

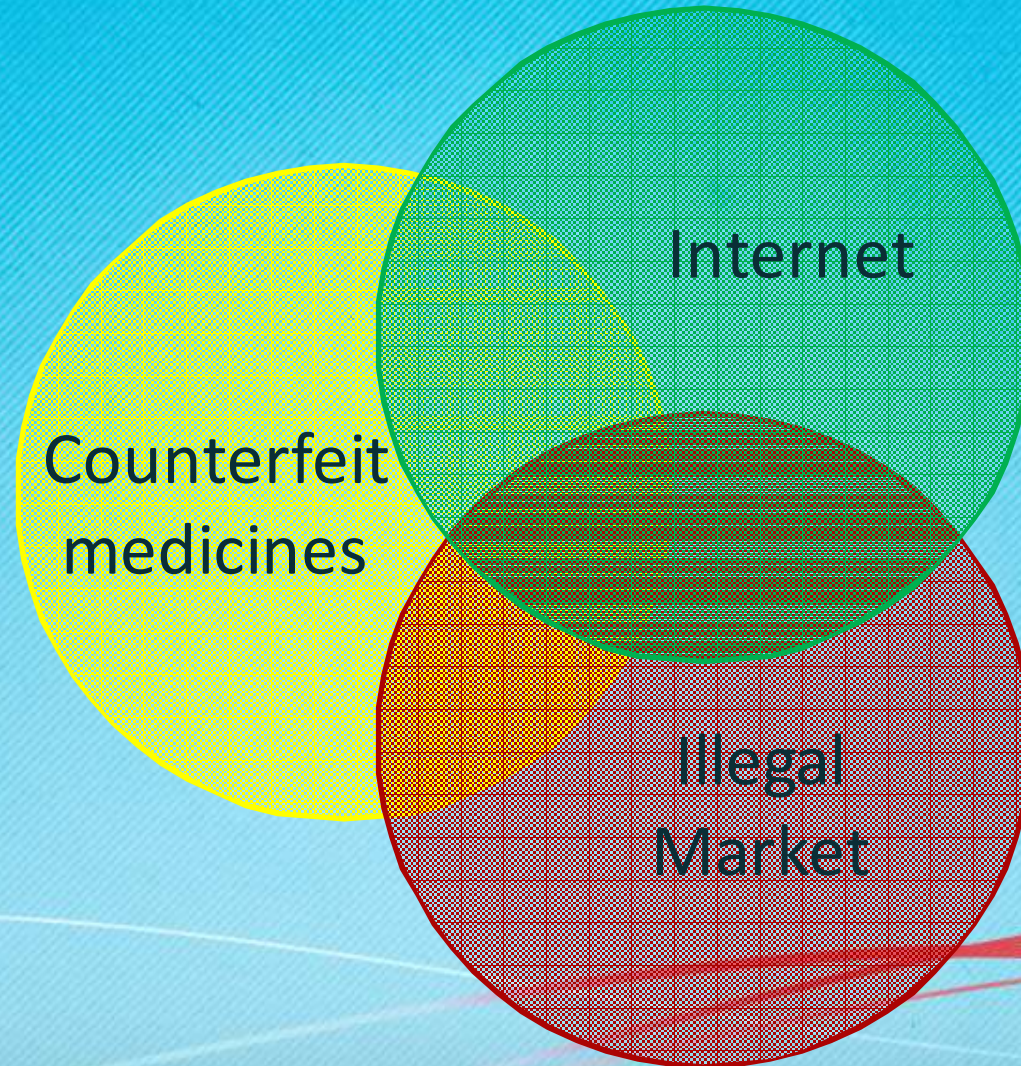


Country specific case studies – Best practices to combat counterfeit medicines and to protect public health

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FIP Project Coordinator



Patient safety and pharmaceutical products

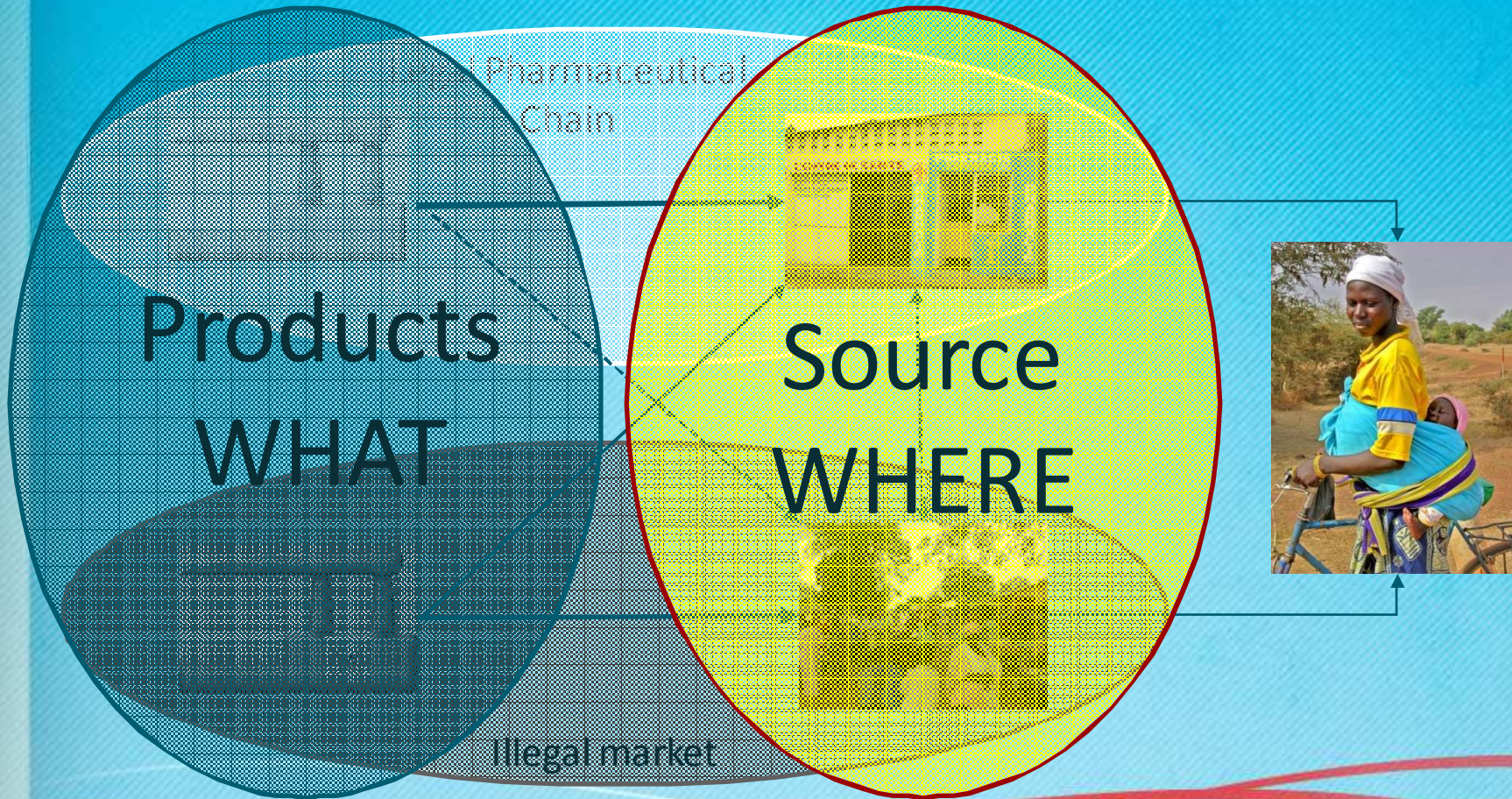




Products
WHAT

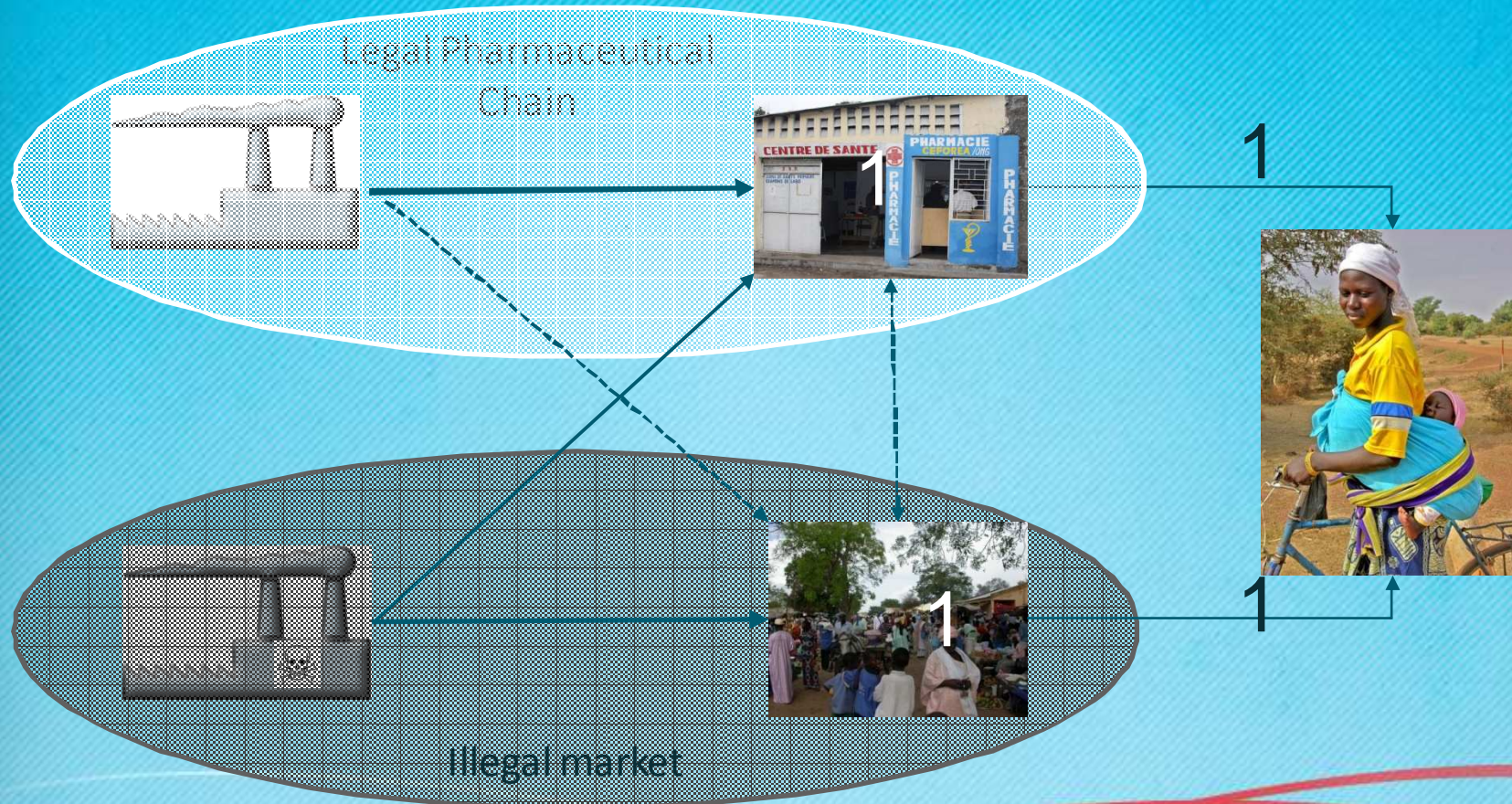
Source
WHERE

African situation



Possible actions

How big the problem is at national level (1)



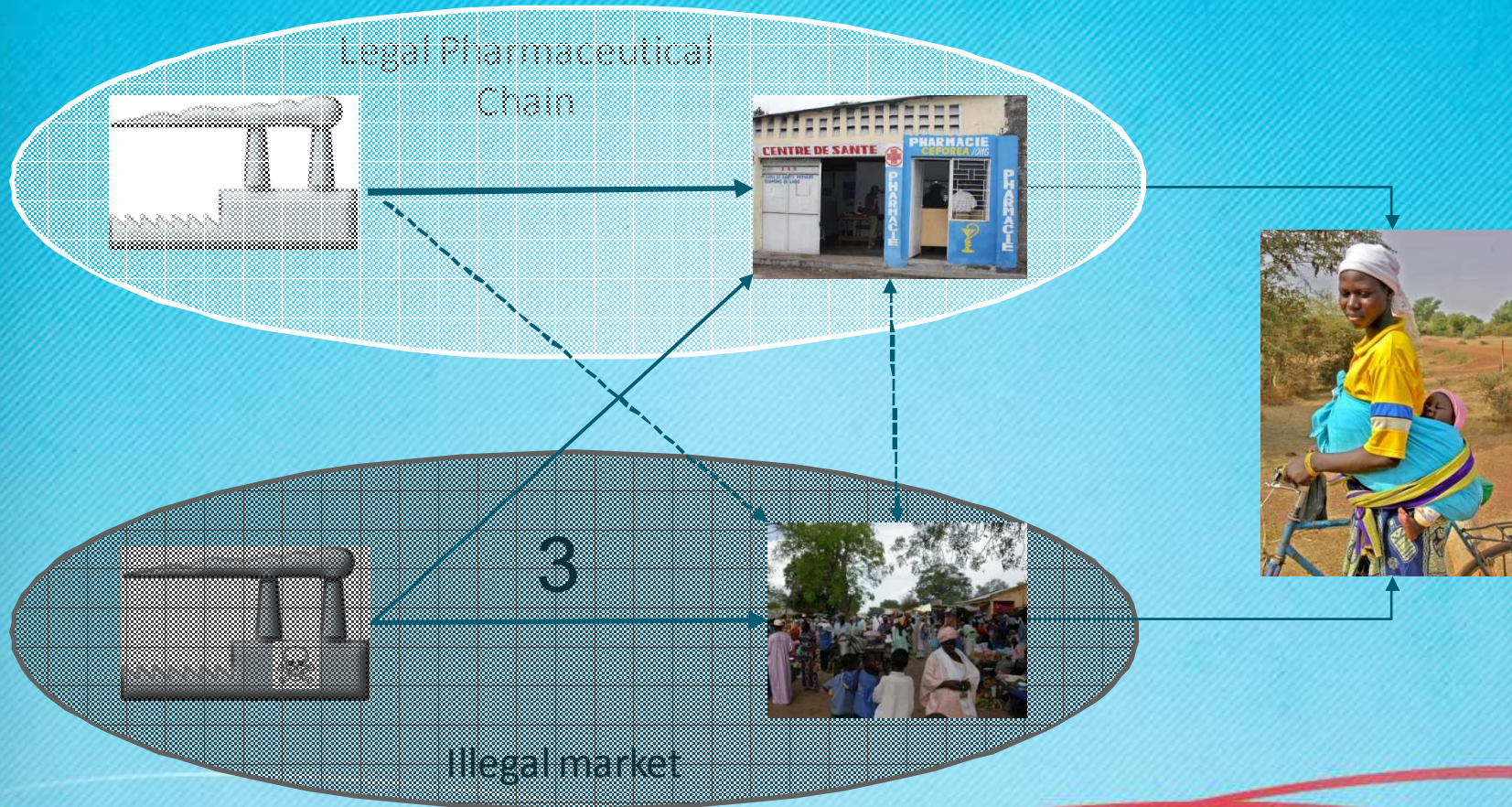
Possible actions

Protect the pharmaceutical chain from counterfeit medicines (2)



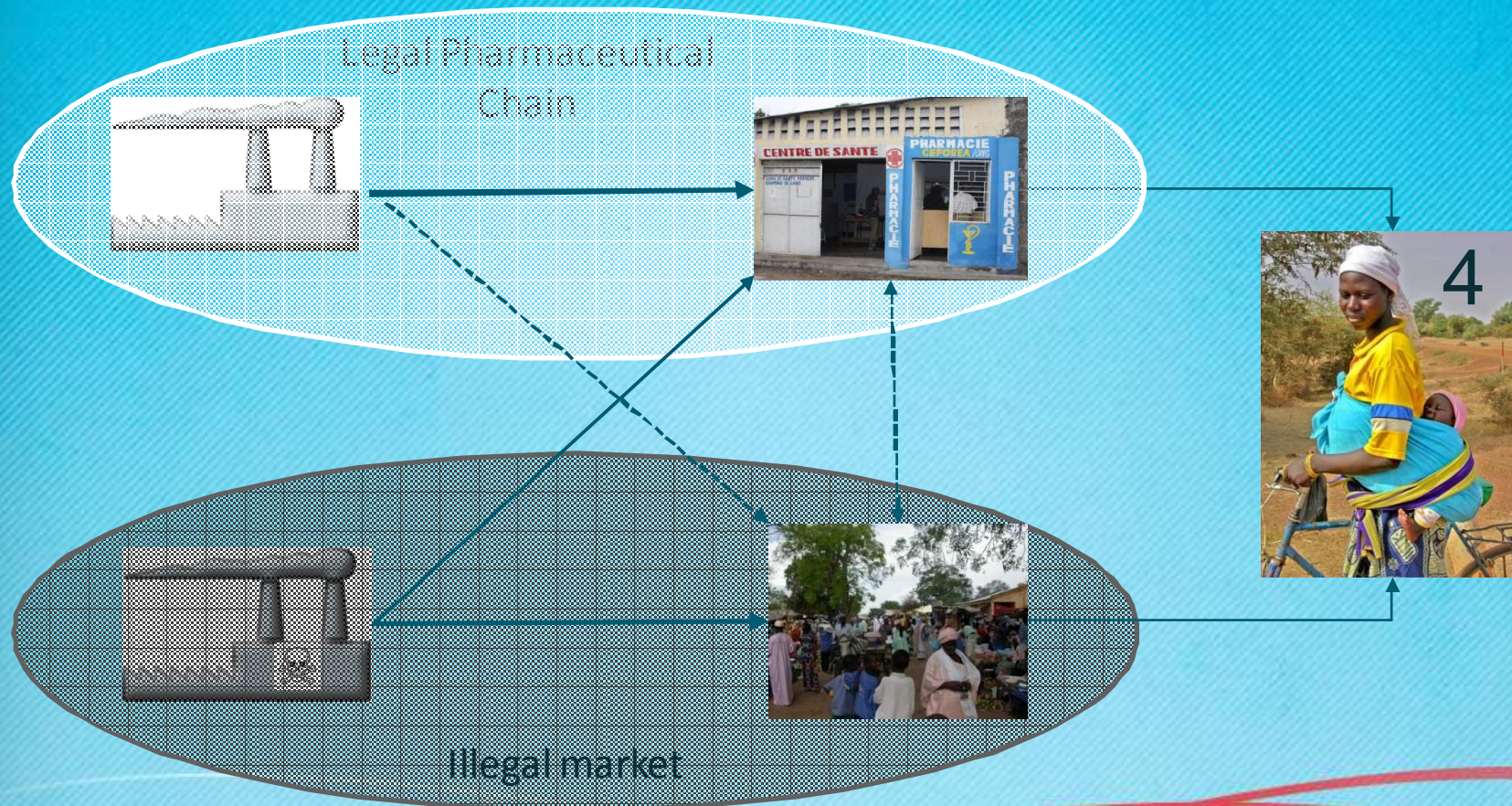
Possible actions

Actions against illegal market (3)



Possible actions

Actions towards patients (4)



1- Determining how big the problem is



- In several countries, evaluation of the incidence of counterfeit medicines as well as communication on this evaluation involve:
 - Drug Regulatory Agency (or Ministry of Health) with the (national) Laboratory for Quality control of medicines
 - And/or Local schools of pharmacies (Professors or Pharmacy Students).
 - And/or Association of pharmacists
- In many cases, such a detection can be helped by a North-South collaboration (and/or by WHO).
- Evaluation of the problem facilitates raising awareness on this issue

1- Determining how big the problem is

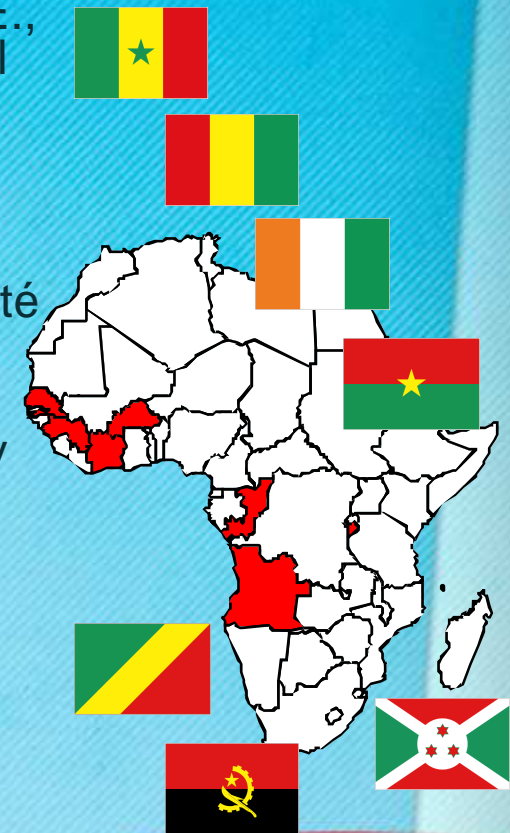


- To determine the problem, several requirements:
 - Capacity in testing drugs:
 - Finances and technology available: chemical analysis, dissolution test, visual inspection (FIP guidelines)
 - At national level or at regional level, or through collaboration with the pharmaceutical industry
 - Methodology:
 - a pro-active method: with blind sampling of products (i.e. India)
 - a reactive one: based on the reports of the inspectorate ... but the results of this reactive method is highly linked to the resources spent on the inspection and control of medicines.
 - Or based on the reports of pharmacists when facing a suspected case of counterfeit.

1- Determining how big the problem is

Examples of studies on counterfeit medicines in Africa

- Gaudiano M.-C., Di Maggio A., Cocchieri E., Antoniella E., Bertocchi P., Alimonti S. and Valvo L. Medicines informal market in Congo, Burundi and Angola: counterfeit and sub-standard antimalarials. *Malaria Journal* 2007, 6:22
- Legris C. La détection des médicaments contrefaits par investigation de leur authenticité. Étude pilote sur le marché pharmaceutique illicite de Côte d'Ivoire. Université Henri Poincaré 16 Dec. 2005
- 6 PharmD Thesis of Pharmacy students at the University of Conakry (Guinea) on counterfeit medicines sold in different markets of Conakry
- PharmD Thesis at the University of Bamako (Burkina Faso)
- Studies run in Senegal and in Côte-d'Ivoire with the collaboration of the local pharmacists associations and schools of pharmacy
- Limited number of published research articles but many grey littérature that are of interest (PharmD thesis, reports...)



2a - Information of all the members of the pharmaceutical chain



- Raising awareness of the members of the pharmaceutical chain and providing recommendations to protect patients from counterfeit medicines:
 - Actions within the pharmaceutical chain:
 - On their sources of medicines
 - On the stock management
 - Actions to relay the information to patients (see latter)

2a - Information of all the members of the pharmaceutical chain

- How?
 - Articles in professional journals
 - Edition of booklets on the issue. These booklets can be adapted from the French or English examples and from the EuroPharm Forum Framework under development.
 - National and international conferences on this issue, like the 8th Forum Pharmaceutique International (Togo, 6-8 June 2007).



2b - Avoid any entrance of the pharmaceutical chain

- Drug Regulatory Authority fight against counterfeit medicines:
 - Requires the support of the government (not only political support but also financial resources)
 - Can be facilitated by partners
 - Is a pre-requisite for any effective actions against counterfeit medicines
 - Activities: inspections, prosecution and banning manufacturers involved in counterfeiting...
 - Nigeria: a very clear example underlining that a tremendous change in the rate of counterfeit medicines in a market has been made under the leadership of Dr. Dora Nkem Akunyili and with the support of the government (rate from 41-80% down to 16%)

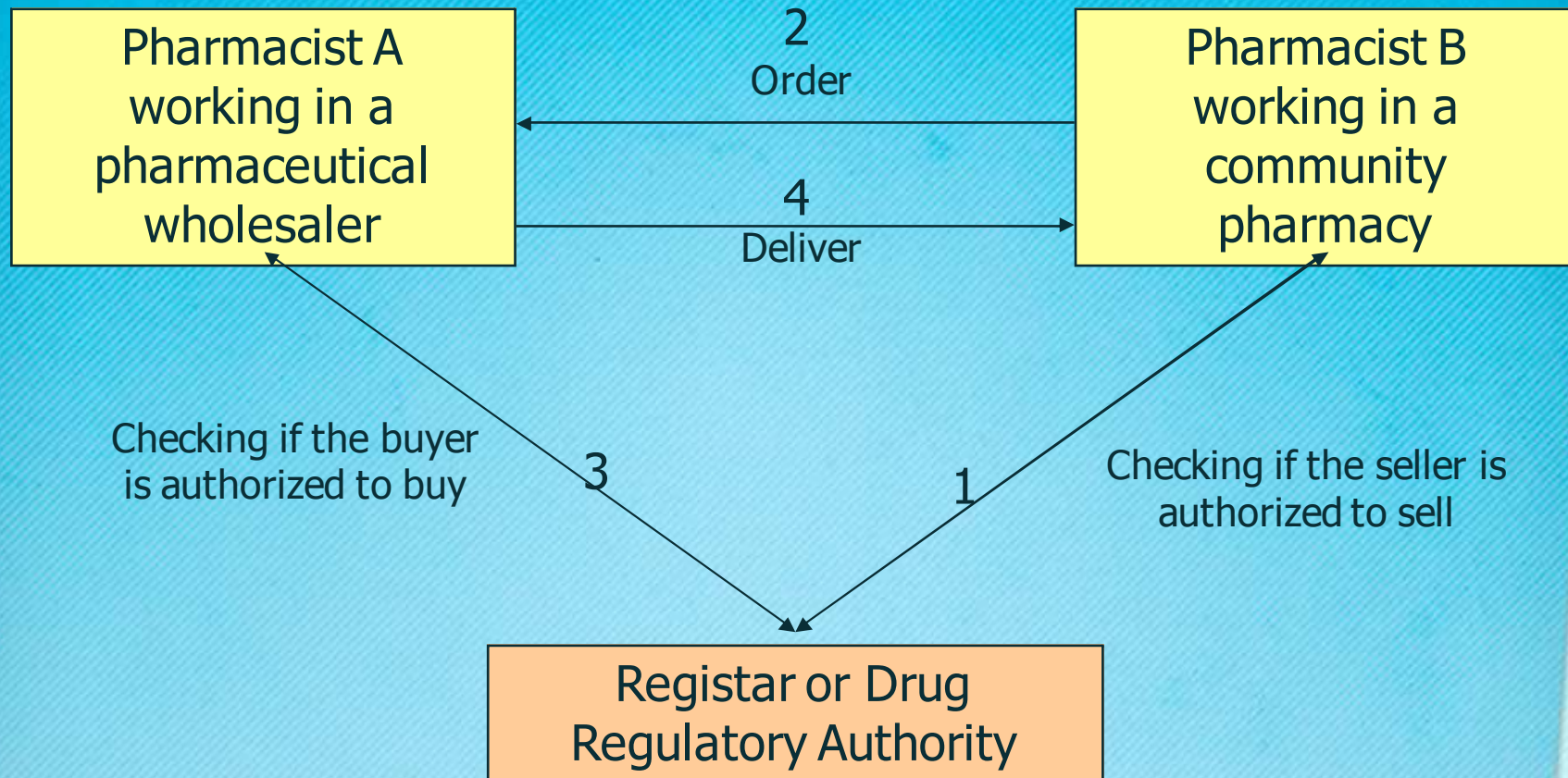


2b - Avoid any entrance of the pharmaceutical chain



- In many countries, pharmacists have to be registered at a Pharmacy Council (under the control of the Ministry of Health) or at a Pharmaceutical Society.
- Through the registration of pharmacists and wholesalers, competent authorities check whether they are allowed to buy from or to sell medicines to other pharmacists (based on national requirements)
- The competent authorities provide pharmacists with means enabling them to determine if a pharmacist / wholesaler/ industry is legally operating in the country for a specific activity (produce/buy/sell medicines).

2b - Avoid any entrance of the pharmaceutical chain



The system enabling a clear identification of the buyers and sellers should be implemented in every country.

2b - Avoid any entrance of the pharmaceutical chain

- To check if a pharmacist is registered, different solutions have been developed:
 - Website (constantly updated)
 - List displayed in journals (like in Kenya)
 - And always the possibility to phone or fax the competent authority to check

Official Journal of The Pharmaceutical Society of Kenya



**PHARMACY AND POISONS BOARD
LIST OF REGISTERED PHARMACISTS IN KENYA
2006**

NO.	NAME	REG. NO.	SERIAL NO.	NO.	NAME	REG. NO.	SERIAL NO.
1	DR. D. M. WARUI	535	000051	42	DR. SUSAN WACHIRA	1095	000092
2	DR. NGODI NDWIGA	538	000052	43	DR. JASON W. WAGURA	1755	000093
3	DR. KIGUONGO GITAH	1011	000053	44	DR. TASNIM S. K. MOHAMED	1700	000094
4	DR. I. M. KALEMIA	643	000054	45	DR. JOSEPH ALOISE MBITHI	1509	000096
5	MR. RAJNIKANT C. SHAH	497	000055	46	DR. TITUS KINYUA KIENI	1462	000096
6	DR. MUKESH N. SHAH	583	000056	47	DR. SHAH DHIRENDRA VELJI	489	000097
7	DR. ELISHBA W. MURINGI	1533	000057	48	DR. JEREMIAH NJOGU NGUGI	1594	000098
8	DR. JAPHET KIRIMI ARITHI	1252	000058	49	DR. JOSEPH W. KAMAMA	1258	000099
9	DR. RAPHAEL M. NYOIKE	1594	000059	50	DR. ALICE G. KAMAU	1384	000100
10	DR. OCHIENG NELSON ODHIAMBO	1397	000060	51	DR. JEAN WAMUYU KAHANYU	1435	000101
11	DR. JAMES N. KITVI	1045	000061	52	DR. HARSHADAN V. MAROO	365	000102
12	RITESH DHIRAJAL PATTNI	1650	000062	53	DR. CATHERINE W. KARUGU	1210	000103
13	DR. ENOCH BOSIRE NYAMUSI	486	000063	54	DR. P. K. J. SHAH	391	000104
14	DR. CHANDNI ROHET SHAH	455	000064	55	DR. BHAVESH P. KOTECHA	1148	000105
15	DR. DANIEL WACHIRA NJIMIA	1165	000065	56	DR. DIVESH P. KOTECHA	1196	000106
16	DR. PANCHOLI PRITESH VASUDEV	1326	000066	57	DR. (MRS.) ILLA G. PATEL	678	000107
17	DR. BARASA S. SITUMA	1499	000067	58	DR. JITENDRA RISHI	1538	000108
18	DR. SAVAN K. DESAI	1783	000068	59	DR. JACKSON MAINA DIRANGU	1295	000109
19	DR. MANISH KUMAR DODHIA	875	000069	60	DR. SIMA SHAH	1229	000110
20	DR. NITINKUMAR D. GORESA	1062	000070	61	DR. THUKU MORRISON	1303	000111
21	DR. PETER M. MUTUA	1771	000071	62	DR. EVANS L. N. MWANGANGI	1644	000112
22	DR. MIWANGI B. M.	1185	000072	63	DR. ASWINKUMAR C. M. SHAH	568	000113
23	DR. PAUL MUSANGO	1085	000073	64	DR. GEORGE MUGI MURIITHI	1043	000114
24	DR. BONIFACE KARIUKI NJENGA	1549	000074	65	DR. TUM HENRY KIMUTAI ARAP	905	000115
25	MRS. NILMA SHAH	1427	000075	66	DR. KULSUM SAFDAR SAEED	688	000116
26	DR. MOHAMED HASSAN MUSA	000076	000076	67	DR. ROBERT KAMAU WILLIE NGIGI	1072	000117
27	DR. MARY NTHAMBI KISINGU	1469	000077	68	DR. JOHN ODHIAMBO ORIGA	1433	000118
28	DR. MICHAEL NJUGUNA KABIRU	1679	000078	69	DR. DANIEL M. MWENDWA	1413	000119
29	DR. STEPHEN KAMAU NJOROGE	1470	000079	70	DR. PETER KARANJA NDERU	1133	000120
30	DR. SHABIR A. DURBAR	1506	000080	71	DR. GEORGE G. MUNGANIA	1410	000121
31	DR. HABIL ONYANGO	594	000081	72	DR. PAUL MUNGA MRUGUA	640	000122
32	DR. JANE WAMBUI	1097	000082	73	DR. ASHOK K. SHAH	587	000123
33	DR. CHRISTINE ATIENO OGOLLA	1756	000083	74	DR. ANNE NYAMBURA MAINA	1219	000124
34	DR. SHAILESH K. N. PATEL	556	000084	75	DR. PATEL ALPESH KUMAR	1430	000125
35	DR. MAGDI REYAD NEEMATALLAH	1278	000085	76	DR. WAFULA RITU	1450	000126
36	DR. PRAKASHCHANDRA K. PATEL	027	000086	77	DR. KIPSANG ROP WILSON	1211	000127
37	DR. VIMAL P. PATEL	934	000087	78	DR. PRAPUL C. RUPARELIA	768	000128
38	DR. SIMEON H. O. ONYANGO	949	000088	79	DR. JESSE KAMAU	1245	000129
39	DR. RICHARD M. GAKUNJU	834	000089	80	DR. JOHN MUNGUTI KISENGI	1757	000130
40	DR. SEJAL MAROO	1149	000090	81	PROF. ISAAC ONSUBO KIBWAGE	689	000131
41	DR. CHRISTINE ONG'AYO	720	000091	82	DR. BHARAT VELJI PATTNI	873	000132

2b - Avoid any entrance of the pharmaceutical chain

- In addition, registration bodies have other major roles to play in the fight against counterfeiting:
 - Through the enforcement of their Codes of Ethics, these bodies are often able to exclude a pharmacist who is involved in counterfeiting.
 - As a representative body of the profession, they are allowed to ask for a prosecution of any person who fakes to be an authorized member of the distribution chain.
- Example: statement of the Conseil national de l'Ordre des pharmaciens of Côte d'Ivoire



2c - Discovery of a counterfeit medicine



- Counterfeit medicines can be discovered or suspected through:
 - Inspections from national DRA, Customs or police (or from neighboring countries)
 - Reports from pharmacists and healthcare professionals (to DRA or to pharmacovigilance centers)
- Patients can also report case of counterfeit medicines either directly or by complaining about a change in a medicine (or its efficacy) to their pharmacists or medical doctors

2c - Discovery of a counterfeit medicine



- Once the DRA is aware of the problem:
 - DRA should take a decision, based on the information available. Such a process is facilitated through a standard procedure
 - DRA should inform healthcare professionals and patients on its decision. To increase the impact of its decision: reliable information system, guidelines for pharmacists already displayed to pharmacists...
 - In accordance to DRA decision, pharmacists may withdraw any suspected product and pay attention to their future deliveries.
 - Depending the danger, pharmacists may be requested to contact patients who received the counterfeit medicines (→ importance of patients records).

3 - Actions regarding the illegal market



- Pushing political leaders to act for the safety of patients, by
 - Raising awareness on:
 - The risks for patients (through ineffective medicines or intoxication) as well as for the whole society (antimicrobial resistance...)
 - Other consequences in terms of taxes, insecurity (attacks of pharmacies) and corruption.
 - Supporting and pushing for changes in regulation and for a better enforcement; WHO develops guidelines on these topics.

3 - Actions regarding the illegal market



- The fight against illegal market is successful only if the activities of the DRA, the customs and the police are coordinated.
- Healthcare professionals can be interesting partners to fight against illegal market.
- As most of the medicines are manufactured abroad, it is advised for Customs to be able to easily access to a pharmacist (e.g. from DRA) who could help to identify suspicious products (expertise sharing).

4 - Actions toward patients

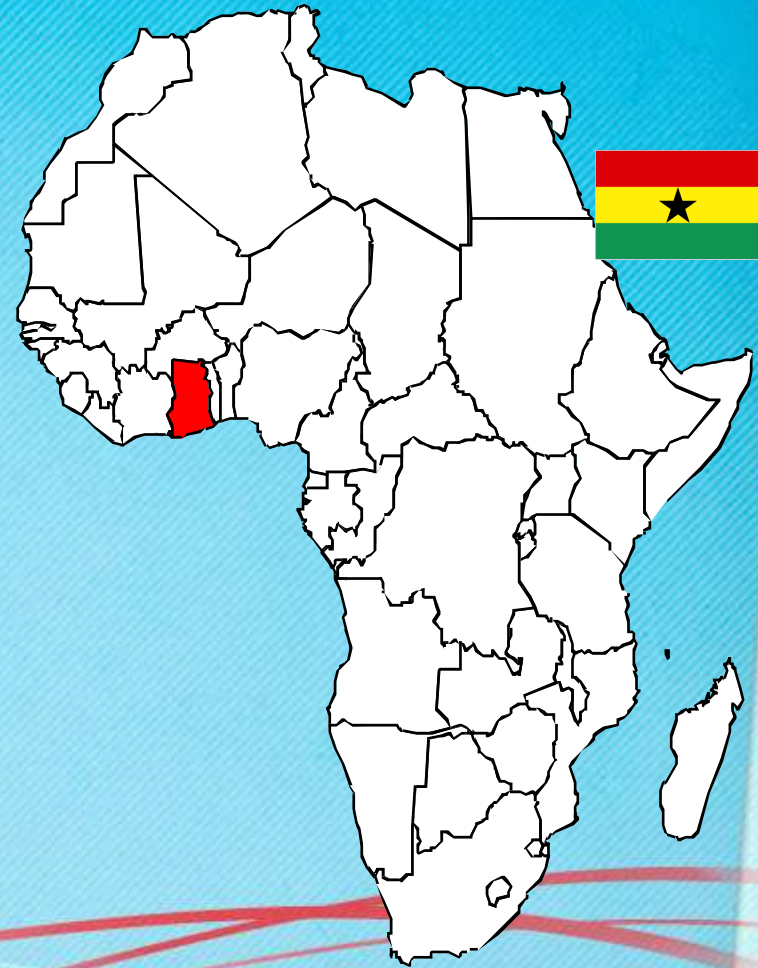
- Educating / raising awareness of patients on the issue of counterfeit medicines:
 - Through communication campaign
 - Through interviews and messages on the radio (like in Madagascar)
 - Through strikes of pharmacists (like in Senegal in May 2008)



4 - Actions toward patients

Awareness campaigns

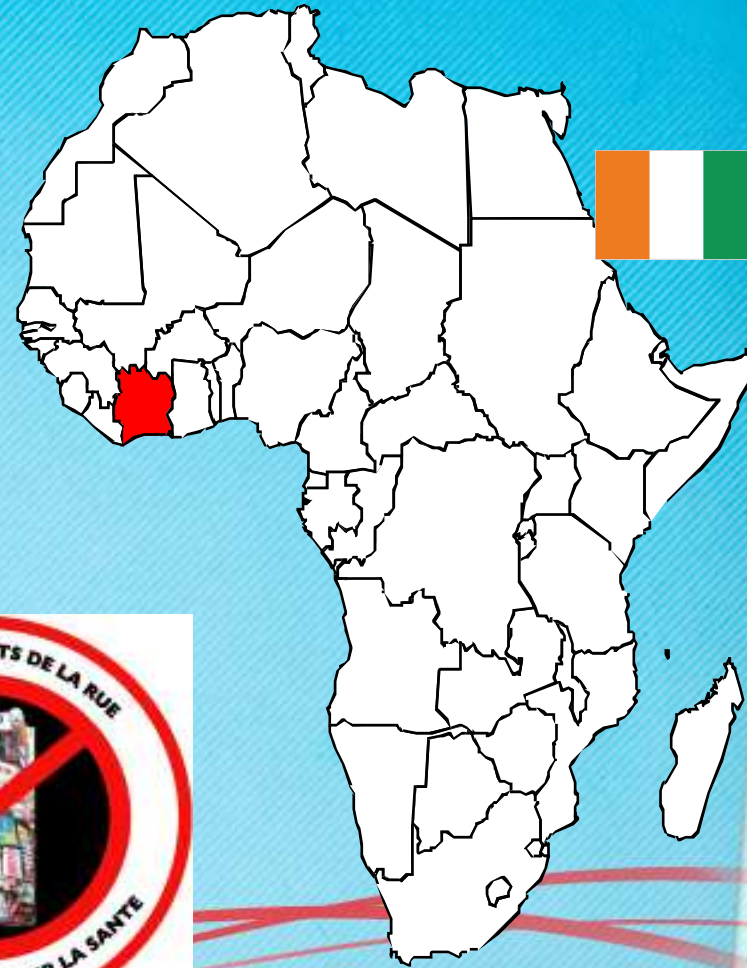
- Example of Ghana
- 31 minute film entitled 'If symptoms persist'
- Gathering representatives of the pharmaceutical society, of the consumers Association as well as ordinary consumers



4 - Actions toward patients

Awareness campaigns

- Example of Côte d'Ivoire.
- A campaign based on key and strong messages to raise awareness on the risks of counterfeit medicines.









**HELAS! IL FAISAIT CONFIANCE
AUX MEDICAMENTS DE LA RUE**



**UNFORTUNATELY, HE TRUSTED MEDICINES
BOUGHT IN THE STREET.**





Message du Conseil National de l'Ordre des Pharmaciens en collaboration avec les Ordres Nationaux,
les Syndicats de Santé et le Ministère de la Santé et de l'Hygiène Publique

4 - Actions toward patients Awareness campaigns



Campaigns from
ReMeD

Medicines bought
in the street kill



La vie passe par la pharmacie !

MÉDICAMENTS
FLA
GARAP
TUM
KISI
YORO

Products
WHAT

Source
WHERE

VIE
NI
DOUNDE
BALLO
VIIM
RAYIWA
BOMOYI
GIGI

Les vrais médicaments sont en pharmacie.
الأدوية في الصيدلية ضمان لصحتي



Conclusion

- Cooperation is a key element for successful actions to combat counterfeit medicines
- Many of the presented activities do not require high financial resources but will and methodology. This methodology can be learned from country experiences and networking... like at the FIP Congress!



THANK YOU FOR YOUR ATTENTION

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