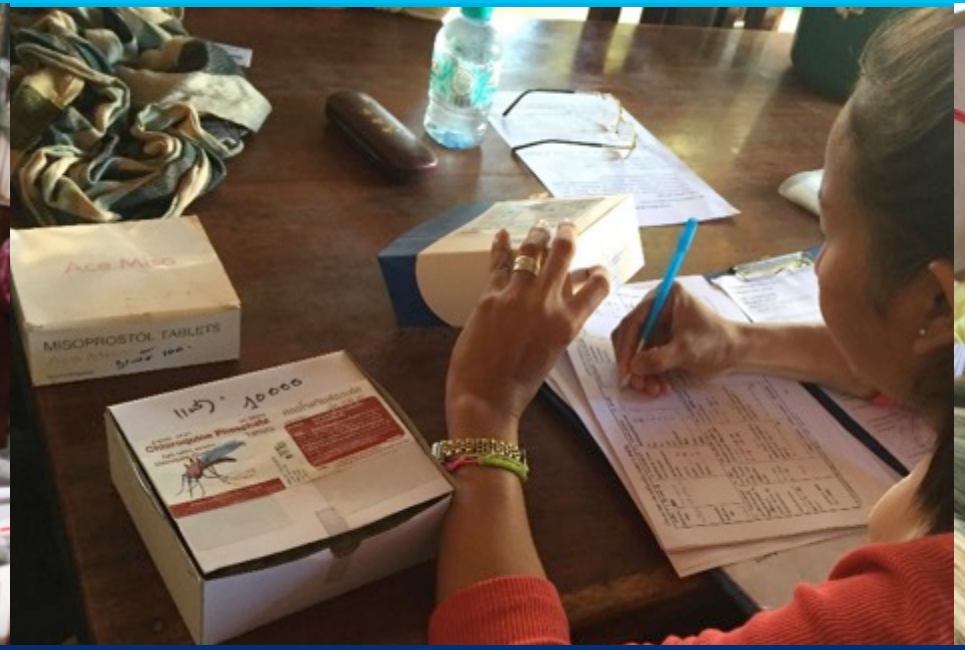





Non-Quality-Assured ACT Availability and Distribution in 8 African Countries: 2009-2015

The ACTwatch Group

16th November, 2016

65th Annual Meeting of the American Society for Tropical Medicine and Hygiene

Atlanta, Georgia

ACTwatch
Evidence for Malaria Medicine Policy

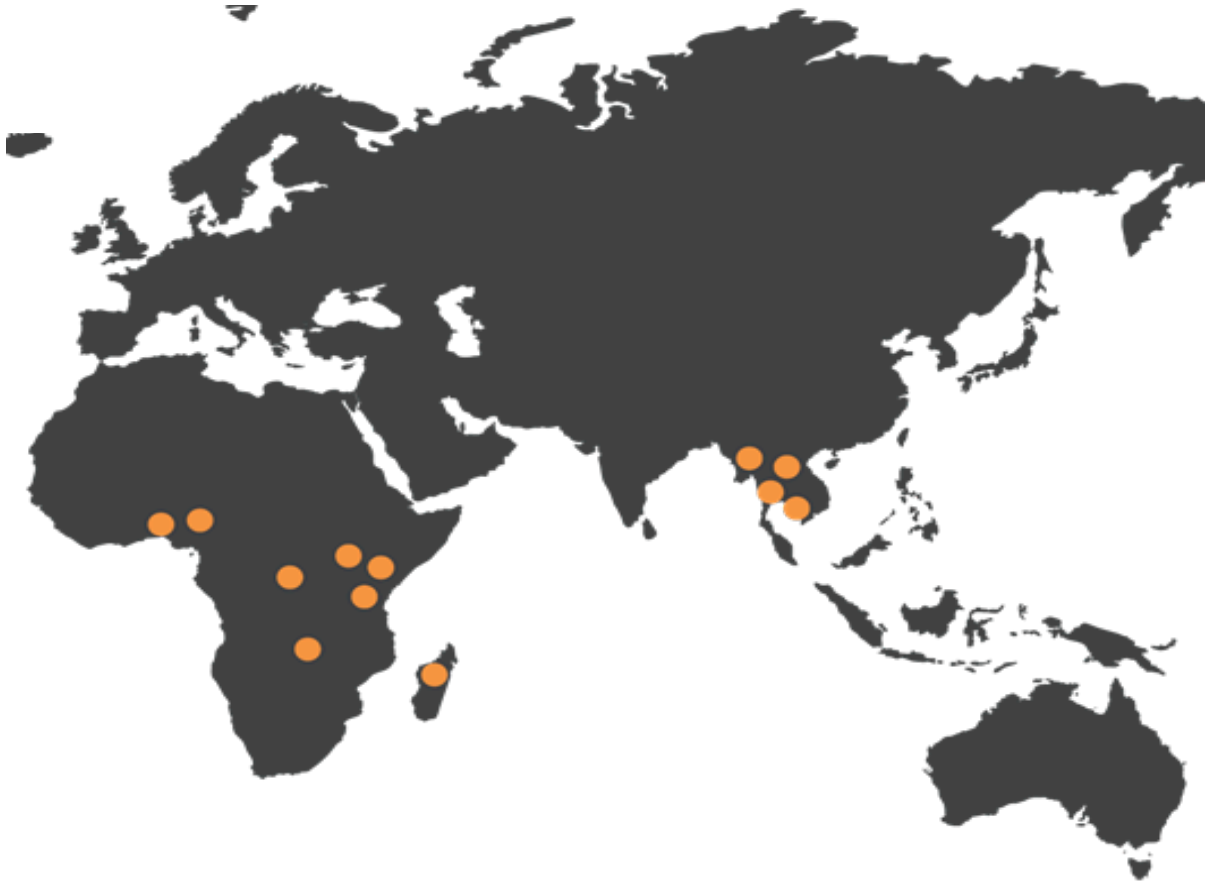
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Background

ACTwatch is a research project implemented by PSI and Ministries of Health in 12 countries

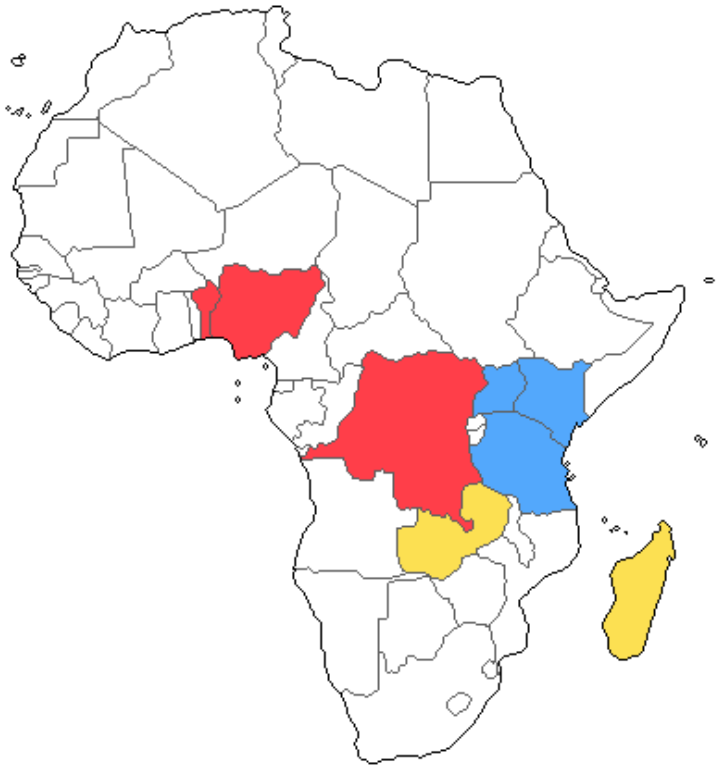
- **~50 malaria outlet surveys** conducted between 2008-2016
- **Total market approach**
- Outlet surveys measure **availability, price, and market share** in the public and private sectors for malaria medicines & diagnostics




LONART
Oral Suspension 60 ml
Artemether 180 mg
+
Lumefantrine 1080 mg
SAMSUNG
DUOS
ACT_USERS
16:40
ACT watch
OUTLET SURVEY
Username
Password
LOGIN

Methods

Study Sites



West & Central Africa
Benin, Nigeria, the DRC

East Africa
Kenya, Tanzania, Uganda

Southern Africa
Madagascar, Zambia

Multiple rounds of data collection between 2009-2015

Nationally representative studies with the exception of DRC
(sub-national studies in Kinshasa & Katanga provinces)

Outlet Survey Population

Study Population:

- Outlets with antimalarials or with malaria blood testing available

What is an outlet?

- Public health facility
- Community Health Worker
- Private for-profit health facility
- Pharmacy
- Drug store
- General retailer
- Itinerant drug vendor



Sampling

- Representative sample of clusters
- Complete a **CENSUS** of all potentially eligible outlets
- **SCREEN** for antimalarials in stock or malaria blood testing available



Audit: All Antimalarial Products in Stock



Audit: All Antimalarial Products in Stock

Formulation (tablet, syrup, injection, etc.)

Brand/generic names

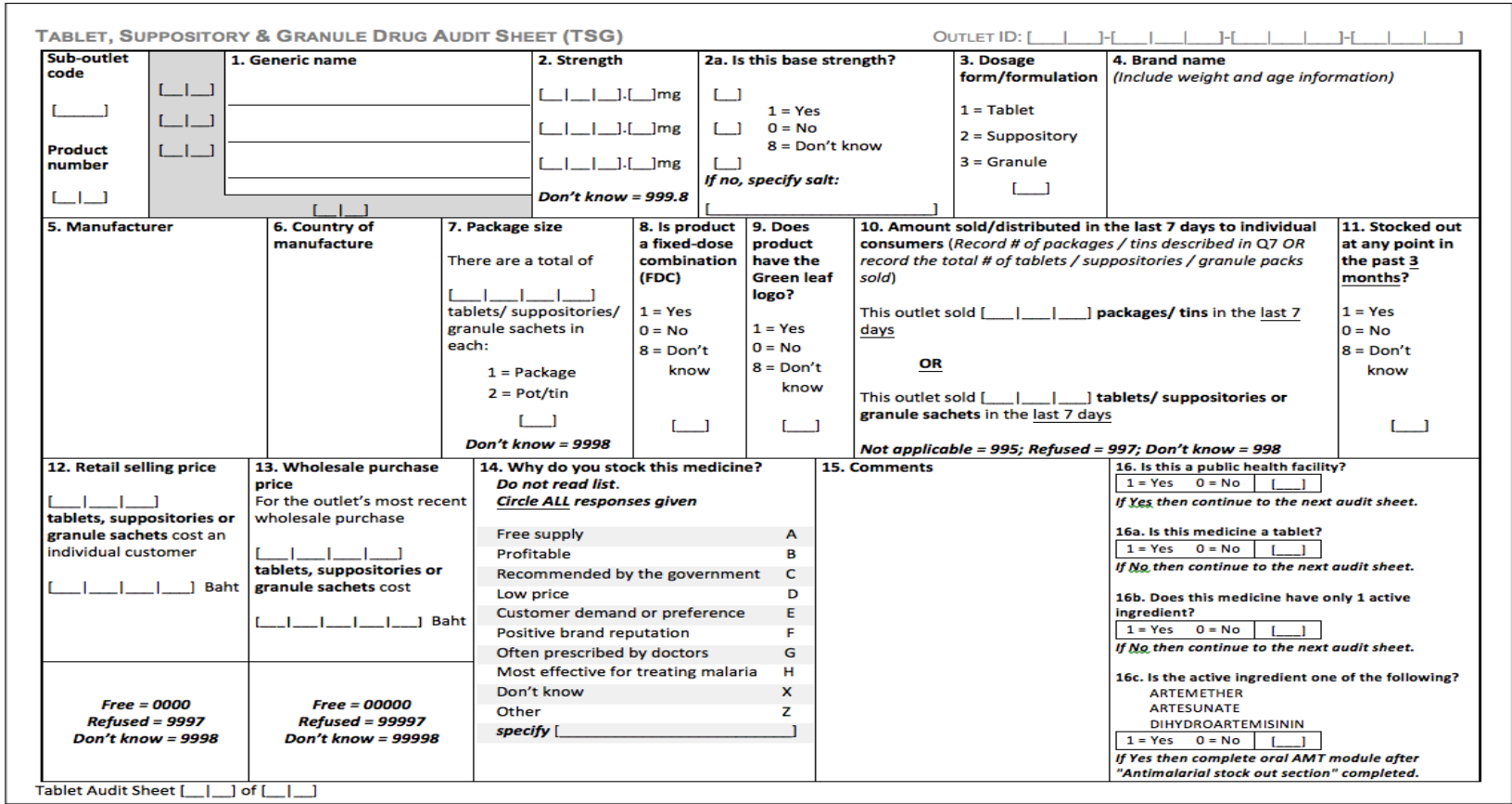
Strength

Manufacturer

Country of manufacture

Amount distributed in the past week

Retail & wholesale price



TABLET, SUPPOSITORY & GRANULE DRUG AUDIT SHEET (TSG)

OUTLET ID: [___|___|___]-[___|___|___|___]-[___|___|___|___]-[___|___|___|___]

Sub-outlet code [_____] Product number [__|__]	[__|__] [__|__] [__|__]	1. Generic name [__|__]	2. Strength [__|__|__].[__]mg [__|__|__].[__]mg [__|__|__].[__]mg *Don't know = 999.8*	2a. Is this base strength? [__] [__] [__] 1 = Yes 0 = No 8 = Don't know *If no, specify salt:* [_____]	3. Dosage form/formulation 1 = Tablet 2 = Suppository 3 = Granule [___]	4. Brand name *(Include weight and age information)*

5. Manufacturer	6. Country of manufacture	7. Package size There are a total of [___|___|___|___] tablets/ suppositories/ granule sachets in each: 1 = Package 2 = Pot/tin [___] *Don't know = 9998*	8. Is product a fixed-dose combination (FDC) 1 = Yes 0 = No 8 = Don't know [___]	9. Does product have the Green leaf logo? 1 = Yes 0 = No 8 = Don't know [___]	10. Amount sold/distributed in the last 7 days to individual consumers (*Record # of packages / tins described in Q7 OR record the total # of tablets / suppositories / granule packs sold*) This outlet sold [___|___|___] **packages/ tins** in the last 7 days **OR** This outlet sold [___|___|___] **tablets/ suppositories or granule sachets** in the last 7 days *Not applicable = 995; Refused = 997; Don't know = 998*	11. Stocked out at any point in the past 3 months? 1 = Yes 0 = No 8 = Don't know [___]

12. Retail selling price [___|___|___] **tablets, suppositories or granule sachets** cost an individual customer [___|___|___|___] Baht *Free = 0000 Refused = 9997 Don't know = 9998*	13. Wholesale purchase price *Do not read list.* For the outlet's most recent wholesale purchase [___|___|___|___] **tablets, suppositories or granule sachets** cost [___|___|___|___|___] Baht *Free = 00000 Refused = 99997 Don't know = 99998*	14. Why do you stock this medicine? *Do not read list.* *Circle ALL responses given*		15. Comments	16. Is this a public health facility? 1 = Yes 0 = No [___] *If Yes then continue to the next audit sheet.* 16a. Is this medicine a tablet? 1 = Yes 0 = No [___] *If No then continue to the next audit sheet.* 16b. Does this medicine have only 1 active ingredient? 1 = Yes 0 = No [___] *If No then continue to the next audit sheet.* 16c. Is the active ingredient one of the following? ARTEMETHER ARTESUNATE DIHYDROARTEMISININ 1 = Yes 0 = No [___] *If Yes then complete oral AMT module after "Antimalarial stock out section" completed.*

Free supply	A
Profitable	B
Recommended by the government	C
Low price	D
Customer demand or preference	E
Positive brand reputation	F
Often prescribed by doctors	G
Most effective for treating malaria	H
Don't know	X
Other	Z
specify [_____]	

Tablet Audit Sheet [__|__] of [__|__]

Quality-assured ACT

- WHO pre-qualified
- In compliance with Global Fund QA Policy and on the list of approved antimalarials for procurement
- Granted regulatory approval by the EMA

Non-quality-assured ACT

- Does not meet QA criteria

How are ACTs classified?

Using information from product packaging to match lists of approved medicines

No drug testing component


Gamalate B6
Ventoline®
100 microgrammes/dose
Coartem 80/480
FALCIDOX®
Traitement curatif du paludisme
DOSE UNIQUE
ARLUMETRIN
AT-200
AT-20
AT-50
ARTÉPIP
P-GVAXIN
MEDITHER FORTE
Arauclav™

Results

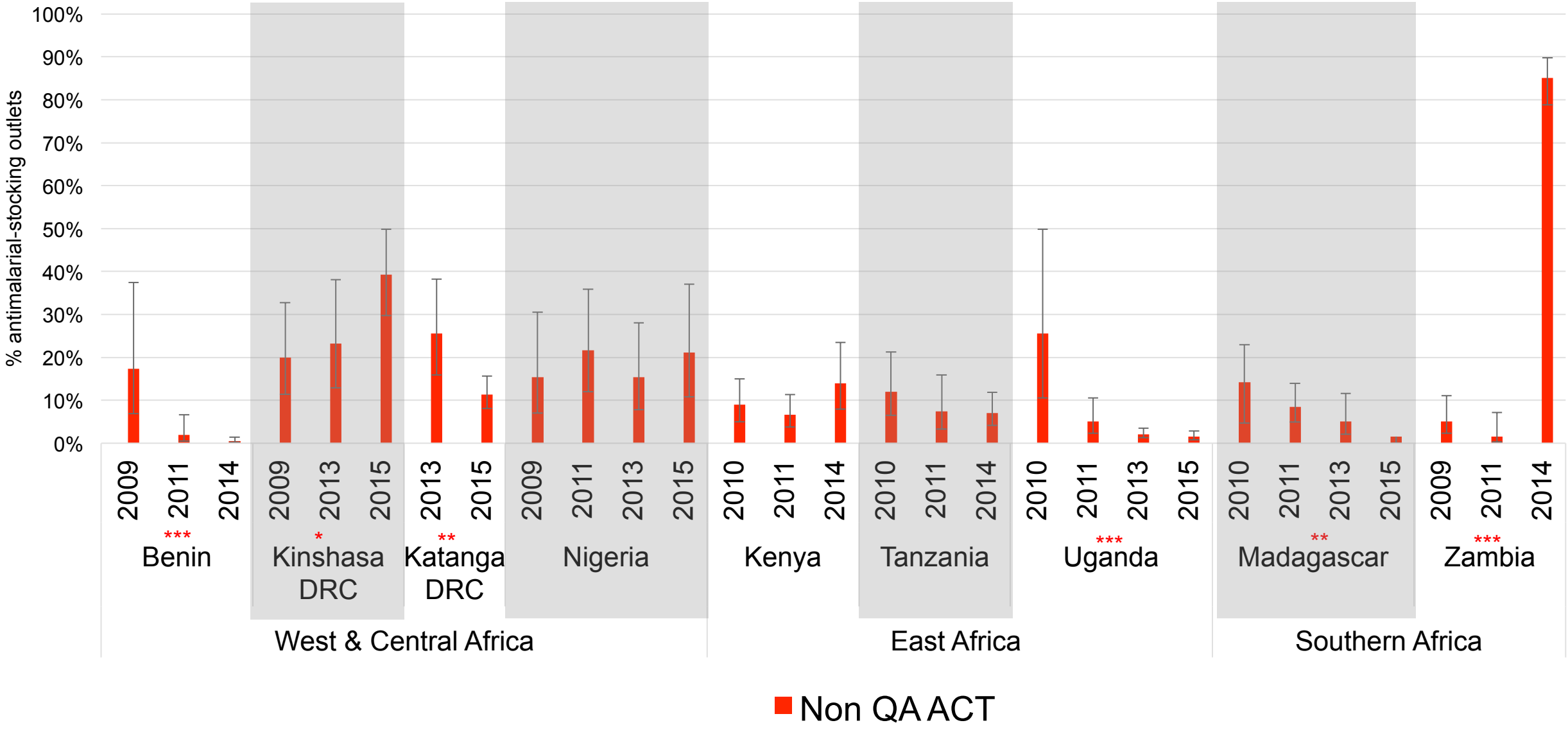


Availability of quality-assured & non-quality-assured ACT



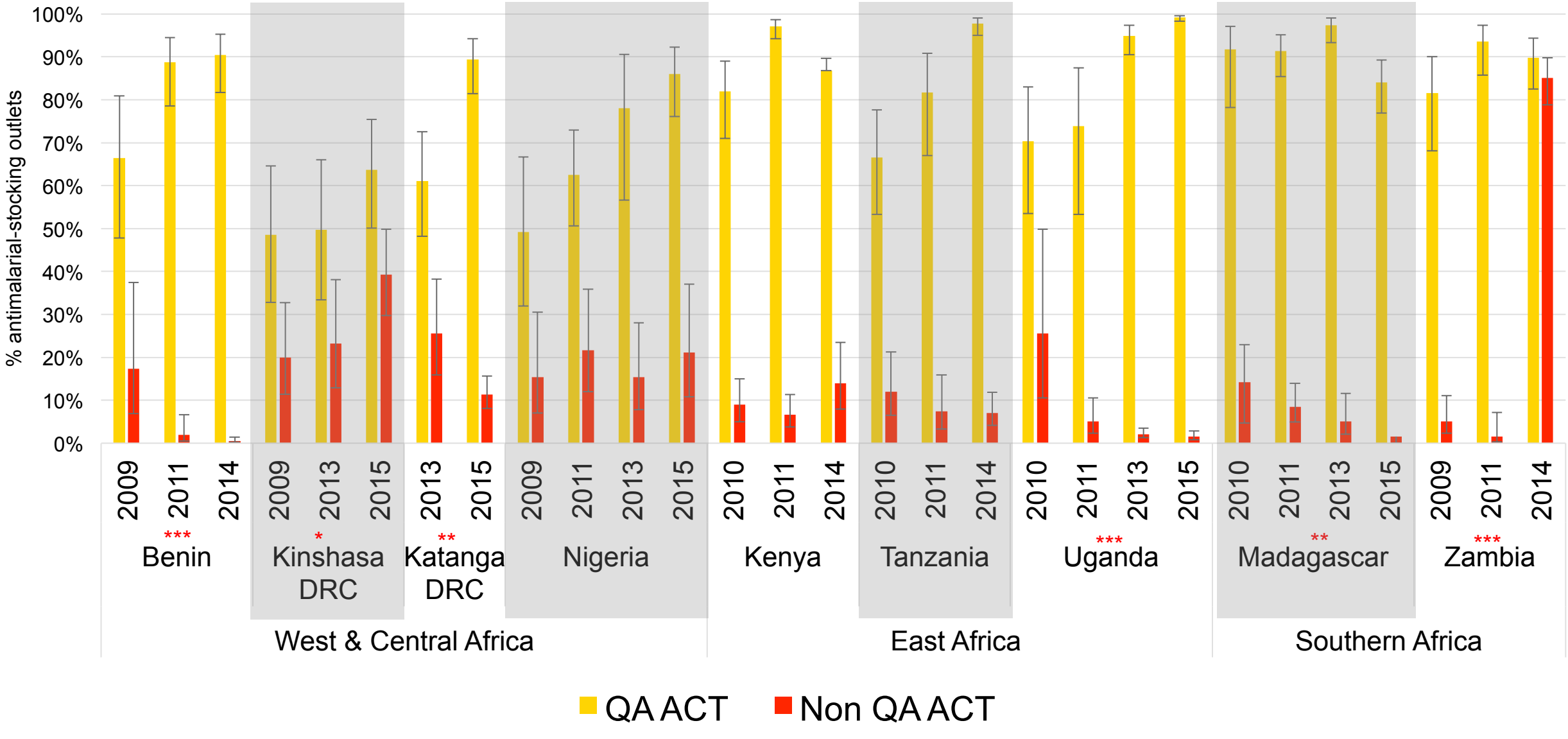
Among outlets with at least 1 antimalarial in stock

Public sector ACT availability



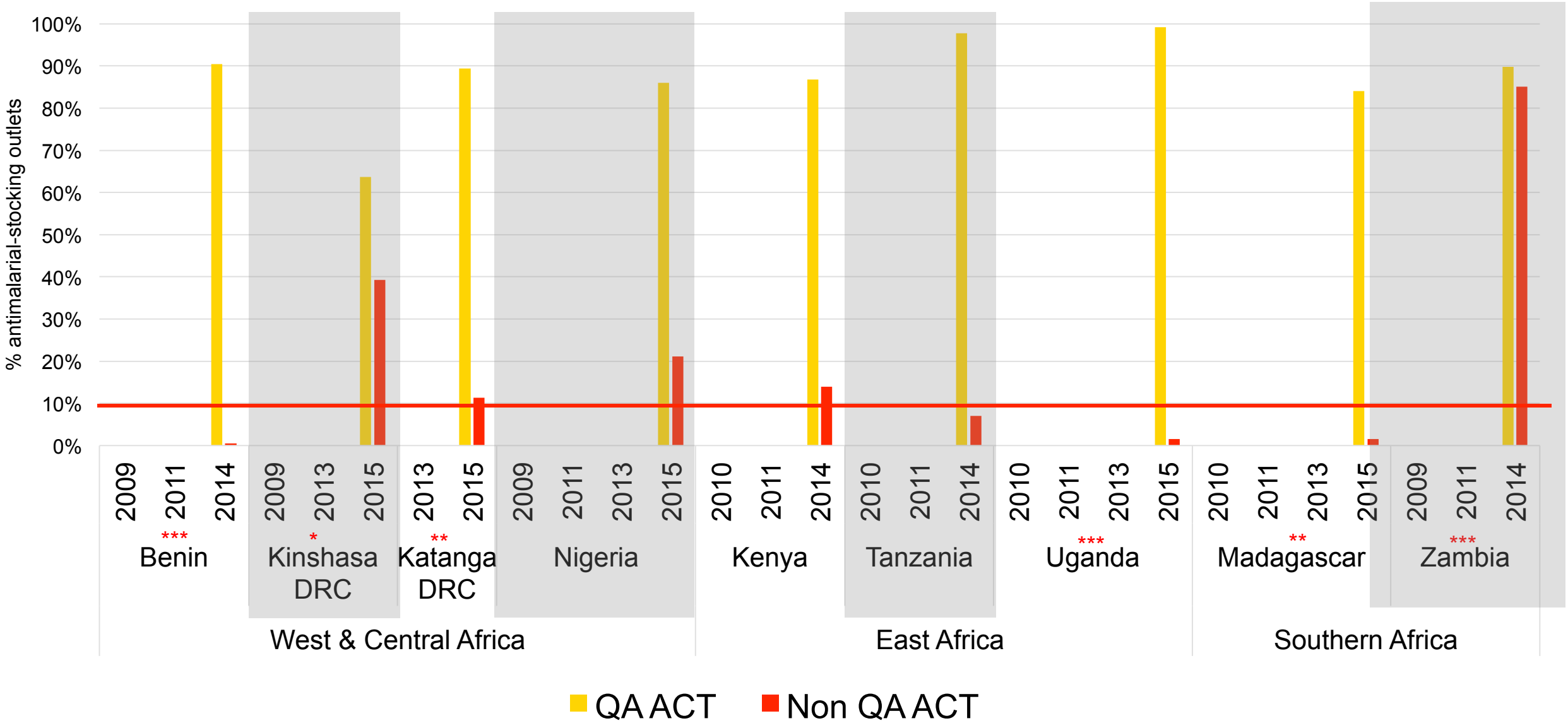
Among outlets with at least 1 antimalarial in stock

Public sector ACT availability



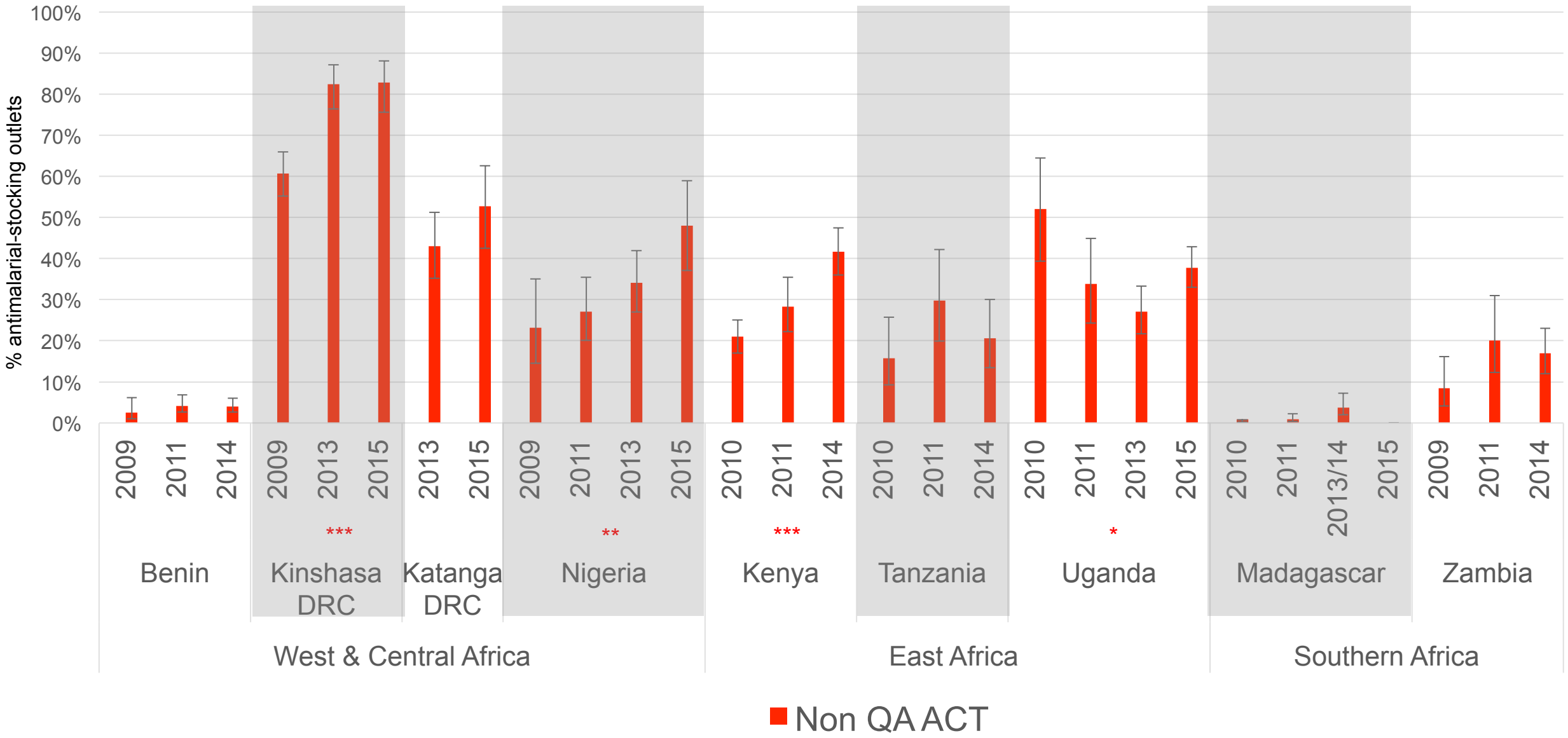
Among outlets with at least 1 antimalarial in stock

Public sector ACT availability



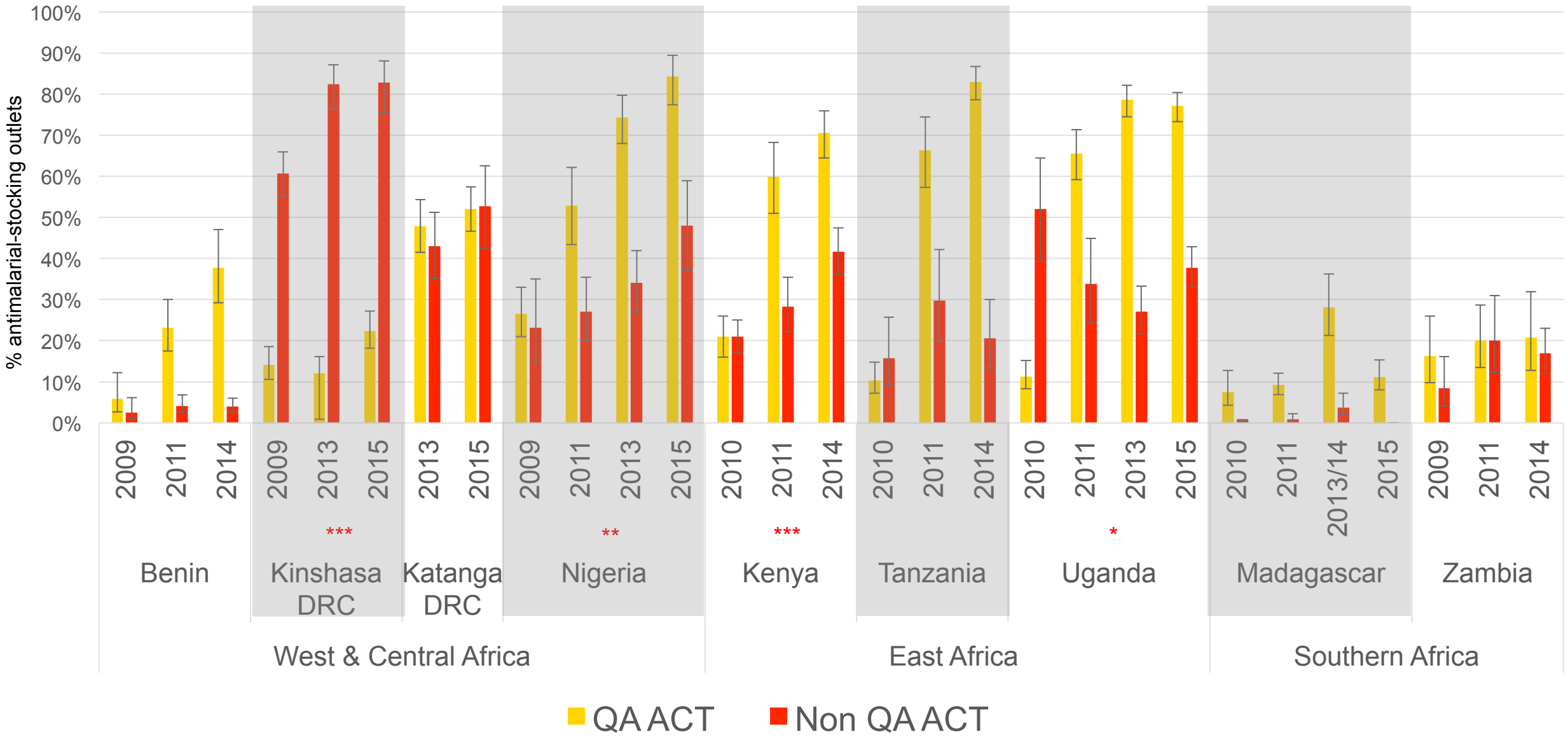
Among outlets with at least 1 antimalarial in stock

Private sector ACT availability



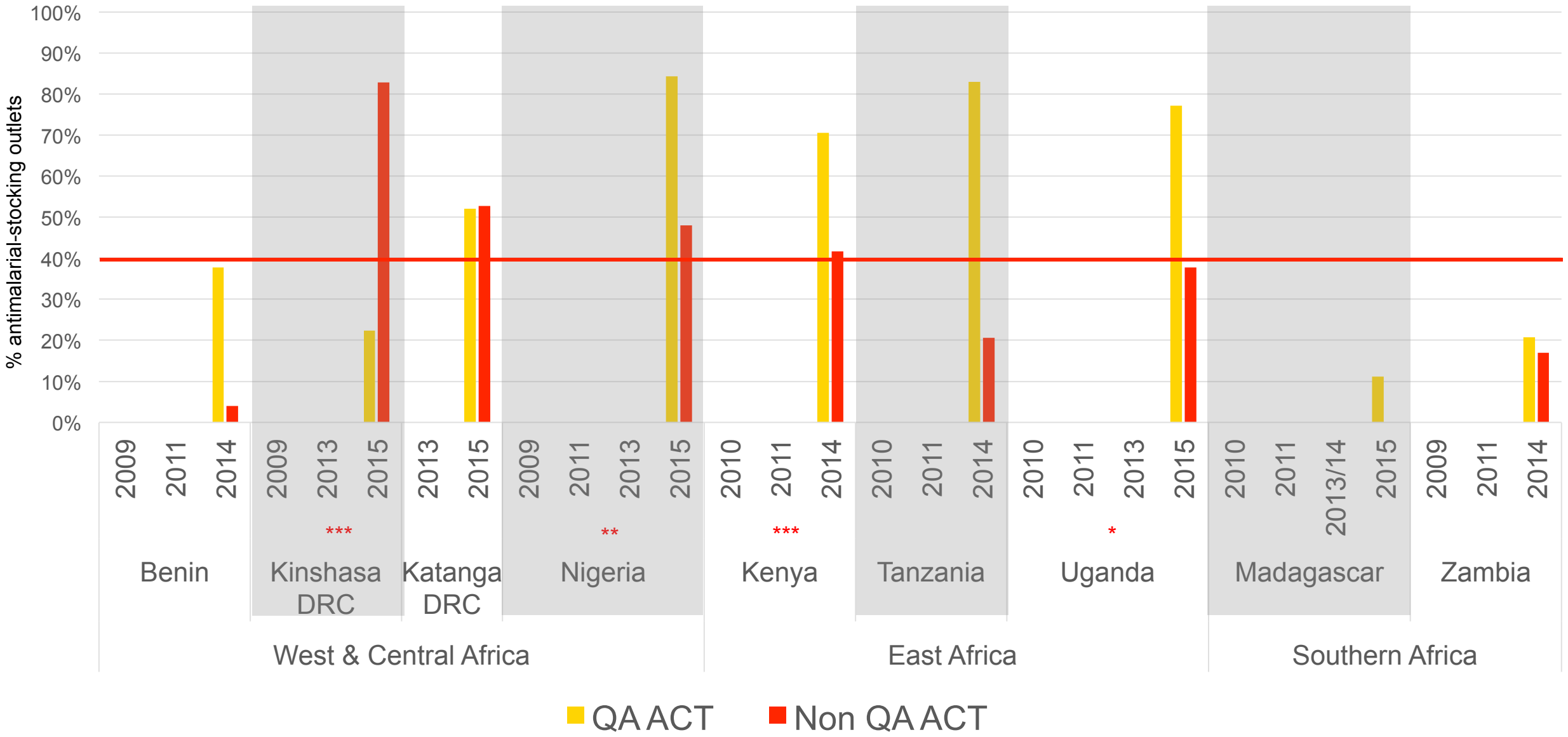
Among outlets with at least 1 antimalarial in stock

Private sector ACT availability



Among outlets with at least 1 antimalarial in stock

Private sector ACT availability

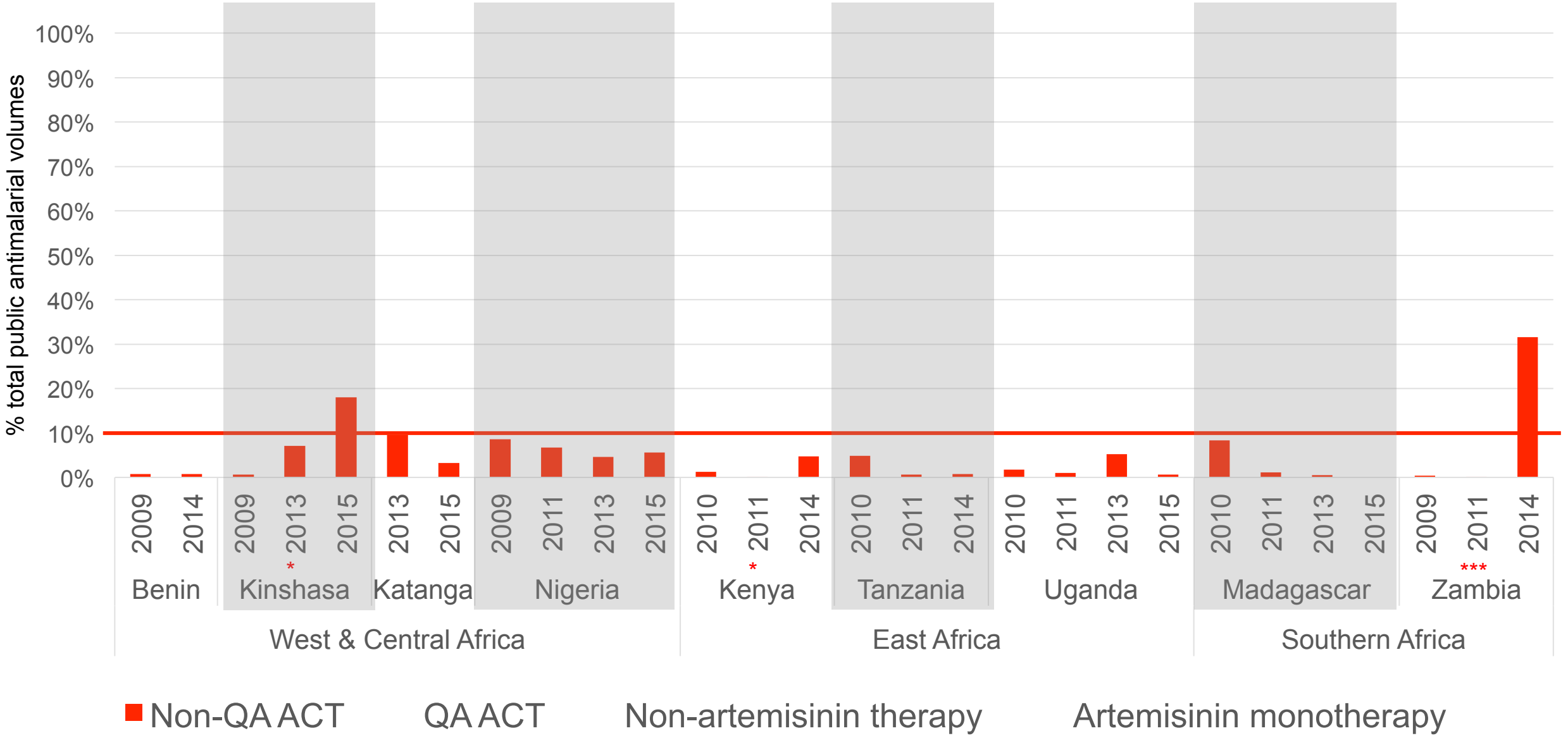


Market share for non-quality-assured ACT



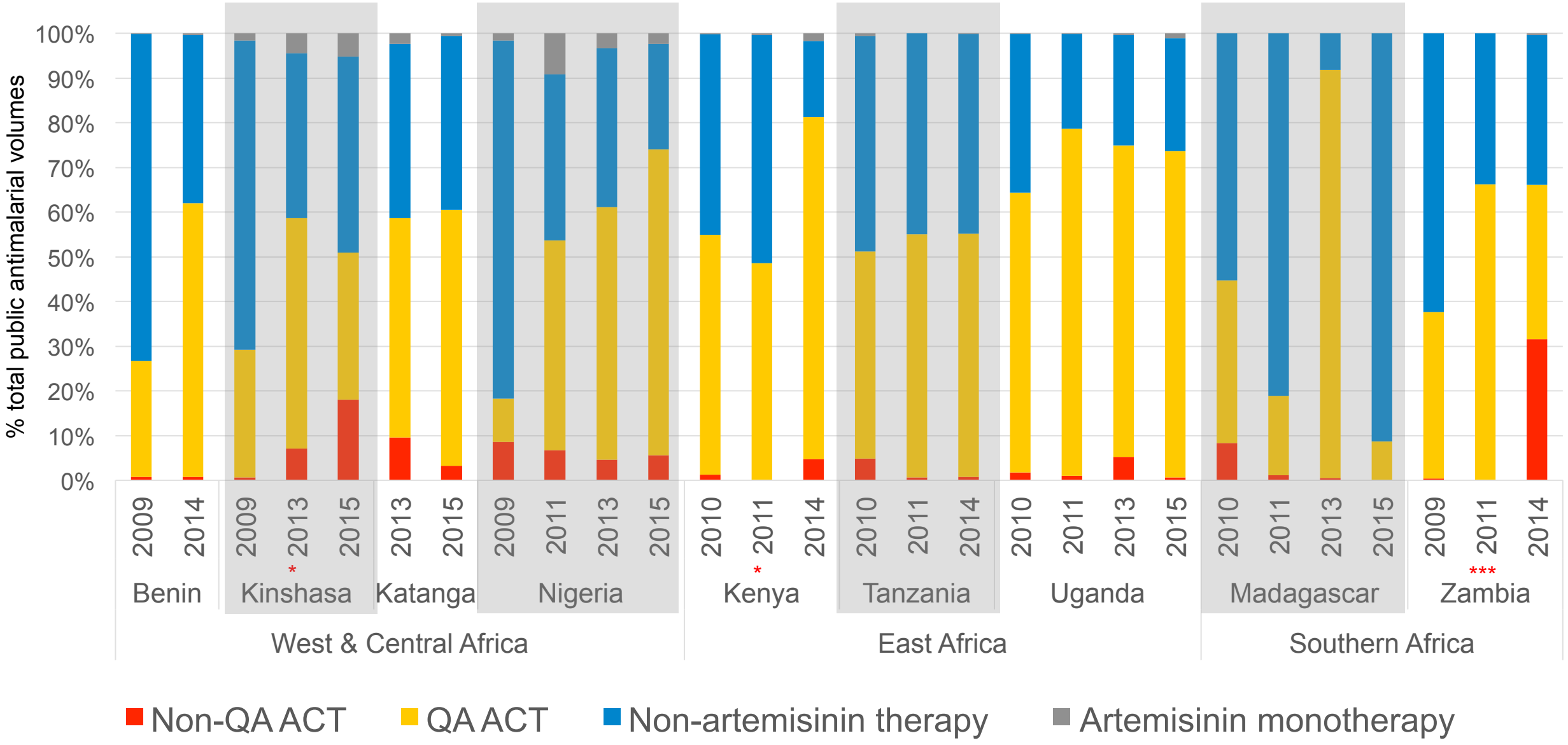
Among outlets with at least 1 antimalarial in stock

Market share in public sector



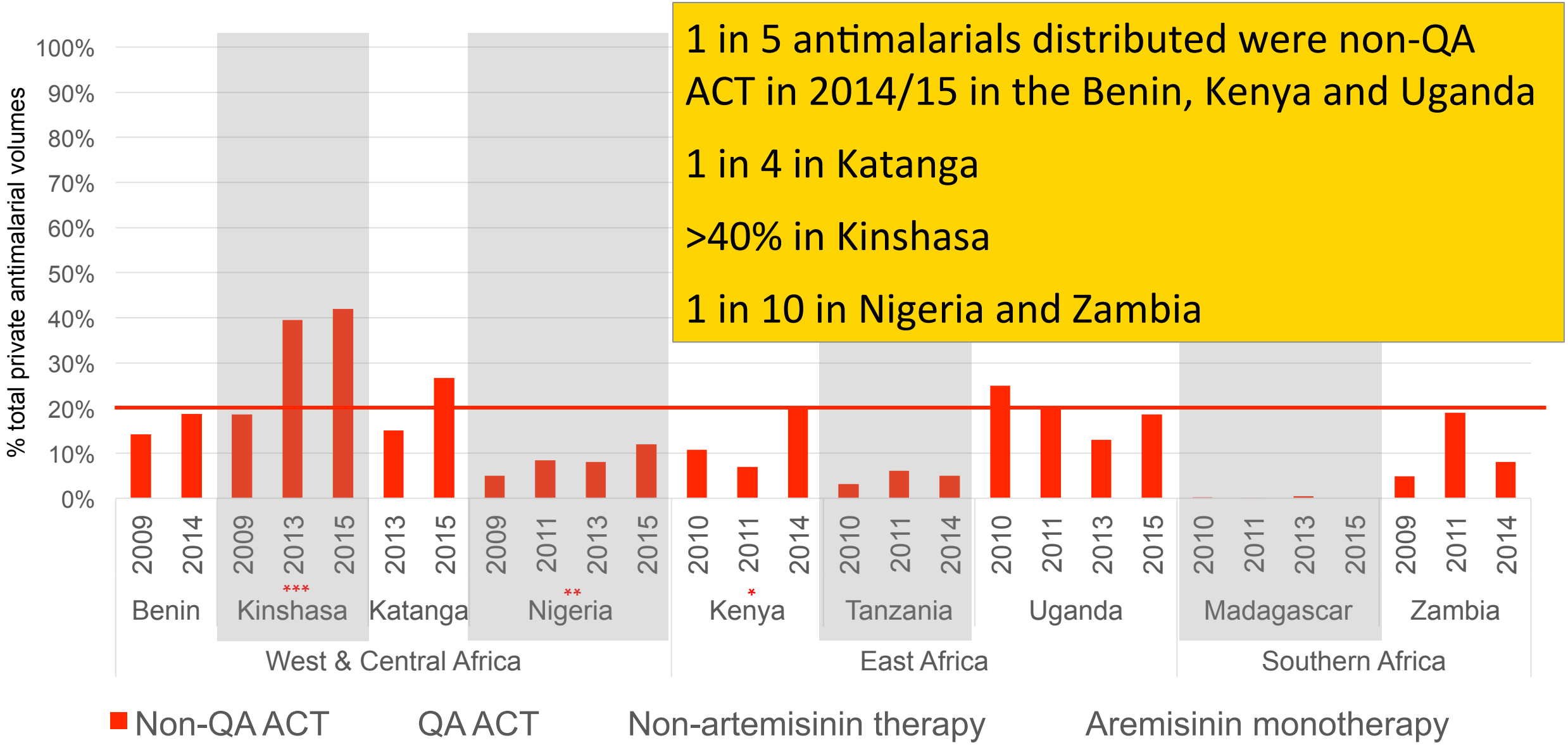
Among outlets with at least 1 antimalarial in stock

Market share in public sector



Among outlets with at least 1 antimalarial in stock

Market share in private sector



Non-artemisinins in the private sector

- **SP** common in all countries except Benin and Madagascar (availability >50%)
- **Chloroquine** common in Benin, Nigeria and Madagascar (availability in >60%)
- **Oral quinine** common in the DRC, Tanzania and Uganda (availability in >50%)







Where are non-QA ACTs distributed?

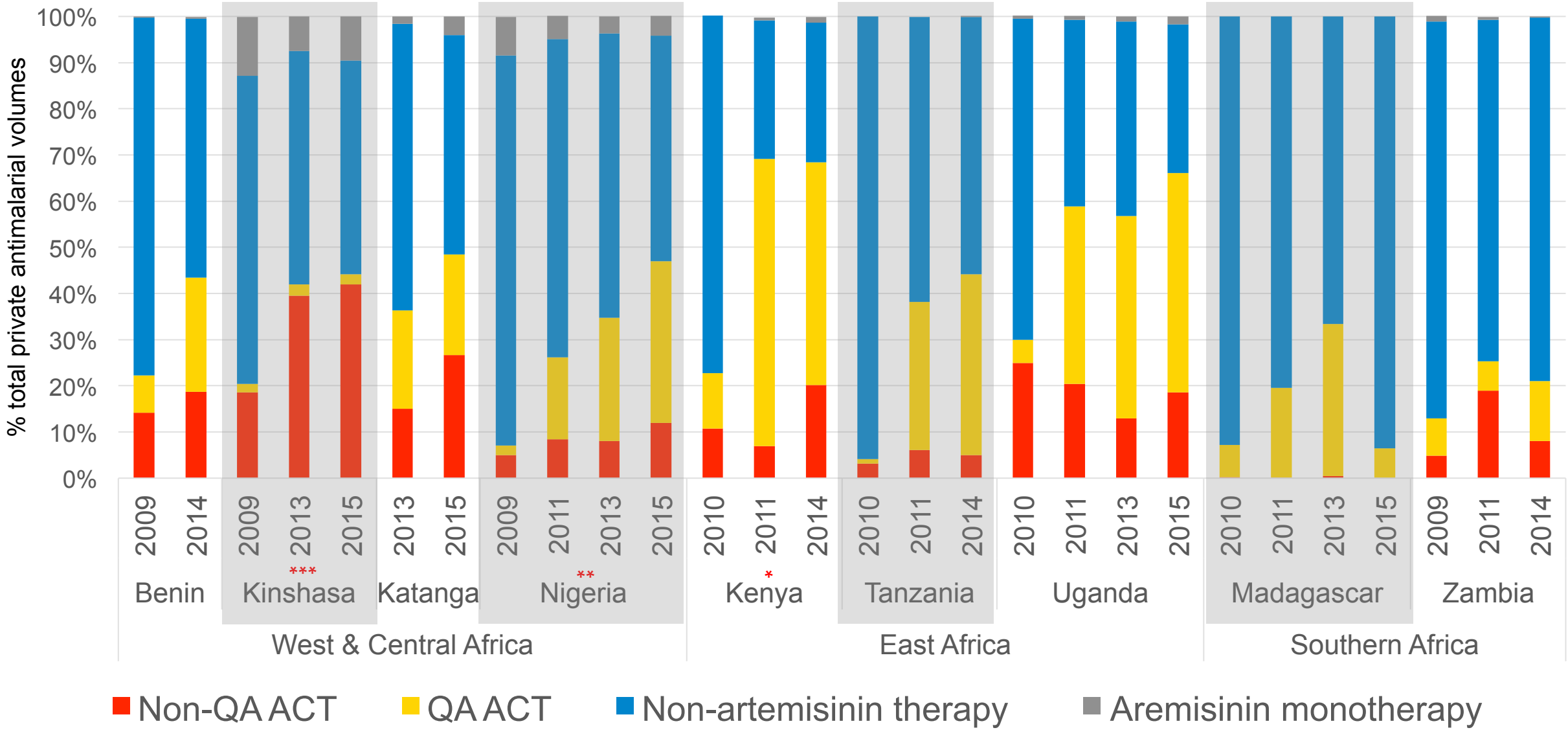




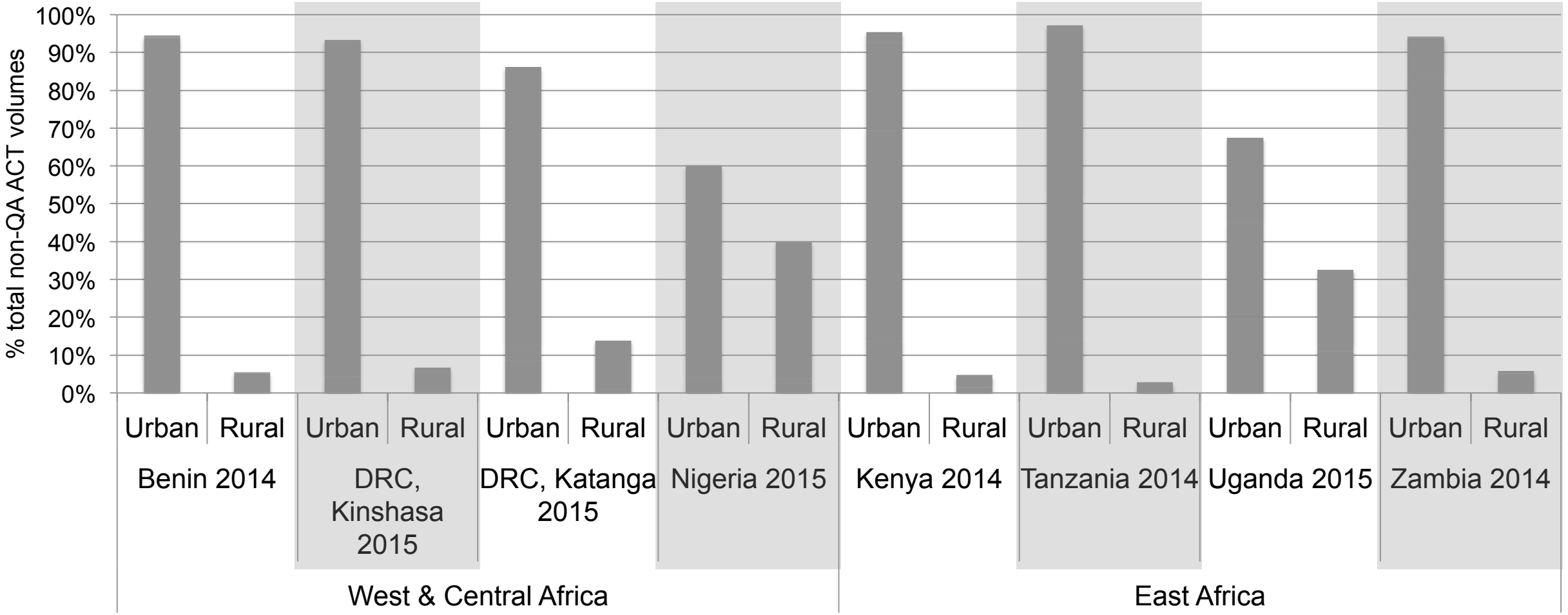
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Among outlets with at least 1 antimalarial in stock

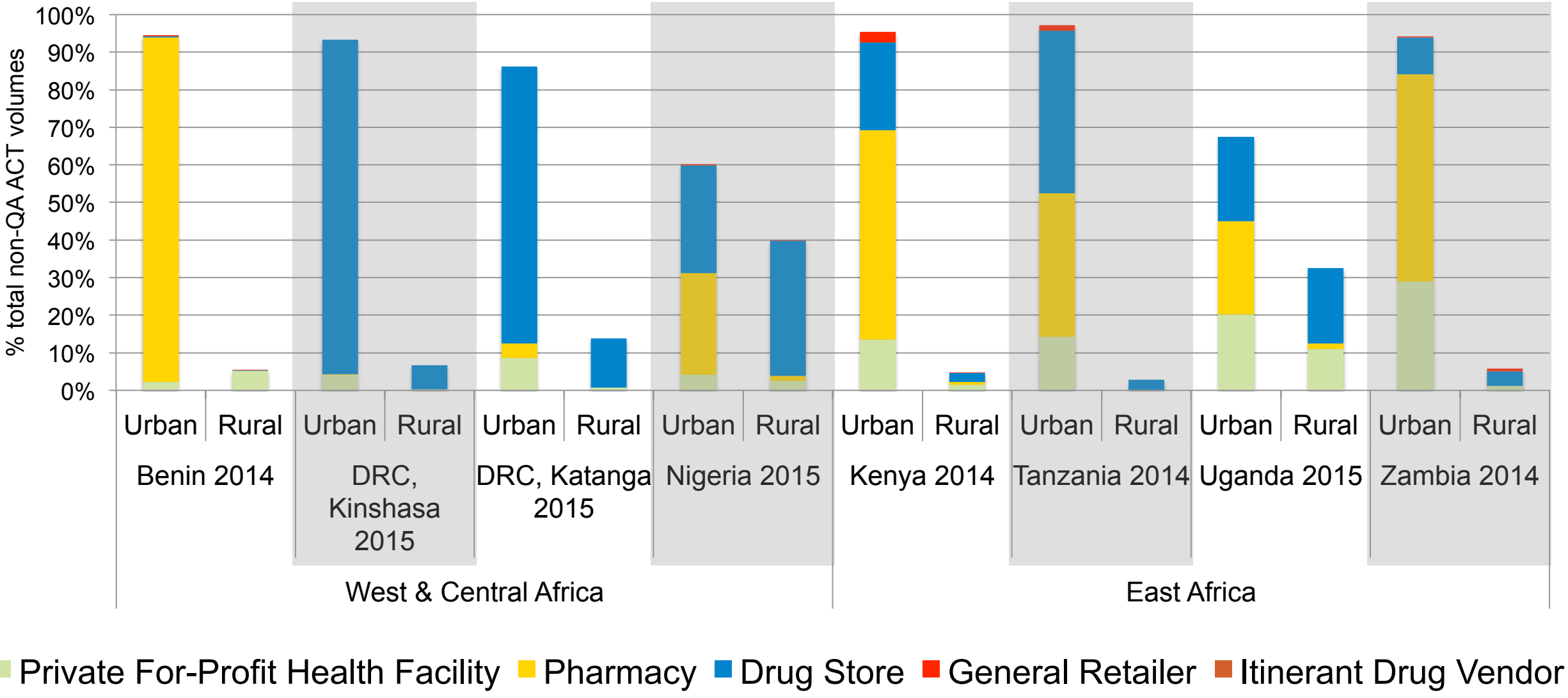
Market share in private sector



Market share for non-QA ACTs



Market share for non-QA ACTs



Non-QA ACT product characteristics

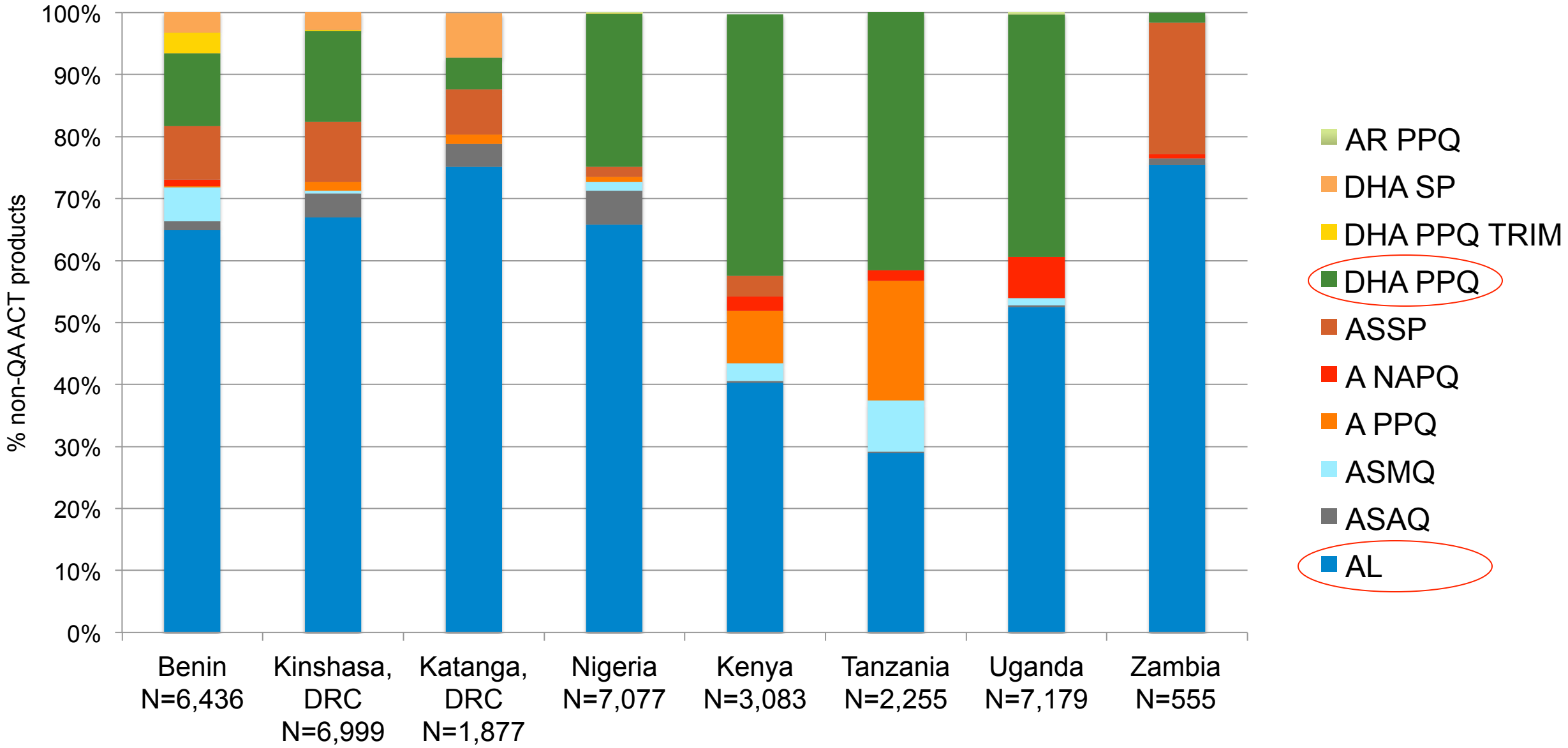




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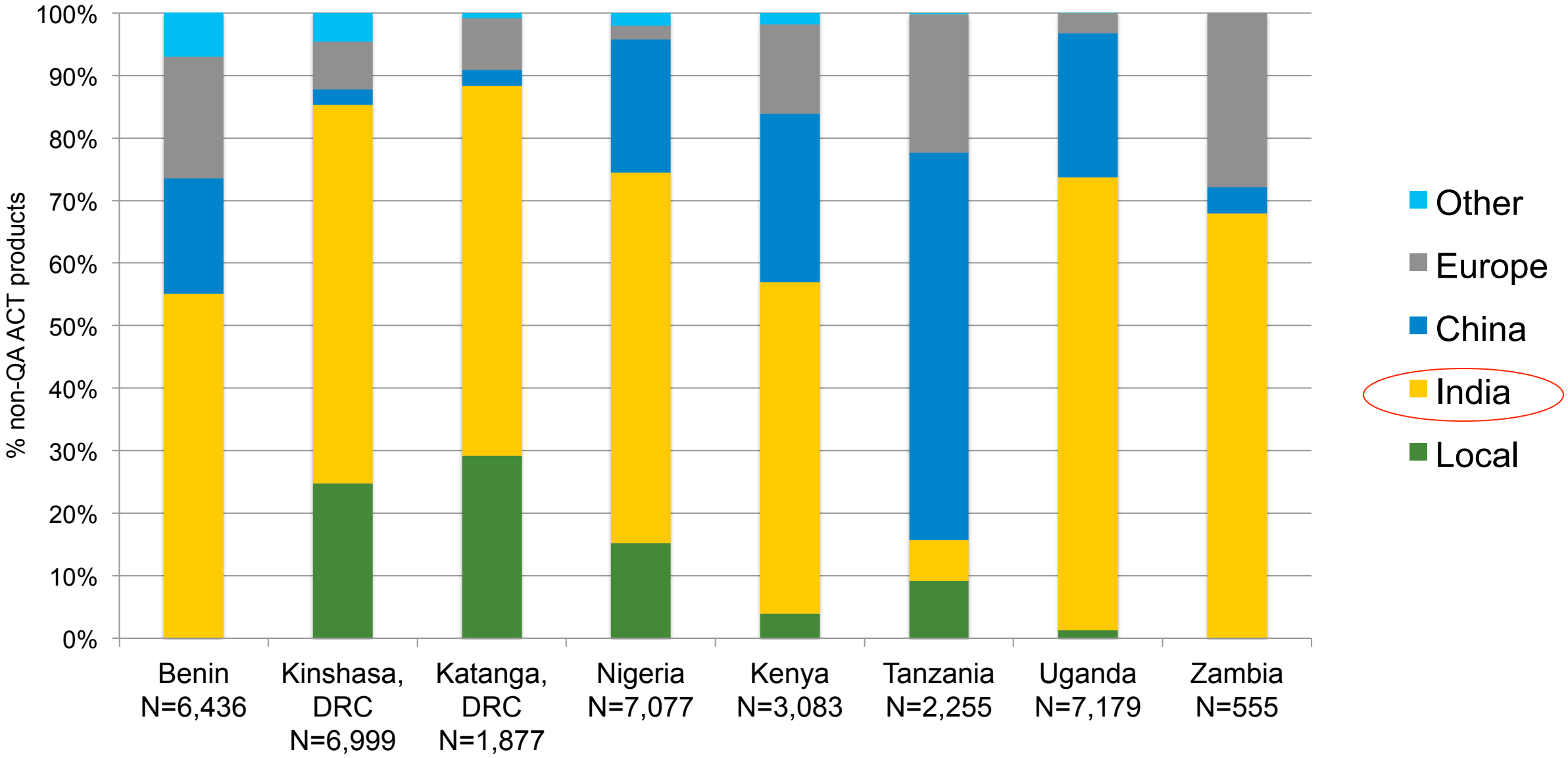
Among all audited non-QA ACT products in the private sector

Generic



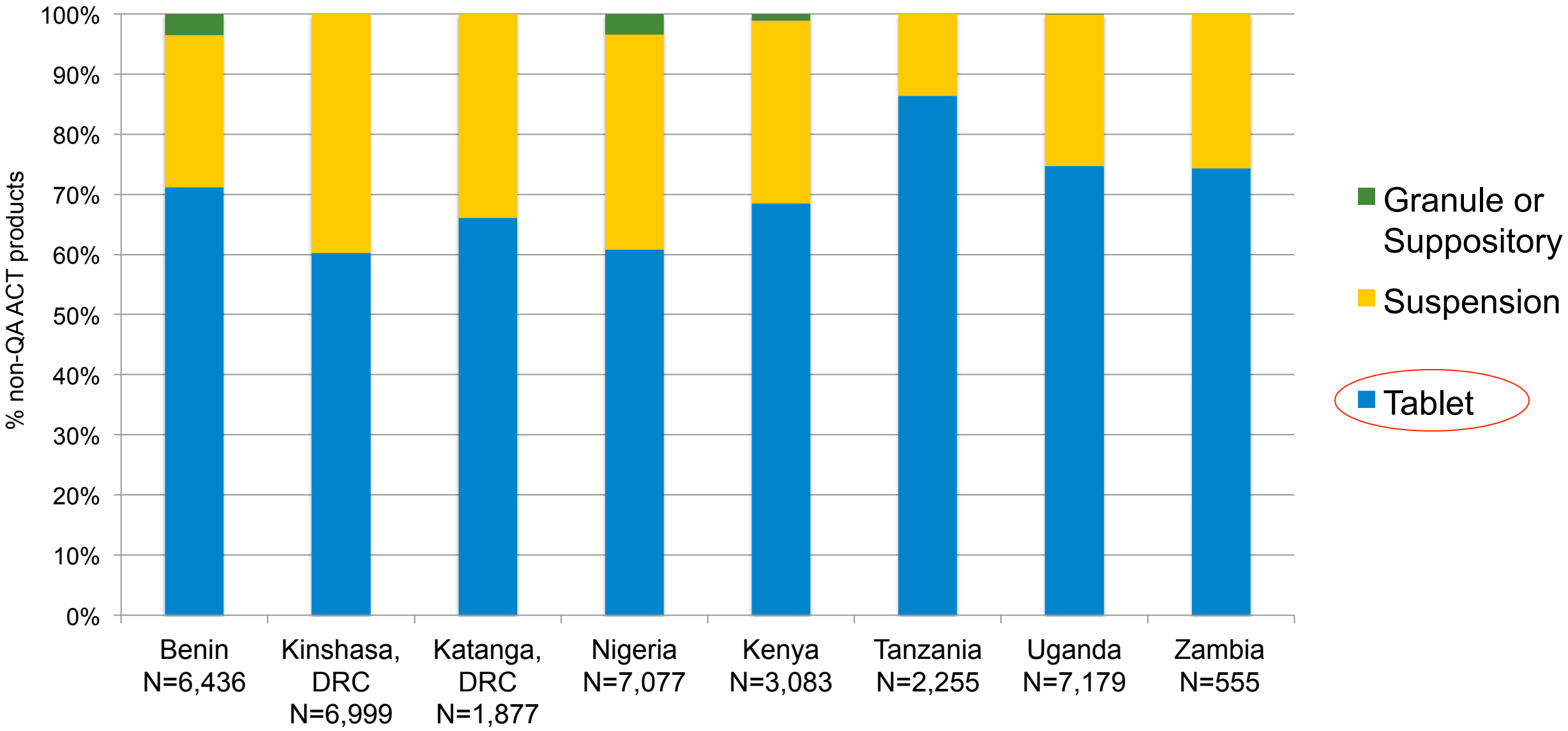
Among all audited non-QA ACT products in the private sector

Country of Manufacture



Among all audited non-QA ACT products in the private sector

Formulation



Non-QA ACT products from Nigeria 2015

Aktemef
Amalar Plus
Amatem
Ambifan
Amdin
Amnoquin
Anate
Andermal
Aquamal
Arcofan
Arenax plus
Artborah
Artcop
Artecxin
Artefan
Artelum
Artemef
Artemelum
Artemether-plus
Artemetrin
Arterakine
Artequick
Artexaten
Arthelad
Artequin
Artheget
Artemetin Beta Plus
Arterine
Artesmodia
Artheget-Ez
Arthemed
Arthemexin
Artrin
Asmether
Atmal
Avormal
Axin
BG Mal
Botamil
Camosunate
Camoquin plus
Cartef
Codisin Plus
Co-artesiane
Co-arinate
Co-dabamal
Co-fanart
Comether
Coatal
Colart
Crotan
Crystal AL
D-artepp
Dart
Diconart
Dipiphate
Dosunate
Droa-quine
Drutemal
Duo-cotecxin
Dyrax
Ediconart
Euromether
Exus Artemether
Falcidin
Fanmet
Famter
Farenax
Faverid
Ferife
Fynale
Fytama
Genaquin
Gimeter
Gloatem
Glosunate
Grotan
Grutha
Gvither Plus
Hanmal
Hatherley
Havax
Indomal
Kart-Lu
Kenmekaxin
Kinotem
Lactomak
Larot
La-Tesen
Loceet
Lokmal
Lomasyl
Lonart
Lufart
Lumaglobe
Lumal
Lumapil
Lumerax
Luter
Lynsunate
Malagard
Malarwaip Plus
Malanter
Malastop
Malaxit
Maltarka
Maxnart
MD artesunate plus
Mefameter
Meflax
Menfacil
Metherine
Mipcon AL
Nancimal
Nartel
Nimartem
Norinate
Ogamal
Orfexine
P-alaxin
Paleuxit
Palumal
Pemametre
Phalertem
Pipart
Pymal
Ravimal
RGI Art-luf
Robamal
Rolother
Romartef Plus
Ronymal
Salumether
Sarmata
Shal'artem
Sivometertrine
Sivoplus
Smt forte
Solartep
Sumether-Plus
Synriam
Tama-ACT
Tamether
Terocan
Telufan
Triact
Ultimar plus
Unother
Uplufa
Upxin
V-martem
Viskart
Voather
Waipa ACT
Winart
Yesmal
Zeramal
Zotin
Zymal


Dermazin
Liquid Paraffin
Emtrim
ARTESUNAT
Panda
Paracetamol Syrup
Colipan
Lumartem
ARTEQUICK
CAMOQUIN
200 mg

Summary

- Non-QA ACT is commonly available in the private sector in Nigeria, DRC, Kenya and Uganda.
- There are multiple generics, brands and manufacturers. AL tablets are most common. In many countries, most products come from India.
- Private sector non-QA ACT distribution is increasing in Nigeria, DRC and Kenya.
  - Most concerning in the DRC where more than 40% of private sector distribution was non-QA ACT
- Non-QA ACT is typically distributed by pharmacies and drug stores in urban areas

Conclusions

- Addressing availability and distribution of non-QA ACT requires private sector engagement with tailored strategies to the country context.
- Availability and use of non-QA ACT, particularly in high burden countries of DRC and Nigeria as well as Kenya and Uganda, presents risks to patient health, effective malaria control, and protection of ACT efficacy.
- Availability and distribution of non-artemisinins is typically more common than non-QA ACT and is also of concern to patient health and effective malaria control.



Thank you

ACTwatch

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