

Deutscher Bundestag

Ausschuss für Gesundheit

Ausschussdrucksache

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13.05.2024



EPN-DIFAEM MINILAB NETWORK

**EPN Initiative in detecting and fighting SF
medicines in Africa**

Dem Ausschuss ist das vorliegende Dokument
in nicht barrierefreier Form zugeleitet worden.

Just and Compassionate Quality Pharmaceutical Services for all

Introduction of the EPN Network

- **We support churches and church health systems** provide just and compassionate quality pharmaceutical services.
- A Network of 140 Members (CHA, DSO, CHI, HSS and Individuals)
- Expansion: 38 Countries, 27 in Africa

Coverage of church health services averages 40%.

More than 300 million people rely on health care provided by our Network

EPN African countries:

Benin, Burkina Faso, Burundi, Cameroon, CAR, Chad, DRC, Egypt, Ethiopia, Ghana, Guinea, Kenya, Lesotho, Liberia, Malawi, Namibia, Niger, Nigeria, Rwanda, Sierra Leone, SA, South Sudan, Tanzania, Togo, Uganda, Zambia & Zimbabwe



Ecumenical Pharmaceutical Network (EPN) is

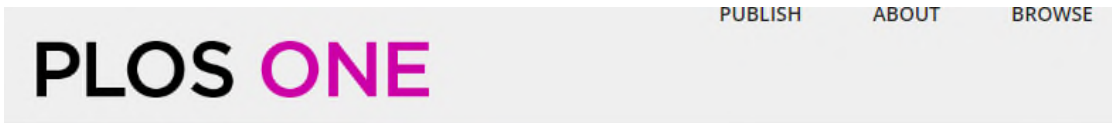
- a Christian,
- not for profit,
- independent organization
- committed to the provision of quality pharmaceutical services
- as a means to achieving global goals and targets on health and access to medicines

Our Network consists of:

- 32 Christian Health Associations(CHAs)
- 25 Health Systems Strengthening (HSS)
- 20 Drug Supply Organisations (DSO)
- 17 Church Health Institutions (CHI)
- 46 Individual Members

Threat of Substandard and Falsified Product in Africa

- According to the 2023 report '**Trafficking in Medical Products in the Sahel**', various studies indicate that the share of medical products that are SF products are between **19-50%**



OPEN ACCESS PEER-REVIEWED

RESEARCH ARTICLE

Substandard and falsified antimicrobials in selected east African countries: A systematic review

Addisu Afrassa Tegegne, Anbessa Bekele Feissa, Gemmechu Hasen Godena, Yesuneh Tefera, Hassen Kebede Hassen, Yildiz Ozalp, Sultan Suleman

Published: January 26, 2024 • <https://doi.org/10.1371/journal.pone.0295956>

This systematic review in PubMed of publications from 2017 to February 2023 reveals for 4 East Africa countries (Ethiopia, Kenya, Rwanda and Tanzania):

22.6% (151/669) of all samples of antimicrobials tested failed at least one quality test (Essay of the API, visual inspection of the package).

<https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0295956>

Up To 500,000 Killed by Fake Medicines in Sub-Saharan Africa

Figures linked to falsified and substandard medicines in Sub-Saharan Africa



Source: UNODC Trafficking in Medical Products in the Sahel

Sahel Countries: Burkina Faso, Chad, Mali, Mauritania and the Niger.

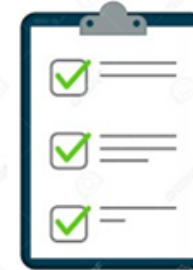
statista

EPN promotes medicine's quality by adopting the GPHF MINILAB

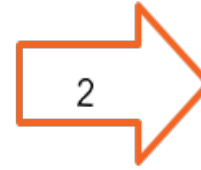
- GPHF Minilab is a cost effective system
- We ensure that medicines entering the CHIs meet the quality standards they claimed to meet.
- We facilitate knowledge-sharing among members using the GPHF Minilab across the African continent and in India.
- Implemented since 2010 with **DIFAEM (German Institute. for Medical Mission)** a member institution of the EPN network
- **Outcome: increased quality awareness** within the faith-based health sectors, and **collaboration** with local authorities.



3 steps of analysis



Visual inspection of product, package and label



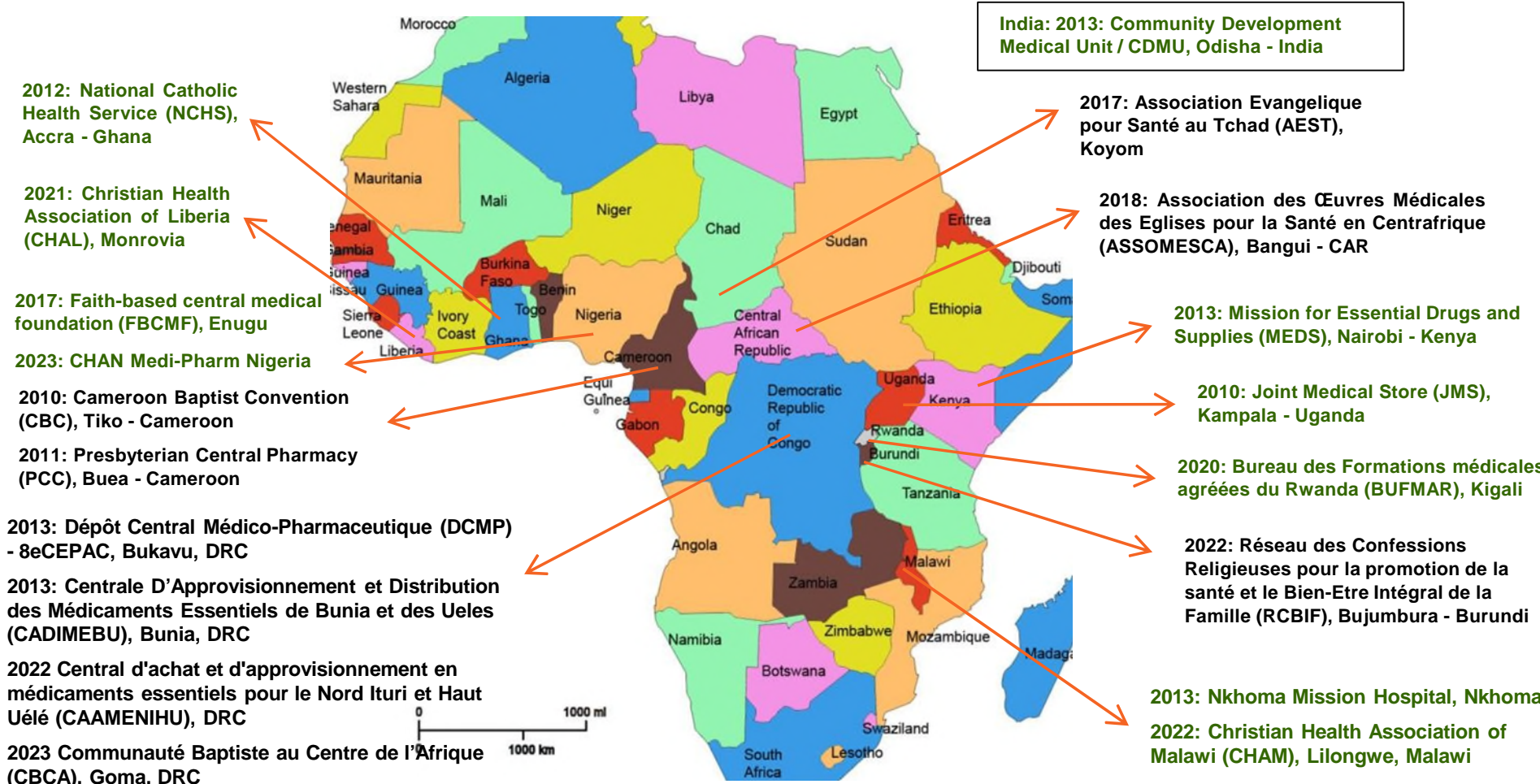
Simplified disintegration testing



TLC (thin-layer chromatographic) analysis

Members of the EPN Minilab Network

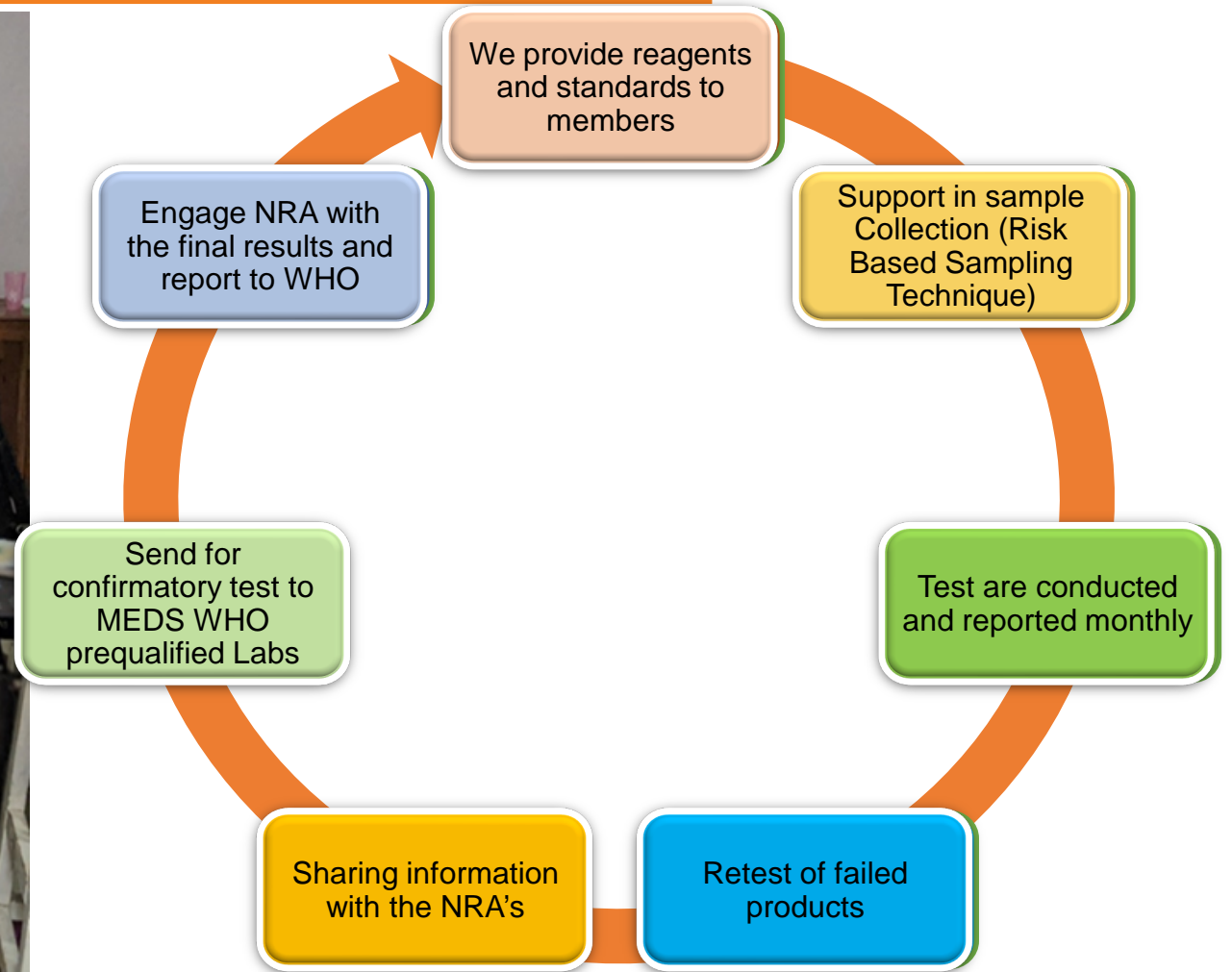
To date: 19 partners in 13 countries



Francophone Countries (5)	Anglophone Countries (5)
Cameroon, Burundi, DRC, CAR, Chad	Ghana, Liberia, Nigeria, Uganda, Rwanda, Malawi

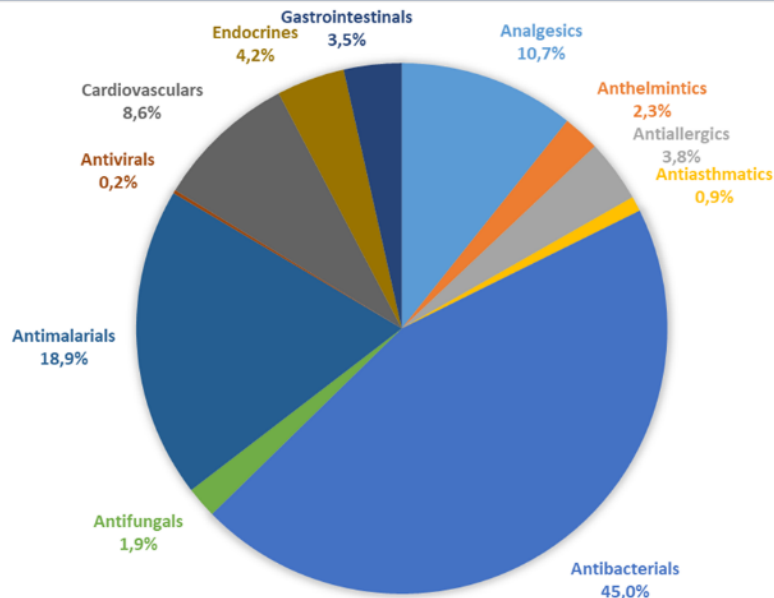


EPN-DIFAEM Minilab Approach



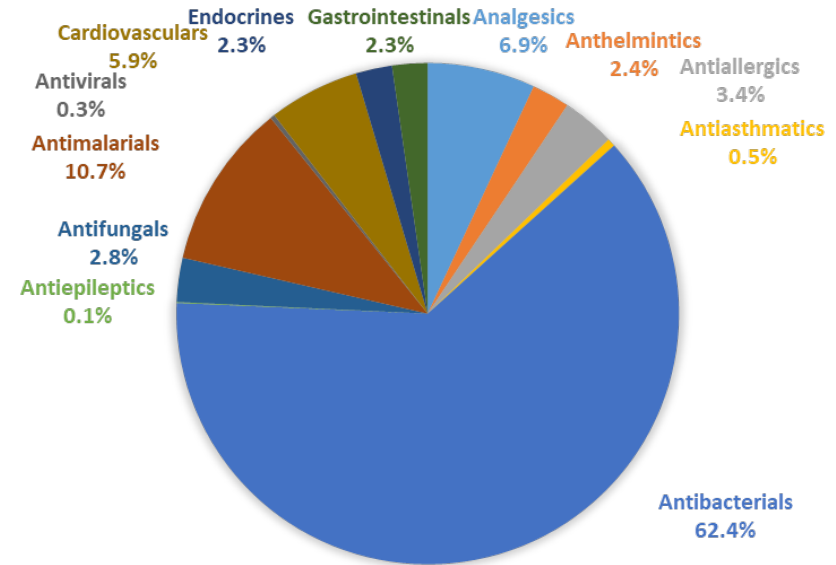
Network Testing Results 2022 - 2023

Results by Therapeutic Category 2022



Partner
AEST Chad
ASSOMESCA CAR
CADIMEBU DRC
CBC Cameroon
CDMU India
CHAL Liberia
DCMP DRC
FBCMF Nigeria
JMS Uganda
MEDS Kenya
NCHS Ghana
NKHOMA Malawi
PCC Cameroon

Results by Therapeutic Category 2023



partner
AEST
ASSOMESCA
BUFMAR
CAAMENIHU
CADIMEBU
CBC
BCA
CHAL
CHAM
CHAN
DCMP
FBCMF
JMS
MEDS
NKHOMA
PCC
RCBIF

2022	Tests conducted	OK	Falsified	Substandard	Further analysis
total	1420	1385	15	18	2

Falsified Cases DRC: 1x Erythromycine, 1x Acetylsalicylic acid, 1xCefixime, 4x Quinine, 1xArthemether/Lumefantrine, 1x Cotrimoxazol

Falsified Cases Nigeria: 6x Cotimoxazol

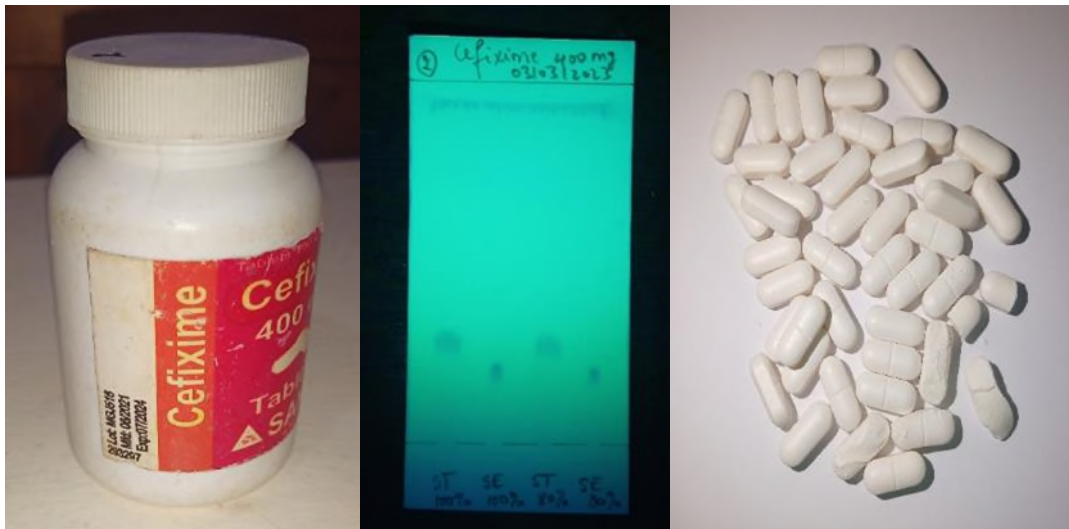
Test result	total	ok	ok in percent	non compliant	non compliant in percent
faith based health facility	347	344	99,1%	3	0,9%
public health facility	108	107	99,1%	1	0,9%
own stock	387	383	99,0%	4	1,0%
licensed private vendor	626	600	95,8%	26	4,2%
unlicensed private vendor	287	264	92,0%	23	8,0%
other	5	5	100,0%	0	0%
total	1760	1703	96,8%	57	3,2%

Recent case from the EPN Minilab Network 2023



- Cefixime 400 mg
- Stated manufacturer: MERCK & CO.EMC
- Batch: not legible
- Mfg. Date: 01/2021
- Exp. Date: 02/2025
- Detected in DRC in February 2023
- HPLC analysis, (MEDS, Nairobi): no API
- Reported to WHO by Difaem

Cefixime 400 mg tablets Found by DCMP, DRC



- Cefixime 400 mg
- Stated manufacturer: Apotex Inc
- Batch: MGJ516
- Mfg. Date: 06/2021
- Exp. Date: 07/2024
- Detected in DRC in February 2023
- HPLC analysis, (MEDS, Nairobi): no API
- Reported to WHO by Difaem



Vitamin A

The products contained 64,4% and 68,6% of Vitamin A respectively.

Ref. RPQ/REG/ISF/Alert N°1.2021

05 March 2021

Medical Product Alert N°1/2021

Falsified VITAMIN A (retinol) identified in WHO region of Africa

Alert Summary

This WHO Medical Product Alert refers to two falsified VITAMIN A (retinol) capsules identified in Chad and reported to WHO in November 2020. Laboratory analysis of recovered samples identified that both products are severely degraded and underdosed – containing less than the stated active ingredient. Both falsified products also carry now defunct logos – the outdated WHO Essential Drugs Programme logo and the outdated Micronutrient Initiative logo. Both falsified products were supplied at patient level and may still be in circulation in the region.

Table 1: Products subject of WHO Medical Product Alert N°1/2021

Product Name	VITAMIN A (RETINOL)	VITAMIN A (RETINOL)
Stated manufacturer	Accucaps Industries Limited	Banner Pharmacaps (Canada) Ltd
Stated active ingredient	Vitamin A (USP) 200,000 I.U. Vitamin E (USP) 40 I.U.	Vitamin A (USP) 200,000 I.U. Vitamin E (USP) 40 I.U.
Batch number	UI4004	39090439
Mfg. date	01/2019	01/2019
Exp date	09/2022	09/2022
Packaging language	English & French	English & French
Identified in	Chad	Chad





Wednesday, 19 July 2023

Medical Product Alert N°5/2023: Substandard (contaminated) syrup medicines

7 out of 34 WHO Medical Product Alerts since 2019 – 2022 are based on reports from our Minilab Network

Total Number of Network testing results 2015 – 2023: **10,580**

This WHO Medical Product Alert refers to a batch of substandard (contaminated) NATURCOLD Syrup identified in Cameroon and first reported to WHO on 13 March 2023. All reasonable precautions have been taken by WHO to verify the information contained in this alert and this may be updated as more information becomes available.

The stated active ingredients of NATURCOLD syrup are listed as paracetamol, phenylephrine hydrochloride & chlorpheniramine maleate. The combination of these three ingredients are used to relieve symptoms associated with the common cold, flu, and allergic rhinitis.

Samples of the NATURCOLD syrup from Cameroon were made available to WHO on 27 June 2023 and analysed in a WHO contracted and prequalified laboratory. The analysis found that the product contained unacceptable amounts of diethylene glycol as contaminants. Diethylene glycol was detected in samples of NATURCOLD as much as 28.6%. The acceptable limit for Diethylene Glycol is no more than 0.10%.

NATURCOLD SYRUP (Paracetamol, Phenylephrine, Chlorpheniramin)

- Stated manufacturer: FRAKEN INTERNATIONAL LONDON, ENGLAND
- Batch: E22053
- Mfg. Date: 03/2022
- Exp. Date: 02/2025



The main drivers behind the production and distribution of falsified medicines

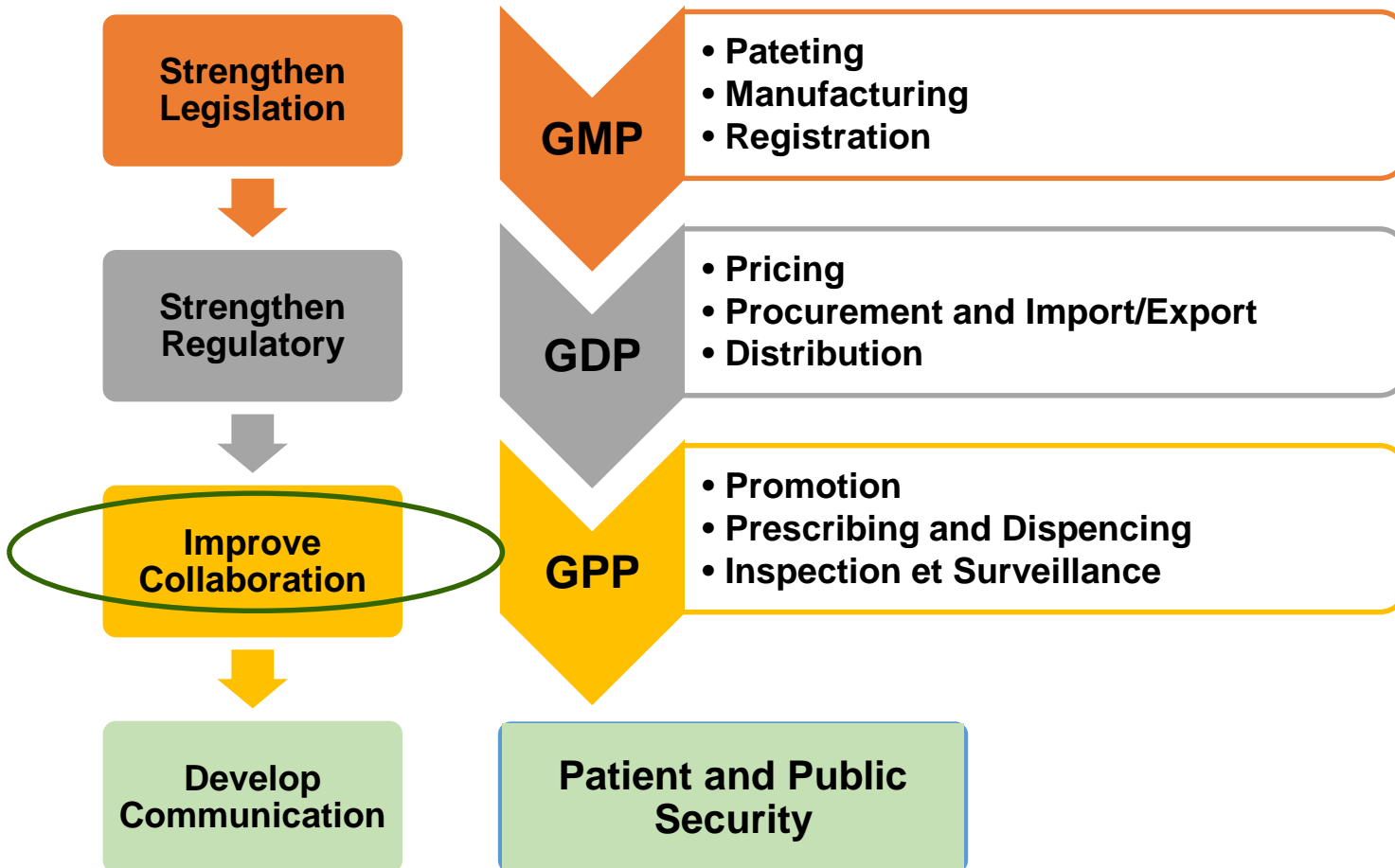
- Relying on imports of medical products
- **Local pharmaceutical** industries in the earlier stages of development.
- **Limited access** : priority on **price** over **quality**
- Poor traceability of medical products – and **post-marketing surveillance** limits
- Weak legislation



From EPN experience:

- ❑ It takes a long time to have a confirmatory test (From WHO Pre-qualified Lab) before WHO Alert
- ❑ It takes a long time for the National Regulatory Authority (NRA) to react and prosecute.
- ❑ Distribution of the EPN GPHF Minilab network in Africa – more countries, great visibility

There is need to increase collaborations in Fighting SF Medicine



Until we successfully collaborate with actors accross sectors

- WHO, Africa CDC, ...
- National Medicine Regulatory Authorities, (National)
- Medicine Control Laboratories
- **Manufacturers through federations and associations**
- **Distributors**, Central Medical Stores
- Civil Society, including Faith-Based Drug Supply Organizations
- Academia/Universities and related associations/initiatives
- Health care providers
- Media

Who is involved - further actors



Funding



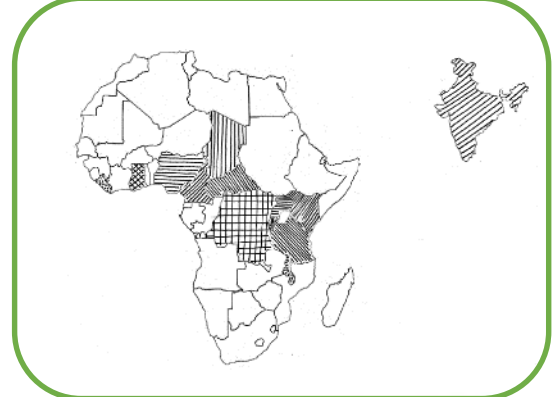

DIFAEM
German Institute
for Medical Mission
Training and Coordination

Supporting structures

Scientific support

Reference Laboratory
Access to WHO-
prequalified
laboratory

Continuous supply of
chemicals, consumables
and reference standards



Your partner for
health projects

Reporting structures



EPN 

40 years of strengthening pharmaceutical services in church health systems

Training, Coordination and
Complementary Projects

Fruitful partnerships in the Minilab Network settings - the Cameroon example (2)

Discovery of suspicious product by PCC



Minilab analysis by PCC



Confirmatory analysis at Tuebingen University (Germany)



National Alert by NMRA



Apr 2019

- ⇒ Quick and efficient process due to previously established collaborations.
- ⇒ The product contained Glibenclamide, an antidiabetic!

What the German Government can do?

- ❑ Support initiatives that strengthen regulation, this remains the ultimate way to increase patients safety
- ❑ Support local production in Africa, it is vital that patents, knowhow and technology have to be shared
- ❑ Support a holistic approach including health system strengthening is important – from the last mile.



Thank you!

