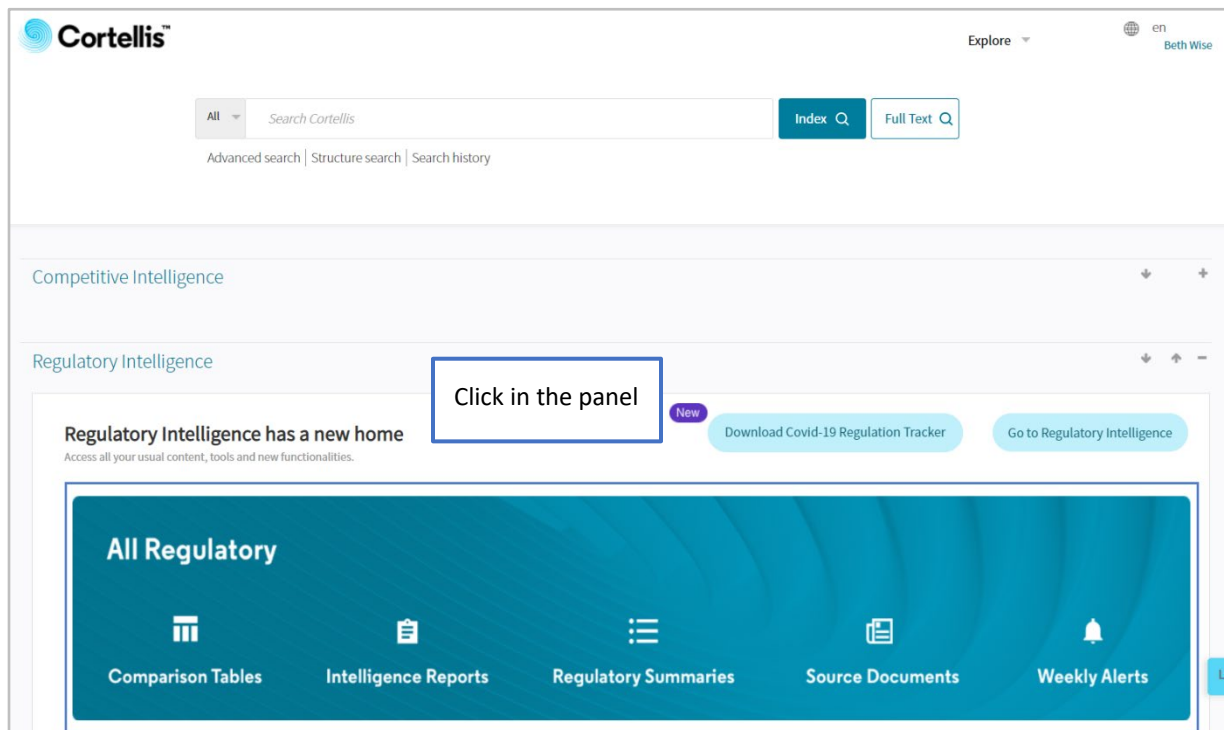


Migrating from GMAS to Cortellis Regulatory Intelligence

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 anywhere in the “All Regulatory” panel to access the Regulatory Home Page. This is where the GMAS content now sits.



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.

Global Comparison

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.

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.

Example of a Health Technology Summary

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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; *Heilmittel 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 and replaced the Ludwig Boltzmann Institute for Health Technology Assessment (LBI-HTA) in March 2020.

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 for public coverage must undergo SV evaluation
- HTA compulsory for reimbursement:** SV recommendations are binding and form the crux of a 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 BeNeLuxA
- Role of horizon scanning:** The Austrian healthcare system relies upon horizon scanning to monitor emerging therapies with notable clinical and budget impact potential, thereby allowing 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 for oncology drugs. BeNeLuxA also continues to develop a horizon scanning database.
- Influence on Pricing:** Pricing is determined separately in line with EU averages; however, the

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 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	Reason for Update
May-2007 (V) (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	N/A
Jan-2012 (V) (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	New on 09-Jul-2021
15-Jan-2021 (V) (FR) (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 Impac	This standard document is intended for manufacturers who submit a budget impact analysis (BIA) in addition to an efficiency	New on 29-Jan-2021

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
Oct-2004 (V) (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
15-Dec-2017 (V) (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 14th Joint European Medicines Agency/European network for Health
19-Sep-2017 (V) (EU) (EN) (RD)	European Medicines Agency - Payer Community Meeting Held on 19-Sep-2017	This document provides information on European Medicines Agency - Payer Community meeting held on 19-Sep-2017.it

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