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Developing, Implementing, Disseminating, and Sustaining Health Economic Evaluation Guidelines



A Scoping Review of International Examples, Process Facilitators, and Barriers

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List of abbreviations

ADP.....Access and Delivery Partnership
AGREE-HS...Appraisal of Guidelines for Research and Evaluation – Health Systems
BCC.....Benefit Coordination Committee (South Korea)
BMGF .....Bill & Melinda Gates Foundation
CADTH .....Canadian Agency for Drugs and Technologies in Health (formerly CCOHTA)
CBA.....Cost-Benefit Analysis
CCA.....Cost-Consequence Analysis
CCOHTA.....Canadian Coordinating Office for Health Technology Assessment
CEA.....Cost-Effectiveness Analysis
CGPE .....China Guidelines for Pharmacoeconomic Evaluations
CHEERS.....Consolidated Health Economic Evaluation Reporting Standards
CMA.....Cost-Minimisation Analysis
CUA .....Cost-Utility Analysis
DERP.....Drug Expenditure Rationalization Plan (South Korea)
DoH.....Department of Health
DREC.....Drug Reimbursement Evaluation Committee (South Korea)
EE.....Economic Evaluation
EEG(s).....Economic Evaluation Guideline(s)
EQ-5D .....EuroQol 5-Dimension questionnaire
EU .....European Union
FY.....Fiscal Year
GDG.....Guideline Development Group
GEAR.....Guide to Health Economic Analysis and Research
GIN .....Guidelines International Network
HE .....Health Economics
HIRA.....Health Insurance Review and Assessment Service (South Korea)
HiTAP.....Health Intervention and Technology Assessment Program (Thailand)
HSG.....Health System Guidance
HTA .....Health Technology Assessment
HTA-SC .....Health Technology Assessment Steering Committee (Ghana)
HTA-TWG....Health Technology Assessment Technical Working Group (Ghana)
HYE .....Healthy Year Equivalent
ICER .....Incremental Cost-Effectiveness Ratio
iDSI.....International Decision Support Initiative
INAHTA.....International Network of Agencies for Health Technology Assessment
ISPOR.....International Society for Pharmaco-economics and Outcomes Research
KNUST .....Kwame Nkrumah University of Science and Technology (Ghana)
LEEG .....Lebanese Economic Evaluation Guideline

LIC(s).....Low-Income Country(ies)
LMIC(s).....Low- and Middle-Income Country(ies)
LSPOR.....Lebanon Chapter of ISPOR
MHLW.....Ministry of Health Labour and Welfare (Japan)
MOH .....Ministry of Health (generic spelling)
MoH .....Ministry of Health (Ghana spelling)
MOHW .....Ministry of Health and Welfare (South Korea)
MoPH.....Ministry of Public Health (Lebanon)
NA .....Not Available/Not Applicable
NHIA .....National Health Insurance Authority (Ghana)
NHIC .....National Health Insurance Corporation (South Korea)
NHIS .....National Health Insurance Scheme (Ghana)
NICE.....National Institute for Health and Care Excellence (United Kingdom)
NIPH.....Norwegian Institute of Public Health
NRDL .....National Reimbursement Drug List (China)
NSSF .....National Social Security Fund (Lebanon)
OECD .....Organisation for Economic Co-operation and Development
PAHO.....Pan American Health Organization
PATH.....Program for Appropriate Technology in Health
PBAC .....Pharmaceutical Benefits Advisory Committee (Australia)
PE.....Pharmacoeconomic
PEG(s).....Pharmacoeconomic Guideline(s)
PLS.....Positive List System (South Korea)
PMAC .....Pharmaceutical Manufacturers Association of Canada
PTCCPA.....Pharmacoeconomics Technical Committee of the Chinese Pharmaceutical Association
QALY.....Quality-Adjusted Life-Year
QOL .....Quality of Life
R&D .....Research and Development
SPH-UG.....School of Public Health-University of Ghana
SR.....Systematic Review
TCM.....Traditional Chinese Medicine
UEBMI.....Urban Employee Basic Medical Insurance (China)
UHC.....Universal Health Coverage
UNDP .....United Nations Development Programme
URBMI .....Urban Resident Basic Medical Insurance (China)
URRBMI.....Urban Rural Resident Basic Medical Insurance (China)
WHO.....World Health Organisation

Zusammenfassung

Kernaussagen

- Österreich benötigt eine nationale Leitlinie zur gesundheitsökonomischen Evaluation (health economic evaluation guideline, HEEG), um das Erstellen gesundheitsökonomischer Evidenz zu standardisieren und faire, transparente Erstattungsentscheidungen zu unterstützen.
- Internationale Erfahrungen zeigen einen gemeinsamen achtphasigen Prozess für die Entwicklung, Implementierung, Dissemination und Aufrechterhaltung (development, implementation, dissemination, and sustainment, DIDS) einer HEEG.
- Governance-Klarheit und eine rechtliche Grundlage sind entscheidend für die Aufrechterhaltung der HEEG.
- Mangel an Expertise und nationalen Kosten- und Nutzwertdaten sind universelle Barrieren.
- Die breite Einbindung von Stakeholdern ist der konsistenteste Förderfaktor für eine erfolgreiche Einführung einer HEEG.
- Österreich sollte Monitoring und Aktualisierungen von Beginn an einplanen.

Hintergrund und Problemdefinition

Gesundheitsökonomische Evaluationen (health economic evaluations, HEEs) spielen bei österreichischen Erstattungsentscheidungen aktuell eine verhältnismäßig geringe Rolle. International haben mehr als 40 Länder und Regionen eigene Leitlinien zur gesundheitsökonomischen Evaluation (HEEGs) entwickelt. Österreich verfügt über keine verbindliche methodische Leitlinie mit definiertem Referenzfall, Kostenermittlungsmethoden oder standardisierten Anforderungen an gesundheitsökonomische Evidenz.

Die Notwendigkeit einer nationalen HEEG ist mit der Einrichtung des Bewertungsboards für ausgewählte Arzneimittel im Jahr 2023 auf Grundlage des Bundesgesetzes über Krankenanstalten und Kuranstalten (KAKuG) dringlicher geworden. Die Entwicklung und Umsetzung einer HEEG erfordert einen strukturierten, evidenzbasierten Prozess für Entwicklung, Implementierung, Dissemination und Aufrechterhaltung (DIDS-Prozess). Dieser Prozess sollte Barrieren und Förderfaktoren berücksichtigen und Expert:innen, sowie Vertreter:innen der Kostenträger transparent und deliberativ einbeziehen.

In diesem Bericht werden folgende Forschungsfragen behandelt:

- Wie können internationale Beispiele den gesamten DIDS-Prozess einer österreichischen HEEG unterstützen, um deren erfolgreiche Umsetzung sicherzustellen?
- Welche Barrieren und Förderfaktoren bestehen im DIDS-Prozess einer HEEG?

Dieser Bericht ist Teil des Projekts „Vorarbeiten für eine gesundheitsökonomische Leitlinie in Österreich“, das die Rolle standardisierter HEEs in der österreichischen Entscheidungsfindung stärken soll.

Methoden

Dieser Bericht basiert auf einem Scoping Review von Publikationen zur Entwicklung und Umsetzung von HEEGs, ergänzt durch Expert:innenwissen. Eine explorative Handsuche in Google Scholar und PubMed identifizierte Publikationen, die den DIDS-Prozess in anderen Ländern beschreiben. Informationen zu den vier DIDS-Dimensionen wurden anhand standardisierter Kategorien wie Organisationsstruktur, Quellen und Rahmenwerke, Prozessschritte, Dissemination und Aufrechterhaltung extrahiert. Die Prozessschritte wurden anschließend chronologisch aufgelistet, länderübergreifend verglichen, in gemeinsame Phasen gruppiert und auf Konsistenz geprüft. Barrieren und Förderfaktoren wurden induktiv gruppiert.

Die Ergebnisse für Österreich wurden anhand von sechs Aspekten interpretiert: Ziele, Umfang und Grundsätze, Teambildung, Einbeziehung von Stakeholdern, Inhalt und Ressourcen, institutionelle Regelungen sowie Monitoring und Evaluierung.

Ergebnisse

Internationale Beispiele

Neun Publikationen zu fünf Ländern (Kanada, Südkorea, Japan, China und Libanon) sowie ein systematischer Review zu Erfahrungen in Ländern mit niedrigem und mittlerem Einkommen (low and middle income countries, LMICs) wurden eingeschlossen. Alle fünf Länder erstellten formale, national bestätigte HEEGs, allerdings mit unterschiedlichen Zeitrahmen.

Die Leitlinienentwicklungsgruppen (guideline development groups, GDGs) umfassten durchgängig Gesundheitsökonom:innen, politische Entscheidungsträger sowie klinische oder methodische Expert:innen, ihre Beziehung zur Steuerungsgruppe variierte jedoch. In Kanada und Libanon entwickelte und beaufsichtigte dieselbe Gruppe die Leitlinie. In Japan erstellten vier Gesundheitsökonom:innen die Leitlinie, während ein 16-köpfiges, von Kostenträgern dominiertes Unterkomitee mit Entscheidungsbefugnis sie steuerte und die Autor:innen als nicht stimmberechtigte technische Expert:innen fungierten. In Südkorea leiteten Expert:innen der nationalen HTA-Agentur die Entwicklung, akademische Expert:innen steuerten die Methodik, und externe Gutachter:innen sorgten für die Qualitätssicherung. In China erstellten Forschende die Leitlinie, unterstützt von einem Expert:innenkomitee mit politischen Entscheidungsträgern nationaler Behörden. Der LMIC-Review stellte fest, dass die meisten Länder die Zusammensetzung von GDG und der Steuerungsgruppe nicht systematisch berichteten.

In allen fünf Ländern hält ein staatlich verbundenes Gremium die letzte Entscheidungsbefugnis, wobei die rechtliche Grundlage von zentralisiert (Südkorea) über föderal beratend (Kanada), bei den Kostenträgern angesiedelt (Japan), ministeriumsgeleitet (Libanon) bis fachverbandsgeführt (China) reicht. Die Unterstützung (Endorsement) erfolgte stets durch ein staatlich verbundenes Gremium, jedoch unterschiedlich operationalisiert. In Kanada war ein zweistufiger Endorsement-Prozess Voraussetzung für die Umsetzung auf Provinzebene, in Südkorea und Japan war die Unterstützung durch das Erstattungskomitee direkt mit Entscheidungen zu Listung und Preisgestaltung verknüpft. Chinas Leitlinie entbehrt einer formalen staatlichen Endorsement-Bekundung, wurde jedoch in nationalen Preisverhandlungen herangezogen, und der Libanon berichtet über die Befürwortung durch das Gesundheitsministerium ohne festgelegte rechtliche Konsequenzen. Der LMIC-Review fand am häufigsten Unterstützung von Gesundheitsministerien, jedoch oft ohne Klarheit darüber, ob die Leitlinien verpflichtend, beratend oder symbolisch waren.

Kosten- und Entscheidungsträger, Industrie, Wissenschaft und Kliniker:innen waren in allen Ländern Stakeholder, Kanada, Südkorea und der Libanon bezogen auch Patient:innen und die Öffentlichkeit ein, und einige Länder konsultierten internationale Expert:innen. Der LMIC-Review stellte fest, dass die Einbeziehung von Stakeholdern nur unzureichend dokumentiert war und ein Drittel der Leitlinien keine sektorübergreifende Einbeziehung aufwies. Vier Zielgruppenkategorien zeichneten sich ab: Entscheidungs- und Kostenträger (in allen Ländern primär), Einreicher aus der Industrie (überall eine Zielgruppe), Forschende und Akademiker:innen sowie Patient:innen (ausdrücklich nur im Libanon). Eine explizite Benennung der Zielgruppen fehlte häufig. Ein gemeinsames zeitliches Muster zeigte sich: GDGs und Steuerungsgruppen wurden zu Beginn gebildet, die Stakeholder-Konsultation folgte in der Regel einem ersten Entwurf, öffentliche Konsultationen waren typischerweise Einzelereignisse, und die Bestätigung erfolgte zuletzt.

Internationale Leitlinien dienten in allen Ländern als gemeinsame Referenz, wobei Tiefe und Transparenz der Quellendokumentation erheblich variierten. Der Libanon wählte den systematischsten, evidenzbasiertesten Ansatz, Japan führte eigene systematische Reviews durch, und Südkorea war das einzige Land, in dem Nutzerfeedback Überarbeitungen beeinflusste. Kanada, Südkorea, Japan und China berichteten nicht über ein explizites methodisches Rahmenwerk, obwohl ihre Prozesse Elemente enthielten, die mit späteren formalen Rahmenwerken übereinstimmten.

Der achtphasige DIDS-Prozess

Trotz Variation in Anzahl, Reihenfolge und Gewichtung der Schritte zeichnete sich ein gemeinsamer achtphasiger Kernprozess ab:

- Eingrenzung (Scoping) und Identifikation eines politischen Bedarfs: Begründung festlegen, den politischen Bedarf formulieren sowie Umfang, Ziele und zentrale methodische Fragen definieren.
- Bildung einer Leitlinienentwicklungs- und Steuerungsgruppe: Ein Kernteam mit relevanter technischer Expertise sowie ein Aufsichts- oder Beratungsgremium einrichten.
- Evidenzsammlung und Literaturreview: Internationale Leitlinien, wissenschaftliche Literatur und nationale Erfahrungen systematisch identifizieren und zusammenführen.
- Erstellung eines ersten Entwurfs und interne Prüfung: Entwurfsversionen erstellen und intern prüfen, bevor eine externe Konsultation erfolgt.
- Stakeholder- und öffentliche Konsultation: Entwürfe über Workshops, Befragungen oder deliberative Prozesse zur externen Stellungnahme zirkulieren.
- Überarbeitung und Finalisierung: Feedback einarbeiten und die abschließende Genehmigung durch die Steuerungs- oder Lenkungsgruppe einholen.
- Bestätigung (Endorsement): Formelle Genehmigung durch eine staatlich verbundene Behörde, die das Mandat zur Anwendung erteilt.
- Dissemination und Aufrechterhaltung: Die Leitlinie für Zielgruppen zugänglich machen und ihre Aktualität durch Updates, Monitoring und Kapazitätsaufbau sicherstellen.

Die Disseminationsmaßnahmen waren in den fünf Ländern relativ gut, im LMIC-Review jedoch nur schlecht in den inkludierten Ländern dokumentiert. Die Aufrechterhaltung war die am wenigsten systematisch dokumentierte Phase, was diese kritische Lücke bestätigt.

Barrieren und Förderfaktoren

Barrieren und Förderfaktoren lassen sich vier Kategorien zuordnen: Expertise, institutionelle Governance und Stakeholdergruppen, Quellen und methodische Rahmenwerke sowie der DIDS-Prozess selbst. Expertisenmangel und Datenlücken sind universelle Barrieren. Alle fünf Länder berichteten über einen Mangel an gesundheitsökonomischer Expertise sowie über fehlende Kosten- oder Nutzwertdaten. Zu den Governance-Barrieren zählten Freiwilligkeit oder fehlende Verbindlichkeit (China), fragmentierte Systeme (Kanada, Libanon), das Fehlen einer nationalen HTA-Agentur (China, LMICs) sowie Widerstand von Industrie oder Ärzt:innenschaft (Japan).

Die Einbeziehung von Stakeholdern ist der am konsistentesten berichtete Förderfaktor. Alle fünf Länder bezogen Industrie, Wissenschaft und Kliniker:innen ein, und der LMIC-Review bestätigte Workshops oder Konsultationstreffen in 9 von 14 Ländern. Weitere Förderfaktoren waren politischer Wille (Südkorea, China), rechtliche Bestätigung durch das Ministerium (Kanada, Libanon, LMICs), Bezug auf internationale Leitlinien und Best-Practice-Rahmenwerke (Libanon), lange Deliberation mit Zwischenberichten (Japan) sowie Transparenzmaßnahmen wie Gutachter:innen-Checklisten und Interessenkonflikt-Richtlinien (Südkorea).

Schlussfolgerungen und Empfehlungen

Governance-Klarheit und eine rechtliche Grundlage oder eine Form institutioneller Rückendeckung, auch ohne formelles gesetzliches Mandat, sind entscheidend für die Aufrechterhaltung einer HEEG. Expertisenmangel und Datenlücken sind universelle Barrieren, die Einbeziehung von Stakeholdern ist der konsistenteste Förderfaktor, und die Aufrechterhaltung ist international die am wenigsten systematisch dokumentierte Phase. Ein erfolgreicher DIDS-Prozess hängt daher von einem klaren rechtlichen oder politischen Mandat, dedizierter institutioneller Verantwortung, Investitionen in lokale Daten und in den Kapazitätsaufbau, inklusiver Stakeholder-Einbeziehung, expliziter Planung der Disseminierung und Aufrechterhaltung sowie pragmatischer Anpassung an internationale Best Practices ab.

Implikationen für Österreich:

- Eine verbindliche HEEG einrichten, die über das Bewertungsboard hinaus auf alle Gesundheitstechnologien in stationären und ambulanten Bereichen ausgeweitet wird, mit verpflichtender Einreichung gesundheitsökonomischer Evidenz durch die Industrie.
- In lokale Daten und Kapazitäten investieren, einschließlich einer nationalen Kostendatenbank, österreichischer EQ-5D-Nutzwertsets zur Darstellung der gesundheitsbezogenen Lebensqualität, einer definierten Referenzmethode und formeller Kapazitätsbildung, aufbauend auf bestehender Expertise in österreichischen akademischen und nichtstaatlichen Organisationen.
- Eine klare Organisationsstruktur und einen strukturierten Engagement-Plan schaffen, der öffentliche Kostenträger, Krankenhausträger, Industrie, klinische Expert:innen, Patient:innenanwaltschaften, andere HTA-Agenturen und die breitere Öffentlichkeit umfasst, mit transparenter Kommunikation darüber, wie Feedback berücksichtigt wurde.
- Institutionelle Verantwortung in einem dedizierten HTA-Institut mit gesetzlichem Mandat zur Entwicklung und Aktualisierung der Leitlinie verankern.
- Eine Strategie für die Dissemination und Aufrechterhaltung von Beginn an gestalten, einschließlich Monitoring, Evaluierung und einer formalen Roadmap für Updates, die im institutionellen Mandat verankert ist.

Österreich kann auf seinen bestehenden Institutionen mit gesundheitsökonomischer Expertise aufbauen und aus internationalen Erfahrungen lernen, während Fallstricke wie eine zu nachsichtige Durchsetzung und mangelnde Berücksichtigung der Aufrechterhaltung der Leitlinie vermieden werden sollten.

Summary

Key messages

- Austria needs a national Health Economic Evaluation Guideline (HEEG) to standardise cost-effectiveness evidence and support fair, transparent reimbursement decisions.
- International experience shows a common eight-phase process for developing, implementing, disseminating, and sustaining (DIDS) a HEEG.
- Governance clarity and a legal basis are decisive for sustainment of the HEEG.
- Shortages of expertise and local cost/utility data are universal barriers.
- Broad stakeholder engagement is the most consistent facilitator of successful adoption.
- Austria should plan for monitoring and updates from the outset.

Background and Problem Definition

Health economic evaluations (HEEs) play only a minor role in Austrian reimbursement decisions. More than 40 countries and regions have developed their own health economic evaluation guidelines (HEEGs). Austria has no binding methodological guideline with a defined reference case, costing approach, or standardised requirements for economic evidence.

The need for a national HEEG has grown more pressing with the 2023 establishment of the appraisal board ("Bewertungsboard für ausgewählte Arzneimittel") under the Federal Hospitals Act. Developing and implementing a HEEG requires a structured, evidence-based development, implementation, dissemination, and sustainment (DIDS) process. This process should account for barriers and facilitators and involve experts and payer representatives in a transparent, deliberative way. Research questions addressed in this report:

- How can international examples inform the whole DIDS (development, implementation, dissemination, and sustainment) process of an Austrian HEEG to ensure its successful adoption?
- Which barriers and facilitators exist in the DIDS process of a HEEG?

This report is part of the project "Preparatory work for a Health Economic Guideline in Austria", which aims to strengthen the role of standardised HEEs in Austrian decision-making.

Methods

This report is based on a scoping review of published literature on HEEG development and implementation, complemented by expert knowledge. An exploratory hand search in Google Scholar and PubMed identified publications describing the DIDS process. Information on the four DIDS dimensions was extracted across standardised categories, such as organisational structure, sources and frameworks, process steps, dissemination, and sustainment. Process steps were then listed chronologically, compared across countries, grouped into common phases, and mapped for consistency. Barriers and facilitators were grouped inductively.

Findings for Austria were interpreted across six aspects: objectives, scope, and principles, team building, stakeholder engagement, content and resources, institutional arrangements, and monitoring and evaluation.

Results

International Examples: Timeline, Organisational Structure, and Sources

Nine publications covering five countries (Canada, South Korea, Japan, China, and Lebanon) plus a systematic review of low- and middle-income country (LMIC) experiences were included. All five produced formal, nationally endorsed guidelines in distinct waves.

Guideline development groups (GDGs) consistently combined health economists, policymakers, and clinical or methodological experts, but their relationship to the steering group varied. In Canada and Lebanon, the same body developed and oversaw the guideline. In Japan, four health economists drafted it while a 16-member, payer-dominated subcommittee with decision-making authority steered it, the authors serving as non-voting technical experts. In South Korea, in-house HTA agency staff led development, academic experts steered methodology, and external reviewers provided quality assurance. In China, researchers drafted the guideline supported by an expert committee including policymakers from national agencies. The LMIC review noted that most countries did not systematically report GDG and steering group composition.

In all five countries, a government-linked body held ultimate decision-making authority, though the legal basis ranged from centralised (South Korea) to federal advisory (Canada), payer-embedded (Japan), ministry-direct (Lebanon), and professional-association-led (China). Endorsement always came from a government-linked body, but its operationalisation differed. In Canada, a two-stage endorsement was a necessary condition for provincial implementation. In South Korea and Japan, reimbursement committee endorsement was directly linked to listing and pricing decisions. China's guideline lacked formal government endorsement but has been followed in national price negotiations. Lebanon reported ministry endorsement without specified legal consequences. The LMIC review found endorsement most commonly by ministries of health, but often without clarity on whether guidelines were mandatory, advisory, or symbolic.

Payers, decision-makers, industry, academia, and clinicians were stakeholders in all countries. Canada, South Korea, and Lebanon also included patients and the public. Some countries also engaged international experts. The LMIC review found stakeholder engagement poorly disclosed, with one-third of guidelines lacking any multisectoral engagement. Four target group categories emerged: decision-makers and payers (primary in all countries), industry submitters (a target group everywhere), researchers and academics, and patients (explicitly included only in Lebanon). Explicit articulation of target groups was often missing. A common timing pattern emerged. GDGs and steering groups were formed at the outset, stakeholder consultation generally followed an initial draft, public consultations were typically single events, and endorsement came last.

International guidelines served as a common reference point in all countries, though the depth and transparency of source documentation varied considerably. Lebanon took the most systematic, evidence-grounded approach, Japan conducted original systematic reviews, and South Korea was the only country where user feedback informed revisions. Canada, South Korea, Japan, and China reported no explicit methodological framework, although their processes included elements that align with later formal frameworks.

The Common Eight-Phase DIDS Process

Despite variation in the number, sequence, and emphasis of steps, a core common eight-phase process emerged:

- Initial scoping and identification of a policy need: establish the rationale, articulate the policy need, and define scope, objectives, and key methodological questions.
- Formation of a guideline development and steering group: establish a core writing team with relevant technical expertise and an oversight or advisory body.
- Evidence gathering and literature review: systematically identify and synthesise international guidelines, academic literature, and domestic experience.
- Drafting and internal review: produce draft versions and review them internally before external consultation.

- Stakeholder and public consultation: circulate drafts for external input through workshops, surveys, or deliberative processes.
- Revision and finalisation: incorporate feedback and obtain final approval from the steering or governing body.
- Endorsement: formal approval by a government-linked authority, providing the mandate for use.
- Dissemination and sustainment: make the guideline accessible to target groups and ensure continued relevance through updates, monitoring, and capacity building.

Dissemination was relatively well documented across the five countries, though poorly reported in the LMIC review. Sustainment was the least systematically documented phase, confirming this as a critical gap.

Barriers and Facilitators

Barriers and facilitators cluster into four categories: expertise, institutional governance and stakeholder groups, sources and methodological frameworks, and the DIDS process itself. Expertise shortages and data limitations are universal barriers. All five countries reported shortages of health economists and a lack of local cost or utility data. Governance barriers included voluntary or non-mandatory status (China), fragmented systems (Canada, Lebanon), absence of a national HTA agency (China, LMICs), and industry or medical opposition (Japan).

Stakeholder engagement is the most consistently reported facilitator. All five countries engaged industry, academia, and clinicians, and the LMIC review confirmed workshops or consultation meetings in 9 of 14 countries. Other facilitators included political will (South Korea, China), ministry endorsement (Canada, Lebanon, LMICs), reference to international guidelines and best practice frameworks (Lebanon), long deliberation with interim reports (Japan), and transparency measures such as reviewer checklists and conflict-of-interest guidelines (South Korea).

Conclusions and Recommendations

Governance clarity and a legal basis, or some form of institutional backing even without a formal legal mandate, are critical to sustaining a HEEG. Expertise and data limitations are universal barriers, stakeholder engagement is the most consistent facilitator, and sustainment is the least systematically documented phase internationally. A successful DIDS process therefore depends on a clear legal or political mandate, dedicated institutional responsibility, investment in local data and capacity building, inclusive stakeholder engagement, explicit planning for dissemination and sustainment, and pragmatic adaptation of international resources.

Implications for Austria:

- Establish a (mandatory) HEEG extending beyond the appraisal board to all health technologies across inpatient and outpatient settings, with mandatory submission of health economic evidence by industry.
- Invest in local data and capacity, including a national cost database, Austrian EQ-5D value sets to quantify health-related quality of life, a defined reference case, and formal capacity building, building on existing expertise in Austrian academic and non-governmental organisations.
- Establish a clear organisational structure and structured engagement plan covering public payers, hospital providers, industry, clinical experts, patient advocacy groups, other HTA agencies, and the broader public, with transparent communication of how feedback was addressed.
- Anchor institutional responsibility in a dedicated HTA unit with a legal mandate to develop and update the guideline.
- Design a dissemination and sustainment strategy from the start, including monitoring, evaluation, and a formal roadmap for updates embedded in the institutional mandate.

Austria can build on its existing institutions with health economic expertise and learn from international experience while avoiding pitfalls such as the guideline's voluntary status and neglection of gaps.

1 Introduction

1.1 General Background

Australia and Canada were the first countries to develop health economic evaluation guidelines (HEEGs) (1992 and 1994 respectively). Since then, more than 40 countries and regions have created their own [1, 2]. Developing and implementing any health system guidance (HSG) document, including an HEEG, requires a structured, evidence-based process. In general, this process consists of four distinct steps:

Australien/Kanada als Vorreiter bei Leitlinienentwicklung

vierstufiger, evidenzbasierter Prozess:

- the development of the guideline, **Entwicklung,**
- implementation activities, such as legal or institutional embedding, **Implementierung,**
- dissemination activities to promote it among affected stakeholders and decision-makers, **Dissemination,**
- and sustainment, in the form of ongoing maintenance and updates in response to scientific developments. **"Erhaltung"**

This development, implementation, dissemination, and sustainment (DIDS) process should carefully account for potential barriers and facilitators, including the active involvement of experts and payer representatives in a transparent and deliberative process [3, 4].

→ DIDS-Prozess

While similar HSG documents, encompassing standards and frameworks for a transparent, deliberative, and evidence-based process, exist for clinical guidelines (CGs) [5-14] and health technology assessment (HTA) guidelines [15-17], there is currently no formal equivalent specifically tailored for HEEGs. Existing resources on the DIDS process in the HEEG context are limited to descriptive overviews of development processes in certain countries [18-22] and frameworks for evaluating and using health economic evidence in decision-making [23-26].

kein formelles Tool zur Entwicklung & Implementierung von gesundheitsökonomischen (ges.ök) Leitlinien …

Moreover, despite the existence of systematic reviews on effectiveness [27], economic evaluations or cost analyses [28], and qualitative studies on barriers to and facilitators of clinical guideline implementation strategies [29], a similar evidence base remains absent for HEEGs.

… & auch keine Evidenz zu Barrieren & Förderfaktoren

1.2 The Austrian Context: Current Situation and Need for HEEG[1]

Österreich: fehlende verbindliche Leitlinien für gesundheitsökonomische Evaluationen

In Austria, health economic evaluations (HEEs) have so far played a minor role in reimbursement decisions, and a HEEG with a reference case including a costing process and approach has not yet been defined or discussed [31-33]. Although a private industry consulting institute has addressed some methodological issues in a consensus document more than 20 years ago [32], it lacks precise methodological direction, and its use remains optional, serving as a recommendation rather than a requirement [31, 33]. In addition, there is a document establishing the legal and organisational framework governing the Reimbursement Code (EKO) for outpatient drugs [34]; it outlines the principles applied to determine whether a medication used in the outpatient sector is eligible for public funding based on pharmacological, medical-therapeutic and economic evaluation. While for some cases manufacturers need to submit a pharmacoeconomic evaluation, taking into account the direct costs accrued from the perspective of social insurance, it does not provide further methodological specifications of health economic evidence typically found in HEEGs internationally. The lack of a systematic approach creates a significant gap in the methodological infrastructure for health economic evaluations in Austria.

Folgen fehlender Standards: Ineffizienz, strategisches Verhalten

mangelnde Vergleichbarkeit ohne einheitliche Methodik

In general, such an absence of formal guidelines creates substantial challenges across multiple dimensions. Without standardised methodological approaches, there is a risk of inconsistent economic evaluations that are difficult to compare, undermining transparency in how evidence is generated and assessed and creating barriers to fair and objective decision-making. This uncertainty affects all stakeholders. Producers of health economic evaluations, including research institutions, pharmaceutical and medical device companies, and developers of other types of health interventions (such as public health programs), lack clear guidance on methodological expectations. This may lead to inefficiencies, as resources are spent on analyses that do not meet decision-makers' needs, or to strategic behaviour, where submitters choose approaches that present their interventions most favourably rather than most appropriately. Conversely, decision-makers and researchers face challenges in evaluating the quality and comparability of economic evidence without a clear benchmark against which to assess submissions [31].

Bewertungsboard 2023: Neuer Impuls für nationale Leitlinie in Österreich

jedoch Bedarf über das Bewertungsboard hinaus gegeben

The need for a national HEEG has been brought into focus by the establishment in 2023 of an appraisal board ("Bewertungsboard für ausgewählte Arzneimittel") under § 62d ff of the Federal Hospitals Act. This board was established to ensure fair and rapid access to selected high-cost and specialised medicines used in hospitals and at the intersection between hospital and outpatient care, as well as to promote nationally consistent use [35]. HTA supports the board's reimbursement decisions, contributing to evidence-based decision-making and greater transparency. These HTAs evaluate multiple dimensions of new health technologies, including health economic evidence. However, the need for a national HEEG should expand beyond the Appraisal Board's specific requirements. Ideally, economic evaluations would be increasingly applied across a wide range of decision-making processes and for a wide range of technologies including medical devices, public health interventions (e.g., screening or vac-

[1] The description of the situation in Austria was taken and adapted from "Overview of National Health Economic Evaluation Guidelines: International Best Practices and Implications for Austria" of the project "Preparatory Work for an Austrian Health Economic Guideline" [30].

cination programs) or health promotion programs, and resource allocation at both regional and national levels. In this context, standardised guidelines would promote the consistent application of health economic evidence across diverse settings, thereby supporting evidence-based healthcare policy more broadly.

europäische Ansätze als Referenz – Anpassung an österreichische Strukturen nötig

Austria shares similar insurance-based structures with other European countries, making these European approaches particularly relevant reference points. However, Austria's specific healthcare structure, including the interface between hospital and outpatient care, the federal organisation of healthcare delivery combined with regional provision, and the particular role of social insurance, requires careful consideration beyond general European approaches. Hence, there is a clear need for nationally consistent approaches to economic evaluation that can be applied across different regions and decision-making contexts. The integration with existing Austrian healthcare decision-making structures is essential, as guidelines must fit within established processes whilst supporting their evolution [31].

1.3 Problem Statement and Rationale of the Project Part

Problem: fehlende klare DIDS-Rahmenwerke für HEEG → Projekt als Grundlage für Österreich

Against the backdrop of a lack of clear frameworks for the DIDS process in a HEEG, this part of the project will lay the foundation for the subsequent steps in the project "Preparatory work for a Health Economic Guideline in Austria" [36]. That project aims to strengthen the role of standardised HEEs in decision-making in Austria. It also provides scientific support for the DDIS process of a HEEG in Austria.

1.4 Objectives and Research Questions

The main aims of this project part are to …

Synthese internationaler Erfahrungen für DIDS-Prozess in Österreich

- Identify a selection of international examples of HEEG DIDS processes.
- Identify facilitators and barriers of the HEEG DIDS process.
- Synthesise the findings to identify the necessary steps for developing, implementing, disseminating, and sustaining a HEEG in Austria.

Forschungsfragen:

The following research questions will be answered with this report:

internationale Beispiele?

1. How can international examples inform the whole DIDS process of an Austrian HEEG to ensure its successful adoption?

Barrieren & Förderfaktoren?

2. Which barriers and facilitators exist in the DIDS process of an HEEG?

2 Method

2.1 Scoping Review

2.1.1 Overview

This report is based on a scoping review of publications on the development and implementation of HEEG across a range of countries, as well as on expert knowledge.

Methode: Scoping Review

The following four steps were conducted:

4 Schritte:

- "Overview of International Examples" (section 2.1.2)
  - Hand search for relevant literature and identify existing DIDS processes.
  - Mapping of the existing literature, data extraction and tabulation of information relevant to guideline DIDS, and identification of facilitators and barriers mentioned in the literature.
  - Narrative summary of the extracted information.
- "Development, Implementation, Dissemination, and Sustainment Process" (section 2.1.3) – Activities from each country's DIDS process were thematically grouped into common phases. Each country's specific activities and steps were then assigned to the phase that best matched their described purpose.
- "Barriers and Facilitators" (section 2.1.4) – Inductive grouping of barriers and facilitators mentioned in the publications regarding the DIDS process.
- "Interpretation of the Findings for the Austrian Context" (section 2.1.5)

Übersicht internationaler Beispiele durch Handsuche & narrative Zusammenfassung der Literatur

thematische Gruppierung der DIDS-Aktivitäten in Phasen

induktive Gruppierung von Barrieren & Förderfaktoren aus der Literatur mit Interpretation für Österreich

2.1.2 Overview of International Examples

Hand Search and Identification

A systematic literature search was not performed, as the aim was not to identify all existing guidelines. The selection of countries for this report was rather based on a scoping approach to identify available evidence on the DDIS processes of HEEG. We conducted an explorative hand search in Google Scholar and PubMed using the following search terms:

explorative Handsuche → kein systematischer Review (SR)

- "health economic guideline" AND development
- "health economic guideline" AND implementation
- "pharmacoeconomic guideline" AND development
- "pharmacoeconomic guideline" AND implementation

Final inclusion criteria were: 1) the availability of a published national HEEG, 2) the availability of a publication describing the DIDS process of that guideline, and 3) the publication was available in English or German. No countries were excluded based on content or quality, other than the absence of sufficient documentation on the DDIS process.

Ein- & Ausschlusskriterien

systematischer Review von Daccache et al. (2022) als ergänzende Quelle

The identified systematic review by Daccache, et al. [2022] was included as a complementary source to broaden the scope to low- and middle-income countries (LMICs), as it systematically reviewed the development processes of HEEGs in 14 LMICs. Furthermore, it served as a further guide to identifying relevant literature on the process.

Data Extraction and Extraction Categories

Kategorien der Datenextraktion:

After the identification of the relevant literature, information on the following categories relevant to the DIDS process was extracted and described[2]:

Table 2-1: Extracted information

Extraction category	Description
General information (country, guideline, duration and timeline)	The duration and timeline category captures the time frame of the guideline development process, including the start and end dates of key phases, the total duration from inception to publication, and the timing of updates or revisions.
Organisational structure within the DIDS process, including …	
■ **Expertise: Authors, guideline development and steering group**[3]	The authors or core GDG are those directly responsible for drafting the guideline. The steering group (where present) provides oversight, methodological guidance, or formal approval.
■ **Institutional governance (decision-makers, legal basis, and interactions) and endorsement**	The institutional governance refers to the institutional arrangements for decision-making, accountability, and legal authority for guideline DIDS. This includes decision-makers, policy-makers, the legal framework, and interactions among the GDG, steering group, and other bodies.
■ **Stakeholder groups involved**[4]	Stakeholder groups are individuals or organisations with an interest in the guideline and its implementation. They are consulted during guideline development to provide input, feedback, and legitimacy, but they typically do not have decision-making authority (unless they hold voting roles on steering groups). Their engagement ensures that diverse perspectives (industry, academia and researchers, clinicians, patients, and payers) are considered, thereby enhancing the guideline's credibility, relevance, and likelihood of successful implementation.
■ **Target groups**[4]	Target groups are the intended users of the guideline after its publication, including decision-makers and payers who use it for reimbursement or pricing decisions, industry submitters who prepare economic evaluations, and researchers who conduct or appraise such evaluations.
Sources and methodological frameworks	This category captures scientific sources and the methodological guidance used to inform guideline development. It includes international guidelines and academic literature consulted, systematic reviews or targeted searches conducted, and formal frameworks or tools applied, such as the WHO handbook for health system guidelines, AGREE-HS, or ISPOR checklists.
Information on the process in each country regarding the DIDS of a guideline (DIDS process[5]**)**	This category provides a general overview of the DIDS process. It describes the sequence of key steps and activities undertaken, from initial acknowledgement of a policy need and scoping through to drafting, consultation, revision, endorsement, publication, and planned updates, capturing the overall flow and structure of the process across countries.

[2] The extracted information is oriented towards six key aspects essential in a guideline development cycle proposed by Botwright, et al. [2025]: 1) Setting objectives, scope, and principles, 2) building a team for a quality guideline, 3) defining a stakeholder engagement plan, 4) developing content and utilising available resources, 5) putting in place appropriate institutional arrangements, and 6) monitoring and evaluating guideline access.

[3] Because the steering group and guideline development group (GDG) overlapped functionally in several countries, they are both summarised under this section.

[4] Stakeholder groups contribute to developing the guideline (consulted for input and legitimacy, without decision-making authority), whereas target groups are the intended users of the guideline after publication (applying it in decisions, submissions, and research).

[5] As the guideline process is in its early stages in Austria, we were interested in more detailed information, especially regarding the DIDS process. While the majority of the available information covers development and implementation aspects of a guideline DIDS process, aspects on dissemination and sustainment of a guideline document were separately extracted.

Extraction category	Description
Dissemination	This category captures how the guideline is made available and accessible to its intended target groups after finalisation. It includes the publication channels used (e.g., agency websites, open access journals), the provision of translations or structured reporting formats, the public availability of review results, and any consultation processes preceding final publication.
Sustainment	This category captures the mechanisms and activities that ensure the guideline remains current, relevant, and actively used over time. It includes formal responsibility for updates assigned to a specific agency, planned revision cycles, re-evaluation of listed technologies, capacity building, data infrastructure development, collaboration with regional or international networks, integration into broader policy frameworks, and identification of barriers and facilitators for implementation.

Abbreviations: AGREE-HS … Appraisal of Guidelines for Research and Evaluation – Health Systems, DIDS … Development, implementation, dissemination, sustainment, GDG … Guideline development group, ISPOR … International Society for Pharmacoeconomics and Outcomes Research, WHO … World Health Organisation

Extraktion der 4 DIDS-Prozess-Dimensionen Entwicklung, Implementierung, Verbreitung & Erhaltung

The extraction covered four DIDS dimensions: development, implementation, dissemination, and sustainment. Information on development and implementation was captured through general country and guideline data, organisational structure, sources and methodological frameworks, and the process description for each country. Dissemination and sustainment were extracted as separate categories as they are usually not systematically covered by HEEG development processes.

The first author extracted data across all categories, including the guideline development and implementation process, to ensure a thorough understanding of the historical context and sequential steps involved.

Unterstützung durch DeepSeek-V4 für einige Extraktionskategorien

DeepSeek-V4 was used as a preliminary extraction tool for data on the following categories:

- General information (country, guideline, duration, and timeline)
- Organisational structure within the DIDS process:
  - Expertise: Authors, guideline development and steering group
  - Institutional governance (decision-makers, legal basis, and interactions) and endorsement
  - Stakeholder groups involved
  - Target groups

manuelle Extraktion der Infos zum DIDS-Prozess mit nachträglicher Validierung

The information on the process in each country regarding the DIDS of a guideline (DIDS process) and information on dissemination and sustainment was extracted manually by the first author. All the information was double-checked by the first author after the completion of the extraction table.

Table A-1 in the Appendix provides the extracted information on the international examples.

2.1.3 Development, Implementation, Dissemination, and Sustainment Process

Vorgangsweise DIDS-Prozess:

All the extracted information, especially the information on processes in each country, was used to derive a common process for HEEG DDIS. Thereby, we followed the following action points:

chronologische Auflistung der DIDS-Prozessschritte

First, the extracted information on the DIDS process was listed in chronological order according to the descriptions in the source publications. Steps ranged from policy needs and scoping activities to final publication, endorsement, dissemination, and sustainment.

iterative Gruppierung der Aktivitäten über Länder hinweg

Second, through an iterative comparison of the extracted steps across all countries, recurrent activities were identified and grouped thematically. This resulted in a set of common phases that appeared consistently across countries, despite differences in terminology, sequencing, and level of detail.

Zuordnung (Mapping) der Länderaktivitäten zu DIDS-Prozessphasen

Third, the extracted steps from each country were mapped to common phases of the DIDS process. A step was assigned to a phase if its described purpose aligned with the phase definition. For example, any activity involving the formation of a writing or oversight body was assigned to "Phase 2: Formation of a Guideline Development and Steering Group", regardless of whether the country named it a "steering committee", "advisory committee", or "expert committee". Steps that did not fit any existing phase led to refining the phase definitions or, in the case of dissemination and sustainment activities, adding an additional phase.

Mapping wurde auf Konsistenz überprüft

Fourth, the mapping was reviewed for consistency. Activities that spanned multiple phases (e.g., a workshop that served both consultation and drafting purposes) were assigned to the primary phase based on the step's main objective as described by the authors. Where a country reported multiple distinct activities within a single phase (e.g., South Korea's open workshop, industry review, and surveys all within Phase 5), all were retained as country examples under that phase.

LMIC-Review als Vergleichsperspektive

Fifth, the LMIC systematic review [37] was used as a comparative lens. Where the review reported aggregate data (e.g., "workshops or consultation meetings in 9 countries"), these were incorporated as additional country examples or as validation that the phase was relevant beyond the five included countries.

deskriptive Kernstruktur mit länderspezifischen Abweichungen

The resulting phases represent a minimum core structure present across all countries, while allowing for country-specific variations in the number, sequence, and emphasis of activities within each phase. The categorisation is descriptive, not prescriptive. It documents what countries did, not what they should have done.

2.1.4 Barriers and Facilitators

Screening auf & Extraktion von Barrieren/ Förderfaktoren

In the third step, the publications were screened for activities and measures that impede (barriers) or enable and accelerate (facilitators) the DDIS process. The extracted items were then grouped according to the categories initially specified (Table 2-1). Categories were refined inductively where new themes emerged from the data.

2.1.5 Interpretation of the Findings for the Austrian Context

Diskussion & Einbettung der Ergebnisse in den österreichischen Kontext

In the last step, the descriptive findings from the previous steps were discussed and embedded in the Austrian context. First, we gave an interpretive summary of the overall findings, and secondly, we embedded the findings in the good practice framework by Botwright, et al. [2025], a task force report by HTAi, HTAisLink, and ISPOR, to translate these insights into actionable guidance for Austria. This framework systematically organises the key considerations for developing or updating HTA guidelines into six key aspects:

Table 2-2: Six key aspects by Botwright et al. [2025]

Six key aspects:
■ Setting objectives, scope, and principles.
■ Building a team for a quality guideline.
■ Defining a stakeholder engagement plan.
■ Developing content and utilising available resources.
■ Putting in place appropriate institutional arrangements.
■ Monitoring and evaluating guideline success.

Einbettung der Ergebnisse in das Botwright-Framework

The framework is particularly valuable because it was developed through literature reviews, key informant interviews, and extensive stakeholder consultation, and it explicitly aims to be relevant across different country contexts and stages of HEEG and HTA institutionalisation. By embedding our empirical findings within this framework, we identified where our synthesis confirms, complements, or challenges Botwright et al.'s [15] recommendations, and derived specific, context-sensitive implications for Austria.

Limitationen & Conclusio

Following this domain-specific discussion, we separately reflected on the implications of the common "Development, Implementation, Dissemination, and Sustainment Process" (Section 2.1.3) for the Austrian context. As the last steps, we provided limitations and conclude.

2.2 Quality Assurance

Qualitätssicherung des Berichts durch interne & externe Begutachtung

As part of quality assurance, the report was reviewed by one internal reviewer (IZK) and an external reviewer (SK). The external reviewer was primarily asked to assess the following quality criteria:

- *Technical correctness:* Is the report technically correct (evidence and information used)? Does the report consider the latest findings in the research area?
- *Adequacy and transparency of method:* Is the method chosen adequate for addressing the research question, and are the methods applied transparently?
- *Logical structure and consistency of the report:* Is the report's structure consistent and comprehensible?
- *Formal features:* Does the report fulfil formal criteria of scientific writing (e.g. correct citations)?

The AIHTA considers external peer review by scientific experts from different disciplines to be a quality assurance method of scientific work. The responsibility for the report content lies with the AIHTA.

3 Overview of International Examples

3.1 Included Publications and Countries

Neun Publikationen aus 5 Ländern & 1 SR identifiziert: Kanada (CA), Südkorea (KR), Japan (JP), China (CN), Libanon (LB)

Overall, nine publications covering five countries (Canada, South Korea, Japan, China, and Lebanon) [2, 18, 20-22, 38-40] and a systematic review [37] covering guideline development process in LMICs were identified and included:

Table 3-1: Overview of identified and included publications

Publication	Year	Country	Publication name
Torrance et al. [18]	1996	Canada	Canadian Guidelines for Economic Evaluation of Pharmaceuticals
Bae & Lee [21]	2009	South Korea	Pharmacoeconomic Guidelines and Their Implementation in the Positive List System in South Korea
Bae et al. [38]	2013		Korean Guidelines for Pharmacoeconomic Evaluation (Second and Updated Version): Consensus and Compromise
Bae et al. [20]	2022		Korean Guidelines for Pharmacoeconomic Evaluations: Updates in the Third Version
Shiroiwa et al. [22]	2017	Japan	Development of an Official Guideline for the Economic Evaluation of Drugs/Medical Devices in Japan
Yue et al. [2]	2021	China	Current Development and Practice of Pharmacoeconomic Evaluation Guidelines for Universal Health Coverage in China
Daccache et al. [39]	2024	Lebanon	Developing the Lebanese Health Economic Evaluation Guideline
Daccache et al. [40]	2025		The Lebanese Health Economic Evaluation Guideline
Daccache et al. [37]	2022	LMICs	The Development Process of Economic Evaluation Guidelines in Low- and Middle-Income Countries: A Systematic Review

Abbrevation: LMICs … Low- and middle-income countries

3.2 General Information: Duration and Timeline

CA als einer der Vorreiter bei ges.ök. Leitlinienentwicklung (1993)

All five countries, Canada [18], South Korea [20, 21, 38], Japan [22], China [2], and Lebanon [39, 40], produced formal, nationally endorsed guidelines. Across these five selected countries, HEEG development occurred in distinct waves. Canada started its guideline process in 1993 (operationalised by 1996), preceded by draft Ontario guidelines as early as 1991 [18]. The Canadian Guidelines for Economic Evaluation of Pharmaceuticals have undergone multiple editions under CCOHTA/CADTH/CDA-AMC[6] since then.

KR Leitlinien erstmals 2006 (Updates 2011 & 2022)

JP offizielle Leitlinie ab 2017

South Korea's Health Insurance Review and Assessment Service (HIRA) guidelines [20, 21, 38] were first published in June 2006, with updates in 2011 and 2022, indicating a sustained commitment to revision. Japan's official guideline for cost-effectiveness evaluation [22] began with a trial implementation in 2016 and was formally published in 2017. Both countries have a development duration of approximately three to four years.

[6] In the early 21st century, the Canadian Coordinating Office for Health Technology Assessment (CCOHTA) became the Canadian Agency for Drugs and Technologies in Health (CADTH) and as of May 1, 2024, it adopted Canada's Drug Agency (CDA-AMC) as operating name. Throughout the report CDA-AMC is used.

China's first edition appeared in 2011, with a major update in 2020 [2], though its explicit development duration is not stated. The publication on the Chinese development process suggests that periodic updates aligned with rapid healthcare system changes are carried out.

CN erste Edition 2011 mit größerem Update 2020

The Lebanese Economic Evaluation Guideline [39, 40] was published between 2024 and 2025, with an inception-to-expert-consultation timeline of about 3.5 years. The publication suggests that the Lebanese guideline also followed a staged release (e.g., a draft followed by a final).

LB: Leitlinie 2024-2025 veröffentlicht

In addition, the LMIC systematic review [37] identified guidelines starting with their development process from the early 2000s onward. However, no systematic duration data were reported, suggesting variable and often undocumented timelines. Among the 14 countries (Bhutan, Brazil, China, Colombia, Cuba, Egypt, India, Indonesia, Malaysia, Mexico, Philippines, Russian Federation, South Africa, Thailand), guideline versions ranged from single editions to multiple updates. Updates were less frequent than in Canada or South Korea, often hampered by limited technical working groups.

LMIC-Review identifizierte 14 Länder mit Leitlinien ab den frühen 2000ern

3.3 Organisational Structure

The organisational structure for HEEG development encompasses four interrelated components 1) Authors, the GDG and the steering group (where present), each with their expertise, 2) institutional governance (decision-makers, legal basis, and interactions among all players, including endorsement by an authority, 3) stakeholder groups, and 4) target groups. Section 3.3.5 "Timing of Involvement" gives an overview of the timing all players are involved.

Organisationsstruktur: Autor:innen/ Entwicklungsgruppe (GDG), institutionelle Governance, Stakeholder & Zielgruppen

3.3.1 Expertise: Authors, Guideline Development and Steering Group

The relationship between the GDG and the steering group varies across countries, ranging from full integration (e.g., Canada, South Korea) to clear separation (e.g., Japan). Across the five countries, GDGs consistently included a mix of health economists, policymakers, and clinical or methodological experts. In countries with dedicated HTA agencies (Canada [18], South Korea [20, 21, 38]), expertise is embedded within steering committees or in-house staff. In countries where guidelines are academically led (Japan [22], China [2], Lebanon [39, 40]), health economists are explicitly named as authors or core GDG members. Besides the commonalities, the composition varied significantly.

GDG-Zusammensetzung länderübergreifend ähnlich, aber Verhältnis von GDG & Steuerungsgruppe variiert

Canada [18] and Lebanon [39, 40] did not separate the GDG from the steering committee. The Canadian steering committee of ten members (government, pricing board, academia[7]) served as the core writing group and oversight body. This was complemented by a large Canadian Collaborative Workshop on Pharmacoeconomics with 73 participants, including major Canadian stakeholders and international experts, which provided input but did not serve as a formal steering group. Lebanon [39, 40] assembled a five-person GDG comprising a

CA: integriertes Modell mit Steuerungsgruppe als GDG

Libanon: fünfköpfige GDG mit Knowledge-Translation-Spezialist & keine Steuerungsgruppe

[7] The national steering committee comprises of people from the National Pharmaceutical Strategy Section of Health and Welfare Canada, the Provincial and Territorial Ministries of Health, the Patented Medicine Prices Review Board (the board that oversees pricing for all patented drugs in Canada), and academia.

pharmacist, a Ministry of Public Health (MoPH) representative, national/international HTA experts, including health economists and an expert in research synthesis, and a knowledge translation specialist. The involvement of a knowledge translation specialist is noteworthy and not explicitly mentioned in the other country guidelines, suggesting attention to dissemination from the outset. The absence of a steering group made the GDG both developer and de facto steering body. In this integrated model, the same individuals develop the guideline and oversee its quality.

Südkorea: HIRA-Mitarbeiter:innen als primäre GDG mit akademischen Expert:innen & externen Reviewer:innen

South Korea [20, 21, 38] relied on in-house HIRA staff as the primary GDG, supplemented by academic health experts and pharmacoeconomists, with additional review by epidemiology and statistic experts. The steering function was distributed. HIRA staff led development, the academic health experts and pharmacoeconomists steered methodology, and external reviewers provided quality assurance. No separate named steering group existed outside these bodies.

JP: GDG forscht, Steuerungsgruppe entscheidet – in bestehendes Erstattungsgremium integriert

Japan [22] has the clearest separation. The GDG was a research team of four health economists funded by the Ministry of Health, Labour and Welfare (MHLW). The steering group was the Subcommittee on Cost-Effectiveness Evaluation of Chuikyo (Central Social Insurance Medical Council), comprising 16 voting members (six payers, six healthcare professionals, four public interest representatives) plus four non-voting industry representatives and three non-voting health economists. The GDG (authors) were embedded within the steering group as non-voting technical experts, while the steering group held decision-making authority. This embeds guideline development within the existing reimbursement decision-making body.

CN: Expert:innengremium mit Politikvertreter:innen als de facto Steuerungsgruppe

China [2] described researchers and scholars in pharmacoeconomics as the GDG supported by an expert committee that included policymakers from four national regulatory agencies[8]. This expert committee functioned de facto as a steering body, but its relationship to the GDG was not specified. China, therefore, employed an overlapping model in which GDG members and expert committee members may have been distinct or shared.

LMICs: unvollständige Berichterstattung zu Gremien & selten dedizierte Gesundheitsökonom:innen/ HTA-Expert:innen

The LMIC systematic review [37] noted that most countries did not systematically report on steering groups and GDG composition. Where reported, teams included academia, public/private sector workers, and program managers, but rarely dedicated health economists or HTA methodologists were reported.

3.3.2 Institutional Governance and Endorsement

Institutional Governance

Modelle: zentralstaatlich (KR), föderal (CA), kostenträgereingebettet (JP), berufsverbandgeführt (CN) ministeriell (LB)

In all five countries, some form of government-linked body (ministry, agency, or reimbursement committee) holds ultimate decision-making authority. However, the legal basis for guidelines varies from legally integrated or centralised government-led (South Korea) to federal advisory (Canada) to payer-embedded (e.g., Japan) to ministry-direct (e.g., Lebanon) to professional association-led (e.g. China).

[8] The expert committee consists of policy makers from medical regulatory agencies (National Development and Reform Commission, National Health Commission, National Medical Product Administration, National Health Security Administration), pharmacoeconomic experts and pharmacy administration (universities worldwide), experts from medical research institutes.

CA: geteilte Zuständigkeit zwischen Bund (Entwicklung, Updates) & Provinzen (Implementierung)

In Canada [18], the guideline is governed federally with shared accountability. After the HEEG was developed, CDA-AMC was given formal responsibility for managing, reviewing, updating, issuing, and monitoring the use and impact. Implementation required endorsement by Deputy Ministers of Health from individual provinces, meaning that the federal-level GDG and steering committee have no direct enforcement power over provincial drug plans. Accountability is split between federal (development, updating) and provincial (implementation).

KR: verteilte, gesetzlich spezifizierte Verantwortlichkeiten

In South Korea [20, 21, 38], no single body holds all authority over the process, but the DIDS process is legally codified with clear sequential handovers. The Ministry of Health and Welfare (MOHW) provided the legal framework. HIRA (in-house GDG) initially developed the guidelines and has been interacting with the Drug Reimbursement Evaluation Committee (DREC; decision-makers) through formal submission and review. DREC interacts with the National Health Insurance Corporation (NHIC) through listing recommendations, and the Benefit Coordination Committee (BCC) operates in parallel for essential drugs. Accountability is distributed but legally specified. The Drug Reimbursement Evaluation Committee, composed of 18 members, decides on listing recommendations. The NHIC negotiates prices. The BCC manages compulsory listing of essential drugs.

JP: Verantwortung bei Chuikyo & MHLW für Finanzierung und Aufsicht

Guideline authority in Japan [22] is payer-embedded within the existing reimbursement decision-making structure and with ministerial oversight. The GDG submitted the draft guideline to Chuikyo and its sub-committee, which addressed content-related questions and approved it. The MHLW provides funding and oversight. Chuikyo, with its subcommittee, is the central governance body and steering group. Accountability rests with Chuikyo and MHLW.

CN: berufsverbandgeführt mit Politikbeteiligung

China [2] has a fragmented governance of the DIDS process. There is no single accountable government body with enforcement authority. The Pharmacoeconomics Technical Committee of the Chinese Pharmaceutical Association (PTCCPA), a professional association, not a government body, started and directs the guideline process. The expert committee included policymakers from four regulatory agencies (the National Development and Reform Commission, the National Health Commission, the National Medical Products Administration, and the National Health Security Administration) as well as academics.

LB: ministeriell geführt ohne HTA-Agentur & ohne formales Mandat

In Lebanon [39, 40], guideline governance is ministry-directed without a dedicated HTA unit. International experts from Maastricht University were consulted. The MoPH initially endorsed adoption. There was no separate steering committee, no legal mandate for HTA, and no permanent HTA agency.

LMICs: ministerielle Führung dominiert, jedoch schwache Rechtsgrundlagen

The systematic review [37] reported that governance of the DIDS process is ministry-led in 10 of 14 countries (the Ministry of Health is responsible). In four countries (China, Colombia, Mexico, Thailand), non-profit independent institutes took governance responsibility. The review noted that the legal basis for guidelines is often absent or weak, and interaction between GDG, steering groups, and policy-makers is rarely described. One-third of guidelines lack any documented multistakeholder governance mechanism.

Endorsement

Formale Zustimmung (Endorsement) variiert von obligatorisch bis symbolisch

Endorsement refers to formal approval by a recognised authority, often a necessary condition for implementation. Across the five countries, endorsement is always granted by a government-linked body (ministry, reimbursement committee, or HTA agency). However, whether endorsement makes the guideline mandatory, necessary, or symbolic differs. [2, 18, 20-22, 37-40].

CA: zweistufiges Endorsement

Canada [18] required a two-stage endorsement. First by CDA-AMC and PMAC (June 1994), then by 13 federal, provincial, and territorial Deputy Ministers of Health (December 1994). Endorsement is explicitly a necessary condition for provincial implementation.

KR & JP: Endorsement durch Erstattungsausschuss

In South Korea and Japan, endorsement by the reimbursement committee was necessary. In South Korea [20, 21, 38], DREC endorsed the guideline. In Japan [22], the Chuikyo general assembly approved the guideline in February 2016. In both countries, endorsement is directly linked to listing and pricing decisions.

CN: kein formales Endorsement (aber Anwendung in Preisverhandlungen)

In China [2], the guideline lacks formal government endorsement (published by PTCCPA, a professional association) but has been followed by negotiation experts in NRDL price negotiations.

LB: MoPH-Endorsement ohne Durchsetzung

Lebanon [39, 40] reports MoPH endorsement, but without specified legal consequences or enforcement.

LMICs: Endorsement überwiegend durch Gesundheitsministerium, jedoch Verbindlichkeit unklar

The LMIC review [37] found that endorsement was most commonly by the Ministry of Health (10 of 14 countries), but did not clarify whether the guideline was mandatory, advisory, or symbolic.

3.3.3 Stakeholder Groups Involved

universelle Stakeholder (Industrie, "Academia", Kliniker:innen) mit variabler Einbindung

Stakeholder groups were engaged across all five countries, but the breadth, inclusiveness, and role in decision-making varied. Across the five countries, industry, academia and researchers, and clinicians are the universal stakeholder groups. Beyond this common core, variation exists. Furthermore, selection criteria were only reported for Lebanon [39, 40]. The selection aimed to ensure diverse representation of those affected by or involved in the guideline's implementation and was based on the stakeholders' relevance to the guideline scope and their ability to represent key perspectives.

Auswahlkriterien nur für LB berichtet

LMICs: Stakeholder-Einbindung unzureichend dokumentiert

The systematic review of LMICs [37] found that stakeholder engagement was poorly disclosed. One-third of guidelines lacked any multisectoral or multidisciplinary engagement. The review noted poor reporting on the sector, interests, and discipline of stakeholders, making it impossible to assess representativeness.

Clinicians and Healthcare Professionals

Kliniker:innnen & Gesundheitsfachkräfte in allen 5 Ländern einbezogen

Clinicians and healthcare professionals were stakeholders in all countries. Canada [18] included physicians, pharmacists, and the Canadian Medical Association and Canadian Society of Hospital Pharmacists. South Korea [20, 21, 38] included physicians. Japan [22] included healthcare professionals (medical associations). Lebanon [39, 40] engaged physicians (oncologist, nephrologist), pharmacists, and nurses. China [2] did not explicitly list clinicians as separate stakeholders but mentioned the inclusion of professional association experts.

Patients and the Public

Patient:innen & Öffentlichkeit in 3 Ländern einbezogen

Patients and the public were included as stakeholders in Canada [18] (patients), South Korea [20, 21, 38] (patient groups and the Korean public as an endorsing body), and Lebanon [39, 40] (patient advocacy for cancer support). In South Korea, the public's role was not deliberative but rather as an endorsing body whose tax contributions funded the system. Lebanon engaged 16 specific stakeholders, including patient advocacy. In China [2], neither patients nor the public were explicitly mentioned.

Decision-makers and Payers

Entscheidungs- & Kostenträger in allen 5 Ländern vertreten

Decision-makers and payers were represented across all countries. Canada [18] included decision-makers for provincial/territorial drug plans, private drug insurance plans, and hospital formulary managers. South Korea [20, 21, 38] included HIRA, DREC, NHIC, BCC, and MOHW. Japan [22] included healthcare payers (insurers). Lebanon [39, 40] provided the most detailed payer representation, including MoPH, NSSF, Civil Servants Cooperative, and Military Funds. China [2] did not explicitly name payers as separate stakeholders.

Academia and Researchers[9]

universelle Einbindung von Akademiker:innen und Forscher:innen

Academia and researchers were stakeholders in all countries. Canada [18] engaged academic experts (domestic and international). South Korea [20, 21, 38] included academics and epidemiology/statistics experts. Japan [22] included academics and health economists. Lebanon [39, 40] included academia, including professionals from the ISPOR Lebanon chapter, pharmacists and bioethicists, the latter being unique to Lebanon. China [2] included scholars, researchers from medical institutions and consulting companies, and HTA/pharmacoeconomics experts from professional associations.

Industry

Industrie in allen 5 Ländern vertreten, mit differenzierter Einbindung

Industry was a stakeholder in all five countries. Canada [18] distinguished between brand drug manufacturers (PMAC) and generic manufacturers, also including the biotechnology industry. South Korea [20, 21, 38] included the pharmaceutical industry in the review process of the guideline draft. Japan [22] included pharmaceutical and medical device manufacturers, with a distinctive feature that manufacturers reviewed the draft guideline and provided comments before finalisation. China [2] included pharmaceutical companies and employees responsible for market access.

International Experts

Internationale Expertise in 3 Ländern

International experts were engaged in Canada [18] (academic experts from abroad), China [2] (worldwide universities), and Lebanon [39, 40] (Maastricht University). South Korea [20, 21, 38] and Japan [22] did not report international expert engagement.

[9] Academia is where scholarly work is institutionally situated. A researcher is someone who performs it. All academics who conduct scholarly work are researchers, but not all researchers are in academia. A researcher systematically investigates questions to generate knowledge. It is a title that can apply inside academia, private industry, government agencies, or non-profits

3.3.4 Target Groups

4 Zielgruppen (Entscheidungsträger, Industrie, Forscher:innen, Patient:innen) mit Variationen in Benennung & Gewichtung, besonders bei Patient:innen

Across the five countries, the target groups of HEEGs fall into four functional categories:

- Decision-makers and payers who use the guideline to inform reimbursement, pricing, or formulary listing.
- Industry submitters (pharmaceutical and medical device companies) who use the guideline to prepare economic evidence for submissions.
- Researchers and academics who conduct or appraise evaluations.
- Patients affected by reimbursement decisions based on HEE, following the guidelines.

However, the explicit articulation of these groups, their hierarchy, and the inclusion of additional groups vary, especially the patient group [2, 18, 20-22, 37-40].

LMICs: fehlende explizite Zielgruppenbenennung

The systematic review of LMICs [37] found that explicit articulation of target groups was often missing. Where reported, researchers and policymakers or reimbursement decision-makers were implied, but the lack of clarity about who should use the guideline and for which specific decisions were identified as a barrier to implementation.

Decision-Makers and Payers

primäre Zielgruppen: Kostenträger (dezentral/zentral) & Erstattungsausschüsse in allen Ländern

In all five countries, government payers or reimbursement committees are identified as primary target groups, reflecting the purpose of HEEGs. In decentralised systems, such as Canada [18], the primary targets are multiple bodies rather than a single national payer, e.g., provincial and territorial drug plans, private insurers, and hospital formularies. In centralised systems with social insurance, such as South Korea [20, 21, 38] and Japan [22], the primary targets are the reimbursement committees (DREC in South Korea, Chuikyo and MHLW in Japan) and price negotiators (NHIC in South Korea). In China [2], the primary target is explicitly the National Healthcare Security Administration with its specific functions: National Reimbursement Drug List (NRDL) updates, drug price negotiation, and drug procurement.

LB: Zielgruppenbeschreibung breit aufgrund früher Institutionalisierungsphase

In Lebanon [39, 40], the primary targets are described more broadly as Lebanese policymakers and payers involved in decision-making and resource allocation, without naming specific committees reflecting an earlier stage of institutionalisation.

CA: Krankenhaus-Arzneimittelmanager als eigene Zielgruppe (föderales System)

A unique characteristic of Canada [18] is the inclusion of hospital formulary managers as a distinct target group, acknowledging that in a federal system, individual hospitals also make listing decisions.

Pharmaceutical and Medical Device Companies

Pharmaindustrie universelle Zielgruppe mit Einreichungsfunktion

Pharmaceutical companies appear as a target group in every single country [2, 18, 20-22, 37-40]. Their role is consistently described as submitters of economic evaluations for new drug listings, price negotiations, or reimbursement submissions. This universality reflects the fundamental regulatory function of HEEGs: to standardise the evidence that industry must generate. However, companies are almost always positioned as secondary to decision-makers. They are expected to follow the guidelines. The one exception is Japan [22], where manufacturers (pharmaceutical and medical device companies) are explicitly listed as target groups alongside MHLW and Chuikyo, but still in the context of submitting cost-effectiveness data.

Moreover, Canada [18] uniquely includes contracted research organisations as a target group, recognising that industry often outsources economic evaluations.

CA: Auftragsforscher:innen als zusätzliche Zielgruppe

Academia, Researchers and Clinicians

Researchers and academics are explicitly named as target groups in Canada [18] (academics, contract research organisations), China [2] (researchers conducting pharmacoeconomic evaluations), and Lebanon [39, 40] (researchers conducting health economic evaluations). In South Korea and Japan, researchers are implicit target groups: the guideline must be usable by those who conduct evaluations for industry submissions, but they are not listed separately.

Forscher:innen explizit in 3 Ländern, implizit in 2 Ländern als Zielgruppe

Canada [39, 40] also includes clinical guideline developers as a secondary target group. This indicates an explicit intention to link economic evidence with clinical practice guidelines and suggests that Canada's guideline was designed not only for reimbursement decisions but also to influence clinical behaviour.

CA: klinische Leitlinienentwickler:innen als sekundäre Zielgruppe

The LMIC systematic review [37] found that researchers were among the most commonly implied target groups, but explicit listing was inconsistent.

LMICs: Forscher:innen implizit, aber selten explizit aufgeführt

Patients

Lebanon [39, 40] is the only country that explicitly includes patients as a target group, described as guideline development and implementation should "optimise healthcare access". Whether this phrasing signals patient-centred policy objectives in the HEEG, remains unspecified. In the other countries, patients appear only as stakeholders consulted during development (Canada [18], South Korea [20, 21, 38]) or are not explicitly mentioned (China [2], Japan [22]).

LB: einziges Land mit Patient:innen als expliziter Zielgruppe, jedoch inhaltlich unbestimmt

3.3.5 Timing of Involvement

Across the five countries, a common pattern emerges regarding when different groups were involved in the guideline development process:

länderübergreifendes Muster beim zeitlichen Einbezug der Gruppen

GDG and steering groups were typically formed at the beginning of the process (Canada [18], China [2], Lebanon [39, 40]) or at least early in the development project (South Korea [20, 21, 38], Japan [22]). This reflects the need for a core team to lead drafting and oversight from the outset.

GDG & Steuerungsgruppe typischerweise zu Beginn gebildet

Stakeholder consultation generally occurred after an initial draft was prepared. In Canada, the workshop took place before the draft was finalised, but the formal draft circulation for comment occurred later. In South Korea [20, 21, 38], expert and industry review, as well as the open workshop, occurred after the first draft. In Japan, manufacturer review took place after the draft was submitted. In China [2] and Lebanon [39, 40], stakeholder feedback was sought after the draft was prepared.

Stakeholder-Einbindung meist nach Entwurfsfertigstellung

Public or open consultations (where they occurred) were typically single events at specific points in the process, rather than ongoing engagement. Canada's [18] workshop and South Korea's [20, 21, 38] open workshop are examples of this.

öffentliche Konsultationen punktuell, nicht als fortlaufender Prozess

Updates and revisions (where documented) involved re-engagement with stakeholders through surveys or advisory meetings, as seen in South Korea [20, 21, 38].

Updates mit erneuter Stakeholder-Beteiligung

Endorsement occurred at the end of the process, after all consultations and revisions were completed.

Endorsement als letzter Schritt

Table 3-2: Timeline of the consultation of included groups

Country	Group	Who was involved	When were they involved
Canada [18]	GDG/Authors	Steering committee (10 members)	From the outset (start in 1993)
	Steering	Same as GDG (integrated model)	Throughout
	Stakeholders	73 workshop participants; draft commenters	June 1993; February 1994
South Korea [20, 21, 38]	GDG/Authors	HIRA in-house staff	From the outset (start in 2003)
		Academic advisory committee	After first draft
	Steering	Distributed (HIRA, advisory committee, external reviewers)	At various points
	Stakeholders	■ Expert/industry reviewers ■ Open workshop participants ■ Survey respondents	■ After first draft ■ June 2005 ■ During updates
Japan [22]	GDG/Authors	Research team (4 health economists)	From the outset (start in 2012)
	Steering	Chuikyo Subcommittee (16 voting + 7 non-voting)	Throughout deliberation (2012-2016)
	Stakeholders	Manufacturers	After draft submission
China [2]	GDG/Authors	Researchers/scholars	From the outset (no specific date reported)
	Steering	Expert committee (de facto)	From the outset
	Stakeholders	Invited stakeholders	After draft prepared
Lebanon [39, 40]	GDG/Authors	Pharmacist, MoPH, HTA experts, KT expert	From the outset (no specific date reported)
	Steering	None separate	Not reported
	Stakeholders	16-stakeholder panel	After draft developed
		Deliberative process participants	After draft developed

Abbreviations: GDG … Guideline development group, HIRA … Health Insurance Review and Assessment Service, HTA … Health Technology Assessment, MoPH … Ministry of Pulic Health

3.4 Sources and Methodological Frameworks Used

3.4.1 Sources

Quellen: bestehende ges.ök. Leitlinien, Fachliteratur, Stakeholder-Input, Reviews von ges.ök. Leitlinien, technische Dokumente

länderübergreifendes Lernen universell

The sources used to inform guideline development include previous guidelines (domestic and international), academic literature, stakeholder input, systematic reviews, and technical documents. Across the five countries and the LMIC systematic review, a clear pattern emerges. International guidelines (particularly from Australia, Canada, and the UK, as well as the ISPOR guideline overview) serve as a common reference point [2, 18, 20-22, 37-40]. Table 3-3 provides an overview of the sources used to develop the national HEEG.

Canada [18] referenced Australian guidelines (1990, 1992, 1995) and earlier methodological works (Drummond, et al. [1987], Detsky and Naglie [1990]). South Korea [20, 21, 38] conducted a review of international guidelines and academic journals. Japan [22] compared international guidelines and reviewed previously proposed Japanese academic guidelines. China [2] explicitly used the ISPOR guideline overview and the latest pharmacoeconomic research. Lebanon [39, 40] drew upon two systematic reviews ([19] and [37]), the ISPOR key features, the WHO handbook, and the Appraisal of Guidelines for Research and Evaluation – Health Systems (AGREE-HS) tool. Thus, cross-country learning is a universal feature.

Despite the commonalities in sources, the depth and transparency of source documentation vary [2, 18, 20-22, 37-40]:

Tiefe &Transparenz der Quellen variieren

- Canada [18] incorporated input from the 73-participant workshop, but this was during initial development rather than as a systematic source for updates. However, Canada [18] did not explicitly report a systematic search strategy; references included proceedings from the Collaborative Workshop (Schubert 1993).

CA: Workshop-Input von 73 Teilnehmern in der Initialphase

- For example, South Korea [20, 21, 38] conducted an open workshop (June 2005) to gather public comments during initial development. For updates (2011 and 2022), the GDG conducted surveys of pharmaceutical companies and decision-makers regarding existing guidelines. This makes South Korea the only country in which user feedback informed guideline revisions.

KR: Nutzer:innen-Feedback durch Workshops & Befragungen bei Entwicklung & Updates

- Japan [22] conducted original systematic reviews using PubMed and the Japanese Ichushi database, as well as reviewing technical documents from HTA agencies.

JP: Systematische Reviews & Ichushi-Datenbank

- China [2] relied on comparison of international guidelines using the ISPOR guideline overview and the latest pharmacoeconomic research but did not report conducting de novo systematic reviews.

CN: internationaler Leitlinienvergleich ohne

- Lebanon [39, 40] conducted two systematic reviews (one on HEEGs in LMICs [19], one on development processes of HEEGs in LMICs [37]), representing the most systematic and evidence-grounded approach among the five countries. The review on the development processes [37] employed a comprehensive search strategy, including MEDLINE, PubMed, EconLit, Embase, the Cochrane Library, grey literature (WHO, ISPOR, iDSI, GEAR, country HTA agencies), and backward citation tracking up to March 2021.

LB: Systematische Reviews zu HEEGs in LMICs & zu Entwicklungsprozessen

Table 3-3: Sources used to develop the national HEEG

Country	International guidelines	Academic literature	Stakeholder/ workshop input	Systematic reviews	Unique source
Canada [18]	Yes	Yes	Yes (73-participant workshop)	Not explicitly	Workshop proceedings
South Korea [20, 21, 38]	Yes	Yes	Yes (Open workshop, surveys for updates)	Not explicitly	Surveys of companies and decision-makers
Japan [22]	Yes	Yes	Not reported	Yes (original SRs)	Japanese database (Ichushi)
China [2]	Yes	Yes	Not reported	Not reported	ISPOR comparative tool
Lebanon [39, 40]	Yes	Yes	Not reported	Yes (two SRs)	ISPOR material

Abbreviations: ISPOR … The Professional Society for Health Economics and Outcomes Research, SR … Systematic review

3.4.2 Methodological Frameworks

LB einziges Land mit expliziter Nutzung formaler Frameworks

Frameworks refer to explicit methodological or process frameworks used to guide guideline development, such as the WHO handbook for HSG [13] or the AGREE-HS tool for reporting quality [11]. Across the five countries, only Lebanon explicitly reported using a formal framework (WHO process and AGREE-HS).

WHO-Handbuch

The WHO process for HSG development includes steps such as

- forming a guideline development group,
- defining rationale and scope,
- conducting evidence searches,
- assessing evidence,
- and translating findings into recommendations via a deliberative process.

AGREE-HS

Additionally, Lebanon used AGREE-HS to guide reporting quality. This represents a significant methodological advance over the other four countries and reflects the global maturation of guideline development standards.

4 Länder mit narrativer Prozessbeschreibung

gemeinsamen Elemente: Evidenzrecherche, Entwurf, Expert:innenreview & Endorsement

As stated, Canada, South Korea, Japan, and China did not report any explicit framework or checklist. Hence, the absence of explicit frameworks is the common pattern among the majority of included countries. Canada [18], South Korea [20, 21, 38], Japan (2016-2017) [22], and China [2] all described their development processes in narrative terms (consultation, workshops, drafting, review, endorsement). Although the four countries did not name a framework, their described processes contain common elements that align with later formal frameworks: 1) initial evidence or literature review, 2) drafting by a core group 3) review by experts or stakeholders, and 4) endorsement or approval by a governing body (see Subsection 4.2 “Overview of Process Phases” for the detailed overview of the processes).

LMICs-Review nutzte AGREE-HS zur Qualitätsbewertung der Leitlinien

Similar to Lebanon, the LMIC systematic review [37] also used the AGREE-HS for quality assessment of the included guidelines, assessing domains such as participants and methods, indicating growing recognition of such tools. The review also mentioned the WHO handbook for HSG as a reference standard. The review found that most LMIC guidelines did not report using such frameworks themselves, which is consistent with the pattern observed in Canada, South Korea, Japan, and China [2, 18, 20-22, 37-40].

4 Development, Implementation, Dissemination, and Sustainment Process

4.1 General Information on the Process

Synthese der Ergebnisse aus Abschnitt 3

The following section synthesises the descriptive overview from Section 3, "Overview of International Examples", into a chronological DDIS process based on the reported steps for each country. This resulted in eight phases. While some repetition is unavoidable, the focus here is on the common pattern rather than country-specific detail.

mehrstufiger sequenzieller Prozess mit länderspezifischen Variationen

The DIDS process steps describe the sequence of activities undertaken to develop, update, and endorse HEEGs. All five countries followed a multi-step sequential process with variation in depth and the number of steps [2, 18, 20-22, 37-40]. Table A-1 in the Appendix provides the detailed list of each single step in each country.

- **CA: zehnstufiger Prozess**
  Canada [18] followed a highly inclusive process with ten steps, including a precursor (Ontario draft guidelines), a large collaborative workshop (73 participants), and a distinctive two-stage endorsement (CDA-AMC and industry, followed by 13 Deputy Ministers of Health).
- **KR: iterativer Prozess mit zwei Updates & Feedback-Mechanismen**
  South Korea [20, 21, 38] reported the most complex and iterative process, with two formal update cycles (2011, 2021), incorporating empirical feedback mechanisms such as surveys of pharmaceutical companies and decision-makers, working-level meetings with industry, and review of past submissions.
- **JP: vierjähriger konsensorientierter Prozess mit 2 Zwischenberichten**
  Japan [22] employed a consensus-driven process embedded within the payer committee (Chuikyo) over four years, featuring two interim reports (2013, 2015) with steps such as consensus on four key methodological points (outcome, costs, comparator, data sources) or a formal manufacturer review of the draft guideline.
- **CN: expertengetriebener, schlanker Prozess**
  China [2] followed a leaner, expert-committee-driven process with monthly progress meetings but no public workshop or open consultation.
- **LB: Surveys, Interviews & Konsens-Workshop**
  Lebanon [39, 40] adopted the WHO health system guideline framework, including a formal deliberative process (surveys, interviews, and a consensus workshop) and transparently noted the pending public consultation.

LMICs: Workshops (9 Länder), internationale Expertise (5) und Organisationen (4), 3 Länder ohne Prozessdokumentation

The LMIC systematic review [37] found that among included countries, workshops or consultation meetings were reported in nine countries, support from international experts in five countries, and support from international organisations in four countries, while three countries reported no process steps at all.

4.2 Overview of Process Phases

DDIS-Prozess mit 8 Phasen

Although the number of steps, the inclusion of public or industry review, the use of interim reports, and the presence of formal update mechanisms vary across countries in detail, timing, and emphasis, a core common eight-phase DIDS process becomes apparent when comparing the five countries. [2, 18, 20-22, 37-40]. Figure 4-1 gives an overview of the conceptualised DIDS process with examples based on the country steps and activities.

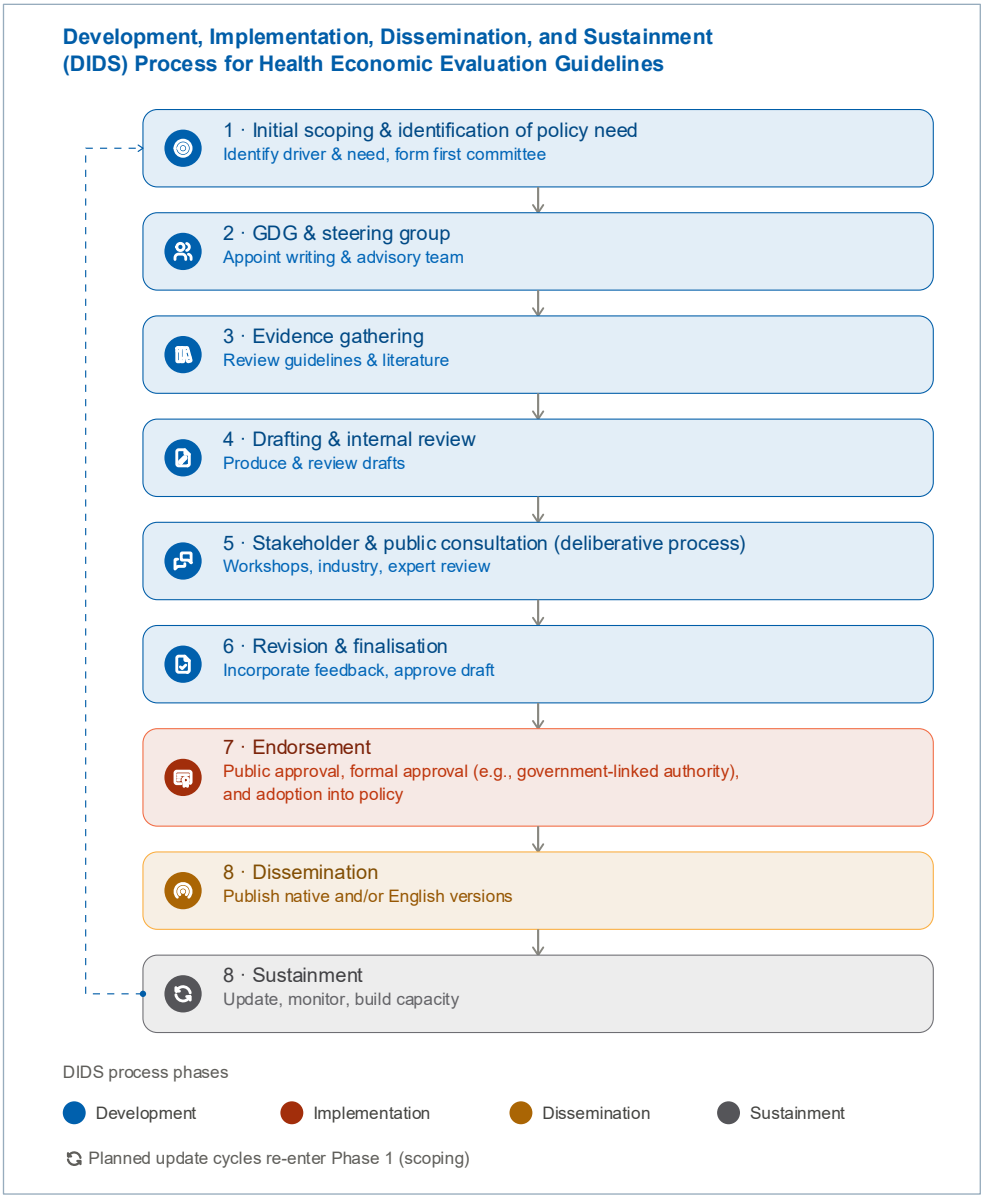


Figure 4-1: DIDS process phases, own conception generated with Claude Opus 4.8

The following subsections present each of the eight phases of the common core process that emerges from the synthesis of all five countries and the LMIC systematic review, with the specific activities assigned to the respective phase:

Phase 1: Initial Scoping and Identification of a Policy Need

Phase 1: Festlegung von Rationale, Bedarf, Umfang & Zielen

The phase in which the rationale for developing a guideline is established, the policy or reimbursement need is articulated, and the scope, objectives, and key methodological questions are defined.

- Identification of a policy need or regulatory driver, e.g., cost-effectiveness as a new reimbursement criterion (e.g., South Korea [20, 21, 38], Lebanon [39, 40]), drug listing requirements (e.g., Canada [18], Japan [22]), or pricing reforms (e.g., Canada [18], South Korea [20, 21, 38], Japan [22]).
- Formation of a steering committee or expert committee (all countries in some form).
- Definition of guideline scope and rationale (e.g., Lebanon [39, 40]), and key methodological questions such as outcome, costs, comparator, and data sources (e.g., Japan [22]).

Phase 2: Formation of a Guideline Development and Steering Group[10]

Phase 2: Zusammenstellung einer GDG & Steuerungsgruppe

The phase in which a core writing team with relevant technical expertise is assembled, and an oversight or advisory body is established to guide and supervise the development process.

- Appointment of a core writing team (GDG) with (health economics) expertise (all countries).
- Establishment of a steering or advisory committee for oversight (e.g., Canada [18], South Korea [20, 21, 38], Japan [22], China [2]).
- Engagement of international experts where needed (e.g., Canada [18], China [2], Lebanon [39, 40]).

Phase 3: Evidence Gathering and Literature Review

Phase 3: Evidenzrecherche & Literatursynthese

The phase in which existing international guidelines, academic literature, and domestic experience are systematically identified, reviewed, and synthesised to inform the guideline content.

- Review of existing international guidelines (all countries in some form: systematic guideline overview, Ontario guideline, ISPOR guideline overview, LMICs review: six countries with review) and existing guidance (e.g., Lebanon [39, 40]: WHO handbook, AGREE-HS).
- Systematic or targeted literature searches in academic databases, grey literature, etc. (e.g., South Korea [20, 21, 38] for updates, Japan[22], Lebanon [39, 40]).
- Review of domestic experience, such as past submissions (e.g., South Korea [20, 21, 38]) or local data.
- Input from (international) experts (all countries in some form).

[10] **Canada**: 10-member steering committee + 73-participant workshop, **South Korea**: In-house HIRA staff + academic advisory committee, **Japan**: 4 health economist authors (GDG) + Chuikyo subcommittee (steering), **China**: Researchers and scholars (GDG) + expert committee (policymakers and academics), **Lebanon**: GDG (pharmacist, MoPH, HTA experts, KT expert); international experts from Maastricht University consulted.

Phase 4: Drafting and Internal Review

Phase 4: Entwurfserstellung mit interner Prüfung

The phase in which the GDG produces one or more written versions of the guideline, which are then reviewed internally by the steering or expert committee before external consultation.

- Production of one or more draft versions by the GDG, including generating research questions, first survey questions and discussion points per section (all five countries).
- Internal review by steering or advisory (expert) committee (e.g., Canada [18], South Korea [20, 21, 38], Japan [22], China [2]).
- Monthly or regular progress meetings (e.g., China [2]).

Phase 5: Stakeholder and Public Consultation

Phase 5: Externe Konsultation & Feedback-Einholung

The phase in which draft versions are circulated to external parties for input, using mechanisms such as workshops, surveys, or deliberative processes to gather feedback from those with an interest in the guideline.

- Circulation of draft for external comment (e.g., Canada [18], South Korea [20, 21, 38], Japan [22], Lebanon [39, 40]).
- Open workshops (e.g., Canada [18], South Korea [20, 21, 38], LMICs review [37]: nine countries) or public consultations (e.g., Lebanon [39, 40]).
- Industry (e.g., Japan [22], China [2]) and expert review (all countries).
- Surveys of decision-makers and submitters (Lebanon [39, 40]).

Phase 6: Revision and Finalisation

Phase 6: Einarbeitung des Feedbacks & finale Freigabe

The phase in which feedback received during consultation is considered and incorporated, revised drafts are produced, and final approval is obtained from the steering or governing body.

- Incorporation of feedback from consultation (all countries, e.g., revision after open workshop and reviews in Canada [18], South Korea [20, 21, 38], China [2], Lebanon [39, 40]).
- Production of revised draft(s), e.g., revision after the open workshop in Canada [18] and South Korea [20, 21, 38], two revised versions in Japan [22], and revision in Lebanon [39, 40] after the deliberative process.
- Final approval by steering or governing body (Canada [18], South Korea [20, 21, 38], Japan [22]).

Phase 7: Endorsement

Phase 7: Endorsement mit Autorisierung

The phase in which the finalised guideline receives formal approval from a government-linked authority, providing the mandate or authority for its use.

- Formal approval by a government-linked authority[11] in all countries, such as a ministry (deputy ministers of health in Canada [18], MoPH in Lebanon [39, 40], LMICs review: endorsement in 10 countries [37]), reimbursement committee (DREC in South Korea [20, 21, 38], Chuikyo

[11] No formal government endorsement in China but publication by PTCCPA and de facto endorsement through use in NRDL negotiations.

in Japan [22]), or HTA agency (CDA-AMC and PMAC in Canada [18], LMICs review [37]: endorsement by independent institutes in four countries).

- Public consultation before final publication (e.g., Lebanon [39, 40]).

Phase 8: Dissemination and Sustainment

Phase 8: Verbreitung & Erhaltung der Leitlinie

The phase in which the guideline is made accessible to target groups through appropriate channels (dissemination), and mechanisms are put in place to ensure its continued relevance through updates, monitoring, and capacity building (sustainment).

Dissemination

Dissemination: Publikation der ges.ök. Leitlinie

- Publication of the guideline in the native language through a recognised agency or ministry website, e.g., publication by CDA-AMC in Canada [18] or on the HIRA website (http://www.hira.or.kr/) in South Korea [20, 21, 38]. Lebanon [39, 40] will also provide a publication.
- Provision of the guideline in English to facilitate international comparison and learning (e.g., South Korea [20, 21, 38], Japan [22], China [2]).
- Specification of a required reporting format or structure for industry submissions (e.g., South Korea [20, 21, 38], Japan [22]).

Sustainment

Erhaltung: formale Zuständigkeiten klären

- Accumulation of domestic experience with the guideline and assignment of formal responsibility for updating and monitoring to a specific agency or body. For example, CDA-AMC was given the responsibility for managing, reviewing, updating, and monitoring use/impact in Canada [18].
- Review or re-evaluation of past submissions against the guidelines and user feedback, e.g., drugs not deemed cost-effective were eliminated or subjected to price cuts in South Korea [20, 21, 38].
- Making evaluations, review results or analysis outcomes publicly available for transparency (South Korea [20, 21, 38], Japan [22]).
- Formal revision project initiated by the responsible agency (e.g., South Korea [20, 21, 38]).
- Capacity building and data infrastructure development, e.g., development of QALYs and cost databases in Japan [22]; Canada [18] initiated a process for developing and maintaining standard costs (similar to the Australian Manual of Resource Items).
- Planned revision cycles or updated editions based on accumulated experience (e.g., in Canada [18], South Korea [20, 21, 38], China [2], and Lebanon [39, 40] recommended). Thereby, the authors recommended regular updates based on issues encountered and progress in research (e.g., ethics, real-world research).
- Collaboration with regional or international HTA networks, e.g., Networking with other Asian HTA agencies, was established in South Korea [20, 21, 38].
- Integration of the guideline into broader policy frameworks (e.g., universal health coverage in China [2]).
- Identification of barriers and facilitators for implementation (e.g., in Lebanon [39, 40] recommended).

Overall, Table 4-1 provides an overview of country alignments with the common process phases and the country-specific content and activities.

Übersicht über länderspezifische Inhalte & Aktivitäten pro Phase

Table 4-1: Country alignment with the common process and country-specific activities

Phase	Canada [18]	South Korea [20, 21, 38]	Japan [22]	China [2]	Lebanon [39, 40]	LMICs [37]
1. Initial scoping and identification of a policy need	✓ (Ontario draft)	✓ (2001 regulation)	✓ (Chuikyo discussions)	✓ (Expert committee)	✓ (Rationale, scope)	~ (Not consistently)
2. Formation of a GDG and Steering Group	✓ (10 + 73 persons)	✓ (HIRA + advisory)	✓ (4 authors + Chuikyo)	✓ (GDG + expert committee)	✓ (GDG + MoPH)	~ (Variable)
3. Evidence Gathering and Literature Review	✓ (Literature)	✓ (Literature, surveys)	✓ (SRs, databases)	✓ (ISPOR tool)	✓ (2 SRs)	✓ (6 countries)
4. Drafting and Internal Review	✓ (Multiple drafts)	✓ (First draft)	✓ (Research questions)	✓ (Monthly meetings)	✓ (Draft)	~ (Not detailed)
5. Stakeholder and Public Consultation	✓ (Workshop, circulation)	✓ (Open workshop, surveys)	✓ (Manufacturer review)	~ (Invited stakeholders only)	✓ (16 stakeholders, deliberative)	✓ (9 countries)
6. Revision and Finalisation	✓ (Feedback incorporated)	✓ (Revision)	✓ (Revised versions)	✓ (Feedback incorporated)	✓ (Draft after deliberation)	~ (Not detailed)
7. Endorsement	✓ (Two-stage)	✓ (DREC)	✓ (Chuikyo)	~ (De facto only)	✓ (MoPH)	✓ (MoH in 10 countries)
8. Dissemination and Sustainment	✓ (Built into CDA-AMC mandate)	✓ (2011, 2021 explicit)	✓ Trial implementation	✓ (2011 → 2020)	X (Not yet demonstrated)	~ (Rarely conducted)

✓	Yes
~	Partially/Not consistenly/Variable/Not detailed/Rarely conducted
X	No

Abbreviations: CDA-AMC … Canada's Drug Agency, GDG … Guideline development group, LMIC … Low and middle-income countries, MoH … Ministry of Health, MoPH … Ministry of public health, SR … Systematic review

5 Barriers and Facilitators of the Process

Barrieren & Förderfaktoren auf mehreren Ebenen (Expertise, Governance, Daten, politischer Wille)

The DIDS processes of HEEGs are influenced by a range of barriers (factors that impede progress) and facilitators (factors that enable or accelerate progress). These operate at multiple levels: technical expertise, governance and stakeholder engagement, data availability, political will and further factors. Across the five countries and the LMIC systematic review, a consistent set of barriers and facilitators emerges, though they vary by context [2, 18, 20-22, 37-40]. Table 5-1 gives an overview of all barriers and facilitators across countries.

5.1 Barriers

Expertise

leichte Expertise-Lücke & fehlende multidisziplinäre Teams in LMICs

Human expertise and resource barriers are equally universal. All countries except Canada (which noted only limited experience with guidelines at the time) reported shortages of health economists or pharmacoeconomic experts [2, 20-22, 38-40]. Japan [22] highlighted that most subcommittee members were not experts in economic evaluation, reflecting a national shortage of experts, and noted limited experience in industry. Lebanon [39, 40] reported varying levels of health economics expertise among stakeholders. In addition, South Korea [20, 21, 38] and China [2] cited limited research experience and few university training programmes. The LMIC systematic review identified a lack of multidisciplinary teams as a recurring barrier [37].

Institutional Governance and Stakeholder Groups

Governance-Barrieren: fehlende Mandatierung, fragmentierte Strukturen, unklare Auslegung

Governance and political barriers were prominent in several countries. Governance barriers include the voluntary or non-mandatory status of guidelines (e.g., China [2]), absence of a national agency to review quality or enforce adherence [2] and many LMICs [37]) fragmented healthcare systems (e.g., Canada [18], Lebanon [39, 40]), and ambiguities in guideline interpretation by stakeholders requiring more specific guidance (e.g., South Korea [20, 21, 38]). China [2] explicitly noted that pharmacoeconomic evaluation is voluntary, not mandatory.

Stakeholder-Barrieren: Widerstand gegen QALY (JP), Fokus auf klinische Indikatoren (CN), mangelndes Engagement (LB), potenzielle Industrie-Einflussnahme (LMICs)

Stakeholder barriers were also prominent in several countries. For example, Japan [22] reported opposition from medical associations and industry to mandatory QALY use, as well as competing interests among committee members and delays in reaching consensus. China [2] noted that policy-makers and clinicians are more inclined to clinical indicators than quality of life measures. Lebanon [39, 40] described stakeholder preoccupation with procuring resources and providing access, difficulty convincing stakeholders to engage, and instances in which consensus was not reached for all discrepancies (e.g., requiring experts' consultation to override the deliberative process). The LMIC review [37] mentioned potential industry influence in some countries during consultation.

Sources and Methodological Frameworks

Datenbarrieren: fehlende Kostendaten, Utility-Werte, Schwellenwerte, Referenzkosten (Unit Cost)

Data (sources) and methodological barriers are reported in every country. These include lack of local cost data or utility value sets (e.g., South Korea [20, 21, 38], Japan [22], China [2], Lebanon [39, 40]), absence of official willingness-to-pay or incremental cost-effectiveness ratio thresholds (e.g., South Korea [20, 21, 38], China [2]), and lack of standardised reference costs or costing manuals (e.g., Canada [18], Lebanon [39, 40]). Canada [18] specifically noted interprovincial variations in health service costs as a barrier, while Lebanon [39, 40] faced unique challenges, including the absence of Lebanese QALY/EQ-5D-5L value sets, no reference cost or costing manuals, and the need for a Lebanese-specific discount rate due to currency hyperinflation and economic crisis. Similarly, China [2] reported limited QALY value sets and noted that cost-utility analysis is rarely performed.

methodische Barrieren: Auslegungsunsicherheite, unzureichende Comparator-Vorgaben, keine Standards für indirekte Vergleiche

Methodological barriers were specifically noted by South Korea [20, 21, 38], which reported a gap between the guideline's societal perspective and applicant submissions (which uses direct medical costs only instead of the recommended indirect costs), as well as ambiguities in interpretation of the first version, controversy over comparator selection (not prescriptive enough), no standard for indirect comparison methods, and the need to address evolution of methodologies since previous versions.

DIDS Process

LB: virtuelle Formate beeinträchtigten deliberativen Prozess

Lebanon reported logistical barriers, including a virtual workshop due to COVID-19, affecting the deliberative process. The LMIC review [37] noted that no standardised framework was followed and that development steps were incomplete.

5.2 Facilitators

Expertise

Länder bauten auf nationale Erfahrungen auf

LB: dedizierter Projektkoordinator

Domestic experience and learning accumulated over time across countries [2, 18, 20-22, 37-40]. South Korea [20, 21, 38] built on accumulated domestic experience with previous pharmacoeconomic submissions. China [2] experienced rapid development and recognition of pharmacoeconomics in the past decade, a growing number of professional workshops, and increasing funding from the National Social Science Fund, National Nature Science Foundation, professional associations, and pharmaceutical companies. Lebanon [39, 40] also benefited from a dedicated project coordinator.

Institutional Governance and Stakeholder Groups

politische Unterstützung & Reformen als fördernde Faktoren in CA, KR & CN

Canada [18] secured endorsement by deputy ministers, and CDA-AMC was given responsibility for maintenance and updates. Furthermore, the guidelines were designed as an integral part of decision-making, not as a free-standing academic exercise. Endorsement by senior civil servants or ministries (Lebanese MoPH) was also present in Lebanon [39, 40] and countries included in the LMIC review [37]. The LMIC review noted that ministry involvement may ensure implementability [37]. South Korea [20, 21, 38] demonstrated a strong

political will to control drug expenditures, driven by pressure from National Health Insurance deficits. Public support for listing only clinically and economically valuable drugs was also noted. China [2] benefited from healthcare reform (2009 onwards), the 13th Five-Year Plan emphasising pharmacoeconomic evaluation for essential drugs and price negotiations, NRDL adjustments (2017, 2019) using pharmacoeconomic principles, the first formal submission window for pharmacoeconomic reports before drug-price negotiation (2019), and a pilot programme for centralised drug procurement in 11 cities (2019).

Stakeholder-Einbindung als durchgängiger Förderfaktor in allen 5 Ländern

Stakeholder facilitators are the most consistently reported across all five countries:

- Canada [18] engaged 73 participants in a broad multi-stakeholder workshop, achieved a high degree of consensus, and circulated drafts widely for feedback.
- South Korea [20, 21, 38] held multiple meetings to reach consensus, conducted stakeholder surveys, and introduced a prior-consultation system.
- Japan [22] benefited from a long deliberation process (4 years), allowing consensus building, gradual understanding of economic evaluation among members, interim reports, and review by manufacturers before finalisation.
- Lebanon [39, 40] reported strong stakeholder interest, an evidence-based deliberative process involving key stakeholders, representation of the target audience in the deliberative process, and support from the Lebanese MoPH.

The LMIC review [37] noted workshops and review of existing guidelines as facilitators.

Sources and Methodological Frameworks

Bezugnahme auf internationale Leitlinien als Förderfaktor

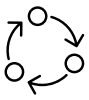
Facilitators related to sources and methodological frameworks include reference to and comparison of international guidelines (e.g., Japan [22], South Korea [20, 21, 38], LMICs [37]), use of WHO and AGREE-HS best practices (e.g., Lebanon [39, 40]), and international support from organisations such as WHO, PAHO, iDSI, NICE, and HiTAP (LMICs [37]). Lebanon [39, 40] also engaged international experts from the Maastricht University.

DIDS Process

Transparenz durch Reviewer-Checklisten, COI-Richtlinien & Dokumentation der Entscheidung

Transparency facilitators as part of the DIDS process were explicitly noted in South Korea [20, 21, 38] (reviewer checklists, conflict-of-interest guidelines, posting decisions on HIRA website) and Lebanon [39, 40] (transparent reporting of GDG composition, evidence-based deliberative process involving surveys, interviews, and a consensus workshop).

Table 5-1: Overview of barriers and facilitators across countries

Category	Barriers	Facilitators
Expertise 	■ Shortage of health economic expertise (KR, JP, CN, LB, LMICs) ■ Limited (research) experience (CA, KR, JP, CN) ■ Varying expertise levels (LB) ■ Lack of multidisciplinary teams (LMICs)	■ Accumulated domestic experience (KR) ■ Professional workshops (CN) ■ International experts (LB, LMICs) ■ Research funding (CN) ■ Dedicated project coordinator (LB)
Institutional Governance and Stakeholder Groups 	■ Voluntary/non-mandatory (CN) ■ Fragmented systems (CA, LB) ■ No national HTA agency (CN, LMICs) ■ Industry/medical opposition (JP) ■ Competing interests (JP) and potential industry influence (LMICs) ■ Variable expertise within stakeholder groups (LB) ■ Potential industry influence (LMICs)	■ Political will (KR, CN) ■ Ministry endorsement (CA, LB, LMICs) ■ Research funding (CN) ■ Healthcare reforms (CN) ■ Broad stakeholder consultation (CA, KR, JP, LB, LMICs) ■ Stakeholder surveys (KR, LB) ■ Deliberative processes (LB)
Sources and Methodological Frameworks 	■ Lack of local cost/QALY data (KR, JP, CN, LB) ■ No ICER threshold (KR, CN) ■ Controversy over comparator selection (KR) ■ No standard costs (CA, LB) ■ Gap between guideline perspective and submissions (KR) ■ No standard for indirect comparison (KR)	■ Reference to international guidelines (JP, KR; LMICs) ■ Use of WHO/AGREE-HS best practices (LB) ■ International (organisation) support (LB, LMICs)
DIDS Process 	■ Ambiguities in guideline interpretation by stakeholder and target groups (KR) ■ Need to address methodological evolution (KR) ■ Virtual workshop constraints (LB) ■ No standardised framework for the process (LMICs)	■ Multiple meetings to reach consensus (KR) ■ Stakeholder surveys (KR) ■ Long deliberation process (JP) ■ Interim reports (JP) ■ Transparent GDG reporting (LB) ■ Evidence-based deliberative process (LB) ■ Transparency measures such as reviewer checklists, COI guidelines, posting decisions (KR) ■ Dedicated project coordinator (LB)

Abbreviations: AGREE-HS … Appraisal of guidelines research & evaluation – Health systems, CA … Canada, CN … China, COI … Conflict of interest, DIDS … Development, implementation, dissemination, sustainment, GDG … Guideline development group, HTA … Health technology assessment, JP … Japan, KR … South Korea, LB … Lebanon, LMICs … Low- and middle-income countries, WHO … World health organisation,

6 Discussion

6.1 Summary of the Findings and General Observations

konsistente Muster aus 5 Ländern & LMIC-Review identifiziert

The synthesis of HEEG development processes across Canada, South Korea, Japan, China, and Lebanon, supplemented with the LMIC systematic review by Daccache, et al. [2022], reveals several consistent patterns and lessons for countries like Austria that are developing or refining their own HEEG and HTA frameworks.

Governance-Klarheit, Endorsement & rechtliche Verankerung als entscheidende Sustainment-Faktoren

Modelle von gesetzlich verpflichtend (KR, JP) bis de facto Applikation ohne Zustimmung (CN)

Sustainment in LB ungeprüft

Governance clarity, endorsement, and legal basis are decisive determinants of sustainment. For example, Canada's federal model achieved implementation but required provincial endorsement [18], while South Korea's legally mandated endorsement linked to reimbursement decisions enabled three guideline updates (2006, 2011, 2021) [20, 21, 38] and Japan's payer-embedded, legally mandatory model ensures direct linkage to reimbursement [22]. In contrast, China's model currently lacks formal enforcement, but pharmacoeconomic evaluation of essential drugs and price negotiations were core pillars of the 13th Five-Year Plan and the healthcare reform, implying a de facto endorsement through use without formal government approval [2]. Lebanon's ministry-direct model without a dedicated HTA unit seems efficient, but sustainment has not yet been tested [39, 40]. Governance of the DIDS process in LMICs is ministry-led in 10 of 14 countries [37]. However, the LMIC review [37] found that legal basis, governance interactions, and endorsement were often absent or poorly documented.

methodische Grundlagen variieren erheblich zwischen Ländern

Sources and methodological frameworks vary considerably across countries. Canada's 1994 guideline [18] relied on key papers and Australian guidelines, while Lebanon's 2024 guideline [39, 40] drew on two systematic reviews, WHO handbooks, and AGREE-HS. Japan's use of systematic reviews [22] and South Korea's surveys [20, 21, 38] represent rigorous approaches.

stufenweises Verfahren: Kernteam erstellt Entwurf, Stakeholder:innen-Review & Überarbeitung

Overall, GDG and steering groups were involved from the outset, while stakeholder groups were primarily engaged after an initial draft was available. This suggests a staged approach: core teams develop the first draft, then external stakeholders are brought in for review and input, followed by revision and finalisation.

DIDS-Prozess mit 8 Phasen von Scoping bis Sustainment als länderübergreifende Mindeststruktur für nachhaltige Implementierung

A closer look at each country's history of guideline development and implementation revealed common process steps. This pattern showed consistency across countries despite considerable variation in the emphasis and sequence of each step, organisational structures, and levels of HEEG and HTA institutionalisation, leading to the identification of an eight-phase process. This process, comprising an initial scoping and identification of a policy need phase, formation of GDG and steering group, evidence gathering, drafting and internal review, stakeholder consultation, revision and finalisation, endorsement, and dissemination and sustainment, represents a minimum viable core for HEEG DDIS. Countries that followed this core process, particularly Canada [18] and South Korea [20, 21, 38], achieved sustained implementation and multiple guideline updates.

nur Kanada & Südkorea mit expliziten Sustainment-Mechanismen

Dissemination was relatively well documented across the five countries, though poorly reported in the LMIC review [37]. Sustainment, however, was less systematically documented. Only Canada and South Korea had explicit, imple-

mented sustainment mechanisms. Canada assigned CDA-AMC formal responsibility for monitoring [18] and South Korea implemented a plan for systematic re-evaluation of 20,000 drugs over five years [20, 21, 38], which sustains the relevance and use of the HEEG. Other countries either only had plans (Lebanon), recommendations (China), or partial measures (Japan). The LMIC review [37] did not report sustainment mechanisms at all, confirming this as a critical gap.

Barrierencluster: Expertise- & Datenmangel (universell)

Förderfaktoren: politischer Wille, Stakeholder-Konsultation & internationales Benchmarking mit Stakeholder-Engagement als konsistentestem Faktor

Barriers and facilitators cluster across four categories: Expertise (shortages of health economists), institutional governance and stakeholder groups (political will, stakeholder engagement, transparency measures), sources and methodological framework (data limitations, international benchmarking), and key process (ambiguities, methodological evolution). Expertise shortages and data limitations are universal barriers. All five investigated countries reported shortages of health economists and a lack of local cost or utility data [2, 20-22, 38-40]. High-income countries like Canada and Japan faced these challenges as well. This suggests that data and expertise are substantial challenges regardless of the country's income level. Facilitators that successfully overcame barriers included strong political will (South Korea, China), broad stakeholder consultation (all five countries), and international benchmarking (Japan, South Korea, Lebanon). Of these, stakeholder engagement is the most consistently reported facilitator. All five countries engaged the industry, academia, and clinicians. Canada's broad workshop model [18], South Korea's open workshop and surveys [20, 21, 38], Japan's manufacturer review [22], and Lebanon's deliberative process [39, 40] all contributed to legitimacy and ensured technical accuracy. The LMIC review [37] confirmed that workshops or consultation meetings were reported in 9 of 14 countries.

6.2 Discussion and Interpretation considering the Six Key Aspects by Botwright et al. (2024)

Handlungsempfehlungen mittels Botwright-Framework

To translate the presented descriptive findings into actionable guidance for Austria, we now discuss them considering the six key aspects proposed by Botwright, et al. [2025] (see Table 2-2).

6.2.1 Setting Objectives, Scope, and Principles

Ziele, Umfang & Prinzipien sollten zu Beginn vereinbart werden

Botwright, et al. [2025] recommend that objectives, scope, and principles be agreed upon at the outset, with a concise summary serving as a reference point throughout the guideline development. They also note that guidelines are more likely to be successful if they aim to promote good practices for HTA broadly, rather than being tied to a single-policy process.

Synthese bestätigt Empfehlung: klare Policy-Trigger fördern Zielsetzung & Stakeholder-Ausrichtung

Our synthesis confirms this recommendation. For example, South Korea's explicit policy trigger, the 2001 regulation introducing cost-effectiveness as a reimbursement criterion [20, 21, 38], enabled the establishment of focused objectives and stakeholder alignment. Similarly, Lebanon's explicit definition of rationale and scope as first steps [39, 40] aligns with best practice. Overall, the LMIC review [37] indicates that guideline development is frequently driven by explicit policy needs, such as expansions of universal health coverage.

gesetzliche Verankerung versus faktische Nutzung als alternative Wege zur Wirkung

Our synthesis also reveals that the binding nature of objectives, i.e., whether the guideline carries a mandatory or advisory status, substantially affects implementation. In South Korea and Japan, where guidelines are linked to legally mandated reimbursement processes, sustained use and updates have been demonstrated [20-22, 38]. Conversely, the voluntary status of China's guideline [2] led to ambiguity regarding its mandate and slower uptake despite technical progress. However, China's de facto endorsement through its use in NRDL negotiations suggests that even without a formal legal mandate, a technically robust guideline can shape policy if it proves useful to decision-makers.

Österreich: Policy-Impuls durch Bewertungsboard aber Nutzung (noch) limitiert

For Austria, identifying a specific policy need, such as integrating cost-effectiveness into decisions on selected medicinal products within the so-called appraisal board has created a further impulse to systematically use HEE in the Austrian decision-making context. The policy need could be extended to further categories of healthcare interventions, such as individual medical services (MELs) for the hospital benefit catalogue. Currently, health economic evidence is used only sparingly, and even within the appraisal board for specific medicines [35, 43, 44], its application remains limited because economic evaluations are often not submitted or submitted with substantial delays by the industry. This limited use stems from the absence of a legally established sanction-mechanism if companies do not submit such evidence and the lack of an up-to-date guideline. A potentially stronger impetus would therefore be the mandatory submission of health economic evidence by industry, coupled with a requirement to adhere to a national HEEG.

Erstattungsprinzipien klären & Leitlinie auf alle Technologien & Sektoren ausweiten

As a first step, Austria should clarify the principles governing reimbursement submissions and decisions to enable successful HEEG development and implementation. Furthermore, following the recommendation of Botwright, et al. [2025] that a HEEG should promote broad good practices rather than serve a single-policy process, a national Austrian HEEG should extend beyond the mentioned appraisal board's scope and address all health technologies across both inpatient and outpatient settings.

6.2.2 Building a Team for a Quality Guideline

Kernteam für technische Inhalte & separates Beratungsgremium für Policy-Kontext

According to the good practice framework by Botwright, et al. [2025], a core team should lead guideline development with oversight from a separate advisory body, with one group contributing technical content expertise and the other providing expert knowledge of the decision-making and policymaking context.

Länderbeobachtungen bestätigen Empfehlung, zeigen aber auch Abweichungen in der Praxis

The observations from the included countries support this recommendation, while revealing that real-world implementation often diverges from this ideal. Canada [18] and Lebanon [39, 40] employed an integrated model combining the GDG and steering function. At the same time, Japan [22] followed a model in which GDG authors served as non-voting members of the payer-dominated steering group. This latter approach most closely aligns with Botwright et al.'s [15] recommendation for separating technical and policy roles. South Korea's model [20, 21, 38] comprising HIRA in-house staff, an academic advisory committee, and external reviewers, also closely aligns with the recommendation by Botwright, et al. [2025].

In addition, Botwright, et al. [2025] recommend either 1) a writing team of subject-matter experts with oversight from stakeholders, or 2) a writing team linked to the policy process supported by an advisory board of subject-matter experts. Our synthesis reveals that countries have successfully used both approaches but also highlights that the presence of a formal steering group separate from the GDG (as in Japan [22]) appears to be associated with clearer role differentiation. However, even Japan faced challenges. Most subcommittee members lacked expertise in health economic evaluation, and medical associations and industry strongly opposed the mandatory use of QALYs [22].

Botwright: entweder Autor:innenteam mit Stakeholder-Oversight oder Autor:innenteam mit Fachberatungsgremium

In general, our synthesis identified a universal shortage of health economists and limited research experience as recurring barriers across examined settings (South Korea [20, 21, 38], Japan [22], China [2], Lebanon [39, 40], and LMICs [37]). Even where dedicated (HTA) agencies existed, as in Canada [18] and South Korea [20, 21, 38], expertise gaps persisted. Botwright, et al. [2025] note that in resource-limited settings, practical governance principles may need to be adapted. Lebanon's approach of convening a small GDG with international expert support [39, 40] offers a pragmatic model for contexts with limited domestic expertise.

Expertise-Lücken bestehen selbst in Ländern mit etablierten HTA-Agenturen

For Austria, expertise on economic evaluation is present in different (academic) non-governmental organisations such as the Austrian Institute for Health Technology Assessment (AIHTA), the Gesundheit Österreich GmbH (GÖG), the Department of Public Health, Health Services Research and Health Technology Assessment at the University for Health Sciences, Medical Informatics and Technology, the Department of Health Economics at the Medical University of Vienna and others. However, within the healthcare administration and among decision-makers, specific expertise on economic evaluation is less present, which can be a barrier in the guideline development and implementation process. This can be overcome through investment in formal capacity-building.

Expertise vorhanden (AIHTA, GÖG, Universitäten), aber Aufholbedarf in Verwaltung & Entscheidungsgremien

Investitionen in Capacity-Building erforderlich

6.2.3 Defining a Stakeholder Engagement Plan

Botwright, et al. [2025] recommend developing a stakeholder engagement plan adapted to the guideline objectives and context, involving at a minimum the end-users, decision-makers, and policymakers. They further emphasise the importance of transparent communication of the engagement mechanisms, the feedback received, and how comments were addressed.

Stakeholder-Engagement-Plan an Leitlinienziele & Kontext anpassen

Stakeholder engagement and articulation of target groups were also the most consistently reported facilitators across all five countries. Botwright, et al. [2025] recommendation to engage direct users, users of HTA outputs, affected stakeholders, and international experts is reflected in practice: Lebanon, for instance, included bioethicists, a knowledge translation expert, and ensured a detailed payer diversity, while Canada and South Korea included patients during the HEEG development.

Stakeholder-Engagement als konsistentester Förderer bestätigt Botwright-Empfehlung

At the same time, notable gaps in engagement were observed. China's omission of patient and public representation [2] and the LMIC review's finding that one-third of guidelines lacked multisectoral engagement [37] highlight the risks of incomplete stakeholder involvement. Botwright, et al. [2025] emphasise that extensive engagement is particularly important in settings at early stages of guideline development. Japan's manufacturer draft review [22], while ensuring technical accuracy, also raises conflict-of-interest concerns that Botwright, et al. [2025] recommend managing through transparent mechanisms.

unvollständiges Stakeholder-Engagement birgt möglicherweise Risiken

These findings reveal that the quality of stakeholder engagement matters as much as its diversity. Furthermore, explicit articulation of target groups is a prerequisite for effective dissemination and implementation. For example, South Korea's [20, 21, 38] transparency measures (reviewer checklists, conflict-of-interest guidelines, and posting decisions on the HIRA website) provided a model for managing conflicts and building trust. Moreover, Lebanon's deliberative process [39, 40] demonstrated that meaningful engagement through surveys, interviews, and consensus workshops is feasible even in a small country with limited resources.

Qualität des Stakeholder-Engagements ebenso wichtig wie dessen Vielfalt

A clear organisational structure clarifying the different roles and a structured stakeholder engagement plan are therefore essential for Austria. This should explicitly include public payers, such as social security institutions or the ministry, hospital providers, the pharmaceutical industry, clinical experts, patient advocacy groups, other HTA agencies and the broader public. In doing so, Austria may adopt South Korea's transparency measures to mitigate industry influence, which was also a concern in the LMIC review [37]. In addition, Botwright et al.'s [15] emphasis on transparent communication of feedback and how comments were addressed is a practice Austria should implement from the outset.

strukturierter Stakeholder-Plan & klare Organisationsstruktur für Österreich essenziell

6.2.4 Developing Content and Utilising Available Resources

Botwright, et al. [2025] recommend contextualising guidelines from other settings to fit existing decision-making structures and leveraging international HTA networks, particularly when considering new approaches. All five countries drew upon international guidelines as a foundation. This measure also aligns with Botwright et al.'s [15] recommendation to efficiently use existing resources[12].

internationale Leitlinien als Grundlage nutzen & an eigene Entscheidungsstrukturen anpassen

Despite the widespread use of international benchmarking, all countries reported significant data limitations, including the lack of local cost data or utility value sets, the absence of ICER thresholds, and no standardised costing manuals (South Korea [20, 21, 38], Japan [22], China [2], Lebanon [39, 40]). Botwright, et al. [2025] note that content should be adapted to local governance requirements and technical capacity, a recommendation that Lebanon's experience underscores. Overall, the LMIC review [37] highlights that many LMICs adopt international frameworks without local adaptation, leading to implementation gaps.

universelle Datenlücken (Kosten, Nutzen, ICER-Schwellenwerte) → Botwright empfiehlt lokale Anpassung

For Austria, developing a national cost database for health services, establishing Austrian-specific EQ-5D utility value sets, and defining a reference case (including discount rates and willingness-to-pay thresholds) should be addressed alongside the DIDS process [36, 45, 46]. In pursuing these objectives, Austria can already build on established scientific sources and publications such as the HEEG overview [30], the report on the international threshold landscape [45], or the overview on health economic reference cases and costing approaches [46]. All these resources can be complemented by frameworks such as the AGREE-HS, which provides a guideline implementation planning checklist [11].

nationale Kostendatenbank, EQ-5D-Werte & Referenzfall entwickeln

bestehende Publikationen nutzen (e.g AGREE-HS als Implementierungs-Checkliste)

[12] Botwright, et al. [2025] provide a comprehensive inventory of resources, confirming the value of cross-country learning.

6.2.5 Putting in Place Appropriate Institutional Arrangements

klare Governance-Strukturen erhöhen Wirksamkeit (eventuell auch ohne formellen rechtlichen Rahmen)

Our findings confirm the recommendation by Botwright, et al. [2025] that while a legal framework is not a mandatory prerequisite, agreed governance arrangements enhance guideline effectiveness. Included countries assigned an agency or institution with the appropriate level of authority, independence, and technical capacity to oversee guideline implementation. However, the different institutional models observed are associated with distinct consequences, as already mentioned. For example, while South Korea's institutional governance model with legal basis enabled three updates [20, 21, 38], Canada's federal model created an implementation hurdle but enabled federal-provincial adaptation, and Japan's payer-embedded model [22] ensures direct linkage to reimbursement.

gesetzliche Mandate fördern Sustainment; aber CN mit pragmatischem Weg

Our synthesis suggests that where legal mandates exist, sustainment also tends to be more robust. However, China's experience supports the pragmatic alternative that even without a formal legal mandate, a guideline can influence policy if it is perceived as useful by decision-makers [2]. Still, a voluntary framework leaves the guideline vulnerable to political shifts. Thus, a clear institutional arrangement is substantial.

dediziertes HTA-Institut mit rechtlichem Mandat als stärkste Basis für Rechenschaftspflicht

Given Austria's social insurance system with multiple payers, a dedicated HTA unit (e.g., AIHTA) holding a (legal) mandate to develop and update the guideline would likely provide the strongest basis for accountability. The Japanese model, with the GDG participating as non-voting members within the payer committee [22], offers a deliberate mechanism for separating technical evidence from political decisions while maintaining direct communication and integration into existing decision-making structures.

6.2.6 Monitoring and Evaluating Guideline Success

Monitoring & Evaluation anhand von 3 Kriterien

Botwright, et al. [2025] recommend monitoring and evaluation of the implementation of a HEEG against three criteria:

1. The extent to which guidelines strengthen systematic and legitimate decision-making,
2. adherence, and
3. improvement in HTA quality derived from the guideline use.

Umsetzungslücke zwischen Empfehlungen & Praxis

While Botwright, et al. [2025] provide a comprehensive framework for evaluation, our findings suggest that many countries struggle to define basic monitoring mechanisms. The LMIC review [37] similarly noted the absence of such reporting as a critical gap.

Monitoring & Updates von Beginn an planen mit klaren Metriken & institutioneller Verankerung

Planning for monitoring and evaluation from the outset, which is part of sustainment, is critical. Thus, key metrics for Austria may include the number and quality of industry submissions prepared in accordance with the guideline and stakeholder feedback on the clarity and usability of the guideline. South Korea's transparency measures (posting review results and structured reporting), for example, provide a practical model for creating an open feedback loop that supports both adherence monitoring and continuous improvement. The presence of multiple guideline editions in certain countries further signals an institutionalised learning process and adaptation to emerging methods (e.g., inclusion of equity aspects such as distributional cost-effectiveness analysis [47]). Overall, a formal roadmap for updates should be embedded in the institutional mandate to ensure the guideline remains a living document [39, 40].

6.3 Limitations

Limitationen: explorative Handsuche statt systematisch, nur 5 Länder; Beschränkung auf englische & deutsche Quellen

Several limitations of this report should be acknowledged. First, the analysis was based on a comprehensive, exploratory hand search and not on systematic literature research. It should be noted that DIDS processes on HEEGs do not appear to be published in peer-reviewed literature. The five countries, Canada, South Korea, Japan, China, and Lebanon, were selected because they represented the only identified and sufficiently documented cases of DDIS processes available. Furthermore, the synthesis is restricted to guidelines available in English and German only.

extrahierte Informationen variieren stark in Detailtiefe & Berichtsqualität

Second, the extracted information relied on published literature and country-specific reports that vary considerably in their level of detail, transparency, and reporting quality. As noted in the LMIC review [37], many countries did not systematically report key aspects of the development process, such as GDG composition, stakeholder engagement, or sustainment mechanisms. We also did not verify how consistently the described process was initially applied and whether it is still applied in the respective countries. Therefore, some information may now be outdated.

Kategorisierung des DIDS-Prozess „nur" (inter)subjektiv gemäß Literatur

Third, the categorisation of activities into the eight-phase common process and the four barrier/facilitator categories involved subjective interpretation, and alternative categorisations may be possible. The resulting discussion and interpretation for Austria are based on the authors' knowledge of the Austrian context and may not capture all nuances of the local health economic and HTA landscape.

Botwright-Framework repräsentiert eine Perspektive unter mehreren

Finally, the Botwright, et al. [2025] framework, while comprehensive, represents one perspective on good practices, and other frameworks or guideline implementation frameworks, such as the AGREE-HS [11], may yield different insights.

7 Conclusion

trotz Kontextunterschiede länderübergreifender DIDS-Prozess mit 8 Phasen konzipiert

This report synthesised the DDIS processes of HEEGs from five countries (Canada, South Korea, Japan, China, and Lebanon) and supplemented these with a systematic review of LMIC experiences. Despite considerable variation in contexts, health economics application and HTA institutionalisation, we developed a common eight-phase DIDS process: policy need identification, GDG formation, evidence gathering, drafting, stakeholder consultation, revision, endorsement, and dissemination and sustainment.

Governance/Rechtsbasis kritisch für Sustainment, Expertise-/Datenmangel universell, Engagement zentral

Botwright-Empfehlungen plus institutionelle Unterstützung förderlich

Key findings indicate that governance clarity and a legal basis are critical for sustainment. Expertise and data limitations are universal barriers. Stakeholder engagement is the most consistent facilitator, and sustainment is the least systematically documented phase. Our synthesis confirms the recommendations by Botwright, et al. [2025] that a successful DIDS process depends on 1) a clear legal or political mandate, 2) dedicated institutional responsibility, 3) investment in local data and capacity building, 4) inclusive stakeholder engagement, 5) explicit planning for dissemination and sustainment, and 6) pragmatic adaptation of international resources. In addition, our analysis identified an additional aspect essential for a HEEG DDIS process: robust sustainability requires some form of institutional backing, even if a formal legal mandate is not in place.

Chancen für Österreich: verpflichtende ges.ök. Leitlinie, lokale Daten/ Capacity-Building, robuste Disseminations- & Sustainment-Strategie

For Austria, the greatest opportunities lie in establishing a mandatory HEEG, investing in local data and capacity, and designing a robust dissemination and sustainment strategy from the start. With a solid foundation provided by several institutions with health economic expertise, Austria can learn from the experiences of other countries, including South Korea's legal mandate and transparency, Japan's payer-embedded model, Lebanon's well-documented roadmap, and challenges such as China's voluntary status and the LMIC review's documentation gaps. By embedding these lessons within the Botwright, et al. [2025] framework and the AGREE-HS checklist, Austria can develop a robust, sustained HEEG to support evidence-informed decision-making.

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Appendix

Extraction table

Table A-1: Extracted information on the DIDS process from included publications

Publication	Torrance et al. [18]	Bae et al. [20, 21, 38]	Shiroiwa et al. [22]	Yue et al. [2]	Daccache et al. [39, 40]	Daccache et al. [37]
Year(s)	1996	2009, 2013, 2022	2017	2021	2024, 2025	2022
Country	Canada	South Korea	Japan	China	Lebanon	Low- and middle-income countries (LMICs)[13]
Guideline	Canadian Guidelines for Economic Evaluation of Pharmaceuticals (1st edition, published November 1994 by CCOHTA/CADTH/CDA-AMC[14])	Health Insurance Review and Assessment Service (HIRA) Guidelines for Economic Evaluation of Pharmaceuticals (first published June 2006, Updates 2011 and 2022)	Japanese official guideline for cost-effectiveness evaluation of drugs and medical devices (trial implementation from 2016)	China Guidelines for Pharmacoeconomic Evaluations (CGPE) – 2020 edition (updated from 2011 edition)	Lebanese Economic Evaluation Guideline (LEEG)	Systematic review of EEGs in LMICs
Duration	Development and Implementation ~18 months (early 1993 to June/November 1994) but precursors already available in 1991 (Ontario draft guidelines)	Development and Implementation ~3-4 years (2003-2006/2007[15])	Development and Implementation ~4 years[16]	Not explicitly stated: First edition released in 2011; 2020 edition based on rapid development in recent years	Not explicitly stated (but time from inception to experts' consultation ~3.5 years)	Not reported systematically
Expertise: Authors, Guideline Development and Steering Group	■ Steering committee (10 members[17]): National Pharmaceutical Strategy Section of Health and Welfare Canada, the Provincial and Territorial Ministries of Health, the Patented Medicine Prices Review Board (the board that oversees pricing for all patented drugs in Canada), academia	■ Guideline development group (GDG) at HIRA (in-house staff). ■ Advisory committee: academia (health and pharmacoeconomics). ■ Experts in epidemiology, statistics, and key industry figures reviewed drafts.	■ 4 authors: Health economists, academic researchers ■ GDG: research team funded by the Ministry of Health, Labour and Welfare (MHLW) ■ Subcommittee of Chuikyo[18]: 16 voting members (6 payers,	■ GDG: researchers and scholars (pharmacoeconomics) ■ Expert committee: Policy-makers from medical regulatory agencies (National Development and Reform Commission, National Health Commission, National Medical Product Administration,	■ GDG: 5 people, Pharmacist, MoPH, (national and international) HTA experts and health economists, expert on research synthesis and knowledge translation	■ Not reported systematically (most LMICs did not explicitly report disciplines of guideline developers; where reported: academia, public/private sector workers, program managers.

[13] Systematic review covering: Bhutan, Brazil, China, Colombia, Cuba, Egypt, India, Indonesia, Malaysia, Mexico, Philippines, Russian Federation, South Africa, Thailand.

[14] In the early 21st century, the Canadian Coordinating Office for Health Technology Assessment (CCOHTA) became the Canadian Agency for Drugs and Technologies in Health (CADTH) and as of May 1, 2024, it adopted Canada's Drug Agency (CDA-AMC) as operating name.

[15] Positive List System (PLS) launched December 2006 and initiated in 2007.

[16] Discussions from 2012 to February 2016, interim reports: September 2013, August 2015, final approval by Chuikyo general assembly: February 2016.

[17] Authors of the publication: Torrance G, Blaker D, Detsky A, Firestone T, Hubbard E, Kennedy W, Konchak R, Menon D, Schubert F, Tugwell P

[18] Chuikyo is the Central Social Insurance Medical Council

Publication	Torrance et al. [18]	Bae et al. [20, 21, 38]	Shiroiwa et al. [22]	Yue et al. [2]	Daccache et al. [39, 40]	Daccache et al. [37]
Expertise: Authors, Guideline Development and Steering Group *(continuation)*	■ Workshop (Canadian Collaborative Workshop on Pharmacoeconomics, June 1993): 73 participants representing major Canadian stakeholders + international experts.		6 healthcare professionals, 4 public interest) plus 4 industry and 3 health economists (coauthors) as non-voting members	National Health Security Administration), pharma-coeconomic experts and pharmacy administration (universities worldwide), experts from medical research institutes.		
Steering group	Steering committee (10 members)	HIRA in-house development team + advisory committee (from academia)	Special Committee on Cost-Effectiveness Evaluation of Chuikyo (16 members: 6 payers, 6 healthcare professionals, 4 public interest) Non-voting: 4 industry representatives, 3 health economists (coauthors)	Expert committee (composition as above) + guideline development group. No separate steering group explicitly named	No separate steering group reported (GDG of 3 persons)	Not reported systematically
Institutional Governance (Decision-Makers, Legal Basis, and Interactions)	■ National steering committee ■ CCOHTA/CADTH/CDA-AMC given responsibility for managing, reviewing, updating, issuing guidelines, and monitoring use/impact ■ Endorsement by Deputy Ministers of Health required for implementation by individual governments	■ HIRA (Health Insurance Review and Assessment Service) develops guidelines and reviews submissions ■ Drug Reimbursement Evaluation Committee (DREC 18 members) decides on listing recommendations ■ National Health Insurance Corporation (NHIC) negotiates prices ■ BCC (Benefit Coordination Committee) for compulsory listing of essential drugs ■ MOHW provides legal basis	■ Chuikyo under MHLW ■ Subcommittee on Cost-Effectiveness Evaluation ■ MHLW funding and oversight	■ Pharmacoeconomics Technical Committee of the Chinese Pharmaceutical Association (PTCCPA) (Professional association, not a government body) ■ Expert committee includes multiple regulatory agencies	■ Ministry of Public Health (MoPH) endorses adoption ■ GDG led development ■ International experts from Maastricht University consulted	■ Ministry of Health responsible in 10/14 countries. ■ Nonprofit independent institutes in 4 countries (China, Colombia, Mexico, Thailand).
Endorsement	■ CCOHTA/CADTH/CDA-AMC and PMAC endorsed soon after completion (June 1994) ■ Subsequently endorsed by 13 federal, provincial, territorial Deputy Ministers of Health (December 1994) ■ Endorsement is a necessary condition for the guidelines to be implemented by individual governments in Canada	DREC endorsed; officially published by HIRA (June 2006)	Officially approved by Chuikyo general assembly (February 2016) under MHLW	PTCCPA. Not formally endorsed by government at time of writing (GL is not mandatory). However, CGPE has been followed by negotiation experts in NRDL price negotiations (2017, 2018, 2019)	Lebanese Ministry of Public Health (MoPH)	Ministry of Health in 10 countries; independent institutes in others. (Not consistently reported)
Stakeholder groups	73 workshop participants from: Health and Welfare Canada (National Pharmaceutical Strategy Section), Pharmaceutical Manufacturers Association of Canada for brand drugs (PMAC), Canadian Drug Manufacturers Association for generics,	HIRA, DREC, NHIC, BCC, MOHW, pharmaceutical industry, academics, experts in epidemiology/statistics, patient groups, physicians, public (Korean people agreed to PLS principle)	Health care payers (insurers), health care professionals (medical associations), public interest (academics), industry (pharmaceutical and medical device manufacturers), health economists.	Invited stakeholders (not further specified). Also: pharmaceutical companies (increasingly funding evaluations), scholars from universities and research institutes, market access/	16 Lebanese stakeholders: decision-makers (n=8, including public payers from MoPH, NSSF, Civil Servants Cooperative, Military Funds), private payers (hospitals, private insurance), academia, bioethicists, nurses,	Not reported systematically (Review notes poor disclosure of sector, interest, discipline. Multisectoral/ multidisciplinary

Publication	Torrance et al. [18]	Bae et al. [20, 21, 38]	Shiroiwa et al. [22]	Yue et al. [2]	Daccache et al. [39, 40]	Daccache et al. [37]
Stakeholder groups *(continuation)*	Industrial Biotechnology Association of Canada, Patented Medicine Prices Review Board, Canadian Medical Association, Canadian Society of Hospital Pharmacists, provincial/territorial health departments, academic experts (Canada and abroad). Also: decision makers for provincial/territorial drug plans, private drug insurance plans, hospital formulary managers, physicians, pharmacists, patients.		Manufacturers reviewed draft guideline	medical research department employees, HTA/pharmaco-economics experts from professional associations, researchers from medical institutions/consulting companies	physicians (oncologist, nephrologist), pharmacists, ISPOR Lebanon chapter, patient advocacy (cancer support)	engagement reported as lacking in one-third of guidelines.)
Target groups	■ Primary: decision makers (provincial/territorial drug plans, private insurers, hospital formularies) ■ Secondary: pharmaceutical companies (R&D, pricing, submissions), academics, contract research organisations, formulary managers, clinical guideline developers	■ Pharmaceutical companies (submitting economic evaluations for new drug listings) ■ Decision-makers: DREC (reimbursement decisions) ■ NHIC (price negotiations)	■ Manufacturers (pharmaceutical companies, medical device manufacturers) submitting cost-effectiveness data to MHLW) ■ MHLW and Chuikyo for decision-making on pricing and reimbursement	■ Pharmaceutical companies (preparing reports, price negotiations, reimburse-ment submissions) ■ Policymakers/regulators: National Healthcare Security Administration for National Reimbursement Drug List updates (NRDL), drug-price negotiation, drug procurement ■ Researchers conducting pharmacoeconomic evaluations	■ Pharmaceutical companies (reimbursement submissions) ■ Lebanese policymakers and payers (decision-making, resource allocation) ■ Researchers (conducting HEE) ■ Patients (optimising healthcare access)	■ Researchers ■ Policymakers and reimbursement decision-makers (implied, but not explicitly listed per country in the review)
Sources used	Not explicitly reported. References include Australian guidelines (1990, 1992, 1995), earlier methodological literature (Drummond, et al. [1987], Detsky and Naglie [1990], Bootman et al. 1991), and proceedings from the Collaborative Workshop.	■ Review of international guidelines, academic journals, related literature. ■ Open workshop (June 2005) for public comments. ■ Update 1 and 2: Review of previous PE submissions; survey of pharmaceutical companies and decision makers regarding existing guidelines.	■ Comparison of international guidelines ■ Previously proposed Japa-nese academic guideline ■ Technical documents from HTA agencies and published articles (PubMed, Ichushi Japanese database); original systematic reviews	■ Comparison of international guidelines (ISPOR comparative tool and latest pharmacoeconomic research)	■ Two systematic reviews: Economic evaluation guidelines in LMICs ([19], Development process of EEGs in LMICs [37] ■ ISPOR key features, WHO handbook, AGREE-HS tool.	Systematic search of MEDLINE, PubMed, EconLit, Embase, Cochrane Library, grey literature (WHO, ISPOR, iDSI, GEAR, country HTA agencies), backward citation tracking. Up to March 2021.
Methodologic al frameworks	No explicit framework reported Process: broad consultation with stakeholders; collaborative workshop; steering committee produced multiple drafts; wide circulation for comment; endorsement by Deputy Ministers of Health (necessary condition for implementation)	No explicit framework reported Process: literature review → issues screening → advisory committee → draft → expert/industry review → open work-shop → DREC endorsement → official publication	No explicit framework reported Process: Driven by Chuikyo (subcommittee) discussions, consensus building among stakeholders, interim reports, and expert input	No explicit framework reported Process: Topics decided by expert committee; draft prepared by contributors from guideline development group; monthly progress meetings; feedback and re-views from expert committee and invited stakeholders.	WHO process for HSG development (guideline development group, rationale, scope, evidence search, assessment, translation into recommendations via deliberative process). AGREE-HS used for reporting quality	AGREE-HS tool used for quality assessment (domains: participants, methods). WHO handbook for HSG mentioned.

Publication	Torrance et al. [18]	Bae et al. [20, 21, 38]	Shiroiwa et al. [22]	Yue et al. [2]	Daccache et al. [39, 40]	Daccache et al. [37]
Information on the process in each country regarding the DIDS of a guideline (DIDS process)	1) Ontario issued draft guidelines (autumn 1991) 2) National steering committee formed to coordinate national approach 3) Canadian Collaborative Workshop on Pharmacoeconomics (June 1993, 73 participants) 4) Steering committee produced multiple drafts 5) Draft widely circulated for comment (February 1994) 6) Feedback incorporated 7) Final version released (late June 1994) 8) Endorsed by CCOHTA/CADTH/ CDA-AMC and PMAC 9) Endorsed by 13 federal, provincial, territorial Deputy Ministers of Health (December 1994) 10) Final version published by CCOHTA/CADTH/CDA-AMC (November 1994).	1) New regulation announced in the end of 2001 introducing cost-effectiveness as reimbursement criterion 2) Literature review and issue screening 3) First draft 4) Advisory committee formed 5) Review by experts and industry 6) Open workshop for public comments (June 2005) 7) Revision 8) Endorsement by DREC 9) Official publication (June 2006) 10) Drug Expenditure Rationalisation Plan (DERP) announced (May 2006) 11) Positive list system (PLS) regulation announced (Dec 2006) 12) PLS initiated (2007). 13) Update 1: Accumulation of domestic experience with first version (2006-2011) 14) Update 1: HIRA initiated revision project 15) Update 1: Meetings with advisory committee held several times 16) Update 1: Working-level meetings with pharmaceutical companies held several times 17) Update 1: Survey of pharmaceutical companies and decision makers regarding existing guidelines 18) Update 1: Second version published (2011). 19) Update 2: Review of previous 50 PE submissions 20) Review of international guidelines and academic literature 21) Surveys and advisory meetings to obtain stakeholder opinions 22) Third version published (January 2021).	1) Subcommittee discussions at Chuikyo (2012-2016) 2) Two interim reports (2013, 2015) 3) Consensus on 4 key points (outcome, costs, comparator, data sources) 4) Research team generated research questions per guideline section 5) Draft guideline submitted to MHLW then subcommittee 6) Review by manufacturers (drugs/medical devices) 7) Revised versions submitted (Nov 2015, Jan 2016) 8) Final approval by Chuikyo general assembly (Feb 2016).	1) Formation of expert committee (policymakers, academics, researchers) 2) Formation of guideline development group 3) Topics decided by expert committee 4) Draft prepared by contributors 5) Monthly progress meetings 6) Feedback and reviews from expert committee and stakeholders 7) Release of 2011 edition 8) Update to 2020 edition based on developments.	1) Rationale identification 2) Guideline scope definition 3) Set up GDG 4) Search for evidence (2 SRs, [19, 37]) 5) Development process and draft 6) Panel selection (16 stakeholders) 7) Survey + support guideline development 8) Deliberative process (survey, in-person interviews, consensus workshop) 9) Draft guideline 10) Expert consultation (public consultation and publication of HEEG was not carried out at time of the publication)	1) Review of national guidelines (6 countries)[19]. 2) Workshops/ consultation meetings (9 countries), 3) Support from international experts (5 countries) 4) Support from international organisations (4 countries: WHO, PAHO, EU, iDSI, HiTAP, NICE). Three countries reported no steps.

[19] The systematic review identified four main steps across included LMICs.

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Dissemination	■ Guidelines published by CCOHTA/CADTH/CDA-AMC (November 1994).	■ Guidelines posted on HIRA website (http://www.hira.or.kr/) ■ Structured reporting format required ■ Detailed review results posted on HIRA website	■ Guideline published in English as open access ■ Reporting style required (8 items modelled on CHEERS) ■ Analysis/review results to be made public	■ English translation of CGPE 2020 added to facilitate international comparison ■ Authors suggest establishing national agency and publishing official research guidelines	■ Will be available for public consultation on MoPH webpage ■ Final version made available thereafter	Not reported
Sustainment	■ CCOHTA/CADTH/CDA-AMC given responsibility for reviewing, updating, issuing guidelines, and monitoring use/impact ■ Process for developing and maintaining standard costs (similar to Australian Manual of Resource Items) ■ Guidelines intended to be updated as appropriate	■ Re-evaluation of all listed drugs (nearly 20,000) over 5 years (by 2011) ■ Drugs not cost-effective eliminated or subject to price cuts ■ Networking with other Asian HTA agencies for collaboration ■ Ongoing revision process anticipated	■ Capacity building noted as needed for sustainment ■ Promotion of data collections (QALYs and costs)	■ Authors recommend regular updates based on issues encountered and progress in research (e.g., ethics, real-world research etc.) ■ Integration of the CGPE with the current framework of universal health coverage (UHC)	■ To initiate the development of Lebanese reference prices or costing manuals (for medical devices, health services, all health interventions other than drugs) ■ To develop national data on average national gross monthly wages and informal care costs ■ To publish national data from other sectors (e.g., transportation) ■ To establish the Lebanese utility value sets with the adoption of EQ-5D-5L ■ To issue a regulation specifying the mandatory recommendation of adopting the LEEG methodology ■ To publish the Lebanese disease management pathways with their epidemiological data (e.g., prevalence and incidence) ■ To include a discounting approach to set a discount rate considering the Lebanese healthcare system, financing mechanisms, and needs ■ To initiate the development of QALY league tables ■ Future updates recommended to better tailor the guideline to the Lebanese national context ■ Further studies identifying barriers and facilitators for implementation necessary	Not reported

Publication	Torrance et al. [18]	Bae et al. [20, 21, 38]	Shiroiwa et al. [22]	Yue et al. [2]	Daccache et al. [39, 40]	Daccache et al. [37]
Barriers[20]	■ Concern over fragmented system if provinces developed own guidelines ■ Interprovincial variations in health service costs ■ Need for standard costs (standardised resource document is developed) ■ Limited experience with guidelines at time of writing	■ Limited human resources/expertise ■ Lack of quality local data ■ Limited research experience ■ No official ICER threshold ■ Gap between guideline perspective (societal) and applicant submissions (direct medical costs only) ■ Controversy over comparator selection (not prescriptive enough) ■ No standard for indirect comparison method ■ Ambiguities in interpretation of first version and need for more specific guidance ■ Evolution of methodologies for estimating effectiveness and costs since previous versions	■ Most subcommittee members not experts in economic evaluation (general shortage of experts in Japan) ■ Competing interests among members ■ Strong opposition from medical associations and industry to mandatory QALY use ■ Delay in reaching consensus ■ Limited experience in industry ■ Insufficient Japanese data on costs and QOL	■ Pharmacoeconomic evaluation voluntary, not mandatory ■ No official research guidelines from government ■ Lack of national agency to review quality ■ Talent shortage in pharmacoeconomics and limited number of universities offering courses ■ Lack of QOL basic data and limited utility value sets (only EQ-5D China weights available) ■ Policy makers/clinicians more inclined to clinical indicators than QOL ■ Lack of threshold research for different regions ■ Cost-utility analysis rarely performed	■ Stakeholder preoccupation with procuring resources and providing access ■ Difficulty convincing stakeholders to engage ■ Fragmented healthcare sector ■ Virtual workshop due to COVID ■ Varying levels of HE expertise among stakeholders ■ Consensus not reached for all discrepancies (experts' consultation overrode deliberative process for those) ■ Lack of Lebanese QALY/EQ-5D-5L value sets ■ Absence of reference cost indexes/costing manuals ■ Need for Lebanese-specific discount rate due to currency hyperinflation and economic crisis ■ Limited local data on average national gross monthly wage and informal care costs ■ Need for updated Lebanese standard care and disease management pathways	■ Scarcity of published information ■ Suboptimal quality of reporting ■ Lack of multidisciplinary teams ■ Incomplete development steps ■ No standardised framework followed ■ Potential industry influence during consultation
Facilitators[20]	■ Broad multi-stakeholder consultation (73 participants) ■ Remarkable degree of consensus at workshop ■ Steering committee with diverse representation ■ Wide circulation of draft for comment and detailed and helpful feedback ■ Endorsement by senior civil servants (Deputy Ministers) ■ CCOHTA/CADTH/CDA-AMC given responsibility for maintenance and updates	■ Strong political will to control drug expenditures ■ Pressure from National Health Insurance deficits ■ Separation of prescribing/dispensing increased costs ■ Public agreement that only clinically/economically valuable drugs be listed ■ Prior-consultation system being introduced ■ Transparency measures (reviewer checklists, conflict-of-interest guidelines, posting decisions on HIRA website)	■ Long deliberation process (4 years) allowing consensus building ■ Gradual understanding of economic evaluation among members ■ Interim reports; support from health economists ■ Reference to and comparison of international guidelines ■ Review by manufacturers before finalisation	■ Rapid development and recognition of pharmacoeconomics in China past decade ■ Healthcare reform (2009 onwards) ■ 13th Five-Year Plan emphasising pharmacoeconomic evaluation for essential drugs and price negotiations ■ NRDL adjustments (2017, 2019) using pharmacoeconomic principles	■ Strong stakeholder interest ■ Support and endorsement from Lebanese MoPH ■ International experts from Maastricht University ■ Dedicated project coordinator ■ Transparent reporting of GDG composition ■ Use of WHO and AGREE-HS best practices ■ Funding from LSPOR (Lebanon chapter of ISPOR)	■ Ministry involvement (may ensure implementability). ■ International support (WHO, PAHO, iDSI, NICE, HiTAP) ■ Workshops ■ Review of existing guidelines

[20] Barriers and facilitators to producing valid health economic evaluations (e.g., missing data for the guideline's reference case or the endorsement by decision-makers) also affect the DIDS process. The availability of valid health economic evaluations and data fosters implementation and sustainment of the guideline, whereas their absence puts it at risk.

Publication	Torrance et al. [18]	Bae et al. [20, 21, 38]	Shiroiwa et al. [22]	Yue et al. [2]	Daccache et al. [39, 40]	Daccache et al. [37]
Facilitators *(continuation)*	■ Guidelines were not developed as a free-standing academic exercise, but designed for an integral part of the decision-making process for those who must pay for drugs	■ Accumulated domestic experience with previous PE submissions ■ Multiple meetings to reach consensus ■ Stakeholder surveys ■ International guideline comparisons		■ First formal submission window for pharmacoeconomic reports before drug-price negotiation (2019) ■ Pilot program for centralised drug procurement (11 cities, 2019) ■ Growing number of professional workshops ■ Increasing funding from National Social Science Fund, National Nature Science Foundation, professional associations, and pharmaceutical companies	■ Evidence-based and deliberative process involving key stakeholders ■ Representation of target audience in deliberative process	

Abbreviations: ADP … Access and Delivery Partnership, AGREE-HS … Appraisal of Guidelines for Research and Evaluation – Health Systems, BCC … Benefit Coordination Committee (South Korea), BMGF … Bill & Melinda Gates Foundation, CADTH … Canadian Agency for Drugs and Technologies in Health (formerly CCOHTA), CBA … Cost-Benefit Analysis, CCA … Cost-Consequence Analysis, CCOHTA … Canadian Coordinating Office for Health Technology Assessment, CEA … Cost-Effectiveness Analysis, CGPE … China Guidelines for Pharmacoeconomic Evaluations, CHEERS … Consolidated Health Economic Evaluation Reporting Standards, CMA … Cost-Minimisation Analysis, CUA … Cost-Utility Analysis, DERP … Drug Expenditure Rationalization Plan (South Korea), DoH … Department of Health, DREC … Drug Reimbursement Evaluation Committee (South Korea), EE … Economic Evaluation, EEG(s) … Economic Evaluation Guideline(s), EQ-5D … EuroQol 5-Dimension questionnaire, EU … European Union, FY … Fiscal Year, GDG … Guideline Development Group, GEAR … Guide to Health Economic Analysis and Research, GIN … Guidelines International Network, HE … Health Economics, HIRA … Health Insurance Review and Assessment Service (South Korea), HiTAP … Health Intervention and Technology Assessment Program (Thailand), HSG … Health System Guidance, HTA … Health Technology Assessment, HTA-SC … Health Technology Assessment Steering Committee (Ghana), HTA-TWG … Health Technology Assessment Technical Working Group (Ghana), HYE … Healthy Year Equivalent, ICER … Incremental Cost-Effectiveness Ratio, iDSI … International Decision Support Initiative, INAHTA … International Network of Agencies for Health Technology Assessment, ISPOR … International Society for Pharmacoeconomics and Outcomes Research, KNUST … Kwame Nkrumah University of Science and Technology (Ghana), LEEG … Lebanese Economic Evaluation Guideline, LIC(s) … Low-Income Country(ies), LMIC(s) … Low- and Middle-Income Country(ies), LSPOR … Lebanon Chapter of ISPOR, MHLW … Ministry of Health, Labour and Welfare (Japan), MOH … Ministry of Health (generic spelling), MoH … Ministry of Health (Ghana spelling), MOHW … Ministry of Health and Welfare (South Korea), MoPH … Ministry of Public Health (Lebanon), NA … Not Available/Not Applicable, NHIA … National Health Insurance Authority (Ghana), NHIC … National Health Insurance Corporation (South Korea), NHIS … National Health Insurance Scheme (Ghana), NICE … National Institute for Health and Care Excellence (United Kingdom), NIPH … Norwegian Institute of Public Health, NRDL … National Reimbursement Drug List (China), NSSF … National Social Security Fund (Lebanon), OECD … Organisation for Economic Co-operation and Development, PAHO … Pan American Health Organization, PATH … Program for Appropriate Technology in Health, PBAC … Pharmaceutical Benefits Advisory Committee (Australia), PE … Pharmacoeconomic, PEG(s) … Pharmacoeconomic Guideline(s), PLS … Positive List System (South Korea), PMAC … Pharmaceutical Manufacturers Association of Canada, PTCCPA … Pharmacoeconomics Technical Committee of the Chinese Pharmaceutical Association, QALY … Quality-Adjusted Life-Year, QOL … Quality of Life, R&D … Research and Development, SPH-UG … School of Public Health, University of Ghana, SR … Systematic Review, TCM … Traditional Chinese Medicine, UEBMI … Urban Employee Basic Medical Insurance (China), UHC … Universal Health Coverage, UNDP … United Nations Development Programme, URBMI … Urban Resident Basic Medical Insurance (China), URRBMI … Urban Rural Resident Basic Medical Insurance (China), WHO … World Health Organisation



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