



GHMC

**THE GLOBAL GUIDE TO
MARKET ACCESS**



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GHMC is the largest and most robust network of independent healthcare agencies worldwide, dedicated to improving outcomes through the delivery of dynamic, health-lingual experiences that drive meaningful global change. With more than 700 health-specialist communications professionals spanning more than a dozen disciplines, from patient engagement to clinical trial recruitment to advertising, the agencies that make up the partnership share a belief in insights-driven strategies and a commitment to collaboration. Today, GHMC has capabilities and reach into more than 60 countries.

THE GLOBAL GUIDE TO MARKET ACCESS

LEGAL DISCLAIMER

This guide is designed to provide information on country-specific processes and regulations regarding the registration, listing and reimbursement of medicines globally. Every effort has been made to ensure that the information contained within is accurate and up-to-date, and that guidance offered is in line with existing regulations.

This document should in no way be seen as a substitute for the relevant regulations or statutes that govern the behaviour of those involved in the negotiation, approval, or promotion of medicines. GHMC cannot accept responsibility for any outcomes that may result from following the advice or guidance in this document.

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FOREWORD

In recent decades, scientific discoveries and advancements in technology have paved the way for greater understanding of human health, and disease, giving the biopharmaceutical industry the foundation to develop groundbreaking new therapies. The benefits the industry provides have never been more tangible than the past year. While the world has grappled with the most urgent public health crisis of our time, the biopharmaceutical industry has emerged as a hero, rapidly developing and deploying diagnostics, treatments and vaccines for COVID-19.

This pandemic has created a highly visible demonstration of the value derived from tremendous investment into research and development. But day-in-and-day-out, industry leaders working across a diverse set of therapeutic categories - from rare diseases to cardiometabolic disorders, oncology to Alzheimer's disease - are working equally as hard to bring forth life-changing therapies. In doing so, they must routinely engage and educate diverse stakeholders to ensure their advancements are recognized and reimbursed, so that patients in need can benefit.

Frequently, the cost of a drug - real or perceived - garners public attention, masking the more critical consideration: recognition - by all decision makers - of the value a treatment brings to healthcare systems and those who need it. To create the proper context for these value-based conversations, companies must engage credibly and responsibly with government health authorities, health technology assessment boards, insurers, shareholders, prescribers and, most importantly, patients.

In global healthcare communications and marketing a successful product must be positioned within the appropriate medical, cultural and value context across the many markets in which it is introduced. Creating the right framework for a value story that translates across borders begins with understanding the dynamics in key countries to help inform development, stakeholder engagement and communications plans that ensure launch strategies run smoothly.

Developed by GHMC experts and partners around the world, The Global Guide to Market Access helps industry leaders understand the key stakeholders, processes and discrepancies in health value definitions within the pricing and reimbursement landscape across priority global markets. Updated for 2021, this new edition provides a window into the biopharmaceutical reimbursement environment in 26 countries, including the addition of four new guides: Chile, Hong Kong, Romania, and South Africa.

We believe that by integrating value-focused strategic communications and marketing further upstream, there is an opportunity to impact audiences in more credible and meaningful ways than ever before.

We hope this invaluable resource will serve as a foundation for formulary success as our partners in the industry bring medicines to market with the potential to vastly improve the health of people worldwide.



Tim Goddard
President, Global Health Marketing & Communications (GHMC)



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AT-A-GLANCE

Despite slowing growth in the sector due to economic problems and the COVID-19 pandemic, Argentina's pharmaceutical market still ranks third in Latin America in terms of overall size, thus presenting an attractive opportunity for global industry players. However, multinational manufacturers face strong competition from robust Argentine competitors, which hold over 50 percent of the market share.

In Argentina, healthcare and medicines are delivered through a fragmented combination of systems that include the public sector, the private sector, and workers' unions, all overseen by the Ministry of Health (MINSAL). Despite the government's guarantee of universal coverage, there is no single governmental payer or roadmap to deliver medicines and health services. Considering the array of different parties with which to negotiate reimbursement, learning to "tango" with the Argentinian healthcare system can appear to be an overwhelming challenge.

ARGENTINA'S PAYER STAKEHOLDERS

There are three main payers that make up the system. The Ministry of Health's Superintendent of Health Insurance (SSS) is responsible for overseeing national social and healthcare services and private health coverage.

- 1. El Estado** - The Argentine government (el Estado) covers approximately 36 percent of the population who otherwise would not possess health coverage. Services include vaccines, primary care, medicines, clinical studies, hospitalization, surgery, and other procedures. Coverage for both acute and chronic conditions ranges from 25 percent to 40 percent.
 - a. Certain programs within the government-run system, including "Remediar" (Remedy), cover 100 percent of medicines, as do funds that focus on specific pathologies.
- 2. Obras Sociales (OS)** - This union-backed health insurance for workers is co-financed by employers and employees. 64 percent of the Argentinean population is covered under OS plans, national, provincial-level coverage, and PAMI (National Institute of Social Services for Retirees and Pensioners), the largest health insurer for elderly people of Latin America.
 - a. Depending on the specific case, medicines are reimbursed under the OS programs at either 40, 70 or 100 percent, depending on the specific case and medical need.
- 3. Prepago** - Private payers, including individuals and companies, which comprise 13 percent of the population via different health plans offered by insurers. The top five private plans cover approximately 60 percent of this "pre-paid" (or prepago) market segment.
 - a. 56 percent of total private spending goes into prepayment (typically monthly).

The Programa Médico Obligatorio (PMO, or Compulsory Medical Program) establishes the basic health services that Obras Sociales and Prepago sectors must guarantee under law.

The remainder is paid at point-of-service via co-insurance. Recent economic problems in Argentina have led to citizens favoring plans with low premiums and prepay, but much higher out-of-pocket expenditures should they get sick. This has further exasperated existing public health concerns in the country as patients try and avoid treatment to avoid high co-pays for public insurance and potentially high out of pocket expenditures for private insurance.

IMPORTANT POINTS TO KEEP IN MIND

Under the Ministry of Health, the National Administration for Medication, Disease and Medical Technology (ANMAT) is the national regulatory agency that approves new medicines. In addition, local jurisdictions can dictate their own specific requirements for approval alongside the national regulations.

ANMAT REVIEW PROCESS

While the synthetic drug evaluation process can take on average 80-180 days, the biologic drug registration process can last up to 210 business days. In the case of specialty medicines or when a drug is imported from a country with high safety standards, an abbreviated registration process can be used. After a product is approved, the company must seek reimbursement with the fragmented health systems independently. ANMAT provides health technology assessment (HTA) documentation to guide agencies' decision-making on certain drugs and devices from a cost-effectiveness perspective, but these documents are not mandatory

REIMBURSEMENT/FUNDING PROCESSES (30-60 BUSINESS DAYS*)

Reimbursement processes vary according to the payer and can take between 60-120 business days to process.*

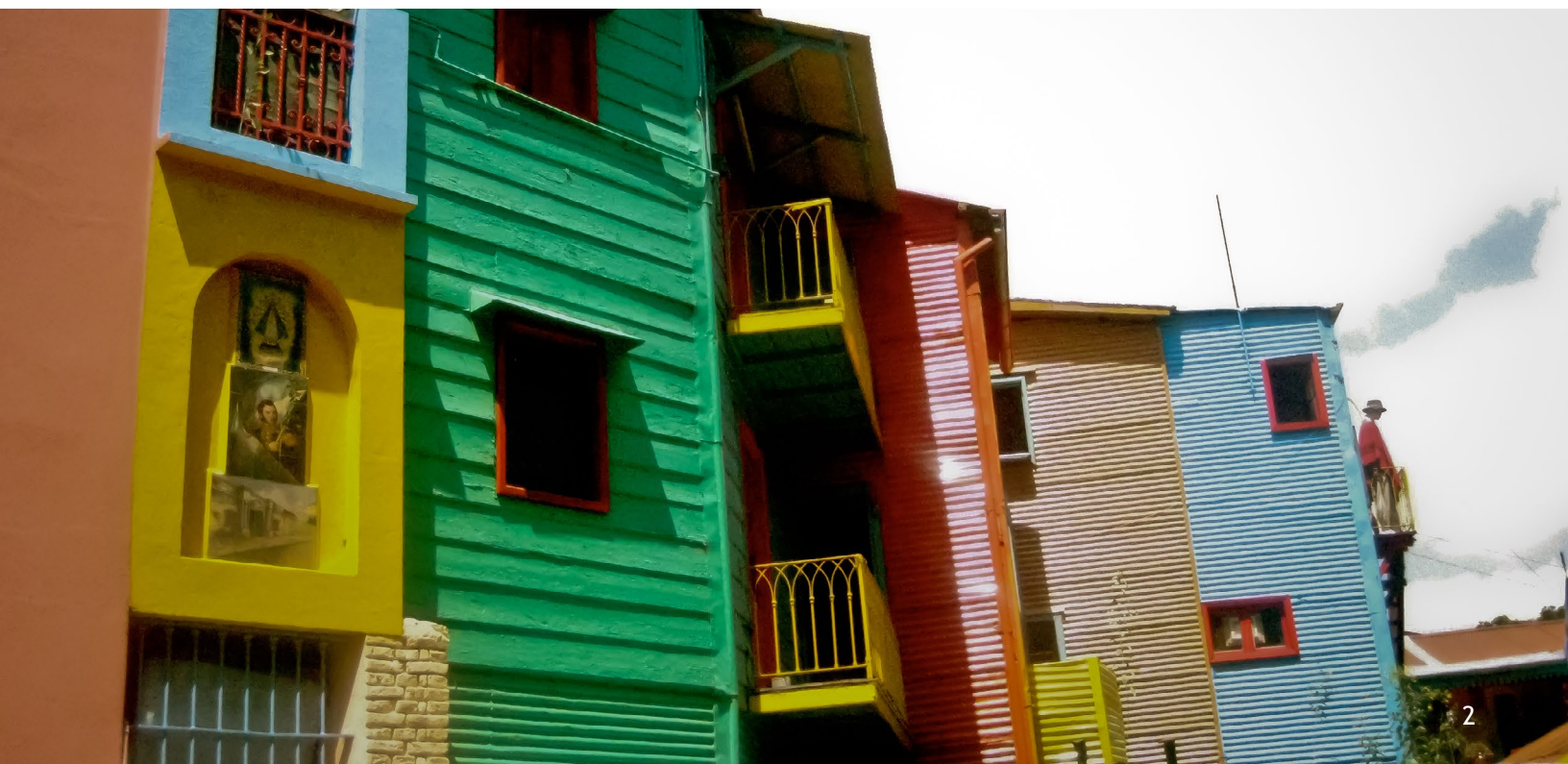
**Reimbursement timelines: 120 business days for public funding decision, 45-60 days for OS insurance, and 30-45 days for private insurance funding decision.*

IMPLICATIONS FOR INDUSTRY

The fragmented schemes that make up the Argentine health system often result in payers denying the appropriate or desired level of reimbursement for certain prescription drugs. In this case, the appeals process can include court action, in a manner like Argentina's neighbor, Brazil. In addition, Argentinean law provides limited patent protection, and requires that drugs be marketed under generic names based on the principal ingredient, making it difficult to introduce branded innovative products into the market.

Due to the recent economic environment and inefficient administration, the Argentinean government has delayed making payments owed to manufacturers. This causes industry to raise drug prices, which impacts the payers who are unable to afford innovation. As a result, legislation has been drafted in Parliament to establish a new HTA agency. In 2018, CONETEC (National Commission for the Evaluation of Health Technologies) was created to carry out evaluations and issue recommendations to the health authority on the incorporation, form of use, financing and coverage policies of health technologies. While CONETEC falls under the Ministry of Health, it is comprised of a diverse range of government and institutional stakeholders, as well as patient associations. The reports and recommendations of this commission are available to the public. CONETEC can intervene as a consulting body in any instance where issues related to these issues are discussed, including judicial processes.

Argentina's varied and diverse pathways to market access and reimbursement are too challenging to tackle with just one strategy, and thus your value communication story and strategy must be designed to reach multiple stakeholders.



AT-A-GLANCE

The Australian pharmaceutical industry comprises domestic and international enterprises. Foreign-owned multinationals dominate overall, and while Australia is a relatively small market in terms of population, it ranks among the top markets worldwide, and is set to surpass AUD 25 billion by the end of 2020.

Australia's national public health program, Medicare, covers a high percentage of the cost of a variety of pharmaceuticals and medical services, as well as the costs of public hospital care nationwide. All services subsidised by the Australian Government under Medicare are listed on the Medicare Benefits Schedule (MBS). The Australian Federal Government also subsidises private health cover through an income-tested rebate system. Private health insurance provides extended coverage for private hospitals, broader medical services and pharmaceuticals beyond the costs covered by Medicare.



AUSTRALIA'S PAYER STAKEHOLDERS

Australia's regulatory medical body, the Therapeutic Goods Administration (TGA), is responsible for the registration of therapeutic goods (such as medicines, medical devices or biologics) in Australia, which are listed on the Australian Register of Therapeutic Goods (ARTG). The Special Access Scheme (SAS) allows certain health practitioners to access therapeutic goods that are not included in the ARTG for a single patient. Therapeutic goods that are not included in the ARTG (and are not otherwise exempt from being in the ARTG) are categorised as 'unapproved'. TGA-approved pharmaceuticals may be government subsidised under the Australian Pharmaceutical Benefits Scheme (PBS) or the National Immunisation Program (NIP).

Recommendations for PBS reimbursement of ARTG products are provided by the Pharmaceutical Benefits Advisory Committee (PBAC), an independent statutory body that reports to the Federal Department of Health. The PBAC accepts established product safety and efficacy as a condition of ARTG registration.

The PBAC typically meets three times a year, when new product submissions, together with new product indications and changes to indications, are reviewed for recommendation, pricing, category placement and repeat access. Medications will fall into one of three categories:

1. Unrestricted
2. Restricted for specific therapeutic uses
3. Authority (medical practitioner approval for use required)

The PBAC also reviews the recommendation of expensive and life-saving medications supply for life-threatening and rare diseases under the Life Saving Drugs Programme (LSDP). Medications that require restricted supply through public and private hospitals include the PBS Section 100: Highly Specialised Drugs Program, or the PBS Section 100: Efficient Funding of Chemotherapy. Other notable influencers include Medicines Australia (MA), which impacts pharmaceutical industry reputation, and regulates the advertising and promotion of prescription products, and NPS MedicineWise, which is responsible for prescribing behaviour in Australia. In particular, the NPS MedicineWise RADAR program regularly publishes online updates offering health professionals timely, independent, evidence-based information on new listings and changes to listings on the PBS.

IMPORTANT POINTS TO KEEP IN MIND

The pricing and reimbursement process for medicines in Australia is often long and complex. It is based on clinical benefit, comparison to medicines in the same therapeutic class, cost-effectiveness, and budgetary implications. Clinical and economic evaluations are initially reviewed by the PBAC's Evaluation Section and Economic Sub-Committee (ESC).

SUBMISSIONS FALL INTO THREE BROAD CATEGORIES FOR BOTH PBS AND NIP FUNDING:

1. **Major submissions** (new listings, new indications, orphan medicines, significant changes to existing listings) - evaluated by the PBAC's Pharmaceutical Evaluation Section and presented to the ESC prior to PBAC evaluation.
2. **Minor submissions** (changes to existing listings that do not change the population or cost-effectiveness, or the listing of a new form or strength of an already-listed medicine that has a bioequivalence or equivalence statement from the TGA) - evaluated directly by the PBAC.
3. **Committee secretariat submissions** - listing changes that do not require comparison of effectiveness, cost-effectiveness or clinical need; there is no difference in patient safety or population for the new item compared to an already-listed item; and there is no financial effect associated with the proposed change to the PBS.
4. **Generic equivalent submissions** - lodged directly with the Department of Health when there is no requirement for consideration by the PBAC as a minor submission.

Companies must provide major submissions 17 weeks prior to a PBAC meeting, and 11 weeks prior for minor submissions. Sponsors are emailed advice of outcomes within one week and receive ratified PBAC minutes for positive recommendations within three weeks post-PBAC meeting. Public summary documents (PSDs) inform the public of PBAC decisions and the basis for each PBAC outcome. PSDs are generally published 16-18 weeks post-PBAC meeting. In the instance where the PBAC must enter into treatment cost negotiations with the manufacturer, such as for PBS Section 100 listings, PBS listings may be delayed or postponed.

In general, new PBS listings are available on the first day of each calendar month prior to a subsequent PBAC meeting, and products may receive listing as early as the calendar month immediately post-PBAC review. The Medicine Status Website (MSW), launched in early 2020, centralises key information on how to list a medicine on the PBS, enables users to track a medicine's progress through the PBS listing process, and provides advice on how consumers can contribute to PBAC decision making.

IMPLICATIONS FOR INDUSTRY

The PBS currently covers up to 80 per cent of prescriptions dispensed in community pharmacies. However, consumers do carry an out-of-pocket cost or co-pay for their medications. The PBS co-payment scheme is adjusted each year in January in line with the Consumer Price Index (CPI).

SUSTAINING THE PHARMACEUTICAL BENEFITS SCHEME

In May 2017, The Australian Government signed a five-year Strategic Agreement with Medicines Australia that included significant PBS process reform and new measures to accelerate patient access to innovative medicines. The agreement aims to ensure the sustainability of the PBS, while maintaining prescriber choice and offering certainty for the Australian pharmaceutical industry through a stable PBS policy environment.

Within a therapeutic group, the PBS subsidises medicines up to the cost of the lowest-priced drug in the group. Those extra costs for medicines carrying a therapeutic group premium are at the expense of the consumer, and do not contribute to the consumer's PBS safety net threshold. Under Therapeutic Group Premium Policy, drug substitution by pharmacists is not permitted (note, under Brand Premium Policy in relation to generics, drug substitution is permitted with consumer consent). As a result, cost-effectiveness plays an important role, not only in determining whether a treatment is PBS listed, but how a brand fits within a tightly regulated pricing scheme. safety net threshold. Under Therapeutic Group Premium Policy, drug substitution by pharmacists is not permitted (note, under Brand Premium Policy as it relates to generics, drug substitution is permitted with consumer consent). As a result, cost-effectiveness plays an important role, not only in determining whether or not a treatment is PBS listed, but how a brand fits within a tightly regulated pricing scheme.

BRAND VALUE BEYOND SAFETY AND EFFICACY

To build and sustain brand value, manufacturers must be willing to reach agreements with Government, invest in life-cycle value management initiatives, and build relationships and advocacy networks with physicians and prescribers. Offering key players best available data, maintaining ongoing brand awareness, reinforcing brand value proposition, and understanding the nuances of the Australian reimbursement environment, can help a brand team sustain volume and value throughout the brand lifecycle. GHMC can help you map out and implement your strategy for engaging and communicating with these key stakeholders at all levels in Australia.

AT-A-GLANCE

Vast regional differences, discrepancies in pricing and reimbursement processes, and contentious right-to-treatment scenarios are just a few of the unique elements that make up the market access and reimbursement landscape in Brazil.

Given Brazil's economic growth over the past twenty years leading to the ascent of the middle class—paired with an aging population—the demand for private hospital provision has risen, but private health insurers struggle to grow their market. In addition, a record number of new competitors have recently entered the Brazilian market. If you are not prepared for success in Brazil, all these factors combine to make a cocktail of market access confusion as potent as a caipirinha on Copacabana Beach.

BRAZIL'S PAYER STAKEHOLDERS

The Brazilian government, through the National Health System (SUS), is the largest purchaser of medicines in Brazil. The government provides health insurance coverage to all the nation's citizens as guaranteed in the country's 1988 Constitution. However, there is great disparity in quality and access to care. Currently, approximately 149 million Brazilians (71.5 percent of the population) rely on the government as their primary health provider. Due to the COVID-19 outbreak, public health officials believe the percentage of citizens who depend on public healthcare services will increase considerably across the next few years.

Private health insurance is gaining momentum and now covers approximately 46 million Brazilians (28.5 percent of the population). Employers comprise the second-largest payer group. However, in some cases citizens invest on their own, thus meaning that the individual payer concept also exists in Brazil.

NATIONAL HEALTH SURVEILLANCE AGENCY - APPROVALS AND PRICING

The National Health Surveillance Agency (ANVISA) oversees drug approvals. The agency is also responsible for establishing regulations applicable to clinical trials and drug pricing, which is carried out by the *Câmara de Regulação do Mercado de Medicamentos* (CMED). CMED is the key launch price decision maker and controls the increase in the maximum approved retail price of established drugs. Increases are sanctioned on an annual basis based upon multiple factors:

- Inflation
- Exchange rate movements
- Degree of generic penetration within relevant drug classes
- A contentious “productivity coefficient” that is applied uniformly across the industry, which has attracted widespread complaints from manufacturers

New drugs can be sold to the private sector upon marketing authorization by ANVISA and receiving CMED approval for a maximum retail price. However, products that seek state-funded reimbursement must overcome additional hurdles:

- *The Comissão Nacional de Incorporação de Tecnologias* (CONITEC) conducts a rigorous pharmaco-economic analysis of the new drug
- Final decision on funding by the Ministry of Health (MOH)

While MOH decisions take CONITEC evaluations into account, political and financial factors can mean a positive CONITEC recommendation does not always lead to a reimbursement listing. The government faces a growing number of legal challenges filed by patients seeking treatment with drugs that have been refused listing on subsidized outpatient formularies.

BENEFIT SCHEMES DESIGNED TO PROTECT PATIENTS

Inpatient drugs are reimbursed in full, but patients must typically pay out of pocket for most drugs prescribed to them on an outpatient basis. Several outpatient benefit schemes designed to protect the patients from catastrophic medical expenses, which drive public sector drug spending. The significant schemes include:

- The national AIDS program, under which some 150,000 patients receive free antiretroviral treatment
- The *Programa de Medicamentos de Alto Custo ou Excepcionais* (PMACE) - program under which the government funds the provision of expensive drugs for the treatment of serious diseases
- The *Farmácias Populares* initiative, under which patients can access a limited range of heavily subsidized drugs, including asthma, rhinitis, glaucoma, osteoporosis, Parkinson's disease, anti-hypertensive and diabetes drugs, and simvastatin from state-owned pharmacies and registered private retail outlets

CONITEC uses a cost-effectiveness model for inclusion on Federal reimbursement list. However, the more complex the medicine, the less this model is used. This has created a movement within the Pharmaceutical Industry Research Association (Interfarma) to lobby the government to use simpler models for value assessment that also include patient value.

IMPORTANT POINTS TO KEEP IN MIND

PRIVATE PLAN NUANCES AND LITIGATION

About 46 million Brazilian patients have private health insurance. Private health plans cover hospital-administered prescription medicines only. As a result, one in three beneficiaries of health plans in São Paulo resort to the National Health System (SUS) or to private healthcare professionals due to delays, problems or denial of care through the accredited network. Lawsuits are a common route for patient access in Brazil. Many new and expensive drugs, including those for rare and chronic diseases, are not included in the SUS list. However, the government is obligated to purchase these medicines when the patient wins the right to treatment in court. In most cases, the Brazilian courts rule in favor of the patient, which has created a veritable litigation industry. Despite being a problem for the government, medicines purchased by court order have become an important source of revenue for industry. The government has recently tried to decrease the number of court cases by creating a law that exempts from court rulings those drugs not yet approved by ANVISA.

UPDATED RARE DISEASE RESEARCH REGULATIONS AND TECHNOLOGY TRANSFER

In 2018, ANVISA established a process for the approval of rare disease clinical trials, reducing the total evaluation time of up to 6 months to an estimated 3 months. This resolution enables access to therapeutic options for the treatment of rare diseases in Brazil, making it an attractive place for rare disease clinical trials to take place. The government is more willing to include products on its purchasing list when it reaches a technology transfer agreement with the pharmaceutical company. A medicine will be included on government formularies and after 10 or 15 years, the government assumes ownership of the technology and production of the product.

IMPLICATIONS FOR INDUSTRY

With price controls in place in Brazil, new drug launches are now the sole driver of real growth. However, the use of the international referencing mechanism limits initial launch price levels. Growing volume and/or capturing market share from competitors have emerged as dominant sources for companies to increase their market value. Understanding the rapidly changing economic, regulatory and judicial landscape is critical to market access success in Brazil. The patient-first approach of seeking court action for access has been successful, but also requires deep knowledge of key actors and influencers at the federal and state levels.

Physicians are not pressured to limit prescribing to certain subgroups of patients in Brazil. Consequently, advocacy groups play an enormously important role in patient access to medicines. GHMC has worked with advocacy groups in all major therapeutic areas in Brazil and can help you connect your brand with the right patients. Most recently, while the Federal Government has already negotiated a supply and licensing deal with AstraZeneca for hundreds of millions of doses of the University of Oxford's COVID-19 vaccine, other states in Brazil have already signed agreements with China and Russia to produce their own coronavirus vaccines through technology transfer contracts. These large investments in COVID-19 vaccines (as well as potential therapeutics) may at some point impact the future reimbursement of other medicines.

Finally, competition, particularly in the biotech sector, is fierce in Brazil. Several new entrants (both startup and international) arrive in Brazil each year. This, combined with a wide-open generics market (with biosimilars imminent), makes it increasingly difficult for companies to stand out. GHMC has years of experience in developing strategies and campaigns to maximize your chances of value recognition and patient access in Brazil.

AT-A-GLANCE

Canada's publicly funded healthcare system is often considered to be a source of national pride. While Canadians benefit from near-universal coverage of physician and hospital services, they are often left to pay out-of-pocket or rely on private insurance for prescription drugs dispensed outside of the hospital setting. Because regulations are divided between federal, provincial, and territorial levels, disparities between public drug plans and unequal access to marketed products are major criticisms of this framework.

In addition to the tremendous repercussions for Canadians in terms of access and affordability, drug manufacturers are also faced with the significant challenge of navigating the complex and fragmented approval processes of multiple independent bodies for the pricing and reimbursement of pharmaceuticals. However, manufacturers equipped to manage this complex environment will find a competitive and attractive business landscape.

Like other healthcare systems, the COVID-19 pandemic has exerted tremendous pressure on already limited resources and exposing horrendous conditions in public and private institutions. This is expected to result in further cost-cutting efforts.

CANADA'S PAYER STAKEHOLDERS

- The Patented Medicines Prices Review Board (PMPRB) is the body responsible for regulating prices of all patented prescription and non-prescription drugs sold in Canada.
- The Canadian Agency for Drugs and Technologies in Health (CADTH) is an independent agency funded by federal, provincial and territorial governments. CADTH is a health technology assessment (HTA) agency that houses services including the Common Drug Review (CDR) and the Pan-Canadian Oncology Drug Review (PCODR).
- CDR provides evidence-based clinical and economic information and expert advice to participating public drug plans (federal, territorial and all provinces except Quebec). While Ontario participates in CDR, certain products may also qualify for their own independent Rapid Review Process. With over 60 per cent of the Canadian population living in Quebec and Ontario these provinces are incredibly important.
 - Conseil du médicament is Quebec's influential HTA body. It recommends drugs to be listed on the Quebec provincial formulary. Final decisions are made by Quebec's Minister of Health. The formulary is published three times per year.
 - The Ontario Ministry of Health's Rapid Review Process applies when a new product will fill a significant unmet medical need, or the listing will result in significant savings for the province. A unique aspect of the Ontario Rapid Review Process is that submissions can be made before the receipt of Health Canada Notice of Compliance (NOC) authorising the drug for sale within Canada.

IMPORTANT POINTS TO KEEP IN MIND

Health Canada is the federal health department responsible for approving new drugs. Health Canada releases a formal marketing and distribution authorisation called Notice of Compliance (NOC) following the satisfactory review of a new product submission.

Pricing and reimbursement are two separate considerations.

PRICING

Pricing approval for patented medicines is regulated by the federal government through the PMPRB. While manufacturers are free to set the prices for their products in theory, the prices of patented medicines are monitored by the PMPRB to ensure that prices are not “excessive.” The PMPRB assesses drug prices in accordance with the level of therapeutic innovation:

- Breakthrough - first to treat a particular illness effectively or address a particular indication effectively
- Substantial Improvement
- Moderate improvement
- Slight/no improvement and line extensions

The prices of “breakthrough” drugs are pegged to the median ex-factory price for the same drug in reference countries. Pricing of other new patented drugs is managed via therapeutic price referencing. Prices are limited so that the cost of the therapy is in the same range as other patented drugs already on sale in Canada. Prices can never exceed the highest referenced price or increase by more than the consumer price index (CPI).

REIMBURSEMENT

Reimbursement prices are not set by the PMPRB nor does it enter pricing arrangements with manufacturers. The reimbursement process is governed by a combination of federal, provincial, and private drug plans. The result is that reimbursement criteria and prices can vary considerably between plans.

Manufacturers should evaluate the potential of accelerated market access via the Ontario Rapid Review Process. A positive decision can shortlist a drug on the formulary and serve as a positive reference to build momentum for the rest of Canada.

Private payers may cover all Health Canada approved drugs, establish their own formularies, or follow the public drug plan in their provinces. In Quebec, private insurers are required to cover at least all drugs listed in the provincial formulary. Many private drug plans ask for submission dossiers and specific requirements vary by plan.

Hospitals maintain their own formularies through Pharmaceuticals and Therapeutics Committees. Dossiers must be submitted to individual hospitals or hospital consortia.

Product listing agreements (PLA) tailored for unique product characteristics and payer concerns can help accelerate market access. These may be an option for overcoming negative CDR recommendations.

IMPLICATIONS FOR INDUSTRY

In December 2017, the federal government proposed amendments to the regulations governing the PMPRB. The amendments that were due to come into effect in July 2020, include three significant changes. The first is on the roster of countries whose drug prices are compared with the proposed Canadian price in the PMPRB’s international comparison. Six lower-price countries are replacing two with higher prices. The effect of the switch will be to reduce the maximum prices for new medicines in Canada to around the median of prices charged in over 30 OECD countries.

The second change is that the PMPRB will be required to assess the “value” of each new drug using cost-effectiveness analyses already reviewed by the Canadian Agency for Drugs and Technologies in Health (CADTH) when it makes its reimbursement recommendations to Canada’s public drug insurance plans (except those in Quebec). CADTH does not set prices but frequently recommends big reductions – 50 to 80 per cent, sometimes over 95 per cent – to achieve cost-effectiveness.

The third major change is a requirement for pharmaceutical manufacturers to divulge information to the PMPRB on confidential rebates and other commercial terms negotiated with Canadian insurance plans.

Additionally, market price restrictions are expected to also impact new drug launches. There is concern that pharmaceutical companies will not seek regulatory approval for their medicines because they view Canada’s market conditions unfavourably. This is already happening in Canada – about 20 per cent of new therapeutic drugs approved in the United States do not come to Canada. Innovative Medicines Canada, the industry association representing Canada’s research-based pharmaceutical companies, has publicly stated that numerous pharmaceutical companies have already decided not to market certain new drugs in Canada. This move will surely impact the health of many Canadians.

GHMC Canada office has more than 30 years of local experience and can help you navigate this challenging environment to reach key healthcare stakeholders and patients via innovative communications and marketing strategies.

AT-A-GLANCE

The Chilean healthcare system is primarily structured by mandatory medical coverage. The law provides for a minimum set of medical benefits and the additional features depend on the health institution and health plan (either public or private) chosen by each citizen. As the population of individuals over the age of 65 continues to increase in Chile, healthcare delivery is becoming more essential, with nearly 60 percent of citizens relying on at least one medicine daily.

The Ministry of Health is the main health authority in Chile, while the Public Health Institute (ISP) is the regulatory authority responsible for enforcing the regulatory framework for pharmaceutical products. Currently, the prices of drugs and devices are not regulated in Chile.

CHILE'S PAYER STAKEHOLDERS

In Chile, there are three types of payers that are financed with workers' contributions (7 percent of taxable salary):

- **Fondo Nacional de Salud (FONASA):** Part of the Ministry of Health, FONASA is a public health insurance which is responsible for funding and insurance for their beneficiaries. The system is stratified into four levels depending on how much an individual earns. FONASA provides coverage to approximately 81 percent of the population in Chile.
- **Instituciones de Salud Previsional (ISAPRE):** Privately run health insurance providers that tend to attract those who are wealthier, younger, and healthier. ISAPREs charge risk-rated premiums and may reject applicants with pre-existing medical conditions. ISAPREs provide health coverage to an estimated 16 percent of the population.
- **Health insurance plans provided by the armed forces:** This system provides medical coverage to 2.4 percent of the population in Chile and accounts for active and retired personnel of the armed forces (army, navy and air force), uniformed police and gendarmerie (prison service). These plans are financed through direct contributions from the State and contributions from civil servants in a pay-as-you-go system in which the state is responsible for costs not covered by contributions.

In addition to the coverage provided by FONASA and the ISAPREs, there are duly registered insurance companies that can provide supplemental healthcare coverage. These are voluntary and can cover medical expenses, oncology, rare disease treatment, dental, hospitalization, etc. Of note, there are usually enrollment restrictions based on age and pre-existing medical conditions.

IMPORTANT POINTS TO KEEP IN MIND

Under the Ministry of Health, the National Administration for Medication, Disease and Medical Technology (ANMAT) is the national regulatory agency that approves new medicines. In addition, local jurisdictions can dictate their own specific requirements for approval alongside the national regulations.

Chile has developed two coverage systems for high-cost medicines and serious, catastrophic illnesses:

- **AUGE, or the Explicit Guarantees System (GES):** A universal health plan which grants beneficiaries access to different health interventions, financial coverage, and quality of care for 80 health problems which have been established by law. All Chilean citizens, whether they seek care through FONASA or ISAPRE, are guaranteed coverage for any of these health conditions. Examples include chronic kidney disease, pediatric cancer, Parkinson's disease, Hepatitis C, HIV/AIDS, Schizophrenia, and traumatic brain injury.
- **Ricarte Soto Law:** According to the Ministry of Health (2015), this bill seeks to “ensure the financing of diagnoses and treatments based on medicines, medical devices and high-cost foods with proven effectiveness, which often have unattainable costs for people and their families.” To qualify for these benefits, an individual's pathology must be covered by the law and the individual must be a contributor to either FONASA, ISAPRES, or the Armed Forces.

IMPLICATIONS FOR INDUSTRY

Although Chile has expanded drug and treatment coverage to all citizens, the system favors those who can pay for higher quality care and, more importantly, to pay for preventative care that can prevent expensive procedures in the future. The State's current efforts have focused both on controlling the market and enacting new laws that promote better cost management.

- **Cenabast Law:** In January 2020, Chile's President enacted this law to slash the price of pharmaceutical drugs by up to 80 percent. The National Health System's Supply Central (Cenabast) acts as an intermediary in purchasing medicine to supply the country's pharmacies. The Cenabast has the power to set price caps and establish an advisory council to recommend the maximum price of a drug, with the aim of making medicines more affordable and reducing out-of-pocket costs.
- **Drugs II Bill:** The Chilean Senate is currently discussing this bill, which includes initiatives that aim to lower drug prices, increase access to medicines, update regulations on bioequivalent medications, and promote competition in the industry.
 - Doctors would be required to write prescriptions under the “International Common Denomination (ICD)” of the compound.
 - Pharmacies would be required to notify customers about the generic versions of the medicines prescribed to them by their physicians.
 - The customer would only be obligated to purchase the amount of medicine he/she needs, not the pre-determined amount in the bottle or container.
 - Patients would be allowed to directly import medicines for their personal use.
 - An international database where patients can compare drug prices.
 - Opening online pharmacies.

Chile is often seen as a beacon within Latin America for communications and the market has seen heavy investments into healthcare by multinational pharmaceutical companies. The GHMC team has years of experience in Chile and can offer valuable insights and regional expertise to your marketing, public affairs and market access teams.



AT-A-GLANCE

With a population of 1.4 billion, China accounts for 18 percent of the world's population and 18 percent of the global pharmaceutical market, valued at \$137 billion. Annual drug expenditures are increasing rapidly. Although these numbers and opportunities are eye-catching, international manufacturers face significant challenges to gain favorable pricing, reimbursement, and market uptake in the country, as more than 90 percent of the drugs registered in the nation are generic.

Within the last five years, the Chinese government has made great strides towards its goal of providing healthcare coverage for all citizens, including those in rural areas, with around 95 percent of population covered under their universal healthcare system. The state's health system and regulatory framework are expected to change even more in the next ten years as the nation moves towards an evidence-based health policymaking strategy with the institution of "Health China 2030" launched in 2016.

CHINA'S PAYER STAKEHOLDERS

In China, the key agencies that play a role in the pharmaceutical registration, pricing, and reimbursement process include the National Medical Products Administration, the National Center for Evaluation of Medicines and Health Technologies, and the National Healthcare Security Administration.

NATIONAL MEDICAL PRODUCTS ADMINISTRATION (NMPA)

The National Medical Products Administration oversees the approval of all new medicines and clinical trials in China. Priority consideration is given to drugs on the essential drug list (EDL), including drugs used to treat rare diseases, chronic diseases, oncology, and pediatrics medicines, along with emergency medicines. All drugs must be approved by the NMPA to be added to the National Reimbursement Drug List (NRDL). The national basic medical insurance then covers between 50 to 70 percent of the drug's cost.

NATIONAL CENTER FOR EVALUATION OF MEDICINES AND HEALTH TECHNOLOGIES

In 2018, the National Center for Evaluation of Medicines and Health Technologies, a formal health technology assessment (HTA) body, was established. The National Center for Evaluation of Medicines and Health Technology assists in the evaluation of clinical necessity (e.g., unmet need), safety profile, clinical effectiveness, and reasonable pricing for drugs with the same indications, following the pharmacoeconomic principle before price negotiation for innovative patent drugs. Additionally, the HTA will have branches focusing on specific disease areas, such as oncology, cardiovascular disease, and pediatrics to act as experts in the review process.

NATIONAL HEALTHCARE SECURITY ADMINISTRATION, NHSA

As of 2018, The National Healthcare Security Administration, NHSA manages the price negotiation, known as the National Reimbursement Drug List. Drugs that make it on this list are covered by national health insurance, available to nearly all Chinese citizens today.

IMPORTANT POINTS TO KEEP IN MIND

PRICING

The Chinese government strictly controls the price of new medicines, and the price-setting process in China takes place separately from reimbursement. In 2017, 36 innovative patent drugs were added after price negotiations with the Ministry of Human Resources and Social Security, now controlled by the National Healthcare Security Administration. Even with a stricter negotiation process, drug prices were cut by an average of 44 percent.

During the negotiation process, manufacturers can submit a package including clinical and safety data, prior sales and sales forecasts, and pricing information with health economic evaluation and budget impacts.

After this decision, companies must enter negotiations with the reimbursement boards of the national and provincial insurance programs.

LONG-AWAITED UPDATES TO THE NATIONAL REIMBURSEMENT DRUG LIST

The National Reimbursement Drug List (NRDL) determines how drugs are covered under both national and provincial health insurance programs in China. Formulated by representatives of five government agencies, the NRDL consists of two parts: List A and B. The NRDL was last updated in 2017 with 339 drugs added, including drugs for oncology, cardiovascular, hematology, neurology, anti-infectives and traditional Chinese medicines.

Provincial Reimbursement Drug Lists - variants of the NRDL - include a slightly expanded portfolio of drugs beyond the NRDL that are deemed important by the provinces for their indigenous populations.

LIST A

List A consists of widely used, mostly inexpensive drugs, generic drugs, which are considered indispensable. These are fully reimbursed by both national and regional hospital systems. One key subset of List A is the Essential Drugs List, which outlines medicines that receive relatively high levels of reimbursement by the government.

While the EDL contains more than 300 Western products, including newly added chemotherapy and cholesterol drugs, this list is dominated by local brands and generics. Inclusion in this list opens the door to the full spectrum of China's pharmaceutical market but tends to be a volume-driven model for growth at generics-level pricing.

LIST B

List B includes premium drugs that are partially reimbursed on average between 50 to 90 percent, with provincial governments given leeway to add or remove about 15 percent of products on their regional lists to account for local disease trends or provincial hospital demand. Reimbursement for medicines falling into this category is partial and sporadic.

IMPLICATIONS FOR INDUSTRY

LOCAL PARTNERSHIPS ARE CRITICAL

For pharma companies, especially multinationals, navigating China's reimbursement system is becoming less complex; however, the key to capturing - or forfeiting - widespread market access comes from local partnerships. Exposure to this multi-tiered system creates significant price pressures and the need to forge strategic partnerships or alliances with local manufacturers and/or distributors, to leverage their market knowledge, geographic access and R&D capabilities to strengthen market entry opportunities.

In China, the most salient feature of its pricing and reimbursement process is the recent adaptation of a formal application process for listing on the NRDL. Every year, the group of government stakeholders responsible for maintaining the NRDL creates a list of candidates for inclusion; an expert advisory board then reviews the list and posts final decisions and corresponding prices.

The institution of a new standardized process for obtaining reimbursement in China underscores the need for a strong local partner with deep stakeholder knowledge and relationships in-market. Further, you must possess the tools to communicate with stakeholders, patients, members of the media and beyond. GHMC can help you map and implement your strategy for engaging and communicating to these key players in China.

AT-A-GLANCE

Pharmaceutical products in Denmark are distributed through two channels - the hospital sector and the primary health sector - with varying reimbursement and access approaches for each. In general, reimbursement is granted for drugs that can prove a superior cost-benefit ratio compared to standard treatment, are used for a well-defined indication and do not put undue pressure on the government's pharmaceutical budgets. For the primary sector, companies are free to set their own prices every two weeks if they notify the Danish Health and Medicines Agency of the pharmacy purchasing price (PPP). Regarding the hospital sector, pharma companies are required to negotiate prices and provide evidence of their drug's cost-effectiveness.



DENMARK'S PAYER STAKEHOLDERS

Denmark has two primary payer stakeholders: the patient and the State (via the regional health authorities' budgets and the national health service). A medicine prescribed by a general practitioner in the primary sector is partially reimbursed by the region, provided it has been granted such status.

THE DANISH MEDICINES AGENCY

In addition to being responsible for legislation concerning pharmaceuticals, medical devices and clinical trials, the Danish Medicines Agency decides which primary sector medicines are to be reimbursed by the state. It is advised by the Reimbursement Committee, comprised of two general practitioner physicians, four specialist physicians and a representative each from the Danish Regions and patients/consumers.

The Reimbursement Committee reviews a new medicine's therapeutic effect, value added and side effects when considering it for reimbursement. The group considers a drug's price and any economic implications, but Denmark's health economic evaluation is far less strict than Sweden's, for example.

Based on the Danish Medicines Agency's priorities, a so-called 'Basic List' is made. The Basic List shows the five Danish regions' local recommendations for first choice of medicines in the primary sector. The Basic List has been prepared in a collaboration between the regions. However, the choice of medicines is made exclusively by the individual region.

AMGROS AND THE DANISH MEDICINES COUNCIL

Medicines used in the hospital sector are fully funded through each region's hospital budgets. Amgros, a pharmaceutical procurement service owned by the Danish Regions, centralizes hospital drug purchasing for all the hospitals in Denmark.

The Danish Medicines Council prioritizes existing medicines and adopts new medicines and new indications for standard treatment. It makes recommendations about hospital pharmaceuticals to the Danish Regions to standardize the use of high-cost drugs among the regions and to increase price negotiating power.

The assessment of a drug includes three major milestones:

- Clinical assessment focusing on the added value of the drug compared with current treatments, in terms of life extension, side effects and health-related quality of life
- Health economic assessment (handled by Amgros)
- Price negotiation with the pharmaceutical company (handled by Amgros)

IMPORTANT POINTS TO KEEP IN MIND

- Pharmaceutical companies seeking access and reimbursement work directly with the Danish Medicines Council. Furthermore, price negotiations are a direct part of the process.
- A patient is responsible for a co-pay for prescription drugs in the primary sector, which gradually decreases as he or she accumulates pharmaceutical expenses during a 12-month period. Once patient expenses reach 3880 DKK (approx. \$620 USD or 520 Euro), the entire cost of prescription drugs is paid for by the State.

The Regional Basic Lists often differ from region to region. This gives the regions possibility to further prioritize choice of medicines in the primary sector.

IMPLICATIONS FOR INDUSTRY

Pharma companies launching hospital sector drugs are required to demonstrate the cost effectiveness of their medicines towards the Danish Medicines Council. The committee has the final say on medicines to be adopted as standard treatment, regardless of pricing. They have a broad representation of stakeholders, with members from Danish health agencies, medical directors from the Danish Regions, patient representatives and a member from the Danish Association for the Pharmaceutical Industry. Considering these factors, having experts on the ground who are familiar with the intricacies of the evolving Danish environment help in achieving access and reimbursement success.



AT-A-GLANCE

New pharmaceutical products in France—including biologics, biosimilars and orphan drugs—must show a significant improvement in therapeutic value to achieve a premium price while being compared to products in the same therapeutic class. Unique to France’s market, regulators look beyond a drug’s clinical trial endpoints and consider if the drug represents an improvement in medical services and cost compared to existing drugs. Therapeutic effect (not just clinical value) expands the definition of “value” in France.

FRANCE’S PAYER STAKEHOLDERS

For new drugs to receive reimbursement in France, a careful review of medical benefit, and medical innovation is conducted by the Transparency Commission, or Commission de la Transparence, which ultimately determines a drug’s maximum price and reimbursement status.

The Transparency Commission considers the level of innovation the drug brings to the market, as well as how important it is to the health of French citizens. It determines the drug’s improvement of medical benefit or amelioration du service medical rendu (ASMR) compared to the current standard of care, and assigns a rating from 1 to 5:

- **ASMR V:** no improvement
- **ASMR IV:** minor improvement
- **ASMR II:** moderate improvement
- **ASMR II:** important improvement
- **ASMR I:** major improvement. This is reserved for an extremely few drugs that have demonstrated effect on mortality in a severe disease.

The ASMR answers the question: does the drug improve patients’ clinical situation as compared to existing therapies? Consequences of ASMR rating and level of price are as follows:

- **ASMR V** - the drug can be listed only if the costs are less than the comparators for cost savings to the French National Health Insurance (NHI). Discounted pricing for the new drug is typical.
- **ASMR IV:** the target population for the new drug is relevant. If the new drug targets the same population as the comparator drug, then a parity price is best possible outcome. Price can be higher than a comparator if the new drug has better effect in a more restricted population.
- **ASMR I, II or III:** Faster access (price notification instead of negotiation) and price consistency with rest of Europe. However, it is increasingly rare to secure ASMR I - III ratings.

The Transparency Commission also determines the product’s medical benefit or service medical rendu (SMR). The SMR answers the question: should the drug be reimbursed? Is the drug clinically differentiated (interesting)? The SMR considers five criteria:

- Severity of the disease to be treated and its impact on morbidity and mortality
- Clinical efficacy/effectiveness and safety of the medicine
- Aim of the drug: preventive, symptomatic or curative
- Therapeutic alternatives? Positioning in treatment strategy for the disease, indication or condition?
- Public health considerations - burden of disease, health impact at the community level, transposability of clinical trial results etc.

The SMR then determines the reimbursement level. The reimbursement rate is as follows:

Actual Benefit (Service Medical Rendu)	Reimbursement Rate
Important	65%
Moderate	30%
Mild	15%
Insufficient	Not included on the positive list (not reimbursed)

The ASMR and SMR ratings described above, are determined concurrently. Once they are determined, the manufacturer enters negotiations with Comité Economique des Produits de Santé (CEPS) to establish the reimbursement price and rate for innovative ambulatory (retail) drugs. The ASMR level determined by the TC and the expected annual sales volume are key considerations for the CEPS when establishing price. There is free (unregulated) pricing for drugs that are not covered by the French reimbursement system.

Hospital-only products, which are mostly reimbursed from the total health care budget allocated to the hospital, are not subject to assessment by CEPS. In France, manufacturers are free to set prices for most hospital drugs. However, hospitals purchase drugs from manufacturers through a competitive bid process which allows them to effectively negotiate these drug prices. While hospital drug pricing remains unregulated, an activity-based costing is implemented in the hospitals. Since 2004, payment for hospital acute care has operated on a type of Diagnosis Related Group (DRG) model. The Tarification à l'Activité (T2A) has strengthened the link between actual activity rates in hospitals and the payment they receive for this activity. For certain innovative and expensive products, there is an override mechanism, known as the "liste en sus" or extra list since 2004. However, a decree from 2016 restricted the conditions for inclusion on the "liste en sus" and introduced inequality in access to these drugs.

IMPORTANT POINTS TO KEEP IN MIND

All drugs must be assessed by HAS (Haute Autorité de Santé) - before inclusion on a positive list of reimbursed products:

- One list for access to hospital pharmacies
- One list for admission to community pharmacies
- Assessment is based on medical evidence.

Reimbursement and price are separately determined - CEPS and HAS are separate bodies.

The French market has a more restrictive approach when it comes to prescription drugs, as it assesses the benefits and risks of products throughout their lifecycle.

The French National Agency of Medicine and Health Products Safety replaced the French Agency for the Safety of Health Products (AFSSAPS) as the drug regulatory body in 2012 in the wake of a scandal involving the diabetes treatment, Mediator. The drug was widely prescribed off label as a weight loss aid. Growing evidence that it caused heart valve damage prompted the United States, Spain and Italy to ban the drug, but France took years longer to act to remove Mediator, manufactured by French company Servier. In addition to conflict-of-interest and transparency rules brought on by the Mediator scandal, manufacturers in France may see previously approved drugs re-evaluated by the French regulatory agency to ensure they meet strict standards of improved medical benefit.

IMPLICATIONS FOR INDUSTRY

Market access in France will continue to require a value-based approach, beyond the measurement on clinical endpoints. Once a drug is priced and published in the Official Journal, it is valid for five years. At the end of this period, the Commission d'Evaluation des Médicaments reevaluates the SMR and ASMR level and the price can be reviewed accordingly. Health technology assessments (pre-launch) and observational studies (post-launch) influence French assessment of value, contribute to approved price and listing on reimbursed drug price list ("positive list" of reimbursed products).

Manufacturers must be able to show clinical and economic benefits of a product, and how each contributes to its value. This is true for new products as well as those undergoing reevaluations. It is important to demonstrate improvements to justify higher price and reimbursement levels.

This process must be reviewed in 2021 to not only be more adaptable to advanced therapy drugs (MTI): gene therapy, CAR-T cells, etc., but also to take into account production in France and in Europe to minimize drug shortages.

AT-A-GLANCE

Germany is the top pharmaceutical market in Europe and one of the largest in the world, but a reformed reimbursement system for drugs makes it one of the most complex for reimbursed pricing and market access. In 2011, the Act on the Reform of the Market for Medicinal Products (AMNOG) was instituted requiring all companies with a new active drug or application to provide strong clinical and economic evidence if they want the best price for their drug. It is now more important than ever for a pharma company to prove a new product's additional benefit over existing treatments to obtain a maximum reimbursed price.

GERMANY'S PAYER STAKEHOLDERS

The Act on the Reform of the Market for Medicinal Products (AMNOG) in early 2011 introduced a mandatory benefit assessment process, which has radically changed the market access environment for products with a new active ingredient in Germany.

Once a new drug is approved in Germany, the pharmaceutical company can set its list price and market it, but only for a limited period. The Federal Joint Committee or Gemeinsamer Bundesausschuss (G-BA) identifies an appropriate comparator to evaluate the additional benefit offered by the new product.

G-BA'S COMPARATOR CONSIDERATIONS

- The existing clinically appropriate standard of care in the indication
- With more than one product, G-BA selects the lowest-price comparator
- If no drug alternative, comparator can be a non-drug treatment

G-BA's decision is guided, in part, by the Institute for Quality and Efficiency in Healthcare (IQWiG), which assesses the additional benefit of the drug.

LEVELS OF ADDITIONAL THERAPEUTIC BENEFIT

1. Major added benefit over comparative therapy
2. Significant additional benefit
3. Marginal additional benefit
4. Unquantifiable additional benefit
5. No additional benefit proven (a negative category)
6. Less than comparator (a negative category)

If the new drug shows additional benefit, the National Association of Statutory Health Insurance Funds, or GKV-Spitzenverband (GKV-SV), negotiates with the pharmaceutical company for a reimbursed price. This negotiation process is highly structured with pharmaceutical companies only having the right to four confidential sessions with the limited potential of a fifth session. If the negotiation process is unsuccessful during the offered sessions, the price is decided by an independent arbitration board and no further negotiation is allowed. Since the first establishment of the price negotiation and benefit assessment structure in 2011, 230 drugs have gone through the negotiation process and only 35 have had their final price decided by arbitration rather than negotiation as of 2019.

IMPORTANT POINTS TO KEEP IN MIND

If the IQWiG assessments acknowledge some level of additional benefit, the pharma company should be able to keep its initial launch price but offer health insurers some sort of discount. The agreed-upon price is then honored by Germany's statutory public insurance program.

Not surprisingly, pharma companies can find themselves at odds with the G-BA on the existing therapy to which their new drug must be compared. Manufacturers must demonstrate head-to-head evidence on endpoints strongly preferred by IQWiG and G-BA for a positive assessment. The G-BA's choice of comparator cannot be challenged.

ORPHAN DRUGS

New drugs to treat rare diseases catch a break in the German market with a simplified submission process. If the new orphan drug costs the statutory health insurance fund less than €50 million annually, it does not need to prove additional benefit to set a price. The additional benefit in general is considered demonstrated by the orphan designation.

This exception applies to orphan drugs if anticipated peak sales stay below the threshold of €50 million a year. If the threshold is exceeded after the G-BA decision, a complete dossier must be submitted by the manufacturer.

IMPLICATIONS FOR INDUSTRY

The right comparator is the single most important factor in AMNOG benefit assessments. "Additional benefit" can go right out the window if the G-BA disagrees with the comparator you've selected for your new drug.

In addition to early alignment with the G-BA on choice of comparator, pharmaceutical companies should consult with the committee on documents and studies to be submitted, methodology to demonstrate additional benefit, clinical trials endpoints and ideal patient sub-population(s), among other considerations.

The best-case scenario for a new drug is to obtain an international reference price through price negotiations with the lead association of the German Sick Funds. To that end, most companies may hold off on a launch in Germany, moving first in countries with more favorable pricing conditions.



AT-A-GLANCE

While Hong Kong occupies a relatively small geographic area, its health system impacts more than 7 million individuals. In Hong Kong, the government is the primary healthcare provider, covering more than 95 percent of the total medical expenditures at a low flat, rate for its population. Notably, this highly regulated system can support most; however, citizens do have the option to pay out-of-pocket and seek medications and services outside of the standard of care.

HONG KONG'S PAYER STAKEHOLDERS

While Hong Kong is a special administrative region of the People's Republic of China, its prescription drug approval and reimbursement systems are different. Within Hong Kong, the Department of Health (DH) is responsible for overseeing the safety, efficacy, and quality of all medicines available in the region, including innovative drugs and Traditional Chinese Medicine products. For a new drug to enter Hong Kong's market, it must first be registered with the Pharmacy and Poisons Board (PPB), which issues a registration number and classification for the new pharmaceutical product.

There are three classifications for innovative (Western) medicines; these categories impact where a drug can be sold and under what conditions.

- **Category 1:** Medicines that require a doctor's prescription and can only be sold in a registered pharmacy under the direct supervision of registered pharmacists. These drugs are used to treat serious diseases, or for drugs where an incorrect dosage could lead to serious health risks.
- **Category 2:** Medicines in this category do not require doctor's prescription but must be sold in registered pharmacies under the supervision of a pharmacist as their method of use or dosage may result in a health risk.
- **Category 3:** Medicines in this category can be sold in pharmacies or medicine stores without resident pharmacists. These are sold as over-the-counter medicines.

For Traditional Chinese Medicine, the Chinese Medicine Ordinance determines approvals and sets separate categories of classification:

- **Schedule 1 Medicines:** These medicines can only be sold with a prescription issued by a registered Chinese medicine practitioner. These medicines often contain toxic ingredients.
- **Schedule 2 Medicines:** These medicines are considered safe with no prescription needed for purchases.

IMPORTANT POINTS TO KEEP IN MIND

Once a drug is registered and approved, the Hong Kong government does not impose any pricing regulations in the private sector. However, The Hospital Authority (HA), public healthcare service provider for more than 90 percent of Hong Kong citizens, establishes the standard of use and cost for prescription drugs for those under its service.

In order for a prescription drug to be available in the Hospital Authority (HA), the Drug Advisory Committee (DAC) must first evaluate and approve the drug for inclusion on the Hospital Authority Drug Formulary, listing standardization of drugs and drug use policies for cost-effect patient care. The DAC reviews several drug criteria before approval, specifically drug information, safety, efficacy, cost effectiveness, international guidelines, advancements in technology and disease state.

Based on the drug criteria and utilization, the drug is either rejected or approved for the HA Drug Formulary and placed into one of four categories.

1. **General drug:** These are drugs with established indications and cost-effectiveness that are available for general use as indicated by patients with relevant clinical conditions and provided at standard fees and costs in public hospitals and clinics.
2. **Special drugs:** These medicines are used under specific clinical conditions under specialist authorizations. These drugs are also provided at standard fees but only for patients who meet a specific clinical condition.
3. **Self-financed Items (SFIs):** These drugs provide a significant clinical benefit but are extremely expensive for the HA to provide as part of its standard services. Therefore, these drugs can only be purchased by patients at their own expense. However, these drugs often have safety nets that provide subsidized funds for patients with financial difficulties.
4. **SFIs without safety nets:** These are drugs with preliminary medical evidence only, with marginal benefits over available alternatives at significantly higher costs, as well as lifestyle drugs. These drugs must be purchased at the patient's expense.

Outside of the Hospital Authority (HA) system, there are several private health system options available to patients should they choose, albeit at higher costs to the patient.

IMPLICATIONS FOR INDUSTRY

In recent years, Hong Kong's Hospital Authority has been under pressure to increase its scope of prescription drug coverage as more drugs are made available for rare diseases, but not to the conditions covered under the HA's system. For example, in 2017, the HA refused to reimburse Afinitor, which had received market approval the year prior. Due to high costs of the tuberous sclerosis complex medicine, the HA refused to support the drug's reimbursement, leading to patient deaths. Pharmaceutical companies with drugs for rare disease and some cancer drugs have now turned to public funds to support patients who need to financially subsidize treatment.

Pharmaceutical companies launching new products in Hong Kong should not only be prepared for presenting a strong clinical case to the Pharmacy and Poisons Board (PPB) but also an economic case to the Hospital Authority to reach the largest patient population.

Having a strategy to communicate value not just with the PPB, DH, and the HA is critically important. GHMC can help you demonstrate and effectively communicate the value of your new product to the Hong Kong market in innovative but compliant ways.



AT-A-GLANCE

It is often said that India is a land of paradox; the country's healthcare landscape, particularly as it relates to prescription medicines, is no exception. With a population of 1.4 billion and a \$280 billion healthcare sector growing at 16.9 percent, India is an attractive pharmaceutical market. It ranks in the top three globally in volume and the top ten in sales. Yet, gaining market access and reimbursement for innovative medicines in India has long been viewed as a challenge by the pharmaceutical industry.

As the Indian government works to provide comprehensive health coverage for all its citizens, disparities persist between poorer and richer states. While new government-financed health insurance programs are increasing coverage, insurance remains limited. Further, India's patent laws strictly limit the protection of medicines when the active ingredients are already known. As a result, branded generics currently make up the lion's share of India's pharmaceutical market.

Entering such a unique market is a difficult proposition. However, rising incomes and life expectancies coupled with increasing rates of diabetes, cardiovascular disease, and other chronic conditions have created a growing need for innovative therapies in the country.

INDIA'S PAYER STAKEHOLDERS

- Only 37 percent of Indian citizens have any form of health insurance, so most healthcare costs have historically been paid out-of-pocket.
- Rashtriya Swasthya Bima Yojna (RSBY), a public health insurance scheme, provides hospital coverage for most diseases and pre-existing health conditions for individuals living below the poverty line, although ambulatory care is not covered. The Employees' State Insurance (ESI) scheme, is organized by the Ministry of Labour and Employment for the workforces of organizations that employ ten or more individuals.
- The Government of India launched Pradhan Mantri Jan Arogya Yojana (PMJAY), the world's largest health insurance scheme fully financed by the government. Poor and vulnerable citizens are eligible for the health benefits covered by this payer, which include, but are not limited to: diagnostics, medicines, hospitalization costs, and medical treatment expenses. PMJAY has been rolled out to the bottom 40 percent of India's poor and vulnerable population.

IMPORTANT POINTS TO KEEP IN MIND

- The drug approval process in India is straightforward. The manufacturer or importer of the medicine applies to the Drug Controller General of India for marketing authorization. Following inspection and approval of a drug's safety, a report is prepared, and a license is granted. Though it may be simple to enter the market, receiving exclusivity is a more difficult task.
- The National Pharmaceutical Pricing Authority (NPPA) was established in 1997 by India's central Government to ensure equitable distribution and availability of medicines at fair prices. The NPPA enforces the Government's Drug Price Control Orders, which determines ceiling prices for "essential and life-saving medicines." Certain rare/orphan medicines, HIV, tuberculosis, cardiovascular and diabetes drugs are not on India's National List of Essential Medicines, and therefore are not subject to the government-determined ceiling prices.



WHY GENERICS MATTER IN INDIA

- 75 percent of India's population lives in rural areas, and average monthly income is around \$143 USD or less, while 46 percent of children remain malnourished. To deal with these challenges, the Indian Government has gained a degree of infamy for invoking Compulsory Licensing provisions under the World Trade Organization's Trade-Related Aspects of Intellectual Property Rights (WTO TRIPS) agreement to allow generic production of medicines, often contrary to conventional patent protections.
- Due to complex patent restrictions in India, branded generics make up 70-80 percent of all drugs sold in India. Unless a product contains an entirely new molecule, it is unlikely to receive patent protection. Roche and Novartis have been engaged in years-long court battles over intellectual property rights for their oncology drugs Tarceva (erlotinib) and Gleevec (imatinib mesylate) against generic versions manufactured by local players, including Glenmark and Dr. Reddy's.
- Biosimilars are entering the fray in India, as well. To-date, there are more than 90 approved biosimilars in India, with at least 50 on the market. Local manufacturers are now extending their reach globally in an attempt to compete with leading patented biologics.
- Biosimilars can only be considered against an authorized reference biologic that has been approved in India. If no reference is marketed in India, the product must be licensed and marketed in another country for at least four years, with significant safety and efficacy data prior to authorization in India.

IMPLICATIONS FOR INDUSTRY

The Indian reimbursement landscape is complex and challenging. Innovation that is rewarded with exclusivity in other parts of the world is often replicated by generics companies, making it a difficult environment for branded pharmaceutical companies to compete. With the Government playing a large role in price regulation and reimbursement, the ability to demonstrate the value of a product is vital to ensure access to the treatments that patients need through the public health system.

Additionally, education—about the need for, and benefits of—a medication is key. To do this effectively, manufacturers need to tailor their communications strategies to reflect the specific channels that various patient populations use to communicate and receive information. With the rise of telemedicine and the e-pharmacy market, a consolidation of the supply chain is likely to happen. With deep local expertise in India, GHMC offers invaluable counsel in communicating your value story to maximize the chances for market access success.



AT-A-GLANCE

To gain access to the Italian market, a pharmaceutical company must be prepared to give payers a money-back guarantee. These “risk-sharing” agreements between central and regional payers and manufacturers are becoming more common in Italy, forcing companies to prove the value proposition of their products, or risk not getting paid. That is why companies must collect outcomes and value-added data early and throughout the development of a compound, through clinical trials and non-clinical studies.



ITALY'S PAYER STAKEHOLDERS

Italian citizens receive free, universal health care, and the Italian Medicine Agency (AIFA, or Agenzia Italiana del Farmaco) manages pharmaceutical marketing authorization, pricing, and reimbursement approvals. AIFA's two committees negotiate with companies to determine the value of a new therapy. The Technical Scientific Committee classifies new drugs into one of three reimbursement categories:

- Class H for hospital use only
- Class A to be dispensed through pharmacies directly to patients - essential drugs and drugs prescribed for chronic diseases, paid by the National Health System
- Class C to be dispensed through pharmacies directly to patients - drugs not included in Class A and OTC drugs, paid by citizens

The Prices and Reimbursement Committee uses a strict health technology assessment (HTA) to arrive at a price. Manufacturers must be prepared to show how a new product delivers value to a specific population and to the Italian health care system. As of late, patient centricity is also influencing market access, and companies often collaborate with patient advocacy groups to collect data and insights that can represent an added value to dialogue with healthcare systems.

REGIONAL AUTHORITIES ACT INDEPENDENTLY

AIFA approval does not automatically make a new drug accessible to all patients in Italy. The country's 21 Regional Authorities each control their own costs and thus manage access to new drugs. Sometimes, a treatment is offered at clinics in one region, but not in another. A manufacturer may need to make a case for its product with all 21 of them.

Manufacturers should prioritize regions in Italy for launch purposes, considering the local economy, the incidence of disease in the region and how many specialty clinics it has, for example. With offices throughout Italy and relationships with key stakeholders, GHMC can help you prioritize regions and navigate the variables to tell an optimal value story.

IMPORTANT POINTS TO KEEP IN MIND

The Italian government aims to keep healthcare costs in check via risk-sharing agreements with pharma companies and by forcing manufacturers to align pricing with cheaper alternatives and with prices negotiated in nearby countries.

Through risk-sharing or “innovative pricing” arrangements, the Italian Medicine Agency and regional bodies agree to cover innovative new drugs on the condition that they prove to benefit patients and cut costs. Data on responding patients and non-responders are perhaps most critical for manufacturers, so you can negotiate a risk-sharing agreement with payers with confidence. If you’re reimbursed only for those patients who actually respond to the treatment, you want to be certain you can identify them.

The Italian Medicine Agency maintains a database that collects data on patients treated with new medicines during the risk-sharing period, to assess the safety and effectiveness of the treatment. This technology is a significant investment in infrastructure, and Italian stakeholders including payers, physicians and pharma companies have access to it.

REFERENCE PRICING IS COMMON

Payers in Italy use “reference pricing” to contain pharmaceutical costs, creating a competitive situation that forces manufacturers to price their products the same as cheaper alternatives. This “therapeutic reference price” is the maximum the Italian National Healthcare Service will pay for a drug.

Through “international reference pricing,” prices in Italy are compared to those in the rest of the region for the same product. The transparent nature of pharmaceutical pricing in the EU means all the other countries know if you gave somebody else a good deal! So, in launching a new product, as in life, timing is everything.

GHMC can help you develop and communicate a global launch sequence strategy to maximize the price for your new product among interdependent markets such as the EU.

IMPLICATIONS FOR INDUSTRY

A market access strategy for Italy requires an understanding of the international implications as well as the variables unique to each of the country’s 21 regions. Risk-sharing is the new norm. Telling your value story early and often will smooth the pathway for access and maximum reimbursement for your product. The GHMC team has years of experience in Italy and in the EU markets. Working with your team and key stakeholders, we can help you build a compelling communications and marketing plan to create optimal conditions for brand success in this important European market.



AT-A-GLANCE

Mexico has the second largest pharmaceutical market in Latin America and ranks 12th globally. As an important producer of medicines, including antibiotics, anti-inflammatories, and cancer treatments among others, Mexico is projected to reach over USD \$13 billion in pharmaceutical sales by 2028. Since 2000, the Mexican healthcare system has evolved with patients being granted improved access to oncology treatments and the widespread availability of generic drugs, all of which has led to increased growth of the country's pharmaceutical industry. More than 128 million Mexican citizens receive their health insurance and prescription drug coverage via two public systems and the private sector. Although an estimated 90 percent of the population is covered for a core set of health services, out-of-pocket payments remain high at a little over 40 percent of the country's total health expenditure.

The divisions within the healthcare system mirror economic divisions in Mexico. The wealthy and upper-middle class have private insurance and utilize private healthcare providers. Middle- and lower-income Mexican citizens use one of the two public-sector insurance programs. Success in the Mexican market requires an access and communications strategy with the flexibility to achieve reimbursement in all three market segments.

MEXICO'S PAYER STAKEHOLDERS

In Mexico's public health system, the federal and state governments are the main payers. Government-sponsored health insurance systems include the Instituto Mexicano de Seguridad Social (IMSS), and the newly implemented Instituto de Salud para el Bienestar (INSABI). The health service for State workers is the Institute of Social Security at the State Workers Service (Instituto de Seguridad Social al Servicio de los Trabajadores del Estado, ISSSTE). The middle class in the formal economy primarily uses the publicly funded IMSS and other government-run systems. INSABI, which replaced Mexico's "Seguro Popular" system in January 2020, offers social security to individuals outside IMSS' and ISSSTE's coverage, which accounts for approximately 69 million Mexicans.

Members of the armed forces have their own health services, including Secretary of the National Defense (Secretaría de la Defensa Nacional, SEDENA) for the army, and Navy Secretary (Secretaría de Marina, SEMAR) for the navy.

The private sector includes independently operated health plans and hospitals like in the United States. Major private-sector providers in Mexico include GNP, AXA, Metlife and Seguros Interacciones. As such, employers and the individual make up the dominant payers for private insurance.

IMPORTANT POINTS TO KEEP IN MIND

The Federal Health-Risk Protection Commission (Comisión Federal para la Protección contra Riesgos Sanitarios, COFEPRIS) is the government regulatory authority responsible for approving new medicines in Mexico. Once products are approved, the General Health Counsel (Consejo de Salubridad General, CSG) is the main decision maker body for new medicines' inclusion on the public drug formularies, called the Health Systems Supply Catalogue (Cuadro Básico y Catálogo de Insumos del Sector Salud).

The process for making a drug available in the public health system is as follows:

1. Secure regulatory approval from COFEPRIS
2. Petition for inclusion in the Health Systems Supply Catalogue
3. Once listed, the drug may be prescribed by any doctor within the public health system

In the case where a drug is not approved for general use, a demonstration of immediate need can be submitted to a Ministry of Health committee for special approval on a case-by-case basis.

Once drugs have been added to the Social Health Services Register, pricing is determined by institutional agreement between the manufacturers and payers. A drug's value and price in the private system is determined by the market and in the public sector via public tender and subsequent negotiations. Though COFEPRIS sets the maximum price limits on drugs and procedures, the shelf price of a drug under this limit is ultimately left up to the manufacturer.

For delivery of medical services, including prescription drugs, those covered under the public health system are limited to attending (and receiving prescriptions from) federal- and state-run hospitals. Federal hospitals accept all forms of insurance, public and private, but private clinics only extend benefits, including medications, to those who have private insurance (or if that person can pay out-of-pocket).

LEGISLATIVE UPDATES

In mid-2020, the federal government signed an agreement with the United Nations Office for Project Services (UNOPS) to collaborate on the international purchase of medicines, medical supplies and vaccines. This has enabled Mexico to join the Regional Revolving Fund for Strategic Public Health Supplies of the Pan-American Health Organization (Fondo Rotatorio Regional para Suministros Estratégicos de Salud Pública de la Organización Panamericana de la Salud). Further, on July 30, 2020, President López Obrador announced that a state company would be created to distribute these internationally purchased medicines across Mexico, especially throughout more remote and isolated areas of the country.

IMPLICATIONS FOR INDUSTRY

Overall, access into the Mexican healthcare market is largely dependent on demonstrated value. Private payers make decisions based on the value of a medication to patients' health, and public health systems choose to include medication in their catalogue based on the value to the population. With a growing population and a health system dedicated to increasing its ability to provide access to healthcare, telling your value story is more important than ever. GHMC has nearly 20 years of successfully creating and communicating the value story to diverse audiences.



AT-A-GLANCE

Poland is one of the most difficult markets in Europe to achieve market access for pharmaceutical products. High prices on branded drugs coupled with an arduous reimbursement process create an environment dominated by generic pharmaceuticals for all but the wealthiest Polish citizens. With limited uptake for innovative new medicines prior to securing reimbursement and very strict laws on marketing of branded products, it is imperative to connect with the right opinion leaders to achieve reimbursement.

POLAND'S PAYER STAKEHOLDERS

- The Polish Ministry of Health determines medications to be reimbursed by The National Health Fund (NFZ), Poland's single payer. The Ministry of Health is advised by the publicly funded HTA Agencja Oceny Technologii Medycznych I Taryfikacji (AOTMiT), government-appointed opinion leaders and government consultants. It also receives informal consultation from non-government key opinion leaders, interest groups and medical associations.
- When a pharmaceutical company submits a drug reimbursement proposal to the Ministry of Health, the AOTMiT issues an official determination on the pharmacoeconomic impact of the drug and its clinical data. The AOTMiT may also consider the drug's impact on the overall budget in rendering a decision. Medical associations play an informal advisory role in the reimbursement decision-making process. Medical and professional associations are among the few groups a pharma company can meet with to discuss its product while the reimbursement review process is underway.
- Companies applying for drug reimbursement must submit their applications online in the Reimbursement List System (System Obsługi List Refundacyjnych).
- There are no private payers in the Polish health system. However, patients may pay out-of-pocket for a medication that is not reimbursed.

IMPORTANT POINTS TO KEEP IN MIND

Pharmaceutical products that receive the green light from the EMEA are automatically approved for use in Poland. From that point, however, it can take the Ministry of Health years to render a reimbursement decision. Companies can appeal reimbursement and pricing decisions to the AOTM, but the Ministry's ruling is rarely overturned. In this case, it is often best to approach the process from a different angle, potentially with a smaller target population or a more limited indication.

If a company is unable to negotiate an agreeable price after re-evaluation, AOTM may consider risk-sharing agreements or limiting the indication and patient population. Risk sharing is more likely in cases where AOTM recognizes that a product adds value. Even if a product is denied reimbursement, gaining AOTM's support for the product makes the government more willing to be flexible regarding indication and risk management.

Marketing regulations in Poland are very strict. It is illegal to mention the name of a new product to anyone other than a physician. This limits a manufacturer's ability to publicize a product and limits the audience scope to professionals and non-government organizations, reducing the effectiveness of more traditional marketing efforts aimed at creating community support for access to a treatment.

Polish patients are often unable to afford a drug that is not reimbursed, and in many cases are not forthcoming about their conditions due to public stigma. As such, pre-reimbursement case studies are difficult to come by, though when available they make for excellent demonstrations of value during the negotiating process.

IMPLICATIONS FOR INDUSTRY

Stiff competition from generics paired with a rigid single payer governance structure can block access and reimbursement in the Polish market. Companies are faced with a lengthy decision-making process, and appeals of unfavorable decisions are rarely successful.

Prepare to be flexible regarding indication and target patient segment to achieve access and reimbursement in Poland. By keeping all options on the table and planning for any possible result of the long reimbursement process, you will be able to effectively respond upon receipt of the Ministry of Health's decision.

To that end, an experienced market access team paired with early public relations efforts to reach out to key stakeholders and opinion leaders can help you leverage small advantages into major successes. Flexibility and creativity in market access strategy are essential for securing reimbursement in an environment as challenging as Poland.



AT-A-GLANCE

The Portuguese pharmaceutical market has seen permanent and intense government intervention since the country's financial crisis in 2011. Portugal's Economic Adjustment Program (EAP) and the international loan agreement were enacted and subsequently prompted health sector reforms. Some of the key EAP measures included reducing pharmaceutical expenditures, cutting healthcare professionals' salaries and increasing co-payments. The EAP also gave new impetus to reforms that had stagnated during the economic downturn. These included a primary care reform to expand enrollment in general practitioner's patient lists and to create Family Health Units, although in practice few opened because of budgetary constraints.

To strengthen preventive care measures, the Government is taking action to bring more general practitioners into the National Health Service (Serviço Nacional de Saúde- SNS), boost patient registrations with GPs, and give municipalities a greater role in primary care planning and management as a step toward further decentralization. Other recent reforms have focused on strengthening public health interventions, on improving access to care and tackling shortages in the healthcare workforce.

PORTUGAL'S PAYER STAKEHOLDERS

The SNS, which is financed by the state budget, covers all Portuguese residents; it is universal, comprehensive and nearly free at the point of use (in accordance with the Portuguese Constitution). New legislation introduced in 2019 has abolished user charges for primary care visits, healthcare procedures and consultations covered by the SNS. Nevertheless, fees can be charged for certain outpatient services; however, they only represent a small part of the cost of the service. Health subsystems are funded mainly through employee and employer contributions (including contributions from the state as the employer of public servants) and can either be public or private. Citizens also have the option to enroll in Private Voluntary Health Insurance (VHI), which is supplementary and may speed up their access to outpatient procedures.

IMPORTANT POINTS TO KEEP IN MIND

REGULATION, PRICING AND REIMBURSEMENT

Pricing and reimbursement are exclusively dealt with at the national level, as they are outside the scope of EU legislation, with the exception of transparency measures and procedural requirements set out by the Council Directive (relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion within the scope of national health insurance systems). Public expenditure cuts have significantly impacted the cost of medicinal products that were being reimbursed by the SNS, which led the government to impose a tax (designated as "a special charge on the pharmaceutical industry"), which was incorporated into the state budget in 2015, and most recently, in 2020.

In Portugal, jurisdiction over medicines and medical devices is centralized in the National Authority for Medicines and Health Products (INFARMED). A national market authorization is valid for five years. INFARMED also plays a role in the renewal of the authorization, through a risk-benefit evaluation of the data collected over the years. The sponsor must submit a renewal request to INFARMED nine months before the marketing authorization is due to expire. Following the first renewal, the authorization is valid indefinitely, unless INFARMED, for pharmacovigilance reasons, demands a renewal request for an additional period of five years.

Prices of drugs are regulated by the System of Assessment of Health Technologies (SiNATS), which was created by Decree-Law 97/2015. A maximum sale price for a prescription drug is determined and subsequently approved by reference to the price applied in reference countries. This price is subject to an annual revision. Spain, France, Italy, and Slovenia were the reference countries under consideration in 2020.

Decree-Law 97/2015 also allows for discounts at all stages of medical distribution, from the manufacturer to the retailer. Discounts applied by pharmacies to the price of medicines partially reimbursed by the SNS are applicable only to the part of the price not subject to reimbursement.

GENERIC PRODUCTS

In 2000, the Ministry of Health strongly pushed for the expansion of generics in the Portuguese market, with several multinational companies bringing them to market. The uptake of generics increased rapidly between 2005 and 2012 but has since levelled off over the past few years. New trade margins for retailers and pharmacies were set in 2011, as well as new prices for generics, with the highest sale price set at least 50 percent lower than that of the reference product (or 25 percent, if the retail price is below €10). Therefore, special provisions to encourage the sale of generics exist in a variety of areas. For example, generics benefit from a simplified pricing and reimbursement structure. Also, by law prescriptions are mandatorily written by a physician in the name of the active substance, rather than the brand name, once a generic is launched in the market. This rule of generic substitution has very few exceptions, which are expressly written into the law. Similar incentives also exist for biosimilars. Moreover, recent measures, such as a €0,35 incentive to pharmacies for each pack of generics sold has also played a role in increasing generic sales.

IMPLICATIONS FOR INDUSTRY

Portugal's Government is committed to improving patient access to medicines and treatments that demonstrate innovation, including orphan drugs and those for specific populations.

The coming years will prove challenging for the pharma and life sciences sector in Portugal, as new cost-effective measures are adopted by public and private healthcare providers, coupled with complex regulations and reform.

GHMC can help you map and carry out your strategy for engaging and communicating to key players at all levels in Portugal.



AT-A-GLANCE

In early 2020, the value of Romania's pharmaceutical market rose to EUR 4.46 billion, which accounts for prescription medicines (EUR 3.35 billion) and drugs sold over the counter (EUR 1.1 billion).

In Romania, private and public medical service providers operate in tandem. Although Romania has a universal health coverage system, not all health care services are covered and additional out of pocket costs are required for certain treatments and prescriptions.

Insured patients can seek medical care in public or private healthcare units, which have reimbursement agreements with either Romania's National Health Insurance House or one of its district health insurance houses. Further, patients insured through Romania's National Health Insurance system can access medicines and certain medical devices from pharmacies that have reimbursement agreements with health insurance houses, either free-of-charge or by making a co-payment.

ROMANIA'S PAYER STAKEHOLDERS

Romania has a highly centralized Social Health Insurance (SHI) system. The Ministry of Health (MOH) is primarily responsible for healthcare governance, while the National Health Insurance House (NHIH) regulates the system. Both the Ministry of Health and NHIH have local level representation, through district health insurance houses (DHIHs) and district public health authorities (DPHAs).

Healthcare services are delivered in 42 districts. DHIHs purchase services from physicians, specialty care practices, hospitals, labs, and other providers at the local level. Furthermore, healthcare providers might be paid by the Ministry of Health under national health programs.

Under the SHI scheme, Romanian citizens who contribute to health insurance are covered, along with their children. Pensioners also have access to a comprehensive benefit package, while those who are uninsured (approximately 10 percent of the population) are only eligible for minimal healthcare services, such as emergency medical care.

IMPORTANT POINTS TO KEEP IN MIND

No medicinal product may be placed on the market unless a marketing authorization has been issued by The National Agency for Medicines and Medical Devices (NAMMD), which was organized in 2010. After a new medicine obtains market authorization from the NAMMD, the marketing authorization holder (MAH) applies to the Ministry of Health to set a price. Prices for OTC drugs are not regulated; however, the MAH is required to notify the MOH of said price within 30 days after the drug has been on the market.

The price of a prescription medicine can be reimbursed at a level of 100 percent, 90 percent, 50 percent, or 20 percent, and is largely dependent on the reimbursement list where the medicine is included. The list of the international non-proprietary names ("INNs") reimbursed in Romania is approved by the Government. Based on the INN Reimbursement List, the NHIH and the MOH distribute the lists providing the trade names and reimbursement values applicable for medicinal products in the social health insurance system and the national health programs.

The price of medical devices is not regulated; however, in the case of reimbursed medical devices, their reimbursement value is approved by the MOH and/or the NHIH. If a medicine is reimbursed in the national health insurance system, its reimbursement price shall be approved according to certain specific rules applicable to each reimbursement list.

As a rule, insured patients obtain the reimbursed medicines free-of-charge or with a price reduction from a pharmacy that has previously concluded a supply (reimbursement) agreement with the NHIH or with the local health insurance house. Pharmacies submit reimbursement data for each month to the relevant health insurance house. The health insurance house should pay the pharmacies the reimbursement amounts within 120 days of submitting the relevant documentation.

In 2009, Romania introduced a claw-back tax, which requires drug manufacturers to pay a quarterly contribution for reimbursed medicines, based on consumption reported by the NHIH. This system has received criticism throughout the years because it does not consider the differences in sales between manufacturers, and generic drug producers were hit the hardest. During the first half of 2020, the tax was reduced to: 15 percent for domestic drug manufacturers (for both generic and innovate medicines), 25 percent for foreign innovative drug manufacturers and 20 percent for foreign generic drug manufacturers.

IMPLICATIONS FOR INDUSTRY

One priority for the Romanian health system is bringing new medications to market that are more effective or present fewer side effects than other existing medications for treating certain diseases. In this regard, streamlining the cost of medicines for which there are generic equivalents could allow new medications with therapeutic benefits to be included in the reimbursement circuit as soon as possible after their registration on the market. The Competition Council of Romania therefore recommended including a drug product on the reimbursement list as soon as it has obtained marketing authorization and a price has been set, according to the provisions of Order 861/2014.

With strong regional and local expertise in Romania, GHMC offers invaluable insight to achieve market access, reimbursement and marketing success.



AT-A-GLANCE

Singapore has one of Asia's fastest growing biopharma industries, with forecasts revealing a two-fold trajectory of \$68.7 billion in market size by the year 2029, and the country's healthcare spending expected to contribute to 5.9 percent of its GDP and rising. With active public-private partnerships enabling a reliable and supportive ecosystem for manufacturing, strong investments toward upgraded research infrastructure, and continuous diversification into advanced manufacturing and digital solutions, Singapore's healthcare sector is poised for rapid growth.

There is tremendous opportunity for pharmaceutical and biotech manufacturers in Singapore, but opportunity breeds competition, with more than 50 biopharma companies having R&D or corporate operations there. For that reason it is essential that pharmaceutical companies effectively communicate their value stories and distinguish their products as being worthy of reimbursement and access in an increasingly crowded market.

SINGAPORE'S PAYER STAKEHOLDERS

CONSUMERS

Singapore's citizens have universal healthcare coverage through a variety of public and private providers. For private insurers, premiums are paid entirely out of pocket, but public insurers offer lower government subsidized rates at the cost of not reimbursing some treatments. Ultimately, 60 percent of healthcare costs for patients come out of pocket as opposed to pure public subsidies. This multi-pronged approach delivers affordable healthcare through the following providers and funds:

- **Direct Government subsidies** on certain medicines.
- **MediShield Life** - The basic health insurance plan administered by the Central Provident Fund (CPF) of Singapore. MediShield Life provides universal coverage for Singaporean citizens. MediShield offers options with higher claim limits for hospital bills and some outpatient treatments in exchange for higher premiums.
- **Private Integrated Shield Plans** - In addition to MediShield Life, there are plans provided by private insurers that often have more expansive coverage.
- **Medisave** - Every citizen contributes between 4 to 10.5 percent of his or her monthly salary to a Medisave account (percentage varies with the individual's age and yearly income). The monthly contribution goes toward future personal healthcare expenses or those of an immediate family member.
- **Medifund** - Medifund provides a safety net for patients who face financial difficulties in paying off their medical bills, even after tapping every other resource available.

MINISTRY OF HEALTH (MOH)

Regulation of the healthcare industry comes under the purview of the Ministry of Health (MOH). The MOH is also the chief authority for determining what medicines, medical devices, and surgeries will be reimbursed by MediShield and by how much healthcare services will be subsidized. Aside from subsidizing healthcare services and governing reimbursement strategy, the MOH distributes grants to innovators whose products in development offer improved efficacy over existing options. This grant process can serve as an initial point of access for innovative products whose price would otherwise disqualify them for reimbursement.

GROUP PROCUREMENT OFFICE AND GROUP PURCHASING OFFICE

These agencies support SingHealth and the National Healthcare Group (NHG), two of the largest government hospital systems, in the bulk purchase of required drugs, medical and surgical equipment and other critical healthcare supplies. Because there is no direct government regulation of prices in Singapore, the collective purchasing power of these hospital networks is the key factor in keeping prices low.

- Private hospitals have more leeway in the purchase and dispensation of medications and devices.

IMPORTANT POINTS TO KEEP IN MIND

Depending on the risk classification of a drug, the target turn-around time for product registration can take anywhere between 50 and 270 working days. Drugs that have been approved in foreign markets can be placed in an abridged evaluation process.

- Private providers often procure drugs at a much higher cost than their peers in the public sector, due to less collective bulk purchasing powers. At the same time, private hospitals and practices are more willing to administer high cost products that the public system considers inefficient.
- Drugs that are listed under the “Standard Drugs List” or “Medication Assistance Fund” are either heavily subsidized or priced at no more than \$1.00 USD per week. The standard drug list is modeled after the WHO essential drug list, but with modifications to suit local disease profiles and practice. It is reviewed on an annual basis by the Drug Advisory Committee

IMPLICATIONS FOR INDUSTRY

Singapore can be an excellent point of entry to the Asian healthcare market due to the well-established existing healthcare infrastructure and the free-trade agreements between Singapore and its neighbors. This eases the process of achieving regulatory approval and expanding a product’s access into the rest of Asia.

The Health Sciences Authority (HSA) strictly monitors safety and efficacy of products as well as modifies buying practices to ensure that drug prices remain relatively affordable for the general population. The marketing and promotion of innovative products is also tightly controlled. For these reasons, local experience is critical to developing a credible value story for products entering the healthcare market in Singapore. Being able to negotiate approval and access with the HSA and MediShield Life, as well as understanding the nuances of post-launch product support and marketing is the key to taking advantage of the opportunities present in the market.



AT-A-GLANCE

In South Africa, the public sector serves the healthcare needs of 84 percent of the population (42 million people) but only accounts for 16 percent (or R6.1 billion) of the total pharmaceuticals expenditure in the country and has access to 2,400 product lines. Public sector medicines are procured through tenders that are administered by the National Department of Health (DoH). Public hospitals can also initiate procurement of medicines from manufacturers and importers through tenders or quotation systems to cater for their own needs. Public healthcare is financed by the government, primarily through taxes.

SOUTH AFRICA'S PAYER STAKEHOLDERS

South Africa's healthcare system is comprised of a public and private sector. Currently, all citizens can access public hospitals, with or without medical insurance. Persons able to afford private medical insurance (approximately 16 percent of the population) do so through Medical Aid Schemes. These plans, which are supervised by the Council of Medicaid Schemes (CMS), maintain their own medicines lists, and usually cover generic medications in full. Branded medicines are subject to varying co-pay amounts, depending on the therapeutic category and plan purchased. The South African Government plans to fully implement a National Health Insurance (NHI) scheme by 2025.

IMPORTANT POINTS TO KEEP IN MIND

PRICING AND REGULATION

Prior to the advent of democracy in South Africa in 1994, the pricing of medicine was largely subject to market forces, with the result that multinational pharmaceutical companies were free to determine the price at which they sold their products in the country. Innovator brands dominated the market while generics held limited market share. Pharmaceutical companies promoted their products directly to doctors and pharmacists, and would offer samples, bonuses, discounts, rebates, and other incentives to encourage the prescription or dispensing of a particular product. This is believed to have led to doctors often prescribing more expensive medicines. In addition, pharmaceutical companies were able to discriminate amongst clients based on volume purchases and other considerations.

Furthermore, due to pharmaceutical companies' ability to discriminate between customers, patients in poor and marginalized areas ended up paying more for medicines than patients in more affluent areas that were more likely to benefit from price and volume discounts. In 1994, the new democratic government undertook to reform the healthcare system. The drafting of the National Drug Policy (1996) sought to increase access to safe, affordable and quality medicines for all South Africans, and laid the foundation for subsequent revisions to legislation and regulations to reduce prices and improve access to pharmaceutical products.

Amendments to legislation in 1997 saw significant changes to the way pharmaceutical products were supplied and marketed in South Africa. In particular, the amendments made provision for the importation of medicines by companies other than the patent holder, prohibited sampling medicines, bonuses, rebates and any other incentive schemes, and made the generic substitution of products mandatory.

The amended legislation further called for the establishment of a Pricing Committee, which was tasked with correcting the pricing distortions in the market by developing a transparent pricing system for all medicines and scheduled substances sold in the country. To this day, the prices of drugs and devices are regulated by this Committee, which consists of 18 members from different industries and professional fields.

This led to the introduction of a Single Exit Price (SEP) regulatory framework in 2004. Under the SEP regime, the price at which manufacturers sell to pharmacies is regulated and cannot be varied according to volume sold. Manufacturers are obliged to supply medicines to wholesalers at the SEP plus logistic fees, and pharmacists must dispense all products to patients at SEPs plus dispensing fees. The objectives of SEP are to ensure price transparency and that manufacturers sell medicine at one price to all customers in the price sector regardless of order size, consumption levels or customer profile. Only scheduled medicines are subject to SEP (Schedule 1-7).

The Minister of Health (through the Pricing Committee) determines an annual percentage increase of SEP that is uniformly applied to all products. In exceptional circumstances (e.g. raw material cost increase), the Minister of Health may permit ad hoc price increases under Regulation 9 of the Medicines Act.

The process to obtain authorization to develop, test, and market a drug, biological or medical device is regulated under The South African Health Products Regulatory Authority (SAHPRA) and the Medicines Act. If approved, a market authorization is valid for five years. The sponsor must submit a renewal request at least 180 days before the license is due to expire.

IMPLICATIONS FOR INDUSTRY

SCOPING STUDY INTO LIFE-SAVING DRUGS

The Competition Commission of South Africa (CCSA) conducted an internal scoping study in May 2017 following widespread complaints about the price of pharmaceutical products, in particular of “life-saving” drugs, and increased pressure from non-Government Organizations (NGOs) for the South African government to institute reforms on patent laws to make life-saving drugs more affordable. The scoping study considered the pricing dynamics as well as identified any potential issues associated with ‘life-saving’ drugs used in the treatment of HIV/AIDS, cancer, hepatitis B and C, and diabetes. Some of the key findings from this study concluded that South Africa was amongst the cheapest for certain drug treatments and the SEP regulatory framework has been successful in constraining the prices charged by manufacturers and retailers.

It is also worth noting that following the 2017 scoping study, the CCSA has decided to broaden its scope of assessment and consider all pharmaceutical drugs whose prices are potentially excessive in South Africa with priority focus on drugs that have high impact in the society (i.e. drugs that are used to treat prevalent diseases in South Africa). The project is still in the early stages.

As the healthcare system evolves in South Africa, GHMC can help you engage with key stakeholders to achieve market access success.



AT-A-GLANCE

South Korea has one of the largest pharmaceutical markets in Asia, with more than 50 million Koreans receiving prescription drug coverage under the single-payer National Health Insurance Program (NHI). The NHI is under the purview of The Ministry of Health and Welfare (MOHW), which also oversees the Korean FDA, responsible for drug approvals, and the Health Insurance Review and Assessment Service (HIRA), which determines a drug's reimbursement. Most drugs that receive approval by the Korea Food and Drug administration are automatically added to the insurance-reimbursement list making it one of the most robust prescription drug lists in the world with 21,000 drugs approved for reimbursement.

SOUTH KOREA'S PAYER STAKEHOLDERS

The NHI provides health insurance for 97 percent of the South Korean population, while the remaining 3 percent, primarily senior citizens, are covered under the Medical Aid program. The NHI is funded by worker payroll taxes and employer contributions.

In the NHI, co-pay is determined based on the patient's financial need, and coverage is guaranteed. The dominant method of payment is reimbursement of fee-for-service, and no Korean citizen covered under the NHI pays completely out-of-pocket for approved medication and procedures. However, the NHI generally has higher co-payments rates of 30 to 60 percent for outpatient procedures, and 20 percent for inpatients. This expense is mitigated for those who receive treatment for cancers and orphan diseases with a reduced payment rate of 5 to 10 percent.

On average, government spending on prescription drugs and medical expenditures has been on the rise due to an aging population. These increased expenses have led the Korean government to take active steps towards reducing the volume of drugs used as well as bringing down drug prices, with a 0.7 percent reduction in health expenditure as a percent of GDP from 2018 to 2019.

IMPORTANT POINTS TO KEEP IN MIND

In South Korea, the reimbursement decision-making process has three distinct steps:

1. The HIRA assesses appropriateness of the reimbursement within 150 days of application
2. The NHI determines the maximum price via negotiation within 60 days
3. After further review the MOHW announces the price to the public within 30 days

Manufacturers must provide pharmacoeconomic evidence to show proof of value of a new drug. HIRA then reviews for the drug's clinical benefit, cost effectiveness, budget impact based on expected sales, international reference price and the general impact on public health to determine reimbursement.

Unfavorable reimbursement decisions from the NHI can be appealed. The process is as follows:

1. The manufacturer submits an application for review to the HIRA
2. The HIRA internal review board has 30 days to review before submission to the NHI for secondary review
3. The results are returned to the manufacturer within 150 days

The NHI desires drugs that are of a high quality, accessible to patients, cost-effective, and encourage the manufacturer to invest revenue in the research and development of new treatment options. To this extent, technologies transfers and in-country investment can often weigh in favor of a company during the pricing and reimbursement negotiation process.

It is important to consider that the MOHW does try to meet the growing demand and expectations of quality healthcare, and demonstrated value is important. Consumers are also invested in the purchase of healthcare services, as they contribute to the system via premiums and co-pay. Having politically active consumers on board with your value story can pressure the MOHW and HIRA into making favorable reimbursement decisions.

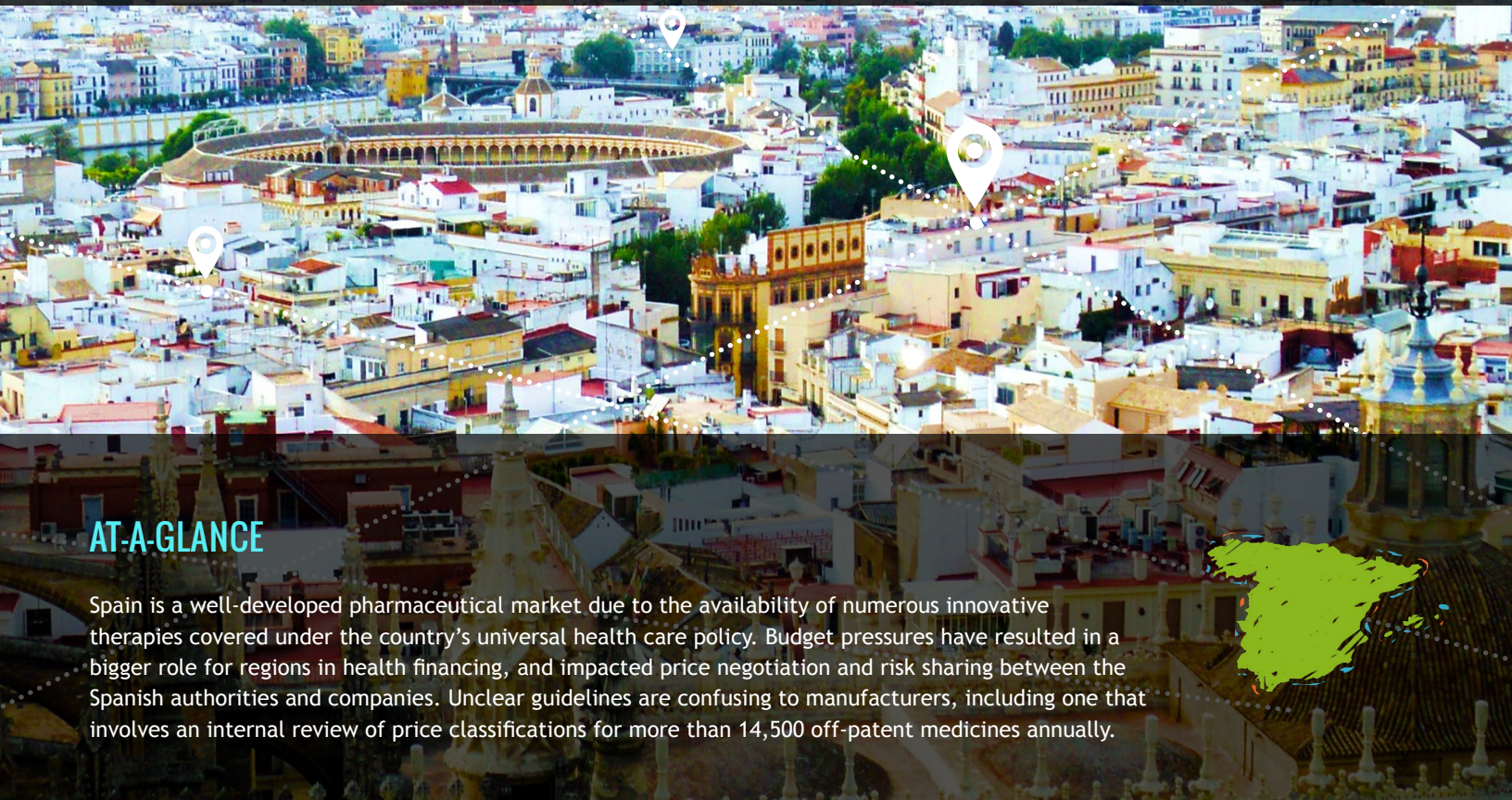
Cost-containment measures are widely practiced in South Korea. For example, when pricing a new drug, South Korean authorities take into consideration the price of the drug that the new product is intended to replace as well as its cost in other countries. Supply-side measures such as price cuts in the years after launch are also common. Finally, at the end of a product's lifecycle, a tiered pricing system is implemented when a drug goes off patent that gradually lowers the price of the branded product until it is equal to that of a generic.

IMPLICATIONS FOR INDUSTRY

In recent years, mounting pressure on the sustainability of the NHI has sparked proposed reforms to the reimbursement structure, including the possible creation of a separate elderly care system, and integration of economic valuations into delivery, approval and pricing of medical devices, procedures and pharmaceuticals. As reforms are implemented, a flexible access strategy will serve prospective new medicine entrants into the Korean market well.

Pharmaceutical companies launching new products in Korea should not only be prepared for market access success, but also for local communications compliance. Having a strategy to communicate value not just with the MOHW and the NHI but also the Korean public is critically important. GHMC can help you effectively articulate the value of your new product to the Korean market in innovative but compliant ways.





AT-A-GLANCE

Spain is a well-developed pharmaceutical market due to the availability of numerous innovative therapies covered under the country's universal health care policy. Budget pressures have resulted in a bigger role for regions in health financing, and impacted price negotiation and risk sharing between the Spanish authorities and companies. Unclear guidelines are confusing to manufacturers, including one that involves an internal review of price classifications for more than 14,500 off-patent medicines annually.

SPAIN'S PAYER STAKEHOLDERS

The government is the primary payer stakeholder, and the National Health Service oversees new drug approvals via the National Agency of Medicines and Medical Devices. The Directorate General for Pharmacy and Health Care Products makes decisions about prices.

Unique to Spain is the role of the 17 regional Autonomous Communities, an administrative division that sits above the provincial level but below the national level. Each Autonomous Community determines its own budget and reimbursement guidelines. Supporting the costs of treatments approved at the national level is a major responsibility for the regional payer authorities. This is important, because, although a drug can be approved nationally, each Autonomous Community has the authority to decide if it will be distributed regionally.

The Interministerial Drug Pricing Commission (*La Comisión Interministerial de Precios de los Medicamentos*, or CIPM) is the entity that determines drug pricing at the national level. It is led by the Ministry of Health in collaboration with other departments, such as the Ministry of Finance. Although the CIPM is a state entity, the fact that the Autonomous Communities are ultimately responsible for facing the cost of medicines means that they have gained influence in the CIPM decision-making in recent years. While some years ago only three Autonomous Communities participated on a rotating basis, now all 17 of them participate.

IMPORTANT POINTS TO KEEP IN MIND

The Directorate General for Pharmacy and Health Care Products can take up to six months to act on a company's dossier for product pricing and reimbursement. In the two-step evaluation process, the Directorate committee determines whether the medicine belongs on the "positive list" or the "negative list."

CRITERIA FOR POSITIVE LIST

- Manufacturer's pricing proposal
- R&D costs
- Cost comparison with other products in Spain (cost per day)
- Price of the product in other EU countries

If a product ends up on the "negative list," the manufacturer is free to set its own price...and kiss its reimbursement chances goodbye. On the other hand, for products on the "positive list," the committee sets a price in each drug category. The process of making this internal determination is not transparent.

IS THIS REALLY "POSITIVE?"

A simple listing on the "positive list" does not guarantee a favorable price point for a company's product. In fact, nearly all new price determinations in Spain today (80 percent) are based on external reference pricing for innovative products.

While reference pricing is common across Europe, it is not always clear in Spain which country's price is to be used as the reference price. The committee may decide based on the lowest available price in the EU.

If a similar comparator exists on the Spanish market at the time of a pricing decision, the authorities will use "internal reference pricing." This means a competing product's price inside Spain serves as the reference price.

CONSIDERATIONS FOR A PREMIUM PRICE

- Prove added therapeutic value over the existing medicine
- Enter into a risk-sharing agreement with the committee
- Negotiate bulk purchases

IMPLICATIONS FOR INDUSTRY

Spain has experienced a rapid transformation in drug pricing and reimbursement over the past years. Even after a reimbursable price is achieved, you may still be subject to cost and demand containment measures before your product reaches the patient. The right preparation and strategies are essential at each of these points along the way.

Companies must also be prepared to engage decision makers at the national level and among Autonomous Community stakeholders. Each region can vary greatly by culture, population and budget.

A clear understanding at the community level is critical, and companies benefit from regional market access, stakeholder engagement and communications expertise to stay on top of all the new developments.



AT-A-GLANCE

The Swedish healthcare payer system is highly decentralized, with 21 self-governed County Councils, each with its own administrative set up for management of drug procurement, use and cost control. Having a drug included in the national reimbursement scheme is only the first step in achieving full access to the Swedish market.

A pharmaceutical company must next convince each regional drug committee of the value of the drug and provide proof that including it will have a reasonable and manageable impact on the regional payers' budgets. Increasingly, payers require real-world data confirming the alleged benefits of the reimbursed drug.

SWEDEN'S PAYER STAKEHOLDERS

NATIONAL DENTAL AND PHARMACEUTICAL BENEFITS AGENCY (TLV)

The Swedish government subsidizes prescription medicines and medical device consumables within a high-cost threshold through funding of the County Councils' budgets. Medicines used for inpatient care are paid in full by the County Councils. The National Dental and Pharmaceutical Benefits Agency (TLV) determines medicines to be subsidized and included in the high-cost threshold. The high-cost threshold refers to the system in which the patient pays a gradually decreasing portion of the medicine or consumable cost prescribed by the doctor. The maximum cost for a patient in the high-cost threshold system is 2,200 SEK during a 12-month period. The State finances the County Councils' expenses for prescription medicines that are covered by the reimbursement scheme through an annual grant.

To achieve reimbursement for a drug in Sweden, the pharmaceutical company must submit an application to the TLV, stating the proposed price of the product and providing health economic documentation. Companies frequently include an analysis of the drug's impact on the healthcare system. TLV prepares a dossier for presentation to the Pharmaceutical Benefits Board, comprised of community clinical experts, which renders a decision regarding reimbursement.

The company's application is approved if TLV determines the requested price is justified and if the pharmaceutical product delivers value in terms of improved health, often measured by Quality Adjusted Life Years (QALY). The reimbursement decision is based on value, and Sweden often applies the Value-Based Pricing of pharmaceuticals. TLV regularly reviews the reimbursement status of medicines to determine if they should remain in the reimbursement system. A decision by TLV may be appealed in an administrative court of law.

COUNTY COUNCILS

Once a drug clears the reimbursement hurdle at the national level in Sweden, the pharma company must next convince the County Councils to adopt it as well. The Councils are the actual payers of the reimbursed medicines, and the degree and rate of a drug's local uptake in the reimbursement scheme may vary between regions. County councils have different budget-planning mechanisms and varying interpretations of TLV assessments.

IMPORTANT POINTS TO KEEP IN MIND

The influence of the County Councils in the reimbursement decision process can be significant, especially if it considers new, expensive drugs.

TLV is working to find collaboration models with the Swedish Association of Local Authorities and Regions (SALAR) to begin price negotiations, which today are not allowed for drugs included in the reimbursement scheme.

The Swedish Process for Managed Introduction of New Drugs headed by the New Therapies (NT) Council of SALAR is a collaboration model that includes not only price negotiations, but also a standardized protocol for the introduction and follow up of actual clinical outcome and risk-sharing agreements.

IMPLICATIONS FOR INDUSTRY

Market access in Sweden requires that companies successfully prove and communicate the added benefits of a drug in several dimensions: clinical outcomes, cost effectiveness and budget impact.

It is critical for companies to have a communications partner familiar with market access in Sweden, and with the necessary expertise to successfully target and meet payers' needs both on national and regional levels.



AT-A-GLANCE

England's health institutions — the National Institute of Health and Care Excellence (NICE) in particular — are key influencers not only in other UK countries, but across Europe and the rest of the world. England's payer decision makers seek to reward innovation while ensuring “value for money spent.” This occurs through several appraisal processes, which are used depending on the type of medicine.

Since January 2002, it has been mandatory for National Health Service (NHS) organisations in England (and Wales) to provide funding for medicines and treatment recommended by NICE in its Technology Appraisal guidance. Furthermore, NHS organisations must review clinical management following publication of NICE clinical guidelines.

The most frequently used process is the NICE Health Technology Assessment (HTA). However, a positive HTA does not always mean a medicine will see full uptake locally, even with NICE stating that local payers have a statutory responsibility to make funding available within the recommended timeframe.

And when NICE determines a medicine is not cost-effective, manufacturers must be prepared to work even harder to get medicine uptake through seeking patient access schemes (PAS), risk-sharing agreements and in-confidence discounts with payers.

ENGLAND'S PAYER STAKEHOLDERS

Once NICE determines a new drug to be cost effective, local-level stakeholders in clinical commissioning groups (CCGs) and hospital trusts implement NICE's guidance. CCGs, led by general practitioners, organise the delivery of approximately £75bn of England's NHS budget. Specialised commissioning (approximately £20bn of the NHS budget) is delivered nationally instead of regionally through NHS England. NHS England, run by the UK Department of Health, is legally in charge of the UK-wide NHS budget and decision making. The NHS in England spends approximately £16bn on drugs, split between GP prescriptions (~£9bn) and hospital treatment (~£7bn), of which about half is directly reimbursed by NHS England's specialised services budget.

WORKING WITH NICE

While NICE does not have a formal role in price setting, the panel gives the critical stamp of approval leading to National Health System use and reimbursement. NICE is the main health technology assessment (HTA) body in England, determining clinical and cost effectiveness of pharmaceutical and biopharmaceutical products. NICE uses quality-adjusted life years (QALYs) to measure burden of illness in terms of shortfall of life and length, and is derived via an incremental cost-effectiveness ratio, or ICER.

The need to prove cost effectiveness to NICE before a drug can be recommended for use by the National Health Service encourages companies to negotiate the price paid to satisfy NICE's criteria. This has also prompted companies to offer deals that have an impact on pricing.

IMPORTANT POINTS TO KEEP IN MIND

Medicines that have been approved but have not yet received NICE guidance see little-to-no uptake, known as “NICE blight.” NHS organisations can technically start using the drug but many wait for NICE guidance, which can take between six months to, in some cases, two years.

For most new medicines, the decisions on use are made at a local level by drugs and therapeutic committees, which include healthcare providers as well as commissioners. Medicines are then further assessed within local health economies before being approved for CCG and hospital drug formularies. With around 200 CCGs, this model means medicine uptake can be inequitable and slower than anticipated.

New medicines where decision on use is made at the national level, through specialised commissioning, also have their own problems. In many cases, this national process is seen as a ‘you only get one chance at approval’ route.

IMPLICATIONS FOR INDUSTRY

Demonstrating the value of a new drug relative to standard of care, which can differ between countries and global regions, and creating effective market access and communications strategies are critical to realising maximum commercial value in England. The Pharmaceutical Price Regulation Scheme (PPRS) plays an important role in shaping the relationship between industry, the NHS and the English healthcare landscape. Knowing the ins and outs of this policy and how it plays out at a local, regional, national and UK-wide level is essential. Finally, identifying and communicating to all relevant key market stakeholders is equally important.

NICE'S ONGOING ASSESMENT

During NICE's HTA appraisal process, manufacturer data is submitted from protocol-driven clinical trials, which are closely monitored under ideal conditions. Post approval, NICE will undertake ongoing assessment at regular intervals and if it finds that the negotiated patient access scheme or criteria differ from real-world outcomes, your product could get dropped from formulary lists. Therefore, it is critical to continue to communicate the value of your product throughout its lifecycle.

Having the right value communications strategy before, during and post-launch is vital for commercial success and maintenance of drug list position. The GHMC team has years of experience in England, the UK and EU markets, and can offer valuable insights to your teams.





AT-A-GLANCE

There is no Northern Ireland equivalent to England's National Institute of Health and Care Excellence (NICE), the Scottish Medicines Consortium (SMC), or the All Wales Medicines Strategy Group (AWMSG). In practice, most NICE decisions are implemented locally, meaning that a positive NICE decision should lead to reimbursement in Northern Ireland. Though this should not affect a brand's overarching UK launch and communications strategy, it is important to know the local stakeholder bodies that operate in Northern Ireland and how they engage with NICE and the National Health Service (NHS).

NORTHERN IRELAND'S PAYER STAKEHOLDERS

In Northern Ireland, the NHS is known as Health and Social Care (HSC). It provides health services and medicines free of charge to residents. These services are delivered by five HSC trusts, distributed by region: Belfast, South Eastern, Southern, Northern, and Western.

Since 2006, the Department of Health, Social Services and Public Safety (HPSS), a part of HSC, reached a formal arrangement in which it reviews NICE decisions to determine whether they are locally applicable. Any required amendments are made, and the decision then ratified and reflected by local HSC trusts. The policy methodology, however, states that it is not a reassessment of NICE evidence but rather a proofing.

IMPORTANT POINTS TO KEEP IN MIND

There is no separate Health Technology Appraisal (HTA) body in Northern Ireland that assesses medicines for use within the HSC. Northern Ireland essentially adopts NICE guidance after confirming it is applicable locally, despite NICE not formally considering Northern Ireland when developing its guidance.

IMPLICATIONS FOR INDUSTRY

For the purposes of reimbursement, you may consider Northern Ireland to be similar to a region of England in that it will mainly adopt NICE guidance and has no set, national methodology for conducting HTA in the absence of NICE guidance. However, awareness of the local context and identification of stakeholders that apply NICE guidance across the UK will help ensure smoother product launch and uptake.

The GHMC team has years of experience across the United Kingdom, as well as the European Union, and can offer valuable insights to your marketing, communications and market access teams.



AT-A-GLANCE

Although companies might not typically consider the UK's individual member countries as separate geographies for launch and communications planning purposes, those seeking to maximise chances for success will understand the importance of Scotland in determining market access for the region. Here is why: the name of the game in often-overlooked Scotland is speed. While the Scottish Medicines Consortium (SMC) may not be as well-known as the National Institute of Health and Care Excellence (NICE), its clear and relatively rapid process means it often publishes decisions significantly earlier than NICE does. This can influence reimbursement considerations in other markets both inside and outside of the UK. Those who know the interplay between Scotland's payer stakeholders and their UK and European counterparts will be better positioned to achieve launch success across the region.

SCOTLAND'S PAYER STAKEHOLDERS

National Health Service (NHS) Scotland is composed of 14 regional Health Boards. While the UK Parliament in Westminster sets NHS Scotland's overall budget, the Scottish Parliament oversees allocating funds across the Health Boards. Each Health Board has an Area Drug and Therapeutics Committee (ADTC), which advises on the use of medicines in the geographic area.

The SMC was established in answer to the problem of inequitable access, in that some medicines are available in some areas but not in others within the same country. SMC is Scotland's answer to the NICE in England and Wales. The SMC is essentially a collaboration between ADTCs, which distinguishes it from a statutory body such as NICE.

Products recommended by SMC are included in ADTC formularies, and patients in Scotland are granted access at a cost reimbursed by the NHS. Conversely, products or indications rejected by SMC are not routinely reimbursed.

The SMC process largely evolved as an attempt to create a more pragmatic and streamlined approach compared to NICE. Now, SMC can publish advice on new technologies faster than its English neighbour. In many cases, it is a precursor to NICE decisions.

The SMC also has a very clear and narrow remit compared to NICE. The SMC is essentially tasked with providing advice on any new medicines or new indications of existing medicines which are launched in Scotland. SMC may recommend a product for use as per the terms of its license, recommend a product for restricted use, or not recommend a product for use within NHS Scotland.

IMPORTANT POINTS TO KEEP IN MIND

The SMC process was initially so successful that NICE essentially copied it for its Single Technology Appraisal (STA) process - a new “one technology, one indication” process. At the time, SMC concurred with NICE in a large majority of cases while taking considerably less time and money to develop. Scotland’s STA decisions stand, regardless of NICE decisions.

SMC is relatively pragmatic and will work with sponsors to help them make the strongest case; however, demonstrating cost effectiveness against current Scottish medical practice is important. Both NICE and SMC favour quality-adjusted life years (QALYs) as a method for comparing the benefit of different treatments across different therapeutic areas. SMC decisions are often published within four months of the sponsor’s submission being received.

IMPLICATIONS FOR INDUSTRY

The main factor to be aware of is that SMC has a remit to appraise all new medicines and new indications. Therefore, if you seek to launch a product in Scotland and want reimbursement within the NHS you will need to prepare a submission for SMC.

The SMC process is relatively straightforward; however, knowing the payer stakeholders and establishing a communications strategy for these players is critical. It is also very important to realise that SMC will assess the technology against current Scottish clinical practice. This may not reflect the comparator technologies used in clinical trials, or even medicines being used within their licensed indications. Rather, SMC will appraise technologies against the reality of what is happening in Scottish clinics.

The set timings of the SMC process can help guide launch planning. There is the opportunity for a positive early news story by submitting in advance of license; conversely, a submission can be delayed to avoid a negative decision before other markets have published advice.

Telling your value story early and often will smooth the pathway for access and maximum reimbursement for your product. The GHMC team has years of experience in Scotland, all the other countries of the UK, and other EU markets and can offer valuable insights to your marketing and market access teams.



AT-A-GLANCE

Although Wales has the power to make reimbursement decisions independently, its National Health Service (NHS) is closely aligned with England's health service. Payer decision maker bodies in Wales represent a potential complementary, alternate route to reimbursement where a National Institute of Health and Care Excellence (NICE) decision may be delayed. As with the Scottish Medicines Group (SMC), Wales's technology evaluation body is more flexible than NICE regarding timings, and the manufacturer plays a key role in setting appraisal timings and scope.

WALES' PAYER STAKEHOLDERS

NHS Wales covers health expenditures, including medicines, through seven Local Health Boards (LHBs) and three local NHS Trusts based on geography. The UK Parliament in Westminster sets the NHS Wales funding level annually. Established in 2002, the All Wales Medicines Strategy Group (AWMSG) advises the Welsh Assembly Government (WAG) on medicines management and prescribing. It originally focused on high-cost treatments only (i.e. those costing above £2000 per patient per annum), filling the gap between launch and publication of NICE guidance. It has since expanded its remit, and now has capacity to conduct 32 appraisals a year.

Despite this, the AWMSG is not intended to be an alternative to NICE, and sponsors are first required to submit information about a product so that AWMSG can decide whether a full submission is necessary. In general, AWMSG is unlikely to appraise a product that is on the NICE technology-assessment work programme unless there is likely to be a large delay before publication of the NICE decision (more than 18 months). The AWMSG appraisal process takes around six months to publish a decision. In contrast to the NICE process, the AWMSG appraisal meeting is held in public.

For AWMSG recommendations, a medicine should be available no later than 60 calendar days after publication of the decision (following ratification of the recommendation by the Welsh Government). A three-month timescale for the introduction of a medicine for use is allowed for in exceptional circumstances, where the scale of service planning required will need longer than two months. In general, AWMSG is intended to complement NICE decisions rather than replace them. Many new technologies will not require the sponsor to submit to AWMSG on their behalf, although this may change in the future as more high-cost treatments are introduced.

IMPORTANT POINTS TO KEEP IN MIND

AWMSG was designed to help “fill the gaps” around NICE decisions, and where NICE will review a medicine, a separate AWMSG review is unlikely unless a long delay in the NICE process is foreseen. It initially requires sponsors of a technology which may meet their criteria for a full submission, to provide more information so AWMSG can decide whether an appraisal is necessary. The AWMSG has neither the resources or remit of NICE (England) or the Scottish Medicines Consortium (SMC) and has only recently increased capacity to undertake up to 32 appraisals a year.

IMPLICATIONS FOR INDUSTRY

In most cases, AWMSG submissions are not required when new products are introduced. The role of AWMSG is increasing, and as more high-cost treatments are introduced it may play a greater role in providing quick advice to NHS Wales in advance of a NICE decision. GHMC can help you assess whether an AWMSG submission is necessary and take the required steps to do so.

Telling your value story early and often will smooth the pathway for access and maximum reimbursement for your product. The GHMC team has years of experience in Wales, all the other countries of the UK, and other EU markets and can offer valuable insights to your marketing and market access teams.



AT-A-GLANCE

The United States is a highly competitive retail market of prescription pharmaceutical products and has only become increasingly crowded with the recent discussions and proposals aimed to limit the runaway, often unchecked increases in drug prices that have affected patients with many serious conditions, regardless of whether they have health insurance or not. While federal and some state regulations have initiated steps to limit drug pricing, most prices in the U.S. still reflect what the manufacturer thinks the market is willing to pay. However, to obtain optimal reimbursement for your product, you must understand that the ecosystem is complex – one of the most complex in the world.

U.S. PAYER STAKEHOLDERS

The three primary U.S. payers are governments, employers and individuals. The public sector is the largest single payer, but private payers cover more than half of those who have health insurance. The Affordable Care Act (ACA), or “Obamacare,” has increased the government’s payer role, but it has not yet surpassed the size of the private system.

The combined federal and individual state governments pay prescription drug benefits primarily through one of two public insurance programs, Medicare and Medicaid.

MEDICARE

Medicare is the federal health insurance program for people over age 65 and people under 65 with long-term disabilities. It is comprised of three parts:

1. Part A (hospital services, supplies and drugs dispensed during inpatient care)
2. Part B (outpatient clinics, doctor offices and payment for some cancer drugs)
3. Part D is the Medicare prescription drug benefit

While most prescription drugs are covered under Medicare Part D, prescription drugs administered by your physician, a dialysis facility, and outpatient prescriptions, such as oral chemotherapy, are covered under Part B Medicare.

MEDICAID

Medicaid is a joint federal and state program that, together with the Children’s Health Insurance Program (CHIP), provides health coverage for some low-income people, families and children, pregnant women, the elderly, and people with disabilities. Each of the 50 states is responsible for the majority of funding for Medicaid, and each determines its level of coverage. Due to the size of the program, medicines covered under Medicaid are subject to government-mandated prices and receive extra rebates from manufacturers to ensure that states get the best price for drugs. As manufacturers compete for business, they frequently offer discounts even beyond these government-mandated “best prices.”

EMPLOYERS

Employment based coverage is the largest sponsor of private health plans in the United States Organizations (companies, government agencies and non-profit organizations) usually purchase group health plans through large commercial providers such as for-profit United Healthcare, Humana, Aetna and others, as well as non-profit organizations such as Blue Cross Blue Shield.

INDIVIDUALS

Individuals pay for prescription drugs by cost sharing (insurance premiums and co-pay or coinsurance when receiving actual care) for part of their cost of care. The healthcare cost, including prescription drugs, is shared between employees and their employers. An individual can also purchase his or her own plan.

IMPORTANT POINTS TO KEEP IN MIND

Unlike in Europe, there is no U.S. pricing and/or reimbursement authority that determines inclusion, price or treatment course on a health plan's drug list. Reimbursement negotiations and decisions are not transparent; they vary greatly according to the payer channel, therapeutic category, unique product attributes and manufacturer strategy. A manufacturer might negotiate with different payer organizations (health plans) with varying degrees of success.

Due to this fragmented market, payers often contract third-party Pharmacy Benefit Managers (PBMs) to negotiate discounts and rebates for a drug on the U.S. market. Additional discounts are also granted to health plans serving Medicaid and other programs. These interdependent actors add to the complexity of the U.S. pricing and reimbursement ecosystem.

DEMAND DRIVES DRUG PRICES

In the United States, drug companies can adjust their prices according to demand, forecast demand or other market forces. This price change could occur based on additional indications, new entrants or the introduction of a generic, for example. As a result, the United States has become the best case study of a market in which demand-side controls, or utilization management techniques, have become necessary to control payers' health care costs.

Demand control is achieved in a number of ways:

- Benefit (health plan) design, cost sharing programs (influencing manufacturers to offer patient assistance initiatives)
- Formulary decisions informed by Pharmacy & Therapeutics Committees within health plans, possibly the closest thing the United States has to Healthcare Technology Assessment (HTA) reviews

IMPLICATIONS FOR INDUSTRY

The United States is known for having some of the highest drug "sticker" prices worldwide. However, these do not reflect the actual prices to U.S. payers. This often leads to incorrect and unrealistic country-to-country price comparisons by the media, policymakers and the public alike. In fact, pharmaceutical company representatives have been called to testify to policymakers on Capitol Hill to defend their medication prices due to inappropriate list price (ex-factory price) comparisons with ex-U.S. price benchmarks and surging prices.

To avoid these pitfalls, you must position your innovation to succeed with all your stakeholders and audiences. You need a partner who knows the complexities of both the U.S. market access and communications landscape.

In the world's largest pharmaceutical market, there is also tremendous opportunity. GHMC has years of experience in communicating complex U.S. stakeholder and patient access landscapes, positioning products for success and defending innovations against critics.



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