The Caribbean Regulatory System Initiative

Country Perspective - Suriname

VIII Conference of the PANDRH

Mexico City, Mexico

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Outline

- Some demographic data
- Pharmaceutical column
- Pharmaceutical Regulation
- Registration challenges
- CRS opportunities for Member States
- Member States Responsibilities
- Prerequisites for succes

SURINAME

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

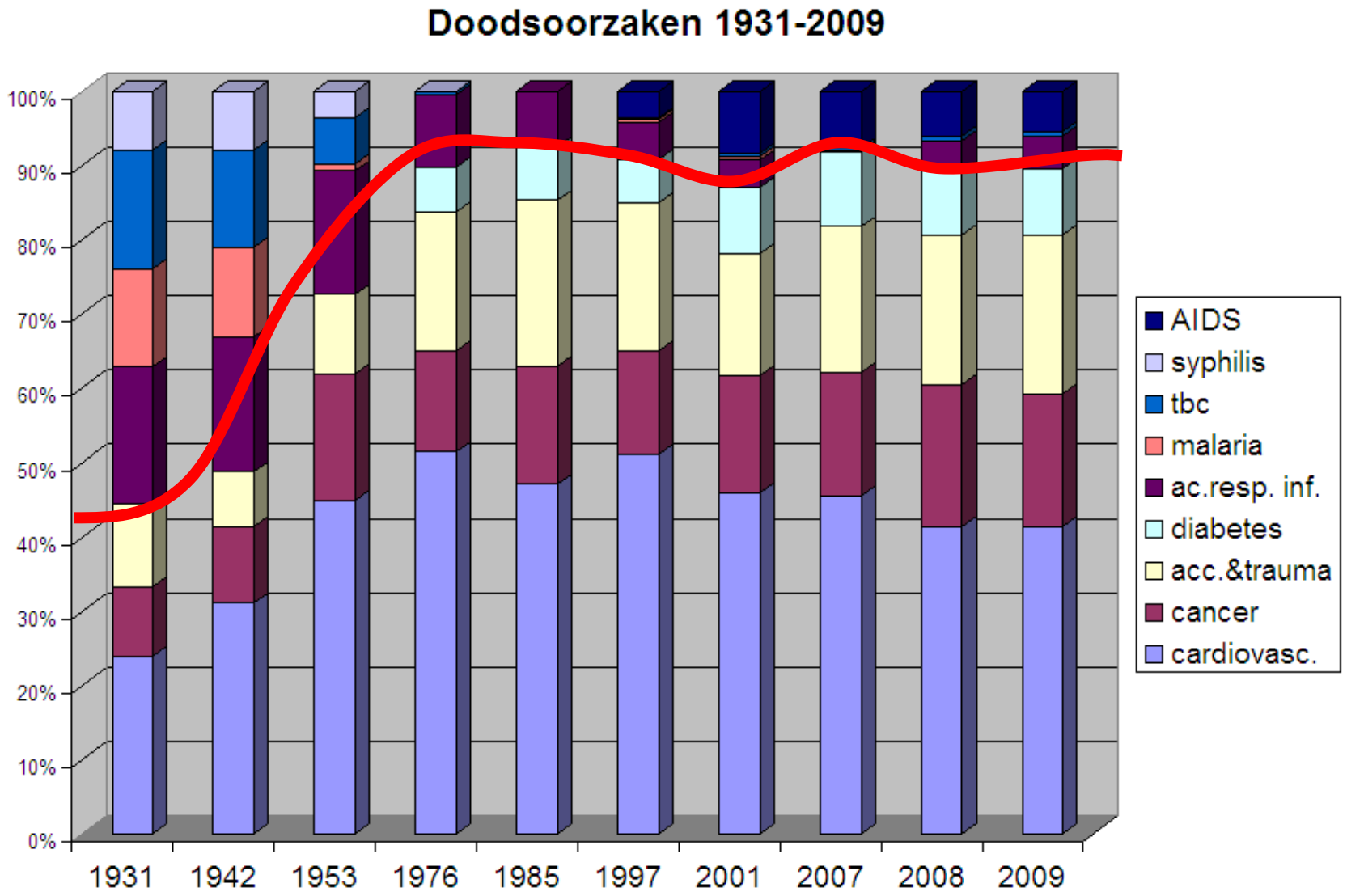
Red PARF
Red Panamericana para la Armonización de la Reglamentación Farmacéutica
Organización Panamericana de la Salud
Organización Mundial de la Salud
Américas

Suriname

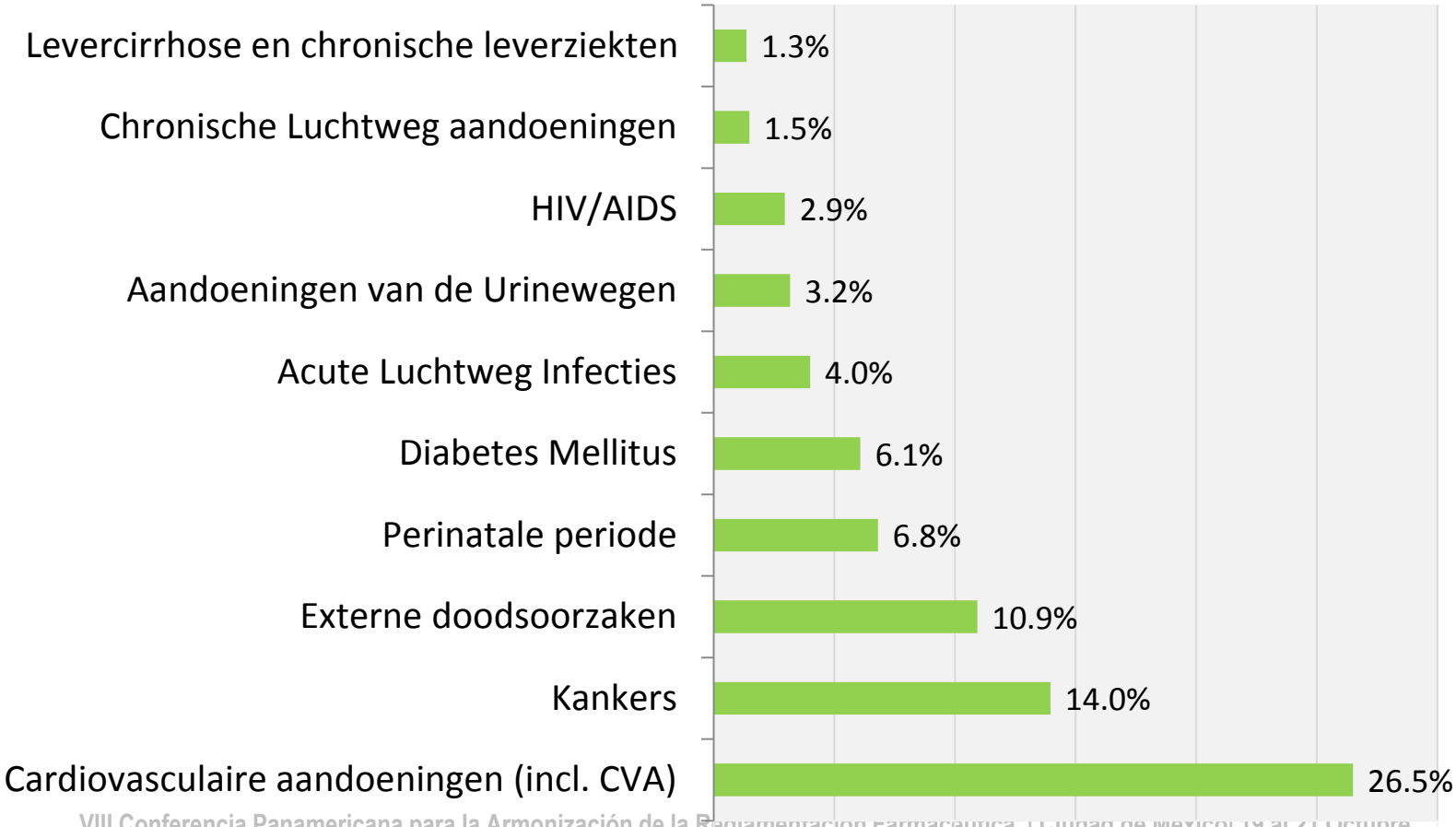
- Area: 63,251 sq mile
- Inhabitants: 541,638 (census 2012)
- Capital Paramaribo: 60% habitants
- Life Expectancy 2012: 72.4 years

  (females: 75.5 , males: 69.4 years)
- GDP: 4.878 billion (world bank 2015)
- Average population growth: 1.2%

Leading causes of deaths



Doodsoorzaken in Suriname, 2013



NMP – Policy components

1. Implementation and management
2. Traditional medicine
3. Funding
4. Procurement and distribution
5. Medicines legislation and regulation (Quality)
   - Additional quality note (2010)
6. Rational medicines use (prescription, dispensing and use)
7. Selection
8. Research and development

PAHO - SUR

MoH - SUR

Prof. dr. E.N. Parabirsing Instituut voor de Farmaceutische Regulatie

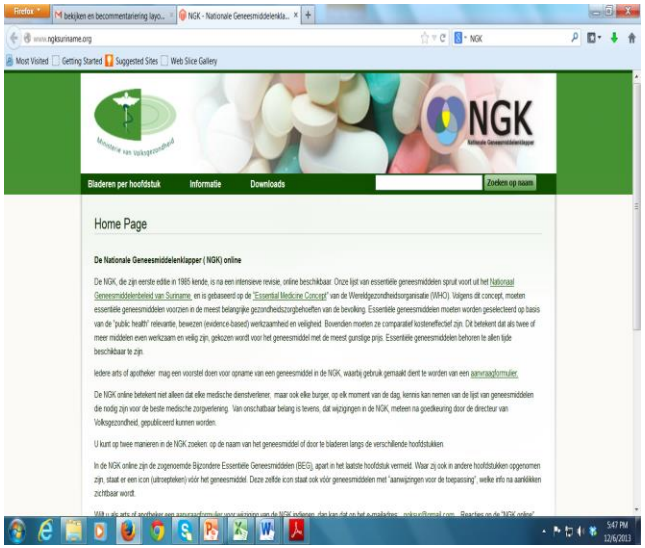
Registration Committee

Quality Control Lab - BGVS

Universal Health Coverage

NGK 4de editie

NGK online: http://www.ngksuriname.org/

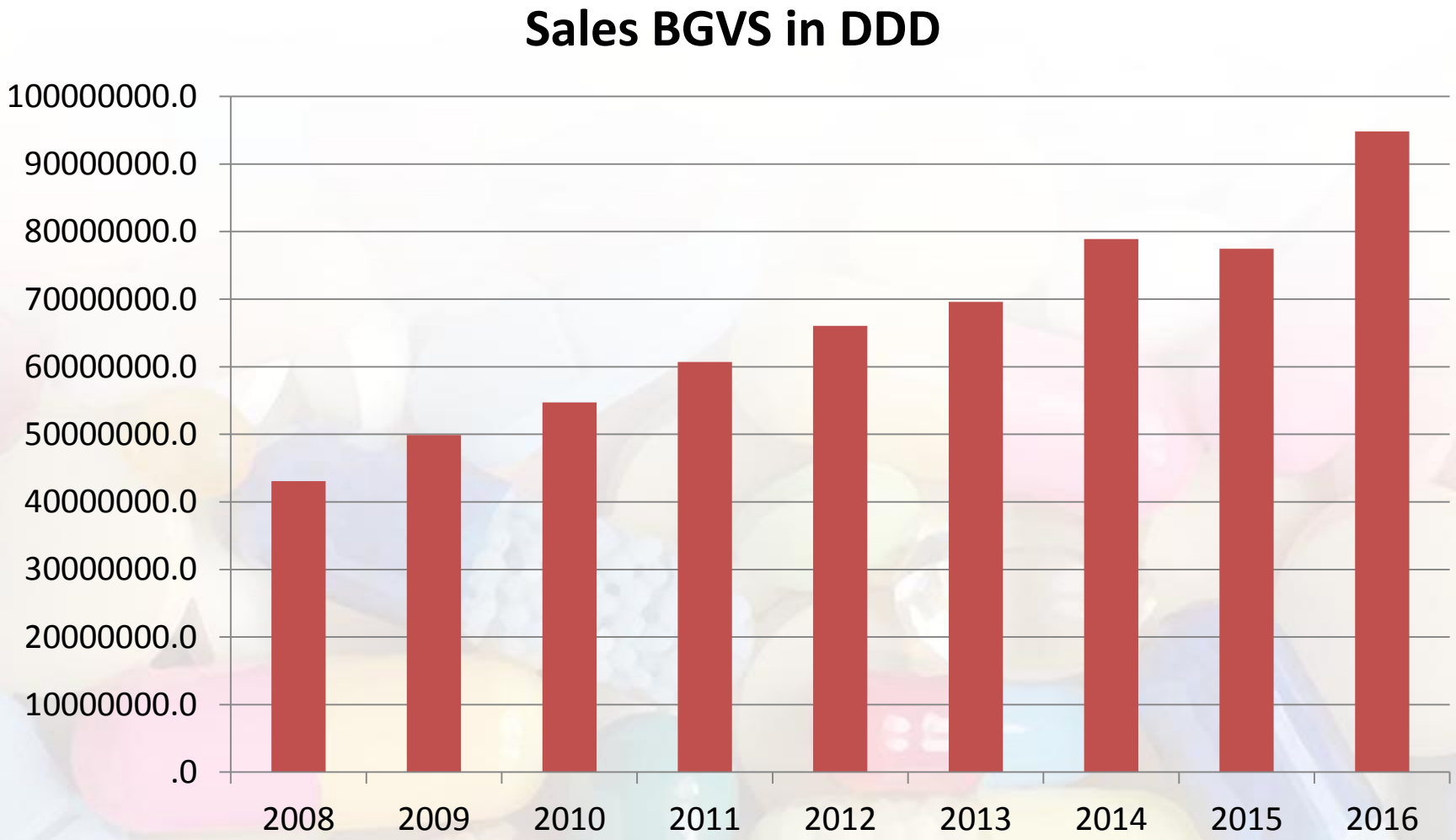


493 medicines/ diagnostics

Pharmaceutical Sector

- **Regulation**
  - Registration Comittee
  - Pharmaceutical Inspectorate (as part of Inspectorate MOH)
  - Pharmacovigilance (passive)
  - QA laboratoratory (Part of PANDRH Lab. network)
- **Market:**
  - Pharmacy licensing responibility of MOT & MOH
  - Importers and wholesalers have to comply with minimal standards (MOH/ PhI)
  - Prive regulation (MOT)
  - Each Medicines Import by permits (MOH/PhI & MOT)/ registered medicines; exemptions based on assessment reference authorities
- **Annual turnover: ca. USD 24-36 million**
  - gvt procurement complany (BGVS) ca. 60-70% (in volume)

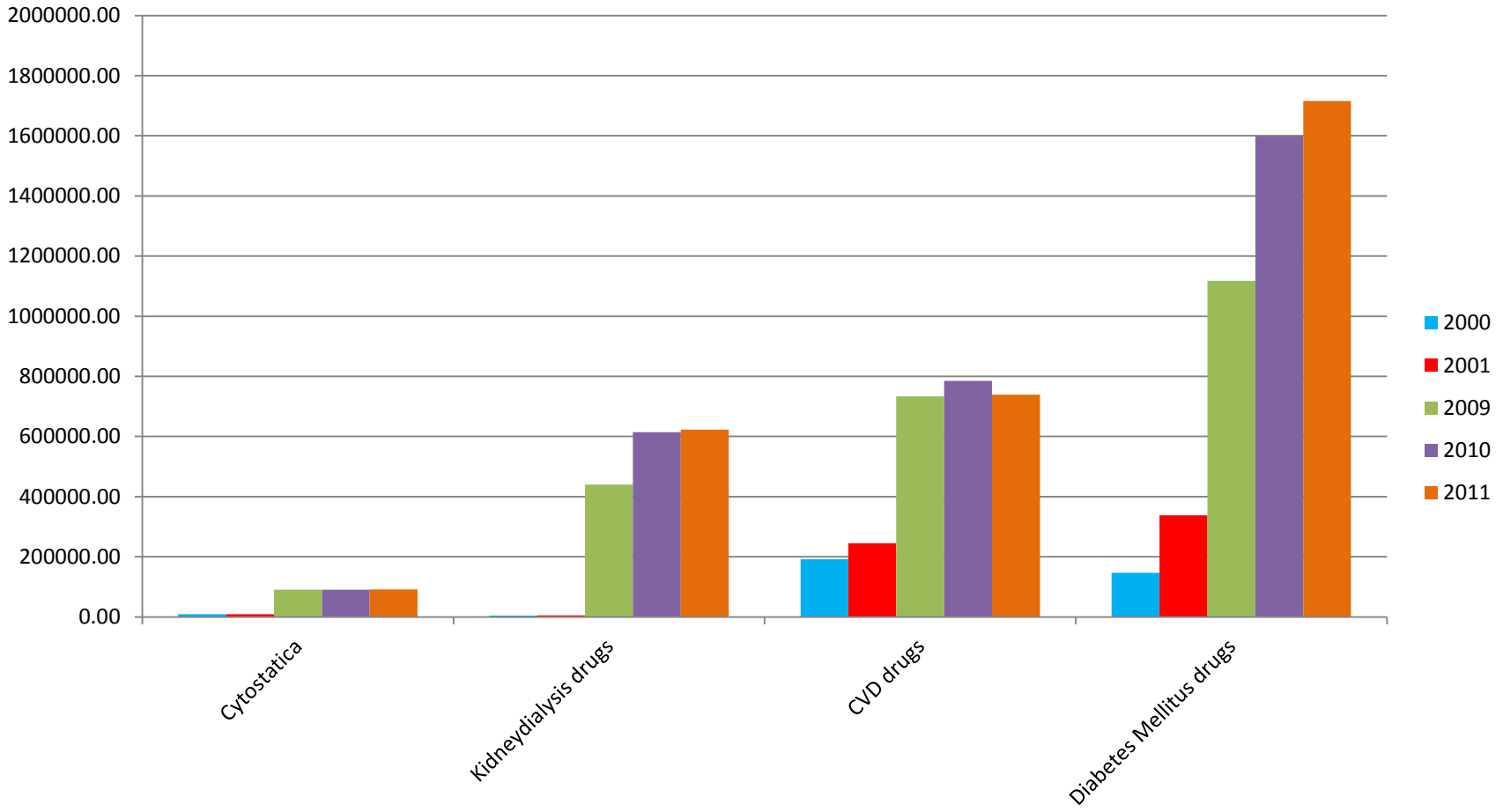
Development volume turnover



BGVS: countries of origin (%)

	DDD's	VALUE
Europe	32.2%	75.7%
India	44.2%	12.0%
America's	4.6%	4.3%
Malaysia	15.8%	6.3%
Other	3.2%	1.7%

Other factors of interests: Access to Quality Medicines



medicines regulatory authority

- network that administers the full spectrum of medicines regulatory activities, usually at a national level, including at least the following functions and sometimes others:
  - Marketing authorization for new products and variation of existing authorizations;
  - Quality control laboratory testing;
  - Good Practice inspections/audits and licensing of manufacturers, wholesalers, other distribution channels, clinical trial centres, and Laboratories responsible for quality control and toxicology testing;
  - Adverse drug reaction monitoring (pharmacovigilance; passive)
  - Provision of medicines information and promotion of rational use of medicines;
  - Control of promotion and advertising (limited)
  - Monitoring of Medicines Utilization;
  - Enforcement operations

PAHO evaluation: Key positive findings

- Elements of a Regulatory System in place
- Legal framework provide overall sustainability
- Registration Committee well established by law and processes well documented
- Inspectorate formed

Suriname registration basics

- Registration since 1980 (by law)
  - QES/ documentary process to be updated
  - Use of CRS template
- Registration Committee (5-7 specialists)
  - Pharmaceutical/ Biological/ Medical Sciences
  - No specific regulatory science competencies
  - Works independently
    - Lack of a system

PAHO evaluation RECOMMENDATIONS

- Define the MNR System
- Update legislation
- Develop quality management system for documentation
- Improve public communication and outreach
- Create code of conduct for regulators
- Enhance MA registry functionality
- Develop guidance to improve MA process as Risk/Benefit assessment
- Improve utilization of regulatory decisions, reports, and background information from other NRAs
- Clarify different requirements for innovative and generic drugs
- Plan for internal human resource development and continuing training
- GMP inspection of local manufacturers and registration of local products

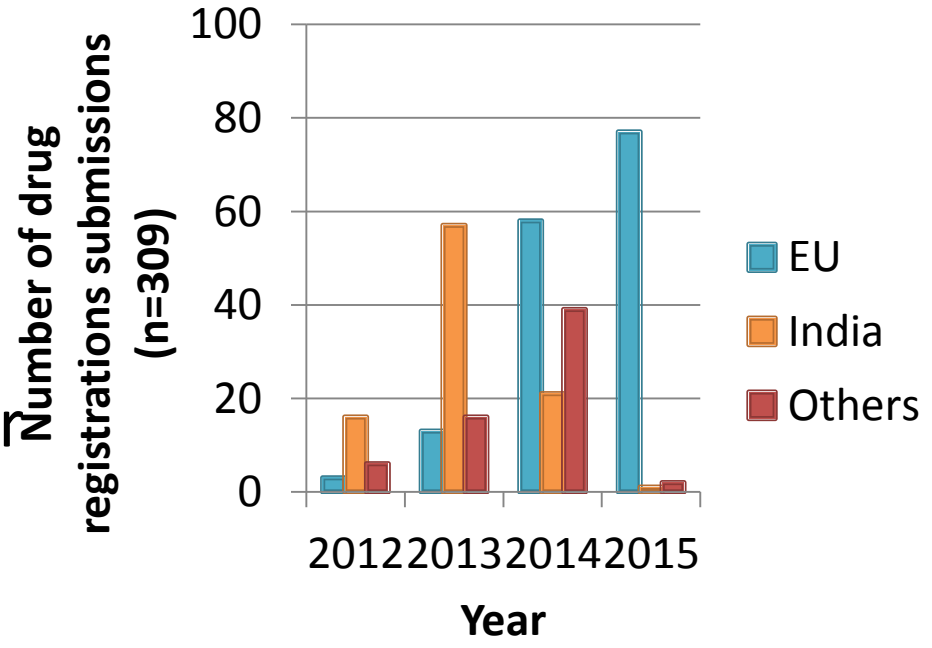
PAHO evaluation RECOMMENDATIONS

- Use of PSUR for safety monitoring
- Create institutional relationship with immunization program related to AEFI
- Establish guidelines for internal procedures on pharmacovigilance Risk/Benefit assessment
- Establish guidelines for regulated MAH
- Define guidelines for GCP
- Develop official guidance for GMP activities
- Implement quality management system for inspections
- Develop risk-based criteria for inspections
- Develop official guidance for using GxP, including training inspectors for these practices
- Implementing the QMS
- Code of conduct and conflict of interest

Current situation

- Maintenance of: 2675 (active) registrations

- Pending admissions:
  - 309 drug registration submissions
  - 151 incomplete dossier submissions
  - 600 variations



Evaluation was done end December 2015

Key bottlenecks

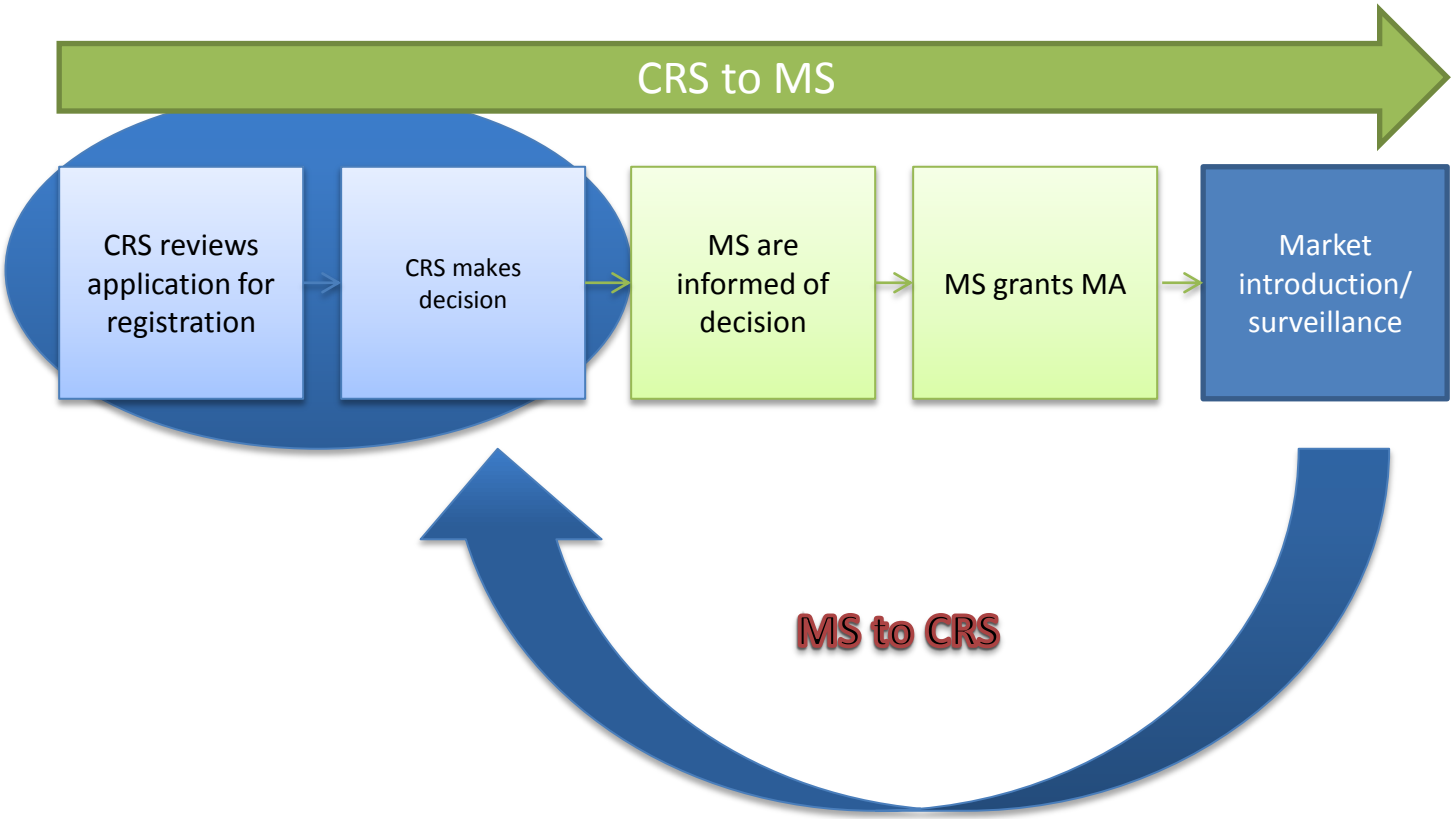
- Maintenance of the registered product dossiers
- Low handling fees
- Insufficient ICT facilities and staff
- Outdated law and policies
- Policy gap on multiple importers vs single MA/ registration holder
- Lack of competent dossier reviewers
- Unclear requirements and guidelines for dossier submission procedure
  - Non-prequalified sources
- Lack of resources for modernization and training
- Not all EML have registered dosage form
  - Admittance of non-registered medicines on the market (PhI/ evaluated by reference NRA

CRS Basis and Justification

- Having limited capacities for the regulation of medicines and other health technologies has a negative impact in public health outcomes and hinder access to essential medical products.
- Developing and strengthening regulatory systems constitute a challenging task in particular for small nations with limited resources.
- Caribbean States have displayed varied degrees of regulatory systems' development.
  - No official regulatory systems with registration of medicines
  - **Insufficient resources including personnel, backlogs of dossiers waiting to be reviewed and/or limited expertise to ensure the safety, efficacy and quality of products that reach the market are not uncommon.**

Strengthening regulatory capacities for medicines and other health technologies has been recognized as a priority for CARICOM

CRS: (Abbreviated) Review Process



Structure and Resource Requirements for Pilot

- The CRS will be comprised of a regulatory unit within CARICOM/CARPHA, and
- It will be resourced with technical and administrative support
- Work closely with NRA's

CRS core principles & opportunities for MS

- Synergistic with national system
  - Evaluation @ CARPHA; MA @ MS
  - Compatible with national legislation & regulations
- MOU defines relationship
  - Mutual responsibilities
  - National authority/ sovereignty
  - Shared PMS
  - Sharing of information

CRS core principles & opportunities for MS

- Ample involvement of NRA in CRS development & implementation
- Development of National Regulatory Capacity & application of regulatory science
- Increase timeliness of evaluation & transfer/ sharing of workload of NRA
- Increased procurement opportunities & economy of scales in provision of essential medicines that comply with standards of QES -> positive price/ quality ratio of EM
- Evolvement of CRS to include non-prequalified medicines and biologicals
- Inclusion of other regulatory functions and health products
- Synergistic with & basis for other projects with PAHO & NRA/r

Pre-requisites for MS

- For pilot phase and evolvement of CRS
- Subscribe to principle
  - COHSOD/ MOU
  - But also technically
- Active sourcing of dossiers of eligible & relevant medicines (EML)
- Uptake by national procurement systems
  - BGVS most important provider of EML and high cost medicines (cancer; kidney dialysis)

Special thanks to

- PAHO/PANDRH
- PAHO medicines department
- CARPHA/ CRS
- NRA/R
- CARICOM
- Colleagues

DANK U WEL
THANK YOU
GRACIAS
OBRIGADO