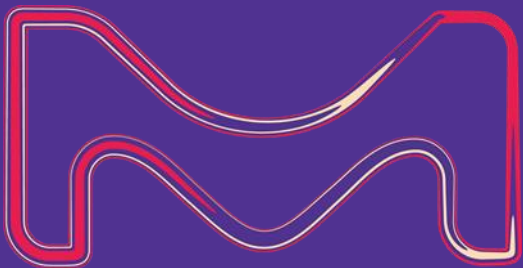


Praziquantel - How much is enough

Johannes Waltz
GSA Meeting Chicago
October 19, 2023



MERCK

PZQ and beyond

01

How we tackle Schistosomiasis

Our goal: **Elimination of schistosomiasis as a public health problem through an integrated approach**

2007

Begin of the donation program in partnership with WHO

47

African countries supplied

250 Million

Committed annual donation

>1.9 Billion

PZQ tablets provided since the beginning of the program

>760 Million

Treatments of school-aged children enabled

>10

R&D projects for innovative products and technologies

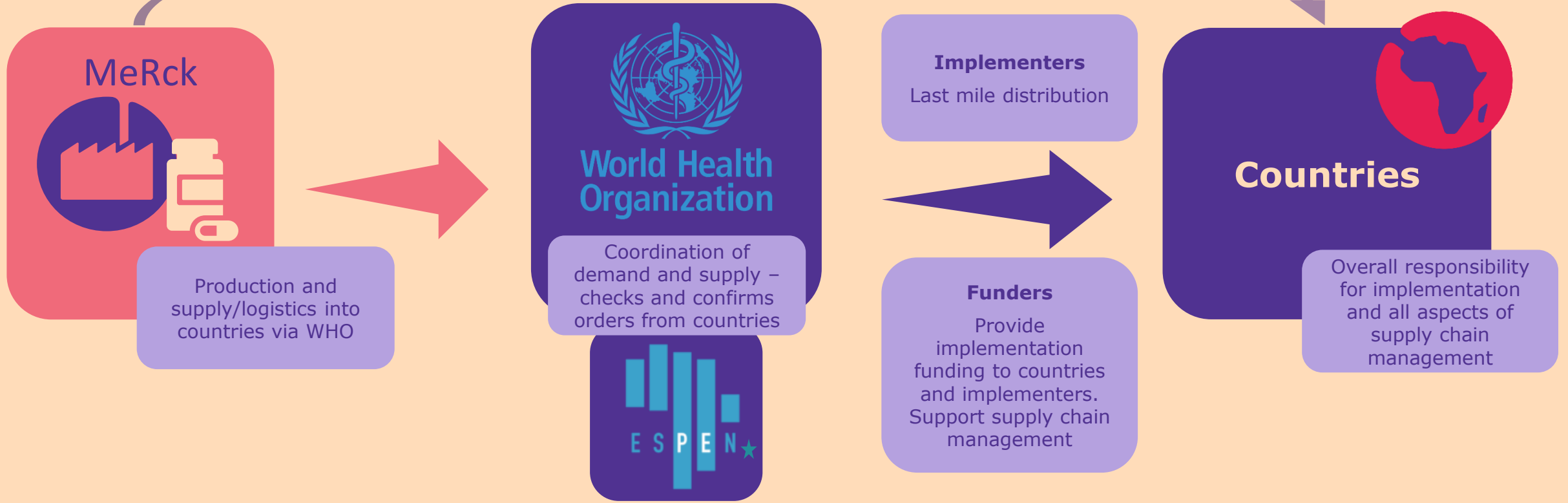
>30

R&D partnerships



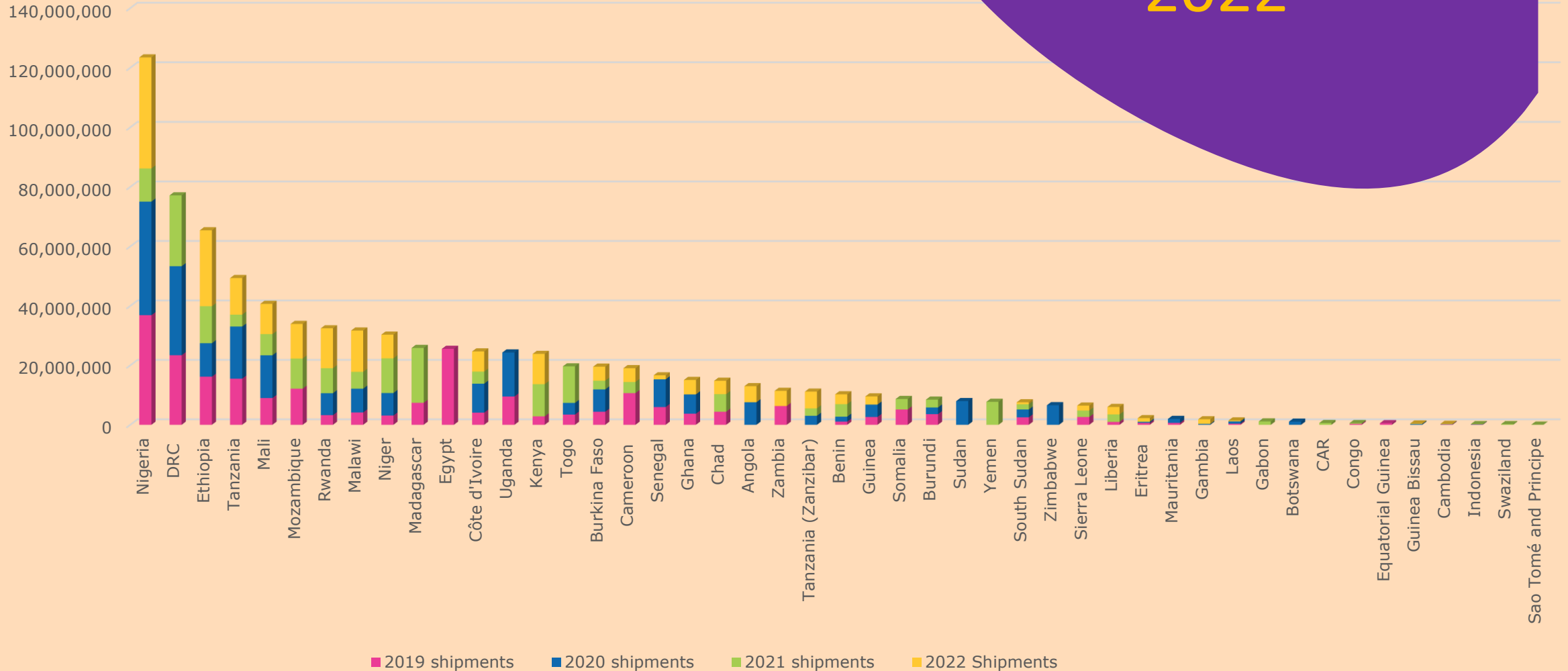
Stakeholder Landscape for PZQ Supply Chain

Monitoring & Evaluation Framework

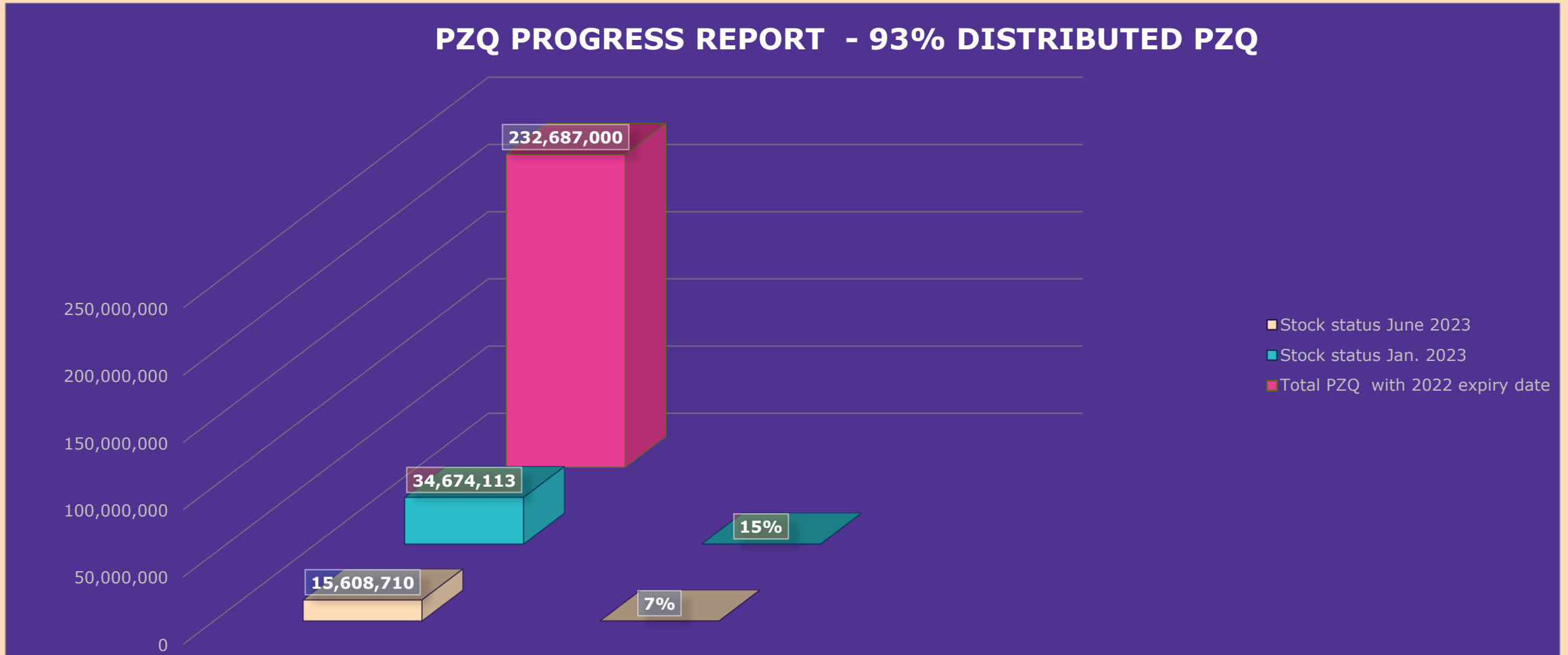


Supplied PZQ to 47 African countries

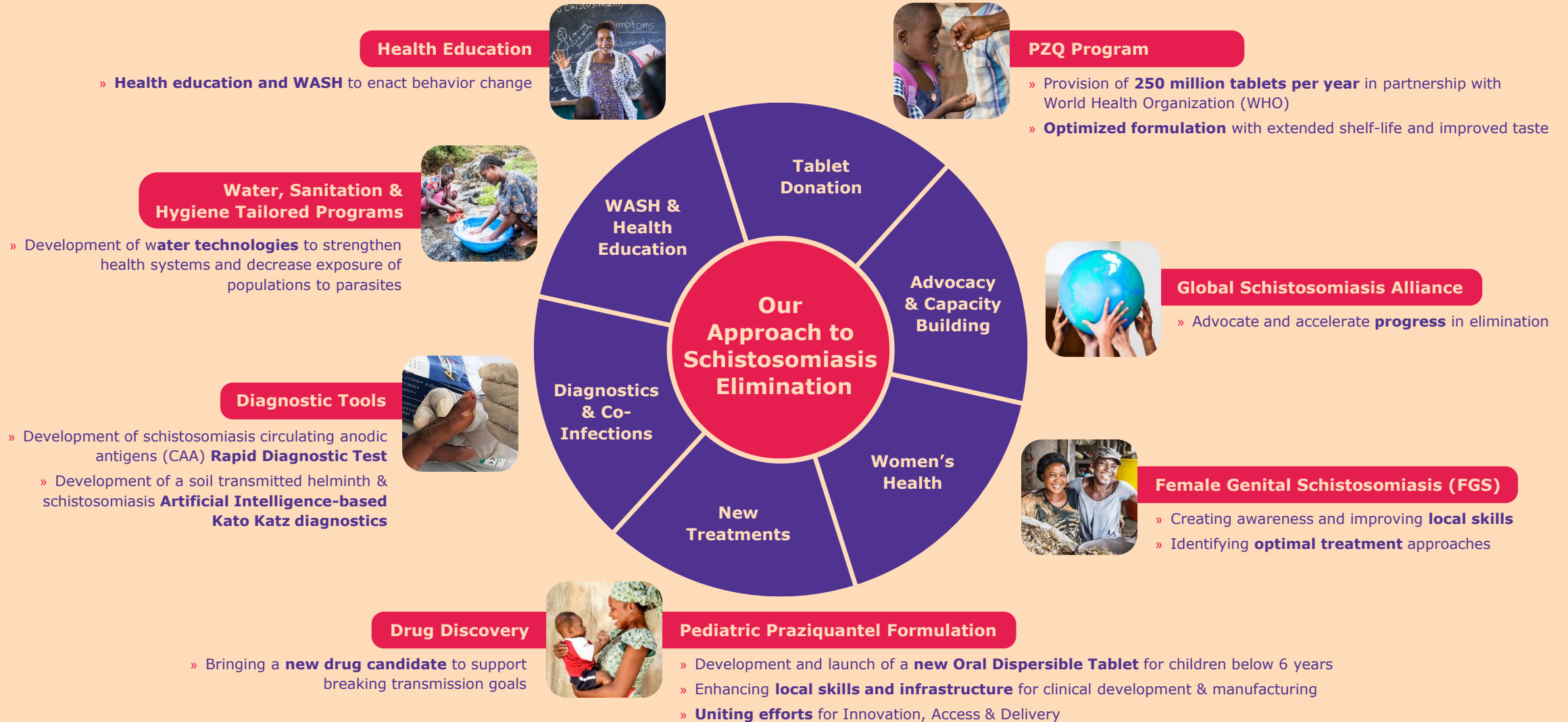
Shipments 2019-2022



Reduction of PZQ at risk of expiry during 2022




Elimination of Schistosomiasis - our integrated approach



02

PZQ across
all age groups

Merck PZQ Portfolio

	Cesol 600	Cesol 600 Improved formulation	Arpraziquantel
Target population	School aged children (SACs >5 years) and Adults	School aged children(SAC) and Adults	Pre-school aged children (Pre-SAC: 0-5 years old)
Population at risk of SCH	Around 220 million	Around 220 million	50 million (0-5 years old), including 26 million (2-5 years old) as first targeted pop.
Treatment mechanism	Mass Drug Administration (MDA)	Mass Drug Administration (MDA)	Mass Drug Administration (MDA) for 2-5 years old
Access model	Donation + New Access Models	Donation + sustainable access where feasible	Sustainable procurement based model
Quantities available/annum	Up to 250 million (2023)	Up to 250 million (as of 2025 onwards)	10 million at launch Scaling up to potentially 60 million
Packaging	1000 tablets per bottle	500 tablets per bottle	150 tablets per bottle

Merck aims to address needs of all targeted populations plus upcoming challenges

Preschool-Aged Children (PSAC)

School-Aged Children (SAC)

Adults

Adult worms

**Pediatric Praziquantel
arPZQ-150 mg**

**Praziquantel (New formulation)
Cesol 600mg**

**Praziquantel (New formulation)
Cesol 600mg**

Addressing transmission blocking & Resistance

Adult & juvenile worms

M4339 - new anti-schistosomiasis preclinical drug candidate

03

PZQ - how much is
enough

Impact of new WHO Guideline



Impact on PZQ demand: "Some 236.6 million people required PC in 2019" – translates into a total of around 650 MT of PZQ – reality checks pending.



Impact on rPZQ demand: potentially considerable – reality checks pending.



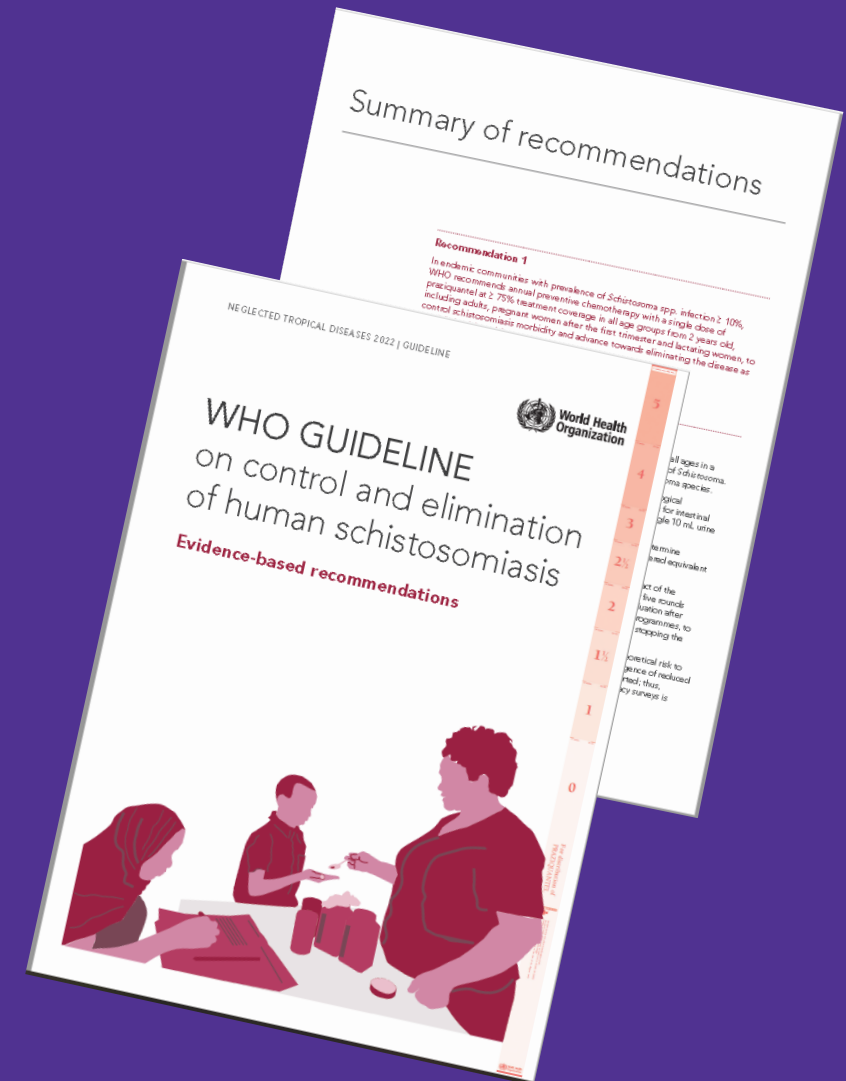
Impact on diagnostics development: guideline clearly requires new diagnostic tools (low transmission areas, evaluation of interruption of transmission).



Impact on countries: some countries will stick to it, others will (have already) develop(ed) their own approach.



Impact on implementers: health facilities are expected to take up treatment role – funding?



Criteria for adult treatment

1. Epidemiological/Elimination Pathways

- In accordance with the new treatment guidelines

2. Settings in which elimination is a feasible target

- Prevalence in school aged children is <10% but prevalence in adults remains high (>10%) or,
- Prevalence in children has stagnated over the last 3 years – requiring adult treatments to interrupt the cycle of transmission and,
- On an elimination pathway where adults remain reservoirs – requires quantification of the prevalence of SCH in adults and,
- Precision mapping conducted to identify treatment foci needed – with a focus on prevalence in adult populations.

3. Policy

4. Prevention Strategy as part of the elimination strategy

5. Financial and Resource availability

- Integration adult treatment platformsCountry has financial commitment (either locally or via funder) to fund the implementation of treatments for the year drugs are requested for.
- Country has defined effective adult treatment plans within their implementation strategies.
- Monitoring and evaluation resources allocated

6. Monitoring and Evaluation

Criteria for adult treatment

Additional Information on use of PZQ in adults

- Total quantity per annum limited to 50 million tablets maximum
- Tablets allocated for SACs treatments are to be used for SACs treatments only. Any remaining tablets should be counted towards the number of tablets available to SAC or Adults for the following treatment round.
- Staggering treatment rounds between SACs and adults may allow for additional tablets to be used for adults or SACs (leftovers from previous round)
- Countries to optimise use of tablets to prevent expiry of tablets.

**PZQ - the new frontier:
Sustainable access to
NTD medicines**

04

Moving from donation to sustainable investment

Social impact

We treat up to **100M school children** p/a. We are moving to an integrated investment strategy and actively mobilize local ecosystems to **eliminate schistosomiasis in endemic African countries by 2030**

Innovative solutions

- Evolving from donation of 250M PZQ tablets p.a. to sustainable investment into a systems-level solution package
- Treating the full age-range of schisto patients in order to move to elimination:
 - Extension to adult treatment
 - Optimized formulation (in 2022)
 - Pediatric formulation (in 2023)
- Introducing a comprehensive PZQ M&E Framework for countries
- Developing digital tools to improve the first and last mile of our PZQ supply chain

Cross-sector engagement

- Partnering with all relevant international stakeholders on schisto to accelerate elimination.
- Achieving higher and measurable efficiency and impacting effectiveness with partners.
- Moving to local systems engagement with co-owned elimination partnership plans, working with African countries on elimination that are conducive to collective action.

"Sustainable Access to NTD Medicines"

- Introduction of differentiated pricing, from cost-free, to cost-price, to low profit and re-investment in NTDs

Increasing the program's **effectiveness for elimination**, and its **sustainability**

Role & activities

Value to pharma co's

Tangible business value/sustainable investment

- Main area of visibility & recognition, hence a commitment to upkeep program and show progress given Merck's giving history
- Improve effectiveness and impact.

- Aiming at higher leverage of co-funders, cost-coverage contribution from, e.g. sale of NTD meds to selected stakeholders and differentiated adult tablet pricing model
- Thought leadership for new co-funded partnership models

(In)tangible value from social investment

Conclusions

05

Conclusions

