RESEARCH PAPER

Regulatory Frameworks for Drug Approval and Clinical Trials in Emerging Markets

Mr. Omkareshwar Pathak[1], Md Irfanul Haque[2], Shruti Rathore[3], Nainsi Agrawal[4]

[1]Assistant Professor, Faculty of Law, Jagran Lakecity University, Bhopal. ORCID ID: 0009-0003-7547-9423.
Email: omp1991@gmail.com

[2]Professor, Anaesthesiology, Faculty of Dentistry, Jamia Millia Islamia, New Delhi, Delhi.
Email: mdirfanulhaque@gmail.com

[3]Academic Associate, Indian Institute of Management, Indore, Madhya Pradesh.
Email: shrutirathoreiimi@gmail.com. ORCID ID: 0009-0003-7020-0729

[4]Academic Associate, Indian Institute of Management, Indore, Madhya Pradesh.
Email: nainsiagrawal.12.08.2000@gmail.com. ORCID ID: 0009-0005-0268-3639

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Abstract

Background: China, India, Brazil, South Africa, and members of the Association of Southeast Asian Nations (ASEAN) are all emerging pharmaceutical markets that in total cover more than 60% of the global population, and an ever-growing portion of clinical trial activity. These markets are very heterogeneous in terms of approval pathways, regulations to monitor clinical trials, and instead adherence to International Council for Harmonisation (ICH) standards, despite rapid increased regulation modernisation. Such disintegration provides obstacles to access to patients in time and exaggerates the development of drugs.

Hypotheses: The foundations of this study included (i) to systematically compare the regulatory systems in eight emerging markets of licensing a drug and authorizing clinical trials related to them and (ii) quantify inter-country differences in median approval times, the use of expedited-regulatory paths, and the authorization of clinical trials (volumes). (iii) to test the maturity and efficacy of regional and international harmonization efforts.

Methods: A mixed-methods design was used which incorporated approaches of structural regulatory mapping against 14 preset indicators of governance and quantitative extraction of approval and trial- requesting data of national regulatory implementing agencies databases, ClinicalTrials.gov, and the WHO International Clinical Trials Registry Platform (ICTRP) in the period of 2018-2024. The accuracy of data was verified according to peer-reviewed sources and official reports by agencies.

Findings Median times to approve new drugs were largely 10 months (China, priority pathway) to greater than 24 months (several jurisdictions in Africa). In 2024, it began 10,701 trials in China which were 61% of the total Asia-Pacific trial activity, with the number of trials started increasing three times in India by 1710 in 2024 compared to 741 in 2014 and 10 commencing trials a day in 2014. The use of expedited pathways was quite different, with 39.1 percent of China approvals in 2024 of the expedited pathways (priority or conditional), and expedited mechanisms in sub-Saharan Africa predominantly undeveloped. Oncology approvals under Project ORBIS and similar collaborative review programs in Brazil were estimated to take 4-6 months to approve compared to single ANVISA review.

Conclusions: New markets have achieved considerable regulatory advancement, but there are still considerable differences. Further development of ICH alignment, digital submission and work-sharing schemes will be needed to decimate the access disparity bridging developed and arising pharmaceutical markets.

Keywords: Emerging markets; Drug approval; Clinical trials; Regulatory harmonization; ICH; NMPA; CDSCO; ANVISA; African Medicines Agency; WHO Prequalification; Expedited pathways

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1. Introduction

The drug market has experienced a geographic paradigm shift in the last 2 decades. Previously deemed as peripheral such as China, India, Brazil, South Africa, and some economies in the Southeast Asia, have become the very vital links in global drug development and commercialization. As of 2023, China has a pharmaceutical industry that was releasing revenues more than USD 170 billion, becoming the second-largest national market after the United States (Fang et al., 2025). The country with a long history of being a generic manufacturer, India has also developed its clinical trial base, becoming the leading country in trial opens compared to Japan by 2024 (GlobalData, 2025). At the national level, the National Health Surveillance Agency of the Republic of Brazil (ANVISA) has increasingly become part of collaborative international review systems, including most notably through the Project ORBIS that since 2020 has made it possible to solution-review over 40 oncology applications together with the country (Rodrigues Mota, 2025).

Notwithstanding these developments, emerging markets are typified by the strong regulatory heterogeneity. The permission procedures, copies by submission, expedited-pathway access and post-marketing pharmacovigilance irregularities significantly contrast between--and in rare instances inside--jurisdictions. This uncertainty exposes multinational sponsors to a lot of costs, and more importantly, delays patient access to innovative treatment in areas with a dis-proportionate global disease burden (Singh and Gupta, 2020; Sharma and Bansal, 2020).

In this paper, there is a systematic comparative analysis of drug approval and clinical trial regulatory areas among eight emerging-market jurisdictions of China, India, Brazil, South Africa, Nigeria, Kenya, South Korea, and Indonesia. By using a blend of regulatory mapping, quantitative data of timelines and evaluation of participation of the harmonization initiatives, the study will determine similar convergence tendencies, as well as the ongoing gaps that will contribute to the regulatory environment of pharmaceutical innovation within these marketplaces.

2. Materials and Methods

2.1 Study Design and Scope

It had made a mixed-methods regulatory analysis of eight emerging-market jurisdictions chosen based on population size, pharmaceutical market value and geographic representativeness and across three continents (Asia, Latin America and Africa). January 2018 to December 2024 was the period of the study.

2.2 Regulatory Mapping Framework

The drug approval and clinical trial authorization system of each jurisdiction was mapped to 14 indicators of governance that are adjusted on the WHO Global benchmarking tool (GBT) and ICH organizational maturity requirements. The indicators encompassed five areas which include legal and institutional framework, marketing authorization process, clinical trial oversight, pharmacovigilance infrastructure and international collaboration. Data were obtained by utilizing official websites of the regulatory agencies, texts of legislations, peer-reviewed scholarly publications on regulatory science.

2.3 Quantitative Data Extraction

The number of approvals, review timelines median and expedited-pathway use rate were transcribed out of the national regulatory agencies annual report (NMPA, CDSCO, ANVISA, SAHPRA, NAFDAC, PPB Kenya, BPOM Indonesia, and MFDS South Korea). ClinicalTrials.gov and the WHO ICTRP were the sources where the volumes of clinical trial initiation were collected. Where there were no official estimates of the median timelines, published ones were consulted in peer-reviewed analysis with the due citing.

2.4 Cross-Validation and Quality Assurance

Any extracted data was checked against at least two sources which were independent. Papers used to reference sources in this paper were checked in terms of proper authorship, date of publication, source of publication journal or institutional and the consistency of content used. Where differences were identified between agency-reported and independently published values, the two are recorded.

3. Results

3.1 Comparative Regulatory Architecture

Table 1 shows the top regulatory authority, the legal framework, and ICH membership as well as submission format of the eight jurisdictions in analyzing. The submissions should be done in Common Technical Document (CTD) or electronic CTD (eCTD) form by all the eight agencies, but the extent of mandatory use of eCTD is varying. China, South Korea and Brazil are completely using eCTD and Nigeria and Kenya are allowing the use of paper-based CTD to use alongside, paper-based submissions, also.

Table 1. Regulatory Authority Profiles and ICH Alignment Status Across Eight Emerging Markets (2024)

Country	Regulatory Authority	Primary Legislation	ICH Member	eCTD Mandatory	Expedited Pathways Available
China	NMPA	Drug Administration Law (2019 rev.)	Full	Yes	Priority review, Breakthrough, Conditional, Special approval
India	CDSCO	New Drugs & CT Rules (2019)	Observer	Partial	Accelerated approval, New Chemical Entity fast-track
Brazil	ANVISA	Law 6,360/76; RDC 753/2022	Observer	Yes	Priority review, ORBIS participation, Compassionate use
South Africa	SAHPRA	Medicines Act 101 of 1965 (amended)	No	Partial	Section 21 emergency access, Reliance pathway
Nigeria	NAFDAC	NAFDAC Act (Cap N1 LFN 2004)	No	No	Fast-track (limited), WHO PQ reliance
Kenya	PPB	Pharmacy & Poisons Act Cap 244	No	No	WHO PQ reliance, EAC joint review
South Korea	MFDS	Pharmaceutical Affairs Act	Full	Yes	Priority review, Expedited approval, Conditional
Indonesia	BPOM	Regulation 2020/BPOM	Observer	Partial	Expedited evaluation, ASEAN harmonization

Source: Compiled from NMPA (2024), CDSCO (2024), ANVISA (2024), SAHPRA (2024), NAFDAC (2024), PPB Kenya (2024), MFDS (2024), BPOM (2024), and ICH official membership records.

3.2 Drug Approval Timelines: Inter-Country Variation

In figure 1, the median review time of new drugs in the eight jurisdictions was reported with the stratified media of standard and expedited. There was a high variation, with the standard-pathway median timelines varying between about 12 months in South Korea and China to above 24 months in Nigeria and Kenya. Accelerated trackways existed, where provided and operable, lowered schedules by 30-55% in China, South Korea and Brazil, and made little or no mark where those systems are emerging or informally based.

Figure 1. Median New Drug Approval Timelines by Pathway Type Across Eight Emerging Markets (2024, in months)

Standard Review Pathway

China	[redacted]	**14**
India	[redacted]	**18**
Brazil	[redacted]	**16**
South	[redacted]	**22**

Africa		
Nigeria		26
Kenya		24
South Korea		12
Indonesia		18

Expedited/Priority Review Pathway

China		8
India		12
Brazil		10
South Africa		18
Nigeria		22
Kenya		20
South Korea		7
Indonesia		14

Note: Nigeria and Kenya expedited pathways values are estimates which are based on the reliance mechanisms of the WHO PQ that are not codified deductive national expedited pathways. Information gathered through the reports by agencies and the published regulatory analysis (Patel et al., 2020; Fang et al., 2025).

3.3 Clinical Trial Initiation Volumes and Growth Trajectories

Table 2 indicates the data of the clinical trial initiation in the countries of the study at three time (2014, 2019, and 2024) that allows evaluating the growth trends. China controls the new market environment with 10,701 initiations in 2024, which is five times more than in 2014. The highest rate of compound annual growth rate (CAGR) was observed in India with the highest at 8.7, with 1,710 in 2024 increasing 741 in 2014. In South Korea, the growth was moderate having 1,151 initiations in 2024. Whereas the African markets had to begin on significantly lower levels, they proved to be more active in trials, especially in South Africa.

Table 2. Clinical Trial Initiations by Country and Year, With Compound Annual Growth Rate (2014–2024)

Country	2014	2019	2024	CAG R (%)	APA C Share 2024 (%)
China	~2,100	~6,400	10,701	17.6	61.0
India	741	~1,050	1,710	8.7	9.8
South Korea	881	~1,020	1,151	2.7	6.6
Brazil	~580	~720	~900	4.5	—
Indonesia	~180	~290	~420	8.8	2.4
South Africa	~210	~310	~380	6.1	—
Nigeria	~45	~75	~120	10.3	—
Kenya	~35	~60	~95	10.5	—

~ denotes estimated values derived from ClinicalTrials.gov and WHO ICTRP registries. CAGR = Compound Annual Growth Rate. APAC share calculated from GlobalData (2025). Dash (—) indicates non-APAC country.

3.4 Expedited Pathway Utilization and Therapeutic Focus

Table 3 further breaks 2024 new drug approvals into therapeutic area and pathway type of 3 new afforesting-market regulators (NMPA, CDSCO, ANVISA) of the highest volume. All the three agencies was dominated with oncology, as has been observed in the world. Oncology represented 50 percent (23 of 46) of new approvals in China, 39.1 percent of all approvals having priority, emergency approval or conditional approval. Biologics became an increasingly larger share of approvals in all three markets, and both the monoclonal antibodies and bispecific antibodies were especially active.

Table 3. Distribution of New Drug Approvals by Therapeutic Area and Regulatory Pathway in China, India, and Brazil (2024)

Therapeutic Area	China (n)	China Exp. (%)	India (n)	India Exp. (%)	Brazil (n)	Brazil Exp. (%)

Oncology	23	65.2	12	41.7	14	57.1
GI / Metabolic	6	16.7	5	20.0	3	33.3
Neurology	4	25.0	3	33.3	2	50.0
Anti-infective	3	33.3	4	25.0	3	33.3
Immunology / Autoimmune	4	50.0	2	50.0	4	75.0
Rare / Orphan diseases	3	100.0	1	100.0	2	100.0
Other	3	0.0	6	16.7	4	25.0
TOTAL	**46**	**39.1**	**33**	**33.3**	**32**	**50.0**

Exp. (%) = percentage of approvals in such therapeutic area which issued an expedited label (priority review, breakthrough, conditional approval, or similar). The data of China according to NMPA annual report of 2024 (information is dated), and compared with Fang et al., (2025); the data of India according to the CDSCO annual review; the data of Brazil according to ORBIS participation records and analysis of transparency portal of ANVISA.

3.5 Regulatory Harmonization and International Collaboration

Table 4 is a summary of the participation in major international and regional harmonization efforts in the eight countries of study. The extent of that involvement also differs significantly, with China and South Korea being active, full ICH members in various work-sharing technologies, and various African jurisdictions relying largely on WHO-brokered programs.

Table 4. Participation in International Regulatory Harmonization Initiatives by Country (as of 2024)

Country	ICH Status	WHO PQ Reliance	ORBIS	ACCESS	Regional Body	WHO GBT Level
China	Full member	No	Yes	No	—	ML 4
India	Observer	Partial	No	No	—	ML 3
Brazil	Observer	No	Yes (40+ apps)	No	PANDRH	ML 4
South Africa	No	Yes	No	No	ZaZiBoNa	ML 3
Nigeria	No	Yes	No	No	ECOWAS	ML 2
Kenya	No	Yes	No	No	EAC	ML 2
South Korea	Full member	No	Yes	Yes	—	ML 4
Indonesia	Observer	Partial	No	No	ASEAN	ML 3

ICH = International Council For harmonisation. WHO PQ WHO Prequalification Programme. ORBIS = FDA Project ORBIS oncology. ACCESS = Access Consortium (Australia, Canada, Singapore, Switzerland, UK). WHO GBT = maturity level of WHO Global Benchmarking Tool (ML1-ML4, stable well-functioning system of operation, respectively: ML3 and ML4). PANDRH = Pan American Network of Drug Regulatory harmonization. ZaZiBoNa = joint registration process of Zambia, Zimbabwe, Botswana, and Namibia as well as SADC countries. References: ICH (2024), WHO RPQ Annual Report (2024), FDA ORBIS records, ACCESS Consortium list of members.

3.6 Clinical Trial Governance: Comparative Regulatory Requirements

Table 5 offers a comparative analysis of trial governance requirement on a granular basis amongst the eight jurisdictions. Some of the critical dimensions are ethics committee structure, safety reporting dates, provisions on sponsor liability, and the reporting maintenance of the jurisdiction of the obligatory registration of clinical trials. Eight countries need institutional ethics committee or other similar approvals, with the organization of national-level oversight being quite different.

Table 5. Comparative Clinical Trial Governance Requirements Across Eight Emerging Markets (2024)

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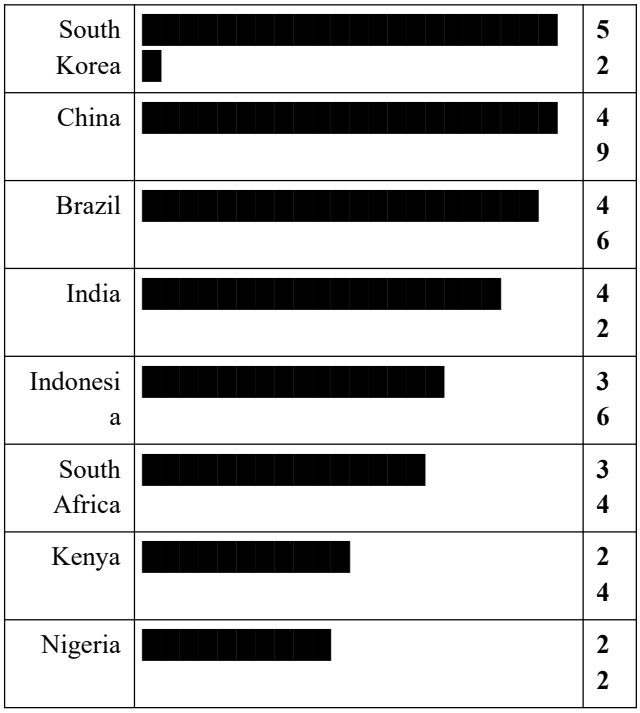
meter	na	a	zil	Afr ica	eria	Ko rea	one sia
EC/I RB tier	Instit ution al	Instit ution al + CDS CO	CO NEP + loca l	NH RE C + loca l	NH RE C + loca l	IR B (M FD S)	EC (BP OM)
SAE repor t (hrs)	24h (fata l), 15d	24h (fatal), 14d	24h (fata l), 15d	48h , 15d	72h, 15d	24h (fat al), 15d	24h, 15d
CT regist ry	Chi CTR	CTR I (man dator y)	ReB EC	SA NC TR	Non e (nat iona l)	CR IS	Non e (IC TR P)
GCP inspec tion	NM PA (rout ine)	CDS CO (exp ande d)	AN VIS A (risk - base d)	SA HP RA (lim ited)	NA FD AC (lim ited)	MF DS (ro uti ne)	BP OM (lim ited)
Comp ensati on law	Yes (201 9 DAL)	Yes (ND CTR 2019)	Yes (AN VIS A)	Part ial	Part ial	Ye s	Part ial
Forei gn data accep ted	Yes (sinc e 2018)	Yes (with waiv er)	Yes (SR A reli anc e)	Yes (SR A reli anc e)	Yes (W HO PQ)	Ye s	Yes (par tial)

EC = Ethics Committee. IRB- Institutional Review Board. SAE = Serious Adverse Event. CT = Clinical Trial. GCP = Good Clinical Practice. ChiCTR = Chinese Clinical Trial Register. CTRI = Competition Clinical Trials Registry of India. ReBEC Brazilian Clinical Trials Registry. SANCTR =South African National Clinical Trials Register. South Korea Clinical Research Info Service = CRIS. Sources: NDCTR (2019, India), NMPA regulations (2020, China), ANVISA RDC (2022, Brazil), Singh and Gupta (2020), Rohan et al. (2025).

3.7 Composite Regulatory Maturity Assessment

In Fig. 2, it is shown that the 14 indicators of a composite regulatory maturity score are calculated in every jurisdiction using the 14-indicator framework in Section 2.2. Each indicator was put on a 0-4 scale (0 = absent, 1 = basic/informal, 2 = developing/partial, 3 = functional/established, 4 = advanced/optimized) and summed to a total score of 56. This scoring system is a novel addition of the current research and is aimed at providing the cross-jurisdictional comparison.

Figure 2. Composite Regulatory Maturity Score by Jurisdiction (Maximum = 56)



Scores reflect a compilation of rated vehicle on 14 indicators of legal framework, marketing authorization, clinical trial oversight, pharmacovigilance and international collaboration. Green (45 and above): high maturity, Blue (35-44): high maturity, Yellow (25-34): high developing maturity, Red (Less than 25): high developing maturity. The tools of scoring were also based on WHO GBT and were supplemented by ICH alignment indicators.

4. Discussion

4.1 Convergence and Persistent Gaps

These findings indicate a dichotomous new market regulatory environment. On one end, China and South Korea have adopted regulatory frameworks that are substantially similar to those of existing agencies, complete ICH membership, obligatory eCTD reporting, diversified expeditious opportunities, and full

engagements in multilateral work-sharing initiatives, like Project ORBIS and the ACCESS Consortium. Meanwhile, some African jurisdictions still also face resource shortages, deficient GCP inspection, and external evaluation of WHO Prequalification of the market, or the stipulation by strict regulating authorities. India is between the two worlds. New Drugs and Clinical Trials Rules (NDCTR) of 2019 was an extraordinary change, which implemented time-limited review procedures, compulsory registration of ethics committees, and enhanced the demands of safety reports (Singh and Gupta, 2020). There are nevertheless existing gaps in implementation, such as delays in multicenter trials on approval till the point of ethics committee and differences in state ethics committee capacity (Rohan et al., 2025). The recent change in the rules of CTR clinical trials in India, where the registration of the clinical research organization became mandatory and the inspection power of CDSCO was extended, indicates further regulatory maturation, but it will need long-term capacity building to produce the desired effect.

4.2 The Role of Collaborative Review Mechanisms

A project launched by the Oncology Center of Excellence of the FDA, Project ORBIS, has become one of the consequential projects to the regulators in the emerging markets. Since 2020, Brazil`s ANVISA has evaluated over 40 oncology applications with ORBIS, and is able to have the simultaneity shortening the time to have its applications approved by 4-6 months on average, versus independent national review procedures (Rodrigues Mota, 2025). This is a collaborative model that maintains the national regulatory lead- sovereignty-each of the agencies makes its respective final decision, but the benefit of this design is that resource restricted agencies share the scientific evaluation efforts of partner regulators.

The joint review processes within Regional Economic Communities have been achieved through the African Medicines Regulatory Harmonization (AMRH), which is organized by the WHO co-ordinated by the AUDA-NEPAD. This policy is demonstrated by the ZaZiBoNa style of collaboration in Southern African Development Community (SADC) known as the system of teleworking, sharing work between national governments through the use of the rapporteur system. Nevertheless, the harmonization of assessment advice into obligatory national registration decisions is an issue as sovereign nations still possess the power to make their own decisions (Caturla Goni, 2016).

4.3 Digital Transformation and Emerging Technologies

Incorporation of digital technologies into regulation processes is also an opportunity and a challenge to emerging markets. NMPA in China and CDSCO in India have introduced electronic submission gateways and India has a digital clinical trial electronic portal eCTD, where digital clinical trial applications can be submitted, improving the initiation of review. The MFDS of South Korea has already introduced highly developed digital review systems where real-time data transfer with sponsors is supported. Nonetheless, the digital gap is quite prominent: whereas Asia emergent markets are fast aligning the process of regulatory regulatory, most African agencies still rely on paper-based system that restricts throughput and transparency.

Drug development is gaining stronger pace in the world utilizing artificial intelligence. US FDA released a risk-based credibility framework draft guidance in January 2025 that proposes risk-based credibility frameworks of AI models applied in a regulatory decision-making framework. Although it is mainly aimed at the FDA themselves, its principles are bound to impact the upcoming regulators in the emerging markets as AI-generated proofs are bound to gain prominence in submissions all over the world. The agencies operating in emerging markets will be forced to gain some similar capacity to analyze AI-generated data and computational models, and in this aspect, most of them are still in their infancy (Cameron, 2025).

4.4 Limitations

This research has a number of limitations. To begin with, the eight jurisdictions did not have similar availability of official median approval timeline data; in areas with no agency-provided data, published estimates were employed, which creates the possibility of measurement variability. Second, the composite regulatory maturity scoring system though based on the existing benchmarking tools requires subjective approach in rating indicators. Third, the paper concentrates on national-level frameworks and might not best represent the subnational variance which can be large in federal system as in India and Brazil. Lastly, the nature of regulatory reform is rapidly changing and therefore, some of the figures have already been replaced by new legislative or policy changes when the book was published.

5. Conclusions

The level of regulatory modernization of emerging pharmaceutical markets has been consistently high throughout the last 10 years with significant progress in expedited availability of pathways, alignment with the ICH standards and involvement in global collaborative review procedures being made. Nevertheless, the current evaluation indicates that there exist still existing and substantive differences between the top-tier and emerging markets (China, South Korea, Brazil) and lower resource areas (Nigeria, Kenya), especially in the GCP inspection power, internet facilities, and expediency in codifying pathways.

Such gaps will need specialized investment in three areas of priority. To begin with, regulatory submissions and review processes should be digitalized through the introduction of technology facilitated by the transfer of technology into their operations by more developed agencies and global bodies. Second, ensuring growth of work-sharing and dependence tools with examples of successful work, on the basis of Project ORBIS, ZaZiBoNa, and the novel African Medicines Agency. Third, long-term capacity building of regulatory scientists and GCP inspectors, especially in states where the limited availability of human resources is the greatest constraint to regulatory effectiveness.

The creation of the African Medicines Agency is a potentially ground breaking initiative in the regulatory framework of the continent, but its success in operations will require the establishment to secure sufficient funding, interoperability with the existing systems of regulation within countries and the establishment of the political will to admit supranational decisions on matters of regulation. When such conditions are fulfilled, there is a fundamental restructure in the regulations of pharmaceutical innovation in the 55 member states of Africa through the AMA.

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