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Paediatric galenics: a challenge and an opportunity proposed by A.P.P.A.® Project for Developing Countries

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(Article begins on next page)

12 October 2024

8th A.It.U.N annual meeting
"Medicines for children's safe: challanges and opportunities"
Pavia, 6-7th March 2014

Paediatric galenics: a challenge and an opportunity proposed by *A.P.P.A.*® Project for Developing Countries

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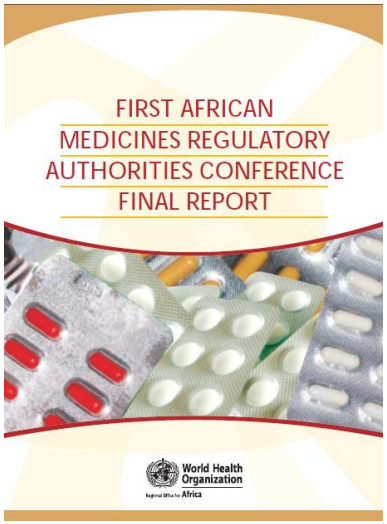
Department of Scienza e Tecnologia del Farmaco, University of Turin, Italy

Alma-Ata Declaration - 1978

*"… **the Primary Health Care**… forms an integral part both of the country's health system, of which it is the central function and main focus, and of the overall social and economic development of the community. It is the first level of contact… with the national health system, **bringing health care as close as possible to where people live and work, and constitutes the first element of a continuing health care service**…"*

TODAY?

2005

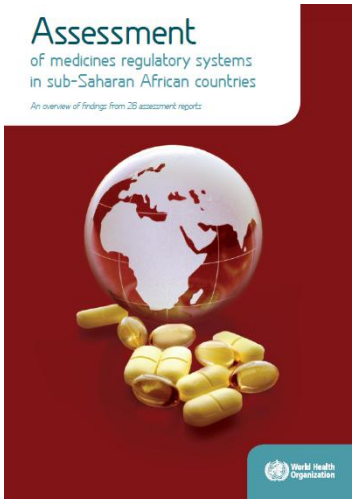


Problem to be addressed

- Weak market control.
- Inappropriate legal status of national medicine regulatory authorities to carry out their regulatory functions.
- Inadequate legislation and regulations.
- Weak quality control laboratories.
- Inadequate regulation of clinical trials.
- Inadequate import and export controls.
- Existence of counterfeit products on national markets.
- Local production firms non-compliant with GMP (ARVs, anti-malarial and anti-TB medicines).

World Health Organization

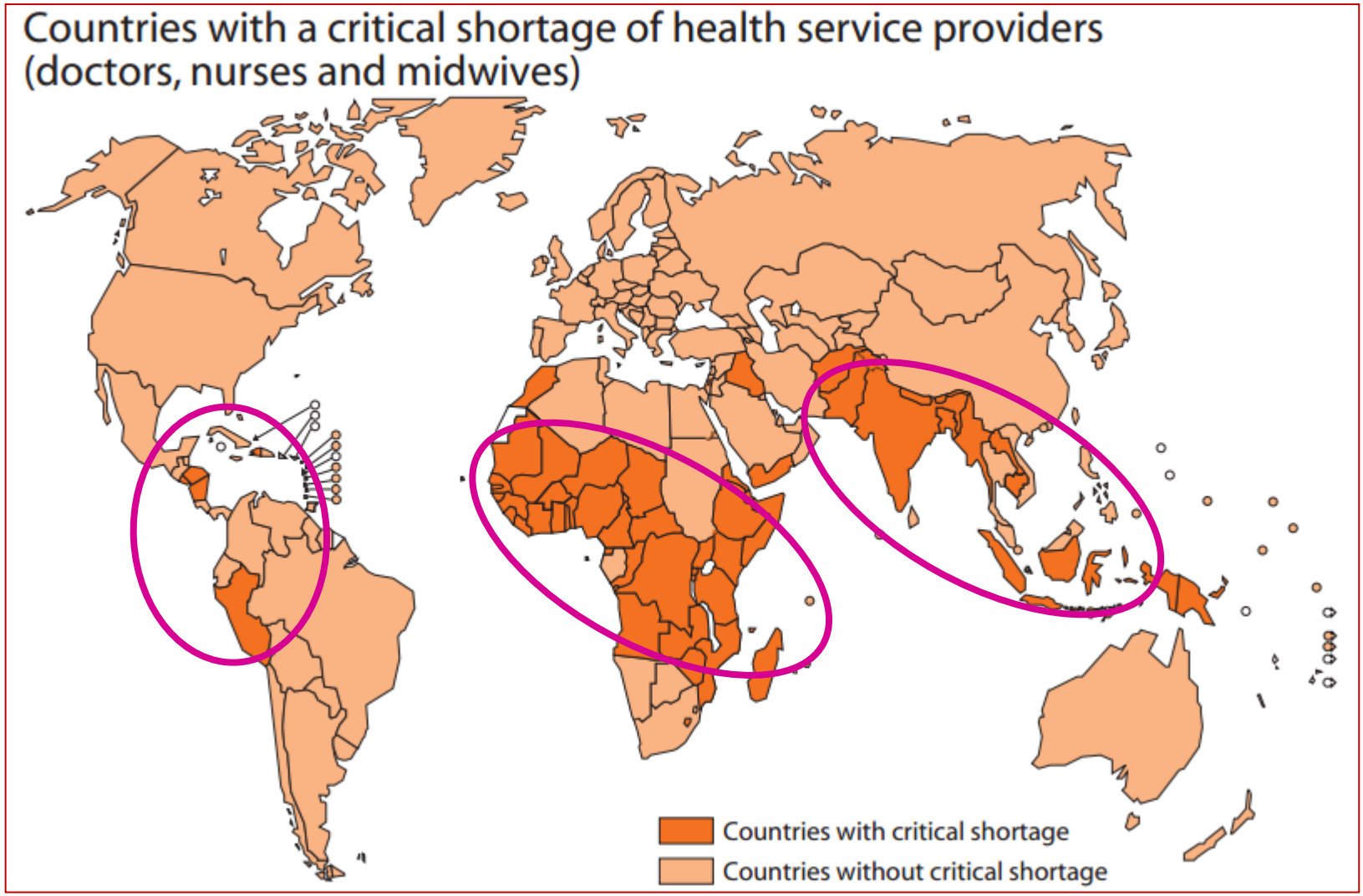
2010



As a result, medicines regulation was not carried out to the full extent required to ensure the quality, efficacy and safety of medicines in African countries. The findings confirm the results of a 2004 questionnaire survey conducted by WHO in 38 African member states, which found that 90% of countries did not provide or enforce adequate regulatory functions

World Health Organization

ACCESS TO HEALTH SERVICES: INEQUALITIES BETWEEN NORTH AND SOUTH OF THE WORLD



The World Health Report 2006 - working together for health
Chapter 1: Health workers: a global profile

PROBLEMS RELATED TO THE LIFE STILE

«…water-borne diseases are not caused by lack of antibiotics but by **dirty water**, and by the political, social, and economic forces that fail to make clean water available to all; heart disease is caused not by a lack of coronary care units but by the **lives people lead**, which are shaped by the environments in which they live; obesity is not caused by moral failure on the part of individuals but by the excess availability of high-fat and high-sugar foods …»

"Closing the gap in a generation: Health equity through action on the social determinants of health" – WHO Commission on Social Determinants of Health - 2008

Borana Singing wells, Kenya

World Health Organization

ESSENTIAL MEDICINES

Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness.

Essential medicines are intended to be available within the context of functioning health systems at all times in **adequate amounts**, in the **appropriate dosage forms**, with assured **quality** and adequate **information**, and at a **price** the individual and the community can afford.

BUT…

World Health Organization
REGIONAL OFFICE FOR Africa

- More than **fifty percent of the population** in the Region **have no regular access to essential medicines.**
- **Medicine supply** and **regulatory systems** are weak
- **Financial** as well as **human resources** are inadequate to ensure delivery of pharmaceutical services and ensure access to essential medicines.
- Circulation of **poor quality medicines**, high medicine **prices**, unethical promotion and **irrational use** of medicines poses additional challenges.

COUNTERFEIT MEDICINES

*A counterfeit medicine is one which is **deliberately and fraudulently mislabeled with respect to identity and/or source**. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.*

WHO - General information on counterfeit medicines

"IMPERFECT" COUNTERFEITS

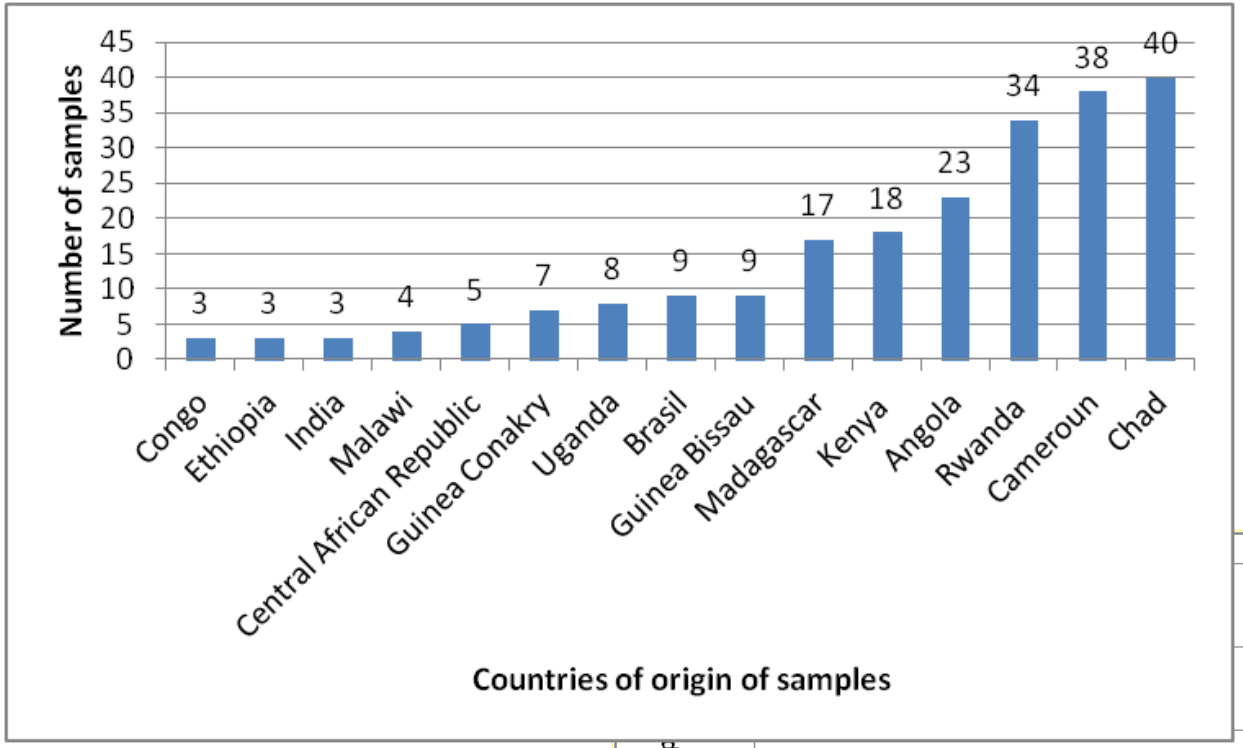
«these products contain the right components, with an incorrect concentration and/or formulation resulting in defective quality specifications. In the vast majority of cases, they are devoid of any therapeutic efficacy»

"CRIMINAL" COUNTERFEITS

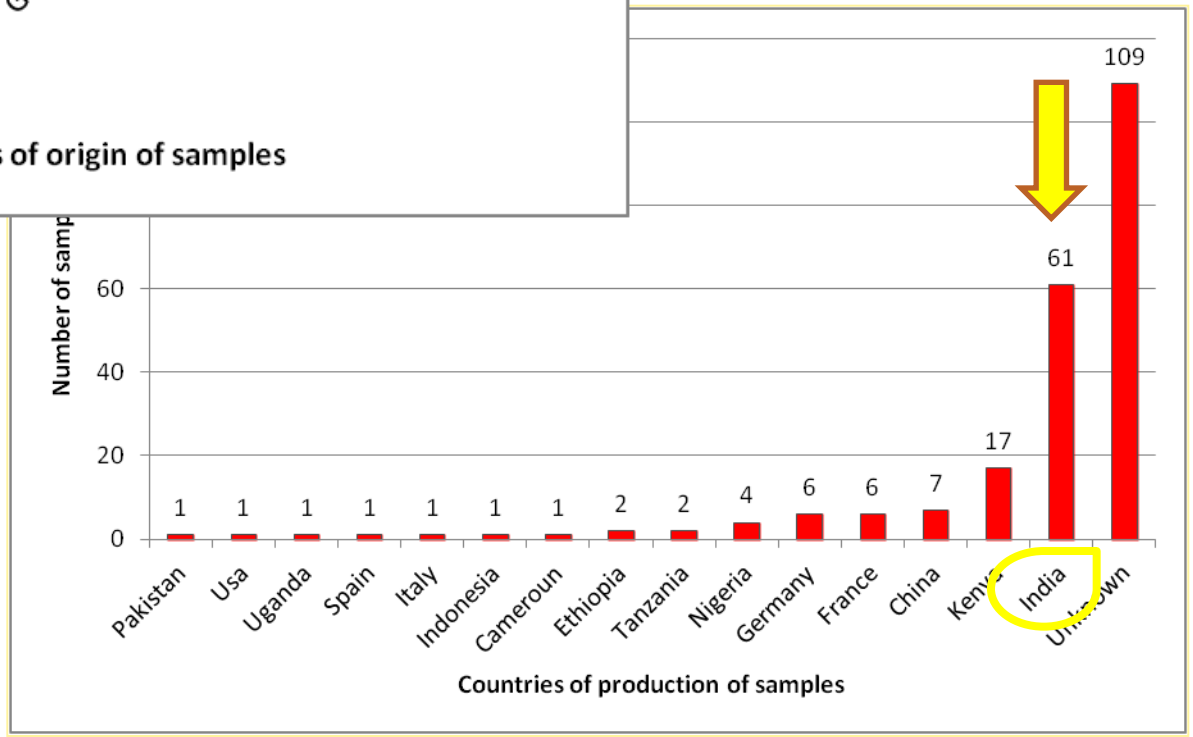
«they are apparently similar to the original medicinal product, but do not contain any active ingredient and can even include harmful or toxic substances. They are usually sold at high prices and for the treatment of serious pathologies. Consequences for users of criminal counterfeits can be fatal»

Di Giorgio D. Counterfeit drugs. The phenomenon and enforcement activities. Milano: Tecniche nuove; 2010.

COUNTERFIET MEDICINES IN DC: ANALYSIS OF THE PHENOMENON



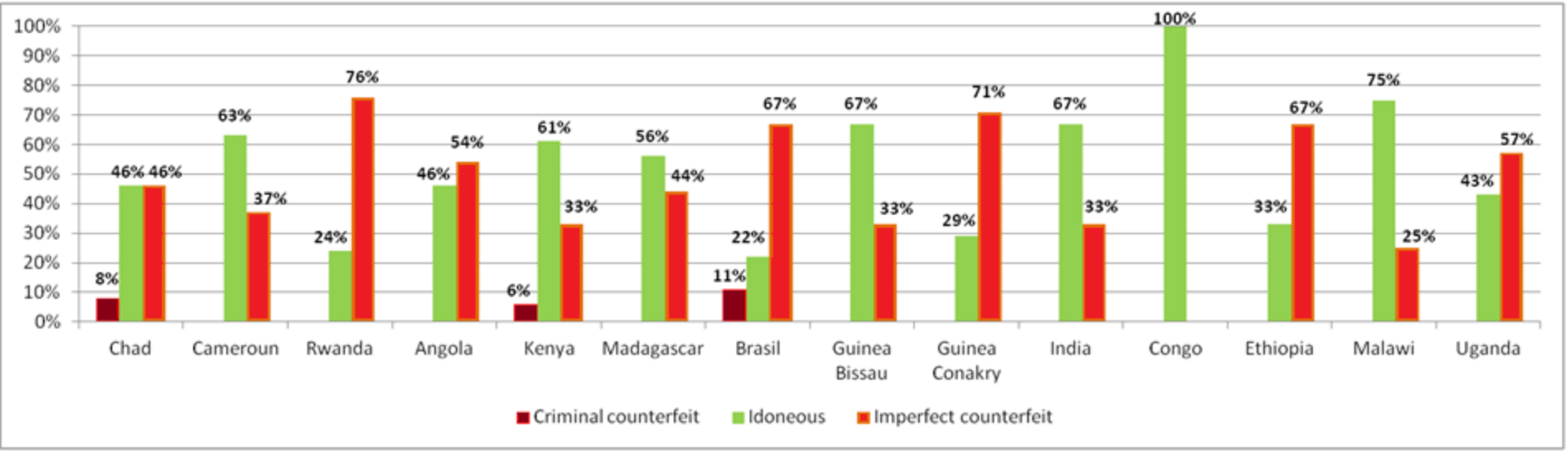
Analysis of 196 samples of medicinal products

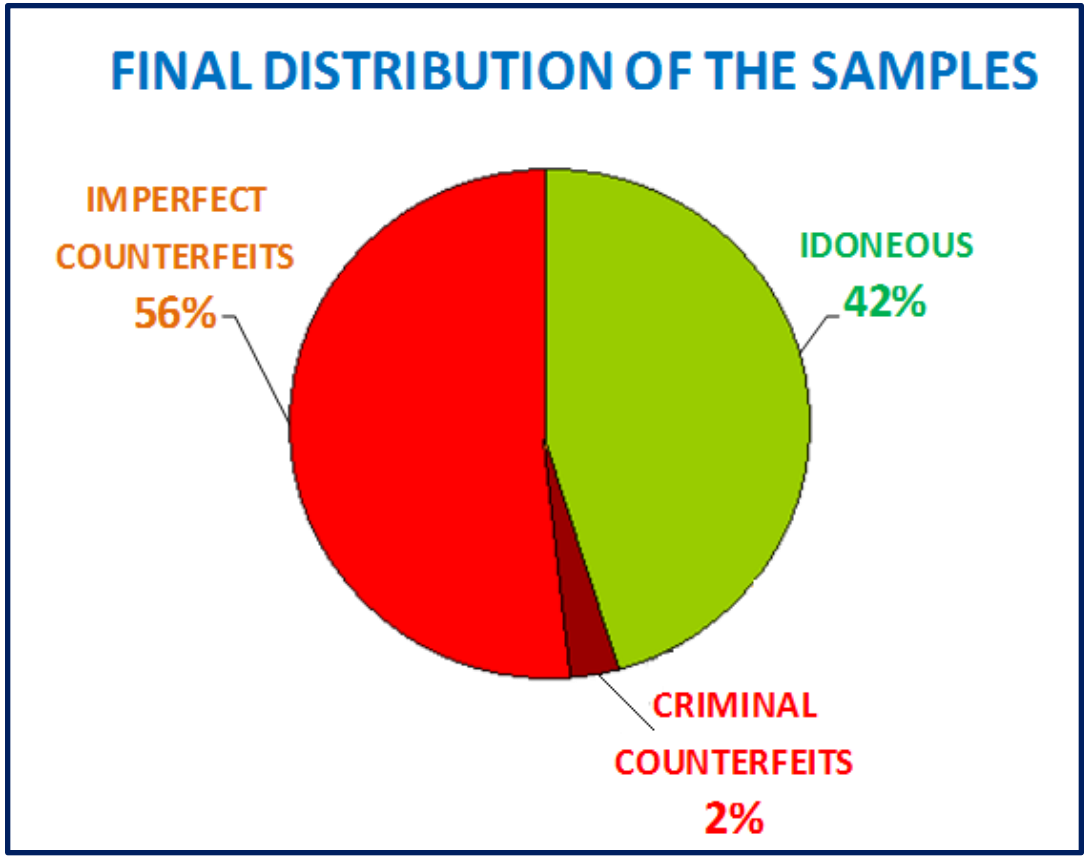


F.Baratta, A. Germano, P. Brusa

Diffusion of counterfeit drugs in developing Countries and stability of galenics stored for months under different conditions of temperature and relative humidity

Croat Med J. 2012; 53: 173-184





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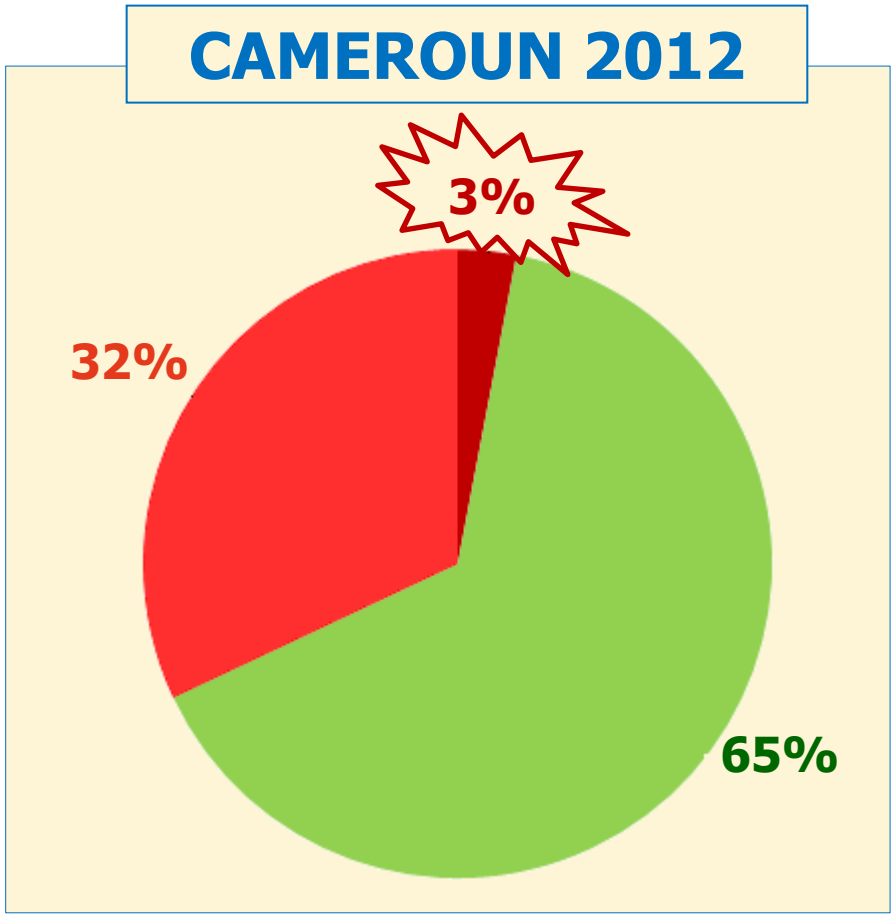
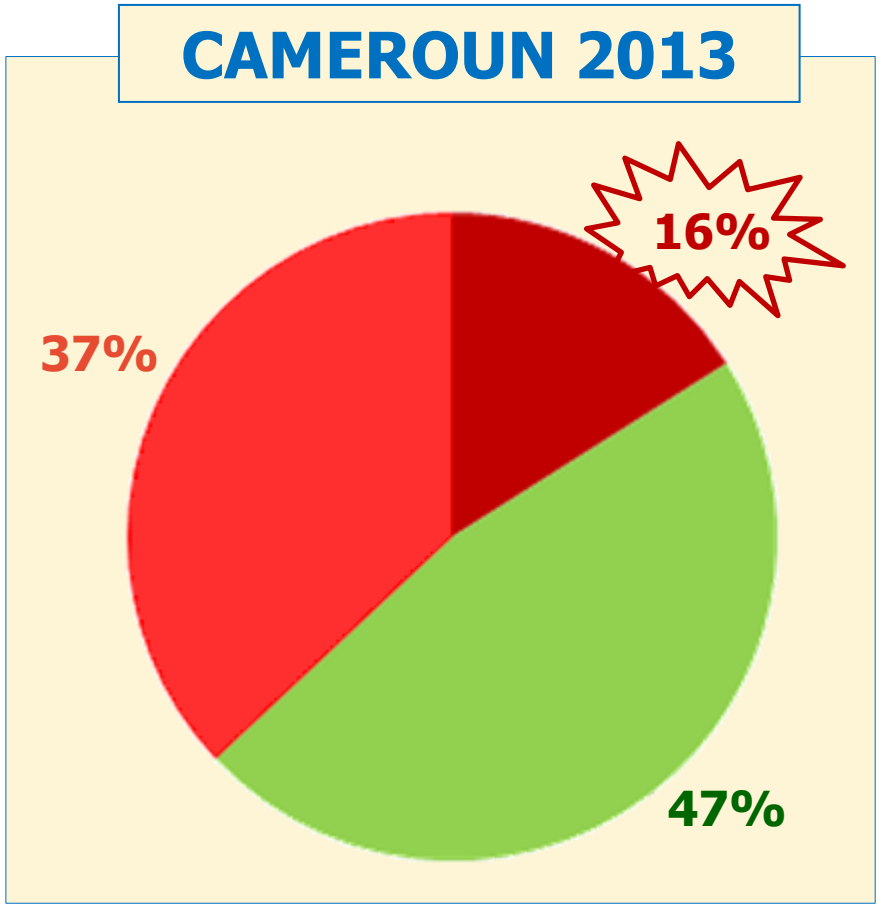


PHARMACEUTICAL FORMS TESTS (Ph Eur)

- Uniformity of content (2.9.6)
- Uniformity of mass (2.9.5)
- Disintegration (2.9.1)
- Friability (2.9.7)
- Hardness (2.9.8)
- Sterility (2.6.1)



Criminal counterfeit

Idoneous

Imperfect counterfeit

CAMEROUN 2013

- Population: 20 million
- Pharmacies on the national territory: 331
- Yaoundé+Douala: 81 pharmacies

HOW MANY ARE THE STREET VENDORS?

PRELIMINARY RESULTS:

- 1047 FAMILIES LIVING IN YAOUNDÉ: THE 99.6%, EVEN IF **SCHOOLED**, BUY MEDICINAL PRODUCTS BY STREET VENDORS
- THE 34% OF SUBJECTS IS **AWARE OF THE RISKS**. THE 60% BUY THESE PRODUCTS DUE TO **FINANCIAL DIFFICULTIES**
- 74 STREET VENDORS HAVE BEEN INTERVIEWED: THE 80% IS **MEDIUM-HIGH CULTURAL GRADE**

A.P.P.A.® PROJECT

PLANNING, CARRYING OUT, STARTING LABS IN ORDER TO PREPARE GALENIC MEDICINAL PRODUCTS AND RELATIVE QUALITY CONTROL IN DEVELOPING COUNTRIES

With the patronage of:

Università degli Studi di Torino

and

FEDERAZIONE ORDINI FARMACISTI ITALIANI

ORDINE DEI FARMACISTI PROVINCIA DI TORINO

CONSORZIO TEFARCO INNOVA

federfarma piemonte

www.progettoappa.it **appa.onlus@unito.it**

PHASES OF *A.P.P.A.®* PROJECT

Phase «zero»

Preliminary pharmaco-economic study which implies a trip of the *A.P.P.A.®* staff on site to value the local situation and recipient areas. Some medicines should be purchased in local pharmacies and sent to the laboratory of the University of Turin to value if these medicinal products, present on the local market, respect the declared characteristics or are counterfeit.

1. Choice of the place where building the galenic lab, choice of medicines needed and of the correct pharmaceutical forms, related to the local pathologies.

2. Stage in *A.P.P.A.®* lab of Turin, for a Pharmacy's student of Pharmacy Faculty of Turin; the stage leads to learn all the necessary to be able to prepare the programmed medicinal products.

3. A technician of the Country holding the lab comes to Italy to learn the procedures of galenic medicines in *A.P.P.A.®* lab of Turin, under a Pharmacy's student supervision. During this period the material needed for galenic lab will be sent to local partners.

4. Training period in the chosen Country, during which the local technician, who has been in Italy to learn galenic methods and procedures, will be coordinated in his work by the Pharmacy's student sent to the *A.P.P.A.®* lab .

5. Quality control of medicinal products routinely prepared in new galenic lab; moreover some sample of these are sent to University of Turin, Pharmacy Faculty, where they are tested to verify their quality.

6. Periodical stages at new lab for Pharmacy's students of Pharmacy Faculty of Turin are performed each year both to give a continuous supervision of medicinal products prepared in the lab and to create new formulations according to the requests of medical doctors responsable of the medical centers.

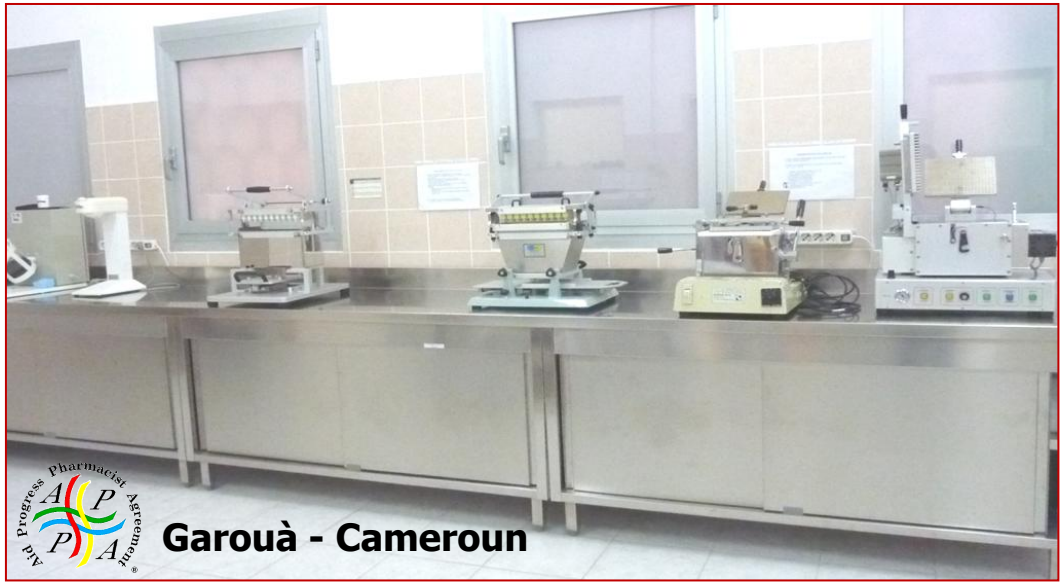
WHY GALENICS IN DC?

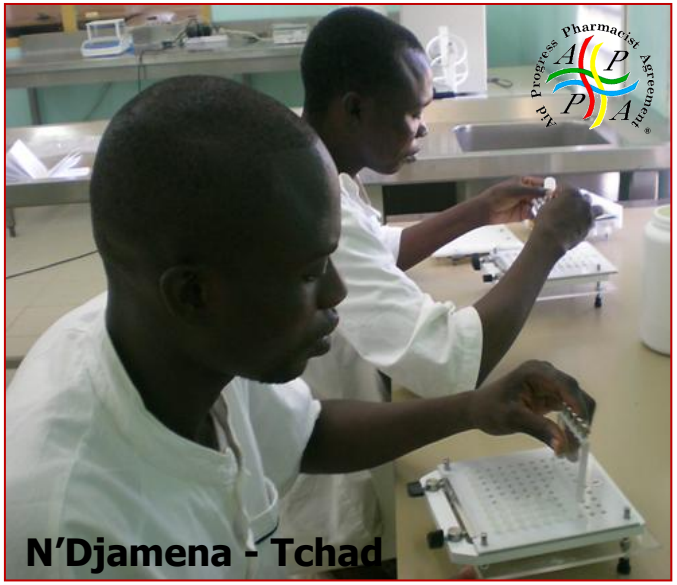
USING LOCAL PERSONAL TEACHING THEM A JOB: AUTONOMY

ALLOWING THE SALE OF CHEAP HIGH QUALITY MEDICINES

AVOIDING THE PURCHASE OF MEDICINES ILLEGALLY IMPORTED

CUSTOMIZING THE DOSAGES AND PHARMACEUTICAL FORMS ACCORDING TO THE ACTUAL NEEDS OF PATIENTS





BASIC CONDITIONS FOR OPENING

A LAB FOR THE PREPARATION OF GALENIC MEDICINAL PRODUCTS

- **HIGH PERCENTAGE OF COUNTERFEIT MEDICINES IN THE AREA**
- **LOCAL POOR AVAILABILITY OF QUALITY MEDICINES**
- **HIGH COST OF INDUSTRIAL MEDICINES**
- **APPROVAL OF LOCAL AUTHORITIES**

AIM

The project was born from the need and the desire to teach a trade to people leaving in Developing Countries and to ensure the production of safe and effective medicines

EASIER ACCESS TO MEDICINES

DECREASE MORTALITY

AFRICA: HIGH PRESENTS OF COUNTERFEIT MEDICINES

NO THERAPEUTIC EFFECT

CASES OF INTOXICATION

ENDEMIC DESEASES IN THE AREA

- MALARIA
- SALMONELLA
- VENEREAL DESEASES
- HEPATITIS A,B,C,D,E,
- HIV
- TUBERCULOSIS
- OTHERS

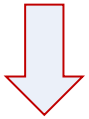
CHOICE OF THERAPEUTIC CLASSES FOR THE GALENIC LAB

- ANTIMALARALS
- TOPICAL ANTIFUNGAL
- TOPCAL AND SYSTEMIC ANTIBIOTICIS
- SYSTEMIC AND TOPICAL NSAD
- ANTIPYRETICS
- ANTIPARASITICS (antihelmintics, antiamebic, scabicidi)
- DISINFECTANTS

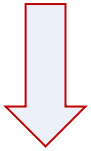
FORMULATION

PHARMACEUTICAL FORM

OINTMENT FOR SKIN APPLICATION



LIQUID
- ORAL
- FOR SKIN APPLICATION



SUPPOSITORY

ORAL SOLID

A.P.P.A.® LABS HANDBOOK

PREPARAZIONI ALLESTITE NEI LABORATORI A.P.P.A.®

INDICE

PREP. SEMISOLIDE PER APPLICAZIONE CUTANEA	CAM 1	CAM 2	HAITI	TCHAD	MAD 1	MAD 2	ANG 1	ANG 2
ac. salicilico – ac. benzoico				X*				
aciclovir crema		X		X*	X	X		
arnica gel								
betametasone crema								
clorexidina crema								
econazolo crema								
gel antiemorroidario								
idrocortisone crema								
iodopovidone unguento								
iodopovidone con glucosio unguento								
ketoprofene gel								
lidocaina gel								
neomicina solfato crema								
neomicina-idrocortisone-prometazina crema								
prometazina crema								
zinco ossido pasta								

PREP. LIQUIDE PER APPLICAZIONE CUTANEA
clorexidina soluzione disinfettante
clorexidina colluttorio
iodopovidone soluzione cutanea (betadine)
ipoclorito di sodio
sapone disinfettante
sospensione di benzile benzoato
soluzione di perossido di idrogeno

PREPARAZIONI SOLIDE
acido acetilsalicilico
acido ascorbico
acido folico
aminofillina
amoxicillina
bisacodile
captopril
carbocisteina
chinina solfato
ciprofloxacina
cloramfenicolo
diclofenac sodico
eritromicina
etambutolo
ferro-acido folico
ferro-acido folico-vitamina C
furosemide
ibuprofene
idroclortiazide
isoniazide
loperamide
magnesio idrossido – alluminio idrossido
magnesio trisilicato - alluminio idrossido
mebendazolo
meflochina
metformina
metoclopramide
metronidazolo
nifedipina
nimesulide
paracetamolo
parasa
praziquantel
prednisolone
primachina
ranitidina
rifampicina - isoniazide
salbutamolo
vit B complesso

	CAM 1	CAM 2	HAITI	TCHAD	MAD 1	MAD 2	ANG 1	ANG 2
carbocisteina	X							
chinina solfato				X	X			
ciprofloxacina				X				
cloramfenicolo		X		X				
diclofenac sodico		X		X				
eritromicina		X		X				
etambutolo				X				
ferro-acido folico		X		X				
ferro-acido folico-vitamina C	X							
furosemide				X				
ibuprofene	X	X	X	X	X			

PREPARAZIONI LIQUIDE AD USO ORALE
SOLUZIONI
captopril
furosemide
SOSPENSIONI
amoxicillina
carbocisteina
cloramfenicolo
eritromicina
magnesio e alluminio idrossido
metronidazolo
vitamina B complex

SCIROPPI	CAM 1
acido ascorbico	
carreonato di potassio	
carbocisteina	X
chinina	X
ferro solfato-vitamina C	
glicerolo	X
ibuprofene	
paracetamolo	X
paracetamolo pediatrico	X
propanololo	
ranitidina	
salbutamolo	
vitamina B6	
vitamina B12-ac.folico	

GOCCE	CAM 1
chinina	X
nifedipina	
ranitidina	
salbutamolo	
vitamina B6	

ALTRE	CAM 1	CAM 2	HAITI	TCHAD	MAD 1	MAD 2	ANG 1	ANG 2
lassativo orale	X							

GEL ORALI	CAM 1	CAM 2	HAITI	TCHAD	MAD 1	MAD 2	ANG 1	ANG 2
clorexidina					X			
lidocaina				X*	X	X		

POLVERI PER USO ORALE	CAM 1	CAM 2	HAITI	TCHAD	MAD 1	MAD 2	ANG 1	ANG 2
chinina								
ibuprofene								
mebendazolo								

PREPARAZIONI RETTALI	CAM 1	CAM 2	HAITI	TCHAD	MAD 1	MAD 2	ANG 1	ANG 2
paracetamolo supposte								X

PREPARAZIONI STERILI	CAM 1	CAM 2	HAITI	TCHAD	MAD 1	MAD 2	ANG 1	ANG 2
sodio cloruro 0,9% 10 ml gtt nasali			X					
sodio cloruro 0,9% 500 ml i.v.				X				
glucosio 5%500 ml i.v.				X				
ringer lattato500 ml i.v.				X				

* preparazioni sospese a periodi alterni in base alle necessità dell'ospedale.

SEMISOLID PREPARATIONS FOR CUTANEOUS APPLICATION
LIQUID PREPARATIONS FOR CUTANEOUS APPLICATION
SOLID PREPARATIONS
LIQUID PREPARATIONS FOR ORAL USE
Solutions
Suspension
Syrups
Drops
ORAL GEL
POWDER FOR ORAL USE
RECTAL PREPARATIONS
STERILE PREPARATIONS
Large volume parenteral solutions

101 FORMULATIONS

Aid Progress Pharmacist Agreement

SAINT DAMIEN PAEDIATRIC HOSPITAL
PORT-AU-PRINCE - HAITI

HAITI: WHY?

MEDICINAL PRODUCTS			
LOT	**API**	**PROVENANCE**	**RESULTS**
6C090	Acetazolamide 250 mg	Haiti	**Unsatisfied:** Uniformity of content (2.9.6), Friability (2.9.7)
0302609	Ampicillin 1g	India	**Unsatisfied**: Bacterial endotixins (2.6.14.)
071202	Chloramphenicol 1g	USA	**Suitable**
09K4840 A	Phenobarbital 30 mg	Haiti	**Unsatisfied**: Friability (2.9.7), Hardness (2.9.8)
08E2978-A	Phenobarbital syrup 18mg/5ml	Haiti	**Suitable**
08111487	Propanolol 40mg	Brasil	**Unsatisfied**: Uniformity of content (2.9.6)
L08111487	Spironolactone 25mg	Domenican Republic	**Suitable**

PAEDIATRICS: WHY?

PREPARATION OF CAPSULES FOR CHILDREN FROM INDUSTRIAL HIGH-DOSE TABLETS

PROBLEMS:

- ✓ Method of preparation
- ✓ Quality of industrial tablets
- ✓ Stability of the preparations
- ✓ Administration of capsules for the neonatal and paediatric treatment

CAPSULES PRODUCED IN 2010			
LOT	**API**	**PROVENANCE**	**RESULTS**
200910-A	Acetazolamide 25 mg	St Damien Hospital	**Unsatisfied**: Uniformity of content (2.9.6)
A-200S10-A	Acetazolamide 25 mg	St Damien Hospital	**Suitable**
121110-B Exp	Captopril 1,25 mg	St Damien Hospital	**Unsatisfied**: Uniformity of mass (2.9.5)
230610-C	Phenytoin 10 mg	St Damien Hospital	**Suitable**
230610-G	Phenytoin 10 mg	St Damien Hospital	**Suitable**

A.P.P.A.® GALENIC LAB IN HAITI: SAINT DAMIEN PAEDIATRIC HOSPITAL

STUDY AND FORMULATION OF ORAL LIQUID PAEDIATRIC FORMULATIONS: METHODOLOGICAL APPROACH

✓In agreement whit local medical doctors the **drugs** for the paediatric therapy are **chosen** and then **formulated**: **liquid oral** formulations are preferred and appropriate excipients are selected.

✓For each formulation a **specific card** (written in **local language**) has been prepared. The card shows the procedure of preparation and the characteristics of each component present in the formulation.

✓Each preparation have been tested to check its **quality** and its **stability** under different environmental conditions in accordance with the EMA guidelines.

PREPARATIONS PEDIATRIQUES	
SIROPS	ACIDE ASCORBIQUE 10 mg/ml
	CANREONATE DE POTASSIUM 1 mg/ml
	FER SULFATE 5 mg/ml
	IBUPROFENE 20 mg/ml
	PROPANOLOL 0,5 mg/ml
	RANITIDINE 15 mg/ml
	SALBUTAMOL 0,4 mg/ml
	VITAMINE B_6 1 mg/ ml
SOLUTIONS	CAPTOPRIL 1 mg/ml
	FUROSEMIDE 1 mg/ml
GOUTTES	NIFEDIPINE 1 mg/gtt
	RANITIDINE 4 mg/gtt
	SALBUTAMOL 0,2 mg/gtt
	VITAMINE B6 0,5 mg/gtt
SUSPENSIONS	VITAMINE B COMPLEX 5,8 mg/ml
	MAGNESIUM ET ALUMINIUM HYDROXYDE 200 mg/ml

PROPANOLOL CHLORHYDRATE SIROP 0,5 mg/ml

Formulation pour 100 ml:

Propanolol chlorhydrate	0,05 g
Carboxyméthylcellulose sodique	1,00 g
Sodium citrate	0,21 g
Acide citrique monohydraté	0,28 g
Eau dépurée	72,28 g
Nipagine sodique	0,07 g
Saccharose sirop	32,23 g

Caractéristiques chimiques-physiques:

Poudre cristalline blanche ou blanchâtre, il est inodeur et avec un goût amer.
Soluble dans l'eau (1:20) et dans l'alcool (1:20).
p.f. = 163-166 °C.

Propriétés pharmacologiques:

Le propranolol a activité β-bloquant, il est un antagoniste compétitif des deux récepteurs β_1 et β_2, non cardiosélectif.
Il est utilisé dans l'hypertension.

Posologie pédiatrique:

2,5-5mg correspondant à 5-10 ml.

Preparation:

1. Solubliser la nipagine sodique dans l'eau dépurée.
2. Ajouter le sodium citrate et l'acide citrique monohydraté dans la solution.
3. Ajouter le propranolol chlorhydrate.
4. Ajouter la carboximéthylcellulose sodique peu à la fois, mélanger très lentament.
5. Ajouter le saccharose sirop.
6. Contrôler le pH. (il ne doit pas être superieur à 4,5).

Instructions et contre-indication:

Contre-indiqué pour les patients avec des maladies obstructives chroniques des voies aériennes.

Stabilité et conservation de propranolol:

Conserver dans des récipients bien fermés, à l'abri de la lumière et de l'air.

STABILITY STUDY OF THE PREPARED LIQUID PHARMACEUTICAL FORMS

Method:

STORAGE CONDITION	T (°C)	RH	PERIOD COVERED BY DATA	ANALYTICAL METHOD
Standard	25±2	60±5%	12 months, analysis at time zero (T0) and every 30 days (from TS-1 to TS-12)	UV-VIS spectrophotometric assay
Refrigerator	5±3	-	12 months, analysis at time zero (T0) and every 30 days (from TR-1 to TR-12)	
Accelerated	40±2	60±5%	3 months, analysis at time zero (T0) and every 30 days (from TA-1 through TA-3)	

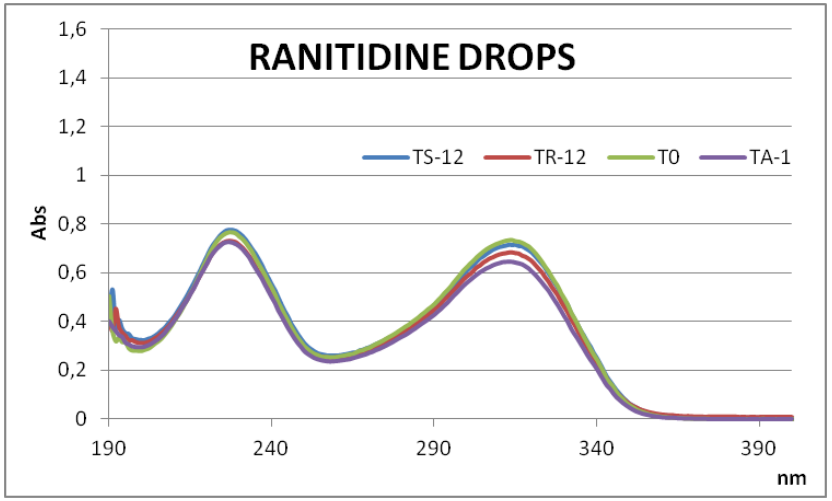
EMA Guideline on stability testing: stability testing of existing active substances and related finished products, 2003, CPMP/QWP/122/02, rev 1 corr

EVALUATION OF THE EXPIRATION DATE

STABILITY STUDY: RESULTS

PREPARATIONS PEDIATRIQUES	
SIROPS	*ACIDE ASCORBIQUE 10 mg/ml*
	CANREONATE DE POTASSIUM 1 mg/ml
	FER SULFATE 5 mg/ml
	IBUPROFENE 20 mg/ml
	PROPANOLOL 0,5 mg/ml
	RANITIDINE 15 mg/ml
	SALBUTAMOL 0,4 mg/ml
	VITAMINE B_6 1 mg/ ml
SOLUTIONS	*CAPTOPRIL 1 mg/ml*
	FUROSEMIDE 1 mg/ml
GOUTTES	*NIFEDIPINE 1 mg/gtt*
	RANITIDINE 4 mg/gtt
	SALBUTAMOL 0,2 mg/gtt
	VITAMINE B6 0,5 mg/gtt
SUSPENSIONS	*VITAMINE B COMPLEX 5,8 mg/ml*
	MAGNESIUM ET ALUMINIUM HYDROXYDE 200 mg/ml

The stability has been demonstrated for **12 MONTHS** for **all formulations**



BUT **housing** and **environmental** conditions are **not suitable** for a proper storage of the preparations

VALIDITY PERIOD: **3 MONTHS**

PAEDIATRIC FORMULATIONS: NON ONLY IN HAITI

EXTEMPORANEOUS SUSPENSION FOR ORAL USE

Total amount of solvent

each notch = 1 dosage unit

CAMEROUN

SUPPOSITORY

ANGOLA

QUALITY CONTROL AND QUALITY ASSURANCE

Galenics, in accord with the European Law (Ph Eur,), must guarantee "the quality as a fundamental support to the security and the efficacy"

D.C.

PHARMACEUTICAL FORMS TESTS

Ointments for skin application; Suppositories:
- Verify of accuracy of followed procedures
- Control of aspect
- Control of the amount to sell
- Control of the solidity of packing

Stiff capsules:
- Verify the accuracy of followed procedures
- Control of aspect and solidity of capsules
- Control of the number of capsules prepared
- Mass uniformity of capsules

Liquid medicinal products:
- Verify the accuracy of followed procedures
- Control of the amount of product to sell
- Control of the solidity of packing

RAW MATERIALS: Organoleptic control
Melting point

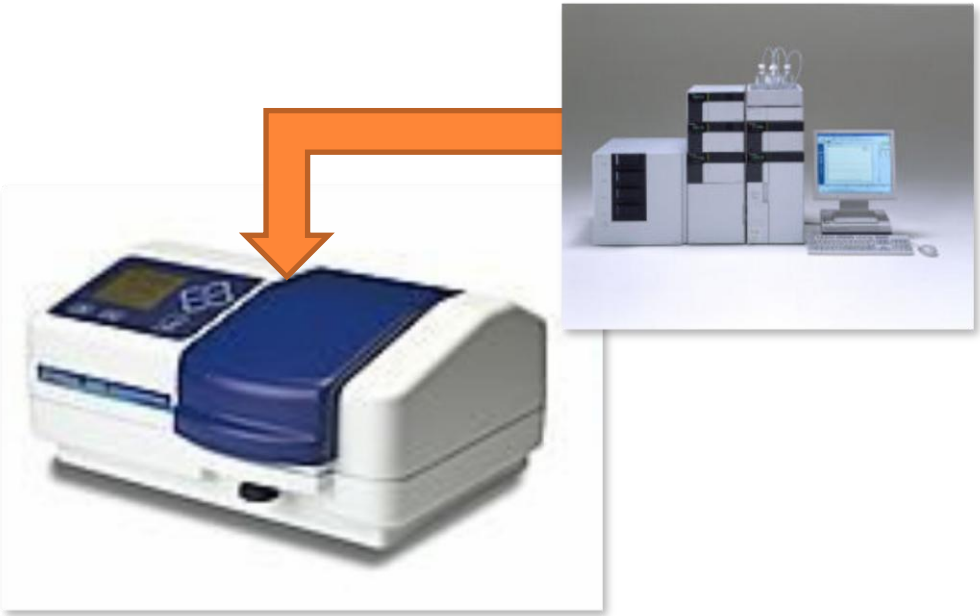
ITALY

STABILITY TESTS (EMA)

PHARMACEUTICAL FORMS TESTS (Ph Eur)
Uniformity of content (2.9.6)
Uniformity of mass (2.9.5)
Disintegration (2.9.1)
Friability (2.9.7)
Hardness (2.9.8)
Sterility (2.6.1)

QUALITY CONTROL AND QUALITY ASSURANCE

ANALYSIS	METHOD REF.	ACCEPTANCE CRITERIA
General aspect	Visual	Posological unit integrity
Uniformity of content	Ph. Eur. 7 ed. Assay 2.9.6	Each individual content is between 85% and 115% of the average content (10 dosage units)

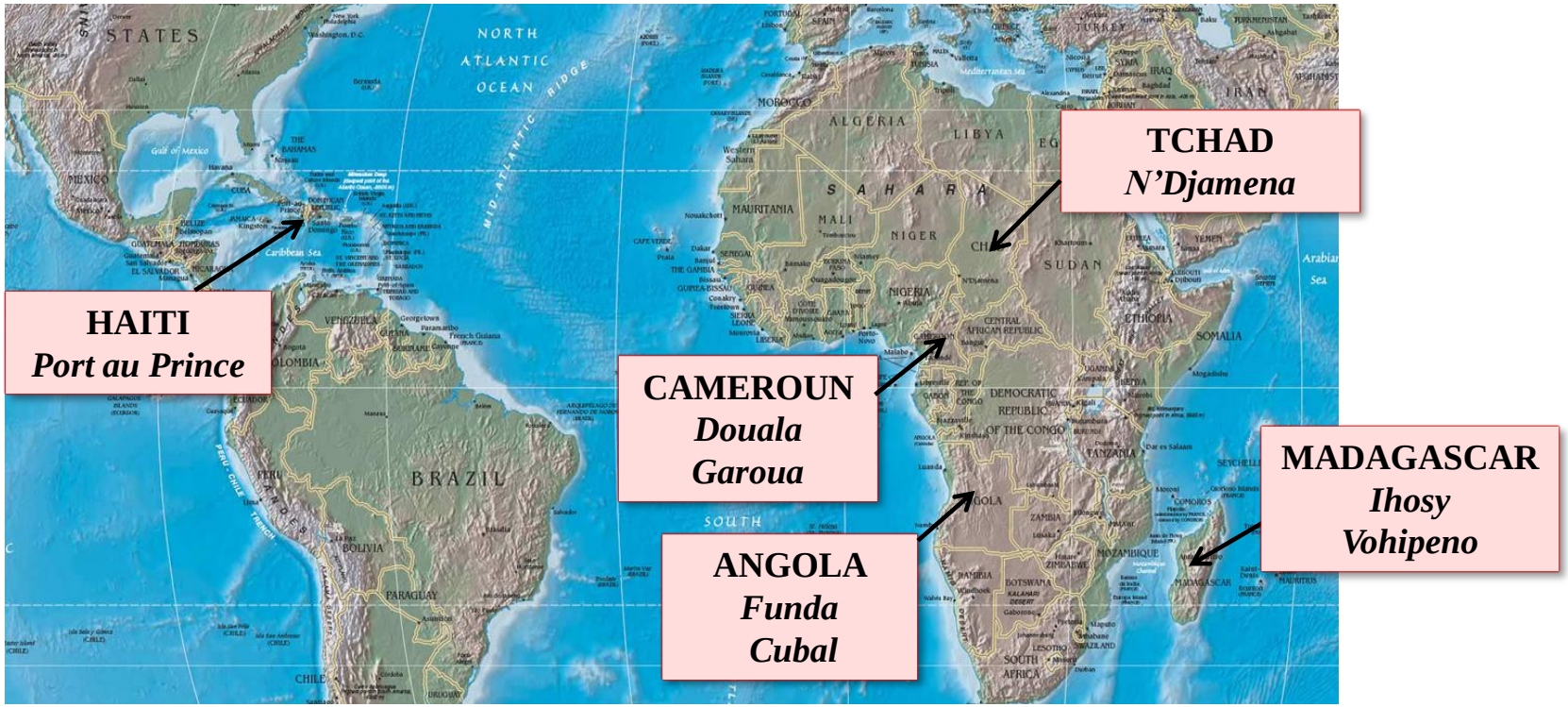


SPECTOPHOTOMETRY UV/VIS

STANDARDIZATION OF RESULTS
LOW COSTS
SIMPLE EXECUTION

*"…reuse, repair equipment and goods instead of throwing them in a landfill, **exceeding the consumerist obsession of the obsolescence of objects** and the tension to the new…"*
A. Salza "Niente. Come si vive quando manca tutto. Antropologia della povertà estrema", Sperling & Kupfer 2009

A.P.P.A.® LABS IN THE WORLD



ANGOLA – Cubal, Nossa Senhora de Paz hospital, Compañia de Santa Teresa de Jesus.
ANGOLA – Funda, A.M.E.N. ONG health care facility.
CAMERUN – Douala, La Bethanie hospital.
CAMERUN – Garoua, Notre Dame des Apôtres hospital, Djamboutou.
CIAD – N'Djamena, Le Bon Samaritain hospital.
HAITI – Tabarre Chateaublond, N.P.H. Saint Damien paediatric hospital.
MADAGASCAR – Vohipeno, Henintsoa hospital.
MADAGASCAR – Ihosy, Eglise Catholique Apostolique Romaine medical center.

A.P.P.A.® 2005-2013

8 GALENICS LABS IN DEVELOPING COUNTRIES

ECONOMIC INVESTMENT IN RAW MATERIALS: ≈ 100.000 €

ADMINISTERED DOSES:
i.e. cps ≈ 7.500.000

A GOOD REASON TO GO ON
BUT WITH THE AIM OF
BECOME LESS AND LESS INDISPENSABLES