Experiences to Improve Maturity Capacity of Pharmacovigilance in Thailand

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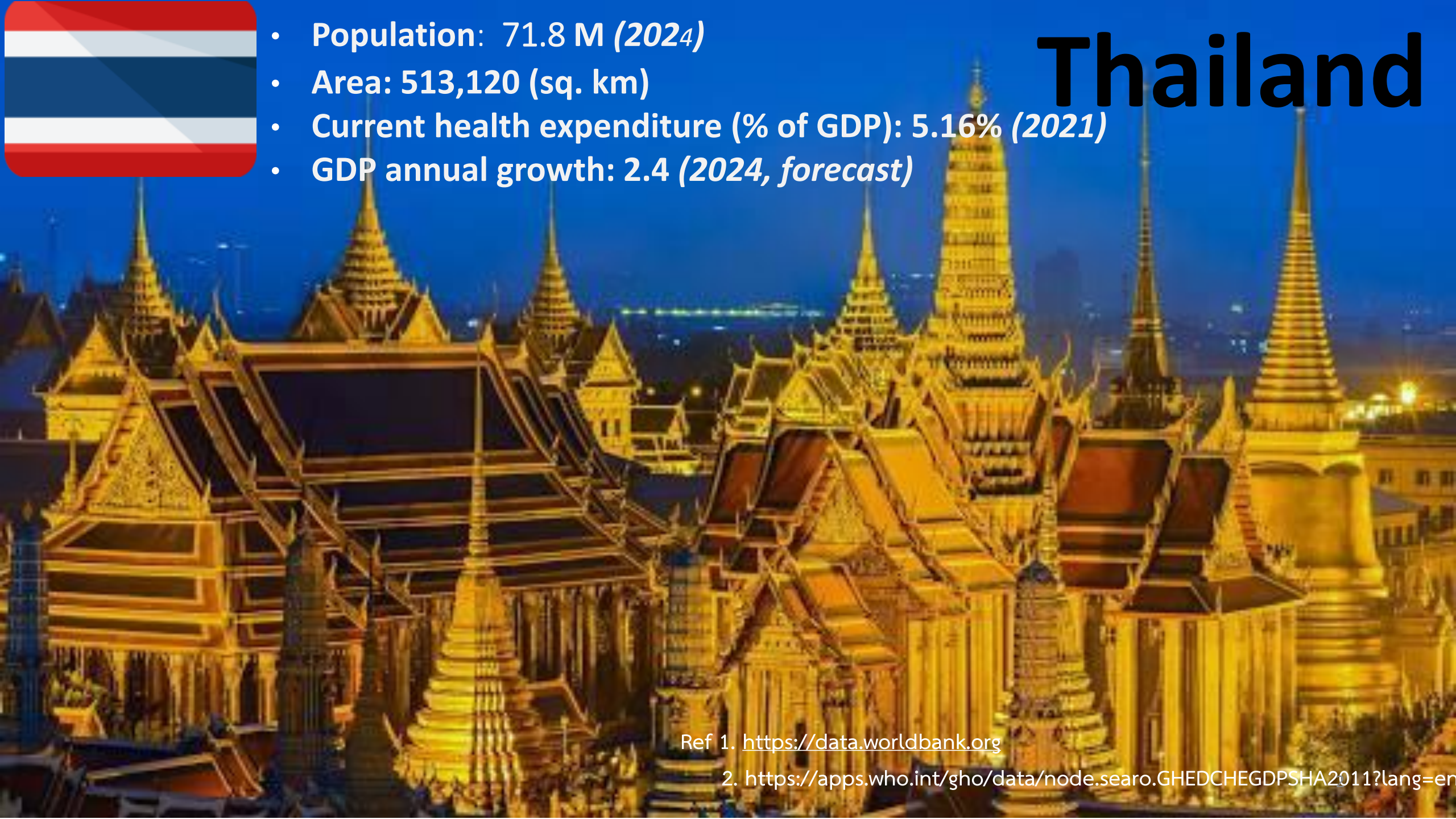


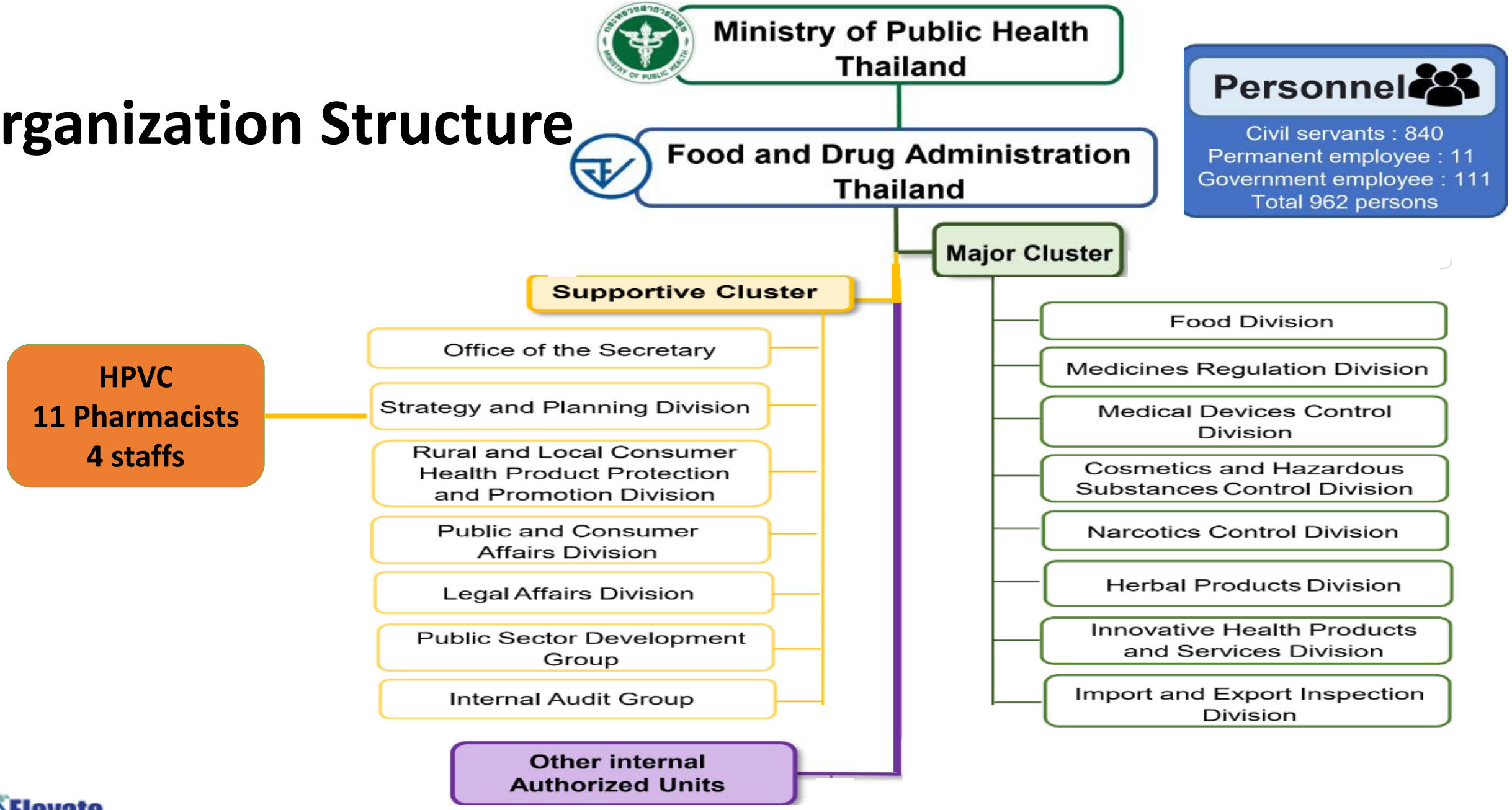
Thailand

- **Population**: 71.8 M *(2024)*
- **Area: 513,120 (sq. km)**
- **Current health expenditure (% of GDP): 5.16%** ***(2021)***
- **GDP annual growth: 2.4** ***(2024, forecast)***

Ref 1. https://data.worldbank.org

2. https://apps.who.int/gho/data/node.searo.GHEDCHEGDPSHA2011?lang=en

Organization Structure



Emerging Innovation Strategies

Health products safety surveillance strategy

Targeted surveillance of Covid-19 medicines

Adverse event reporting system for consumer

Dataset AE reporting system

Translation the MeDRA term in Thai language

Guidelines for Medicinal Products Under Exemption Authorization

Upgraded Reporting Systems

Risk management plan for medicines and biologicals

Good Pharmacovigilance Practice for Thailand

12/11/2024

Good Pharmacovigilance Practices (GVP)

1. Development and Stakeholder Input

- HVPC reviewed international PV guidelines, including those from EMA, US.FDA, WHO, and other stringent agencies.
- Draft GVP guidance was shared with stakeholders for feedback, which was incorporated into the first edition in 2024.

2. Purpose and Benefits

- The guidance outlines optimal approaches for ensuring the safety and effectiveness of medicinal products.
- Serves as a reference for best practices in pharmacovigilance tailored to product stages and risk levels.

3. Content Overview

Chapter 1	Chapter 2	Chapter 3	Chapter 4	Chapter 5
Pharmacovigilance System and Quality	**Pharmacovigilance System Master File**	**Inspection**	**Audit**	**Safety Reporting Requirement**
Chapter 6	Chapter 7	Chapter 8	Chapter 9	Chapter 10
Risk Management Plan (RMP)	**Safety Communication**	**Periodic Benefit Risk Evaluation Report (PBRER)**	**Post Authorization Safety Study (PASS)**	**Signal Management**

4. Implementation Plan

Thai FDA aims to operationalize the GVP guidance by 2027 through strategic planning and execution

Status of Regulatory Vigilance (VL) functions from WHO Global Benchmarking Tool (Vaccine)

Year	Subindicators implemented/ expected to be implemented	Indicators implemented/ expected to be implemented	Subindicators implementation %
2018	24.0/25	6 out of 6	96.0%
2021	25.75/26	6 out of 6	99.0%

Key challenges and Solutions (ML2 ----> ML3)

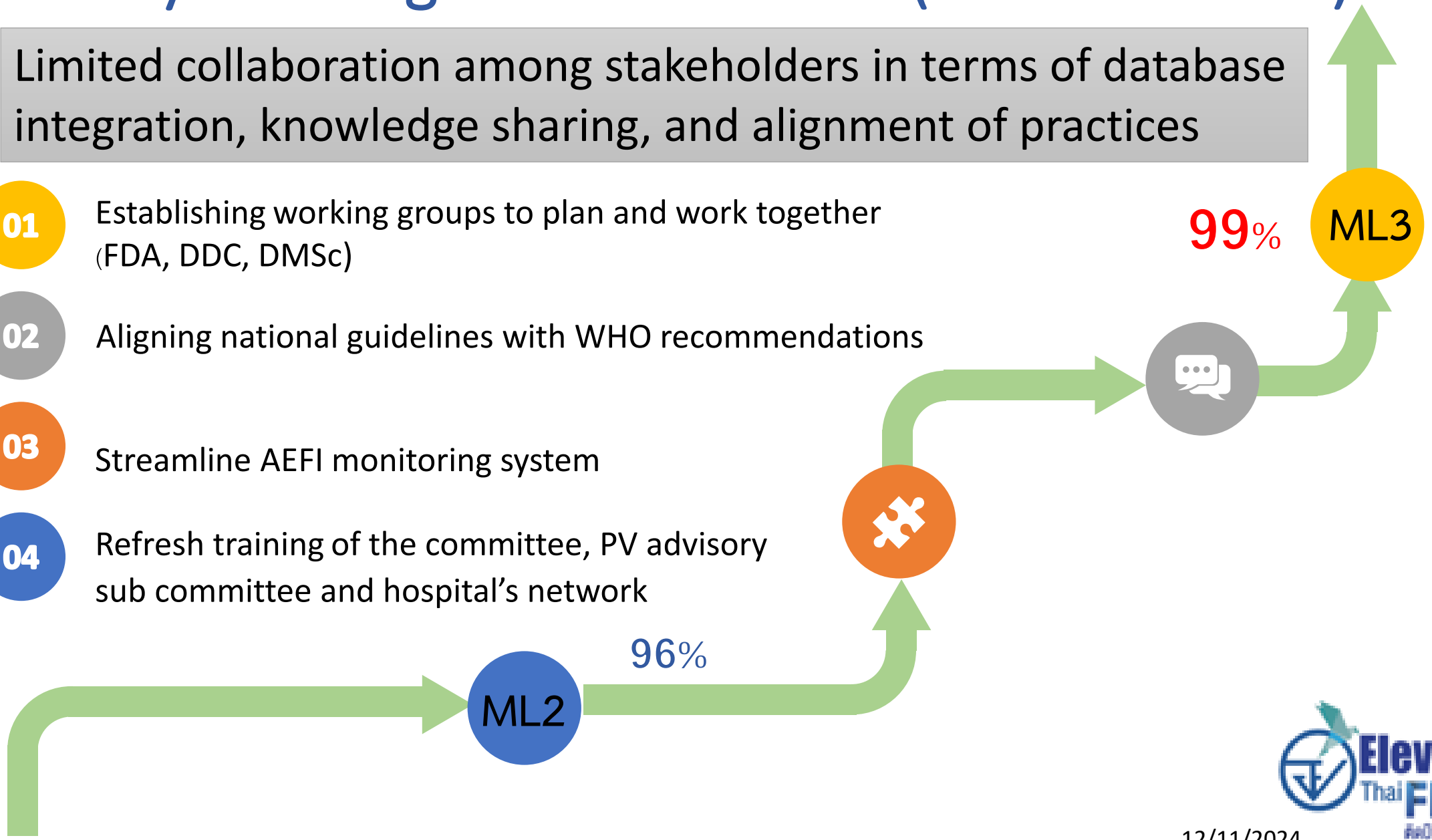
Limited collaboration among stakeholders in terms of database integration, knowledge sharing, and alignment of practices

01 Establishing working groups to plan and work together (FDA, DDC, DMSc)

02 Aligning national guidelines with WHO recommendations

03 Streamline AEFI monitoring system

04 Refresh training of the committee, PV advisory sub committee and hospital's network



Improving Pharmacovigilance System

Self-Assessment:

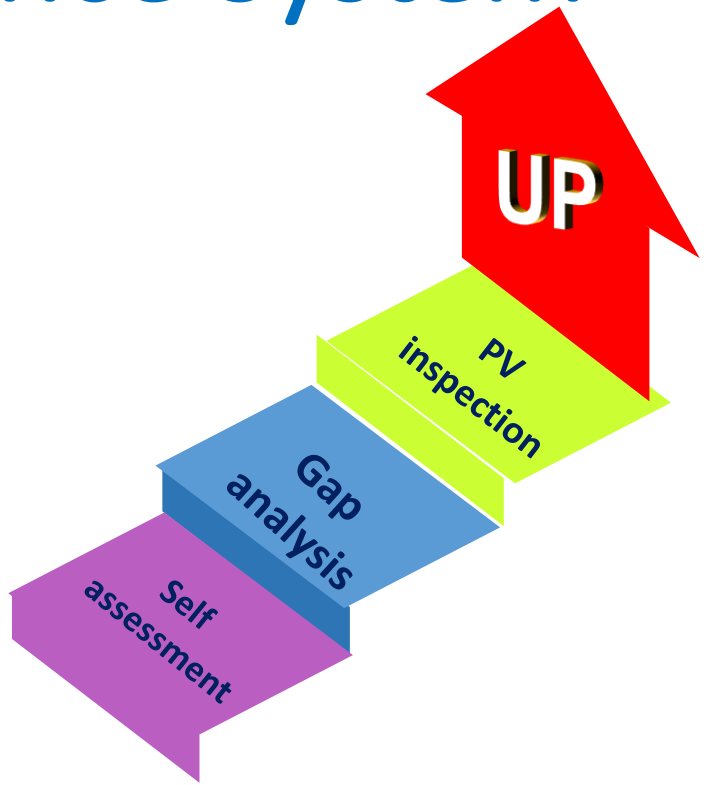
Thai FDA conducted a WHO-GBT self-assessment for achieving goal by 2027

Gap Analysis:

Identifying Gaps and Setting Priorities, The major finding that is still gap is PV inspection

Priority Measure:

Setting up a PV inspection system



Key Enablers

- Executive policy
- Stakeholder Involvement
- Capacity building

Collaborative Approach

Key strategies to foster long-term capacity development among Thai FDA, relevant organizations, and industry sectors

Clear Guidelines and Joint Training

Developing precise guidelines for PV activities and conducting joint training programs to bridge knowledge and skill gaps among stakeholders

Collaborative plan

Establishing a stakeholder working group for coordinated planning of PV activities, including resource allocation

Multi-Sectoral Coordination

Engaging government agencies, medical professionals, and industry representatives to ensure a harmonized and effective approach

Elevate Thai FDA

Consumer are Safe, Prosperous Entrepreneurs and Sustainable Thai Consumer Protection System