

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

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。

The screenshot displays the Cortellis Regulatory Intelligence web application interface. At the top, there are navigation tabs for 'Regulatory', 'Analytics Tools', and 'CMC Intelligence'. On the right, there are checkboxes for 'Drugs & Biologics' and 'Medical Devices & IVDs', both of which are checked. Below these are navigation links for 'All', 'Comparison Tables', 'Intelligence Reports', 'Regulatory Summaries', and 'Source Documents'. The main section is titled 'Quick Search' and includes a search input field with the placeholder text 'Quick search English keywords', a 'Search' button, and an 'Advanced search' button. Below the search field, there is a 'Filter' section with several filter buttons: 'Country/Region', 'Topic', 'Document Type', 'Document Category', 'Date', 'Translation Status', and 'All other filters'. A 'Reset Filters' button is also present. To the right of the search area, there is a blue and purple banner that says 'Try our NEW Regulatory Assistant'. Below the search and filter section, there is a search results area with a search icon, a 'Select all' checkbox, a 'Clear all' button, and a 'Sort by' dropdown menu set to 'Frequency'. The search results are displayed as a grid of topic buttons, each with a count in parentheses. The topics and their counts are: Generics and Biosimilars (17473), Distribution (17200), Packaging and Labelling (15434), Other Topic (9919), Prescription Requirements (9822), Pediatrics (9512), Import Export (9355), GXP (8675), Fees (7687), eHealth (6647), Active Pharmaceutical Ingredient (6598), Pricing Reimbursement HTAs (6369), Orphan Products (5055), Advertising and Promotion (4917), GMP (4623), Non Clinical Studies (4382), CMC (3226), Environment (2858), Device Classification (2669), and GCP (1858). At the bottom of the filter section, there are 'Cancel' and 'Apply' buttons.

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

The screenshot shows the 'Regulatory' search interface. At the top, there are navigation tabs for 'Analytics Tools' and 'Covid-19 Regulation Tracker', and checkboxes for 'Drugs & Biologics' (checked) and 'Medical Devices & IVDs'. Below this is a navigation bar with 'All', 'Comparison Tables', 'Intelligence Reports', 'Regulatory Summaries', and 'Source Documents'. The main search area has a search bar with the placeholder 'Document title, topic, country, reference' and a 'Search' button. Below the search bar is a 'Filter' menu with options: 'Country/Region', 'Topic', 'Document Type', 'Document Category', 'Date', and 'All other filters'. The 'Topic' filter is active, and a list of topics is displayed below, including 'Generics and Biosimilars (14134)', 'Distribution (14032)', 'Packaging and Labelling (12709)', 'GXP (11896)', 'Other Topic (10325)', 'Prescription Requirements (8721)', 'Pediatrics (7856)', 'Import Export (6729)', 'Fees (6233)', 'Active Pharmaceutical Ingredient (5315)', 'Pricing Reimbursement HTAs (5080)', 'Orphan Products (4297)', 'Advertising and Promotion (4045)', and 'Non Clinical Studies (3244)'. The 'Pricing Reimbursement HTAs (5080)' filter is highlighted with a red box. At the bottom of the filter menu are 'Cancel' and 'Apply' buttons, with a mouse cursor pointing to 'Apply'.

- 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Filter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を組み合わせることで文書を絞り込んでください。

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
- 対象モジュール：
Drugs & Biologics

Market Access Guidance

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

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
Continuously monitored and updated



**Pricing and Reimbursement Overview
(France)**

Reason for update	Date	Reason for update description
Content Update	2021-10-13	Updated to include HAS Guideline: Early Access to Medicinal Products: Support for Laboratories_07-Sep-2021 (IDRAC 334863) in Q3.1.1.
Content Update	2021-09-09	Updated to include HAS Guideline: Submission of applications to the Transparency Commission (in view of Inclusion of the Lists of Reimbursable Specialities provided by 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 word).
New	2021-07-09	

Q1 Healthcare System

Q1.1 Legal basis

France offers citizens universal coverage at the point of care through a statutory health system (Assurance Maladie, established in 1945), with the private sector providing complementary 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 Insurance: Economic Evaluation of Products Demanding ASMR or ASA of Levels I, II and III](#) (IDRAC 172520)
- [Decree 2012-1033: Relating to Procedure for Monitoring Sworn Agents of Local Health Insurance, 07-Sep-2012](#) (IDRAC 149811)
- [Decree 2015-179: Laying Down the Procedures Applicable to the Management of the Social Security Code, 16-Feb-2015](#) (IDRAC 208476)
- [Decree 2008-108: Implementation of the Article L. 5125-23-1 of the Public Health Code, 20-Feb-2008](#) (IDRAC 80129)
- [Decree no. 2020-1090 of 25-Aug-2020 on Various Measures regarding the Coverage of Medicinal Products](#) (IDRAC 317457)
- [Law 2020-1576: Social Security Financing for the Year 2021, 14-Dec-2020](#) (IDRAC 317457)
- [2015 Social Security Finance Bill \(Le Projet de Loi de Financement de la Sécurité Sociale\)](#) (IDRAC 206499)

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

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

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) is responsible for evaluating the therapeutic benefit of medicinal products for which are requested:

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	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

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へのアクセス方法

Regulatory

All Comparison Tables Intelligence Reports **Regulatory Summaries**

Browse Search

Filter by Country / Region

Drugs and Biologics Medical Devices and

Authorities and Organizations

- Competent Health Ministries and Regulatory Agencies | Country Summaries
- European Institutions and Bodies | Overview
- European Heads of Medicines Agency | Overview

Medical Devices Regulation

Algeria, Argentina, Australia, Colombia, Costa Rica, Croatia, Czech Republic, Denmark, European Union, Finland, France, Germany, Greece, Guatemala, Hong Kong, Hungary, Iraq, Ireland, Israel, Jordan, Kenya, Latvia, Lebanon, Lithuania, Malaysia, Morocco, New Zealand, Nigeria, Norway, Panama, Peru, Portugal, Romania, Serbia, Singapore, Slovakia, Slovenia, Tunisia, Ukraine, United Arab Emirates, United Kingdom, Venezuela, Vietnam

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

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

Market Access Guidance

- Pricing and Reimbursement Overview

Argentina, Australia, Austria, Belgium, **Brazil**, Canada, Chile, China, Colombia, France, Germany, India, Indonesia, Italy, Japan, Mexico, Netherlands, Philippines, Poland, Saudi Arabia, South Africa, South Korea, Spain, Sweden, Switzerland, Taiwan, Thailand, Turkey, USA, United Kingdom, Venezuela, Vietnam

Pricing and Reimbursement System and Policy Overview

Algeria, Bulgaria, Costa Rica, Croatia, Czech Republic, Denmark, Egypt, Estonia, European Union, Finland, Greece, Guatemala, Hong Kong, Hungary, Iraq, Ireland, Israel, Jordan, Kenya, Latvia, Lebanon, Lithuania, Malaysia, Morocco, New Zealand, Nigeria, Norway, Panama, Peru, Portugal, Romania, Serbia, Singapore, Slovakia, Slovenia, Tunisia, Ukraine, United Arab Emirates

国名をクリックして
該当レポートを開く

Regulatory Summary
Continuously monitored and updated

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Pricing and Reimbursement Overview (Brazil)

Reason for update	Date	Reason for update description
Content Update	2025-10-02	This revision introduced the content of the summary. This revision reorganized the content of the summary between [sections Qxxx and Qxxx/other RS to specify].
Content Update	2025-08-18	The regulatory summary has been updated to add the following reference documents with no impact to the content: <ul style="list-style-type: none">Resolution CMED 2 (IDRAC 411429): Establishes the Medicinal Products Market Follow-up System (Sistema de Acompanhamento do Mercado de Medicamentos-SAMMED), 23-Feb-2015 (Official Consolidated Version Up to Amendments Brought by Resolution CM-CMED 2/2025 of 03-Jun-2025) in section Q3.1;Resolution CMED 3 (IDRAC 411430): Approves the Criteria for Price Definition of Medicinal Products Regulated by ANVISA and Subject to CMED's Price Control, 23-Feb-2015 (Official