



PANDRH Update

GCG/ICH

Brussels, May 2005

PANDRH CONFERENCES

- **I Conference: November 1997**
 - Establishment of an Hemispheric Forum
- **II Conference: November 1999**
 - Establishment of PANDRH
- **III Conference: April 2002**
 - Support to harmonization processes in the Americas and preliminary proposals from priority PANDRH WGs
- **IV Conference: March 2005**
 - Review of 10 technical documents prepared by PANDRH WGs

STEERING COMMITTEE

2005 - 2007

NRA

NA:

CA*:

CR*:

ME*:

AA:

Members

Mexico

Costa Rica

Trinidad & Tobago

Argentina

Colombia

Alternate

USA

Panama

Barbados

Chile

Bolivia

Pharmaceutical Industry

One rep from FIFARMA

One rep from ALIFAR

PANDRH Support to NRA

GMP: Guideline for GMP Inspection (Final)

Study Initial (1997); Follow up (in process)

Proposal for NRA structure for QA (draft)

GCP: Good Clinical Practice (Final)

Study Initial (2000)

**BE: Scientific criteria and strategy to
implement BE studies (Draft)**

Study Initial (2000) and follow up (2004)

PANDRH Support to NRA

- **Drug Counterfeiting**
 - **Road Map (final)**
 - **Executive Unit (final)**
 - **Definition and classification (final)**
 - **Indicators (final)**

- **Pharmacopoeia**
 - **Process for harmonized monographs**

- **External Quality Control Program**

PANDRH Support to NRA

- **Registration:**
 - Common requirements (draft)
 - Comparative Study (2003)

- **Classification:**
 - Criteria for classification to OTC (Final)
 - Definition and criteria for promotion (final)
 - Information Requirement in labels and prospects (final)

PANDRH Support to Training

DEVELOPED

- GMP (Basic & Validation (WHO))
- GMP (FDA))
- BE (Basic & In vitro method (FDA))
- HPLC Practical Application

IN PROCESS

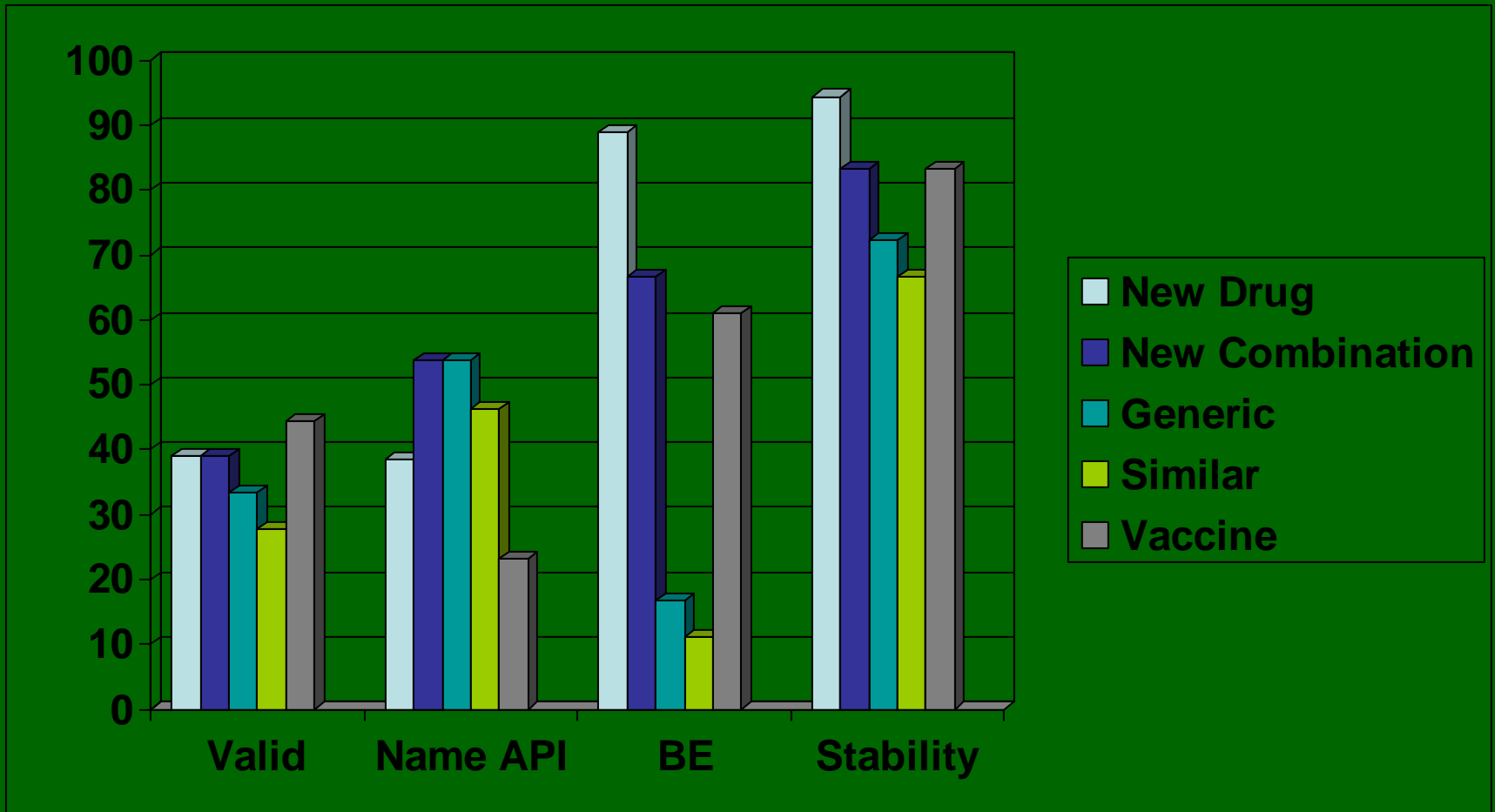
- GMP Guideline Implementation
- Combat drug counterfeiting
- GCP for NRA
- GLP
- Drug Registration/ Evaluation of dossiers
- BE Module 2 & 3 (in vivo & data analysis)

PANDRH WORKING GROUPS

1. GMP
2. BE
3. GCP
4. Counterfeit
5. Classification
6. Registration
7. Pharmacopoeia
8. Medicinal Plant
9. Pharmacovig
10. Vaccine
11. GLP
12. Drug promotion

REGIONAL DRUG REGULATION

Registration requirements



Criteria by Product

1. Drug

**New, Generic, Similar,
Essential**

**Changes: composition,
indication, Strength**

Association

Change to OTC

2. Biologics

Vaccine

Hemoderivate

Biologic

1. Herbal product

Herbal-medicine

2. Cosmetics

Cosmetic-Drug

3. Food

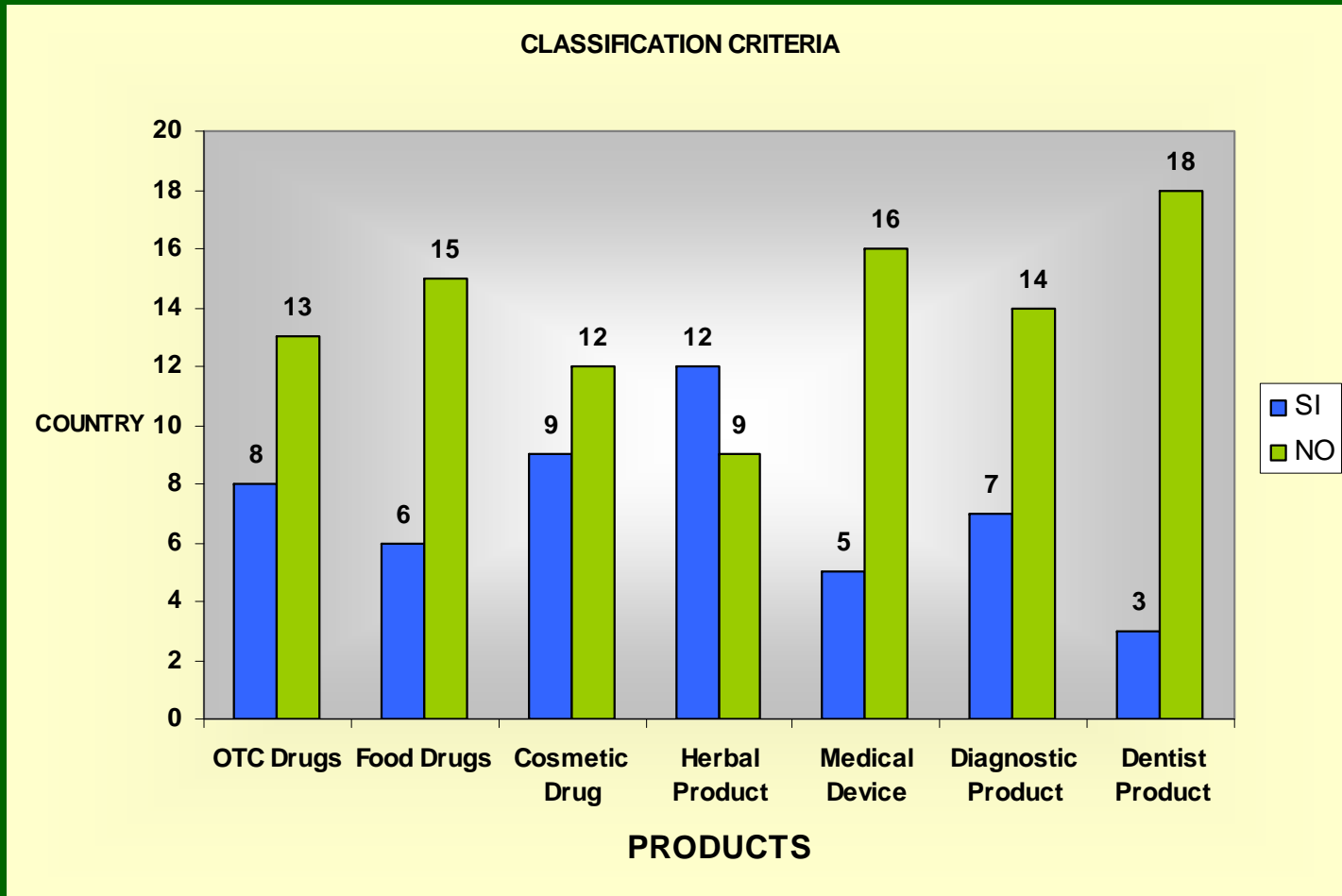
Food-Drug

4. Medical Devise

5. Diagnostic

6. Dentist drug products

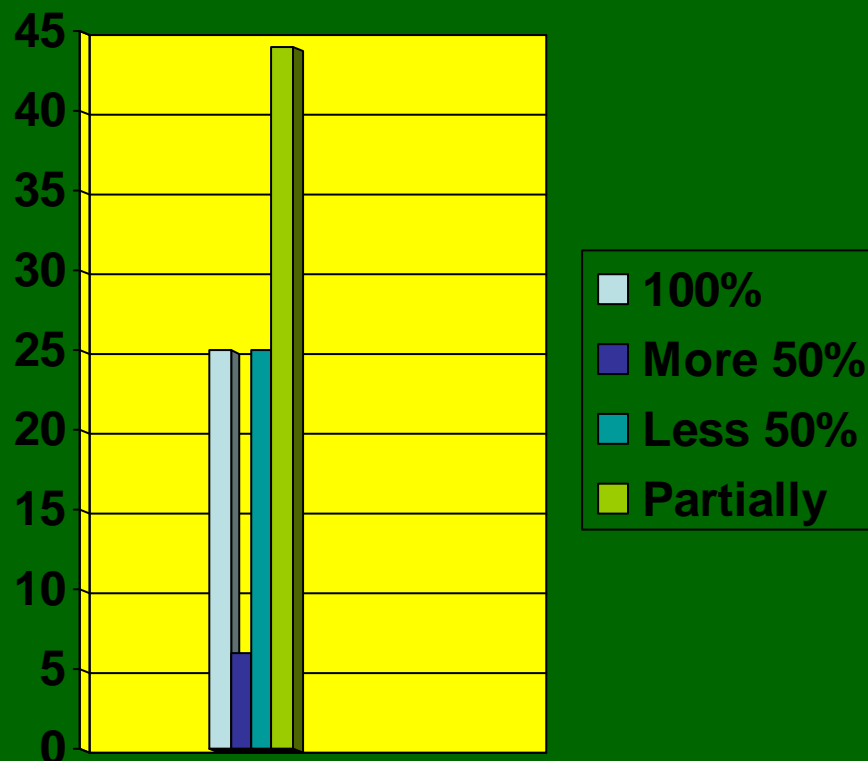
Criteria for Classification



GMP: WHO 32 Report-Annex 32 (1992)*

Areas of differences:

- Active ingredients
- Inspection and quality audits
- Contract production
- Sterile products



EQCP: ASSESMENT*

- **100%** High-performance liquid chromatography (HPLC)
- **24%** Staff to implement the GLP
- **95%** Equipment for dissolution tests
- **43%** Self-financed
- **29%** Operational Manuals as required by ISO
- **24%** Adequate buildings to implement the GLP

WG/GCP Clinical Trials

- **Until recently clinical trials were concentrated in developed countries**
- **The number of patients enrolled in international multi-centre clinical trials has increased in some countries of the Americas**
- **In 1993 2.1% of clinical trials were done in LA; in 1997: 5.1% and in 2000: 7.5%. (IMS Health)**
- **L.A. has been included in early phases of new drug development. There are more sites, investigators, committees, CROs, and research-related staff in pharmaceutical companies**

WG/BE Study on BE in the Americas*

20 countries responded the survey (18 represents 70% of population of LC%C)

NRA are increasinly developing legislations for BE studies (compared with survey in 2000)

50% NRA have legislations on BE

45% NRA have resources to authorize and evaluate protocols & final reports

20% NRA have resources to inspect BE study implementation

40% NRA have training activities in BE (Statistic)

Application WHO list of API for BE requirements in American Region*

- Most countries require BE studies on drugs used for high health risk.
- Four of the 96 API commonly require BE studies in all 10 countries: valproic acid, carbamazepine, cyclosporine and phenytoin.
- USA has the higher number of API (88) requiring BE studies followed by Canada (60)
- LA countries with more API requiring BE studies: Cuba (40), Mexico (39) and Brazil (32)
- LA countries with less number of API with BE study requirements: Colombia (5) and Costa Rica (7).

NEXT STEPS for PANDRH

IMPLEMENTATION and continue the
DEVELOPMENT of norms, guidelines, new
proposals

THANK YOU