Windrose Consulting Group
Global News Roundup: Q1-Q3 2021

Canadian Government announces several drug pricing reforms to reduce cost of patented drugs

DETAILS

- In 2020, the Canadian Government announced several drug pricing reforms, which are expected to save the healthcare system billions of dollars on the cost of patented drugs; compliance with the new PMPRB (Patented Medicines Prices Review Board) guidelines have been continually delayed due to the ongoing COVID-pandemic, but are expected to be implemented in July 2022
- A key change to the guidelines includes a reform of international reference price (IRP) rules for both new and Grandfathered (authorized prior to August 2019) drugs
  - The countries included in the PMPRB reference basket have been amended so that markets with traditionally high prices (such as the US and Switzerland) have been replaced by markets with traditionally lower prices (such as Spain and Belgium)
  - An interim maximum list price (iMLP) will be set by referencing the median price within the reference basket at launch; however, several re-referencing events are also expected following launch, which may result in further list price erosion over time

INDUSTRY IMPLICATIONS

- Manufacturers must carefully evaluate the implications of the new IRP methodology when launching drugs and medicines globally; however, since prices in Canada are rarely referenced by other markets, the key impact will be on the list price established in Canada itself
- The exclusion of the US and Switzerland from Canada's reference basket will likely result in lower list prices being established for new drugs at launch, but could also result in list price erosion of Grandfathered medicines
- The frequency of re-referencing and the impact that lower list prices may have on net price negotiations is currently unclear, though manufacturers should be prepared for these discussions during price negotiations

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PATENTED GUIDELINES

CANADIAN GOV'T DECISION

Newly formed German Government set to reduce costs to the health system

DETAILS

- The newly formed German government are likely to implement cost-containment measures within the healthcare system, aimed at reducing overall spend; key changes could include an end of free pricing for high-priced drugs, and more stringent evaluation of orphan drugs
- The orphan drug designation (ODD) clause, which guarantees orphan drugs to at least an unquantifiable benefit, is expected to be eliminated as early as April 2022, with orphan drugs being subject to a traditional benefit assessment like all other drugs
- In addition, some government ministers have signalled a desire to shorten the 12-month period of free pricing that manufacturers are currently granted while the benefit assessment and price negotiations are underway

INDUSTRY IMPLICATIONS

- An end to the ODD clause may impede the surge in orphan drug development observed over the past decade, as manufacturer return on investments may be more limited; an additional benefit will be required for manufacturers to negotiate premium prices with the GKV-SV, which will coincide with much more stringent evidence requirements than is currently expected
- Shortening the 12-month period of free pricing may impact manufacturer launch sequencing and drive global price erosion over time
  - Germany is typically prioritized as a launch market, given the ease of access and period of free pricing; however, it may become less attractive for manufacturers to launch in Germany first given the reduced free pricing, and requirement for evidence during pricing and reimbursement negotiations
  - The list price in Germany is heavily referenced by other markets through international price referencing (IRP); a shorter period of free pricing may result in more markets referencing the post-AMNOG price

ADDITIONAL RESOURCES

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PRESS RELEASE AT G-BA

Spain reforms its Therapeutic Positioning Reports (IPTs) to simplify and speed up pricing and reimbursement decisions

DETAILS

- A new pharmaceutical evaluation network called REvalMed-SNS has been set up to co-ordinate the IPT process; REvalMed-SNS comprises teams from General Directorate of Common Portfolio of Services of the National Health and Pharmacy System (DGCYF), AEMPS (Spanish Agency of Medicines and Medical Products), and the autonomous communities (CCAAs)
- The methodology by which IPTs are evaluated has been improved, including development of a scoring system to prioritize reports which reduces timing of evaluations
- In addition, economic evaluation has been incorporated into IPTs, including a proposed cost-effectiveness threshold, cost-minimization analysis, budget impact analysis and long-term health costs and outcomes evaluation (at both a national and regional level)

INDUSTRY IMPLICATIONS

- Time to access in Spain is likely to reduce through the streamlined process, while the engagement of regional committees throughout the IPT evaluation may lead to a more centralized health system
- IPTs will be structured relative to current therapeutic alternatives, there will be greater emphasis on independent, third-party sources of information, and national and regional HTAs may restrict treatment to specific sub-populations
- Introduction of cost-effectiveness analyses may shift Spain from its traditional budget impact archetype towards a more health economic archetype, providing greater hurdles for manufacturers in terms of evidence requirements

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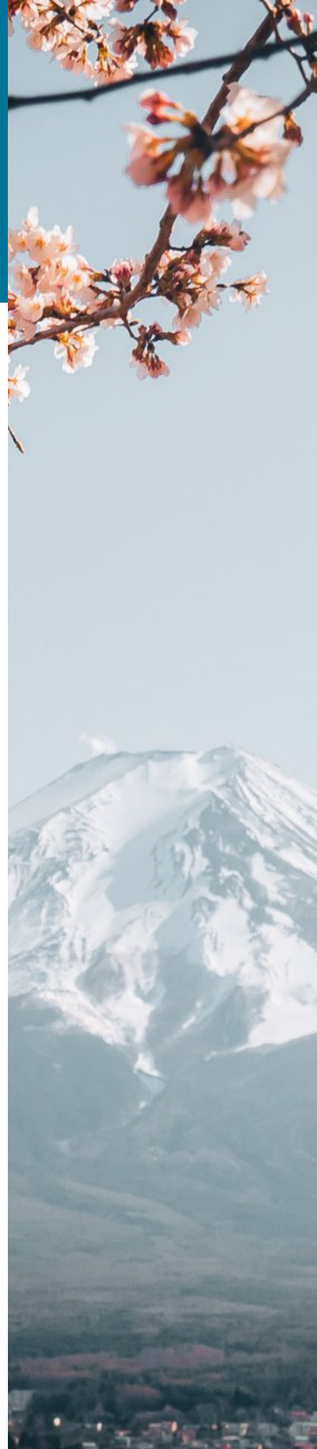
WINDROSE'S TAKE ON IPT

REVALMED SNS PLAN

Japan introduces cost-effectiveness into its health technology assessment (HTA) to limit rising healthcare expenditure



DETAILS

- In April 2019, Japan formally introduced a new cost-effectiveness analysis (CEA) into its HTA in order to limit the spiralling healthcare costs associated with an ageing population, and reimbursement of innovative medicines
- Manufacturers will have 9 months to submit a CEA for high-cost drugs that are already marketed, and newly launched products selected to undergo CEA; price adjustments will be implemented based on ICER thresholds and profitability
- In April 2021, the Ministry of Health, Labour and Welfare (MHLW) published the first price adjustments for several listed agents, including a 4.7% reduction for Novartis' Kymriah, and a 0.5% reduction for GlaxoSmithKline's Trelegy

INDUSTRY IMPLICATIONS

- Despite being a lucrative market that rewards innovation, manufacturers may face challenges when launching new products into the market
- As such, to prepare for future product launches, manufacturers should:
  - Assess if products will need to undergo a CEA early on, and ensure all relevant health economic evidence is available and provided upon dossier submission
  - Assess opportunity to demonstrate superiority over comparators and data to support an associated premium pricing strategy
  - Consider establishing local health economic capabilities to ensure submitted analyses are robust and acceptable

ADDITIONAL RESOURCES

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WINDROSE'S TAKE ON HTA

In Poland, the 2017 policy for Emergency Access to drug technologies has resulted in limited benefit to patients

DETAILS

- Emergency Access to drug technologies is a policy that was introduced in Poland in 2017 in order to improve patient access to expensive, rescue therapies
- However, to date, only a fraction of eligible patients are benefitting under this procedure, estimated to be <10% of total applicants in 2018
- The procedure authorizes the Minister of Health to issue an individual consent to cover the cost of a drug not reimbursed in a given indication, if, 1) it is necessary to save the patient's life or health and 2) provided that all available medical technologies financed from public funds have already been exhausted
    - This procedure is considered provisional, ensuring access to effective treatment while the reimbursement application is being prepared and undergoes subsequent formal assessment by the Agency for Health Technology Assessment in Poland (AHTAPol)

INDUSTRY IMPLICATIONS

- Even with a legislative procedure in place under the Emergency Access scheme, many hurdles exist to patient access
- Manufacturers providing treatments under this scheme may need to consider assisting hospitals with the high administrative and more importantly, budget burden they face when utilizing this pathway

ADDITIONAL RESOURCES

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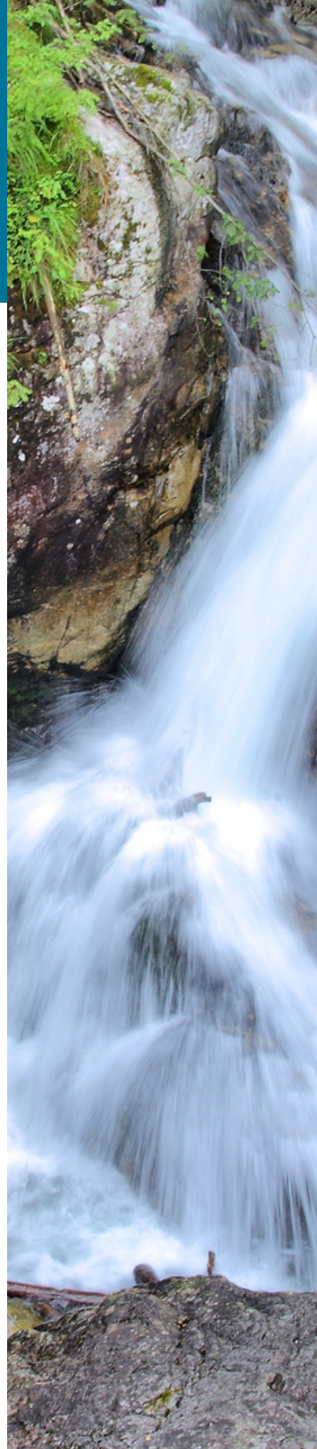
AOTMIT



Saudi Arabia updates guidelines for the pricing of pharmaceutical products

DETAILS

- On January 14, 2021, Saudi Arabia introduced a new pricing policy, updating the guidelines for drug pricing and reducing their external price reference basket
- Without unlocking completely from an external reference pricing system, the Kingdom is becoming more HTA-focused when establishing price
- An informal cost-effectiveness threshold has been introduced, and there is an expectation that the (Saudi Food and Drug Authority) SFDA will evaluate clinical value relative to appropriate comparators

INDUSTRY IMPLICATIONS

- The new shrunken reference basket (from 30 countries to 20) has excluded countries such as Egypt, Turkey, and Argentina, which have caused extreme downward price impact in the past
- Nonetheless, historically, international reference pricing (IRP) rules have been applied informally, and Saudi may still reference countries outside of the reference basket

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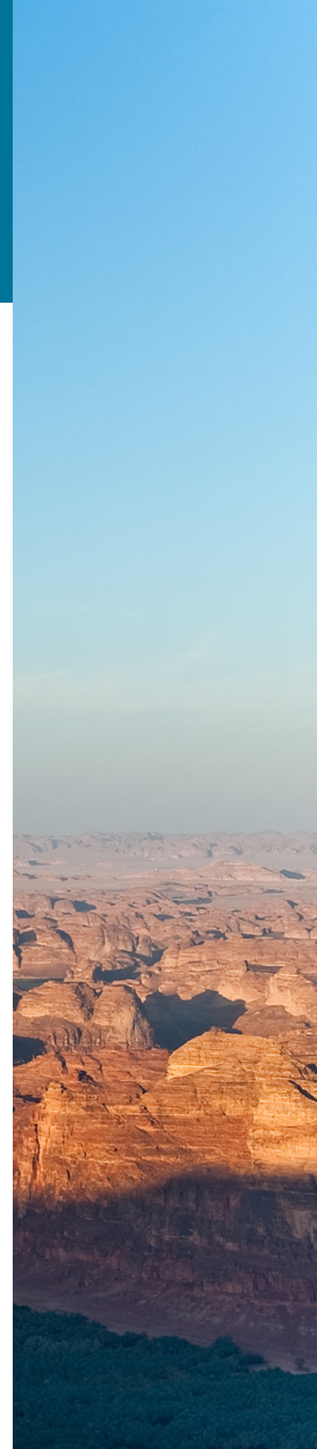
SFDA WEBSITE



China implements its Diagnosis Related Groups (DRGs) pilot scheme nationwide

DETAILS

- As China moves into the simulation and implementation phase of the Diagnosis Related Groups (DRGs) pilot scheme, concern has been raised that the new hospital payment policies could change physician behaviour by creating a focus on limiting costs and length of stay (LOS)
- The pilot of DRGs in 30 major cities across China was officially announced in June 2019 by state administrations including National Healthcare Security Administration (NHSA), National Health Commission (aka Ministry of Health) and Ministry of Finance
- The ambition is to switch from the current Fee-for-Service model to the DRG payment scheme during this year (2021) after a 3-year simulation in the pilot cities

INDUSTRY IMPLICATIONS

- Manufacturers need to be prepared to engage with local experts and opinion leaders to build their drugs into local guidelines and ensure that these clinical pathways are being implemented within the DRG framework over and above limiting hospitalization costs and LOS

ADDITIONAL RESOURCES

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CHINA'S PLANS FOR DRG

Finland introduces joint procurement mechanisms for hospital drugs

DETAILS

- In September 2020, university hospital procurement rings began joint contract negotiations for the procurement of new, expensive hospital drugs in order to standardize the prices of medicines across the nation
  - A joint national drug advisory board of hospital districts has also been established to review the outcome of the negotiations
- In the past, procurement decisions were made in a decentralized manner and joint national positioning on prices or other terms of contracts did not materialize
  - The prices of expensive medicines used in hospitals and other contract terms were determined in procurement procedures in hospital districts or in the procurement rings of ERVA (special catchment areas)
  - As such, hospital medicines were able to be priced differently and come into use at different times in different parts of Finland, putting both patients and payers in a regionally unequal position

INDUSTRY IMPLICATIONS

- The change will improve patient equity, early access to major new drug innovations, and curb uncontrolled growth in drug spending
- Joint procurement on larger, combined volumes will likely lead to tougher negotiations on price with manufacturers

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PHARMA INDUSTRY FINLAND

In Brazil, the National Agency for Supplementary Health (ANS) introduces 61 new health technologies that must be covered

DETAILS

- The National Agency for Supplementary Health (ANS) is a national regulatory agency linked to Brazil's Ministry of Health, in charge of the country's private health plan sector
  - The ANS defines the list procedures, which is the basic reference for the mandatory minimum coverage of private plans and is normally updated every two years
- ANS establishes two criteria for analyzing the incorporation of new procedures: effectiveness of the treatment and financial impact
- In February 2021, the ANS approved a new list of mandatory coverage procedures by health plans
- The agency received 30,658 contribution proposals to update the list, but only 61 new health technologies were included; of those, 24 were oral oncology drugs and 21 were drugs for the treatment of chronic inflammatory and autoimmune diseases
  - Among the medical procedures denied inclusion in the list was surgical treatment for patients with Type 2 Diabetes who cannot control the disease through medication
  - Erenumab a CGRPR antagonist for the treatment of migraine, was also denied access to the list

INDUSTRY IMPLICATIONS

- It has been claimed that the non-recommendation of metabolic surgery demonstrates that the ANS is failing to listen to the scientific community
- In addition, private plan operators claim that new inclusions come with a price tag, which impacts operating costs and will be shared by everyone i.e., in order for high-cost treatments to be included on a plan, the monthly fee contribution will increase across all costumers
- Manufacturers seeking access to Brazil's private health insurance sector for drugs not covered under the public health system, face a high barrier to entry; the result is that many drugs, notably outpatient drugs, remain out-of-pocket to patients

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ANS NEW HEALTH PLAN

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