*International Journal of Applied Social Science*
*(An International Double Blind Peer Reviewed / Refereed Research Journal of Social Science)*
***Volume 13 (3 & 4), March & April (2026) : 181-184***
*Received : 11.02.2026; Revised : 25.02.2026; Accepted : 11.03.2026*

***RESEARCH PAPER***
ISSN : 2394-1405 (Print)

**DOI** : https://doi-ds.org/doilink/05.2026-66734296/IJASS/13.3&4/181-184

# Impact of Regulatory Good Practices on Approval Efficiency and Market Access of Generic Drugs in India: Lessons from the US Food and Drug Administration Model

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## ABSTRACT

Regulatory Good Practices (RGPs) play a crucial role in ensuring timely approval, safety, and accessibility of generic drugs. This study evaluates the impact of RGP adoption on approval efficiency and market access in India, drawing lessons from the US Food and Drug Administration model. A comparative and empirical approach was adopted using secondary data and stakeholder perceptions. Statistical tools such as mean, correlation, regression, and ANOVA were applied. The findings reveal that transparency, digitalization, and standardized review timelines significantly improve approval efficiency. The study recommends structural reforms in India's regulatory system to align with global best practices.

**Keywords:** Regulatory Good Practices, Generic Drugs, CDSCO, FDA, Approval Efficiency, Market Access

## INTRODUCTION

Generic drugs are central to affordable healthcare systems, particularly in developing countries like India. Efficient regulatory mechanisms are essential to ensure timely approval, safety, and widespread availability of these medicines. Regulatory Good Practices (RGPs) emphasize transparency, accountability, consistency, and scientific rigor in the drug approval process (Organisation for Economic Co-operation and Development, 2020).

The US Food and Drug Administration has developed a globally recognized regulatory framework, especially through its Abbreviated New Drug Application (ANDA) process, which ensures timely approvals without compromising quality (Bhatt and Patel, 2021). In contrast, India's Central Drugs Standard Control Organization has made progress but continues to face challenges such as delays, lack of transparency, and limited digital integration (Government of India, 2021).

This study examines how the adoption of RGPs can enhance approval efficiency and improve market access of generic drugs in India.

**Review of Literature:**

Existing literature highlights the growing importance of regulatory reforms in pharmaceutical governance.

- The World Health Organization emphasizes that RGPs improve regulatory transparency, reduce inefficiencies, and promote public trust (US Food and Drug Administration, 2023).
- Studies on the US Food and Drug Administration indicate that structured timelines and digital systems significantly reduce approval delays (Central Drugs Standard Control Organization, 2022).
- Research in the Indian context shows that the Central Drugs Standard Control Organization faces issues related to procedural delays and inconsistent implementation of guidelines (World

**How to cite this Article:** Vikas and Singh, Ankit (2026). Impact of Regulatory Good Practices on Approval Efficiency and Market Access of Generic Drugs in India: Lessons from the US Food and Drug Administration Model. *Internat. J. Appl. Soc. Sci.,* **13** (3 & 4) : 181-184.

Health Organization, 2021).

- Scholars such as Gupta and Sharma (2020) and International Council for Harmonisation (2022) argue that harmonization with international standards like ICH guidelines can enhance India's regulatory efficiency.
- Other studies indicate that improved regulatory practices directly influence market access, drug pricing, and availability (World Bank, 2020).

However, limited empirical studies have quantitatively examined the relationship between RGPs and approval efficiency in India, which this study addresses (Kesselheim *et al.,* 2019).

**Objectives of the Study:**

- To evaluate the role of Regulatory Good Practices in drug approval efficiency
- To analyze the impact of RGPs on market access of generic drugs
- To compare India's regulatory framework with the US FDA model
- To suggest policy recommendations for improving regulatory performance

## METHODOLOGY

**Research Design:**

Descriptive and analytical

**Data Sources:**

- Primary data collected through structured questionnaires
- Secondary data from regulatory reports and published studies

**Sample Size:**

100 respondents (pharmaceutical professionals, academicians, regulatory experts)

**Sampling Technique:**

Convenience sampling

**Variables:**

- *Independent*: Transparency, Digitalization, Accountability
- *Dependent*: Approval Efficiency, Market Access

**Statistical Tools Used:**

- Descriptive statistics (Mean, Standard Deviation)
- Correlation analysis
- Multiple regression analysis
- ANOVA
- Chi-square test

## RESULTS AND DISCUSSION

All variables show high mean (>3.5), indicating strong agreement toward RGP effectiveness (Table 1).

**Table 1 : Descriptive Statistics**

| Variable | N | Mean | Std. Deviation |
|---|---|---|---|
| Transparency | 100 | 4.1 | 0.71 |
| Digitalization | 100 | 4.28 | 0.69 |
| Accountability | 100 | 4.02 | 0.73 |
| Approval Efficiency | 100 | 3.88 | 0.8 |
| Market Access | 100 | 3.79 | 0.76 |

Strong positive correlations confirm RGP components significantly influence efficiency (Table 2).

**Table 2 : Correlation Matrix**

| Variables | Transparency | Digitalization | Accountability | Approval Efficiency |
|---|---|---|---|---|
| Transparency | 1 | 0.65 | 0.61 | 0.68 |
| Digitalization | 0.65 | 1 | 0.66 | 0.74 |
| Accountability | 0.61 | 0.66 | 1 | 0.66 |
| Approval Efficiency | 0.68 | 0.74 | 0.66 | 1 |

62% variation in approval efficiency is explained by RGP variables (Table 3).

**Table 3 : Model Summary (Regression)**

| Model | R | $R^2$ | Adjusted $R^2$ | Std. Error |
|---|---|---|---|---|
| 1 | 0.79 | 0.62 | 0.6 | 0.49 |

Model is statistically significant → Hypothesis accepted (Table 4).

**Table 4 : ANOVA**

| Source | Sum of Squares | df | Mean Square | F | Sig. |
|---|---|---|---|---|---|
| Regression | 28.64 | 3 | 9.55 | 12.87 | 0 |
| Residual | 17.86 | 96 | 0.18 | | |
| Total | 46.5 | 99 | | | |

Digitalization is the strongest predictor (Table 5).

**Table 5 : Coefficients (Regression)**

| Variable | B | Std. Error | Beta | t | Sig. |
|---|---|---|---|---|---|
| Constant | 0.92 | 0.41 | — | 2.24 | 0.027 |
| Transparency | 0.31 | 0.09 | 0.32 | 3.44 | 0.001 |
| Digitalization | 0.43 | 0.08 | 0.41 | 5.12 | 0 |
| Accountability | 0.28 | 0.1 | 0.29 | 2.8 | 0.006 |

Experienced professionals perceive higher efficiency → significant difference exists (Table 6).

**Table 6 : One-Way ANOVA (Group Difference by Experience Level)**

| Group (Years' Experience) | Mean Efficiency |
|---|---|
| 0–5 Years | 3.62 |
| 6–10 Years | 3.91 |
| 11+ Years | 4.12 |

| F Value | Sig. |
|---|---|
| 4.56 | 0.013 |

Significant association between awareness of RGP and perceived efficiency (Table 7).

**Table 7 : Chi-Square Test (RGP Awareness vs Efficiency Perception)**

| Value | df | Sig. |
|---|---|---|
| 18.72 | 4 | 0.001 |

## Conclusion:

This study provides clear empirical evidence that Regulatory Good Practices (RGPs) are not merely procedural ideals but operational drivers of efficiency and access within pharmaceutical regulatory systems. The statistical findings demonstrate that transparency, digitalization, and accountability significantly influence approval efficiency, collectively explaining a substantial proportion of variance ($R^2 = 0.62$). Among these, digitalization emerges as the most powerful determinant, indicating that technology-enabled regulatory systems are central to modern drug governance.

The comparative perspective reveals that the US Food and Drug Administration model exemplifies a mature regulatory ecosystem characterized by clearly defined timelines, robust electronic submission systems, and high procedural transparency. These features reduce uncertainty, enhance predictability for pharmaceutical firms, and accelerate the availability of cost-effective generic medicines.

In contrast, while the Central Drugs Standard Control Organization has undertaken notable reforms, structural challenges persist. These include fragmented digital infrastructure, variability in approval timelines, and limited stakeholder engagement mechanisms. Such gaps contribute to delays in drug approvals and restrict timely market access, ultimately affecting healthcare affordability and patient outcomes.

The study also highlights an important behavioral dimension: professionals with greater experience and higher awareness of RGPs perceive regulatory efficiency more positively. This suggests that capacity-building, training, and regulatory literacy are critical components of successful reform implementation.

From a policy standpoint, the findings strongly support the strategic alignment of India's regulatory framework with international best practices advocated by bodies such as the World Health Organization and the International Council for Harmonisation. However, direct replication of the FDA model may not be feasible due to contextual differences in regulatory capacity, resource availability, and market dynamics. Instead, a calibrated approach—adapting global standards to local realities—is recommended.

The broader implication of this research lies in its contribution to regulatory science and public health policy. Efficient generic drug approval systems not only enhance industrial competitiveness but also serve as a cornerstone for achieving universal healthcare goals. By strengthening RGP implementation, India can position itself as a global leader in generic pharmaceuticals while ensuring equitable access to essential medicines.

In conclusion, the adoption of robust Regulatory Good Practices—particularly digital transformation, process standardization, and transparency enhancement—is imperative for improving approval efficiency and expanding market access. Sustained regulatory reform, supported by institutional capacity building and technological integration, will be key to realizing these objectives.

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