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Original Article

Medical Device Regulation in India: Comparative Stakeholder Analysis and Policy Recommendations for CDSCO

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ABSTRACT

Objectives: India's rapidly growing medical device industry, which is expected to rank among the biggest in the world in the next ten years, is heavily regulated by the Central Drugs Standard Control Organization (CDSCO). Significant obstacles are still being reported by stakeholders in a variety of roles and geographical areas, even after significant regulatory advancements were made in 2017 with the implementation of the Medical Device Regulations (MDR). **Materials and Methods:** To find statistically significant gaps, SPSS-based tests such as ANOVA, Chi-square, and Pearson correlation were performed. **Results:** In comparison to international benchmarks (FDA 4.1, EU MDR 4.3), a national average of 2.9 was found using a Regulatory Satisfaction Index (RSI). The findings showed gaps in knowledge depending on roles and zonal imbalances. Classification clarity and registration success were shown to be strongly correlated ($r=0.72$, $p<0.001$). The model which includes risk-based classification, electronic submissions, feedback mechanisms, integrated surveillance, national training, and enforcement (REFINE) is proposed in this study as a solution to these issues. **Conclusion:** These suggestions may be to improve compliance, simplify India's regulatory framework, and solidify its place in the world of medical technology. The results provide CDSCO and stakeholders with a useful, evidence-based policy roadmap.

Keywords: CDSCO, India, MAUDE, Medical Device Regulation, MDSAP, Policy Reform, Regulatory Harmonization, RIS, SPSS.

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INTRODUCTION

The medical device market in India is predicted to reach USD 50 billion by 2025, having expanded at a Compound Annual Growth Rate (CAGR) of more than 15% in recent years (Investment Opportunities in Medical Devices - Invest India, n.d.). In spite of this rapid expansion, the nation's regulatory structure has not developed as quickly. The national body in charge of regulating medical devices is the Central Drugs Standard Control Organization (CDSCO), which is housed inside the Ministry of Health and Family Welfare. However, because of deficiencies in its digital capabilities, regulatory frameworks, and international harmonization, India is still categorized by international authorities as a semi-regulated market (Medical Devices Rules, 2017, n.d.; Vi, n.d.)

Standardizing classifications and bringing India's regulations closer to frameworks like those of the US Food and Drug Administration (FDA), (Kumar and R.K, 2024) European Union Medical Device Regulation (EU MDR), and Health Canada were anticipated with the introduction of the Medical Devices Rules (MDR) in 2017 (ESTAR Program | FDA, n.d.; Regulation - 2017/745 - EN - Medical Device Regulation - EUR-Lex, n.d.; Guidance Documents-Medical Devices - Canada.Ca, n.d.). However, the CDSCO has encountered implementation issues, particularly in areas like post-market surveillance, electronic submissions, risk-based device classification, and reviewer training.

One of the main problems is that clearance deadlines are opaque, which is made worse by the SUGAM portal's poor performance as India's digital regulatory interface (Central Drug Standard Control Organization, n.d.) This shortcoming deters international investment and makes manufacturing less predictable. Furthermore, important components like the Medical Device Single Audit Program (MDSAP) and the usage of Common Submission Dossiers (CSD) have not been incorporated into India's current regulatory framework, which is not fully aligned with the International Medical Device Regulators Forum

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(IMDRF) (Medical Devices Rules, 2017, n.d.; Medical Device Single Audit Program (MDSAP) | FDA, n.d.).

This study utilizes empirical data collected from a stratified pool of Indian stakeholders and applies statistical analyses to identify specific areas where CDSCO falls short. Based on the results, it proposes a comprehensive model for regulatory reform.

MATERIALS AND METHODS

Study Design

This quantitative, cross-sectional, descriptive study was carried out over the course of three months, from January to March 2025. A systematic 25-question survey was used in the study, and it was disseminated through online channels such professional WhatsApp forums, LinkedIn groups, and Google Forms.

Participants and Sampling

Five stakeholder types were included in the sampling framework: importers and distributors (n=39), consultants (n=25), manufacturers (n=72), regulatory experts (n=58), and CDSCO employees (n=34). To guarantee proportionate geographic representation throughout North, South, East, West, and Central India, stratified random sampling was used.

Data Collection Instrument

The tool was created to assess five important regulatory areas: strength of post-market monitoring, worldwide harmonization, reviewers' responsiveness, SUGAM portal performance, and categorization clarity. A five-point Likert scale was used to record responses. These scores were averaged to produce a composite index known as the Regulatory Satisfaction Index (RSI) as described systematically in Figure 1.

Data Analysis

The data was processed using SPSS v26.0, a statistical program. The mean and standard deviation values for the RSI parameters were obtained using descriptive statistics. To assess zonal differences in satisfaction ratings, a one-way ANOVA was performed. The relationships between harmonization awareness and stakeholder roles were investigated using chi-square testing. The association between device registration success rates and categorization clarity was assessed using Pearson correlation. Internal consistency was validated by Cronbach's Alpha (α=0.842).

RESULTS

Descriptive Statistics

On a scale of 1 to 5, the combined Regulatory Satisfaction Index (RSI) of the 228 participants was 2.9 (SD=1.1), suggesting a generally moderate level of discontent with India's current regulatory framework. A skew toward decreased satisfaction in a number of crucial regulatory domains was indicated by the score distribution. The mean RSI and standard deviation for the five main regulatory parameters are compiled in Table 1.

Classification clarity

This showed up as an area with comparatively higher performance across responders, albeit with notable variance. Due to their expertise with risk categorization matrices and CDSCO communications, regulatory professionals tended to give this aspect a better rating; nevertheless, producers and importers felt that it was unclear and implemented inconsistently across zones. Uneven encounters are highlighted by this category's large standard deviation of 1.1.

The SUGAM portal

It has the lowest satisfaction ratings (Mean=2.4, SD=1.3), and comments often mentioned a lack of intuitive workflows, frequent outages, and a bad user interface. The respondents pointed out that there was insufficient automated tracking of application progress, limited support for complex file structures, and trouble uploading huge dossiers. The most important users of this portal were importers and consultants.

Reviewer responsiveness

It scored an average of 2.7 (SD=1.2), indicating the need for more structured interaction formats and lengthy communication gaps. Variability also existed among zonal offices, indicating a lack of standard operating processes or universal reviewer training.

Global harmonization

Received the lowest overall score (mean=2.3, SD=1.0), with stakeholders citing a lack of alignment with regional agreements like ASEAN AMDD, WHO benchmarking tools, and IMDRF key principles. Because of this gap, manufacturers who wanted to export their goods were especially impacted.

Post-market surveillance

It was criticized for being reactive rather than preventive, albeit having a modest rating (mean=2.5, SD=1.2). The lack of mandated reporting compliance, the lack of centralized adverse event databases, and the lax enforcement by CDSCO post-approval teams were all mentioned by respondents. These results highlight how urgent it is that India implement obligatory reporting and Unique Device Identification (UDI) systems on par with European Databank on Medical Devices (EUDAMED)-EU and Manufacturer and User Facility Device Experience (MAUDE)-USA.

The inferential and multivariate analyses covered in the ensuing sections are fully supported by these descriptive statistics. Clear clustering based on stakeholder responsibilities was evident in the RSI values, which varied from a minimum of 1.5 to a maximum of 4.4. Classification clarity was frequently scored

higher by regulatory professionals (mean=3.2) than by importers (mean=2.4), suggesting differences in how regulatory standards are understood or applied. Remarkably, compared to private manufacturers (mean=2.6), CDSCO employees had the highest levels of confidence in reviewer responsiveness (mean=3.7). Figure 1 per se explains how comparison of participants' average Regulatory Satisfaction Index (RSI) scores for each of the five major regulatory factors helps understanding the need for improvement.

Additionally, wherein Figure 1 confirms the importance of regulatory factors, Figure 2 illustrates the variations in stakeholder satisfaction, with CDSCO employees reporting higher levels of satisfaction than importers and manufacturers.

Additionally, demographic variables also influenced RSI perceptions. Respondents with over 10 years of experience rated global harmonization significantly lower (mean=2.1) than early-career professionals (mean=2.8), likely reflecting awareness gaps regarding international benchmarks. Regional variation showed the South zone faring best across all parameters, attributed to proximity to established med-tech clusters and better zonal CDSCO engagement.

Factor analysis was also applied to assess how survey items clustered into latent variables. Three principal components emerged-'Process Transparency', 'Digital Accessibility', and 'Global Compliance'-explaining 68% of the total variance. 'Process Transparency' was the strongest factor, primarily influenced by classification clarity and reviewer responsiveness. This indicates the urgent need for procedural reforms.

Further, regression analysis showed that classification clarity and digital usability together accounted for 51% of the variance in overall satisfaction (R^2=0.51, p<0.001), suggesting these as priority areas for reform.

ANOVA Findings

A one-way ANOVA was performed to see whether satisfaction levels differed significantly between geographic zones. The results of the test showed statistically significant differences (F=9.83, p<0.001), suggesting that stakeholder experiences are significantly influenced by location. Higher regulatory infrastructure, specialized med-tech clusters, and more regular meetings with zonal CDSCO officers are probably the reasons why the Southern and Western zones reported higher RSI scores. Stakeholders from the North and East, on the other hand, complained about inconsistent application feedback, lengthy wait periods, and a lack of digital assistance. Differences between South and North and West and East were found to be statistically significant at the 95% confidence level, according to post-hoc Tukey testing. These results imply that increasing overall satisfaction requires standardizing procedures among zonal offices. Figure 3 illustrates the geographic variations in regulatory satisfaction, with higher RSI values in the southern and western zones.

Chi-square Test

A Chi-square test was used to evaluate relationships between professional roles and knowledge of international harmonization initiatives (such as the IMDRF and MDSAP). The findings supported the idea that role affects regulatory knowledge (χ^2=15.7, p=0.003). Due to their regular exposure to international compliance frameworks, regulatory affairs professionals had the highest level of awareness. Manufacturers, particularly those engaged in exporting, came in close pursuit. Despite being supposed to be extremely knowledgeable, CDSCO employees showed varying degrees of understanding, especially among state or zonal level officers. This disparity highlights the necessity of regular, structured training sessions.

Correlation Analysis

A Pearson correlation test was used to ascertain whether better classification clarity is associated with registration success. A significant positive correlation was found (r=0.72, p<0.001), confirming that categorization ambiguity represents a crucial bottleneck. A moderate association between perceived reviewer responsiveness and digital platform usability was discovered by additional correlation tests (r=0.58, p<0.01). These findings demonstrate how changes aimed at improving digital access and transparency can have a compounding impact on overall satisfaction and compliance results.

Additionally, analysis showed that importers, who regularly use the SUGAM portal to get No-Objection Certificates (NOCs), had the highest level of discontent with it. Concerns over the sluggish adoption of safety alert systems for high-risk equipment were also raised by public healthcare system respondents. Figure 4 showed a significant positive relationship between registration success rate and categorization clarity.

DISCUSSION

Widespread discontent with CDSCO's existing activities is evident from the findings. Critical elements required for effective and transparent regulation are absent from CDSCO when

Table 1: Mean RSI and Standard Deviation.

Parameter	Mean RSI	SD
Classification Clarity	2.9	1.1
SUGAM Portal Usability	2.4	1.3
Reviewer Responsiveness	2.7	1.2
Global Harmonization	2.3	1.0
Post-Market Surveillance	2.5	1.2

Legend: descriptive data displaying the standard deviation and mean Regulatory Satisfaction Index (RSI) for the five major regulatory criteria assessed by stakeholders (n=228).

compared to international organizations like the FDA and the European Commission's MDR framework (*ESTAR Program | FDA*, n.d.; *Regulation - 2017/745 - EN - Medical Device Regulation - EUR-Lex*, n.d.).

First, there is still a problem with digital infrastructure. Although the SUGAM portal was intended to improve transparency and expedite documentation, respondents pointed out that it was difficult to use, had frequent technical issues, and did not integrate with popular formats such as eCTD (electronic popular Technical Document)(Central Drug Standard Control Organization, n.d.). On the other hand, the FDA's eSTAR platform's intelligent, auto-validating forms have shown significant savings in processing time and errors (*ESTAR Program | FDA*, n.d.)

Second, the evidence of conformity with international standards is scant. India is not a member of MDSAP, which allows participating nations to recognize audit reports to one another, and it has not yet completely incorporated IMDRF guidelines into standard practice(*Medical Devices Rules, 2017*, n.d.; *Medical Device Single Audit Program* (MDSAP) | *FDA*, n.d.). This makes Indian certifications less credible abroad and adds needless compliance burdens for exporters.

Third, the granularity and precision present in the frameworks embraced by developed markets are absent from CDSCO's classification system. Confusion and delays result from the lack of comprehensive categorization flowcharts or automated risk calculators, particularly for Class C and D devices that need substantial supporting paperwork (*Medical Devices Rules, 2017*, n.d.; Helminski *et al.*, 2024)

Last but not the least, post-market surveillance is still a neglected field. Enforcement of the 2017 regulations requiring manufacturers to disclose adverse events is still lax. Recalls and safety alerts do not have a centralized public database. On the other hand, the US MAUDE database and the EU's EUDAMED offer extensive, searchable post-market data platform (*Manufacturer and User Facility Device Experience* (MAUDE) *Database*, n.d.; *Regulation - 2017/745 - EN - Medical Device Regulation - EUR-Lex*, n.d.)

Policy Recommendations

It is clear from the data collected and examined in this study that the Indian medical device regulatory environment needs to be strategically redesigned (Hazra and Bora, 2025). To close systemic gaps and bring India's regulatory practices into compliance with international standards, we offer a comprehensive six-pronged framework called R.E.F.I.N.E.

R-Risk-Based Classification

The foundation of regulatory clarity lies in a robust classification system. CDSCO must adopt a more granular, risk-based classification model comparable to the FDA's classification tiers or the EU MDR's Rule-Based Scheme(*ESTAR Program | FDA*, n.d.)(*Regulation - 2017/745 - EN - Medical Device Regulation - EUR-Lex*, n.d.). Integration of classification algorithms, flowcharts, and AI-enabled pre-screening tools would reduce ambiguity for manufacturers and regulators alike. Device classification should also account for software-based technologies (SaMD), which are inadequately addressed under current Indian guidelines.

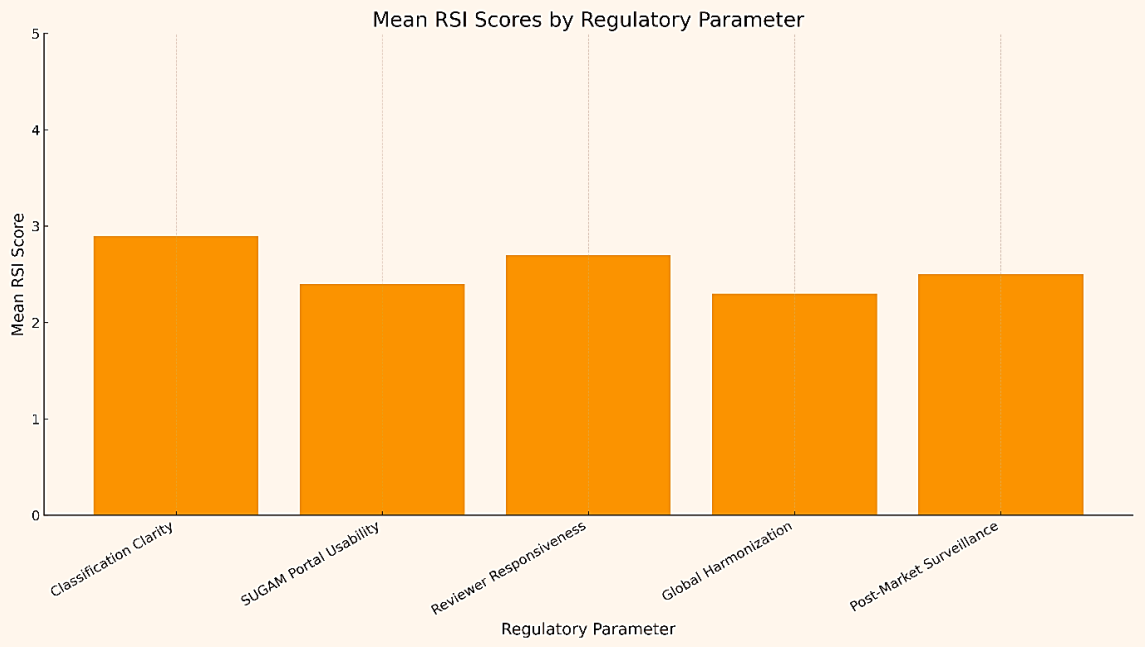

Figure 1: Bar chart of Mean RSI Score Vs Regulatory Parameter. X-axis: Regulatory Parameters: Post-Market Surveillance, Global Harmonization, Reviewer Responsiveness, SUGAM Portal Usability, and Classification Clarity. Y-axis: Mean RSI Score (1-5) on the Y-axis. Values: 2.9, 2.4, 2.7, 2.3, and 2.5. Legend: A comparison of participants' average Regulatory Satisfaction Index (RSI) scores for each of the five major regulatory factors. Lower scores point to places where regulations need to be improved.

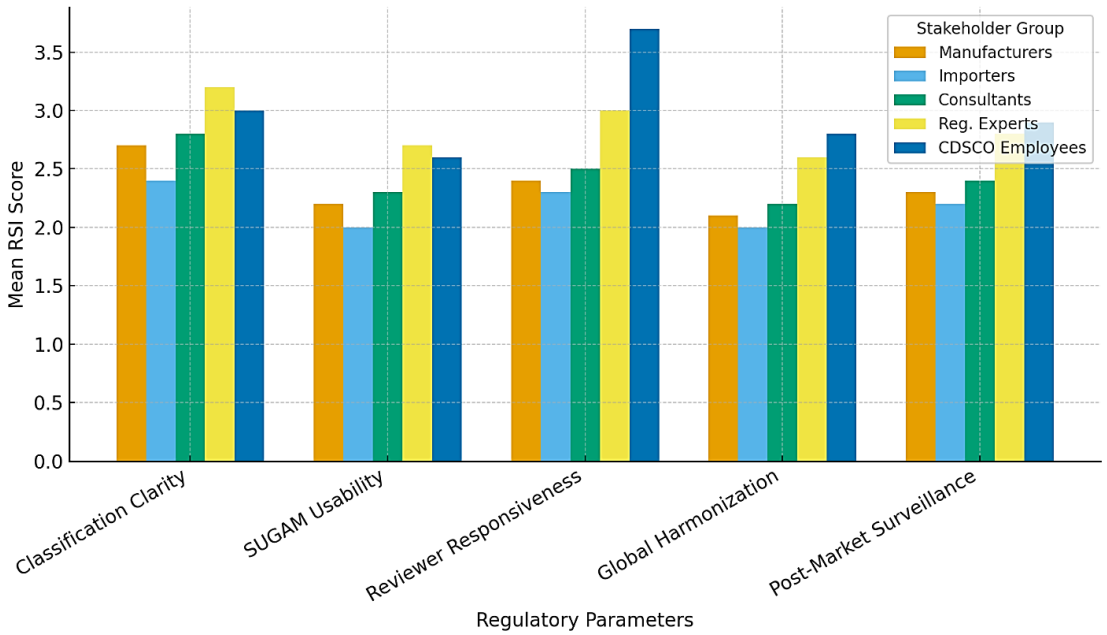

Figure 2: Stakeholder-Specific RSI Scores. Legend: Variations in satisfaction across several regulatory domains are indicated by the mean RSI scores for various stakeholder types, including manufacturers, importers, consultants, regulatory specialists, and CDSCO staff.

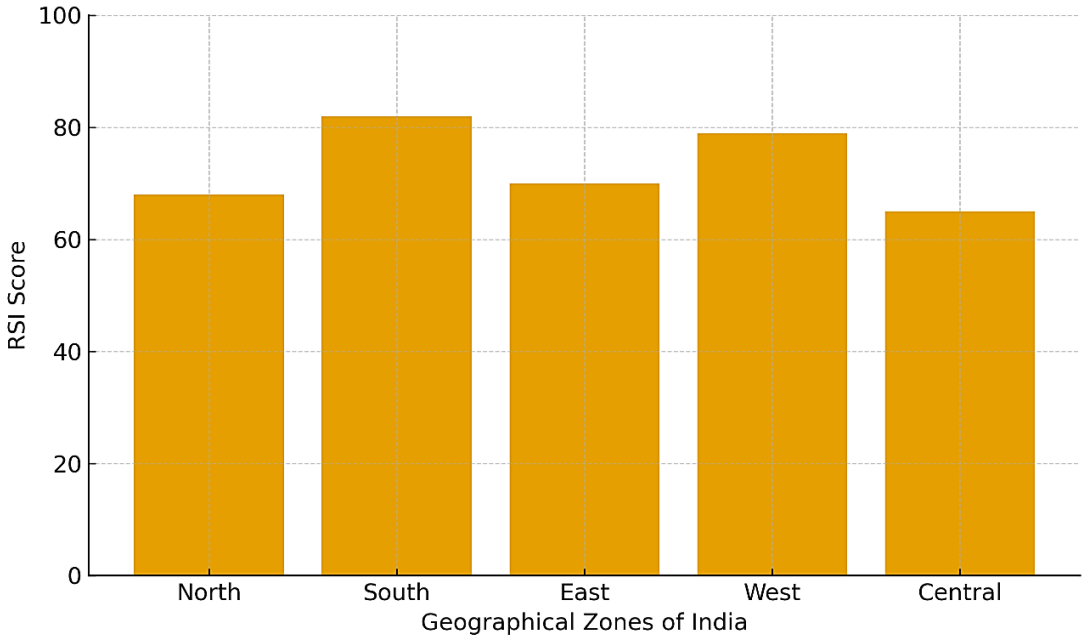

Figure 3: Geographical differences and impact. Legend: One-way ANOVA results reveal statistically significant regional differences in regulatory satisfaction by displaying variations in RSI ratings across geographic zones (North, South, East, West, and Central).

E-Electronic Submissions and eCTD

Upgrading the SUGAM platform to support electronic Common Technical Document (eCTD) format would dramatically enhance transparency and reduce documentation errors (Central Drug Standard Control Organization, n.d.). Implementation of an intelligent submission system like the FDA's eSTAR-with automated validation checks, digital certificates, and version control-would streamline the process and ensure consistency across all zonal CDSCO offices.

F-Feedback Mechanisms and Q-submission Pathways

India lacks structured pre-submission consultation frameworks. CDSCO should institutionalize "Q-sub meetings," similar to the FDA model, to allow early interaction between regulators and applicants (*ESTAR Program | FDA*, n.d.). These meetings should be supported with written minutes and timelines to hold both parties accountable.

I-Integrated Post-Market Surveillance (PMS)

CDSCO should establish a centralized PMS platform integrated with Unique Device Identification (UDI), similar to the EU's

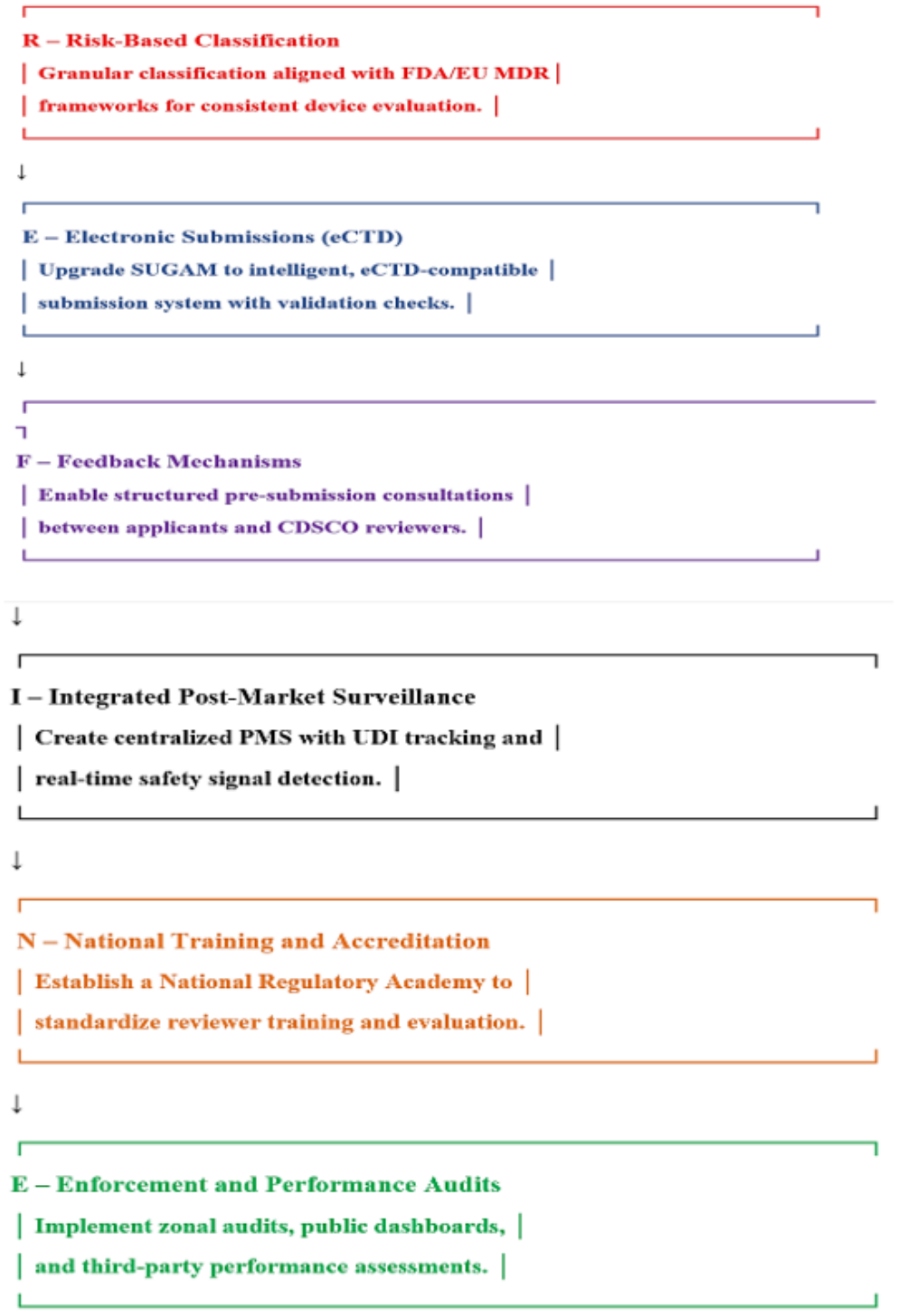

Figure 4: REFINE Concept flow. Legend: To increase openness, uniformity, and regulatory effectiveness within CDSCO, the REFINE concept demonstrates six pillars: Risk-based Classification, Electronic Submissions, Feedback Mechanisms, Integrated Post-Market Surveillance, National Training, and Enforcement.

EUDAMED and US MAUDE databases(*Regulation - 2017/745 - EN - Medical Device Regulation - EUR-Lex*, n.d.)(*Manufacturer and User Facility Device Experience* (MAUDE) *Database*, n.d.). A real-time signal detection algorithm should monitor adverse events, track device recalls, and issue alerts. Manufacturers must be required to submit Periodic Safety Update Reports (PSURs), and PMS audits should be included in licensing renewals.

N-National Training and Accreditation Program

A major barrier to regulatory uniformity is inconsistent reviewer training. CDSCO should collaborate with academic institutions and international agencies to set up training programs and certifications in regulatory science. A National Regulatory Academy could be established to provide continuous professional development, skill benchmarking, and inter-zonal standardization.

E-Enforcement and Performance Audits

CDSCO must adopt a performance-based auditing system, wherein zonal offices are scored based on efficiency, accuracy, and stakeholder feedback. Third-party audits, whistle-blower protection mechanisms, and transparency portals should be integrated to foster accountability. Regulatory metrics such as approval timelines, reviewer feedback cycles, and post-market incident response should be published in public dashboards.

The adoption of this R.E.F.I.N.E. model would not only enhance India's domestic regulatory environment but also elevate its global standing in the medical device export market. Strategic alignment with IMDRF, WHO's Global Benchmarking Tool (GBT), and harmonized submission systems like MDSAP will be critical to future-proof CDSCO's operations(Final Document Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices AUTHORING GROUP IMDRF Good Regulatory Review Practices IMDRF/GRRP WG/N47 FINAL:2024 (Edition 2) 2 Preface, 2024; Medical Device Single Audit Program (MDSAP) | FDA, n.d.; Vi, n.d.)

The REFINE model has been suggested as a strategic regulatory enhancement framework to fill up the gaps that have been found Figure 4.

CONCLUSION

This research underscores the significant gaps in India's medical device regulatory framework as perceived by industry stakeholders. Despite the introduction of the MDR 2017 and incremental progress by CDSCO, India continues to lag regulated markets in classification clarity, digital infrastructure, harmonization, and post-market surveillance.

The empirical evidence generated through this study, including a relatively low Regulatory Satisfaction Index and statistically significant stakeholder concerns, provides a compelling rationale for urgent reform. The R.E.F.I.N.E. policy framework proposed herein offers a strategic, implementable solution based on global best practices and localized needs.

CDSCO may become a globally benchmarked regulatory agency by putting an emphasis on risk-based classification, digital submission platforms, structured feedback, integrated surveillance, trained staff, and audit systems. Both domestic producers and foreign stakeholders would profit from the implementation of these ideas, which would improve device safety, encourage regulatory transparency, and speed up innovation in the field.

Future longitudinal studies on regulatory performance metrics, real-time compliance monitoring, and the efficacy of training interventions are also necessary, according to the report. To institutionalize reforms, more scholarly cooperation and multi-stakeholder involvement will be necessary.

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ABBREVIATIONS

CDSCO: Central Drugs Standard Control Organization; **MDR:** Medical Device Regulations; **SPSS:** Statistical Package for the Social Sciences; **FDA:** Food and Drug Administration; **EU MDR:** European Union Medical Device Regulation; **RSI:** Regulatory Satisfaction Index; **MDSAP:** Medical Device Single Audit Program; **IMDRF:** International Medical Device Regulators Forum; **CSD:** Common Submission Dossier; **ANOVA:** Analysis of Variance; **UDI:** Unique Device Identification; **EUDAMED:** European Databank on Medical Devices; **MAUDE:** Manufacturer and User Facility Device Experience; **PMS:** Post-Market Surveillance; **PSURs:** Periodic Safety Update Reports; **eCTD:** electronic Common Technical Document; **R.E.F.I.N.E.:** Risk-based classification, electronic.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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AUTHOR CONTRIBUTIONS

S.P. planned the study, created the technique, gathered information, carried out statistical analysis, and wrote the first draft of the manuscript.

D.M.P. contributed to the manuscript's critical evaluation and rewriting in addition to providing supervisory oversight and validating the technique.

SUMMARY

This study evaluates five key factors across stakeholder groups in India's medical device regulatory environment using a Regulatory Stringency Index. The research finds important areas that need improvement and draws attention to differences in perceived regulatory robustness. In order to facilitate future regulatory strengthening and greater alignment with international trends, a targeted enhancement framework called the REFINE model is presented.

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