

# Evolving regulatory and reimbursement landscape – an APAC overview

China, Hong Kong, Japan, Singapore, South Korea and Taiwan

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## **Background**

Cancer is increasingly becoming a significant burden in the Asia-Pacific (APAC) region, with an estimated 8.8 million new cases and approximately 5.5 million cancer deaths per year [1]. Additionally, the rise in the ageing population, rising incomes, a surge in chronic illness as well as increased government health expenditures are boosting the demand for pharmaceutical products and services across the APAC region [2], [3].

To meet this rapid growth, some markets are expanding and adapting by implementing reforms for greater patient coverage and better access to treatment. There is therefore a need to understand the reforms/policies in place from regulations to pricing and reimbursement across different markets such as China, Hong Kong, Japan, Singapore, South Korea and Taiwan to meet the growing healthcare demands.

## **Methodology**

Cerner Enviza<sup>SM</sup> performed a purposive narrative literature review across markets such as China, Hong Kong, Japan, Singapore, South Korea and Taiwan to further understand the current regulatory, pricing and reimbursement landscape. PubMed, Cochrane and Medline were searched for empirical and peer-reviewed literature. Conference abstracts, EconLit, websites of government ministries, cancer registries, palliative or hospice care societies and local organizations, among others, were searched for grey literature. Non-systematic searches were also performed on Google and Google Scholar. The search strategy was constructed using combinations of various key terms for oncology, reimbursement, market access, policies, Asia-Pacific, HTA evolution and real-world evidence. The search terms were used to find useful information on the policy changes throughout the regulatory and reimbursement processes in different countries in the Asia-Pacific region. It also provided an overview of any changes specifically pertaining to oncology and non-oncology drugs.

## Results

Cancer is a healthcare priority in all APAC markets, with different policies in place for cancer prevention or control:

### China

Reduction of the incidence and mortality rate of cancer as medium and long-term goals for the “14th Five-Year Plan” [4]

### Hong Kong

The Hong Kong Cancer Strategy to reduce cancer burden in the local population, improve the quality of life and survivorship of cancer patients [5]

### Japan

Third term of the basic plan to promote cancer control programmes aimed at cancer prevention and improvement of cancer treatment [6]

### Singapore

Cancer control programmes by the government establishing comprehensive cancer centres, active rehabilitation services and hospice to care for patients in the terminal stage [7]

### South Korea

National Cancer Control Programme to improve the understanding of cancer and develop better ways to diagnose and treat cancer on individual, regional and national levels [8]

### Taiwan

Cancer Prevention and Control Policy Commission to formulate cancer prevention and control policy, evaluate the cancer control budget, and review related matters such as manpower, guidelines on cancer diagnosis and treatment, and cancer screening projects [9]

To bring marketed products up to international standards of efficacy, safety and quality, as well as to speed up the approval process, different markets have undergone certain reforms with respect to regulatory approval pathways for drugs with “significant clinical value” or novel drugs that could treat severe diseases, including different cancers. Products that qualify for the accelerated approval pathways benefit from shortened regulatory timeframes throughout development and approval.

Following are some insights on the different reforms that have taken place in recent years to enable the faster approval of novel products across different markets.

Reforms to smooth the path to regulatory approval in China, Japan, South Korea, Singapore, Taiwan and Hong Kong.



	Accelerated regulatory pathways	Key highlights
<b>China</b>	Priority review system	Duration is 130 days, compared to a standard process of 200 days.
<b>Japan</b>	Priority review system	Duration is nine months, compared to standard process of 12 months.
	Orphan designation	Duration is nine months, compared to standard process of 12 months.
	Sakigake designation	Duration of priority review is six months, compared to standard process of 12 months.
	Conditional early approval	Duration is nine months, compared to standard process of 12 months.
<b>South Korea</b>	Expedite approval for orphan drugs	Duration is 187 days, compared to standard process of 365 days.
<b>Taiwan</b>	Priority review	Duration is 240 days, compared to standard process of 360 days.
	Abbreviated review	Duration is 180 days, compared to standard process of 365 days.
<b>Singapore</b>	Priority/expedited review pathway	Duration is 120 days, compared to standard process of 180 days.
	Cell, tissue and gene therapy (ctgt) regulation	A potential pathway specifically for cell and gene therapy is under development.
<b>Hong Kong</b>	-	-

Table 2: Summary of the different accelerated pathways in APAC

### China

A priority review system was proposed in China to reduce the backlog of drug registration applications. One of the seven eligibility criteria for priority review is if the drug is for the treatment of cancer, rare diseases, children's diseases, viral hepatitis or HIV and has significant clinical benefit [10]. The duration of a priority review is kept to around 130 days, compared to a standard application, which lasts 200 days [11].

## **Japan**

Similarly, Japan has several accelerated approval processes, such as

- Priority review
- Orphan designation
- Conditional early approval
- Sakigake designation

The duration of priority review, orphan designation and conditional approval is shorter in Japan, i.e., nine months compared to the standard approval process of 12 months. Additionally, medical products granted orphan designation automatically benefit from a priority review. The conditional, term-limited approval is generally granted based on promising results of exploratory phase I/II trials in terms of efficacy and safety. Another accelerated review process is the Sakigake designation, which is similar to the breakthrough designation in the U.S. It has a review time of six months, compared to 12 months for the standard approval process. All the different approval processes have sets of requirements to be fulfilled for a drug to be granted a particular designation [12].

## **South Korea**

South Korea grants orphan designation to drugs that are used to treat diseases affecting 20,000 or fewer patients, and for drugs that are used to treat diseases for which appropriate therapies and pharmaceutical drugs have not been developed, or that have been significantly improved in terms of safety and/or efficacy compared to the existing alternatives. Drugs that qualify for orphan designation are approved through an expedited review process, which takes an average of 187 days, compared to the standard 360 days [13].

## Taiwan

Taiwan has implemented several pathways for the faster approval of drugs. The Taiwan Food and Drug Administration (TFDA) has developed pathways to facilitate and expedite the development and review of new drugs to address the unmet medical need in the treatment of serious or life-threatening conditions, such as priority review and abbreviated review [14]. Priority review takes around 240 days and abbreviated review around 180 days, compared to the standard review of 360 days.

For priority review, there is a need to meet any of the three following criteria:

- New chemical entity, new combination, new indication or new administration route
- The drug addresses an unmet medical need in the treatment of serious conditions and, if approved, would provide major clinical advance
- The drug addresses an unmet medical need and is under special national scientific research and development programmes

For abbreviated review, the drug needs to:

- Have approval from two of the three regulatory agencies (U.S. FDA, EMA or MHLW/PMDA) and a bridging study waiver
- Provide full review reports from two of the three regulatory agencies (U.S. FDA, EMA or MHLW/PMDA)
- Provide risk management plans and updated post-marketing commitment reports requested by two of the three regulatory agencies (U.S. FDA, EMA or MHLW/PMDA)

## Singapore

Singapore also has a priority review system for therapeutic products for serious life-threatening conditions, where the approval process is reduced from 180 working days for the standard approval process to 120 days [15]. Therapeutic products may be eligible for priority/ expedited review if they could address local unmet needs, such as absence of a treatment option or a lack of safe and effective treatments such that the drug would be a significant improvement compared to available market products [16]. In Singapore, recently there has also been discussion regarding a new regulation for cell, tissue and gene therapy products (CTGTP).



CTGTP pathway has been an interesting one given CAR-T therapies such as Kymriah have gotten approval in Singapore through this pathway in March 2021<sup>[17]</sup>.



This regulation will facilitate access to medically important therapies that meet the appropriate standards of safety, efficacy and quality and provide a fit-for-purpose regulatory framework that supports product development and facilitates product commercialization.

# Changing landscape of pricing and reimbursement and real-world evidence (RWE) in Asia



## Hong Kong

Interestingly, while most are moving towards accelerating approvals for novel products, markets like Hong Kong are still in the process of establishing formal reforms for an accelerated approval process or priority review system (standard drug approval process takes around 18 to 24 months) [18].

The road to health technology assessment (HTA) has taken different paths in the APAC region.

Key stakeholders in HTA	
<b>China</b>	The National Centre for Medicine and Health Technology Assessment
<b>Japan</b>	Chuikyo Drug Pricing Organization (DPO)
<b>South Korea</b>	Health Insurance Review & Assessment Service (HIRA) Reimbursement Advisory Committee Anti-Cancer Committee Economic Evaluation Committee
<b>Taiwan</b>	National Institute for Health Technology Assessment (NIHTA) Drug Benefit Committee (DBC)
<b>Singapore</b>	The Agency for Care Effectiveness (ACE) Drug Advisory Committee (DAC)

Table 3: Summary of some of the key stakeholders in the HTA process in APAC

## China

Since 2017, China has made substantial changes to the market access process, including the introduction of price negotiation and the use of health economics to evaluate the value of new medicines. Medicines for cancers, rare diseases, chronic diseases and children's diseases have been prioritized for price negotiations in China. One of the key elements of this process is not simply lowering prices but negotiations underpinned by evidence generated under a formal HTA process [19]. The National Centre for Medicine and Health Technology Assessment, which was endorsed by the National Health Commission of the People's Republic of China (NHC), was launched in 2018 under the China National Health Development Research Centre (CNHDRC). This national HTA agency is responsible for assessing new medicines to inform decisions on what goes on the National Essential Medicines List (EML) and to guide regional policies to ensure that priority-setting is based on value [20].

With HTA involvement in the reimbursement process, there are new challenges for pharmaceutical companies in gathering local data and using health economic modelling to provide economic and clinical value evidence. There is also an increased volume and variety of RWE in China, as the country made healthcare big data a national priority in 2018. In 2019, the CNHRDC led the incorporation of RWE in assessments, which began to highlight the importance of HTA in the real-world setting [21], [22].

## Japan

There have been significant reforms in pricing and reimbursement process in Japan as well. From the pilot implementation of HTA in 2016 to its full implementation in 2019, unlike in other markets, HTA has been used for post-launch price adjustment and not for reimbursement decision. Price adjustment based on economic evaluation is applied only after official prices are determined and products are listed in the formulary [23].

**The incremental cost-effectiveness ratio (ICER) thresholds vary for cancer drugs versus standard products, with a 1.5-fold increase for cancer drugs.**

With the emergence of value-based payments, there is an increasing opportunity to leverage real-world evidence to obtain accelerated market access, which can facilitate the payers' substantiation of drug pricing and reimbursement. In 2017, Japan started its "Rational Medicine" initiative, which aims to make the Japanese healthcare system more patient-centric and evidence-based. Japan has since then had several registries and databases [24].

## South Korea

In South Korea, HIRA is mainly involved in the reimbursement decision, along with other sub-committees. For oncology drugs, the anti-cancer committee within HIRA is involved in the assessment of drugs' benefit based on their clinical utility, cost-effectiveness comparison with analogues, comments from academic societies, expected budget expenditure and other factors [25]. For drugs determined to be reimbursable, the National Health Insurance Service (NHIS) and the pharmaceutical companies negotiate the prices after estimating the financial impact of the addition of the new drug to the system. There is no threshold for the incremental cost-effectiveness ratio because HIRA makes flexible judgments alongside other criteria, such as disease severity and innovation. Nevertheless, a benchmark of around one multiplied by the gross domestic product per capita has evolved as a general reference value [26]. Besides the main body, HIRA, other supportive bodies, which participate in the reimbursement decision, include the Reimbursement Advisory Committee, Cancer Committee for Cancer Drugs and Economic Evaluation Committee. The final notification of reimbursement is made by the Ministry of Health and Welfare (MHLW). Like in Japan, real-world data (RWD) are also available in South Korea and can be used as inputs for health economics studies. As the interest in health economics studies continue to increase in APAC, leveraging the RWD will be important to provide relevant inputs on healthcare resource use (HRU) and costs for such studies [27].

## Taiwan

In Taiwan, the reimbursement of new drugs is decided by NHIA. The HTA process is very much incorporated in Taiwan's reimbursement landscape, wherein studies have shown that new drug reimbursement applications conducting HTA with local pharmacoeconomic analysis were on average granted a higher reimbursement rate compared to those cases without local pharmacoeconomic analysis. This highlights the importance of the HTA process in the Taiwanese pricing and reimbursement system [28]. In Taiwan, different sources of RWD are linked together with the Office of Statistics within the Department of Health to improve its usability. RWE is used both for research and HTA purposes.

## Singapore

Singapore is also making its way towards incorporating RWE [24]. The Agency for Care Excellence (ACE), an HTA agency in Singapore, utilizes clinical, epidemiological and health economic information to determine how best to allocate resources [29]. Potential drug topics for technology evaluation are identified predominantly through annual applications by public health care professionals (such as clinicians or pharmacists). Once a topic is selected, an expedited or full evaluation is conducted, depending on the estimated budget impact and uncertainty around the clinical and cost parameters for each drug [30].

## Discussion

With innovative drugs coming to the market, governments across APAC continue to look for market access strategies that would serve the dual role of increasing access while achieving fiscal sustainability. Thus, overall pharmacoeconomic evidence is increasingly becoming important for P&R decision in the APAC region. The increased emphasis on HTA assessment, such as cost-effectiveness, might create hurdles to market entry in this region. Many country-specific factors could play a role in the relative value of the technology to the decision makers, e.g., differences in the importance of local pharmacoeconomic data, differences in relevance of ICER thresholds, etc. On the other hand, there will also be an increasing importance of multilevel stakeholders (e.g., increasing importance of local health economists, potential role of patient advocacy groups as patient voices in the future, formation of different committees to evaluate oncology versus non-oncology drugs, etc.) and providing access to drugs through innovative access schemes. It is also important to note that with the penetration of the HTA framework in the APAC region, the use of HTA is expected to be quite dynamic, given that different markets are progressing at different rates.

Additionally, RWE has a potential to transform the way in which drugs demonstrate clinical and economic value. RWE data have been a part of the HTA system in Europe within markets like the UK, Germany, France or Sweden, where they're often used in pharmacoeconomic analysis [31]. Given the increasing importance of RWE in the APAC region, inclusion of RWE data could help address some of the payers' concerns in assessing new innovative drugs, such as uncertainties related to clinical and economic benefits of the products in the real world.

## **Case studies**

Cerner Enviza has done several projects in the field of market access and RWE in the APAC region. Our work ranges from understanding the market access landscape or informing market access strategy across publicly reimbursed or self-pay markets to conducting non-interventional studies such as preference studies to support future HTA for pharmaceutical products.

Below are a few examples of the work done by Cerner Enviza in the APAC region to support the evolving market access needs in this region.

## **Policy and market access – oncology policy landscape assessment Japan, China, Korea, Taiwan, Singapore, Hong Kong**

### **The issue**

The client has a strong pipeline of products for solid cancers and haematological malignancies.

A regional market access team was brought onboard to map out key policy issues across multiple different cancer indications that the client could leverage or influence to accelerate access for their products.

- Policies/strategies to access novel cancer therapies
- Reforms accelerating the approval process for oncology drugs
- Pricing and reimbursement reforms for oncology drugs
- Regulatory and reimbursement landscape for biomarkers
- Future healthcare priorities
- Role of different stakeholders

### **The approach**

Cerner Enviza designed a multi-phased engagement:

Environmental scan using comprehensive literature review across publicly available sources (e.g. government websites, white papers, media, etc.)

Interviews with payers, policy makers and key opinion leaders

### **The solution**

Cerner Enviza identified key policy opportunities that our client could potentially leverage, and challenges that would limit the accessibility of their products

# Informing a Gene Therapy's Market Access Strategy across Reimbursed and Self-Pay Markets in Asia

Malaysia, Indonesia, Philippines, Singapore, Thailand, Vietnam

## The issue

A leading pharma biotech company was preparing to launch a gene therapy in Asia. The company wanted to gain an in-depth market assessment of the opportunity in Asia and needed to understand the following areas:

- Is there an opportunity (looking at epidemiology considerations, challenges along the journey and reactions to TPP)?
- How can they drive access and funding?
  - Identify barriers/opportunities to access opportunities
  - Funding schemes and PAG initiatives to access treatment
  - Case study of treatment receiving funding
  - Stakeholder involvement

## The approach

Cerner Enviza designed a multi-phased engagement:

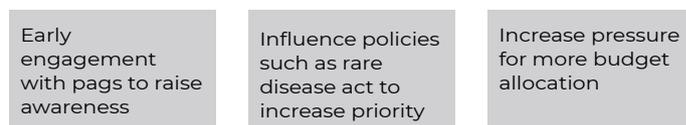
Extensive desk research using published information and grey literature

Discussions with key stakeholders:

- Geneticists, paediatric neurologists who are key treaters / decision makers
- KOL experts
- PAG representatives
- Payers/ex-payers

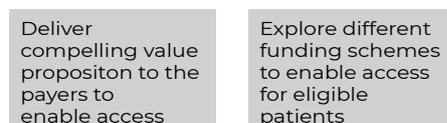
## The solution

This study enabled client to identify key leverage points to drive access and funding



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Disease state prioritisation



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Access

## **Patient and physician preference study for treatment of nmCRPC**

Japan

### **The issue**

A global pharmaceutical company assessed patients and physicians' preferences for the attributes of treatment for nmCRPC

Information from this study will help support the value of their product. This information is also valued by the HTA agency in Japan

There were no data available on both patient and physician preferences for nmCRPC treatment locally in Japan

### **The approach**

Cerner Enviza designed a multi-phased engagement:

- Concept Elicitation Phase: To explore the list of treatment attributes. Qualitative, 45 mins
- Cognitive Phase: To ensure the questionnaire performs adequately among the potential survey respondents. Qualitative, 45 mins
- Discrete Choice Experiment (DCE): To elicit preferences in treatment for nmCRPC from both patients and physicians. Quantitative, 30 mins

### **The solution**

Cerner Enviza has published an article on physician preference study in a peer-reviewed journal. The article is currently in production

Cerner Enviza has also submitted a manuscript for patient preference study, which is under review

Findings from these studies helped the client better understand the patient and physician preferences for treatment of nmCRPC

# Real-world survey: Assess the Clinical and Economic Burden Associated with Multiple Fractures among Osteoporosis Patients

Japan

## The issue

A global pharmaceutical company wanted to have a better understanding of the knowledge gaps on the clinical and economic burden associated with fractures and unmet needs in osteoporosis management in Japan.

Information from this study will help support the information gaps in the value dossier to be submitted to the HTA agency in Japan.

There were no available data on the clinical and economic burden associated with fractures among osteoporosis patients in Japan.

## The approach

Cerner Enviza designed a multi-phased engagement:

- The Japan National Health and Wellness Survey (NHWS) was used for analysis, with a sample size of 1107 patients
- The study population included those who had completed the NHWS survey, aged 50 years or above, and self-reported diagnosed of osteoporosis by physicians.

## The solution

Cerner Enviza has published an article in a peer-reviewed journal.



## Conclusion

Overall, the regulatory as well as the pricing and reimbursement landscape is changing across different markets in APAC with emerging healthcare policies. Although the policies are not specifically focused on oncology drugs, the shifts in policies have also impacted registration of and access to oncology drugs indirectly. However, some countries do have some direct policies/ reforms that could impact access to oncology drugs. For example, Japan has set up different ICER thresholds for oncology versus non-oncology drugs, while South Korea has a separate anti-cancer committee to evaluate the reimbursement of oncology drugs compared to non-oncology drugs. But overall, local knowledge to identify the structure, process and different stakeholders involved currently and in the next few years is critical given the evolving nature of these countries. One commonality that can be seen across most of the countries is that RWE is gaining immense interest in the Asian markets to provide more certainty about the effectiveness of the technologies in the local settings and inform their appropriate use. This underscores the need to keep abreast of the rapidly changing dynamics in the structure, process and role of stakeholders in these countries.

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