In order to provide the evidence for health decision makers.

**Section 1: Overview of HTA processes in Japan**

- **Objective:** To describe the impact of HTA on the development and market access of new pharmaceutical products in Japan, South Korea, Taiwan, Thailand, and France.

- **Methods:** A comparative exercise was conducted to analyze the differences in the HTA processes and the impact on market access.

- **Results:** The impact of HTA on market access varied significantly across the countries, with Japan showing the most stringent requirements.

- **Conclusions:** The need for more standardized and transparent HTA processes is recognized to facilitate global access.

**Section 2: Regulatory Framework in Japan**

- **Objective:** To analyze the regulatory framework in Japan, focusing on the HTA processes and market access.

- **Methods:** A comprehensive review of regulatory guidelines and publications was conducted.

- **Results:** The regulatory framework in Japan is highly complex, with multiple levels and agencies involved.

- **Conclusions:** The complexity of the regulatory framework in Japan poses challenges for market access.

**Section 3: HTA Impact on选定 products**

- **Objective:** To assess the impact of HTA on specific products.

- **Methods:** A detailed analysis of selected products was conducted, focusing on the impact on market access.

- **Results:** The impact of HTA varied significantly, with some products achieving early approval and others facing delays.

- **Conclusions:** The impact of HTA is influenced by various factors, including the strength of evidence and the regulatory requirements.

**Section 4: Future Directions**

- **Objective:** To discuss future directions for HTA in Japan.

- **Methods:** A forward-looking analysis was conducted, focusing on emerging trends and potential improvements.

- **Results:** Improvements in HTA frameworks, increased transparency, and more coordinated efforts are needed.

- **Conclusions:** Enhancing HTA processes is essential to support patient access to innovative therapies.