

Evaluation of the Next Generation of Rotavirus Vaccines

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WHO recommends the inclusion of rotavirus vaccination of infants into all national immunization programs

2009, 84, 213–236

No. 23



World Health
Organization

Organisation mondiale de la Santé

Weekly epidemiological record Relevé épidémiologique hebdomadaire

5 JUNE 2009, 84th YEAR / 5 JUIN 2009, 84^e ANNÉE

No. 23, 2009, 84, 213–236

<http://www.who.int/wer>

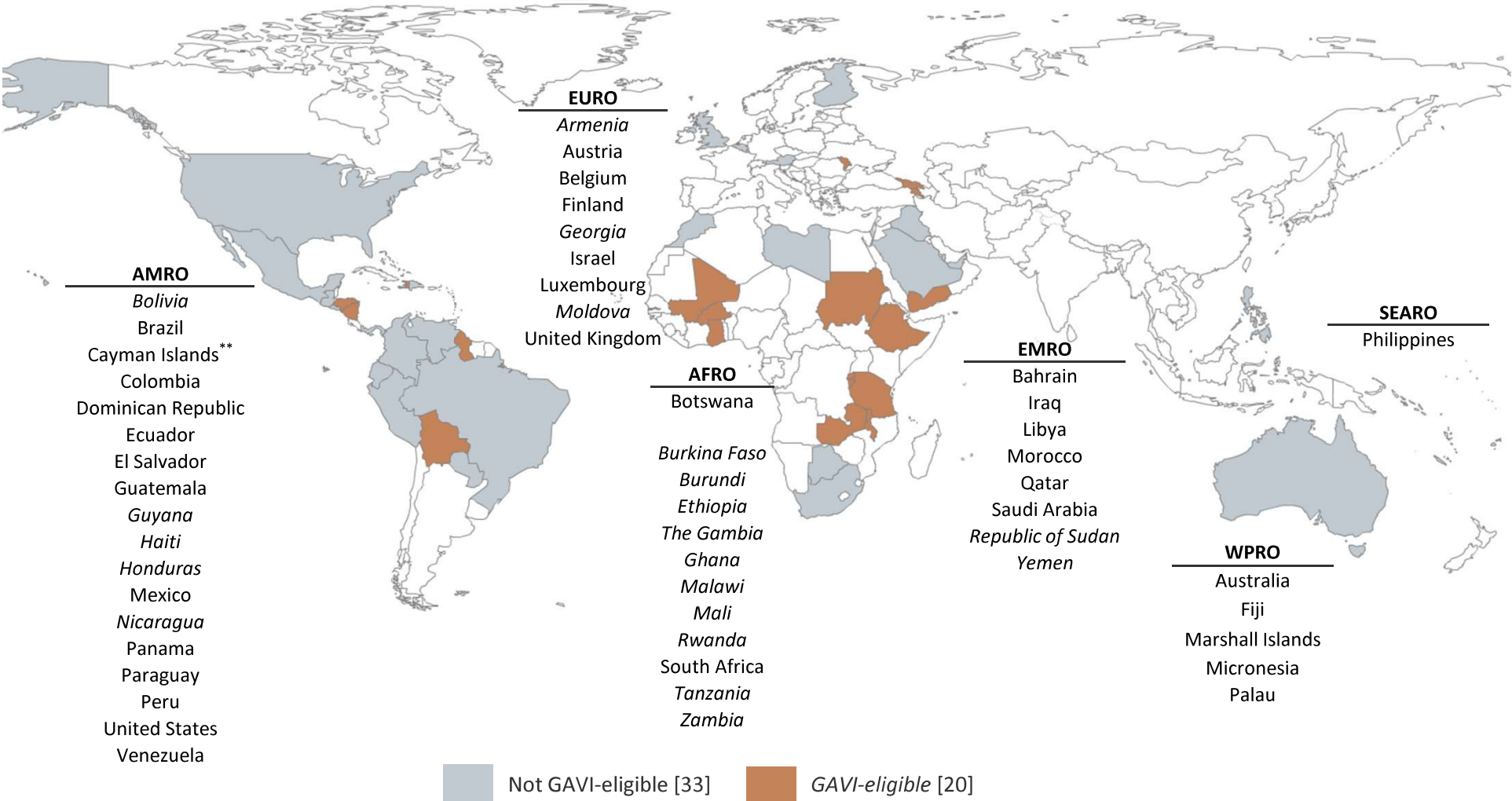
Rotavirus vaccination

Data from trials in Latin America, Europe and the United States of 2 oral, live, attenuated rotavirus vaccines, Rotarix (GlaxoSmithKline) and RotaTeq (Merck & Co., Inc.) were reviewed by SAGE in 2005.⁸ Noting the variable efficacy of live, oral vaccines in different populations, SAGE considered that the introduction of vaccines would be appropriate only in regions where successful phase III efficacy trials had been conducted. SAGE therefore recommended that rotavirus vaccines be included in national immunization programmes in countries where data on vaccine efficacy suggest a significant public health impact; SAGE also noted the need to urgently generate such data in Africa and Asia.

Vaccination antirotavirus

En 2005, le SAGE a examiné les données d'essais cliniques menés en Amérique latine, en Europe et aux États Unis concernant 2 vaccins antirotavirus vivants atténués pour voie orale, le Rotarix (GlaxoSmithKline) et le RotaTeq (Merck & Co. Inc.).⁸ Notant que l'efficacité des vaccins vivants pour voie orale variait selon les populations, le SAGE a estimé judicieux de les adopter seulement dans les Régions où des essais d'efficacité de phase III avaient été effectués avec succès. Il a par conséquent recommandé que les vaccins antirotavirus soient inclus dans les programmes de vaccination nationaux des pays où les données sur l'efficacité des vaccins semblent indiquer qu'ils ont des répercussions importantes en santé publique; il a par ailleurs noté qu'il était urgent d'obtenir des données de ce type en Afrique et en Asie.

National RV introductions by WHO region: 53 countries*

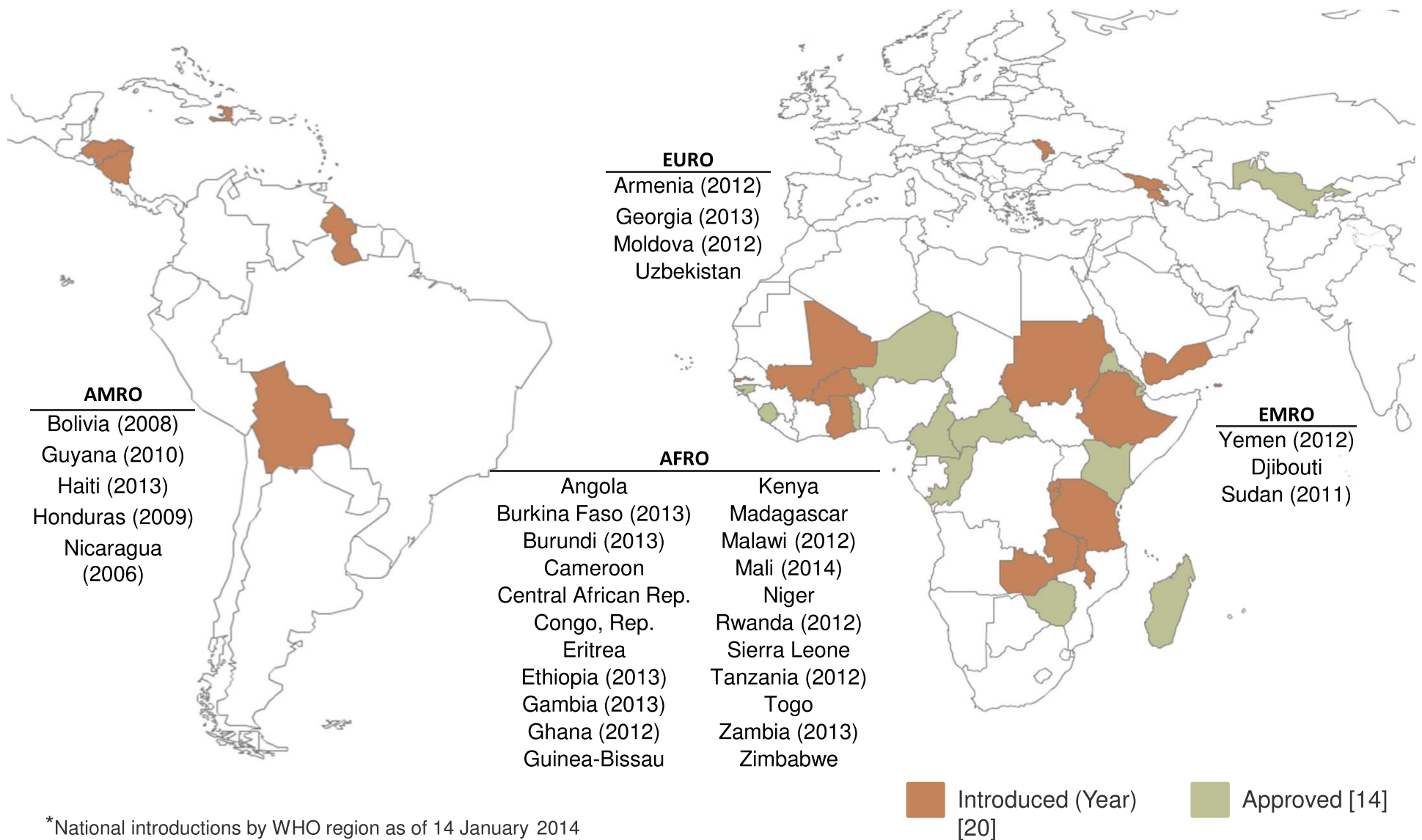


*National introductions by WHO region as of 14 January 2014

**Not a WHO member state

RV= rotavirus vaccine

GAVI-supported RV introductions by WHO region: 20 countries*



*National introductions by WHO region as of 14 January 2014

RV = rotavirus vaccine

Currently licensed & prequalified rotavirus vaccines

Name: Rotarix®



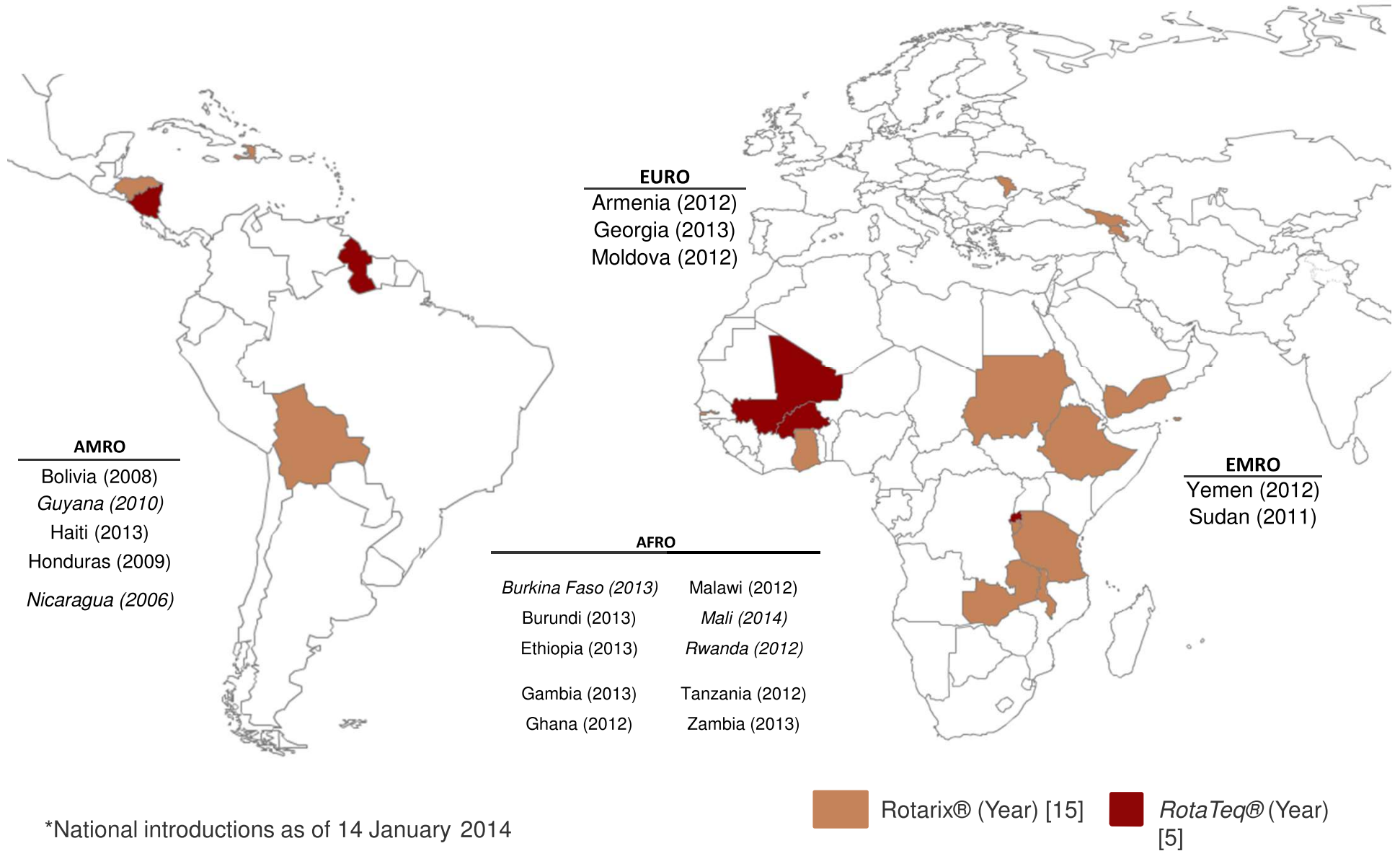
- **Manufacturer:** GlaxoSmithKline
- **Date prequalified:** Mar 12, 2009
- **Presentation:** 1-dose plastic tube, liquid
- **VVM:** Type 14
- **GAVI price:** \$2.50 per dose
- **Shelf life:** 36 months @ 2-8°C
- **Cold chain volume per dose:**
 - 1-dose carton: 115.3 cm³
 - 10-dose carton: 43.3 cm³
 - 50-dose carton: 17.1 cm³

Name: RotaTeq®



- **Manufacturer:** Merck & Co. Inc.
- **Date prequalified:** Oct 7, 2008
- **Presentation:** 1-dose plastic tube, liquid
- **VVM:** none
- **GAVI price:** \$3.50 per dose
- **Shelf life:** 24 months @ 2-8°C
- **Cold chain volume per dose:**
 - 10-dose carton: 75.3 cm³
 - 25-dose carton: 46.3 cm³

Rotavirus vaccine product choice in GAVI-eligible countries*

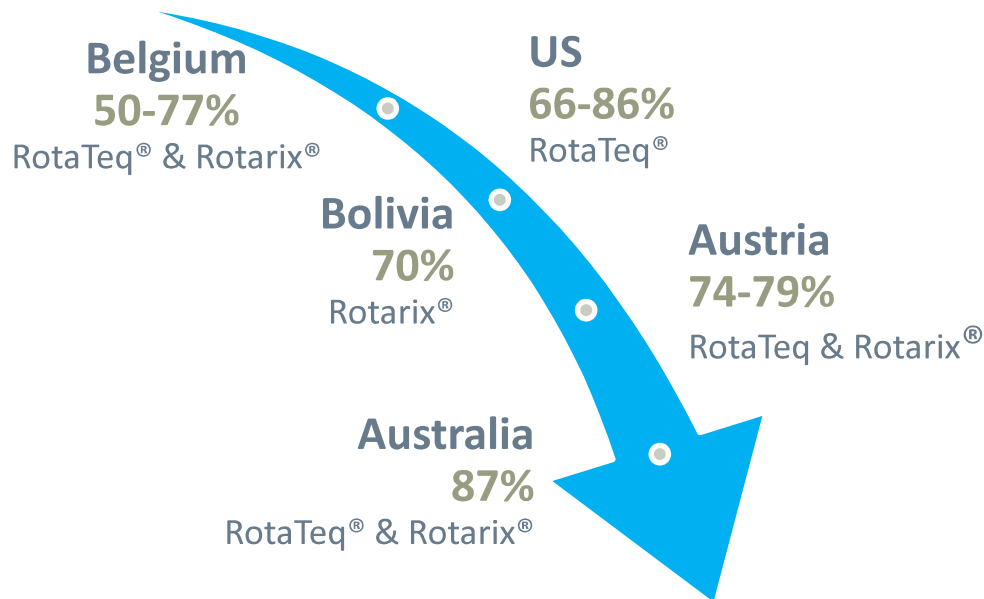


*National introductions as of 14 January 2014

Significant declines in diarrhea hospitalizations

*Rotavirus hospitalizations:
reductions of 50% or more in
children 0-2 years old following
rotavirus vaccination*

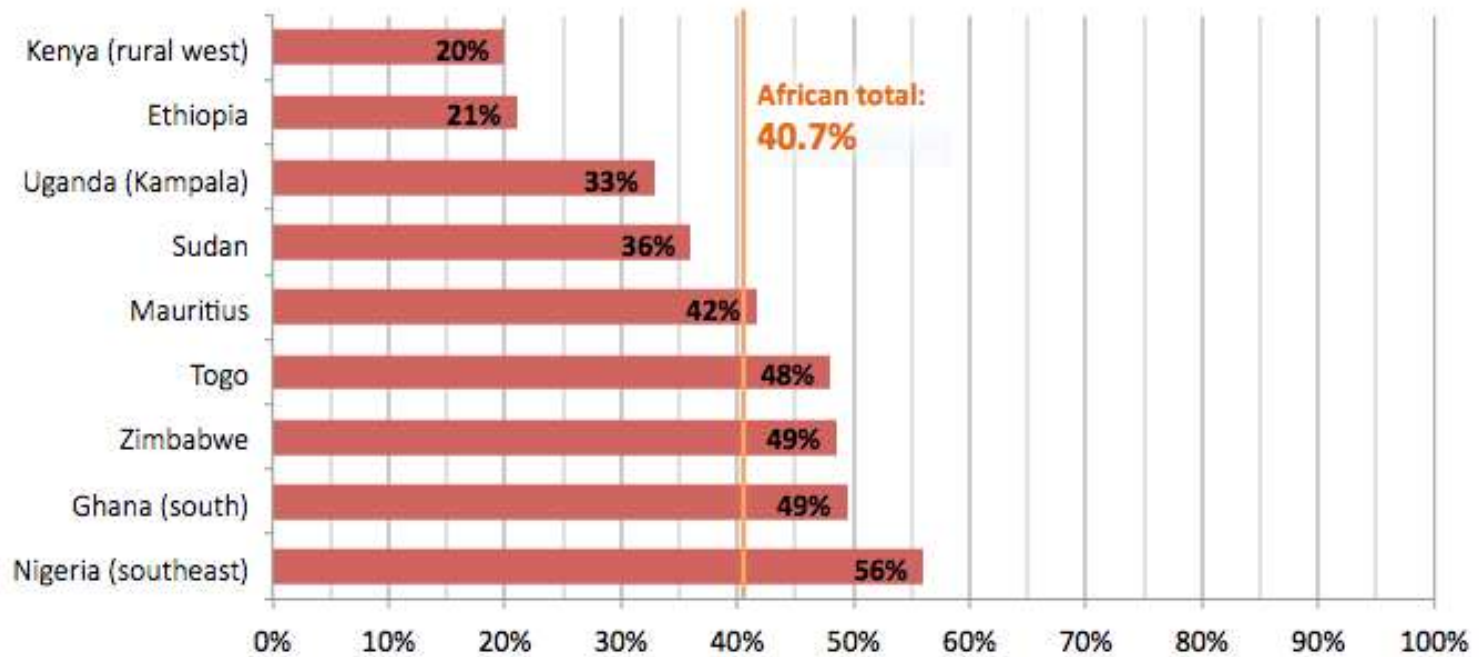
*All-cause diarrhea hospitalizations:
reductions of nearly 20% or more in
children 0-2 years old following
rotavirus vaccination*



Note: Data derived from Table 2 from Patel MM, Glass R, Desai R, Tate JE, Parashar UD. Fulfilling the Promise of Rotavirus Vaccines: How Far Have We Come Since Licensure? The Lancet Infectious Diseases. 2012;12(7):561-570.

Percentage of hospitalized diarrhea due to rotavirus in African countries in WHO-coordinated Global Rotavirus Surveillance Network (GRSN), 2006-2012

Hospital-based gastroenteritis cases positive for rotavirus



March 2014: Where are we now with rotavirus vaccines?

- Global recommendation for rotavirus vaccine introduction
- 53 countries have introduced rotavirus vaccines into their national immunization programs
- 13 additional GAVI-eligible countries approved to introduce in 2014/2015
- Impact has been demonstrated – while substantial, efforts to further reduce severe disease in low resource countries warranted
- Two pre-qualified rotavirus vaccines
- No correlate of protection

What are the potential advantages or challenges of “new” rotavirus vaccines?

- More effective at preventing severe rotavirus gastroenteritis?
- Cross-protection?
- Longer lasting immunity (second year of life)?
- Safety?
- Mode of administration?
- Logistics/cold chain?
- Lower cost and more stable supply?

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- Logistics/cold chain/vaccine delivery?
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What are the relative trade-offs
of the above characteristics?

How will/should products be compared?

How will/should safety be assessed?