Alignment Between Health Technology Assessment (HTA) Requirements and Current Practices in Global Value Dossier (GVD) Development

HTA43

Mona Patel, RPh; Adina Rojubally, PhD; Michael York, MBA; Joette Gdovin Bergeson, PhD, MPA; Meg Franklin, PharmD, PhD

Franklin Pharmaceutical Consulting LLC, Cary NC, USA

BACKGROUND

Introduction

- Health Technology Assessment (HTA) agencies have specific assessment requirements for evaluating submissions for new drugs.[1-3]
- Global Value Dossiers (GVDs) are developed by pharmaceutical companies to provide country affiliates with information necessary to populate HTA submissions.
- Given the significant resources invested in developing GVDs and HTA submissions, enhancing alignment would be beneficial.

Objective

- Investigate alignment between HTA requirements and current practices in GVD development to identify trends and propose improvements.

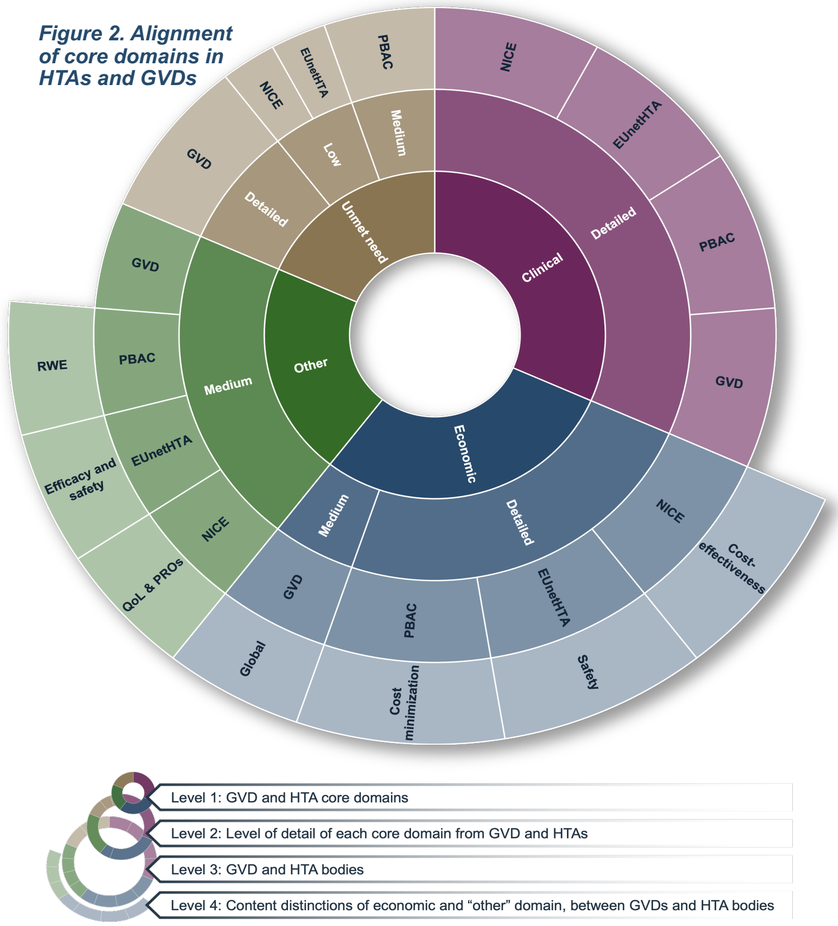
METHODS

- HTA submission guidelines from Australia (PBAC guideline V5.0), the European Union (EUnetHTA HTA Core Model Version 3.0), and England (NICE Feb 2022) were evaluated and summarized (Figure 1).
- Qualitative descriptive analysis was used to compare the amount of information (low, medium, or detailed) required by HTAs to the core domains in a GVD.
- Similarities and differences were evaluated to identify areas of alignment for content across 4 domains: unmet need, clinical effectiveness and safety, economic, and “other evidence” (e.g., PROs & RWE).

RESULTS

- HTAs consistently require a similar amount of information across domains with some overlap, however, diversity in the types of data was noted (Figure 2).
- **Unmet need domain:** two HTA agencies seek low level of detail, and one medium-level, while GVDs are more detailed.
- **Clinical effectiveness and safety domain:** align in the detailed amount of information.
- **Economic domain:** exhibits variability in types of information required. Areas emphasized included safety (EUnetHTA), cost minimization (PBAC), and cost-effectiveness (NICE). Both HTAs and GVDs include detailed cost-effective analysis.
- **“Other evidence”:** domain requirements vary; EUnetHTA focuses on cost-effectiveness integrating efficacy and safety; PBAC mandates budget impact analyses based on RWE; NICE emphasizes cost utility analyses including PROs and quality of life.

Figure 2. Alignment of core domains in HTAs and GVDs



CONCLUSIONS

- Both HTAs and GVDs focus on demonstrating clinical value.
- Divergences were observed in the economic and unmet need sections.
- Despite these differences, shared focus was observed on comprehensive assessments, evidence-based evaluations, and both clinical and economic outcomes.
- This review offers valuable insights for optimizing GVDs to ensure better alignment with HTA standards ensuring timely patient access to medicines.

RECOMMENDATIONS

- Develop a "living” GVD with a standardized yet flexible framework.
- Monitor evolving HTA guidelines to inform living GVD.
- Foster stakeholder collaboration for greater synergy between GVDs and HTAs.

Figure 1. Summary of GVD domains compared to HTA frameworks

GVD DOMAINS

UNMET NEED
Description of disease; pathophysiology; burden of disease (clinical, humanistic and economic); epidemiology; current treatment options and guidelines

CLINICAL EVALUATION
Product description, mechanism of action; key clinical trials with efficacy safety and outcomes; comparative efficacy

ECONOMIC VALUE
Evaluate economic value through cost-effectiveness and health economic data; include budget impact model to project impact on healthcare budgets

ADDITIONAL SUPPORTING EVIDENCE
Real-world evidence; post-marketing studies, observational research; patient reported outcomes and health-related quality of life in clinical practice

	EUnetHTA[1]	NICE[2]	PBAC[3]
UNMET NEED	•Health problem and current use of technology •Pathophysiology, epidemiology •Guidelines and utilization •Alternative treatments	•Describe the technology and impact on clinical care pathway •Alignment and variations with NICE guidelines	•Define clinical issue, comparators, & management using PICO framework •Outline proposed medicine details and funding rationale
CLINICAL EVALUATION	•Description, technical characteristics and use of technology •Safety & clinical effectiveness •Comparators	•Clinical effectiveness and adverse events •NICE prefers randomized controlled trials data, systematic reviews and comprehensive evidence	•Systematic literature search •Analysis of evidence, clinical evaluation (prefers direct trials) •Assess evidence applicability for economic evaluation
ECONOMIC VALUE	•Integrate safety & efficacy in cost-effective healthcare decisions •Economic evaluations for efficient use of resources •Balance societal goals	•Cost effectiveness of the appraised technology •Summary of studies that inform the economic analysis of the product	•Conduct cost-effectiveness analysis, integrating cost minimization principles •Economic evaluations and assess impacts on resources
ADDITIONAL SUPPORTING EVIDENCE	•Consider societal values, prioritize patients concerns •Organizational readiness •Legal frameworks and ethics for technology implementation	•Detail costs, resources and patient reported outcomes •Include real-world data, economic model and health related quality of life data for cost utility analyses	•Utilize real-world data for informed decision-making •Consider financial impact, quality use, and healthcare system implications

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REFERENCES, SUPPLEMENTAL INFO, & CONTACT