Emerging-Market Payer Needs: How Should These Countries Be Included in Dermatology Drug Development Plans?

Catherine Copley-Merriman,[1] Susan Zelt,[2] Glenda Stone,[2] Stephanie M Barrows,[1] Margaret M Mordin,[1] Susan L Hogue[3]

[1]RTI Health Solutions, Ann Arbor, MI, United States; [2]Stiefel, A GSK Company, Research Triangle Park, NC, United States; [3]RTI Health Solutions, Research Triangle Park, NC, United States

BACKGROUND

- Health technology assessment (HTA) is a rapidly growing field, and countries in the Asia Pacific region and Latin America are in the process of developing economic assessment guidelines for pharmaceuticals. It is increasingly important to include these regions early in the drug development process to plan for market access considerations.

OBJECTIVE

- To determine how emerging-market payer needs should be included in drug development plans.

METHODS

- Brazil, China, India, Japan, and South Korea were the emerging markets of interest.
- Dermatology was chosen as the example therapeutic area.
- For each country, local market access experts and decision makers provided overviews of the health care system and HTA process. Payer needs were evaluated through desktop research of published literature, HTA reports, and third-party websites.
  - On a disease-specific level, the following were identified: local epidemiology; economic burden; treatment patterns and clinical guidelines; and insurance coverage.
- Internal country affiliate surveys evaluated country needs regarding comparators, study endpoints, and recommendations for supportive data.
- Based on the local country situation and payer needs, a process map was developed outlining the steps and timeline for including country-specific needs into drug development plans.

RESULTS AND DISCUSSION

Country Summaries

Brazil

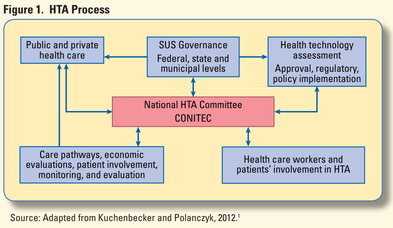
Overview of the Health Care System

- Public health care is administered through the Sistema Único do Saúde (SUS), which covers 150 million users.
- Supplementary health coverage (health plans, health maintenance organizations, self-management plans, and other private health companies) is held by 47 million users.

Evidence Review

- The formal reimbursement submission process is conducted through the Comissão Nacional de Incorporação de Tecnologias (National Committee for Incorporation of Technologies; CONITEC) within the SUS (Figure 1). CONITEC makes appraisal decisions based on cost-effectiveness and budget-impact analyses.
- Market access strategies require securing a positive recommendation from CONITEC to ensure consideration for public funding and commercialization.

Figure 1. HTA Process



Source: Adapted from Kuchenbecker and Polanczyk, 2012.[1]

Key Learnings

- Manufacturers should allocate sufficient time and resources to engage key stakeholders in understanding evidence needs for the future reimbursement submission (early scientific advice). Stakeholders include CONITEC, the Ministry of Health, and key opinion leaders (KOLs).
- Because appraisal decisions are based on cost-effectiveness and budget-impact analyses, manufacturers should have an evidence dossier that incorporates clinical evidence, economic impact, and price.
- Knowledge of public versus private health care systems and national versus local systems may affect the choice of population and comparator for pivotal trials.
  - A key factor for a positive reimbursement decision is having the right comparator.

China

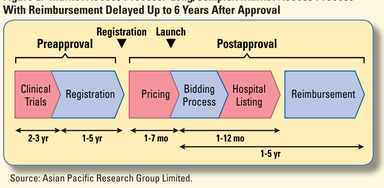
Overview of the Health Care System

- China has a highly regionalized health care system with 31 provinces.
  - There is significant variation between regions.
  - There is relatively low uptake of high-tech medical products in the poorer Western regions and in rural areas.
- Despite health reforms in China, there is still significant out-of-pocket spending.
- There is a mix of Western and Eastern philosophies in medicine in China.

Evidence Review

- The reimbursement system is fragmented and still under formation, resulting in diversity of coverage and pricing between cities and provinces.
- The Ministry of Health with the National Development and Reform Commission (NDRC) set pricing guidelines by defining and publishing procedure charge codes in the Green Book. These agencies delegate the final authority of price setting and reimbursement to provincial-level health and pricing bureaus.
  - Until a product is listed in the Green Book, patients must pay full cost, out of pocket, for the product.
  - Green Book updates can be unpredictable but generally occur every 1 to 2 years.
- Health economic data are required in negotiations at the provincial or city level for high-priced products but are not required at the central level.
- Figure 2 presents the market access process in China.

Figure 2. Market Access Process: Long/Complex Market Access Process With Reimbursement Delayed Up to 6 Years After Approval



Source: Asian Pacific Research Group Limited.

Key Learnings

- With health care reform in China, there appear to be more opportunities for funding.
- Relationship building will need to take place at the local level; engagement with key stakeholders and community clinics will help to establish credibility.
  - Market uptake will be driven by clinician demand and reimbursement at the provincial level.
  - Obtaining pricing and reimbursement in a few key provincial regions will facilitate successes in other regions.

India

Overview of the Health Care System

- India has a self-pay system: the consumer is the payer. There are low levels of private health insurance coverage and high levels of out-of-pocket payments for health care.
- Generic medication usage is predominant.

Key Learnings

- It is difficult to accurately determine key comparators that may be used consistently across the regions.

Japan

Overview of the Health Care System

- The government is the payer for health care goods and services purchased at hospitals, clinics, and prescription pharmacies.
- The Ministry of Health, Labor, and Welfare (MHLW) determines coverage policy and pricing.
- Pricing is established by the Central Social Insurance Medical Council (CHUIKYO), a separate body within the MHLW.
- Mandatory social health insurance provides universal coverage for Japanese citizens that is financed by employer contributions, payroll deductions, taxes, and patient copayments.

Key Learnings

- Treating physicians are the primary adoption influencers.
- Building KOL support and physician society support is essential to product success in the Japanese market.
- Japan requires all foreign companies to partner with a marketing authorization holder before a product can be marketed, which can be time-consuming.

Republic of Korea (South Korea)

Overview of the Health Care System

- In 1977, Korean National Health Insurance was introduced as the first social insurance program. Initially, it covered only corporate employees; by 1989, it covered the entire population. The program is controlled by the Ministry of Health and Welfare.
- The Health Insurance Review and Assessment (HIRA) Service and the Drug Benefit Coverage Assessment Committee decide whether to list a drug in the formulary of reimbursed drugs (positive list).

Evidence Review

- There is a formal HTA process in South Korea, and careful planning is required to prepare for a submission and ensure that appropriate comparators are chosen.
- Reimbursement status and price decisions are assessed separately.
  - The National Health Insurance Corporation (NHIC) oversees price negotiations.
  - HIRA oversees reimbursement assessment.
- HIRA considerations include clinical usefulness, cost-effectiveness, disease severity, financial impacts, reimbursement status, and pricing in foreign countries.
  - HIRA prefers to see clinical data from head-to-head clinical trials.
- The timing of the positive list system is as follows:
  - A decision about listing the drug in the positive list by HIRA and Drug Benefit Coverage Assessment Committee occurs in 150 days.
  - Price negotiations between the NHIC and the manufacturer occur over 60 days.
  - If HIRA does not recommend reimbursement, a request for a second review can be submitted by the manufacturer within 30 days; the resubmission process takes 120 days.

Key Learnings

- Careful planning will be required to prepare for a submission and ensure that appropriate comparators are chosen.
  - Second reviews by HIRA can be time-consuming.
- South Korea, like Brazil, has a formal process based on cost-effectiveness or cost-minimization analysis.
- Manufacturers should have an evidence dossier that incorporates clinical evidence and therapeutic benefit, treatment alternatives, cost-effectiveness, budget impact, and price.

Country Affiliate Input Into Drug Development Plans

- Input was obtained across the key emerging markets.
- Country-specific information considered critical to understand included obtaining the most appropriate populations and the most appropriate comparators for the clinical trials.
- Data needs for evidence generation varied based on country-specific HTA requirements.
- Most countries acknowledged that collection of pharmacoeconomic data could potentially influence market access when new compounds launch.
- Figure 3 is an example of a survey to solicit country affiliate input across the key markets.

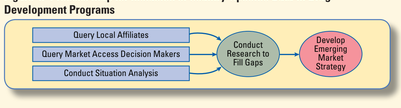
Figure 3. Example Country Input Survey

Environmental landscape/insights
Environmental trends
What are the key trends and assumptions relevant for consideration of this product at time of launch?
Are there environmental changes (e.g., changes in HTA requirements) that will affect review of this product at the time of launch?
Disease-specific information
How does this product fit in with evolving treatment?
What are the patient populations currently being treated?
What are the main cost drivers/utilization patterns in this disease area?
What are the differences in cost drivers/utilization patterns in this disease area across markets?
What are the unmet needs in this disease area within and across markets?
Product-specific insights
Clinical evidence for product
What are the safety and efficacy benefits?
What is the most appropriate patient population to be studied?
What is the most appropriate comparator(s) in the markets of interest?
Humanistic evidence
What are the most appropriate patient-reported outcomes measures (quality of life, satisfaction, symptoms, productivity) to assess in this disease?
Are outcomes measures such as impact on caregivers important in this disease?
Customer insights
How compelling are the value proposition and value messages to the decision makers: public, private, national, regional, local?
Economic evidence
Payer insights
Would payers consider and reimburse this product?
What are the key clinical and overall health care cost drivers for reimbursement decisions?
Market access/HTA objectives
What are the budget impact and cost-effectiveness modeling needs for this product?
How important is it to shows decreases in health care utilization?
How can this product be differentiated?

Process Map

- Development of a process map should anticipate the following:
  - Information may be used for different purposes across a product's life cycle (e.g., initial HTA analysis, formulary placement, physician prescribing, patient advocacy, and policy influence).
  - Information on products may be at different stages of development and have different levels of complexity, so that all appropriate data can be synthesized into an impactful value proposition (Figure 4).
    - Query local operating company representatives to strengthen understanding of health care systems in the respective countries
    - Understand country-specific opportunities and what will matter to country-specific health care systems over the next 3 to 5 years
    - Conduct internal cross-functional team situation analysis to assess gaps in data needed to understand the current and launch environments and to conduct research to fill these gaps
    - Demonstrate product value; doing so is increasingly material to the evaluation, placement, and reimbursement of treatments
    - Develop clear and quick communication platforms of a treatment therapy's unique value story

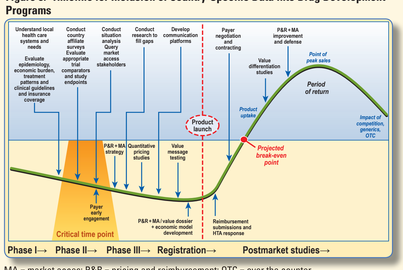
Figure 4. Process Map for Inclusion of Country-Specific Data in Drug Development Programs



Timeline

- Timing is critical when developing the necessary information to support a new product. Figure 5 illustrates the timing of the process map on the continuum of the product development cycle.

Figure 5. Timeline for Inclusion of Country-Specific Data into Drug Development Programs



MA = market acces; P&R = pricing and reimbursement; OTC = over the counter.

CONCLUSIONS

- It is critical to understand payer decision makers' needs. There is much variation in evidence needs across countries in emerging markets and within the countries at the national, regional, and local level.
- There are multiple access pathways that manufacturers will need to thoroughly understand. Keys to success include the following:
  - Manufacturers working closely with country affiliates to better understand needs across and within regions
  - Following a process of capturing needs of decision makers and incorporating them into the clinical development program
- Timely inclusion of the various payer and decision maker needs into the drug development process is critical for market access with emerging markets.
- Relationship building alongside country-specific evidence is critical for market access success.

REFERENCE

1. Kuchenbecker R, Polanczyk CA. Value Health Regional Issues. 2012;1(2):257-61.

CONTACT INFORMATION

Catherine (Kati) Copley-Merriman
Vice President, Market Access and Outcomes Strategy

RTI Health Solutions
Phone: +1.734.213.5429
E-mail: kcmerriman@rti.org

ISPOR 19th Annual International Meeting
May 31-June 4, 2014
Montreal, QC, Canada