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Research Article

## Review on Regulatory Aspects of Drug Delivery Systems in Emerging Markets

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### Abstract

This review explores the regulatory challenges and opportunities for the development of drug delivery systems (DDS) in emerging markets such as India, China, and Brazil. It highlights the evolving regulatory frameworks, the harmonisation of national standards with international guidelines, and the rapid growth of healthcare infrastructure in these regions. Despite challenges like resource constraints, the lack of specialised regulations for novel DDS technologies, and the prevalence of counterfeit drugs, the increasing demand for advanced therapies presents significant opportunities for pharmaceutical companies. Regulatory reforms, including fast-track approval processes and investment in healthcare, create a conducive environment for the growth of DDS, especially in chronic disease management, targeted drug delivery, and biologics.

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**KEYWORDS:** Drug delivery systems, emerging markets, regulatory frameworks, harmonisation, healthcare infrastructure, pharmacovigilance, modified-release formulations, nanomedicines, biosimilars, China, India, Brazil, regulatory challenges, fast-track approval.

## INTRODUCTION

The global pharmaceutical industry is undergoing a significant transformation, with emerging markets such as India, China, Brazil, Russia, and South Africa becoming critical players in the development, production, and distribution of pharmaceutical products. These markets, collectively known as the BRICS countries, along with others like Mexico and Southeast Asia, have seen rapid growth in healthcare access, a rising middle class, and increasing demand for advanced therapies (Babu et al., 2020; Hassan et al., 2021). As the world's population continues to age and the burden of chronic diseases, such as cardiovascular disorders, diabetes, and cancer, rises, the demand for sophisticated drug delivery systems (DDS) has also increased (Soni et al., 2022).

Drug delivery systems, including modified-release formulations, nanomedicines, and biologics, offer significant advantages over traditional dosage forms by enhancing the bioavailability, stability, and therapeutic outcomes of drugs. These advanced systems enable the targeted delivery of therapeutics to specific tissues or organs, thus improving efficacy and reducing side effects (Patel et al., 2020). Modified-release formulations, for instance, offer prolonged drug release, reducing dosing frequency and enhancing patient compliance, which is particularly beneficial for chronic disease management (Vogel et al., 2019). Similarly, nanomedicines, which utilise nanoparticles to encapsulate therapeutic agents, provide new avenues for treating cancers, autoimmune diseases, and other complex conditions (Barenholz, 2012).

However, the approval and regulation of DDS in emerging markets present significant challenges due to the variability in regulatory frameworks across different countries. These challenges arise from differences in regulatory standards, clinical trial requirements, infrastructure, and resources dedicated to ensuring the safety and efficacy of drug products. While regulatory agencies in these regions are striving to harmonise their guidelines with international standards, there remains a gap between the regulatory capacity of developed and developing markets (Patel & Mehta, 2021).

In emerging markets like India, China, and Brazil, regulators have been working toward establishing clear and effective regulatory guidelines for DDS. Despite the progress, challenges such as the lack of specific regulations for novel DDS technologies (e.g., nanomedicines), the slow pace of approval processes, and limited post-market surveillance systems persist. Moreover, emerging markets are dealing with the dual challenge of rapidly adopting new technologies while simultaneously addressing issues such as counterfeit drugs, substandard formulations, and limited access to healthcare in rural areas (Tiwari et al., 2019; Zhang et al., 2020).

This review seeks to explore the regulatory aspects surrounding DDS in these emerging markets, emphasising the approval processes, regulatory frameworks, challenges, and opportunities. The objective is to highlight the unique barriers that these regions face in adopting advanced DDS technologies and explore how regulatory bodies are responding to the growing demand for innovative drug delivery options.

## 1. Regulatory Frameworks for Drug Delivery Systems in Emerging Markets

The regulatory approval of drug delivery systems (DDS) in emerging markets involves navigating complex guidelines that differ significantly from those in developed markets such as the U.S. (FDA) or the European Union (EMA). While regulatory agencies in these regions have made significant strides toward standardisation, they still face challenges due to limited resources, evolving regulations, and varying interpretations of global standards. This section delves into the regulatory processes in India, China, and Brazil, examining the approval procedures, guidelines for DDS, and the challenges faced by these regions.

### 1.1. India

#### Central Drugs Standard Control Organisation (CDSCO)

The CDSCO is India's apex regulatory body, tasked with overseeing the approval of pharmaceutical products, including DDS. It follows a regulatory process that largely mirrors the guidelines set by the World Health Organisation (WHO), though certain local nuances are incorporated to account for regional healthcare needs and the dynamic pharmaceutical landscape.

#### The process of approval includes multiple stages:

- Preclinical and Clinical Trials
- Bioequivalence Studies for Generics
- Post-Marketing Surveillance

#### Modified Release Formulations in India

India has implemented guidelines specific to modified-release formulations, including extended-release, sustained-release, and controlled-release products. These formulations are assessed based on:

- **Drug Release Profile:** In vitro testing and dissolution profiles.
- **Clinical Pharmacokinetic Data:** Ensuring the formulation achieves the intended therapeutic outcomes over an extended period.
- **Post-marketing Surveillance:** To monitor safety and efficacy in real-world settings (Sundar et al., 2019).

#### Challenges

Despite the progress, several challenges remain in India's regulatory framework:

- **Need for Comprehensive Guidelines for Novel DDS Technologies:** Current guidelines primarily focus on conventional formulations, leaving a gap in the approval process for novel DDS such as **nanomedicines**, which require specialised safety and efficacy evaluations (Bhatia et al., 2021).
- **Bridging Industry Innovation with Regulatory Practices:** Rapid innovation in drug delivery technology often outpaces regulatory adaptations, causing delays in the approval of new DDS technologies (Gupta et al., 2020).

## 1.2. China

### National Medical Products Administration (NMPA)

The NMPA, formerly known as the China Food and Drug Administration (CFDA), is the regulatory authority responsible for overseeing drug approvals in China. In recent years, NMPA has made substantial progress in streamlining the drug approval process, aligning it more closely with international standards such as those set by the FDA and EMA (Wu et al., 2021). NMPA has introduced specific guidelines for novel DDS, such as nanocarriers, liposomes, and sustained-release formulations, which include comprehensive preclinical and clinical trial requirements for safety, efficacy, and stability of DDS products.

### Regulatory Developments

China has made significant strides in recent years to improve the transparency and efficiency of the approval process. Recent reforms include:

- **Accelerated Approval Pathways:** Special pathways for innovative drugs, particularly those targeting unmet medical needs (Tang et al., 2020).
- **Reduction of Approval Times:** NMPA has introduced measures to reduce the time it takes to approve new DDS, significantly improving access to innovative therapies (Zhou et al., 2020).

### Challenges

While regulatory reform has progressed, China still faces challenges:

- **Balancing Innovation with Safety:** China's desire to rapidly integrate innovative DDS into the market must be balanced with rigorous safety and efficacy assessments (Feng et al., 2019).
- **Limited Regulation Specific to DDS:** Although NMPA has addressed DDS in certain guidelines, there remains a lack of comprehensive regulations specifically tailored to novel DDS technologies such as **3D-printed medications** or **biologic DDS** (Yang & Li, 2021).

## 1.3. Brazil

### National Health Surveillance Agency (ANVISA)

ANVISA regulates pharmaceutical products, including DDS, in Brazil. The agency follows international standards set by the International Council for Harmonisation (ICH), ensuring that its approval process aligns with global best practices (Silva et al., 2020).

### ANVISA's drug approval process includes:

- **Preclinical Studies:** In vitro and in vivo testing of new DDS formulations.
- **Clinical Trials:** Multi-phase trials to establish safety, efficacy, and pharmacokinetics.
- **Post-Marketing Surveillance:** Continuous monitoring of drug safety and effectiveness once the product is on the market.

### Regulatory Guidelines

ANVISA follows ICH guidelines closely and provides specific regulations for the approval of DDS, including nanomedicines and modified-release formulations. Regulatory submissions include:

- **Stability Testing:** Requirements for stability studies for DDS products, including long-term stability and accelerated testing.
- **Bioavailability/Bioequivalence Studies:** These are critical for the approval of generic modified-release formulations (Júnior et al., 2021).

### Challenges

#### Brazil faces several regulatory challenges:

- **Variability in Regulatory Capacity:** Different regions within Brazil have varying levels of regulatory capacity, which can cause discrepancies in the approval timelines and consistency (Lopes et al., 2021).
- **Need for Local Clinical Trials:** Due to the diverse population and environmental factors in Brazil, there is a strong demand for local clinical trials to ensure the safety and efficacy of DDS products in the Brazilian market (Costa et al., 2020).

Table 1: Comparison of Regulatory Frameworks for DDS in India, China, and Brazil

Aspect	India (CDSCO)	China (NMPA)	Brazil (ANVISA)
Regulatory Authority	Central Drugs Standard Control Organisation (CDSCO)	National Medical Products Administration (NMPA)	National Health Surveillance Agency (ANVISA)
Key Guidelines	Modified-release formulations, Nanomedicines	Nanocarriers, Modified-release formulations	ICH guidelines, Nanomedicines, Modified-release formulations
Approval Process	Preclinical, Clinical Trials, Post-marketing surveillance	Accelerated approvals, Special pathways for innovation	Preclinical, Clinical Trials, Post-marketing surveillance
Challenges	Need for guidelines for novel DDS technologies, Bridging industry innovation with regulatory practices.	Balancing innovation with safety, Limited specific DDS regulations	Variability in regulatory capacity, Need for local clinical trials
Innovative Drug Pathways	Limited for novel DDS technologies	Accelerated approval for innovative drugs	Special focus on ICH-compliant clinical trials
Post-Marketing Surveillance	Active monitoring, though less robust than in developed markets	Improving, but regulatory capacity remains a challenge	Continuous monitoring, particularly for safety and efficacy

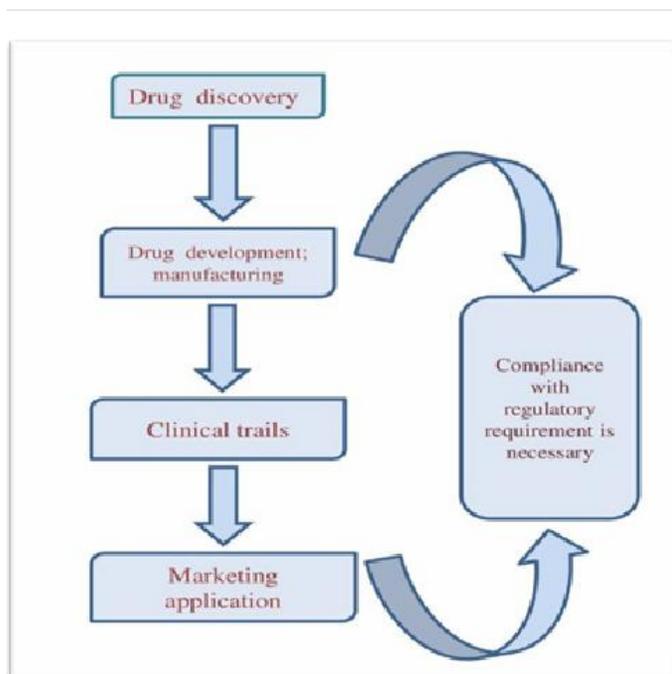


Figure 1: Regulatory Frameworks for DDS in Emerging Markets

## 2. Approval Processes for Drug Delivery Systems (DDS)

The approval of drug delivery systems (DDS), especially innovative and complex products like nanomedicines, requires a thorough evaluation by regulatory agencies. However, the approval process in emerging markets often faces significant delays due to a lack of harmonisation across regions, limited resources, and the continuous evolution of regulations to address new technologies. The complexity and diversity of DDS products necessitate specialised regulatory frameworks, which can be inconsistent across emerging markets.

### 2.1. Modified Release Systems (MRDs)

Modified-release dosage forms, such as extended-release (ER), sustained-release (SR), and controlled-release (CR) systems, are increasingly common in the treatment of chronic diseases due to their ability to provide prolonged drug release, reduce dosing frequency, and enhance patient compliance (Sundar et al., 2019). Regulatory bodies in emerging markets, including CDSCO (India), NMPA (China), and ANVISA (Brazil), have established specific guidelines to evaluate these systems, with an emphasis on demonstrating therapeutic equivalence.

#### • Regulatory Guidelines:

Regulatory agencies require companies to submit detailed data on the release mechanism, stability, bioavailability, and pharmacokinetics of MRDs. In some cases, *in vitro* drug release profiles are compared to *in vivo* data to demonstrate the therapeutic equivalence of the formulation.

- **India:** The CDSCO requires submission of dissolution testing, stability studies, and bioavailability data for MRDs, with a strong emphasis on bioequivalence for generics (Kohli et al., 2020).

- **China:** The NMPA follows international guidelines and requires comprehensive data on the drug release profile, pharmacokinetics, and long-term stability of MRDs (Zhou et al., 2020).
- **Brazil:** ANVISA requires the demonstration of therapeutic equivalence, especially for modified-release formulations, which includes pharmacokinetic studies and stability assessments (Júnior et al., 2021).

#### • Bioequivalence Studies:

In markets like India, **bioequivalence studies** are critical, particularly for generic MRDs. These studies compare the pharmacokinetic profiles of the generic and reference drug under similar conditions to demonstrate similar efficacy and safety (Sundar et al., 2019).

#### Challenges:

- **Bioequivalence Testing:** Aligning bioequivalence testing methods with international standards remains challenging in emerging markets. The complexity of MRDs, especially those with intricate release profiles, complicates the design of universally accepted testing protocols (Gupta et al., 2020).
- **Clinical Efficacy and Patient Population:** Demonstrating clinical efficacy in specific patient populations can be difficult due to variations in genetic factors, comorbidities, and the concurrent use of other medications in different regions (Bhatia et al., 2021).

### 2.2. Nanomedicines

Nanotechnology-based DDS, such as liposomes, micelles, and polymeric nanoparticles, offer novel solutions for targeted drug delivery, improving the efficacy and safety profiles of drugs. Despite their potential, the regulatory landscape for nanomedicines is still developing in many emerging markets.

#### • Regulatory Framework:

Regulatory bodies are refining or developing guidelines to evaluate the safety, efficacy, and pharmacokinetics of nanomedicines. For instance:

- **India and China** have issued preliminary guidelines, but Brazil still lacks comprehensive regulations for nanotechnology-based DDS (Feng et al., 2019).
- **NMPA** has introduced basic guidelines for nanomedicines, covering toxicity studies, long-term stability testing, and detailed characterisation of nanoparticles, including size, charge, and surface modifications (Wu et al., 2021).

#### Challenges:

- **Lack of Specific Regulatory Guidance:** Despite growing interest in nanomedicines, many emerging markets still lack clear and specific regulatory guidance. This leads to regulatory uncertainty, delayed approvals, and inconsistent decision-making (Yang & Li, 2021).
- **Complexity in Safety and Toxicity Assessment:** The unique physicochemical properties of nanoparticles, such as their small size and large surface area, raise concerns about their long-term toxicity, accumulation in tissues, and

potential environmental impact. Regulatory agencies need to develop specialised methods for assessing these factors (Li et al., 2020).

- **Need for Specialised Equipment and Expertise:** Evaluating nanomedicines requires advanced laboratory equipment and highly trained personnel to conduct toxicity and efficacy studies, which can be challenging in regions with limited resources (Zhou et al., 2020).

### 2.3. Biologics and Biocompatible DDS

Biologics, including monoclonal antibodies, vaccines, and gene therapies, represent an exciting frontier in DDS. These products require specialised regulatory approaches due to their complex nature, particularly when delivered through novel DDS such as liposomal formulations or other biocompatible carriers.

- **Regulatory Guidelines for Biologics:**

Regulatory authorities in emerging markets generally follow international standards for biologics, guided by agencies like the FDA and EMA. However, regional variations exist, and approval processes are often influenced by local factors such as clinical trial infrastructure and public health priorities (Lopes et al., 2021).

- **Clinical Trial Requirements:** Many emerging markets, including India and Brazil, require local clinical trials for biologics to demonstrate safety and efficacy in their specific populations. These trials often focus on immune responses, long-term safety, and the scaling-up of production processes (Silva et al., 2020).

#### Challenges:

- **High Costs of Clinical Trials:** Biologic products are expensive to develop, and conducting large-scale clinical trials in emerging markets presents significant financial challenges. These high costs can delay approval and limit availability (Júnior et al., 2021).
- **Infrastructure Limitations:** Some regions lack the specialised infrastructure required for the development and approval of biologics, such as manufacturing facilities, advanced diagnostic testing, and cold-chain logistics for vaccine storage (Kohli et al., 2020).
- **Regulatory Gaps:** Many emerging markets have yet to establish comprehensive guidelines for biologics delivered through DDS (e.g., liposomal formulations), leading to delays and inconsistent regulatory decisions (Costa et al., 2020).

### 3. Post-Market Surveillance and Regulatory Challenges

Once DDS products are approved, regulatory agencies must ensure their continued safety and effectiveness in real-world settings. Post-market surveillance (PMS) is essential to identify any unforeseen side effects, ensure compliance with safety standards, and facilitate swift corrective actions. In emerging markets, however, the PMS process faces several hurdles, including limited infrastructure, resource constraints, and a lack of regulatory coordination.

### 3.1. Safety Monitoring

Post-market surveillance (PMS) plays a critical role in ensuring that DDS products maintain their safety profiles after they reach the market. Emerging markets often face significant challenges in establishing effective PMS systems due to limited resources, infrastructure, and regulatory capacity.

- **Regulatory Requirements:**

Many emerging markets, including India and China, have introduced **pharmacovigilance programs** to monitor the safety of DDS products post-approval. These programs typically gather data from healthcare professionals, patients, and pharmaceutical companies to identify adverse drug reactions (ADRs), product quality issues, and emerging safety concerns. These programs are designed to ensure the continued safety and efficacy of drugs once they are in wide use (Sundar et al., 2019).

- **India:** The **Central Drugs Standard Control Organisation (CDSCO)**, through the **Pharmacovigilance Programme of India (PvPI)**, monitors adverse drug reactions (ADRs) and updates safety information. However, the program faces challenges, particularly in rural areas, where there is low reporting of adverse events (Kohli et al., 2020).
- **China:** The **National Medical Products Administration (NMPA)** has established pharmacovigilance guidelines that include adverse event reporting systems. However, these systems remain less robust in certain regions due to inconsistent implementation (Feng et al., 2019).

#### Challenges:

- **Data Collection and Reporting:** Effective data collection and analysis are critical to identifying safety issues. However, many emerging markets struggle with incomplete reporting systems, poor public awareness, and underreporting of adverse reactions. Inconsistent reporting standards and inadequate public engagement contribute to significant gaps in the safety monitoring process (Bhatia et al., 2021). For instance, in India, underreporting of ADRs remains a significant issue due to limited awareness among healthcare providers and patients (Gupta et al., 2020).
- **Resource Constraints:** The lack of infrastructure and trained personnel in many emerging markets limits the capacity to track and evaluate safety data efficiently. Many countries face challenges in integrating modern technologies, such as electronic reporting systems and automated data analysis, to ensure comprehensive safety surveillance (Júnior et al., 2021). The shortage of trained staff and the absence of dedicated pharmacovigilance units further compound the issue.

### 3.2. Counterfeit and Substandard Products

Counterfeit and substandard DDS products are a major issue in emerging markets, posing significant risks to patient safety and the efficacy of treatments. These products often enter the

market in regions with weaker regulatory enforcement, leading to serious public health concerns.

- **Prevalence of Counterfeits:**

The World Health Organisation (WHO) estimates that as much as **10%** of medicines in low- and middle-income countries are counterfeit, and this number is likely higher for certain types of drugs, including DDS (**WHO, 2017**). Counterfeit medicines are particularly common in regions where regulatory oversight is limited or inconsistent. These products can undermine the efficacy of treatments, potentially leading to therapeutic failure and adverse health outcomes. In some extreme cases, counterfeit DDS products may contain harmful substances or incorrect dosages, leading to serious health complications (**Sundar et al., 2019**).

**Challenges:**

- **Supply Chain Oversight:**

Ensuring the integrity of the pharmaceutical supply chain is one of the most pressing challenges for emerging markets. Counterfeit DDS products often enter the market through informal supply chains, and many regions lack the resources to monitor all stages of the drug distribution process effectively. In addition, there is often inadequate verification of the authenticity of drugs, which can result in counterfeit products reaching healthcare facilities and patients (**Li et al., 2020**). Furthermore, many emerging markets face difficulties in tracking distribution channels, as products may be transported across borders and sold through informal or illicit channels (**Gupta et al., 2020**).

- **Regulatory Enforcement:**

While some emerging markets have established dedicated agencies to combat counterfeit medicines, enforcement remains inconsistent. A lack of coordination between national and regional authorities often leads to ineffective implementation of anti-counterfeit measures. Furthermore, the capacity of regulatory bodies to inspect manufacturing facilities and distribution networks is often limited, which makes it difficult to enforce penalties for counterfeiters effectively.

- In **India**, the **Ministry of Health and Family Welfare** has been working to strengthen anti-counterfeit measures, but challenges remain due to the sheer volume of medicines being manufactured and distributed (**Kohli et al., 2020**).

- **China** has increased efforts to combat counterfeit products, including stricter regulations and penalties for manufacturers found guilty of producing substandard medicines. However, challenges persist in ensuring compliance across vast geographical regions (**Feng et al., 2019**).

#### 4. Opportunities for Growth in Emerging Markets

Despite the regulatory challenges and infrastructure limitations in emerging markets, these regions offer significant growth opportunities for the pharmaceutical industry, especially for

**drug delivery systems (DDS)**. The combination of growing healthcare access, an expanding patient base, and a rising demand for advanced therapies positions emerging markets as attractive destinations for pharmaceutical companies developing DDS. As these markets continue to mature, the potential for innovative drug delivery solutions is becoming more apparent.

#### 4.1. Evolving Regulatory Environment

The regulatory environment in emerging markets is evolving rapidly. Many of these regions are modernising their regulatory frameworks to attract more foreign investment, speed up drug approvals, and provide access to cutting-edge therapies. This evolving regulatory landscape offers opportunities for pharmaceutical companies to bring DDS products to market more quickly and efficiently.

- **Harmonisation with International Standards:**

Regulatory agencies in emerging markets, such as India's CDSCO, China's NMPA, and Brazil's ANVISA, are making concerted efforts to harmonise their regulations with international standards, such as those set by the **FDA (U.S.)** and **EMA (Europe)**. This alignment is intended to simplify the approval process for novel DDS technologies and ensure that emerging markets are more integrated into the global pharmaceutical landscape. For example:

- **China's Recent Pharmaceutical Reforms:** One of the most notable efforts is China's recent pharmaceutical reforms aimed at accelerating drug approval timelines. The country has streamlined its regulatory processes, offering faster approval for innovative drugs and DDS, especially those that target unmet medical needs. These reforms also include the introduction of a fast-track approval process for high-need therapeutic areas like oncology and rare diseases (**Zhou et al., 2020**).

- **India's Generic Drug Regulations:** India has a strong generics market, and its regulatory body, **CDSCO**, has strengthened guidelines for modified-release formulations and other DDS. This is part of an effort to bring more advanced therapies to market, including those in the **biosimilars** and **nanomedicine** categories (**Sundar et al., 2019**).

- **Brazil's Push for Innovation:** Brazil has shown a growing focus on enhancing its regulatory capacity, particularly for advanced DDS. The country has invested in streamlining regulatory approval processes for novel drug delivery technologies, which can help drive future growth in the biologics and biosimilars sectors (**Júnior et al., 2021**).

- **Example of Regulatory Reform in China:**

China's **National Medical Products Administration (NMPA)** has been one of the leaders in pushing regulatory reforms to attract innovation and new therapies. Recent initiatives to fast-track the approval of DDS, such as **nanomedicines** and **biologics**, offer drug developers opportunities to bring novel products to

market with reduced timelines. These reforms also enhance transparency and regulatory efficiency, thus strengthening the overall healthcare system. For instance:

- **Breakthrough Therapy Designation:** Under China's reforms, drugs that meet certain criteria, such as targeting serious diseases, can receive **Breakthrough Therapy Designation** to expedite their regulatory review. This move benefits both **nanomedicines** and **modified-release DDS**, which often target complex diseases such as cancer and diabetes (Wu et al., 2021).
- **Harmonisation Benefits:** The ongoing harmonisation of regulatory practices offers several benefits to drug developers:
  - **Reduced Time to Market:** By aligning with international standards, emerging markets can expedite the approval process, allowing companies to introduce their DDS products more quickly (Zhou et al., 2020).
  - **Enhanced Global Access:** As emerging markets follow global guidelines, pharmaceutical companies benefit from smoother pathways to sell their products not only in these regions but also in developed markets (Sundar et al., 2019).
  - **Increased Investment:** A predictable and transparent regulatory environment can attract more investment from both local and international pharmaceutical companies, facilitating the growth of DDS development (Feng et al., 2019).

#### 4.2. Growing Healthcare Infrastructure

As emerging markets continue to experience economic growth, healthcare infrastructure in these regions is rapidly improving. Increased government spending on healthcare, the development of healthcare facilities, and the expansion of medical access in urban and semi-urban areas are all contributing to the growth of DDS in these regions.

- **Urbanisation and Healthcare Expansion:**
  - The growth of urban and semi-urban populations in countries like India, China, and Brazil is driving an increased demand for advanced healthcare services and therapies. Urbanisation leads to better healthcare access, creating new opportunities for innovative DDS to reach larger patient populations.
  - **India:** India's healthcare infrastructure is improving, particularly in metropolitan areas where there is an increasing demand for modified-release formulations and targeted drug delivery systems. The rise of private healthcare facilities, medical tourism, and the expansion of diagnostic networks in cities like Delhi, Mumbai, and Bengaluru are creating significant opportunities for DDS (Kohli et al., 2020).
  - **China:** China's healthcare infrastructure is undergoing massive upgrades, with an increasing emphasis on **smart healthcare technologies** and biotechnology. This opens doors for **nanomedicines**, **biologics**, and other novel DDS technologies, especially in high-demand

therapeutic areas like oncology and cardiovascular diseases (Wu et al., 2021).

- **Brazil:** Brazil has been expanding its healthcare system, particularly in regions that were previously underserved. The government's investment in public health insurance and expansion of private hospitals has resulted in greater demand for advanced drug delivery technologies (Júnior et al., 2021).

#### Growing Demand for Advanced Therapies:

As populations in emerging markets continue to grow and age, there is an increasing demand for chronic disease management solutions. This includes:

- **Modified-release DDS:** With the rise in chronic diseases like **diabetes**, **hypertension**, and **arthritis**, there is a growing need for **modified-release formulations** that can manage drug delivery over extended periods, reduce dosing frequency, and improve patient adherence (Sundar et al., 2019).
- **Targeted Drug Delivery Systems:** Targeted drug delivery technologies, especially those based on **nanomedicines**, are also in high demand due to their ability to deliver therapeutics to specific sites in the body, minimising side effects and maximising efficacy. These systems are particularly valuable for treating **cancer** and **neurological disorders** (Bhatia et al., 2021).

#### The Rise of Telemedicine and Digital Health:

The integration of **digital health solutions**, including **telemedicine** and **health apps**, has also increased in many emerging markets, especially in the wake of the **COVID-19 pandemic**. This trend is contributing to the need for more **patient-centred drug delivery systems** that can be monitored remotely or customised according to individual needs. For instance:

- **Telemedicine-Integrated DDS:** The rise of telemedicine in countries like India and China is encouraging the development of DDS that can be used in conjunction with digital health monitoring platforms, offering more personalised and efficient healthcare solutions (Li et al., 2020).

#### Rural Health Expansion:

Although much of the healthcare infrastructure development is focused on urban and semi-urban areas, there is also an effort to extend healthcare services to rural populations. This expansion is vital for improving access to DDS products in underserved regions, where there is often a high burden of diseases like **tuberculosis**, **malaria**, and **HIV/AIDS**. For example:

- **Mobile Health Clinics:** Mobile health clinics in remote areas are starting to integrate advanced drug delivery systems, ensuring that patients in rural regions can access life-saving therapies that were previously unavailable (Feng et al., 2019).
- **Opportunities for Pharmaceutical Companies:**

The expanding healthcare infrastructure in emerging markets presents an array of opportunities for pharmaceutical companies:

- **Increased Market Penetration:** As healthcare access expands, DDS companies have an opportunity to penetrate new regions and reach more patients.
- **Collaborations with Government and Private Sector:** Governments in emerging markets are actively seeking partnerships with pharmaceutical companies to expand healthcare coverage, creating opportunities for collaboration on DDS products that target high-burden diseases (Wu et al., 2021).

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