



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

AN OVERVIEW

By:

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*WHO Collaborating Centre
for Regulatory Control of
Pharmaceuticals*



*Member of Pharmaceutical
Inspection Cooperation
Scheme*



SIRIM

*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



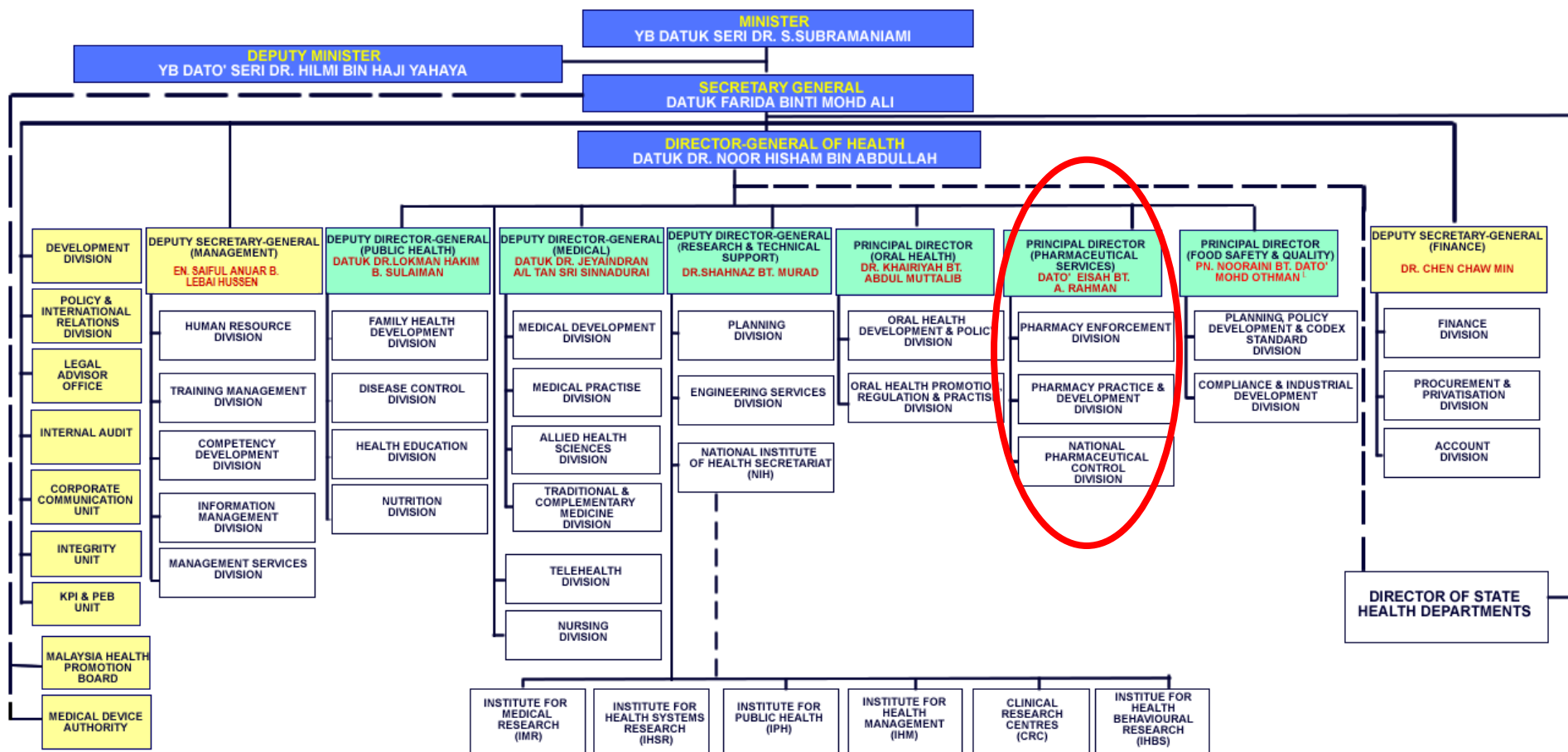


*INTRODUCTION

Organisation Chart

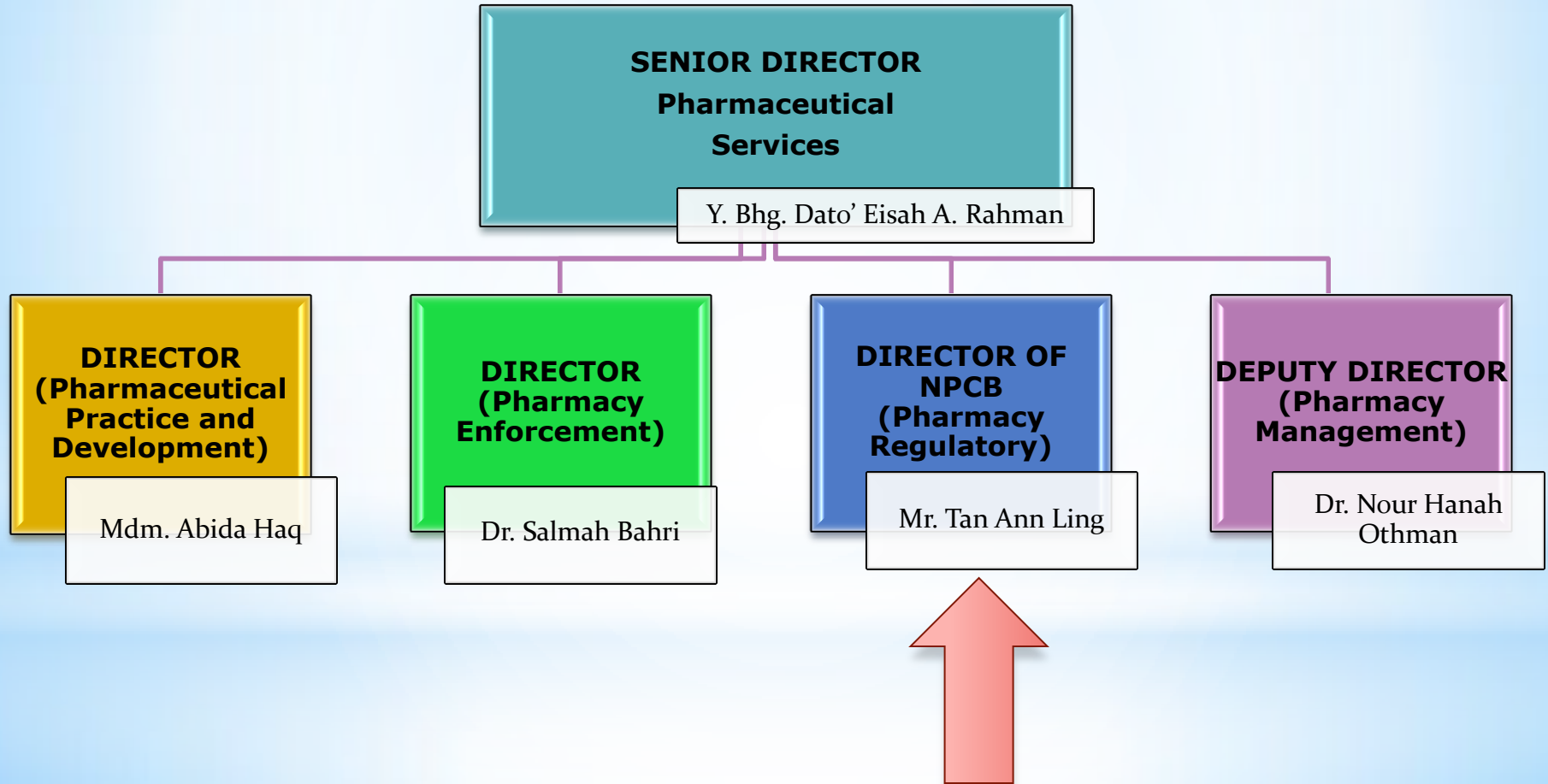
Ministry of Health Malaysia

MINISTRY OF HEALTH ORGANISATION CHART



(Updated on Jan 23, 2015)

Pharmaceutical Services Division



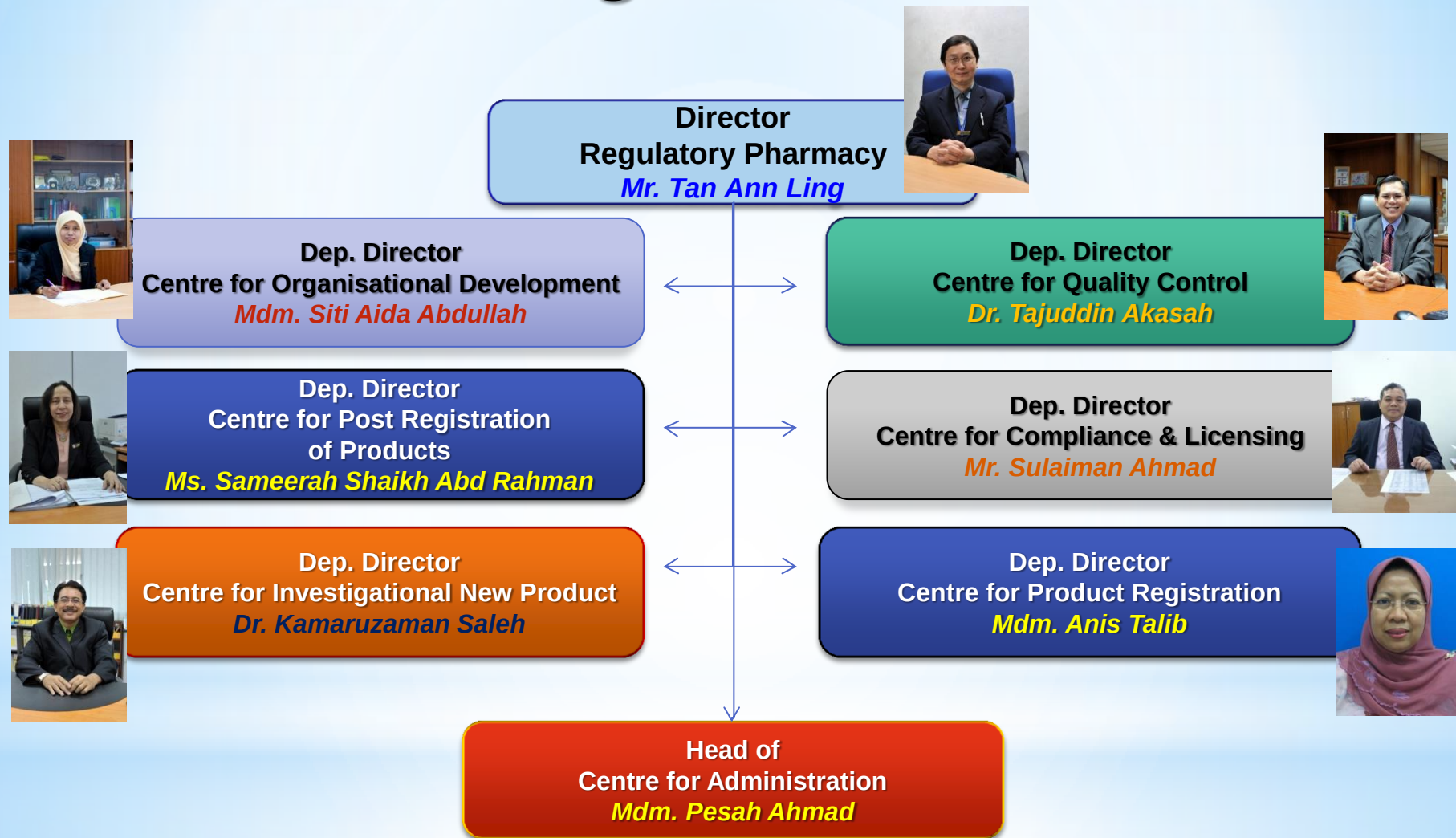
NPCB – the Organisation

- 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



Vision & Mission Statement

VISION

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

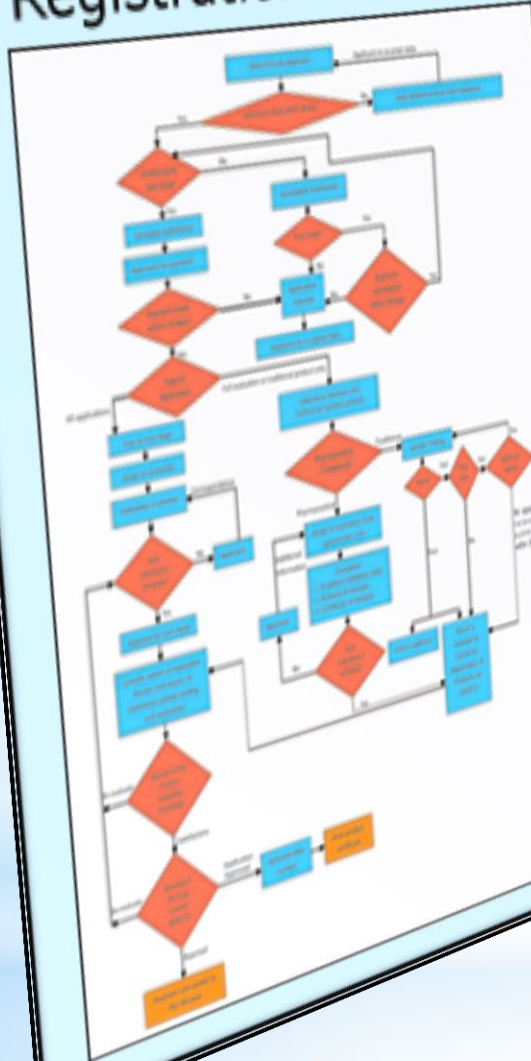
MISSION

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 Flowchart



* **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

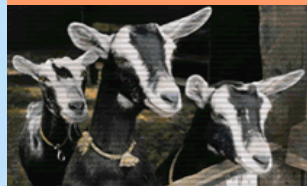
Legislation: Control of Drugs and Cosmetics Regulations 1984, promulgated under the Sale of Drugs Act 1952

NEW PRODUCTS

BIOTECHNOLOGY



VETERINARY MEDICINE



ACTIVE PHARMACEUTICAL INGREDIENTS



Phase 1

Registration
Aug 1985
(Prescription
Drugs)

Licensing
May 1987

Surveillance
1990

Phase 2

Registration
1988
(OTC)

Licensing
1992

Surveillance
1995

Phase 3

Registration
Jan 1992
(Traditional
Medicine)

Licensing
Manufacturer
Importers
Jan 1999

Licensing
Wholesalers
July 2002
Surveillance
2000

Phase 4

Registration
Feb 2002
(Cosmetics)

Licensing
Jan 2004

Surveillance
2005

Phase 5

Registration
Aug 2007
(Veterinary)

Licensing
1 July 2015

Surveillance
(to be
announced)

Phase 6

Registration
Jan 2012
Active
Pharmaceuti-
cal Ingredient
(API)*

No licensing
Requirements
as registration
of API is
linked to
products

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

Evaluation of application dossier

- Verification of GMP status
- CPP
- Protocol evaluation and sample testing
- New Chemical Entity (NCE) – sent to panel of experts for comments.

Product Evaluation Committee
(within NPCB)

Applicant can appeal through Minister
of Health for review of DCA's decision

Drug Control Authority
(DCA)
*(decision making body
-meets monthly)*

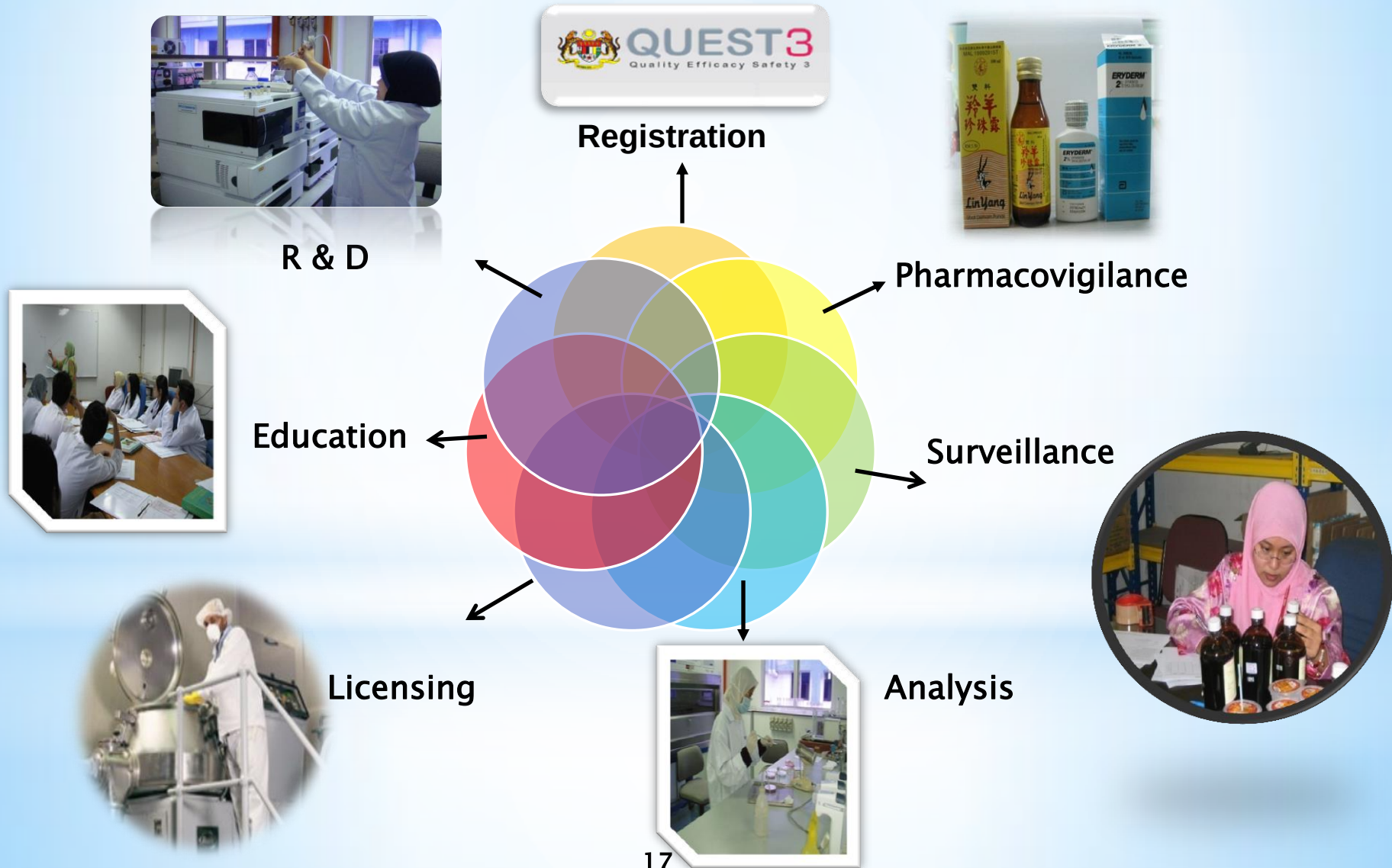
Application rejected

Registered (MAL)



*CORE FUNCTIONS

Regulatory Components



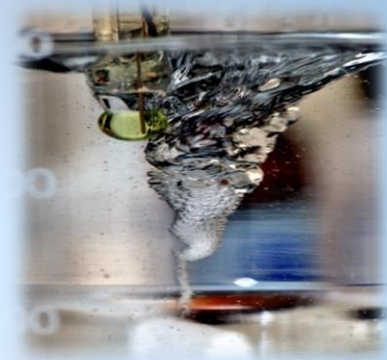


Product Registration

- 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

[English] [A] [A+] [A++]

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Ensuring the Quality and Safety of Pharmaceutical, Traditional and Cosmetic Products

ANNOUNCEMENTS **PRESS RELEASE** **CIRCULARS** **DIRECTIVES** **DRGD**

Press Reviews – QUBAN SHUANG PRODUCTS MERCURY (17 Mar, 2012) **NEW**
Press statement : Produk Kosmetik Yang Dikesan Mengandungi Merkuri (03 Feb, 2012)
PRESS STATEMENT PAO NI KANG (20 Jan, 2012)
TRADITIONAL PRODUCT "TWEH HONG SUAH" RECALLED (29 Dec, 2011)
Review for a Press statement regarding Johnson's Baby ... (04 Nov, 2011)
Press statement of cosmetic products which have been found ... (11 Aug, 2011)
[more...](#)

Quest System [Information for New Users](#)

[Product Registration & Cosmetic Notification](#)
[License Application](#)
[For Enforcement Pharmacy](#)

 [Client Charter & Achievements](#)  [Statistic Online Transactions](#)  [Feedback Form](#)

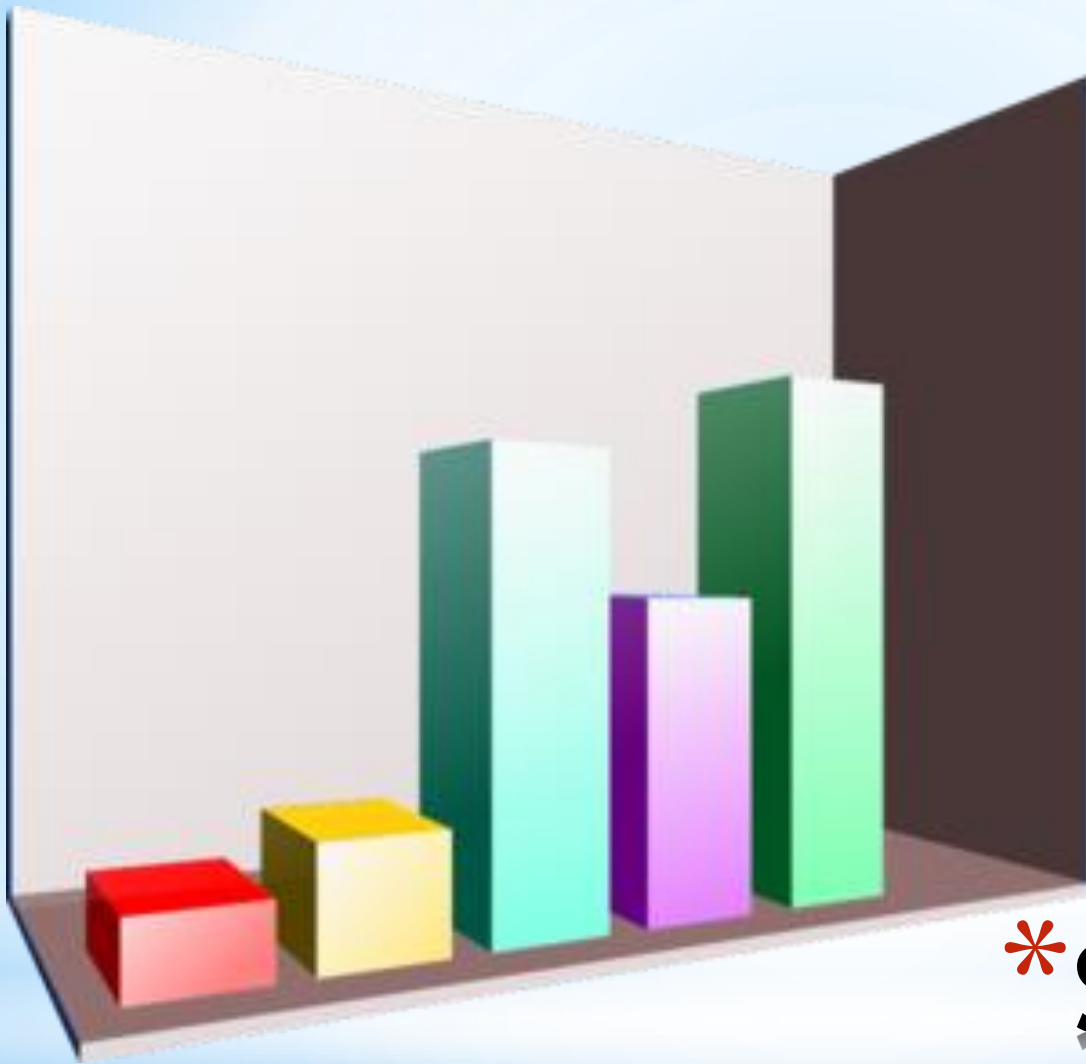
 **QUEST**
PRODUCT SEARCH

 **PRODUCT CANCELLATION**
REGISTERED/NOTIFIED PRODUCTS

 **Reporting medication problem**
ADR Reporting & Product Complaints

 **Helpdesk**
ENQUIRY & COMPLAINTS

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*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)

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



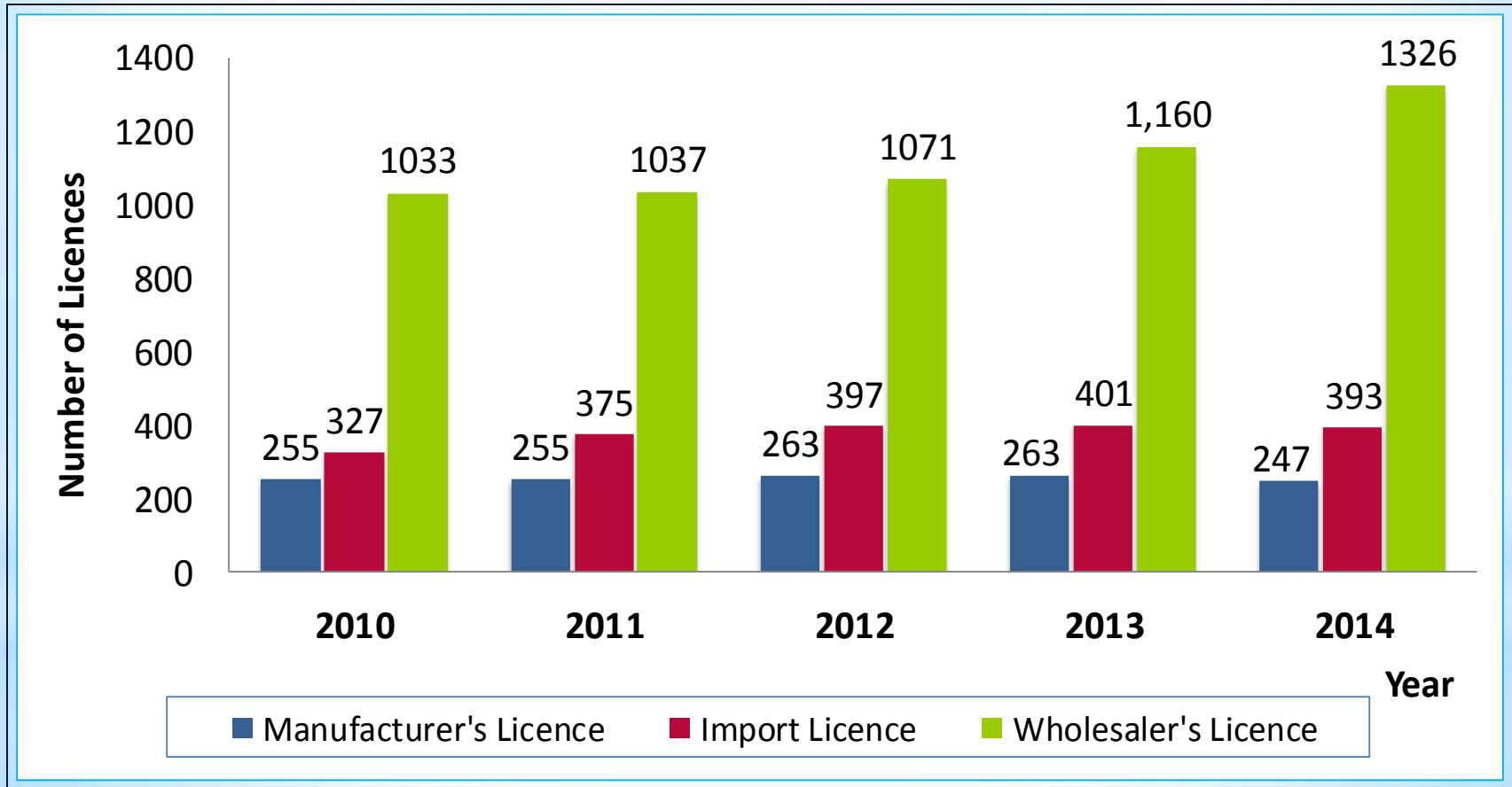


Registered Products / Notified Cosmetics from Japan

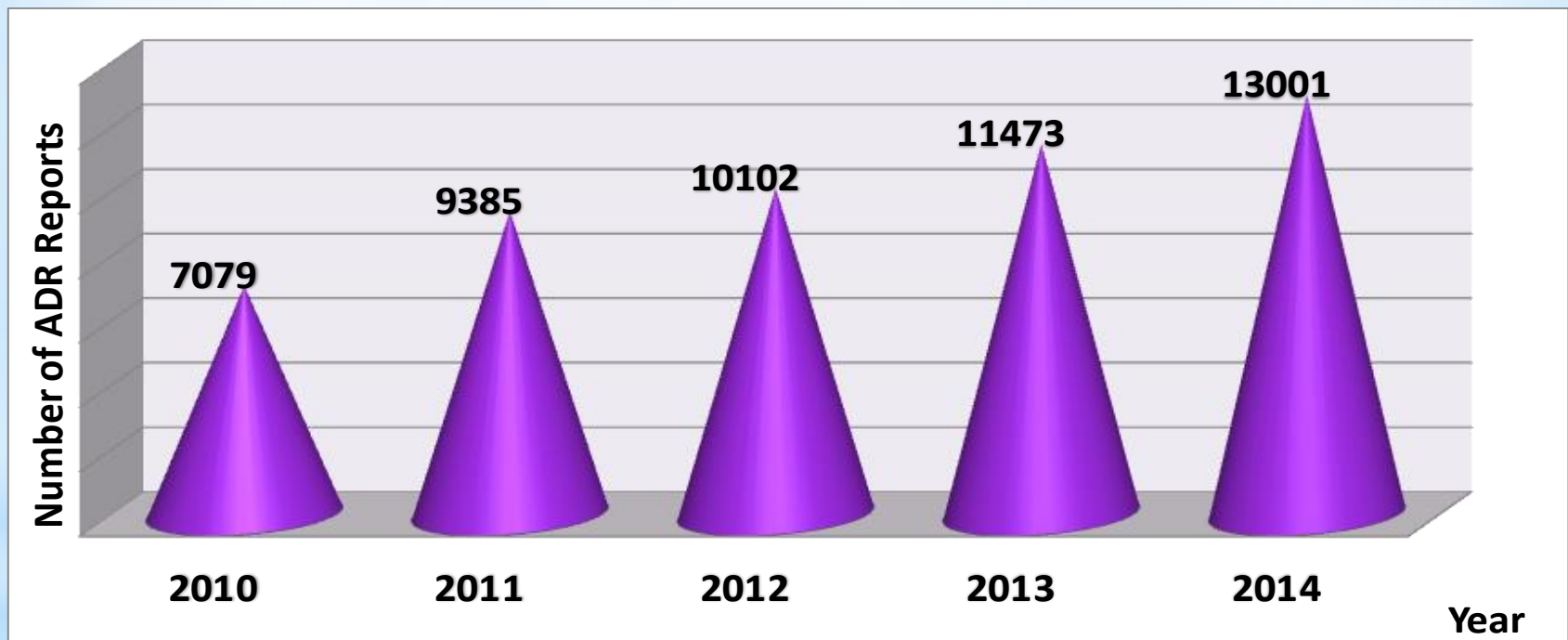
	Prescription (A)	Non- prescription (X)	Traditional (T)	Health Supplements (N)	Total
Number of registered products from Japan (as at 28 Feb. 2015)	64	41	31	3	139

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

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



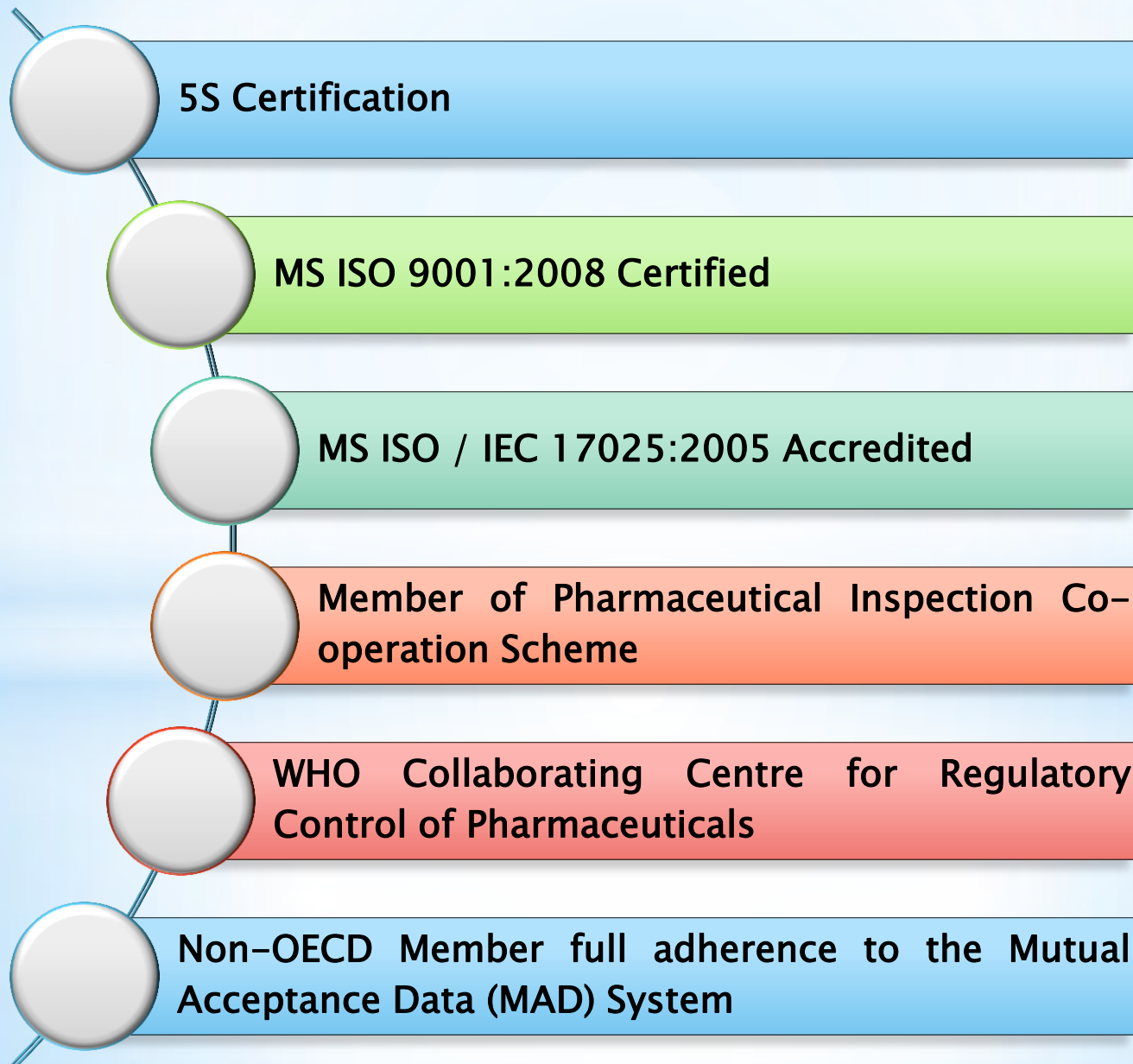
Adverse Drug Reaction Reports Received from NPCB (2010 – 2014)





*Recognition and Collaborations







Pharmaceutical Inspection Cooperation Scheme

46 Members of PIC/S – July 2014



OECD – MAD System

www.oecd.org/env/ehs/malaysia-joins-oecd-agreement-on-mutual-acceptance-of-chemical-safety-data.htm

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Chemical safety and biosafety

- > Biodiversity, water and natural resource management
- Chemical safety and biosafety**
 - > Testing of chemicals
 - > Assessment of chemicals
 - > Risk management of chemicals

Malaysia joins OECD agreement on mutual acceptance of chemical safety data

10/04/2013 - Malaysia has joined the OECD system for the [Mutual Acceptance of Data \(MAD\)](#) in the Assessment of Chemicals, ensuring that its non-clinical safety data related to the protection of human health and the environment will be accepted by all 40 countries adhering to MAD.

The MAD system – a multilateral agreement - allows participating countries to share the results of various non-clinical safety tests done on chemicals and chemical products, such as industrial chemicals and pesticides. This collaboration saves governments and chemical producers around [€150 million annually](#).

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

What's
new?

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

WHAT'S
NEXT?

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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