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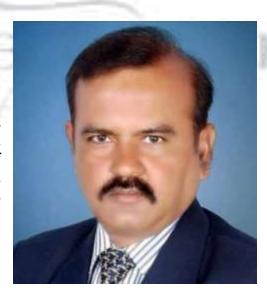


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ABOUT US

WHITE BLACK LEGAL is an open access, peer-reviewed and refereed journal providededicated to express views on topical legal issues, thereby generating a cross current of ideas on emerging matters. This platform shall also ignite the initiative and desire of young law students to contribute in the field of law. The erudite response of legal luminaries shall be solicited to enable readers to explore challenges that lie before law makers, lawyers and the society at large, in the event of the ever changing social, economic and technological scenario.

With this thought, we hereby present to you

LEGAL

FORECASTING CYBER CRIMES AND LEGAL CHALLENGES IN PHARMACEUTICAL METAVERSE

AUTHORED BY - MADHU MATI. A

Abstract:

Metaverse, the collective virtual shared space created by the convergence of physical and virtual reality, is a fully immersive and interactive 3D environment that can be accessed through virtual reality headsets, augmented reality devices, or traditional computer screens. The COVID-19 pandemic has spurred up the users and usages of digital health and telehealth, which altered the medical experience from face-to-face interactions to a hybrid mode using telecommunications and digital platforms. Metaverse is thus the obvious next step in the development of the pharmaceutical industry. Tools such as VR, AR, MR, and AI are utilized in developing hardware and software required to develop technologies such as digital twinning, which aids the pharmaceutical industry in drug development, testing, research, marketing, etc. Patients and physicians can access 'metapharmacy' to get appropriate medicines, treatments, or therapy, as well as to understand how a particular medicine works. Although the development of metapharmacy is in its infancy, the pace of development is quite rapid. As the pharmaceutical sector increasingly embraces virtual environments for research, development and commerce, the need for robust cybersecurity measures, and a comprehensive legal framework becomes paramount. This paper aims to examine the latest developments in the pharmaceutical industry using the concepts and tools of the metaverse. This research paper explores the burgeoning intersection of cyber-crimes and the pharmaceutical industry within the metaverse, delving into the potential threats and the legal challenges that arise in this evolving landscape. The paper shall attempt to forecast the cybercrimes and legal challenges that may arise with the further development of metapharmacy. This paper shall also review the relevancy and applicability of existing cyber laws over the forecasted legal issues. This paper also aims to determine whether or not the development of metapharmacy shall require the development of special laws to govern the same.

Keywords:

Cyber-crimes, Cybersecurity, Metaverse, Metapharmacy, Pharmaceutical industry, Legal framework.

Introduction:

In the recent years, the global landscape of the pharmaceutical industry has undergone a paradigm shift with the integration of virtual environments, collectively known as the metaverse. This metamorphosis, fueled by technological advancements and the pursuit of innovation, has not only revolutionized how pharmaceutical research and development are conducted, but has also given rise to a new frontier for potential cyber threats. As the pharmaceutical sector enthusiastically embraces the metaverse to streamline operations, enhance collaboration, and accelerate drug discovery, the concomitants urge in cyber-crimes poses unprecedented challenges that demand meticulous scrutiny and pro-active mitigation strategies.

The term 'metaverse' was coined and used in the novel 'Snow Crash', by author Neil Stephenson, in 1992¹. He defined metaverse as a vast virtual environment that coexists with the physical world and in which people converse through digital avatars. In other words, it's three-dimensional, interactive virtual space, in which the users may communicate and interact through Virtual Reality (VR), Augmented Reality (AR), Mixed Reality (MR), and Artificial Intelligence (AI). Metaverse impacts the cognitive processes and stimulates the users to feel the sense of presence or 'being there'.^{2 3 4}

The pharmaceutical metaverse is a virtual space where researchers, developers, and stakeholders engage in activities ranging from drug design simulations to virtual clinical trials, which presents a unique set of vulnerabilities. On the other hand, metapharmacy refers to a virtual pharmacy which could be accessed by patients and stakeholders, through real-time interactions, with the aid of VR, AR, AI tools. In this context, cyber threats may manifest in diverse forms, jeopardizing the integrity

¹ N. Stephenson. (1994). Snow Crash. Penguin Books Limited. [Online]. Available: https://books.google.co.in/books?id=inYs79gV4UQC

² L.-H. Lee, T. Braud, P. Zhou, L. Wang, D. Xu, Z. Lin, A. Kumar, C. Bermejo, and P. Hui, "All one needs to know about metaverse: A complete survey on technological singularity, virtual ecosystem, and research agenda," 2021, arXiv:2110.05352.

³ G. Riva and B. K. Wiederhold, "What the metaverse is (really) and why we need to know about it," Cyberpsychol., Behav., Social Netw., vol. 25, no. 6, pp. 355–359, Jun. 2022.

⁴ T.-C. Wu and C.-T.-B. Ho, "A scoping review of metaverse in emergency medicine," Australas. Emergency Care, Aug. 2022, doi: 10.1016/j.auec.2022.08.002

of sensitive data, the authenticity of virtual avatars used in the industry in this regard, and the very fabric of the drug development and distribution processes. The fusion of cutting-edge technologies with the intricate workings of the pharmaceutical industry creates an intricate tapestry where malicious actors find fertile ground for exploitation.

This paper endeavors to dissect the multi-faceted landscape of cyber-crimes within the pharmaceutical metaverse, aiming to provide a comprehensive understanding of evolving threats, relevance of the existing legal framework and the potential legal challenges that arise in this dynamic space.

Related Works:

Pharmaceutical applications in metaverse, however promising, have had a slow-paced development. There are only a handful of pharmaceutical entities globally, that have started to invest and embrace the metaverse, since the last decade. Prior to that, remote access operations relating to this industry was limited to telecommunications, such as telephone ordering of medicines, advertisements in television, etc. With the advent of computers and internet, began the era of digital medicines, wherein the marketing, distribution and sales of medicines became possible through websites, known as digital pharmacies, such as Medplus. The pharmaceutical applications, too, were limited to the usage of internet to enhance and aid the process of drug development, marketing and sales.

After the global pandemic, COVID-19, pharmaceutical giants such as Pfizer, Novartis, Janssen Pharmaceuticals, etc., have begun investing in metaverse applications and tools, in order to explore and expand their entities. As such, there have been some studies and papers that have appeared recently. However, there were very limited papers that were relatively more appropriate to this research paper, which are listed below in Table 1, along with the lacunas found in the context of this research paper.

All these papers provide a very general outline as to what constitutes metaverse, applications of healthcare applications in metaverse, potential technical risks and challenges of VR, AR and MR with respect to healthcare sector. Furthermore, pharmaceutical sector has been subsumed into the healthcare sector for the purpose of research in these papers, which has resulted in lack of exclusive

focus upon the various pharmaceutical applications of metaverse. Thus, instead of focusing upon the technical aspects of metaverse or the healthcare applications of metaverse, as was done in the mentioned papers in Table 1, this research paper shall focus on understanding the essential concepts of metaverse and delving into various processes in the pharmaceutical industry which could be aided, enhanced, modified or replaced with, in the metaverse. Furthermore, in addition to the mentioned potential legal challenged with the advent of pharmaceutical metaverse, this paper shall examine and analyze the relevance of current legal framework to the rise of potential cybersecurity threats and cyber-crimes in the pharmaceutical metaverse.



S. NO	TITLE	AUTHOR	JOURNAL / YEAR	FOCUS / DESCRIPTION	RESEARCH GAP
1	Healthcare in Metaverse : A Survey on Current Metaverse Applicatio ns in Healthcare 5		IEEE, Nov, 2022	examines the latest metaverse developments in the healthcare industry in 7 domains, including pharma	Very little focus on pharma; and no mention of legal aspects
2	Unveiling the Metaverse : Exploring Emerging Trends, Multifacet ed Perspectiv es, and Future Challenge s ⁶	Mueen Uddin, Selvakumar Manickam, Hidayat Ullah	IEEE, May 2023	Elaborate on the fundamental concepts and intricacies of the metaverse, encompassing its comprehensive design, defining characteristics, advanced technologies facilitating its existence, and the latest and innovative examples of metaverse applications today. Indicate future metaverse research avenues for creating an efficient, private, secure realm	An exhaustive list of potential risks - incomplete Has no legal connotation
3	Role of Quantum Computin g and Metaverse	Adarsh Singh Bajkoti, Shaurya Tiwari, Tanishq	IEEE, 2023	Outline of quantum computing's current state and metaverse innovation in the healthcare & pharmaceutical industry, counting the different applications and utilizing cases.	No specific relevance to the pharma industry No separation of the

	in the Field of Healthcare and Medicine ⁷	Ranjan		Examines the (technical, legal) challenges and impediments of these innovations and the long- haul scope for their selection in healthcare.	pharma and healthcare sector
4	The MetaPhar macy: What Happens When Big Pharma Goes Virtual?8	Brenda K. Wiederhold	Liebertpub. com Mary Ann Liebert, Inc	A basic comparison of the current state of the pharma industry and the metapharmacy Available and potential usages and challenges in metapharmacy	No legal connotation
5	A Review on: Metaverse in Health Care and Pharma ⁹	Athmaja Shetty, Gururaj S Kulkarni, Rakesh Babu, Padma M Paarakh	Journal of Community Pharmacy Practice, 2023	Gives a tentative outline as to the growth of metaverse applications of pharmaceutical industry, by elaborating on different key concepts relating to metaverse such as VR, AR, AI, etc.	Offers little to no light on potential threats and the strategies needed to mitigate through them.

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⁵ G. Bansal et al.: Healthcare in Metaverse: A Survey on Current Metaverse Applications in Healthcare, IEEE, 2023.

⁶ M. Uddin et al.: Unveiling the Metaverse, IEEE, 2023

⁷ Adarsh Singh Bakjoti et al.: Role of Quantum Computing and Metaverse in the Field of Healthcare and Medicine, Proceedings of the 5th International Conference on Inventive Research in Computing Applications (ICIRCA 2023)

⁸ Brenda K. Wiederhold,: The MetaPharmacy: What Happens When Big Pharma Goes Virtual?, CYBERPSYCHOLOGY, BEHAVIOR, AND SOCIAL NETWORKING Volume 25, Number 12, 2022 ^a Mary Ann Liebert, Inc. DOI: 10.1089/cyber.2022.29262.

⁹ Athmaja Shetty et al.: A Review on: Metaverse in Health Care and Pharma, Journal of Community Pharmacy Practice ISSN: 2799-1199 Vol: 03 , No. 01 , Dec 2022-Jan 2023 https://journal.hmjournals.com/index.php/JCPP DOI: https://doi.org/10.55529/jcpp.31.1.11

6	'Metahealt	J. Thomason	J.	Elaborates on applications of metaverse	Excludes
	h-how will		Metaverse,	in various domains of healthcare such as	telemedicine, clinical
	the		2021	education, clinical care, physical well-	trials, and sheds very
	metaverse			being, and mental wellness	little light upon
	change				pharmaceutical
	health				metaverse
	care? ¹⁰				
7	Utilization	J. O. Yang	Korean J.	Analyses the role of AR, VR, MR, XR in	No mention of
	exercise	and J. S. Lee	Sport	the healthcare industry	potential challenges,
	rehabilitati	Que.	Biomechani	0	both technical and
	on using		cs, 2021		legal, and very little
	metaverse	/ \			significance to
	(VR, AR,	/ \			pharmaceutical
	MR, XR) ¹¹	-	b 4		industry

Research Problem:

Based on the literature review, there are no research papers that focus exclusively on the pharmaceutical applications in the metaverse. Moreover, the existing relevant papers offer little to no clarity on the legal aspects or legal challenges that may arise with the advent of Metapharmacy.

This paper aims to focus exclusively on the pharmaceutical applications in the metaverse, and potential legal issues and cyber-crimes that may take place related the metapharmacy.

Research method and methodology:

This research paper is based on qualitative methodology of research, through a combination of

¹⁰ Journal of Community Pharmacy Practice ISSN: 2799-1199 Vol: 03 , No. 01 , Dec 2022-Jan 2023 http://journal.hmjournals.com/index.php/JCPP DOI: https://doi.org/10.55529/jcpp.31.1.11

¹¹ J. O. Yang and J. S. Lee, "Utilization exercise rehabilitation using metaverse (VR·AR·MR·XR)," Korean J. Sport Biomechanics, vol. 31, no. 4, pp. 249–258, 2021.

systematic literature review and narrative literature review. The data for this research paper was solely sourced from various secondary sources in the forms of articles, journals, and online studies. The method of obtaining references was through a comprehensive and rigorous examination of the relevant literature: a. Explore related keyword combinations b. Locate and distinguish articles with relevant keyword phrases appearing in both the title and content of the paper c. Eliminate articles that contain relevant keywords but have no substantive connection to the realm of the Metaverse d. Group together the relevant papers. Comprehensive research was performed for relevant literature by exploring various online databases, including:

- a. IEEEXplore (https://ieeexplore.ieee.org).
- b. Google Scholar

This paper is based on meticulous efforts of sourcing from several online platforms to collect relevant information and articles to support the paper's objectives. The objective of this research paper was to forecast the potential legal issues that could arise with the advent of pharmaceutical metaverse, and the analysis of the existing legal framework relating to cybersecurity and cyber-space and its relevance in the pharmaceutical metaverse.

Fundamental Concepts:

In order to comprehend the various facets of this paper, it is essential to gain a deep understanding of fundamental concepts of the metaverse. This section of the paper shall delve into metaverse and the various components of metaverse, relevant to the applications of pharmaceutical industry.

1. Metaverse:

The term metaverse, as mentioned earlier, was initially coined by author Neil Stephenson in his novel, 'Snow Crash', in 1992. The metaverse is an evolving concept that visualizes a virtual reality space where users can engage with a computer-generated environment and interact with other users in real-time. It presents a vision of a collective digital realm that transcends the limitations of physical reality, offering immersive and interactive experiences¹². At its core, the metaverse is a convergence of

¹² K. Lippert, M. N. R. Khan, M. M. Rabbi, A. Dutta, and R. Cloutier, "A framework of metaverse for systems engineering," in Proc. IEEE Int. Conf. Signal Process., Inf., Commun. Syst. (SPICSCON), Dec. 2021, pp. 50–54.

various technologies, including virtual reality (VR), augmented reality (AR), artificial intelligence (AI), blockchain, and the Internet of Things (IoT). These technologies work together to create a seamless and interconnected virtual world where users can navigate and participate in a multitude of activities. One of the key aspects of the metaverse is the creation and customization of avatars, digital representations of users that allow them to interact with the virtual environment and other users. Avatars can be personalized to reflect individual identities, enabling self-expression and a sense of presence within the metaverse. ¹³ ¹⁴ Within the metaverse, users can explore diverse virtual environments that cater to different interests and purposes. These environments range from social spaces where users can meet and interact with friends and strangers, to gaming realms where they can engage in immersive and competitive experiences. Additionally, the metaverse can extend to educational platforms, virtual marketplaces, collaborative workspaces, and even virtual replicas of real-world locations.

However, the development of the metaverse raises important considerations. Privacy and data protection are crucial, as users' personal information and interactions are stored and processed within the virtual environment. Content moderation and the establishment of rules and regulations to ensure a safe and inclusive metaverse are also essential. Moreover, interoperability between different metaverse platforms is a significant challenge. As the metaverse evolves, it is important to establish standards that enable seamless movement and interaction between different virtual worlds, allowing users to carry their digital identities and assets across platforms. The vision of the metaverse represents a paradigm shift in how people experience and interact with digital technology. It offers the potential to transform entertainment, education, communication, and commerce, creating new opportunities and challenges. While the metaverse is still in its early stages, it presents an exciting glimpse into the future of digital experiences, where the boundaries between the physical and virtual worlds blur, and users can explore, create, and connect in unprecedented ways.

2. Virtual Reality (VR):

Virtual reality has the capacity to radically transform how humans interact with digital technology and simulated environments. Fundamentally, VR puts the users fully within immersive and interactive

¹³ I. Nikolaidis, "Networking the metaverses," IEEE Netw., vol. 21, no. 5, pp. 1–2, Sep. 2007.

¹⁴ . Owens, A. Mitchell, D. Khazanchi, and I. ZIgurs, "An empirical investigation of virtual world projects and metaverse technology capabilities," ACM SIGMIS Database, DATABASE Adv. Inf. Syst., vol. 42, no. 1, pp. 74–101, Feb. 2011.

three-dimensional virtual worlds, through sophisticated sensory stimulations. VR aims to convince the user that the computer-generated reality is as realistic as the physical world. The existing VR head-mounted displays employ dual high-resolution displays rapidly rendering stereo images for each eye, integrated head tracking for natural head movements to move one's virtual "camera" in real-time, surround sound spatialized for directional audio cues, and in some cases haptic feedback to provide a sense of touch. All these combined, these VR systems can generate persuasive synthetic realities that actively respond to a user's movements, gaze, and inputs through motion controllers.

As the technology improves and prices fall, embracing VR is happening at a steadfast pace across various sectors. In the gaming/ entertainment sector, VR enhances user-experience through interactive worlds and multiplayer platforms. The medium adopts new forms of experiential storytelling as well. Training and simulations through VR is beneficial to several professions including aviation, engineering, and medicine by allowing the users to learn from their mistakes in virtual stand-ins for real-world equipment or scenarios. VR is also vital for emerging metaverse concepts bringing virtual shared spaces to social platforms, work, and more.

VR is incredibly promising in revolutionizing how we engage with immersive media and synthetic spaces. With the rapid advancement of the technologies that enable VR, VR's role in the digital lives of people will amplify, by emphasizing the need for monitoring both applications and implications to guide responsible progress. Virtual reality is indubitably an evolving frontier that could extremely transform human experience.

3. Augmented Reality (AR):

Augmented Reality refers to a system which enables the users to coexist in the real, physical world, as well as the virtual world, by combining real and virtual objects and services simultaneously. ¹⁵ It enhances the perceptual information, such as images, videos, and location-based data, over the actual environment, in real-time. While VR is a fully immersive system, AR retains an anchor to physical reality. AR can be experienced through various gadgets, such as smart phones, smart glasses, etc. A very common, yet catchy example would be Snapchat, which allows the users to capture real-time

¹⁵ R. Azuma, Y. Baillot, R. Behringer, S. Feiner, S. Julier, and B. MacIntyre, "Recent advances in augmented reality," IEEE Comput. Graph. Appl., vol. 21, no. 6, pp. 34–47, Nov. 2001.

images and videos, but with an addition of funny or festive filters. Thus, AR aims to enhance the real-world experience, rather than switching into a completely different virtual world. An advantage of AR over VR is its nature to retain spatial and environmental context from the real world, while still actively operating the virtual aids. This permits the digital enhancing features to correspond accurately with the physical world's positioning, scaling and lighting, for conceivably 'anchored' visuals. Google Maps would be a pretty accurate instance to this. AR combines the virtual and real environments, which creates new models of immersive experiences for the users, requiring dynamic registration and alignment between the virtual and physical environments. This offers some unique benefits such as telepresence and interactive manuals.

4. Mixed Reality (MR):

It is a combination of augmented and virtual reality, which takes place in both actual and virtual worlds. MR blends the components of VR and AR into new sorts of hybrid experiences. With the advancement of tracking technologies, MR has emerged as a category that covers the whole spectrum of experiences between AR and VR. At its core, MR is an interactive virtual space, that is enabled according to the physical environment through positional tracking. Unlike AR, MR can transition between the physical and virtual spaces, rather than always remaining "anchored" to the real world. This is becoming more prevalent, as it is more flexible in experience designing. MR enables the users to seamlessly switch perspectives of natural vision, which could be enhanced with the digital overlays. Fostering new sensory combinations is possible in MR, by embedding real objects within the virtual world.

MR can be pro-actively used in fields like manufacturing, medicine, pharmaceuticals, education, etc., by combining the strengths of immersive VR simulation with AR, grounded in unabridged environmental contexts. For instance, advanced sensing and imaging technology enables the users to interact with objects and surroundings in both physical, as well as, virtual environments. ¹⁶ ¹⁷

¹⁶ Learn More About This Landscape and the Requirements for a Computing System That Can Handle the Demands of These New, Immersive Experiences, 'Virtual Reality vs. Augmented Reality vs. Mixed Reality' https://www.intel.com/content/www/us/en/tech-tips-and-tricks/virtual-reality-vs-augmented-reality.html

¹⁷ U. Tripathi, R. S. J, V. Chamola, A. Jolfaei, and A. Chintanpalli, "Advancing remote healthcare using humanoid and affective systems," IEEE Sensors J., vol. 22, no. 18, pp. 17606–17614, Sep. 2022

5. Extended reality (XR):

Extended Reality (XR) is a fusion of VR, AR, and MR. In the theory of reality-virtuality continuum, as proposed by Paul Milgram, which covers the entire spectrum from the 'complete reality' to 'complete virtuality', XR is the superset that contains everything in between. Unlike VR, AR, or MR, XR seamlessly combines and integrates the virtual and real environments.

XR pushes the user experience in metaverse beyond boundaries. For example, in healthcare, surgeons can use XR to overlay patient's data in real-time during surgeries, which enhances the precision and efficiency, and also significantly reduces the margin for error. It empowers remote collaboration and remote access to market, education, healthcare, entertainment, etc., as it brings together people from farther geographic locations into a uniform, convergent virtual space, designated for a particular purpose.

6. Artificial Intelligence (AI):

Artificial Intelligence is a transformative field of computer science that aims to create intellectually superior machines, that are capable of performing tasks that typically require human intelligence. AI simulates human intelligence through data, algorithms, and computational power. Deep learning, is the feature that distinguishes AI from the other traditional computer programs. It is a method by which a machine or system learns and improves it own performance over time, based on the collected data, without any explicit programming. Applications of AI are extremely diverse, ranging from routine, simple tasks, such as generating answers, to extreme cutting-edge research. AI has become an integral part of the virtual world, as it's ability to process huge amounts of data instantaneously, as well as precisely, enables the users to increase their efficiency significantly. AI has the capacity to streamline operations, and to identify intricate patterns, that may elude human analysis.

An extremely significant facet of AI is Natural Language Processing (NLP), which allows the machines to understand, interpret, interact, and generate human language. Common examples of NLPs are virtual assistants such as Siri, which has rendered the communication between people and machines more personal and intuitive.

Pharmaceutical Metaverse and Metapharmacy:

The intersection of pharmaceuticals and the metaverse, portrays a futuristic landscape, wherein the development, testing, marketing, sales and purchasing of drugs by the pharma companies is done with the realms of the metaverse. Pharmaceutical metaverse comprises of all the applications possible relating to the pharmaceutical industry in the metaverse, using tools of VR, AR, MR, AI, XR, etc. Metapharmacy, on the other hand, maybe understood as a pharmacy operating within the metaverse, from which the patients can access prescribed medicines, as well as digital therapies, in the same manner as in the real physical world.

In the pharmaceutical metaverse, drug discovery undergoes a transformative shift. Virtual Reality (VR) facilitates the creation of immersive simulations where researchers can visualize and interact with molecular structures in three-dimensional space. This spatial understanding accelerates the drug development process, enabling more informed decisions and potentially expediting the arrival of novel therapies. Clinical trials, a cornerstone of pharmaceutical research, become more patient-centric in the metaverse. Augmented Reality (AR) applications guide patients through trial protocols, providing real-time information and support. Virtual environments simulate various trial scenarios, enhancing patient understanding and adherence. This not only improves the efficiency of clinical trials but also fosters a more inclusive and participatory approach to medical research. Patient education enters a new dimension within the pharmaceutical metaverse. VR and AR technologies create immersive experiences that educate patients about their conditions, treatment options, and medication regimens. Visualizing complex medical information in a virtual space enhances comprehension and empowers patients to actively manage their health. In the pharmaceutical supply chain, the metaverse introduces enhanced tracking and security measures. Blockchain technology, integrated into virtual environments, ensures the transparency and integrity of the drug supply chain. This not only combats counterfeit drugs but also streamlines logistics and distribution processes.

Telemedicine experiences a metamorphosis in the metaverse. Virtual clinics and consultation rooms become commonplace, providing a seamless interface for remote healthcare interactions. Patients can engage with healthcare providers in a more immersive and personalized manner, fostering a sense of presence and connection despite physical distances. Mental health interventions find a novel platform in the pharmaceutical metaverse. VR therapy environments offer immersive spaces for treating

conditions like anxiety, phobias, and PTSD. The ability to create controlled, customizable settings within virtual reality enhances therapeutic interventions, providing a powerful tool for mental health professionals. Patient support groups and communities flourish in the metaverse. Virtual spaces allow individuals facing similar health challenges to connect, share experiences, and access valuable resources. This sense of community, facilitated by immersive technologies, contributes to emotional well-being and can be a crucial aspect of holistic healthcare.

A significant discovery involving the use of a 3D virtual environment to monitor chemical constituents in novel drugs has been made by Sygnature Discovery, an English drug discovery business, by using the capabilities of metaverse. Noman Qureshi's Pharmacy Group is being supported by Metaverse Advisory Group (MAG), a subsidiary of iMining Technologies [134]. It promises to increase drug adherence by allowing patients to schedule automatic refill reminders for prescription medications delivered directly to their homes. Customers can also make appointments for pharmacy services through the Metaverse pharmacy, such as online consultations with licensed pharmacists. EaseVR is a convergence of cutting-edge technology and proven therapeutic techniques, offering a comprehensive solution for patients suffering from back pain.

Existing legal framework for the pharmaceutical industry in India:

In general, pharmaceutical industry in India is governed by the Drugs and Cosmetics Act, 1940¹⁸. This act governs the manufacturing, sale, and distribution of drugs and cosmetics in India. This Act aims to fix liability upon the medical technologies and pharmaceutical companies, in case of negligence and sub-standard service provided, and to prevent adulteration of drugs. Under this Act, three wings are established, along with proper authorities, in order to ensure proper regulation and implementation of the provisions of the Act. The Advisory wing consists of the Drug Technical Advisory Board and the Drug Consultative Committee, which act as advisories to the Central and State Governments with respect to drugs and cosmetics. The Analytical wing comprises of the Central Drug Laboratory, Government Analysts, and the drug testing labs for the States. Finally, the administrative wing consists of individuals, who are responsible for the administration of the

THE DRUGS AND COSMETICS ACT, 1940 cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download file division.jsp?num id=OTIyNw

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regulations laid under the Act, including the Drugs Controller General of India, the Drugs Control and Licensing Authorities of States, and the Drug Inspectors of central and state governments¹⁹. Thus, this Act is the primary legal framework for the pharmaceutical industry in India.

The Drugs and Cosmetics Rules, 1945²⁰ categorized the drugs into schedules and provided regulations for the sale, storage, and prescription of each category. These rules provide detailed guidelines and procedures for the implementation of the Drugs and Cosmetics Act, 1940. The rules encompass various aspects of the pharmaceutical industry, including the import and manufacture of drugs, clinical trial requirements, and pharmacovigilance.

The New Drugs and Clinical Trials (Third Amendment) Rules, 2022²¹ is a set of regulations introduced by the Ministry of Health and Family Welfare in India to further streamline and improve the clinical trial process in the country. The new Drugs and Clinical Trial Regulations, 2019 are modified by these regulations. The New Drugs, Medical Devices and Cosmetics Bill 2022 highlights regulations for conducting clinical trials for new drugs and medical devices. According to Chapter IV of the draft, the central licensing authority will be required to grant mandatory approval for clinical trials or research involving medications and medical equipment. These rules recognize the issue of e-pharmacies²² and states that the Union government would come up with rules and regulations to regulate the online sale of drugs. It asserts, "Unless in accordance with a license or permission issued in such manner as may be prescribed, or by any other person acting on his behalf, no person shall sell, stock, exhibit, offer for sale, or distribute any drug by online mode." Furthermore, it also prohibits such sales of medical devices.

Indian Council of Medical Research (ICMR) is the regulating body which primarily issued guidelines related to traditional clinical research and trials conducted in real-world settings. These guidelines were designed for conducting clinical trials involving pharmaceuticals, medical devices, and

²⁰ THE DRUGS AND COSMETICS RULES, 1945 2016DrugsandCosmeticsAct1940Rules1945.pdf (cdsco.gov.in)

¹⁹ Drugs and Cosmetics Act, 1940 https://blog.ipleaders.in/drugs-and-cosmetics-act-1940/

The New Drugs and Clinical Trials (Third Amendment) Rules, 2022 cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download file division.jsp?num id=OTEzO
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https://health.economictimes.indiatimes.com/news/medical-devices/new-drugs-medical-devices-and-cosmetics-bill-2022-key-highlights/92852245

healthcare interventions within physical healthcare facilities. Indian Council of Medical Research (ICMR) Ethical Guidelines for Biomedical and Health Research Involving Human Participants²³ provide ethical standards to the pharmaceutical companies, for conducting research involving human participants, including clinical trials. ICMR They cover topics such as informed consent, participant protection, and the role of ethics committees.

Central Drugs Standard Control Organization (CDSCO) the regulatory authority responsible for medical devices and pharmaceuticals in India. It oversees the approval and regulation of medical devices, including digital health technologies. The CDSCO has recognized the concept of Software as a Medical Device (SaMD). SaMD refers to software that is intended for medical purposes and can be regulated as a medical device. The regulatory requirements for SaMD may vary depending on its classification and risk level. Similarly, Pharmacovigilance Program of India (PvPI) is another legal framework that operates under the guidance of the Central Drugs Standard Control Organization (CDSCO). It is a national pharmacovigilance program in India that collects, monitors, and analyzes adverse drug reactions (ADRs) to ensure the safety of pharmaceutical products. The Indian Pharmacopoeia is an official compendium of standards for drugs in India. It includes specifications for the identity, purity, and quality of pharmaceutical substances and products. National Pharmaceutical Pricing Authority (NPPA) regulates the prices of pharmaceutical products in India to ensure affordability and accessibility to the general public. It sets price controls on essential medicines and monitors price changes.

All these pertain to the traditional pharmaceutical industry. However, there are a few legislations governing digital pharmaceutical technologies in India. Medical Devices Rules, 2017 regulates the digital health products and medical devices, including software-based medical devices. The rules define what constitutes a medical device and outline regulatory requirements for their import, manufacture, sale, and distribution. Telemedicine Guidelines, 2020, issued by the Ministry of Health and Family Welfare provides guidance on the practice of telemedicine in India. These guidelines are relevant to digital health services and telemedicine platforms.

²³ ICMR Bioethics Unit <u>ICMR Ethical Guidelines (ncdirindia.org)</u>

Legality of Pharmaceutical Metaverse and Metapharmacy:

The rise of pharmaceutical metaverse and Metapharmacy is still in its infancy in India. There are no major investments by the Indian Pharmaceutical Giants in the metaverse applications. However, the walls between the real world and the metaverse is coming down at an accelerated pace in India, which would soon impact the pharmaceutical sector as well. Given the situation and the understanding of how a pharmaceutical metaverse and metapharmacy would operate, a whole new set of legal issues arise, as the metaverse involves the usage of computers, gadgets and cyberspace. Currently, the Information Technology Act, 2000 governs the matters related to cybercrime and e-commerce. Under this Act, for any crime involving a computer, computer resource, or a computer network located in India, Indian, as well as foreign nationals can be charged.

However, in order to charge a metapharmacy or any individual in the pharmaceutical metaverse, it must first be determined whether metaverse could be brought under the scope of intermediaries, as specified in the Information Technology Act of 2000's Section 2(1)(w). According to the provision, an intermediary as a person who receives, stores or transmits any electronic record and provides any service relating to such record on the behalf of another person Network service providers, telecom companies, internet service providers, search engines, web hosting companies, online marketplaces, online auction sites, online payment sites, and cyber cafés are examples of intermediaries. ²⁴ Intermediaries perform functions such as hosting content, collecting information and evaluating information, facilitating communication and information exchange, facilitating the use of the internet etc. Examples of intermediaries include social media platforms and e-commerce sites. E-commerce websites and social media platforms are two examples of intermediaries. An intermediary is immune from liability under Section 79(1) for any information, data, or communication connection provided by a third party that he hosts or makes available. The following requirements must be met, according to Section 79(2), in order to insulate an intermediary from liability:

- 1. The intermediary's function is limited to providing access to a communication system over which information made available by third parties is transmitted, hosted or stored;
- 2. The intermediary does not:

²⁴ Regulating digital intermediaries: IT Act and the new intermediary guidelines; <u>Regulating digital intermediaries</u>: <u>IT Act and the new intermediary guidelines - iPleaders</u>

- initiate the transmission,
- select who receives the transmission, and
- select or modify the information contained in the transmission,
- 3. The intermediary observes due diligence while performing his duties under this Act and also observes such other guidelines prescribed by the Central Government.

The metaverse has a lot of applications and any of its operations could easily be brought under the scope of intermediaries as defined under the Act. However, the metaverse is a parallel digital universe that necessitates the use of extremely personal data for smooth provision of services, as well as other sensors and software, all of which increase the difficulty of managing these platforms.²⁵. Thus, it is debatable whether a separate "world" could be considered as an intermediary. Therefore, it is necessary to monitor search data, biometric, facial recognition, body language, and other personal data in order to prevent data breaches and mitigate regulatory loopholes. If such kind of data is not protected, businesses could steal it and use it to make targeted advertisements and increase revenue through efficient advertising campaigns.

The Digital India Act is a new digital law that categorizes all online intermediaries into different buckets, such as cloud service providers (CSPs), social media platforms, internet service providers (ISPs), metaverse, OTT providers, online gaming, and more1. The act is expected to replace the existing Information Technology Act, 2000²⁶. Nevertheless, the Information Technology Act, 2000 shall operate, until such Act is passed.

Forecast of the Potential legal challenges in the Metapharmacy and the Pharmaceutical Metaverse, and the Relevance of Existing Legal Framework

While the legal landscape is continually evolving, here are some new legal issues that could arise with the advent of a pharmaceutical metaverse:

²⁵ Metaverse: Legality & Regulatory Concerns In India <u>Legality of Metaverse - Regulatory Concerns In India</u> (ksandk.com)

²⁶ Digital India Act Will Monitor Social Media, Metaverse, OTT Platforms: Report; <u>Digital India Act To Monitor Social Media, Metaverse, OTT (inc42.com)</u>

1. Regulatory Framework:

Developing a regulatory framework to govern pharmaceutical activities within the metaverse will be a significant challenge. Regulators will need to determine how to apply existing pharmaceutical regulations to virtual environments, including clinical trials, drug manufacturing, and marketing, in the context of cyber laws.

2. Patient Data and Privacy:

The collection, storage, and transmission of patient data within the pharmaceutical metaverse must adhere to data privacy and security laws. Ensuring patient privacy and data protection in a virtual environment will be crucial. It is anticipated that the Metaverse would have a large amount of sensitive personal data on it given the anticipated number of users. Every AR-VR gadget's privacy policy typically states that the device will collect information on a person's biological makeup, physical environment, and other personal details. Given that biometric data of this kind is being gathered, it would be considered "sensitive personal data" as defined by the IT Rules. The government may make orders for information interception and decryption to "ensure the security, sovereignty, or integrity of the state" under Section 69 of the IT Act. Data in the Metaverse environment is subject to government monitoring; if it is determined to be against public policy, it may be withheld, and the corporation may face penalties for noncompliance. It is anticipated that the law will evolve in the metaverse period to strike a balance between the protection of the public interest and fundamental rights like freedom of expression, however it is unclear how successful this will be in practice.

3. Virtual Clinical Trials:

Conducting virtual clinical trials raises questions about the validity and reliability of trial data. Ensuring the integrity of clinical trial results in a virtual setting and addressing issues of participant consent and data security will be essential. The ICMR regulations must be amended accordingly so as to include the guidelines relating to virtual clinical trials.

4. Telemedicine Regulations:

Integrating telemedicine and telehealth services into the pharmaceutical metaverse may require adapting and expanding existing telemedicine regulations. The Telemedicine Guidelines, 2020 must be amended to include the sale and purchase of medicines in the metapharmacy.

5. Pharmacovigilance and Safety Reporting:

Establishing mechanisms for pharmacovigilance and adverse event reporting within the metaverse will be necessary to monitor and ensure the safety of pharmaceutical products. However, Pharmacovigilance Program of India (PvPI) already exists. Thus, minor changes to incorporate the metaverse applications shall suffice.

6. Product Liability:

Determining liability in the event of harm or injury resulting from the use of pharmaceutical products within virtual environments will be a complex legal issue. For instance, a patient who has undergone a traumatic car accident can purchase medicines for his injuries in the Metapharmacy, by simply ordering his prescription, and also rent or buy a collection of therapy videos in the metapharmacy for treating his mental health. He could therapize himself using such prescribed videos, that he purchased using his avatar, operating in the metaverse. Now, lets' say the metapharmacy accidentally dispensed the wrong medicines or the wrong therapy video to the patient. Due to this, the patient maybe severely affected. In this case, on what basis can product liability be fixed, and upon whom can it be fixed? This still remains a grey area in the Indian Legal System.

7. Advertising and Marketing:

Regulating the marketing and advertising of pharmaceutical products within the metaverse will be challenging, especially concerning the reach and influence of virtual marketing campaigns. For this purpose, the primary Act governing the Pharmaceuticals, the Drug and Cosmetics Act, 1940 must be amended so as to include the sale, import, and distribution of drugs in the metaverse.

8. Ethical Concerns:

Ethical considerations, including informed consent, transparency, and responsible use of virtual pharmaceutical applications, will need to be addressed.

9. Cross-Border Legal Challenges:

The global nature of the metaverse may give rise to cross-border legal issues related to jurisdiction, data transfer, and regulatory compliance.

10. Standardization and Interoperability:

Establishing industry standards and ensuring interoperability among different virtual pharmaceutical platforms will be essential for seamless operations and data exchange.

11. Cybersecurity:

Protecting virtual pharmaceutical environments from cyber threats and data breaches will be a critical aspect of ensuring the safety and integrity of pharmaceutical activities.

Conclusion:

Thus, based on the extensive research on the subject, there is no specific legal framework in India, that currently governs or regulates the Pharmaceutical Metaverse, or just Metaverse in general. This means, the nature or legal capacity of metaverse is yet to be determined, and remains vague and unresolved under the existing legal framework. As mentioned above, metaverse is still under development in India, which means that there is less dependency or interaction in it, making this the perfect time for the government to lay down guidelines and a solid legal framework for the pharmaceutical metaverse and the metapharmacy. Based on the research, the forecasted legal challenges could be resolved or prevented with a few amendments in the existing legal framework mentioned above, and by incorporating cyber-related provisions in the pharmaceutical legislations. However, since this is an unprecedented landscape, the forecast of cyber-crimes and legal challenges are only tentative, and not conclusive in nature. The accuracy and relevance of this paper could be tested only with the development of the pharmaceutical metaverse.

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