

# MAKING GENERIC MEDICINES

# **AVAILABLE FOR ALL**

Oxfam India Rapid Survey Of Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana in the Aspirational Districts of Uttar Pradesh, Bihar, Chhattisgarh and Odisha

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#### **EXECUTIVE SUMMARY**

The Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana (PMBJP) is India's flagship program to make generic medicines of all therapeutic groups accessible for all sections of the population. It also involves awareness generation around generic medicines and creation of individual entrepreneurs. The scheme has been expanding rapidly from 1080 centers in 2016-17 to 8675 in 2021-22. Since the scheme is evolving and expanding, it is important to assess its functioning and recommend strategies to the government for strengthening the initiative.

The main aim of this study is to assess the implementation of the PMJBP scheme, identify potential challenges and provide recommendations on improved availability of generic medicines, increase awareness and generic prescriptions to reduce out of pocket expenditure in four select states of India viz., Bihar, Chhattisgarh, Odisha and Uttar Pradesh from the list of 10 least performing states listed by the NITI Aayog.

A cross-sectional quantitative study was carried out in all the 41 aspirational districts of four states of India, namely Bihar, Chhattisgarh, Odisha and Uttar Pradesh to carry out a rapid assessment of existing Jan Aushadhi Kendras (JAKs) to identify possibilities for improvement. Out of the 216 JAKs reported functional by the Jan Aushadhi website, 88 JAKs were selected using random sampling and covered in this study. A total of 52 pharmacists, 181 doctors and 445 patients/ caregivers/ customers were covered in this study.

The most important finding of this study is that 36 out of these 88 JAKs were found to be closed on the day of data collection and a total of 19 JAKs were found to be permanently closed due to an inappropriate location viz. these locations also had a free drug distribution run by the state government which leads to no demand for the generic drugs. This calls for a more fair and open process for allotment of JAKs. 67% of patient respondents reporting generic medicine as their choice due to affordability making the scheme relevant. Only 50% of doctors reported their satisfaction with the current form of the PMBJP scheme and many suggestions for improvement emerged from all stakeholders. While state samples were low, there are also indications of state differences.

The following are some of the key findings of this study included:

- Out of total 52 studied JAKs, only three JAKs were found to be owned by women which suggests male domination in ownership of JAKs.
- JAK pharmacists report an average annual net profit of INR 89,897.
- 46% of pharmacists still do manual billing. They feel that their order sizes are not large to take up the effort of computerized billing. Plus, they also feel some problems in handling BPPI software.
- 60% of pharmacists report stockouts and 64% report receipt of short-expiry and damaged medicines for up to 20% of their orders. Only 40% of pharmacists report acceptance of unused and expired medicines by their suppliers.
- 44% of pharmacists report delays in receiving subsidies despite repeated requests. 33% of pharmacists report that they do not receive any generic prescriptions. 50% of pharmacists even believe that branded medicines would be more profitable for them.
- 61.8% is the overall availability of selected medicines reported by pharmacists on the day of the visit. This is considerably below the WHO voluntary target of 80% for essential medicines.
- 72% of doctors reported being aware of a Jan Aushadhi Kendra nearby.
- 60% of government doctors report receiving government guidelines on the PMBJP scheme but none of them was able to recall their contents.
- 50% of government doctors report issuing up to 20% of their prescriptions with generic medicines. 65% of both private and government doctors feel that generic medicines are quite limited in number and don't cover all the therapeutic areas.
- 51% of patients were found to be aware about the PMBJP scheme. Word of mouth was the biggest source of information.
- 67% of patients reported generic medicine as their choice due to their greater affordability.
- 44% of patients reported that their doctors did not prescribe any generic medicines and 55% of them even reported getting chemist recommendations from their doctors.
- Awareness about generic medicines was the lowest among the poor people including BPL (Below Poverty Line) cardholders, wage employed, low-income group, Muslims, Scheduled Castes and the Scheduled Tribes due to low accessibility and literacy.

Several recommendations have been provided based on the findings of the study. These included the need to expand coverage, build awareness about the scheme and tweak messaging to improve effectiveness, promote generic prescriptions, improve generic medicine supply chains and enhance overall JAK management. It is hoped that this study helps in improving the scheme and in turn, help poor people in reducing their healthcare expenses.

# INTRODUCTION

#### Background of the study

As per the 71st round of the National Sample Survey Organization<sup>1</sup> (NSSO) report on Health in India, the purchase of medicine accounted for 72% and 68% of the costs of non-hospitalized treatment of ailments in the rural and urban sectors respectively. Despite being one of the leading exporters of generic medicines to the world, the majority of Indians have no access to affordable medicines<sup>2</sup>. A major proportion of medicines (around 52%<sup>3</sup>) are procured through out-of-pocket payments, which account for nearly 43%<sup>4</sup> of the total health expenditure of households. As many as 23% of Indians forgo treatment when sick because they cannot afford it<sup>5</sup>. High out of pocket expenditure contributes to plunging 55 million Indians into poverty every year<sup>6</sup>.

#### **Generic Medicines**

The WHO defines a generic drug<sup>7</sup> as a pharmaceutical product usually intended to be interchangeable with the originator brand product manufactured without a license from the originator manufacturer and marketed after the expiry of the patent or other exclusivity rights. In the post-expiry phase, other drug-makers may manufacture the same drug and sell it under an international nonproprietary name, usually at a significantly lower cost. A generic drug contains the same active substances that the branded version does and gives the same clinical results.

The companies advertise their branded medicines to make them popular, influence the prescription behaviour to increase the sale of their own branded medicine, and once the brand is established, make money out of it by pricing their branded medicines exorbitantly<sup>8</sup>. In the Indian context, the cost of

study/articleshow/64564548.cms

<sup>&</sup>lt;sup>1</sup> https://www.niti.gov.in/sites/default/files/2019-01/NSSO\_71st\_Round%20\_Final.pdf

<sup>&</sup>lt;sup>2</sup> https://www.telegraphindia.com/opinion/india-may-be-the-global-pharmacy-but-indians-have-poor-access-to-drugs/cid/1689296

<sup>&</sup>lt;sup>3</sup> https://thewire.in/health/who-is-paying-for-indias-healthcare

<sup>&</sup>lt;sup>4</sup> https://www.downtoearth.org.in/dte-infographics/india\_s\_health\_crisis/index.html

<sup>5</sup> https://www.tribuneindia.com/news/archive/comment/medical-debt-a-major-cause-of-poverty-in-india-866182

<sup>&</sup>lt;sup>6</sup> https://timesofindia.indiatimes.com/india/health-spending-pushed-55-million-indians-into-poverty-in-a-year-

<sup>&</sup>lt;sup>7</sup> https://www.who.int/medicines/areas/access/NPrices\_Glossary.pdf

<sup>&</sup>lt;sup>8</sup> Science.gov. US: Generic Drugs: The Same Medicine for Less Money. [Last accessed on 2017 Apr 19]. available

from: http://www.consumerreports.org/health/resources/pdf/best-buy-drugs/money-saving-guides/english/GenericDrugs-FINAL.pdf . [Ref list]

generic drugs is up to 91% less than that of branded medicines<sup>9</sup>. As such, reducing out of pocket expenditure on medicines in India entails improving the provision of generic medicines.

India is the world's third-largest provider of generic medicines by volume, contributing to a 20% share of total global pharmaceutical exports<sup>10</sup>. Indian pharmaceuticals serve over 200 countries<sup>11</sup> served by Indian pharma exports. Generic medicine is an important policy option to reduce the nearly two-third<sup>12</sup> of out-of-pocket expenditure due to medicines and address the inequalities exacerbated by the same.

The National Health Policy 2017 highlighted the need to provide free medicines in public health facilities by stepping up funding and improving drug procurement and supply chain mechanisms. The Medical Council of India amended the code of conduct for doctors in October 2016 to recommend that every physician should prescribe drugs with generic names legible and he or she shall ensure that there is a rational prescription which promotes the use of generic drugs<sup>13</sup>. At the same time, a range of efforts have been taken to standardize the quality of generic drugs<sup>14</sup>.

#### The Jan Aushadhi Scheme

To make generic medicines available to the population, the Department of Pharmaceuticals and the Government of India launched the Jan Aushadhi Scheme (JAS) in 2008<sup>15</sup> which sought to make quality generic medicines (for both acute and chronic diseases) available at affordable prices to all the citizens of India through a specialized outlet called as Jan Aushadhi Kendra. The original plan was to open these Kendra in each of the 630 districts of the country with a view of eventually extending it further to sub-divisional village levels, major towns and village centers. There were only about 149 stores in 2012; half closed in 2012-13. In 2014, 99 Jan Aushadhi Kendras were selling only 200 different medicines with only 50% availability<sup>16</sup>. This was because of a range of reasons including poor support from state governments, poor supply-chain management, and lack of awareness and non-prescription of generic

<sup>&</sup>lt;sup>9</sup> Lopes Gde L. Cost comparison and economic implications of commonly used originator and generic chemotherapy drugs in India. Ann Oncol. 2013;24(Suppl 5):v13-6.

<sup>&</sup>lt;sup>10</sup> https://www.ibef.org/exports/pharmaceutical-exports-from-india

<sup>&</sup>lt;sup>11</sup> https://www.investindia.gov.in/sector/pharmaceuticals

<sup>12</sup> https://thelogicalindian.com/health/household-out-of-pocket-expenses-on-health-services-plunge-55-million-indians-into-poverty-34850

<sup>&</sup>lt;sup>13</sup> http://www.thehansindia.com/posts/index/Civil-Services/2017-05-09/An-analysisof-generic-medicines-in-India/298834 <sup>14</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6515776/#ref5

<sup>15</sup> https://en.wikipedia.org/wiki/Pradhan\_Mantri\_Bharatiya\_Janaushadhi\_Pariyojana

<sup>&</sup>lt;sup>16</sup> https://www.mygov.in/48months/wp-content/uploads/2018/06/1000000001971510612.pdf

medicines by doctors. The scheme was reviewed in 2014 when only 80 Jan Aushadhi Stores were operational in India.

The scheme saw changes in 2015 and in 2016 it was revamped and relaunched as Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana (PMBJP) to provide better support and incentives for JAKs. The scheme has expanded rapidly since. On 31<sup>st</sup> January 2022, 8,675 PMBJP Kendras are functional across India<sup>17</sup>. The basket of medicines and equipment was also expanded and stands at 1450 drugs and 240 surgical equipment; 75 Ayurvedic drugs are also part of the product basket<sup>18</sup>. The plan is to ensure that all the districts in India have at least one Kendra so 10,000 Kendras become functional by the end of 31<sup>st</sup> March 2024 and to increase the product portfolio to 2000 medicines and 300 surgical products, covering all therapeutic groups. <sup>19</sup>



Expansion of the PMBJP Scheme<sup>20</sup>

<sup>&</sup>lt;sup>17</sup> http://janaushadhi.gov.in/pdf/Presentation%20on%20PMBJP\_15022022.pdf

<sup>&</sup>lt;sup>18</sup> http://janaushadhi.gov.in/Data/Annual%20Report%202021-22\_04052022.pdf

<sup>&</sup>lt;sup>19</sup> http://janaushadhi.gov.in/Data/Annual%20Report%202019-20\_21052020.pdf

 $<sup>^{20}\</sup> http://janaushadhi.gov.in/pdf/Presentation\%20on\%20PMBJP\_15022022.pdf$ 

The following are the objectives of the PMBJP scheme<sup>21</sup>:

- To ensure access to quality medicines for all the sections of the population especially for the poor and the deprived ones through exclusive Jan Aushadhi Kendras, to reduce the out-ofpocket health expenditure.
- To create awareness about generic medicines through education and publicity to counter the common perception that quality is synonymous with high price, thereby increasing demand for generic medicines through medical practitioners as well.
- To generate employment by engaging individual entrepreneurs in opening Jan Aushadhi Kendras.
- To make all commonly used generic medicines covering all therapeutic groups available along with healthcare products at affordable prices.

Its key features include<sup>22</sup>:

- Pharmaceuticals & Medical Devices Bureau of India (PMBI), erstwhile Bureau of Pharma PSUs of India (BPPI) is the implementing agency of the PMBJP.
- In order to increase the reach to the general public and to create employment opportunities,
   PMBJP Kendras are allowed to be opened by individual entrepreneurs, NGOs, societies,
   Institutions, pharmacists, government bodies etc. at any suitable place.
- In addition to medicines and surgical items supplied by PMBI, Jan Aushadhi Kendras have also been allowed to sell allied medical products commonly sold in chemist shops to improve the viability of Kendra. The PMBJP's product basket currently consists of 1451 medicines and 240 surgical equipment and consumables.
- A medicine is priced on the principle of a maximum of 50% of the average price of the top three brands of the said medicine. Thus, the prices of Jan Aushadhi Medicines are cheaper at least by 50% and in some cases, by 80% to 90% of the market price of the branded medicines<sup>23</sup>.
- Procurement of products from Vendors/ Suppliers/ Manufacturers having WHO-GMP (World Health Organization Good Manufacturing Practices) certified facilities through the e-tender portal (CPPP) of the Govt. of India. PMBI has been allowed to source medicines from private companies as well but for only those products which are not manufactured by PSUs.

<sup>&</sup>lt;sup>21</sup> http://janaushadhi.gov.in/pmjy.aspx

<sup>&</sup>lt;sup>22</sup> http://janaushadhi.gov.in/Data/Annual%20Report%202019-20\_21052020.pdf

<sup>&</sup>lt;sup>23</sup> https://im4change.org/upload/files/Unstarred%20Question%201622%20Lok%20Sabha%2011%20February%202022.pdf

- Supply chain has been improved by establishing central warehouses, Cleaning and forwarding
  agents and distributors at different locations in all states and union territories with a quality
  certification process accredited by NABL (National Accreditation Board for Testing and
  Calibration Laboratories).
- Since the year 2019, 7<sup>th</sup> March is being celebrated as Jan Aushadhi Diwas every year<sup>24</sup>
- PMBI has also been undertaking suitable media activities to spread the message of generic medicines and achieve the objective of the PMBJP scheme.
- 20% margin is provided to retailers and 10% to distributors along with up to 2% compensation for losses.
- Incentive provided to the PMBJP Kendra owners has been enhanced from Rs. 2.5 Lakh to up to Rs. 5 Lakh, to be given @ 15% of monthly purchases made, subject to a ceiling of Rs. 15,000/per month, w.e.f. April 2021.
- An additional one-time grant for up to 2 lakhs for furniture and IT equipment has also been provided to support the opening of the Kendras
- Credit facility of 30 days has been provided to retailers and 60 days to distributors along with training programs for upskilling.
- Encourage opening of centres by entrepreneurs who are women, persons with disabilities, SCs and STs and entrepreneurs opening stores in aspirational districts, Himalayan, Island territories and the North-Eastern States,
- PMBI spreads awareness about generic medicines through various types of advertisements such as TV, FM Radio, Auto wrapping, Cinema, Bus branding, State Transport Bus Stands, Digital Screen Advertisements at Railway Stations, etc. In addition, PMBI also educates the public regularly about usage of Jan Aushadhi generic medicines through various social media platforms like Facebook, Twitter, Instagram, YouTube, etc. The Bureau also organizes seminars and workshops to spread awareness about the scheme.

# **PROGRESS ACHIEVED**

The government reports the following impact of the scheme

- In the financial year 2019-20, PMBJP has achieved sales of Rs. 433.61 crores (at MRP). This is reported to have contributed to savings of approximately Rs. 2500 Crore of the common citizens of the country as these medicines are cheaper by 50% to 90% of the average market price. In the financial year 2020-21, the sale of Rs. 665.83 Crore was made, which led to savings of about Rs. 4000 Crore to the citizens as compared to the branded medicines. In 2021-22 (till 31.01.2022), PMBI has made sales of Rs. 751.42 Crore which led to savings of approximately Rs. 4500 Crore to the citizens.
- This scheme is reported as also contributing to self-employment. Average sales per store per month are reported to have grown to Rs 1.50 lacs (including OTC & other products) as per a survey.

An Information Technology (IT) enabled end-to-end supply chain system with Point-of-Sale (POS) application for value-added services has been implemented in PMBJP. PMBI has four modern warehouses at Gurugram, Bengaluru, Guwahati and Chennai for the storage and distribution of drugs to all Kendras across the country.

PMBI procures medicines only from WHO-GMP certified suppliers and tests each batch of drugs at laboratories accredited by NABL before dispatching them to PMBJP Kendras. It is also spreading awareness about the salient features of the PMBJP scheme through various types of advertisement, outdoor publicity and social media platforms on regular basis.

Janaushadhi Sugam App (for Android and iOS) has been launched for the general public by which they can locate nearby Jan Aushadhi Kendras, get direction guidance through Google Maps for the location, search Jan Aushadhi generic medicines, do product comparisons of generic vs branded medicine in form of MRP & overall Savings, etc.

# **THE COVID-19 PANDEMIC**

In the wake of the COVID 19 crisis in 2020-21, BPPI is reported to have sold about 15 lacs Face masks, 80 lacs tablets of Hydroxychloroquine and 100 lacs Paracetamol Tablets, which saved around Rs. 1,260 crores of the citizens<sup>25</sup>. The Union Health Minister Harsh Vardhan highlighted<sup>26</sup> that Janaushadhi Kendras rendered essential services amid the COVID-19 pandemic, maintained regular operations and made medicines available to people, sale at these stores increased during the nationwide lockdown. Despite this, the COVID 19 pandemic saw spiraling medicine costs. This was also highlighted by the standing committee on Chemicals and Fertilizers which recommended the capping of the price of key medicines required for COVID 19 treatment<sup>27</sup>. After the third wave of the pandemic, India's drug authority<sup>28</sup> allowed a price hike of 10.7%.<sup>29</sup> for scheduled drugs.<sup>30</sup>

# **EXISTING RESEARCH ON JAKS**

Not enough research exists on the implementation of the scheme, especially since the state of its rapid expansion. Existing research has included several small-scale studies looking at the prescription patterns and patient perceptions about generic medicines that reference the JAK program. Other pieces have compared prices of selected drugs in JAK and the market and found the former to be cheaper<sup>3132</sup>. Other studies have compared the quality of JA and branded drugs and found them to pass pharmacopoeial tests<sup>3334</sup>. A vital study is a web-based analysis of the perspective of JAK owners across India which highlighted some of the measures that need to be undertaken to improve the scalability of

<sup>27</sup> https://timesofindia.indiatimes.com/city/mumbai/panel-asks-govt-to-cap-prices-of-key-covid-drugs-med-devices/articleshow/90694606.cms

<sup>&</sup>lt;sup>25</sup> http://janaushadhi.gov.in/Data/Annual%20Report%202020-21\_09032022.pdf

<sup>&</sup>lt;sup>26</sup> https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/janaushadhi-kendras-rendered-essential-services-in-covid-19-pandemic-union-health-minister/articleshow/81378255.cms?from=mdr

<sup>&</sup>lt;sup>28</sup> https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/essential-medicines-to-get-expensive-from-april/articleshow/90446347.cms

<sup>&</sup>lt;sup>29</sup> https://www.newindianexpress.com/nation/2022/apr/01/800-plus-essential-drugs-to-increase-by-107-per-cent-from-friday-2436615.html

<sup>&</sup>lt;sup>30</sup> Schedule drugs are drugs which cannot be purchased over the counter without the prescription of a qualified doctor. For more details- https://www.findlaw.com/legalblogs/law-and-life/drug-schedules-explained/

<sup>&</sup>lt;sup>31</sup> Nallani VR. Cost analysis study of oral anti-diabetic drugs available in Indian govt. generic (Jan Aushadhi, Jeevandhara) drugs and brand drugs market in rural/urban area of Guntur, Andhrapradesh, India. Value Health 2015;18:A717.

<sup>&</sup>lt;sup>32</sup> Janodia M. Differences in price of medicines available from pharmaceutical companies and "Jan Aushadhi" stores. Value Health 2015;18:A850.

<sup>&</sup>lt;sup>33</sup> Singh B, Nanda A, Budhwar V, Marwaha RK. A comparative evaluation of the quality & price of generic medicine with their branded counterparts. PharmaTutor 2016;4;43-9

<sup>&</sup>lt;sup>34</sup> Singhal GL, Kotwani A, Nanda A. Jan Aushadhi stores in India and quality of medicines therein. Int J Pharm Pharm Sci 2011;3:204-7

JAKs across the country.<sup>35</sup> Much of the research, furthermore, either predates or is immediately after the strategic refresh of the scheme in 2015.

# CONCLUSION

It is heartening to see the rapid expansion of the scheme bringing with it the promise of ensuring availability of generic medicines, reduction of out of pocket expenditure and the social and economic consequences of catastrophic health expenditure. While doing so it would be important to understand what can be done to strengthen its implementation and recommend strategies for strengthening the initiative. This is the purpose of this research.

<sup>&</sup>lt;sup>35</sup> https://www.cjhr.org/temp/CHRISMEDJHealthRes5128-1916297\_051922.pdf

#### **ASPIRATIONAL DISTRICTS**

The government of India launched the Transformation of Aspirational Districts programme in 2018 to improve India's rankings under the Human Development Index by bringing together various stakeholders to improve the living standards of people in a few developmentally lagging districts. 115 aspirational districts have been identified from 28 states based on 49 indicators focusing on improving people's health & nutrition, education, agriculture & water resources, financial inclusion & skill development, and basic infrastructure. The map below shows the better and bottom 20 districts on health ranking. The research focuses on these districts.



# THE STUDY

# Aim and Objectives

This study aims to assess the implementation of the PMJBP scheme, identify potential challenges and provide recommendations on improved availability of generic medicines to reduce out of pocket expenditure in four select states of India viz., Bihar, Chhattisgarh, Odisha and Uttar Pradesh.

Following are the specific objectives of this study:

- Assess availability and supply of key medicines (from the Essential Drugs List) at the Jan Aushadhi Store to analyze the probable factors influencing the PMBJP scheme.
- To assess the awareness of patients or caregivers and health professionals regarding generic medicines under the scheme.
- To assess the factors influencing the prescription of generic drugs.

# Research methodology

The present study was undertaken in August 2021 by Mr. Himanshu Gupta, an independent consultant and his team. Oxfam India supported the research and provided oversight during data collection. The original report submitted research by the team was edited, some sections re-analyzed and recommendations redrafted.

The research was a cross-sectional quantitative study which used both primary and secondary data. It was carried out in four states, namely Bihar, Chhattisgarh, Odisha and Uttar Pradesh to obtain a rapid assessment for identifying the current challenges in the functioning of existing Jan Aushadhi Kendras. These four states are selected from the list of 10 worst performing states listed in NITI Aayog. All 41 aspirational districts from these four states have been included in this study because most of these districts lie in the bottom-most 20 districts of the health ranking defined by NITI Aayog.

A total of 216 Jan Aushadhi Kendra (JAK) have been reported functional by the PMBI website (<u>www.janaushadhi.gov.in</u>). Out of these 216, 88 JAKs have been covered under this study using a random sampling method based on the following criteria:

• Number of Jan Aushadhi Kendra (JAK) in a district:

Number of JAKs in a District	Number of JAKs selected in sample
1-2	1
3-5	2
6-10	3
11-20	4
>20	5

• Distance from the district hospital and coverage of the complete district using Google map location provided by Jan Aushadhi Sugam Mobile App.

Considering the objective of evaluating the availability and supply of medicines at the Jan Aushadhi Kendra, it was imperative to sample medicines from the National List of Essential Medicines (NLEM). 55 allopathic medicines and healthcare products were selected for this study using random sampling considering the following criteria:

- Coverage of all the categories of medicines from NLEM, 2011.
- Coverage of all forms of medicines like tablets, syrup, injections, creams, etc.
- Coverage of combo medicine, if available in the PMBJP list.
- Coverage of all diseases like cardiovascular medicines- for heart attack, blood pressure, lipid control, etc.
- Coverage of medicines by their potency such that medicines of different potency levels have been selected in different categories.

The details of the JAKs and medicines sampled can be accessed <u>here</u>.

#### **Respondents-**

Respondents for this study included pharmacists at the JAK, doctors and patients. One pharmacist, two doctors (one government and one private) and five patients/caregivers near JAK were covered at each of the 88 locations using purposive sampling. A total of 52 pharmacists have been covered in this study due to the closure of the remaining 36 JAK. Apart from the pharmacists, 181 doctors and 445 patients have been covered using semi-structured interviews and surveys in this study.



#### PROFILE OF JAKS AND RESPONDENTS

The following section provides a brief profile of Jan Aushadhi Kendra (JAK) and all three respondents viz. pharmacists, doctors and patients/caregivers.

Only 52 JAKs were covered under this study out of the planned 88 due to closed centres. Only three JAKs were covered from Odisha as the others planned were found closed.

The majority 42% (22) JAKs were started in 2019-2020. This means that most of these JAKs are quite recent and they will require much more time and support to be successful.

# Jan Aushadhi Kendra State-wise

#### Pharmacists

52 pharmacist's interviews were carried out with the person present at the Jan Aushadhi Kendra at the time of the visit. These included the owner, relative, and employee apart from the officially appointed pharmacists (60%, 31 JAKs) themselves. The profile here is presented for the pharmacists.

A majority of 94% (49) of pharmacists are male and only three are female. Only 3% of JAK in India are owned by unemployed pharmacists, women entrepreneurs and eligible women from marginalized communities according to the review of the PMBJP undertaken by the Standing Committee on Chemicals and Fertilizers<sup>36</sup>. This had recommended that special drives be undertaken by the Department to attract more SC/ST/women and persons with disabilities.

58% (30) pharmacists hold bachelor's degrees whereas 39% (20) pharmacists hold diplomas in pharmacy. Only 2 pharmacists had obtained a master's degree. On average, pharmacists had 7.3 years



of experience with a range from 1-42 years. Pharmacists in Bihar had 9.6 years of experience while pharmacists from the other three states had approximately 6 years of experience on average.

<sup>&</sup>lt;sup>36</sup> https://im4change.org/upload/files/17\_Chemicals\_And\_Fertilizers\_17.pdf

181 allopathic doctors were covered in this study. A majority of 31% (5of 6) doctors were covered in Bihar. This is followed by 27% (48) doctors from Chhattisgarh and 26% (47) doctors from Uttar Pradesh.





88% of (159) doctors covered in this study were male.

72% (131) were working in private hospitals or had private clinics. 28% (50) of doctors covered in this study were working with the government since government doctors were slightly apprehensive about filling out the survey. 66% (1of 19) doctors covered in this study had MBBS degrees and the remaining 34% (62) had postgraduate qualifications.



#### **Patients**

445 patient surveys were carried out in this study. Respondents for the patient surveys included relatives, friends, caregivers and a majority of 70% (313) were the patients themselves.



A majority of 30% (13of 3) patients were covered from Bihar in proportion to the number of locations covered. This is followed by 27% (1of 22) patients from Chhattisgarh and 26% (115) from Uttar Pradesh.

68% (304) of patients covered in the study were male. The average age of the patients covered in this study was 35.3 years with the range of 18-80 years. A majority 32% (141) were graduates followed by 19% (83) who have completed senior secondary. 9% (3of 9) patients were post-graduates.



60% (269) of patients reported themselves as being BPL. In Bihar, a majority 55% reported themselves to be APL (Above Poverty Line) whereas in all other states the majority reportedly belonged to BPL. Chhattisgarh had the highest 82% (100) BPL patients. A majority of 38% (167) of patients were OBCs followed by 28% (125) in the general category.



Religion and Caste Category	Bihar	CG	Odisha	UP	Grand Total
General	40	18	23	44	125
Muslim	19		1	14	34
OBC	60	45	19	43	167
PWD (Person with disability)				1	1
SC	13	7	15	13	48
ST	1	52	17		70
Grand Total	133	122	75	115	445

# Limitations of the study

Apart from the limitations of bias and translation, this study was particularly affected by the Covid-19 situation and flood warnings. Extreme caution was taken and all COVID protocols were followed as responses were also collected from district hospitals functioning as COVID care units. Some of the JAKs had refused to participate in this study so they were replaced from the buffer list that was also prepared using random sampling using the same criteria mentioned above. Some government doctors also refused to participate in this study so they had to be replaced with private doctors at the same location. All the JAKs refused to provide stock data from their BPPI software.

# THE FINDINGS

#### **1.CLOSURE OF THE JAN AUSHADHI KENDRAS**

One of the most important observations that came out of this study was the permanent closure of 41% (36) JAKs out of the 88 planned to be included in this study. This is significant because these have been shown to be functional in government records i.e., the PMBI website (<u>www.janaushadhi.gov.in</u>).

The graph shows the state-wise distribution of Jan Aushadhi Kendras that are found to be permanently closed. State-wise, 80% (12 out of 15) of JAKs were found to be permanently closed in Odisha followed by 46% (11 out of 24) JAKs in Chhattisgarh.

While this could partly be a result of the overall disruption caused by COVID-19, it still implies that the government website is not reliable to understand the real-time status (opening/closure) of the JAKs, and the mechanism to supervise day to day functioning of the JAKs need to be strengthened.



The chart points to the different reasons for the various JAKs that are found permanently closed.

a) 53% (19 out of 36) JAKs seem to have closed due to inappropriate location viz. these locations also had a free drug distribution run the by state government which leads to no demand for the generic drugs. As per guidelines<sup>37</sup>, the location of the JAK should be either on the hospital premises or near the hospital, if this is not possible then it should be located at a place where footfall happens and is easily accessible to people with good



Austradtu Misting, also the medicines which not ontern by distribution. approximate 5 to 6 Jan , had infai 1 didnit Satys Brat phitria Rajapur, chilrakoot.

site visibility. This identifies a need for a feasibility check before opening JAKs either by the applicant or the government.

<sup>&</sup>lt;sup>37</sup> http://janaushadhi.gov.in/pdf/State\_PMBJP.pdf

- b) Six JAK owners reported heavy losses due to receipt of damaged medicines and medicine expiry due to the non-return policy of the suppliers. This hints at supply chain and demand assessment issues for JAKs.
- c) All the Jan Aushadhi Kendra in the Nawada district of Bihar seem to have been closed during the period of investigation. Only three JAKs were to be included in this study from Nawada, but it would appear all nine JAKs were closed. As per the Jan Aushadhi website, all nine JAKs have been allotted to the same person, Newspaper reports allege that the person allotted these JAKs has absconded<sup>38</sup> <sup>39</sup>. This calls for more transparency in the allocation process.

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Search F	MBJP Kendra Deb	ali :			
Sr. No.	Store Code	District	Kendra Address	Pin Code	Contact Pa
1	PMBJK03889	Nawada	In front of PHC Roh, Po Roh, Ps Roh, Newade	805141	Pawan Kum
2	PMBJK03890	Nawada	Rupau, Nawada	805107	Pawan Kum
з	PMBJK03891	Nawada	Hospital road, Pakribawan, Nawada	805124	Pewan Kum
4	PMBJK03892	Newada	Jaii rood, Hospital road, Neweda	805110	Pawan Kun
5	PMBJK03893	Navada	Main road bus stand, Nadriganj, Nawada	805109	Pawan Kum
6	PMBJK03894	Novada	Thana road, Kawakol, Nawada	805106	Pawen Kum
7	PMBJK03895	Nawada	Panchu more, Hisua, Nawada	805103	Pawan Kum
	PMBJK03896	Novada	in front of Mazar akbarpur, Akbarpur, Nawada	805126	Pawan Kun
9	PMBJK64716	Novoda	Takutand, Rajouli, Nawada	805125	Pawen Kun
Publish	Date:Thu, 20 M	May 2021	12:47 AM (IST) Author: Jagran		

The evidence of closed centres is particularly unfortunate given that the scheme has far from reaching the scale needed; indeed, the Parliamentary Standing Committee on Chemicals and Fertilizers had recommended considering block-level coverage. Only five states viz. Gujarat, Karnataka, Kerala, Tamil Nadu and Uttar Pradesh have more than 500 PMBJP outlets. At present, the total consumption of medicines in the country is nearly Rs. 1.5 lakh crore in a year but the contribution of PMBJP was only Rs.433.60 crore during 2019-20<sup>40</sup>. As such, India needs many more JAKs.

<sup>40</sup> https://im4change.org/upload/files/17\_Chemicals\_And\_Fertilizers\_17.pdf

<sup>&</sup>lt;sup>38</sup> https://www.jagran.com/bihar/nawada-jan-aushadhi-center-running-on-paper-21659270.html

<sup>&</sup>lt;sup>39</sup> https://www.jagran.com/bihar/nawada-patients-are-buying-expensive-medicines-due-to-lack-of-jan-aushadhi-center-in-nawada-22684922.html

#### 2. PERSPECTIVES OF PHARMACISTS RUNNING THE JAKS

### Issues pertaining to economic viability of JAKs:

19% (10) pharmacists reported taking credit to the tune of INR 1,00,000 to INR 10,00,000 to start the Kendra. 70% have completed repayment and the remaining three were repaying their instalments regularly. The average annual net profit is reported to be INR 89,897 after deducting all costs. Taking even underreporting into account, this is on the lower side. In contrast, a retail pharmacist in India appears to earn Rs. 284,862.<sup>41</sup>

Due to this, some of the Jan Aushadhi Kendras have reported themselves to be on the verge of closure due to low sales and profits. This is similar to the national study of JAK owners which highlighted low net profits and high hurdles in running stores.<sup>42</sup>

Odisha's JAKs appear to have been performing better in terms of sales since these are located in market areas with a lot of private doctors who bring new patients. This stresses the importance of the selection of location for starting a JAK.

56% (29) of pharmacists reported receiving incentives/reimbursements on time from the government. The remaining 44% report significant delays even after repeated requests. The majority 57% of the Chhattisgarh pharmacists reported experiencing delays in receiving the same.

56% (29) of pharmacists report receiving subsidies on time from the government. The remaining 44% report significant delays, often even after repeated requests. The majority 57% of the Chhattisgarh pharmacists report delays in receiving subsidies.

<sup>41</sup>Retail Pharmacist Salary. PayScale. Available from: http://www.payscale.com/research/IN/Job=Retail\_Pharmacist/Salary. ] <sup>42</sup> https://www.cjhr.org/temp/CHRISMEDJHealthRes5128-1916297\_051922.pdf 88% (46) of pharmacists report having experienced audits from BPPI in the past. However, none reported a visit by anyone in the last year. This could, however, have been due to COVID and the lockdown situation as well.



# Patient footfall and customer perceptions

On average, pharmacists report that 67 people visited their shop daily; the range is 2-200 out of which around 59% (39) come with prescriptions from doctors in the private sector. Uttar Pradesh's pharmacists report the highest footfall of approximately 95 people daily and Chhattisgarh's report the lowest footfall of approximately 31 people. Chhattisgarh's pharmacists, however, report the highest percentage of 84% (25) people on average visiting JAK with a prescription. According to the Department of Chemicals and Pharma, around 1800 to 2000 people purchase medicines from one PMBJP outlet in a month.<sup>43</sup>

56% (29) pharmacists report a positive perception of the patients' buying medicines from their shop. The rest were unsure because patients wanted the medicines prescribed by doctors or they are concerned about the quality of generic medicines.

<sup>&</sup>lt;sup>43</sup> https://im4change.org/upload/files/17\_Chemicals\_And\_Fertilizers\_17.pdf

# Inadequate prescriptions for generic medicines

33% (17) pharmacists said that they did not receive any prescriptions with generic names of medicines. The rest of them also report receiving generic prescriptions only 5-20% of the time. This points toward the need to influence doctors to increase the number of generic prescriptions. Another study conducted on JAKs in 2017 also found that 83.3% of doctors did not prescribe<sup>44</sup> generic medicines and 93.75% did not make patients aware of this scheme.



50% of pharmacists feel that branded medicines

generate more profitability than generic medicine. Indeed, one of the pharmacists has opened two shops side by side one with JAK and another chemist shop selling other medicines. It has been also



44 http://njppp.com/fulltext/28-1493609998.pdf

seen that many complaints have been filed by the people<sup>45</sup> to the state drug control department of Kerala on selling branded drugs in JAK.

However, in Bihar, the majority 63% (12 out of 19) of pharmacists, thought that generic medicines too are profitable. This points towards a need to increase awareness of pharmacists on profitability as well. Awareness campaigns need to focus on these aspects to correct misconceptions.



# Staffing

Jan Aushadhi Kendras on average had 2.1 staff per center with the range being 1 to 4. Chhattisgarh JAKs had a lesser average of 1.6 staff than JAKs in other states.

# **Procurement and Billing**

46% of pharmacists report doing manual billing due to low sales and transaction amounts.100% (52) of the JAKs report accepting cash payments from their customers. UPI Unified Payment Interface) and card payments are reported by only 60% (31) and 13% (7) JAKs respectively. Nine JAKs also reported giving medicines on credit as well.

29

<sup>&</sup>lt;sup>45</sup> https://timesofindia.indiatimes.com/city/thiruvananthapuram/complaints-of-fleecing-against-jan-aushadhistores/articleshow/61748004.cms

A majority of 73% (3of 8) pharmacists reportedly send their medicine requisition to their distributors after only some pieces are left. However, 14% (7) of pharmacists reportedly didn't have any system for medicine requisition: Six out of these seven pharmacists belonged to Bihar.

21% (11 out of 52) pharmacists reported problems in using BPPI software. Six pharmacists each reported facing problems in managing inventory and billing. Five pharmacists faced problems in



procurement and three in managing returns. One pharmacist reported not having received any software from BPPI. They report that inventory is not timely updated, procurement forms are complex to understand, billing small transactions is very tedious and no proper systems for returns and tracking orders.

90% (47) of pharmacists reported forecasting their requirements in advance. Out of these 47, a majority 34% (16) of pharmacists do it bi-monthly. State-wise, the majority of pharmacists in Bihar, Chhattisgarh and Uttar Pradesh do their forecasting weekly, monthly and bi-monthly respectively. They reported doing this according to the lead time taken by suppliers to send their orders. A majority of 60% (31) pharmacists experiencing stockouts were in Uttar Pradesh. This suggests the need for better measures for inventory management on the part of pharmacists and a reduction in lead time by the suppliers. To cope with this situation, pharmacists either get the medicine from somewhere else or get it from the warehouse themselves rather than waiting for the supplier to send them. 71% (37) pharmacists reported using indenting for medicine requisition. They used some kind of form to request medicines from the distributor or BPPI.

Some of the problems listed above could be addressed by providing capacity building to the JAK staff. However, there is no institutional training mechanism for operators of JAKs given that the Kendra owner is expected to be a trained pharmacist or to employ one. General guidelines are provided on the operational management of the Kendras and seminars are organized from time to time to disseminate updates, and best practices to boost morale. An IT training is expected to be provided for point-of-sale software installation, ticket management, support and related issues.<sup>46</sup> Strengthening capacity building initiatives may be explored.



# Supply Chain

For the sources of medicines, 33% (17) pharmacists report dependence on BPPI/PMBI and 27% (14) relied on state distributors. The remaining 40% (21) reporting receiving medicines from both PMBI and distributors.

<sup>31</sup> 

<sup>&</sup>lt;sup>46</sup> https://im4change.org/upload/files/17\_Chemicals\_And\_Fertilizers\_17.pdf

With regards to the discrepancy in sending orders by the supplier against the indented one, only 27% (14) pharmacists report no problems. The remaining pharmacists report problems with 5%-20% of their orders. This suggests the need for improvements in the standard operating procedures for suppliers.



60% of pharmacists report stockouts. Other research highlights occasional delays. A recent reply to a Lok Sabha question reported that on receipt of an order from a store owner it generally takes 6-7 days to supply medicines to a JAK in Maharashtra<sup>47</sup>.

64% report receiving short-expiry and damaged medicines. 64% (33) of the pharmacists report receiving short-expiry medicines 5-20% of the time for which they don't get returns, leading to great losses for JAK owners. A similar trend is observed in the case of damaged medicines. One of the pharmacists who had to close his shop due to losses reported receiving a huge lot of damaged medicines for which he is still fighting a case in court. This suggests the need for improvement in the micro-management of stocks at the suppliers' end to reduce such incidents.

Only 40% (21) pharmacists report that their suppliers accept the return of unused and expired medicines. In Bihar, only one pharmacist reports experiencing a good return policy as he had not faced any problems up till now. The remaining pharmacists appear to suffer a lot of wastage and hence losses. This suggests the need for a proactive return policy for JAKs to help them to become sustainable. They either destroy, dispose or discard any expired and waste/damaged medicines. Pharmacists also need to be made aware of the proper disposal of medical waste.



Only 42% (22) of pharmacists reported being aware of inventory management techniques like placing the medicine near expiry in front. The rest of the pharmacists either do random placement of the new stock or their old stock keeps on piling up and the new stock gets used first.

<sup>&</sup>lt;sup>47</sup> https://im4change.org/upload/files/Unstarred%20Question%203444%20Lok%20Sabha%2017%20December%202021.pdf

# Suggestions for prospective government interventions to strengthen the JA scheme

This section provides an analysis of the steps suggested by the JAK pharmacists for improving the

implementation of the scheme. For them increasing awareness about the scheme (83%, 43), enhancing the number of medicines covered under the scheme (71%, 37), enhancing incentives (62%, 32) and improving the supply chain (73%, 38) are the top four steps reported. In Uttar Pradesh, however, more pharmacists want the government to increase margins & subsidies, reduce prices, and allow the sale of other products, increasing the profitability of JAKs. Pharmacists who had taken credit to start JAKs are particularly looking to the government for increasing margins and subsidies.







#### 3. AVAILABILITY AND SUPPLY OF KEY MEDICINES

The present product basket of PMBJP consists of 1250 medicines and 204 surgical instruments. DoP is set to enhance it up to 2000 medicines and 300 surgical products by the end of 31st March 2024 so that all essential medicines covering therapeutic groups. The following is the plan for the expansion of the product basket<sup>48</sup>.

Details	2020-21	2021-22	2022-23	2023-24	2024-25
Product Basket					
(a) Medicines	1400	1600	1800	2000	2000
(b) Surgicals	220	240	280	300	300

According to the responses given by the pharmacists, the average availability of all the medicines covered under this study is found to be 61.8%. 80% (44 out of the 55) of medicines covered in the study were not available due to temporary/frequent supply shortages. This is significantly lower than the 80% voluntary target WHO set for the availability of affordable essential medicines in the public and private sectors of all the countries by 2025. While this analysis is limited by the fact that the actual stock of medicines was not observed, the findings suggest the need for urgent steps to improve the supply chain of medicines.

A shortage in the availability of some essential medicines for chronic diseases, such as hypertension, cardiac diseases, asthma, diabetes, psychiatric illnesses and hypercholesterolemia was observed during this research. These diseases generally require continuous, lifelong treatment making it critical for the JAKs to ensure their stock.

The lack of affordable medicine in the JAKs and increased access to higher-priced medicine in the private sector are complementary issues. Considering the economic condition of these patients they may not be able to access medicines that are necessary to treat their illnesses if they are unavailable in the JAK. Fundamental improvements in the availability of essential medicines through the JAKs would be critical.

<sup>35</sup> 

<sup>&</sup>lt;sup>48</sup> https://im4change.org/upload/files/17\_Chemicals\_And\_Fertilizers\_17.pdf

# 4. DOCTORS' PERSPECTIVES

The following section provides the perspective of 181 doctors on the Jan Aushadhi scheme and the various issues pertaining to it.

## Awareness about JAKs and generic medicines:

72% (130) of doctors reported being aware of a Jan Aushadhi Kendra nearby. As a majority of JAKs in Odisha were closed, the awareness level of doctors about nearby JAKs was quite low at 40%. Among the locations where the JAK is not closed, only three out of 105 doctors reported being not aware of it. A higher percentage of government doctors (82% of 50) were aware than private doctors (68% of 131).

According to the PMBJP scheme structure, the state government need to issue guidelines for government doctors to promote generic medicines.



In the present research, 60% of government doctors reported receipt of state government guidelines around the PMBJP scheme, but none of them were able to recall its contents. This requires urgent attention from the state governments to make these guidelines public and prioritize increasing awareness among doctors about generic prescriptions.

# **Prescription of Generic Medicines:**

A majority of 65% (117) of doctors issued only up to 20% of their prescriptions with generic medicines.

This is slightly lower at 50% (25) in the case of government doctors. State-wise, Uttar Pradesh has the highest percentage (87% of 47) of doctors falling under this category while Chhattisgarh has the lowest at 33% of 48 doctors.

Many other studies<sup>49505152</sup> have similarly highlighted the need to enhance awareness about the scheme among doctors and medical students/interns. However, doctors<sup>53</sup> also expressed concerns about poor techniques used while manufacturing generic



drugs. In a study in Jammu, 16.66% of respondents felt that branded medicines are better than Jan Aushadhi generic medicines.<sup>54</sup> In another survey, doctors also shared concerns about poorer drug parameters such as taste, pharmacokinetic and physical factors, poorer effectiveness and a greater number of adverse effects of generic medicines<sup>55</sup>. Concrete steps to address these concerns would be needed to ensure an increase in the prescription of generic medicines. At the same time, prescribing brand name medicines carries clear incentives<sup>56</sup> and many doctors are aware of the brand names of drug combinations and not their generic counterparts.

<sup>&</sup>lt;sup>49</sup> https://www.bibliomed.org/?mno=38428

<sup>&</sup>lt;sup>50</sup> https://www.picronline.org/preprintarticle.asp?id=316110

<sup>51</sup> 

https://www.researchgate.net/publication/324066906\_A\_study\_on\_assessment\_of\_awareness\_on\_generic\_drugs\_among\_doctors\_in \_a\_tertiary\_care\_teaching\_hospital\_in\_north\_India

<sup>&</sup>lt;sup>52</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8140226/

<sup>53</sup> https://www.picronline.org/preprintarticle.asp?id=316110

<sup>54</sup> http://njppp.com/fulltext/28-1493609998.pdf

<sup>&</sup>lt;sup>55</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4365676/

<sup>&</sup>lt;sup>56</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5642129/

In May 2016, the Drugs Technical Advisory Board of India considered amending<sup>57</sup> Rule 65 (11A) of the Drugs and Cosmetics Act 1940 such that pharmacies sell generic drugs to patients even if the prescriptions specify the branded versions. In a public statement on April 17, 2017, PM Narendra Modi acknowledged the need for a law that mandates doctors to prescribe generic drugs when possible<sup>58</sup>. The Medical Council of India has amended the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 on 08.10.2016 to provide a new para 1.5 regarding the use of generic names of drugs which provides as under: "Every physician should prescribe drugs with generic names legibly and preferably in capital letters and he/she shall ensure that there is a rational prescription and use of drugs<sup>59</sup>." The Medical Council of India released a circular addressed to the medical community, stating: "For any doctor found violating clause 1.5 of Ethics Regulation, suitable disciplinary action would be undertaken by the concerned SMC/MCI<sup>60</sup>." The Tele-Medicine Guidelines 2020; notified on 22nd May 2020, also directs all the RMPs to use Generic Names of the drugs in capital letters on the prescription format as appended with the document.<sup>61</sup>

Adherence with this standard must be ensured. The Parliamentary Standing committee has recommended that the "nexus between the pharmaceutical mafia and the medical professionals needs to be broken with a heavy hand because only that can ensure affordable medicine for every citizen of our country. Therefore, the Committee recommend that the Department of Pharmaceuticals and the Ministry of Health and Family Welfare should draw out a strategy which ensures that prescriptions without the generic name are not permitted at all. If required, a new law should be brought to the House on an urgent basis to enforce the same<sup>62</sup>". The government has also authorized State Medical Councils to punish errant doctors with anything from suspending their license to terminating it<sup>63</sup>.

64% (115) of the doctors feel that pharmacists can be allowed to substitute the medicine prescribed by them with medicine having the same composition. This percentage is more for the government (74% of 50) than private doctors (60% of 131). Another study had earlier highlighted that 44% of physicians

<sup>&</sup>lt;sup>57</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6515776/

<sup>&</sup>lt;sup>58</sup> https://www.thehindu.com/sci-tech/health/narendra-modihints-at-rules-for-doctors-to-prescribe-genericdrugs/article18076794.ece

<sup>&</sup>lt;sup>59</sup> https://im4change.org/upload/files/17\_Chemicals\_And\_Fertilizers\_17.pdf

<sup>&</sup>lt;sup>60</sup> https://taxguru.in/corporate-law/prescribe-generic-drugs-or-face-disciplinary-action-mci-to-doctors.html

<sup>&</sup>lt;sup>61</sup> https://pib.gov.in/PressReleasePage.aspx?PRID=1705065

<sup>&</sup>lt;sup>62</sup> https://im4change.org/upload/files/17\_Chemicals\_And\_Fertilizers\_17.pdf

<sup>&</sup>lt;sup>63</sup> https://science.thewire.in/health/what-you-need-to-know-about-generic-drugs-and-why-they-matter/

agreed/strongly agreed that pharmacists should be permitted to substitute branded drugs with generic medicines and among those who agreed/strongly agreed reported that patients will get cheap drugs (48.4%) as the main reason; the majority (76.1%) believed that patients will accept substitution of branded with generic medicines.<sup>64</sup>

10-25% of doctors are concerned about the efficacy, quality, action and even pricing of the generic medicines. They think that generic medicines can lead to therapeutic failures, might act slowly to relieve the patient and might not be even safe in having more side effects than the branded ones. New awareness campaigns should focus on these aspects to correct misconceptions. More needs to be done



to enhance doctors' confidence in generic medicines.

50% (91) of doctors reported their satisfaction with the current form of the PMBJP scheme. The major reasons for dissatisfaction reported included low awareness about the scheme and less availability, outreach and number of medicines. Satisfaction is only 18% (9/51) among the doctors who are not aware of a JAK nearby. Only 34% (26/76) of doctors reported satisfaction where JAK is reported to be permanently closed in this study.

<sup>39</sup> 

<sup>&</sup>lt;sup>64</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8140226/

# Factors influencing prescription of generic drugs

This section provides a description of various factors influencing the prescription of doctors and the problems they perceive in providing generic prescriptions.

Among the factors influencing doctor's prescriptions, 76% (138) and 75% (135) marked severity of disease and symptoms as major factors. However, increasing the number of generic prescriptions requires going beyond these factors to include drug availability (60%, 108), availability of drug samples (35%, 63), cost of medicines (34%, 61), government regulations (23%, 42) and availability of drug test reports (21%, 38).

Doctors Factors influencing prescription Symptoms to treat Severity of disease Duration of treatment Drug sample availability Drug availability nearby Cost of medicines fedicine manufacturer **Diagnostic reports** Peer Influence Drug test reports Guidelines of treatment Patient awareness nt's economic condition Government regulations Patient demand 0% 20% 40% 60% 80% source: primary survey (Universe: 181)

State-wise, more doctors in Chhattisgarh seem

to consider the cost of medicines as an important factor due to the poor economic conditions of most of their patients than in any other state. None of the doctors in Odisha considered the medicine manufacturer, availability of drug test reports and patient's awareness about pharma company while prescribing. Gender-wise, none of the female doctors reported considering peer influence and patients' awareness about pharma companies as factors while prescribing medicines. A majority (64% of 130) of doctors who are aware of JAK nearby consider drug availability nearby while prescribing medicine to their patients. Many doctors report challenges prescribing generic medicines. 65% (117) of doctors found that generic medicines were quite limited in number and did not cover all the diseases. Furthermore, they reported that non-availability of drug samples for the doctors (37%, 67), low awareness among people about the scheme (33%, 60), and no details on a test conducted for the efficacy of drugs (30%, 55) and no incentivization like gifts, free trips for the doctors (24%, 44) were problems in prescribing generic medicines.



State-wise, doctors in Chhattisgarh (21%, 10/48) were much more concerned about therapeutic failures due to generic medicines than doctors in other states. The majority of doctors from Bihar were much more concerned about the non-availability of drug samples to the doctors (54%, 30/56), low awareness among people about the scheme (52%, 29/56) and difficulty in writing the generic names of the medicines (14%, 8/56). The majority of doctors from Uttar Pradesh reported problems with similar pricing between generic and branded medicines (36%, 17/47) and non-availability of combination tablets in generic medicines (34%, 16/47).

More doctors report the problem of a limited number of generic medicines if they are aware of a JAK nearby (77%, 100/130). The trend holds for both locations where JAKs are found and where they are permanently closed.

## Satisfaction with PMBJP:

50% doctors reported being satisfied with the current form of the PMBJP scheme. Their major reasons for dissatisfaction included low awareness among patients, less availability of generic medicines, a limited number of JAKs and a limited number of medicines leading to low coverage of diseases.

Doctors suggested the following measures to strengthen the scheme: increasing awareness (76%, 138), increasing availability of medicines in JAKs (72%, 130), and increasing community outreach (64%, 116) and the number of medicines (62%, 113). Other important considerations were the need for rigorous quality testing, considering the reputation of manufacturing companies of generic medicines and the provision of drug samples to doctors which have been suggested by 59% (106), 58% (105) and 51% (92) of doctors respectively.



State-wise, doctors of Chhattisgarh and Uttar Pradesh are more concerned about ensuring that medicines were supplied by what was seen to be reputed manufacturers and quality testing than the doctors from Bihar and Odisha. More private (52%, 68/131) and graduate doctors (55%, 66/119) were more concerned about getting drug samples than government (48%, 24/50) and post-graduate doctors (42%, 26/62).

#### Doctors' Perspectives



#### **5.PATIENTS' PERSPECTIVES**

The following section provides the perspective of 445 patients/caregivers about the Jan Aushadhi scheme and the various issues pertaining to it.

### Awareness about generic medicines:

The extent of awareness: 51% of the patient respondents were found to be aware about the PMBJP scheme. 56% (248) respondents reported being aware of generic medicines. For the latter, the level decreases to 41% where the JAKs were found to be permanently closed. Awareness levels were somewhat higher than in other published research. In another study, 75% of patients were unaware of the JAS scheme and 82% were unaware of a JAS store in the vicinity<sup>65</sup>.

State-wise, awareness about generic medicines was highest in Uttar Pradesh (73%- 83/115) and the



lowest in Chhattisgarh (44%, 54/122). Awareness was low among poor people for whom the scheme is developed (Below Poverty Line - 41%, 111/269), the daily wagers (28%, 35/125), low-income group (45%, 94/208) and marginalized communities (Muslims - 44% 15/34; SC - 42%, 20/48; & ST 33%, 23/70). As expected, those lacking an education (19%, 12/63) and respondents completing only primary education (41%, 24/58) reported the lowest awareness along with the locations where JAK is found to be closed (38%, 69/184).

# Source of information:

31% reported word of mouth as their source of knowledge. Patients' friends and relatives made them aware of the benefits of the PMBJP scheme. 26% and 23% of patient respondents respectively also reported advertisements and doctors as their source of knowledge. Patients also reported being aware of advertisements on TV, on road hoardings, in hospitals etc. They also reported that both government and private doctors made them aware of the scheme. Advertisement seems to have been more successful in increasing the awareness among educated graduates (37%, 37/99) and post-graduates (48%, 13/27). The Parliamentary Standing Committee had recommended a significant increase in the financial allocation for wider publicity of the PMBJP scheme to popularize generic medicines and

<sup>65</sup> http://njppp.com/fulltext/28-1493609998.pdf

address any concerns about the quality of generic medicines<sup>66</sup>. More targeted awareness campaigns focusing on the urban poor and disadvantaged sections would be needed<sup>67</sup>.

# Doctors' prescriptions about generic medicines:

44% (152) of patient respondents reported that their doctors never prescribed any generic medicines. Out of these 152 patient respondents, 55% (83) reported that doctors even recommended a specific chemist shop to buy from. This points towards a major hurdle in increasing generic prescription as doctors get incentives from pharma companies and chemist shops for recommending a specific medicine or shop.



# **Preference for Generic Medicines:**

67% (299) of patients reported generic medicine as their choice due to its greater affordability. 57% of (252) respondents report that generic medicines are cheaper than branded ones. 43% (192) of patient respondents understood that generic medicines are similar in action and effectiveness to branded ones.

<sup>&</sup>lt;sup>66</sup> https://im4change.org/upload/files/17\_Chemicals\_And\_Fertilizers\_17.pdf <sup>67</sup> https://im4change.org/upload/files/17 Chemicals And Fertilizers 17.pdf



#### **Misconceptions:**

Among the patients, 10-20% of the respondents were reportedly not buying generic medicines due to fears of low efficacy, quality, local manufacturer, and unappealing packaging. Some even reported no difference in pricing. Understanding is quite low about the fact that generic medicines use the same material (13%, 59) and have the same or fewer side effects (36%, 159). This suggests the need for any new awareness campaigns to target these specific points. As expected, the understanding was lower in locations where JAKs were closed.

# Concerns of Marginalized Communities:

The majority of the different marginalized sections including Muslims (56%, 19/34), OBCs (58%, 97/167), SCs (67%, 32/48) and STs (70%, 49/70) included in this study were concerned about the effectiveness of generic medicines in comparison to the general category respondents (45%, 56/125). A similar trend is seen for quality as well. Higher patient concerns around quality and effectiveness among the less educated (respondents with secondary education and lower) and low-income group respondents (less than INR 10,000).



## **Prescription of Generic Medicines**

Majority 46% (155) report non-prescription by the doctors as the

reason for not buying generic medicines, followed by non-availability of JAKs nearby (27%, 89). Another prominent reason to consider is the non-availability of stock at JAKs reported by 21% (of 71) respondents.



When patients were asked what could convince them to switch from branded to generic medicine, the top four reasons identified included being convinced about the reputation of the manufacturer of generic medicine (45%, 199), more marketing and awareness (43%, 192), lowering of price (32%, 142) and the introduction of medicines with combination (two or more drugs in one medicine) (30%, 132). More females are ready to switch at low prices than males. The majority of BPL card holders (22%, 58/269) provide better packaging as a reason in comparison to APL patients (7%, 13/176). Thus, although 67% indicated their choice for generic medicines, more patient respondents may switch to generic medicines if they get to know that they are being manufactured by reputed companies, prices are lowered further, and more marketing is carried out to increase awareness and remove misconceptions.

#### Perceptions of marginalized communities:

- BPL: 60% of patient respondents belonged to the BPL category. 41% of BPL card holders report being aware of generic medicine. 22% of BPL card holders provide better packaging as a reason to switch to generic medicines, a response higher than APL respondents.
- 2. Muslims: 7.6% of patients identified themselves as Muslims in the study. They report the lowest awareness of generic medicines. The majority of them are also concerned about the effectiveness and quality of generic medicines.
- 3. OBCs, SCs & STs: The majority of patients from marginalized communities report low awareness of generic medicines. They were also concerned more about the effectiveness and quality of generic medicines.

#### **PATIENTS' PERSPECTIVES AND AWARENESS**



# **SNAPSHOT OF FINDINGS**

The following section provides a snapshot of the findings against the seven extended OECD<sup>68</sup> criteria:

#### Color coding:

	Good	Fair	Poor			
Parameter	Evaluation					
Inclusiveness	None of the stakeholde However, only three J ownership of JAKs.	rs reported explicit discrimination anywh	ere in terms of caste, gender or religion. en which suggests male domination in			
Relevance	67% of patients repor relevance the of PMBJ	ted generic medicine as their choice de Pscheme and Jan Aushadhi medicines.	ue to its affordability. This shows the			
Effectiveness	54% of pharmacists ar pharmacists report pro- medicine requisition. 7 time. 90% of pharmaci to stop stock outs. Only Only 40% of pharmacists 44% of pharmacists rep able to manage their in not found available due of this highlights the im 72% of doctors reporte medicines are quite lim 56% of patient respond scheme is developed i.4	e using a computerized billing method p oblems in using BPPI software. 71% of p 3% of pharmacists can send their medicin sts report forecasting requirements in ad- 27% pharmacists report zero discrepancie ts report that their suppliers accept the re- port significant delays in receiving subsidie wentory properly. 80% of the 55 medicine to temporary/frequent supply shortages aportance of improving the Jan Aushadhi se to temporate of a Jan Aushadhi Kendra re- nited in number which is why they do not dents reported being aware of generic me e., the BPL card holders, wage employed, for the lowest awareness in their respecti	brovided by the BPPI software. 21% of obarmacists report using indenting for the requisition to distributors at the right wance but they expressed their inability es in supplied medicines vs the required. eturn of unused and expired medicines. s. Only 42% of pharmacists report being es covered in the study were reportedly with an overall availability of 61.8%. All supply chain. hearby. 65% of doctors find that generic cover all the diseases. edicines. The poor people for whom the low-income group and the marginalized ve categories.			
Efficiency	Jan Aushadhi Kendra o INR 22,338 last month costs. Taking even und small family. State-wise other states.	n average reported sales revenue of INR They also report an average annual net erreporting into account, this is quite lov e, Odisha's JAKs were performing better t	87,823 and an average sales margin of profit of INR 89,897 after deducting all v considering the sustenance of even a than the JAKs in aspirational districts of			

<sup>68</sup> https://www.oecd.org/dac/evaluation/daccriteriaforevaluatingdevelopmentassistance.htm

	A majority 60% of the pharmacists report stockouts and 64% report receipt of short-expiry and damaged
	medicines further reducing the efficiency. So, there is a need to consider diverse factors before opening
	a Jan Aushadhi Kendra. This requires capacity building of the pharmacists/ JAK owners, feasibility studies
	and other support from the government.
	On average JAK pharmacists report 67 people visiting their shop daily out of which 59% come with a
	doctor's prescription. State-wise, Uttar Pradesh's pharmacists report the highest footfall of
	approximately 95 people daily and Chhattisgarh's pharmacists report the lowest footfall of
	approximately 31 people daily. Chhattisgarh's pharmacists, however, reported 84% daily average visiting
	the JAK with prescription.
Impact	
	50% doctors reported their satisfaction with the current form of the PMBJP scheme. The major reasons
	for dissatisfaction reported included low awareness, less availability, outreach and number of medicines.
	Although the affordability of medicines wasn't covered as a part of this study, it is quite evident that
	generic medicines are more affordable than branded ones.
	To strengthen the implementation of the scheme, the government needs to partner with doctors,
	understand and resolve their issues.
Convergence	
	Although pharma companies were not included in this study, taking other public reports into
	consideration, floating open tenders for procurement is a positive sign of convergence.
	With 41% of the 88 Jan Aushadhi Kendra covered under this study being found closed and more on the
Sustainability	verge of closure, the sustainability of JAK and the PMBJP scheme is in question. This requires urgent by
	the government.

# **STATE DIFFERENCES**

#### a. Bihar

19 JAKs, 56 doctors and 133 patients were covered in this study are from Bihar. As reported earlier, all the JAKs in the Nawada district are allotted to the same person and all of them are closed. 6 out of the 7 pharmacists who don't have a proper system of medicine requisition were from Bihar. Weekly forecasting was done by pharmacists in the aspirational districts of Bihar. Doctors from the aspirational districts of Bihar perceive no drug sample availability and low awareness as major reasons to lower generic prescriptions than other states. For patients, the trend in Bihar is very similar to the overall observations.

#### Chhattisgarh

13 JAKs, 48 doctors, and 122 patients were covered from the aspirational districts of Chhattisgarh. 46% (11 out of the 24 planned) JAKs were found to be permanently closed which is the second-highest among the four states. Only 1.6 staff on average were found to be running the JAKs which is the lowest among the states. They also report the lowest footfall of only 31 people daily on an average per JAK. However, they had the highest percentage of people visiting with prescriptions. Pharmacists forecast monthly as the supply and subsidies were quite delayed.

Chhattisgarh reports the lowest overall availability of medicines at just 41.5%. More doctors in the aspirational districts of Chhattisgarh seem to consider the cost of medicines as important factors due to the poor economic conditions of most of their patients than in other states. They were also more concerned about therapeutic failures due to generic medicines. Patients also report the lowest awareness (44%).

#### Odisha

Three JAKs, 30 doctors and 75 patients were covered from Odisha. 12 out of 15 JAKs planned to be covered under the study were found to be permanently closed. This is the highest among all the four states but the three JAKs opened were performing better than those of other states in terms of profitability. The availability of medicines is second-lowest among the four states at 58.2%.

As the majority of JAKs in Odisha are closed, the awareness level of doctors about nearby JAKs was quite low at 40%. They do not consider medicine manufacturers, availability of drug test reports and patients' awareness about pharma companies while prescribing.

#### Uttar Pradesh

16 JAKs, 47 doctors and 115 patients were covered from Uttar Pradesh. Uttar Pradesh's pharmacists reported the highest average daily footfall of approximately 95 people. They do bi-monthly forecasting. They report stockouts for the maximum time. Pharmacists here are looking for incentives and subsidies more than that in other states. They report the overall availability of 65% of all the medicines covered.

Uttar Pradesh reported the lowest percentage of doctors writing generic prescriptions. The majority of doctors reported problems with similar pricing and the non-availability of combination tablets. They are also concerned about the medicine manufacturer and quality testing more than other states. However, Uttar Pradesh's patients reported the highest awareness of 73% of patients.

#### State-wise major differences





# RECOMMENDATIONS

The establishment of Jan Aushadhi Kendras across the country holds the potential for reducing patients' financial burden. The study has highlighted the need to take some concrete steps at policy and implementation levels to ensure that the scheme fulfils its true potential.

#### Policy level recommendations

#### 1. Expanding coverage

- The JAK is a good scheme that needs to be expanded to every block of the country to ensure everyone can access cheaper medicines.
- Increasing number of stores: Although the government has been steadily increasing the number of stores, they also need to look at the ones which are getting closed and not getting updated in their records.
- Adding more medicines: The addition of more medicines has been one of the priorities of the government but they should look at adding more combo medicines as well. Apart from addition, they need to make the doctors and pharmacists aware of their availability.
- Public diagnostic labs: PMBJP scheme is quite relevant to the needs of people in increasing accessibility of affordable medicines to the poor people. To improve the affordability of overall healthcare, the government can look to start public diagnostic labs on similar lines to Jan Aushadhi Kendras.

#### 2. Promoting generic prescriptions

- Produce and disseminate updated educational material on generic medicines for doctors working in public and private healthcare systems which will enhance the knowledge and confidence among doctors to prescribe the generic medicines.
- Initiate regulatory or law enforcement policies which may include mandatory generic substitution laws to which pharmacists must adhere.
- Reinforce existing rules and regulations on controlling the incentivization of doctors by pharma companies to influence their sales.
- Ensure quality with strict regulatory mandate and providing updated information regarding the generic drugs to doctors through MCI (Medical Council of India) will eventually enhance the prescription of generic drugs.

- Initiate regulatory or law enforcement policies which may include mandatory generic substitution laws to which pharmacists must adhere.
- Overcoming incentivization: The government needs to be proactive to address loopholes regarding low generic prescriptions by doctors in the face of incentivization by pharma companies by engaging local elected members and Rogi Kalyan Samiti for monitoring and supporting JAK.
- Drug test reports: The government should take steps to make bio-equivalence of generic medicines information public for all the generic medicines from all manufacturers. This can constitute a public drug formulary which is made public by the government on a portal. The general public can be made aware about it. If test reports are available, they should be made public immediately.
- Drug samples: Another problem in generic prescribing, doctors report they evaluate each medicine on a few of their patients through the samples they receive from pharma companies. They say it becomes extremely important in the case of narrow therapeutic index (NTI) medicines like carbamazepine as in them the therapeutic value varies a lot from manufacturer to manufacturer. The government can think about providing samples of at least NTI medicines for up to three patients, by the government guidelines<sup>69</sup>.
- De-branding essential medicines may eventually be explored. Conditions required for effective functioning of de-branding include stringent control on fake and spurious drugs, only GMP and ISI compliant pharma manufacturers, public availability of all drug test reports, no shortage of essential drugs, incorruptible system and high level of awareness etc. If these conditions are met, then doctors would have no choice but to write generic prescriptions and the pharma companies wouldn't be able to incentivize doctors due to indifference to medicines. By meeting these conditions, the government can consider the de-branding of all essential medicines through regulation or high tax imposition.

<sup>&</sup>lt;sup>69</sup> https://theprint.in/health/pharma-firms-want-govt-to-tweak-ethics-code-allow-free-samples-educational-foreign-trips/350867/

#### B. Implementation level recommendations

#### 1. Increasing awareness

- Develop and implement rigorous and continuous mass awareness campaigns and using various types of advertisement, outdoor publicity and social media platforms which build awareness among people about generic medicines.
- Tweak the messaging of the same. Currently, advertisements target mostly the affordability of generic medicines. Quality, effectiveness, side-effects, manufacturer, material etc. need to also be addressed in addition to the question of cost to remove misconceptions among specific stakeholders. Thus, it might be worthwhile to declare the therapeutic value of generic NTI (Narrow Therapeutic Index)<sup>70</sup> drugs to doctors, compare the inactive material composition of generic and branded drugs, and use bio-equivalence test results in advertisements with doctors.
- Correct misconceptions: Specific misconceptions prevail among pharmacists, doctors and patients and new awareness campaigns need to specifically address those aspects. Concerns on quality, effectiveness, action, side-effects, manufacturer and material need to be addressed by making information on these parameters publicly available. For the general public too, advertisements need to address dimensions like the efficacy of generic vs branded drugs public, showcase experiment results with side-effects of generic vs branded drugs and make the list of generic drug manufacturers public.
- Location of advertisements: Among the sources of awareness, patients highlighted private doctors and hospitals as sources of knowledge. So, it would be good for campaigns to focus on these areas.
- Increasing word of mouth: Word of mouth is the most prominent source of knowledge reported by patient respondents. Therefore, there is a need to focus on increasing word of mouth about the PMBJP scheme and generic medicines. Word of mouth can be increased by encouraging stories and reviews from stakeholders, stories from healthcare professionals and influential people speaking on the matters of concern. These stories can be promoted over social media, TV, radio and print media.

<sup>&</sup>lt;sup>70</sup> Narrow therapeutic index (NTI) drugs are defined as those drugs where small differences in dose or blood concentration may lead to dose and blood concentration dependent, serious therapeutic failures or adverse drug reactions. Serious events are those which are persistent, irreversible, slowly reversible, or life-threatening, possibly resulting in hospitalization, disability, or even death. For more details- <u>https://go.drugbank.com/categories/DBCAT003972</u>

 Convergence: New generation startups like Generic Aadhar, StayHappi, Dava India, etc. are coming up with innovative ways to overcome concerns about generic medicines. Government can think of tying up with these startups to explore synergies and strengthen convergence.

#### 2. Improving the generic medicine supply chain

- Demand assessment studies: Problems of stockouts and expiry have been highlighted as the most important problems by pharmacists. PMBI and pharmacists both need to conduct demand assessment studies for the various medicines and then ensure their availability accordingly.
- Return policy: The government needs to adopt a slightly liberal return policy at least for a five-year period so that JAKs get established successfully.
- Distributor feasibility assessment: An important factor in ensuring availability is the location of distributors and suppliers to minimize the lead time for JAKs. A small feasibility assessment can go a long way in minimizing stockouts as well.
- Set up standards protocols to maintain high standards for safety, efficacy, and quality in the review of generic drugs.
- Provide technical and financial support to Indian generic drug manufacturers for ensuring the quality of generic medicines.

#### 3. Enhancing JAK management

- Audits: Organize regular and timely financial and social audits of each JAKs for ensuring its functioning. None of the pharmacists reported any audit or visit by any person from BPPI or government or third party in the last year. It might have been due to COVID but audits should be conducted every year. And, these audits should especially note problems faced by the pharmacists as well as this study found that 41% of JAKs closed.
- JAK feasibility assessment: 19 of the 36 JAKs were found to be permanently closed due to inappropriate location. A short feasibility assessment by either pharmacist or BPPI will help in identifying the future success of JAK. Such a feasibility assessment needs to address the location, demand, supply, number of doctors and hospitals etc. to improve their sustainability.

- Easing processes: Pharmacists report several problems with the BPPI software in managing inventory, procurement, billing and returns. While the present research did not evaluate the software due to its non-accessibility, BPPI should conduct a study to identify these problems in greater detail and ease them out for successful JAK management.
- Establish a mechanism to review the functioning of JAKs on regular basis not only through national and state-level meetings but also to plan a visit of government officials and parliamentarians.
- Training of pharmacists: Training for pharmacists should also be conducted before starting a JAK and subsequently every year to make them aware of new practices to run the store smoothly. Several patients reported some stores being attacked by crowds due to wrong medicine being dispensed by them. This makes training more essential.
- Form a public forum for raising grievances/experiences of patients while availing the services from the JAKs. As well as provide a helpline or single-window mechanism to register written or oral complaints.
- Set up a grievance redressal mechanism for pharmacists/owners of the JAKs to enable them to file complaints against medicines suppliers, software management system providers and doctors.
- Credit support: To incentivize pharmacists more, the government can look to subsidize interest rates so that a greater number of pharmacists from the underprivileged can start JAKs, promoting entrepreneurship as well.

The study was limited to aspirational districts of Bihar, Chhattisgarh, Odisha and Uttar Pradesh; however, it indicates the overall functioning of the scheme. Further research can be carried out in other states and include more stakeholders like pharma companies and policymakers. Further research can also consider focusing on specific diseases. It would also be useful to attempt to establish causal analysis using regression or other estimation methods. Continuous observation and evidence-based policy interventions are critical to improving the implementation of public health policies in India.