulatory system	1A	Number of countries using the GBT	Quantitative
	1B	Number of NRAs that have reached ML3 or ML4 since 2018	Quantitative
	1C	Progress on implementation of WHO-Listed Authority (WLA) initiative	Quantitative
	1D	NRA and procurer/donor rating and perception of the utility of regulatory system strengthening activities	Perception
	1E	Case study on a country that successfully strengthened its regulatory system (Ghana)	Case study

Exhibit 4: Number of countries using the GBT



Source: Interviews with RSS (Nov 30, 2022), WHO data (December 6, 2022)

Exhibit 5: Number of NRAs that have reached ML3 or ML4 since 2018

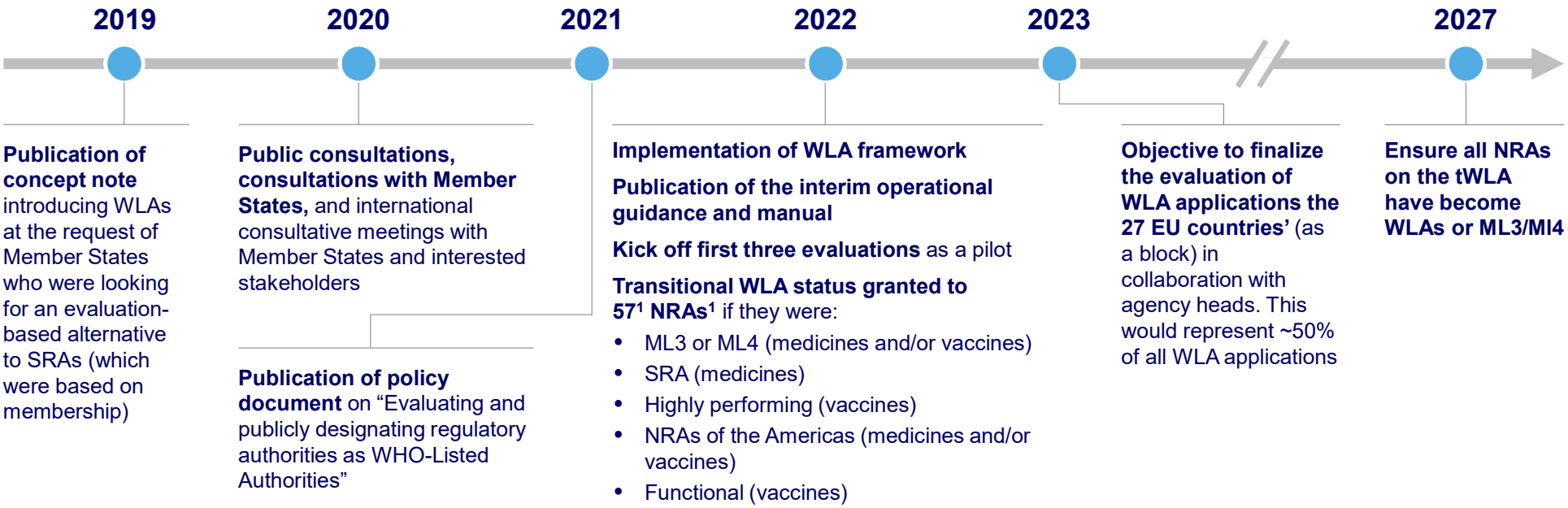


1. India received ML3 status in 2017

Source: Interviews with RSS (Nov 30, 2022); WHO data (December 6, 2022)

Exhibit 6: Introduction to WLAs and the outlook of the concept

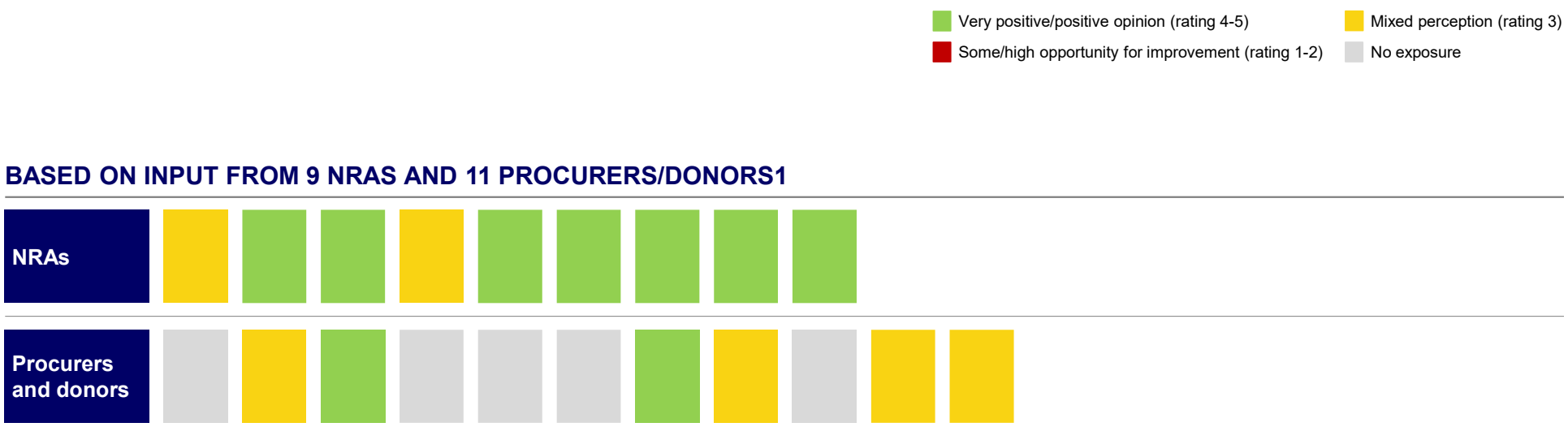
Introduction of WLAs and the outlook of the concept



1. Includes one regional regulatory system – European Medicines Regulatory Network

Source: Interviews with RSS (Nov 30, 2022), WHO data (December 6, 2022)

Exhibit 7: NRA and procurer/donor scoring and perception of the utility of regulatory system benchmarking activities



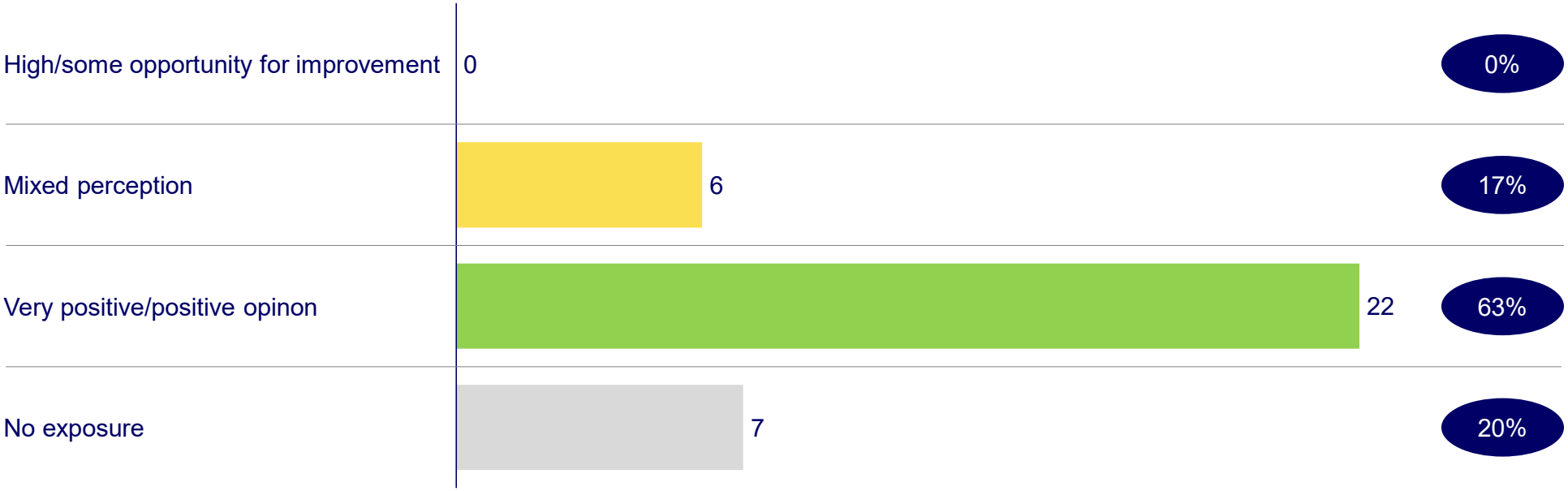
1. 14 separate interviews with 11 different procurers/donors

Source: Interviews with NRAs, procurers, and donors conducted in December 2022 and January 2023

Exhibit 8: Survey results on how the GBT and its applications have strengthened and improved MLs for your NRA

On a scale from 1 to 5[2], how would you rate the impact the GBT and its applications have had in strengthening and improving maturity levels for your NRA?

Number of responses, n=35[1]



1. Four answers were excluded based on the absence and/or invalid (e.g., country context limitations not related to RPQ) of rationale provided
2. 5 being the best

Source: Survey administered to NRAs for Impact assessment of WHO Prequalification and systems, Jan 2023

Contents

World Health Organization

Exhibit 9: Key metrics covered and the methodology for the assessment under Theme 2

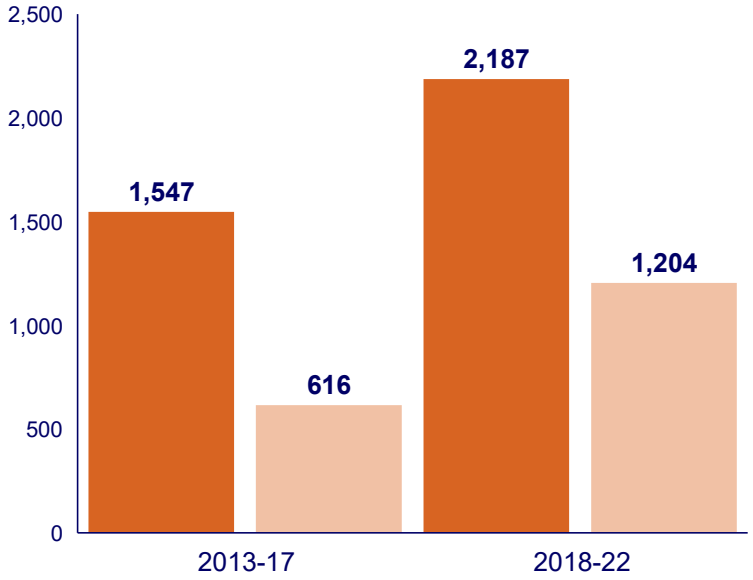
Topics	No.	Metric	Metric type
Improving the management of Substandard and Falsified (SF) medical products and incidents	2A	Number of incidents and SF products recorded in the global surveillance and monitoring system	Quantitative
	2B	Number of global medical product alerts issued by the Incidents and Substandard and Falsified Medical Products (ISF) team	Quantitative
	2C	Case study of a country with a national strategy or plan to strengthen prevention, detection, and response for SF medical products (Tanzania)	Case study
	2D	Two case studies of LMICs that have improved the management of SF incidents (Nigeria and Brazil)	Case study

Exhibit 10: Number of products and incidents recorded on the GSMS between 2013 and 2022, and the geographical breakdown between all six WHO regions in the 2018 to 2022 period

Total products Total incidents AMRO AFRO EURO EMRO SEARO WPRO

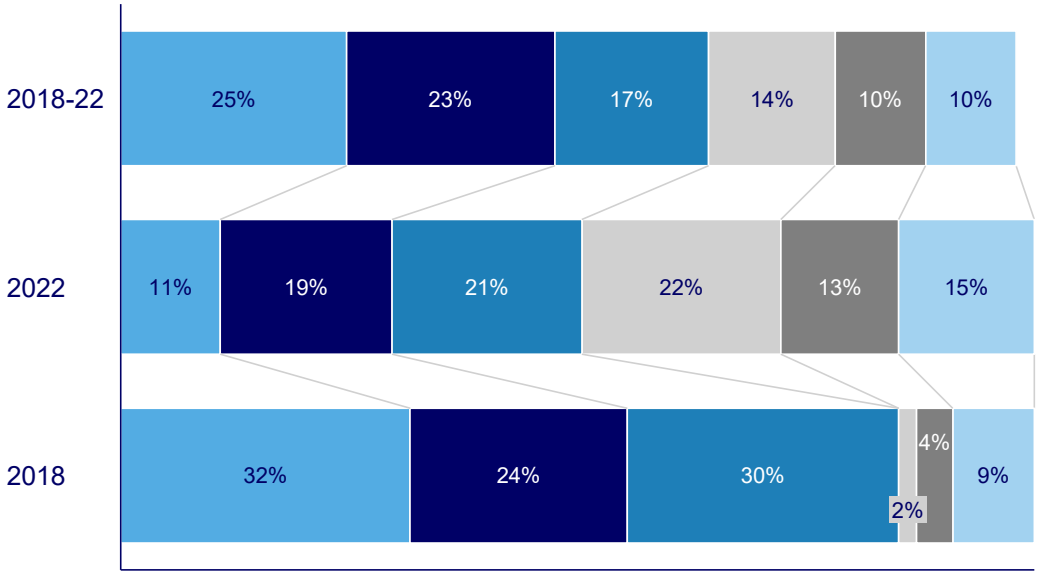
1,204 incidents and 2,187 products have been recorded on the GSMS since 2018 …

Total number of incidents and products recorded on the GSMS between 2013-17 and 2018-22



… and they are detected worldwide

Recorded incidents on the GSMS by WHO regions 2018-22, average

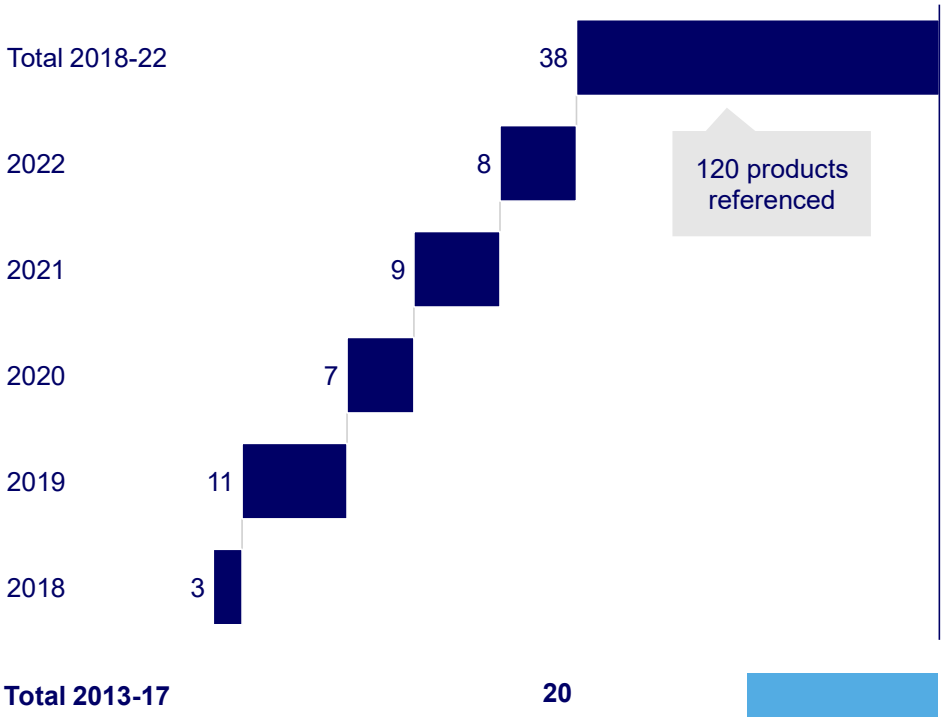


Source: Data from the WHO ISF team

Exhibit 11: Total number of global medical product alerts issued between 2013 and 2022, and the geographical breakdown between all six WHO regions between 2018 and 2022

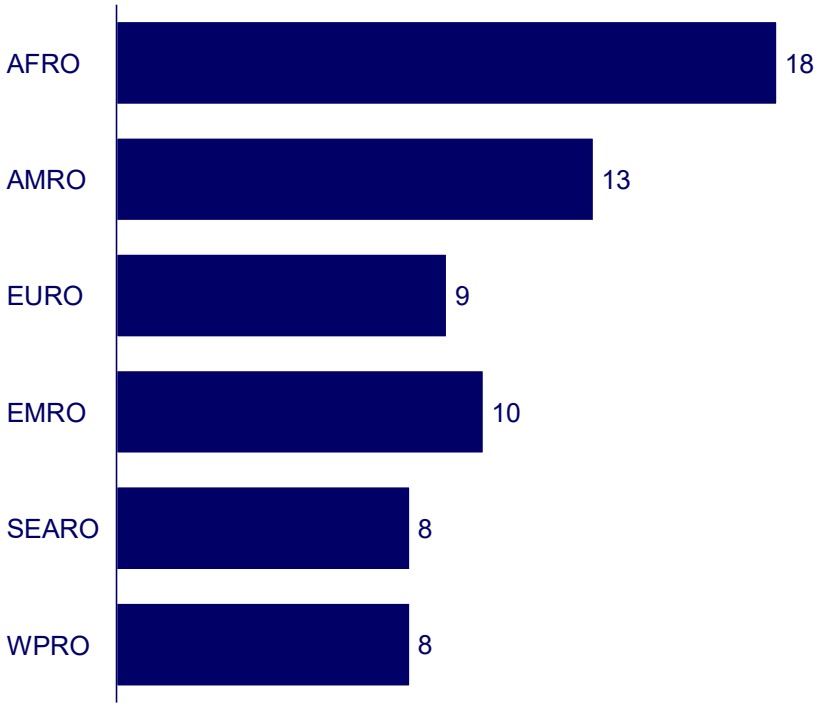
38 global medical product alerts have been issued since 2018 …

Number of product alerts launched per year, 2018-2022



… across all / by WHO regions

Count of product alerts recorded per WHO regions, 2018-2022



Source: Data from the WHO ISF team

Contents

World Health Organization

Exhibit 12: Key WHO activities related to medicines, vaccines, and IVD QCLs delete this version and replace with the 2nd version below

Service provided by WHO LNS team Service provided by WHO PQT IVD assessment team Service provided by WHO REG ISF team

	Medicines QCLs	Vaccines NCLs	IVD Reference Labs
Capacity building services provided to labs	• Provide technical support through peer audits and training to increase the capacity of national medicines QCLs and become compliant with international standards and PQ requirements • Foster twinning with PQ-ed NQCLs • Support annual medicines QCL meeting • Develop guidance on laboratory design • Develop case studies for training purposes	• Provide technical support through training to increase the capacity of NCLs for biologicals, harmonization of testing procedures, reducing animal testing, promoting international standards • Support annual WHO Network of National Control Laboratories for Biologicals (NBB) meeting • Maintain the WHO NNB SharePoint • Provide ad-hoc testing support following adverse events	• Provide technical support and trainings together with regional offices
WHO assessments of QCLs	• N/A • Inspections conducted by PQT INS	N/A	• N/A
Support provided to WHO PQ teams	• Review PQ applications of QCLs and conduct/coordinate the assessment for PQ • Maintain the list of prequalified medicines QCLs through annual reviews • Provide ad-hoc testing support (e.g., following adverse events)	Support the PQ process • Organize and coordinate laboratory testing as part of (pre-/post-) PQ • Maintain a list of WHO contract laboratories that are regularly audited to ensure that they adhere to WHO standards • Provide ad-hoc testing support following adverse events	IVD assessment • Organize and coordinate laboratory testing as part of (pre-)PQ., following complaints, quality surveys, etc. • Maintain a list of selected WHO contract laboratories that are audited to ensure adherence to WHO standards ISF Post market surveillance assessment., • General, PMS activities, following complaints, quality surveys, etc.

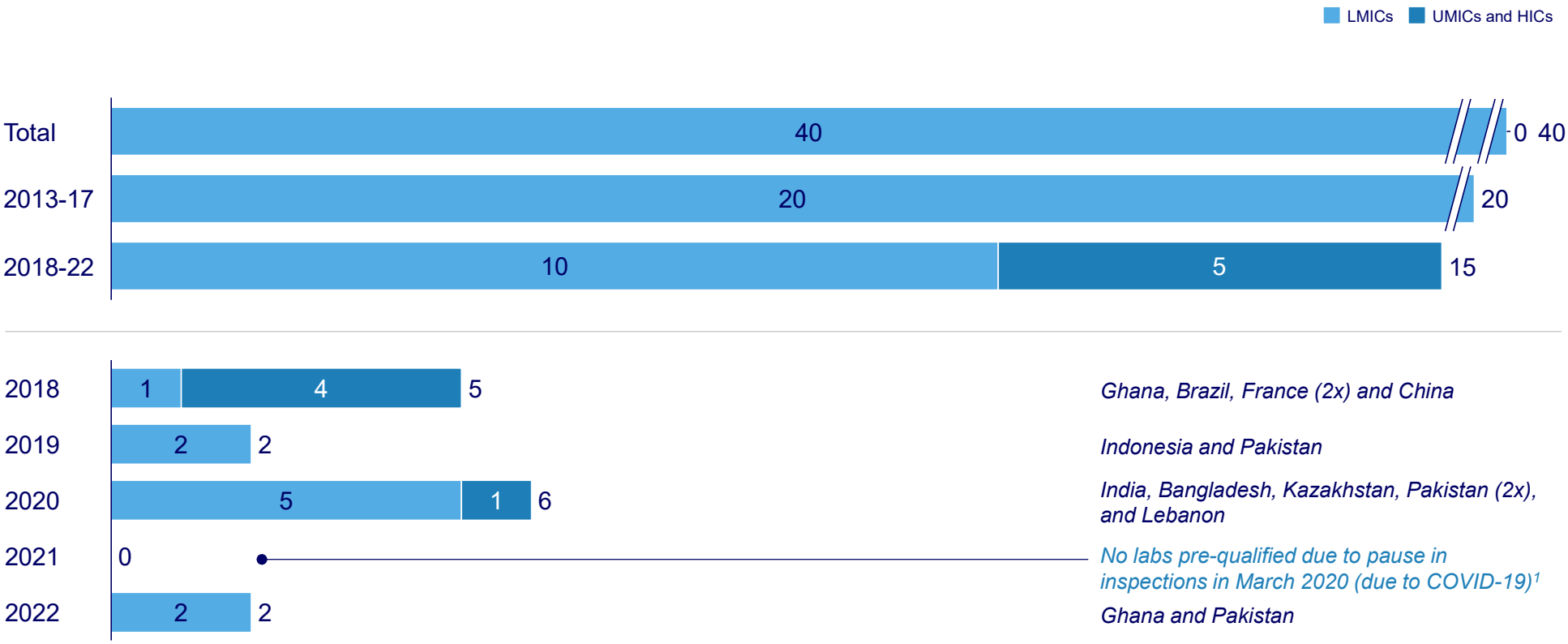
Source: Interview with Laboratory network and services (December, January 2022)

Exhibit 13: Key metrics covered and the methodology for the assessment under Theme 3

Topics	No.	Metric	Metric type
Increasing compliance of laboratories with required standards in LMICs	3A	Absolute number and percentage of quality control laboratories (QCLs) for medicines prequalified in LMICs (of the total qualified)	Quantitative
	3B	Case study of an LMIC that is a prequalified medicines QCL (China)	Case study
	3C	Absolute number and percentage of members of WHO Network of National Control Laboratories for Biologicals that are located in LMICs (out of the total members)	Quantitative

Exhibit 14: Number of QCLs for medicines that have received prequalification

Number of medicines QCLS that have received PQ

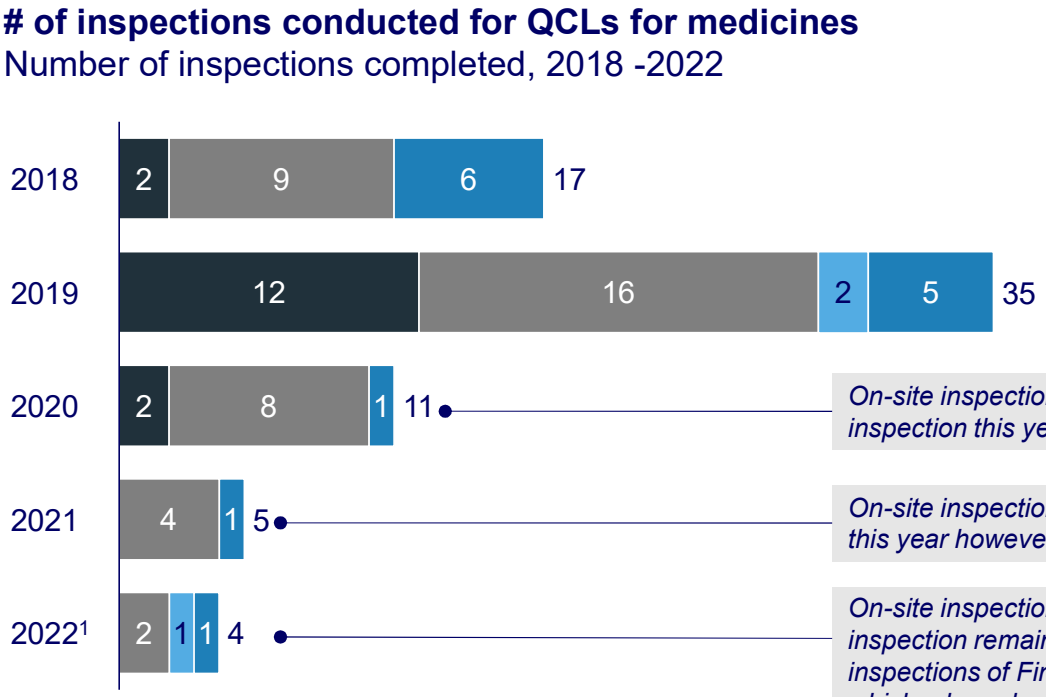


1. Discussed in additional detail in following exhibit

Source: Interview with Laboratory network and services (December 1, 2022), WHO data

Exhibit 15: Number of inspections completed (by type of inspection) for medicines QCLs

# of inspections conducted for QCLs for medicines
Number of inspections completed, 2018 -2022



On-site inspections are paused March 2020 due to COVID-19; only one pre-PQ inspection this year for a lab in Pakistan; lab was pre-qualified in 2020

On-site inspections resumed in limited number of countries; only one pre-PQ inspection this year however, lab was found non-compliant and has not yet received PQ

On-site inspections resumed in larger number of countries, however uptick for lab inspection remains low due to competing priorities for inspections team such as inspections of Finished product, API and CRO sites used for bioequivalence studies, for which a large backlog had accumulated since March 2020.

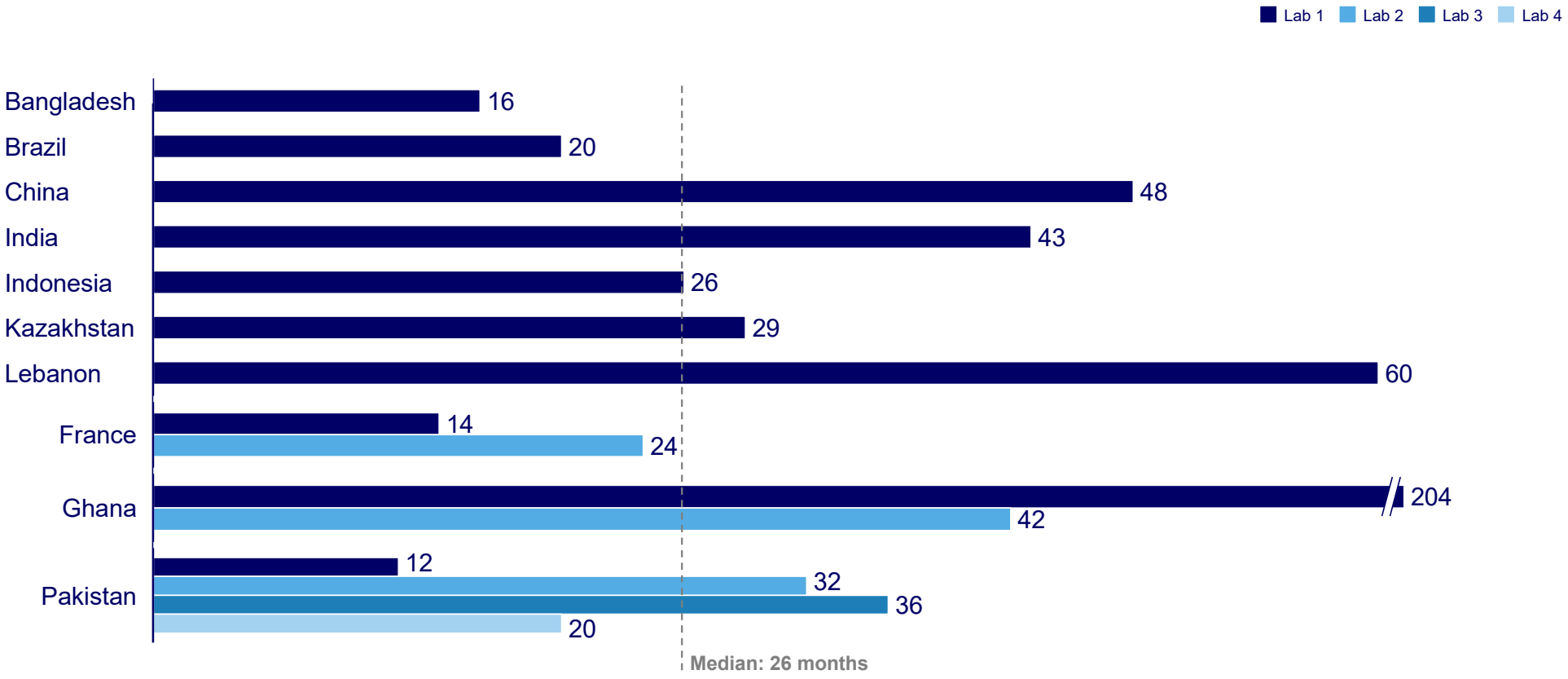
Two pre-PQ inspections this year – one resulting in PQ in November 2022, and in the lab was found non-compliant and has not yet received PQ

1. 7 inspections are under progress (in addition to the 4 completed ones reported in this exhibit)

Source: WHO data and interviews

Exhibit 16: Time to receive PQ in months by country and by lab between 2018 and 2022

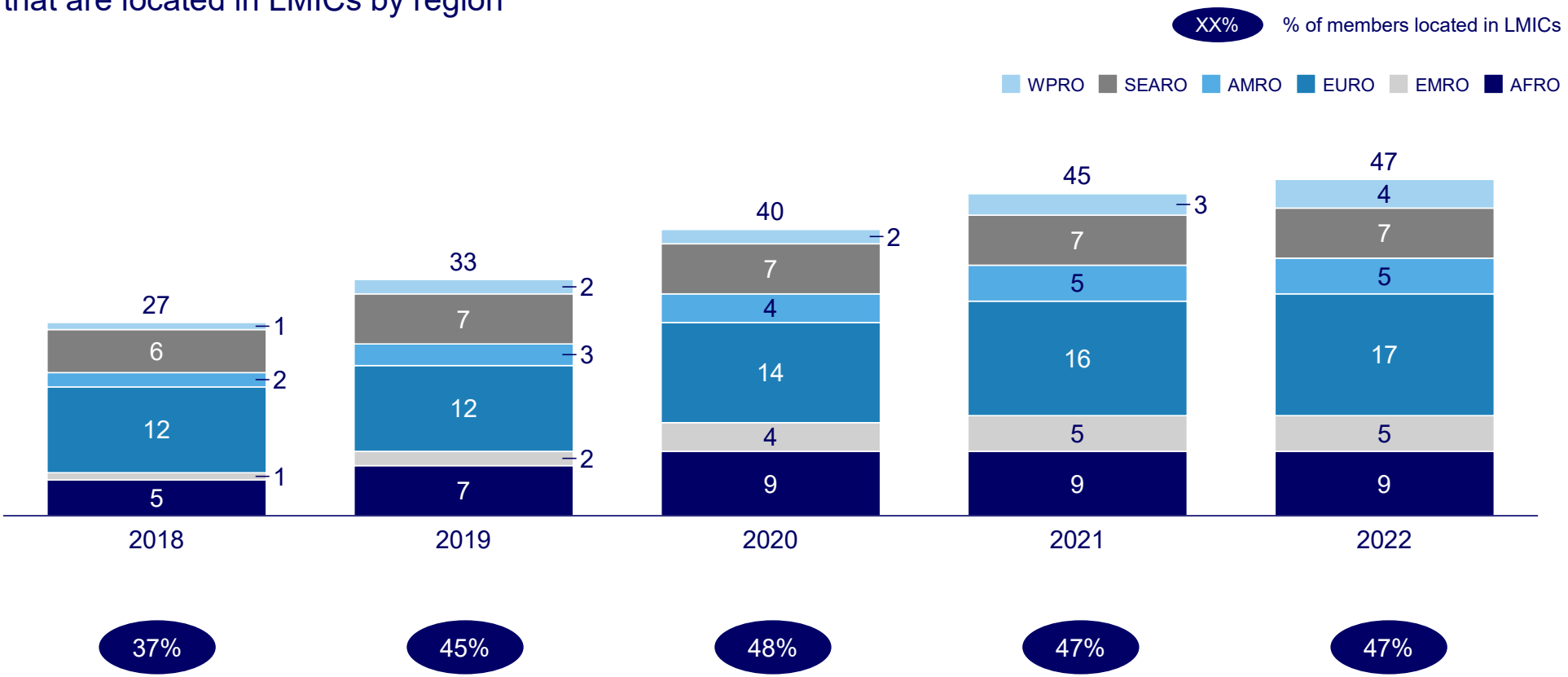
Time to receive PQ in months by country and by lab between 2018-22, starting from EOI



Source: Interview with Laboratory network and services (December 1, 2022), WHO data

Exhibit 17: Number of members of WHO Network of National Control Laboratories for Biologicals that are located in LMICs by region

Cumulative number of members of the WHO Network of National Control Laboratories (NCLs) for Biologicals that are located in LMICs by region



Source: WHO data

Contents

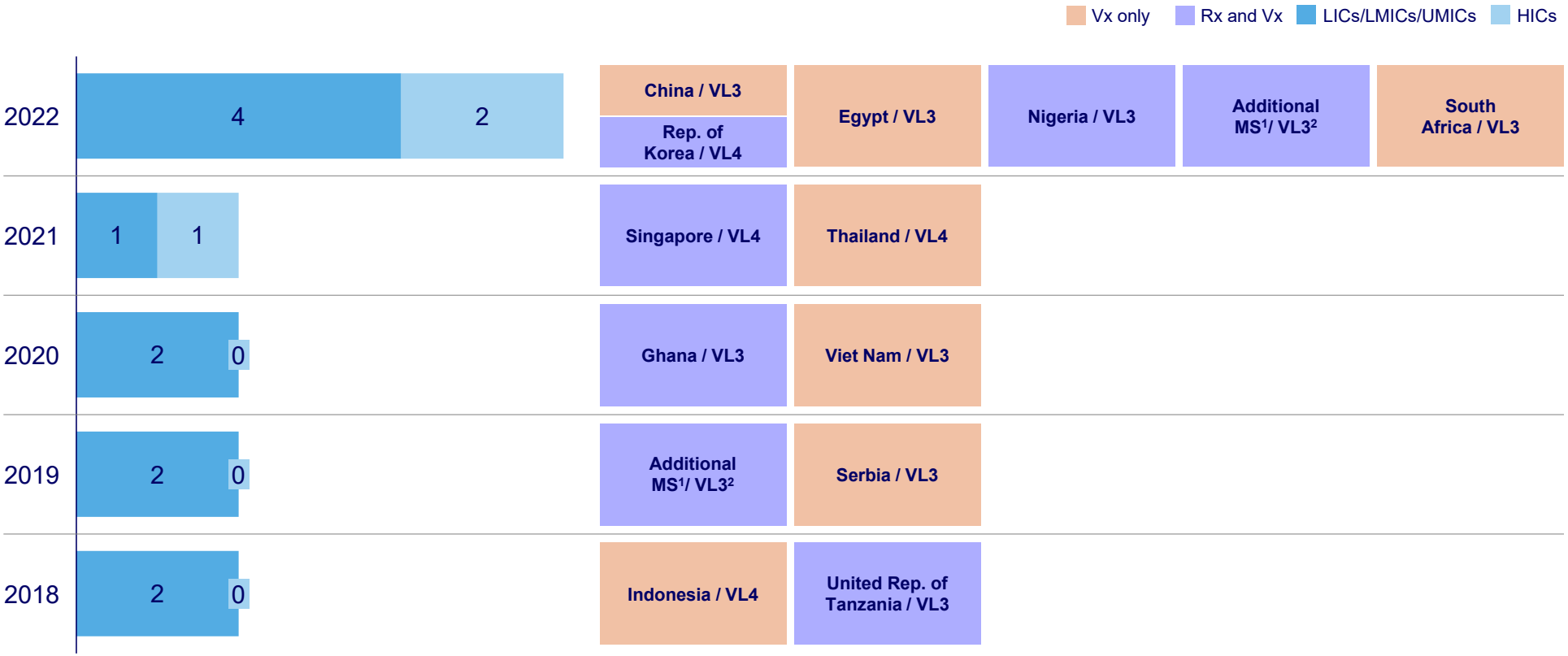
World Health Organization

Exhibit 18: Key metrics covered and the methodology for the assessment under Theme 4

Topics	No.	Metric	Metric type
Strengthening pharmaco-vigilance	4A	Number of countries with functional PV systems (VL3 and above)	Quantitative
	4B	Number of case safety reports in the WHO global database	Quantitative
	4C	Number of countries that have websites meeting WHO best-information-practice criteria	Quantitative
	4D	Number of countries implementing active surveillance mechanisms	Quantitative
	4E	Manufacturer, procurer/donor, NRA perception of the utility of PV activities	Perception

Exhibit 19: Number of new countries achieving VL3/4 per year between 2018 and 2022

Number of new countries achieving VL3/4 per year, 2016-2022

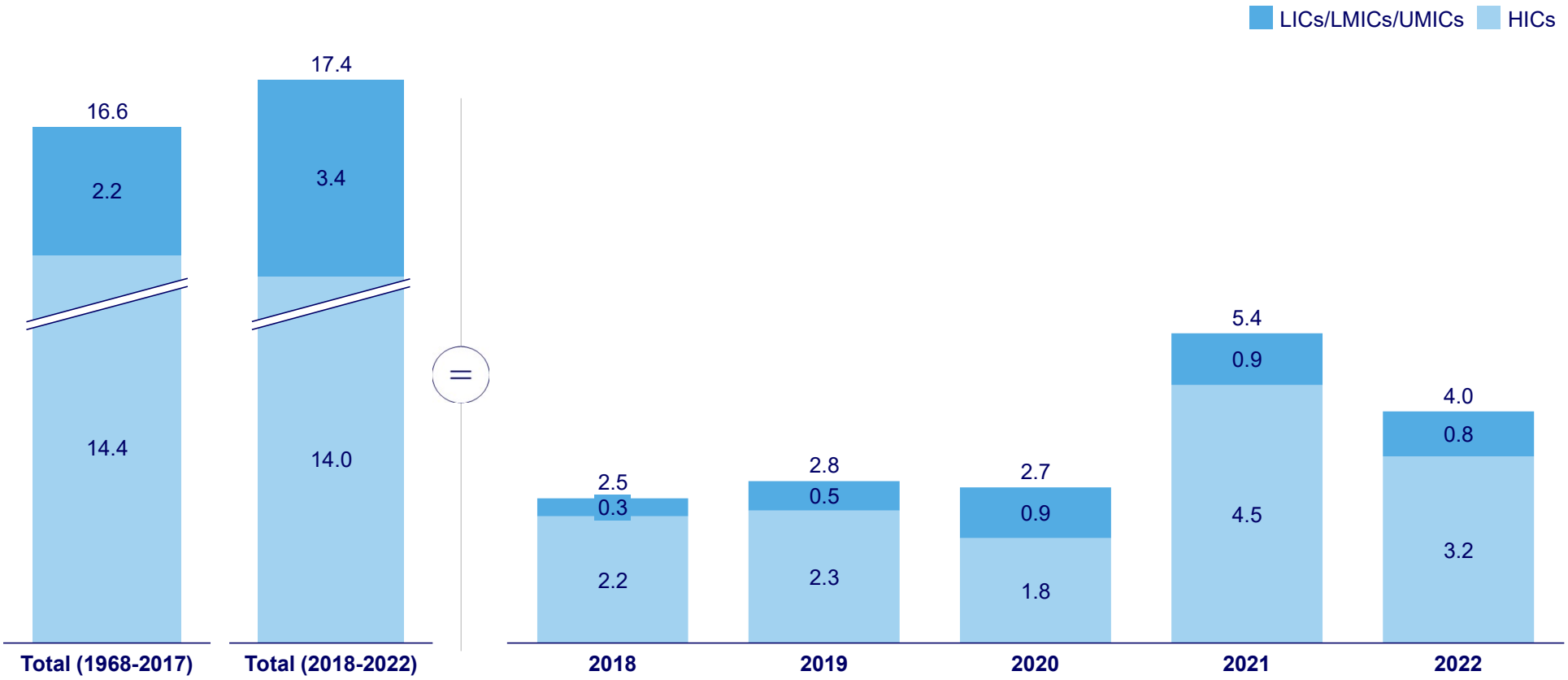


1. Additional Member State cannot be disclosed for confidentiality reason
2. countries with functional PV system (VL3/4) and ML level less that 3

Source: Interview with WHO PV team (Dec 5, 2022), WHO data

Exhibit 20: Number of ICSRs in VigiBase between 1968 and 2022

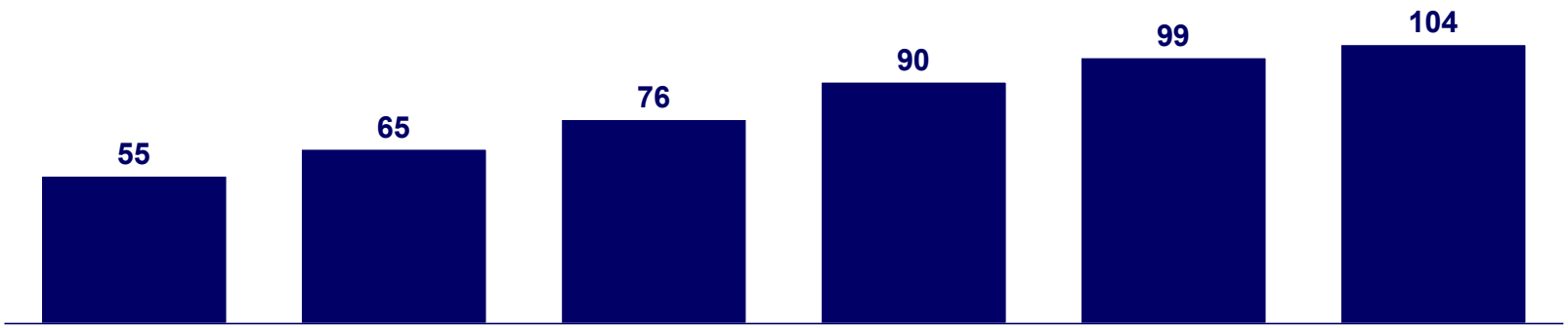
Total number of Individual Case Safety Reports (ICSRs) reports in Vigibase, in million, 1968-2022



Source: Interview with WHO PV team (Dec 5, 2022), WHO-UMC Vigibase

Exhibit 21: Number of websites represented in the VSN

Number of websites represented in the Vaccine Safety Net, # of websites, 2017-2022



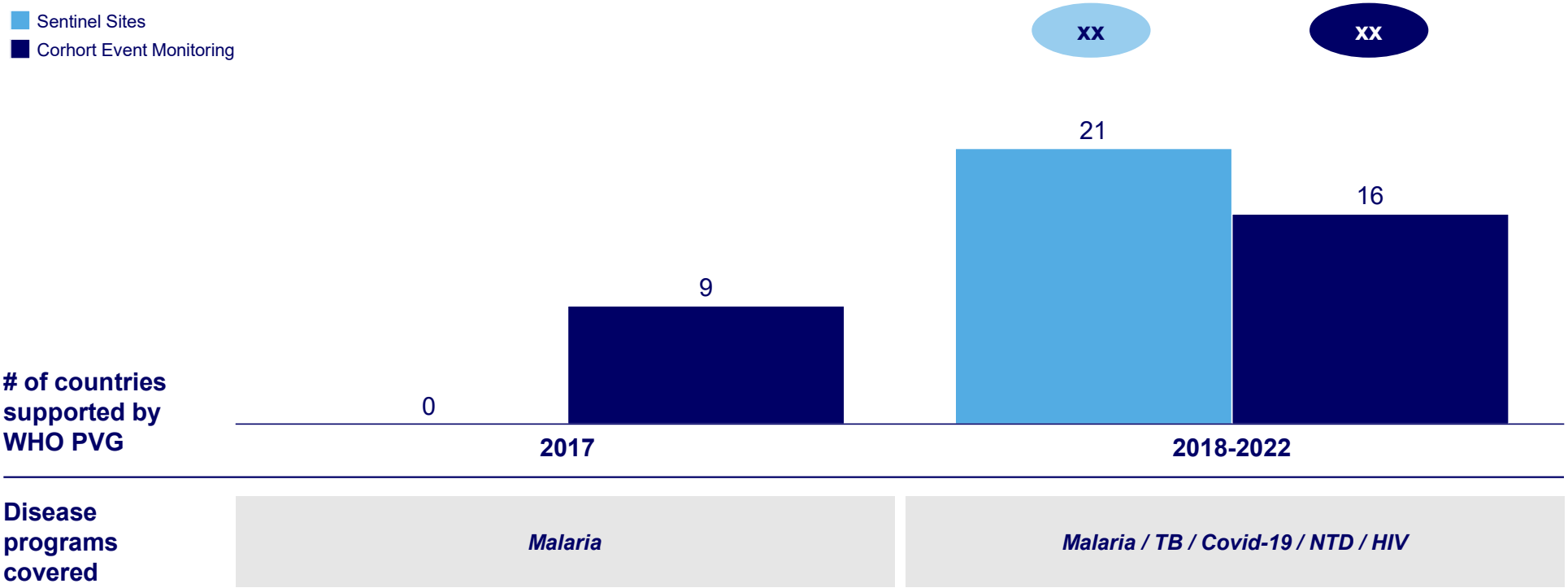
	2017	2018	2019	2020	2021	2022
# of countries represented by websites on the VSN	29	31	35	40	42	44
% of LICs/LMICs/UMICS	28%	32%	31%	40%	43%	43%

- An estimated 6.5 million users access vaccine safety information made available by VSN members every month
- VSN websites represent 36 world languages, with English representing the largest number of websites
- Amongst the 10 most populated countries in the world, Pakistan, Indonesia, and Bangladesh do not host a VSN member website

Source: Interview with WHO PV team (Dec 5, 2022), WHO Data, Vaccine Safety Net

Exhibit 22: Number of LICs, LMICs, and UMICs that implemented and/or experienced some form of active surveillance

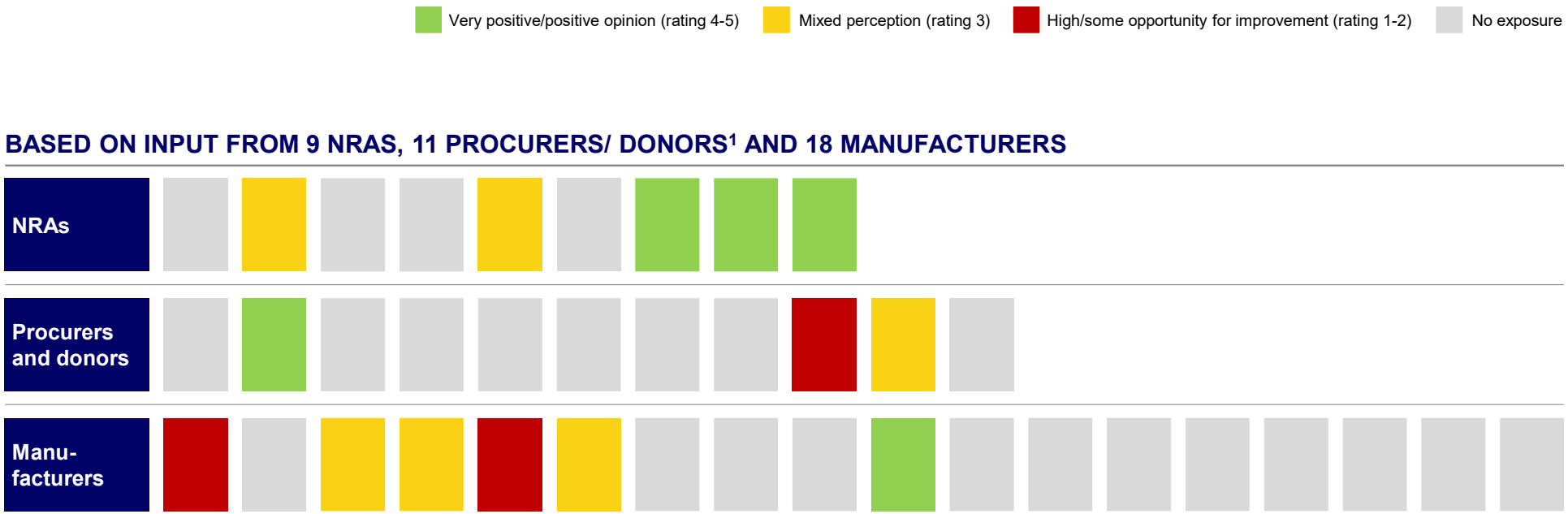
Number of LICs, LMICs, UMICs that have implemented and/or experienced some form of active surveillance, # LICs, LMICs, UMICs in 2017 and 2022, # of SS and CME



1. xx of the countries are in very early stages
2. xx of the countries are in very early stages

Source: Interview with WHO PV team (Dec 5, 2022), WHO Data, Vaccine Safety Net

Exhibit 23: Manufacturer, procurer/donor, NRA perception of utility of PV activities



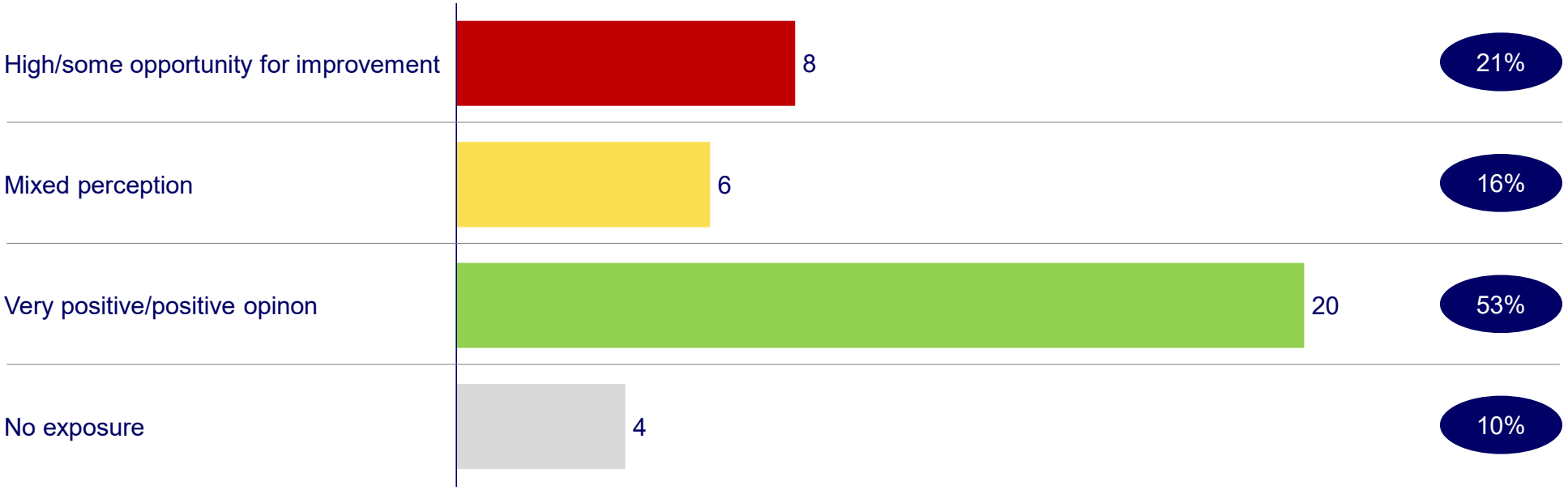
1. 14 separate interviews with 11 different procurers/donors

Source: Interviews with NRAs, procurers, donors and manufacturers taken in Dec 2022 and January 2023

Exhibit 24: Survey results on how the WHO's PV activities have impacted NRAs

On a scale from 1 to 5[2], how would you rate the impact WHO's PV activities have had in your country?

Number of responses, n=38[2]



1. 5 being the best
2. One grade disregarded due to reference to ISF products in comment

Source: Survey administered to NRAs for Impact assessment of WHO Prequalification and systems, Jan 2023

Contents

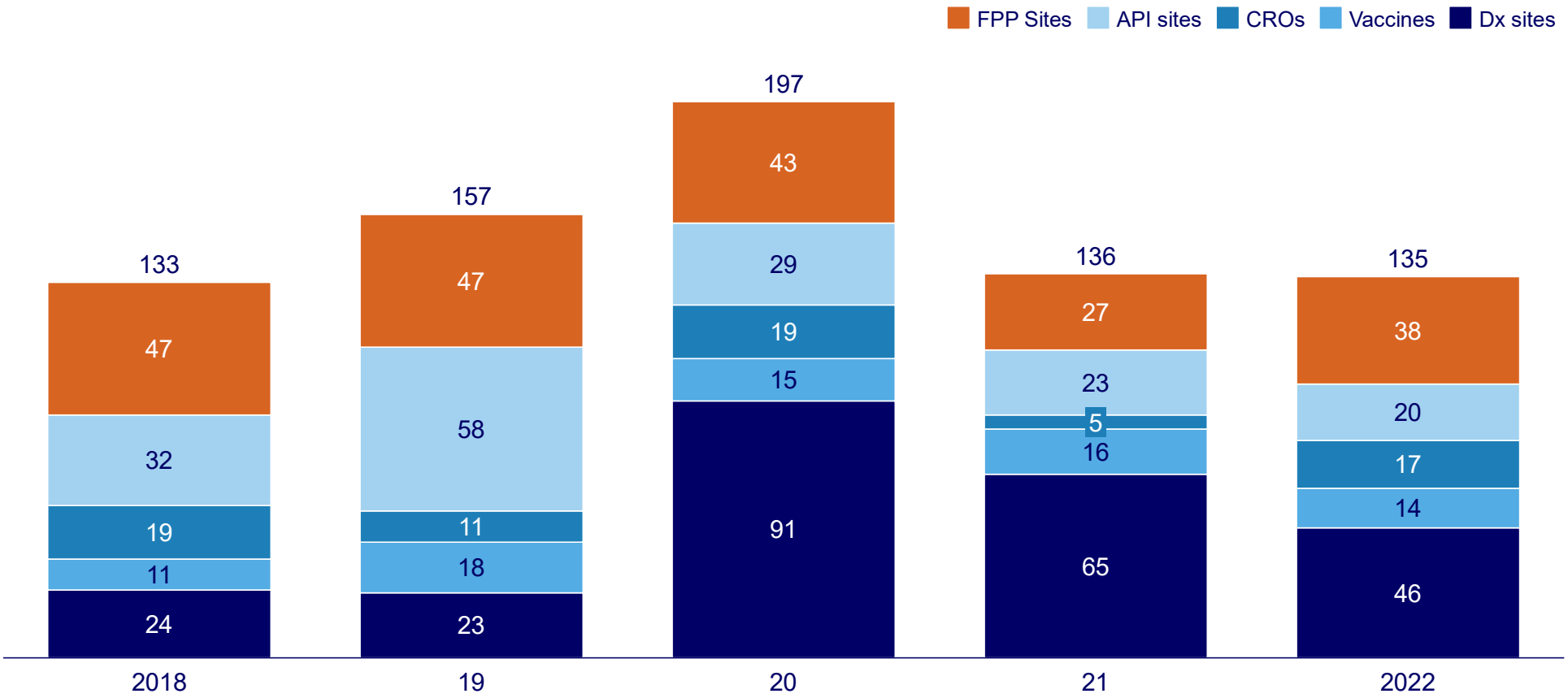
World Health Organization

Exhibit 25: Key Metrics covered and the methodology for the assessment under theme 5

Topics	No.	Metric	Metric type
Prequalification of medical products	5A	Number of products that have been prequalified or EUL-listed	Quantitative
	5B	Number of major donors requiring PQ for procurement	Quantitative
Collaborative Registration Procedure	5C	Number of accelerated product registrations in countries under CRP	Quantitative
	5D	Manufacturer, procurer/donor, and NRA/SRA perception of value-add of CRP of streamlining downstream approvals	Perception
Product registrations through other FPI pathways	5E	Number of product registrations that were accelerated for in-country introduction through other FPI pathways	Quantitative
	5E	Number of product registrations in countries during public health emergencies that are accelerated using facilitated pathways supported by FPI, such as COVAX and CRP	Quantitative

Exhibit 26: Number of inspections completed in support of PQ assessments (2018-2022)

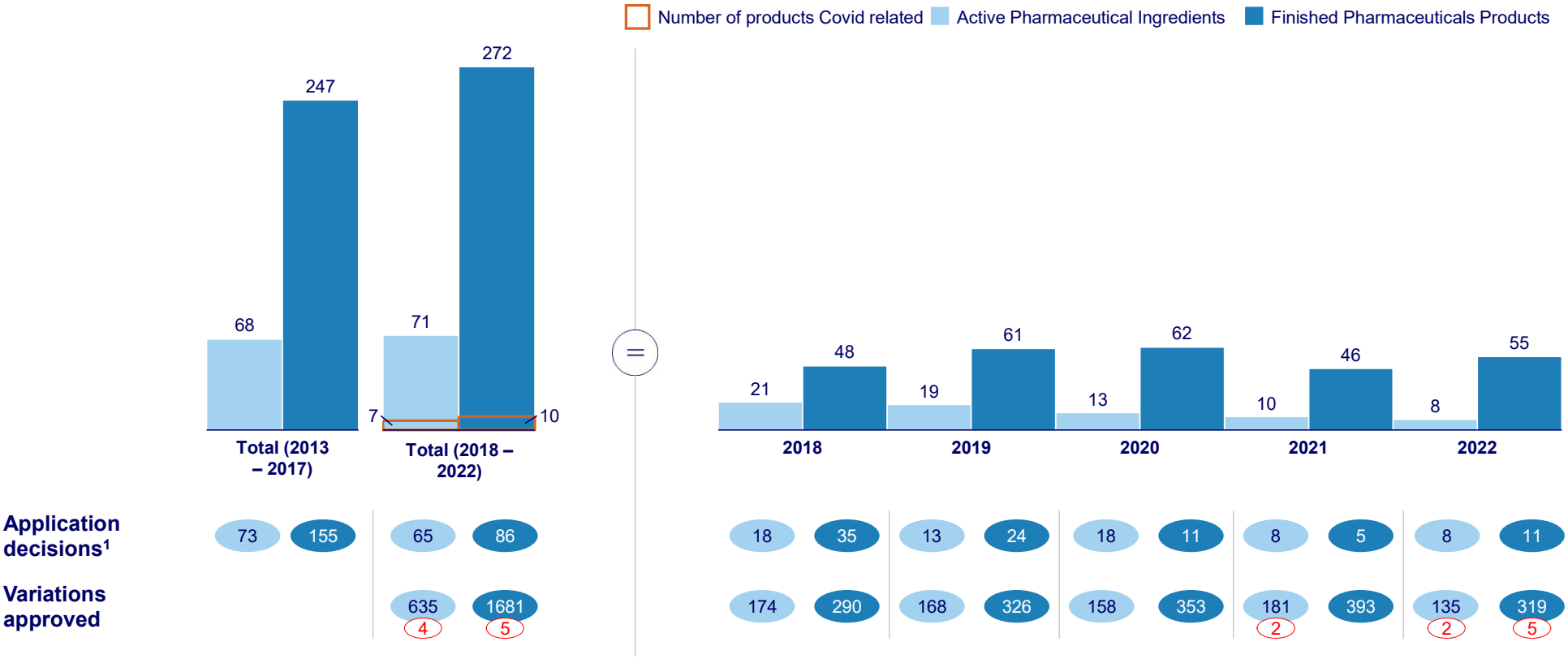
Total number of completed inspections, 2018-2022



Source: WHO Data

Exhibit 27: Number of FPPs and APIs prequalified between 2013 and 2022

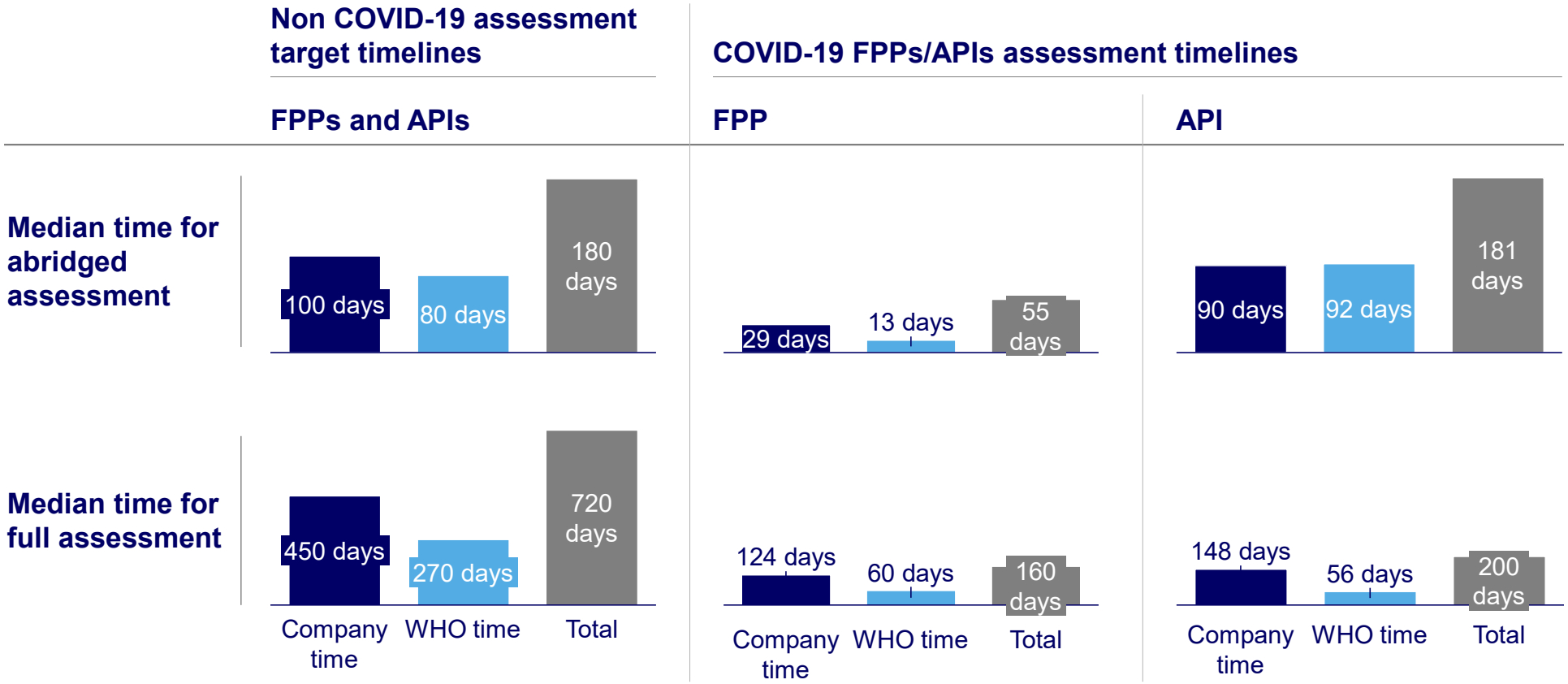
Number of FFPs and APIs prequalified between 2013 and 2022, 2013-2017, 2018-2022



1. Numbers represent dossiers either rejected during screening or withdrawn/cancelled at any time during assessment (but before prequalification)

Source: Data from WHO RPQ Medicine Assessment team

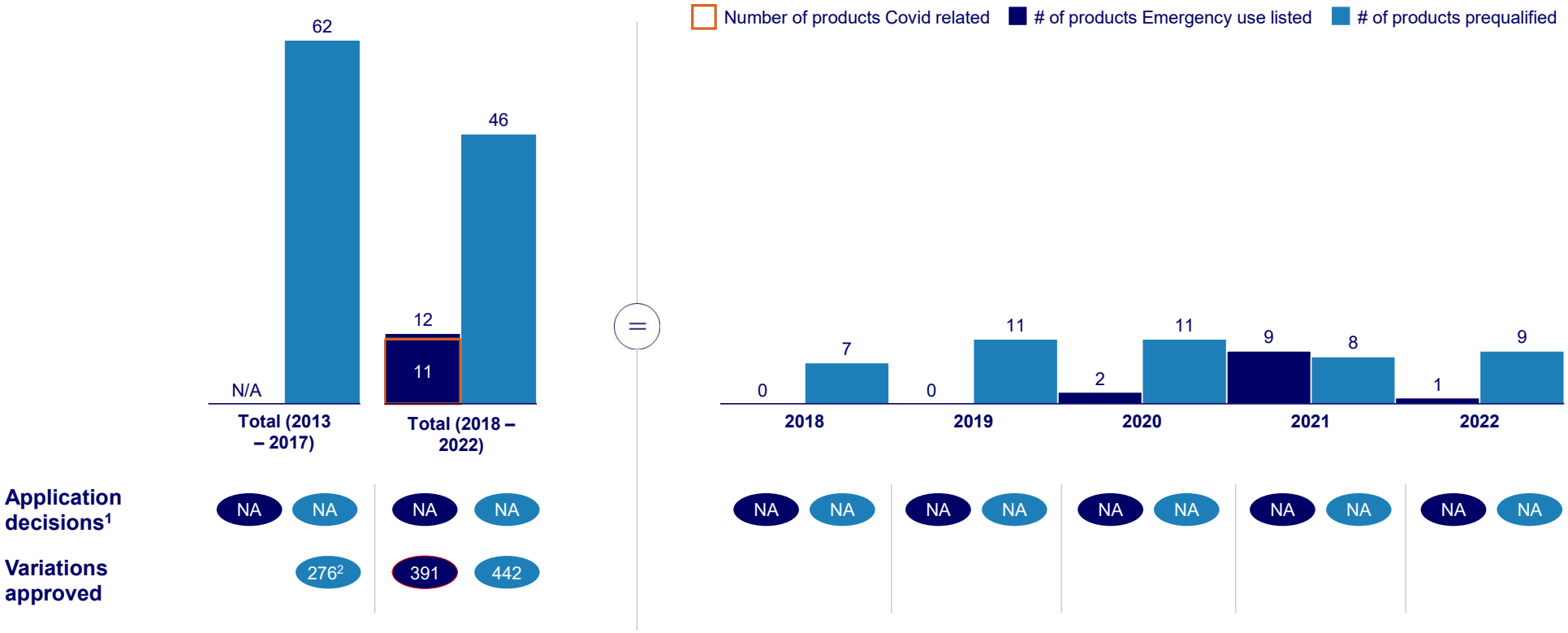
Exhibit 28: Median time for abridged assessment and full assessment for COVID-19 and non-COVID-19 FPPs and APIs



Source: Data from WHO RPQ Medicine Assessment Team

Exhibit 29: Number of vaccines prequalified or EUL listed and prequalified between 2013 and 2022

Number of Vaccines emergency use listed and prequalified between 2013 and 2022, 2013-2017, 2018-2022

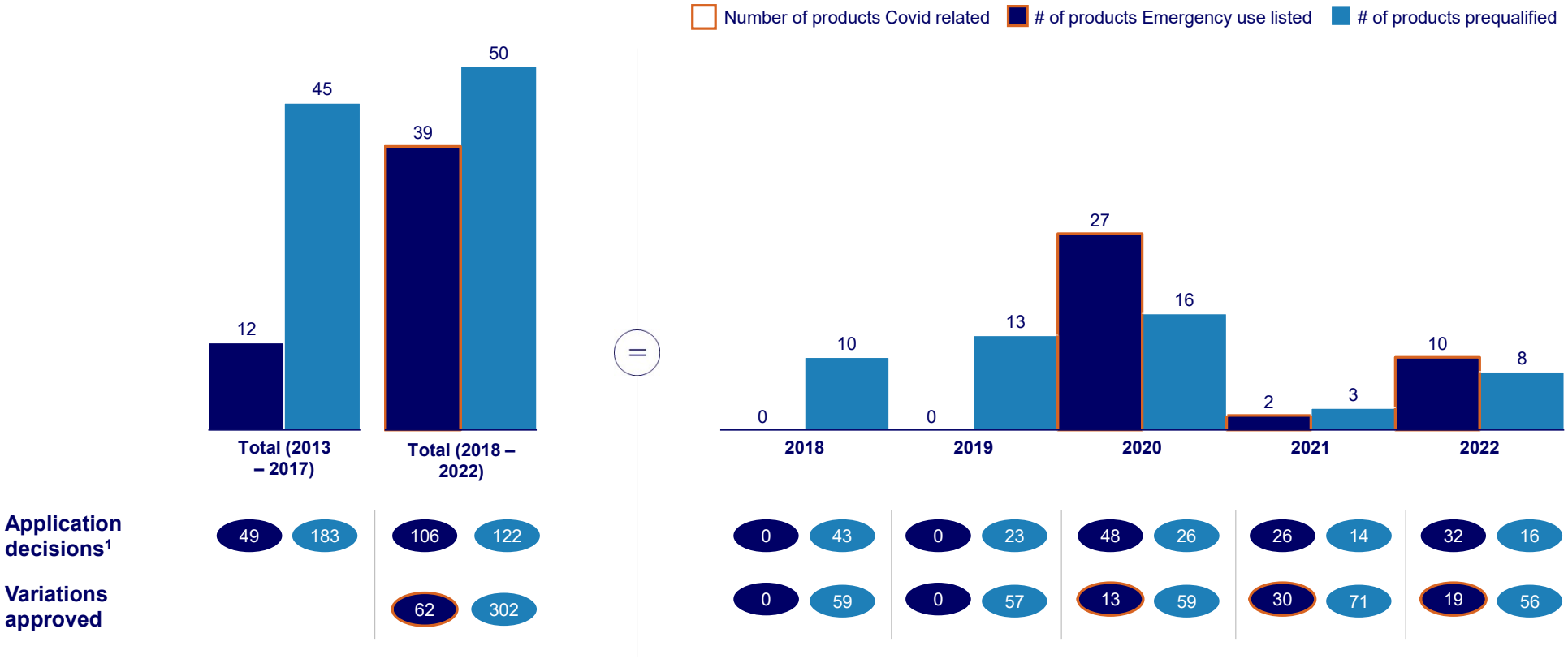


1.In case of vaccines (different from PQ process for medicines and IVDs), there is a mandatory requirement of the product meeting NRA criteria. In case an application is received that is not under oversight by an NRA it is not accepted. As a result, the application decisions over the last 5 years are the same as the number of PQ approved and EUL listed products in the graph
2.Does not include 2013 data due to unavailability

Source: Data from WHO RPQ Vaccines & Immunization Devices Assessment team

Exhibit 30: Number of diagnostics products EUL listed and prequalified between 2013 and 2022

Number of Diagnostics products emergency use listed and prequalified between 2018 and 2022, 2013-2017, 2018-2022



1. This data includes the failed and listed products. It does not include the withdrawals and renewals.

Source: Data from WHO RPQ IVD Assessment Team

Exhibit 31: Overview of major donors requiring PQ for the procurement of medicines

Donor/ procurer perspective on PQ — New compared to 2018

Organization	HIV/AIDS	TB[2]	MALARIA	RH	Contingency approval process
PEPFAR	FDA (NDA or ANDA or tFDA [1])	-	-	-	-
PMI	-	-	PQ or SRA approval	-	Test prior or concurrent to shipment
USAID	FDA (NDA or ANDA or tFDA	-	PQ and SRA approval and preapproved by a USAID wholesaler	FDA NDA or ANDA or PQ or SRA approval	UNFPA ERP[2] (for RH only)
UNFPA	-	-	-	WHO/UNFPA PQ or SRA approval	UNFPA ERP or pre-shipment inspection of pharmaceuticals
Unitaid	PQ or SRA approval	PQ or SRA approval	PQ or SRA approval	-	ERP
unicef	PQ or SRA approval	PQ or SRA approval	PQ or SRA approval	PQ or SRA approval	ERP
The Global Fund	PQ or SRA approval	PQ or SRA approval	PQ or SRA approval	-	ERP or meet various ISO standards and GHTF authorization[3]
Stop TB Partnership GLOBAL DRUG FACILITY	-	PQ or SRA approval	-	-	ERP
MEDECINS SANS FRONTIERES	PQ or SRA approval or tFDA[1]	PQ or SRA approval or tFDA[1]	PQ or SRA approval or tFDA[1]	PQ or SRA approval or tFDA[1]	ERP[3] or MSF qualification process[2]
UNDP	PQ or SRA approval	PQ or SRA approval	PQ or SRA approval	PQ or SRA approval	ERP
Pan American Health Organization	PQ or SRA approval (PQ preferred)	PQ or SRA approval (PQ preferred)	PQ or SRA approval (PQ preferred)	PQ or SRA approval (PQ preferred)	Internal PAHO mechanisms for quality assurance with NRAs
ICRC 6	PQ or SRA approval	PQ or SRA approval	PQ or SRA approval	PQ or SRA approval	-
IPPF	-	-	-	WHO/UNFPA PQ or SRA approval	ERP

1. Tentative FDA; 2. Includes a preassessment based on product and manufacturer questionnaires, a Good Manufacturing Practices (GMP) of the manufacturing site, a product evaluation based on product and/or manufacturer questionnaire(s) according to standards set by WHO, and based on a standard Product Questionnaire common to the Interagency Pharmacist Group (UNICEF, ICRC, The Global Fund, WHO procurement center, UNFPA, GDF and MSF) and active monitoring and follow up; 3. Expert Review Panel; 4. Specifically, the "WHO certification scheme on pharmaceuticals moving in International Commerce"; 5. Good Manufacturing Practice; 6. Details provided based on interviews with WHO colleagues / could not be validated with publicly available information

Source: Donor/procurer publications; web search; expert interviews

Exhibit 32: Overview of major donors requiring PQ for procurement of vaccines

	Donor/ procurer perspective on PQ	Contingency approval process
Gavi The Vaccine Alliance	Only PQ accepted	Specific exemption to procure non-prequalified products possible under defined criteria
unicef supply	Only PQ accepted	-
Pan American Health Organization	PQ or SRA approval (PQ preferred)	Internal PAHO processes for the assurance of quality
MEDECINS SANS FRONTIERES	PQ or SRA approval or tFDA[1]	ERP[2] or MSF qualification process[3]
ICRC[4]	PQ or SRA approval	
International Coordinating Group (ICG) on Vaccine Provision[4]	PQ or SRA approval (PQ preferred)	Products listed under EUAL[5] or final written acceptance of product and manufacturer by the recipient country and WHO final procurement procedures

New compared to 2018

1. Tentative FDA 2 Expert Review Panel 3 Includes a preassessment based on product and manufacturer questionnaires, a Good Manufacturing Practices (GMP) of the manufacturing site, a product evaluation based on product and/or manufacturer questionnaire(s) according to standards set by WHO, and based on a standard Product Questionnaire common to the Interagency Pharmacist Group (UNICEF, ICRC, The Global Fund, WHO procurement center, UNFPA, GDF and MSF) and active monitoring and follow up 4 Details provided based on interviews with WHO colleagues / could not be validated with publicly available information 5 Emergency Use Assessment and Listing

Source: Donor/procurer publications; web search; expert interviews

Exhibit 33: Overview of major donors requiring PQ for procurement of diagnostics

	Donor/ procurer perspective on PQ				
Organization	**HIV/AIDS**	**TB[2]**	**MALARIA**	**RH**	**Contingency approval process**
unicef [1]	PQ	-	PQ	PQ	GHTF authorization[3] or ERP[4]
UNDP	Only PQ accepted	-	Only PQ accepted	Only PQ accepted	-
UNFPA	Only PQ accepted	-	Only PQ accepted	PQ or SRA approval	-
The Global Fund	PQ	WHO endorsement	PQ	PQ	GHTF authorization or ERP
PEPFAR	Only PQ accepted	-	-	-	PEPFAR Formal review process
PMI	-	-	PQ	-	Other USAID/ CDC approval[5]
MSF	PQ or SRA approval	PQ or SRA approval	PQ or SRA approval	PQ or SRA approval	GHTF authorization or MSF's qualification scheme
Unitaid	PQ or SRA approval	WHO endorsement	Only PQ accepted	-	ERP
Elizabeth Glaser Pediatric AIDS Foundation [6]	PQ or SRA approval	-	-	-	ERP
USAID	US FDA PMA/510k[1] and PQ	FDA or PQ or WHO recommended[2]	-	-	-
IPPF	-	-	-	WHO/UNFPA PQ or SRA approval	Products that are CE marked or have equivalent certification or licensing[3]

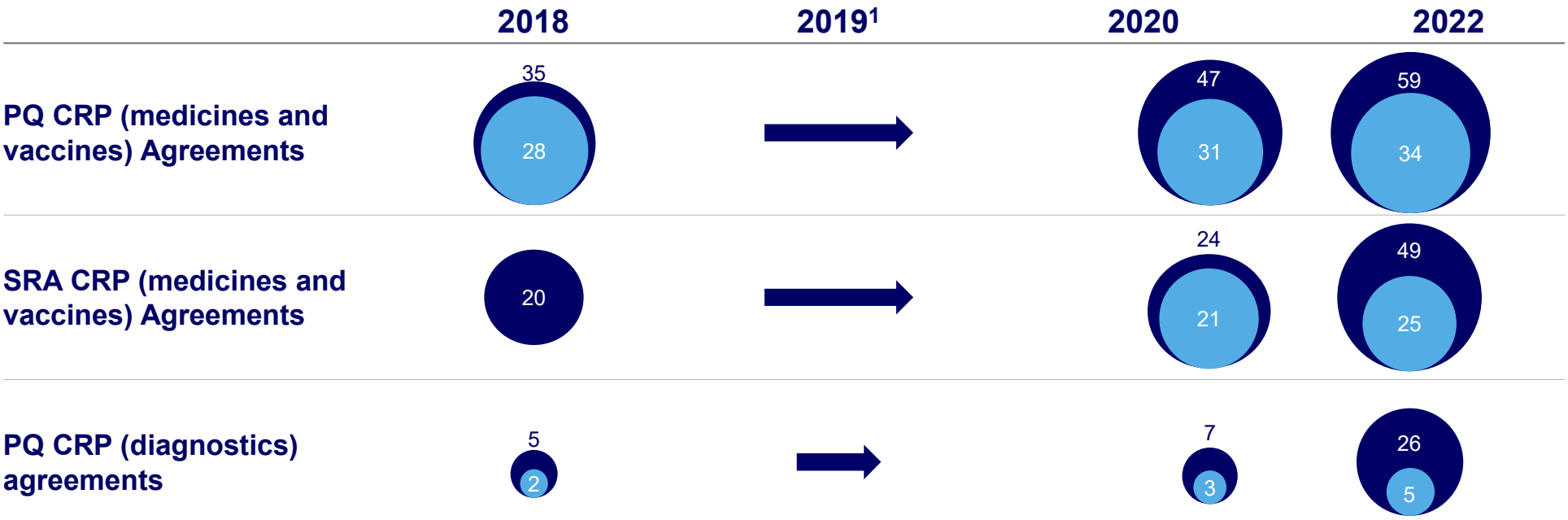
New compared to 2018

1. For projects with UNITAID and CHAI, SRA approval or ERP are also used 2. Dx TB is not covered by PQ but by TB WHO guidelines (and associated standards) on tuberculosis, 3. For intro-vitro diagnostics, authorization for use by one of the Regulatory Authorities of the Founding Members of Global Harmonization Task Force (GHTF) (EU, USA, Canada, Australia, and Japan). Dx that are not IVD only have meet ISO 9000 manufacturing requirements; 4. Expert Panel Review, 5. PQ is accepted, but other products based on USAID/CDC requirements can be accepted too. CDC will soon start malaria RDT performance evaluations for PQ; 6. Details provided based on interviews with WHO colleagues / could not be validated with publicly available information

Source: Donor/procurer publications; web search; expert interviews

Exhibit 34: Number of countries that have signed PQ CRP agreements for vaccines and medicines and diagnostics, and SRA CRP agreements for vaccines and medicines between 2018 and 2022

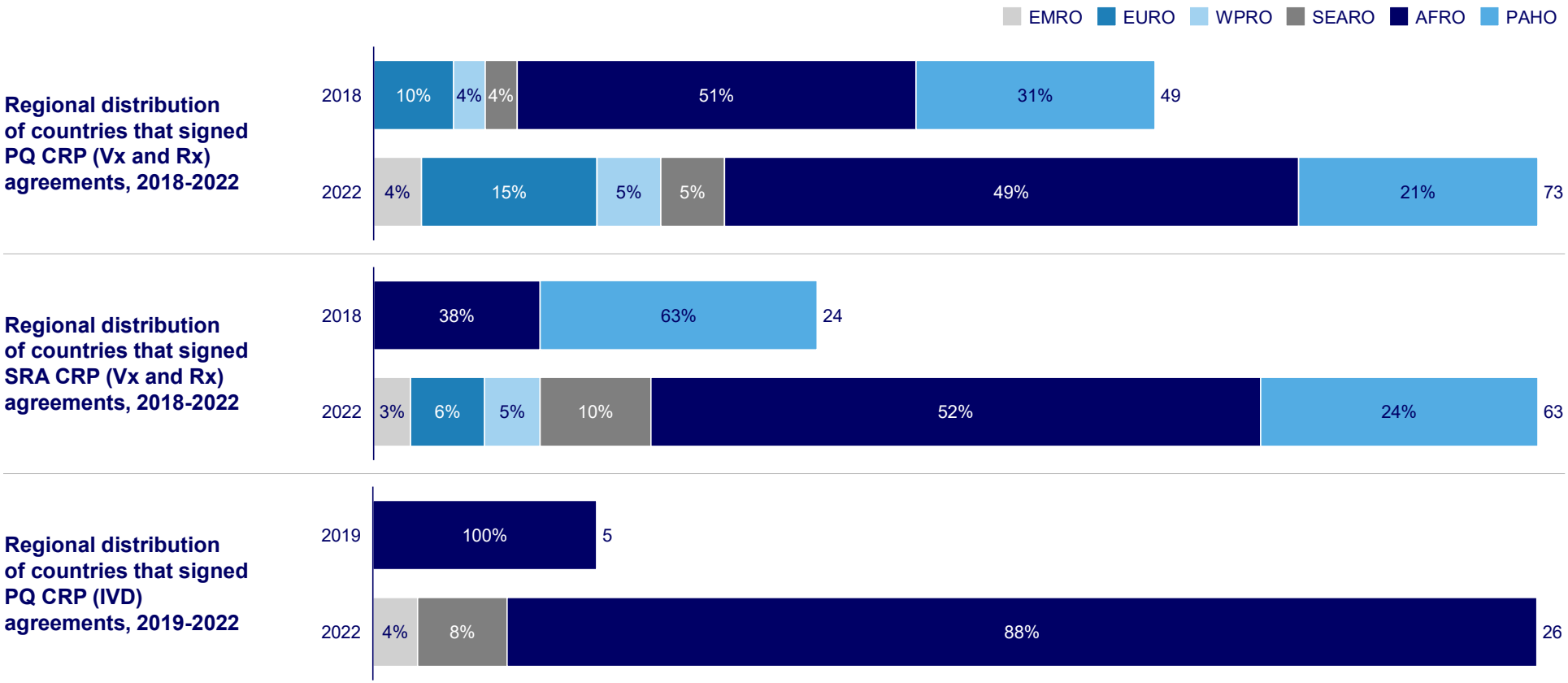
Cumulative number of countries signing CRP agreements and subsequently registering products using them, 2018-2022



1. PQ CRP for diagnostics started in 2019

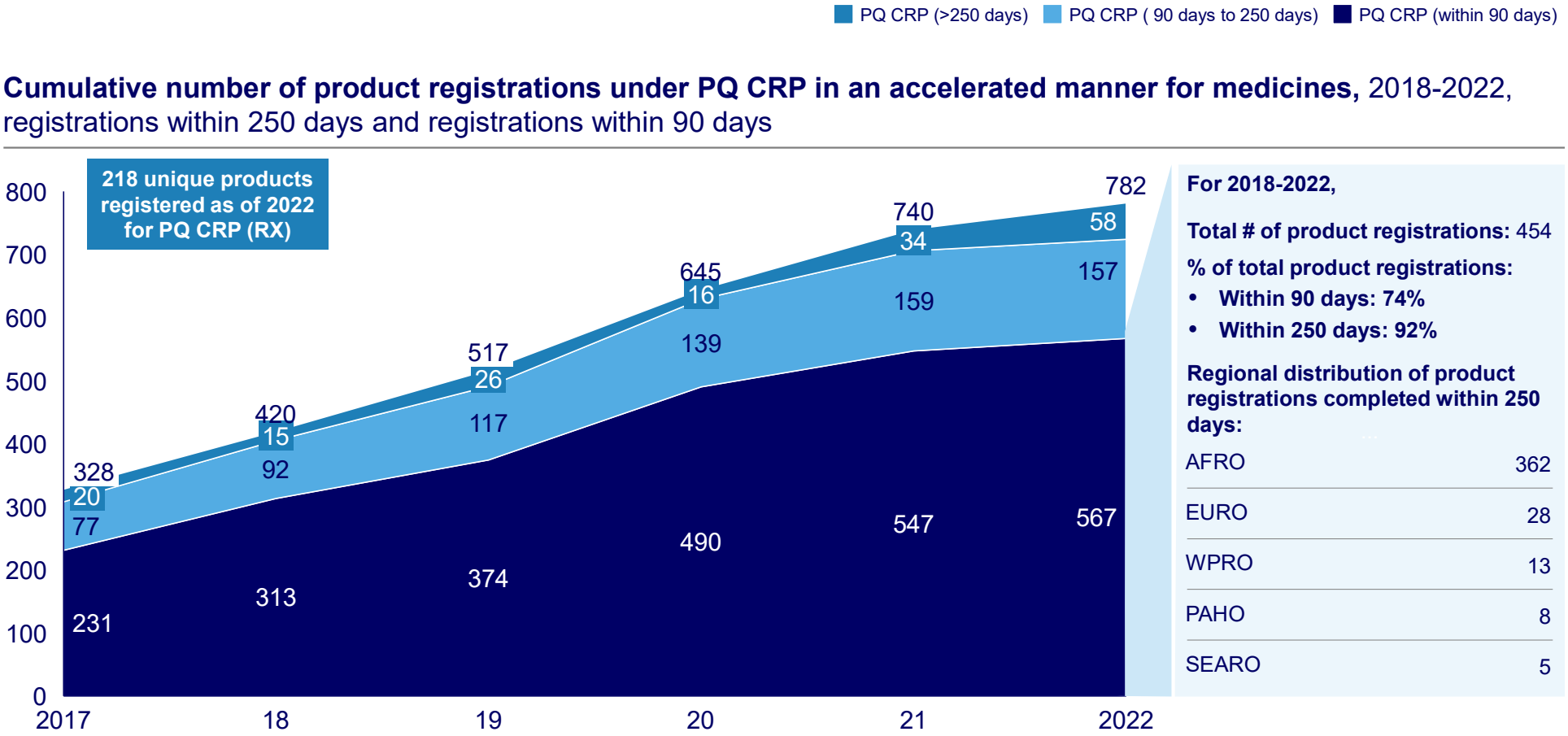
Source: Data from WHO FPI team

Exhibit 35: Breakdown of number of countries that have signed various CRP agreements between 2018 and 2022 by WHO region



Source: Data from WHO FPI team

Exhibit 36: Cumulative number of accelerated product registrations under PQ CRP for medicines



Cumulative number of product registrations under PQ CRP in an accelerated manner for medicines, 2018-2022, registrations within 250 days and registrations within 90 days

For 2018-2022,

Total # of product registrations: 454

% of total product registrations:

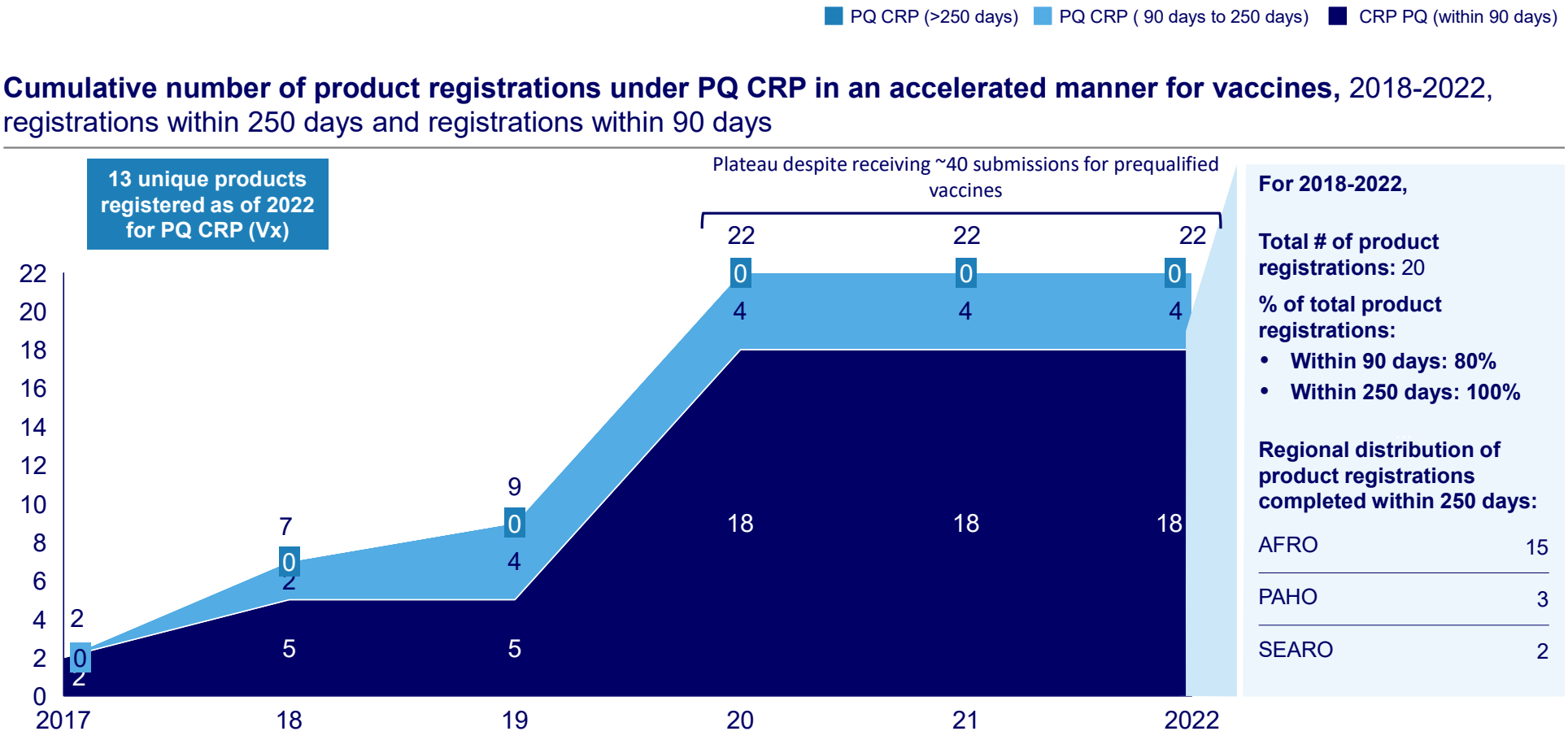
- **Within 90 days: 74%**
- **Within 250 days: 92%**

Regional distribution of product registrations completed within 250 days:

AFRO	362
EURO	28
WPRO	13
PAHO	8
SEARO	5

Source: Data from WHO FPI team

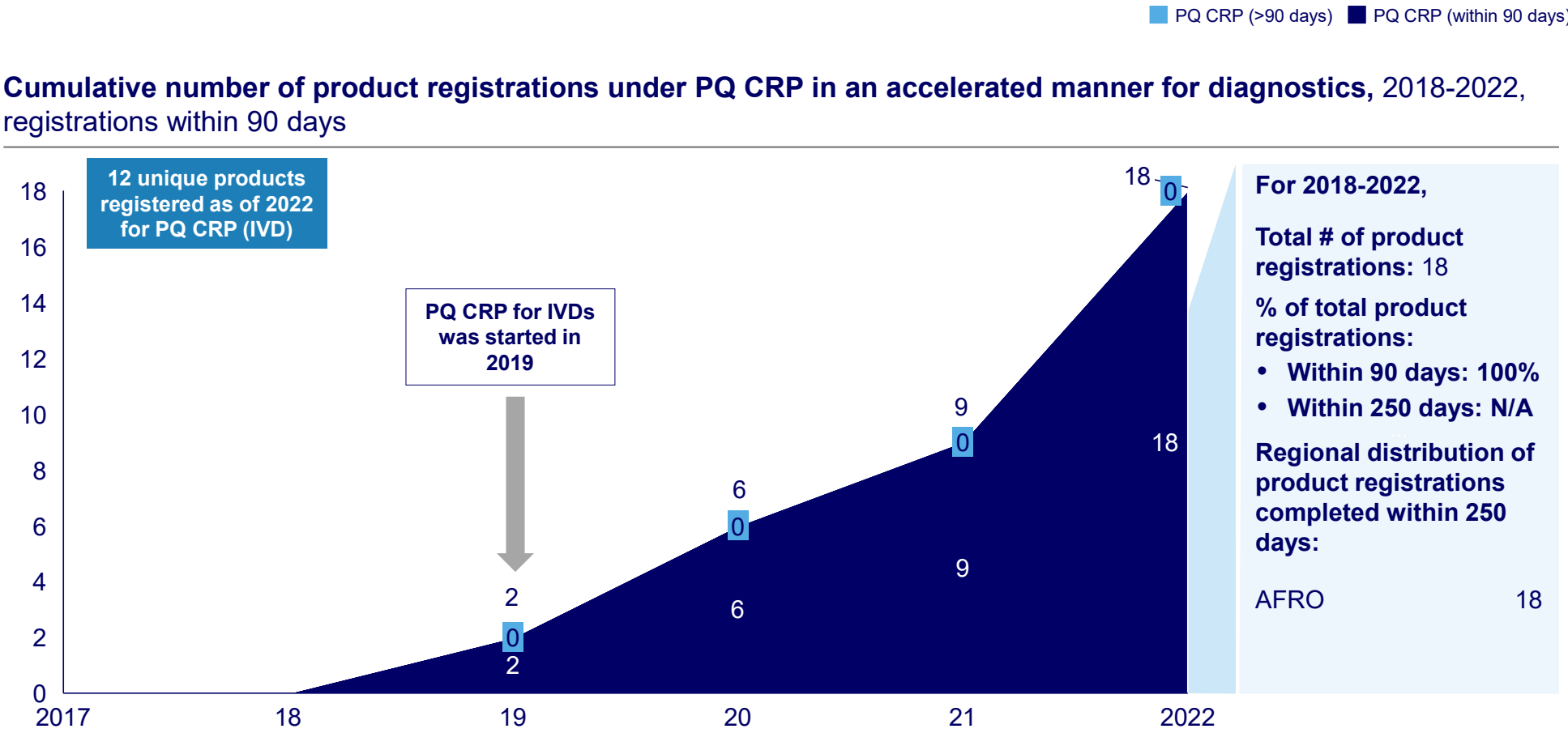
Exhibit 37: Cumulative number of accelerated product registrations under PQ CRP for vaccines



Cumulative number of product registrations under PQ CRP in an accelerated manner for vaccines, 2018-2022, registrations within 250 days and registrations within 90 days

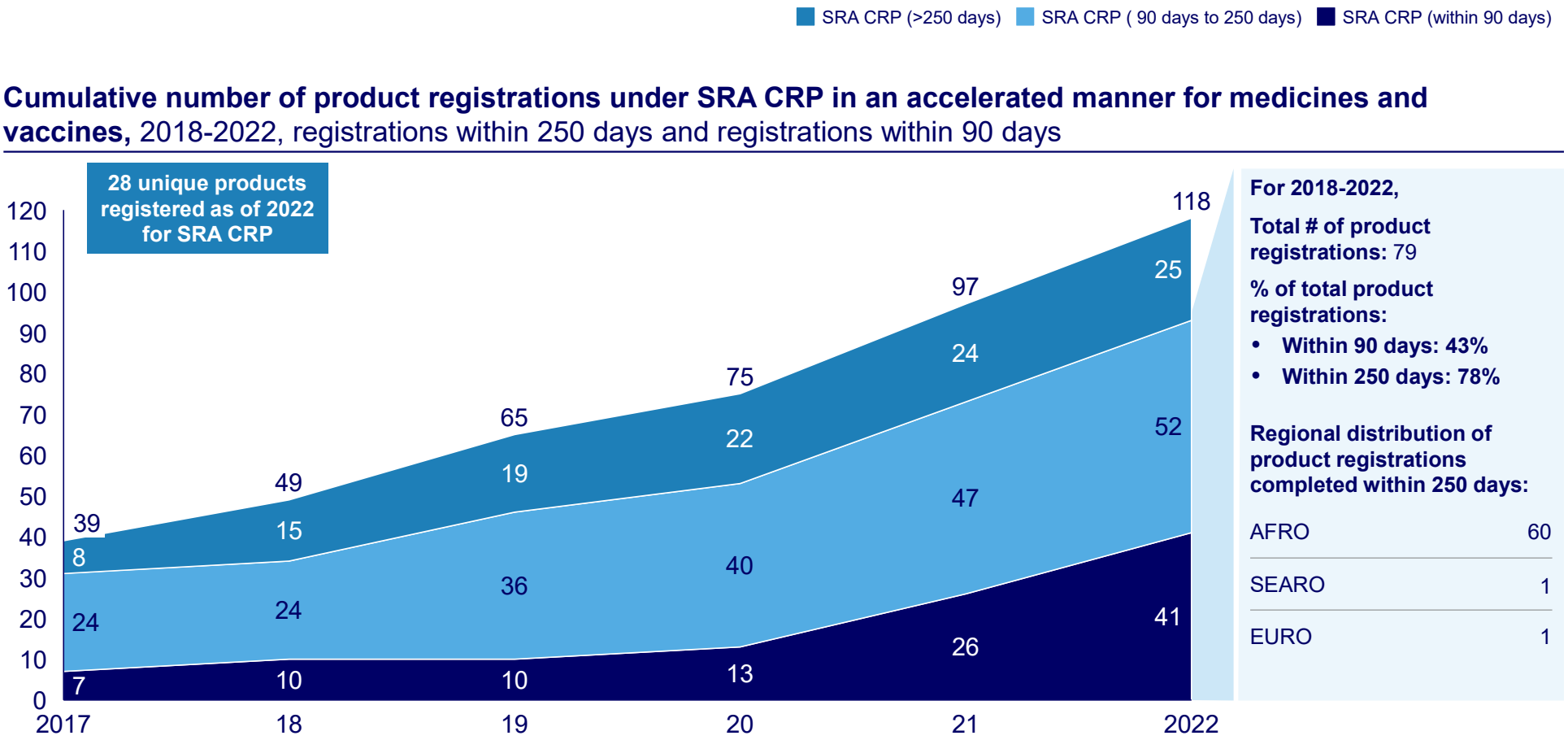
Source: Data from WHO FPI team

Exhibit 38: Cumulative number of accelerated product registrations under PQ CRP for diagnostics



Source: Data from WHO FPI team

Exhibit 39: Cumulative number of accelerated product registrations under SRA CRP for medicines and vaccines



Cumulative number of product registrations under SRA CRP in an accelerated manner for medicines and vaccines, 2018-2022, registrations within 250 days and registrations within 90 days

For 2018-2022,

Total # of product registrations: 79

% of total product registrations:

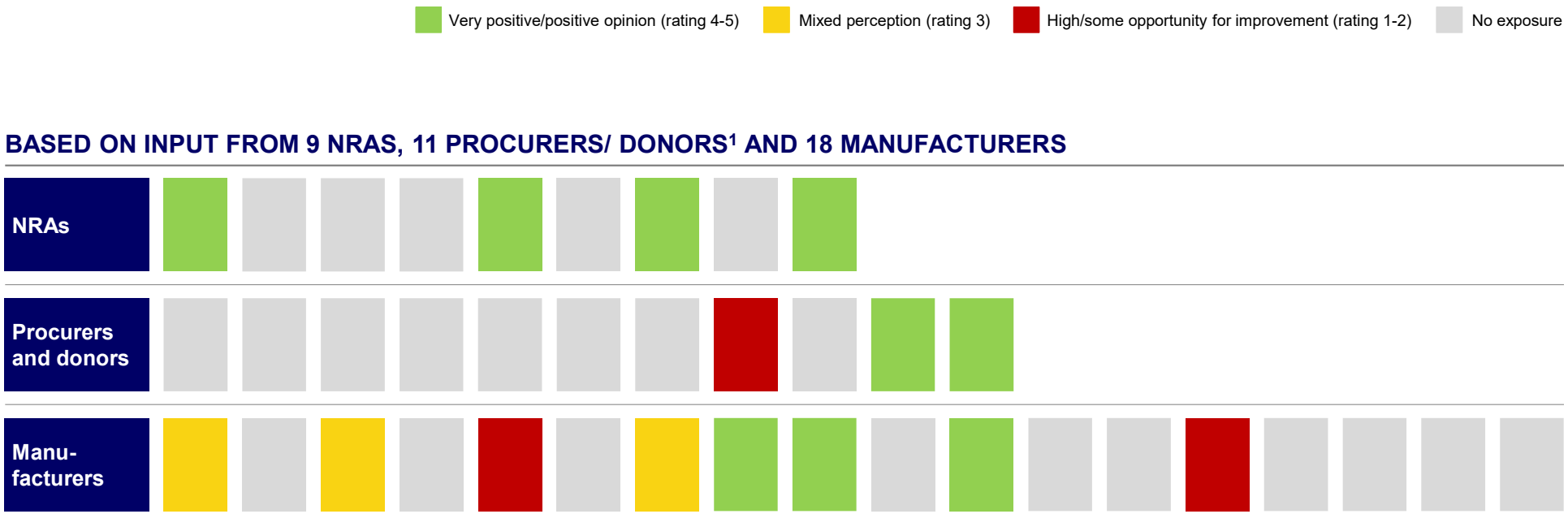
- **Within 90 days: 43%**
- **Within 250 days: 78%**

Regional distribution of product registrations completed within 250 days:

AFRO	60
SEARO	1
EURO	1

Source: Data from WHO FPI team

Exhibit 40: Manufacturer, procurer/donor, NRA/SRA perception of the added value of CRP in streamlining downstream approvals



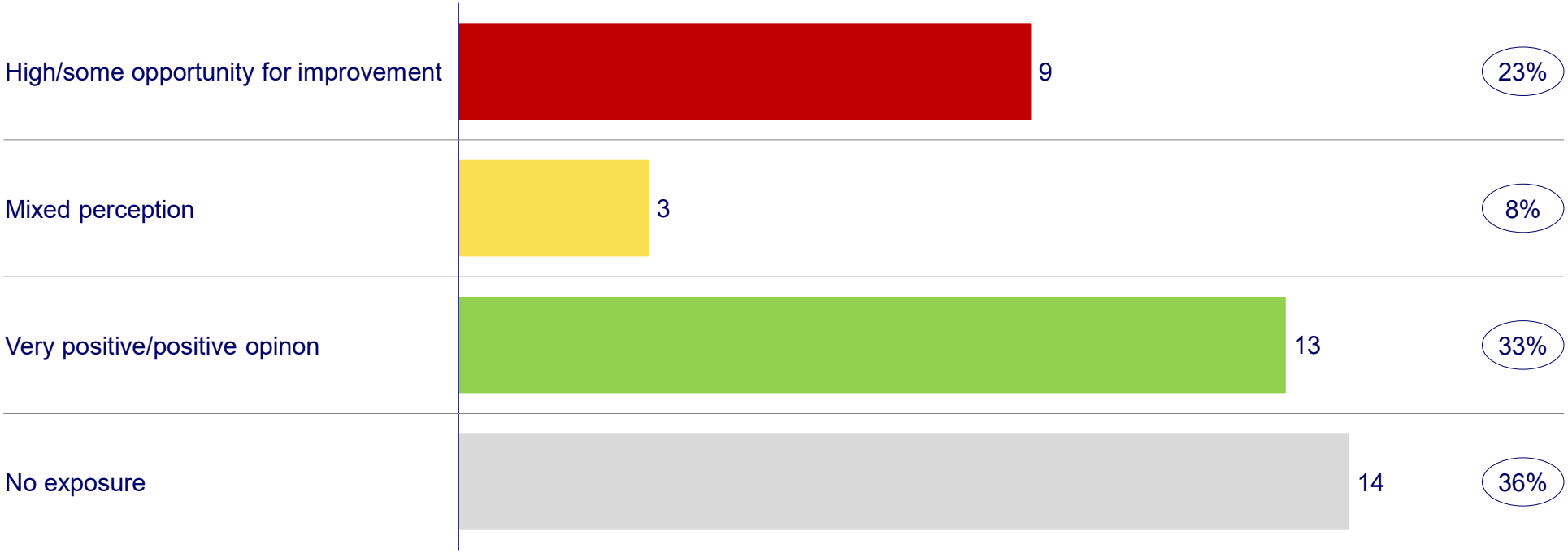
1. 14 separate interviews with 11 different procurers/donors

Source: Interviews with NRAs, procurers, donors and manufacturers taken in Dec 2022 and January 2023

Exhibit 41: Survey results on how the collaborative procedure for CRP have had in streamlining downstream approvals

On a scale from 1 to 5[2], how would you rate the impact that collaborative procedure for CRP have had in streamlining downstream approvals in your country?

Number of responses, n=39



1. Excluding N/A
2. 5 being the best

Source: Survey administered to NRAs for Impact assessment of WHO Prequalification and systems, Jan 2023

Exhibit 42: Timeline of the introduction and implementation of Reliance

Timeline of the introduction and implementation of reliance

2019

Throughout: collection of recommendations from stakeholders, concept note on regulatory reliance principles, PAHO, and the Pan American Network for Drug Regulatory Harmonization

September: stakeholder consultation

2020

Throughout: development of WHO GreIP including two public consultations

October: approval of practices by the WHO Expert Committee on Specification for Pharmaceutical Products

2021

March: publication of GreIP

June: webinar on GReIP and implementation plans

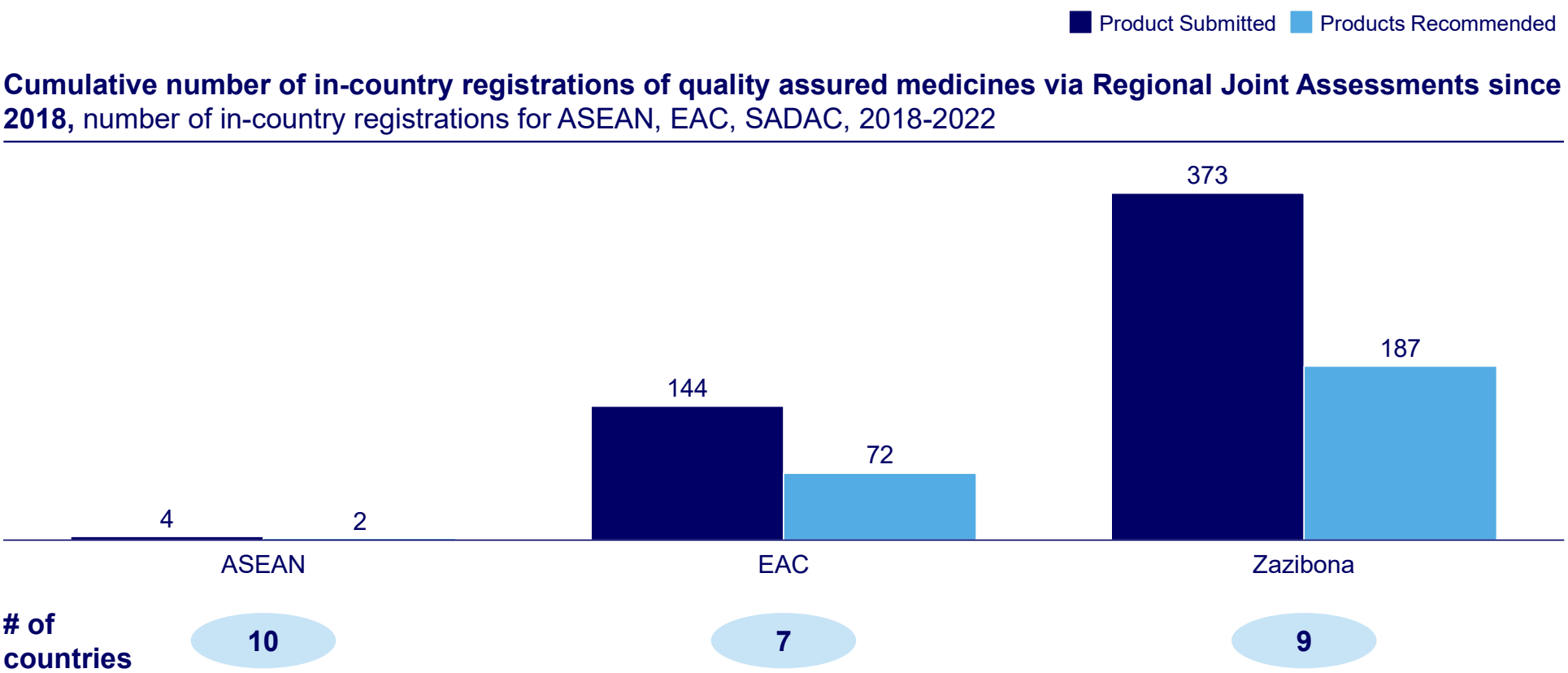
2022

October: launch of dedicated e-learning course[1]

1. https://openwho.org/courses/good-reliance-practices

Source: WHO data (December 8, 2022)

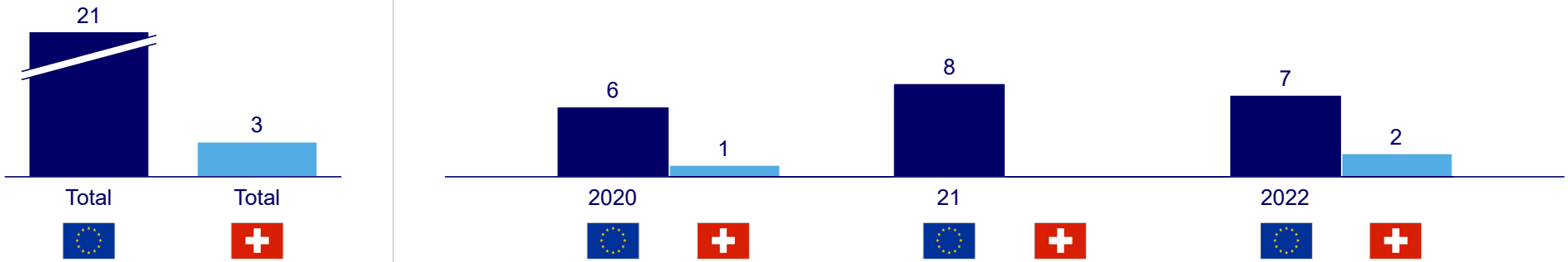
Exhibit 43: Number of in-country registrations of quality-assured products jointly assessed and recommended by countries via the ASEAN, EAC, and Zazibona Regional Joint Assessments since 2018



Source: Data from WHO FPI team

Exhibit 44: Products reviewed under EU-M4all and MAGHP between 2020 and 2022

Products reviewed under EU-M4all and MAGHP 2020-22
Number of products



EU-M4all: Resulting in **158 authorizations in 93 countries**[1] around the world (including 5 products submitted via SRA CRP resulting in 24 authorizations in 15 countries)

MAGHP: Resulting in **3 product authorizations in 3 countries** (all through SRA CRP)

1. 88 Africa, 21 Central and South America, 31 in Middle East and Asia, 18 in non-EU Europe and Central Asia

Source: WHO data (December 8, 2022)

Exhibit 45: Number of country registrations facilitated for COVID-19 vaccine donations/allocations (As of December 31, 2022)

Snapshot of registrations facilitated for COVID-19 vaccine donations/allocations (As of 20 Feb 2023)[1]

AstraZeneca (incl. SII)	Johnson & Johnson	Moderna	Pfizer	Sinopharm	Sinovac	Novavax
2,157 Regulatory Clearances	**1,124** Regulatory Clearances	**865** Regulatory Clearances	**995** Regulatory Clearances	**99** Regulatory Clearances	**137** Regulatory Clearances	**59** Regulatory Clearances

=

5,436

Regulatory clearances

1. Numbers will be readjusted to 31 Dec 2022

Source: WHO data

Contents

World Health Organization

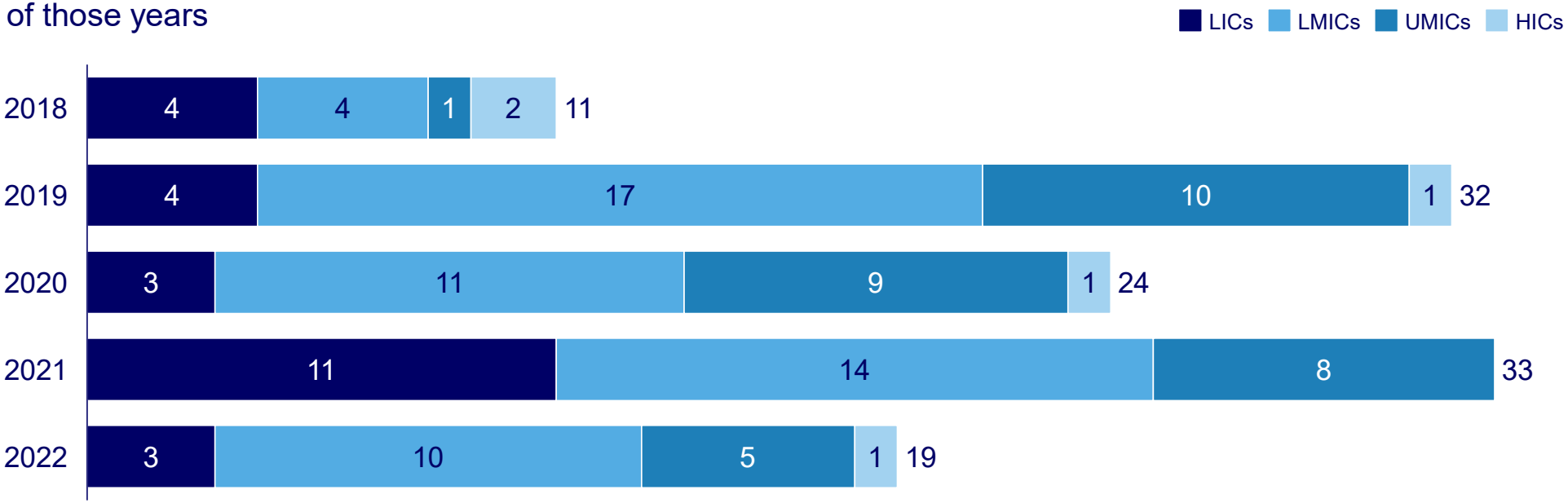
Exhibit 46: Key metrics covered and the methodology for the assessment under Theme 6

Topics	No.	Metric	Metric type
Improving regulatory preparedness for public health emergencies	6A	Number of countries assisted and supported in adapting their regulatory requirements to effectively address public health emergencies	Quantitative
	6B	Number of countries with improved regulatory capacity preparedness for public health emergencies	Quantitative
	6C	Case study on how a country improved its regulatory preparedness for public health emergencies (Pakistan)	Case study

Exhibit 47: Number of countries assisted and supported in adapting their regulatory requirements to effectively address public health emergencies

Countries assisted and supported in adapting their regulatory requirements to effectively address public health emergencies

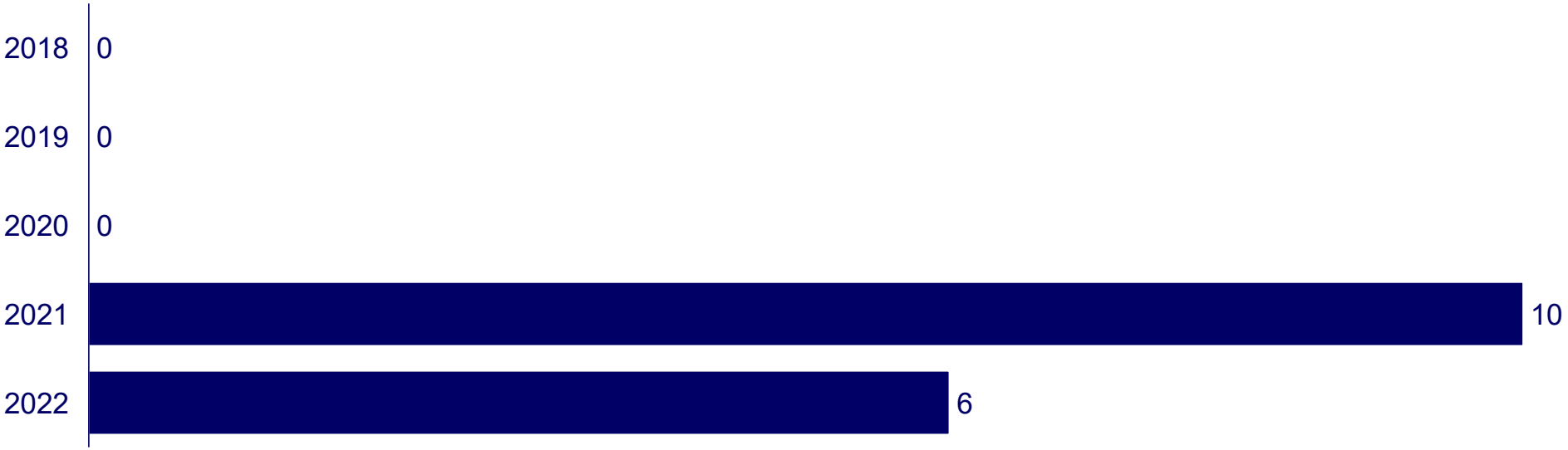
Number of countries when countries received support over multiple years, they have been included for each of those years



Source: Interviews with RSS (Nov 30, 2022); WHO data (December 6, 2022)

Exhibit 48: Number of countries with improved regulatory capacity and preparedness for public health emergencies

Countries with improved regulatory capacity preparedness for public health emergencies
Number of countries



Source: Interviews with RSS (Nov 30, 2022); WHO data (December 6, 2022)

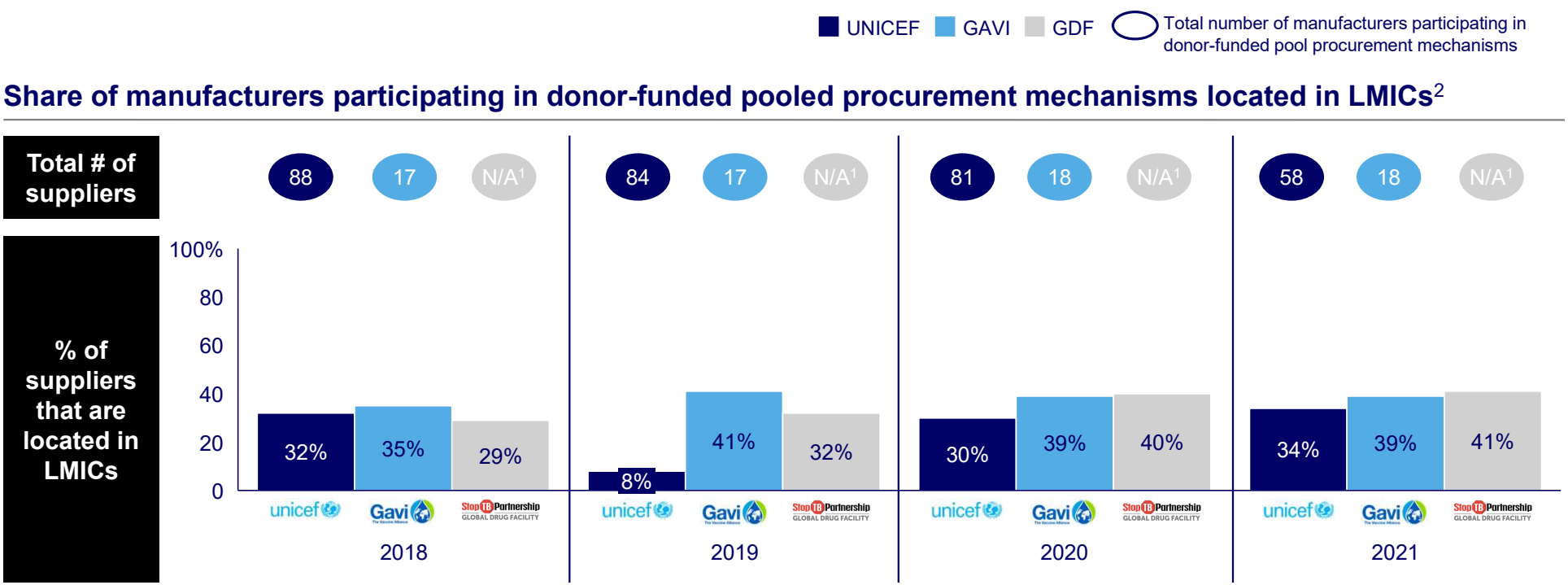
Contents

World Health Organization

Exhibit 49: Key metrics covered and the methodology for the assessment under theme 7

Topics	No.	Metric	Metric type
Improving access to donor funded procurement markets	7A	Ratio of LMICs to non-LMIC manufacturers participating in donor-funded pooled procurement mechanisms	Quantitative
	7B	Case study of a manufacturer from an LMIC that has recently participated in donor-funded pool-procurement mechanisms (Serum Institute of India)	Case study

Exhibit 50: Absolute number of manufacturers located in LMICs participating in donor-funded pooled procurement mechanisms



1. Absolute numbers for GDF are not available due to confidentiality reasons
2. The World Bank's FY2021-22 income classification was used across all years to calculate the percentage of manufacturers that are from LMICs

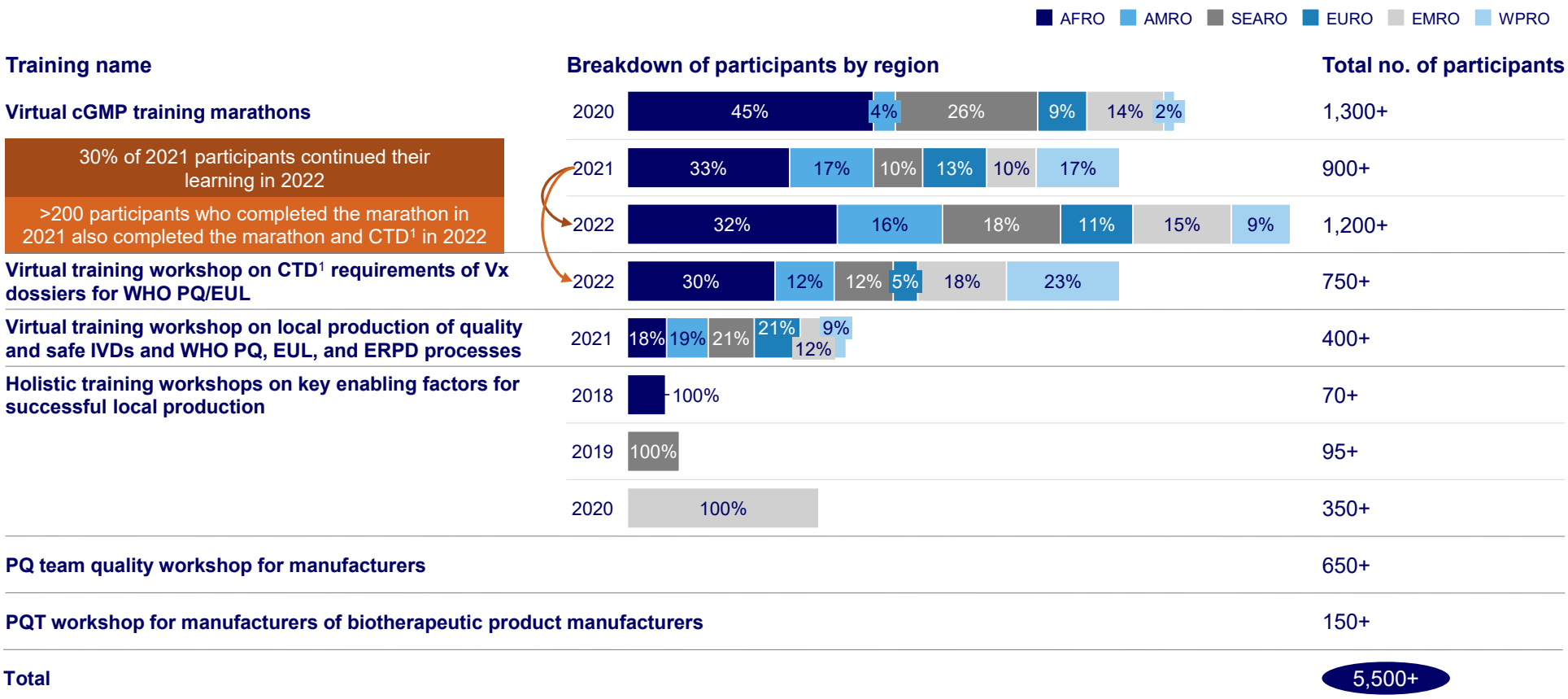
Source: UNICEF Supply annual reports (UNICEF Supply Division), GDF procurement team, GAVI procurement team

Contents

Exhibit 51: Key metrics covered and the methodology for assessment under Theme 8

Topics	No.	Metric	Metric type
Supporting member states to build the ecosystem and capacities for quality and sustainable local production	8A	Number of manufacturers and other stakeholders trained by WHO RPQ in good manufacturing practices (GMP), other regulatory standards, and quality workshops	Quantitative
	8B	Number of manufacturers that received PQ-/EUL-related technical assistance	Quantitative
	8C	Number of countries that received ecosystem assessments for quality and sustainable local production	Quantitative
	8D	Manufacturer, procurer/donor, and NRA perception of general manufacturing practices	Perception
	8E	Case study on supporting a Member State to strengthen local production and the impact of the WHA74.6 resolution on local production	Case study

Exhibit 52: Overview of training sessions related to sustainable quality local production

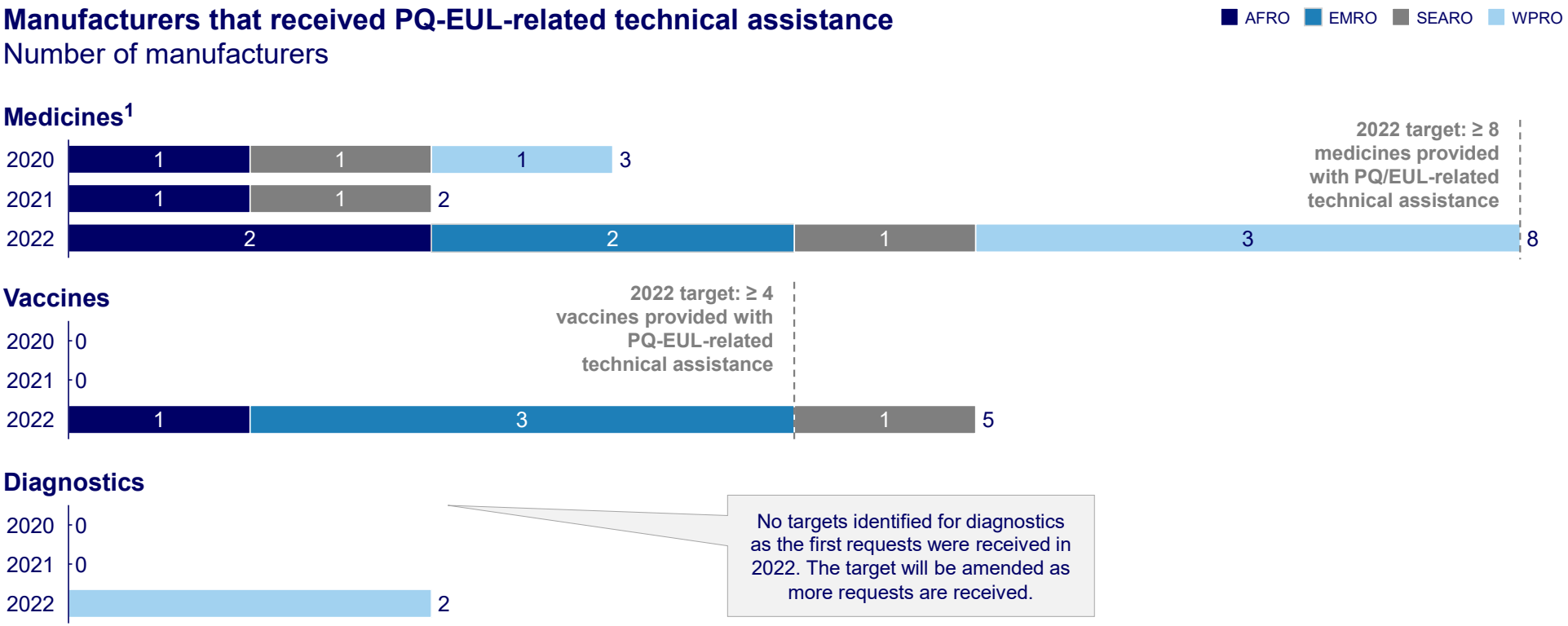


1. Common Technical Document

Source: WHO data

Exhibit 53: Number of manufacturers that received PQ-/EUL-related technical assistance

Manufacturers that received PQ-EUL-related technical assistance
Number of manufacturers



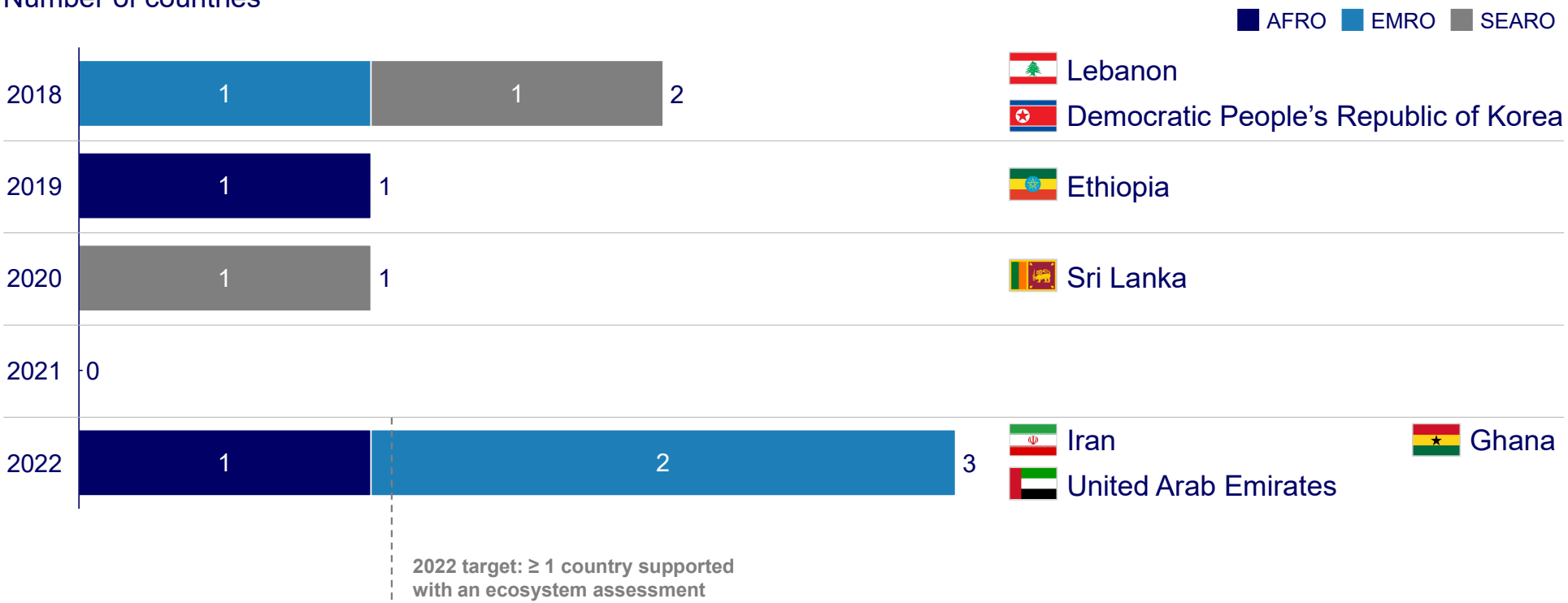
1. Number of unique manufacturers in each year, i.e., started with 3 in 2020, 2 new manufacturers in 2021, and 6 more new manufacturers in 2022

Source: WHO data (December 5, 2022)

Exhibit 54: Number of countries that receive ecosystem assessment for quality and sustainable local production

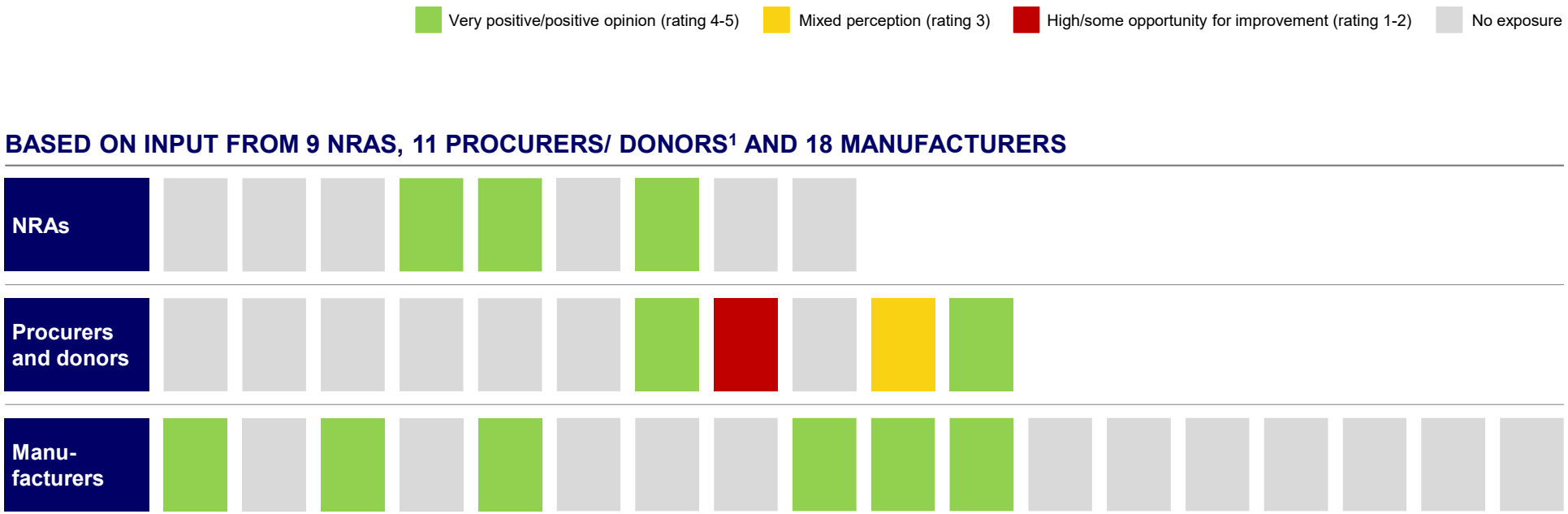
Countries that received ecosystem assessments for quality and sustainable local production

Number of countries



Source: WHO data (December 5, 2022)

Exhibit 55: Manufacturer, procurer/donor, and NRA perceptions on GMP standards



1. 14 separate interviews with 11 different procurers/donors

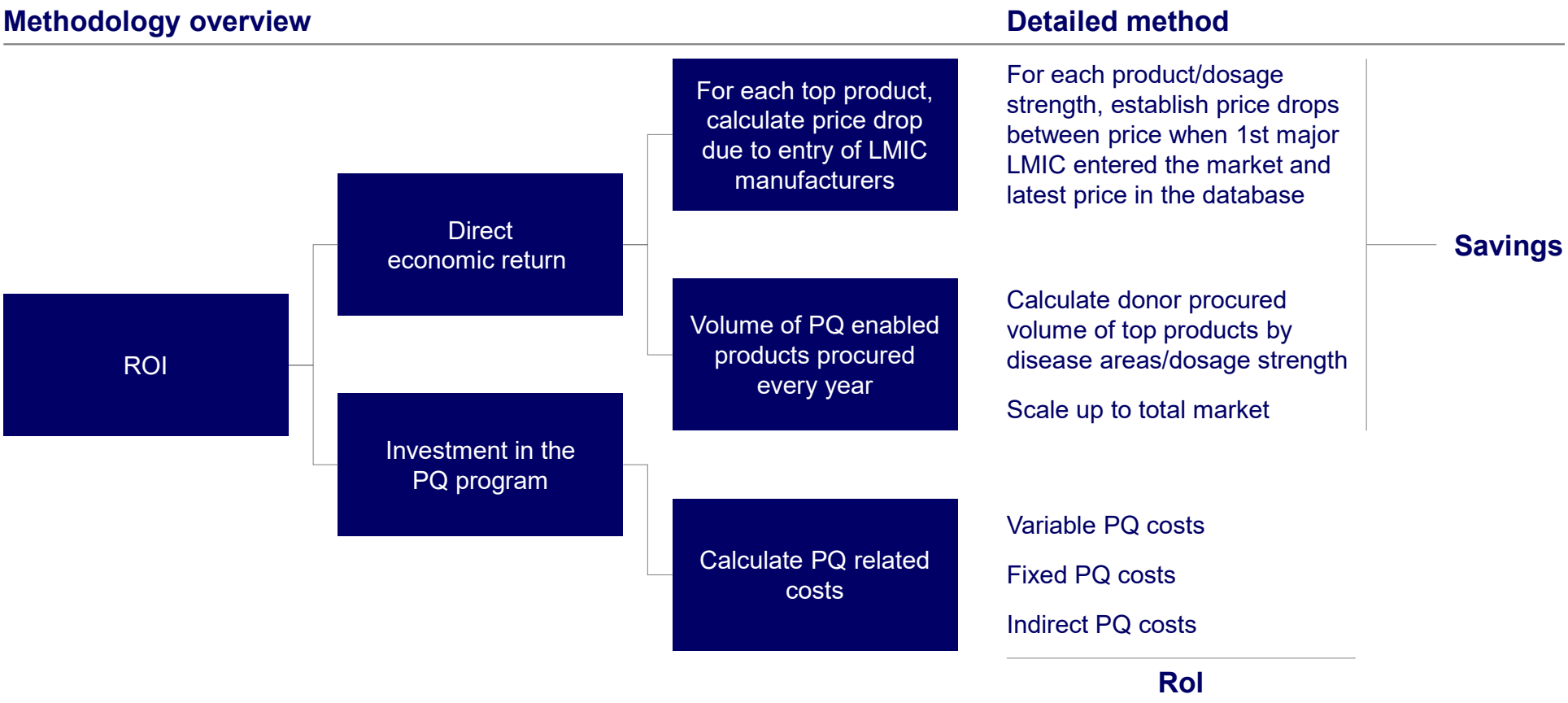
Source: Interviews with NRAs, procurers, donors, and manufacturers conducted in December 2022 and January 2023

Contents

Exhibit 56: Key metrics covered and the methodology for assessment under Theme 9

Topics	No.	Metric	Metric type
Assessing the economic return on investment (RoI) savings generated by WHO PQ system	9A	Economic return on investment: Savings generated by WHO PQ system	Quantitative

Exhibit 57: RoI methodology high-level overview



Contents

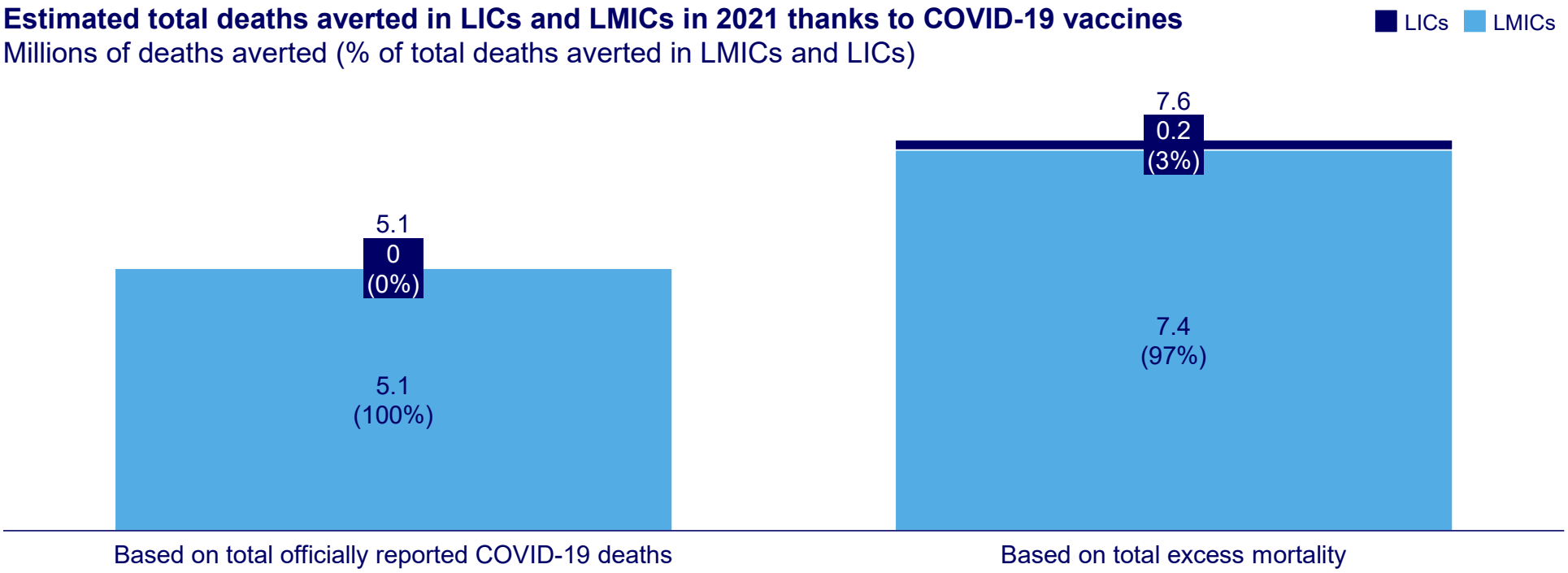
World Health Organization

Exhibit 58: Key metrics covered and the methodology for assessment under Theme 10

Topics	No.	Metric	Metric type
Contributing to saving lives	10A	Estimated deaths averted in the first year of COVID-19 vaccinations in LMICs	Quantitative
	10B	Patients accessed/lives saved as a result of increased affordability	Quantitative

Exhibit 59: Estimated total deaths averted in 2021 due to COVID-19 vaccines

Estimated total deaths averted in LICs and LMICs in 2021 thanks to COVID-19 vaccines
Millions of deaths averted (% of total deaths averted in LMICs and LICs)



Source: Global impact of the first year of COVID-19 vaccination: a mathematical modelling study, The Lancet (2022)

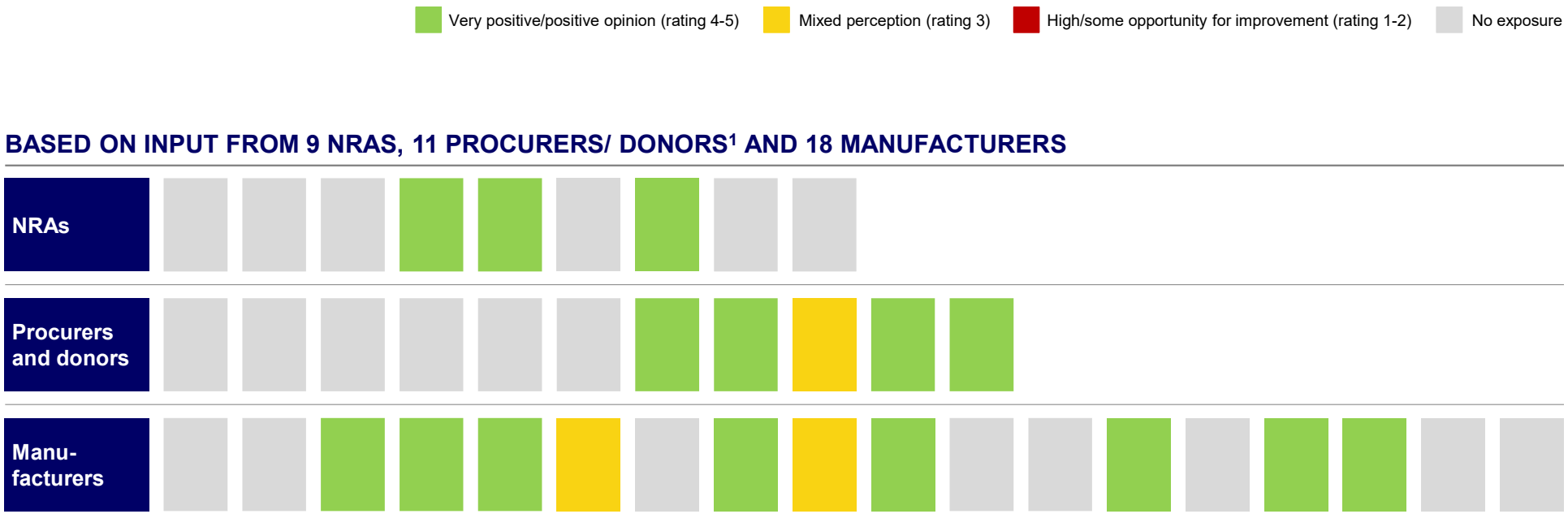
Contents

World Health Organization

Exhibit 60: Key metrics covered and the methodology for assessment under Theme 11

Topics	No.	Metric	Metric type
Increasing adoption of WHO guidelines and technical standards	11A	Manufacturer, procurer/donor, and NRA perception of overall WHO guidelines and technical standards	Perception
	11B	NRA perception of usefulness of specific guidelines	Perception

Exhibit 61: Manufacturers', procurers'/donors', and NRA perceptions on WHO guidelines and technical standards



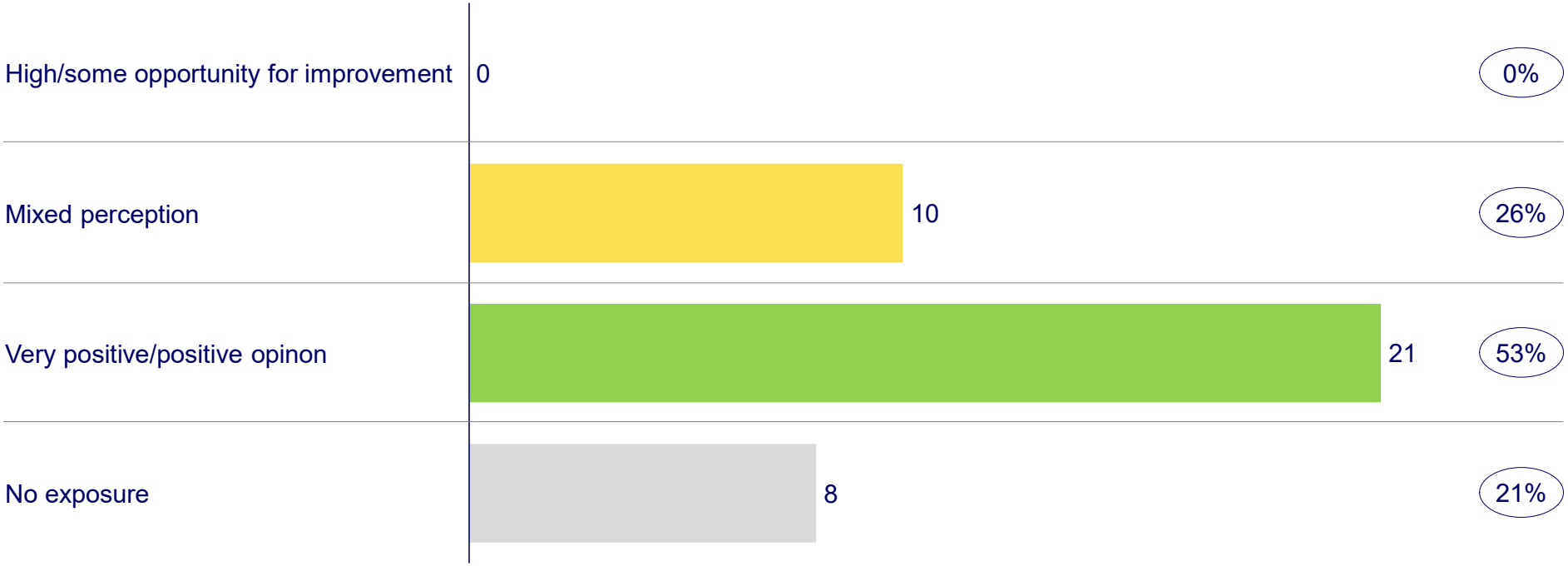
1. 14 separate interviews with 11 different procurers/donors

Source: Interviews with NRAs, procurers, donors, and manufacturers conducted in December 2022 and January 2023

Exhibit 62: Survey results on the impact of WHO N&S for NRAs

On a scale from 1 to 5[2], how would you rate the impact that N&S for health products published by WHO have had for your NRA?

Number of responses, n=39



1. Excluding N/A
2. 5 being the best

Source: Survey administered to NRAs for Impact assessment of WHO Prequalification and systems, Jan 2023

Exhibit 63: Survey results on the usefulness of select WHO guidelines for NRAs

On a scale from 1 to 5[2], to what extent does your organization find the WHO guidelines mentioned below useful?
Number of respondents, n=39

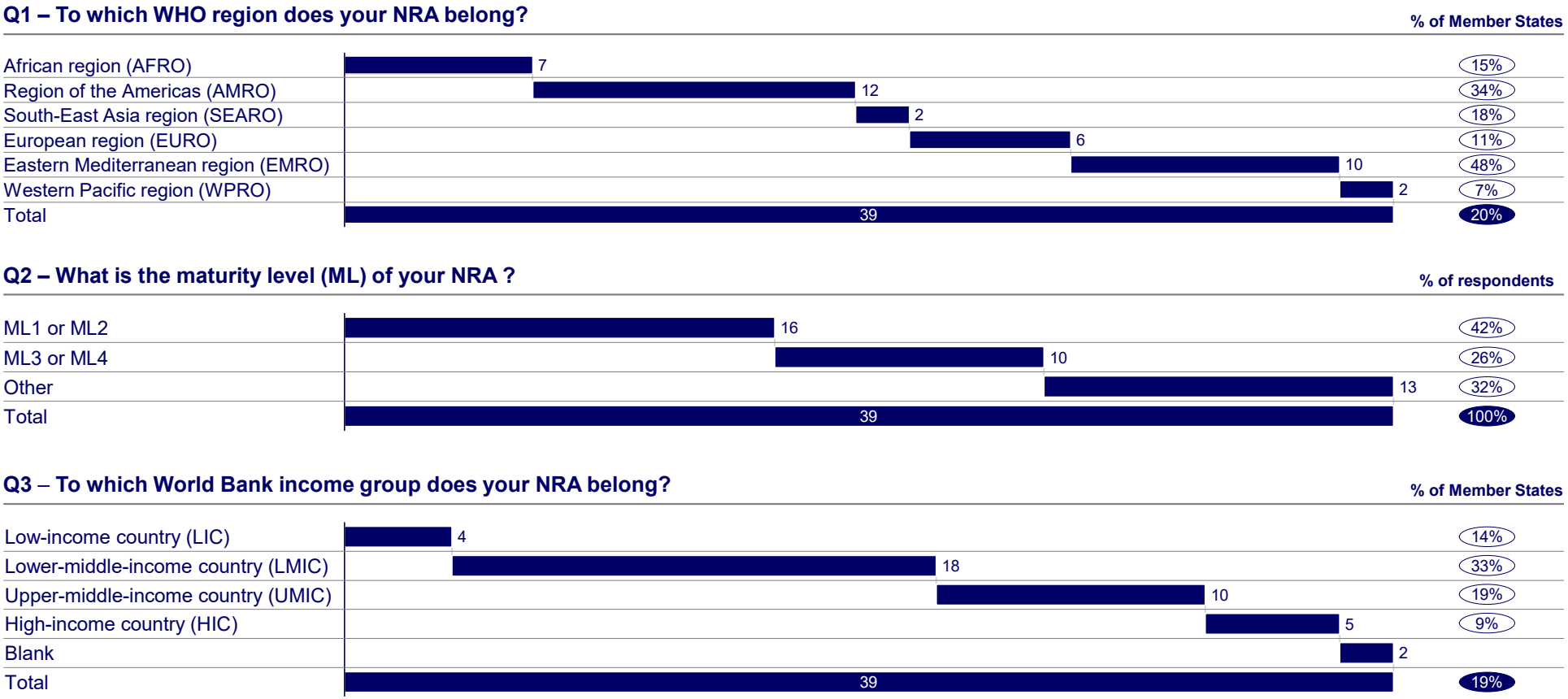
	n=	Survey average perception score[1]
WHO GMP guidelines for pharmaceutical products: main principles	32	4.2
The International Pharmacopoeia	32	4.1
WHO GMP guidelines for biologicals, including vaccines	32	4.1
WHO guidelines/recommendations to assure the quality, safety, and efficacy of vaccines	34	4.1
WHO guidelines for multisource products to demonstrate interchangeability (bioequivalence)	31	4.0
WHO guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product: quality part	30	4.0
WHO guidelines on biological (including biotherapeutic products)	33	4.0
WHO International Measurement Standards for biologicals, including vaccines, biotherapeutic products, blood products, and IVD	28	3.8
WHO GMP guidelines for blood establishment	21	3.7
WHO recommendation on the production, control, and regulation of human plasma for fractionation	24	3.7
WHO guidelines on increasing the supply of PDMPs in LMICs through fractionation of domestic plasma, 2021	21	3.6

1. Excluding N/A
2. 5 being the best

Source: Survey administered to NRAs for Impact assessment of WHO Prequalification and systems, Jan 2023

Contents

Exhibit 64: Distribution of the 39 survey respondents

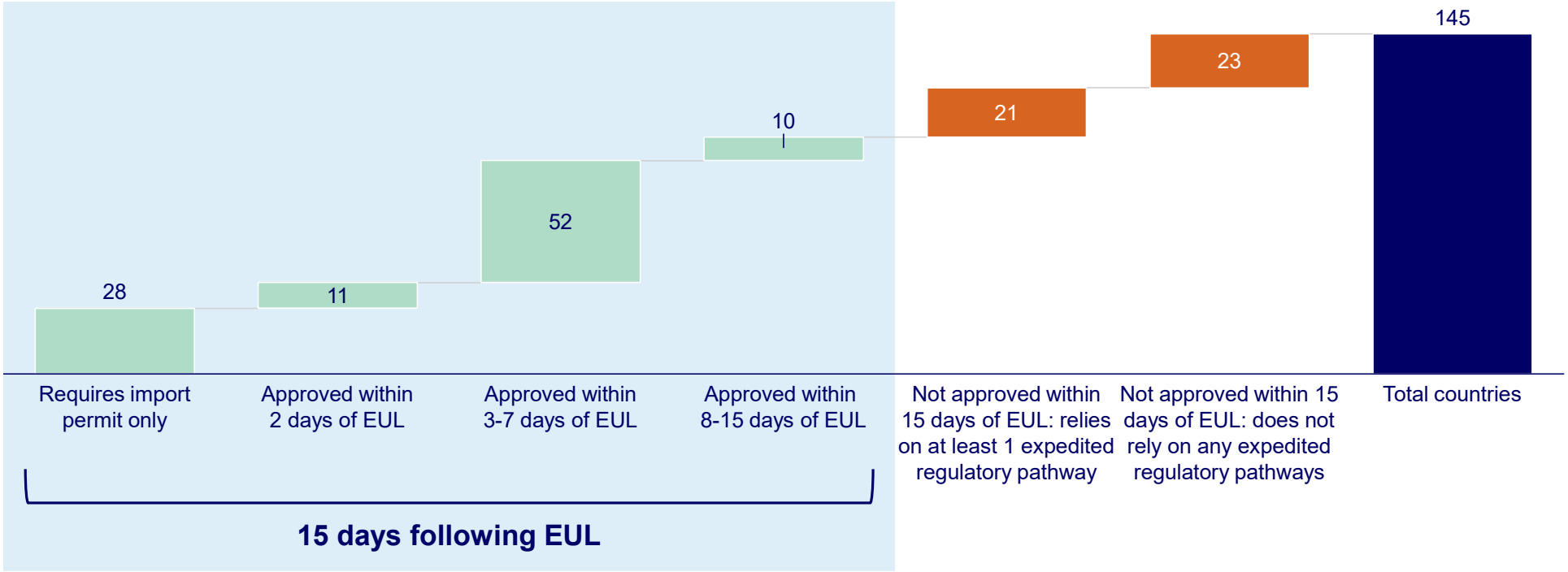


Source: Survey administered to NRAs for Impact assessment of WHO Prequalification and systems, Jan 2023

Exhibit 65: Overview of approval of AstraZeneca and Serum Institute of India doses within 15 days following WHO EUL

Case study on improving regulatory preparedness for public health emergencies at a global level

Overview of approval of AstraZeneca and Serum Institute of India doses within 15 days following WHO EUL
Number of countries



Source: WHO

Exhibit 66: Step one – Calculate savings for top products

Calculate savings for product dosage strength | Scale up to total savings for product stream/disease area | Calculate RoI for PQ program & PQ related activities

1. Calculate weighted average unit price per dosage strength for top 3 products by donor-funded sales
   - Top 2 product types[1] for Rx-RH and diagnostics
   - Top 5 products for vaccines
2. For each product/dosage strength, establish price differential post-prequalification and before
3. Multiply with volume of sales to obtain total savings for selected products

Example: Rx-HIV: EFV/3TC/TDF[2] (600mg + 300mg +300mg)

Unit price drop (USD)

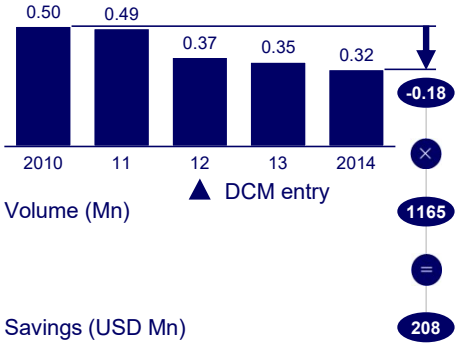


Exhibit 67: Step two – Scale up to total donor-funded PQ-Enabled LMIC Market

Calculate savings for product dosage strength → **Scale up to total savings for product stream/disease area** → Calculate RoI for PQ program & PQ related activities

1. Sum savings of all dosage strengths for top 3 products
   - Top 2 product types[1] for Rx-RH and diagnostics
   - Top 5 products for vaccines
2. Scale up savings of top products of disease area to total donor funded PQ approved LMIC market (based on 2014 market share)
   - Higher bound: savings to sales ration of top products considered equal for other products
   - Lower bound: no savings for non-top products considered

Example: Rx-HIV – Higher bound Σ
USD mn

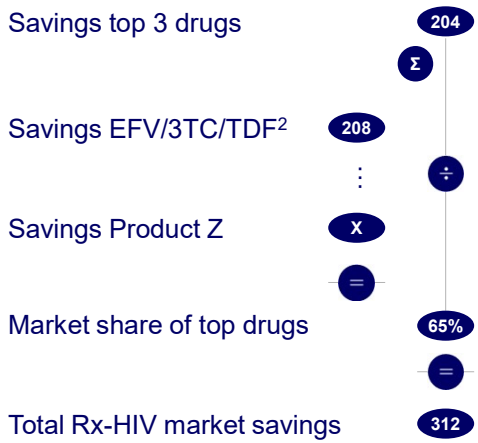


Exhibit 68: Step three – Calculate return on investment

Calculate savings for product dosage strength → Scale up to total savings for product stream/disease area → **Calculate RoI for PQ program & PQ related activities**

1. Sum savings across all product streams
2. Calculate PQ related costs
   - Variable PQ costs
   - Fixed PQ costs
   - Indirect PQ costs
   - Non-PQ RHT costs are excluded
3. Determine return on investment

PQ program – Higher bound
USD mn

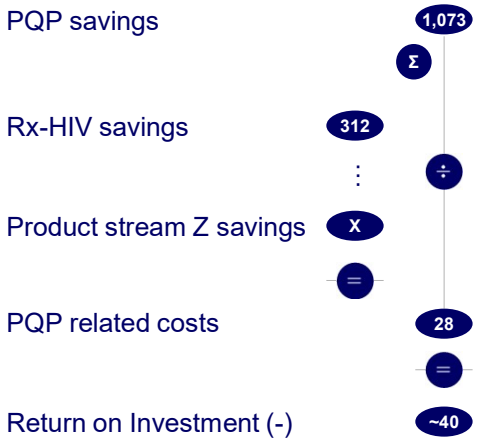
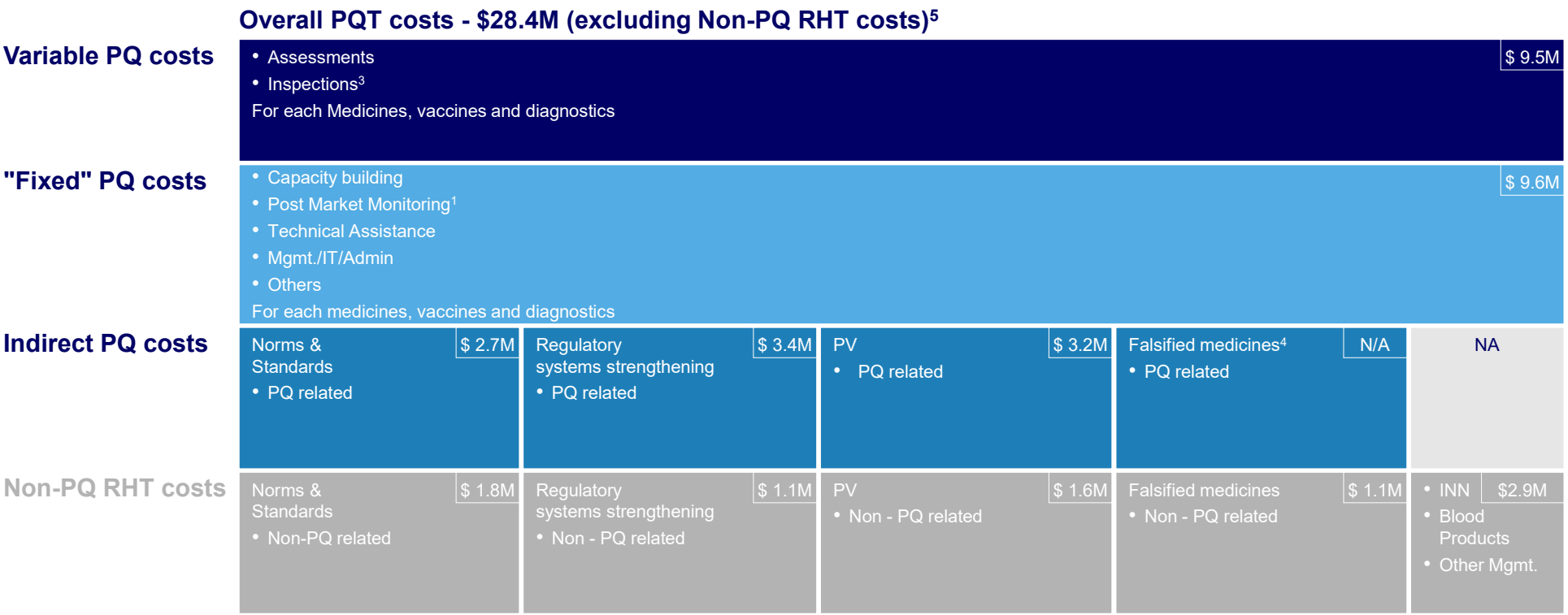


Exhibit 69: Overview of WHO PQT/RHT cost components in scope for RoI



1. Excluding Pharmacovigilance costs associated with PQ products;
2. INN is self-funded through its activities
3. Falsified medicine costs may include some cost of follow-up of relevant complaints involving potential conterfeits
4. Includes regional office costs that are funded from PQT budget; Some of these activities are simply regions executing for HQ

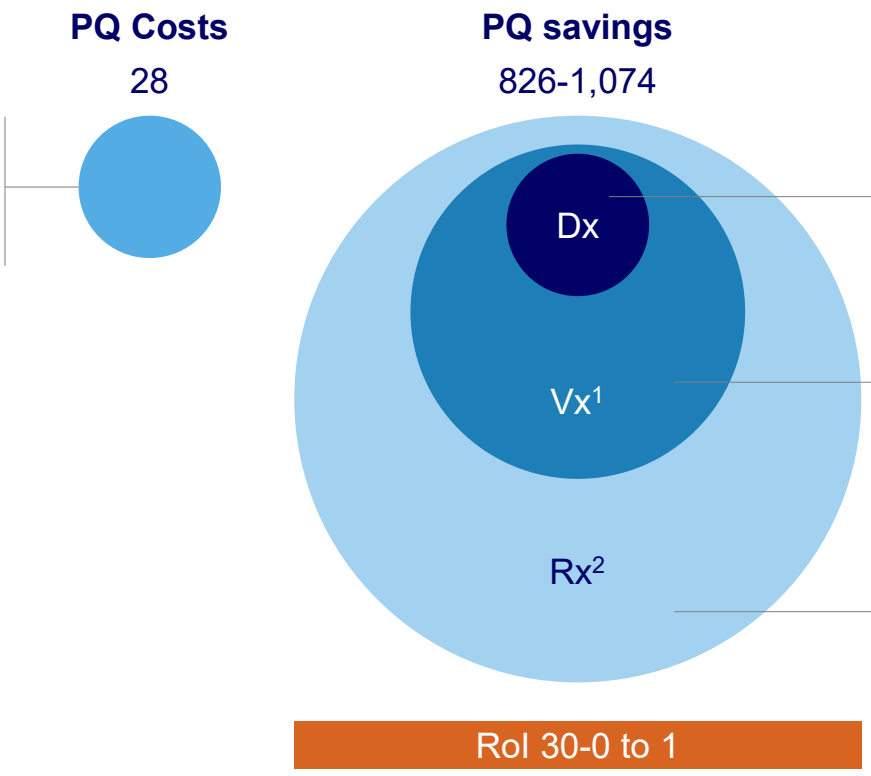
Source: WHO Prequalification team

Exhibit 70: RoI analysis output

USD Mn

VISUALIZATION NOT TO SCALE

- PQ costs include direct (variable and fixed) and indirect RHT PQ costs



- Limited unit price drop given each diagnostics method has 1 MNC with > 50% market share
- Conservative value as a limited time interval (2012- 2014[2]) and only HIV diagnostics is considered
- Key driver is high volume DTP-HepB-Hib[3] accounts for majority of savings
- Rx-HIV and Rx-Malaria comprises > 80% of savings
  - Rx-HIV key driver is high volume
  - Rx-Malaria key driver is large unit price drop
- No savings Rx-RH considered despite injectables price drop, however these are mostly supplied by MNCs (90%+)

1. Not including PCV and Rotavirus despite price drop, because price drop attribution to PQ is questionable
2. Due to the lack of a reliable dataset, for other products the time interval 2004-2014 is considered
3. Also referred to as pentavalent vaccine