Regulatory and HTA landscape in Asia and Latin America:

How are regulatory and HTA aligning to ensure both availability and access to new medicines?

25th November & 9th December 2021

Workshop Report

CIRS Centre for Innovation in Regulatory Science

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Report details

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About CIRS

The Centre for Innovation in Regulatory Science (CIRS) is a neutral, independent UK-based subsidiary of Clarivate plc. CIRS' mission is to maintain a leadership role in identifying and applying scientific principles for the purpose of advancing regulatory and Health Technology Assessment (HTA) policies and processes. CIRS provides an international forum for industry, regulators, HTA and other healthcare stakeholders to meet, debate and develop regulatory and reimbursement policy through the innovative application of regulatory science. It is governed and operated by Clarivate for the sole support of its members' activities. The organisation has its own dedicated management and advisory boards, and its funding is derived from membership dues, related activities and grants.

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Section 1: Executive Summary

Background to the workshop

As regulatory systems mature with demand for new innovative treatments, jurisdictions are seeking to introduce more comprehensive healthcare systems; this is often accompanied by efforts to initiate health technology assessment (HTA) within countries. In 2014, member states of the World Health Organisation (WHO) passed a resolution that advised of the need to integrate concepts and processes of HTA into strategies for universal health coverage.

HTA is increasingly being used as a means of horizon scanning and determining access to health technologies including medical products. HTA could be seen as a bridge between the regulatory decision and coverage or reimbursement decision making, which countries need to make to ensure appropriate utilisation of healthcare resources.

HTA in many countries in Asia, Latin America, the Middle East and Africa is non-existent, and the role of procurers is key for the reimbursement of medicines. In some countries HTA is nascent and focused on specific priority areas e.g. Saudi Arabia, Vietnam, Indonesia. While some countries have more experience but are still in evolving e.g. Singapore, China, Malaysia, others have been established for some time e.g. South Korea, Taiwan, Thailand and Brazil. As countries develop their HTA systems, there is a wide range of international experiences to learn from.

As HTA evolves there need to be evaluation frameworks in which, as expected of regulatory review, the HTA process is predictable, transparent and follows good practices. In addition, as with regulatory performance, HTA processes should be timely, engage with stakeholders and publish performance metrics e.g. time of review, decision process, recommendations made. It is also important that the evidence generation standards and methodologies used during product development do not conflict even though regulatory approval and HTA assessment require independent assessment and evaluation processes.

As the regulatory and HTA landscape evolves within maturing markets, there is growing interest in how HTA will develop. Alignment between the regulatory process and HTA mechanism is important to ensure not just timely availability of new medicines but also access. The aim of this workshop was to provide a platform for discussion of the changing regulatory and HTA environment within maturing countries and the role of HTA and regulatory agencies.

Workshop objectives

- Discuss the current and future regulatory and HTA landscape within maturing jurisdictions and how or if these are aligned.
- Identify through case studies different models and maturity of systems within countries as well as the challenges and opportunities.
- Discuss what can be learnt across jurisdictions from the current initiatives to inform the future evolution of the regulatory-HTA landscape in maturing countries.

Venue/format

The workshop was held virtually over two days; attendees situated in Asia participated on 25th November 2021 while those situated in Latin America participated on 9th December 2021. This report provides an account of presentations and discussions from both days.

Workshop Programme

Affiliations are stated as they were at the time of the meeting.

25th November 2021 (Asia)

Session 1: The current regulatory and HTA landscape in maturing markets for the assessment of medicines: how is it changing and what are the considerations?	
CIRS welcome and introduction	**Anna Somuyiwa,** *Head, CIRS*
Session Chair introduction	**Prof Tracy Merlin,** *Chair, International Network of Agencies for Health Technology Assessment (INAHTA); Director, Adelaide Health Technology Assessment (AHTA); Head, School of Public Health, University of Adelaide, Australia*
A comparison of the regulatory and HTA systems in Asia by archetypes and taxonomies: what are the current models and how do these compare to mature systems/models?	**Dr Neil McAuslane,** *Director, CIRS*
Development of the HTA landscape in Asia for the assessment of new medicines: what are the needs, challenges and opportunities?	**Prof Brendon Kearney,** *Clinical Professor in the Faculty of Medicine, University of Adelaide, Australia*
How is the regulatory landscape in Asia evolving for the assessment of new medicines?	**Prof John Lim,** *Executive Director, Centre of Regulatory Excellence (CoRE), Duke-NUS Medical School and Senior Advisor, Ministry of Health, Singapore*
Good HTA practice: what needs to be considered and why is this important for maturing HTA agencies?	**Prof Finn Børlum Kristensen,** *Professor, Danish Centre for Health Economics, Faculty of Health Sciences, University of Southern Denmark*
Good HTA practice: how do companies perceive the evolution of HTA in Asia - what needs to be considered?	**Tania Krivasi,** *Market Access Lead, Singapore and Asia Area, AstraZeneca, Singapore*
Session 2: Aligning regulatory and HTA needs – what needs to be considered at a jurisdictional level?	
Session Chair introduction	**Adj Prof John Skerritt,** *Deputy Secretary for Health, Products Regulation, Department of Health, Australia*
Alignment between regulatory and HTA agencies in medicine assessment: what does this mean in practice and why is there a need?	
Mature country regulator/HTA perspective - UK Innovative Licensing and Access Pathway	**Dr Nick Crabb,** *Programme Director, Scientific Affairs, National Institute of Health and Care Excellence (NICE), UK* **Dr Daniel O'Connor,** *Medical Assessor,* Medicines *and Healthcare products Regulatory Agency (MHRA), UK*

Jurisdictional case studies – how are regulatory and HTA interactions/alignment evolving, what is occurring now and what are the future plans?	
Finding efficiencies with HTA processes - experience from Taiwan	**Dr Li-Ying Huang,** *Director, Division of Health Technology Assessment, Center for Drug Evaluation, Taiwan – Chinese Taipei*
What is HITAP's role in informing the reimbursement of medicines and does this include interactions between regulatory and the HTA? If not, what are the future considerations?	**Kanchanok Sirison,** *Project Associate, Health Intervention Technology Assessment Program (HITAP), Ministry of Public Health, Thailand*
HTA assessment in the Philippines: what are the key challenges faced and what interactions/alignment is there with the regulators and what changes may occur in the future?	**Marita Reyes,** *Chair, Health Technology Assessment Council, The Philippines*
The regulatory review and HTA assessment of a new medicine in Asia: the current experiences from companies and the implications for future alignment?	**Vicky Han,** *Head of Regulatory Policy & Intelligence for Asia Pacific, Janssen, Singapore*
Use of real-world data and evidence to support regulatory and reimbursement decision making in Asia: is this an area for coordination between regulators and HTA in Asia?	**Dr Raoh-Fang Pwu,** *Adjunct Assistant Professor Taipei Medical University, Taiwan*

Panel discussion - each panellist had 5 minutes to provide their thoughts on:

- **Reflections from the day and/or**
- **What can be learnt from current initiatives within their jurisdictions to inform the future evolution or direction of regulatory-HTA interactions in maturing countries.**
- **Recommendations of possible research for CIRS and other groups to undertake to support/inform/enable future regulatory-HTA interactions.**

European HTA agency perspective: Niklas Hedberg, *Chief Pharmacist, Dental and Pharmaceutical Benefits Agency (TLV), Sweden*

European regulator perspective: Michael Berntgen, *Head of the Evidence Generation Department, European Medicines Agency (EMA)*

Asia HTA agency perspective: Fiona Pearce, *Senior Adviser, Agency for Care Effectiveness (ACE), Ministry of Health, Singapore*

Company perspective: Junil Kim, *Director/Market Access Asia-Pacific, Bayer, Singapore*

Academic perspective: Prof Adrian Towse, *Emeritus Director and Senior Research Fellow. Office of Health Economics, UK*

9th December (Latin America)

Session 1: The current regulatory and HTA landscape in maturing markets for the assessment of medicines: how is it changing and what are the considerations?	
CIRS welcome and introduction	**Anna Somuyiwa,** *Head, CIRS*
Session Chair introduction	**Professor Hans-Georg Eichler,** *Consulting Physician, Association of Austrian Social Insurance Bodies, Austria*
A comparison of the regulatory and HTA systems in Latin America by archetypes and taxonomies: what are the current models and how do these compare to mature systems/models?	**Tina Wang,** *Senior Manager, HTA programme and Strategic Partnerships, CIRS*
Development of the HTA landscape in Latin America for the assessment of new medicines: what are the needs, challenges and opportunities?	**Dr Hector Castro,** *Head, LATAM Health Policy, Roche/Genentech, Colombia/USA*
How is the regulatory landscape in the Americas evolving for the assessment of new medicines?	**Dr Analía Porrás,** *Unit Chief, Medicines and Health Technologies, Health Systems and Services Department, Pan American Health Organisation/World Health Organisation, USA*
Good HTA practice: what needs to be considered and why is this important for maturing HTA agencies?	**Don Husereau,** *Adjunct Professor of Medicine, School of Epidemiology, Public Health and Preventive Medicine, University of Ottawa, Canada*
Good HTA practice: how do companies perceive the evolution of HTA in Asia - what needs to be considered?	**Dr Diego Guarin,** *Executive Director, Regional Market Access Latin America, Merck & Co, USA*
Session 2: Aligning regulatory and HTA needs – what needs to be considered at a jurisdictional level?	
Session Chair introduction	**Dr Sean Tunis,** *CEO, Rubix Health, USA*
Alignment between regulatory and HTA agencies in medicine assessment: what does this mean in practice and why is there a need?	
Mature country regulator/HTA perspective - Alignment in Canada's prescription drug chain: why is there a need and what are the implications?	**Dr John Patrick Stewart,** *Director General, Therapeutuc Products Directorate, Health Canada* **Suzanne McGurn,** *President and CEO,* Canadian *Agency for Drugs and Technologies in Health (CADTH)*
Jurisdictional case studies – how are regulatory and HTA interactions/alignment evolving, what is occurring now and what are the future plans?	
How is the regulatory interactions landscape changing in Brazil and does this include interactions between regulatory and HTA? If not, what are the future considerations?	**Gustavo Mendes Lima Santos,** *General Manager, Office of Medicines and Biological Products, Brazilian Health Surveillance Agency (ANVISA), Brazil*

HTA assessment in Colombia: what are the key challenges faced, what interactions/alignment is there with the medicines regulators and what changes may occur in the future?	**Dr Adriana María Robayo García**, *Executive Director, Institute of Health Technology Assessment (IETS), Colombia*
HTA assessment in Mexico: what are the key challenges faced, what interactions/alignment is there with the regulators and what changes may occur in the future?	**Dr María-Cristina Gutiérrez-Delgado,** *Faculty of Sciences, National Autonomous University (UNAM), Mexico*
Regulatory review and HTA assessment of a new medicine in Latin America: the current experiences from companies and the implications for future alignment	**Dr Karina Hansen**, *Head of Health Economics, Global Health Economics and Outcomes Research, AbbVie, France*
HTA and regulatory evidentiary requirements: where are the gaps and how can this be aligned? A case study on Mexico	**Dr María-Cristina Gutiérrez-Delgado,** *Faculty of Sciences, National Autonomous University (UNAM), Mexico*

Panel discussion - each panellist had 5 minutes to provide their thoughts on:

- **Reflections from the day and/or**
- **What can be learnt from current initiatives within their jurisdictions to inform the future evolution or direction of regulatory-HTA interactions in maturing countries.**
- **Recommendations of possible research for CIRS and other groups to undertake to support/inform/enable future regulatory-HTA interactions.**

Latin American HTA agency perspective: Prof Dr Andres Pichon-Riviere, *Director of HTA and Health Economics Department, Institute for Clinical Effectiveness and Health Policy, Argentina*

Company perspective: Cammilla Horta Gomes, *LATAM Regulatory Policy Lead, Roche, Brazil*

Academic perspective: Don Husereau, *School of Epidemiology, Public Health and Preventive Medicine, University of Ottawa, Canada*

Key points from presentations

Please note that the following summaries represent the views of the individual presenter and do not necessarily represent the position of the organisation they are affiliated with. Affiliations are stated as they were at the time of the meetings (25th November & 9th December 2021).

Session 1: The current regulatory and HTA landscape in maturing markets for the assessment of medicines: how is it changing and what are the considerations?

Tina Wang, *Senior Manager, HTA Programme and Strategic Partnerships, CIRS,* and **Dr Neil McAuslane,** *Director, CIRS,* presented the results of a CIRS study that systematically mapped regulatory and reimbursement systems in Asia and Latin America. This showed different levels of HTA involvement across the regions; four archetypes of regulatory-HTA system were identified in Asia and five in Latin America. The increasing regulatory and HTA interactions and collaborations that are occurring in Europe could have learnings for Asia and Latin America in relation to process, exchange of knowledge and information, early advice and life cycle management/pathways.

Prof Brendon Kearney, *Clinical Professor in the Faculty of Medicine, University of Adelaide, Australia,* gave an overview of the impact that COVID-19 was having on the regulatory-HTA landscape in Asia. Speed has been a key focus for approving COVID-19 products; most Asian countries have developed emergency pathways and, in many cases, bypassed the HTA process. Different models may need to be developed to support sustainability, such as rapid HTAs and emergency processes. Regulatory-HTA alignment and streamlining regulatory and reimbursement processes will be important for responding to future public health emergencies.

Dr Hector Castro, *Head, Latam Health Policy, Roche/Genentech, Colombia/USA,* spoke about the needs, challenges and opportunities for the HTA landscape in Latin America. HTA in Latin America is mainly being used post approval once the medicine is on the market, though this is changing. In 5-10 years, one can expect the HTA ecosystem to be stronger, broader in remit and mostly consist of country-based institutions. Regulatory and HTA systems are heavily connected and there are many opportunities to be more proactive, integrated and efficient.

Prof John Lim, *Executive Director, Duke-NUS Centre of Regulatory Excellence (CORE), and Senior Advisor, Ministry of Health, Singapore,* gave an overview of the evolving Asia Pacific regulatory landscape and possible lessons for the HTA space. As HTA faces challenges unique and somewhat distinct from regulation, examples from the regulatory experience need to be contextualised. The nature of HTA makes harmonisation, convergence and reliance harder compared to regulation, but cooperation and collaboration among HTA agencies is both possible and desirable to bring about greater development of the HTA ecosystem. As jurisdictions in the Asia Pacific develop their regulatory and HTA frameworks and draw from the pandemic experience, opportunities exist to explore synergies

Analia Porras, *Unit Chief, Medicines Health and Health Technologies, Pan American Health Organisation (PAHO),* gave an overview of the evolving Latin American regulatory landscape. Although the regulatory capacity of the region has improved considerably in the last decade, continued investment in regulatory system strengthening is needed. There are opportunities for interactions between HTA agencies and regulatory authorities in several areas: early dialogue, alignment of evidentiary needs, pre-market evaluation, parallel licensing and adaptive licensing.

Prof Finn Børlum Kristensen, *Professor of Health Services Research and HTA, University of Southern Denmark, and European Network for HTA (EUnetHTA) Lead 2006-2016,* spoke about good HTA practices and why these are important for maturing HTA agencies. Good practices have been developed in areas of assessment and defining HTA processes, however, are lacking in the organisational aspects of HTA, the use of deliberative processes and measuring the impact of HTA. Focus should be shifted

from producing guidance on HTA research practices to policy processes that ensure the output of assessment is brought into decision making.

Prof Don Husereau, *Adjunct Professor, School of Epidemiology and Public Health, University of Ottawa,* spoke about good HTA practices and why these are important for HTA agencies in Latin America. Good practices have been established for HTA assessment and some aspects of defining HTA processes including scoping. In Latin America, achieving consensus on the approach to HTA through good processes of deliberation is key; this requires capacity, mechanisms to reduce influence of interest groups, appropriate supporting structures and governance, and adherence to principles of deliberative democracy. Established HTA programmes should not necessarily be seen as exemplars, as documented deliberative processes for HTA are still evolving and are rarely observed in full operation.

Tania Krivasi, *Market Access Lead, Asia and Singapore, AstraZeneca,* gave a company perspective on what is needed to continue evolving HTA in Asia. As well as increasing capacity and capability, adaptive HTA pathways need to be developed to accommodate small biomarker-driven populations and rare diseases. Decision making must also be guided by all relevant stakeholders and multiple criteria, such as clinical, economic, social and scientific and other robust and relevant evidence, must be considered. It is essential that HTA is seen as a means to creating patient access rather than limiting access or serving cost containment objectives.

Dr Diego Guarin, *Executive Director, Regional Market Access - Latin America, Merck, USA,* gave a company perspective on what is needed to continue evolving HTA in Latin America. Continuous dialogue has allowed different stakeholders to share their perspectives and find common ground to improve how HTA is being implemented in Latin America. However, there are still opportunities to discuss specific issues at the country level given the wide diversity of health systems, HTA agencies and governance processes that limit the adoption of the recommendations made in regional meetings. As some countries progress faster than others in ensuring HTA is fit for purpose, more collaboration between stakeholders is needed to avoid leaving patients behind in countries with less technical and economic resources.

Session 2: Aligning regulatory and HTA needs – what needs to be considered at a jurisdictional level?

Dr Daniel O'Connor, *Medical Assessor, Licensing Division, Medicines and Healthcare products Regulatory Agency (MHRA), UK,* and **Dr Nick Crabb,** *Programme Director, Scientific Affairs, National Institute of Health and Care Excellence (NICE), UK,* spoke about the Innovative Licensing and Access Pathway (ILAP) in the UK, which is promoting system alignment between the MHRA, NICE, Scottish Medicines Consortium and All Wales Therapeutic and Toxicity Centre as well as early engagement with industry. Through ILAP, novel methods and tools have been developed that accelerate availability of robust data including the development of a specific roadmap tailored to the needs of each innovative product. It is hoped that ILAP can facilitate earlier decision making in the drug development paradigm.

Dr John Patrick Stewart, *Director General, Therapeutic Products Directorate, Health Canada,* and **Suzanne McGurn**, *President and CEO, CADTH, Canada,* described how regulatory-HTA alignment in Canada is helping to create efficiencies and maximise patient outcomes. Many players are involved in giving patients access to safe, high quality and efficacious products and there must be continued recognition of the independent and complementary roles each player has in this process. As more products move through the access process, it is important that patients, payers, manufacturers and clinicians have the information they need in order to understand these advances.

Dr Li Ying (Grace) Huang, *Director, Division of HTA, Center of Drug Evaluation, Taiwan,* gave an overview of HTA in Taiwan and where there may be opportunities for increased efficiency. Article 17-1 of the National Health Insurance Drug Dispensing and Fee Schedule aims to accelerate the process of reimbursement for local R&D products and keep their prices as high as feasible. Horizon scanning,

managed entry agreements and reassessments are being used to increase patients' access to new drugs. Future opportunities for HTA in Taiwan include regulatory-HTA collaboration, guidance on parallel consultation and parallel scientific advice.

Kanchanok Sirison, *Health Intervention Technology Assessment Programme (HITAP), Ministry of Public Health, Thailand,* described how the Health Intervention Technology Assessment Programme (HITAP) has been working to evolve the use of HTA in healthcare decision making in Thailand. Key focus areas include developing a fundamental system for HTA, strengthening capacity, HTA research and dissemination, knowledge management and building an HTA network. Future considerations for HTA in Thailand are the use of early HTA, life cycle management and real-world evidence in decision making.

Marita Tolentino-Reyes, *Chair, HTA Council (HTAC), Philippines,* gave an overview of HTA in the Philippines and the roles and interactions of its regulatory and HTA agencies. While the Philippines Food and Drug Administration (FDA) gives market approval to products, the HTAC generates evidence-based recommendations for health technologies to be financed by Department of Health and PhilHealth. Challenges between FDA and HTAC during the COVID-19 pandemic have been data/document sharing, unclear regulatory standards for some technologies, alignment of processes and overlapping responsibilities. HTAC plans to revisit the current HTA process, alter topic prioritisation and make governance and organisational changes in future.

Gustavo Mendes Lima Santos, *General Manager of Medicines and Biological Products, Brazilian Health Regulatory Agency (ANVISA),* spoke about the regulatory-HTA landscape in Brazil and how several trends are anticipated over the next ten years that present common challenges and opportunities to the Brazilian regulator and HTA agency. These include the use of digital tools and big data for decision making; stimulating patient engagement in regulatory and HTA actions; developing and stimulating the use of data modelling, simulation and extrapolation techniques; use of real-world data/evidence for regulatory and HTA purposes; and leveraging information to build scientific knowledge.

Adriana María Robayo García, *Executive Director, Institute of Health Technology Assessment (IETS), Colombia,* gave an overview of HTA in Colombia, which is carried out by IETS. IETS evaluates health technologies based on effectiveness, equity and budget impact and faces challenges including estimating the cost-effectiveness threshold, updating methodological manuals, incorporating equity into HTA and assessing the drug price regulation policy. In future, there may be changes such as a more systematic process for horizon scanning of health technologies, more automated real-world evidence and deliberative processes, and the development of methods for HTA of personalised medicines, digital technology and genomic therapies.

Dr María Cristina Gutiérrez Delgado, *Faculty of Sciences, National Autonomous University (UNAM), Mexico,* gave an overview of the HTA process in Mexico, which involves public institutions and the HTA agency, the National Centre of Technological Excellence in Health (CENETEC). Challenges faced in the HTA assessment are Mexico being part of multicentre clinical trials; lack of solid evidence on safety, efficacy and cost-effectiveness for the Mexican context; and that HTA results are not binding for public procurement. Potential changes to HTA in Mexico include the use of utility and quality of life measures, reviewing the use of GDP as the cost-effectiveness threshold and a migration towards multicriteria analysis.

Vicky Han, *Senior Director, Head of Asia Pacific Regulatory Policy and Intelligence, Global Regulatory Affairs, Janssen,* gave a company perspective on the regulatory and HTA landscapes in Asia and considerations for future alignment. Regulatory and HTA landscapes across Asia are dynamic and diverse, though there may be more development in the area of regulation than in HTA. Currently regulatory review and HTA assessment is sequential and there is a lack of coordination among government and company stakeholders in Asia. Therefore early engagement and a more synchronised

approach is needed between regulatory and HTA stakeholders in both government agencies and companies. Regular multi-stakeholder dialogue and communication is key to ensuring access.

Dr Karina Hansen, *Head of Health Economics, Global Health Economics and Outcomes Research, Abbvie,* gave a company perspective on the regulatory and HTA landscapes in Latin America and considerations for future alignment. The value assessment must not compromise the breadth or speed of access to appropriate treatment and there must be a broad recognition of value going beyond clinical outcomes. The input of relevant stakeholders, including patients, caregivers, clinicians, payers and industry, should be included early on and continue with meaningful involvement. In addition, HTA systems should be independent from coverage and reimbursement determinations.

Raoh-Fang (Jasmine) Pwu, *Director, Taiwan National Hepatitis C Program Office, Ministry of Health and Welfare, Taiwan, and Adjunct Associate Professor, Taipei Medical University,* spoke about real-world evidence (RWE) in decision making in Asia and whether this may be an area for coordination between regulatory and HTA agencies. It is not necessary for Asian agencies to make decisions early (earlier than the EU or US), or to make decisions entirely based on local evidence and context. Gaps and challenges exist to be able to use RWE to make decisions, including capability to excel in methodologies, long capacity building period and difficulties to build a trustworthy information system. Regulatory and HTA agencies in Asia must acknowledge the need to reform and re-structure the responsibility of using RWE.

Dr María Cristina Gutiérrez Delgado, *Faculty of Sciences, National Autonomous University (UNAM), Mexico,* described a collaborative study between public, academic and private stakeholders in Mexico that generated the first social value set representing the stated preferences of the Mexican adult population. The resulting social value set will strengthen the HTA process in Mexico and allow international comparisons of results at the quality-adjusted life year level.

Panel discussions

Panellists representing industry, regulatory agencies, HTA agencies and academics were asked to provide their thoughts on what can be learnt from current initiatives within their jurisdictions to inform the future evolution or direction of the regulatory-HTA interactions in Asia and Latin America. A graphical summary of key points from this discussion can be found on the following page, with further detail provided on p56-58.

Summary of panel discussions

Stakeholder reflections on the evolution of regulatory and HTA systems in Asia/Latin America and potential learnings from Europe

Academic

For HTA recommendations to be adopted, there needs to be a clear decision maker at the end of the HTA process.

HTA

To improve regulatory-HTA interactions, HTA agencies need to be strengthened and the HTA process must be institutionalised within each country.

Regulator/HTA

Joint work of the EMA and EUnetHTA cooperation has been the foundation for establishing mutual trust and understanding between regulators and HTA agencies in Europe.

HTA

There is a need to build HTA capability in some countries, not just within agencies but also within companies who often do not have technical staff locally.

Academic

Collaborations must have clear objectives, avoid duplication and work towards supporting best practices.

Industry

Companies should position themselves as healthcare partners to help make health systems more resilient.

HTA

While there have been great advances in the regulatory environment, this has not happened for HTA.

Industry

There is a need for greater stakeholder engagement including engaging with patients.

Regulator/HTA

EUnetHTA21 will build on achievements and learnings from EUnetHTA and deliver joint HTA assessments to support the EU cooperation on HTA.

Industry

Companies are increasingly focusing on sustainability goals, giving an opportunity for all stakeholders to work together to support sustainable patient access.

HTA

RWE plays a key role in addressing evidence gaps due the lack of RCTs conducted in Asia and genetic differences that mean results cannot be generalised to Asian populations.

Industry

There are ongoing efforts to make HTA systems in Asia more systematic and transparent.

Section 2: Presentations

Please note that the following presentation summaries represent the views of the individual presenters and do not necessarily represent the position of the organisation they are affiliated with.

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Session 1: The current regulatory and HTA landscape in maturing markets for the assessment of medicines: how is it changing and what are the considerations?

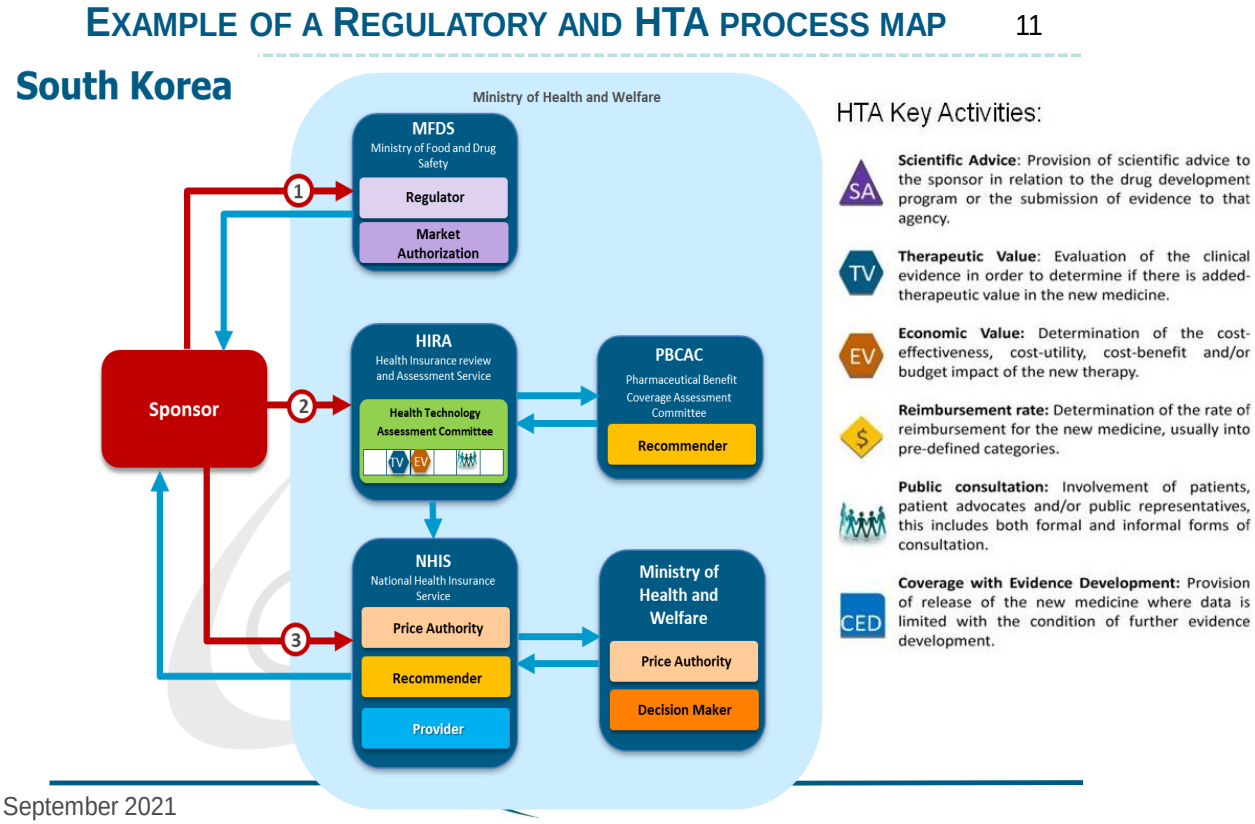
Archetypes and taxonomies of the regulatory and HTA systems in Asia and Latin America: what are the current models and how do they compare to mature system models?

Tina Wang, *Senior Manager, HTA Programme and Strategic Partnerships, CIRS,* and **Dr Neil McAuslane,** *Director, CIRS*

The aims of the CIRS HTA research programme are to advance interaction between regulatory and agencies and to improve understanding of HTA and coverage processes as well as decision making. As HTA agencies evolve across Asia and Latin America, there is a need to map where HTA sits in each health system and the type of HTA that is being conducted. Therefore CIRS conducted a systematic mapping exercise of the regulatory/HTA landscapes of Asia and Latin America to provide a baseline for assessing future changes.

Mapping methodology

CIRS has developed a systematic methodology to map regulatory and reimbursement pathways and facilitate comparisons of different health systems [1]. Once the different organisations involved in the health system have been identified, the core functions of each organisation and key HTA activities are mapped (see example below). To maximise comparability of the maps, the scope of the methodology is limited to regulatory and reimbursement processes for the review of new active substances (NAS). The methodology has now been applied to over 75 jurisdictions and the generated maps are available in the CIRS Regulatory and Reimbursement Atlas [2].



Archetypes of regulatory/HTA systems in Asia and Latin America

Comparing regulatory and reimbursement decision making processes from the process maps has allowed two sets of taxonomy to be developed: the system taxonomy and HTA taxonomy [3]. The system taxonomy focuses on the position of the HTA agency within the national reimbursement system according to the relationship between the regulator, HTA agency and reimbursement decision-making coverage body [3]. The system taxonomy set contains four groups including HTA and a fifth group for systems that use external HTA. The HTA taxonomy set focuses on the relationship between the HTA appraisal, therapeutic assessment and economic evaluation, if present.

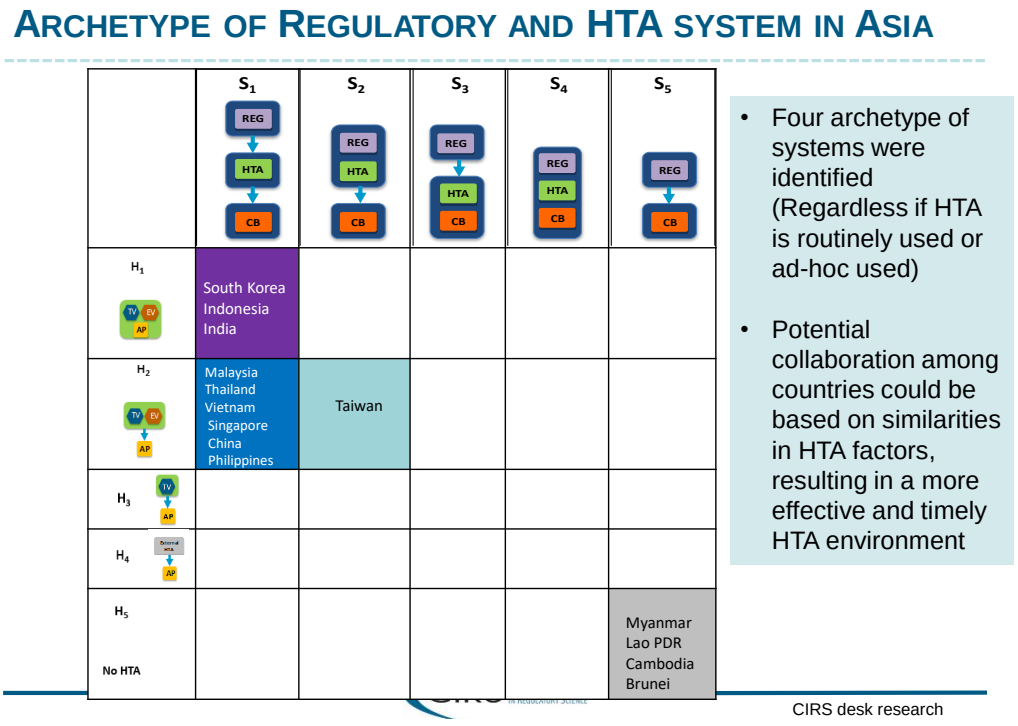
CIRS applied these taxonomies to the process maps for countries in Asia and Latin America and identified four and five archetypes, respectively (see below). Potential collaboration among countries could be based on similarities in HTA factors.

Landscape changes in the EU

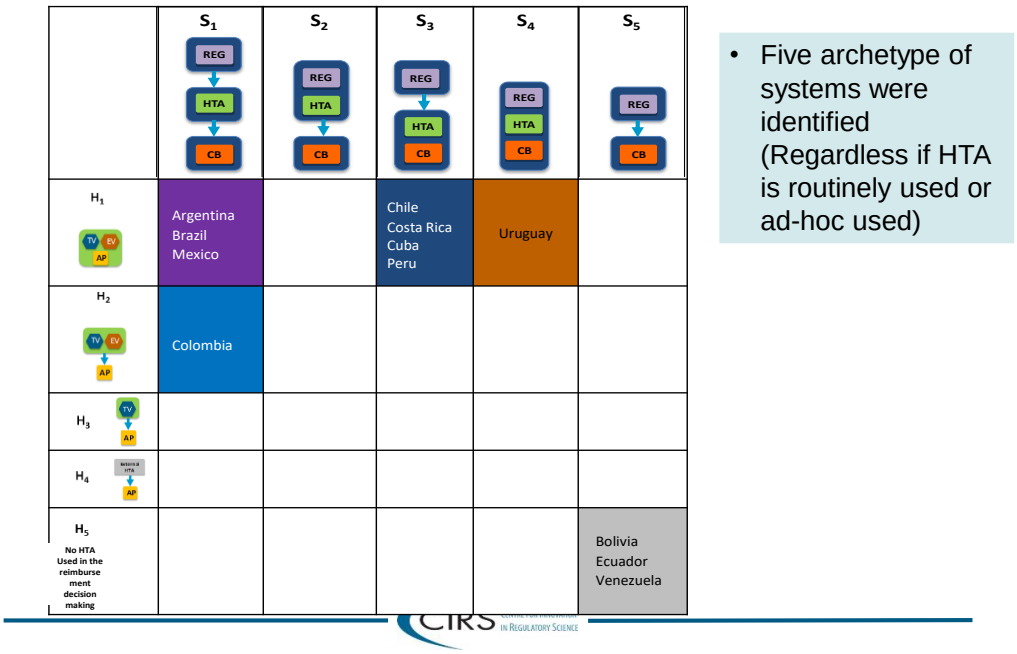
The regulatory and HTA landscape in Europe, although more mature, is also evolving, which could have useful learnings for Asia and Latin America. For example, regulatory-HTA alignment is increasing in the Netherlands with the introduction of regulatory-HTA parallel review and the work of EUnetHTA has led to more reliance on multiple HTA joint assessments. Different types of early advice have emerged, e.g. joint regulatory/HTA advice, national HTA advice, multiple HTA advice, as well as new lifecycle pathways e.g. the Innovative Licensing and Access Pathway (ILAP) in the UK.

Summary

CIRS conducted systematic mapping of regulatory and reimbursement systems in Asia and Latin America, which showed different levels of HTA involvement. Four archetypes of regulatory-HTA system were identified in Asia and five in Latin America. Increasing regulatory and HTA interactions and collaborations are occurring in Europe, which could have learnings for Asia and Latin America in relation to process, exchange of knowledge and information, early advice and life cycle management/pathways.



ARCHETYPE OF REGULATORY AND HTA SYSTEM IN LATAM



- Five archetype of systems were identified (Regardless if HTA is routinely used or ad-hoc used)

References

[1] CIRS. R&D Briefing 63 – HTA Process Maps: Identifying Similarities and Differences for Alignment. Centre for Innovation in Regulatory Science (CIRS), London, UK. 2017. Accessed 24th May 2022 at: https://cirsci.org/publications/cirs-rd-briefing-63-hta-process-maps/

[2] CIRS. Regulatory and Reimbursement Atlas. Accessed 24th May 2022 at: https://cirsci.org/atlas/

[3] Allen N, Pichler F, Wang T, Patel S, Salek S. Development of archetypes for non-ranking classification and comparison of European National Health Technology Assessment systems. Health Policy. 2013;113(3):305-312. doi:10.1016/j.healthpol.2013.09.007

Development of the HTA landscape in Asia for the assessment of new medicines: what are the needs, challenges and opportunities?

Impact of the COVID-19 pandemic

Prof Brendon Kearney, *Clinical Professor in the Faculty of Medicine, University of Adelaide, Australia*

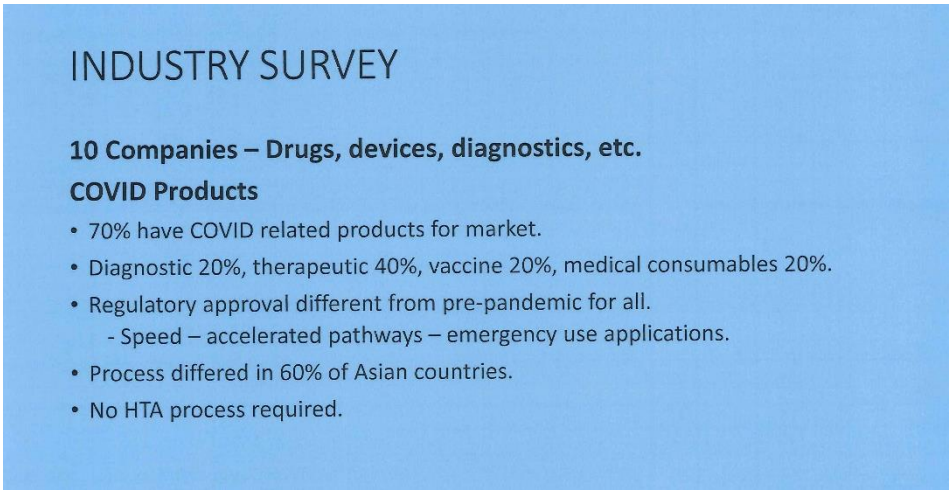
The COVID-19 pandemic has significantly disrupted health services in Asia, causing reductions in staff availability, outpatient volume and inpatient volume. One of the key lessons learned early in the first wave of COVID-19 infections was the importance of social distancing; although an essential public health response, this had a dramatic impact on access to health services.

Towards the end of 2020, countries in Asia experienced a second wave of infections. This was quickly met with the availability of vaccines, which were developed in an unprecedented amount of time (less than 12 months). Soon it was possible to show that people who died or were hospitalised were mainly those who were unvaccinated.

The COVID-19 virus then changed and become more infectious; the Delta variant became globally dominant and dramatically increased the number of cases per population as well as the death rate, particularly in unvaccinated people. As Asia and the rest of the world are currently entering a third wave of infections, there is increasing focus on treatments for COVID-19, including monoclonal antibodies, antivirals and immune modulators, in addition to booster doses of vaccines.

A study involving 10 companies that are active in Asia showed that 70% have COVID-19 products on the market, with the experience of regulatory approval and reimbursement for these products being different to pre-pandemic experiences (see below). Speed has been key, with most Asian regulatory agencies developing and using accelerated pathways or emergency use applications, and HTA processes being bypassed. In contrast, for non-COVID-19 products, the same pre-pandemic regulatory and HTA processes have applied but operated at a much slower rate. While priority is being given to COVID-19 products, the implementation of new non-COVID-19 related technologies is being delayed.

In summary, COVID-19 is challenging the sustainability of traditional healthcare systems. Speed has been a key focus for approving COVID-19 products; most Asian countries have developed emergency pathways and, in many cases, bypassed the HTA process. Different models may need to be developed to support sustainability, such as rapid HTAs and emergency processes. Regulatory-HTA alignment and streamlining regulatory and reimbursement processes will be important for responding to future public health emergencies.



Regulatory and HTA landscape in Latin America – what are the needs, challenges and opportunities?

Dr Hector Castro, *Head, Latam Health Policy, Roche/Genentech, Colombia/USA*

Decision making in healthcare is a complex process taking place along a continuum that moves from evidence generation, deliberation and communication of the decisions made. In many low- and middle-income countries (LMICs) around the world, including in Latin America, this process is not often systematic, deliberative or transparent.

HTA landscape in Latin America

The importance of HTA is increasing across Latin America, though different countries are at different stages of HTA development. While some countries have little or no awareness of HTA as a policy solution, others are close to establishing national HTA agencies e.g. Chile and Peru or have already established national HTA agencies e.g. Argentina and Mexico. Only a few mature HTA systems that inform value-based healthcare exist in Latin America e.g. Brazil and Colombia.

Barriers to establishing HTA include lack of financial support, policy/political support, local capacity, data quality and implementation strategy (see below). For example, in Colombia, major policy changes over the last decade have boosted HTA development and local policy support from governmental institutions have granted funding for HTA work for capacity building [1].

HTA can be used for many different purposes, from priority setting to purchasing decisions to quality improvement. In Latin America, HTA has been mostly used to inform benefit packages. While there is growing interest in using HTA to inform purchasing for procuring vaccines and in delisting or disinvesting in technologies, there has been limited use for quality improvement such as establishing quality outcome frameworks or pay for performance mechanisms.

HTA harmonisation and collaboration

Collaboration between HTA agencies in Latin America is currently very limited, however, there have been regional efforts for HTA harmonisation through the HTA Network of the Americas (RedETSA). RedESTA has been working to strengthen local HTA capacities, establish an inventory of regional capabilities and facilitate information sharing.

In 2020, an international joint task group co-led by the International Network of Agencies for Health Technology Assessment (INAHTA) and Health Technology Assessment International (HTAi) published a new and internationally accepted definition of HTA [2]. However, outdated definitions of HTA are still being used in some Latin American countries. Therefore, there is need within the region to advance and evolve the definition and application of HTA as per current international standards and best practices.

There have been also some global efforts to advance the institutionalisation of HTA in many LMICs. A roadmap for establishing HTA in LMICs has been developed, which outlines opportunities to align the processes of national regulators and HTA mechanisms [2].

Regulatory-HTA alignment

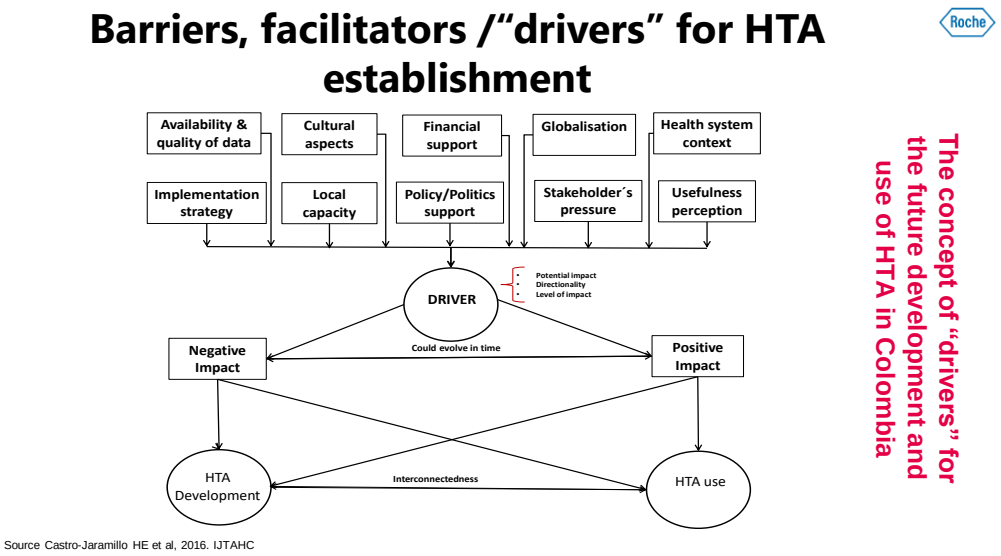
Currently HTA is conducted in most Latin American countries after regulatory approval. However this is changing in some countries, such as Brazil and Colombia, with efforts to promote regulatory-HTA alignment and therefore make pricing decisions closer to regulatory approval. While there have been attempts to mimic value-based market access models used in Europe, such as in Germany and France,

the process has been too narrow and lacked stages of the full life cycle approach including horizon scanning, early dialogues, full negotiations, or the use of real-world evidence.

There may be opportunities for HTA agencies to align and leverage information from regulators, for example, from early research into the innovation, or from information already submitted via the dossier that could be used in the HTA decision-making process. Reliance in HTA is not common practice, however, there could be an opportunity to explore a 'core' regional model similar to the EU.

Summary

HTA in Latin America is mainly being used post approval once the medicine is on the market, though this is changing. In 5-10 years, one can expect the HTA ecosystem to be stronger, broader in remit and mostly consist of country-based institutions. Regulatory and HTA systems are heavily connected and there are many opportunities to be more proactive, integrated and efficient.



Source Castro-Jaramillo HE et al, 2016. IJTAHC

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The evolving Asia Pacific regulatory landscape for assessment of new medicines – possible lessons for the HTA space

Prof John Lim, *Executive Director, Duke-NUS Centre of Regulatory Excellence (CORE), and Senior Advisor, Ministry of Health, Singapore*

Across the Asia Pacific region, there are wide disparities in regulatory systems, with economies like Australia, Japan, Singapore and South Korea having significantly more developed systems. Regulatory agencies within the Association of South-East Asian Nations (ASEAN) tend to have staff strengths ranging from 30 to 300 people who are responsible for the full spectrum of pre- and post-marketing activities. Economic disparities among member states result in large differences in healthcare spending, which in turn affects healthcare outcomes.

Key challenges in the Asia Pacific

There are three key challenges facing the medicines regulatory landscape in the Asia Pacific: insufficient regulatory knowledge and capacity, fragmentation in terms of national regulatory requirements and a lack of regulatory science and policy innovation [1]. While these challenges largely apply to national regulatory agencies and systems, lack of regulatory professional capability and knowledge is also an industry issue. Regulatory cooperation is a key solution to these challenges. Although significant achievements have been made, there is still a need for more convergence and harmonisation and to go beyond information sharing to work sharing, reliance and recognition models.

Regulatory cooperation vs HTA cooperation

The factors that influence cooperation between regulators are fundamentally different to factors influencing cooperation between HTA agencies. Health products regulation is largely associated with intrinsic factors within the health products themselves, which facilitates alignment of assessment criteria and considerations across jurisdictions. Compared to HTA agencies, it is relatively easier for regulators to create international and regional platforms for collaboration and work sharing, to directly draw on and reference international efforts and best practices of trusted reference agencies, and to coordinate and support one another in training and capacity building. While resource factors affect regulatory capacity, the social, cultural, economic, political factors that influence HTA decision making have less direct impact on the regulatory assessment and decision-making process because this is largely anchored on intrinsic product safety, efficacy and quality.

Regional HTA collaboration issues

Promoting HTA harmonisation, convergence and reliance is comparatively harder than for health products regulation, as HTA requires both the direct and indirect impact of a health technology to be assessed and different jurisdictions may look at different parameters. Even where parameters are the same, weights may differ due to different socio-cultural-economic-political considerations. Nevertheless, collaboration and coordination are feasible in areas such as capacity building for skillsets to create a HTA framework or perform HTA assessments.

Opportunities for alignment and extrapolating between regulatory and HTA

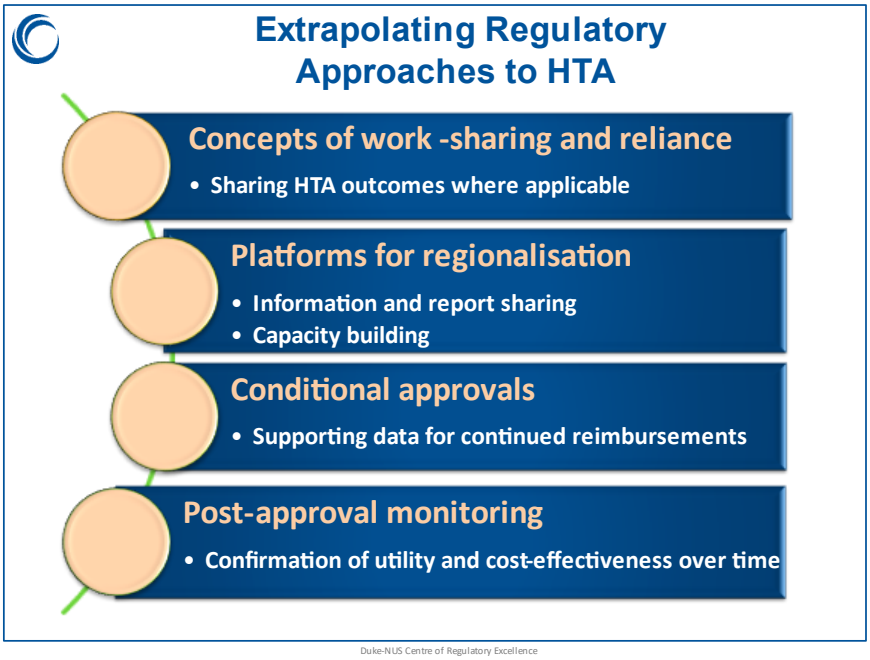
While parallel reviews can take place without formal interaction between regulatory and HTA agencies, coordination would reduce duplication and better align assessed parameters, such as primary and surrogate endpoints. Coordination and collaboration between regulatory and HTA agencies could also present opportunities related to the collection of real-world data, conditional approvals and post-approval monitoring. In addition, there may be other opportunities arising from changed healthcare priorities and regulatory agilities from the COVID-19 pandemic and the increasing focus on regional patient

engagement and patient-centric initiatives. The fact that national and regional regulatory and HTA agencies engage common stakeholders and have common understanding of local culture, medical needs and healthcare systems should also give greater opportunity for alignment.

Regulatory concepts of work sharing and reliance could be extrapolated to HTA, as well as the use of regionalisation platforms for information sharing and capacity building. Although regulatory and HTA systems are different, there may also be opportunities for them to work together to share data from conditional approvals and post-approval monitoring (see below).

Conclusion

Experience from health products regulation has demonstrated that cooperation and collaboration can bring benefits and overcome challenges, with trust being a key enabler. As HTA faces challenges unique and somewhat distinct from regulation, examples from the regulatory experience need to be contextualised. Although the nature of HTA makes harmonisation, convergence and reliance harder compared to regulation, cooperation and collaboration among HTA agencies is both possible and desirable to bring about greater development of the HTA ecosystem. As jurisdictions in the Asia Pacific develop their regulatory and HTA frameworks and draw from the pandemic experience, opportunities exist to explore synergies; this should be proactively encouraged for the benefit of patients and populations.



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How is the regulatory landscape in the Americas evolving for the assessment of new medicines and what does the future ecosystem look like?

Analia Porras, *Unit Chief, Medicines Health and Health Technologies, Pan American Health Organisation (PAHO)*

A stable, well-functioning and integrated national regulatory system is underpinned by a series of key principles: independence, equity, transparency, ethics, code of conduct, no conflict of interest, risk management, accountability and regulatory science. For essential regulatory functions to operate, legal bases, standards, resources, quality assurance, workforce and an information system need to be in place.

Regulatory landscape in Latin America

A recent PAHO study examined the processes and practices of national regulatory authorities (NRAs) in Latin America to better understand the regulatory landscape of the region and highlight opportunities for regulatory strengthening [1]. The findings demonstrated that the greater the NRA's prominence was within its health system, the stronger the NRA's regulatory capacity tended to be. There were varying levels of legal and organisational structures for regulating medicines across the region, with 23% countries having highly comprehensive frameworks and 20% having none at all.

Prior to the COVID-19 pandemic, Latin America was predicted to be one of the fastest growing regions in the pharmaceutical market, with a predicted growth of 7% from 2018-2023 [1]. Relatively low levels of generic penetration in reference NRA markets compared to others outside of Latin America suggest that there are opportunities to increase the uptake of safe, quality and effective generic products, which may help to encourage competition and reduce prices.

Latin America has eight reference NRAs, which cover 82% of the population of the region, but only represent 23% of NRAs [1]. Most of these reference NRAs actively participate in international harmonisation activities, which have helped to promote convergence amongst them. Although the eight reference NRAs have invested significant time and human resources in improving their capacities, their budgets have remained relatively static over the past five years. As their resources are mostly invested in pre-market to market entry functions, the reference NRAs are not as advanced in the post-marketing and surveillance space compared to other international reference NRAs.

Opportunities for reliance

NRAs in Latin America need to become more efficient with the limited resources that they have. Reliance and work sharing are key to this; NRAs need to make risk-based decisions and follow reliance principles to develop legal frameworks and regulatory practices. Industry can play a critical role and contribute to regulatory efficiencies by embracing transparency and enabling information sharing amongst NRAs.

HTA in Latin America

HTA is evolving across Latin America, through the support of PAHO and the HTA Network of the Americas (RedESTA). While 63% of countries have a body that coordinates HTA to support decision making for the incorporation of health technologies, only 27.8% have an established prioritisation process to define which health technologies are evaluated. Key challenges and limitations to the use of HTA in the region include knowledge on the relevance of HTA, institutionalisation of HTA, qualified human resources, mandate of public authorities and political support.

Potential interactions between HTA bodies and NRAs could focus on improving understanding and clarifying expectations (early dialogue), harmonising evidentiary requirements and establishing a coherent

policy framework to create a common understanding of what is required upstream of generating evidence for regulatory and payer assessment. In addition, parallel licensing and adaptive licensing are also important areas for NRAs and HTA bodies to collaborate on.

Summary

Prior to the COVID-19 pandemic, Latin America was predicted to be one of the fastest growing regions in the pharmaceutical market. Although the regulatory capacity of the region has improved considerably in the last decade, continued investment in regulatory system strengthening (RSS) is needed. There are opportunities for interactions between HTA bodies and regulatory authorities in several areas: early dialogue, alignment of evidentiary needs, pre-market evaluation, parallel licensing and adaptive licensing.

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Good HTA practice – what needs to be considered and why is this important for maturing HTA agencies?

Prof Finn Børlum Kristensen, *Professor of Health Services Research and HTA, University of Southern Denmark, and European Network for HTA (EUnetHTA) Lead 2006-2016*

HTA is globally defined as a "multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its life cycle" [1]. The purpose is to inform decision making to promote an equitable, efficient, and high-quality health system. The overall value may vary depending on the perspective taken, the stakeholders involved, and the decision context.

HTA components within the healthcare decision-making process

HTA informs policy-making decisions and HTA processes occur in parallel with those decision-making steps (see below). Learnings from EUnetHTA on developing joint scientific and technical work and joint clinical assessment demonstrate that framing and scoping are very important in determining the role of the HTA, the key questions to answer and the output required to support the decision maker. Key questions relate to the population, intervention, comparator and outcome. Comparator can be a challenge for HTA work across jurisdictions because each jurisdiction may not have the same current technologies available, so clarification of the comparator is important.

For the HTA assessment, there are well-defined guidelines on the identification and interpretation of research, as well as standards/checklists for researchers. Peer review of HTA research and the use of experts or expert panels are also valuable tools during assessment.

Contextualisation is where the output of the scientific assessment is taken into an appraisal process and is translated into the consequences of implementing the technology on the specific health system. There are several methods and approaches that can be applied, such as committee work, deliberative processes, voting rules, weighing or nominal group techniques. It may also be important to understand how HTA from other jurisdictions can be adapted and how budget impact should be considered. Contextualisation is an area where the HTA community needs to have more clarity and alignment about what requirements should be.

Moving towards constructive HTA processes

The move to early dialogue and scientific advice on evidence generation can be seen as advancement toward more constructive HTA processes, where alignment between patients, payers, regulators, and technology producers is created through shared information requirements and collaborative planning [2]. Transparency and good governance are key to such multi-stakeholder cooperation and collaboration.

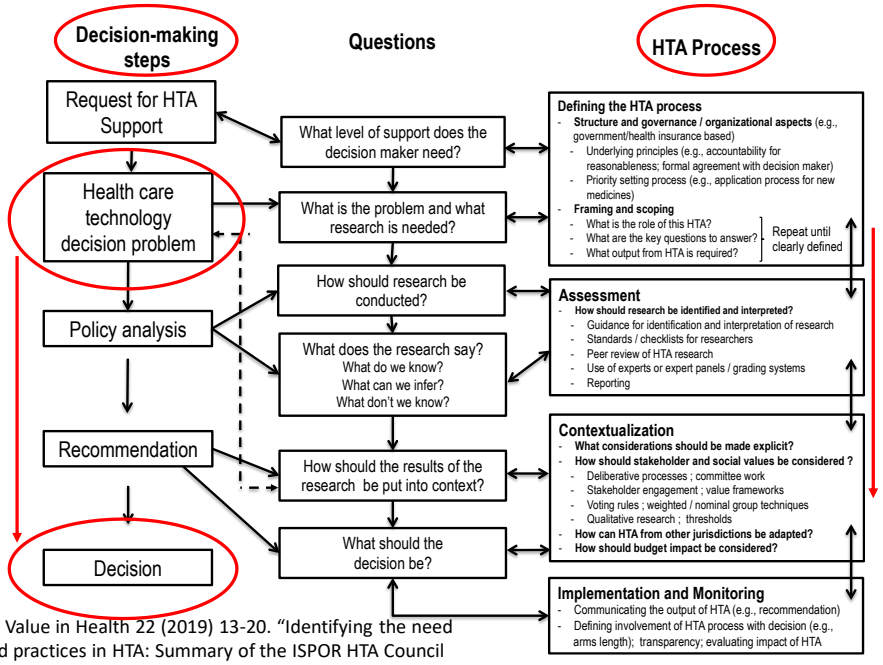
Good HTA practices

Findings from the Professional Society for Health Economics and Outcomes Research (ISPOR) HTA Council Working Group suggest that although good practices have been developed in many areas of assessment and some aspects of defining HTA processes, there are also many areas where good practices are lacking. This includes good practices on governance, defining the organisational aspects of HTA, the use of deliberative processes and measuring the impact of HTA. Rather than focusing on guidance production for HTA research practices e.g. evidence review and synthesis, outcomes research and health economics, there is a need to focus on developing good practices in using evidence to support decision making through monitoring of HTA implementation and its input in various types of decision making.

Summary

Key steps of the HTA process are defining the process, assessment, contextualisation, implementation and monitoring. Good practices have been developed in areas of assessment and defining HTA processes, however, are lacking in the organisational aspects of HTA, the use of deliberative processes and measuring the impact of HTA. Focus should be shifted from producing guidance on HTA research practices to policy processes that ensure the output of assessment is brought into decision making.

Components of HTA within the healthcare decision-making process



Source: Value in Health 22 (2019) 13-20. "Identifying the need for good practices in HTA: Summary of the ISPOR HTA Council Working Group Report".

Finn Børlum Kristensen | Science & Policy | www.scienceandpolicy.dk

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Good HTA practice – what needs to be considered and why is this important for maturing HTA agencies?

Prof Don Husereau, *Adjunct Professor, School of Epidemiology and Public Health, University of Ottawa*

HTA processes are divided into several stages, beginning with defining the HTA process. This considers the accountability and organisational structure of the HTA process, its budget, how it informs decisions, what technologies are assessed, and its relationship to the decision making. The next stage is the HTA assessment itself, where it is key to define how the research will be conducted, by whom and the standards and guidance to be adhered to. After the assessment, contextualisation takes place; this is often called 'appraisal' and helps to put the research results into the local context by considering stakeholder and social values as well as budget impact. The final step of the HTA process is implementation and monitoring, which involves communicating the outputs of HTA and evaluating the impact of HTA.

Good HTA practices

A review commissioned by the Professional Society for Health Economics and Outcomes Research (ISPOR) HTA Council showed that good practices have been developed in many areas of HTA assessment and some aspects of defining HTA processes, such as priority setting and framing/scoping [1]. However, there are several areas in which good practices are lacking, including structure, governance or organisational aspects, the use of deliberative processes and measuring the impact of HTA.

Deliberative processes for HTA

Deliberation in HTA is the informed and critical examination of an issue and the weighing of arguments and evidence to guide a subsequent decision. It can be used to define the HTA process as well as to achieve consensus on methods of assessment, contextualisation and implementation and monitoring. Deliberation is applicable to all stages of HTA, from the identification of topics all the way to monitoring and evaluation. It presents an opportunity for participatory decision making, which can enhance the legitimacy and acceptance of HTA.

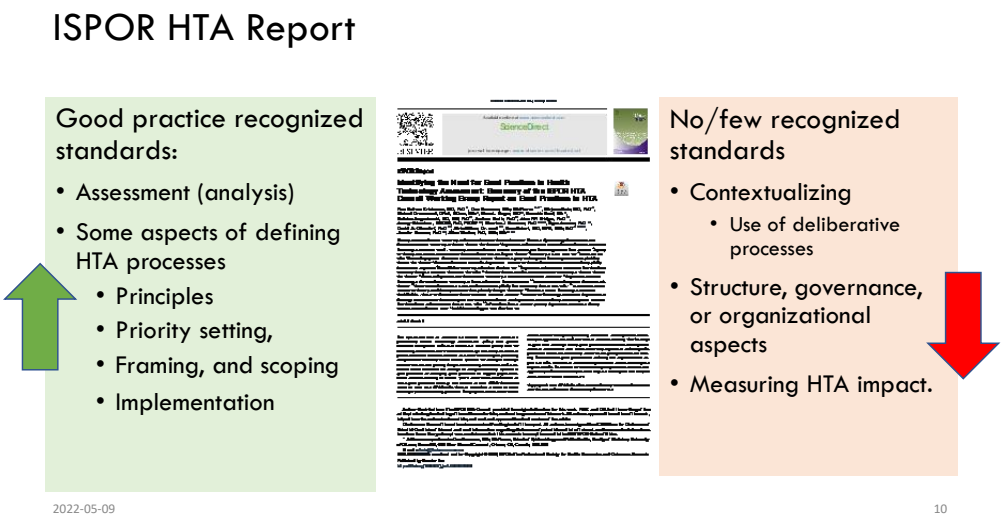
Opportunities for Latin America

A survey of Latin American countries highlighted strong preferences for a future of transparent timelines and HTA recommendations [2]; this could be achieved by improving deliberative processes. Mechanisms to manage stakeholder influence are key, as there is a concern that certain stakeholders in Latin America, such as politicians, ministers of finance, industry, patients and care providers, have an excessive influence on setting the agenda for prioritisation of technologies to be assessed [3]. There may be greater opportunity for change in countries in earlier stages of developing HTA systems than those with established institutions and processes.

In addition to deliberative processes for HTA, there are opportunities for Latin America to have greater regulatory-HTA alignment, parallel HTA/collaborative review and to increase the scope of HTA, for example to inform quality improvement and care pathways. There could also be an opportunity for early scientific advice, though this would need to be carefully coordinated and may not be as feasible or impactful in Latin America compared to other regions.

Summary

Good practices have been established for HTA assessment and some aspects of defining HTA processes including scoping. In Latin America, achieving consensus on the approach to HTA through good processes of deliberation is key; this requires capacity, mechanisms to reduce influence of interest groups, appropriate supporting structures and governance, and adherence to principles of deliberative democracy. Established HTA programmes should not necessarily be seen as exemplars, as documented deliberative processes for HTA are still evolving and are rarely observed in full operation.



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Good HTA practice: how do companies perceive the evolution of HTA in Asia - what needs to be considered?

Tania Krivasi, *Market Access Lead, Asia and Singapore, AstraZeneca*

HTA is becoming more established across Asia, though there are still varying levels of HTA maturity between jurisdictions. For example, India and the Philippines have made progress towards HTA implementation but do not yet have established systems. Countries such as Vietnam, Indonesia, Malaysia and Singapore have experience in HTA assessments to inform resource allocation but with varying levels of influence and rigour. In contrast, Thailand, Taiwan and South Korea have established and robust HTA systems that have high influence on public funding decisions.

HTA and decision-making criteria

Decision-making criteria must be aligned and linked to HTA, and the metrics used should not be limited to only single and cost-based only metrics. For example, single cost per quality-adjusted life year (QALY) thresholds, which are applied regardless of the disease area or patient population, can be seen as tools for limiting reimbursement or creating price pressure rather than a means of creating access.

Within HTA, there should be recognition of the value of different perspectives including the patient perspective. This is particularly important in countries with mixed pay systems where patients are making co-payments. If used, willingness-to-pay thresholds should have a degree of flexibility based on different predetermined criteria. This will help to allow for value-based solutions for coverage decisions that can address uncertainty.

HTA processes and methods

A key issue in HTA processes across the Asia region is lack of stakeholder engagement, including with industry, specialist healthcare professionals and patient advocacy groups. In addition, horizon scanning, prioritisation and assessment discussions are not broadly communicated and HTA processes can be long and initiated too late.

Good HTA practice is to have transparent methodologies and processes, starting from horizon scanning to prioritisation, as well as from assessment to evaluation or appraisal. Broad stakeholder involvement should also be integrated into HTA processes. In addition, there may be opportunities for HTA agencies to leverage clinical evaluations that have been conducted by regulators and to potentially start the HTA process earlier, such as through company-led submissions.

Capacity, capability and data availability

The diversity of healthcare systems in Asia means a one-size-fits-all approach to HTA institutionalisation is not feasible. In addition, many countries have issues with capacity and back logs due to the COVID-19 pandemic. While there have been advances in some markets e.g. company-led submissions in Singapore, applying sophisticated HTA processes to all new technologies may not be practical, particularly in markets with a lack of academic infrastructure to support the HTA agency. Therefore HTA implementation roadmaps from similar sized and resourced countries may be more relevant and useful than sophisticated frameworks based on mature HTA systems.

In addition to HTA at the ‘macro level’, there could be local level HTA depending on where the technology is going to be implemented i.e. in the hospital or community. There are also opportunities for more Association of Southeast Asian Nations (ASEAN) collaborations, which could work similarly to the European Network of HTA (EUnetHTA) model, to increase efficiencies and evaluations.

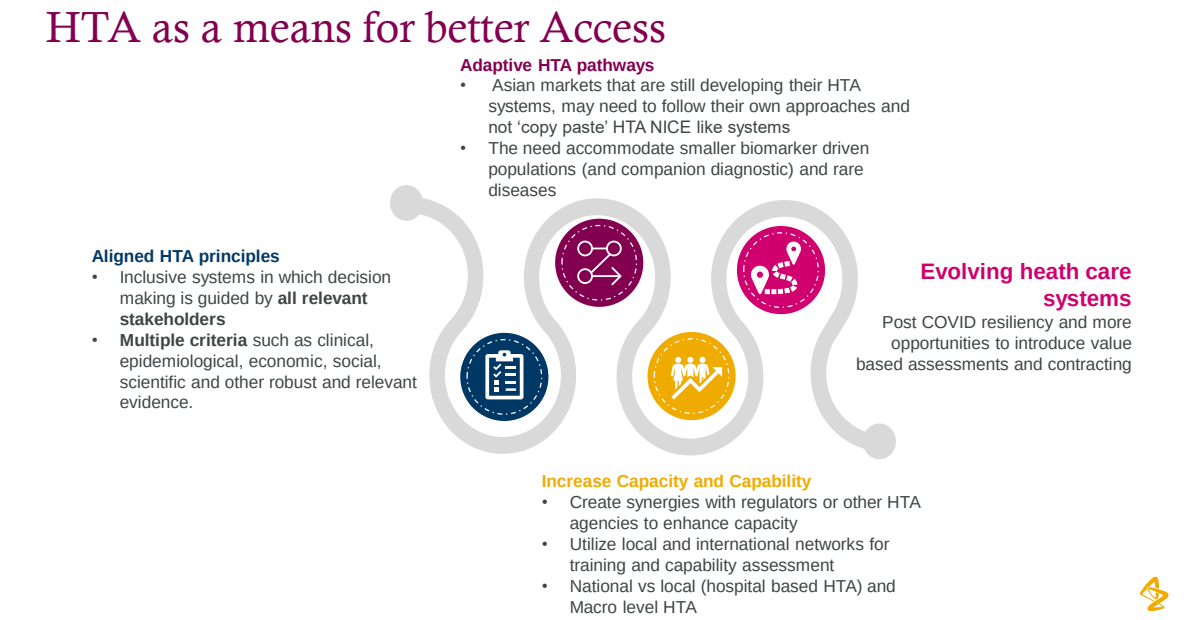
HTA specialised pathways

HTA in Asia has mainly focused on drug evaluations, while other elements that require evaluation are lagging e.g. diagnostics, treatment pathways, digital health technologies. Rare disease or precision oncology pathways are also not yet established. For personalised medicine, different evidentiary requirements for regulatory vs HTA agencies are challenging for industry; for example, single arm studies and surrogate endpoints based on biomarker responses may now be accepted by the regulator but are still facing challenges in HTA in proving cost effectiveness.

Good HTA practice should be to implement alternative value frameworks and pathways for rare diseases and small biomarker-driven populations like in oncology. Emerging HTA systems should look to learn from other more mature systems in this area and consider using risk-sharing models to address uncertainties.

Summary

To continue evolving HTA in Asia, there must be an increase in capacity and capability, which could be by creating synergies with regulators or other HTA agencies as well as utilising local and international networks for training. There is a need for inclusive systems in which decision making is guided by all relevant stakeholders and multiple criteria, such as clinical, economic, social and scientific and other robust and relevant evidence, are considered. In addition, HTA systems in Asia need to adapt their pathways to accommodate small biomarker-driven populations and rare diseases and leverage opportunities from the COVID-19 pandemic where possible. Finally, HTA needs to be seen as a means to creating patient access rather than limiting access or serving cost containment objectives.



Good HTA practices: how do companies perceive the evolution of HTA in Latin America – what needs to be considered?

Dr Diego Guarin, *Executive Director, Regional Market Access - Latin America, Merck, USA, and Co-Chair, Value and Access to Innovation Working Group, Latin American Federation of the Pharmaceutical Industry (FIFARMA)*

The history of HTA in Latin America dates back to the late 1990s when HTA units were created in Ministries of Health with technical support from the Pan American Health Organisation (PAHO). The first HTA agency, the National Centre for Health Technology Excellence (CENETEC) was established in Mexico in 2004, followed by the Commission for Incorporation of Technologies (CITEC) in Brazil in 2008, which was later replaced by the National Committee for Technology Incorporation (CONITEC) in 2011. The Institute of Health Technology Assessment (IETS) was also launched in Colombia in 2011.

HTA has been used in Latin America to inform decision makers at different stages of the technology life cycle. For example, after regulatory approval but before commercialisation to provide pricing recommendations (Brazil); after commercialisation to inform coverage decisions (Brazil, Colombia, Mexico); and after inclusion in health benefit plans or formularies to influence adoption (Brazil, Colombia, Mexico). Most agencies conduct cost-effectiveness analysis to determine 'willingness to pay' together with budget impact analysis to determine 'ability to pay', following methodologies adopted in other jurisdictions. However, given data gaps, technical limitations and decision makers' interests, the implementation of HTA has resulted in delays to patient access and is perceived by industry more as a cost containment policy than a value assessment tool, questioning whether the way HTA has been implemented in the region is fit for purpose [1].

HTA best practices

HTA best practices involve suitable methodologies, flexible processes, appropriate resources and personnel capabilities, and external stakeholder involvement. A taxonomy study of seven value assessment frameworks in Latin America demonstrated that although most frameworks had a clear definition of purpose, there were opportunities to improve value dimensions, methods and scope [2]. A lack of human resources and stable funding are critical barriers for establishing sustainable HTA agencies in Latin America as well as in other regions.

HTA should be an unbiased exercise and publicly funded HTA agencies can reduce perception of bias by operating independently from the body that will fund and implement HTA recommendations. However, in Latin America, most HTA agencies operate within and are fully funded by their governments; the IETS in Colombia is one of the few public-private agencies, although private funding share is marginal.

Many HTA agencies globally recognise the importance of multiple stakeholder perspectives, including the patient perspective. For example, CONITEC in Brazil has introduced formal processes to obtain patient input. In addition to individual patient submissions, patient experts are invited to participate in CONITEC committee meetings, though this is on a case-by-case basis. Therefore, there is still room for improvement and HTA agencies in Latin America could learn from others like the National Institute for Health and Care Excellence (NICE) in the UK.

Future vision for Latin America

In 2016, Heath Technology Assessment International (HTAi) launched the Latin American HTA Policy Forum, to provide a neutral setting for decision makers, HTA agencies and health technology producers to engage in strategic discussions on topics selected by the participants. The first working paper addressed HTA Good Practices [3], with the participation of 10 countries and 42 representatives including

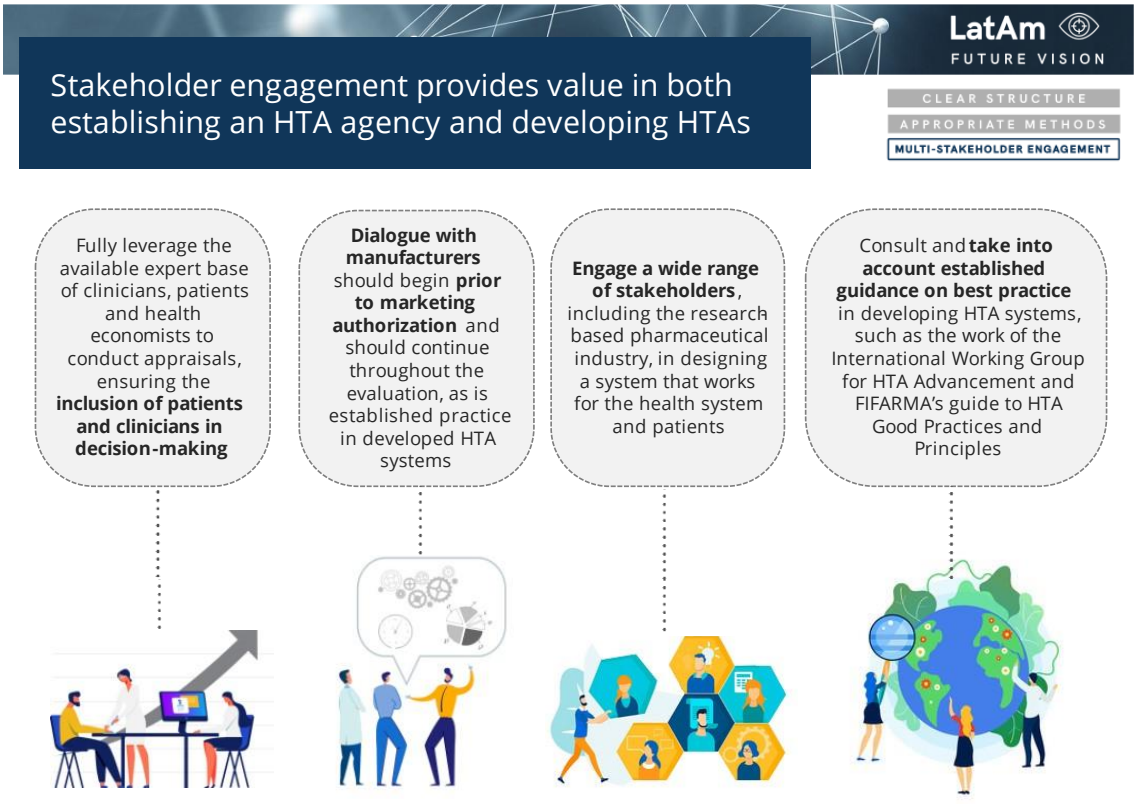
HTA agencies, public payers, PAHO, academia and industry. After a deliberative process, five principles were prioritised based on their potential to address the main gaps in HTA implementation in Latin America:

1. Transparency in the production of HTA and the communication of results
2. Involvement of relevant stakeholders in the HTA process
3. Existence of mechanisms for appeal
4. Existence of clear mechanisms for priority setting in HTA
5. Existence of clear links between the assessment and decision making.

Additional working papers by the Latin American HTA Policy Forum had been produced including on stakeholder involvement in HTA [4], value frameworks in Latin America to inform resource allocation [5], HTA and decision making [6], criteria for HTA prioritisation [7] and deliberative processes to inform decision making [8].

Summary

In summary, continuous dialogue has allowed different stakeholders to share their perspectives and find common ground to improve how HTA is being implemented in Latin America. There are national forums and international platforms, such as HTAi and the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), that are being used to keep the stakeholders involved. However, there are still opportunities to discuss specific issues at the country level given the wide diversity of health systems, HTA agencies and governance processes that limit the adoption of the recommendations made in regional meetings. As some countries progress faster than others in ensuring HTA is fit for purpose, more collaboration between stakeholders is needed to avoid leaving patients behind in countries with less technical and economic resources.



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Session 2: Aligning regulatory and HTA needs – what needs to be considered at a jurisdictional level?

UK Innovative Licensing and Access Pathway (ILAP) – a streamlined approach to regulation and patient access

Dr Daniel O'Connor, *Medical Assessor, Licensing Division, Medicines and Healthcare products Regulatory Agency (MHRA), UK,* and **Dr Nick Crabb,** *Programme Director, Scientific Affairs, National Institute of Health and Care Excellence (NICE), UK*

The Innovative Licensing and Access Pathway (ILAP) aims to deliver safe, early and financially sustainable patient access to innovative medicines. The key components of ILAP are a new designation called the **Innovation Passport**; the **Target Development Profile (TDP)** roadmap; a **toolkit**; and an **integrated pathway** pulling together expertise from across the MHRA, NICE, Scottish Medicines Consortium (SMC) and All Wales Therapeutic and Toxicity Centre (AWTTC) in the wider healthcare system including the National Health Service in England and Scotland.

Innovation Passport

The Innovation Passport enables access to ILAP and future activities in the TDP. It has built-in flexibility, with multiple entry points along the pathway and can be applied for with non-clinical data or clinical trial evidence, or by a commercial or non-commercial applicant. The principles of this new designation are:

- Broad and inclusive definition of innovation in order to capture a wide range of products, including drug repurposing
- Non-clinical entry point provides ambition for long-term interactions
- Thinking about the patient from the start
- Encourages structured engagement between the MHRA, HTA body and drug developer
- Joint decision making between MHRA, NICE, SMC and AWTTC.

Three criteria must be met for a positive opinion on the Innovation Passport. The first is to demonstrate that the condition is life-threatening or seriously debilitating, or that there is a significant patient or public health need. The second is to show that the medicine is either innovative; being developed in a clinically significant new indication; being developed for a rare disease and/or other special population; or being developed in line with objectives for public health priorities. The third is to demonstrate the potential benefit to patients; applicants are strongly encouraged to include the views from patients or patient organisations in their evidence.

Target Development Profile (TDP)

The TDP defines key regulatory, access and development features, identifies potential pitfalls and creates a road map for delivering early patient access, using tools from the toolkit. The TDP includes how the company can work together with other UK stakeholders for coordinated and efficient evidence generation and evaluation. The TDP step can only be accessed via the Innovation Passport and allows high-level consideration of a broad range of issues impacting product development, licensing and access allowing end to end planning.

ILAP toolkit

A wide range of tools are available or are being developed under ILAP. These include adaptive inspections; novel clinical trial methodology and design support; Rapid Clinical Trial Dossier pre-assessment service; enhanced patient engagement; new licensing procedures, such as rolling review; and a UK HTA Access Forum.

Activity to date

Since ILAP was launched on 1st January 2021, 65 Innovation Passport applications have been received from companies of various sizes, including one from a spinout from a leading UK university. These applications included oncology products for FDA Project Orbis as well as products for rare and common diseases. The first Innovation Passport issued was for a treatment for adults with a rare disease called von Hippel Lindau disease.

What does ILAP mean for its stakeholders?

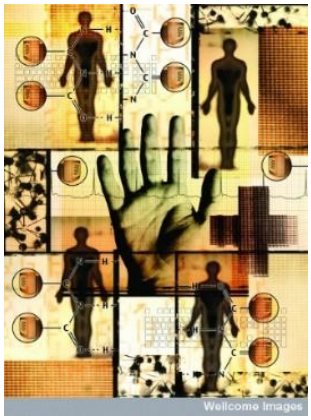
Patients are central to ILAP and provide input in decisions to grant Innovation Passports as well as the ILAP Patient and Public Reference Group. For the life sciences industry, ILAP gives the opportunity for earlier engagement in the design of innovative and efficient clinical trials and on evidence requirements across regulatory and HTA needs. In addition, it offers expedited regulatory routes and early access planning including evidence development, managed access and commercial considerations. For the MHRA, UK HTA agencies and UK payers, ILAP facilitates collaboration and alignment on evidence requirements, including planning for real world evidence collection, as well as alignment of regulatory, HTA and commissioning timelines.

Summary

ILAP offers an ambitious route to medicines approval and access. It recognises that innovative products require innovative approaches and promotes system alignment between MHRA, NICE, SMC and AWTTC as well as early engagement with industry. Through ILAP, innovative methods and tools have been developed that accelerate availability of robust data including the development of a specific TDP roadmap tailored to the needs of each innovative product. It is hoped that ILAP can facilitate earlier decision making in the drug development paradigm.

What is the ILAP?

- Opportunity to think and practice differently after UK exit from the European Union
- Key aspect is the partnership between the MHRA and three UK HTA bodies; NICE, SMC and AWTTC; and patient input
- The ambition is to deliver safe, early and financially sustainable patient access to innovative medicines
- Alignment of evaluation and access activities throughout the development pathway – integration of regulation and HTA
- The NHS in England and Scotland are closely engaged, along with the Accelerated Access Collaborative and other UK health system partners



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Alignment in Canada's prescription drug chain: why is there a need and what are the implications?

Dr John Patrick Stewart, *Director General, Therapeutic Products Directorate, Health Canada,* and **Suzanne McGurn**, *President and CEO, CADTH, Canada*

Canada's prescription drug chain is made up of many players that each have a different, independent role. Health Canada is responsible for verifying that drugs meet safety, efficacy and quality requirements. This evaluation leads to a decision on whether to issue a Notice of Compliance (NOC), which allows a sponsor to sell a drug in Canada.

Once regulatory approval is received, the Canadian Agency for Drugs and Technologies in Health (CADTH) and the National Institute of Excellence in Health and Social Services (INESSS) carry out their HTA assessments, which focus on comparative effectiveness and cost-effectiveness analyses. The HTA agencies regularly engage experts, including patients and clinicians, to understand how a new product will be used based on current standard practice. The main output is a reimbursement recommendation, which could be positive, negative, or positive with conditions.

The next step is for the Pan-Canadian Pharmaceutical Alliance to enter price negotiations on behalf of most provinces in Canada. Finally, individual Ministries of Health for the provinces make their own public plan decisions about which products go on their formularies.

Regulatory-HTA alignment

Traditionally, regulatory and HTA review processes in Canada were largely sequential and interactions between Health Canada and the HTA agencies were mainly informal and ad hoc. To improve collaboration (while maintaining independence) and to help reduce delays in patient access, an aligned review process was implemented in June 2018. This gave sponsors the option to express interest in a parallel regulatory-HTA review when considering filing a new drug in Canada. The aligned review process was enabled by the development of a formal consent for information sharing between Health Canada and each HTA agency, which is also signed by the sponsor. This ensures that all stakeholders are looking at the same information, helping to minimise duplication and misinterpretation.

The impact of the parallel regulatory-HTA review process has so far been positive. From June 2018 to October 2021, 73 aligned reviews were completed and the average time between NOC issuance and HTA recommendation decreased by over 60%. For example, for CADTH, the average time from NOC issuance to HTA recommendation was 316 days for sequential reviews but only 43 days for parallel, aligned reviews. Despite this clear benefit, companies are still choosing not to opt into aligned reviews for several reasons, including concerns about downstream information sharing and influence of the HTA agencies on the regulatory review. Health Canada continues to work with industry to better understand these concerns and find potential solutions to increase uptake of parallel reviews.

Evolving health context

Increasingly complex and personalised products, which often come with high price tags, are challenging the sustainability of health systems around the world. There is growing pressure to approve these products on less or more preliminary data, which is resulting in uncertainty being passed down to payers. New collaborative approaches are needed to address these challenges, though it is important that the roles of regulator and payer are kept distinct and independent.

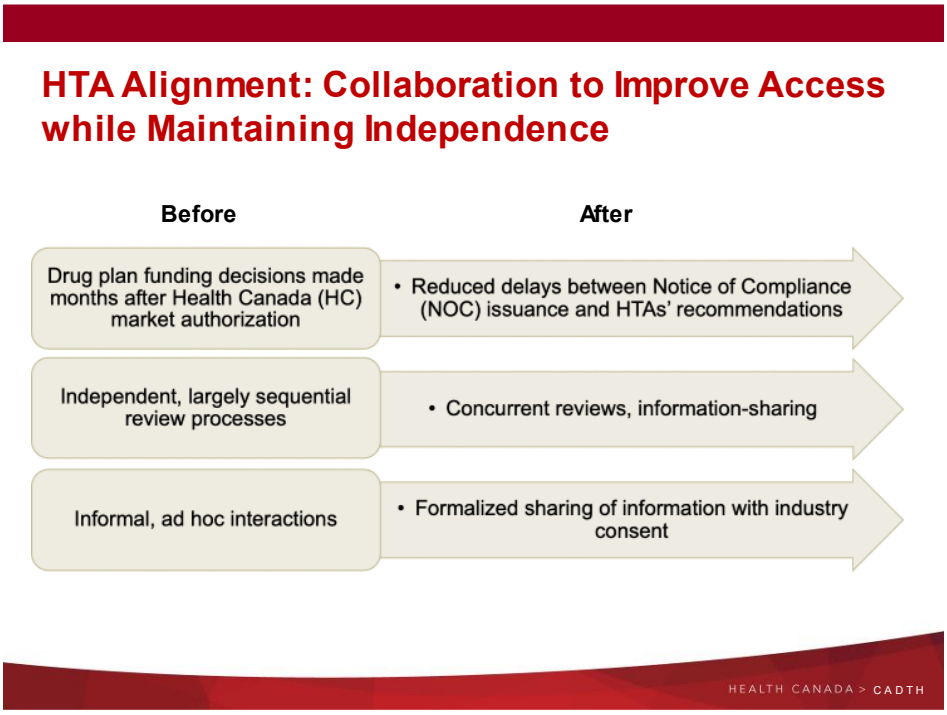
In response to these issues, Health Canada has developed a Regulatory Innovation Agenda, which aims to provide more regulatory flexibility to support innovative research and health product development. This is made up of five key pillars:

- modernising clinical trial regulations
- enabling advanced therapeutic products
- agile licensing for drugs
- agile licensing for medical devices
- information to Canadians (mobile strategy).

The pathway for advanced therapeutic products will be an integrated health system approach, facilitating early alignment with HTA bodies, payers and international regulators. Work is underway to use agile licensing to better patient outcomes, including leveraging new regulatory tools to gather more precise information that may support downstream decisions by other stakeholders. As this work progresses, it will be important for each stakeholder group to understand their role and how they can best support each other. The COVID-19 pandemic has provided opportunities to experiment with new approaches, including rolling reviews, through various interim orders.

Summary

Many players are involved in giving patients access to safe, high quality and efficacious products. There must be continued recognition of the independent and complementary roles each player has in this process. Regulatory-HTA alignment in Canada has shown that collaboration and alignment help to create efficiencies and maximise patient outcomes. As more products move through the access process, it is important that other key stakeholders such as patients, payers, manufacturers and clinicians have the information they need in order to understand these advances.



Finding efficiencies with HTA processes – experience from Taiwan

Dr Li Ying (Grace) Huang, *Director*, *Division of HTA, Center of Drug Evaluation, Taiwan*

Taiwan started conducting HTAs in 2007 to support the National Health Insurance Administration (NHIA) in its drug reimbursement policies by considering the health and well-being of all citizens, medical ethics, and cost-effectiveness within the financial framework of the National Health Insurance (NHI) programme. The HTA process in Taiwan drew reference from HTA agencies in Australia, Canada and the UK.

Pricing policies to promote local R&D products

Article 17-1 of the NHI Drug Dispensing and Fee Schedule aims to accelerate the process of reimbursement for local R&D products that are first entrants to the international market and to keep their prices as high as feasible. As other countries will also use these higher prices, this is beneficial to the local manufacturer and therefore provides an incentive to produce a high-quality product.

Tools and approaches to increase patient access

Taiwan uses horizon scanning mechanisms to inform its policy makers about innovative technologies that can be expected for NHI coverage in the next two years and have the lead-in time to undergo budget planning in the next year. This involves identification of target products, filtration processes and the publication of a horizon scanning report.

Managed entry agreements (MEAs) are mutual agreements between the NHIA and pharmaceutical companies that may be used when there is uncertainty in clinical evidence, cost-effectiveness and/or budget impact. MEA models in Taiwan are either financial-based (fixed rate payback), performance-based (payback based on response rate etc) or mutual share by negotiation (mutual share of the payback among pharmaceutical products with the same ingredient or pharmacological category). Since 2019, financial-based MEAs have been used to give patients in Taiwan access to three innovative oncology drugs covering eight indications.

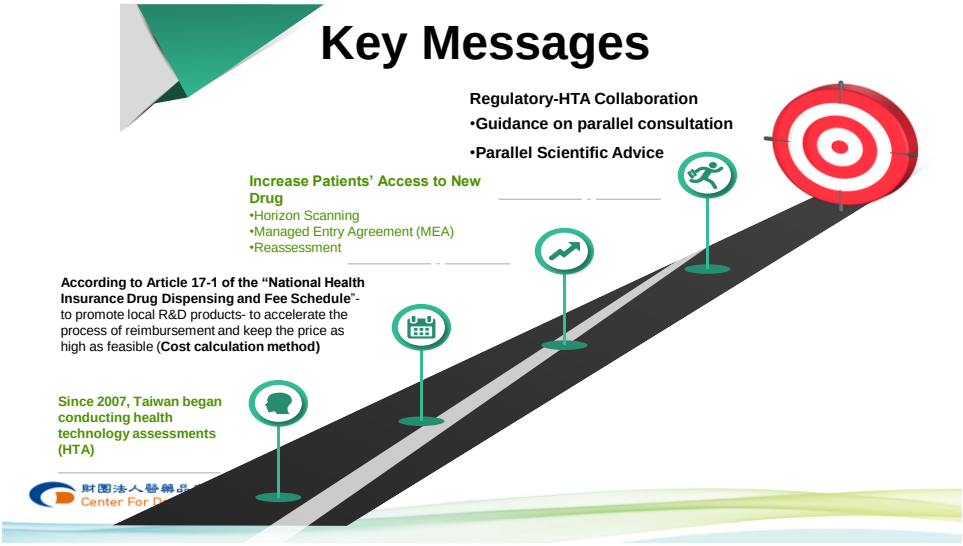
The NHIA has used reassessment and disinvestment strategies to manage uncertain clinical and cost benefits associated with immune checkpoint inhibitors. The NHIA developed a preliminary review system for cancer immunotherapy applications, to keep track of fund uses and the number of uses, as well as to collect real-world data (RWD) on patients using drugs to assess the overall payment benefits of immune checkpoint inhibitors [1]. The NHIA has regularly invited oncologists, pharmacy experts, and methodology experts for meetings to comprehensively consider the RWD of medication-using patients in Taiwan, the latest developments in international treatment guidelines and clinical trials, and the current situation in health insurance financial controls. Ongoing rolling reviews are conducted, and benefit packages adjusted accordingly.

Future vision for HTA in Taiwan

The future vision for Taiwan is to enhance regulatory-HTA cooperation and alignment initiatives, using learnings from other countries, for example, in the EU. In the next two years, Taiwan aims to implement parallel scientific advice and earlier engagement mechanisms that will facilitate input on health system needs, monitoring for novel products and the production of guidance documents for manufacturers and other stakeholders.

Summary

Taiwan began conducting HTAs in 2007 to support the NHIA's reimbursement decisions for drugs. Article 17-1 of the NHI Drug Dispensing and Fee Schedule aims to accelerate the process of reimbursement for local R&D products and keep their prices as high as feasible. Horizon scanning, MEAs and reassessments are being used to increase patients' access to new drugs. Future opportunities for HTA in Taiwan include regulatory-HTA collaboration, guidance on parallel consultation and parallel scientific advice.



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HTA for reimbursement decisions and future directions in Thailand

Kanchanok Sirison, *Health Intervention Technology Assessment Programme (HITAP), Ministry of Public Health, Thailand*

Thailand provides universal healthcare to its citizens through three public health insurance schemes. The majority of the population are covered by the Universal Coverage Scheme (80% coverage), which was initiated in 2002. Currently HTA is applied to pharmaceutical products (National List of Essential Medicines (NLEM)), vaccines (National List of Essential Vaccines), non-pharmaceutical and non-vaccine products (benefit package under the Universal Coverage Scheme) and public policy evaluations.

Role of HITAP in informing medicine reimbursement

The Health Intervention Technology Assessment Programme (HITAP) was established as a semi-autonomous, non-profit institute under the Thailand Ministry of Public Health in 2007. HITAP conducts HTAs, health service research and capacity building activities and currently has approximately 70 staff.

HITAP contributes to HTA in Thailand through its work in five strategic areas:

- Research and development of a fundamental system for HTA
- Capacity strengthening for HTA at individual, organisational and health system levels
- Assessing health technologies and policies as to public priority
- Research dissemination to policy makers, healthcare professionals and the general public
- Organisational management and promotion of connections between academics and both national and international HTA organisations.

HITAP has partnerships with a range of global and national partners, including the Thai Health Systems Research Institute, Philippines Department of Health, National University Singapore School of Public Health, World Health Organisation and HTAsiaLink.

HTA governance and process

The governance structures supporting the use of HTA in Thailand are made up of several stakeholders, including healthcare professionals, health ministers, the Thai Food and Drug Administration (FDA) and the three health insurance schemes which govern the reimbursement budget. The technical body supporting the HTA process for the NLEM is the Health Economic Working Group, with the Thai FDA serving as the secretariat and HITAP as co-secretariat. In addition to the Health Economic Working Group for the NLEM, HITAP also serves as the secretariat for the Health Economic Working Group for the Universal Coverage Benefit Package.

As part of the Health Economic Working Group process, a selected research team at a public agency or non-profit organisation conducts a pharmacoeconomic study on the drugs being evaluated. This study must follow Thailand's methodological and process guidelines on HTA and so will involve stakeholder consultations, research quality inspection and writing up of the study report including an executive summary and policy recommendation.

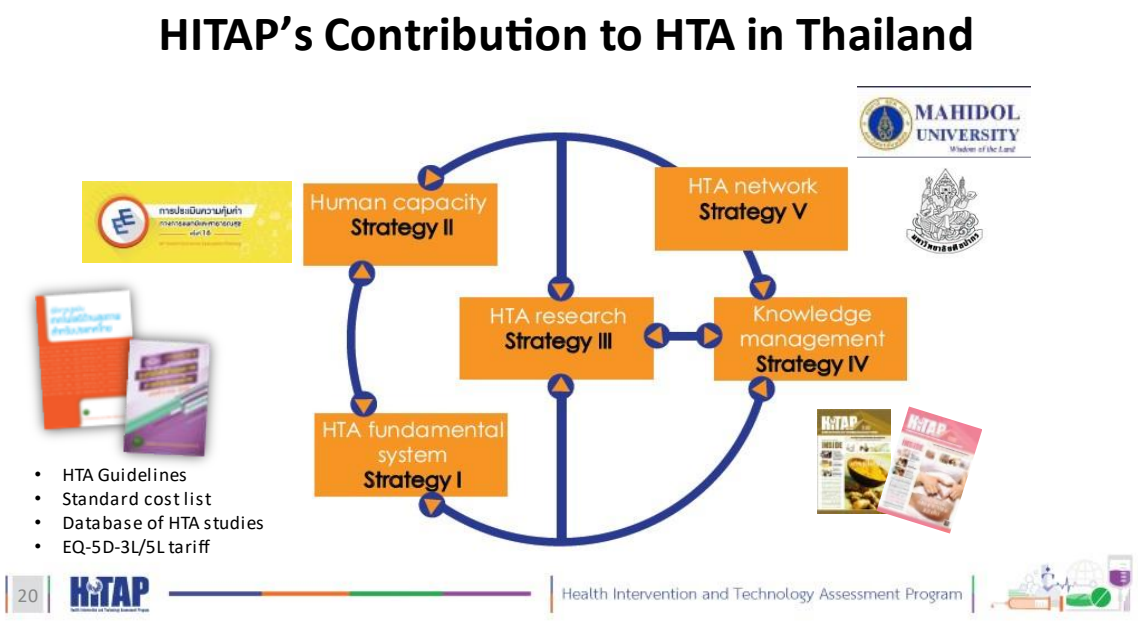
Future considerations for HTA in Thailand

HITAP would like to build on learnings from early HTAs conducted for COVID-19 medicines and vaccines and expand early HTA to other therapeutic areas. HTA reassessments, use of real-world evidence in reimbursement decision making, digital health and personalised medicine are also areas for future consideration. In addition, HITAP is assessing the impact of Thailand's increase in cost-effectiveness

threshold on drug prices submitted by manufacturers, the probability of high-cost drugs being included in the NLEM and the size of the drug budget.

Summary

Since its establishment in 2007, HITAP has been working to evolve the use of HTA in healthcare decision making in Thailand. Key focus areas include developing a fundamental system for HTA, strengthening capacity, HTA research and dissemination, knowledge management and building an HTA network. Future considerations for HTA in Thailand include use of early HTA, life cycle management and real-world evidence in decision making.



HTA in the Philippines

Marita Tolentino-Reyes, *Chair, HTA Council (HTAC), Philippines*

HTA was institutionalised in the Philippines through the Universal Health Care Act of 2019. This intended to progressively realise universal health care through a systems approach and by clearly delegating the roles of different stakeholders, in order to ensure equitable access to quality and affordable health care and protection against financial risk.

Section 34 of the Universal Health Care Act stipulates that HTA shall be a priority-setting mechanism that makes recommendations to the Department of Health and Philippine Health Insurance Corporation (PhilHealth) to guide coverage decisions. It highlights the importance of the HTA process adhering to scientific and ethical principles and describes the creation of the HTA Council (HTAC), which consists of a core committee and seven subcommittees representing different health technologies. These are supported by a technical secretariat and a unit that has evidence generation and policy development capability (see diagram below).

Regulatory and HTA roles and interactions

The Philippines Food and Drug Administration (FDA) is tasked with safeguarding the public by regulating products in the market, while the HTAC guides the Department of Health and PhilHealth on the efficient use of limited resources. The FDA only evaluates the safety, efficacy, and quality of products whereas the HTAC contextualises use of the product within the health system, evaluating clinical, economic, ethical, legal, social and health system impacts.

The HTAC committees are supported by regular resource persons including representatives from the FDA, PhilHealth and patient groups, which help to facilitate alignment between HTA and other stakeholders. Representatives from professional societies are also invited to give input into the committees. In addition, the HTA Network, which is made up of academic and research professionals, is an important resource for the technical secretariat and evidence generation and policy development unit.

Challenges during the pandemic

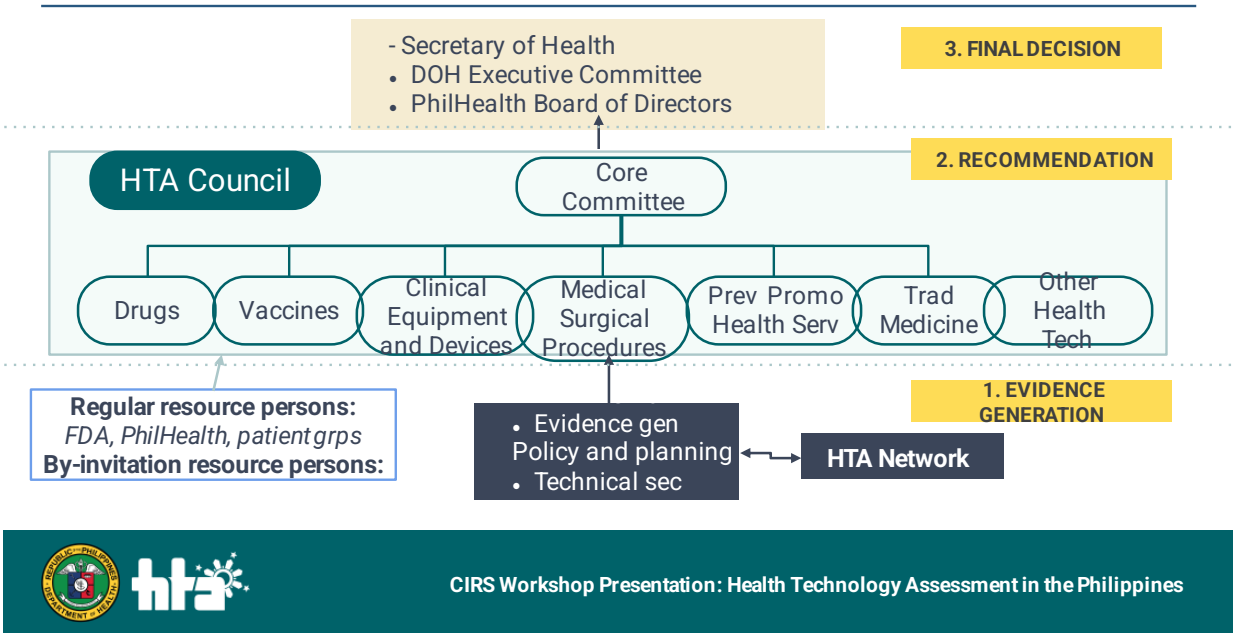
Key challenges between the FDA and HTAC during the COVID-19 pandemic were related to data/document sharing, unclear regulatory standards for some technologies, alignment of processes and overlapping responsibilities. There is a need for the FDA and HTAC to streamline the process for sharing confidential documents or data so that reviews and assessments can be more in parallel. In addition, HTAC's role must be better cemented within the health system to avoid overlap and confusion over responsibilities.

Future plans for HTA

HTAC plans to review and potentially revise the current HTA process to ensure best practices are adopted and that learnings from expedited COVID-19 products and vaccines can be applied to non-COVID technologies where possible. In 2022, there will be a shift in topic prioritisation, with new topic nominations being accepted, as well as governance and organisational changes due to transitions from the Department of Health to the Department of Science and Technology. In addition, national elections in May 2022 may lead to new political leadership.

Summary

The Philippines Food and Drug Administration (FDA) gives market approval to products while HTAC generates evidence-based recommendations for health technologies to be financed by Department of Health and PhilHealth. Challenges between FDA and HTAC during the COVID-19 pandemic have been data/document sharing, unclear regulatory standards for some technologies, alignment of processes and overlapping responsibilities. HTAC plans to revisit the current HTA process, alter topic prioritisation and make governance and organisational changes in future.



Regulation and HTA in Brazil: trends and challenges

Gustavo Mendes Lima Santos, *General Manager of Medicines and Biological Products, Brazilian Health Regulatory Agency (ANVISA)*

All stages of drug development should comply with national and international regulations. For clinical trials to take place in Brazil, ANVISA must have approved the trial protocols. The agency takes into consideration study design, including primary and secondary outcomes and statistical approach; safety, such as outcomes of previous phase studies; pharmaceutical studies, such as data on production and quality; and Good Clinical Practices including data traceability and reliability. When a sponsor applies for marketing authorisation, ANVISA will conduct a benefit risk assessment based on the data collected and the intention of use in Brazil.

Traditionally, regulatory decisions in Brazil have been largely based on data from randomised clinical trials. However, ANVISA is becoming more open to literature data as a source of information for its decisions. This is an area where there could be opportunities for ANVISA to interact with the HTA institution in Brazil, the National Committee for Health Technology Incorporation (CONITEC), as HTA commonly consider a range of sources of information in their decision making. Several trends are anticipated in Brazil over the next ten years that present common challenges and opportunities to ANVISA and CONITEC.

Digital tools and big data

Data is being generated in an increasing amount and speed; the use of this ‘big data’ represents a major challenge for regulatory and HTA action. It is necessary to develop tools that can transform big data into scientific data that can help in regulatory and HTA decision making.

Patient engagement

Patients and patient groups are key stakeholders to both ANVISA and CONITEC. The real-life experience of patients, as well as their expectations and points of view, are considerations that can help in the decision making of the agencies. Patient participation in committees, as well as in the generation of data that can be used for regulatory and HTA decisions, should be promoted.

Data modelling and extrapolation

There is a need to develop and stimulate the use of data modelling, simulation and extrapolation techniques. These techniques can contribute to the efficiency of discovering new drugs and in optimising the design of clinical studies. In addition, they may generate opportunities to optimise evaluations and analyses used for HTA decisions.

Real-world data/evidence

The discussion on the use of real-world data/evidence (RWD/E) sources, such as digital devices, data from health insurers, patient databases etc for the demonstration of efficacy and safety of medicines, has advanced in recent years. It is essential to define strategies for the validation and traceability of this data for regulatory and HTA purposes.

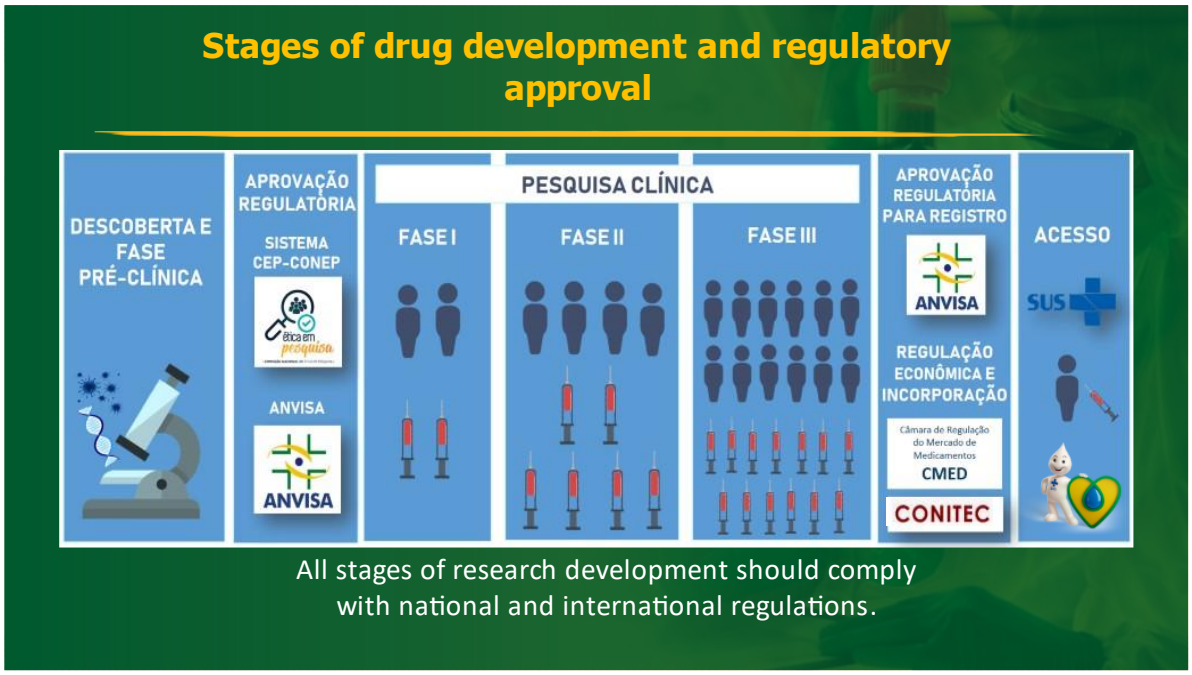
Leveraging to advance science

Stimulating partnerships between universities and ANVISA to carry out regulatory science is fundamental, since this aims to advance research topics that help the agency's actions in its mission to protect and

promote the health of the population. Like ANVISA, CONITEC has a wealth of information and experience that could be leveraged to build scientific knowledge.

Summary

Several trends are anticipated over the next ten years that present common challenges and opportunities to the regulatory and HTA agencies of Brazil. These include the use of digital tools and big data for decision making; stimulating patient engagement in regulatory and HTA actions; developing and stimulating the use of data modelling, simulation and extrapolation techniques; use of RWD/E for regulatory and HTA purposes; and leveraging information to build scientific knowledge.



HTA assessment in Colombia

Adriana María Robayo García, *Executive Director, Institute of Health Technology Assessment (IETS), Colombia*

The research and health ecosystem in Colombia is made up of several different players including government departments, research institutions, universities, hospitals, health insurance schemes, the National Food and Drug Surveillance Institute (INVIMA) and the Institute of Health Technology Assessment (IETS). For a health technology to enter the Colombian market, first INVIMA assesses its safety, efficacy and quality, and then IETS evaluates its effectiveness, equity and budget impact.

What key challenges are being faced?

IETS is being challenged to review the estimation of the cost-effectiveness threshold for Columbia and update its methodological manuals to consider ethical, organisational and legal aspects. This includes manuals for budget impact and health economic analysis manuals as well as the creation of a new manual on patient participation in HTA. IETS is also assessing Colombia's drug price regulation policy and conducting an impact assessment of public policy on the progressive updating of the benefit plan. In addition, web page automation software for price consultation is being introduced, which could have a role in horizon scanning. Making use of HTA and academic networks in Colombia and in Latin America more widely could be a potential opportunity for IETS.

Colombia is an ethnically diverse country and health equity is a key issue. There may be questions to help apply criterium of equity within Colombia's HTAs, such as do the recommendations derived from the HTAs address priority problems for disadvantaged populations? Are there reasons to anticipate different therapeutic effects in population subgroups and can these be measured? Are additional efforts required to overcome implementation barriers in population subgroups?

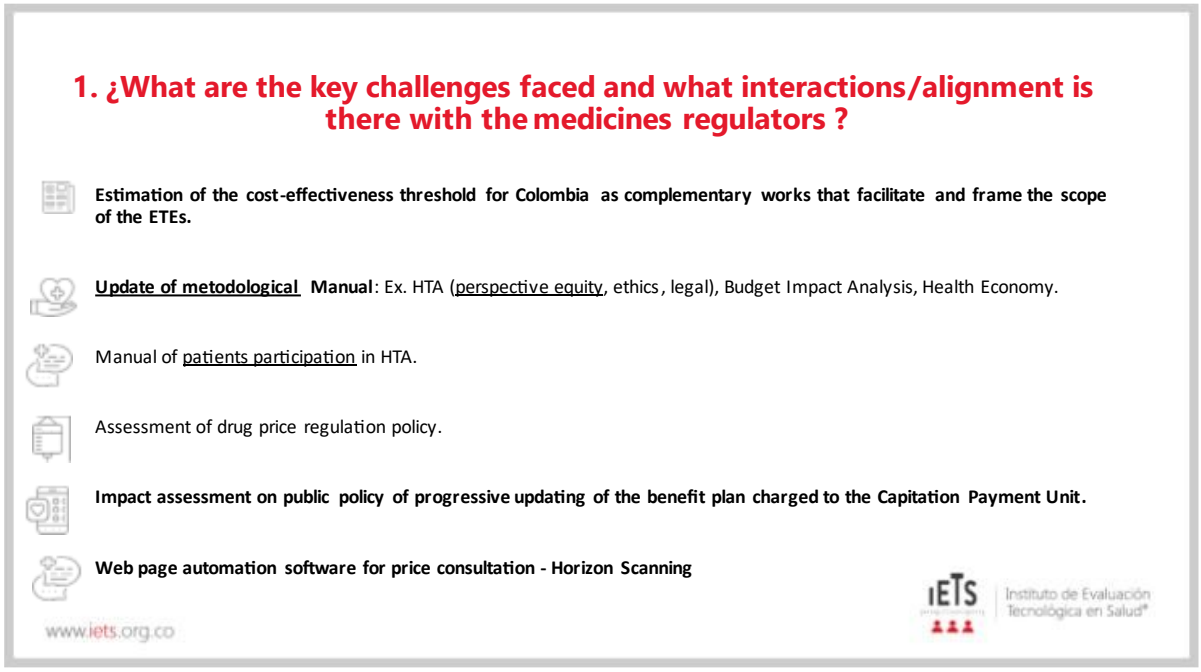
What changes may occur in future?

A future change for HTA in Colombia may be altering the therapeutic value in maximum budgets and introducing a systematic process for horizon scanning of health technologies. Use of real-world evidence (RWE) and deliberative processes may become more automated and HTA methods for personalised medicine, digital technologies and genomic therapies may need to be developed.

Innovation in precision medicine is likely to have challenging implications for HTA agencies including IETS. Considerations that need to be taken into account in the future HTA of precision medicine include the evaluation of evidence vs experience, real life data methodological challenges, the role of context, preferences and values, and sustainability of the health system [1].

Summary

HTA in Colombia is carried out by IETS, which evaluates health technologies based on effectiveness, equity and budget impact. Key challenges faced by IETS include estimating the cost-effectiveness threshold, updating methodological manuals, incorporating equity into HTA and assessing the drug price regulation policy. In future, there may be changes such as a more systematic process for horizon scanning of health technologies, more automated real-world evidence and deliberative processes, and the development of methods for HTA of personalised medicines, digital technology and genomic therapies.



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HTA assessment in Mexico

Dr María Cristina Gutiérrez Delgado, *Faculty of Sciences, National Autonomous University (UNAM), Mexico*

Mexico has a fragmented health care system made up of private and public subsystems. Governance structures include the Secretariat of Health, General Directorate of Social Security Institutions and General Health Council (GHC). The national regulatory agency, the Federal Commission for the Protection against Sanitary Risks (COFEPRIS), is part of the Secretariat of Health and is responsible for granting authorisation for commercialisation of a health technology.

Once COFEPRIS grants authorisation to a health technology, it can be marketed in the private sector immediately. However, for public services, the procurement of a new technology requires a process for inclusion in the National Compendium of Health Supplies, which is overseen by the GHC. This process is a full HTA process with input from public institutions and the National Centre of Technological Excellence in Health (CENETEC), which analyses the evidence presented by the producers of the technology and issues observations as well as a technical opinion. Members of the public institutions then consider this opinion and vote for or against the technology.

Alignment with regulators

The HTA assessment is based on a series of regulations by COFEPRIS and the GHC (see below). There are several guidelines and laws that producers need to aware of and comply to. These regulations intend to incorporate international practices as well as pertinent suggestions from most Mexican stakeholders.

Key challenges faced

A key challenge for the Mexican HTA assessment, which is also shared by many other Latin American countries, is a lack of information for the Mexican population generated from multicentre clinical trials. This lack of information in turn makes it difficult to obtain solid evidence on safety, efficacy and cost effectiveness for the Mexican context.

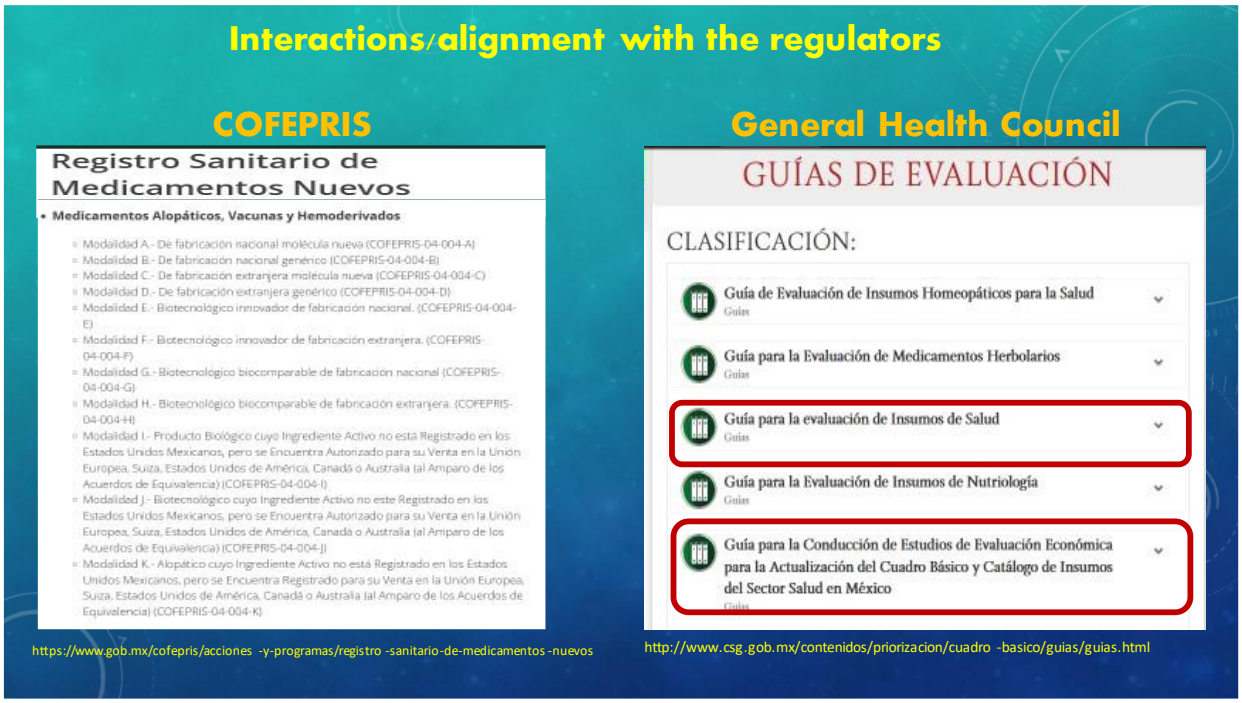
Another key issue is that HTA results and CENETEC opinions are not binding for public procurement decisions. To address this challenge, there needs to be political willingness and greater appreciation of the HTA process, as well as adjustments to the organisation of the public procurement process and who should participate in decision making.

Changes in the pipeline

Changes that are being implemented in the HTA process in Mexico include changes to the use of quality of life and utility measures. There will also be a review of the use of GDP per capita as a threshold, not just among the HTA community in Mexico but also in several other Latin American countries. In addition, there are likely to be adjustments to the traditional HTA process in order to adapt to the emerging challenges of rare diseases, combination therapies, oncology and end of life technologies. The use of multicriteria analysis in HTA is being discussed in several Latin American countries and may have an impact on the guidelines for HTA economic evaluations, which are due to be updated in 2022.

Summary

For a health technology to be included in the National Compendium of Health Supplies in Mexico, it must have marketing authorisation from the national regulatory agency, COFEPRIS, and have undergone a full HTA process involving public institutions and the HTA body, CENETEC. Challenges faced in the HTA assessment are Mexico being part of multicentre clinical trials; lack of solid evidence on safety, efficacy and cost-effectiveness for the Mexican context; and that HTA results are not binding for public procurement. Potential changes to HTA in Mexico include the use of utility and quality of life measures, reviewing the use of GDP as the cost-effectiveness threshold and a migration towards multicriteria analysis.



Regulatory review and HTA assessment of a new medicine in Asia: current experiences from companies and implications for future alignment

Vicky Han, *Senior Director, Head of Asia Pacific Regulatory Policy and Intelligence, Global Regulatory Affairs, Janssen*

The current regulatory landscape in Asia is dynamic and diverse but moving towards greater harmonisation, with many regulators adopting international standards and becoming members of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). Reliance and collaboration models have also been adopted as well as expedited pathways, parallel reviews and new technologies/initiatives such as real-world evidence, digital endpoints and complex clinical trial designs.

The HTA landscape in Asia is also very dynamic and diverse though may be advancing at a slower pace than the regulatory landscape, mainly due to economic pressures such as aging populations, increased healthcare costs and higher patient expectations. The key elements for access to new medicines are time, price and volume; time is a proxy for the rapid adoption of high-quality treatments, and price and volume together represent the cost to the health system. Currently, the hybrid payment model exists in Asia in terms of self-pay, commercial insurance and the public health scheme. HTA is emerging gradually in Asia but is in need of further development.

Regulatory vs HTA/payer landscape – example from Japan

The Pharmaceuticals and Medical Device Agency (PMDA) in Japan is recognised as a mature regulatory agency; the agency is a founding member of ICH, and its Certificate of Pharmaceutical Product (CPP) can be accepted as a first country CPP. The Japan Ministry of Health, Labour and Welfare (MHLW) conducts its reimbursement evaluation in parallel with PMDA's review. Although HTA in Japan has been established fairly recently, mainly for products with high volume and/or price, it does not currently lead to access delays. However, the Japanese government has introduced budget control meaning products are repriced after launch, which could have a potential impact on access.

Regulatory vs HTA requirements

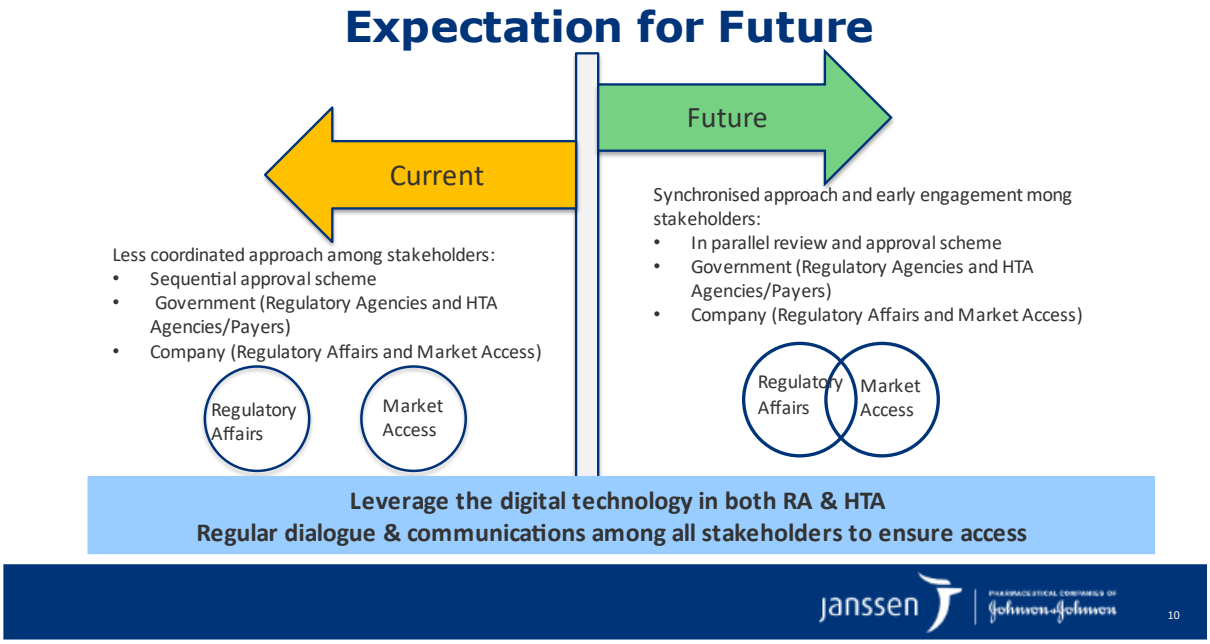
Evidentiary requirements for clinical and economic evaluations can be classed into five key areas: population, clinical trial design, comparator, endpoint and statistics. While all these areas are relevant to both regulators and HTA/payers, differences in stakeholder needs often mean a lack of alignment on evidentiary requirements. For example, single-arm studies are increasingly being accepted by regulators, especially in the case of rare diseases or high unmet need, but HTA/payers do not usually accept these types of studies as they are unable to show relative effect and therefore value.

Expectations for the future

Currently in Asia, regulation and HTA are not very coordinated between governmental organisations, such as regulatory agencies, HTA agencies and payers, as well as between the regulatory affairs and market access teams of companies. In future, there must be a synchronised approach that involves early engagement among stakeholders and parallel review and reimbursement processes. Digital technology should also be leveraged by both regulatory and HTA stakeholders.

Summary

Regulatory and HTA landscapes across Asia are dynamic and diverse, though there may be more development in the area of regulation than in HTA. Currently regulatory review and HTA assessment is sequential and there is a lack of coordination among government and company stakeholders in Asia. Therefore early engagement and a more synchronised approach is needed between regulatory and HTA stakeholders in both government agencies and companies. Regular multi-stakeholder dialogue and communication is key to ensuring access.



Regulatory review and HTA assessment of a new medicine in Latin America: current company experiences and implications for future alignment

Dr Karina Hansen, *Head of Health Economics, Global Health Economics and Outcomes Research, Abbvie*

In mature markets, there has been a paradigm shift towards greater regulatory-HTA alignment on evidence requirements. Although there are interactions between regulatory review and HTA assessment in Latin America markets, there are barriers that need to be overcome to ensure optimal and timely access, early stakeholder engagement and independence.

Optimal and timely access

The review times of reference regulatory authorities in Latin America are significantly longer than those set out in regulations, suggesting that the authorities could find more ways to gain efficiencies [1]. Regulators across Latin America should consider embracing international standards such as the Common Technical Document (CTD) more broadly to enable quicker and more streamlined review of marketing applications. The increased discussion of reliance mechanisms as a potential way to speed up the review process has been seen as a positive move by different stakeholders, but many regulators are still hesitant to fully embrace reliance.

Increased regulation has contributed to the increased efficacy and safety of medicines entering Latin America but has also made access to these medicines more difficult in many markets. National budgets are under pressure, particularly with the COVID-19 pandemic, limiting the access and funding of new and innovative medicines for patients in the region. Recent price regulations have become drastic, resulting in delayed or no access at all to certain medicines.

Early engagement

Early engagement with experts as well as stakeholders is key, as it helps to generate the targeted evidence that is needed to demonstrate the value of a new medicine for patients. Regulation of early interactions with experts is restrictive in some Latin American markets, hindering more appropriate evidence generation.

Pre-submission meetings are a useful tool that allow industry to provide additional information to the regulators about the information included in the dossier or possible facilitated regulatory pathways. However, regulations often prohibit interactions with HTA stakeholders prior to regulatory approvals, thereby slowing down access to the detriment of patients. In addition, expert and stakeholder awareness around the HTA processes in Latin America is limited. Therefore, there is an opportunity for more effective collaborations with patients, physicians, payers and regulators to improve access and health system performance, for example, by facilitating the conduct of local studies on burden of disease and patients' perspectives.

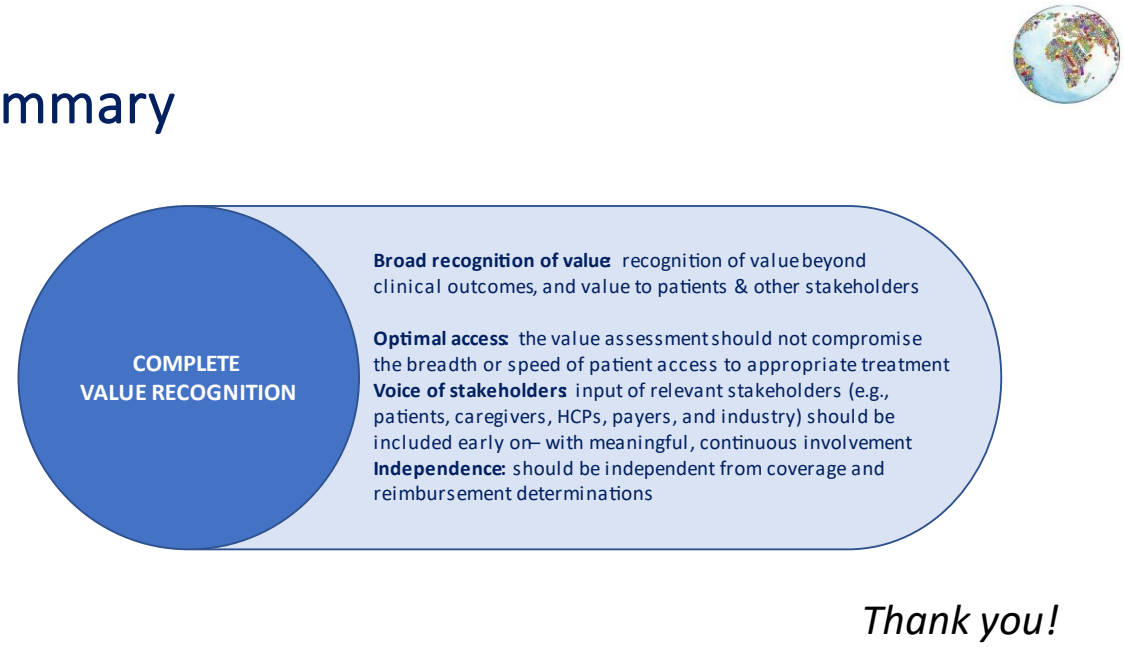
Independence of HTA

Industry is urging independence of government led HTA systems from the local regulatory process. HTA systems should be an unbiased exercise, operating independently from the body that will fund and implement HTA recommendations to reduce any perceived bias. While it is beneficial for HTA agencies in Latin America to learn from mature markets, for example, by considering the work of the International Working Group for HTA Advancement and FIFARMA's guide to HTA Good Practices and Principles, they must ensure to adapt this work to their local health systems.

Transparency around the HTA evaluation process in Latin America is limited and HTA content is not always publicly available. This needs to be optimised not only by HTA agencies but also by industry. The more transparency around the HTA evaluation process, the better industry can prepare, learn and generate good quality evidence and submissions.

Summary

For future regulatory-HTA alignment in Latin America, there must be a broad recognition of value going beyond clinical outcomes, and the value assessment should not compromise the breadth or speed of access to appropriate treatment. The input of relevant stakeholders, including patients, caregivers, clinicians, payers and industry, should be included early on and continue with meaningful involvement. In addition, HTA systems should be independent from coverage and reimbursement determinations.



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Use of real-world data and evidence to support regulatory and reimbursement decision making in Asia: is this an area for coordination between regulatory and HTA in Asia?

Raoh-Fang (Jasmine) Pwu, *Director, Taiwan National Hepatitis C Program Office, Ministry of Health and Welfare, Taiwan, and Adjunct Associate Professor, Taipei Medical University*

There is growing interest globally in real-world data (RWD) and real-world evidence (RWE), however their impact on policy is not yet clear. There are six key areas for using RWE in decision making: drug development, regulatory approval decisions, post-approval monitoring of safety signals, HTA and payer initial coverage decisions, HTA and payer reassessment decisions, and outcomes-based contracting.

Many regulatory and HTA agencies globally have released guidance on RWD/RWE. The Real-World Data in Asia for Health Technology Assessment in Reimbursement (REALISE) working group is a collaboration between global experts and leaders from health technology assessment (HTA) agencies in Asia, which is seeking to develop non-binding guidance that will provide a framework to generate and use RWD/RWE in a consistent and efficient manner for decision making in Asia [1].

Barriers to regulatory and HTA agencies in using real-world data/evidence

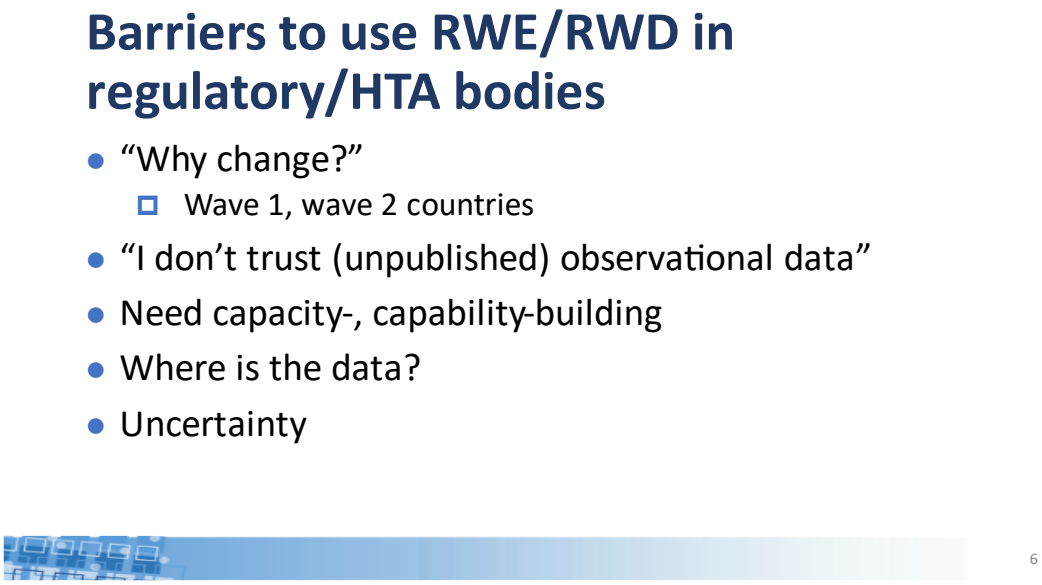
The mindset of agencies and their committees/reviewers could be a potential barrier to using RWD/RWE if there are questions or opposition to change. There may also be a lack of trust of observational data, particularly if it has not been published, and uncertainty in using unfamiliar data sources. In addition, agencies are likely to face capacity and capability barriers to using RWD/RWE.

Real-world data in Taiwan

In Taiwan, the National Health Insurance (NHI) database includes claims data from more than 99% of the population and collects information on several aspects of healthcare from pharmacy dispensing to dental care to traditional medicine. More than 6500 research articles have been published in the international journal based on the NHI database since 2005. Taiwan also has several government and non-government sources of RWD including national health surveys, patient registries and electronic medical records. For example, the NHI-based nationwide registry for hepatitis C is monitoring the long-term safety and effectiveness of directly acting antivirals in the treatment of chronic hepatitis C patients. The resulting real-world data evidence is used to support reimbursement policy for these drugs in treating chronic hepatitis C.

Summary

RWE is supposed to link with certain ‘decisions’, otherwise it is just results of analysis. In Asia, it is not necessary for agencies to make decisions early (earlier than the EU or US), or to make decisions entirely based on local evidence and context. Gaps and challenges exist to be able to use RWE to make decisions, including capability to excel in methodologies, long capacity building period and difficulties to build a trustworthy information system. Regulatory and HTA agencies in Asia must acknowledge the need to reform and re-structure the responsibility of using RWE.



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HTA and regulatory evidentiary requirements: where are the gaps and how can these be aligned? A case study on Mexico

Dr María Cristina Gutiérrez Delgado, *Faculty of Sciences, National Autonomous University (UNAM), Mexico*

When HTA was first implemented in Mexico in 2003, cost effectiveness analysis based on disability-adjusted life years was used as the main evidence for economic evaluation. This decision was made due to the lack of validated utility instruments and information for the Mexico population in terms of quality of life. In addition, there was also no participation of patients in the HTA process. These gaps created a challenge for the General Health Council (GHC) and the Mexican HTA agency, the National Centre for Health Technology Excellence (CENETEC), in being able to adopt internally recognised HTA methodology based on cost-utility or value-based analysis.

Collaborative project on social values

To address this challenge and strengthen the HTA process, the GHC promoted collaborative work between a variety of public, academic and private stakeholders (see below). In 2019 a study was carried out to generate the missing information on quality of life for the Mexican population by using the EuroQol Group's international EQ-5D-5L valuation protocol and software [1]. Pain/discomfort was highlighted as the most important EQ-5D-5L domain to the Mexican population, followed by anxiety/depression. International comparisons showed that Mexico and the US both rated pain/discomfort as the most important domain.

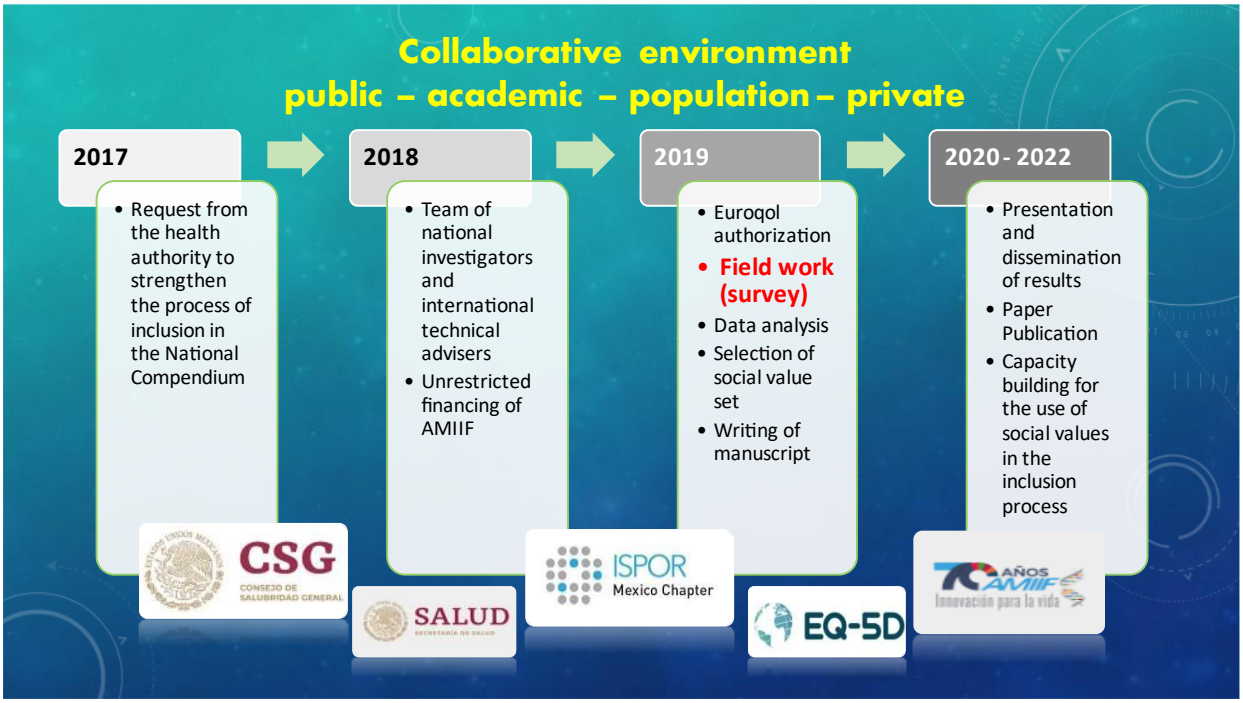
Impact of the project

The generation of the Mexican social value set is an essential step towards continuous improvement of health systems, which is particularly important in Latin American countries that generally have very restricted resources. Key to success was the willingness and openness of the GHC to put together a multidisciplinary team focused on addressing the technical gap in the Mexican HTA process. The generated Mexican social values not only allow international comparisons of results at the quality-adjusted life year (QALY) level, but also strengthen the HTA process allowing the incorporation of the patient's perception, potential development of value-based analysis, use of cost-utility analysis as key evidence of economic evaluation, and availability of validated utility instruments for use in population-based surveys.

The results of the collaborative project can already be used in ongoing or completed multicentre clinical trials and economic evaluations development under the EuroQol framework. For example, at least two innovative pharmaceutical companies are in the process of updating their cost-effectiveness analyses to include this information and in resubmitting some of their products for inclusion on the National Compendium of Health Supplies.

Summary

Previously in Mexico there was a lack of information to develop cost-utility or value-based analysis, no patient participation in the HTA process and no utility instrument to use in population-based surveys. To address these gaps, the GHC promoted collaborative work between public, academic and private organisations, which led to a study that generated the first social value set representing the stated preferences of the Mexican adult population. The resulting social value set will strengthen the HTA process in Mexico and allow international comparisons of results at the QALY level.



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Section 3: Panel discussions

Summary of panel discussions

Each panellist was asked to provide their thoughts on:

- Reflections from the workshop
- What can be learnt from current initiatives within their jurisdictions to inform the future evolution or direction of the regulatory-HTA interactions in maturing countries
- Recommend possible research areas for CIRS and other groups to undertake to support/inform/enable future regulatory-HTA interactions.

A summary of key points from each panellist/presentation is provided below.

European regulatory/HTA agency perspective

Michael Berntgen, *Head of the Evidence Generation Department, EMA*

Niklas Hedberg, *Chief Pharmacist, TLV, Sweden*

- The joint work of the EMA and European Network for Health Technology Assessment (EUnetHTA) cooperation has been the foundation for establishing mutual trust and understanding between regulators and HTA agencies in Europe.
- Based on these experiences (see technical report), priority areas for future collaboration between regulators and HTA agencies at the European level are being developed.
- The EUnetHTA21 consortium for the "Service Contract for the Provision of Joint Health Technology Assessment (HTA) Work Supporting the Continuation of EU Cooperation on HTA" will be instrumental in this delivery.

Asia HTA agency perspective

Fiona Pearce, *Senior Adviser, Agency for Care Effectiveness (ACE), Ministry of Health, Singapore*

- HTA is usually a national priority in Asian countries where governments are the principal payer for healthcare, however, interest in HTA is growing across the region.
- There is a need to build HTA capability in some countries, not just within agencies but also within companies who often do not have technical staff locally.
- Real-world evidence (RWE) plays a key role in addressing evidence gaps due the lack of randomised controlled trials (RCTs) conducted in Asia and genetic differences that mean results cannot be generalised to Asian populations.
- Efforts are ongoing in some countries to expand stakeholder engagement e.g. with patients and industry.
- HTA agencies are gradually adapting to uncertainty arising from fast-tracked technologies by moving towards risk-sharing arrangements or periodic assessments.

Industry perspective

Junil Kim Director/Market Access APAC, Bayer, Singapore

- There are ongoing efforts to make HTA systems in Asia more systematic and transparent.
- Pharmaceutical companies are increasingly focusing on Environmental, Social and Governance (ESG) e.g. sustainability goals to provide medicine to more patients.
- This provides an opportunity for companies, regulators, HTA agencies and payers to work together to support sustainable patient access.

Academic perspective

Prof Adrian Towse, *Emeritus Director and Senior Research Fellow, Office of Health Economics, UK*

- There are different dimensions of collaboration:
  - Vertical e.g. relationship between regulator and HTA agency within a jurisdiction
  - Horizontal e.g. regulator with regulator, HTA with HTA
  - Regional/geographical
  - Areas/topics e.g. horizon scanning, scientific dialogue during development, assessment of clinical evidence, post-licensing evidence generation
- Important for collaborations to have clear objective, avoid duplication and work towards supporting best practices.
- CIRS could build on its mapping exercise to identify areas where there is potential for collaboration or reliance between regulators and HTA agencies.

Latin American HTA agency perspective

Prof Andres Pichon-Riviere, *Director of HTA and Health Economics Department, Institute for Clinical Effectiveness and Health Policy, Argentina*

- Many countries in Latin America do not have formal coverage systems, which is a weakness for HTA.
- While there have been great advances in the regulatory environment, this has not happened for HTA.
- There are opportunities for regulators and HTA agencies to be more aligned, integrated and efficient e.g. in areas of evidentiary requirements.
- To improve regulatory-HTA interactions, HTA agencies need to be strengthened and the HTA process must be institutionalised within each country.

Industry perspective

Cammilla Horta Gomes, *LATAM Regulatory Policy Lead, Roche, Brazil*

- Companies should position themselves as healthcare partners to help make health systems more resilient.
- Regulators and HTA agencies in Latin America need to increase their interactions while maintaining their autonomy.
- Communication and experience sharing is key to supporting innovation and promoting comprehensive universal healthcare coverage as a benefit and not a cost.
- There is a need for greater stakeholder engagement including engaging with patients.
- CIRS and other groups should leverage learnings from regulators e.g. use of reliance, guidance on good practices, to help promote HTA practices.

Academic perspective

Don Husereau, *School of Epidemiology, Public Health and Preventive Medicine, University of Ottawa, Canada*

- Improving public policy and growing HTA are slow processes; multiple steps are needed to achieve regulatory-HTA alignment.
- For HTA recommendations to be adopted, there needs to be a clear decision maker at the end of the HTA process.
- Latin America is making progress in its HTA environment but needs to continue strengthening and socialising HTA amongst stakeholders.

Summary of panel discussions

Stakeholder reflections on the evolution of regulatory and HTA systems in Asia/Latin America and potential learnings from Europe

Academic

For HTA recommendations to be adopted, there needs to be a clear decision maker at the end of the HTA process.

HTA

To improve regulatory-HTA interactions, HTA agencies need to be strengthened and the HTA process must be institutionalised within each country.

Regulator/HTA

Joint work of the EMA and EUnetHTA cooperation has been the foundation for establishing mutual trust and understanding between regulators and HTA agencies in Europe.

HTA

There is a need to build HTA capability in some countries, not just within agencies but also within companies who often do not have technical staff locally.

Academic

Collaborations must have clear objectives, avoid duplication and work towards supporting best practices.

Industry

Companies should position themselves as healthcare partners to help make health systems more resilient.

HTA

While there have been great advances in the regulatory environment, this has not happened for HTA.

Industry

There is a need for greater stakeholder engagement including engaging with patients.

Regulator/HTA

EUnetHTA21 will build on achievements and learnings from EUnetHTA and deliver joint HTA assessments to support the EU cooperation on HTA.

Industry

Companies are increasingly focusing on sustainability goals, giving an opportunity for all stakeholders to work together to support sustainable patient access.

HTA

RWE plays a key role in addressing evidence gaps due the lack of RCTs conducted in Asia and genetic differences that mean results cannot be generalised to Asian populations.

Industry

There are ongoing efforts to make HTA systems in Asia more systematic and transparent.

Appendix: Workshop attendees

Affiliations are stated as they were at the time of the meeting.

Regulatory agencies		
Kwame Dei Asamoah-Okyere	*Chief Regulatory Officer, Monitoring and Evaluation Division*	*Food and Drugs Authority (FDA), Ghana*
Zeti Hulwani Baba	*Senior Principal Assistant Director*	*National Pharmaceutical Regulatory Agency (NPRA), Malaysia*
Michael Berntgen	*Head of the Evidence Generation Department*	*European Medicines Agency (EMA), The Netherlands*
Jayne Crowe	*Senior Clinical Assessment Advisor*	*Health Products Regulatory Authority (HPRA), Ireland*
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Wan-Hui Lu	*Associate Reviewer*	*Food and Drug Administration (FDA), Taiwan – Chinese Taipei*
Siti Kamilah Malik	*Principal Assistant Director*	*National Pharmaceutical Regulatory Agency (NPRA), Malaysia*
Maslinda Mahat	*Head of Policy & Strategic Planning Section*	*National Pharmaceutical Regulatory Agency (NPRA), Malaysia*
Tan Jas Min	*Senior Principal Assistant Director*	*National Pharmaceutical Regulatory Agency (NPRA), Malaysia*
Khirul Falisa Mustafa	*Senior Principal Assistant Director*	*National Pharmaceutical Regulatory Agency (NPRA), Malaysia*
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