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

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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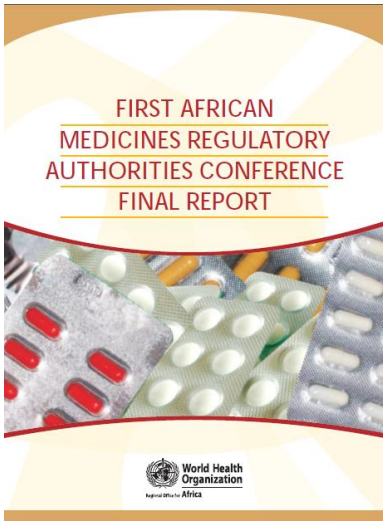
# Alma-Ata Declaration - 1978

*"… **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

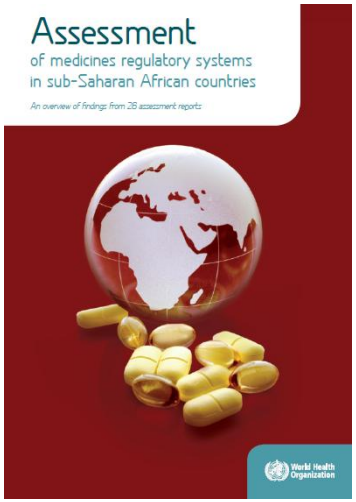



**Problem to be addressed**

- 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

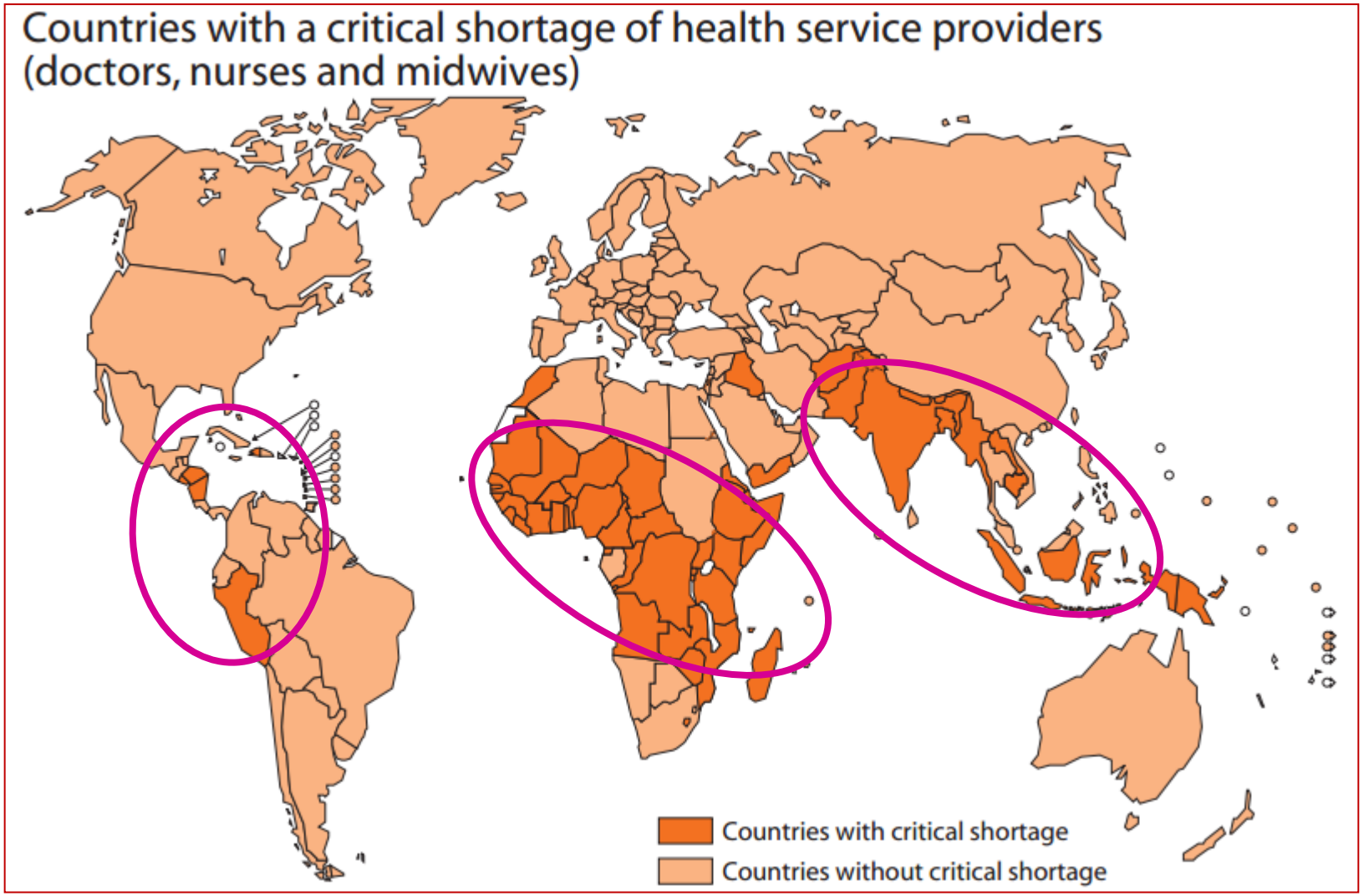
# 2010




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

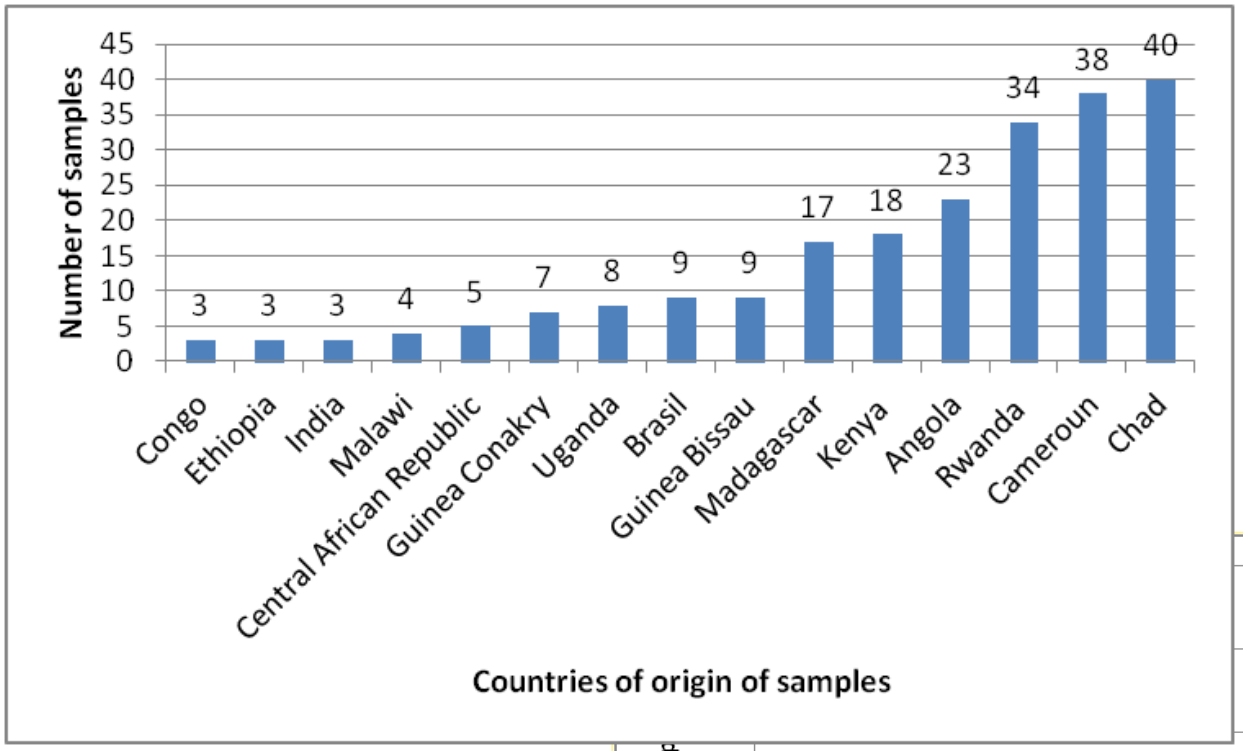
*«these products contain the right components, with an incorrect concentration and/or formulation resulting in defective quality specifications. In the vast majority of cases, they are devoid of any therapeutic efficacy»*

## "CRIMINAL" COUNTERFEITS

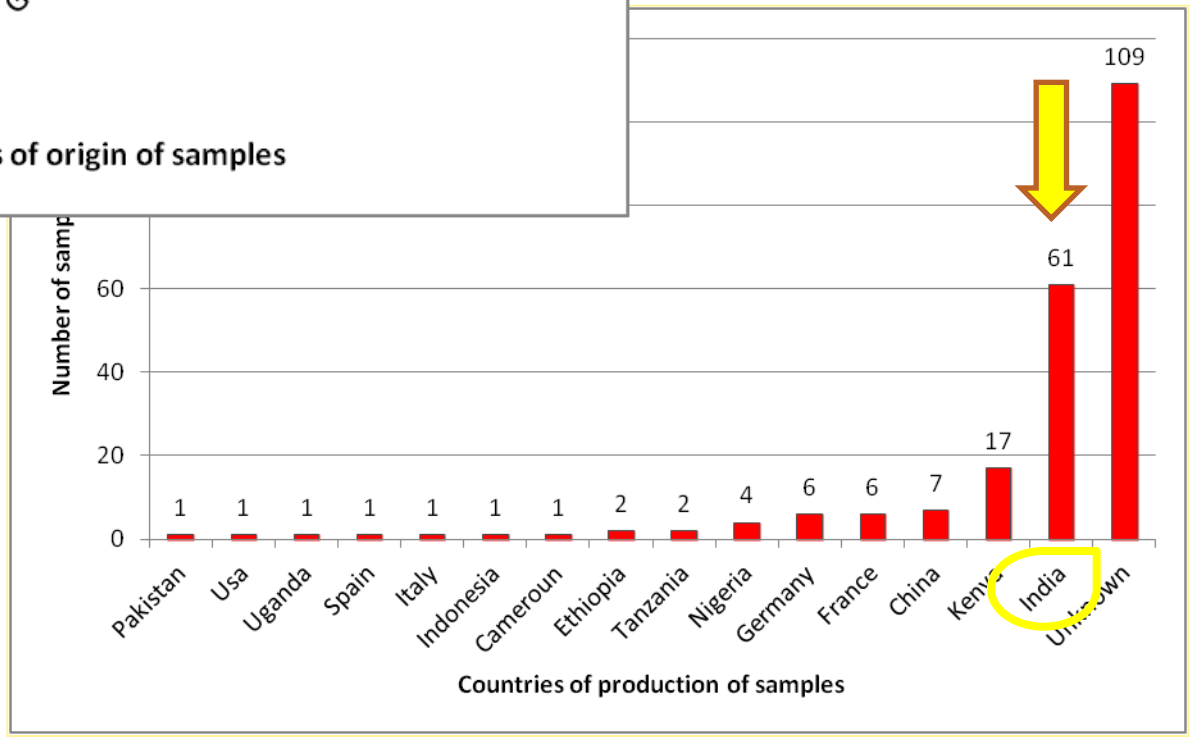
*«they are apparently similar to the original medicinal product, but do not contain any active ingredient and can even include harmful or toxic substances. They are usually sold at high prices and for the treatment of serious pathologies. Consequences for users of criminal counterfeits can be fatal»*

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

# COUNTERFIET MEDICINES IN DC: ANALYSIS OF THE PHENOMENON



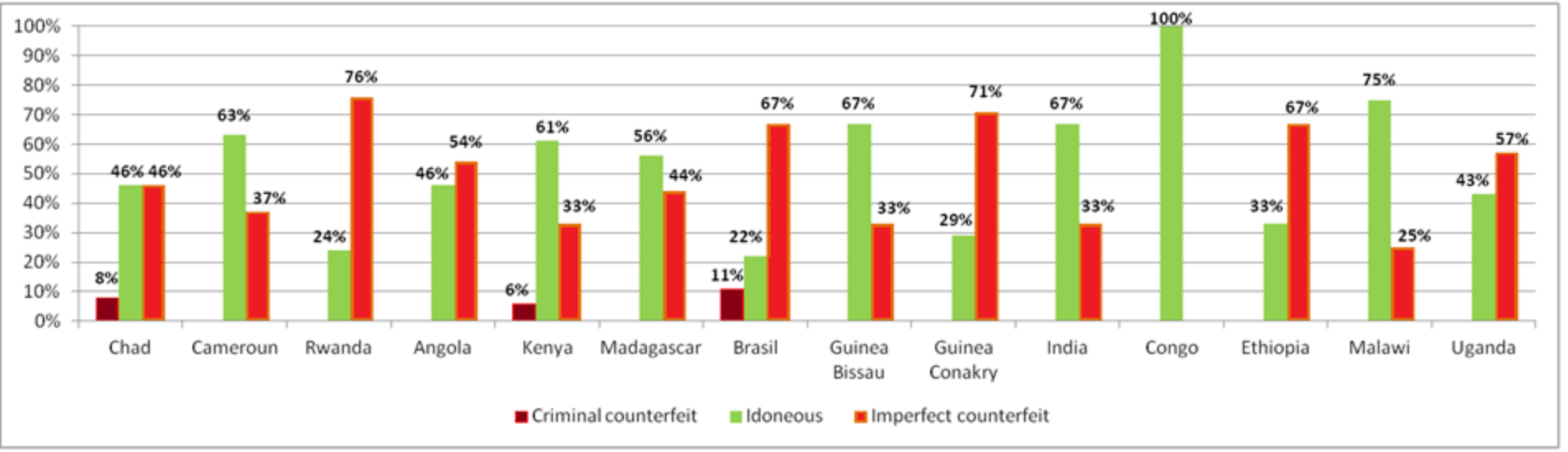

**Analysis of 196 samples of medicinal products**

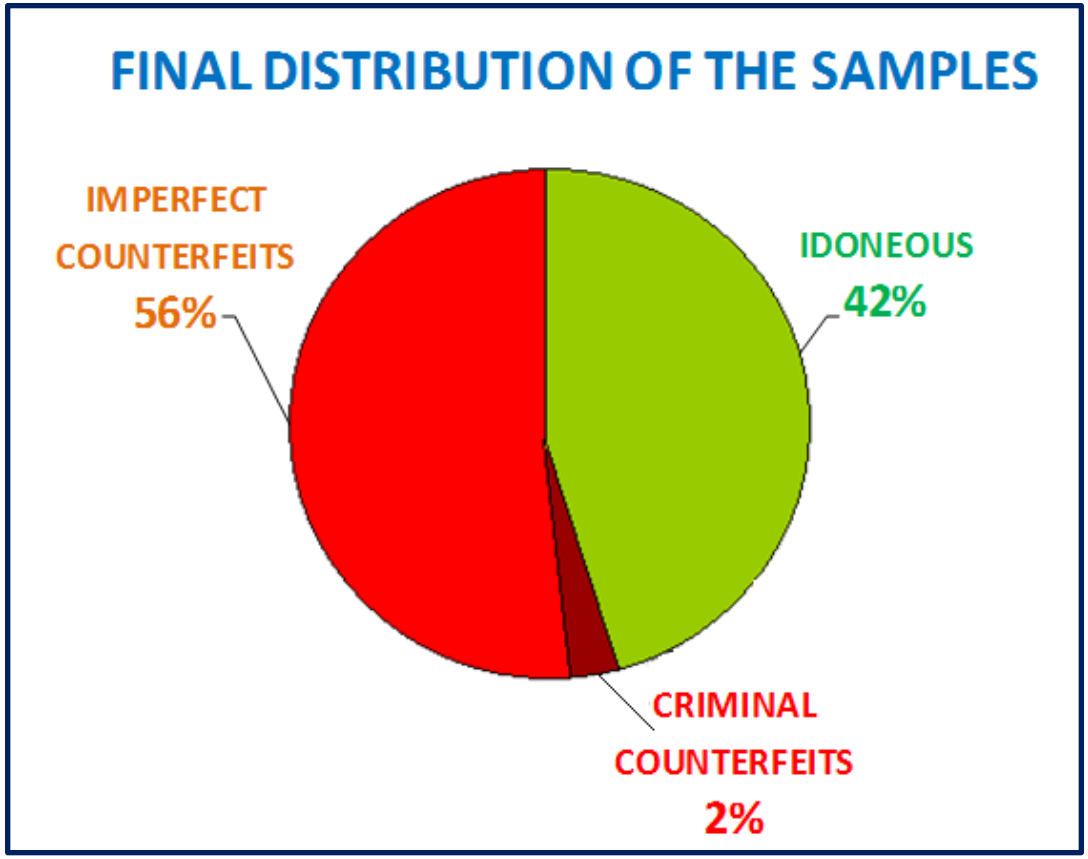



F.Baratta, A. Germano, P. Brusa

**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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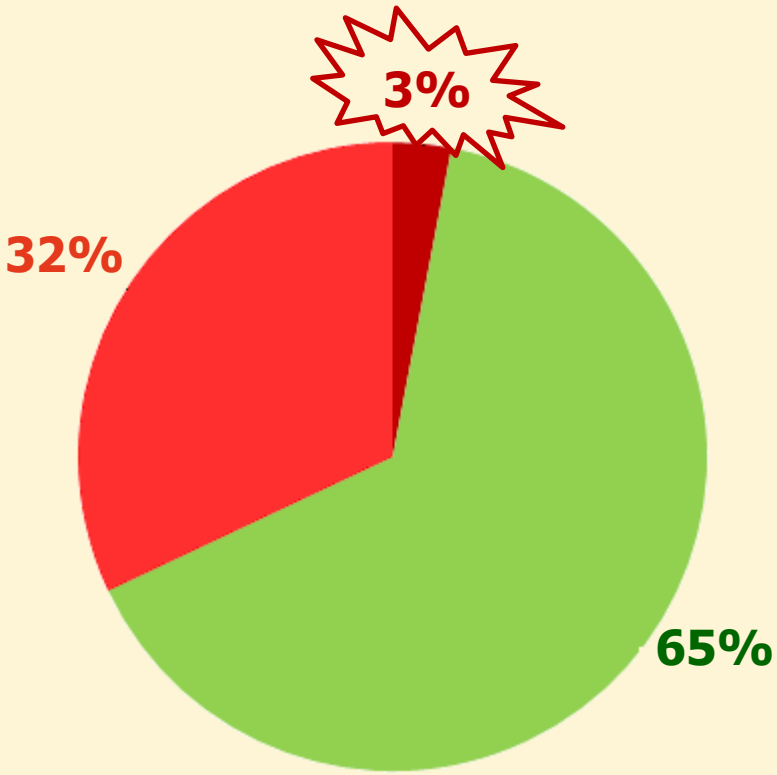
## CAMEROUN 2012




Criminal counterfeit

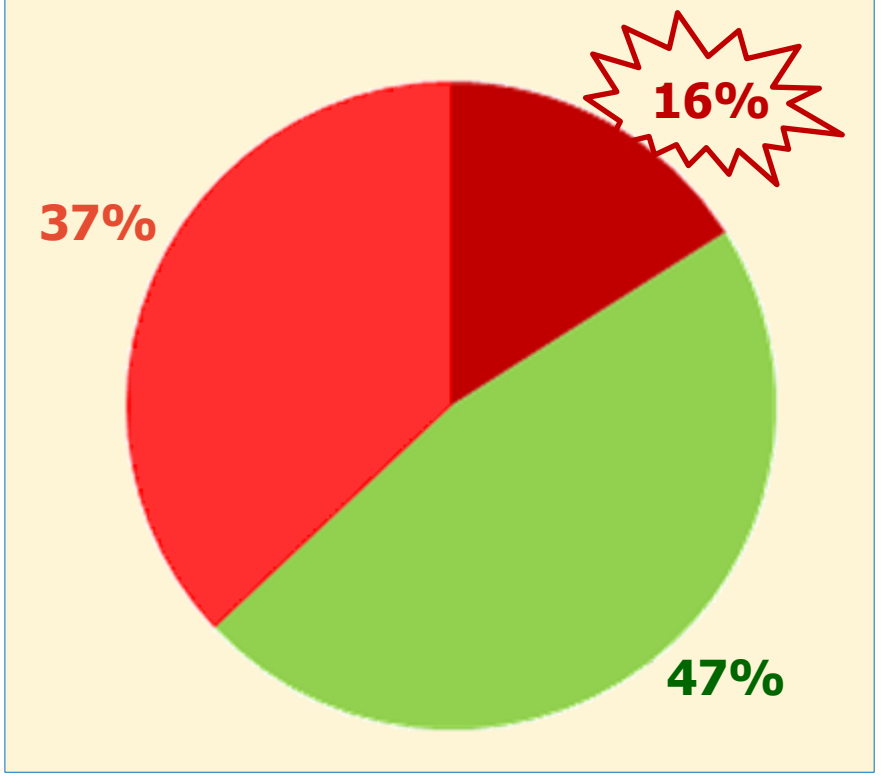
Idoneous

Imperfect counterfeit

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)

## CAMEROUN 2013



# 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.

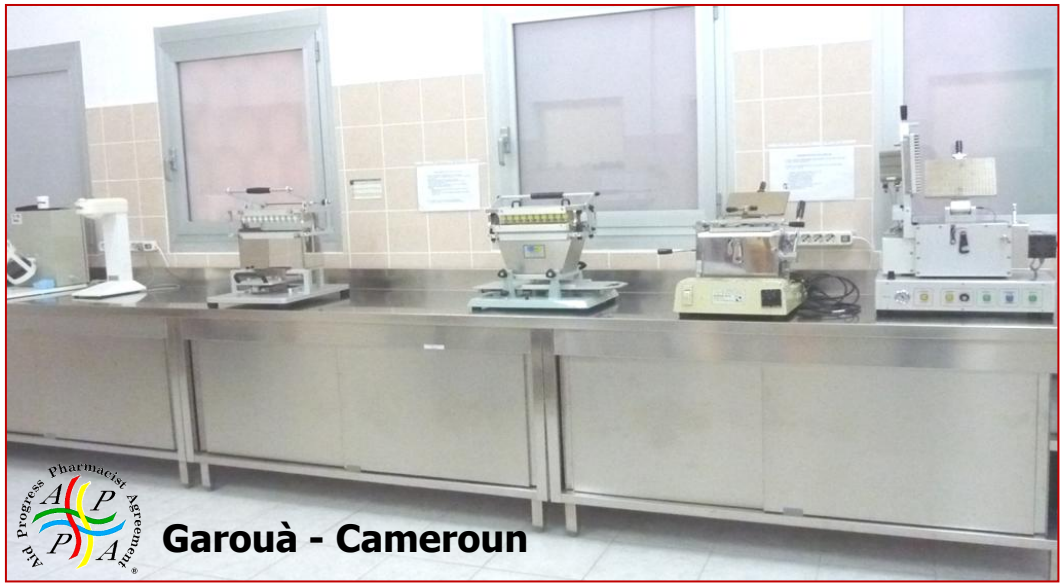
# WHY GALENICS IN DC?

**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

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 | 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 | | | |
| 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 | | | | | | | | |

| PREPARAZIONI LIQUIDE AD USO ORAL |
|---|
| SOLUZIONI |
| captopril |
| furosemide |
| SOSPENSIONI |
| amoxicillina |
| carbocisteina |

| | |
|---|---|
| cloramfenicolo | |
| eritromicina | |
| magnesio e alluminio idrossido | |
| metronidazolo | |
| vitamina B complex | |
| SCIROPPI | CAM 1 |
| acido ascorbico | |
| carbonato 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 | X |
| ranitidina | X |
| salbutamolo | X |
| vitamina B6 | X |

| 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.

# *A.P.P.A.*® LABS HANDBOOK

**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**

# *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 $\beta_1$ et $\beta_2$, 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) | |

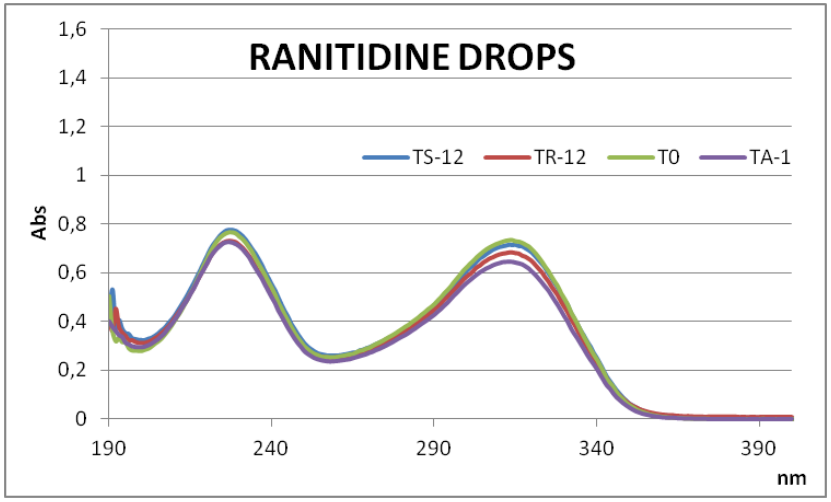
**EMA Guideline on stability testing**: stability testing of existing active substances and related finished products, 2003, CPMP/QWP/122/02, rev 1 corr

## 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

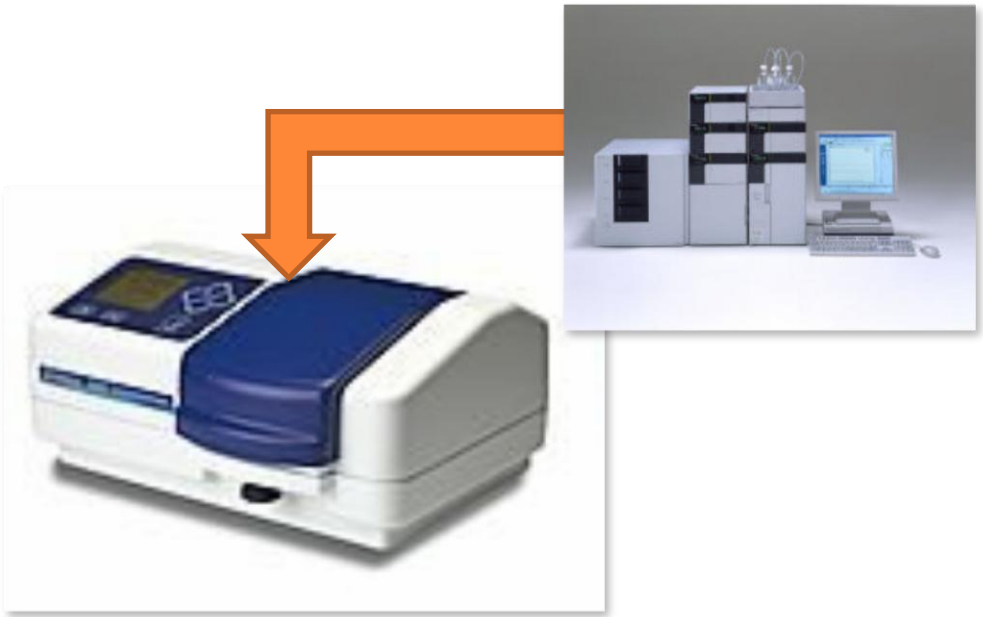
ITALY

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) |

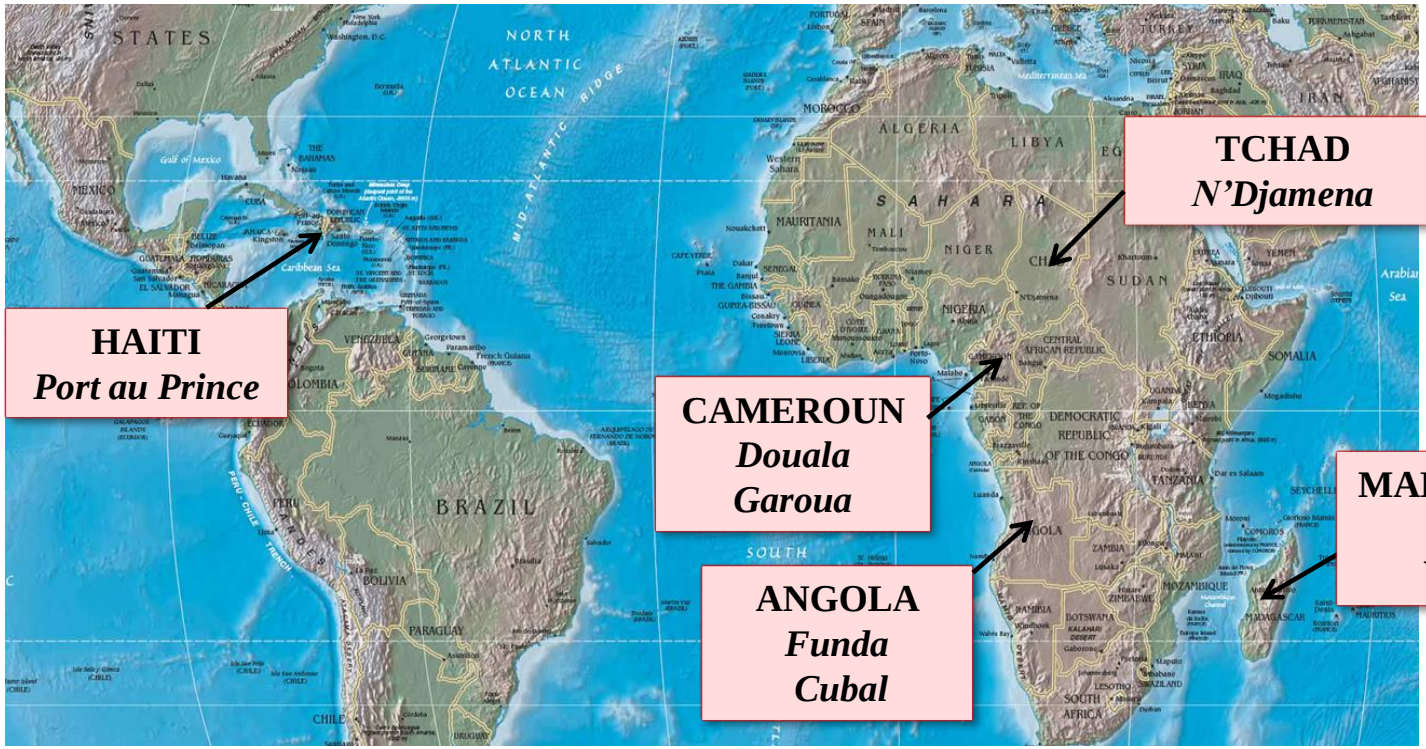


**SPECTOPHOTOMETRY UV/VIS**

**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**