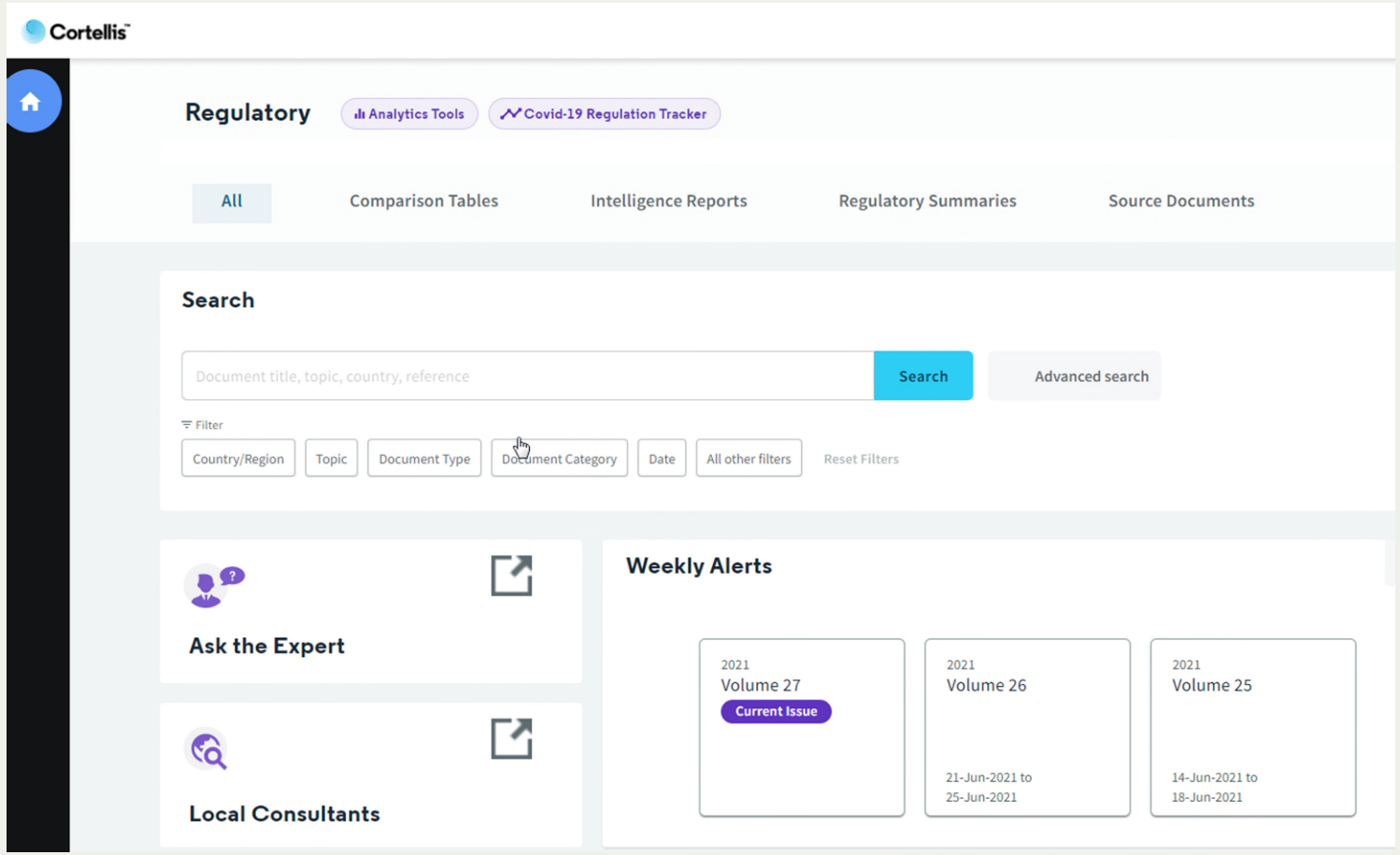
市場アクセス戦略立案に活かす
Cortellis Regulatory Intelligence

- Pricing and Reimbursement
- HTA

2022年1月

薬価・保険償還・HTAプロセス情報の大型アップデート



- Cortellis Regulatory Intelligenceの収録範囲を拡大し、薬価決定プロセス、保険償還システム、医療技術評価（HTA）に関するレポートを追加収録しました

新コンテンツは市場アクセスの計画立案に寄与

- 各国で異なる医療システム、薬価および保険償還制度など、市場アクセスの影響要因の全体像を把握したい
- HTAは本格導入されているか、HTA機関による評価結果は保険償還にどれくらいの影響力があるのか知りたい
- 薬価・保険償還決定、HTAのプロセスやタイムラインを知りたい
- 各国の医療費抑制策など市場参入の障壁は何か
- 保険償還の意思決定に影響を与えるキードライバーは何か
- どのような臨床試験や経済性評価モデルが求められるのか、RWEの活用はどれくらい進んでいるのか

etc.

Cortellis Regulatory Intelligenceの新規コンテンツ

Cortellisに従来収録されていた情報から大幅に強化され、市場アクセス戦略に役立つインサイトを提供します。
各レポートは随時更新され、現地のガイドラインの変更等の最新情報が反映されます。

- 各国関連当局の文書を追加収録
- 新規分析レポート（全8種）
  - Regulatory Summary
    - Pricing and Reimbursement Overview
    - Health Technology Assessment Summary
  - Regulatory Intelligence Report
    - Pricing and Reimbursement Flowchart
    - Market Access Overview
    - Market Access Challenges and Opportunities
    - Market Access Commercialization Outlook
  - Global Regulatory Comparisons (Comparison Table)
    - Health Technology Assessment Overview
    - Pharmaceutical Pricing and Reimbursement Overview

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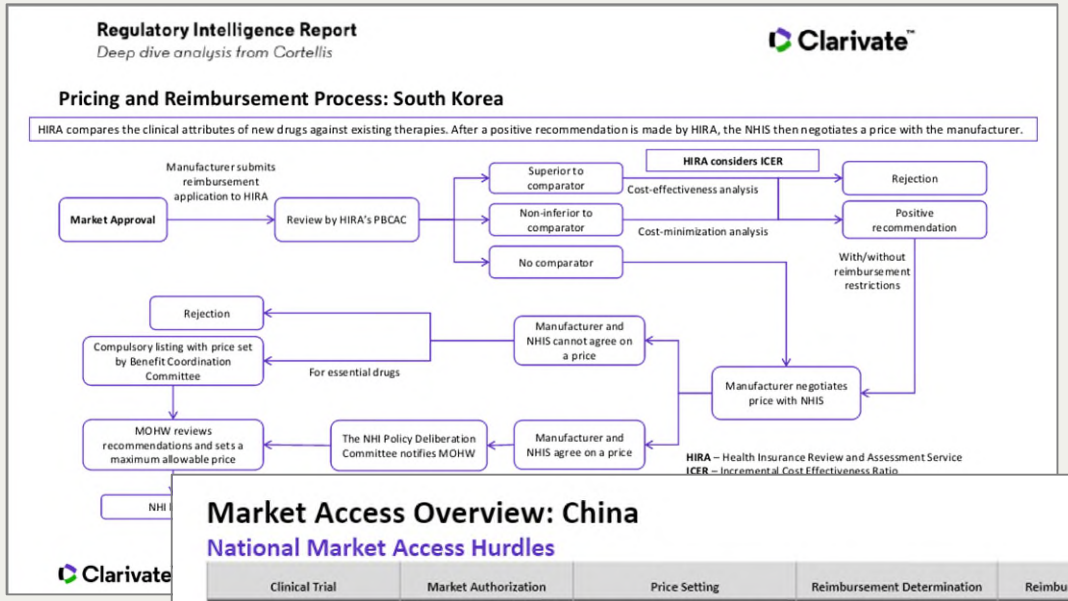

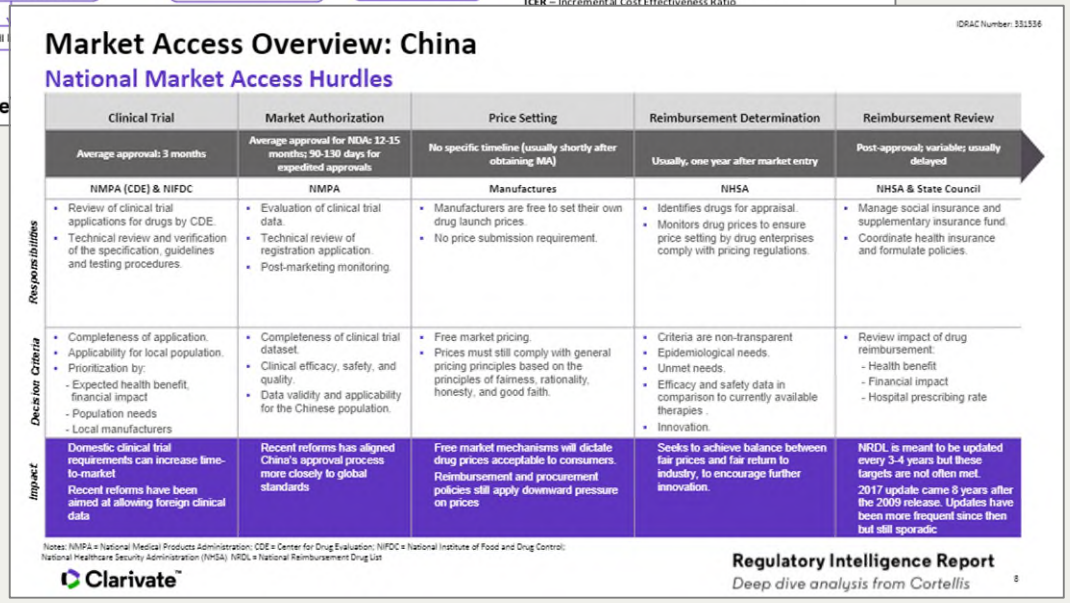

市場アクセス関連コンテンツ拡充対象国

33カ国（Drugs & Biologicsモジュール）

North America

- Canada, United States

Europe

- Austria, Belgium, France, Germany, Italy, Netherlands, Poland, Russia, Spain, Sweden, Switzerland, Turkey, UK

Asia Pacific

- Australia, China, India, Indonesia, Japan, Philippines, South Korea, Taiwan, Thailand, Vietnam

Latin America

- Argentina, Brazil, Chile, Colombia, Mexico, Venezuela

Middle East, Africa

- Saudi Arabia, South Africa

- Pricing & Reimbursement関連情報
  - 33カ国を対象にコンテンツ拡充
- HTA関連情報
  - 21カ国を対象にコンテンツ拡充

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各国の薬価・保険償還・HTA制度の把握や審査プロセス対応に役立つ解説コンテンツ
Regulatory Summaries

Regulatory Summaries

- 解説文トピックに新カテゴリ”Market Access Guidance”が登場
- 2種類の新規解説文を追加
- 対象モジュール：Drugs & Biologics

- Market Access Guidance
  1. Pricing and Reimbursement Overview
     - 医療制度の概要、薬価算定基準とそのプロセス、薬価改定制度、保険償還システムや償還への影響要因（HTA, 医療費抑制政策 etc.）、フォーミュラリーなど
     - 33カ国で提供
  2. Health Technology Assessment Summary
     - HTA制度の概要、意思決定者、評価プロセス、評価申請要件、申請書添付データ要件、臨床効果および経済効果評価要件など
     - 21カ国で提供

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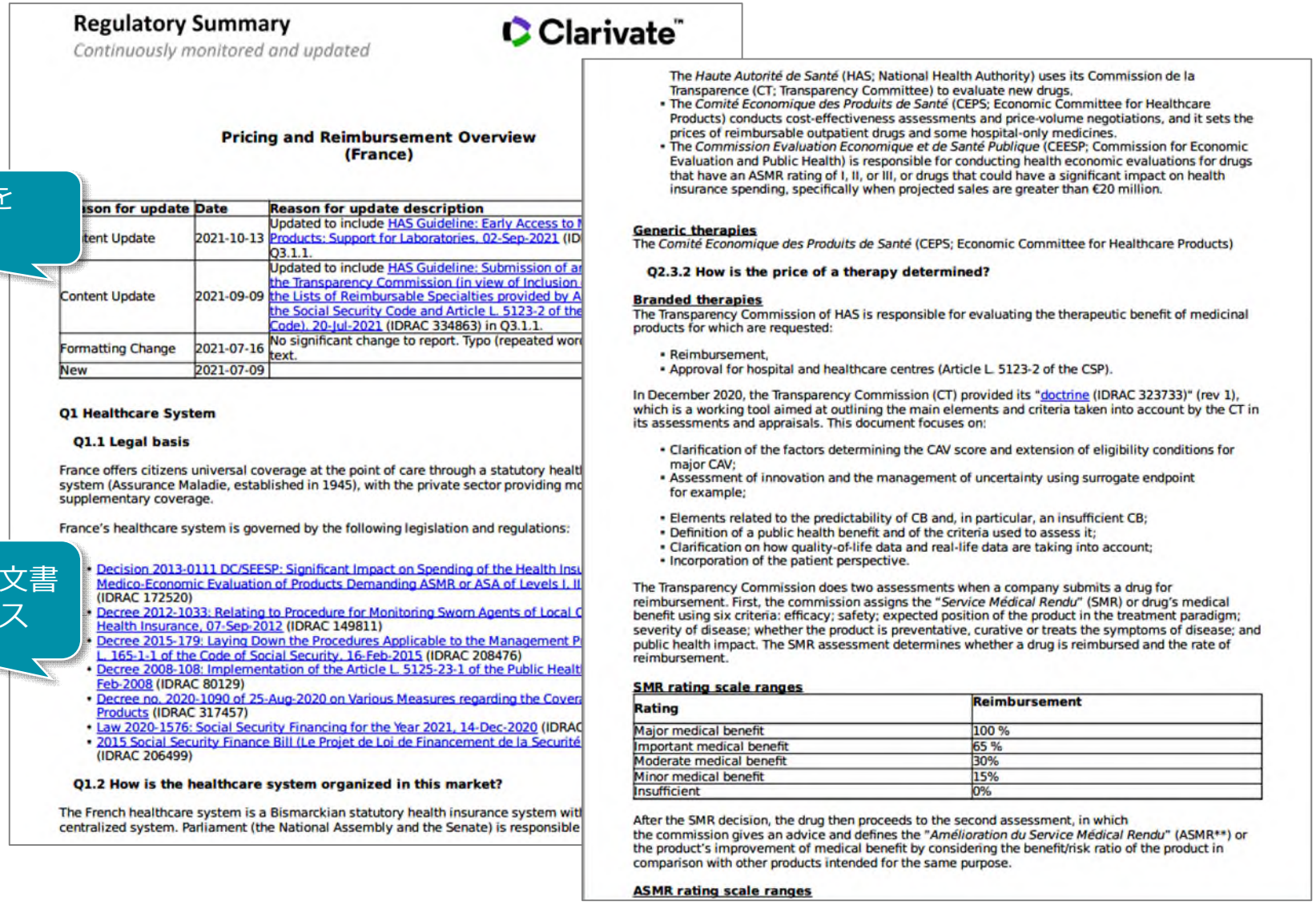
収録レポートの例

各国の”Regulatory Summary”では、薬価・保険償還・HTA制度についてのより詳細な解説に加え、現地規制文書へのアクセスを提供します

最新情報を随時反映

関連する規制文書へのアクセス



Regulatory Summary

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Pricing and Reimbursement Overview (France)

ason for update	Date	Reason for update description
tent Update	2021-10-13	Updated to include HAS Guideline: Early Access to M Products: Support for Laboratories, 02-Sep-2021 (ID Q3.1.1.
Content Update	2021-09-09	Updated to include HAS Guideline: Submission of ar the Transparency Commission (in view of Inclusion the Lists of Reimbursable Specialties provided by A the Social Security Code and Article L. 5123-2 of the Code), 20-Jul-2021 (IDRAC 334863) in Q3.1.1.
Formatting Change	2021-07-16	No significant change to report. Typo (repeated wor text.
New	2021-07-09	

Q1 Healthcare System

Q1.1 Legal basis

France offers citizens universal coverage at the point of care through a statutory healt system (Assurance Maladie, established in 1945), with the private sector providing mo supplementary coverage.

France's healthcare system is governed by the following legislation and regulations:

- Decision 2013-0111 DC/SEESP: Significant Impact on Spending of the Health Insu Medico-Economic Evaluation of Products Demanding ASMR or ASA of Levels I, II (IDRAC 172520)
- Decree 2012-1033: Relating to Procedure for Monitoring Sworn Agents of Local C Health Insurance, 07-Sep-2012 (IDRAC 149811)
- Decree 2015-179: Laying Down the Procedures Applicable to the Management P L. 165-1-1 of the Code of Social Security, 16-Feb-2015 (IDRAC 208476)
- Decree 2008-108: Implementation of the Article L. 5125-23-1 of the Public Healt Feb-2008 (IDRAC 80129)
- Decree no. 2020-1090 of 25-Aug-2020 on Various Measures regarding the Cover Products (IDRAC 317457)
- Law 2020-1576: Social Security Financing for the Year 2021, 14-Dec-2020 (IDRAC
- 2015 Social Security Finance Bill (Le Projet de Loi de Financement de la Securité (IDRAC 206499)

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

The French healthcare system is a Bismarckian statutory health insurance system wit centralized system. Parliament (the National Assembly and the Senate) is responsible

The *Haute Autorité de Santé* (HAS; National Health Authority) uses its Commission de la Transparence (CT; Transparency Committee) to evaluate new drugs.

- The *Comité Economique des Produits de Santé* (CEPS; Economic Committee for Healthcare Products) conducts cost-effectiveness assessments and price-volume negotiations, and it sets the prices of reimbursable outpatient drugs and some hospital-only medicines.
- The *Commission Evaluation Economique et de Santé Publique* (CEESP; Commission for Economic Evaluation and Public Health) is responsible for conducting health economic evaluations for drugs that have an ASMR rating of I, II, or III, or drugs that could have a significant impact on health insurance spending, specifically when projected sales are greater than €20 million.

Generic therapies

The *Comité Economique des Produits de Santé* (CEPS; Economic Committee for Healthcare Products)

Q2.3.2 How is the price of a therapy determined?

Branded therapies

The Transparency Commission of HAS is responsible for evaluating the therapeutic benefit of medicinal products for which are requested:

- Reimbursement,
- Approval for hospital and healthcare centres (Article L. 5123-2 of the CSP).

In December 2020, the Transparency Commission (CT) provided its "doctrine (IDRAC 323733)" (rev 1), which is a working tool aimed at outlining the main elements and criteria taken into account by the CT in its assessments and appraisals. This document focuses on:

- Clarification of the factors determining the CAV score and extension of eligibility conditions for major CAV;
- Assessment of innovation and the management of uncertainty using surrogate endpoint for example;

- Elements related to the predictability of CB and, in particular, an insufficient CB;
- Definition of a public health benefit and of the criteria used to assess it;
- Clarification on how quality-of-life data and real-life data are taking into account;
- Incorporation of the patient perspective.

The Transparency Commission does two assessments when a company submits a drug for reimbursement. First, the commission assigns the "*Service Médical Rendu*" (SMR) or drug's medical benefit using six criteria: efficacy; safety; expected position of the product in the treatment paradigm; severity of disease; whether the product is preventative, curative or treats the symptoms of disease; and public health impact. The SMR assessment determines whether a drug is reimbursed and the rate of reimbursement.

SMR rating scale ranges

Rating	Reimbursement
Major medical benefit	100 %
Important medical benefit	65 %
Moderate medical benefit	30%
Minor medical benefit	15%
Insufficient	0%

After the SMR decision, the drug then proceeds to the second assessment, in which the commission gives an advice and defines the "*Amélioration du Service Médical Rendu*" (ASMR**) or the product's improvement of medical benefit by considering the benefit/risk ratio of the product in comparison with other products intended for the same purpose.

ASMR rating scale ranges

Regulatory Summaries

- Market Access Guidance

1. Pricing and Reimbursement Overview

- **Q1 Healthcare System**
  - 医療システム、医療保険制度、制度の根幹をなす法的な枠組み etc.

- **Q2 Pricing System**
  - Q2-1. Pricing system background
    - 薬価制度を取り巻く法規制、関与する現地当局、薬価決定のプロセスとタイムライン etc.
  - Q2-2. Managed entry agreements
  - Q2-3. Price determination at launch
    - 薬価がどのように決定されるか、薬価への影響要因（参照価格制度など）、高薬価獲得のためのドライバーは何か etc.
  - Q2-4. Post-launch price changes
    - 市販後の薬価改定、薬価の引き上げの可能性

- **Q3 Reimbursement**
  - Q3-1. Reimbursement system
    - 保険償還に関わるキーステークホルダー、償還対象の医薬品カテゴリ、RWEの利用状況、国家の薬剤費抑制策、HTA制度の導入状況、費用対効果評価モデル etc.
  - Q3-2. Drug lists and formularies
    - 保険償還対象医薬品リスト、償還除外医薬品リストの運用 etc.

Regulatory Summaries

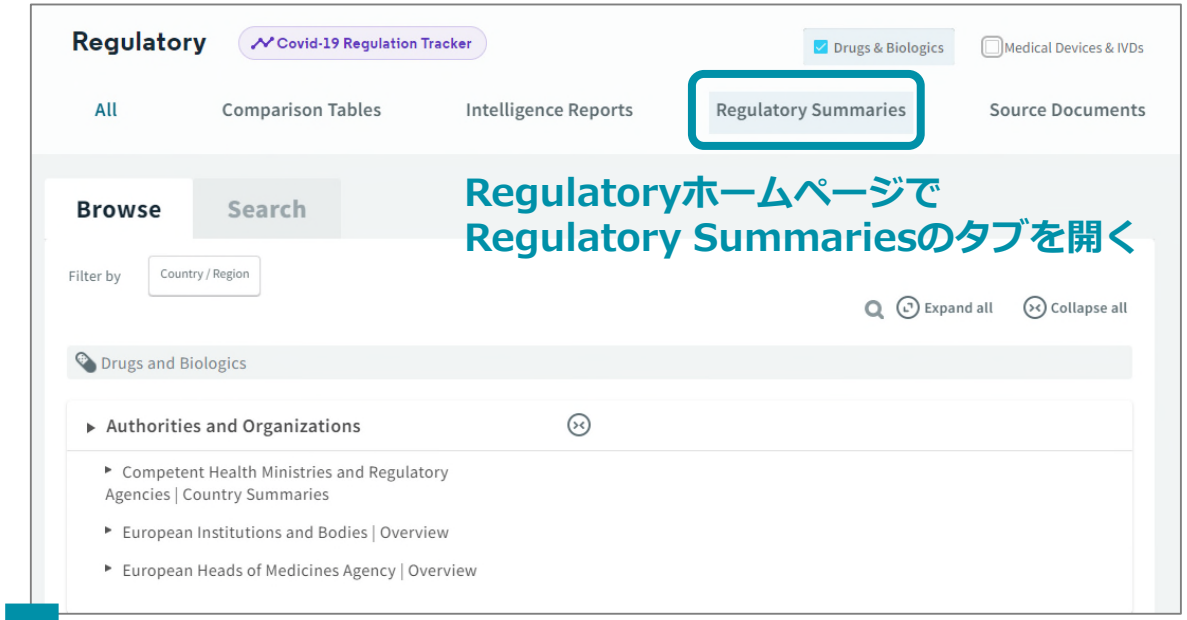
- Market Access Guidance

2. Health Technology Assessment Summary

- **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?
    - 薬価・保険償還意思決定にHTAが用いられているか？
  - Q1.2 Background and organization of HTA
    - HTA制度の特色、意思決定者、評価基準、製薬企業の関与可能性 etc.
  - Q1.3 What influence do various stakeholders have in the HTA process?
    - 各ステークホルダーがHTA審査プロセスに与える影響
  - Q1.4 Process & timelines
    - STA (Single-technology assessment), HTA審査プロセス、申請書類の有無および記載内容、審査タイムライン、MTA（Multi-technology assessment) etc.

- **Q2 HTA guidelines**
  - Q2.1 What guidelines are used to assess therapies?
  - Q2.2 Clinical Assessment within HTA
    - 臨床的価値評価機関、要求されるデータ、望ましい臨床試験デザイン、比較対照治療、価値評価基準 etc.
  - Q2.3 Economic assessment within HTA
    - 経済性評価モデル、評価機関、評価の基準、要求されるデータ etc.

Regulatory Summariesへのアクセス方法



Regulatoryホームページで
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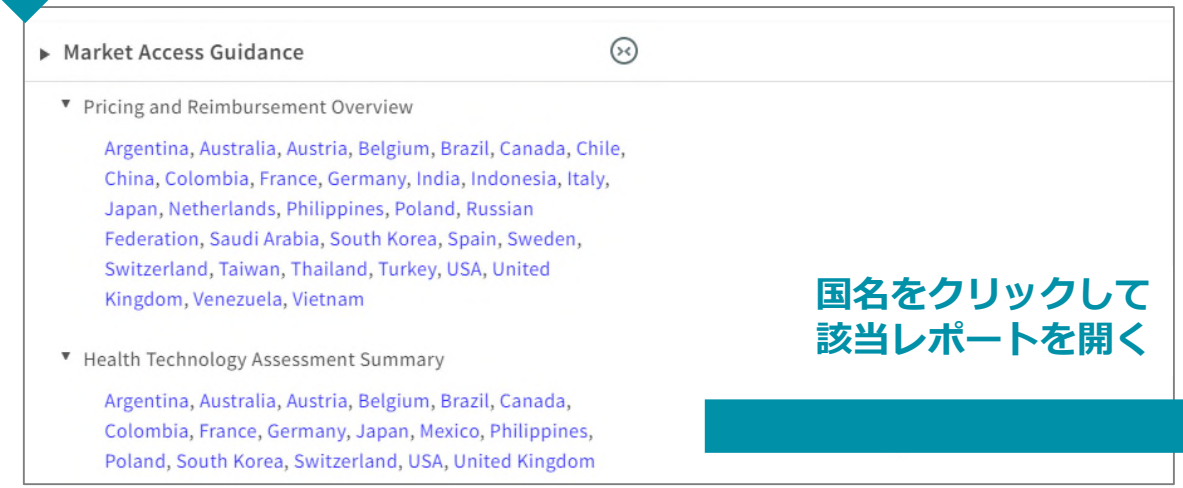

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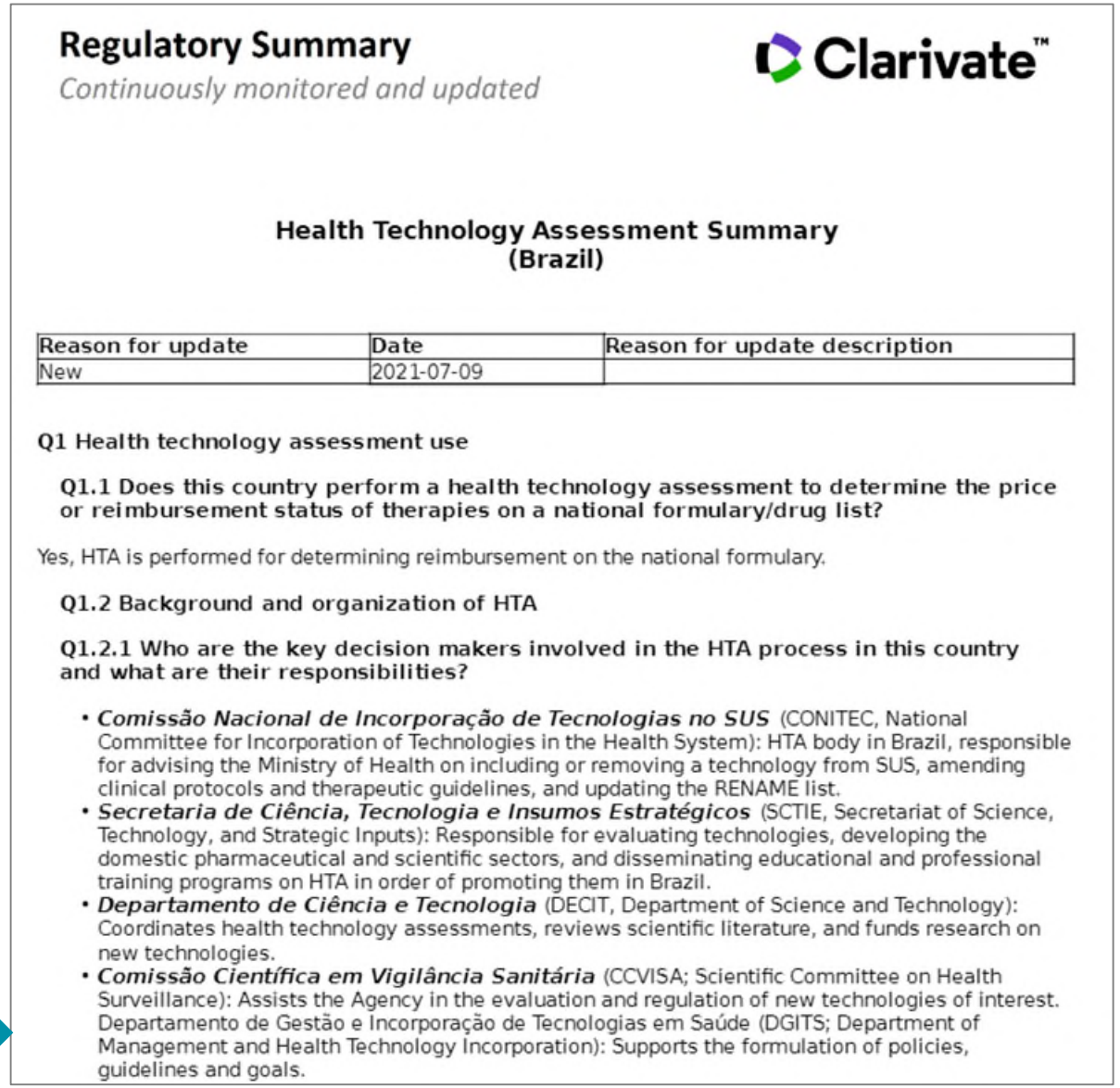

Regulatory Summary

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Health Technology Assessment Summary (Brazil)

Reason for update	Date	Reason for update description
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?

Yes, HTA is performed for determining reimbursement on the national formulary.

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?

- ***Comissão Nacional de Incorporação de Tecnologias no SUS*** (CONITEC, National Committee for Incorporation of Technologies in the Health System): HTA body in Brazil, responsible for advising the Ministry of Health on including or removing a technology from SUS, amending clinical protocols and therapeutic guidelines, and updating the RENAME list.
- ***Secretaria de Ciência, Tecnologia e Insumos Estratégicos*** (SCTIE, Secretariat of Science, Technology, and Strategic Inputs): Responsible for evaluating technologies, developing the domestic pharmaceutical and scientific sectors, and disseminating educational and professional training programs on HTA in order of promoting them in Brazil.
- ***Departamento de Ciência e Tecnologia*** (DECIT, Department of Science and Technology): Coordinates health technology assessments, reviews scientific literature, and funds research on new technologies.
- ***Comissão Científica em Vigilância Sanitária*** (CCVISA; Scientific Committee on Health Surveillance): Assists the Agency in the evaluation and regulation of new technologies of interest. Departamento de Gestão e Incorporação de Tecnologias em Saúde (DGITS; Department of Management and Health Technology Incorporation): Supports the formulation of policies, guidelines and goals.

市場参入計画、戦略立案に役立つ分析を提供する Regulatory Intelligence Reports

Intelligence Reports

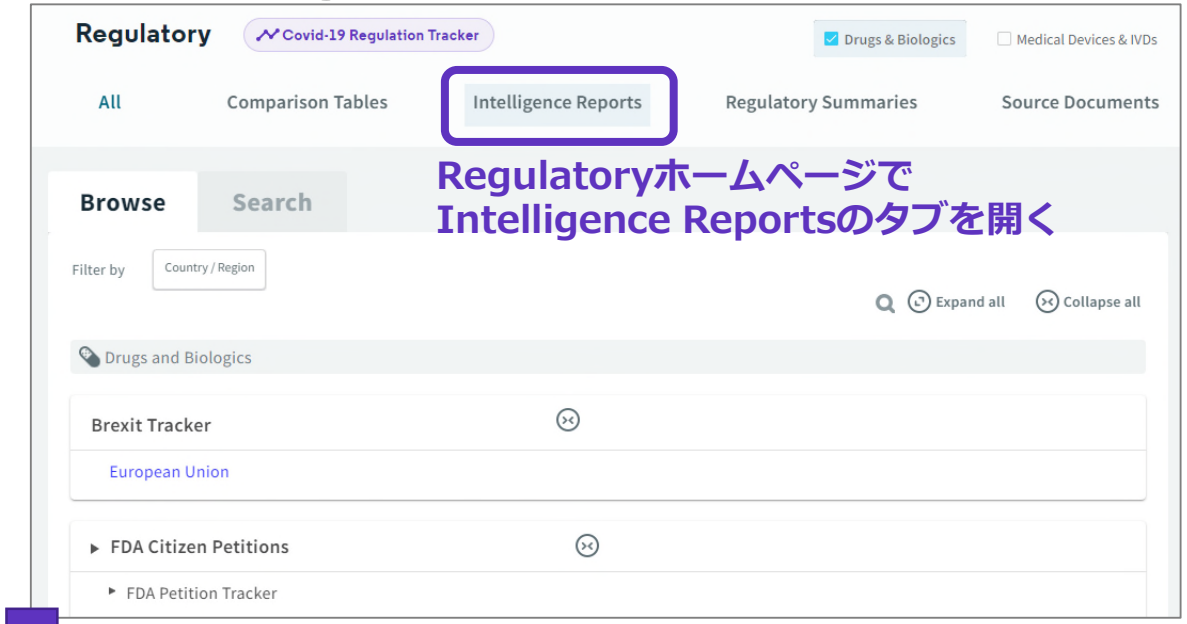
- 分析レポートに新規カテゴリ”Global Market Access Insights”が登場
- 4種類の新規レポートを追加
- 対象モジュール：Drugs & Biologics

- Global Market Access Insights – 33カ国
  - Pricing and Reimbursement Flowchart
    - 医薬品承認取得後の薬価決定プロセスや保険償還プロセスの全体像を俯瞰
  - Market Access Overview
    - 医療制度、市場参入に関わるステークホルダー、薬価制度、保険償還、HTA、参入障壁等をまとめたサマリーレポート
  - Market Access Challenges and Opportunities
    - 各国市場のビジネス上の課題や機会についてサマリーした外部環境分析レポート
  - Market Access Commercialization Outlook
    - 市場アクセス戦略検討に際して念頭に置くべきポイントを簡潔にまとめたExecutive Summary

収録レポートの例

“Market Access Overview”は各国の医療制度、薬価・保険償還、HTAの制度、評価プロセスや意思決定権者、制度改革や医療費抑制政策等の参入障壁 etc.の概要をレポートします

Intelligence Reportsへのアクセス方法



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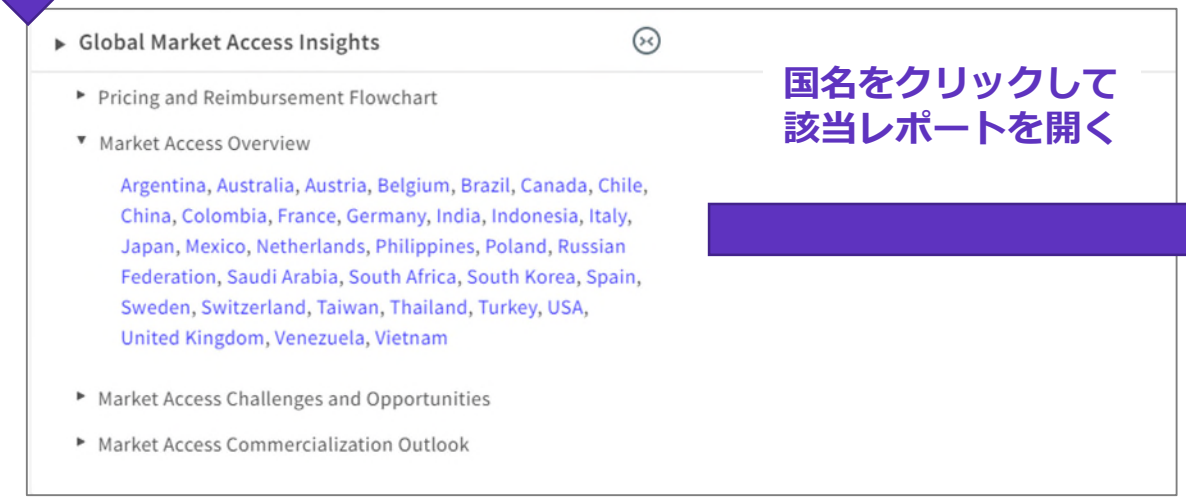

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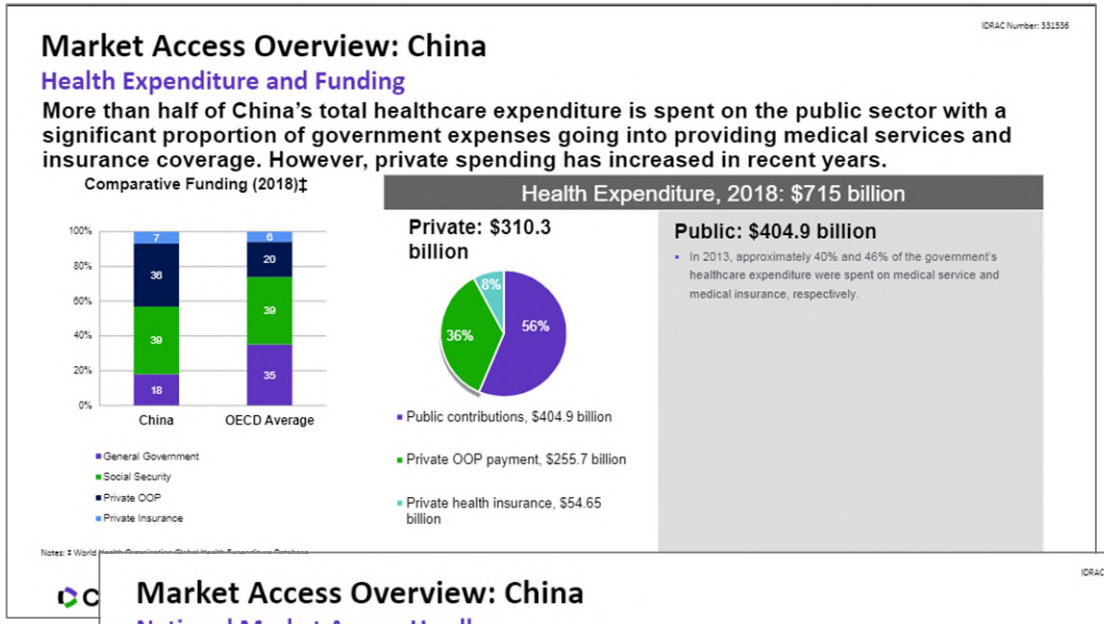

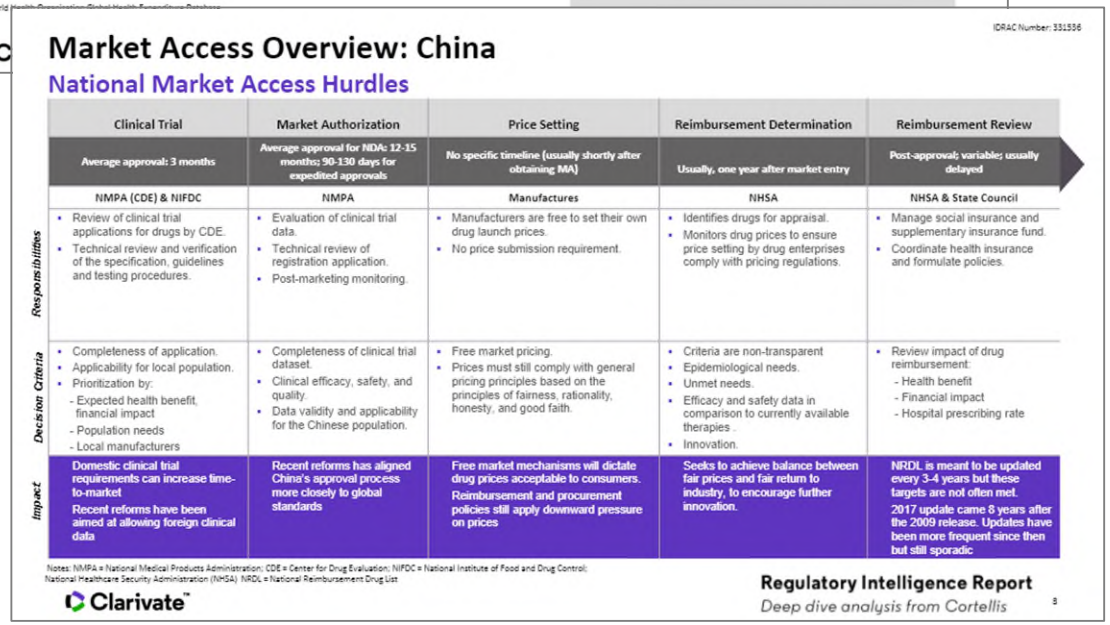

複数国の薬価制度やHTAプロセスの違いを俯瞰する Comparison Tables

Comparison Tables

- 規制の比較表に新規カテゴリ”Market Access Guidance”が登場
- 2種類の新規比較表を追加
- 対象モジュール：Drugs & Biologics

- Market Access Guidance
  1. Pharmaceutical Pricing and Reimbursement Overview
     - 薬価算定、保険償還プロセスの各国比較
     - 意思決定ステークホルダー、HTAの位置づけ、RWEの評価有無、償還決定までのタイムライン、外国参照価格、フォーミュラリー etc. についてのハイレベルな比較
     - 33カ国で提供
  2. Health Technology Assessment Overview
     - HTAの影響力、求められる臨床データ、比較対象とすべき治療、経済効果評価モデル、費用対効果指標、評価タイムラインなどの各国比較
     - 21カ国で提供

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収録レポートの例

“Health Technology Assessment Overview”では各国のHTA機関の評価の特性を比較し、
エビデンス構築の計画や、参入順序の検討、リスク分析等をサポートします

Global Comparison

My Regions

Apply Filters

Country/Region	HTA compulsory or not	Role of horizon scanning	Opportunities for early engagement from industry	Trial data and evidence accepted	Preferred comparator	Economic models used	Explicit or implicit cost-effectiveness threshold
Argentina	Compulsory	Indirectly used. CONETEC, issues proposals for technologies to evaluate ...	No opportunities.	- Randomized controlled trials (RCTs)- Observational studies- Other studies in	Routine care/most commonly prescribed therapy.	- Cost-utility - Cost-effectiveness - Budget impact	Implicitly 1 GDP per capita, (US $14,000 per quality-adjusted life year added.
Australia	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	U$45,000 to AU$60,000 per QALY gained (estimated).
Austria	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	No official threshold.
Belgium	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	No official threshold.
Brazil	Compulsory	CONITEC highlights the need to rely on horizon scanning to optimize the ...	No opportunities.	- Randomized controlled trials- Meta-analysis of indirect trials- Observational	Routine care/most commonly prescribed therapy.	- Cost-utility- Cost-effectiveness- Budget impact- Cost-consequence- Cost-	BRL 20,000 per QALY gained (implicit).

Comparison Tables

- 規制の比較表に新規カテゴリ”Market Access Guidance”が登場
- 2種類の新規比較表を追加
- 対象モジュール：Drugs & Biologics

Market Access Guidance

1. Pharmaceutical Pricing and Reimbursement Overview
   - 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
   - Use of external reference pricing
   - Main drug list or formulary
   - Key cost-containment measures
2. Health Technology Assessment Overview
   - 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
   - Explicit or implicit cost-effectiveness threshold
   - Perspective used
   - Estimated timeline for review

Comparison Tablesへのアクセス方法

Regulatoryホームページで
Comparison Tablesのタブを開く

スクロールして”Market Access Guidance”のトピックを表示

トピック名をクリックして
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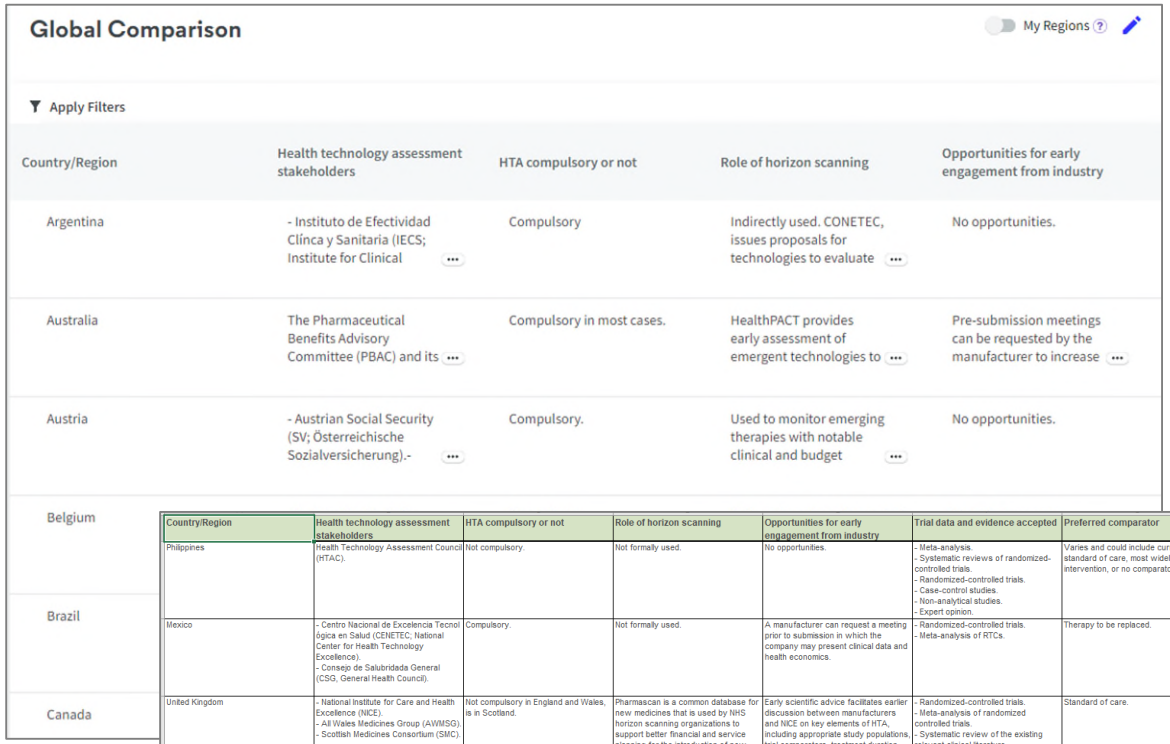
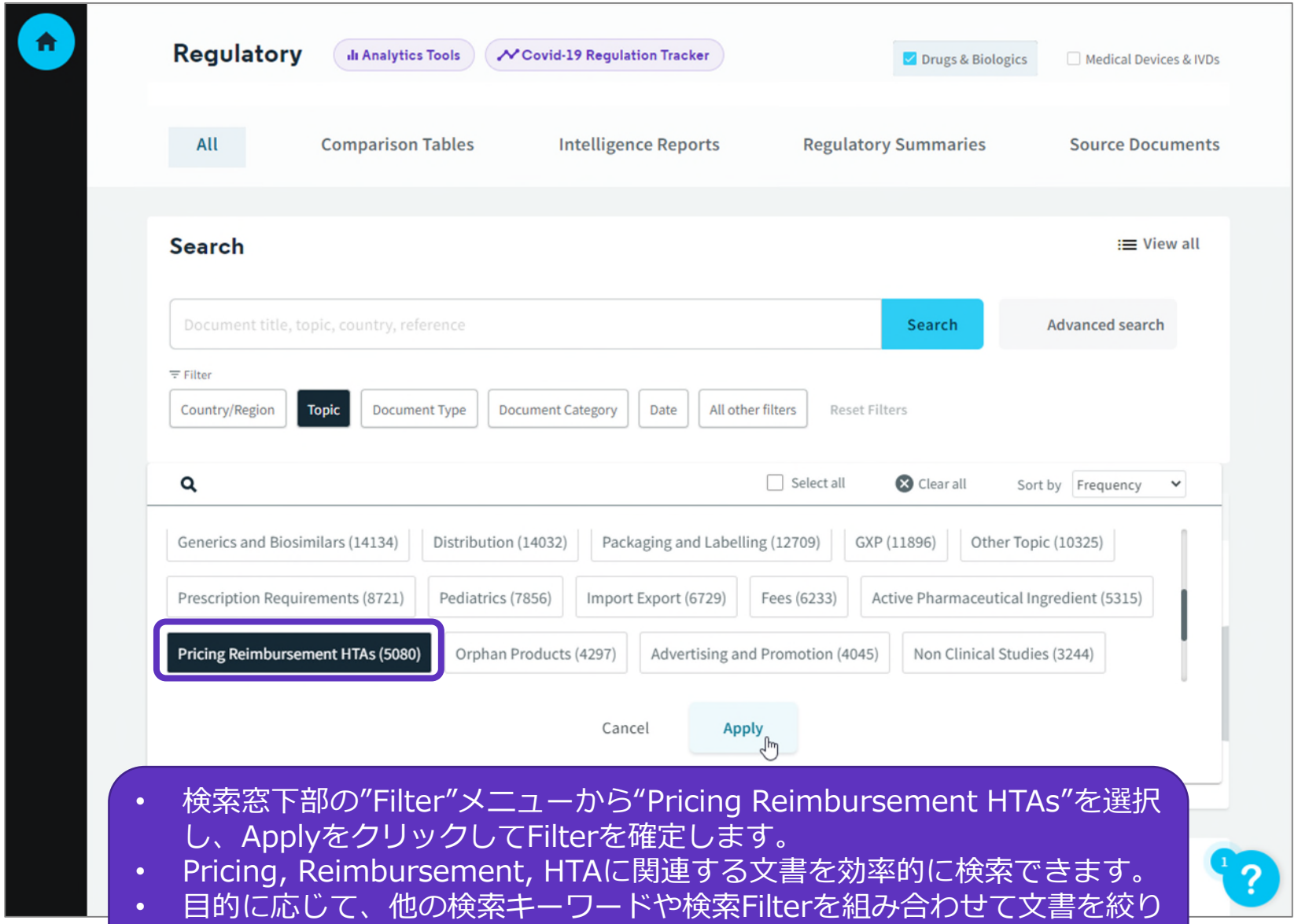


Country/Region	Health technology assessment stakeholders	HTA compulsory or not	Role of horizon scanning	Opportunities for early engagement from industry	Trial data and evidence accepted	Preferred comparator
Philippines	Health Technology Assessment Council (HTAC).	Not compulsory.	Not formally used.	No opportunities.	- Meta-analysis. - Systematic reviews of randomized-controlled trials. - Randomized-controlled trials. - Case-control studies. - Non-analytical studies. - Expert opinion.	Varies and could include current standard of care, most widely used intervention, or no comparator.
Mexico	- Centro Nacional de Excelencia Tecnol ógica en Salud (CENETEC; National Center for Health Technology Excellence). - Consejo de Salubridada General (CSG; General Health Council).	Compulsory.	Not formally used.	A manufacturer can request a meeting prior to submission in which the company may present clinical data and health economics.	- Randomized-controlled trials. - Meta-analysis of RTCs.	Therapy to be replaced.
United Kingdom	- National Institute for Care and Health Excellence (NICE). - All Wales Medicines Group (AWMSG). - Scottish Medicines Consortium (SMC).	Not compulsory in England and Wales, is in Scotland.	Pharmascan is a common database for new medicines that is used by NHS horizon scanning organizations to support better financial and service planning for the introduction of new medicines into the NHS.	Early scientific advice facilitates earlier discussion between manufacturers and NICE on key elements of HTA, including appropriate study populations, trial comparators, treatment duration, endpoints, and economic analysis.	- Randomized-controlled trials. - Meta-analysis of randomized controlled trials. - Systematic review of the existing relevant clinical literature. - Indirect methods; Non-randomized and non-controlled evidence.	Standard of care.
Canada	- Canadian Agency for Drugs and Technologies in Health (CADTH) (nationally). - Institut national d'excellence en santé et en services sociaux (INESSS; National Institute for Excellence in Health and Social Services) (Quebec).	Not compulsory but HTA highly facilitates the process.	CADTH uses horizon scanning to identify new health technologies likely to have an impact on the Canadian landscape.	The Scientific Advice Program is a consultative fee-for-service program provided by CADTH that allows pharmaceutical companies to receive guidance on early drug development plans to ensure that sufficient evidence is obtained for a complete health technology assessment.	- Preferred trials are pivotal, completed randomized clinical trials (this includes phase 2, 3, or 4 studies and any institution - or investigator-initiated RCTs). - Non-randomized studies. - Extension phase studies. - Ongoing RCTs, non-RCTs, and extension phase studies.	Routine care/therapy to be replaced.
South Korea	Health Insurance Review and Assessment (HIRA).	Compulsory	In development.	Pre-submission consulting meetings with HIRA to introduce their drug and discuss submission requirements, including choice of utility weights, and direction of analysis.	- Systematic review of randomized controlled trials - Randomized controlled trials - Quasi-randomized controlled trials - Cohort and case control studies - Case series - Expert opinion	Routine care/most commonly prescribed therapy.
Japan	- Chuikyo (Central Social Insurance Medical Council). - National Institute of Public Health Center for Outcomes Research and Economic Evaluation for Health (C2H).	Compulsory for selected therapies.	Not formally used.	Pre-analysis discussions with manufacturers undergoing CEA are intended to resolve any differences in the assumptions of the cost-effectiveness model before moving on to formal evaluation.	- Randomized-controlled trials - Unpublished clinical studies/trials if they are deemed appropriate	Therapy to be replaced.
Belgium	- National Institute for Sickness and Disability Insurance (INAMI/RIZIV). - Medicines Reimbursement Committee (CRM).	Compulsory	Both nationally and as part of BeNeLuxA.	Manufacturers can engage with the CRM earlier in the development process to ensure optimal trial design and optimal comparators, as well as to provide them with information such as details on efficacy and safety data from the pivotal studies, the number of patients expected to use their drug, and likely price discounts.	- Randomized-controlled trials. - Systematic review of the existing relevant clinical literature. - Indirect methods; Non-randomized and non-controlled evidence. - Qualitative research.	Therapy to be replaced.

検索索引の追加

- 収録文書に付与されるTopic索引に“Pricing Reimbursement HTAs”が追加され、検索効率の向上に寄与します
- 対象モジュール：Drugs & Biologics



- 検索窓下部の”Filter”メニューから“Pricing Reimbursement HTAs”を選択し、Applyをクリックしてを確定します。
- Pricing, Reimbursement, HTAに関連する文書を効率的に検索できます。
- 目的に応じて、他の検索キーワードや検索Filterを組み合わせて文書を絞り込んでください。