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DEPARTMENT OF
ADMINISTRATIVE REFORMS &
PUBLIC GRIEVANCES



Viksit Bharat-
Secure and Sustainable
e-Service Delivery

COMPENDIUM

of e-Governance Initiatives 2024

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Authors:

1. **Shri Kamlesh Kumar Pant**, Chairman NPPA
2. **Dr. Vinod Kotwal**, Member Secretary, NPPA
3. **Shri G.L. Gupta**, Director, NPPA
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Abstract:

The National Pharmaceutical Pricing Authority (NPPA) established in 1997 by the Government of India regulates and monitors the drug prices to ensure the availability and affordability of essential drugs. NPPA's key responsibilities include fixing and revising drug prices as per the provisions of the Drugs Prices Control Order (DPCO), monitoring compliance, and rendering advise on pharmaceutical policies.

The Integrated Pharmaceutical Database Management System (IPDMS) 2.0, implemented by NPPA is a comprehensive digital platform designed to manage, regulate, and monitor various aspects of pharmaceutical products related to their prices and availability. Key features include a centralized database, real-time data collection, automated reporting, compliance monitoring, advanced data analytics, and a stakeholder portal. IPDMS 2.0 enhances transparency, efficiency, and accountability. The Pharma Sahi Daam (PSD) mobile app, integrated with IPDMS 2.0 allows consumers to verify drug prices, compare brands, and access information in real-time, thus promoting transparency and informed decision-making.

The impact of IPDMS has been substantial, with over 1,523 companies registered, and listing of 98,528 medical devices and 133,697 medicines. The system has processed 145,161 forms and addressed 4,976 overcharging cases, ensuring compliance with pricing regulations. Currently, implementation of IPDMS 2.0 has significantly improved regulatory oversight and in future it will shape the service delivery further with advanced data analytics and integration with other government database(s).

Keywords: Digital platform, Drugs Prices Control Order (DPCO), Essential drugs, Integrated Pharmaceutical Database Management System (IPDMS), Pharma Sahi Daam (PSD)

Introduction:

The Indian pharmaceutical industry is a significant player in the global pharmaceutical landscape and ranks 3rd globally in pharmaceutical production by volume [1]. India accounts for 60 percent global vaccine production and thus has the world's largest vaccine production facility by volume. India is also the largest global supplier of generic medicines, having a 20-22 per cent share in the global supply of generic drugs in terms of volume. This has earned it the sobriquet the “pharmacy of the world” [2]. It contributes a significant 1.72% to the India's GDP [3]. In terms of its size, the Indian Pharmaceutical Industries is currently valued at \$ 50 Billion and is expected to reach \$ 130 billion by 2030 [4]. Indian medicines reach 200+ countries contributing to availability of affordable quality medicines, wellness products, bulk drugs, and intermediates. The Indian Pharmaceutical Industries played a very significant role in supply of drugs during COVID pandemic. India produces more than 500 APIs and 60,000 generic drugs across 60 therapeutic categories. The Indian pharmaceutical industry includes a network of 3,000 companies and 10,500 manufacturing units [5].

While the pharmaceutical sector was growing, the government was cognizant of its role in providing affordable healthcare to its people. The World Health Organisation (WHO) guideline on country pharmaceutical pricing policies (2020) notes that affordable access to safe and efficacious pharmaceutical products is at the core of global efforts towards achieving universal health coverage [6]. Keeping in view the socio-economic milieu, the government is aware about the importance of keeping drugs affordable and through various policy interventions since early 1960's has ensured the availability, affordability and accessibility of drugs [7].

The New Drug Policy, 1994 envisaged the setting up of National Pharmaceutical Pricing Authority (NPPA). It was set-up in 1997 as an independent body of experts in the Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals (DoP). NPPA was delegated the powers to implement and enforce the then extant Drugs (Prices Control) Order 1995 [8]. The functions of NPPA, inter-alia, include fixation and revision of prices of scheduled formulations under the Drugs (Prices Control) Order (DPCO), as well as monitoring and enforcement of prices. NPPA also provides inputs to the Government on pharmaceutical policy and issues related to the affordability, availability and accessibility of medicines.

The Government notified National Pharmaceutical Pricing Policy, 2012 (NPPP- 2012) with an objective to put in place a regulatory framework for pricing of drugs so as to ensure availability of “essential medicines” at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of the industry, thereby meeting the goals of employment and shared economic well-being for all [9]. Based on the NPPP, 2012, the Government notified Drug (Prices Control) Order, 2013 on 15th May, 2013 in supersession of DPCO, 1995. NPPA is currently implementing the DPCO, 2013, which regulates and monitors the prices of pharmaceutical as well as medical devices sectors. Ceiling prices of ‘essential drugs’ as listed in the First Schedule of DPCO, 2013 are fixed based on ‘market-based data’. Price control is applied to specific formulations

with reference to the medicine (active pharmaceutical ingredient), route of administration, dosage form / strength as specified in the First Schedule. The prices of other drugs are monitored.

Apart from consumers/patients, pharmaceutical and medical devices industries are important stakeholders being regulated entities. As per various provisions of DPCO, 2013 there are regulatory Forms to be submitted by the companies as part of regulatory compliance. To facilitate regulatory compliance and 'ease of doing business', NPPA implemented Integrated Pharmaceutical Database Management System (IPDMS) in 2015. This comprehensive online system which was envisaged as Pharma Data Bank (PDB) provided a platform to the Pharmaceutical Manufacturer/ Marketing/ Importer/ Distributor Companies to file mandatory returns prescribed in Form II, Form III and Form V of Drugs (Prices Control) Order, 2013 (DPCO, 2013) [10]. However, this online system was not capturing the full gamut of Forms to be filed by the companies. Hence, an upgraded version i.e. IPDM 2.0 looking at service delivery of tomorrow was launched in 2022.

Integrated Pharmaceutical Database Management System (IPDMS) 2.0:

It is well-documented that information technology can potentially be used effectively to facilitate regulatory information management and compliance assistance [11]. Hence, IPDMS 2.0 an initiative of the NPPA is a comprehensive digital platform designed to manage, regulate, and monitor prices of pharmaceutical products and medical devices. The system is a significant step towards enhancing transparency, efficiency, and accountability in the pharmaceutical and medical devices sector. IPDMS 2.0 allows the companies to submit all the Forms related to pricing of pharma products and medical devices in an online mode with user friendly interface. Submission of these forms is a major regulatory compliance requirement under the DPCO.

The multi-instance architecture of IPDMS 2.0 has the capability to give multiple users access over a public network infrastructure. It is based on Relational Database Management System (RDBMS) for easy retrieval of information and better performance. The application has been developed by Centre for Advance Computing (C-DAC) [12]. Further, this cloud-based application was implemented to strengthen the internal processes followed in the NPPA through existing system of monitoring and controlling prices of drugs and medical devices. With a view to provide the NPPA with an enabled and capable system, IPDMS 2.0 also integrates Web and Mobile Apps developed and deployed for complaint management and instant availability of drug prices related information.

Key Features of IPDMS 2.0:

Centralized database and application server: All application servers, database and system components are hosted centrally. The IPDMS provides a centralized repository for all pharmaceutical and medical devices data, including sales, production, and pricing related data. This centralization ensures that all data is easily accessible and can be efficiently managed and analysed.

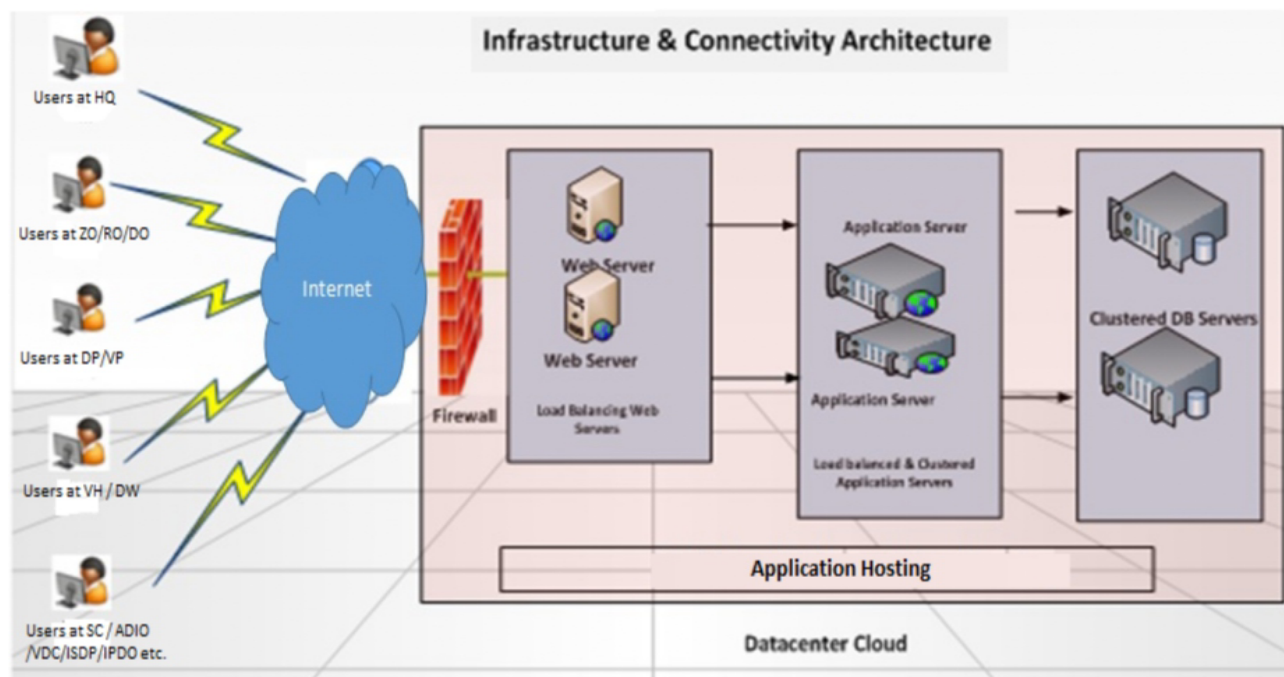


Figure 1: IPDMS 2.0 deployment architecture

Security: Authentication of users is through login and passwords and role/rule-based access controls. Sensitive data is encrypted and data sent across the network cannot be modified by a tier. Role based access and Web-Security Audits, User log of important transactions, OTP and Captcha authentications are other important features of the application. There is comprehensive audit trail and audit log system.

Real-Time Data Collection: The companies are required to submit their data in real-time. This includes information on drug production, sales, and pricing. Real-time data collection helps NPPA to monitor and regulate the market more effectively particularly for ensuring the availability of drugs.

Automated Reporting: The system automates the reporting process, reducing manual errors and ensuring timely submission of necessary data. Automated reporting also allows for quicker data analysis and decision-making.

Compliance Monitoring: IPDMS tracks compliance with the Drug Price Control Order (DPCO) and other regulatory guidelines.

Data Analytics: The system includes advanced data analytics tools that help in analysing trends, identifying anomalies, and making informed decisions. These tools can generate various reports and dashboards to assist NPPA in monitoring the pharmaceutical market effectively.

Stakeholder Portal: IPDMS provides a dedicated portal for stakeholders, including pharmaceutical companies, Price Resource Monitoring Units (PMRUs) in different States/UTs, staff of NPPA and the

public. This portal enhances transparency and allows stakeholders to access relevant information, submit data, and communicate with NPPA.

Alerts and Notifications: The system can send automated alerts and notifications to stakeholders about important updates, compliance deadlines, or any anomalies detected in the data. This ensures timely action and keeps all parties informed.

Public Awareness and Transparency: IPDMS implemented by NPPA enhances public awareness and transparency by providing accessible, real-time data on drug pricing and availability. This transparency empowers stakeholders to make informed decisions and fosters accountability among pharmaceutical companies.

Key Functions of IPDMS 2.0:

IPDMS 2.0 has been designed to automate the workflow of various functions performed by NPPA like fixation of prices; monitoring of prices; handling of complaints; supervising the activities of PMRUs, etc. By automating the workflow of different divisions of the NPPA, IPDMS 2.0 streamlines processes and reduces manual intervention in different activities. All the divisions are interconnected to process different routine activities which are otherwise processed through manual isolated files. This helps in improving efficiency and reducing the time required to complete tasks. The IPDMS also addresses the issue of duplicity of work by centralizing and standardizing data and processes.

Complaint management and monitoring is done through following:

Complaint Management System (CMS): A robust CMS is built in IPDMS to manage and address grievances related to drug pricing, availability, and compliance with regulatory requirements. This system ensures that stakeholders, including consumers, companies, and healthcare providers, can report issues and seek resolutions efficiently. The entire work flow from lodging of complaint and ticketing system to tracking of complaints till resolution is automated.

Notice Management System (NMS): NPPA monitors the prices of essential medicines covered under the DPCO to ensure compliance with price caps and ceiling prices. When the companies are found to be selling drugs above the permissible prices, NPPA issues overcharging notices to notify the concerned companies of the violations. The entire process of generating the different notices like Preliminary Notices (PN), Show-cause Notices (SCN), and Demand Notices (DN), dissemination and receiving replies from the companies is digitised as part of IPDMS 2.0.

Regulatory Compliance: IPDMS 2.0 facilitates the pharmaceutical and medical devices companies in complying with the various provisions of DPCO. It tracks the compliance status of each company and highlights any deviations from the prescribed norms, facilitating timely intervention by the regulatory authority.

Market Analysis: By analysing production and sales data, NPPA can identify market trends, assess the availability of essential drugs, and prevent shortages, if reported.

Decision Support: The analytics and reporting capabilities of IPDMS provide crucial support for decision-making. NPPA can use the insights gained from the system to formulate policies, set price caps, and undertake regulatory actions that ensure the availability of affordable medicines.

Consumer Protection: An important function performed by IPDMS 2.0 is to protect the consumers by ensuring that medicines are priced fairly and this information is easily accessible and available to them.

Integration of IPDMS 2.0 with Pharma Sahi Daam (Mobile Application):

Upgraded version of Pharma Sahi Daam (PSD) mobile application was launched by the NPPA along with the IPDMS 2.0. PSD is available on Android as well as iOS platforms. This app is designed to empower consumers and stakeholders by providing real-time information on prices of scheduled medicines. Pharma Sahi Daam and IPDMS are inter-connected with the Complaint Management System (CMS).

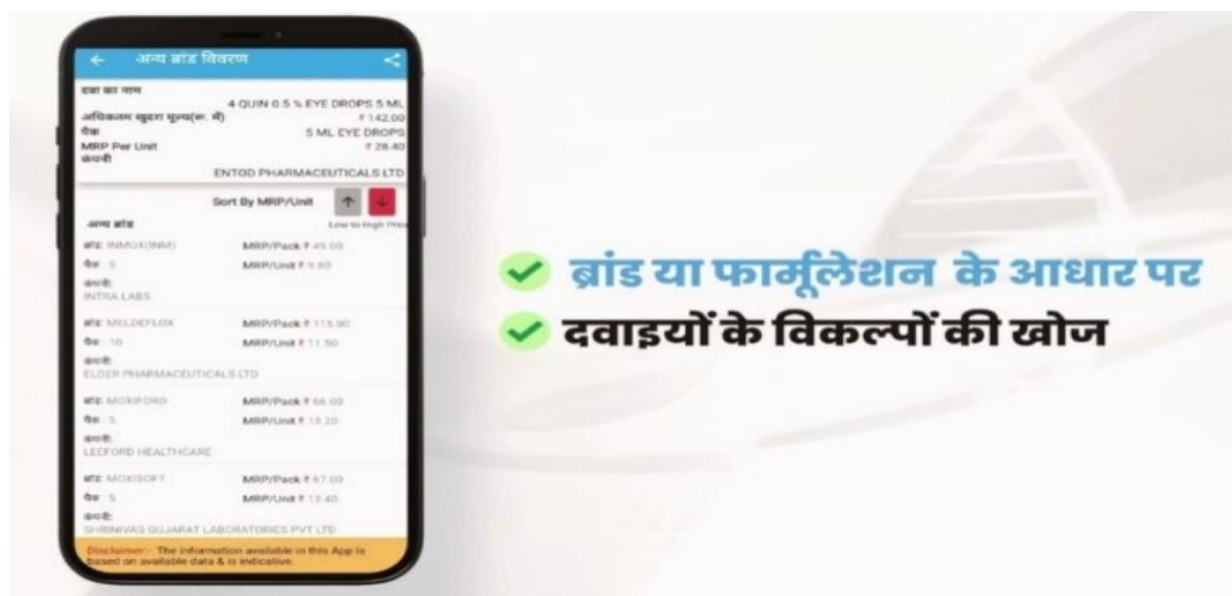


Figure 2: Search feature of PSD

The uses and the salient features of PSD are:

- PSD facilitates consumer to verify the ceiling prices for a particular medicine
- Users can search for the prices of different brands by formulation name, and can also define the dosage form and strength of the formulation
- Users can search for medicines by their generic names or brand names and compare prices across different brands or generic versions
- Users can compare the prices of alternate brands for the same formulation
- User can also search a particular medicine by voice search (Speech recognition)
- User can share the information regarding a particular medicine with their doctors, friends and family members and they can also bookmark medicine frequently bought by them
- User can lodge a complaint also through the App
- PSD can be accessed in two languages, English & Hindi.

Overall, Pharma Sahi Daam is the digital tool for promoting transparency in drug pricing and empowering consumers to make informed choices while purchasing medicines. It aligns with NPPA's efforts to ensure affordability and accessibility of essential medicines in India's healthcare system.

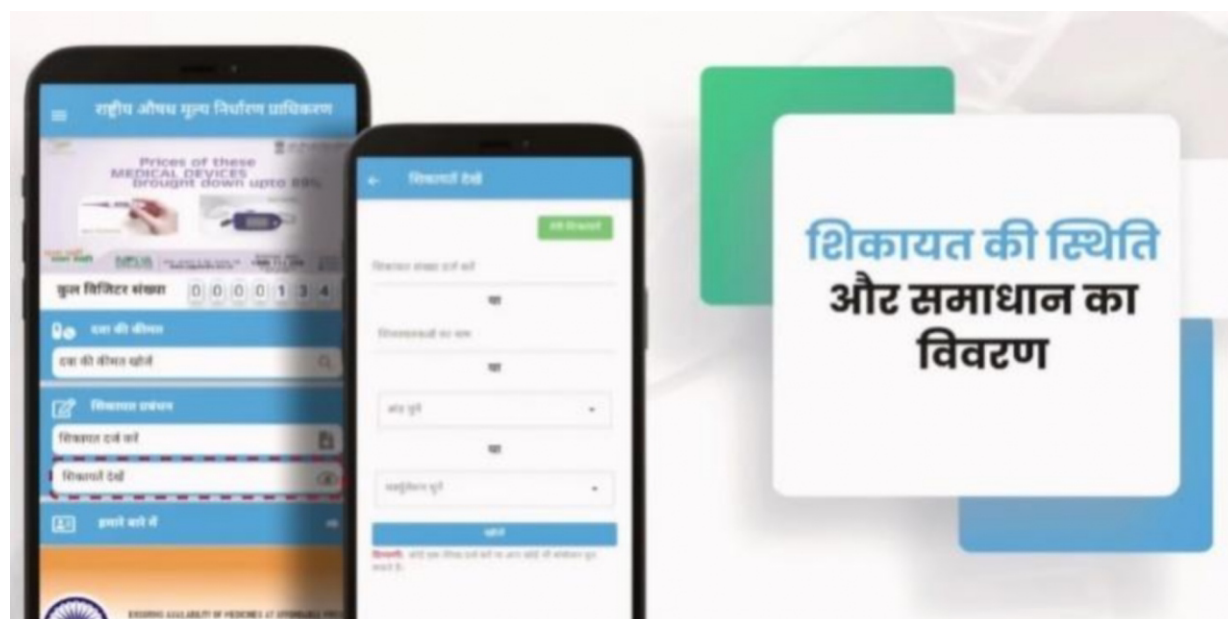


Figure 3: Complaint registering feature of PSD

User training and stake holder participation:

To make the initiative more successful, it is essential to enhance digital capacity of all the stakeholders. The detailed plan and administrative & technical guidance about the IPDMS 2.0 were discussed/explained through various audio-video conferences, meetings, online-offline training sessions, demonstration of the application, audio-video/textual manuals to the stakeholders. The support documents are easily accessible and downloadable from IPDMS 2.0 portal itself.

Stakeholder Collaboration and Training Programs: Engaging stakeholders through collaboration and providing comprehensive training programs has ensured successful adoption and implementation of IPDMS.

Continuous Monitoring and Feedback Mechanisms: Establishing continuous monitoring and feedback mechanisms through dedicated IT Cell with members drawn from NPPA and CDAC team has allowed for timely addressing the issues raised by the stakeholders and opportunities for continuous improvement.

Data Security and Privacy Measures: Implementing robust data security and privacy measures to protect sensitive information garnered confidence in the stakeholders.

Acceptance of the IPDMS 2.0: The impact of implementation of IPDMS 2.0 can be significant, particularly in terms of its demographic and geographical reach. Here's how the IPDMS has impacted different demographics and geographical regions:

Demographic Reach: Urban and Rural Populations, Low-Income Groups: The innovation could have a positive impact on low-income groups by ensuring that essential drugs are available at affordable prices and by reducing the potential for data non-congruencies or price manipulation.

Geographical Reach: Remote and Rural Areas, Across States and Regions: The IPDMS shall have a positive impact in remote and rural areas, across States and regions by ensuring availability of price related information of essential drugs on finger tips.

Key Statistics

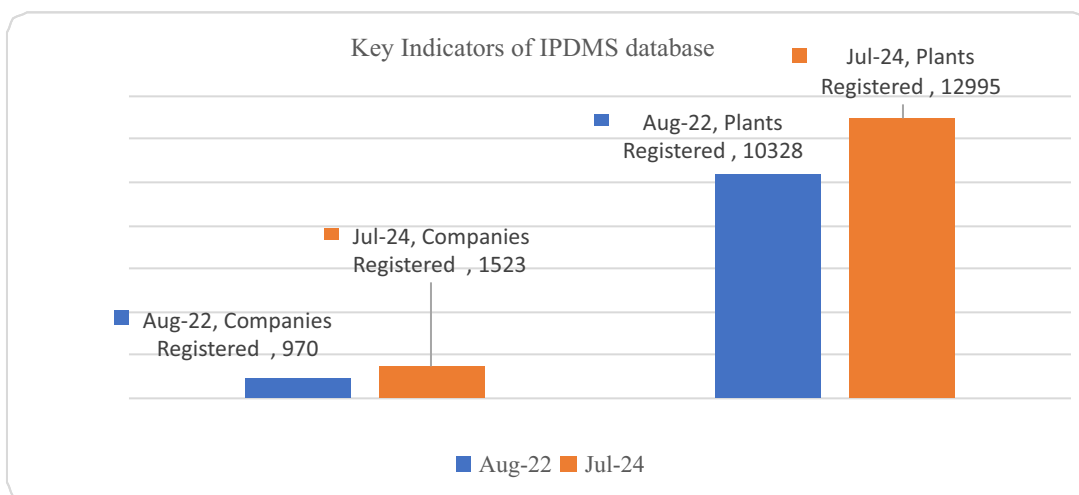
A total of 1523 pharmaceutical and medical devices companies are registered on the IPDMS as on 15.07.2024 (**Chart -1**). These companies have registered 1,33,697 medicines (**Table 2**) and 98,528 medical devices (**Table 2**) till date. The companies have filed a total of 1,45,601 forms (**Form I to VI of DPCO, 2013**) in IPDMS as given in Table 1 below.

Form as per DPCO,2013	Number in IPDMS 2.0
Form-I	407
Form-II	13289
Form-III	37062
Form-IV	108
Form-V	60056
Form_VI	34679
Total	145601

Table 1: Status of submission of various forms in IPDMS 2.0

Indicator for pharma	August-22	July-24
Companies Registered	970	1361
Plants Registered	10328	12561
Products Registered	107331	133697
Indicator for medical devices	August-22	July 2024
Companies Registered	-	162
Plants Registered	-	434
Products Registered	-	98528

Table 2: Key indicators of IPDMS 2.0 database for pharma and medical devices companies



A total of 4976 alleged overcharging cases were received on IPDMS 2.0 from PMRUs, State Drug Controllers, and the public.

As per the current DPCO provisions non-filling of forms and information by the manufactures/marketers on IPDMS 2.0 does not attract any penalty. Hence compliance in terms of coverage i.e. numbers of companies and products are low and filling of various forms is also irregular.

Way forward: Decoding data and Integration:

Efforts are afoot to integrate the IPDMS 2.0 database with Sugum portal of Central Drugs Standard Control Organisation (CDSCO) where data is captured at the time of granting licences to various pharma products. In addition, there is further scope for integration of IPDMS 2.0 with the State Level Licensing Authorities (SLAs) and the National Health Authority (NHA).

Notwithstanding this the learning's from current data being collected in IPDMS 2.0 has the tremendous potential to tailor future service delivery systems. Nitin Seth, the author of the book Mastering the Data paradox: The key to winning in the AI Age, calls our age the "data-first world" and emphasises the value of data and the quality of data being collected. It is also important to use this data to convert it into actionable insights. In the context of IPDMS 2.0, this can be explained further with an example. Data regarding production of drugs categorised as 'essential' as per DPCO, 2013 is collected and a number of analytics can be run on it to provide information on availability of stocks of these drugs; an increase/decrease in their production; geographical distribution of companies manufacturing these drugs, etc. In case of decrease in production of any drug, system can generate an alert that can be analysed further to establish whether the decrease is temporary or there are any underlying systemic issues. Similarly, mapping of information based on geographical location of a company can be useful for making these drugs available in case of complaints of non-availability of drugs received from consumers in the PSD.

Conclusion:

As stated earlier, the stated objective of NPPP, 2012 is to strike a balance between the growth of the industry and the public's need for affordable healthcare. IPDMS 2.0 collects data not only from the Pharmaceutical & Medical device companies but also consumers. The implementation of the IPDMS 2.0 by the NPPA epitomizes the transformative power of e-governance in the pharmaceutical sector and marks a significant advancement in the regulation of drug prices in India. This digital platform has brought about a paradigm shift in how data is managed, monitored, and analysed, ensuring greater transparency, efficiency, and accountability. This digital platform has streamlined the processes of monitoring and compliance enforcement, ensuring that the objectives of the DPCO are met with greater precision and efficiency.

This e-governance initiative has not only streamlined internal processes within NPPA but also provided a robust platform for compliance tracking and enforcement, ensuring that pharmaceutical companies adhere to pricing norms as stipulated under the Drug Price Control Order (DPCO), safeguarding the interests of consumers and ensuring the availability of essential medicines at reasonable prices.

The integration of the Pharma Sahi Daam mobile application with IPDMS 2.0 has further democratized access to drug price information, enabling consumers to make informed decisions and fostering a culture of transparency and accountability within the pharmaceutical sector. With over 1,523 companies registered and thousands of formulations and medical devices listed, IPDMS has become a cornerstone in the regulatory landscape of India's pharmaceutical industry.

Going forward, the continued success of IPDMS 2.0 will depend on sustained stakeholder engagement, ongoing enhancements to the system's capabilities, and robust data analytics and security measures. Further, work will have to be undertaken to integrate other government database(s) so that a unified solution digital platform can evolve. By maintaining its commitment to innovation and regulatory excellence, NPPA can ensure that the benefits of IPDMS 2.0 are fully realized, ultimately contributing to a more equitable and accessible healthcare system for all Indians.

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