INCREASING USE OF REAL WORLD EVIDENCE: MALAYSIAN REGULATORY PERSPECTIVE

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NEW DRUG PRODUCT SECTION

CENTRE OF PRODUCT AND COSMETIC EVALUATION

NATIONAL PHARMACEUTICAL REGULATORY AGENCY (NPRA)

MINISTRY OF HEALTH MALAYSIA

DISCLAIMER

The opinions expressed in this presentation are those of the presenter and do not necessarily reflect the views of the Government of Malaysia or the National Pharmaceutical Regulatory Agency (NPRA). The information presented is for educational and informational purposes only and should not be construed as legal or professional advice.

OUTLINE

1. Introduction to National Pharmaceutical Regulatory Agency (NPRA)
2. Definitions of Real World Data (RWD) & Real World Evidence (RWE)
3. Application of RWD/RWE in the Malaysian Regulatory Setting
4. Challenges of Using RWD/RWE in Malaysia

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CLOSER LOOK TO NATIONAL PHARMACEUTICAL REGULATORY AGENCY (NPRA)

NPRA is a government agency under the Pharmaceutical Services Programme, Ministry of Health Malaysia

Formerly known as National Pharmaceutical Control Bureau (NPCB), was set up in Oct 1978

Executing the regulatory requirements provided for in Sales of Drugs Act 1952 via Control of Drugs and Cosmetics Regulation 1984 (CDCR 1984)

Scope of Service

- Regulation of pharmaceutical and traditional products through registration, licensing and surveillance activity
- Regulation of cosmetic products via notification

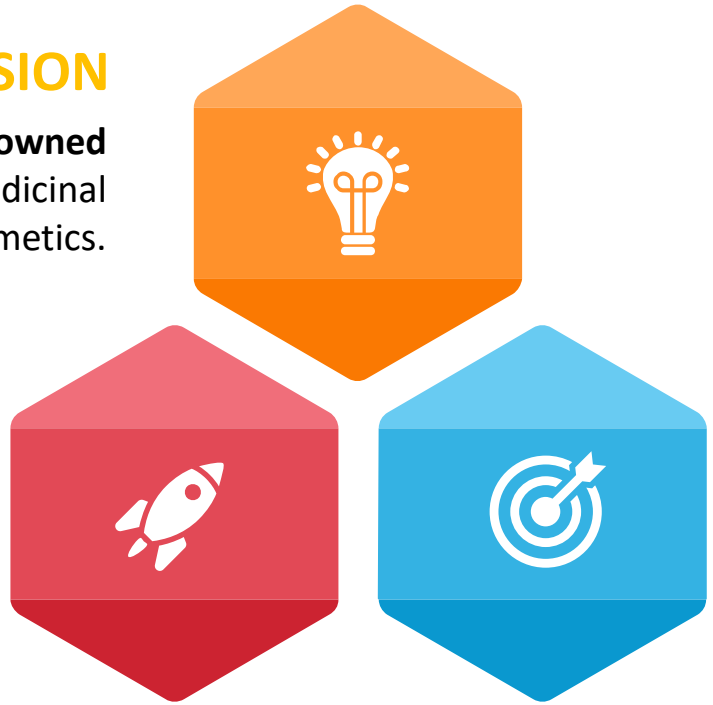
NPRA'S COMMITMENT TO HEALTHCARE REGULATION : VISION, MISSION & OBJECTIVE

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

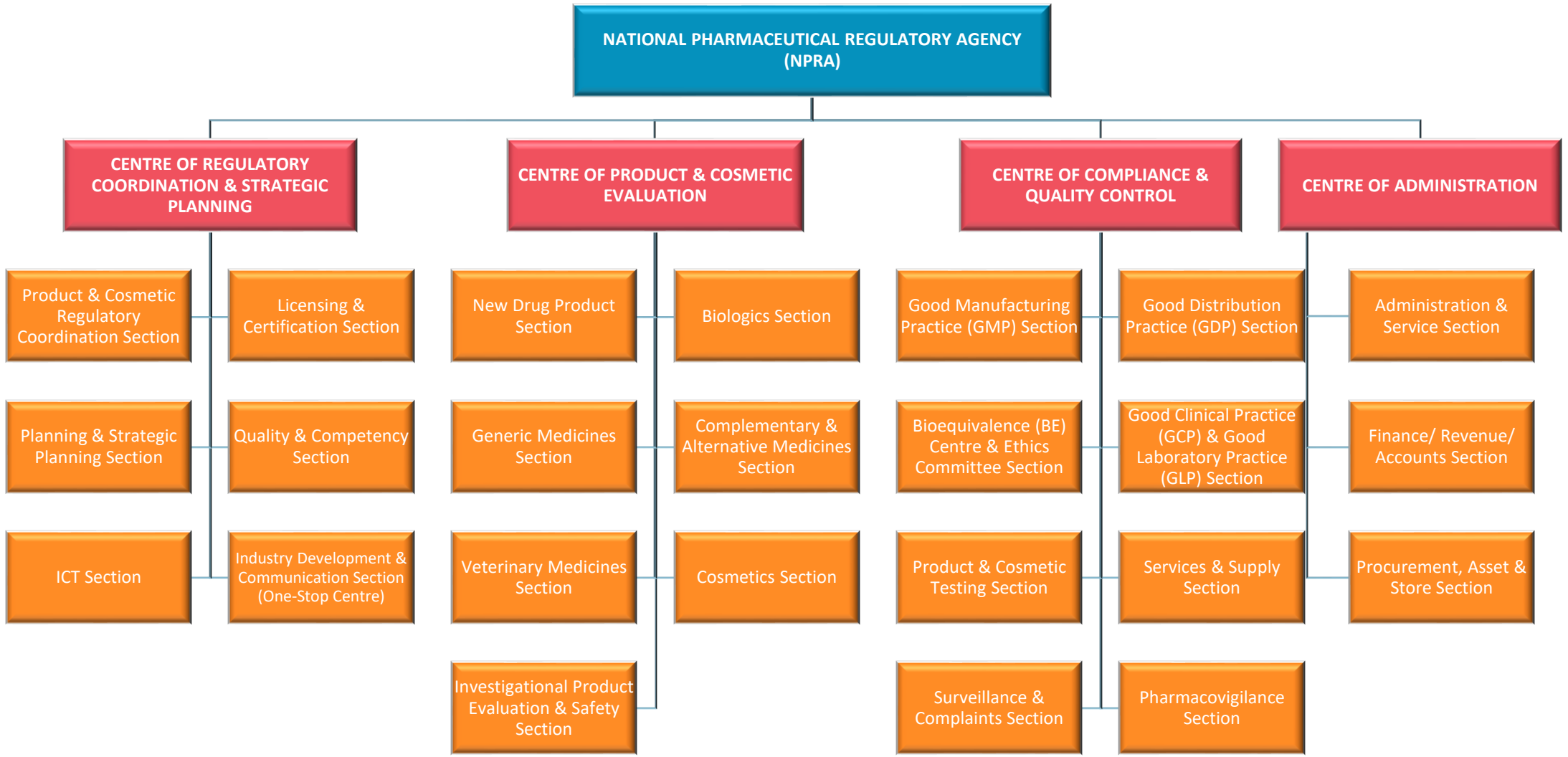


OBJECTIVE

To ensure that **therapeutic substances approved for the local market are safe, effective and of quality** and also to ensure that **cosmetic products approved are safe and of quality**

https://www.npra.gov.my/index.php/en/about/addons-list-6/vision-mission-and-objective.html

UNDERSTANDING THE FUNCTIONS OF NPRA THROUGH ITS ORGANISATION CHART



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DEFINITIONS OF REAL WORLD DATA (RWD) & REAL WORLD EVIDENCE (RWE)

REAL WORLD DATA (RWD)

Data relating to patient health status and/or the delivery of health routinely collected from a variety of sources[1]

Electronic health records

Claims and billing systems

Product and disease registries

Patient-generated data

Data gathered from other sources, such as mobile devices

REAL WORLD EVIDENCE (RWE)

Clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of RWD[1]

[1] *US FDA definitions*

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APPLICATION OF RWD/RWE IN THE MALAYSIAN REGULATORY SETTING

1

Post-market safety surveillance

RWD of adverse events are routinely collected to monitor safety of registered drugs in post-market setting

2

Pre-market efficacy assessment

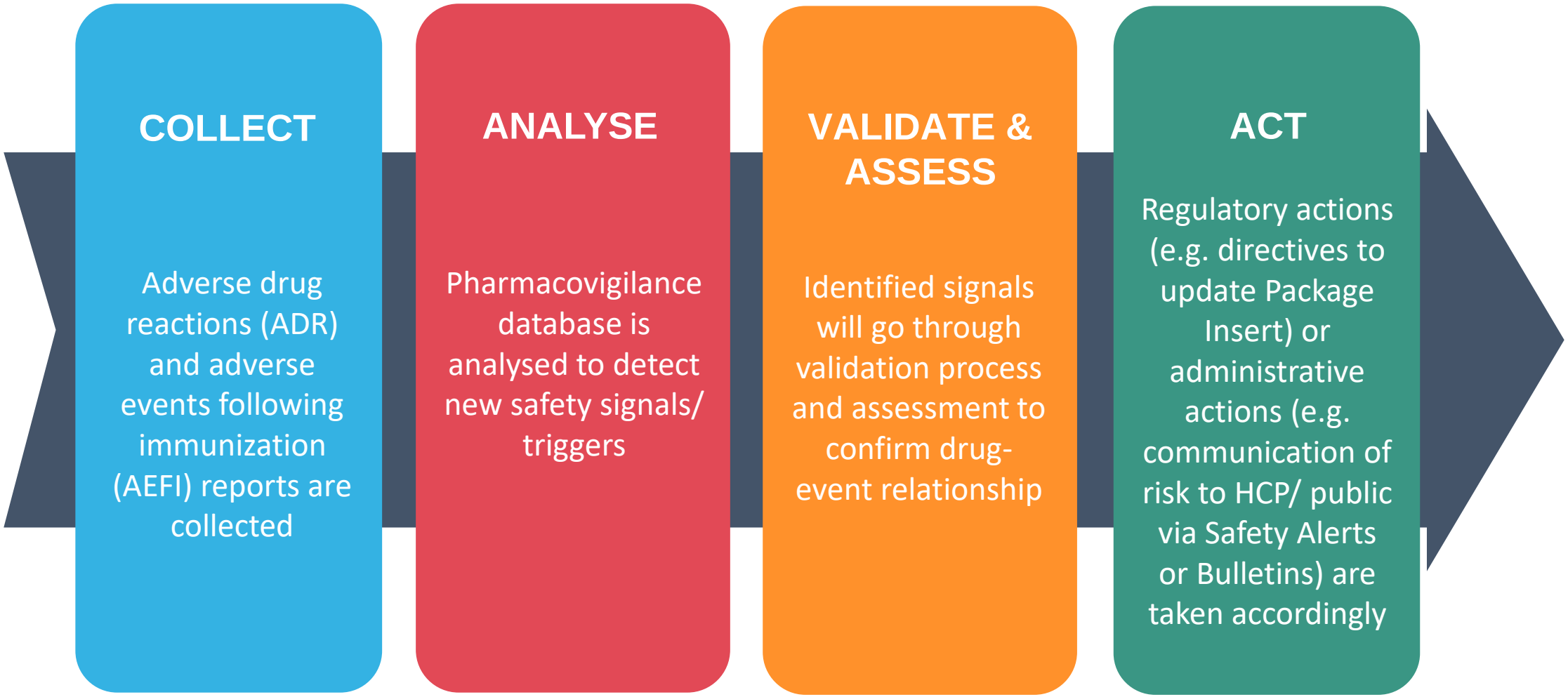
RWE has been accepted as supplemental evidence to clinical trials to support regulatory approval of new drugs

3

Change of approved product label

RWE generated via post-authorization studies imposed as conditions for registration provides additional evidence to support post-approval changes/variations

RWD/RWE IN POST-MARKET SAFETY SURVEILLANCE



OVERVIEW TO NPRA ADR/AEFI REPORTING SYSTEM

REPORTERS :

Healthcare professionals

Pharmaceutical companies

Consumers

Consumers via MySejahtera App

report AEFIs

National ADR Monitoring Centre NPRA

Feedback given to reporters/ registration holders

Review ADR/AEFI reports

Follow-up for further information if required/ INVESTIGATIONS (Investigation Team)

Causality assessment

Feedback on reporting statistics and quality

Data entry into Malaysian database

Indexing and Data Extraction

Regulatory action & Policy implementation

Drug Control Authority (DCA)

recommendations

MADRAC meeting

submission

WHO International Database

USING RWE TO SUPPORT DRUG REGISTRATION / POST-APPROVAL CHANGE

DRUG REGISTRATION

- NPRA accepts RWE to supplement clinical trial for new drug approval
  - As historical control for single arm trial (e.g. rare diseases, oncology)
  - Prior approval by at least one of the Drug Control Authority (DCA) reference agencies is required

POST-APPROVAL CHANGE

- RWE from post-authorization studies imposed as part of the conditions for registration provides additional evidence to support post-approval change
- NPRA accepts RWE to support expansion of use in certain populations excluded from RCTs (e.g. children, pregnant women)
  - Prior approval by at least one of the DCA reference agencies is required

EXAMPLES OF RWE-SUPPORTED APPROVAL IN NPRA

Product	Indication	Source of RWD
Capmatinib	Metastatic NSCLC whose tumours have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping	Non-interventional medical record review of patients with NSCLC harbouring MET exon 14 skipping mutation treated in oncology centres (as external benchmark or natural history study)
Inactivated SARS-CoV-2 vaccine (CoronaVac)	Active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 5 years of age and older.	Observational study of the effectiveness of an inactivated SARS-CoV-2 vaccine in children and adolescents (as supportive efficacy study)

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CHALLENGES OF USING RWD/RWE IN MALAYSIA

RWE generated from foreign data may not be representative of local populations

Limited accessibility to data

Local regulatory framework for RWE has yet to be developed

WAY FORWARD

Encourage data-sharing by promoting collaboration among stakeholders

Develop local regulatory framework for RWE

THANK YOU