THE PHARMACEUTICAL ASSOCIATION OF THAILAND
UNDER ROYAL PATRONAGE
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Value-Based Procurement Framework

for GLP-1RA Complex Generics Procurement

A consensus framework from the Thai Hospital Pharmacists' Consortium, developed via MCDA methodology with 27 specialist hospital pharmacists.

Prepared for hospital Pharmacy & Therapeutics Committees.

TABLE OF CONTENTS

01 บทสรุปผู้บริหาร

ยากลุ่ม Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs) ถือเป็นกลุ่มยาที่มีบทบาทสำคัญและถูกใช้อย่างแพร่หลายสำหรับการรักษาโรคเบาหวานชนิดที่ 2 และโรคอ้วนทั้งในประเทศไทยและทั่วโลก ส่งผลให้มีการพัฒนาและขึ้นทะเบียนผลิตภัณฑ์เลียนแบบ (Follow-on) ของ GLP-1 RAs จำนวนมาก ทั้งในรูปแบบ Generic, Complex generic และ Biosimilar เพื่อเพิ่มทางเลือกในการรักษาและส่งเสริมการเข้าถึงยาของผู้ป่วย อย่างไรก็ตาม GLP-1 RAs เป็นผลิตภัณฑ์ยาประเภทเปปไทด์ที่มีความซับซ้อนทั้งด้านโครงสร้าง โมเลกุล และกระบวนการผลิต ซึ่งอาจส่งผลต่อคุณลักษณะของผลิตภัณฑ์ ประสิทธิภาพทางคลินิก และความปลอดภัยของผู้ป่วย ดังนั้นการตัดสินใจจัดซื้อผลิตภัณฑ์ยา GLP-1 RAs ในโรงพยาบาลจึงควรพิจารณาคุณค่าของผลิตภัณฑ์อย่างรอบด้าน โดยประเมินคุณภาพของผลิตภัณฑ์ สมรรถนะทางคลินิกและความปลอดภัย ควบคู่กับการพิจารณาด้านราคา เพื่อให้ประสิทธิภาพในการรักษาและความปลอดภัยของผู้ป่วยเป็นปัจจัยสำคัญสูงสุดในการคัดเลือกผลิตภัณฑ์ยา

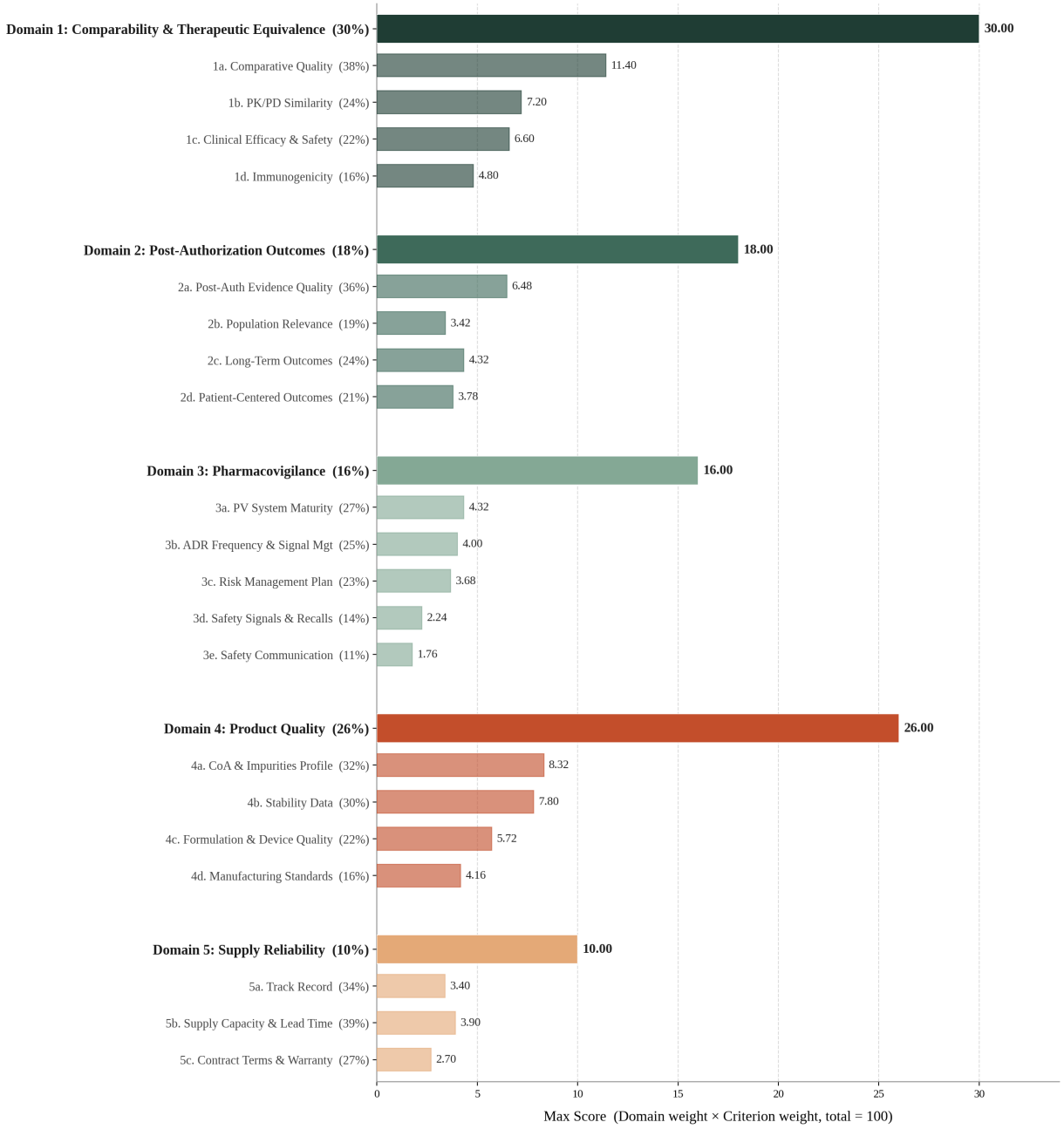
คณะผู้จัดทำได้ดำเนินการพัฒนากรอบการพิจารณาสำหรับกระบวนการจัดซื้อผลิตภัณฑ์ยาที่มีความเหมาะสมกับบริบทของระบบสาธารณสุขไทย โดยใช้ระเบียบวิธีวิจัยแบบผสมผสาน (Mixed method) บนพื้นฐานของหลักฐานเชิงประจักษ์จากการทบทวนวรรณกรรมอย่างเป็นระบบ (Literature review) ร่วมกับข้อเสนอแนะจากการประชุมคณะที่ปรึกษา (Advisory board) จากนั้นจึงนำกรอบการพิจารณาดังกล่าวเข้าสู่กระบวนการสร้างฉันทามติ (Consensus) ผ่านการประชุมเชิงปฏิบัติการของคณะเภสัชกรโรงพยาบาลผู้เชี่ยวชาญทั่วประเทศไทยจำนวน 27 ท่าน โดยประยุกต์ใช้แนวทางการประเมินตามคุณค่า (Value-Based Procurement; VBP) ควบคู่กับการวิเคราะห์การตัดสินใจแบบหลายเกณฑ์ (Multi-Criteria Decision Analysis; MCDA) เพื่อให้เภสัชกรผู้เชี่ยวชาญร่วมกันกำหนดเกณฑ์การประเมินและค่าน้ำหนักของเกณฑ์การประเมินแต่ละโดเมน ด้วยวิธีการให้คะแนนอย่างเป็นระบบ โปร่งใส และลดอคติจากการใช้ดุลยพินิจส่วนบุคคล

เอกสารเชิงวิชาการและสมุดปกขาว (White paper) ฉบับนี้จึงนำเสนอแนวทางการพิจารณาคัดเลือกยากลุ่ม GLP-1 RAs เข้าสู่บัญชียาของโรงพยาบาลอย่างเป็นระบบที่ครอบคลุมทั้งด้านคุณค่าและราคา โดยมีข้อเสนอแนะที่สำคัญ ดังต่อไปนี้

ข้อเสนอแนะที่สำคัญ

- **การประยุกต์ใช้กรอบการประเมินคุณภาพผลิตภัณฑ์ที่เข้มงวด** โดยพิจารณาข้อมูลเชิงวิเคราะห์ในหลายมิติและใช้ Orthogonal analytical methods (การใช้วิธีที่เป็นอิสระต่อกันตั้งแต่ 2 วิธีขึ้นไปที่มีหลักการพื้นฐานทางฟิสิกส์เคมีต่างกัน มาใช้วัดคุณลักษณะสำคัญเดียวกัน) เพื่อตรวจสอบความถูกต้องและยืนยันความเหมือนของสารสำคัญออกฤทธิ์ทางเภสัชกรรม (Active Pharmaceutical Ingredient; API) รวมถึงประเมินสิ่งเจือปนที่เกี่ยวข้องกับเปปไทด์ (Peptide-related impurities) และความเสี่ยงต่อการรวมตัวของเปปไทด์ (Fibrillation) ซึ่งเป็นปัจจัยสำคัญที่อาจส่งผลต่อคุณภาพ ประสิทธิภาพ และความปลอดภัยของผลิตภัณฑ์ GLP-1 RAs ที่ผลิตด้วยกระบวนการการสังเคราะห์
- **การพิจารณาหลักฐานจากสถานการณ์จริง (Real-World Evidence; RWE) ประกอบกับการประเมินความเสี่ยงด้านการกระตุ้นภูมิคุ้มกัน (Immunogenicity)** สำหรับการตัดสินใจในกระบวนการจัดซื้อผลิตภัณฑ์ยา โดยให้ความสำคัญกับข้อมูลการเกิดแอนติบอดีต่อยา (Anti-drug antibodies; ADAs) ในระดับต่ำ ตลอดจนผลลัพธ์ด้านหัวใจและหลอดเลือดและเมแทบอลิก จากการศึกษาในประชากรไทยหรือประชากรเอเชีย
- **การประยุกต์ใช้การประเมินข้อเสนอที่ให้ประโยชน์สูงสุดทางเศรษฐกิจ (Most Economically Advantageous Tender; MEAT) และวิธีการวิเคราะห์การตัดสินใจแบบหลายเกณฑ์ (MCDA)** ร่วมกับการประเมินค่า**ประสิทธิภาพต่อราคา (Performance-to-Price) ด้วยสัดส่วนไม่ต่ำกว่า 70:30** เพื่อให้น้ำหนักแก่คุณภาพผลิตภัณฑ์ สมรรถนะทางคลินิก และความปลอดภัยของผู้ป่วย เหนือกว่าปัจจัยทางด้านราคา
- **การให้ความสำคัญกับการจัดซื้อผลิตภัณฑ์ยาที่ได้รับการขึ้นทะเบียนและอนุมัติอย่างถูกต้อง** โดยหลีกเลี่ยงการใช้ผลิตภัณฑ์ยาปรุงเฉพาะราย (Compounded products) ที่อยู่นอกระบบการกำกับดูแล ทั้งนี้ เพื่อป้องกันการใช้ยานอกข้อบ่งใช้ (Off-label use) อย่างไม่เหมาะสม เพิ่มประสิทธิภาพการใช้ทรัพยากรและงบประมาณของโรงพยาบาล และคุ้มครองผู้ป่วยจากความเสี่ยงด้านคุณภาพ ประสิทธิภาพ และความปลอดภัยของผลิตภัณฑ์ยา

โครงสร้างของระบบการประเมินตามแนวทาง MCDA ซึ่งพัฒนาขึ้นผ่านกระบวนการสร้างฉันทามติของคณะเภสัชกรโรงพยาบาลผู้เชี่ยวชาญ ได้รับการออกแบบให้เหมาะสมกับการคัดเลือกผลิตภัณฑ์ยากลุ่ม GLP-1 RAs โดยเฉพาะ ประกอบด้วยเกณฑ์การประเมิน (Criteria) และค่าน้ำหนัก (Weights) ดังแสดงในภาพ



ภาพที่ 1: เกณฑ์และค่าน้ำหนักรวมของโดเมน MCDA ทั้ง 5 ด้าน ที่ได้รับการรับรองโดยฉันทามติของคณะเภสัชกรจำนวน 27 ท่าน

01 EXECUTIVE SUMMARY

Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs) currently play a pivotal role in the therapeutic management of type 2 diabetes mellitus and obesity, both in Thailand and globally. The introduction of follow-on GLP-1 RA products presents a significant opportunity to expand therapeutic alternatives and broaden patient access. However, GLP-1 RAs are complex peptide-based pharmaceutical products, exhibiting intricacies in their structural, molecular, and manufacturing profiles, which can significantly impact product attributes, clinical efficacy, and patient safety. Therefore, the procurement decision-making process for GLP-1 RA products in hospitals should encompass a comprehensive evaluation of product value by assessing product quality, clinical performance, and safety in conjunction with pricing considerations, ensuring that therapeutic efficacy and patient safety remain the paramount factors in the medication selection process.

To address this challenge, a mixed-methods approach was executed to establish an evidence-based framework tailored for the Thai healthcare context. This initiative began with a comprehensive literature review of relevant studies and regulatory documents, combined with recommendations from an advisory board meeting to define localized criteria. Subsequently, this evaluation framework was then finalized during a structured stakeholder consensus workshop featuring a panel of 27 hospital pharmacists across Thailand. Utilizing a value-based procurement (VBP) approach alongside Multi-Criteria Decision Analysis (MCDA). This allowed the expert pharmacists to collaboratively determine the evaluation criteria and the weightings for each domain through a systematic and transparent scoring method, thereby minimizing subjective bias.

Consequently, this White Paper presents a systematic guideline for the selection of GLP-1 RAs for hospital formularies, comprehensively addressing both value and cost, with the following key recommendations.

Key recommendations include the following:

- **Application of a rigorous product quality assessment framework** that reviews multi-dimensional analytical data and utilizing orthogonal analytical methods (employing two or more independent techniques with fundamentally distinct physicochemical principles to measure the same critical quality attribute) to verify Active Pharmaceutical Ingredient (API) sameness, as well as to evaluate peptide-related impurities and fibrillation risks, which are critical factors potentially affecting the quality, efficacy, and safety of synthetically manufactured GLP-1 RA products.
- **Considering Real-World Evidence (RWE) and immunogenicity risk assessments** in medicine procurement decisions, with a strong focus on data demonstrating low anti-drug antibodies (ADAs) formation and cardiometabolic outcomes relevant to the Thai or Asian populations.
- **Implementation of the Most Economically Advantageous Tender (MEAT) criteria and Multi-Criteria Decision Analysis (MCDA) methodologies** to shift hospital procurement towards a minimum **70:30 Performance-to-Price ratio (70% performance; 30% price),** facilitating a transparent evaluation process that prioritizes product quality, clinical performance, and patient safety over price-driven factors.
- **Utilizing digital formulary guidance and prioritizing approved, registered formulations** over unregulated compounded products to mitigate off-label misuse, optimize hospital budgets, and safeguard patients from potential safety risks.

Based on the consensus of expert hospital pharmacists, an MCDA framework structure specifically aligned with the selection of GLP-1 RAs was developed, with its criteria and weights presented in the figure below.

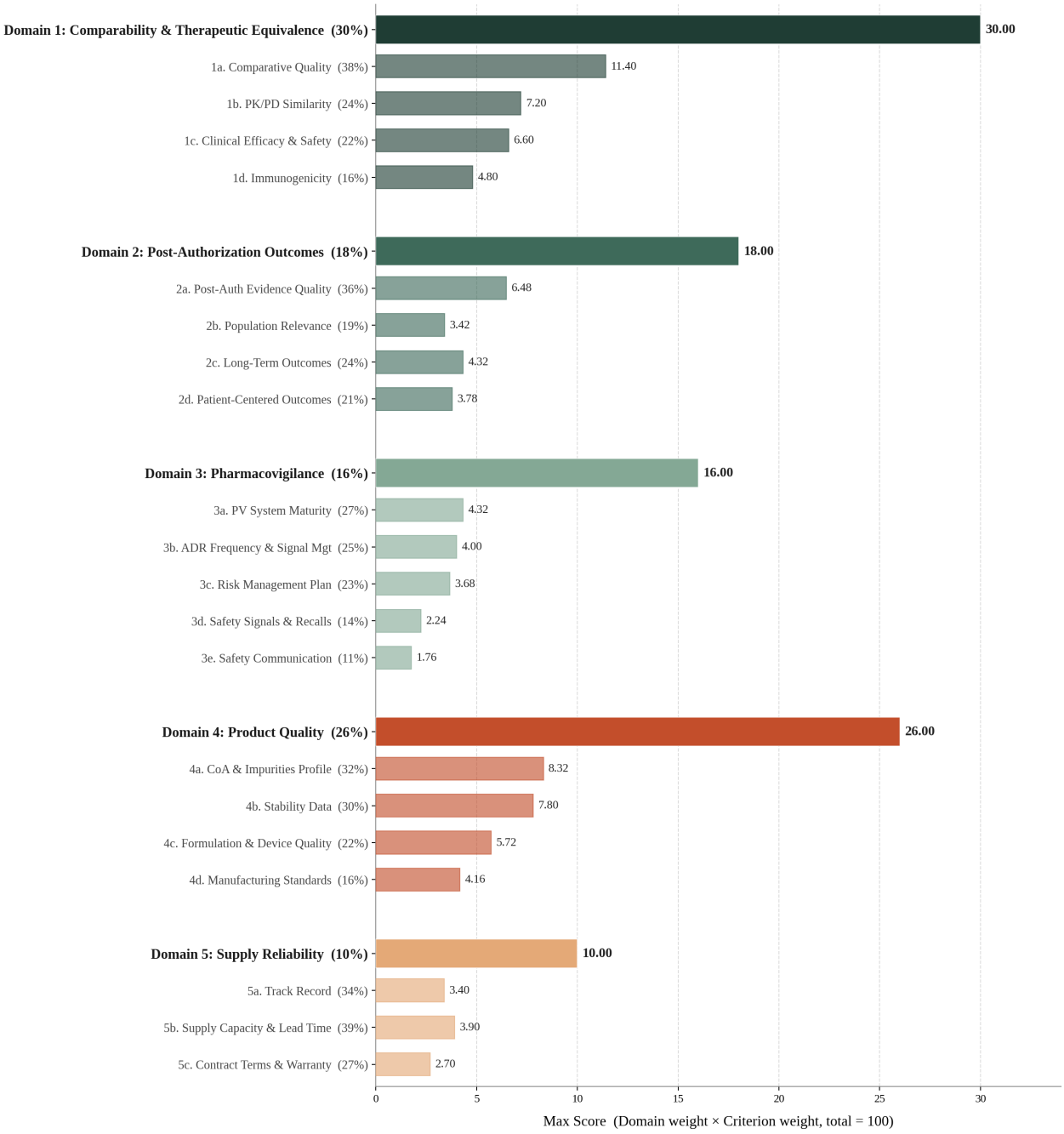


Figure 1: Overall weights of the five MCDA domains, as ratified by the 27-pharmacist consensus panel.

02 BACKGROUND

Glucagon-like peptide-1 receptor agonists (GLP-1 RAs) are a class of peptide therapeutics used in the management of type 2 diabetes mellitus (T2DM) and obesity, as well as for cardiovascular risk reduction for some patient groups (1, 2, 3, 4). Their clinical value extends beyond glycemic control, as they also improve body weight and support cardiometabolic health (5, 6, 7). The number of patients treated with GLP-1 RAs increased by 744.6% between 2018 and 2023 (8). As a result, GLP-1 RAs have become an important therapeutic option in both endocrine and cardiometabolic practice.

Despite their clinical importance, patient access in Thailand remains constrained by high costs and fragmented reimbursement policies. Treatment is primarily available to Civil Servants Medical Benefit Scheme (CSMBS) beneficiaries and self-paying patients. In contrast, most individuals covered by the Universal Coverage Scheme (UCS) and the Social Security Scheme (SSS) face limited access. This disparity contributes to a significant care gap and challenges hospitals to balance financial constraints and supply limitations with the evidence-based prescribing of high-cost therapies (9).

Driven by high demand, follow-on products, also known as complex generics, are now being introduced to the market (10). Although these complex generics make medication more affordable and improve patient access, ensuring their safety and clinical efficacy remains a primary concern. Originator products are typically biologics produced via recombinant DNA technology (11). In contrast, complex generics or follow-on peptide products are often manufactured using chemical synthesis, semisynthetic processes or alternative manufacturing routes, which can make it much more difficult to reproduce the reference product's structural integrity, impurity profile, and stability characteristics (12).

These differences matter because peptide medicines are highly sensitive to variations in sequence fidelity, purification, aggregation, and formulation design (13). Even minor manufacturing deviations can generate related peptide species or alter the drug's higher-order structure, which may negatively affect drug absorption, receptor binding, and overall potency (14). Additionally, aggregates and other structural variants can increase immunogenicity risk, which is a critical safety

concern for chronic therapies intended for long-term use (13, 15). For this reason, the evaluation of follow-on GLP-1 RAs requires a careful assessment of critical quality attributes, comparability data, and manufacturing controls, rather than reliance on the assumptions typically used for conventional generics (13, 14).

As hospital interest grows and GLP-1 RA complex generics begin entering the Thai market in the near future, the healthcare system faces the challenge of balancing clinical needs, supply continuity, and budget impact when adopting newer follow-on products (16, 17). Existing procurement frameworks designed for conventional generics or biosimilars are inadequate for this structurally distinct category of medicines. This is particularly relevant for institutions seeking a value-based procurement (VBP) approach that evaluates medicines not only by acquisition price, but also by total clinical value, quality assurance, and implementation feasibility (16, 18).

Therefore, this white paper focuses on developing a VBP model specifically tailored to the context of Thailand's healthcare system. The structural design of these evaluation criteria incorporated the Most Economically Advantageous Tender (MEAT) framework and Multi-Criteria Decision Analysis (MCDA) principles. This establishes rigorous scientific and regulatory requirements to safeguard patient safety and therapeutic efficacy.

03 METHODOLOGY

This study employed a mixed-methods approach to ensure a comprehensive and operationally acceptable framework. The research was conducted through the following three key phases:

1 Literature Review

An extensive review of existing literature and regulatory documents was conducted from inception up to May 8, 2026, to establish the scientific foundation and policy context.

2 Advisory Board Meeting

An expert advisory panel, including pharmacists from 10 institutions, was convened to evaluate the current procurement landscape, confirm existing challenges, and establish the critical need for developing a VBP framework for drug selection.

3 The Thai Hospital Pharmacists' Consortium Consensus Workshop

An expert consensus workshop, including twenty-seven specialist hospital pharmacists and a physician from eighteen institutions across Thailand. The workshop was organized to develop a VBP model tailored to the context of Thailand's healthcare system.

This workshop utilized MCDA methodology in accordance with International Society for Pharmacoeconomics and Outcomes Research (ISPOR) guidelines (19, 20). Five evaluation domains were identified through prior desk research, each containing multiple criteria whose relative importance was established through the MCDA consensus method, to gather anonymous expert opinions and achieve a unified consensus.

04 FRAMEWORK & RESULTS

The Complexity of Follow-On GLP-1 RAs and Regulatory Frameworks

A literature review of current evidence identified the distinct challenges associated with follow-on GLP-1 RAs. While originator GLP-1 RAs are typically biologics produced via recombinant DNA technology, most follow-on products and complex generics are manufactured through chemical synthesis (11, 13). These fundamental differences in manufacturing processes may result in variations in structural integrity, molecular characteristics, and product purity compared with the reference products (14, 15). Analytical studies have revealed that follow-on GLP-1 RAs frequently exhibit divergent impurity profiles, containing novel peptide-related impurities, high molecular weight proteins, trace metals, and varying formulations that were not present in the originator products (13, 14).

These manufacturing deviations can alter the drug's higher-order structure and lead to peptide fibrillation (aggregation into insoluble beta-sheet structures), which impairs drug absorption, receptor binding, and bioavailability. Furthermore, these aggregates and new impurity sequences carry a significantly heightened risk of triggering immunogenicity, such as the production of anti-drug antibodies (ADAs), which poses a critical safety concern for chronic therapies (13, 14).

> Real-world safety data from the US FDA's Adverse Event Reporting System (FAERS) revealed 711 total adverse event reports, of which 672 were serious. Most critically, 15 deaths were recorded, representing a 2% mortality rate among reported cases with the use of compounded and unapproved synthetic GLP-1 RA products (21).

To mitigate the risks associated with complex generics, international regulatory authorities have established rigorous evaluation pathways:

The US FDA delineates approval pathways based on the product's characteristics. A proposed generic synthetic peptide that demonstrates active ingredient sameness to an rDNA-origin reference listed drug (RLD) can be submitted via the 505(j) Abbreviated New Drug Application (ANDA) pathway. The FDA requires strict control over impurities, mandating that any new specified peptide-related impurity must not exceed 0.5% of the drug substance, and must be fully characterized to ensure it does not increase immunogenicity risks (e.g., lacking T-cell epitopes). Alternatively, if the product possesses differences that require new clinical investigations to prove safety and effectiveness, it must be submitted under the 505(b)(2) New Drug Application (NDA) pathway (22, 23).

The European Medicines Agency (EMA) employs the Article 10(3) "Hybrid Application" pathway for products that do not strictly meet the definition of a generic medicine, or where bioequivalence cannot be demonstrated through standard bioavailability studies alone. This pathway allows applicants to rely partially on the reference medicinal product's dossier, supplemented by the results of appropriate new non-clinical and/or clinical studies to justify changes in the active substance, strength, pharmaceutical form, or route of administration (24).

The Thai Food and Drug Administration (Thai FDA) has adopted a pragmatic, risk-based "Hybrid Application" pathway to regulate these complex generics. Recognizing that Thailand is primarily an importing nation receiving dossiers formatted under both US FDA and EMA standards, the Thai FDA's hybrid pathway provides the flexibility to evaluate submissions from disparate regulatory backgrounds. However, to ensure uncompromised safety and efficacy, the Thai FDA enforces a highly stringent requirement for "orthogonal analytical methods" (5) (16, 17). Applicants must utilize multiple advanced, multi-dimensional laboratory techniques to conclusively prove API sameness and thoroughly characterize the impurity profile, thereby ensuring that the synthetic follow-on product matches the originator's quality before market authorization is granted (16).

The MEAT VBP Framework and MCDA Methodology

Because existing procurement frameworks designed for conventional small-molecule generics were inadequate for structurally distinct peptide medicines, a more sophisticated procurement approach was required. The MEAT VBP Framework provided a highly practical and adaptable means of imposing both structure and rigor on the value analysis process. Furthermore, it allowed for a comprehensive qualitative assessment of the potential value impact of complex therapeutic agents, such as GLP-1 RAs, ensuring that the procurement decisions delivered optimal benefits for patients, healthcare professionals, healthcare providers, and the overall health system (25). To address this, the MEAT framework was integrated with MCDA principles. MCDA is a systematic, evidence-based methodology that allowed hospital Pharmacy and Therapeutics Committees (PTC) to evaluate multiple conflicting criteria such as clinical efficacy, safety, product quality, and supply continuity simultaneously (26).

To develop a consensus-driven model, the Thai Hospital Pharmacists' Consortium conducted structured workshops utilizing the MCDA consensus method via the Mentimeter platform. Through iterative voting rounds, a panel of specialist pharmacists and physicians critically appraised, refined, and weighed the evaluation criteria, ultimately achieving a unanimous consensus on the framework's structural design as shown in **Figure 2**, **Table 1,** and **Table 2.**

The Thai Hospital Pharmacists' Consortium recommended that GLP-1 RA procurement transition from traditional cost-based purchasing to a VBP approach. The consensus panel proposed at least a Performance-to-Price ratio of 70:30 (70% performance; 30% Price) as an optimal benchmark for hospital guidelines, helping ensure that verified clinical performance, product quality, and patient safety appropriately balance baseline acquisition costs. Within this framework, the 70% performance component can be systematically evaluated utilizing a 5-Domain MCDA tool, applying the finalized consensus weightings tailored specifically for the clinical and operational context of GLP-1 RAs.

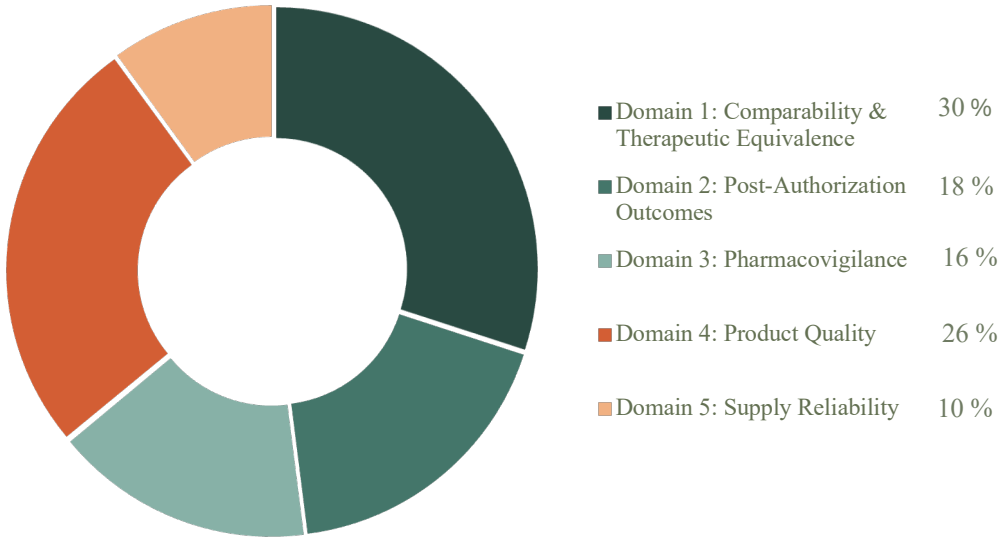


Figure 2: Overall weights of domains.

The consortium distributed the performance component to heavily prioritize clinical assurance and product manufacturing integrity: Domain 1 (Comparability & Therapeutic Equivalence) weighted highest at 30%, highlighting the critical importance of verifying similarity against the reference biologic. Domain 2 (Post-Authorization Outcomes) was allocated 18% to ensure that real-world patient data and clinical outcomes remain central to the product evaluation. Domain 3 (Pharmacovigilance) was assigned 16% to prioritize active post-market safety signal tracking and risk management compliance. Domain 4 (Product Quality) received 26%, emphasizing the structural, manufacturing, and engineering complexities inherent to synthetic generic peptides. Domain 5 (Supply Reliability) comprises the remaining 10% of the model to safeguard institutional logistics and protect against product shortages.

Within the individual criteria weights (**Table 1**), the panel prioritized specific high-impact technical metrics rather than a uniform distribution: comprehensive analytical data covering structural and functional similarity emerged as the primary driver under Domain 1 (38% internal weight), while batch-specific impurity profiles and robust stability data dominated Domain (32% and 30%). For post-market and operational metrics, the panel designated the data quality of large-scale evidence cohorts (36%) and pharmacovigilance master file maturity (27%) as primary indicators concluding with logistical resilience under Domain 5, which prioritizes active production capacity and minimal delivery lead times (39%).

Table 1: Weighting and relative contribution of criteria.

Domain / Criteria	Weight within domain	Overall Weight
Domain 1: Comparability & Therapeutic equivalence (30%)		
1a. Comparative quality and structural/functional similarity	38%	11.4%
1b. PK/PD similarity	24%	7.2%
1c. Clinical efficacy and safety comparability	22%	6.6%
1d. Immunogenicity	16%	4.8%
Domain 2: Post-Authorization Outcomes (18%)		
2a. Post authorization evidence quality	36%	6.5%
2b. Population relevance	19%	3.4%
2c. Long-term outcomes	24%	4.3%
2d. Patient-centered outcomes & adherence	21%	3.8%
Domain 3: Pharmacovigilance (16%)		
3a. PV system maturity	27%	4.3%
3b. ADR frequency assessment & signal management	25%	4.0%
3c. Risk management plan	23%	3.7%
3d. Safety signals and product recalls	14%	2.2%
3e. Safety communication	11%	1.8%
Domain 4: Product Quality (26%)		
4a. Certificate of analysis & impurities profile	32%	8.3%
4b. Stability data	30%	7.8%
4c. Formulation, device & physical quality	22%	5.7%
4d. Manufacturing standards	16%	4.2%
Domain 5: Supply Reliability (10%)		
5a. Track record	34%	3.4%
5b. Supply capacity and lead time	39%	3.9%
5c. Contract terms and warranty	27%	2.7%

Note: “Weight within Domain” showed how much each criterion counts inside its own domain (summing to 100% within each domain). “Overall Weight of Total Score” showed how much each criterion contributed to the final 100-point MCDA score (all 20 criteria sum to 100%).

Table 2: The final MCDA tool.

Each criterion was scored against five evidence tiers (100% – 0%). The committee assessed submitted bidder evidence to the applicable tier to derive the awarded score.

Domain 1 · Comparability & Therapeutic Equivalence — 30%		
Criterion	**Tier**	**Evidence description**
1a. Comparative quality and structural/functional similarity *Weight 38% · Max 11.4*	**100%**	Comprehensive analytical comparability data covering primary structure, peptide mapping, purity, aggregation, HMW species, charge variants, degradation profiles, and residual solvents/elemental impurities per ICH Q3A/Q3B/Q3C/Q3D or relevant pharmacopoeial standards. A potency assay (cell-based or receptor binding) demonstrates GLP-1 receptor activation comparable to the reference within an acceptable range, aligned with the latest FDA PSG and EMA guidance. *Score: 11.4*
	75%	Comprehensive structural and potency comparisons are provided, but aggregation/impurity data are limited in certain aspects or analyzed for only specific batches; comparability reports after process/site changes do not cover all critical parameters. *Score: 8.55*
	50%	Fundamental identity, assay, purity and impurity data meet pharmacopoeial standards, but lack in-depth comparative assessment of aggregation/charge variants against the reference; a distinct bioassay for activity comparison is absent. *Score: 5.7*
	25%	CoA primarily indicates "conforms" without numerical values for several key quality attributes; systematic comparability documentation against the reference is lacking. *Score: 2.85*
	0%	No comparative quality data against the reference product is available, or the manufacturer failed to provide sufficient evidence. *No score awarded.*
1b. PK/PD similarity *Weight 24% · Max 7.2*	**100%**	A comparative PK/PD study designed per the latest PSG/guidelines (randomized, appropriate crossover/parallel design, sufficient sample size). The 90% CI of the geometric mean ratio for AUC and Cmax falls within the acceptable limit (typically 80–125%). Relevant PD markers show a response pattern comparable to the reference with no clinically significant differences. *Score: 7.2*

	75%	A high-quality comparative PK study is available, but PD data is limited or measured only for secondary endpoints/subgroups; sample size borders the minimum threshold or high statistical uncertainty exists. *Score: 5.4*
	50%	A comparative PK study exists but sample size is lower than recommended, or the design has limitations (e.g., single-dose when PSG recommends multiple-dose); PD data is unavailable or misaligned with PSG/EMA-recommended endpoints. *Score: 3.6*
	25%	Only a population PK model or retrospective analyses comparing systemic drug exposures are available; prospective head-to-head trials against the reference are absent. *Score: 1.8*
	0%	No comparative PK/PD data against the reference product exists. *No score awarded.*
1c. Clinical efficacy and safety comparability *Weight 22% · Max 6.6*	100%	At least one RCT demonstrating non-inferiority or equivalence head-to-head against the reference in the primary indication (T2DM or obesity). Primary endpoints (HbA1c, body weight, or composite CV outcomes) indicate non-inferiority within an appropriate margin. Safety profile (GI events, hypoglycemia, pancreatitis, gallbladder disease, thyroid events, suicidality) is comparable with no novel safety signals. *Score: 6.6*
	75%	An RCT comparing the product against standard of care or another GLP-1 RA class agent (excluding the direct reference), complemented by robust PK/PD and comparative quality data allowing strong inference of equivalent efficacy and safety. *Score: 4.95*
	50%	Cohort studies, registries, or observational data providing indirect comparisons with the reference or historical GLP-1 RA cohorts; product-specific RCT data is scarce. *Score: 3.3*
	25%	Only single-arm studies, case series, or open-label studies without a comparator exist; follow-up is short (<6–12 months) and fails to capture CV outcomes or long-term safety. *Score: 1.65*
	0%	No product-specific clinical efficacy or safety data is available, relying exclusively on extrapolation from other agents within the class. *No score awarded.*

1d. Immunogenicity *Weight 16% · Max 4.8*	**100%**	Immunogenicity assessments are incorporated into both PK/PD studies and pivotal clinical trials, monitoring ADA and neutralizing antibodies for ≥6–12 months. Incidence rates are not significantly elevated versus the reference, with no novel ADA-related adverse event patterns. *Score: 4.8*
	75%	ADA data from pivotal trials is available, but follow-up is short or the sample designated for immunogenicity evaluation is constrained; data does not encompass all target populations/indications. *Score: 3.6*
	50%	ADA screening is confined to small-scale PK studies or specific subgroups; real-world or registry immunogenicity data is absent or minimal. *Score: 2.4*
	0%	Immunogenicity data is sourced sporadically from post-marketing/case reports lacking systematic trial design; standardized ADA assays were not employed, or no data is available. *No score awarded.*

Domain 2 · Post-Authorization Outcomes — 18%

Criterion	Tier	Evidence description
2a. Post authorization evidence quality *Weight 36% · Max 6.48*	**100%**	At least one meta-analysis or network meta-analysis of GLP-1 RAs in relevant indications includes the product's data or provides distinct subgroup reporting. Large-scale cohort studies/registries (n ≥ 1000) evaluating primary outcomes (weight, HbA1c, MACE, HF) with appropriate confounder controls are available; real-world outcomes align with the magnitude and trajectory of pivotal RCTs. *Score: 6.48*
	75%	Medium-scale cohort studies/registries (n = 300–999) evaluating partial primary outcomes (e.g., weight + HbA1c, lacking CV data); multivariable or propensity score analyses control for confounders to some degree. *Score: 4.86*
	50%	Single-center or small-scale observational studies (n = 100–299) reporting weight, HbA1c, or surrogate markers; may be restricted to specific sub-cohorts or lack a defined comparator. *Score: 3.24*
	25%	Only case series, small retrospective reviews, or single-center real-world data lacking confounder adjustment; outcomes focus strictly on short-term surrogate markers. *Score: 1.62*
	0%	No product-specific post-authorization evidence exists, or available data is insufficient. *No score awarded.*
2b. Population relevance *Weight 19% · Max 3.42*	**100%**	Post-authorization data/studies using the product for T2DM/obesity in Thai or Asian populations (including registries/claims) are available, covering weight, HbA1c, and safety — or a definitive Asian subgroup analysis exists from pivotal trials reinforced by supplemental evidence. *Score: 3.42*
	75%	Data available from other Asian countries (China, Japan, Korea) with similar characteristics to Thai patients (comparable comorbidity patterns, lower BMI profiles vs. Western demographics). *Score: 2.57*

	50%	Data is exclusive to Western populations, but RCTs/evidence show no statistically significant outcome variance across ethnicities and the mechanism is not profoundly dependent on pharmacogenomics. *Score: 1.71*
	25%	Data restricted to populations vastly divergent from the target demographic (extremely high BMI cohorts, fundamentally different healthcare infrastructures), with no supplementary Asian data. *Score: 0.86*
	0%	No relevant population data is available, or comparability cannot be conclusively established. *No score awarded.*
2c. Long-term outcomes *Weight 24% · Max 4.32*	**100%**	Long-term data ≥36 months (RCT + post-authorization evidence) demonstrates significant MACE reduction in high-risk patients, sustained weight reduction, and cardiometabolic risk factor improvement; long-term safety metrics align with the reference profile. *Score: 4.32*
	75%	12–36 months data demonstrating sustained weight/HbA1c efficacy and CV risk-reduction trends, but missing comprehensive hard endpoint outcomes. *Score: 3.24*
	50%	6–12 months follow-up demonstrates weight and HbA1c reductions, but systematic evaluation of CV or HF outcomes is absent. *Score: 2.16*
	25%	Data duration is <6 months or relies solely on short-term trials/real-world data that do not reflect chronic usage. *Score: 1.08*
	0%	No long-term clinical outcome data is available. *No score awarded.*
2d. Patient-Centered Outcomes & Adherence *Weight 21% · Max 3.78*	**100%**	Patient-Reported Outcomes assessed via standardized psychometric instruments (SF-36, EQ-5D, obesity/diabetes QoL questionnaires) show statistically significant QoL/satisfaction improvement. Robust real-world adherence/persistence data (PDC, 12-month persistence) delineates usage patterns and clinical impact. *Score: 3.78*
	75%	Partial PRO/QoL data from RCTs or observational studies, though standardized tools may not be fully used; real-world adherence data exists but is confined to specific populations or short periods. *Score: 2.84*

50%	Adherence data calculated via PDC/MPR from a single database is available, but lacks correlation with clinical outcomes. *Score: 1.89*
0%	Only theoretical adherence/persistence assumptions based on dosage form, devoid of direct post-authorization data — or no data concerning patient-centered outcomes/adherence. *No score awarded.*

Domain 3 · Pharmacovigilance — 16%

Criterion	Tier	Evidence description
3a. PV System Maturity *Weight 27% · Max 4.32*	**100%**	An up-to-date Pharmacovigilance System Master File (PSMF) compliant with regulatory mandates is maintained. A highly effective signal detection system routinely monitors safety databases (FAERS, EudraVigilance, VigiBase) specifically for GLP-1 RAs, with a safety review committee documenting minutes and trackable action plans. *Score: 4.32*
	75%	Safety tracking for GLP-1 RAs is operational, but signal detection/analysis does not encompass all databases or lacks full systematic integration. *Score: 3.24*
	50%	A fundamental PV framework exists, fulfilling basic ADR reporting obligations, but lacks systematic signal analysis tailored for GLP-1 RAs. *Score: 2.16*
	25%	Critical gaps exist within the PV system; documentation is incomplete and there is no specialized surveillance plan for GLP-1 RAs. *Score: 1.08*
	0%	No verifiable PV system is in place. *No score awarded.*
3b. ADR Frequency Assessment & Signal Management *Weight 25% · Max 4.0*	**100%**	ADR frequencies are explicitly documented in the package insert, coupled with consistent ADR reporting. Disproportionality analysis (ROR/PRR) or equivalent methods are used for GLP-1 RAs, with findings actively applied to update labeling or the RMP. *Score: 4.0*
	75%	Safety signals from external databases are monitored, although systematic disproportionality analyses are not yet routinely executed. *Score: 3.0*
	50%	ADR reporting occurs but lacks consistency; no specific signal analysis for GLP-1 RAs is conducted and regulatory responses to signals are predominantly reactive. *Score: 2.0*
	25%	ADR report volume is negligible relative to market share, and signal tracking relies fundamentally on regulatory-authority summaries. *Score: 1.0*

	0%	No product ADR reports or evaluable safety data are available. *No score awarded.*
3c. Risk Management Plan *Weight 23% · Max 3.68*	**100%**	A comprehensive RMP explicitly detailing GLP-1 RA safety concerns, aligned with current safety literature, is established. At least one Post-Authorization Safety Study (PASS) is operational, with continuous reporting to regulators. *Score: 3.68*
	75%	The RMP addresses primary identified risks and features Routine Risk Minimization Measures (e.g., MEN2 contraindications, GI/pancreatitis warnings), but a specific PASS is absent or strictly preliminary. *Score: 2.76*
	50%	A rudimentary RMP exists covering label-identified risks, but lacks a dedicated monitoring strategy or timely updates responding to emerging EMA/FDA signals. *Score: 1.84*
	25%	The RMP contains outdated, rudimentary data and fails to encompass contemporary GLP-1 RA safety concerns. *Score: 0.92*
	0%	No RMP exists, or the current RMP omits GLP-1 RAs. *No score awarded.*
3d. Safety Signals and Product Recalls *Weight 14% · Max 2.24*	**100%**	Zero product recalls associated with GLP-1 RA quality/safety over the past 3 years; no significant confirmed safety signals (contamination, potency discrepancies, device malfunction). Systematic anti-counterfeiting measures are employed. *Score: 2.24*
	75%	History includes only Class III recalls or minor device/packaging deviations posing no meaningful impact to patient safety or clinical efficacy. *Score: 1.68*
	50%	History of a Class II recall (out-of-specification potency, minor device mechanics affecting dose accuracy) effectively remediated without recurrent failure. *Score: 1.12*
	25%	History of a Class I recall (serious health risks, critical contamination, or severe pen dose errors), despite subsequent corrective actions. *Score: 0.56*

	0%	Multiple recalls or recurrent severe safety signals indicative of chronic quality/safety infrastructure failures. *No score awarded.*
3e. Safety Communication *Weight 11% · Max 1.76*	**100%**	The manufacturer executes timely safety communications (DHPCs, labeling updates, regulatory notifications) predicated on the latest safety data, via accessible, verifiable channels with rapid response times. *Score: 1.76*
	75%	Safety communications are executed solely upon regulatory-authority mandate (reactive), lacking a consistent proactive posture. *Score: 1.32*
	50%	Communications exist but suffer from delays or incompleteness; end-users rely heavily on regulatory-authority portals for critical data. *Score: 0.88*
	25%	Manufacturer responses to safety inquiries are sluggish or fail to provide definitive information. *Score: 0.44*
	0%	No verifiable safety communication infrastructure exists. *No score awarded.*

Domain 4 · Product Quality — 26%

Criterion	Tier	Evidence description
4a. Certificate of Analysis & Impurities Profile *Weight 32% · Max 8.32*	**100%**	The batch-specific CoA explicitly quantifies strength, providing discrete numerical values for peptide-related impurities, HMW aggregates, residual solvents, and elemental impurities per ICH guidelines, specifying limits aligned with the reference and rigorously defined BDL/BRT parameters. *Score: 8.32*
	75%	Quantitative values are reported for major impurities and HMW aggregates, but certain minor parameters are reported simply as "conforms". *Score: 6.24*
	50%	The CoA provides gross assay (%) and total impurities data, omitting detailed breakdowns of individual impurities and lacking explicit aggregation reporting. *Score: 4.16*
	25%	The CoA is incomplete (deficient in critical impurity/aggregation metrics) or extensively relies on "conforms" without verifiable numerical data. *Score: 2.08*
	0%	No verifiable CoA is provided, or the manufacturer refuses to disclose data. *No score awarded.*
4b. Stability Data *Weight 30% · Max 7.8*	**100%**	Injectable finished products possess shelf-life and long-term stability at 2–8°C equivalent to the reference, with comprehensive accelerated stability per ICH Q1A. In-use stability verifies room-temperature device storage equivalent to the reference. For oral semaglutide, complete stability data for the semaglutide + SNAC co-formulation is available, backed by dissolution/PK data. *Score: 7.8*
	75%	Shelf-life, long-term stability, and/or in-use stability parameters are shorter than the reference, with limited data on specific conditions (e.g., heat excursions). *Score: 5.85*
	50%	Long-term stability satisfies minimum regulatory requirements, but device in-use stability data remains incomplete across all clinical dosages/environmental conditions. *Score: 3.9*

	25%	Only 6-month accelerated stability data is available while real-time long-term studies are ongoing; the proposed full shelf-life cannot yet be definitively validated. *Score: 1.95*
	0%	Insufficient stability data, or the provided data contradicts the Summary of Product Characteristics/label. *No score awarded.*
4c. Formulation, Device & Physical Quality *Weight 22% · Max 5.72*	**100%**	The delivery device meets ISO or equivalent standards, with robust testing on dose accuracy, robustness, and usability; comparative device data vs. the reference and comprehensive manuals are provided. Zero significant complaints regarding malfunction, leakage, or dose inaccuracy over 3 years; physical quality is consistent throughout shelf-life. *Score: 5.72*
	75%	The device meets baseline standards with adequate usability studies; minor user-related errors or operational complaints exist within acceptable tolerance. *Score: 4.29*
	50%	The device functions adequately but lacks definitive usability/human-factor data, or minor mechanical issues are periodically reported. *Score: 2.86*
	0%	Recurrent complaints regarding malfunction/dose inaccuracy are documented, or physical quality is unacceptable, or a history of Class I/II recalls due to device/dose failure exists. *No score awarded.*
4d. Manufacturing Standards *Weight 16% · Max 4.16*	**100%**	The manufacturing facility holds PIC/S GMP certification and has passed stringent EMA/FDA/WHO inspections specifically for peptide/biological manufacturing, with cold chain and environmental monitoring systems implemented for manufacturing, aseptic filling, and storage. *Score: 4.16*
	—	Lower tiers not specified in the source consensus document.

Domain 5 · Supply Reliability — 10%

Criterion	Tier	Evidence description
5a. Track Record *Weight 34% · Max 3.4*	**100%**	Zero shortage reports or Medicines Supply Notifications over the preceding 3 years involving the manufacturer's GLP-1 RA product; the product has never appeared on national/international drug shortage registries. *Score: 3.4*
	75%	History of limited/transient shortages (≤1 event/year) actively managed with definitive mitigation strategies (quota allocations, advance notifications). *Score: 2.55*
	50%	History of ≥2 supply interruptions in the past 3 years requiring dispensing restrictions or onboarding suspension, though supply was restored within 3–6 months. *Score: 1.7*
	25%	History of severe, protracted shortages (>6 months) or a declared "national shortage" encompassing the manufacturer's specific product. *Score: 0.85*
	0%	The manufacturer exhibits chronic supply failures or cannot present a credible remediation/capacity plan. *No score awarded.*
5b. Supply Capacity and Lead Time *Weight 39% · Max 3.9*	**100%**	The manufacturer consistently fulfills requisitions with buffer capacity for demand surges, supported by registered back-up manufacturing/fill-finish sites. Standard lead time ≤30 days from PO to delivery readiness, fortified by redundant contingency systems. *Score: 3.9*
	75%	Standard lead time is 30–60 days. During elevated demand, allocation measures may apply, but the manufacturer maintains transparent distribution policies and defined quota frameworks. *Score: 2.92*
	50%	Lead time is 60–90 days; the manufacturer must periodically renegotiate delivery volumes due to strained production lines or CDMO capacity limits. *Score: 1.95*
	25%	The manufacturer cannot formally guarantee required volumes within the contract, or a lead time >90 days is standard. *Score: 0.98*

	0%	The manufacturer cannot guarantee supply or is undergoing continuous resolution of serious capacity constraints. *No score awarded.*
5c. Contract Terms and Warranty *Weight 27% · Max 2.7*	100%	The contract incorporates a definitive minimum supply commitment and explicit penalty clauses for delayed/incomplete deliveries; return and exchange are guaranteed for cold-chain deviation or recalls. *Score: 2.7*
	75%	Standard terms with basic warranties are provided but lack explicit punitive clauses for supply failure. *Score: 2.03*
	50%	Contract terms are heavily manufacturer-favored (lacking minimum volume commitments or cold-chain warranty parameters). *Score: 1.35*
	25%	No definitive warranties are provided, or contract terms significantly compound the hospital's financial risk. *Score: 0.68*
	0%	Contract conditions are entirely unacceptable, or the manufacturer refuses to provide a written, binding agreement. *No score awarded.*

Abbreviation: HMW = High Molecular Weight, GLP-1 = Glucagon-like Peptide-1, PSG = Product Specific Guidance, FDA = Food and Drug Administration, EMA = European Medicines Agency, CoA = Certificate of Analysis, PD = Pharmacodynamics, PK = Pharmacokinetics, AUC = Area Under the Curve, RCT = Randomized-controlled Trial, T2DM= Type 2 Diabetes Mellitus, HbA1c = Hemoglobin A1C, GI = Gastrointestinal, ADAs = Anti-Drug Antibodies, MACE = Major Adverse Cardiovascular Events, HF = Heart Failure, CV = Cardiovascular, BP = Blood Pressure , LDL-C = Low-Density Lipoprotein Cholesterol, PROs = Patient-Reported Outcomes, QoL = Quality of Life, PDC = Proportion of Days Covered, MPR = Medication Possession Ratio, PV = Pharmacovigilance, ADR = Adverse Drug Reaction, ROR = Reporting Odds Ratio, PRR = Proportional Reporting Ratio, RMP = Risk Management Plan, PASS = Post-Authorization Safety Study, MEN2 = Multiple Endocrine Neoplasia Type 2, SNAC = Sodium N-(8-[2-hydroxybenzoyl] amino) caprylate, CDMO = Contract Development and Manufacturing Organization.

05 APPLICATION OF THE VALUE-BASED PROCUREMENT FRAMEWORK

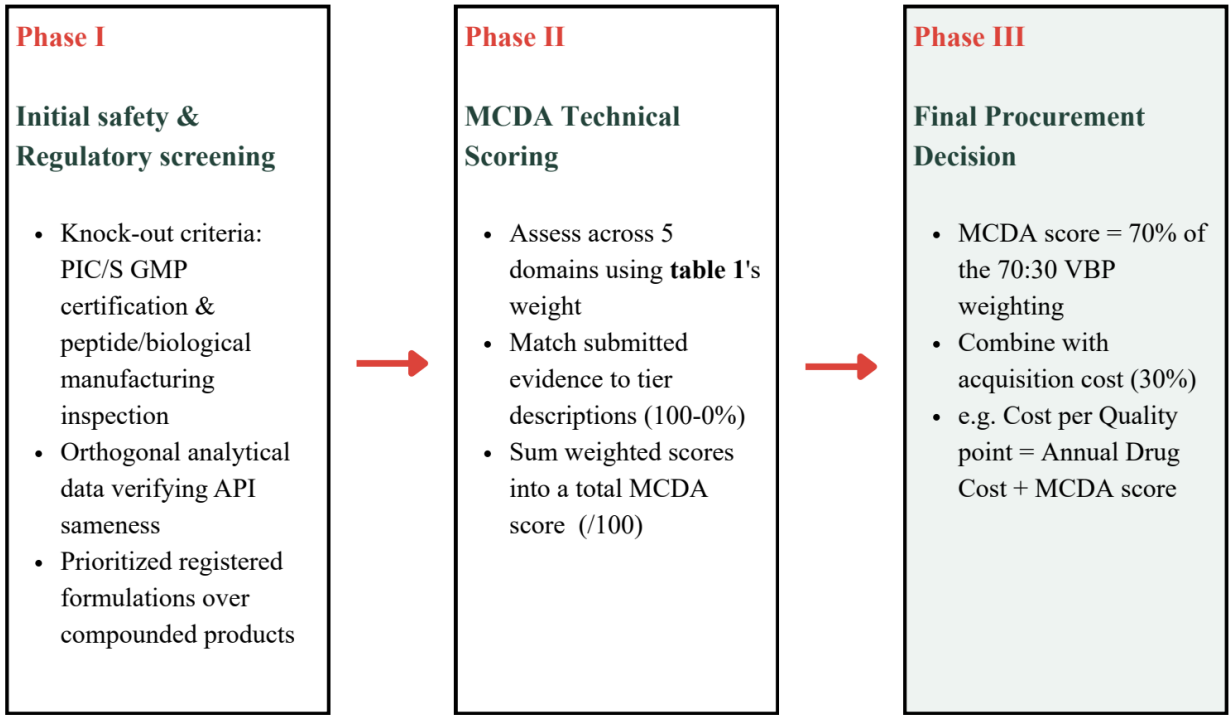


Figure 3: Assessment process flowchart for hospital implementation.

The integration of the MCDA tool (**Table 1 and Table 2**) and the assessment process flowchart (**Figure 3**) provided hospital PTC with a systematic, evidence-based roadmap for procuring GLP-1 RA complex generics. The practical application of these tools was implemented through the following sequential three phases.

Phase I: Initial safety & regulatory screening

Before applying the scoring system, the evaluation process begins with an initial screening phase. It is highly recommended that products should meet basic technical criteria to be considered for formal procurement evaluation:

- **Knock-out criteria:** The product should align with fundamental regulatory and safety prerequisites. For example, as outlined in the MCDA tool (Criterion 4d), the manufacturing facility must hold PIC/S GMP certification and pass stringent inspections for

peptide/biological manufacturing; these benchmarks exclude the product from further technical scoring rounds.

- **Orthogonal analytical data:** PTCs are encouraged to request multi-dimensional analytical data from manufacturers to verify API sameness and structural integrity. Applications lacking clear, orthogonal verification may be deferred or declined.
- **Prioritizing Approved Formulations:** It is recommended to prioritize registered commercial formulations over unregulated compounded GLP-1 RAs due to the potential risks associated with impurity and unverified safety profiles in compounded formats.

Phase II: MCDA technical scoring

Once a follow-on product passes the initial screening, the PTC evaluated its technical and clinical performance using the 5-Domain MCDA tool detailed in **Table 1.**

- **Domain evaluation:** The product is assessed across five consensus-derived domains: Comparability & Therapeutic Equivalence (30%), Post-Authorization Outcomes (18%), Pharmacovigilance (16%), Product Quality (26%), and Supply Reliability (10%).
- **Tier-Based scoring:** Each criterion features predefined evidence tiers ranging from 100% to 0%. The committee must match the submitted evidence to the appropriate tier description. For instance, if a product demonstrates non-inferiority via a head-to-head RCT in its primary indication, it achieves the 100% tier for Clinical Efficacy (Criterion 1c) and is awarded the full 6.6% weight. If the data relies only on indirect cohort studies, it drops to the 50% tier and receives half the respective points.
- **Score calculation:** The score for each criterion is calculated by multiplying its assigned maximum weight by the achieved tier percentage. These individual scores are then summed across all domains to produce a total MCDA score (out of 100).

Phase III: Final procurement decision (Minimum 70:30 Value-Based Procurement Model)

The total MCDA score quantitatively represented the product's overall clinical and technical performance. In the final procurement decision, this score constitutes the 70% performance component of the recommended minimum 70:30 performance-to-price weighting. To evaluate overall value, hospitals can integrate the MCDA total score with the product's acquisition cost.

This can be calculated using the Cost per Quality Point method (Annual Drug Cost / MCDA Total Score) or a balanced Value Score formula. By applying this minimum 70:30 VBP model, hospitals can ensure that procurement choices are guided by a balanced evaluation of cost, proven quality, therapeutic equivalence, and supply reliability.

06 RECOMMENDATION & IMPLEMENTATION

To facilitate the safe, rational, and cost-effective integration of GLP-1 RA complex generics into hospital formularies, PTCs are encouraged to review the following strategic recommendations. These guidelines serve to align regulatory standards with practical hospital procurement workflows.

Procurement Strategy and VBP Adoption

- **Adopt a minimum 70:30 Value-Based Procurement model:** It is recommended that hospitals should transition from traditional cost-driven purchasing to a comprehensive value-based approach. Procurement scoring should ideally be standardized using a minimum 70:30 ratio (70% performance; 30% price), whereby at least 70% of the weight is assigned to clinical and technical performance metrics, with the remaining 30% allocated to price.
- **Prioritize Registered Formulations Over Compounded Products:** Hospital procurement frameworks are encouraged to prioritize officially registered and approved GLP-1 RA formulations over unapproved compounded alternatives. Utilizing unregulated formulations as a cost-saving option presents notable clinical risks. Safety registry data linked unapproved synthetic compounded products to severe adverse events, making regular commercial channels the preferred choice for patient safety.

Quality and Safety Assurance

- **Request Orthogonal Analytical Data for API Sameness:** Because conventional bioequivalence testing may not fully account for the properties of complex peptides, hospitals are advised to request multi-dimensional analytical data from manufacturers. PTCs should seek robust, orthogonal verification of API sameness, structural integrity, and low fibrillation/aggregation risks during their reviews.

- **Incorporate Immunogenicity and Impurity Risk Assessments:** Procurement evaluations should prioritize products that provide comprehensive clinical safety data demonstrating a low risk of ADA formation. Follow-on synthetic products should ideally

demonstrate that their peptide-related impurities and high molecular weight proteins do not exceed acceptable reference parameters or trigger new immunogenic responses.

- **Support Localized Risk Management Implementation:** Manufacturers should be encouraged to submit a localized Risk Management Plan (RMP) relevant to the Thai healthcare context. Hospitals can further protect patient health by actively tracking long-term adverse events and specific safety signals through continuous clinical pharmacovigilance.

Operational Control and Capacity Building

- **Utilize Formulary Guidance for Rational Prescribing:** To prevent off-label misuse and promote sustainable departmental resource allocation, hospitals can implement supportive digital tracking features within their health information systems (such as prescriber specialization verification indicators). This measure helps ensure that high-cost GLP-1 RAs are prescribed exclusively by clinical specialists for approved indications, such as specified criteria for T2DM and obesity management.

- **Support Pharmacist Capacity Building:** As the responsibility for evaluating complex generics increasingly relies on hospital committees, institutions are encouraged to support targeted training programs for their pharmacy staff. Developing competencies for hospital pharmacists to evaluate complex orthogonal analytical data, interpret stability profiles, and execute VBP technical reviews serves as a vital operational safeguard for patient care.

07 LIMITATION

While this study establishes a robust, structured framework for evaluating GLP-1 RA complex generics, several contextual boundaries should be noted to guide its application and future refinement. First, while MCDA provided a highly systematic approach to multi-attribute decision-making, the selection of criteria and the assignment of weights reflected the consensus of the specific multi-disciplinary panel involved. These parameters were inherently shaped by the clinical priorities and operational experiences within the participating institutions. Second, because the underlying literature review and regulatory analysis were bound by a specific chronological cutoff date, the framework was designed as a dynamic model. It was intended to undergo periodic updates to incorporate emerging clinical data, real-world evidence, and updated guidance from international regulatory bodies.

Furthermore, the operational utility of certain parameters, particularly within the post-authorization outcomes and supply reliability domains, remained contiguous with the availability and transparency of manufacturer-submitted data during the tendering process. Finally, because approved follow-on GLP-1 RA formulations had not yet widely entered the localized market at the time of this framework's development, immediate empirical validation through real-world comparative procurement scenarios was precluded. Consequently, this proactive framework served as a pre-validated baseline model. Future research remains recommended to evaluate its feasibility, discriminatory power, and long-term impact on institutional expenditures and patient outcomes upon the market entry of these complex generic peptides.

08 CONCLUSION

Applying the VBP framework for the selection and procurement of GLP-1 RA products represents a valuable milestone for the healthcare system. Follow-on GLP-1 RAs are classified as complex generics and are often manufactured using chemical synthetic processes. This manufacturing pathway introduces unique technical criteria compared to originator biologics, such as specific peptide-related impurities, aggregation parameters, and immunogenicity profiles. Therefore, traditional procurement frameworks designed for conventional small-molecule generics or standard biosimilars can be optimally updated to safely evaluate this distinct category of medicines.

By implementing the VBP framework, which integrates the MEAT principles and MCDA, hospital Pharmacy and Therapeutics Committees gain a systematic, evidence-based tool. Utilizing a consensus-driven Performance-to-Price ratio of at least 70:30 ensures that purchasing decisions are well-rounded and not driven solely by cost reduction. Instead, this approach comprehensively evaluates clinical value, product quality, pharmacovigilance, and supply reliability to support therapeutic efficacy and patient safety.

The developed VBP framework features a flexible structure, providing a highly adaptable model for evaluating the value of other follow-on products and complex generics entering the market in the future. To successfully apply this framework to other drug classes, the following future directions were suggested:

- **Periodic reassessment of criteria:** The landscape of complex generics and follow-on products is rapidly evolving. Therefore, the evaluation criteria and weighting parameters should be reviewed regularly to ensure ongoing alignment with new clinical evidence, post-market safety data, and updated guidelines from international regulatory bodies.
- **Expansion to Broader Procurement Standards:** Beyond peptide therapeutics, this VBP model can be adapted to establish updated benchmarks for evaluating other complex health technologies and medical supplies, helping to shift the overall hospital purchasing ecosystem toward a comprehensive VBP approach.

- **Continuous Capacity Building:** Future institutional efforts should consider supporting hospital pharmacists in proficiently evaluating complex quality data. Enhancing their skills to assess multi-dimensional laboratory techniques (e.g., orthogonal analytical data) will empower pharmacists to utilize this VBP framework as a rigorous and effective technical screening tool before procurement decisions are finalized.

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10 LIST OF EXPERTS

Assoc.Prof. Dr.Burin T. Sriwong
Faculty of Pharmacy, Silpakorn University

Pakwan Bunupuradah
Ramathibodi Hospital

Anyamanee Pinnoi
Chompoonut Amatayakul
Jiranuch Wongworakul
King Chulalongkorn Memorial Hospital

Nidtaya Dawvongyad
Rapeeporn Jearakul
Sunpasitthiprasong Hospital

Kannika Pongthranggoon
Thammasat University Hospital

Chaitawat Sawatphanit
Central Chest Institute of Thailand

Dr.Warawan Chungsivapornpong
Yiamrung Wongkumhaeng
Veteran General Hospital

Pansu Chumworathayi
Phiangkwan Nakornratanachai
Monchanok Chartchamni
Srinagarind Hospital

Napat Aphaiphak
Panuwit Srisena
Chaopraya Yommaraj Hospital

Dr.Anunchai Assawamakin
Faculty of Pharmacy, Mahidol University

Dusit Supawatanawong
Songklanagarind Hospital

Premjit Suttipoom
Santi Wongsa
Siriraj Hospital

Jitsomanus Suporn
Suchada Thanapatkawin
Vajira Hospital

Asst.Prof. Dr.Suntara Eakanunkul
Faculty of Pharmacy, Chiang Mai University

Nuttapong Chailungkar
Cheeratikarn Phithakham
Maharat Nakhon Chiangmai Hospital

Pathomrat Thongruang
Nakhon Pathom Hospital

Sukanda Denjanta
Chiangrai Prachanukroh Hospital

Lt.Col. Dr.Parinya Samakkarnthai
Phramongkutklao Hospital

Photo 1: The participants of the Thai hospital pharmacists' consortium on the establishment of Value-Based Procurement framework for GLP-1 RA complex generics procurement, which took place in Bangkok on the 9th of May 2026

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