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Right To Health And Access To Advanced Drug Delivery Technologies In India: A Legal And Human Rights Analysis

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Abstract
Advanced drug delivery technologies have transformed modern healthcare by enabling targeted, controlled, sustained and more efficient delivery of therapeutic substances. Technologies such as nanotechnology-based delivery systems, controlled-release formulations, targeted drug delivery, and personalised delivery mechanisms offer significant potential to improve treatment outcomes and reduce adverse effects. However, technological advancement does not automatically ensure equitable access. High development and treatment costs, regulatory complexities, limited healthcare infrastructure and socio-economic inequalities may prevent large sections of the Indian population from benefiting from these innovations. The right to health, recognised internationally and progressively developed under Article 21 of the Constitution of India, requires the State to take appropriate measures to ensure accessible, affordable and quality healthcare. This paper examines access to advanced drug-delivery technologies from legal and human rights perspectives. It analyses the constitutional framework, international human rights standards and India's pharmaceutical regulatory framework, including the Drugs and Cosmetics Act, 1940 and the New Drugs and Clinical Trials Rules, 2019. The paper argues that India's existing legal framework addresses drug safety and regulatory approval but does not sufficiently address equitable access to emerging drug-delivery technologies. It further examines affordability, availability, patient safety, informed consent, intellectual property and socio-economic inequality. The paper proposes a rights-based regulatory approach that balances pharmaceutical innovation with affordability, patient protection and public health.

Keywords: ***Right to Health, Drug Delivery Technologies, Human Rights, Access to Medicines; Pharmaceutical Regulation; Patient Safety, Article 21, etc.***

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.1. INTRODUCTION

The development of pharmaceutical science has significantly changed the manner in which medicines are administered and absorbed by the human body. Traditional methods of drug administration have increasingly been supplemented by advanced drug delivery technologies designed to improve therapeutic effectiveness, reduce adverse effects and enhance patient compliance. Targeted drug delivery, controlled-release formulations, sustained-release systems, nanotechnology-based delivery and other novel drug delivery systems represent important developments in modern healthcare. These technologies seek not merely to introduce a medicine into the body but to control when, where and how a therapeutic substance reaches its intended site of action.

The Central Drugs Standard Control Organisation (CDSCO) recognises Novel Drug Delivery Systems and various modified dosage forms, including sustained-release, extended-release, gastro-retentive and other specialised delivery systems within the regulatory framework governing new drugs. The regulatory recognition of such technologies demonstrates that drug-delivery innovation has become an important component of contemporary pharmaceutical development.

However, technological innovation raises an important legal and human-rights question: Who can actually access these technologies? A medical innovation may provide considerable therapeutic benefits, but its contribution to public health remains limited if it is available only to economically privileged sections of society or only in advanced urban healthcare institutions. The problem, therefore, extends beyond scientific innovation and enters the domain of constitutional law, public health policy, and human rights.

Access to medicines is an important component of universal health coverage. The World Health Organisation emphasises that universal health coverage requires affordable access to safe, effective and quality medicines and health products[1]. Access cannot therefore be understood merely as the physical existence of a medicine. Availability, affordability and quality are all relevant dimensions. WHO's methodology for measuring access to medicines similarly treats availability and affordability as essential components of meaningful access[2].

[1] https://www.who.int/our-work/access-to-medicines-and-health-products?

[2] https://www.who.int/tools/monitoring-and-evaluation/access-indicators?

In India, the right to health has been significantly shaped by judicial interpretation of Article 21 of the Constitution. While there is no explicit fundamental right to health in the Constitution, the Supreme Court has interpreted the right to life as including essential elements of healthcare and medical treatment. Additionally, the Directive Principles of State Policy establish constitutional duties for the State related to public health and population welfare. Against this background, this article examines whether India's existing legal framework can ensure equitable access to advanced drug-delivery technologies. It argues that pharmaceutical innovation must be accompanied by a rights-based approach to access, ensuring that developments in drug delivery contribute not only to technological progress but also to equality, patient safety and the realisation of the right to health.

The paper adopts a doctrinal and analytical methodology. It examines constitutional provisions, Indian pharmaceutical legislation, judicial decisions, international human rights instruments, and relevant policy principles concerning access to medicines and health technologies.

2. UNDERSTANDING ADVANCED DRUG DELIVERY TECHNOLOGIES

2.1 Meaning and Evolution

Drug delivery involves the method by which an active pharmaceutical ingredient is administered and reaches the target site of action. Traditional systems like tablets, capsules, and other dosage forms can have limitations, such as fluctuating drug levels, low bioavailability, the need for frequent dosing, and undesirable systemic exposure.[3]. To address these limitations, advanced drug-delivery systems have been developed to better control the rate, duration, and location of drug release, thereby enhancing therapeutic effectiveness and safety.[4]

The evolution of drug-delivery technology has progressed from conventional dosage forms towards controlled, targeted and increasingly sophisticated delivery mechanisms. Modern systems are designed to deliver therapeutic substances at a predetermined rate or to specific tissues and cells. Controlled drug-delivery technologies, for instance, seek to maintain drug concentrations within an appropriate therapeutic range for longer, thereby reducing fluctuations and potentially decreasing the frequency of administration. This development has particular relevance to chronic diseases and other conditions in which prolonged or precisely controlled drug exposure is therapeutically desirable.

The emergence of nanotechnology has further expanded the possibilities of drug delivery. Nanomaterials may be used as carriers for active pharmaceutical ingredients and can possess physical, chemical and biological characteristics different from those of conventional materials. Such characteristics may be utilised to improve drug solubility, bioavailability, targeting and controlled release[5]. However, the distinctive properties of nanomaterials may also create questions concerning safety, efficacy, quality and regulatory assessment.[5]

2.2 Major Types of Advanced Drug Delivery Systems

Advanced drug-delivery technologies encompass a diverse range of systems, including targeted drug delivery, controlled-release and sustained-release formulations, transdermal systems, implantable delivery systems and nanotechnology-based drug delivery. Controlled-release systems are designed to regulate the release of therapeutic substances over a specified period, while targeted delivery seeks to concentrate the therapeutic agent at a particular biological site[6].

Nanotechnology-based drug delivery has attracted particular attention because nanoscale carriers can be engineered to transport therapeutic substances and, in some circumstances, facilitate their delivery to particular tissues or cells. Nanocarriers may include lipid-based nanoparticles, polymeric nanoparticles, dendrimers and other nanoscale systems[7]. The United States Food and Drug Administration (FDA) has recognised that nanomaterials may be used in drug products as active ingredients, inactive ingredients or carriers containing an active pharmaceutical ingredient, and has emphasised the need to assess their particular characteristics in relation to safety, effectiveness and quality[8].

Another important development is personalised drug delivery, in which treatment may increasingly be adapted to the biological characteristics and therapeutic requirements of individual patients. Such approaches form part of the broader movement

[3] Adepu S, Ramakrishna S. Controlled Drug Delivery Systems: Current Status and Future Directions. Molecules. 2021 Sep 29;26(19):5905. doi: 10.3390/molecules26195905. PMID: 34641447; PMCID: PMC8512302.

[4] Ezike TC, Okpala US, Onoja UL, Nwike CP, Ezeako EC, Okpara OJ, Okoroafor CC, Eze SC, Kalu OL, Odoh EC, Nwadike UG, Ogbodo JO, Umeh BU, Ossai EC, Nwanguma BC. Advances in drug delivery systems, challenges and future directions. Heliyon. 2023 Jun 24;9(6):e17488. doi: 10.1016/j.heliyon.2023.e17488. PMID: 37416680; PMCID: PMC10320272.

[5] U.S. Food and Drug Administration, *Drug Products, Including Biological Products, that Contain Nanomaterials: Guidance for Industry* (2022).

[6] Jain KK. An Overview of Drug Delivery Systems. Methods Mol Biol. 2020;2059:1-54. doi: 10.1007/978-1-4939-9798-5_1. PMID: 31435914.

[7] Babu, S. and Ravi, P.S. (2026), Nanotechnology-Based Drug Delivery Systems: Advances and Challenges. Polym Adv Technol, 37: e70563. https://doi.org/10.1002/pat.70563

[8] U.S. Food and Drug Administration, *Drug Products, Including Biological Products, that Contain Nanomaterials: Guidance for Industry* (2022).

towards precision medicine and may potentially improve therapeutic outcomes by reducing unnecessary exposure and tailoring treatment to individual needs[9].

The Indian regulatory framework also expressly recognises advanced delivery technologies. Under Rule 2(w)(iv) of the New Drugs and Clinical Trials Rules, 2019, drugs proposed to be marketed with modified dosage forms, including sustained-release dosage forms and Novel Drug Delivery Systems (NDDS), fall within the definition of "new drug" for the purposes of the regulatory framework.[9] The Central Drugs Standard Control Organisation (CDSCO) specifically identifies sustained-release, extended-release, gastro-retentive, prolonged-release and delayed-release formulations, as well as NDDS, within this regulatory context.[1]

2.3 Potential Benefits

The principal objective of advanced drug-delivery technologies is to improve the therapeutic performance of medicines. Controlled and targeted delivery may help maintain appropriate therapeutic concentrations, reduce fluctuations in drug levels and limit unnecessary exposure of healthy tissues[10]. These characteristics may contribute to improved therapeutic effectiveness and reduced adverse effects in appropriate clinical circumstances.

Another potential benefit is improved patient compliance. Where a delivery system permits medication to be released gradually over an extended period, the frequency of administration may be reduced. This may be particularly beneficial for patients requiring long-term treatment for chronic conditions.

For diseases such as cancer and other serious or chronic conditions, targeted and nanotechnology-based delivery systems may offer important therapeutic possibilities. Recent research has demonstrated the potential of nanocarriers to improve drug loading, stability, bioavailability, controlled release and targeting[11]. Nevertheless, these potential benefits must be evaluated through appropriate scientific and regulatory processes before widespread clinical use.

From a human-rights perspective, these developments are significant because improved therapeutic technologies may contribute to the effective realisation of the right to health. However, the existence of technological benefits alone is insufficient. Their significance for human rights ultimately depends upon whether patients can access such technologies safely, affordably and without unjustified discrimination.

2.4 Challenges

Despite their potential benefits, advanced drug-delivery technologies create significant scientific, regulatory and social challenges. Their development may require sophisticated research, specialised manufacturing processes and extensive testing. Nanotechnology-based systems, in particular, may raise questions concerning particle characteristics, stability, toxicity, immunogenicity and changes in behaviour during manufacturing and storage.

Regulatory assessment may also be more complex because emerging technologies may possess characteristics that differ substantially from those of conventional pharmaceutical products. The FDA, for example, notes that nanomaterials may exhibit distinctive properties that require particular consideration in evaluating safety, effectiveness and quality[12]. Similar concerns are relevant to regulatory authorities in India as advanced drug-delivery systems increasingly enter pharmaceutical research and development.

The cost of research, manufacturing and regulatory compliance may also influence the final price of advanced therapies. Consequently, technological innovation may create a tension between pharmaceutical advancement and equitable access. If advanced drug-delivery technologies remain prohibitively expensive or are concentrated in specialised urban healthcare facilities, their benefits may not reach economically disadvantaged or geographically remote populations.

Therefore, the legal question is not simply whether India should encourage pharmaceutical innovation, but also how the benefits of such innovation can be distributed in a manner consistent with equality, patient safety and the right to health. This question provides the foundation for the subsequent examination of India's constitutional and human-rights framework governing access to healthcare.

3. INTERNATIONAL HUMAN RIGHTS FRAMEWORK ON ACCESS TO MEDICINES AND HEALTH TECHNOLOGIES

3.1 Right to Health under International Human Rights Law

The right to health is recognised as an important human right under international law. The Universal Declaration of Human Rights, 1948 recognises the right to a standard of living adequate for health and well-being, including medical care[13]. Similarly, the International Covenant on Economic, Social and Cultural Rights, 1966 recognises the right of everyone to the enjoyment of the highest attainable standard of physical and mental health[14].

[9] Matteo Puccetti, Aurélie Schoubben, Biologics, theranostics, and personalised medicine in drug delivery systems, Pharmacological Research (2024).

[10] Akash Srivastava, Asad Ahmad, Shaiber Siddiqui, Anas Islam, Innovations in targeted drug delivery: From nanotechnology to clinical applications, Next Nanotechnology (2023) https://doi.org/10.1016/j.nxnano.2025.100336.

[11] Id.

[12] Id.

[13] Universal Declaration of Human Rights, 1948, art. 25.

[14] the International Covenant on Economic, Social and Cultural Rights, 1966. Art.12.

The Committee on Economic, Social and Cultural Rights, in General Comment No. 14, clarified that the right to health extends beyond the mere provision of healthcare services. It includes the availability and accessibility of health facilities, goods and services. Accessibility further includes non-discrimination, physical accessibility, economic accessibility or affordability, and access to health-related information[15]. These principles provide a useful framework for examining access to advanced drug-delivery technologies in India.

3.2 Access to Medicines as a Component of the Right to Health

Access to safe, effective and affordable medicines is an important component of the realisation of the right to health. The World Health Organization emphasises that essential medicines should be available in adequate quantities, of assured quality and at prices affordable to individuals and health systems[16]. The same principles are relevant when considering advanced drug-delivery technologies, particularly where such technologies offer significant therapeutic advantages over conventional treatment.

However, advanced technologies may initially be expensive and may not fall within conventional categories of essential medicines. Therefore, their inclusion within a rights-based access framework should depend upon factors such as clinical effectiveness, therapeutic necessity, safety, affordability and public-health relevance.

3.3. Sustainable Development Goal 3

The international commitment to equitable access to medicines is also reflected in Sustainable Development Goal 3, which seeks to ensure healthy lives and promote well-being for all. Target 3.8 specifically calls for universal health coverage, including access to safe, effective, quality and affordable essential medicines and vaccines for all[17]. Target 3.b further encourages research and development of medicines and calls for access to affordable essential medicines, particularly in developing countries[18].

These objectives demonstrate that pharmaceutical innovation and equitable access should not be treated as competing goals. Rather, innovation should ultimately contribute to improved health outcomes and universal access.

3.4 Human Rights Principles Relevant to Advanced Drug Delivery

The international framework therefore provides four particularly important principles for analysing advanced drug-delivery technologies: availability, accessibility, affordability and quality[19]. These principles require States to progressively develop healthcare systems capable of making beneficial health technologies reasonably accessible while ensuring their safety and quality.

For India, this framework is particularly relevant because advanced drug-delivery technologies may otherwise widen existing inequalities in healthcare. A human-rights approach requires technological progress to be accompanied by measures addressing economic and geographical barriers. Thus, the international right to health provides an important normative foundation for assessing whether India's pharmaceutical policies adequately balance innovation, patient safety and equitable access.

4. RIGHT TO HEALTH UNDER THE INDIAN CONSTITUTIONAL FRAMEWORK

4.1 From the Right to Health to Equitable Access to Medical Innovation

The judicial expansion of Article 21 creates an important normative foundation for examining advanced drug-delivery technologies. The constitutional question is not whether every patient has an enforceable right to demand the latest pharmaceutical innovation. Rather, the question is whether the State has a responsibility to ensure that clinically beneficial healthcare innovations are not made inaccessible by avoidable economic, geographical or institutional barriers.

This distinction is important. Advanced drug-delivery technologies may initially be expensive, experimental or available only in specialised institutions. The State cannot necessarily be expected to provide every emerging technology immediately. However, as technologies become scientifically established and increasingly integrated into mainstream healthcare, public-health policy should progressively address their affordability and availability.

The combined reading of Articles 14 and 21 and Article 47 therefore supports a rights-based approach. Article 21 provides the substantive protection of life and health; Article 14 requires equality and protection against arbitrary exclusion; and Article 47 reinforces the State's constitutional responsibility to improve public health.

Consequently, the constitutional framework should encourage a balance between pharmaceutical innovation and social justice. Technological progress should not create a two-tier healthcare system in which advanced treatment is effectively available only to those who can afford it. The ultimate constitutional objective should be to ensure

[15] Committee on Economic, Social and Cultural Rights, General Comment No. 14, *The Right to the Highest Attainable Standard of Health*, UN Doc. E/C.12/2000/4 (2000), para. 12.

[16] https://www.who.int/news-room/fact-sheets/detail/essential-medicines.

[17] United Nations, *Transforming Our World: The 2030 Agenda for Sustainable Development*, UN Doc. A/RES/70/1 (2015), Goal 3, Target 3.8.

[18] Ibid.

[19] Committee on Economic, Social and Cultural Rights, supra note 3, para. 12; World Health Organisation, *Access to Medicines and Health Products*.

that advances in pharmaceutical science contribute to the dignity, health and well-being of the population as a whole.

4.1.1 Article 21 and the Constitutional Right to Health

The Constitution of India does not expressly recognise the "right to health" as a separate fundamental right[20]. However, the Supreme Court has progressively expanded the scope of Article 21, which guarantees the right to life and personal liberty, to include the right to health and access to medical care. The expression "life" has been interpreted to mean more than mere animal existence; it includes living with dignity and access to conditions necessary for a meaningful life[21].

The formal acknowledgement of health rights takes on particular importance with the advent of advanced drug-delivery methods. While these new technologies can provide safer, more efficient, or more targeted treatments, disparities in access might raise concerns about the actual realisation of the right to health. However, Article 21 should not be understood as providing an immediate entitlement to all new medical technologies. Instead, it imposes a broader duty on the State to gradually enhance healthcare services and prevent arbitrary or discriminatory denial of access.

In *Paschim Banga Khet Mazdoor Samity v. State of West Bengal*, the Supreme Court held that the government has a constitutional obligation to provide adequate medical services and that failure to provide timely medical treatment may violate Article 21[22]. The judgment is significant because it established that healthcare is not merely a matter of governmental discretion but has constitutional relevance.

Similarly, in *State of Punjab v. Mohinder Singh Chawla*[23], the Supreme Court expressly observed that the right to health is integral to the right to life under Article 21. The decision reinforces the principle that the preservation and protection of health are an essential component of the constitutional protection of life.

The constitutional understanding of the right to health under Article 21 has continued to develop in recent Supreme Court jurisprudence. The Court's recent decisions demonstrate that the right to health is not confined to the provision of emergency medical treatment but encompasses broader conditions necessary for health, dignity and well-being.

A significant recent development is *In Re: Right to Menstrual Health for Women and Girls of India*[24], where the Supreme Court, in its judgment dated 30 January 2026, recognised the State's positive obligation under Article 21 to protect the health of girl children. The Court's approach is significant because it links health protection with dignity, equality and the specific needs of vulnerable groups. This reasoning is relevant to the present study because access to healthcare cannot be considered in isolation from the particular circumstances of vulnerable populations. Where advanced drug-delivery technologies provide clinically significant benefits, similar constitutional principles may support measures to prevent their exclusion of disadvantaged sections of society.

Another important recent decision is *Sukdeb Saha v. State of Andhra Pradesh*, decided by the Supreme Court[25] in July 2025. The Court recognised mental health as an integral component of the right to life under Article 21 and issued directions concerning psychologically safe environments for students and young persons. The judgment demonstrates the continuing expansion of Article 21 from a narrow protection against physical deprivation towards a broader conception of health and human well-being. The significance of these recent decisions lies in the Court's recognition that the right to health may require positive State action. The constitutional obligation is therefore not limited to refraining from interfering with an individual's health; it may also require the State to create appropriate conditions, policies and institutional mechanisms that enable individuals to enjoy healthcare and live with dignity. This evolving jurisprudence provides an important foundation for examining access to advanced drug-delivery technologies. It would, however, be incorrect to argue that Article 21 creates an absolute right to every new pharmaceutical technology. Advanced technologies must satisfy requirements of scientific validity, safety, efficacy and regulatory approval. Nevertheless, once a technology becomes clinically established and is capable of making a meaningful contribution to healthcare, questions of affordability, availability and equitable access acquire greater constitutional significance.

The recent jurisprudence therefore supports a progressive interpretation of the right to health. The State's responsibility should evolve alongside developments in medical science so that technological progress does not deepen existing healthcare inequalities. In this context, the right to health should encompass not merely access to conventional medical treatment but, progressively and subject to clinical and regulatory considerations, reasonable access to beneficial innovations in healthcare.

4.1.2 Article 14 and Equality in Access to Healthcare

[20] *Francis Coralie Mullin v. Administrator, Union Territory of Delhi*, (1981) 1 SCC 608.

[21] The Constitution of India, 1950, art.21.

[22] *Paschim Banga Khet Mazdoor Samity v. State of West Bengal*, (1996) 4 SCC 37.

[23] *State of Punjab v. Mohinder Singh Chawla*, (1997) 2 SCC 83.

[24] *Dr. Jaya Thakur v. Government of India & Ors.* (decided on January 30, 2026).

[25] *Sukdeb Saha v. State of Andhra Pradesh & Ors.*, 2025 INSC 893, Judgment dated 25 July 2025.

The Constitution of India ensures that everyone is equal before the law and receives equal protection under it[26]. In the healthcare context, this constitutional guarantee requires the State to ensure that access to healthcare is not affected by arbitrary or unjustified discrimination. Equality, however, should not be understood merely as identical treatment of every individual. Substantive equality may require special attention to individuals and communities facing greater economic, geographical or social barriers.

This principle becomes particularly important in relation to advanced drug-delivery technologies. Such technologies are often expensive and may initially be available only in specialised hospitals or urban healthcare centres. If access is determined primarily by a patient's ability to pay, economically disadvantaged persons may be effectively excluded from the benefits of pharmaceutical innovation.

The constitutional principle of equality therefore requires policymakers to consider whether emerging healthcare technologies are reasonably accessible to different sections of society. A regulatory framework that encourages innovation but ignores substantial inequalities in access may fail to address the social-justice dimension of healthcare.

4.1.3 Directive Principles and State Responsibility

The constitutional commitment to public health is reinforced by the Directive Principles of State Policy. It specifically directs the State to regard the improvement of public health as among its primary duties[27]. The Constitution of India further require the State to promote social justice and reduce inequalities[28].

Although the Directive Principles are not enforceable by courts in the same manner as fundamental rights, Article 37 makes clear that they are fundamental in the governance of the country and that it is the duty of the State to apply them in making laws. They therefore provide an important constitutional policy framework for interpreting State responsibilities relating to healthcare.

In the context of advanced drug-delivery technologies, Article 47 assumes particular significance. The State's responsibility to improve public health cannot remain confined to traditional healthcare infrastructure when new technologies become increasingly important to diagnosis and treatment. At the same time, public health policy must take into account available resources and competing healthcare priorities. The constitutional objective should therefore be progressive and equitable access, rather than an unrestricted entitlement to every emerging technology.

5. JUDICIAL RECOGNITION OF THE RIGHT TO HEALTH

Indian judicial decisions have progressively transformed the right to health from a largely policy-oriented concept into an important constitutional entitlement.

In *Consumer Education & Research Centre v. Union of India*, the Supreme Court recognised the protection of health as an important component of the right to life under Article 21[29]. The Court's reasoning demonstrates that the constitutional protection of life encompasses measures necessary to protect human health and dignity.

In *Parmanand Katara v. Union of India*[30], the Supreme Court emphasised the paramount importance of preserving human life and held that every doctor has a professional obligation to extend medical assistance to preserve life.[7] Although the case concerned emergency medical treatment, its underlying principle that preservation of life must receive priority has broader relevance to the development of a rights-based healthcare system.

The judicial expansion of Article 21 therefore provides a constitutional basis for examining access to modern medical technologies. However, courts have generally stopped short of recognising an unrestricted individual right to every form of medical treatment. Access must be understood within the framework of reasonable State obligations, available resources, public health priorities, and equality.

Accordingly, the constitutional framework suggests that advanced drug-delivery technologies should be approached as part of the progressive development of healthcare rather than as an automatic entitlement to every technological innovation. Where such technologies become clinically established and significantly contribute to the prevention or treatment of serious diseases, the State should increasingly consider their affordability, availability, and equitable distribution in public health policy.

This constitutional perspective provides the foundation for examining the international human-rights framework on access to medicines and healthcare in the next section.

6. INDIAN LEGAL AND REGULATORY FRAMEWORK GOVERNING ADVANCED DRUG DELIVERY TECHNOLOGIES

6.1 Drugs and Cosmetics Act, 1940

The Drugs and Cosmetics Act, 1940 constitutes the principal legislative framework governing the import, manufacture, distribution and sale of drugs in India. Its regulatory objective is to ensure that pharmaceutical products available to patients meet prescribed standards of quality, safety and efficacy[31]. The Act therefore provides the basic statutory foundation for regulating emerging

[26] Art.14.
[27] Art. 47.
[28] Art. 48,49.
[29] *Consumer Education & Research Centre v. Union of India*, (1995) 3 SCC 42.
[30] *Parmanand Katara v. Union of India*, (1989) 4 SCC 286.
[31] The Drugs and Cosmetics Act, 1940, Act No. 23 of 1940.

pharmaceutical technologies, including advanced drug-delivery systems.

6.2 New Drugs and Clinical Trials Rules, 2019

The New Drugs and Clinical Trials Rules, 2019 (NDCTR) provide a more specific regulatory framework for new drugs and clinical trials. Rule 2(w)(iv) expressly includes a modified or sustained-release form of a drug or a Novel Drug Delivery System (NDDS) within the definition of a "new drug"[2]. CDSCO further identifies sustained-release, extended-release, gastro-retentive, prolonged-release and delayed-release formulations within this category[32].

This provision is particularly significant because it demonstrates that Indian pharmaceutical law recognises advanced drug-delivery systems as requiring regulatory scrutiny rather than treating them simply as conventional formulations.

6.3 Role of CDSCO

The Central Drugs Standard Control Organisation (CDSCO), functioning under the Ministry of Health and Family Welfare, plays a central role in the regulation of new drugs in India. Its New Drugs Division processes applications relating to the approval of new drugs, clinical trials and post-marketing surveillance under the NDCTR framework[33].

For advanced drug-delivery technologies, regulatory evaluation is particularly important because changes in dosage form, release mechanism or route of administration may influence the safety, efficacy and therapeutic performance of a medicine.

6.4 Medical Devices Rules, 2017

Certain advanced drug-delivery systems may also involve or incorporate medical-device components. Where a product falls within the legal definition of a medical device, the Medical Devices Rules, 2017 become relevant. CDSCO states that medical devices in India are regulated under the Drugs and Cosmetics Act, 1940 and the Medical Devices Rules, 2017[34].

This creates an important regulatory consideration because emerging technologies may combine pharmaceutical substances with technological or device-based components. Appropriate classification is therefore necessary to determine the applicable safety, quality and approval requirements.

6.5 Pharmacovigilance and Post-Market Surveillance

Regulation should extend beyond market approval of advanced drug-delivery products. Ongoing monitoring is essential to detect adverse effects and safety issues that may surface only after broader use. The CDSCO's regulatory system encompasses post-marketing surveillance and safety monitoring of new drugs[35].

This is especially crucial for advanced technologies, as their long-term impacts might not be fully known at the point of initial approval. Therefore, effective pharmacovigilance is a key aspect of the State's duty to ensure patient safety.

6.6 Regulatory Gaps and the Right to Health

Although India's regulatory framework provides mechanisms for evaluating the quality, safety and efficacy of advanced drug-delivery systems, the framework is less directly concerned with their affordability and equitable access. This distinction is important for the present article.

Regulatory approval confirms that a product meets particular legal and scientific standards; however, it doesn't guarantee that all patients will have economic or geographic access to the product. Consequently, a rights-based approach suggests that pharmaceutical regulation should be supported by public health policies that focus on affordability, availability, and equality.

India faces the challenge of creating a regulatory framework that supports pharmaceutical innovation, ensures patient safety, and provides equitable access. This strategy would align pharmaceutical regulation more closely with the constitutional and international conception of the right to health.

7. HUMAN RIGHTS CHALLENGES IN ACCESS TO ADVANCED DRUG DELIVERY TECHNOLOGIES

7.1 Affordability and Economic Inequality

A key obstacle to accessing advanced drug-delivery technologies is their cost. These innovative systems often entail high research, development, manufacturing, and regulatory expenses. When such costs are passed on through treatment prices, financially disadvantaged patients may be unable to access these options. Consequently, the right to health involves not only the availability of these technologies but also their affordability for patients[36].

7.2 Availability and Geographical Inequality

Access is also affected by the unequal distribution of specialised healthcare facilities. Advanced drug-delivery technologies may require specialised

[32] The New Drugs and Clinical Trials Rules, 2019, r. 2(w)(iv), G.S.R. 227(E), Ministry of Health and Family Welfare, Government of India (2019).

[33] Central Drugs Standard Control Organisation, *New Drugs*, Ministry of Health and Family Welfare, Government of India.

[34] Central Drugs Standard Control Organisation, *Medical Device & Diagnostics: About Medical Devices*, Ministry of Health and Family Welfare, Government of India.https://www.cdsco.gov.in/opencms/opencms/en/Medical-Device-Diagnostics/Medical-Device-Diagnostics/?utm_

[35] Lahiry S, Thakur S, Chakraborty DS. New Drugs and Clinical Trials Rules-2019: What academicians need to know. Indian J Dermatol Venereol Leprol 2020;86:445-448

[36] *S. Katrina Perehudoff, Brigit Toebes, and Hans Hogerzeil,* Essential Medicines in National Constitutions: Progress Since 2008, Health and Human Rights 18/1, (2016).https://www.hhrjournal.org/2016/05/04/essential-medicines-in-national-constitutions-progress-since-2008/

hospitals, diagnostic facilities and trained healthcare professionals, which are more readily available in metropolitan and urban areas. Patients in rural and remote regions may consequently experience greater barriers to accessing advanced treatment.

This highlights a key aspect of equality related to the right to health. The constitutional obligation to promote equality, as described in Article 14 along with Article 21, requires that healthcare policies address major disparities rather than allowing technological progress to benefit only certain geographic or economic groups.

7.3 Patient Safety and Quality

The right to health necessarily includes access to safe, high-quality healthcare. Advanced drug-delivery systems may involve novel materials, modified release mechanisms, or specialised administration methods, raising safety questions that may not arise in the same way with conventional formulations.

India's regulatory system requires continuing safety monitoring of approved medicines. CDSCO's post-marketing surveillance framework requires pharmacovigilance mechanisms for collecting and reporting adverse drug reactions[37]. Such monitoring is particularly important for advanced technologies whose long-term safety profile may become clearer only after wider clinical use.

7.4 Right to Information and Informed Consent

Patients receiving advanced drug-delivery technologies should be provided with adequate information concerning the nature of the treatment, its potential benefits and risks, and available alternatives. This is particularly important where the technology is relatively new or involves uncertainties concerning long-term effects.

Informed consent, therefore, represents an important link between patient autonomy and the right to health. A rights-based approach should ensure that technological advancement does not reduce the patient to a passive recipient of pharmaceutical innovation.

7.5 Intellectual Property and Access

Intellectual property protection may encourage pharmaceutical innovation by providing incentives for research and development. At the same time, patent protection may contribute to higher prices, thereby creating barriers to access.

The legal challenge is therefore to maintain an appropriate balance between protecting pharmaceutical innovation and safeguarding public health. Intellectual property rights should not be considered in isolation from the State's broader responsibility to promote affordable access to essential healthcare.

7.6 Vulnerable and Disadvantaged Groups

The consequences of unequal access are likely to be greatest for economically weaker households, rural populations, children, elderly persons and persons with disabilities. A formal policy of equal access may not be sufficient where these groups face substantially greater barriers to healthcare.

Accordingly, a human-rights approach should incorporate substantive equality, requiring targeted measures where necessary to ensure that disadvantaged groups are not excluded from the benefits of pharmaceutical innovation.

7.7 The Need for a Rights-Based Approach

The central challenge is therefore to ensure that technological advancement does not produce a two-tier healthcare system in which advanced treatment is effectively available only to those who can afford it or live in areas with specialised facilities.

India's pharmaceutical regulatory framework already places significant emphasis on safety, quality and efficacy, while CDSCO's current regulatory functions include approval of new drugs, clinical trials and post-marketing safety monitoring[38]. However, equitable access requires a broader approach that also considers affordability, geographical availability, equality and patient autonomy.

Thus, advanced drug-delivery technologies should be evaluated not merely as pharmaceutical innovations but as emerging components of healthcare whose distribution can directly affect the practical enjoyment of the right to health.

8. GAPS IN THE INDIAN LEGAL AND REGULATORY FRAMEWORK

Despite a comprehensive pharmaceutical regulatory system, India lacks a framework that specifically addresses the legal and regulatory dimensions of advanced drug-delivery technologies. The major gaps are as follows:

8.1 Lack of a Specific Regulatory Framework

The New Drugs and Clinical Trials Rules, 2019 recognise Novel Drug Delivery Systems within the definition of new drugs[39], but do not provide a comprehensive framework specifically governing the development and regulation of emerging drug-delivery technologies.

8.2 Regulatory Classification Difficulties

Advanced systems might integrate pharmaceutical substances with nanomaterials, devices, or other technologies. This integration can lead to uncertainty in their regulation, as it may be unclear which standards and regulatory bodies apply.

8.3 Inadequate Long-Term Regulatory Oversight

Existing approval mechanisms may not fully address the long-term risks associated with emerging technologies. Continuous post-market

[37] Central Drugs Standard Control Organisation, *Post Marketing Drug Safety Monitoring*, Ministry of Health and Family Welfare, Government of India.

[38] Id.

[39] The New Drugs and Clinical Trials Rules, 2019, r. 2(w)(iv), G.S.R. 227(E), Ministry of Health and Family Welfare, Government of India (2019).

monitoring and pharmacovigilance therefore require further strengthening.

8.4 ***Limited Regulatory Guidance for Emerging Technologies***

Rapid developments in nanotechnology, targeted delivery and personalised medicine may outpace existing regulatory guidance. Clearer, regularly updated standards are necessary to provide certainty for researchers, manufacturers and regulators.

8.5 Limited Collaboration Between Regulatory Agencies

Advanced drug-delivery technologies may involve multiple regulatory dimensions, including drugs, clinical trials, medical devices and intellectual property. Greater institutional coordination is therefore necessary to avoid regulatory uncertainty and ensure effective oversight.

8.6 Need for Technology-Specific Standards

Emerging delivery systems might need specialised standards for manufacturing, quality control, clinical evaluation, and safety assessment. Creating technology-specific guidance could enhance India's regulatory ability and promote responsible pharmaceutical innovation.

9. RECOMMENDATIONS: TOWARDS A RIGHTS-BASED FRAMEWORK FOR EQUITABLE ACCESS

To ensure that advances in drug-delivery technologies meaningfully contribute to the right to health, India requires a regulatory approach that balances innovation, safety, and equitable access. The following measures may strengthen the existing framework.

9.1 ***Develop Clear Regulatory Guidelines***

Develop specific, regularly updated guidelines for emerging drug-delivery technologies, especially nanotechnology-based, targeted, and personalised systems. This approach would enhance regulatory clarity and ensure patient safety.

9.2 Integrate Accessibility into Health Policy

Regulatory and health policies need to address not just the safety and effectiveness of advanced technologies, but also their accessibility and cost. Decisions about adopting clinically beneficial technologies should also incorporate public health priorities.

9.3 ***Strengthen Public Investment and Research***

Greater investment in public institutions and collaborative research can promote the development of cost-effective drug-delivery technologies suited to India's healthcare needs. Public–private partnerships may also facilitate affordable innovation.

9.4 Strengthen Pharmacovigilance

Post-market monitoring should be enhanced to better detect adverse effects linked to new drug-delivery systems. Implementing robust reporting and monitoring processes can lead to improved patient safety and increased public trust.

9.5 Promote Equitable Distribution

Government healthcare programmes should progressively incorporate clinically established advanced technologies where they provide significant therapeutic benefits. Special attention should be given to underserved regions and vulnerable populations.

9.6 ***Balance Intellectual Property and Public Health***

Patent protection should continue to encourage pharmaceutical innovation while ensuring that intellectual property does not create unjustifiable barriers to access. Existing public-health safeguards under Indian law should be effectively utilised where necessary.

9.7 Enhance Patient Engagement

Patients should receive clear information about the benefits, risks and alternatives associated with advanced drug-delivery technologies. Informed consent and patient autonomy should remain central to their clinical use.

9.8 Adopt a Human-Rights-Based Approach

Ultimately, pharmaceutical regulation ought to be rooted in the principles of equality, affordability, accessibility, safety, and human dignity. This approach would guarantee that advancements in technology promote the gradual fulfilment of the constitutional right to health, rather than exacerbating existing healthcare disparities.

10. CONCLUSION

Advanced drug-delivery technologies are a key advancement in contemporary pharmaceuticals, enabling targeted treatment, controlled drug release, enhanced therapeutic outcomes, and fewer side effects. Nevertheless, evaluating their value requires more than just scientific and technological considerations. It is essential to also consider principles like accessibility, affordability, safety, equality, and human dignity.

The Indian constitutional framework offers a robust basis for this approach. By gradually interpreting Article 21, the Supreme Court has acknowledged the right to health as a vital part of the right to life. Articles 14 and 47 also emphasize principles of equality and State accountability in public health. Recent judicial decisions show that the constitutional view of health is broadening towards a more complete understanding of dignity, autonomy, and proactive State duty.

India has established important regulatory mechanisms through the Drugs and Cosmetics Act, 1940 and the New Drugs and Clinical Trials Rules, 2019. These mechanisms provide essential safeguards concerning the quality, safety and efficacy of emerging pharmaceutical products. Nevertheless, regulatory approval alone does not guarantee equitable access. The absence of specific mechanisms to address advanced drug-delivery technologies, affordability, long-term oversight, and equitable distribution remains a significant concern.

The challenge is to find a balance between pharmaceutical innovation and social justice. India needs a rights-based regulatory framework that promotes research and innovation, while also making clinically beneficial technologies accessible to those in need. Achieving this requires stronger regulatory guidance, increased public investment, pharmacovigilance, equitable distribution, and a careful balance of intellectual property rights with public health priorities.

Ultimately, the advancement of drug-delivery technology should serve not merely as an achievement of pharmaceutical science but as an instrument for improving human health. Technological innovation becomes meaningful from a human-rights perspective only when its benefits reach people irrespective of their economic or geographical circumstances. A healthcare system that combines innovation with affordability, equality, safety and dignity would therefore be better placed to fulfil India's constitutional commitment to the right to health.