**OBJECTIVE**

To assess 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. A mix of Western and Eastern philosophies in health care was observed across the region. Brazil, China, India, Japan, and South Korea were the key markets.

**RESULTS AND DISCUSSION**

Country Summaries

**Brazil**

- Overview of the Health Care System
  - Public health care is administered through the Sistema Único de Saúde (SUS), which covers 158 million users.
  - Supplementary health care coverage is provided by private health insurers and other private health companies.

- Market access strategies require a positive recommendation from CNES to ensure consideration for public funding and reimbursement.

**India**

- Overview of the Health Care System
  - The government is the payer for health care goods and services provided at hospitals, clinics, and prescription pharmacies.

- The Ministry of Health, Labor, and Welfare (MHLW) administers the Green Book and other market access policies.

- Pricing is legislated by the Social Insurance Foundation (National Health Insurance) within the MHLW.

- Mandatory social health insurance provides universal coverage for Japanese citizens that is financed by employer and employee contributions, payroll deduction taxes, and state and patient copayments.

- Treatments are primary adoption influences.

- Building RDs, supporting physician society support is essential to address the high cost of access in the Green Book.

- Japan requires all foreign companies to partner with a Japanese company to be reimbursed by the NHI, which can then be marketed, which is time-consuming.

**Republic of Korea (South Korea)**

- Overview of the Health Care System
  - The government is the payer for health care goods and services provided at hospitals, clinics, and prescription pharmacies.

- The Ministry of Health and Welfare.

- The Health Insurance Review and Assessment (HIRA) performs the final review.

- HIRA is a stand-alone body that is independent of the Ministry of Health and Welfare.

- The National Health Insurance Corporation (NHIC) oversees price negotiations.

- The Ministry of Health, Labor, and Welfare (MHLW) administers the Green Book and other market access policies.

**Key Learnings**

- Companies should allocate sufficient time and resources to engage key stakeholders and understand evidential needs within each region.

- Understanding key HTA requirements is critical to success. HTA requirements in the key HTA agencies are outlined in Table 1.

- HIRA recommendations include clinical usefulness, cost-effectiveness, and price. HIRA prefers to see clinical data from head-to-head clinical trials.

- The timing of the positive list system is critical:
  - A decision on listing the drug in the positive list by HIRA and Drug Benefit Coverage Assessment Committee occurs within 120 days.
  - A second review can be submitted by the manufacturer within 30 days; the resubmission process takes 120 days.

- Key findings:
  - Careful planning will be required to prepare for submission and ensure that appropriate comparators are chosen.
  - HIRA recommends one clinical trial for health care goods/products, at least 3 years.

- Data needs the evidence generation balanced across country-specific HTA requirements.

- Manufacturers working closely with country affiliates to better understand needs across and within regions.

- Key challenges across and within regions include:
  - Patient access
  - Pivotal trials
  - Health care reforms

**CONCLUSIONS**

- It is critical to understand payer decision makers’ needs. There is increasing market access risk, which requires close interaction with emerging markets and within the countries at the national, regional, and local level.

- There are multiple access pathways that manufacturer and companies need to thoroughly understand. Keys to success include:
  - Understanding local health technology assessment (HTA) systems and key stakeholders and communities to be engaged.
  - Engaging proactively with key opinion leaders (KOLs).

- Recommendations for supportive data.

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**Notes:**