1st Malaysia – Japan Symposium on Pharmaceutical Regulatory System 2015
10 March 2015

NATIONAL PHARMACEUTICAL CONTROL BUREAU (NPCB)
MINISTRY OF HEALTH, MALAYSIA

AN OVERVIEW

By:
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Deputy Director, Centre for Organisational Development,
National Pharmaceutical Control Bureau (NPCB)

WHO Collaborating Centre for Regulatory Control of Pharmaceuticals

Member of Pharmaceutical Inspection Cooperation Scheme

MS ISO 9001:2008 Certified
Cert No.: AR 2293

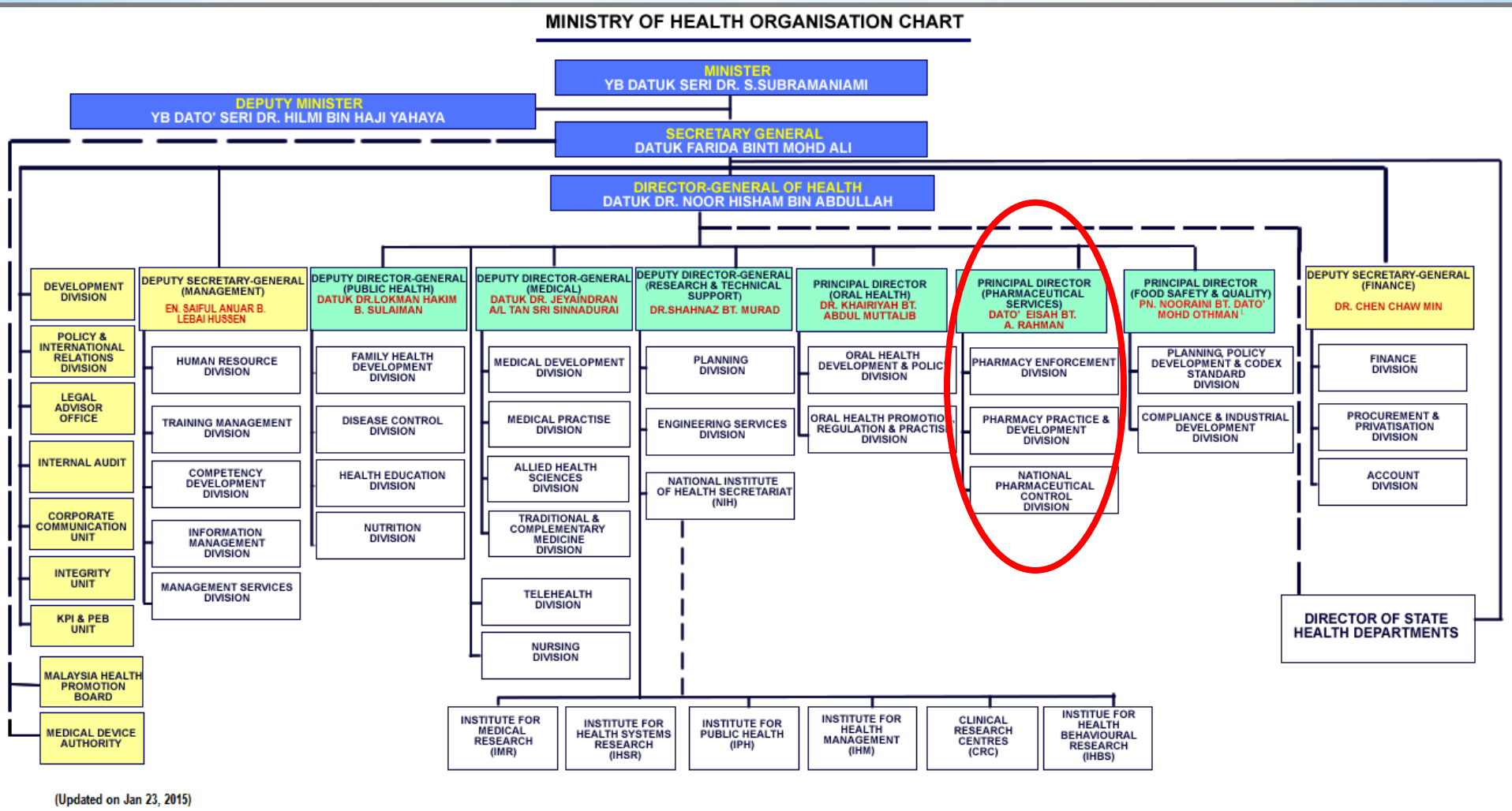
Non-OECD Member full adherence to the Mutual Acceptance Data (MAD) System

Presentation Outline

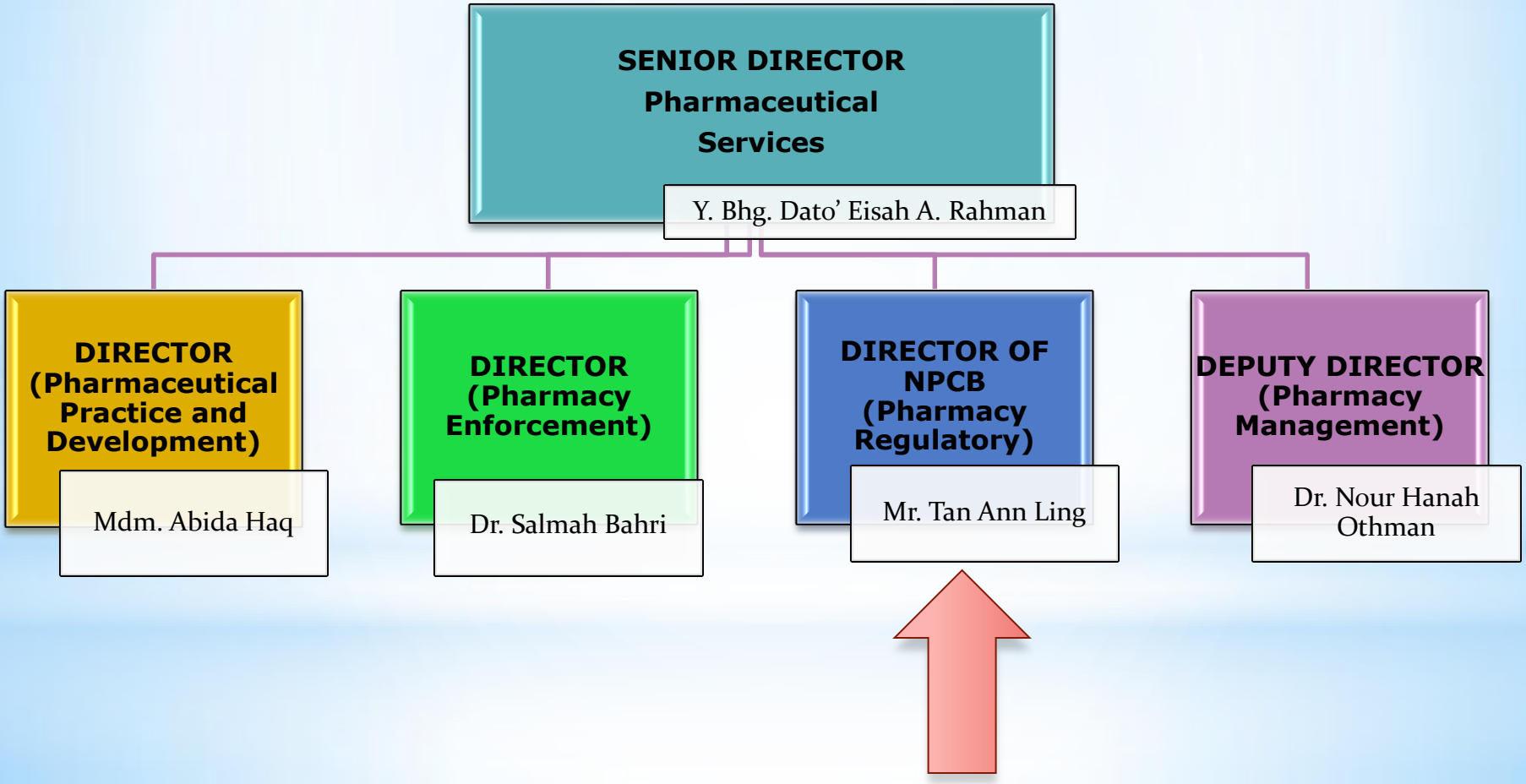
1) **Introduction**
2) **Registration Process**
3) **Core functions of the NPCB**
4) **Statistics**
5) **Recognition and Collaboration**
6) **Updates and Way Forward**

*INTRODUCTION

Organisation Chart
Ministry of Health Malaysia



Pharmaceutical Services Division



NPCB – the Organisation

- Government agency under the Ministry of Health, Malaysia
- Depends fully on government funding for day-to-day operations
- Annual revenue collected totals approximately 1/3 of annual operating allocation

	2011	2012	2013	2014
Allocation (RM)	30,083,025	26,709,917	35,380,133	37,547,222
Revenue (RM)	11,498,772	12,220,975	12,216,435	11,965,723

- Plans to increase future revenue – implementation of fee for activities currently done without charge (e.g. classification of products, variation, etc…)

NPCB Organisation Chart

Director
Regulatory Pharmacy
Mr. Tan Ann Ling

Dep. Director
Centre for Organisational Development
Mdm. Siti Aida Abdullah

Dep. Director
Centre for Quality Control
Dr. Tajuddin Akasah

Dep. Director
Centre for Post Registration of Products
Ms. Sameerah Shaikh Abd Rahman

Dep. Director
Centre for Compliance & Licensing
Mr. Sulaiman Ahmad

Dep. Director
Centre for Investigational New Product
Dr. Kamaruzaman Saleh

Dep. Director
Centre for Product Registration
Mdm. Anis Talib

Head of
Centre for Administration
Mdm. Pesah Ahmad

Vision & Mission Statement

VISION

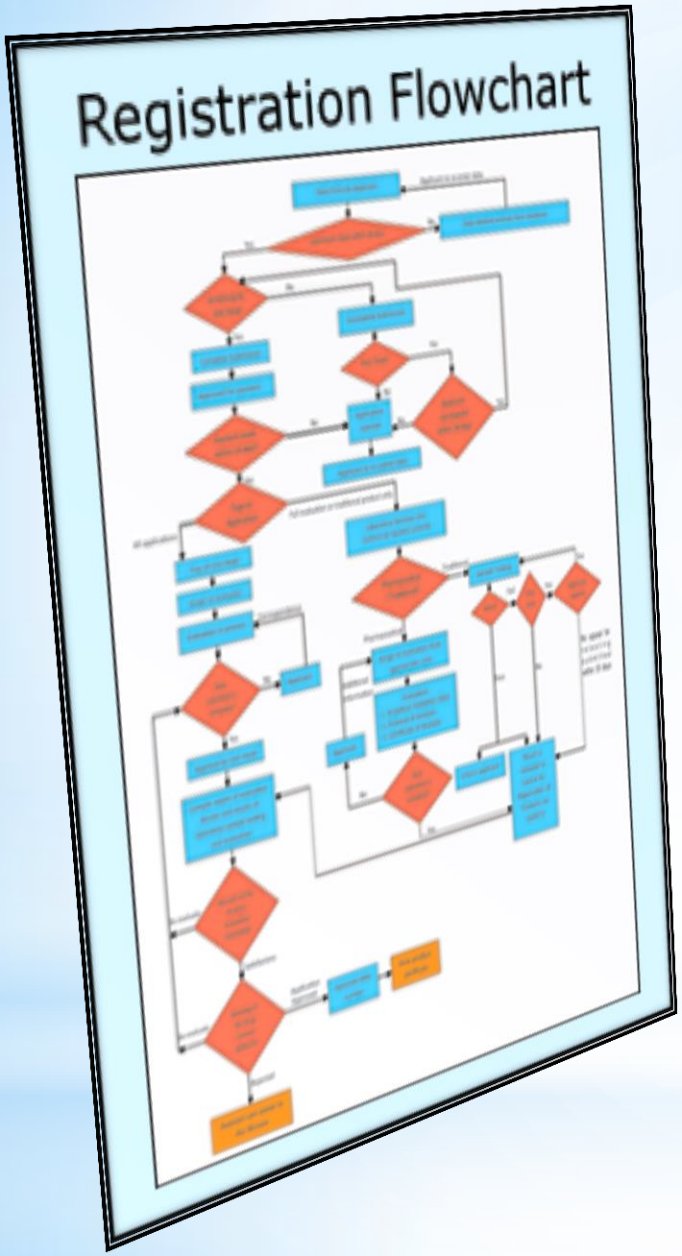
To be an internationally renowned regulatory authority for medicinal products and cosmetics.

MISSION

To safeguard the nation's health through scientific excellence in the regulatory control of medicinal products and cosmetics.

NPCB Staff Strength (2010 –2014)

Personnel	2010	2011	2012	2013	2014
Pharmacist	179	184	191	229	238
Assistant Pharmacist	79	79	77	84	79
Support Staff	58	56	54	67	71
TOTAL	**316**	**319**	**322**	**380**	**388**



*REGISTRATION PROCESS

Criteria

Quality

All products

Safety

All products

Efficacy

Not evaluated for Traditional Meds. and Cosmetics

Legal Requirement

The Control of Drugs and Cosmetic Regulations 1984 was promulgated under the Sale of Drugs Act 1952 (Revised 1989)

- **Subregulation 7(1)**
  - No person shall manufacture, sell, supply, import or possess or administer any product unless,
  - The product is a registered product ;
  - The person holds the appropriate licence issued under this regulation.

- **Subregulation 8(1)**
  - The Authority may, on application made in such manner or form as it may require, register any product subject to such conditions as it may impose.

Drug Control Authority (DCA)

OBJECTIVE:

- Established for the purpose of making policies
- Authority in registration of products

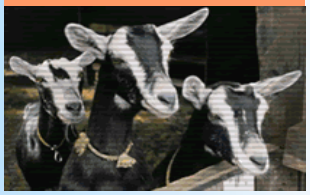
MEMBERS:

- Director-General of Health (chairman);
- Senior Director of Pharmaceutical Services (alternate chair);
- Director of the NPCB; and
- 8 other members appointed by the Minister of Health

NPCB functions as the secretariat of the DCA

Registration Phases

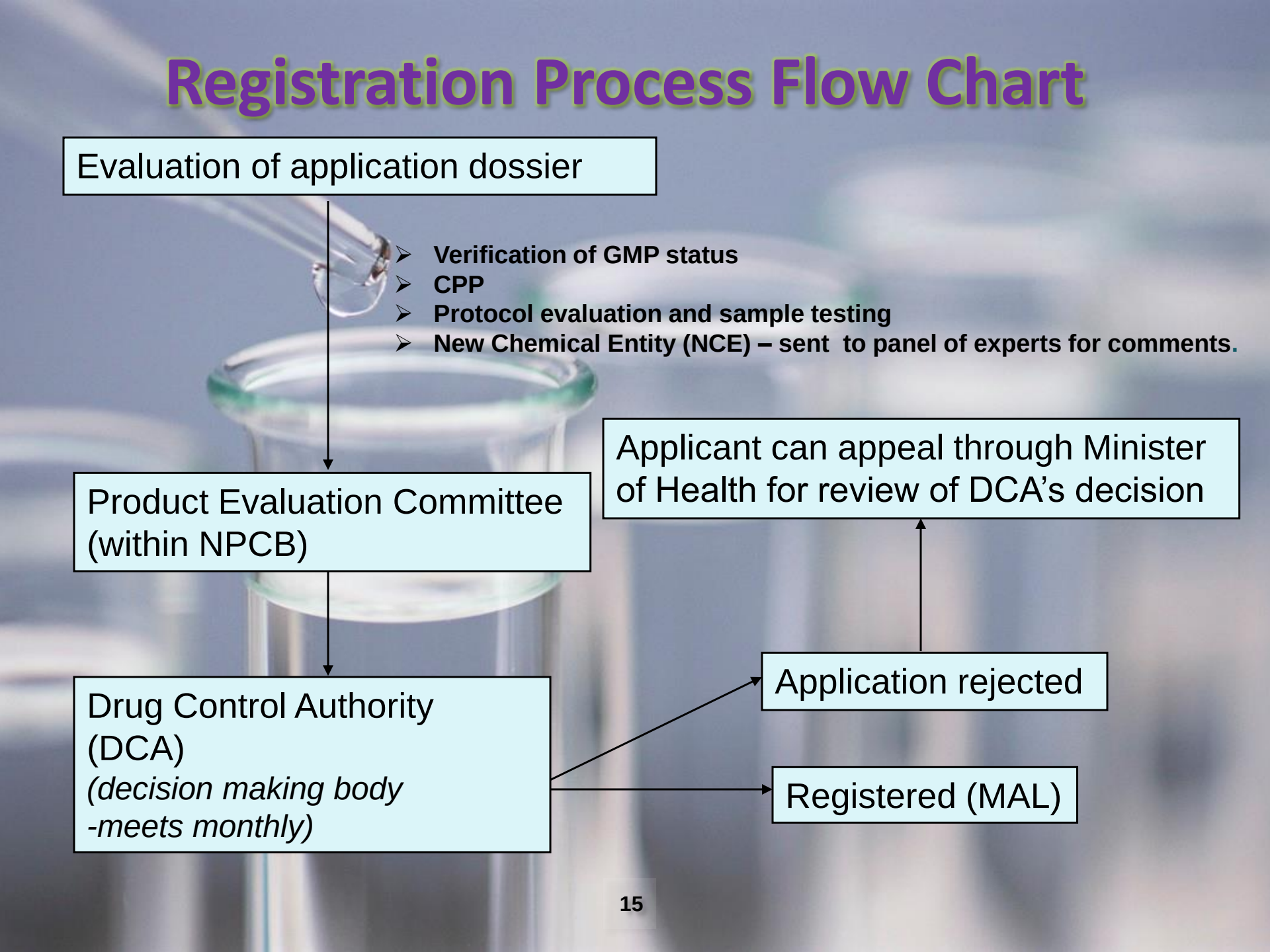
Legislation: Control of Drugs and Cosmetics Regulations 1984, promulgated under the Sale of Drugs Act 1952

NEW PRODUCTS	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5	Phase 6
BIOTECHNOLOGY 	Registration Aug 1985 (Prescription Drugs)	Registration 1988 (OTC)	Registration Jan 1992 (Traditional Medicine)	Registration Feb 2002 (Cosmetics)	Registration Aug 2007 (Veterinary)	Registration Jan 2012 Active Pharmaceuti-cal Ingredient (API)*
VETERINARY MEDICINE 	Licensing May 1987	Licensing 1992	Licensing Manufacturer Importers Jan 1999	Licensing Jan 2004	Licensing 1 July 2015	No licensing Requirements as registration of API is linked to products
ACTIVE PHARMACEUTICAL INGREDIENTS 	Surveillance 1990	Surveillance 1995	Licensing Wholesalers July 2002 Surveillance 2000	Surveillance 2005	Surveillance (to be announced)	Surveillance (to be announced)

1st January 2008 – Registration of Cosmetics replaced by NOTIFICATION

*** Voluntary registration of API commenced in April 2011. Registration of generic API will be announced at a later date.**

Registration Process Flow Chart



*CORE FUNCTIONS

Regulatory Components

R & D

QUEST3
Quality Efficacy Safety 3

Registration

Pharmacovigilance

Education

Surveillance

Licensing

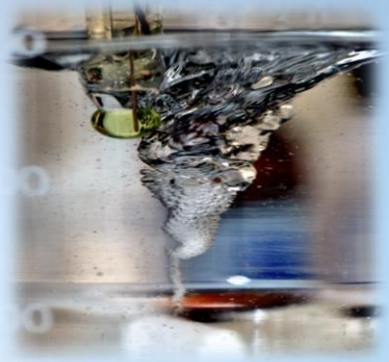
Analysis

Product Registration

- Evaluation of dossiers, BA/BE Study Reports
- On-line registration (QUEST 2 --> QUEST 3)
- Product Classification
- Additional Indication of New Chemical Entities (NCEs) & Biotech Products
- *Certificate of Pharmaceutical Product (CPP), Certificate of Free Sale (CFS)*

Quality Control & Analysis

- Evaluation of protocols of analysis and Analytical Method Validation Data
- Sample testing → Pre-registration, Post market surveillance, Enforcement *[screening for adulterants]*
- Inspection of QC facilities
- Production of reference standards



Compliance and Licensing

- Inspections → pre-licensing, surveillance, verification, investigation,
- Issuance of Licences → Manufacturers, Importers, Wholesalers
- Adopts PIC/S GMP
- Inspections conducted based on a matrix system → frequency schedule, risk matrix, categorisation of non-conformities
- GMP dialogues, guidance and consultations

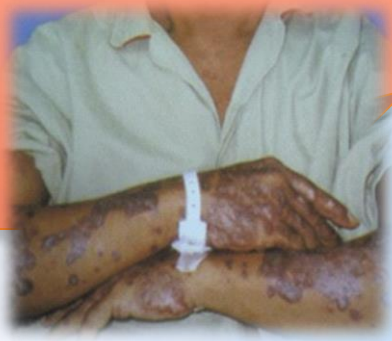
Post Registration Activities

1. Surveillance

- Product sampling
- Quality assessment and profiles
- Product verification
- Screening of labels and package inserts
- Handling product complaints
- Investigations
- Punitive actions – warnings, product Recalls

2. Pharmacovigilance

- Adverse Drug Reactions (ADR) Monitoring System
- Malaysian Adverse Drug Reactions Advisory Committee (MADRAC) propose recommendations to DCA
- Safety issues – revocation, suspension, immediate recall
- Participate in WHO Drug Safety Program



Investigational New Products

- Evaluation of dossier for application of Clinical Trial Import License (CTIL) & Clinical Trial Exemption (CTX)
- Issuance of CTIL & CTX
- Evaluation of Variation application for CTIL & CTX
- Good Clinical Practice (GCP) Inspection at the clinical trial site, sponsor, Contract Research Organisation's (CRO)
- NPCB is the Malaysian Compliance Monitoring Authorities (CMA) to conduct the GLP Inspection and certification of Test Facilities

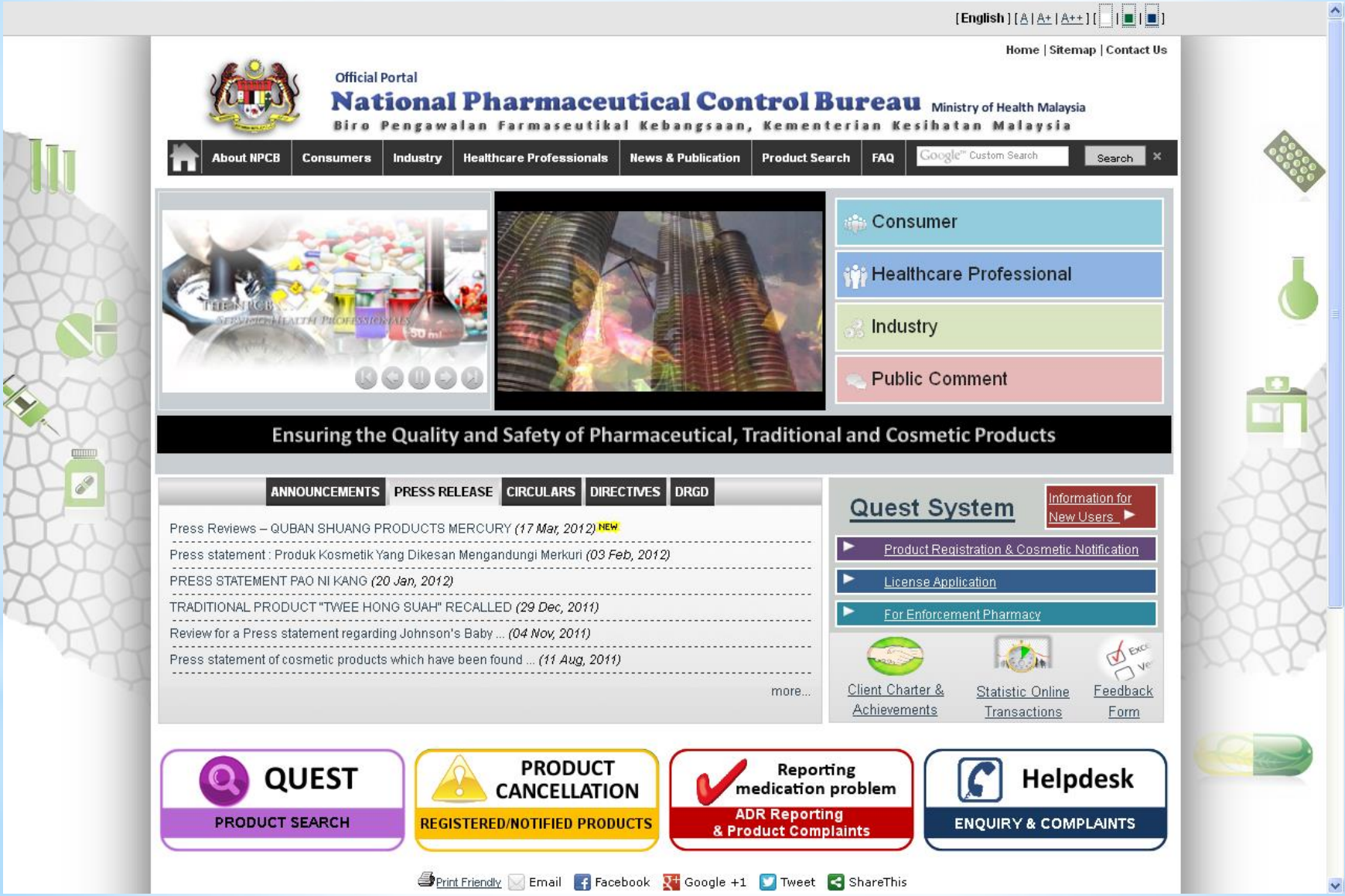
Organisational Development

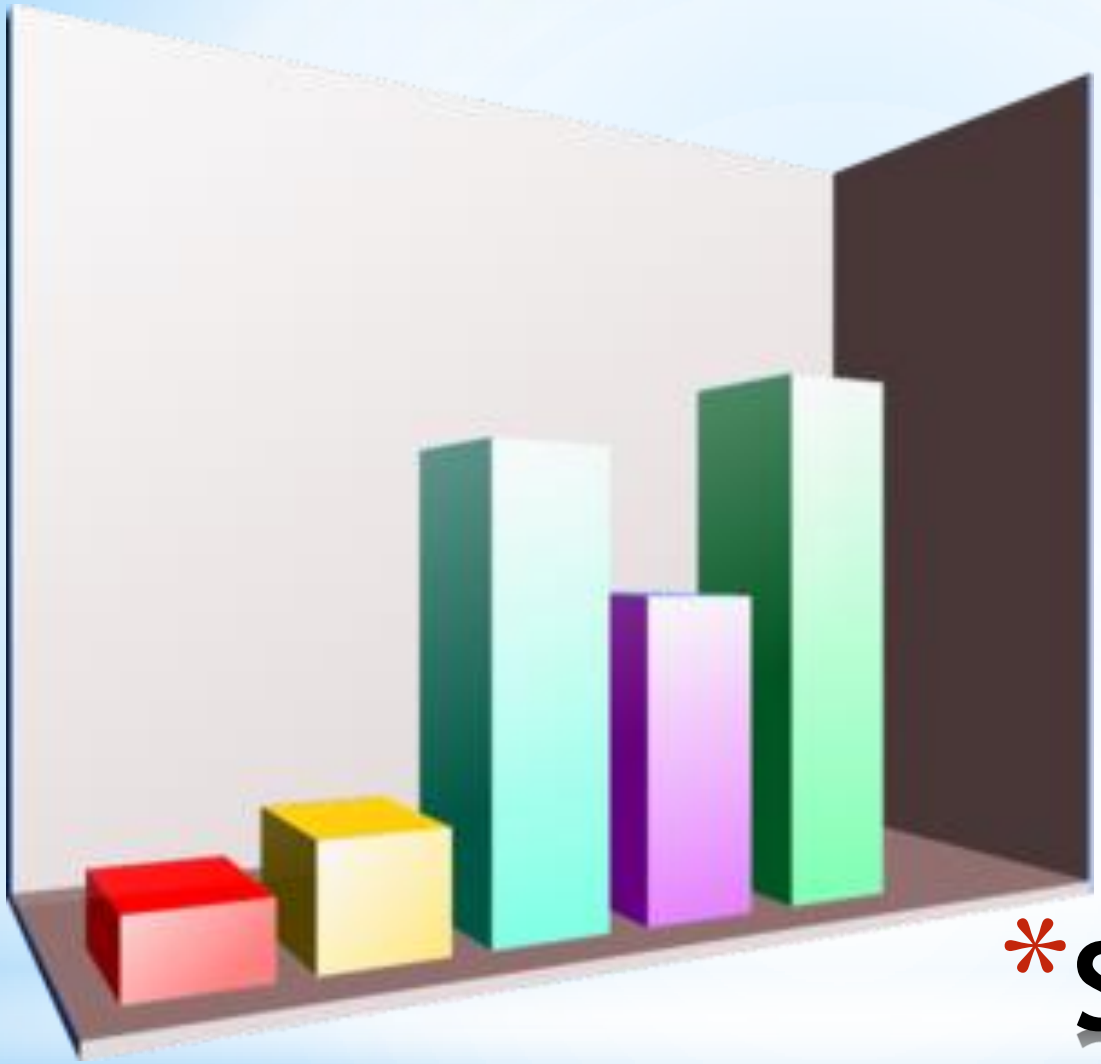
- Maintain the NPCB website
- ICT System (QUEST)
- Quality Initiatives (ISO)
- Organize Continuous Medical Education (CME) sessions
- Policy and Inter-relation Unit
- Handle enquiries from consumers, health professionals and industry (Helpdesk)
- Publications:
  - DCA Newsletters
  - Annual Reports – NPCB, WHO

QUEST 3

- On-line web-based system since:
  - 2002 – QUEST 2
  - 2010 – QUEST 3
- Submission of data can be done at anytime - 24 hours a day, 365 days a year, from any part of the world
- QUEST 2 is an online registration system for all categories of products (A, X, T and K) except for New Chemical Entity and Biotechnology products.
- It was then upgraded to QUEST 3 system starting end of 2010 – online registration for all category of products

*NPCB Website: www.bpfk.gov.my





*STATISTICS

Product Registration Statistics (2008 –2014)

Year / Category	2008	2009	2010	2011	2012	2013	2014
Poison	409	412	441	325	357	241	235
Non-Poison	272	313	235	55	83	54	52
Traditional	953	1,040	582	467	565	578	590
Veterinary	-	-	54	52	45	63	207
Health Supplement	(used to be under Non-Poison)			168	161	85	128
Total	1,634	1,765	1,312	1,067	1,211	1,021	1212
Cumulative	40,737	42,502	43,814	44,881	46,092	47,113	48,325

Existing Registered Products (as of 31 Dec 2014)

Product Category	Local		Import		Total
	No.	%	No.	%	
Poison	1,472	20.65	5,656	79.35	7,121
Non-Poison	2,268	54.57	1,888	45.43	4,156
Traditional	9,069	74.88	3,042	25.12	12,111
Veterinary	241	57.24	180	42.76	421
Health Supplement	167	30.93	373	69.07	540
Total	13,217	54.27	11,139	45.73	24,356

Notification of Cosmetics (2010 –2014)

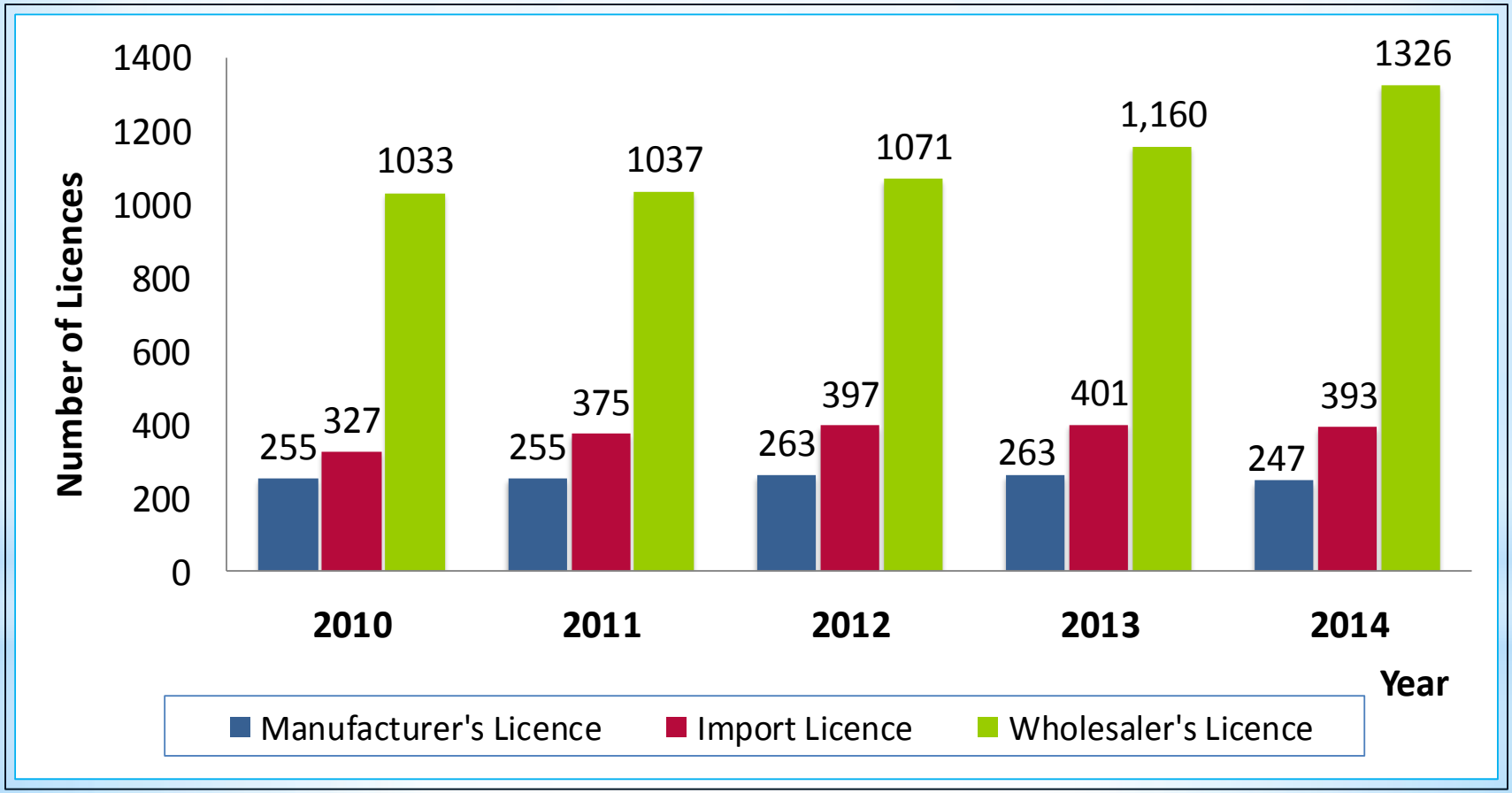
YEAR / PRODUCT	2010	2011	2012	2013	2014
Number of applications for notification of cosmetics	53,262	69,747	66,913	69,925	78,465

Registered Products / Notified Cosmetics from Japan

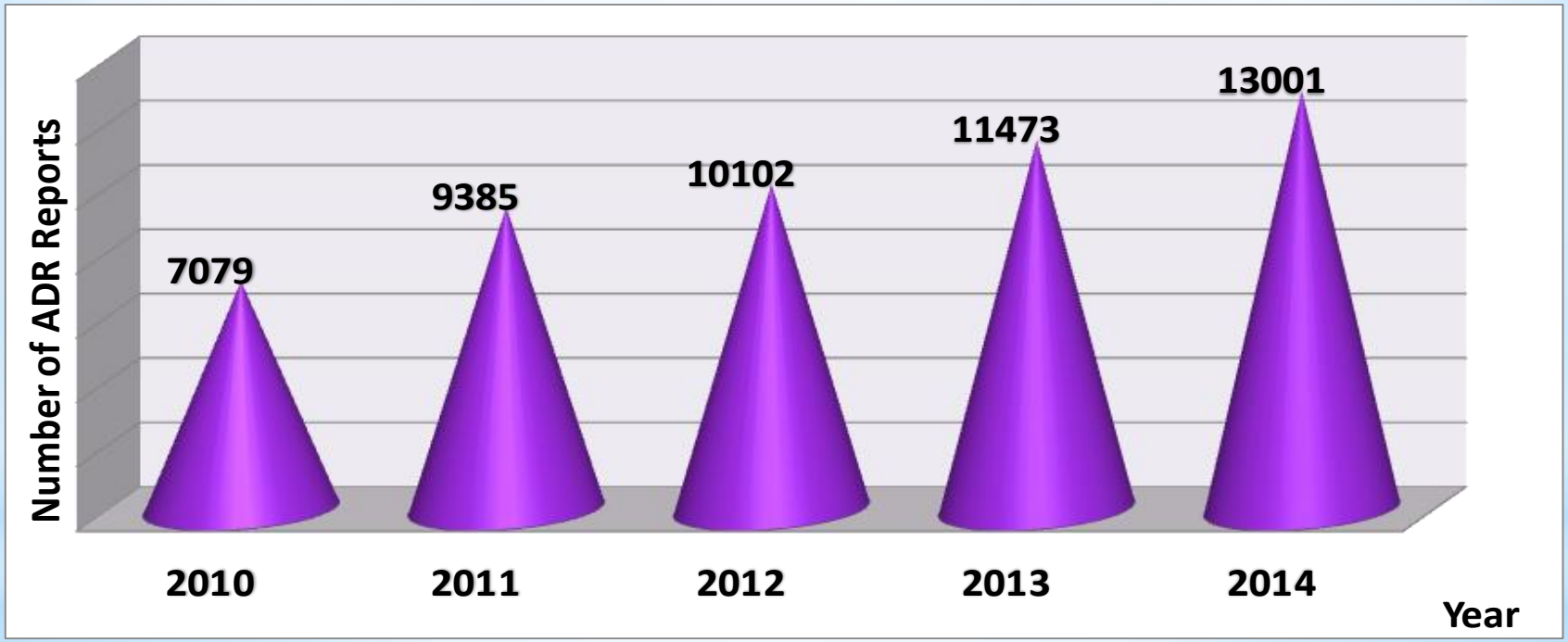
	Prescription (A)	Non-prescription (X)	Traditional (T)	Health Supplements (N)	Total
Number of registered products from Japan (as at 28 Feb. 2015)	64	41	31	3	139

	Total
Number of notified cosmetics from Japan (as at 28 Feb. 2015)	119

Manufacturer's, Import & Wholesaler's Licenses Issued (2010 – 2014)



Adverse Drug Reaction Reports Received from NPCB (2010 – 2014)



*Recognition and Collaborations

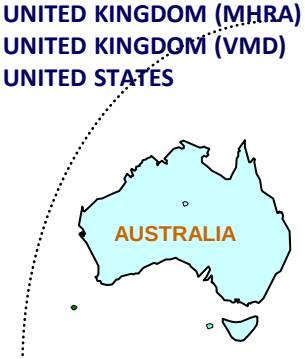
RECOGNITION

- 5S Certification
- MS ISO 9001:2008 Certified
- MS ISO / IEC 17025:2005 Accredited
- Member of Pharmaceutical Inspection Co-operation Scheme
- WHO Collaborating Centre for Regulatory Control of Pharmaceuticals
- Non-OECD Member full adherence to the Mutual Acceptance Data (MAD) System

Pharmaceutical Inspection Cooperation Scheme

46 Members of PIC/S – July 2014

ARGENTINA
AUSTRALIA
AUSTRIA
BELGIUM
CANADA
CYPRUS
CZECH REP. (SUKL)
CZECH REP. (ISCVBM)
DENMARK
ESTONIA
FINLAND
FRANCE (ANSM)
FRANCE (ANSES)
GERMANY
GREECE
HUNGARY
ICELAND
INDONESIA
ISRAEL
IRELAND
ITALY
JAPAN
KOREA
LATVIA
LIECHTENSTEIN
LITHUANIA
MALAYSIA
MALTA
NETHERLANDS
NEW ZEALAND
NORWAY
POLAND
PORTUGAL
ROMANIA
SINGAPORE
SLOVAK REPUBLIC
SLOVENJIA
SOUTH AFRICA
SPAIN
SWEDEN
SWITZERLAND
TAIWAN
UKRAINE
UNITED KINGDOM (MHRA)
UNITED KINGDOM (VMD)
UNITED STATES



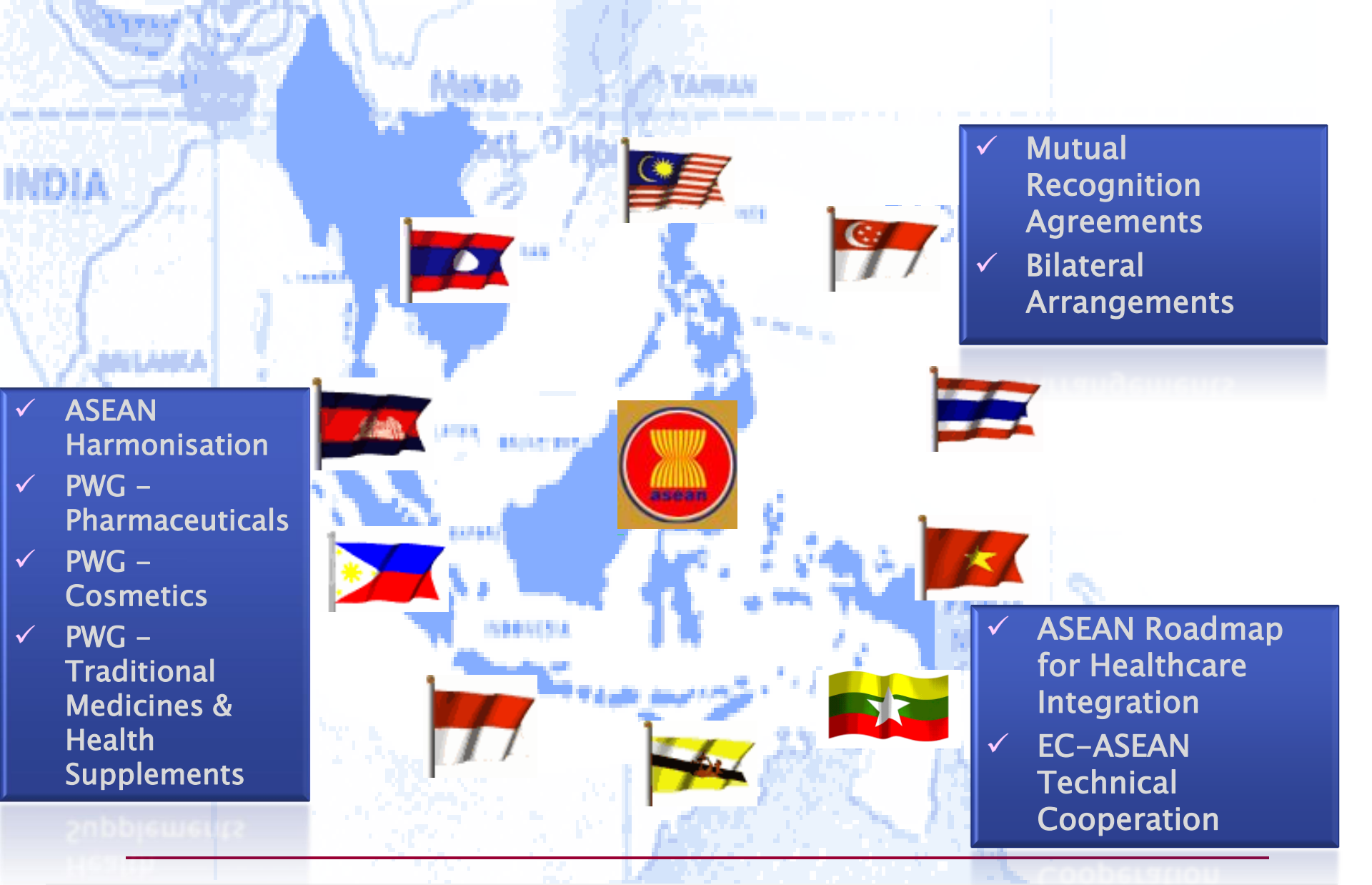
OECD – MAD System

34 Member countries

AUS, AU, BE, CAN, CZ, DK, FIN, FR, GER, GR, HU, ICL, IRE, IT, IS, JP, KO, LU, MEX, NL, NO, NZ, PO, PT, SK, SP, SWE, SWI, SLO,TU, UK, USA

Non-Member countries

- South Africa 2003
- Singapore 2010
- India March 2011
- Brazil March 2011
- Argentina Aug 2011
- Malaysia March 2013



- ✓ Mutual Recognition Agreements
- ✓ Bilateral Arrangements

- ✓ ASEAN Harmonisation
- ✓ PWG – Pharmaceuticals
- ✓ PWG – Cosmetics
- ✓ PWG – Traditional Medicines & Health Supplements

- ✓ ASEAN Roadmap for Healthcare Integration
- ✓ EC–ASEAN Technical Cooperation

STRENGTHENING REGIONAL REGULATORY FRAMEWORK THROUGH COOPERATION AMONG MEMBER STATES

Updates and Way Forward

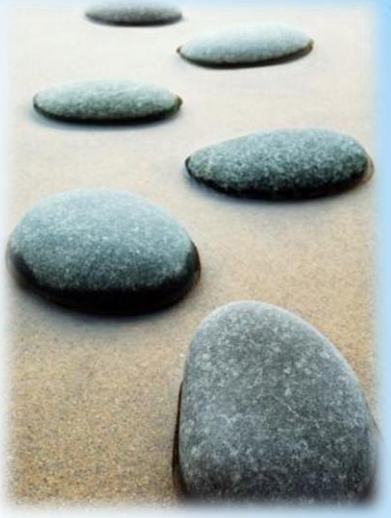
Regulatory Updates

- Hosted the 21st ACCSQ-PPWG (17 – 20 June 2014)
- Regulatory Control of API for generics – parenterals (1 July 2014)
- Good Distribution Practice (GDP) requirements for cold-chain products [starting with vaccines] → 1 July 2014
- Lot Release of Imported Vaccines [pilot project] → 1 July 2014
- 3rd Technical Bilateral Meeting between NPCB-HSA (15 August 2014)

Upcoming Events

1st Malaysia - Japan Symposium on Pharmaceutical Regulatory System 2015	March 2015
Hosting of the ACCSQ-TMHS	June 2015
Organising the National Regulatory Conference (NRC) 2015	August 2015

The Way Forward



Control of Cellular & Gene Therapy Products (CGTP)

Lot release for imported vaccines (full phase)

Registration of high / medium claims for herbal products

New Pharmacy Bill

THANK YOU

Arigatō

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