



Quality Workstream - Update

Concept Foundation

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Recap of progress so far

2005

The 1st study and landscaping of global RH manufacturers conducted by Concept Foundation with support from UNFPA and IPPF

2006

RHSC opens its membership to manufacturing companies

RHSC agrees to Bonn Consensus at October Annual Meeting

WHO launches its Prequalification Programme (PQP) for Essential Reproductive Health Medicines

WHO launches 1st RH Expression of Interest for hormonal contraceptives in October

2009

Assessing Quality Assured Supplies (AQAS) - review of manufacturing landscape to assess WHO PQP potential

2011

Launch of RHSC's Quality of Reproductive Health Medicines Programme (QuRHM)

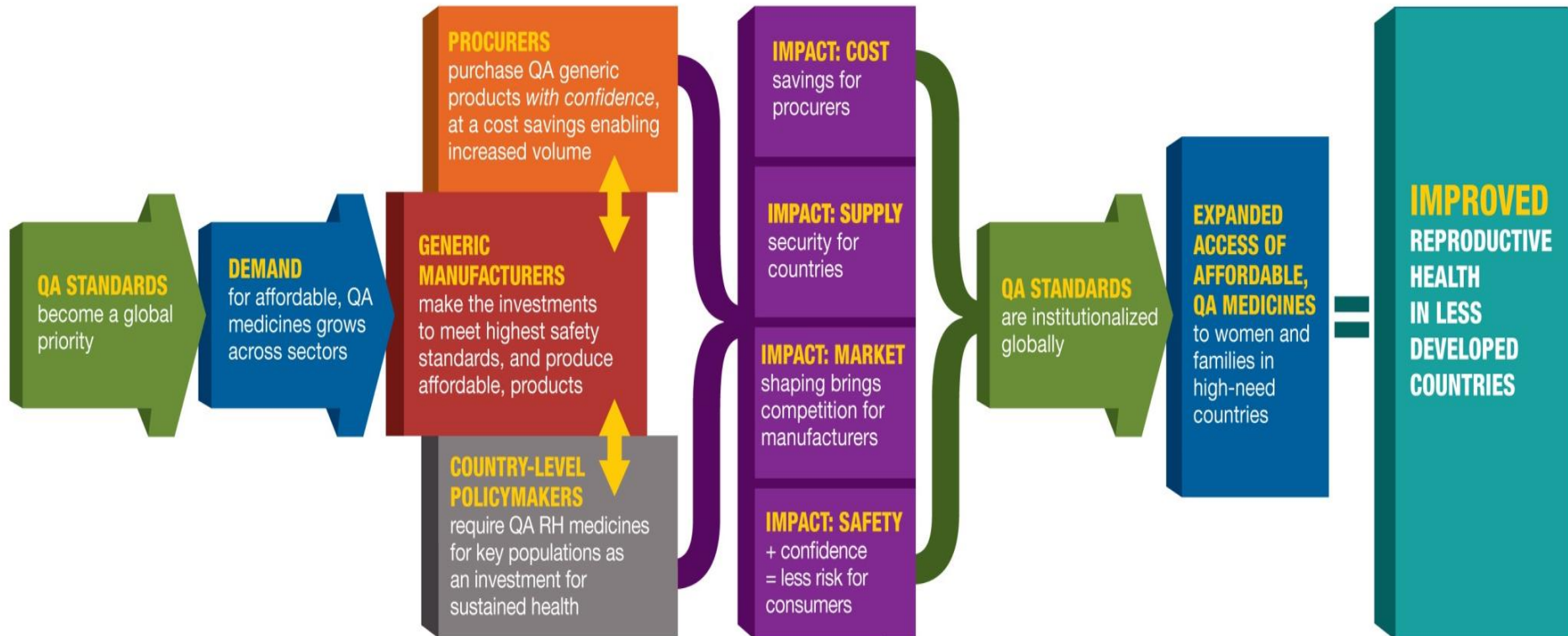
2012

London Family Planning Summit

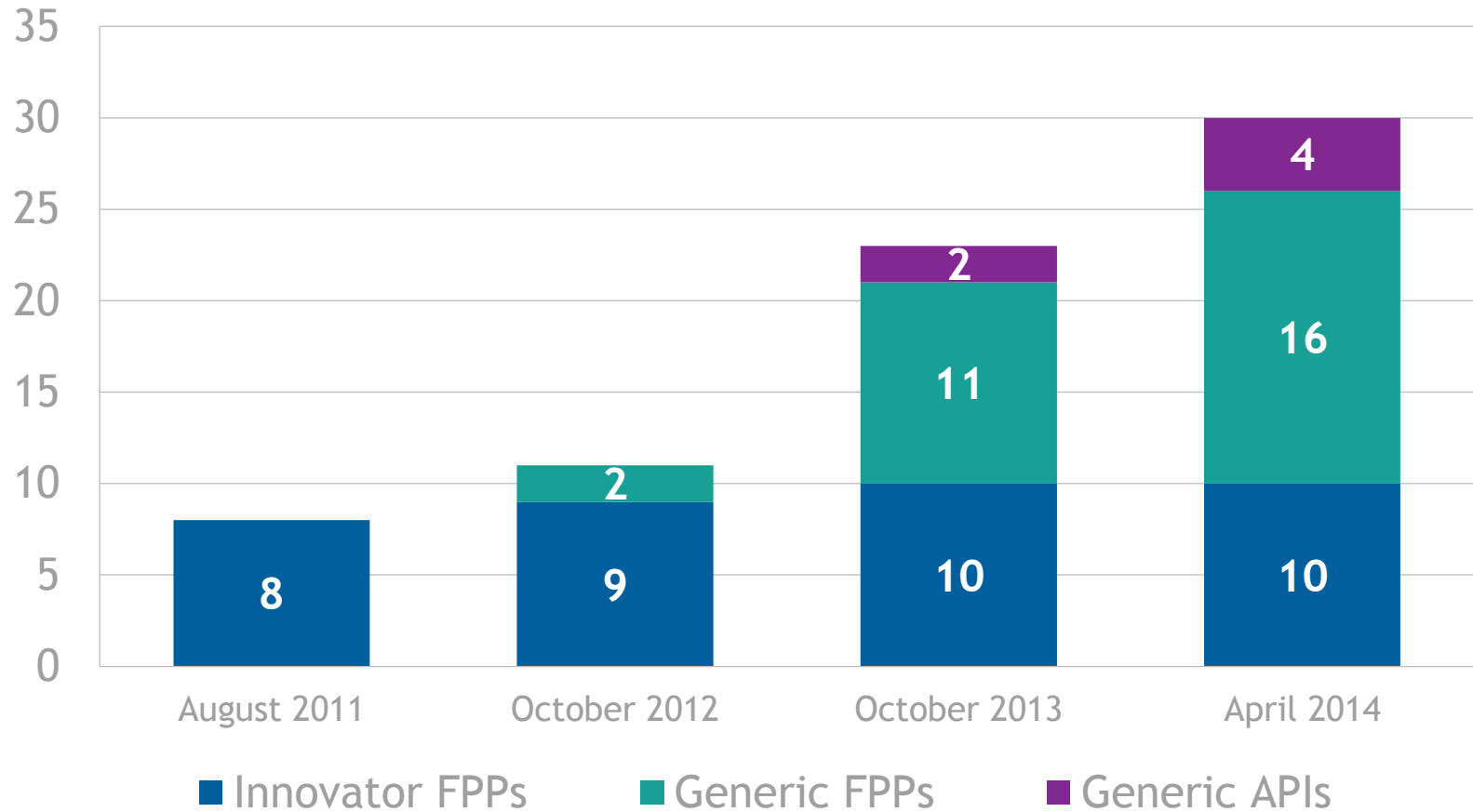
Launch of Family Planning 2020 (FP2020)

Launch of UN Commission for Life-saving Commodities

Recap of progress so far



Recap of progress so far



Where are we now?

- Significant progress has been made in the last half decade;
 - Continuing to work towards increasing the availability of quality assured RH products → misoprostol, oxytocin, magnesium sulphate, DMPA
- Forecasting → injectable contraception; validating the market need
- Procurement at the country level for MH products → Uganda meeting (UNCO/GRAMPS)

Where are we now?

- PQ as the starting point → significant issues remain around **access to markets**
- Focus on **country registration** of RH products → mapping the regulatory pathway for key RH products in target markets; working with manufacturers and country regulators/WHO Collaborative Registration
- Conduct of **country level research** to better understand the stakeholder perceptions of quality assured generic RH products and their availability

Visibility of QA generics at the country level - outline of methodology

Phase 1 Interviews

Preliminary Research

(March 10 – April 13, 2015)

Research conducted in 10 markets – Burkina Faso, Ghana, Kenya, Malawi, Nepal, Nigeria, Senegal, Tanzania, Uganda and Zambia

5 interviews were completed face-to-face in each market

Phase 2 Interviews

Expanded Country-Based Interviews

(June 8 – August 17, 2015)

20 additional interviews in each of the 9 African markets

Research in **Nepal** was suspended after the April 2015 earthquake

A total of **228 interviews** completed in the 9 African markets (across phases 1 & 2)

Visibility of QA generics at the country level - outline of methodology

Stakeholder Groups

Key decision-makers and stakeholders in:

- government,
- manufacturing and the private sector, and
- NGOs, CSOs, media, academia, and think tanks

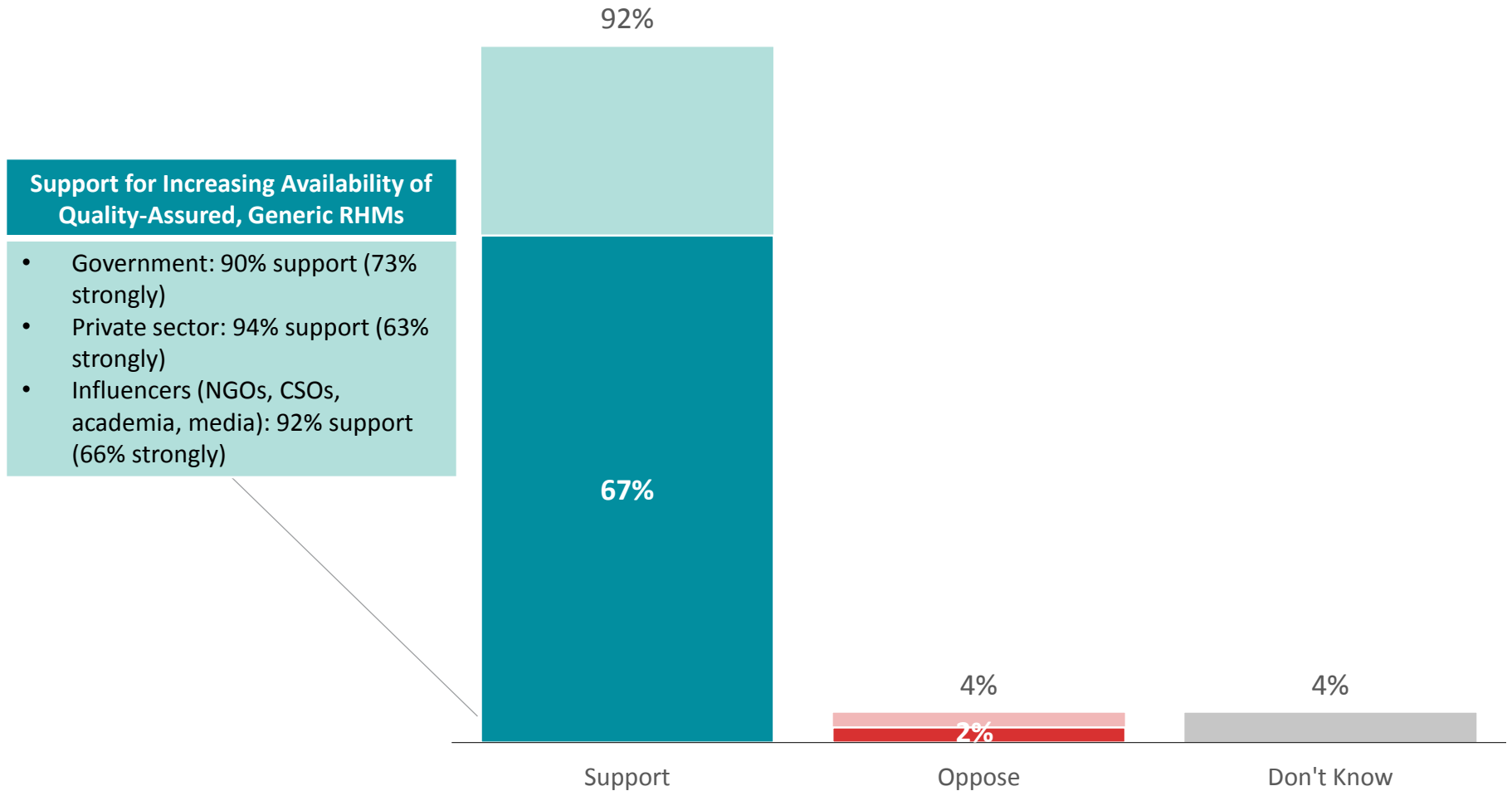
All have subject-matter expertise in the reproductive health space and reproductive health medicines and decision-making authority within their organizations

Note: throughout the report, these individuals are often referred to as “key stakeholders”

Key finding:

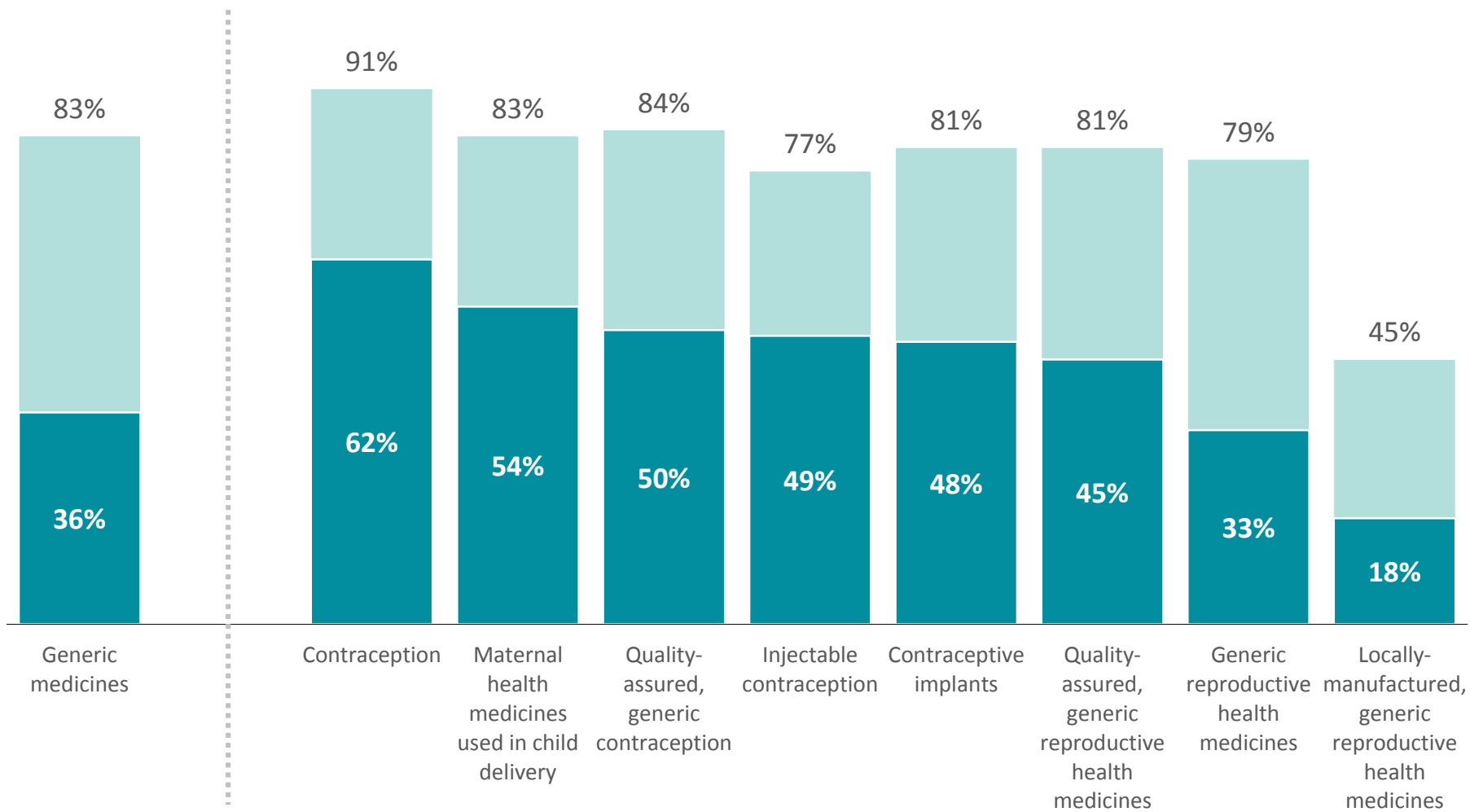
Overwhelming support for expanding availability of QAGRHM

Support for Increasing the Availability of Quality-Assured, Generic Reproductive Health Medicines

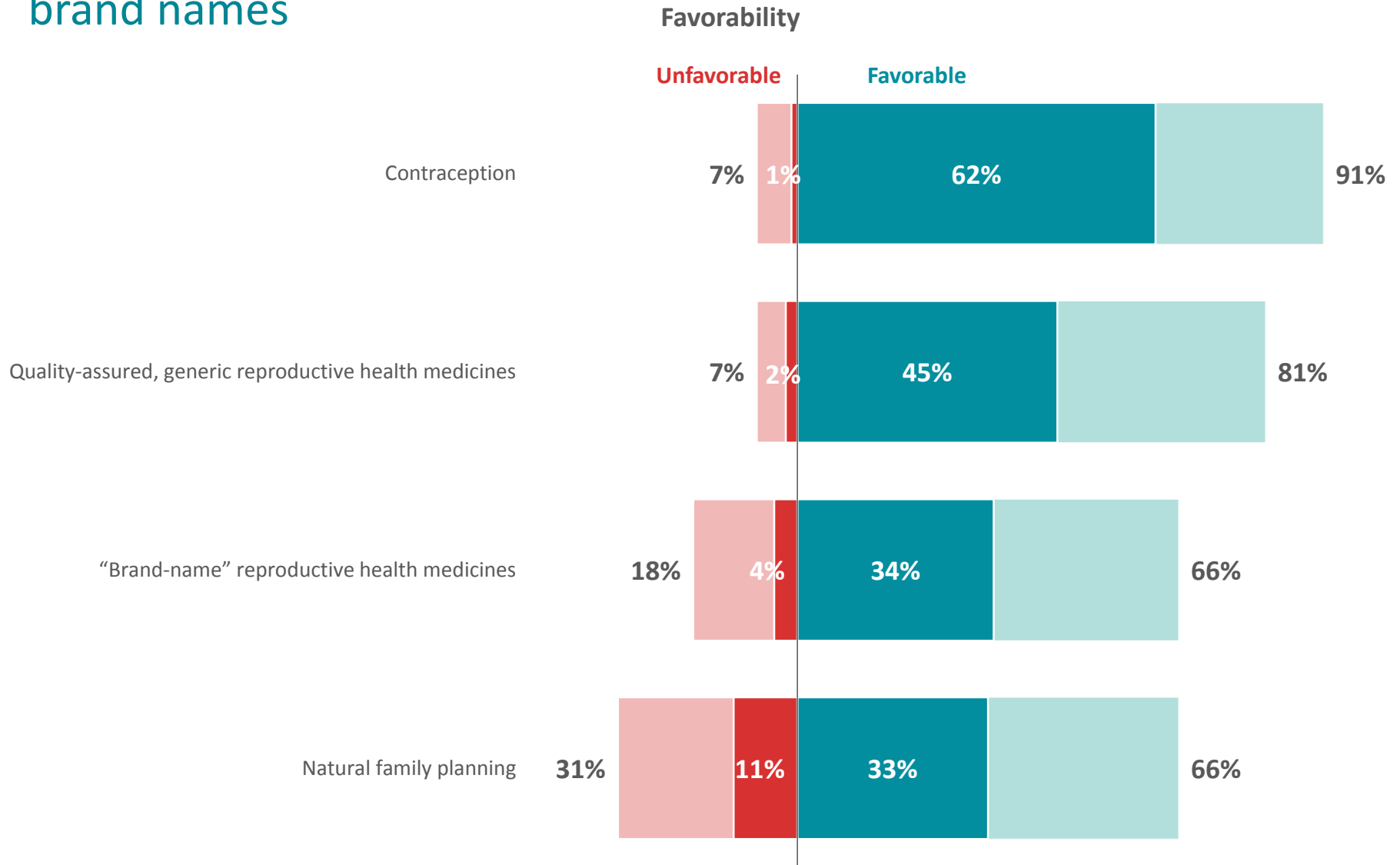


Key finding: Impressions of actors/concepts/products

Favorability
(Showing Very Favorable, Very/Somewhat Favorable)



Key Finding: Idea of Quality-Assured Generic RH Medicines more favorable than brand names

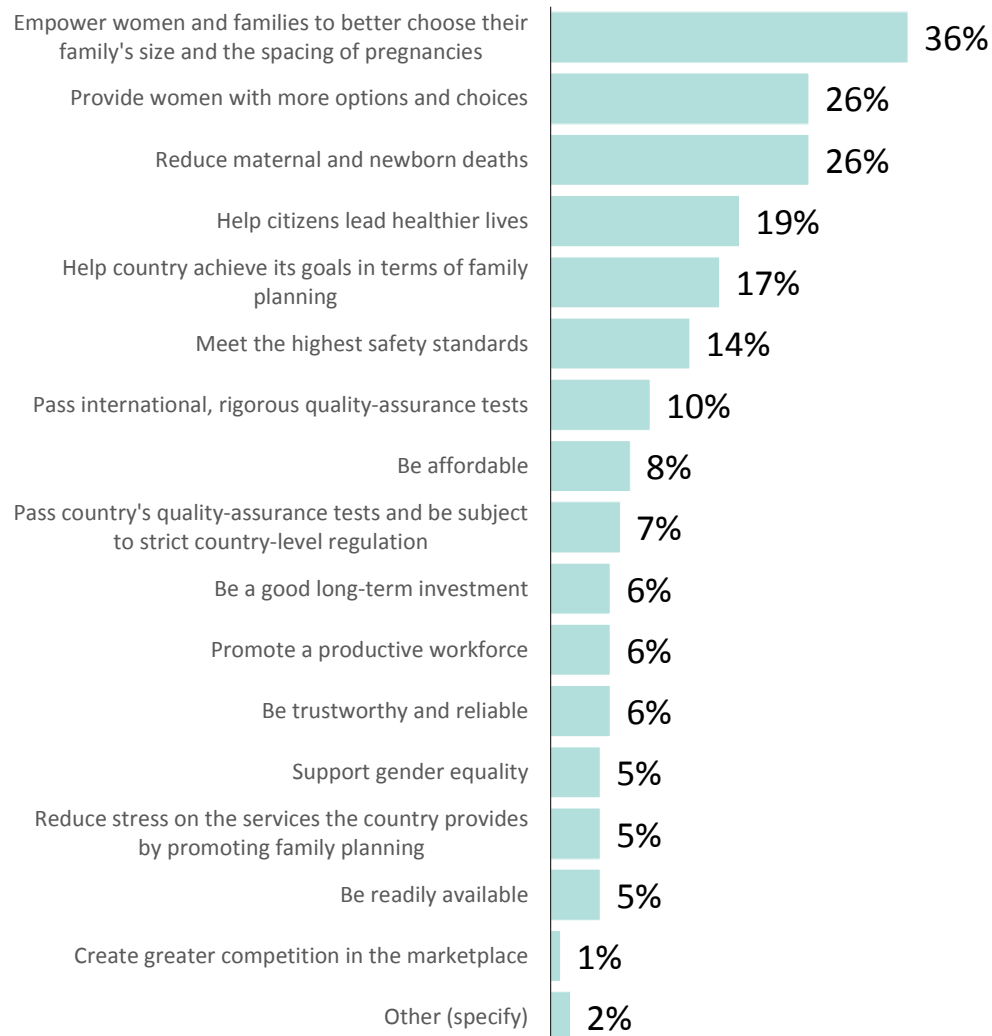


Key finding:

Empowering women/families to choose family size and space births save lives is a powerful narrative

Associations with Quality-Assured, Generic RHMs	Very Well	Total Well
Provides women with more options and choices	61%	92%
Empowers women and families to better choose their family's size and the spacing of pregnancies	61%	90%
Helps the country achieve its goals in terms of family planning	51%	89%
Reduces maternal and newborn deaths	51%	84%
Helps citizens lead healthier lives	47%	83%
Affordable	40%	76%
Meets the highest safety standards	40%	73%
Passed country's quality-assurance tests and are subject to strict country-level regulation	38%	74%
A good long-term investment for the country	37%	75%
Passed international, rigorous quality-assurance tests	37%	71%
Readily available	37%	68%
Reduces stress on the services the country provides by promoting family planning	31%	68%
Promotes a productive workforce	29%	73%
Supports gender equality	26%	56%
Trustworthy and reliable	25%	74%
Creates greater competition in the marketplace	21%	50%

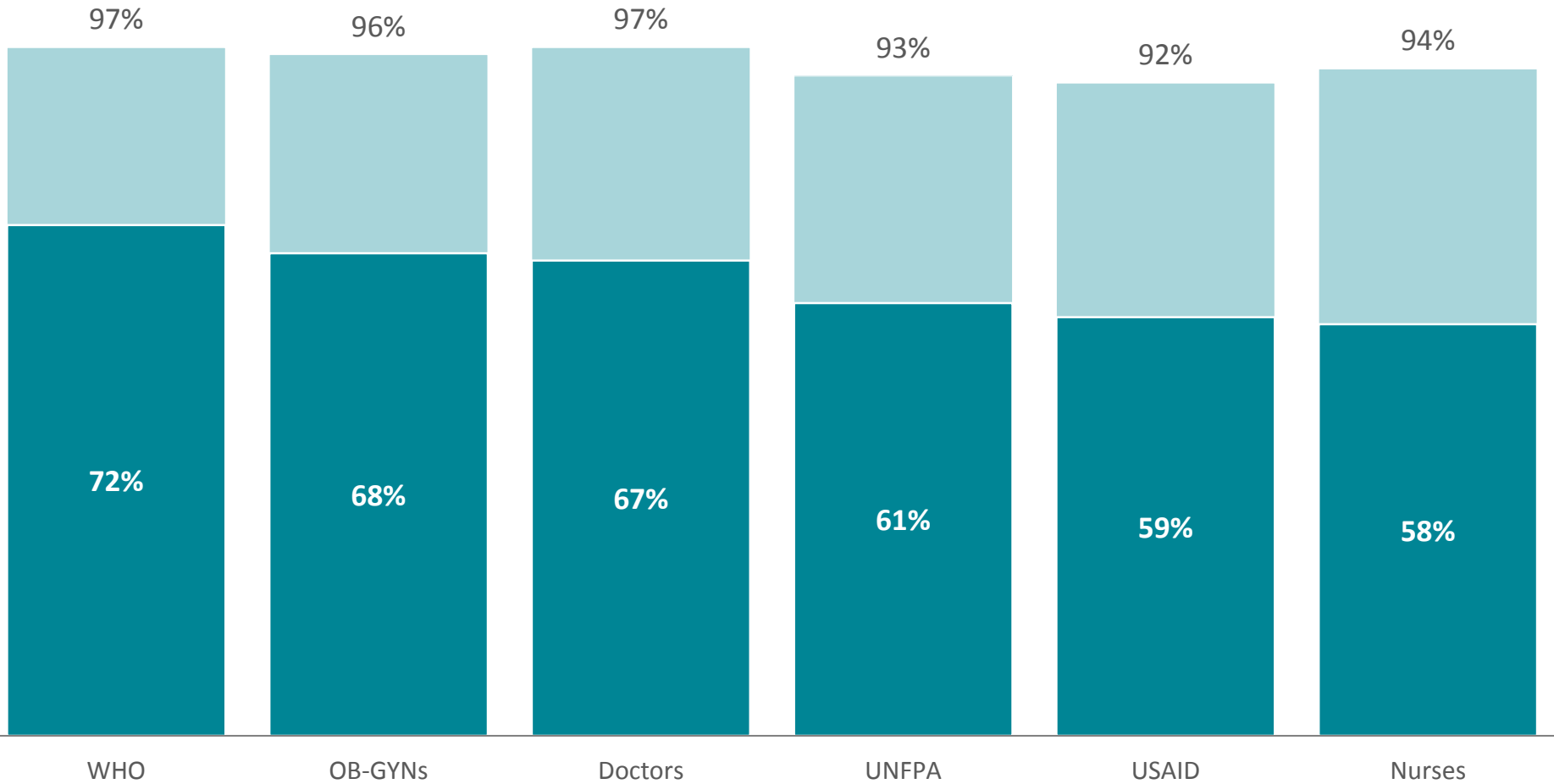
Important For Quality-Assured, Generic RHMs To Do



Key finding:

WHO and medical professionals are most trusted validators

Top-Tier Trustworthy Sources
(Showing A Lot, A Lot/Somewhat)



Forward challenges

- Supplier base remains an issue
- Uptake by procurers at the national/international level
- National registrations; barriers to market
- Raising awareness of QA generic RH medicines at national level
- As new technologies come on stream →
 - Ensuring access by women in LMICs
 - Supply security
 - Competition
 - Price