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

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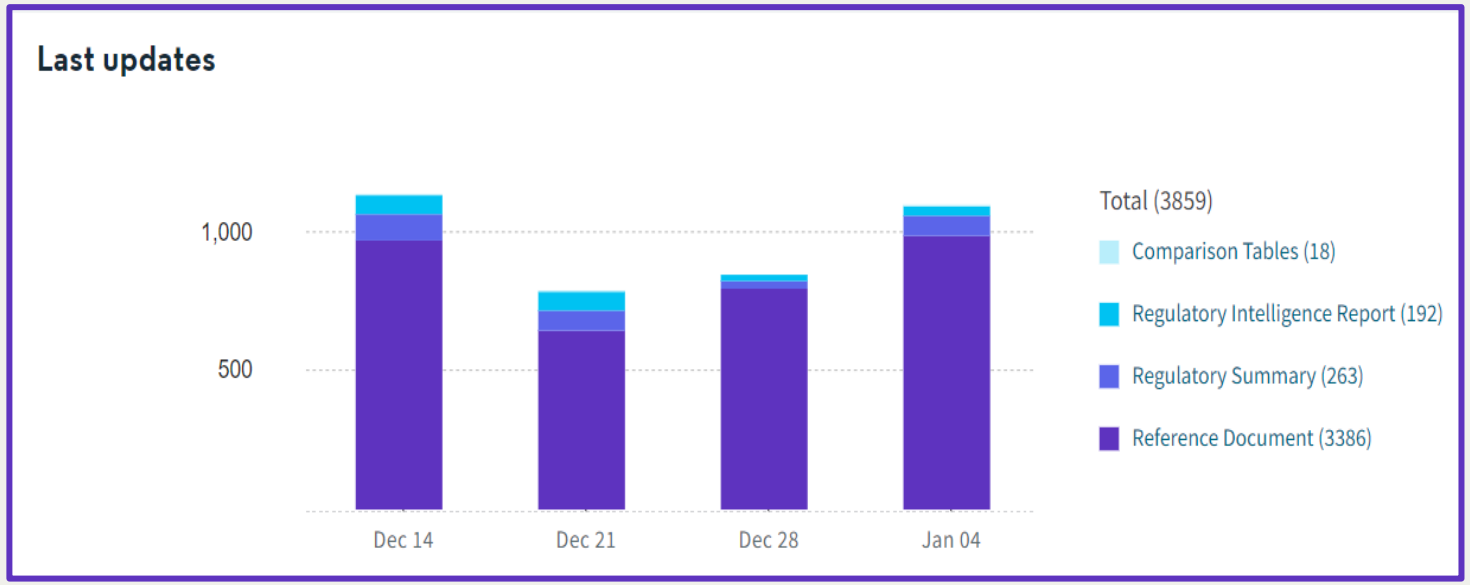
What is Cortellis Regulatory Intelligence?

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:

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- Understand a competitor product's path to approval
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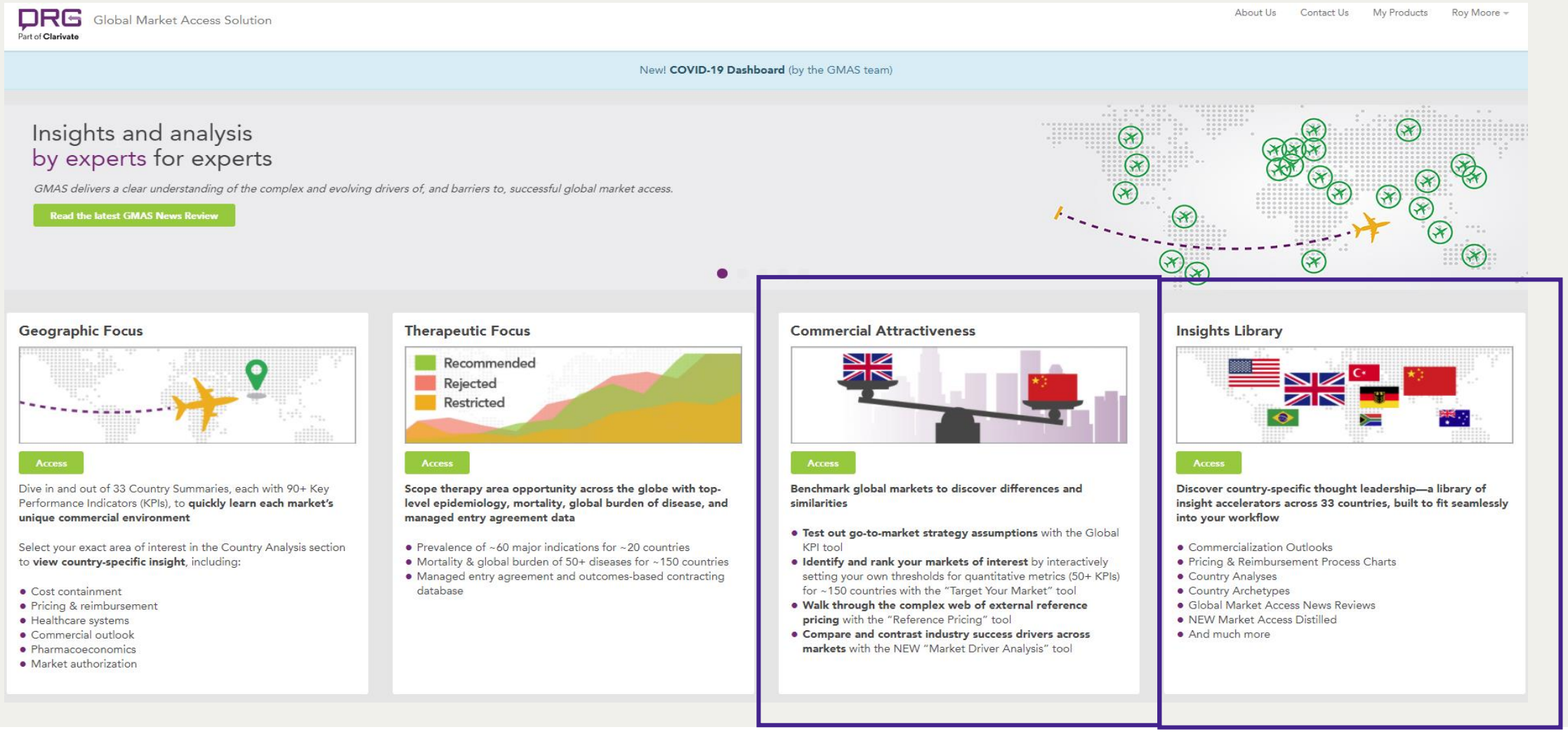
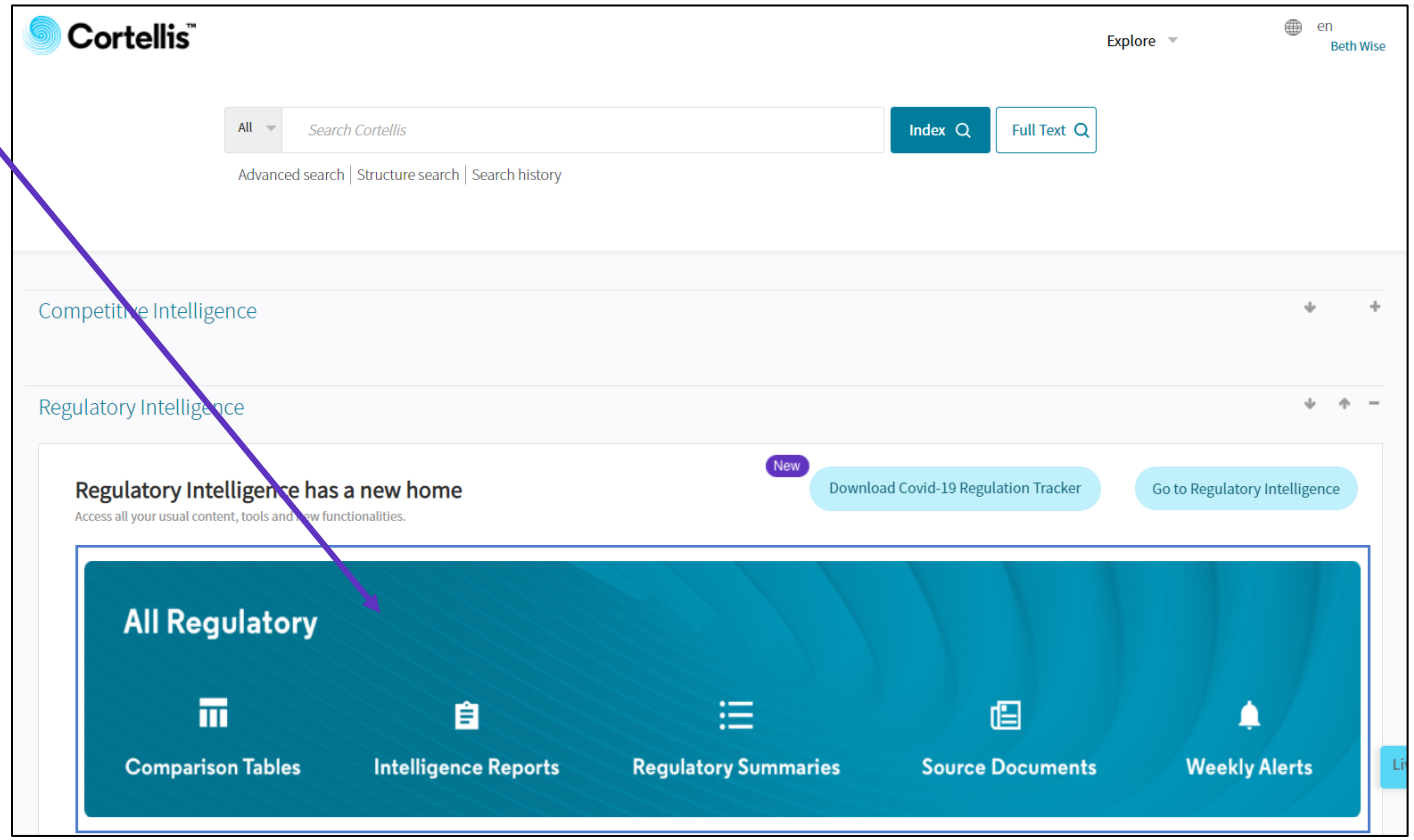
GMAS Content in Cortellis

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



Cortellis Home Page

Click panel to access Cortellis Regulatory Intelligence

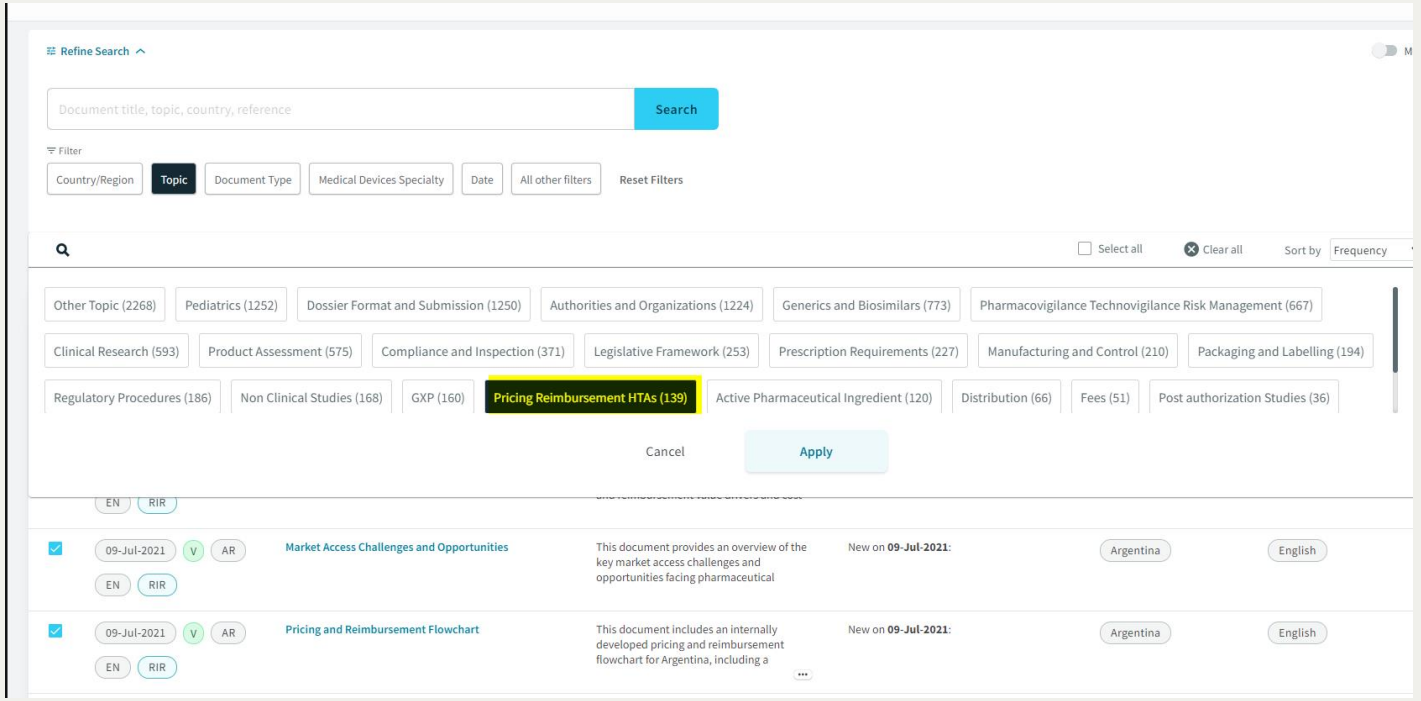


GMAS Content in Cortellis

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



Market Access Overview

IDRAC Number: 331532

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.

IDRAC Number: 331532

es 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). nto 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.

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 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.

Pricing and Reimbursement flowcharts

Regulatory Intelligence Report
Deep dive analysis from Cortellis

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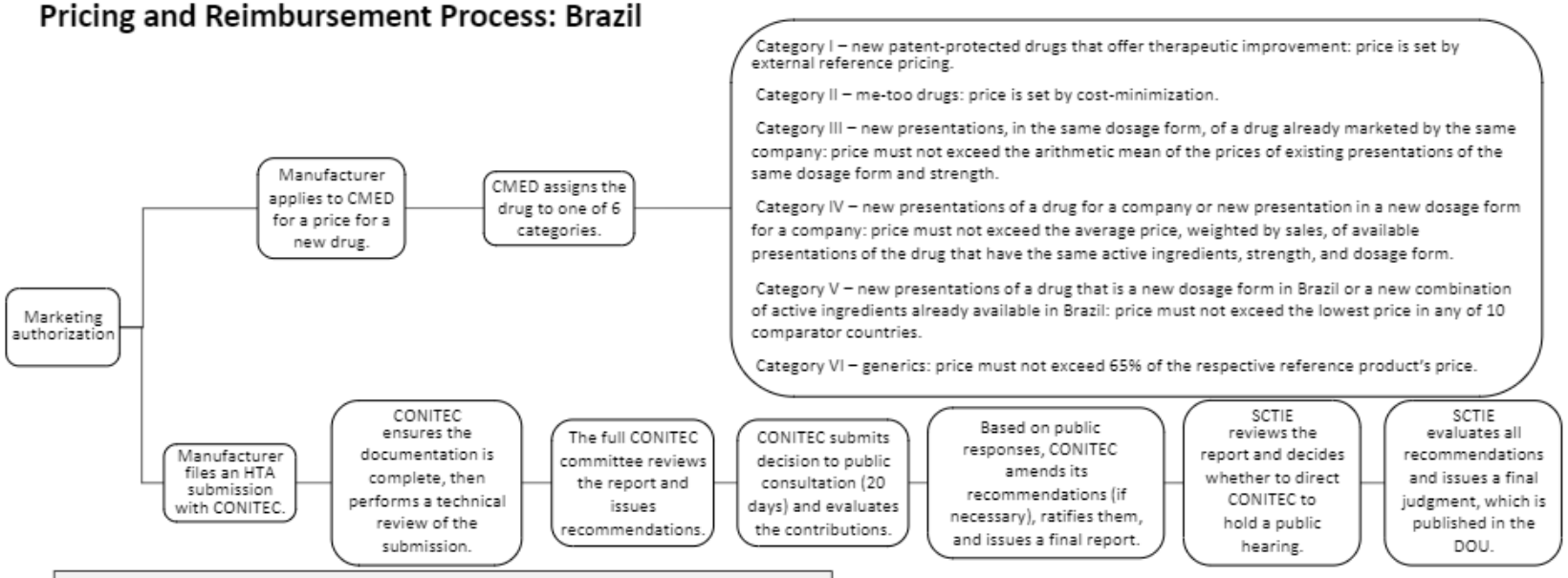
Pricing and Reimbursement Process: Brazil



CMED = *Câmara de Regulação do Mercado de Medicamentos* (Pharmaceutical Market Regulation Council)
CONITEC = *Comissão Nacional de Incorporação de Tecnologias no SUS* (National Committee for Incorporation of Technologies in the Health System)
DOU = *Diário Oficial da União* (*Official Gazette of Brazil*)
SCTIE = *Secretaria de Ciência, Tecnologia e Insumos Estratégicos* (SCTIE, Secretariat of Science, Technology, and Strategic Inputs)

CONITEC's appraisals form the basis for biennial updates to the *Relação Nacional de Medicamentos Essenciais* (RENAME; National List of Essential Medicines).

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 mortalit
  increasing number of prevalent diseases in the country. In 2018, Total health expen
  about 8% of GDP wherein private spending accounted for 4.4% of GDP and public sp
  3.8% of the GDP.
- Growing affluence will expand the patient population that is able to afford internation
  medicines and will likely also increase the prevalence of disorders associated with we
  obesity, type 2 diabetes, cardiovascular disease).
- The increase in life expectancy will boost demand for treatments for geriatric ar
  disorders (e.g., Alzheimer's disease, Parkinson's disease, certain cancers).
- Products developed through the Public-Private Partnerships are given preference in public
- Drugs produced nationally are eligible to receive an additional preferred margin to t
  based on their lowest price abroad.
- As the world's sixth most populated country, Brazil represents the biggest market opp
  Latin America for multinational pharma companies with value of US$ 24.3 billion (2019).
- Continued resistance to further improvements in IP and draft proposals to ban secon
  polymorph patents.
- ANVISA'S establishment of regulation (RDC 205/2017) on special procedures for the a
  clinical trials, certification of good manufacturing practices, and registration of new dru
  treatment, diagnosis or prevention of rare diseases, reducing the total evaluation time
  months to an estimated 3 months. This resolution enables access to therapeutic optic
  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

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.

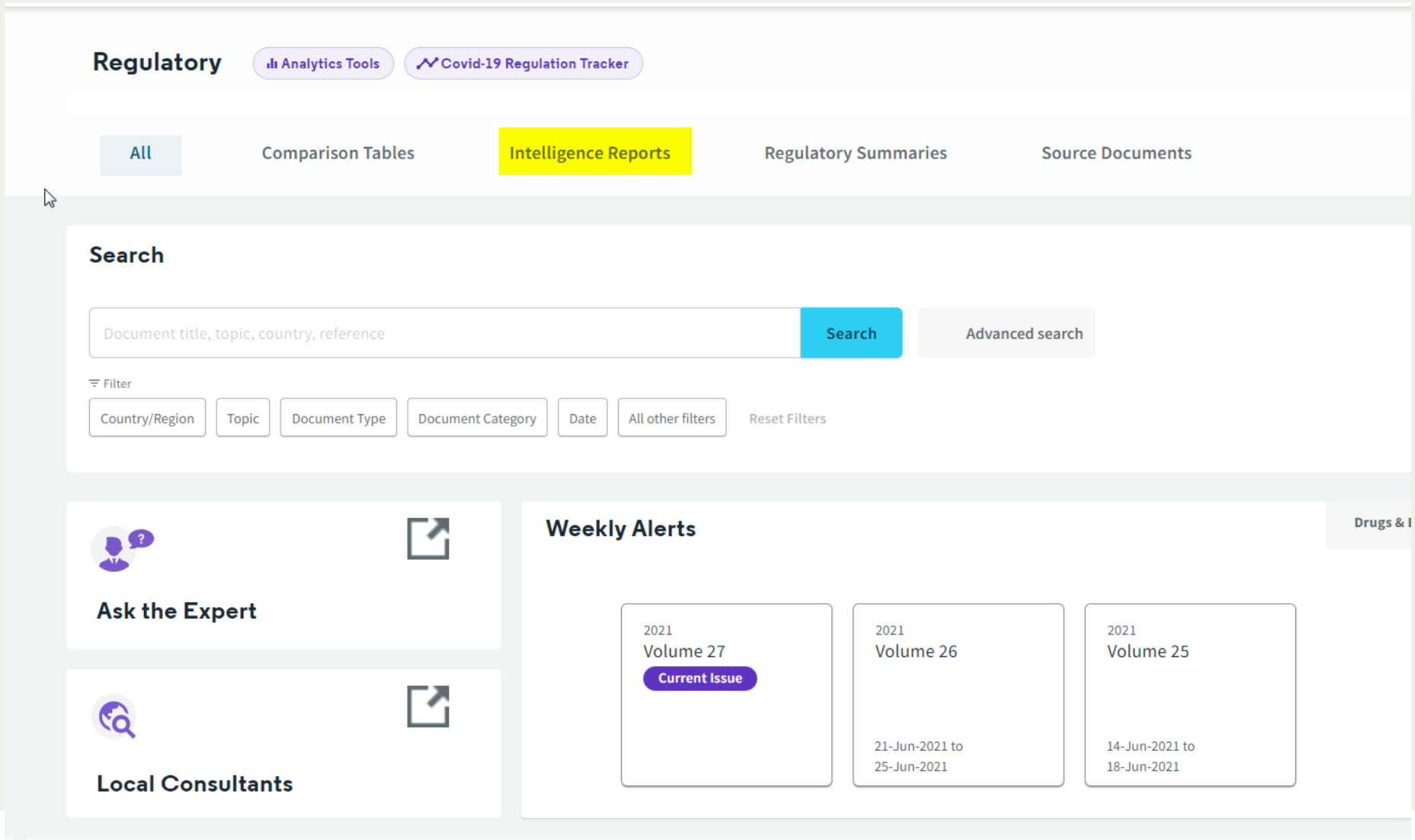
Among world's largest pharmaceutical markets

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



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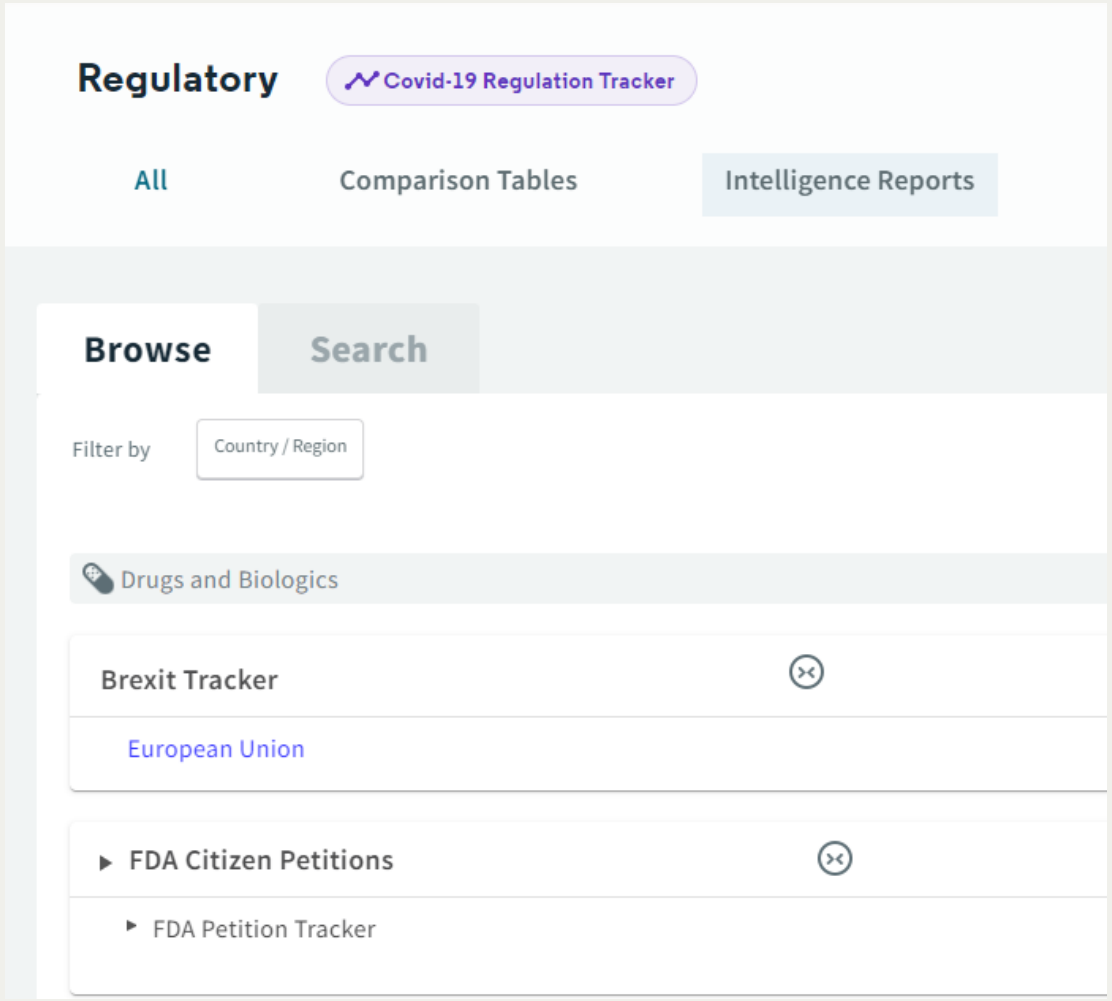
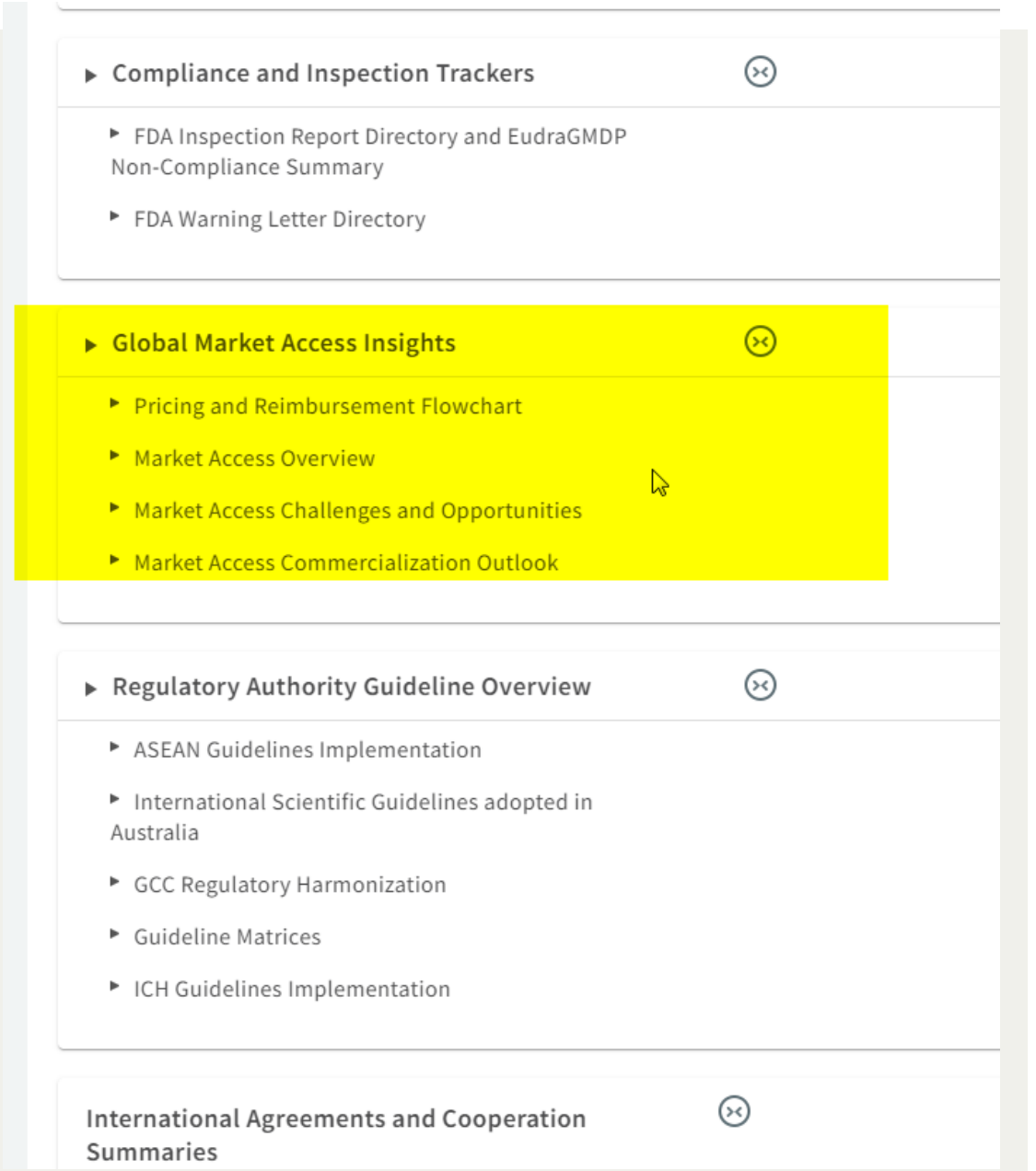




GMAS Content in Cortellis

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 the conditions for the promotion, protection, and recovery of health, the organization a the corresponding services, and other measures. This law structure the Brazilian Natio (*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 throug *Único de Saúde* (SUS, National Health System), covering inpatient andoutpatient care f private sector provide supplemental insurance. A private health sector (~25% of citize supplemental coverage, mainly specialist care at private hospitals. Ratified on Oct. 5, Brazilian constitution guarantees universal healthcare to all Brazilians, with the activiti government on health care based on multiyear plans approved by the national congres periods. Current Brazilian Constitution led to the creation of the National Health Systen No. 8080 of Sept. 19, 1990). Brazil relies on both public and private networks to deliver people. With the new constitution, Brazil switched from a Bismarckian health model to Law No. 8,080 of Sept.19, 1990 (IDRAC 52290) provides for the conditions for the prom and recovery of health, the organization and operation of the corresponding services, a measures through SUS *(Sistema Único de Saúde*). Brazil's public healthcare adheres to model healthcare system, combining parts of private and public insurance, guaranteei healthcare to all citizens. The system is decentralized, with decisions made at a federa municipal level.
Cities, states and the federal governmental are responsible to manage the SUS. The Ba Normative 01 (IDRAC 30829) of 05-Nov-1996 (the operational normative of the SUS) er decentralization process. The institutions of the SUS at the city level do not have to be government structure. They may be a state, federal or even private units hired by the S management 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 citize to use it. It is intended to cover all medical services and part of the medicine's costs. P

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 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 technologie the perspective of the Unified Health System. Before issuing a final opinion on each tec analyzed, CONITEC's reports are submitted to public consultation for 20 days. Contribu population are organized and included in technical reports for analysis by CONITEC me discussing the scientific evidence and contributions received, the CONITEC issues the fi recommendation on the evaluated technology. The report with the final recommendatic 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 Hea 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 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

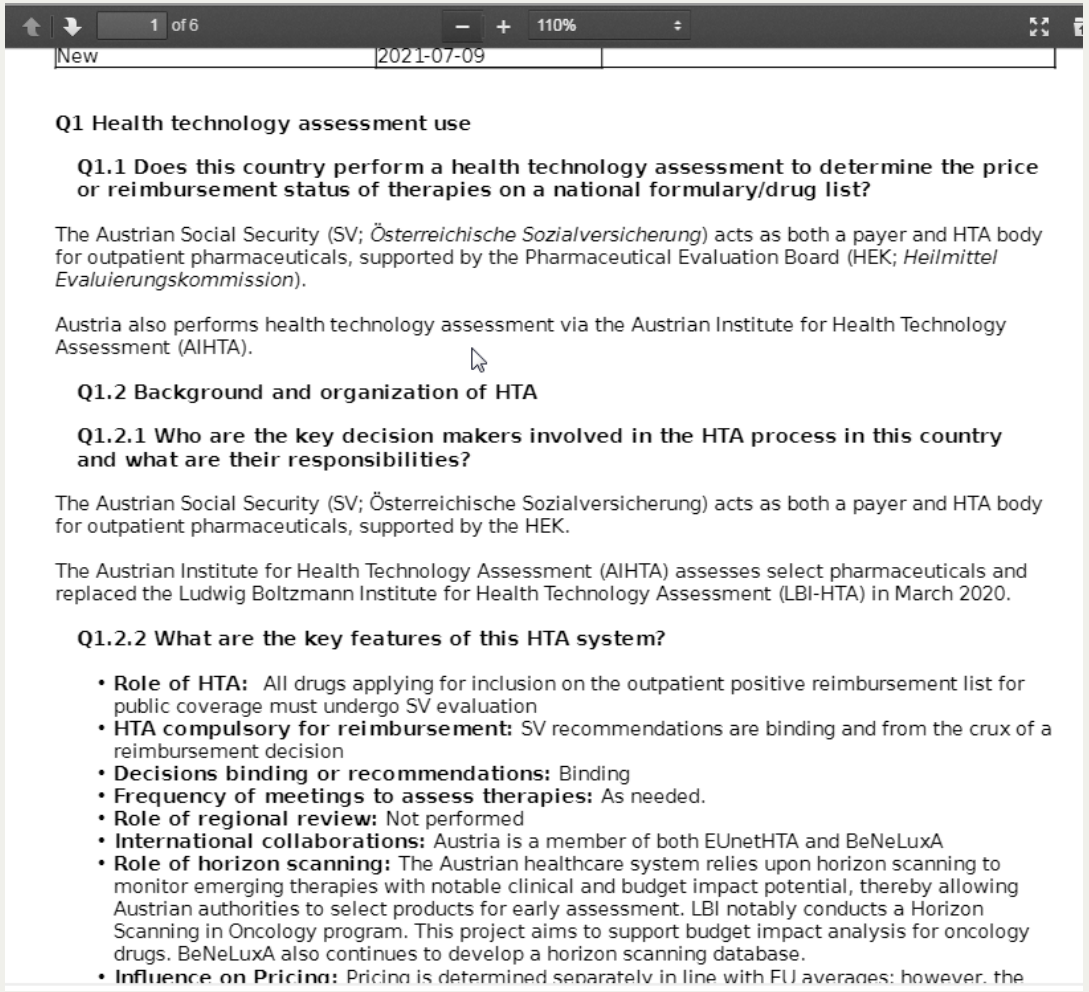
Q2.2 Managed entry agreements

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 area 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 from 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.

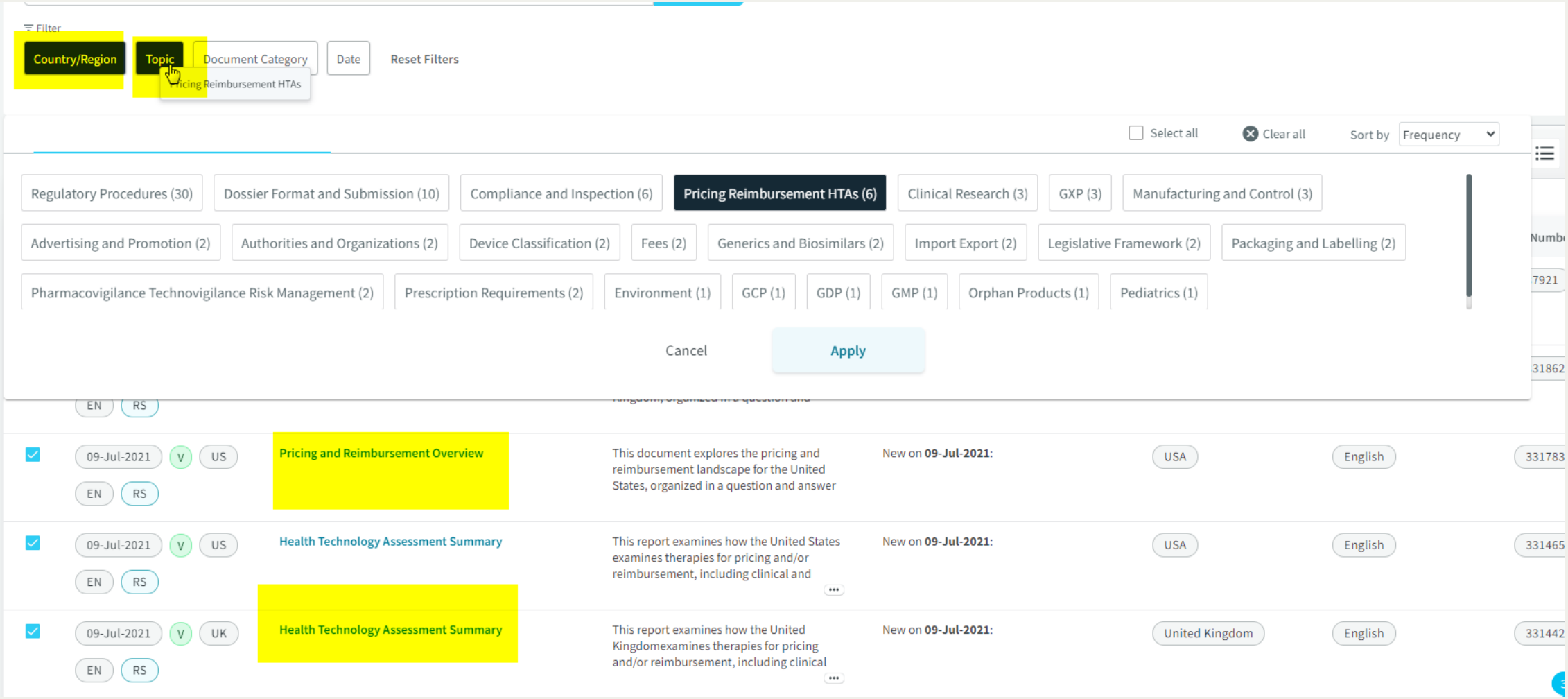
Q2.2.2.2 What trial types are preferred, allowed, or discouraged in this country?

Preferred:

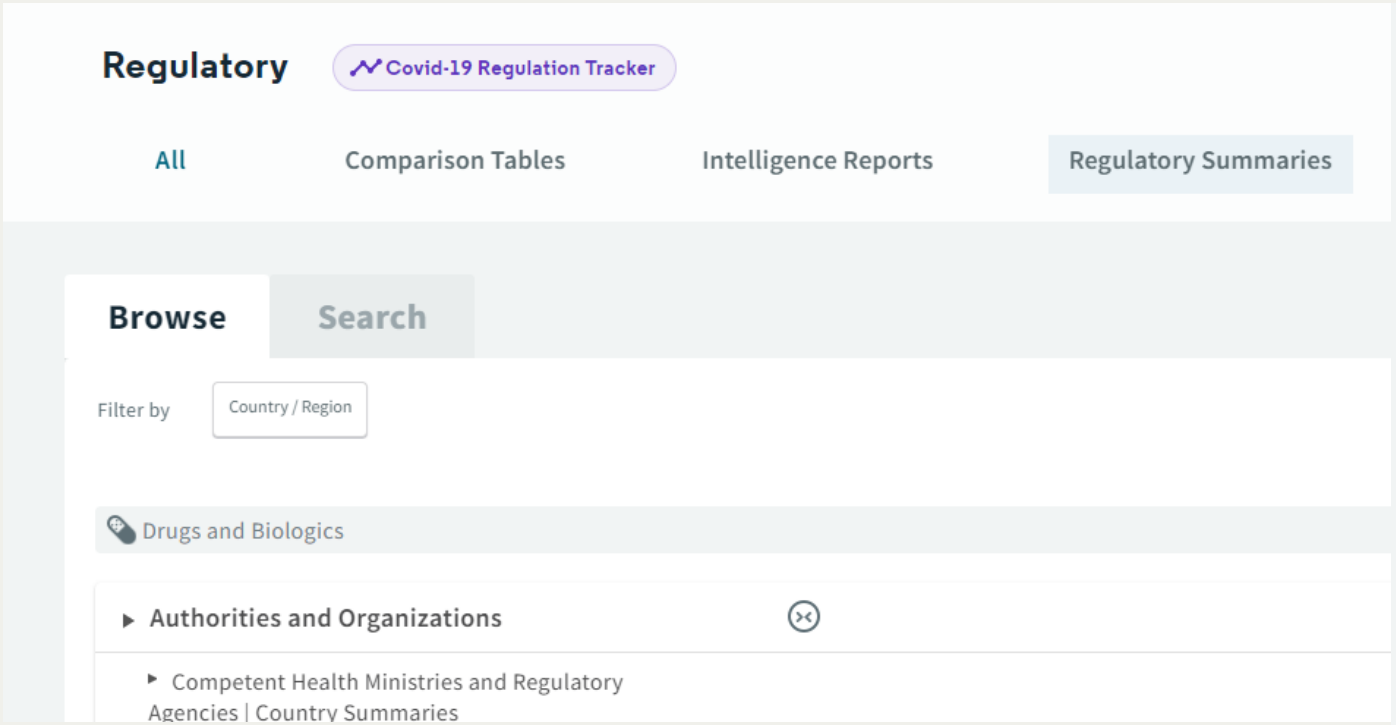
- Prospective, randomized controlled clinical trials with masked outcome assessment in a representative population, large data or meta-analyzes of such studies
- Systematic reviews (e.g. Cochrane review) with meta-analyzes of numerous studies with large patient numbers / numbers of patients, evidence 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)

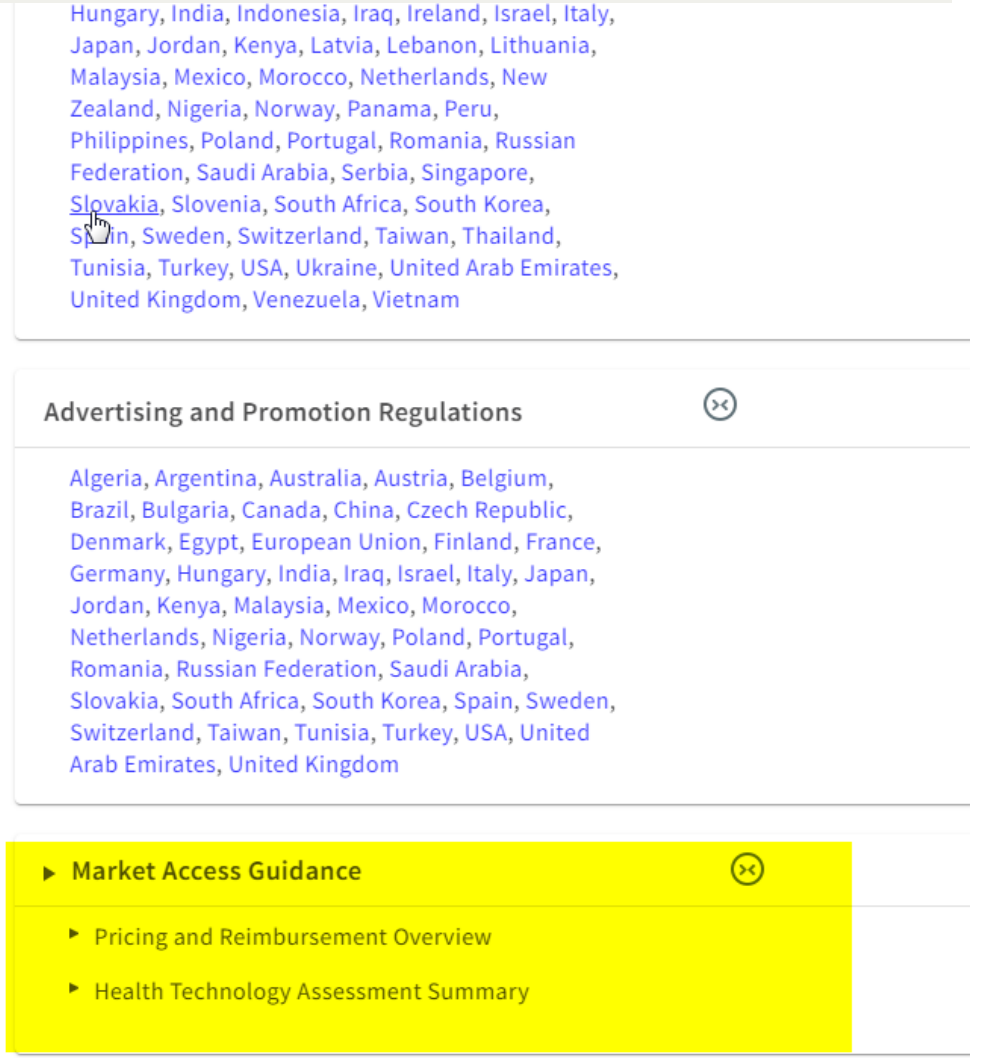
Accepted:

Finding the Regulatory Summaries



Finding the Regulatory Summaries





Cortellis Value Add

GMAS Content in Cortellis

Comparison Tables

Pharmaceutical Pricing and Reimbursement Overview

Compare key data across countries and regions

Country/Region	orld 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	nent process, in the •••	60-120 days.	Not commonly used.	Not formally used.	National Drug Formulary.	• Emerging use of health technology assessments. • National policy to promote	Pricing and Reimbursement Flowchart
Australia	for reviewing a nent decision of a years.	270 days.	Primarily financial ones (risk-sharing agreements).	Not formally used	The Pharmaceutical Benefits Scheme (PBS).	• 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).	• External reference pricing.• HTA and pharmacoeconomics.•	Pricing and Reimbursement Flowchart
Belgium	evidence is used, in the nt 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 reimbursement	180-270 days.	Not commonly used.	Formally used for price setting.	National List of Essential Medicines (Relação Nacional	• Price caps. • Mandatory rebates/discounts. •	Pricing and Reimbursement Flowchart

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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

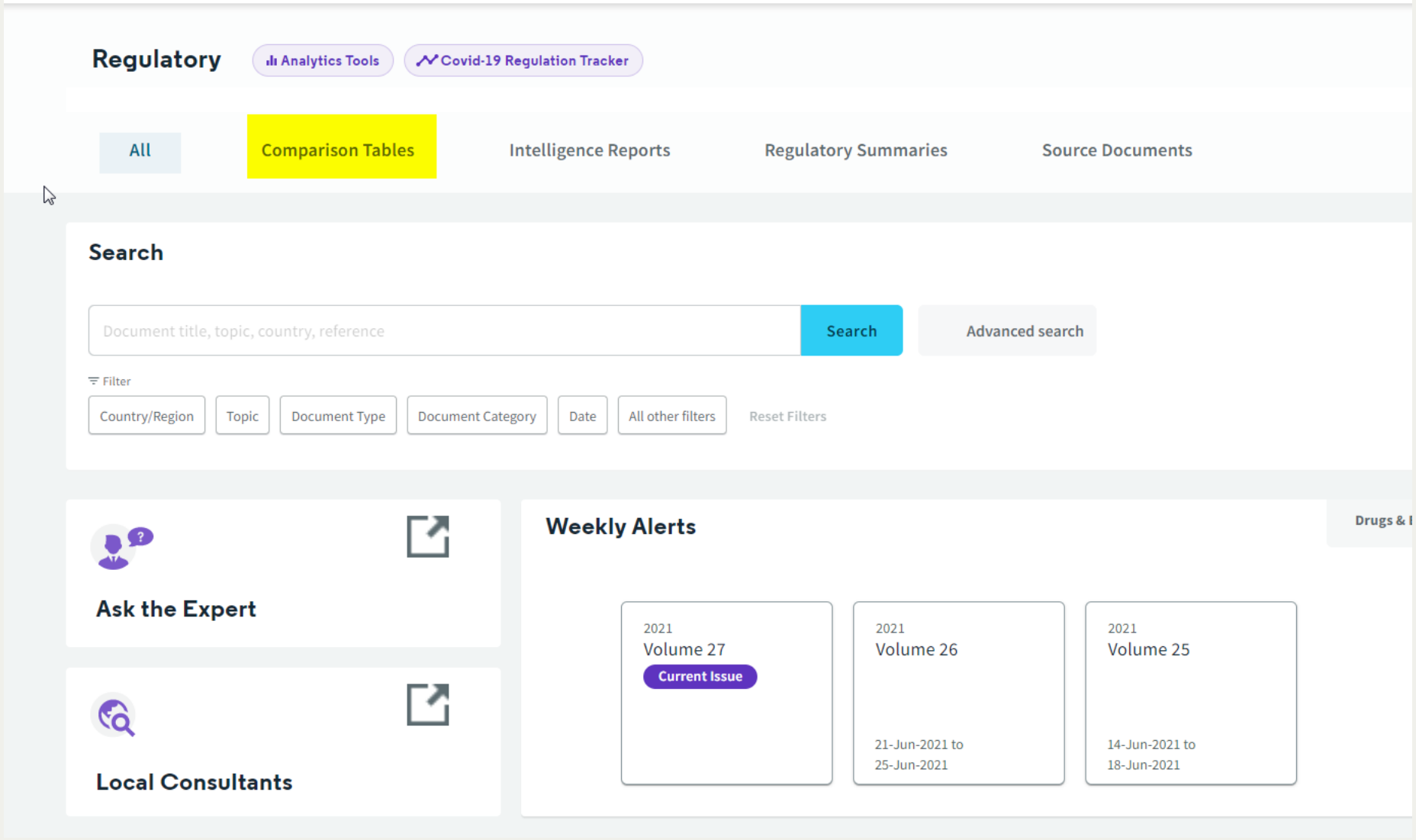
Global Comparison

My Regions

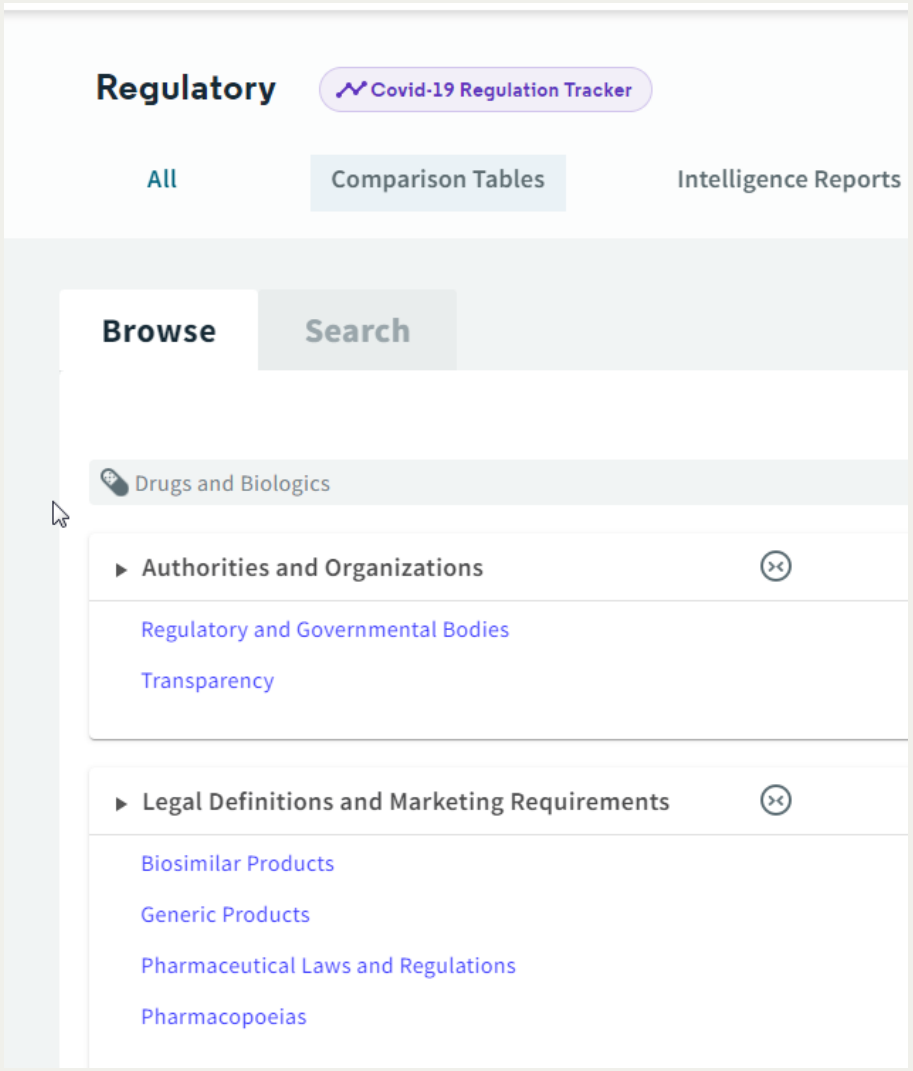
Apply Filters

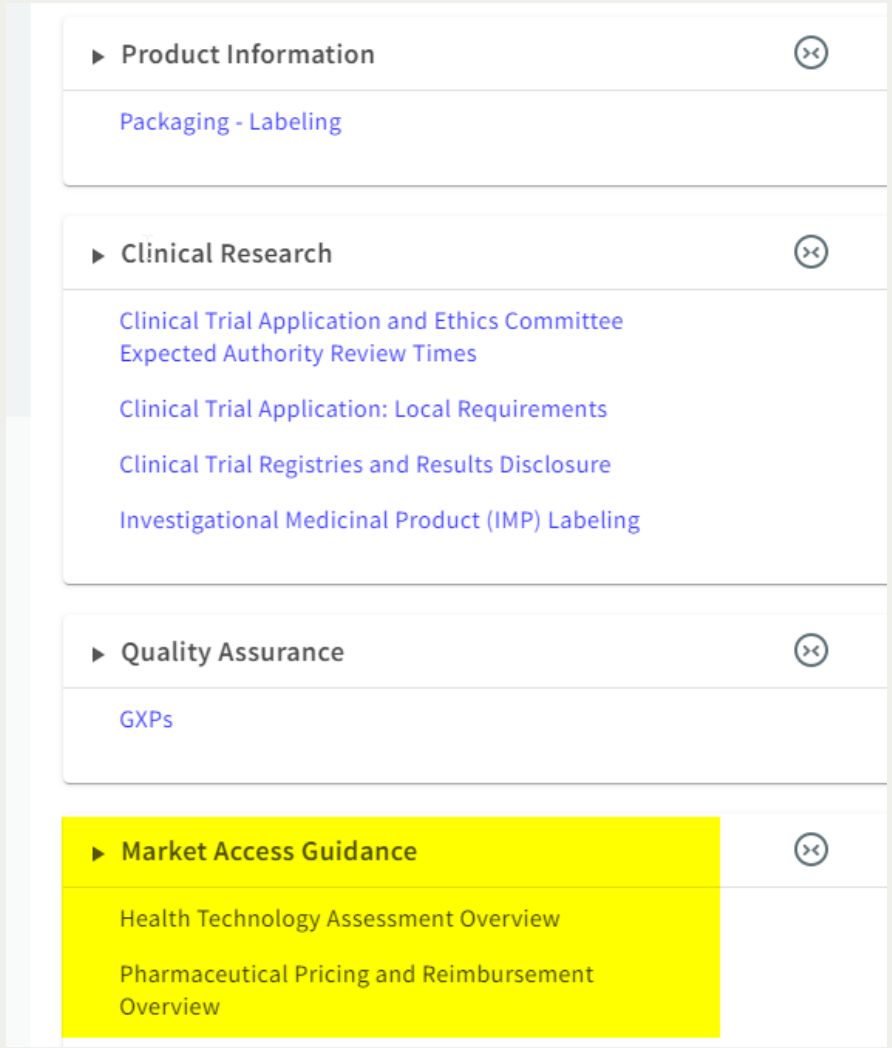
Country/Region	Health technology assessment stakeholders	HTA compulsory or not	Role of horizon scanning	Opportunities for early engagement from industry	Trial data and evidence accepted	Preferred comparator	Economic models used
Argentina	- Instituto de Efectividad Clínca y Sanitaria (IECS; Institute 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



Finding the Comparison tables

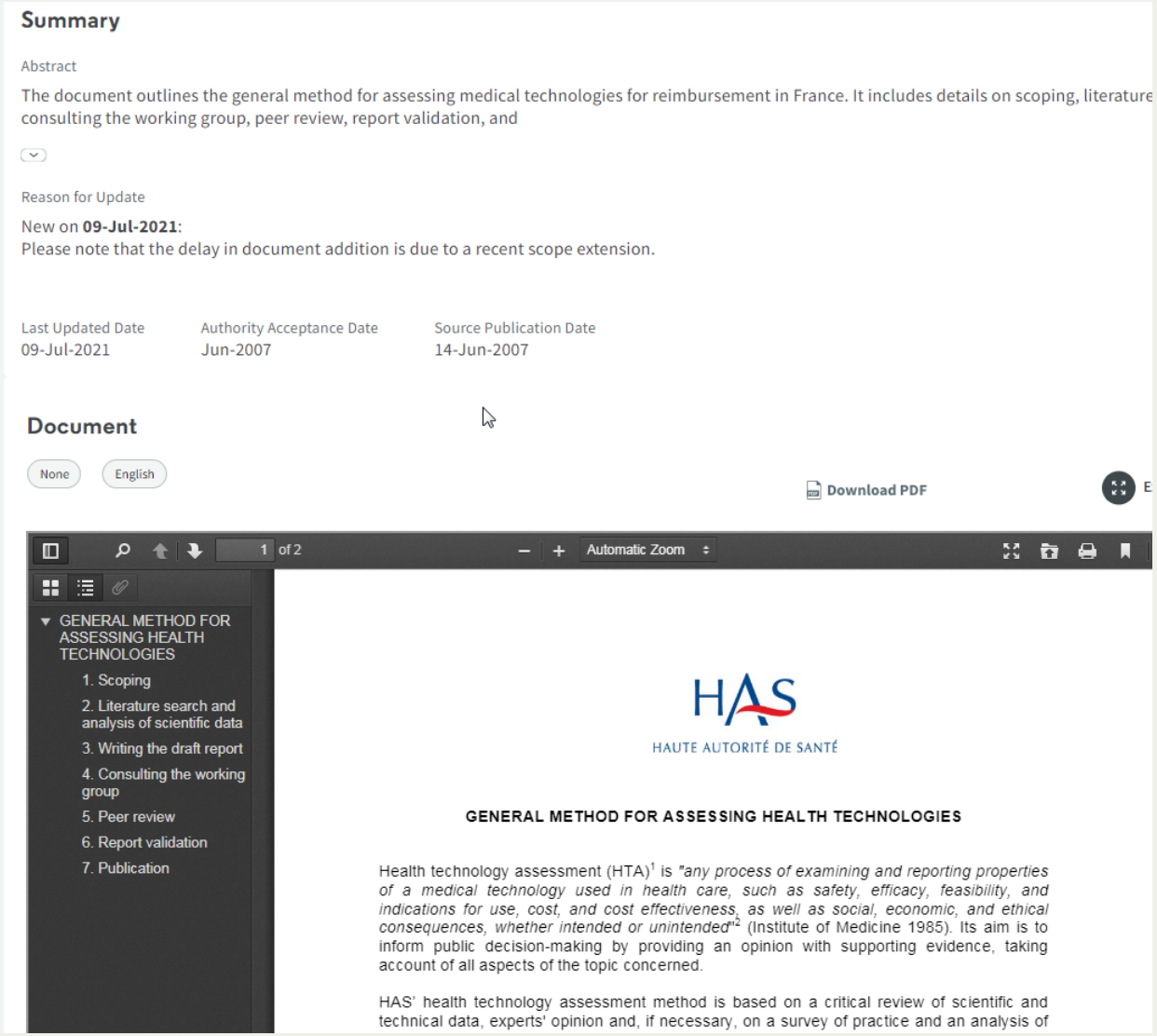




View official documents directly in Cortellis

- 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

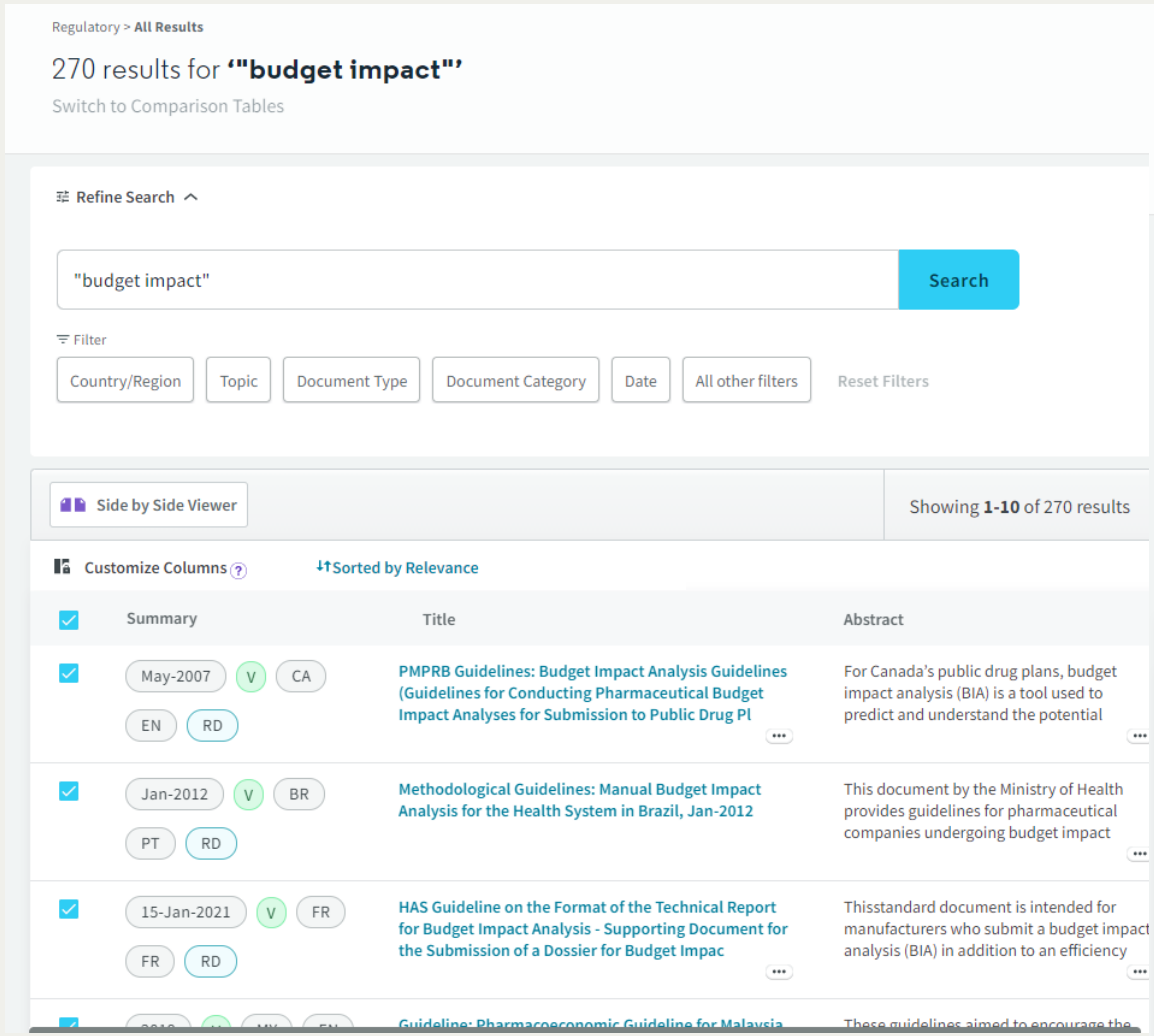
View official documents directly from Cortellis

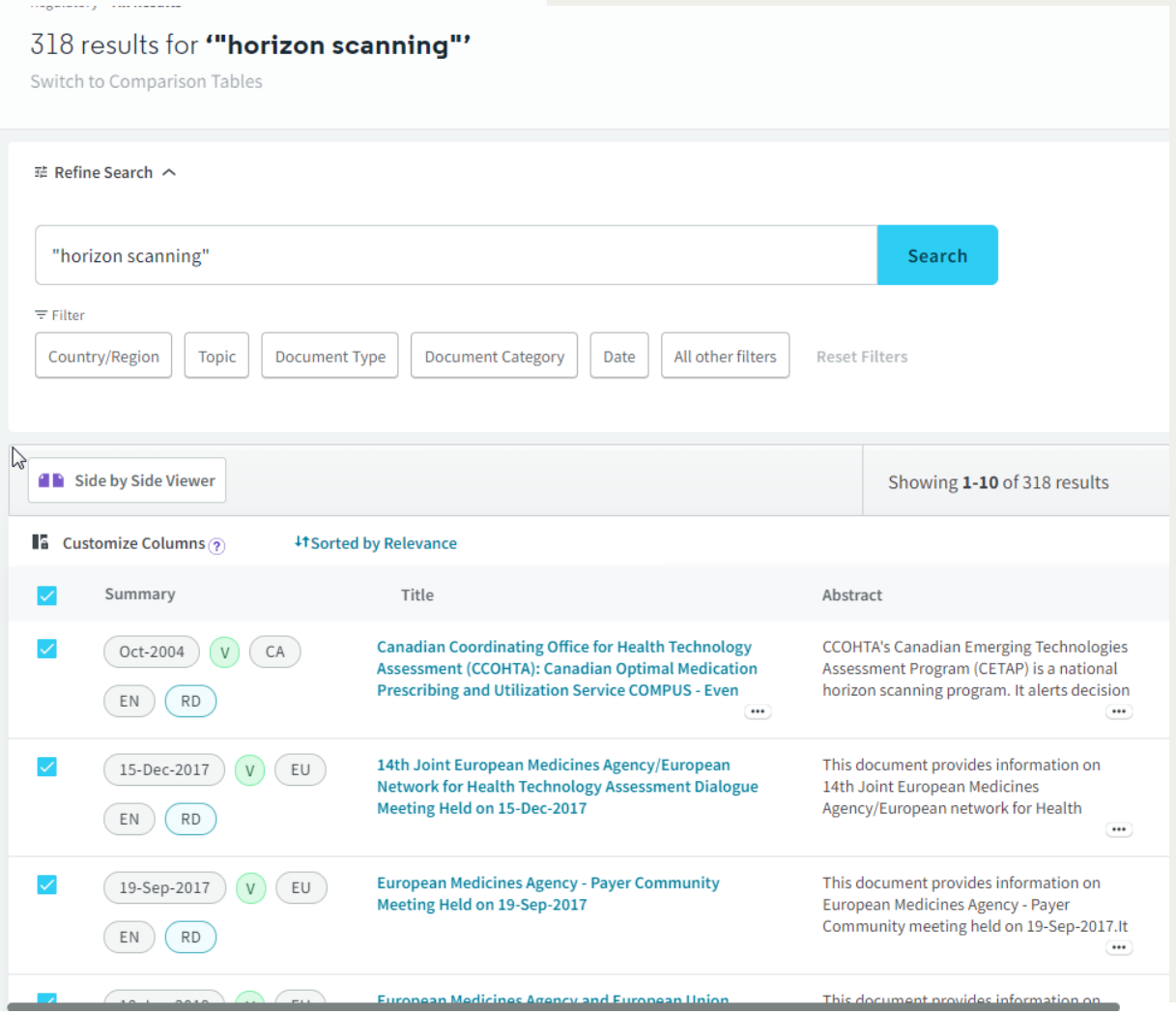


Cortellis value-add: functionality

- **Dynamic Search** – keywords and filters help you locate documents quickly and easily
- **Email alerts** – never worry about missing an update again
- **Cortellis Regulatory Intelligence Mobile App** – receive updates on your mobile device
- **Includes all legacy Cortellis Regulatory Intelligence reports**
- **Access all Cortellis modules from one platform** – Competitive, Clinical Trials and so on (as permitted by your subscription)

Dynamic Search





Weekly Alert – non-customizable update bulletin direct to your email

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

CA Cortellis Alerts <cortellis.alerts@clarivate.com>
To
Sun 8:39 PM

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

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 Landsca
highlighting the latest documents added to *Cortellis Regulatory Intelligence*.

The Cortellis Regulatory Intelligence Team

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PRODUCT NEWS

CORTELLIS REGULATORY INTELLIGENCE ESSENTIALS (DRUGS & BIOLOGICS):

- On-demand training session **Register**

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

International (2)	USA (83)	Canada (19)	
EUROPE			
European Union (144)	Finland (9)	Luxembourg	Slovenia (2)
EAEU	France (9)	Malta	Spain (3)
Austria (1)	Germany (7)	Netherlands	Sweden (1)
Belgium (2)	Greece (1)	Norway (8)	Switzerland (12)
Bulgaria (3)	Hungary	Poland (2)	Turkey (3)
Croatia (3)	Iceland	Portugal	Ukraine (2)
Cyprus	Ireland (5)	Romania	United Kingdom (5)
Czech Republic (1)	Italy (4)	Russian Federation (8)	
Denmark (1)	Latvia	Serbia (4)	
Estonia	Lithuania	Slovakia (6)	
ASIA - PACIFIC			
Asean	India (2)	New Zealand (2)	Taiwan (4)
Australia (16)	Indonesia	Philippines (1)	Thailand (3)
China (11)	Japan (11)	Singapore	Vietnam
Hong Kong (6)	Malaysia (9)	South Korea (5)	
LATIN AMERICA			
Mercosur	Brazil (7)	Costa Rica	Panama
SICA	Chile (2)	Guatemala	Peru (2)
Argentina	Colombia (2)	Mexico (1)	Venezuela
AFRICA - MIDDLE EAST			
Gulf Cooperation Council	Israel (7)	Morocco	Tunisia
Algeria (1)	Jordan (3)	Nigeria	United Arab Emirates
Egypt	Kenya	Saudi Arabia	
Iraq	Lebanon	South Africa (7)	

ADCOMM Advance and ADCOMM Bulletin emails

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

CA Cortellis Alerts <cortellis.alerts@clarivate.com>
To

PDF 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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Note
Users will receive duplicate alerts when FDA Advisory Committee meetings cover both Drug and Medical Device conte
Devices and IVDs content.

orward

12/2021 6:25

our emails.

Medical

AdComm Bulletin
Read it first. Read it fast.

Clarivate Analytics

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)

Today's Headline: Harnessing Real-World Evidence to Improve Safety Assessments of Pediatric Cancer Drugs

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.

Cortellis value add content

- **Trial requirements for a country** - affects what evidence you need to put forward
- **Timelines for regulatory approval** - affects when to file a P&R submission
- **Early access/compassionate use programs** - can you get those drugs reimbursed?
- **Product approval documents for seven countries/regions** - US, EU, China, Japan, Taiwan, Brazil and Canada

Live Demo

Customizable email Alerts

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03-Aug-2021

REGULATORY SEARCH ALERT

Your DAILY alert contains information that was updated on 02-Aug-2021

Name: P&R Source Docs Alert
Owner: Beth Wise
Contact: beth.wise@clarivate.com

2 new 2 updated 4 total.

NEW - SINCE LAST ALERT

View in Cortellis

2 Reports were new to your results set in this time period.

Lebanon - **Decision No. 893: Pricing of Locally Manufactured Sera, 16-Jul-2021**			
Abstract	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: - 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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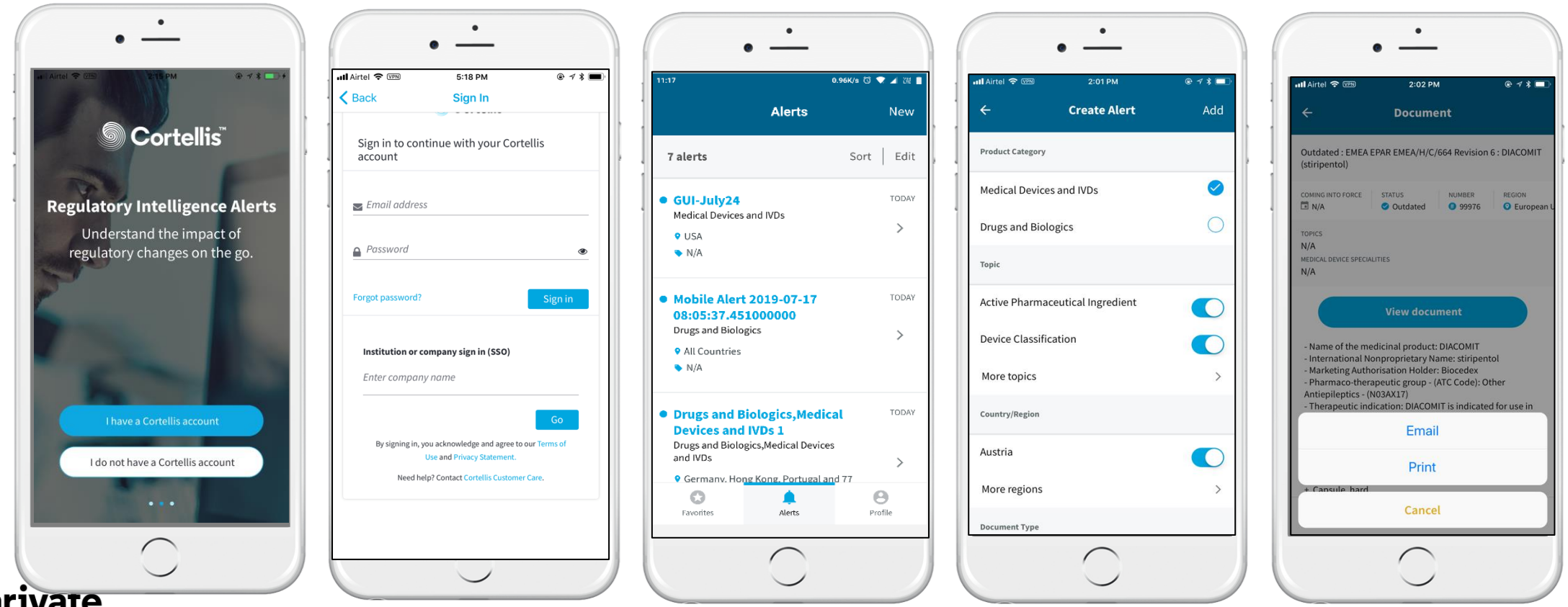
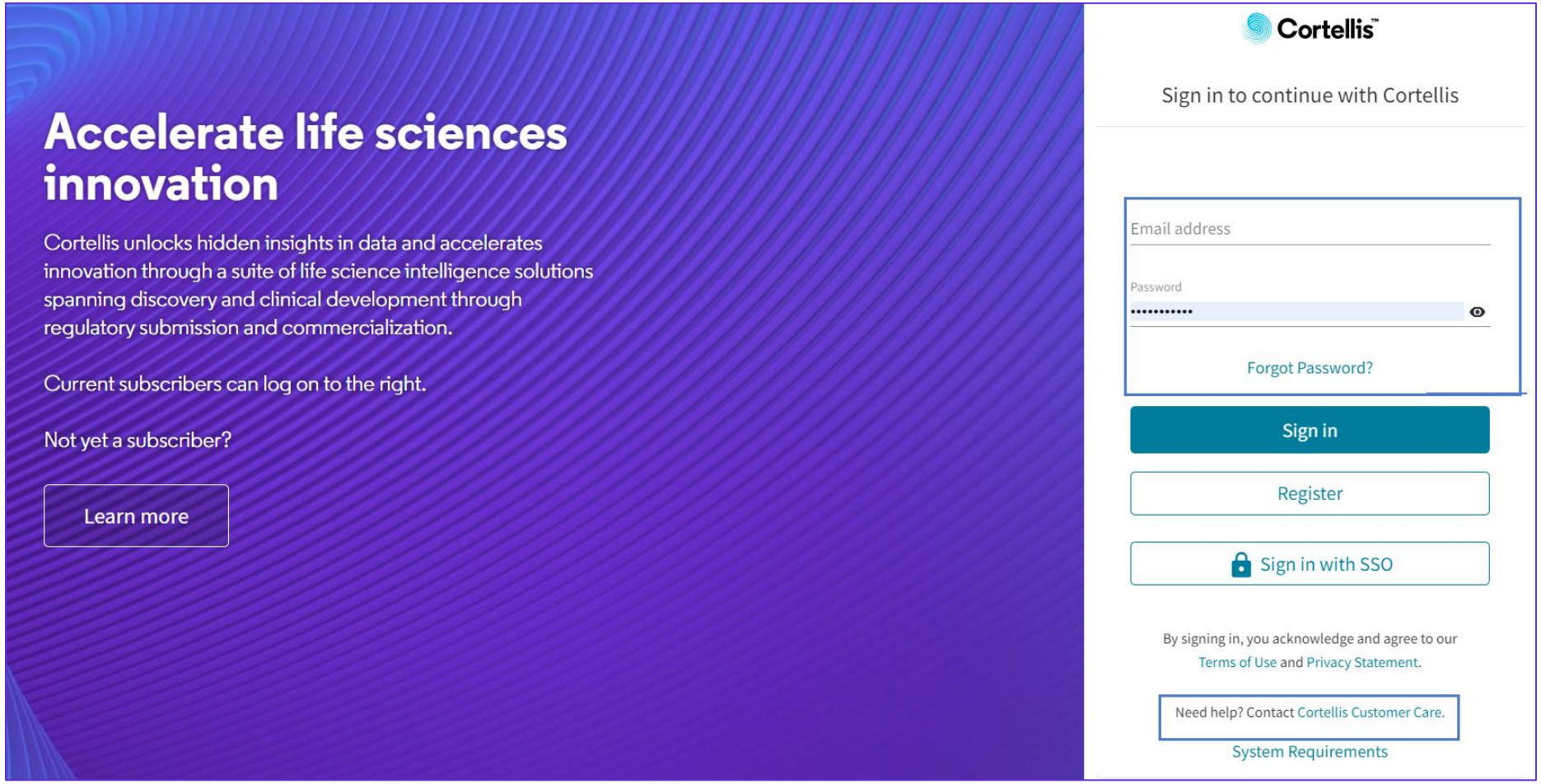


How can I access Cortellis?



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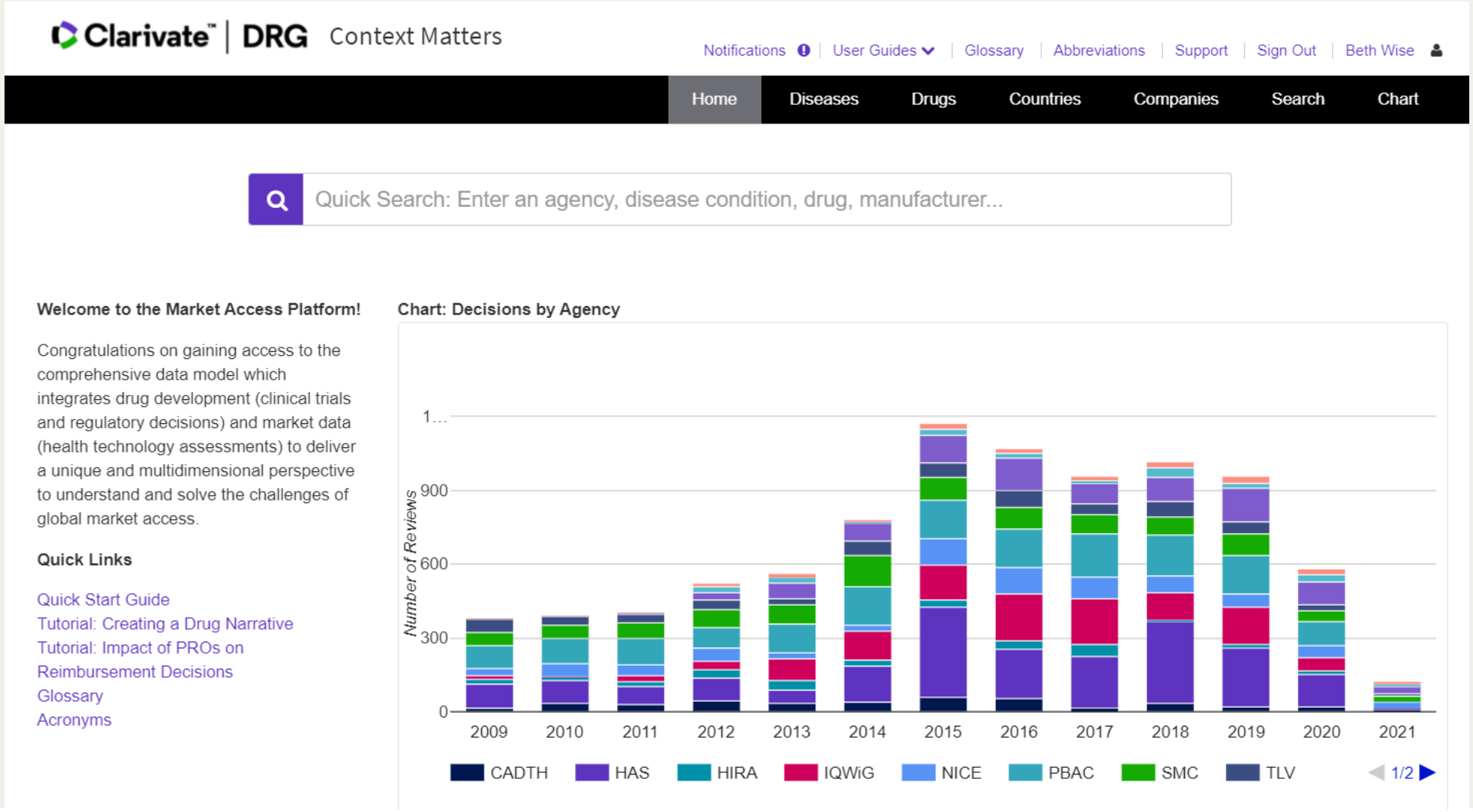
Managed Entry Agreements – now in Context Matters

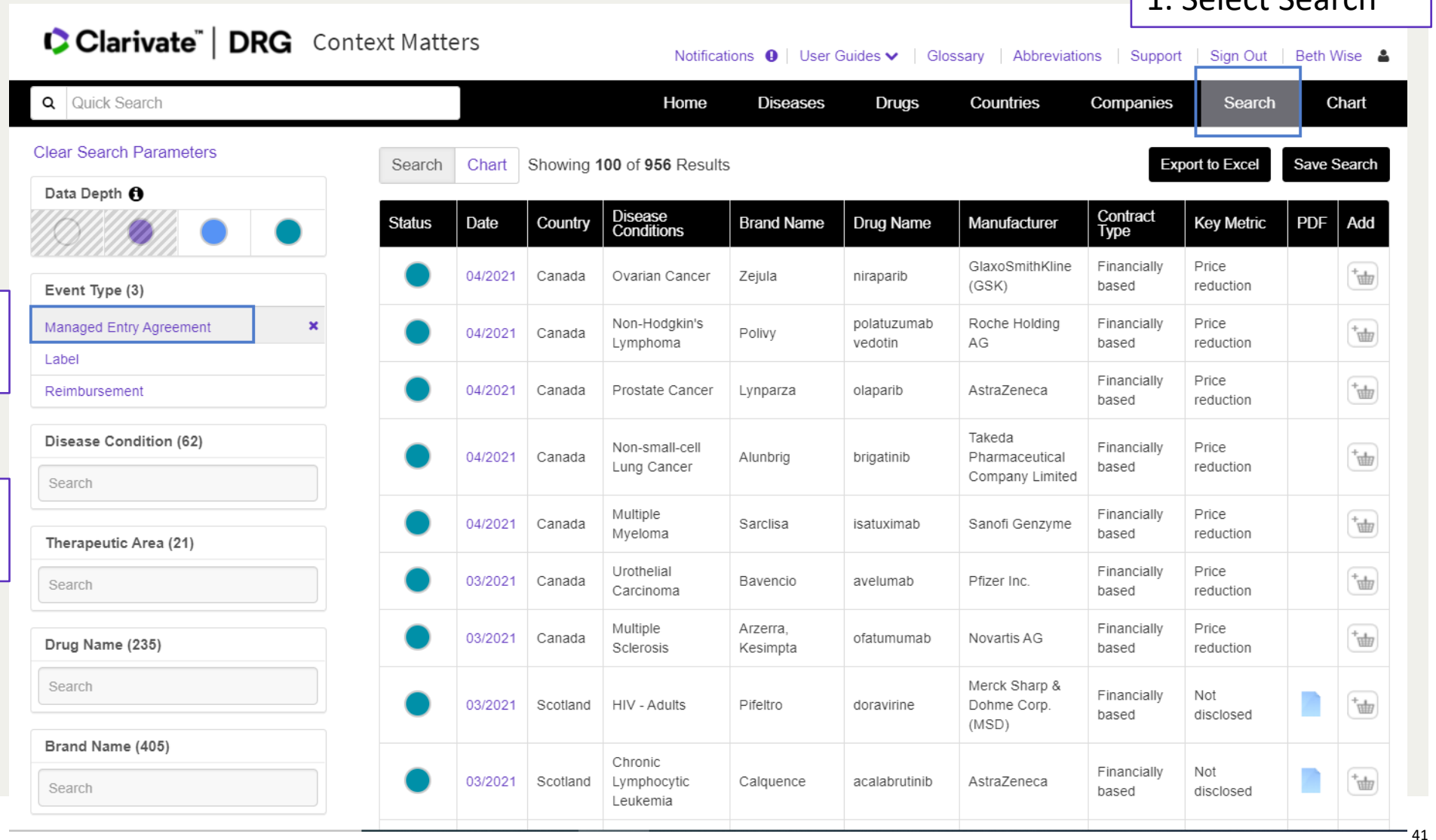


Managed Entry Agreements – now in Context Matters

1. Select Search

2. Click Managed Entry Agreement

3. Apply additional filters as required



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
- Live Demo
- Wrap-up and Q&A

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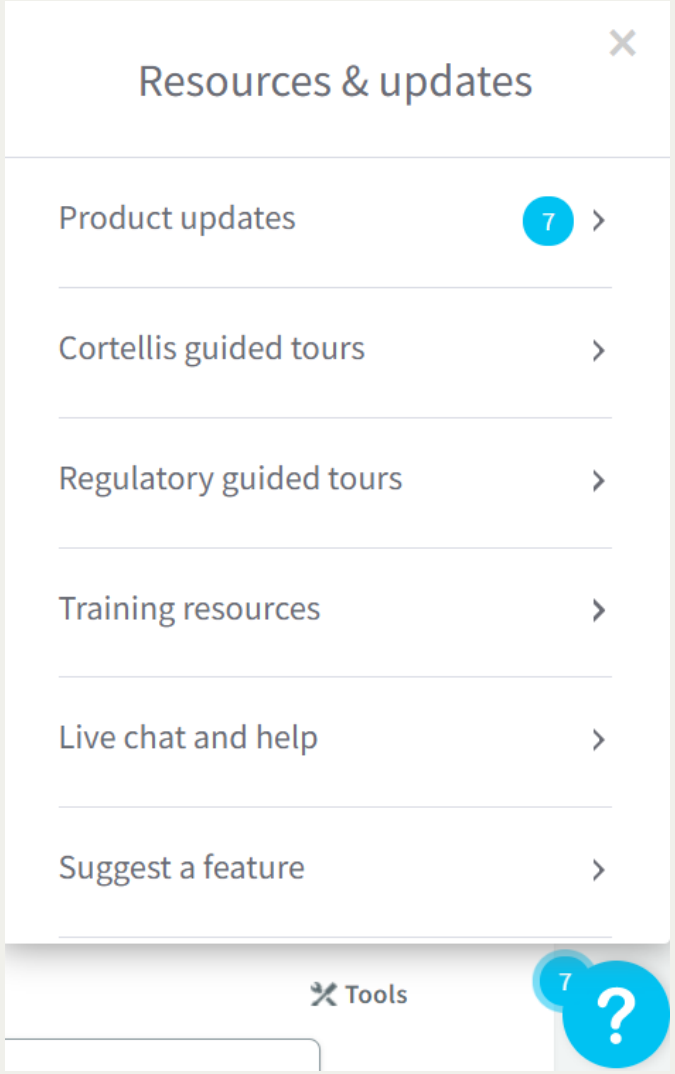
In-product guidance to walk you through the changes



- Contact us – contact Customer Support through Live Chat available 24/5, Phone or Email
- Regulatory guided tours – walk through the new interface
- Training resources – recorded trainings, Quick Guides and short videos

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Thank you…questions?

Beth Wise
Beth.wise@clarivate.com