Introduction

- Diseases such as type 2-diabetes mellitus (T2DM) and rheumatoid arthritis (RA) are becoming increasingly prevalent in countries in the Asia Pacific. Chronic infections, such as human immunodeficiency virus (HIV) and hepatitis C virus (HCV), are also threats to public health.
- Large numbers of treatments are available for these diseases and infections. However, historically, there has been a delay between the marketing approval of drugs in Western countries and other markets worldwide, such as Asia.
- The objective of this analysis was to investigate patterns of drug approval in Western and Asian countries in these disease areas.

Methods

- National drug regulatory authority websites were searched for new drug approval dates in five Asian countries (Japan, Hong Kong, Indonesia, Singapore) and four Western markets (United States (US) and the European Union (EU) for drugs approved to treat T2DM, RA, HIV-1, HCV, and HBV).
- For drugs with at least one marketing approval in each region, we analysed how the delay in average approval date between the West and Asia changed over time.
  - The mean of the dates for the European Medicines Agency (EMA) and Food and Drug Administration was used to generate a single date for the West. The mean of the dates for Hong Kong, Indonesia, Japan, and Singapore was used to generate a single date for Asia. The delay in marketing approval between the West and Asia was defined as the difference between these two dates.
- Regression analysis and Spearman rank correlations were performed to investigate the relationship between the date of first marketing approval in any included country and the delay in marketing approval between the West and Asia.
- A sensitivity analysis was performed to investigate the relationship between the delay in marketing approval and the GDP per capita of each country.

Results

- Of the 73 drugs studied, more had been approved in the US and EU than in any of the Asian countries studied. Indonesia had the least number of marketing approvals for the included drugs, with only 28.
- At least one Western and one Asian approval was recorded for 59 drugs out of the 73 included in the analysis. The mean approval delay for both indications was less than one year, due to a greater rate of increase in the delay in the FDA approval for Asian countries.
- Investigating the observed trend in drug approval for the treatment of RA demonstrated that the approval was considerably longer in the US than in any of the other countries studied. Although the delay was strongly influenced by the lowest economic developed country (Indonesia), the inclusion of additional Asian and Western markets would be needed to ascertain if this trend is reflective of their more stringent approval process, requiring more efficacy and safety data.
- Some important new therapies were absent from the analysis as they are yet to be approved in any of the four Asian countries included, such as recently launched nelaphostin (Selumetinib, HCV) and volasertib/costeffect/lorlatinib/entrectinib (GSK309, HIV-1).

Discussion

- The delay in the average approval date of drugs in Asian and Western markets has decreased dramatically over the past 20 years, although this pattern varied between disease areas. However, regulatory authorities are still required to approve new therapies in all Asian markets in order to launch them.

Conclusion

- The average delay between the date of drug approvals in Asian and Western markets has decreased dramatically over the past 20 years, although this pattern varied between disease areas. However, regulatory authorities are still required to approve new therapies for Asian drug markets; additional approvals are needed to launch these medicines in Asian markets.

References


Copyright © Costello Medical Singapore Pte Ltd, Singapore.