

# Access to Tranexamic Acid (TXA)

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Product Introduction: Insights from Market Research and Local Leadership - Parallel Session

## Access to tranexamic acid (TXA), introduction

- Developed early 1960's TXA is an antifibrinolytic agent that is indicated in multiple situations to prevent or treat bleeding (e.g., accident and trauma, surgery, dentistry etc.).
- TXA is an essential drug for reducing many forms of bleeding; it is inexpensive, not difficult to manufacture, comprising TXA API and water for injection, does not require cold chain storage and is relatively easy to administer by IV infusion.
- In 2017, following the publication of the WOMAN trial results in The Lancet, WHO recommended intravenous TXA administration for PPH treatment, in addition to oxytocin and other standard treatment options.
- While TXA has been in the market for many years for other indications, this was the first time its use became a strong recommendation for PPH treatment. Subsequently, TXA was included in the WHO Essential Medicines List and an expression of interest to manufacturers for WHO prequalification was issued.
- TXA not labelled for obstetric indications. Use for PPH treatment is off-label.

# TXA and Concept - completed activities

DOI: 10.1002/ijgo.14197

SUPPLEMENT ARTICLE



## Quality of oxytocin and tranexamic acid for the prevention and treatment of postpartum hemorrhage in Kenya, Nigeria, South Africa, and Tanzania

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AUTHOREA

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### The compatibility of oxytocin and tranexamic acid injection products when mixed for co-administration by infusion for the treatment of postpartum haemorrhage: an in vitro investigation

BASIC SCIENCE | LABOUR: MANAGEMENT | MATERNAL MORTALITY | OBSTETRIC HAEMORRHAGE

Peter Lambert, Alessandra Tomazzini, Philip Wright, Claire McEvoy, Ioannis Gallos, Anne Ammerdorffer , Lester Chinery, Arri Coomarasamy, Ahmet Gulmezoglu

DOI: 10.1002/ijgo.14269

SUPPLEMENT ARTICLE



## Challenges in updating national guidelines and essential medicines lists in Sub-Saharan African countries to include WHO-recommended postpartum hemorrhage medicines

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Abstract

#RHSUPPLIES2023

# Understanding TXA Quality, Interactions & Regulatory Pathways

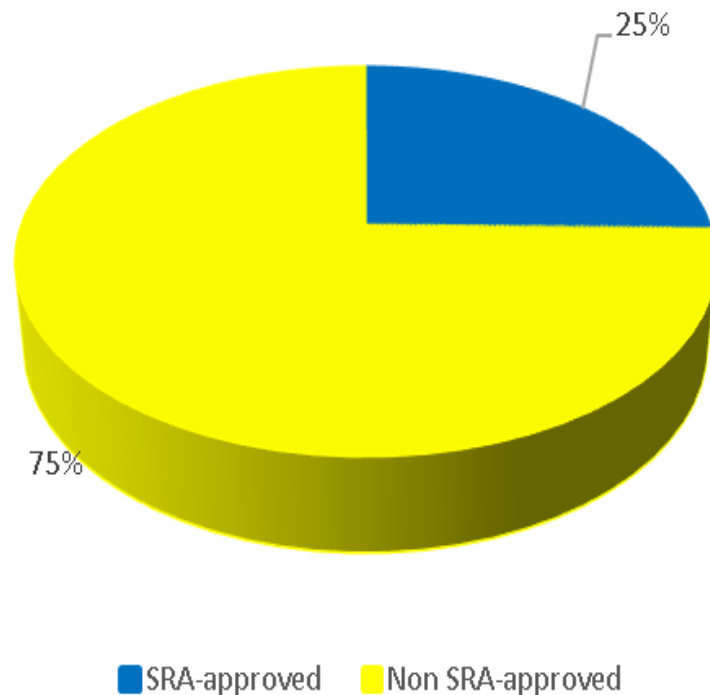
Funded by the Bill & Melinda Gates Foundation

## Objectives

- I. Assessing the compatibility of oxytocin-TXA & heat-stable carbetocin-TXA co-administration
  - Expanded confirmatory study of compatibility between TXA and uterotonics and root cause analysis from observed negative interactions
  
- II. Establishing the pathway for LMIC availability of quality assured TXA products for obstetric use
  - Global mapping of TXA manufacturing to identify shortlist of candidate companies for forward engagement
  - Identify current TXA registration status in 21 high-burden LMIC/mapping to MMR.
  - Detail TXA regulatory requirements in target countries
  - Develop forward strategies for TXA innovations
  
- III. Identify and define potential implications of the investment activities - strategic analysis of TXA health systems pathways to scale and market shaping intervention options.

# Global mapping of TXA manufacturing

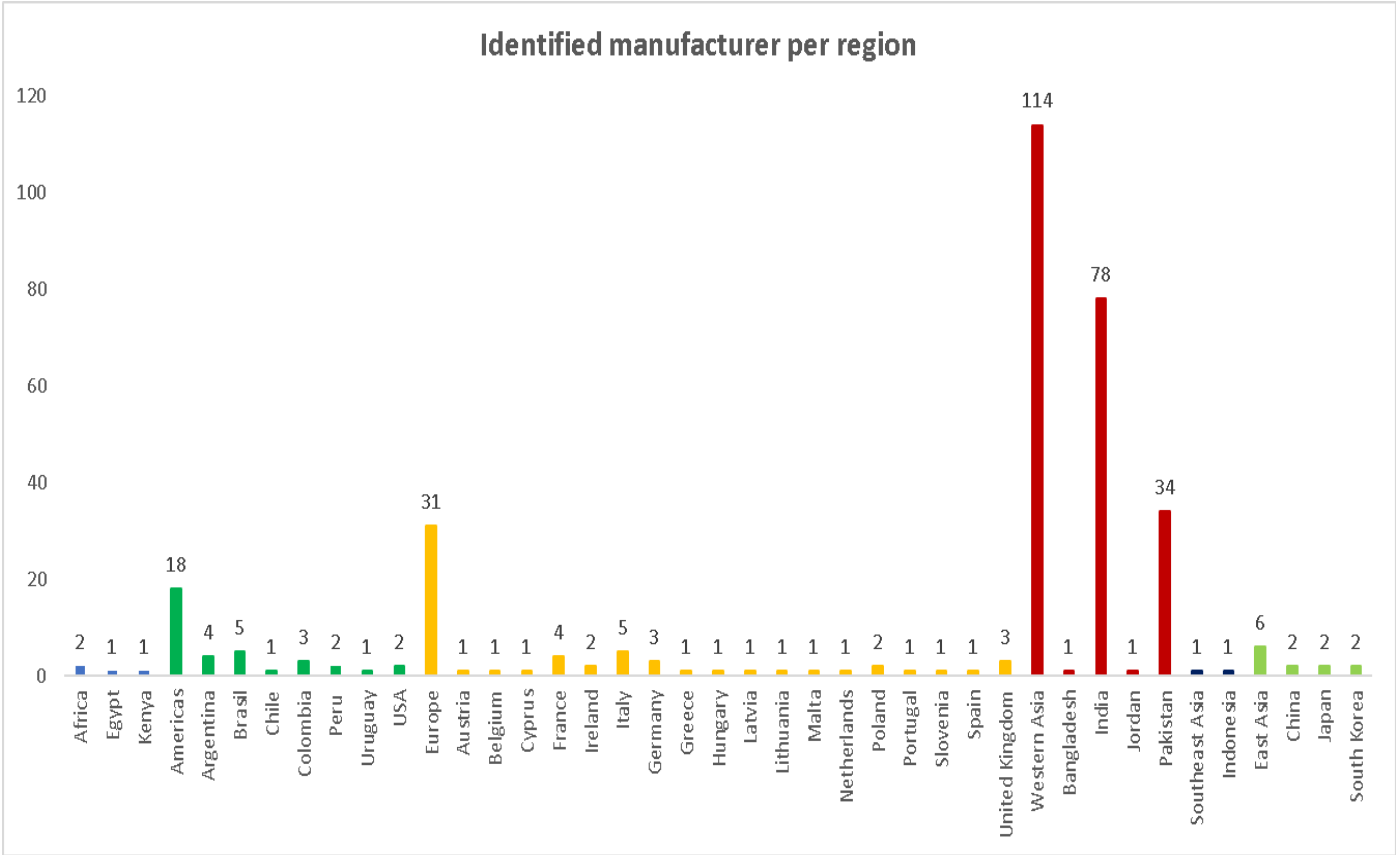
Classification of identified manufacturers



- Outcomes
- 172 distinct TXA manufacturers,
- Producing and marketing
- 226 TXA products (some manufacturers producing multiple brands)
- Further 60 identifiable injectable TXA products\*
- Total of 286 identifiable products in global markets
- Majority - 75% not QA!

\*Where the marketing authorization holder and country registration/availability is known, but where the specific manufacturing company/site could not be identified and/or verified

# Global mapping of TXA manufacturing



- Manufacturing across 35 different countries
- 114 located in Asia, overwhelmingly India (78) and Pakistan (34)
- Europe 31
- Americas 18
- Only 2 manufacturers were identified in Africa

# Availability vs. Need in 21 SSA countries

Country	MMR Category	Registered Injectable TXA Products
Chad	Extremely High (>1000)	1
Nigeria	Extremely High (>1000)	2
Central African Republic	Very High (500-999)	0
Guinea	Very High (500-999)	0
Kenya	Very High (500-999)	18
Benin	Very High (500-999)	0
Burundi	High (300-499)	0
Côte d'Ivoire	High (300-499)	4
Mauritania	High (300-499)	1
Sierra Leone	High (300-499)	0
Niger	High (300-499)	0
Mali	High (300-499)	1



+ 95% of registered products not quality assured

# Market Characterization

## Significant global manufacturing

- 172 companies across 35
- Countries - + 286 products
- 75% NOT quality-assured

## Identified quality concerns

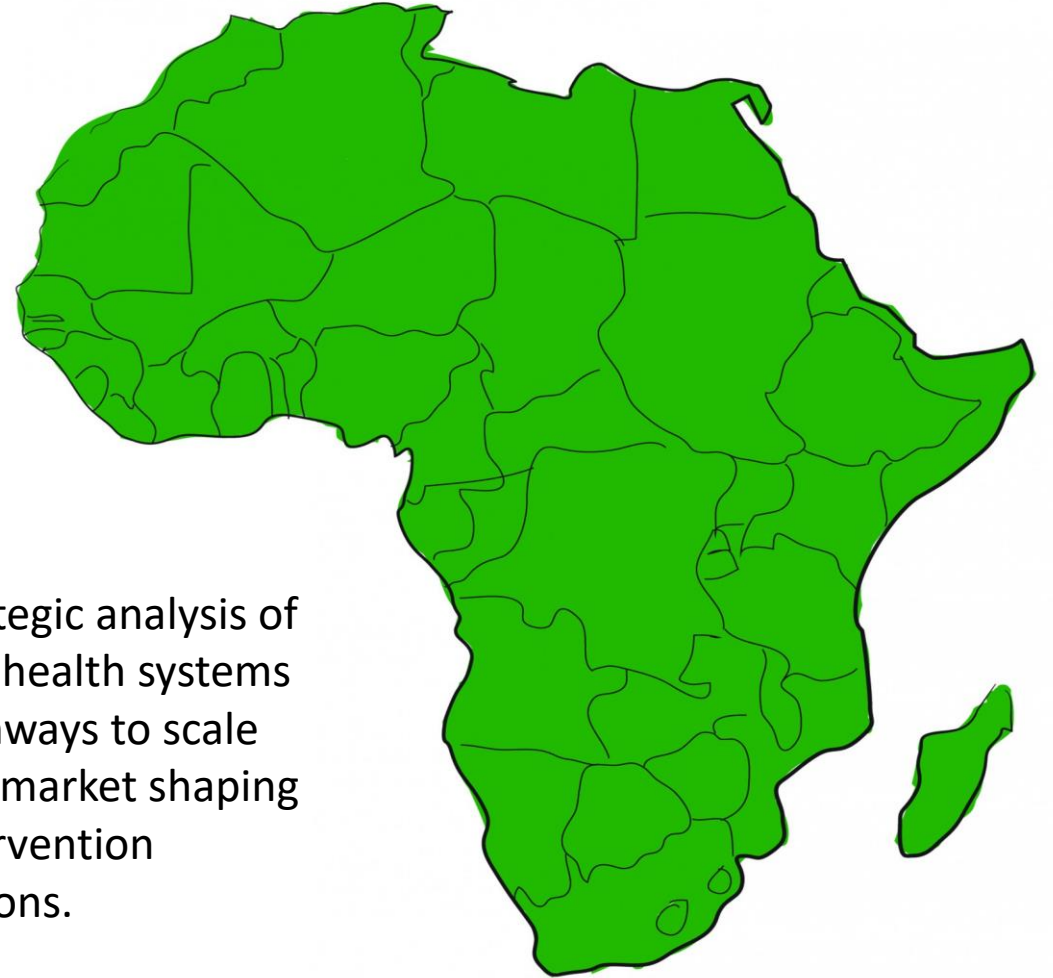
- CF past studies
- Post marketing
- Compatibility with oxytocin

## Limited availability where most needed

- Registration insufficient in
- 81% target countries
- No WHO-PQ TXA products

## Evidence of uptake and use of oral TXA in response to recommendations

- Nigeria



Strategic analysis of TXA health systems pathways to scale and market shaping intervention options.



# Towards a healthy market

Step 1 - developing the business case for TXA manufacturers.

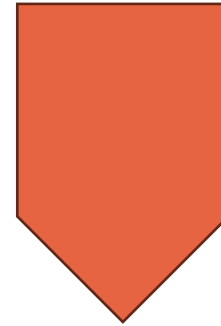
Step 2 - expand engagement with candidate manufacturers who currently have products approved by an SRA - to facilitate and support fast-track registration in high-burden SSA.

Step 3 - provision of technical manufacturing support to selected candidates to achieve WHO compliant GMP, followed by regulatory support for submission to WHO-PQP until prequalified - support fast-track registration in SSA.

Step 4 - continued collaboration with TXA innovators, providing technical advice on forward clinical study requirements, batch manufacturing and scale-up, engagement with regulators.

## TXA Candidate selection - steps 2 and 3

- Long list of 172 companies
- Reduced to +/- 30 based upon criteria
- Expression of interest + technical questionnaire

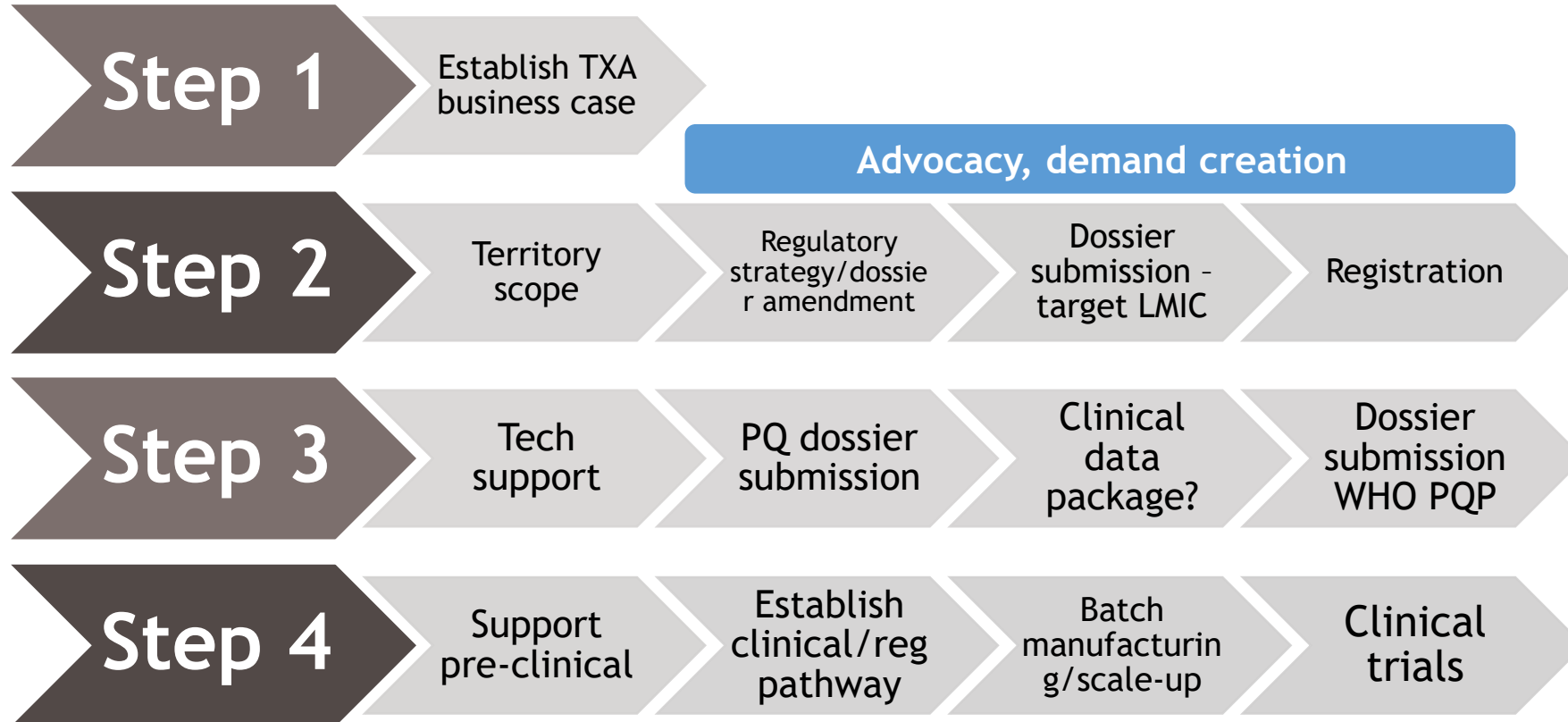


6 companies willing to participate

- 4 with existing SRA TXA registrations
- 1 manufacturing TXA with other products prequalified by WHO
- 1 African manufacturer

# TXA Market Shaping

## STRATEGY OVERVIEW



For further information on our TXA initiatives, contact  
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