The CIRS Regulatory and Reimbursement Atlas™

CIRS Regulatory and Reimbursement Atlas

The pathways to access are at hand™

Follow the complex interactions of regulatory, HTA and payer processes Successful medicine development results from the ability to effectively navigate regulatory, HTA, and payer pathways throughout a product's lifecycle.

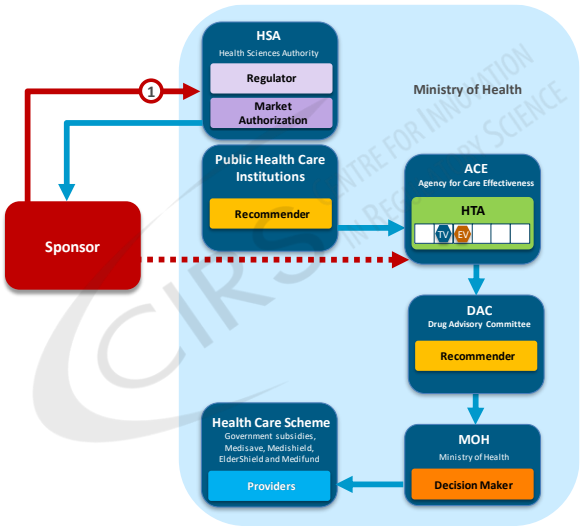
As the global development environment becomes more complex, the need to understand the confluence of these pathways has become a driver of the medicines development process. And as these processes evolve and transform in response to changing local, regional and global influences, it becomes increasingly difficult to monitor and comply with the development routes to be followed within each jurisdiction. Answering simple questions about each agency's responsibilities can be time consuming and confusing. Furthermore, conducting true head- to-head comparisons of these pathways among countries has been virtually impossible with existing resources.

See the big picture in small detail Now there is a simple, yet comprehensive way to view the approval and reimbursement pathways in jurisdictions all around the world in a single, up-to-date compendium. Over the past 17 years, CIRS – the Centre for Innovation in Regulatory Science, has collaborated with more than 75 regulatory and payer agencies to understand the nature of their activities.

Using our proprietary methodology to map regulatory, HTA and payer pathways and to illustrate the core functions of each agency, CIRS has developed a simple, globally recognised approach to understanding this diverse landscape.

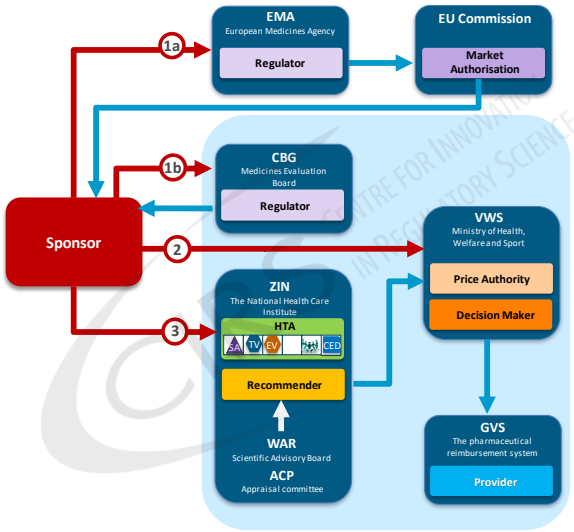
Sample Atlas maps

Singapore



Agency (Committee)	Function	Key activity
HSA Health Sciences Authority	Regulator	The HSA regulates health products including drugs, therapeutics and medical devices to ensure they meet the required safety, efficacy and quality standards.
	Market Authorisation	The HSA is responsible for the market authorisation of medicines and medical devices.
Health Care Scheme	Provider	The Ministry of Health Standard Drug List comprises the essential drugs to meet the health care needs of the majority of the population and to ensure that essential drugs are available at affordable prices. The Standard Drugs List (SDL) is reviewed annually. Applications to include a new drug are submitted by clinicians from public health institutions. The SDL contains two lists: list 1 is formed of essential first line drugs, and list 2 contains higher priced essential drugs that require the patient to cover half the costs.
Public healthcare institutions	Recommender	Health care professionals (such as clinicians or pharmacists) identify patients' needs for new drugs and apply for the drugs to be included in the Standard Drug List. New and emerging drugs that might be suitable for evaluation are also identified through literature searches and horizon scanning by the ACE technical team.
ACE Agency for Care Effectiveness	HTA	The ACE assesses the therapeutic benefit, cost-effectiveness and budget impact of drugs submitted for inclusion in the standard drug list. The evaluation branch of ACE conducts health technology assessments and develops guidance for drugs, devices and medical services, as well as appropriate care guides. They are also the secretariat for the relevant advisory committees in MOH.
DAC Drug Advisory Committee	Recommender	The DAC prioritises drug applications which hold potential for driving significant improvement in health outcomes, appraises the effectiveness of drugs based on specific therapeutic, clinical and pharmacoeconomic evidence and provides drug listing recommendations to the Ministry of Health, including conditions and/or criteria for subsidy.
Ministry of Health	Decision Maker	The Ministry of Health reviews the DACs recommendation and also considers the therapeutic need and affordability of the drug before determining the final listing decision. The Ministry of Health also reviews drugs already listed in the SDL for removal if they are no longer required.

Netherlands



Agency (Committee)	Function	Key activity
CBG/MEB Medicines Evaluation Board	Regulator	The CBG/MEB is part of Ministry of Health, Welfare and Sport that regulates medicinal products for human use.
	Market Authorisation	The CBG/MEB is responsible for market authorisation of pharmaceuticals, registration of medical devices and monitoring the safety of medicines.
ZIN The National Health Care Institute	HTA	The National Health Care Institute produces therapeutic, cost-effectiveness and budget impact assessments for new pharmaceuticals and provides advice on reimbursement to VWS. For outpatient pharmaceuticals the company applies for reimbursement, for inpatient pharmaceuticals ZIN selects technologies for assessment and plans activity.
	Recommender	The National Health Care Institute provides recommendations to the VWS for reimbursement decisions.
WAR Scientific Advisory Board	Committee	The Scientific Advisory Board (WAR) is an integral assessment committee, which provides scientific advice both in the area of package management and quality. The WAR consists of various experts such as doctors, scientists, researchers and policy advisers in healthcare.
ACP Advisory Commission Package	Committee	The Advisory Commission Package (ACP) issues recommendations to ZIN. These recommendations relate to intended reports and reports in which ZIN advices VWS about proposed policy concerning the basic package or about developments that could lead to changes to the package.
VWS Ministry of Health, Welfare and Sport	Decision maker	The VWS makes decisions on the reimbursement category and reference reimbursement price.
GVS The pharmaceutical reimbursement system	Provider	The GVS is a system for claiming the drug reimbursement. Once a medicine is included on the GVS, it is eligible for the reimbursement and belongs either to 1) List 1A, which collects therapeutically interchangeable drugs reimbursed according to the reference price system (reimbursement limit), 2) List 1B, which collects drugs with added therapeutic value that cannot be reimbursed according to the reference price system (no reimbursement limit); and 3) List 2, which includes specialist drugs that are only reimbursed under specific circumstances.

Use the CIRS Regulatory and Reimbursement Atlas™ to:

- Determine the sequence of interactions with agencies in each jurisdiction, while understanding each agency's particular functions
- Plan your development strategy by identifying potentially rate-limiting process steps
- Compare processes between jurisdictions to facilitate simultaneous development programmes
- Train staff on the requirements for medicine development in specific countries; inform work colleagues of intricacies of each jurisdiction's access processes

More than just maps

- Embedded hyperlinks point to current information for each agency
- Graphical icons provide simple visual clues to each agency's specific roles and activities
- "Sticky notes" function on web lets you annotate your password-protected maps based on your needs and goals
- "Compare" function permits side-by-side comparison of up to four jurisdictions

R&D briefing and Peer reviewed publications

The methodology used in the Atlas has been developed over the past decade using a systematic approach that has been recognized as a global standard. This comprehensive publication illustrates the development of the methodology and utility of the process maps.

R&D briefing 63: HTA Process Maps: Identifying similarities and differences for alignment

The approach used by the Atlas has formed the basis for several innovative peer reviewed publications

- A comparison of 33 European national HTA and decision-making systems
- A Comparison of Recommendations by European HTA Agencies
- Factors Influencing Divergent HTA Reimbursement Recommendations

Jurisdictions included in the Atlas as of 1st June 2019

- Argentina
- Australia
- Austria
- Belgium
- Brazil
- Bulgaria
- Canada: CDR and pCODR
- Canada, Alberta
- Canada, British Columbia
- Canada, Manitoba
- Canada, New Brunswick
- Canada, Newfoundland and Labrador
- Canada, Northwest Territories
- Canada, Nova Scotia
- Canada, Nunavut
- Canada, Ontario
- Canada, Prince Edward Island
- Canada, Quebec
- Canada, Saskatchewan
- Canada, Yukon
- Chile
- China
- Colombia
- Croatia
- Cyprus
- Czech Republic
- Denmark
- England
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Iceland
- Ireland
- Italy (national)
- Japan
- Latvia
- Liechtenstein
- Lithuania
- Luxembourg
- Malta
- Mexico
- Netherlands
- New Zealand
- Norway
- Peru
- Philippines
- Poland
- Portugal
- Romania
- Saudi Arabia
- Scotland
- Singapore
- Slovakia
- Slovenia
- South Korea
- Spain (national)
- Sweden
- Switzerland
- Taiwan
- Thailand
- Turkey
- USA CMS (Medicare /Medicaid)
- Wales

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