



Migrating from Global Market Access Solution to Cortellis Regulatory Intelligence

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Agenda

- What is Cortellis?
- Finding Global Market Access Solutions content in Cortellis Regulatory Intelligence
- Cortellis added value
- Live Demo
- Wrap-up and Q&A

Unlock hidden insights and bring life to science

Make data-driven decisions with speed and certainty

Supporting your needs across the drug/device development lifecycle



Discovery & Preclinical Development

Clinical Development & Regulatory

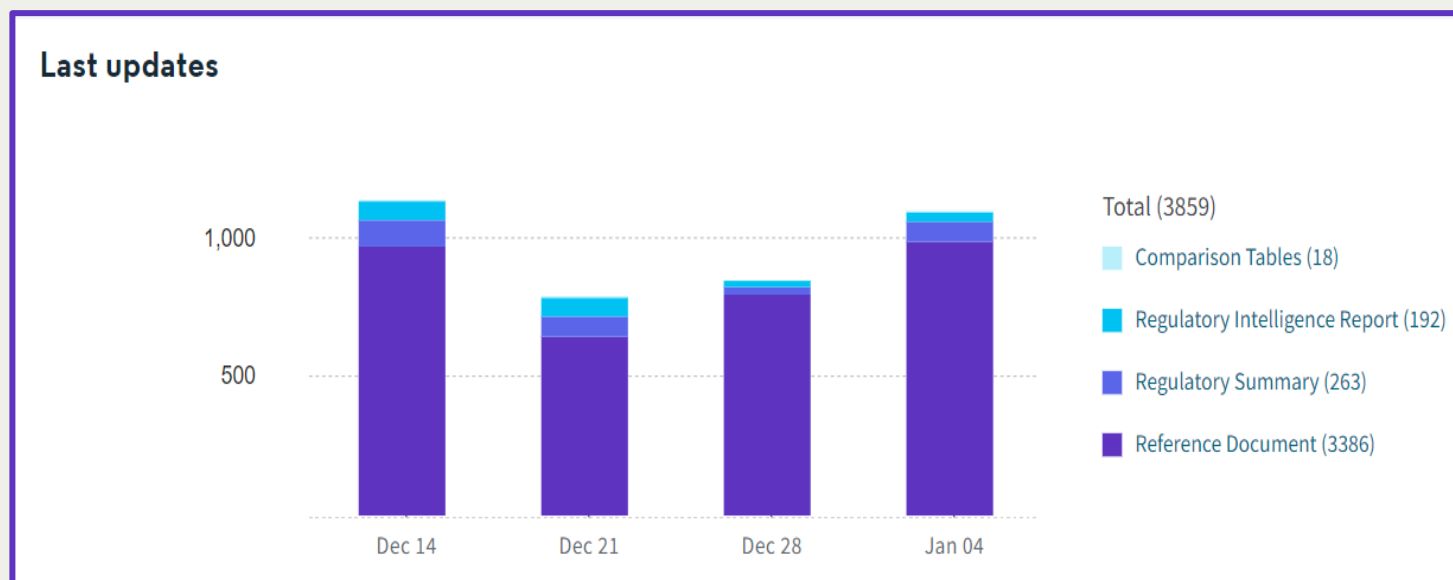
Portfolio Strategy & Business Development

Generics Strategy & Development

<<<<< Data | Insights | Analysis | Benchmarking >>>>>

What is Cortellis Regulatory Intelligence?

Cortellis Regulatory Intelligence includes over **240,000 official documents and exclusive value add regulatory reports** focusing on drugs and biologics covering over 80 countries and regions for drugs and biologics and 74 for medical devices and IVDs.




Use it to:

- Find up to date and historical guidelines, regulations and more official documents directly in Cortellis
- Consult exclusive value-add reports that save time
- Compare similarities & differences of key requirements across countries & regions
- Understand a competitor product's path to approval
- Be notified when regulatory changes take place - Alerts

GMAS Content in Cortellis

GMAS content migrated to Cortellis Regulatory Intelligence: *Commercial Attractiveness and Insights Library*



Global Market Access Solution
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New! COVID-19 Dashboard (by the GMAS team)

Insights and analysis by experts for experts

GMAS delivers a clear understanding of the complex and evolving drivers of, and barriers to, successful global market access.

[Read the latest GMAS News Review](#)

Geographic Focus



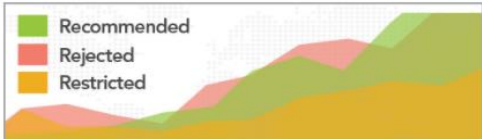
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Dive in and out of 33 Country Summaries, each with 90+ Key Performance Indicators (KPIs), to **quickly learn each market's unique commercial environment**

Select your exact area of interest in the Country Analysis section to **view country-specific insight**, including:

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- Pricing & reimbursement
- Healthcare systems
- Commercial outlook
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Scope therapy area opportunity across the globe with top-level epidemiology, mortality, global burden of disease, and managed entry agreement data

- Prevalence of ~60 major indications for ~20 countries
- Mortality & global burden of 50+ diseases for ~150 countries
- Managed entry agreement and outcomes-based contracting database

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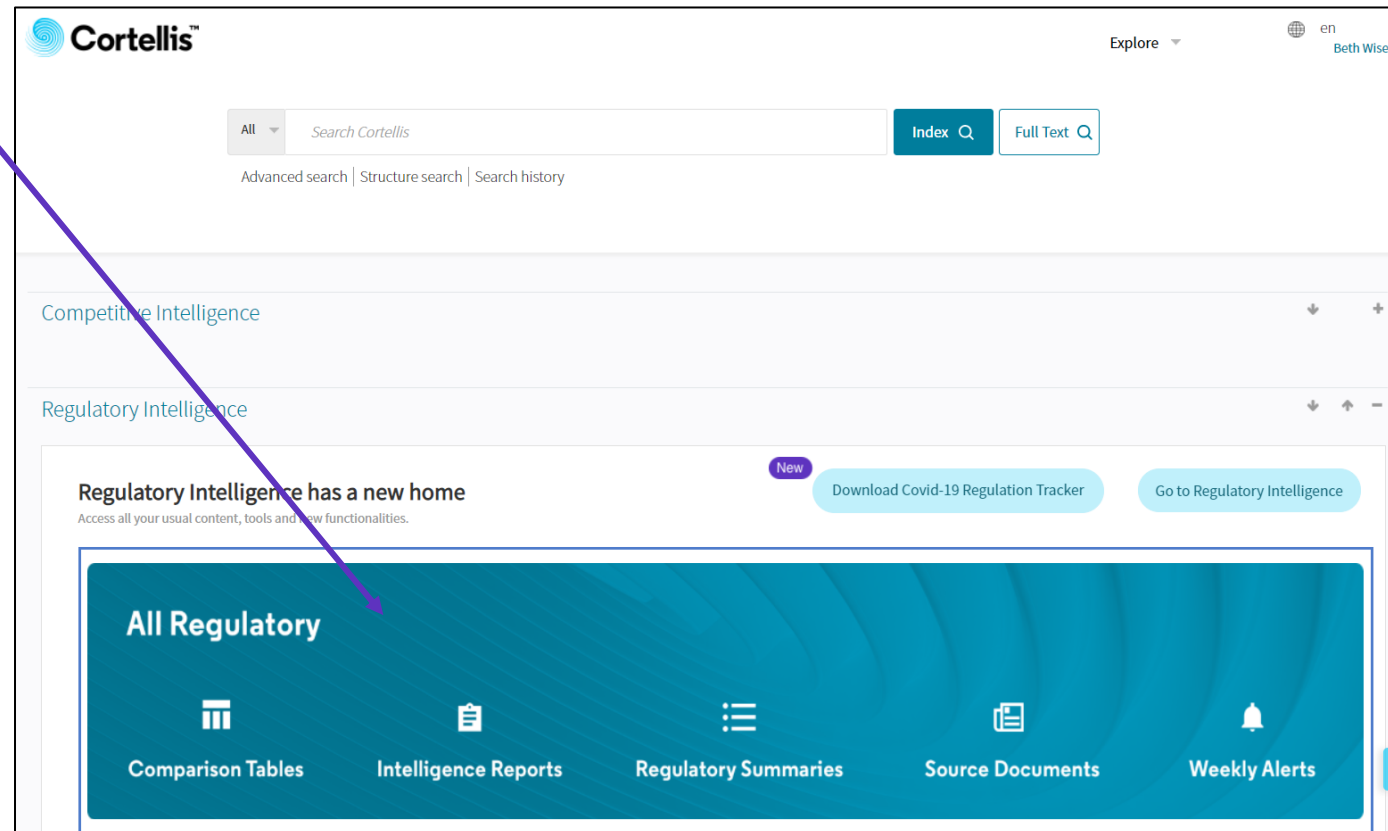
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Discover country-specific thought leadership—a library of insight accelerators across 33 countries, built to fit seamlessly into your workflow

- Commercialization Outlooks
- Pricing & Reimbursement Process Charts
- Country Analyses
- Country Archetypes
- Global Market Access News Reviews
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- And much more

Cortellis Home Page

Click panel to access Cortellis Regulatory Intelligence



GMAS Content in Cortellis Regulatory Intelligence Reports

Regulatory Intelligence Reports: 4 reports migrated from GMAS

- Market Access Overview
- Pricing and Reimbursement flowchart
- Commercialization Outlook
- Market Access Challenges and Opportunities

Refine Search ^

Document title, topic, country, reference Search

Filter

Country/Region **Topic** Document Type Medical Devices Specialty Date All other filters Reset Filters

q Select all Clear all Sort by Frequency

Other Topic (2268) Pediatrics (1252) Dossier Format and Submission (1250) Authorities and Organizations (1224) Generics and Biosimilars (773) Pharmacovigilance Technovigilance Risk Management (667)

Clinical Research (593) Product Assessment (575) Compliance and Inspection (371) Legislative Framework (253) Prescription Requirements (227) Manufacturing and Control (210) Packaging and Labelling (194)

Regulatory Procedures (186) Non Clinical Studies (168) GXP (160) **Pricing Reimbursement HTAs (139)** Active Pharmaceutical Ingredient (120) Distribution (66) Fees (51) Post authorization Studies (36)

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EN RIR

<input checked="" type="checkbox"/>	09-Jul-2021 V AR	Market Access Challenges and Opportunities	This document provides an overview of the key market access challenges and opportunities facing pharmaceutical	New on 09-Jul-2021:	Argentina	English
<input checked="" type="checkbox"/>	09-Jul-2021 V AR	Pricing and Reimbursement Flowchart	This document includes an internally developed pricing and reimbursement flowchart for Argentina, including a	New on 09-Jul-2021:	Argentina	English

Market Access Overview

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	Mexico	Colombia	Chile	Canada	England	France	Italy
Clinical 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.

High-cost drugs

Nationally produced 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.
- Preferred margin. Nationally produced products such as those produced through PDPs or technology transfer agreements are eligible for preferred price margins, which may vary between 8% and 25% and are calculated based on the lowest price of the product found abroad.

as for both public and private sectors. The el of innovation.

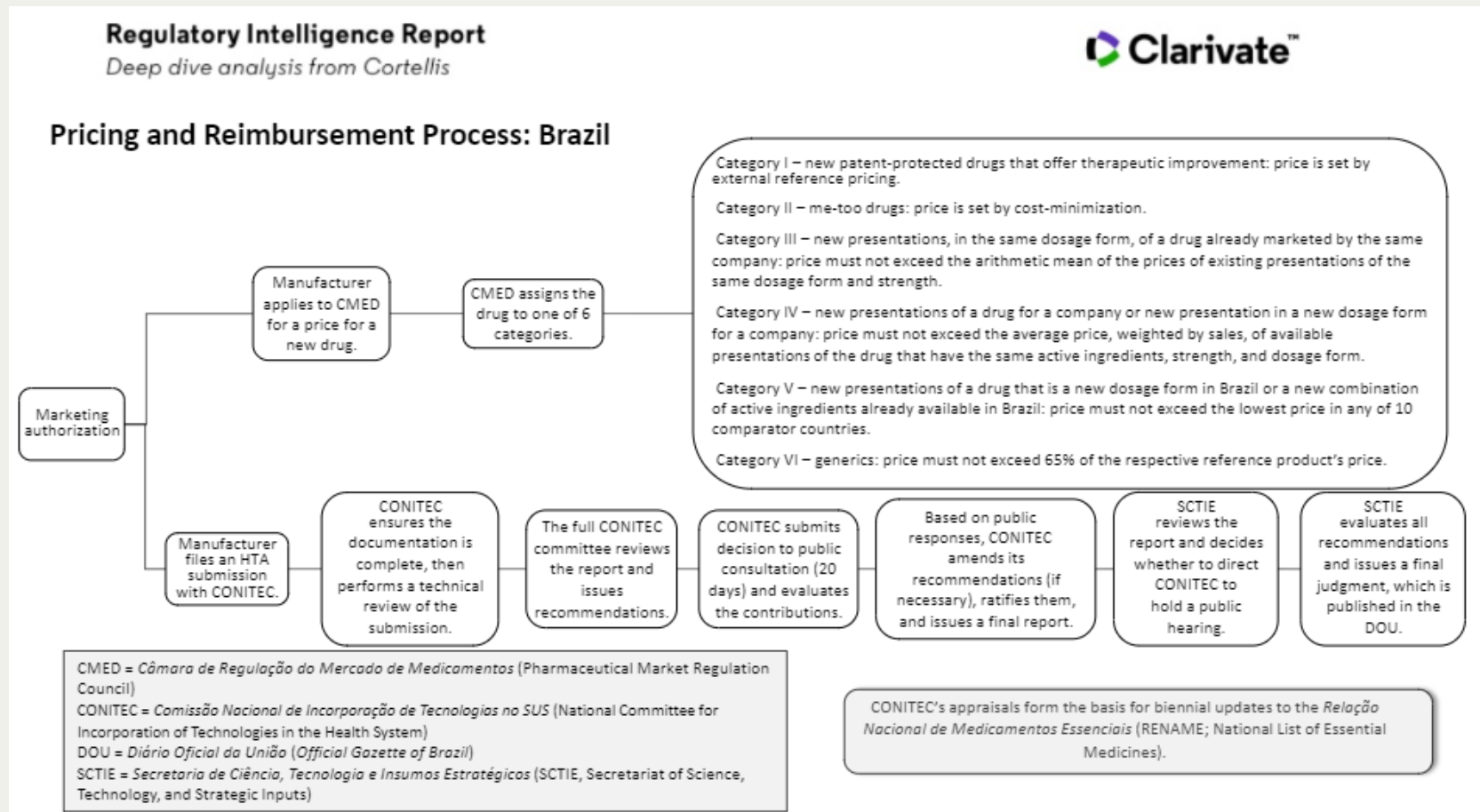
es and always below the lowest price found (categories I & II). NCEs presenting ies used for the same therapeutic indication (category I) wil have the highest prices, while e set taking in account the prices of other therapeutic alternatives through a cost-minimization

novelty in Brazil, and combination of active ingredients (categories III, IV & V). 1to consideration the average price of similar medicines, the sales of similar medicines, and

ric (Category VI). The price for generics will be ≤65% of the price of the reference drug.

ng prices, reflecting discounts. The acquisition of medicines is made through a tendering acturer price.

Pricing and Reimbursement flowcharts



Market Access Challenges and Opportunities

Market Access Challenges and Opportunities

1. Opportunities for pharmaceutical companies

- Per capita health expenditure in Brazil is increasing, majorly due to the growing mortality increasing number of prevalent diseases in the country. In 2018, Total health expenditure about 8% of GDP wherein private spending accounted for 4.4% of GDP and public spending 3.8% of the GDP.
- Growing affluence will expand the patient population that is able to afford international medicines and will likely also increase the prevalence of disorders associated with wealth (e.g., obesity, type 2 diabetes, cardiovascular disease).
- The increase in life expectancy will boost demand for treatments for geriatric disorders (e.g., Alzheimer's disease, Parkinson's disease, certain cancers).
- Products developed through the Public-Private Partnerships are given preference in public procurement.
- Drugs produced nationally are eligible to receive an additional preferred margin to that based on their lowest price abroad.
- As the world's sixth most populated country, Brazil represents the biggest market opportunity in Latin America for multinational pharmaceutical companies with value of US\$ 24.3 billion (2019).
- Continued resistance to further improvements in IP and draft proposals to ban secondary patents.
- ANVISA'S establishment of regulation (RDC 205/2017) on special procedures for the approval of clinical trials, certification of good manufacturing practices, and registration of new drugs for treatment, diagnosis or prevention of rare diseases, reducing the total evaluation time from 12 months to an estimated 3 months. This resolution enables access to therapeutic options for the treatment of rare diseases in Brazil.
- Efforts to fight the patent backlog, National Institute of Industrial Property's (INPI) adopt measures to expedite examination time and narrow the timeframe for issuing final decisions.

2. Challenges for pharmaceutical companies

- Health spending as a share of GDP is much lower than in the United States and in a number of European markets.
- Access to many high-cost drugs in the public sector is limited to the compliance with strict criteria defined in the treatment protocols.
- Despite changes in the approval process, approval of new drugs is still long.
- The inclusion of drugs in the reimbursement list requires a clear advantage over the other available treatments.
- The launch prices of patent-protected molecules take in consideration the prices in a set of countries of reference, and price readjustments are frequently below inflation.
- Obligation to offer a discount (CAP) on the price of certain medicines.
-

1

IDRAC 329443

High tax burden - Although Brazil's corporate tax rate is 15%, the country levies taxes on companies in many other ways including on imports, exports, transactions, properties, services, income, and the pharmaceutical taxes are among the highest in the world. With a high tax burden, that pharmaceutical companies need to invest a significant amount of money in human capital to support the tax system and avoid penalties.

Market Access Commercialization Outlook

Market Access Commercialization Outlook

1. Key factors for devising market access strategy

Healthcare coverage is universal

Brazil provides universal healthcare to its population through the Unified Health System; Sistema Único de Saúde (SUS) as a social right under the constitution and spends 9.5% of GDP on healthcare spending. The government pays about half of total health expenditures and slightly more than half are paid privately. Out of pocket expenditures are high (53% of private health expenditures). Private prepaid insurance accounts for 47% of private expenditures. Approximately 75% of Brazilian citizens rely solely on SUS. Barriers in access and dissatisfaction with health services have prompted middle-income and high-income households to seek private care.

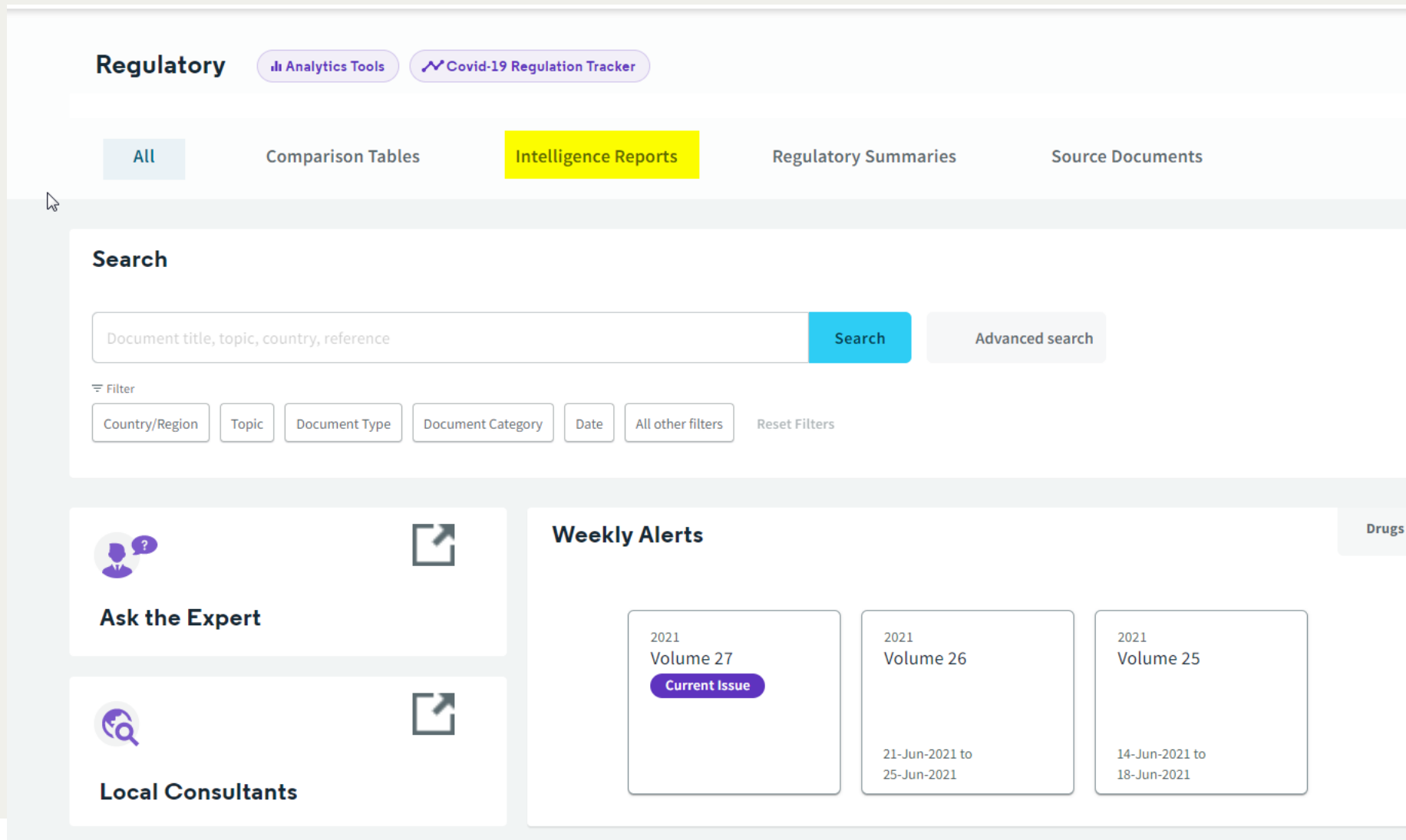
Among world's largest pharmaceutical markets

In 2019, the Brazilian pharmaceutical market had the highest market value in Latin America with value of US\$ 24.3 billion. In 2018, Brazil pharmaceutical market ranked seventh in global market and dropped to ninth in 2019. Pharmaceutical spending is expected to increase at a compound annual growth rate of 7% to 10% from 2018-2022.

Rapidly growing generics sector

Brazil created a generics industry in 1999 (Law 9787) in order to replace similares on the market with products that had demonstrated bioequivalence and interchangeability with reference drugs. In Brazil, there are 90 manufacturers of generics, responsible for more than 3,700 drug registrations that derive more than 21,700 commercial presentations. According to the generics industry trade organization, PróGenéricos, generics generated BRL\$ 11.2 billion (US\$ 1.9 billion) during Oct. 2019-Oct. 2020. In 2020, industry data calculated the generic sales in units, throughout the Brazilian pharmaceutical market, to account for 38% of the total market (source: <https://www.progenericos.org.br/mercado>).

Locating the Regulatory Intelligence Reports



The screenshot displays the 'Regulatory' section of a web application. At the top, there are two tabs: 'Analytics Tools' and 'Covid-19 Regulation Tracker'. Below these, a navigation bar contains five items: 'All', 'Comparison Tables', 'Intelligence Reports' (highlighted in yellow), 'Regulatory Summaries', and 'Source Documents'. A mouse cursor is positioned over the 'All' tab. The main content area features a 'Search' section with a text input field labeled 'Document title, topic, country, reference', a blue 'Search' button, and a grey 'Advanced search' button. Below the search bar is a 'Filter' section with buttons for 'Country/Region', 'Topic', 'Document Type', 'Document Category', 'Date', and 'All other filters', along with a 'Reset Filters' link. The bottom of the interface is divided into three columns. The left column contains 'Ask the Expert' (with a person icon) and 'Local Consultants' (with a magnifying glass icon). The right column is titled 'Weekly Alerts' and contains three boxes for '2021 Volume 27' (labeled 'Current Issue'), '2021 Volume 26' (with dates 21-Jun-2021 to 25-Jun-2021), and '2021 Volume 25' (with dates 14-Jun-2021 to 18-Jun-2021). A partially visible 'Drugs & I' tab is on the far right.

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2021
Volume 25
14-Jun-2021 to 18-Jun-2021

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Brexit Tracker 

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Compliance and Inspection Trackers 

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Global Market Access Insights 

[Pricing and Reimbursement Flowchart](#)

[Market Access Overview](#)

[Market Access Challenges and Opportunities](#)

[Market Access Commercialization Outlook](#)

Regulatory Authority Guideline Overview 


[ASEAN Guidelines Implementation](#)

[International Scientific Guidelines adopted in Australia](#)

[GCC Regulatory Harmonization](#)

[Guideline Matrices](#)

[ICH Guidelines Implementation](#)

International Agreements and Cooperation Summaries 

GMAS Content in Cortellis

Regulatory Summaries

Regulatory Summaries – GMAS content adapted from DRG Country Analysis Reports to Cortellis Q&A format

- *Pricing and Reimbursement Overview*
 - Healthcare system organization
 - Pricing
 - Reimbursement
 - HTA
 - Drug lists/formularies
 - Cost containment measures
- *Health Technology Assessment Summary (20 countries)*
 - Key stakeholders
 - Process and timelines
 - Clinical and economic criteria
 - Features such as scoping process, horizon scanning, evidence considerations, economic thresholds

Pricing and Reimbursement Overview

every person and the duty of the state. The [Law No. 8,080 of Sept. 19, 1990](#) (IDRAC 522) sets the conditions for the promotion, protection, and recovery of health, the organization of the corresponding services, and other measures. This law structures the Brazilian National Health System (*Sistema Único de Saúde*; SUS), ensuring universal access to health.

Q1.2 How is the healthcare system organized in this market?

Via a Beveridge healthcare model, Brazil offers its citizens universal healthcare through the *Sistema Único de Saúde* (SUS, National Health System), covering inpatient and outpatient care. The private sector provides supplemental insurance. A private health sector (~25% of citizens) provides supplemental coverage, mainly specialist care at private hospitals. Ratified on Oct. 5, 1988, the Brazilian constitution guarantees universal healthcare to all Brazilians, with the activities of the government on health care based on multiyear plans approved by the national congress. Current Brazilian Constitution led to the creation of the National Health System (Law No. 8,080 of Sept. 19, 1990). Brazil relies on both public and private networks to deliver healthcare to people. With the new constitution, Brazil switched from a Bismarckian health model to a Beveridge model. [Law No. 8,080 of Sept. 19, 1990](#) (IDRAC 52290) provides for the conditions for the promotion and recovery of health, the organization and operation of the corresponding services, and measures through SUS (*Sistema Único de Saúde*). Brazil's public healthcare adheres to a model healthcare system, combining parts of private and public insurance, guaranteeing healthcare to all citizens. The system is decentralized, with decisions made at a federal, state, and municipal level.

Cities, states and the federal government are responsible to manage the SUS. The [Brazilian Normative 01](#) (IDRAC 30829) of 05-Nov-1996 (the operational normative of the SUS) regulates the decentralization process. The institutions of the SUS at the city level do not have to belong to the government structure. They may be a state, federal or even private units hired by the government as a third party or a unit working under outsourcing agreements. Order 1559 of 01-Aug-2008 established the Brazilian Policy of the SUS Regulation.

The healthcare services delivered by the SUS are universal, meaning that all the citizens have the right to use it. It is intended to cover all medical services and part of the medicine's costs. Private health insurance is complementary to the SUS.

Q2.1.4 What are the processes and timelines to determine a drug's price and reimbursement?

Brazil follows a separate process for pricing and reimbursement with the latter including health technology assessment review.

Pricing

Following receipt of market authorization by the INVSA, a manufacturer will inform the CMED of its intention to launch a new drug or presentation, beginning the pricing and reimbursement process. The [CMED Resolution no. 2 of Mar. 5, 2004](#) (IDRAC 53728) (amended by [CMED Resolution No. 4 of Jun. 15, 2005](#) (IDRAC 53718) and for [CMED Resolution No. 4, of Dec. 18, 2006](#) (IDRAC 84888)), establishes the criteria for setting prices of new products and new presentations by the Pharmaceutical Market Regulation Council (*Câmara de Regulação do Mercado de Medicamentos*; CMED) with reference to [art. 7 of Law 10.742 of Oct. 6, 2003](#) (IDRAC 41408).

For drugs at launch, therapies are classified into six categories, further divided into two groups: new molecules (Categories I and II) and new presentations (Categories III, IV, V and VI).

- **Category I:** new patent-protected drugs that offer an advance in efficacy and/or safety relative to established treatments of the same therapeutic indication
- **Category II:** new products that do not have a patent or do not offer a therapeutic improvement relative to established treatments (i.e., me-too drugs)
- **Category III:** new presentations, in the same dosage form, of a drug already marketed by the same company
- **Category IV:** new presentations of a drug for a company or new presentation in a new dosage form for a company
- **Category V:** new presentations of a drug that is a new dosage form in Brazil or a new combination of active ingredients already available in Brazil
- **Category VI:** new generic drugs

Pricing and Reimbursement Overview

Reimbursement

For reimbursement under the SUS, the manufacturer and applicant can submit an application to the National Commission for the Incorporation of Technologies in the Unified Health System (CONITEC; *Comissão Nacional de Incorporação de Tecnologias no SUS*), created in accordance with [Law No. 12,401 of Apr. 28, 2011](#). The agency is responsible for advising the Ministry of Health in the process of incorporating, excluding or changing pharmaceuticals offered under the Brazilian National Health System (*Sistema Único de Saúde*; SUS). See [CONITEC-FAQ, Flow of incorporation of technologies in the SUS follows careful steps](#).

To deliver recommendations, the CONITEC considers evidence based on the analysis of scientific evidence available in the literature on the efficacy, effectiveness, accuracy, a pharmaceuticals, as well as on the evaluation of economic studies of these technologies from the perspective of the Unified Health System. Before issuing a final opinion on each technology analyzed, CONITEC's reports are submitted to public consultation for 20 days. Contributions from the population are organized and included in technical reports for analysis by CONITEC members. After discussing the scientific evidence and contributions received, the CONITEC issues the final recommendation on the evaluated technology. The report with the final recommendation is submitted for decision by the Secretary of Science, Technology, Innovation and Strategic Inputs of Health. The final decision of incorporation in the SUS is delivered by the Ministry of Health. The complete process is completed within a period, not exceeding 180 days.

Timelines

180-270 days for both pricing and reimbursement. Pricing is typically accomplished in 180 days (below) while covered drugs must become available in the SUS within 180 days.

ANVISA's CMED timelines are as follows:

Product category	Approval time (days)
I and II	90
IV, V and III	60

Q2.2 Managed entry agreements

Q2.2.1 To what extent are managed entry agreements (MEAs) used?

Use of MEAs

Italy uses both financial-based and performance-based agreements extensively ([source](#) (IDRAC 304650)). Managed entry agreements negotiated between AIFA and pharmaceutical manufacturers have been utilized in Italy since 2006 but are becoming increasingly common, particularly for innovative therapies. These agreements are established on a case-by-case basis to facilitate public sector expenditure and address uncertainties concerning a drug's clinical results and/or budget impact. Agreements include cost-sharing (i.e., a discount is applied to therapy for all eligible patients), risk-sharing (a discount is applied for therapy for non-responder patients), pay-for-performance (i.e., a total refund is applied to the initial cycles of therapy for non-responder patients), budget caps, price-volume agreements (PVAs), and monitoring registries in order to manage uncertainty around utilization and cost effectiveness. Patient eligibility for treatment is typically monitored through the *registri farmaci sottoposti a monitoraggio* and demands physician certification (and pharmacy validation) that the patient meets the prescribing requirements for the drug. A main goal of the creation of the registries is to provide data to support the evaluation of a drug's clinical and cost effectiveness. They track patient eligibility for drugs and treatment pathways in order to evaluate effectiveness and to gather epidemiological data. They also allow AIFA to monitor appropriateness of use according to approved indications. The data is owned by AIFA, and manufacturers are responsible for covering costs through maintenance fees. Registries in Italy span disease areas such as anti-diabetics, oncology drugs, orphan drugs and more, with oncology being the most common. Italy has the highest use of MEAs in Europe, and as of March 2015, AIFA has established a total of 180 registries by drug and indication. In addition to the registries, Italy has also implemented an initiative known as the Regional Dashboard.

Health Technology Assessment Summary

1 of 6 110%

New 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; *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.

Q2.2.2.2 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:

Finding the Regulatory Summaries

Filter

Country/Region Topic Document Category Date Reset Filters

Pricing Reimbursement HTAs

Select all Clear all Sort by Frequency

Regulatory Procedures (30) Dossier Format and Submission (10) Compliance and Inspection (6) Pricing Reimbursement HTAs (6) Clinical Research (3) GXP (3) Manufacturing and Control (3)

Advertising and Promotion (2) Authorities and Organizations (2) Device Classification (2) Fees (2) Generics and Biosimilars (2) Import Export (2) Legislative Framework (2) Packaging and Labelling (2)

Pharmacovigilance Technovigilance Risk Management (2) Prescription Requirements (2) Environment (1) GCP (1) GDP (1) GMP (1) Orphan Products (1) Pediatrics (1)

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EN	RS						
<input checked="" type="checkbox"/>	09-Jul-2021	V	US	Pricing and Reimbursement Overview	This document explores the pricing and reimbursement landscape for the United States, organized in a question and answer	New on 09-Jul-2021:	USA English 331783
<input checked="" type="checkbox"/>	09-Jul-2021	V	US	Health Technology Assessment Summary	This report examines how the United States examines therapies for pricing and/or reimbursement, including clinical and	New on 09-Jul-2021:	USA English 331465
<input checked="" type="checkbox"/>	09-Jul-2021	V	UK	Health Technology Assessment Summary	This report examines how the United Kingdom examines therapies for pricing and/or reimbursement, including clinical	New on 09-Jul-2021:	United Kingdom English 331442

Finding the Regulatory Summaries

Regulatory

Covid-19 Regulation Tracker

All

Comparison Tables

Intelligence Reports

Regulatory Summaries

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Drugs and Biologics

► Authorities and Organizations

► Competent Health Ministries and Regulatory Agencies | Country Summaries

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Advertising and Promotion Regulations

Algeria, Argentina, Australia, Austria, Belgium, Brazil, Bulgaria, Canada, China, Czech Republic, Denmark, Egypt, European Union, Finland, France, Germany, Hungary, India, Iraq, Israel, Italy, Japan, Jordan, Kenya, Malaysia, Mexico, Morocco, Netherlands, Nigeria, Norway, Poland, Portugal, Romania, Russian Federation, Saudi Arabia, Slovakia, South Africa, South Korea, Spain, Sweden, Switzerland, Taiwan, Tunisia, Turkey, USA, United Arab Emirates, United Kingdom

► Market Access Guidance

► Pricing and Reimbursement Overview

► Health Technology Assessment Summary

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Cortellis Value Add

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Comparison Tables

Pharmaceutical Pricing and Reimbursement Overview

Compare key data
across countries and
regions

Country/Region	World evidence	Estimated timelines for pricing and reimbursement	Use of managed entry agreements	Use of external reference pricing	Main drug list or formulary	Key cost-containment measures	Pricing and Reimbursement Flowchart
Argentina	Reimbursement process, in the ...	60-120 days.	Not commonly used.	Not formally used.	National Drug Formulary.	<ul style="list-style-type: none"> Emerging use of health technology assessments. National policy to promote 	Pricing and Reimbursement Flowchart
Australia	for reviewing a reimbursement decision of a year.	270 days.	Primarily financial ones (risk-sharing agreements).	Not formally used	The Pharmaceutical Benefits Scheme (PBS).	<ul style="list-style-type: none"> Price ceilings. Price cuts. Risk-sharing agreements. 	Pricing and Reimbursement Flowchart
Austria	reimbursement	90-300 days.	Primarily financial ones.	Formally used for price setting.	Reimbursement Code (EKO; Erstattungskodex).	<ul style="list-style-type: none"> External reference pricing. HTA and pharmacoeconomics. 	Pricing and Reimbursement Flowchart
Belgium	evidence is used, in the reimbursement process.	180 days.	Primarily financial ones.	Informally used for price setting.	National List of Reimbursable Medicine.	HTA and Pharmacoeconomics. Reference pricing.	Pricing and Reimbursement Flowchart
Brazil	evidence may be used for reimbursement	180-270 days.	Not commonly used.	Formally used for price setting.	National List of Essential Medicines (Relação Nacional de Medicamentos Essenciais).	<ul style="list-style-type: none"> Price caps. Mandatory rebates/discounts. 	Pricing and Reimbursement Flowchart

Health Technology Assessment Overview

Compare key data
across countries and
regions

Abstract

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 for additional information. This comparison table covers 20 countries. Coverage is currently limited to these countries in alignment with Regulatory Summary new content.

Last Updated Date
12-Jul-2021

Global Comparison

☐ My Regions ?

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Country/Region	Health technology assessment stakeholders	HTA compulsory or not	Role of horizon scanning	Opportunities for early engagement from industry	Trial data and evidence accepted	Preferred comparator	Economic models used
Argentina	- Instituto de Efectividad Clínica y Sanitaria (IECS; Institute for Clinical ...	Compulsory	Indirectly used. CONETEC, issues proposals for technologies to evaluate ...	No opportunities.	- Randomized controlled trials (RCTs) - Observational studies	Routine care/most commonly prescribed therapy.	- Cost-utility - Cost-effectiveness - Budget impact
Australia	The Pharmaceutical Benefits Advisory Committee (PBAC) and its ...	Compulsory in most cases.	HealthPACT provides early assessment of emergent technologies to ...	Pre-submission meetings can be requested by the manufacturer to increase ...	- Randomized trials with direct comparison of intervention and ...	Therapy to be replaced.	- Cost-utility - Budget impact - Cost-minimization
Austria	- Austrian Social Security (SV; Österreichische Sozialversicherung).- ...	Compulsory.	Used to monitor emerging therapies with notable clinical and budget ...	No opportunities.	- Randomized controlled trials - Systematic reviews - Non-randomized or ...	Standard of care.	- Cost-effectiveness - Cost-minimization - Budget impact
Belgium	- National Institute for Sickness and Disability Insurance (INAMI/RIZIV).	Compulsory	Both nationally and as part of BeNeLuxA.	Manufacturers can engage with the CRM earlier in the ...	- Randomized-controlled trials.- Systematic review of the existing relevant ...	Therapy to be replaced.	- Cost-utility - Budget impact - Cost-minimization
Brazil	Comissão Nacional de Incorporação de Tecnologias no SUS ...	Compulsory	CONITEC highlights the need to rely on horizon scanning to optimize the ...	No opportunities.	- Randomized controlled trials - Meta-analysis of indirect	Routine care/most commonly prescribed therapy.	- Cost-utility - Cost-effectiveness - Budget impact

Finding the Comparison tables


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Volume 27
Current Issue


2021
Volume 26

21-Jun-2021 to
25-Jun-2021

2021
Volume 25

14-Jun-2021 to
18-Jun-2021

Drugs & I




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- Laws establishing pricing rules/authorities
- Regulations over international reference pricing (e.g. basing the price you pay on what other countries pay)
- Laws/decrees/public presentations on the healthcare system organization
- Laws/decrees establishing HTA or reimbursement processes
- Guidelines for submitting applications for P&R
- Approval documents for 7 countries/regions

View official documents directly from Cortellis

Summary

Abstract

The document outlines the general method for assessing medical technologies for reimbursement in France. It includes details on scoping, literature consulting the working group, peer review, report validation, and

Reason for Update

New on **09-Jul-2021**:
Please note that the delay in document addition is due to a recent scope extension.

Last Updated Date

09-Jul-2021

Authority Acceptance Date

Jun-2007

Source Publication Date

14-Jun-2007

Document

None

English

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1 of 2

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GENERAL METHOD FOR ASSESSING HEALTH TECHNOLOGIES

1. Scoping

2. Literature search and analysis of scientific data

3. Writing the draft report

4. Consulting the working group

5. Peer review

6. Report validation

7. Publication

HAS

HAUTE AUTORITÉ DE SANTÉ

GENERAL METHOD FOR ASSESSING HEALTH TECHNOLOGIES

Health technology assessment (HTA)¹ is "any process of examining and reporting properties of a medical technology used in health care, such as safety, efficacy, feasibility, and indications for use, cost, and cost effectiveness, as well as social, economic, and ethical consequences, whether intended or unintended"² (Institute of Medicine 1985). Its aim is to inform public decision-making by providing an opinion with supporting evidence, taking account of all aspects of the topic concerned.

HAS' health technology assessment method is based on a critical review of scientific and technical data, experts' opinion and, if necessary, on a survey of practice and an analysis of

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270 results for **"budget impact"**

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Refine Search

"budget impact"

Search

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<input checked="" type="checkbox"/>	Summary	Title	Abstract
<input checked="" type="checkbox"/>	<div>May-2007</div> <div>EN</div> <div>RD</div>	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
<input checked="" type="checkbox"/>	<div>Jan-2012</div> <div>PT</div> <div>RD</div>	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
<input checked="" type="checkbox"/>	<div>15-Jan-2021</div> <div>FR</div> <div>RD</div>	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
<input checked="" type="checkbox"/>	<div>2018</div> <div>EN</div> <div>RD</div>	Guideline: Pharmacoeconomic Guideline for Malaysia	These guidelines aimed to encourage the

Regulatory > All Results

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

<input checked="" type="checkbox"/>	Summary	Title	Abstract
<input checked="" type="checkbox"/>	<div>Oct-2004</div> <div>EN</div> <div>RD</div>	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
<input checked="" type="checkbox"/>	<div>15-Dec-2017</div> <div>EN</div> <div>RD</div>	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
<input checked="" type="checkbox"/>	<div>19-Sep-2017</div> <div>EN</div> <div>RD</div>	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
<input checked="" type="checkbox"/>	<div>13-Jan-2018</div> <div>EN</div> <div>RD</div>	European Medicines Agency and European Union	This document provides information on

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Cortellis Regulatory Intelligence Weekly Alert - Drugs and Biologics - Volume ...

CA

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To

Cortellis Weekly Alert - Drugs and Biologics - 2021 Volume 7.html

2 MB

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Sun 8:39 PM

Dear Cortellis Regulatory Intelligence User,

Please find attached our **Weekly Alert - Drugs and Biologics**, 2021 Volume 7 of 08-Feb-2021 - 12-Feb-2021.

The Cortellis Regulatory Intelligence Weekly Alert provides you with a survey of the Global Regulatory Landscape highlighting the latest documents added to Cortellis Regulatory Intelligence.

The Cortellis Regulatory Intelligence Team

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2021, Volume 7 of Monday 08 February to Friday 12 February 2021

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		Slovenia (2) Spain (3) Sweden (1) Switzerland (12) Turkey (3) Ukraine (2) United Kingdom (5) Taiwan (4) Thailand (3) Vietnam Panama Peru (2) Venezuela Tunisia United Arab Emirates


ADCOMM Advance and ADCOMM Bulletin emails

AdComm Bulletin - Drugs and Biologics - Harnessing Real World Evidence to Improve Safety Assessments of Pediatric Cancer Drugs



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To



Harnessing Real World Evidence to Improve Safety Assessments of Pediatric Cancer Drugs.pdf

218 KB

Dear Cortellis Regulatory Intelligence - Drugs and Biologics User,

Today's **AdComm Bulletin - Drugs and Biologics** is attached.

This FDA Advisory Committee Meeting Summary is also available from *Cortellis Regulatory Intelligence*.

The Cortellis Regulatory Intelligence Team

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AdComm Bulletin

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12/2021 6:25

The latest developments from US FDA drug, biologic, and medical device advisory committee meetings.

May 12, 2021

Meeting Begin Time: 12:00 p.m. | End Time: 4:20 p.m.

IN THIS ISSUE

Meeting of the Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee (Day 2 of 2)

[AdComm Profiles and Voting Histories—Drugs/Biologics](#) (IDRAC 175864)

Subject: Topics concerning real-world evidence (RWE) for regulatory use in pediatrics, real-world data (RWD) resources, and RWD and RWE to advance pediatric safety assessments of oncology drug products in children within the context of the FDA Framework for RWE.

Announced in the Federal Register
[April 13, 2021](#) (IDRAC 328305)
(Volume 86, Number 69)

Decision/Voting

There was no formal vote during this “particular matters” meeting of the Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee (PedsODAC). Panelists discussed the advancement of pediatric safety assessments of oncology drug products in children through the [FDA Framework for Real-World Evidence](#) (IDRAC 291580) (RWE) for regulatory use in pediatrics and real-world data (RWD) resources.

The PedsODAC considered the potential of existing and future RWD resources that may provide RWE to support pediatric cancer drug development programs. Panelists said that RWE has the potential to enrich the characterization of rare molecular subtypes of pediatric cancers, ultimately informing regulatory decision-making. Current limitations include the quality of the datasets (e.g., genetic datasets) used to improve predictions of response and identify biomarkers for future clinical trial risk stratification. The PedsODAC recommended expanding studies to include functional genetics, which would enhance targeted therapies for patients.

Using the European Union’s (EU’s) General Patient Data Regulations (GPDR) as a model, the FDA asked panelists to discuss the real and perceived limitations of RWE from existing and developing registries in the development of drugs to treat pediatric cancer. PedsODAC members expressed concerns that the GPDR data may be highly restrictive, and that these strict regulations could limit access to data. They also highlighted patients’ right to erase their data, which could negatively impact studies, particularly those with small populations.

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03-Aug-2021

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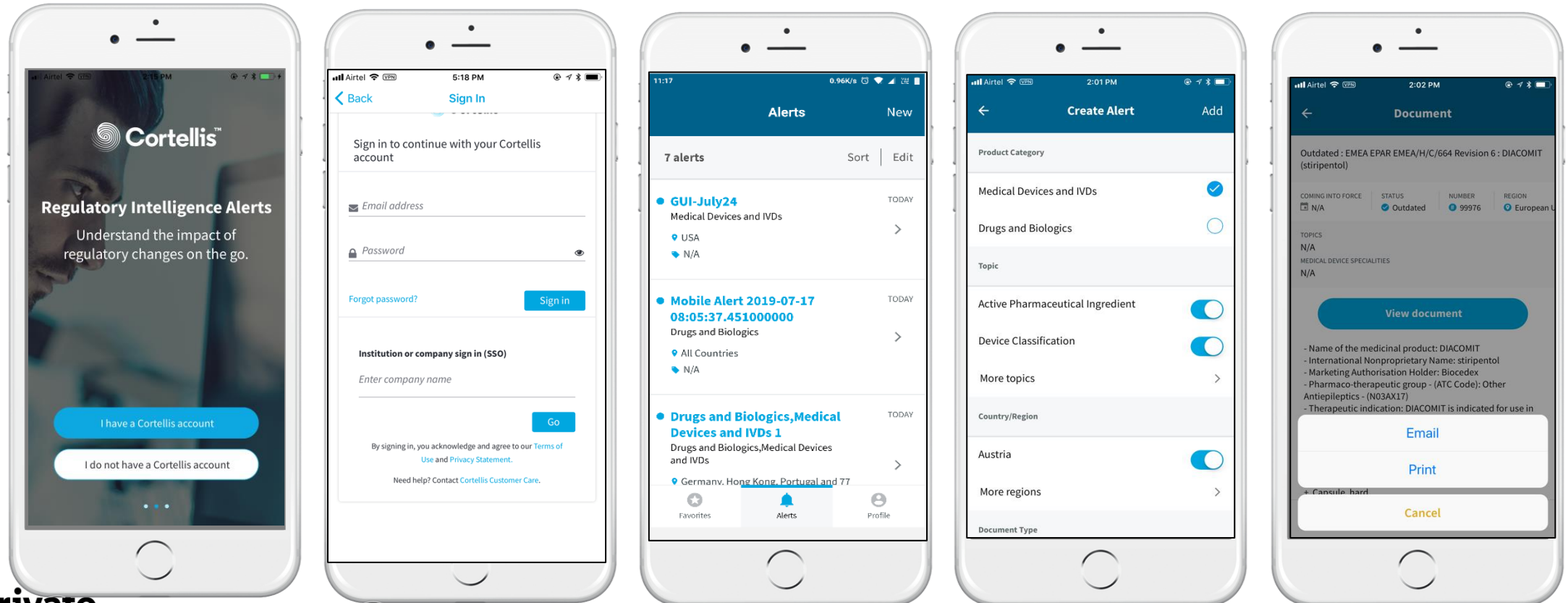
Lebanon - Decision No. 893: Pricing of Locally Manufactured Sera, 16-Jul-2021			
Abstract	<p>The Ministry of Public Health published this decision to inform the industry that the following pricing requirements are applicable to all sera products manufactured locally:</p> <ul style="list-style-type: none">- for the distributor: a maximum of 7% margin should be applied to the ex-factory price approved by the MoPH;- for the pharmacist (private or in hospitals): a maximum of 20% margin should be applied to reach the proposed price and within 80% of USD price applicable in reference countries, validated monthly by the MoPH.		
Reason for Update	New on 02-Aug-2021:		
IDRAC Number	333789	Document Date	16-Jul-2021
Document Category	Reference Document		
Document Type	Decision		
Regulatory Version	None	Languages	Arabic

Japan - Notification: HPB No. 0730/1, PSEHB/PED No. 0730/4: Handling of Off-label Use of Ethical Drugs Used in Fertility Treatment, 30-Jul-2021	
	This notification announces application of medical insurance and

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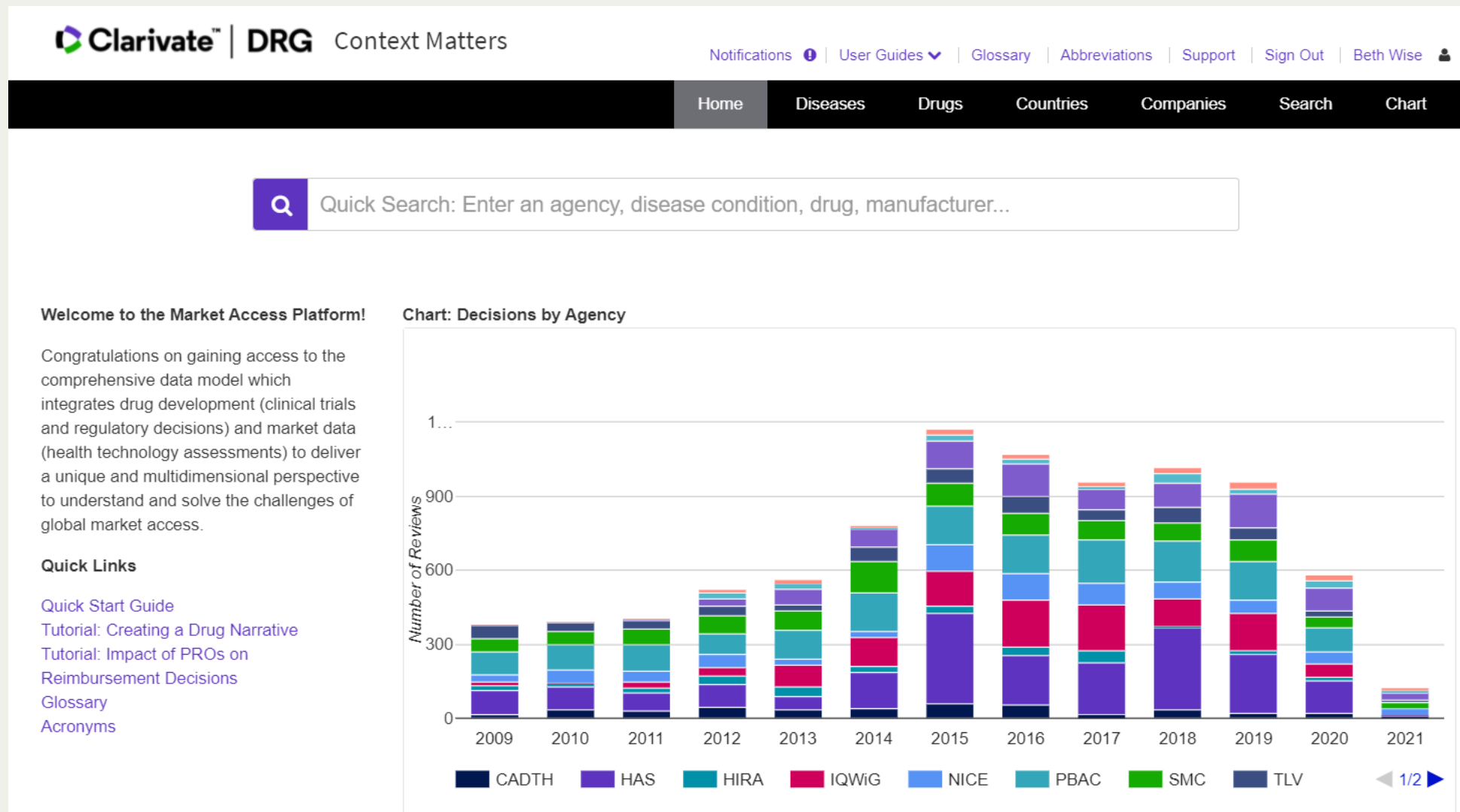
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Disease Condition (62)

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Therapeutic Area (21)

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Drug Name (235)

Search

Brand Name (405)

Search

Search Chart Showing 100 of 956 Results

Export to Excel Save Search

Status	Date	Country	Disease Conditions	Brand Name	Drug Name	Manufacturer	Contract Type	Key Metric	PDF	Add
●	04/2021	Canada	Ovarian Cancer	Zejula	niraparib	GlaxoSmithKline (GSK)	Financially based	Price reduction		+
●	04/2021	Canada	Non-Hodgkin's Lymphoma	Polivy	polatuzumab vedotin	Roche Holding AG	Financially based	Price reduction		+
●	04/2021	Canada	Prostate Cancer	Lynparza	olaparib	AstraZeneca	Financially based	Price reduction		+
●	04/2021	Canada	Non-small-cell Lung Cancer	Alunbrig	brigatinib	Takeda Pharmaceutical Company Limited	Financially based	Price reduction		+
●	04/2021	Canada	Multiple Myeloma	Sarclisa	isatuximab	Sanofi Genzyme	Financially based	Price reduction		+
●	03/2021	Canada	Urothelial Carcinoma	Bavencio	avelumab	Pfizer Inc.	Financially based	Price reduction		+
●	03/2021	Canada	Multiple Sclerosis	Arzerra, Kesimpta	ofatumumab	Novartis AG	Financially based	Price reduction		+
●	03/2021	Scotland	HIV - Adults	Pifeltro	doravirine	Merck Sharp & Dohme Corp. (MSD)	Financially based	Not disclosed		+
●	03/2021	Scotland	Chronic Lymphocytic Leukemia	Calquence	acalabrutinib	AstraZeneca	Financially based	Not disclosed		+

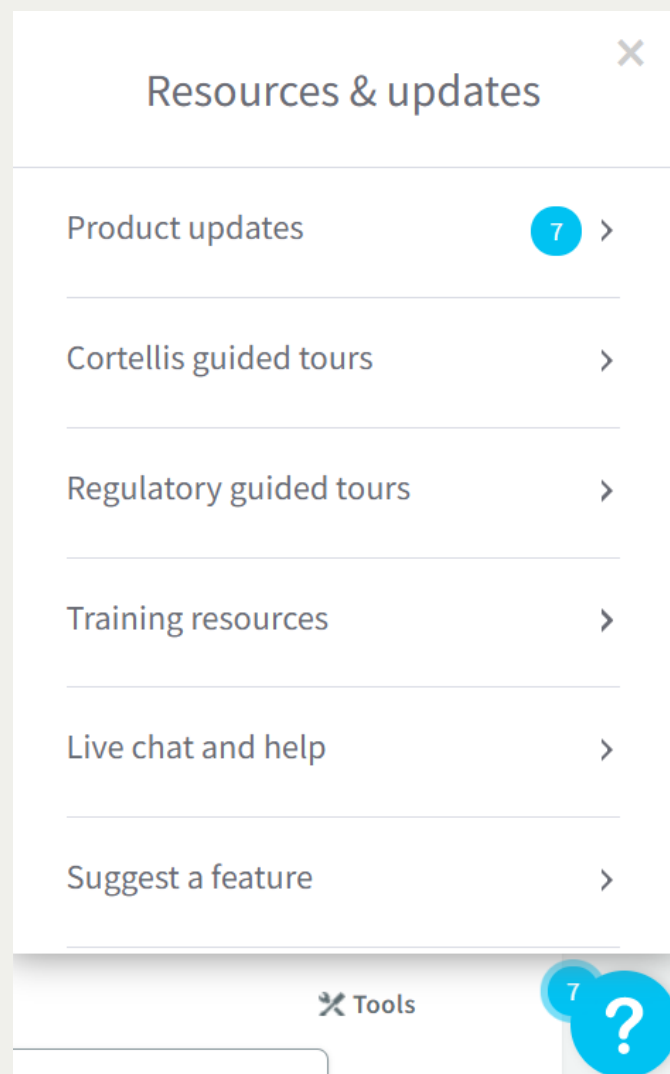
Wrap-up

- What is Cortellis?
- Finding Global Market Access Solutions content in Cortellis Regulatory Intelligence
- Cortellis added value
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- Wrap-up and Q&A

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Thank you...questions?

Beth Wise

Beth.wise@clarivate.com