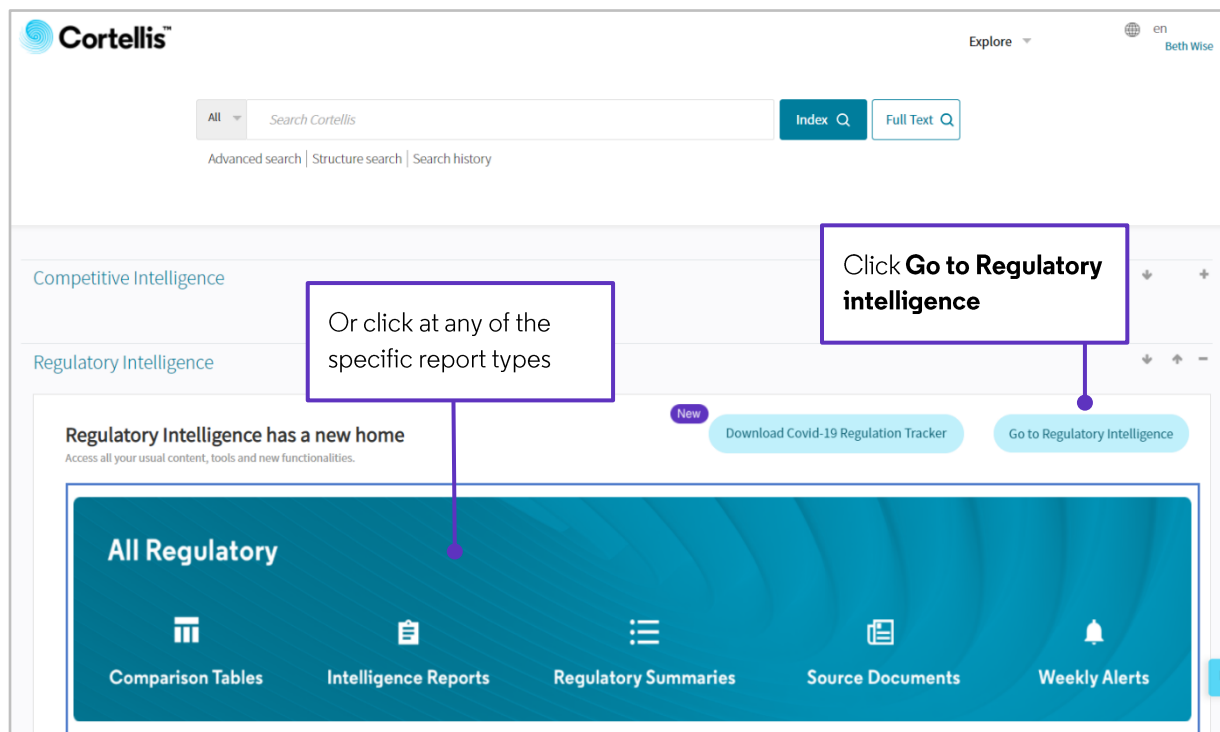


# Migrating from GMAS to Cortellis Regulatory Intelligence

This guide shows Global Market Access Solution customers how to access this content on the Cortellis platform.

If your account is entitled to access more than one Cortellis module (Regulatory plus Competitive Intelligence for instance) you will see the Cortellis Homepage upon logging in. Otherwise, you will land directly on the Cortellis Regulatory Homepage and you can skip this first step.

**Click “Go to Regulatory Intelligence” to access the Regulatory Home Page.** This is where the GMAS content now sits. You can also go directly to a specific regulatory report type by clicking “Comparison Tables”, “Intelligence Reports” or “Regulatory Summaries” in the panel.



Under the **Comparison Tables** Tab find two tables created from GMAS content comparing key Pricing and Reimbursement and Health Technology Assessment content in English across different countries and regions.

The screenshot displays the 'Market Access Guidance' section of a regulatory website. The page is titled 'Regulatory' and includes a 'Covid-19 Regulation Tracker' link. The 'Comparison Tables' link is highlighted, and the 'Market Access Guidance' section is expanded. The 'Health Technology Assessment Overview' and 'Pharmaceutical Pricing and Reimbursement Overview' sections are visible. The 'Pharmaceutical Pricing and Reimbursement Overview' section includes an abstract, a last updated date, and a 'Global Comparison' table. The table compares healthcare systems, pricing and reimbursement stakeholders, use of HTA, ability to seek regulatory approval, use of real-world evidence, estimated timelines for pricing and reimbursement, and use of managed entry agreements across Argentina, Australia, and Austria. Annotations with arrows point to various elements: 'Click Comparison tables' points to the 'Comparison Tables' link; 'Scroll down the page to the Market Access Guidance Heading' points to the 'Market Access Guidance' heading; 'Click the links to open the documents' points to the 'Health Technology Assessment Overview' and 'Pharmaceutical Pricing and Reimbursement Overview' sections; 'Set up email alerts and download to Excel' points to the email alert and download icons; and 'Quickly compare key data across countries on your topic' points to the 'Global Comparison' table.

Click Comparison tables

Scroll down the page to the Market Access Guidance Heading

Click the links to open the documents

Set up email alerts and download to Excel

Quickly compare key data across countries on your topic

Regulatory Covid-19 Regulation Tracker

All Comparison Tables Intelligence Reports

Browse Search

Drugs and Biologics

Authorities and Organizations

Health Ministry and Regulatory Agency Directory

Transparency

Legal Definitions and Marketing Requirements

Biosimilar Products

Generic Products

Market Access Guidance

Health Technology Assessment Overview

This subject provides key features of the use of health technology assessment in select geographies, including preferred comparator, economic models and thresholds for cost-effectiveness. Links to related Regulatory Summaries and quoted reference documents are included.

Pharmaceutical Pricing and Reimbursement Overview

This subject provides key features of the healthcare organization, pricing and reimbursement system, and national formularies in select geographies. These features include key stakeholders, use of health technology assessment, the ability to obtain seek regulatory.

Pharmaceutical Pricing and Reimbursement Overview

299397 Drugs and Biologics Market Access Guidance

Abstract

This subject provides key features of the healthcare organization, pricing and reimbursement system, and national formularies in select geographies. These features include key stakeholders, use of health technology assessment, the ability to obtain seek regulatory approval and reimbursement simultaneously, and cost-containment measures that affect the pricing and reimbursement landscape. Links to related Regulatory Summaries and quoted reference documents are included for additional information. This comparison table covers 33 countries. Coverage is currently limited to these countries in alignment with Regulatory Summary new content.

Last Updated Date

12-Jul-2021

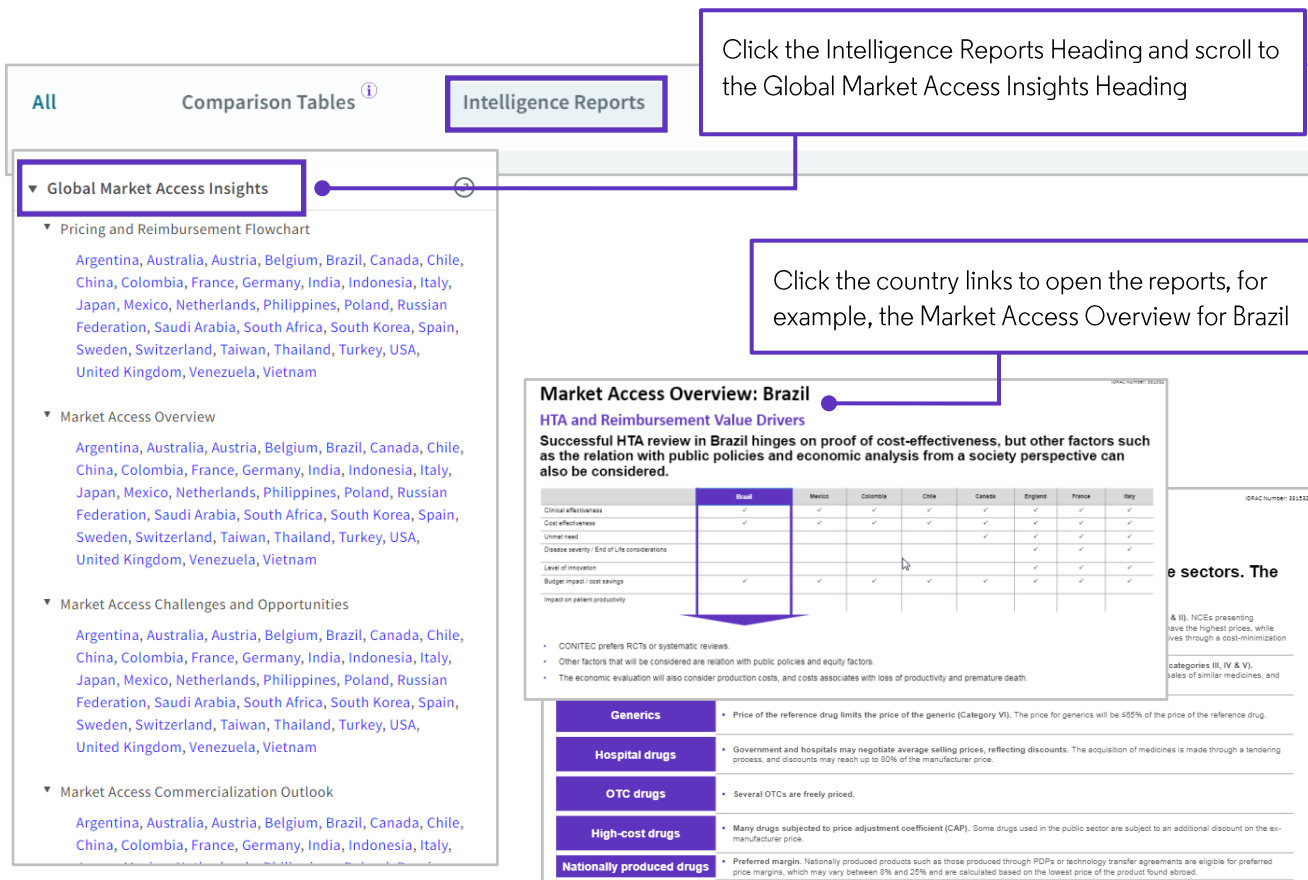
Global Comparison

Apply Filters

My Regions

Country/Region	Healthcare system organization	Pricing and Reimbursement stakeholders	Use of HTA	Ability to seek regulatory approval and reimbursement at same time	Use of real-world evidence	Estimated timelines for pricing and reimbursement	Use of managed entry agreements
Argentina	Bismarckian model healthcare system.	• Superintendencia de Servicios de Salud (SSSaLud; Health Services)	Used to some degree for reimbursement.	Not possible.	Used in the reimbursement process, particularly in the	60-120 days.	Not commonly used.
Australia	Beveridge model healthcare system.	Pharmaceutical Benefits Advisory Committee (PBAC).	HTA is used for pricing and reimbursement.	TGA-PBAC parallel process is available.	RWE is used for reviewing a reimbursement decision of a drug after 2 years.	270 days.	Primarily financial ones (risk-sharing agreements).
Austria	Bismarckian model healthcare system.	• Federal Ministry of Health and Ministry of Labour, Social Affairs and	HTA is used for pricing and reimbursement.	Not possible.	Used in the reimbursement process.	90-300 days.	Primarily financial ones.

Here's how you can find the **Market Access Overview, Pricing and Reimbursement flowcharts, Commercialization Outlook and Market Access Challenges and Opportunities** reports migrated from GMAS.



Click the Intelligence Reports Heading and scroll to the Global Market Access Insights Heading

Click the country links to open the reports, for example, the Market Access Overview for Brazil

**Market Access Overview: Brazil**  
**HTA and Reimbursement Value Drivers**  
 Successful HTA review in Brazil hinges on proof of cost-effectiveness, but other factors such as the relation with public policies and economic analysis from a society perspective can also be considered.

	Brazil	Brazil	Colombia	Costa Rica	Canada	England	France	Italy
Cost-effectiveness	✓	✓	✓	✓	✓	✓	✓	✓
Cost-effectiveness	✓	✓	✓	✓	✓	✓	✓	✓
Unmet need					✓	✓	✓	✓
Disease severity / End of Life considerations					✓	✓	✓	✓
Level of innovation					✓	✓	✓	✓
Budget impact / cost savings	✓	✓	✓	✓	✓	✓	✓	✓
Impact on patient productivity					✓	✓	✓	✓

- CONITEC prefers RCTs or systematic reviews.
- Other factors that will be considered are relation with public policies and equity factors.
- The economic evaluation will also consider production costs, and costs associates with loss of productivity and premature death.

**Generics** • Price of the reference drug limits the price of the generic (Category VI). The price for generics will be 55% of the price of the reference drug.

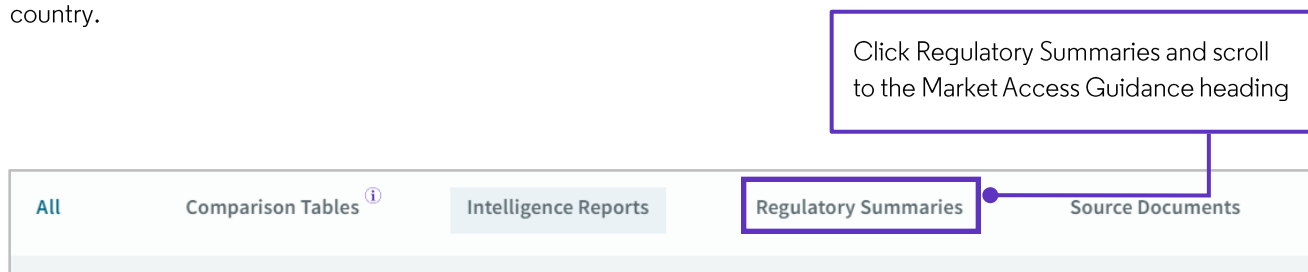
**Hospital drugs** • Government and hospitals may negotiate average selling prices, reflecting discounts. The acquisition of medicines is made through a tendering process, and discounts may reach up to 80% of the manufacturer price.

**OTC drugs** • Several OTCs are freely priced.

**High-cost drugs** • Many drugs subjected to price adjustment coefficient (CAP). Some drugs used in the public sector are subject to an additional discount on the ex-manufacturer price.

**Nationally produced drugs** • Preferred margin. Nationally produced products such as those produced through PDIs or technology transfer agreements are eligible for preferred price margins, which may vary between 5% and 25% and are calculated based on the lowest price of the product found abroad.

**The Regulatory Summaries on Pricing and Reimbursement and Health Technology Assessment have been created from the Country Assessment reports in GMAS and follow the consistent Cortellis Q&A format.** Regulatory Summaries are English language “how to” documents on policy that help you with your local submissions. They also include links to the official documents from the authorities and are a great way to become familiar with a topic for a country.



Click Regulatory Summaries and scroll to the Market Access Guidance heading

Market Access Guidance

Pricing and Reimbursement Overview

[Argentina, Australia, Austria, Belgium, Brazil, Canada, Chile, China, Colombia, France, Germany, India, Indonesia, Italy, Japan, Netherlands, Philippines, Poland, Russian Federation, Saudi Arabia, South Africa, South Korea, Spain, Sweden, Switzerland, Taiwan, Thailand, Turkey, USA, United Kingdom, Venezuela, Vietnam](#)

Health Technology Assessment Summary

[Argentina, Australia, Austria, Belgium, Brazil, Canada, Colombia, France, Germany, Italy, Japan, Mexico, Philippines, Poland, South Korea, Spain, Switzerland, USA, United Kingdom](#)

Click the country links to open the reports

1 of 6

2021-07-09

### Q1 Health technology assessment use

**Q1.1 Does this country perform a health technology assessment to determine the price or reimbursement status of therapies on a national formulary/drug list?**

The Austrian Social Security (SV; *Österreichische Sozialversicherung*) acts as both a payer and HTA body for outpatient pharmaceuticals, supported by the Pharmaceutical Evaluation Board (HEK; *Pharmazeutische Evaluierungskommission*).

Austria also performs health technology assessment via the Austrian Institute for Health Technology Assessment (AIHTA).

**Q1.2 Background and organization of HTA**

**Q1.2.1 Who are the key decision makers involved in the HTA process in this country and what are their responsibilities?**

The Austrian Social Security (SV; *Österreichische Sozialversicherung*) acts as both a payer and HTA body for outpatient pharmaceuticals, supported by the HEK.

The Austrian Institute for Health Technology Assessment (AIHTA) assesses select pharmaceuticals. AIHTA replaced the Ludwig Boltzmann Institute for Health Technology Assessment (LBI-HTA) in May 2018.

**Q1.2.2 What are the key features of this HTA system?**

- Role of HTA:** All drugs applying for inclusion on the outpatient positive reimbursement list must undergo SV evaluation.
- HTA compulsory for reimbursement:** SV recommendations are binding and form the basis for reimbursement decision.
- Decisions binding or recommendations:** Binding.
- Frequency of meetings to assess therapies:** As needed.
- Role of regional review:** Not performed.
- International collaborations:** Austria is a member of both EUnetHTA and BeNeLux.
- Role of horizon scanning:** The Austrian healthcare system relies upon horizon scanning to monitor emerging therapies with notable clinical and budget impact potential, therefore Austrian authorities to select products for early assessment. LBI notably conducts a Horizon Scanning in Oncology program. This project aims to support budget impact analysis of new drugs. BeNeLux also continues to develop a horizon scanning database.
- Influence on Pricing:** Pricing is determined separately in line with EU averages; however, the HTA process can influence pricing.

Example of a Health Technology Summary

The submission should include a Summary of Product Characteristics, European Public Assessment Report, and up to three key clinical studies.

For the health economic evaluation, the MAH should provide clinical, economic and epidemiological data. All the data sources used must be described exactly, their choice justified and their suitability and validity assessed. This involves scrutinizing both internal and external validity. Data demonstrating added therapeutic benefit, should display technical characteristics of the technology; efficacy/effectiveness; safety; health problem; and other evidence (e.g. patient aspects). In Austria, economic data is not systematically recorded or published. For this reason, health economic evaluations should refer primarily to data from the following sources:

- Austrian data from cost calculations published in cost studies
- Global schedule of fees of the Central Association or a mixed tariff from several schedules of fees (e.g. Vienna, Upper Austria, Styria and Tyrol) or a tariff list from a regional health insurance fund
- All tariff and price lists of social insurance institutions, hospitals, care homes, rehabilitation centers, geriatric centers, health spa clinics and chambers of physicians and pharmacists (e.g. list of products).
- LKF [Austrian DRG System] list of public fund hospitals
- Data from cost calculation by hospitals
- Cost estimates from Delphi surveys
- Empirical surveys
- Expert opinions.

#### Q2.2.2.2 What trial types are preferred, allowed, or discouraged in this country?

##### Preferred:

- Prospective, randomized controlled clinical trials with masked outcome assessment in a representative population, large data or meta-analyses of such studies
- Systematic reviews (e.g. Cochrane review) with meta-analyses of numerous studies with large patient numbers / numbers of patients, evidence of clearly defined endpoints that provide clear indications for the population for which the recommendations are being made
- Randomized controlled trials (RCTs), smaller data sets (fewer or smaller RCTs, or results inconsistent or study population does not match the target population of the recommendations)

##### Accepted:

You may also use the dynamic Search from the Regulatory Home Page to find documents containing specific keywords and phrases. In addition to the documents already discussed you are also able to find official documents.

Regulatory > All Results  
270 results for **"budget impact"**  
Switch to Comparison Tables

Refine Search

"budget impact"

Search

Filter

Country/Region
Topic
Document Type
Document Category
Date
All other filters
Reset Filters

Side by Side Viewer

Showing 1-10 of 270 results

Customize Columns

Sorted by Relevance

Summary	Title	Abstract
<input checked="" type="checkbox"/> May-2007 CA EN RD	PMPRB Guidelines: Budget Impact Analysis Guidelines (Guidelines for Conducting Pharmaceutical Budget Impact Analyses for Submission to Public Drug PI)	For Canada's public drug plans, budget impact analysis (BIA) is a tool used to predict and understand the potential impact of new drugs on the public drug plan.
<input checked="" type="checkbox"/> Jan-2012 BR PT RD	Methodological Guidelines: Manual Budget Impact Analysis for the Health System in Brazil, Jan-2012	This document by the Ministry of Health provides guidelines for pharmaceutical companies undergoing budget impact analysis (BIA) in addition to an efficiency analysis.
<input checked="" type="checkbox"/> 15-Jan-2021 FR RD	HAS Guideline on the Format of the Technical Report for Budget Impact Analysis - Supporting Document for the Submission of a Dossier for Budget Impact	This standard document is intended for manufacturers who submit a budget impact analysis (BIA) in addition to an efficiency analysis.
<input checked="" type="checkbox"/> Guideline: Pharmacoeconomic Guideline for Malaysia	These guidelines aimed to encourage the use of cost-effective drugs in the public sector.	

318 results for **"horizon scanning"**  
Switch to Comparison Tables

Refine Search

"horizon scanning"

Search

Filter

Country/Region
Topic
Document Type
Document Category
Date
All other filters
Reset Filters

Side by Side Viewer

Showing 1-10 of 318 results

Customize Columns

Sorted by Relevance

Summary	Title	Abstract
<input checked="" type="checkbox"/> Oct-2004 CA EN RD	Canadian Coordinating Office for Health Technology Assessment (CCOHTA): Canadian Optimal Medication Prescribing and Utilization Service COMPUS - Even	CCOHTA's Canadian Emerging Technologies Assessment Program (CETAP) is a national horizon scanning program. It alerts decision makers to new technologies that may have the potential to improve patient care.
<input checked="" type="checkbox"/> 15-Dec-2017 EU EN RD	14th Joint European Medicines Agency/European Network for Health Technology Assessment Dialogue Meeting Held on 15-Dec-2017	This document provides information on the 14th Joint European Medicines Agency/European network for Health Technology Assessment Dialogue Meeting.
<input checked="" type="checkbox"/> 19-Sep-2017 EU EN RD	European Medicines Agency - Payer Community Meeting Held on 19-Sep-2017	This document provides information on the European Medicines Agency - Payer Community meeting held on 19-Sep-2017. It discusses the importance of payer engagement in the regulatory process.
<input checked="" type="checkbox"/> European Medicines Agency and European Union	This document provides information on the European Medicines Agency and the European Union's efforts to improve patient access to medicines.	

For more information contact Customer Service at **LS Product Support**.

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