Measuring time to market for new medicines in 7 Asian countries between 2016-21, following review by US FDA or EMA

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Background

Measuring changes in agency processes, regulatory review times, and the time to market for New Active Substances (NASs) is of growing importance to agencies, companies, patients, and other stakeholders.

Highlighting where time is devoted and identifying areas for development can help to ensure and improve the effectiveness and efficiency of these processes, ultimately facilitating faster access to medicines for patients.

CIRS has been tracking roll-out times across the Asia region for over a decade, and previously observed review times in India, Malaysia, Singapore, South Korea, and Taiwan converging to a mean of 400-500 calendar days[1].

CIRS Growth & Emerging Markets Metrics Programme database currently contains regulatory submission and approval data provided annually by participating companies for 20 jurisdictions across LatAm, EMEA, and Asia.

Objectives

To investigate the trend in roll-out time (comprised of submission lag and regulatory review time), between 2016-21 in seven Asian countries, for new active substances (NASs) approved first by US FDA or EMA; and to investigate the characteristics of the applications behind the trends.

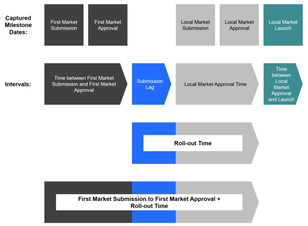
Methods

Data was collected on application submissions and approvals from seventeen major pharma companies that participated in a CIRS benchmarking programme. Analysis focused on three-year rolling means of intervals calculated from key milestone dates for NASs approved in one or more of seven Asian countries.

In total, 352 NAS applications approved by the local markets between 2016 and 2021 met the criteria of having the requisite milestone dates to enable calculation of specific intervals between the first market approval of the application (by US FDA or EMA) and the local market approval of the application (*Fig. 1*). Three-year rolling means were calculated from these intervals based on the year of local market approval.

In addition, three deficiency question milestones within the review period were captured and analysed: time to receive first question following application submission, time between receiving the first question to last response being submitted to the local market agency, and time to approval following submission of last response to the local market agency. Lastly, the following application characteristics captured in the database were analysed: active substance type (chemical or biological entity), use of reliance pathway, use of priority review pathway, and whether the sponsor internally fast-tracked submission of the application to the local market authority.

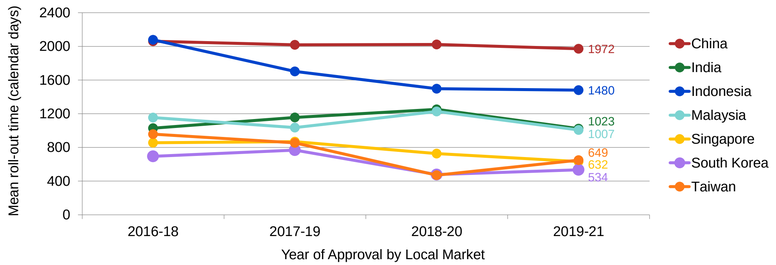
Fig. 1: Key intervals and the constituent milestones enabling their calculation ('Local Market Launch' shown but not included in this analysis)



Results

Seven Asian countries were analysed: China (65 NAS approved 2016-21), India (39), Indonesia (36), Malaysia (52), Singapore (51), S. Korea (44), and Taiwan (64). Between 2016-21, roll-out time (time between first market approval and local market approval as a 3-year rolling mean) decreased across the seven countries (-81 days; -7%). For Indonesia, Malaysia, Singapore, S. Korea, and Taiwan, specifically, roll-out times decreased notably (*Fig. 2*).

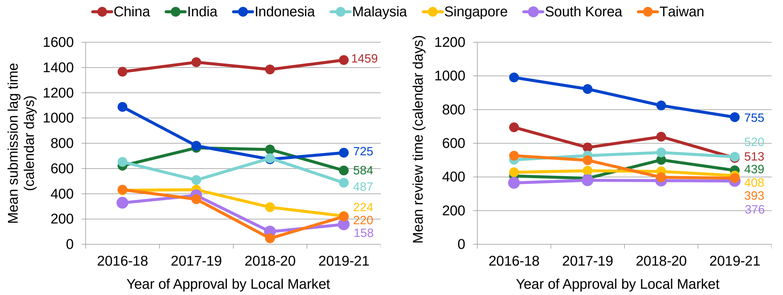
Fig. 2: Trend in roll-out time (three-year moving mean) for products approved between 2016-21, following approval by US FDA and/or EMA



Roll-out time was divided into submission lag (first market approval to local market submission) and review time (local market submission to approval). For the former, this decreased by 40 days (6%) between 2016 and 2021, most notably in Indonesia, Malaysia, Singapore, S. Korea, and Taiwan. For the latter, this decreased by 50 days (9%) over the same time period, most notably in China, Indonesia, and Taiwan (*Fig. 4*).

Fig. 3: Trend in submission lag (three-year moving mean) for products approved between 2016-21, following approval by US FDA and/or EMA

Fig. 4: Trend in review time (three-year moving mean) for products approved between 2016-21, following approval by US FDA and/or EMA



The decrease in roll-out time to Malaysia was associated with a decrease in submission lag (*Fig. 5*), and similar was true for Singapore (-204 days; -48%) and S. Korea (-171 days; -52%). For Indonesia and Taiwan, decreased roll-out time was associated with decreased time for both constituting intervals.

Review time was sub-divided into three intervals: time to receive first question following application submission, time between receiving the first question to last response being submitted to the agency, and time to approval following submission of last response. For Indonesia, the decrease in review time was associated with a decrease in the time to receive first question following application submission, and the time to approval following submission of last question response (*Fig. 6*).

Fig. 5: First market submission to First market approval + overall roll-out time (three-year moving mean) for products approved between 2016-18 and 2019-21, following approval by US FDA and/or EMA

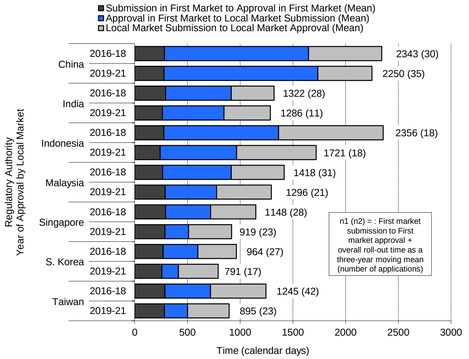
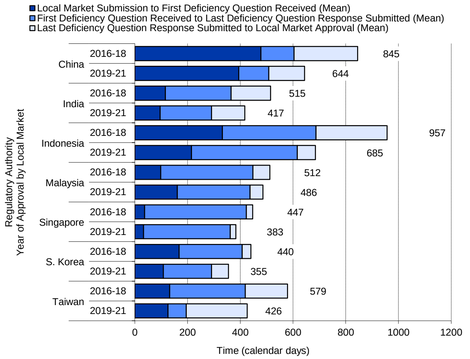


Fig. 6: Review time (shown in blue on Fig. 5) sub-divided into the time between deficiency questions milestones for products approved 2016-18 and 2019-21, following approval by US FDA and/or EMA



Results were examined further to understand whether trends in roll-out time and the constituting intervals correlated with changes in product or process characteristics (analysis not displayed). Where a decrease in roll-out time was associated with a decrease in review time, no notable differences were observed in the use of formal reliance routes. The type of NAS (chemical/biologic) generally did not have a clear impact on review time, however there was some evidence to suggest a correlation between increased proportions of priority reviews and faster review times in certain markets. Where there was a change in the proportion of sponsors indicating that they had fast-tracked submission of the application, there was no major impact on submission lag.

Conclusions

- Roll-out time decreased in general across the seven countries between 2016-21. This was primarily associated with a decrease in submission lag, although shorter regulatory review times were contributing factors for Taiwan and Indonesia.
- There was no consistent impact on submission lag or review time based on product characteristics or pathways utilised.
- Studying the impact of company strategy and local agency requirements on submission lag may provide further context on changes in roll-out time.
- Deeper like-for-like comparisons of regulatory review times could be achieved by analysing the major components of the review process (validation, scientific assessment, and authorisation) and total agency time during scientific assessment via CIRS' Optimising Efficiencies in Regulatory Agencies (OpERA) methodology (*Fig. 7*).
- Highlighting where time is devoted and identifying areas for development could help to ensure and improve the effectiveness and efficiency of these processes, ultimately facilitating faster access to medicines for patients.

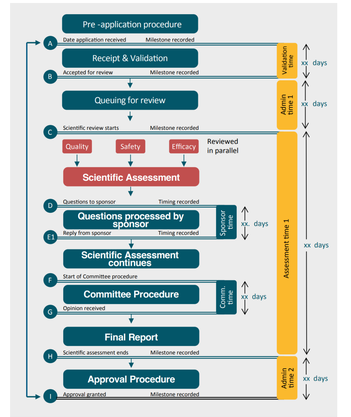


Fig. 7: Milestones within the OpERA Metrics Methodology[2]

References

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2. Centre for Innovation in Regulatory Science (2023) R&D Briefing 87: Roadmap for Regulatory Strengthening: CIRS Tools for Measuring and Optimising Regulatory Performance to support practices in line with the World Health Organization (WHO) Global Benchmarking Tool (GBT) indicators. Centre for Innovation in Regulatory Science (CIRS), London, UK.