



MEDICINE IN INDIA: Challenges in Affordability & Accessibility

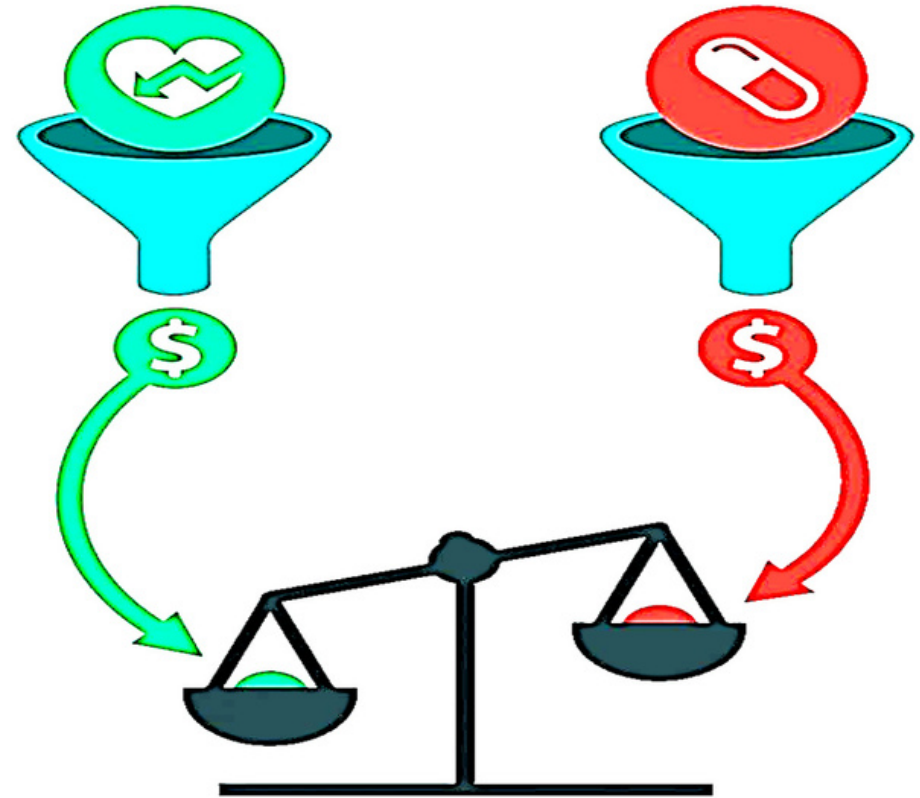
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HEALTH ECONOMICS

Health economics is a branch of economics concerned with issues related to efficiency, effectiveness, values, and behavior in the production and consumption of health and health care.



$$\text{Benefits} - \text{Costs} = \text{Net Benefits}$$

PHARMACOECONOMICS

Pharmaco-economics refers to the scientific discipline that compares the value of one pharmaceutical drug or drug therapy to another. It is a sub-discipline of health economics.



THE CHALLENGE OF CARING FOR A BILLION

- India is the second most populous country in the world.
- The death rate has declined but birth rates continue to be high in most of the states.
- Health care structure in the country is over-burdened by increasing population

AVAILABILITY

ACCESSIBILITY

AFFORDABILITY

ACCEPTABILITY

Make sure new medicines are present in countries

Make sure people can get hold of the medicine

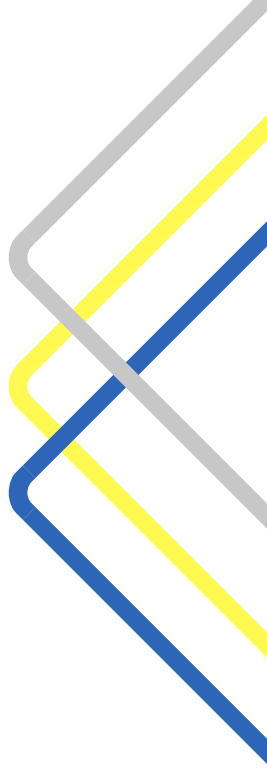
Make sure people have enough money to buy the medicine

Make sure people are willing and able to use the medicine



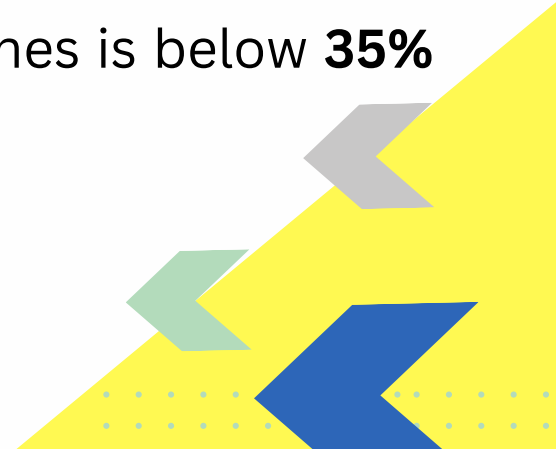
AVAILABILITY

Essential medicines are intended to be available within the functioning healthcare systems at all times, **in adequate amounts, in appropriate dosage forms, with assured quality, and at a price the individual and community can afford.**



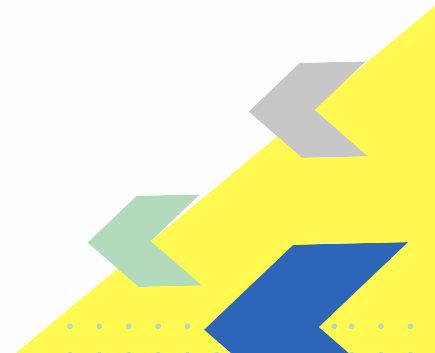
ACCESSIBILITY

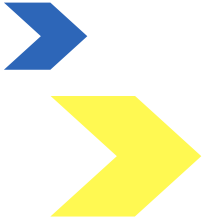
- The issue of access to medicine is a primary cause of the skewed healthcare utilization pattern in India.
- According to **National Sample Survey Organization (NSSO)**, public facilities accounted for only **30%** of the overall healthcare services in the year 2017–18.
- Majority of the people had to obtain healthcare including medicines from private providers.
- According to an estimate, access to essential medicines is below **35%** in India.



ACCEPTABILITY

- **European Medicines Agency (EMA)** defines patient acceptability as “the overall ability and willingness of the patient to use and its caregiver to administer the medicine as intended”.
- Acceptability is also considered to be “**driven by the characteristics of the user (age, ability, disease type and state) and by the characteristics of a medicinal product**”.
- Palatability, swallowability, appearance, complexity of modification before administration, required dose, container or administration device use and mode of administration are proposed as characteristics of the medicinal product.
- Consideration of patient acceptability is necessary to **optimize patient adherence** in order to reach the efficacy and safety of medicines.

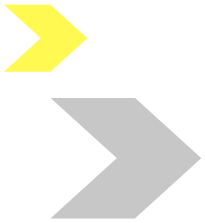




AFFORDABILITY

- Indian Government spending on health at **~3.01%** of GDP is among the lowest in the world persistently low Government spending on health has constrained the **capacity and quality** of healthcare services offered in the public system.
- **Overburdened** public hospitals often divert individuals to seek treatment in the costlier private sector.
- Almost **60%** of all hospitalizations, and **70%** of out-patient services are delivered by the private sector (**NSSO's 75th Round survey on Social Consumption of Health, 2017-18**).

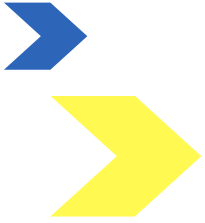




AFFORDABILITY

- Household's **out-of-pocket expenditure (OOPE)** on healthcare has always been a major contributor to India's total health expenditure.
- While the figure has improved over the years to **48.21%** in 2018-2019 from **69.4%** in 2004-2005, according to the **National Health Accounts**, it still remains high. This runs a severe risk of pushing people into poverty.
- High OOPE on health is impoverishing around **55 million Indians** annually, with over **17% households** incurring catastrophic levels of health expenditures every year, a **World Health Organization (WHO)** report from March 2022 estimated.





AFFORDABILITY

- Indian households spent around **2875 billion INR** on healthcare services, accounting for a major chunk of the total health expenditure.
- In comparison, the country's Current Health Expenditure is **5402 billion INR**, where the government has contributed **2422 billion INR** including capital expenditure.
- The recent report from the **National Health System Resource Centre (NHSRC) India** states that current OOPes account for **58.7%** of national health expenditure in India.
- Medicines being the largest component of **OPE**, there is a major concern in the affordability of the same, especially on low-income group.



Percentage break-up of hospitalization expenses, by state/UT, for Public Hospital in Rural sector

State/UT	Percentage break-up of hospitalization expenses						
	package component	doctor's/ surgeon's fee	medicines	diagnostic tests	bed charges	other	total
Andhra Pradesh	16.5	6.4	46.6	15.7	2.1	12.7	100.0
Arunachal Pradesh	4.7	3.0	53.9	19.2	4.6	14.6	100.0
Assam	10.0	4.7	44.2	22.2	2.8	16.0	100.0
Bihar	21.2	1.4	47.5	16.1	0.3	13.5	100.0
Chhattisgarh	32.9	6.0	34.3	8.3	4.4	14.1	100.0
Delhi	21.6	0.0	69.5	3.4	0.0	5.5	100.0
Goa	0.0	3.6	73.6	8.9	0.0	14.0	100.0
Gujarat	0.0	3.1	55.6	20.0	4.2	17.0	100.0
Haryana	9.2	7.0	48.7	13.8	2.1	19.2	100.0
Himachal Pradesh	14.9	6.7	46.0	16.7	1.3	14.4	100.0
Jammu & Kashmir	0.9	1.4	58.0	20.9	0.5	18.3	100.0
Jharkhand	11.0	2.8	58.9	12.0	1.3	14.0	100.0
Karnataka	2.1	6.6	49.0	18.4	3.4	20.5	100.0
Kerala	7.4	7.6	41.2	23.7	5.8	14.3	100.0
Madhya Pradesh	7.5	1.5	62.3	14.3	0.7	13.6	100.0
Maharashtra	7.9	8.5	41.5	21.6	8.6	11.8	100.0
Manipur	1.9	0.9	69.0	19.4	1.0	7.7	100.0
Meghalaya	13.8	1.6	60.6	9.3	0.8	13.9	100.0
Mizoram	22.1	5.2	56.7	10.8	0.0	5.2	100.0
Nagaland	22.9	12.5	34.3	11.4	7.2	11.7	100.0
Odisha	2.2	2.3	68.3	18.5	1.0	7.8	100.0
Punjab	15.8	3.8	35.6	26.6	5.6	12.6	100.0
Rajasthan	17.2	0.7	61.2	14.3	0.2	6.5	100.0
Sikkim	7.7	0.0	50.8	18.0	0.0	23.6	100.0
Tamil Nadu	1.8	0.8	26.5	32.1	3.6	35.2	100.0
Telangana	0.4	2.5	53.2	20.2	0.9	22.8	100.0
Tripura	0.1	1.6	71.8	23.1	0.4	3.0	100.0
Uttarakhand	0.0	5.6	58.5	23.1	5.1	7.7	100.0
Uttar Pradesh	11.6	5.7	50.6	15.3	4.6	12.3	100.0
West Bengal	4.1	1.1	54.5	23.0	0.5	16.9	100.0
A & N Islands	47.1	0.0	50.1	0.0	1.8	0.8	100.0
Chandigarh	0.0	0.1	47.6	25.5	3.8	23.1	100.0
Dadra & Nagar Haveli	0.0	2.8	6.7	13.9	52.2	24.5	100.0
Daman & Diu	0.0	0.0	86.7	0.0	0.0	13.3	100.0
Lakshadweep	0.0	0.0	36.5	44.8	0.0	18.8	100.0
Puduchery	0.0	17.6	20.3	2.9	1.3	58.0	100.0
All-India	9.9	4.0	51.8	18.6	2.7	12.9	100.0

Source: NSSO's 75th Round survey on Social Consumption of Health, 2017-18

Percentage break-up of hospitalization expenses, by state/UT, for Private Hospital in Rural sector

State/UT	Percentage break-up of hospitalization expenses						
	package component	doctor's/surgeon's fee	medicines	diagnostic tests	bed charges	other	total
Andhra Pradesh	14.4	23.4	25.9	14.4	14.6	7.3	100.0
Arunachal Pradesh	18.9	11.1	23.6	14.8	18.0	13.6	100.0
Assam	38.9	17.0	20.6	8.6	8.5	6.4	100.0
Bihar	33.5	15.5	23.3	9.5	9.3	9.0	100.0
Chhattisgarh	20.0	16.7	29.7	7.0	15.5	11.1	100.0
Delhi	66.3	3.0	20.7	3.7	3.6	2.7	100.0
Goa	16.4	28.6	19.4	9.1	17.5	9.0	100.0
Gujarat	29.9	22.2	21.0	7.9	11.2	7.9	100.0
Haryana	21.7	16.8	24.3	11.0	15.7	10.6	100.0
Himachal Pradesh	28.0	8.1	33.8	11.0	9.5	9.5	100.0
Jammu & Kashmir	63.9	6.9	7.6	5.9	2.7	13.1	100.0
Jharkhand	21.7	25.9	24.1	6.5	14.3	7.6	100.0
Karnataka	14.5	24.6	27.2	11.0	14.4	8.4	100.0
Kerala	17.1	19.5	25.4	11.5	12.8	13.6	100.0
Madhya Pradesh	24.2	17.0	23.9	11.4	13.0	10.4	100.0
Maharashtra	15.6	23.7	28.5	9.5	14.2	8.5	100.0
Manipur	86.6	2.5	5.2	3.2	2.1	0.4	100.0
Meghalaya	43.8	17.0	13.2	7.5	12.6	5.9	100.0
Mizoram	41.8	16.3	23.6	7.1	5.6	5.6	100.0
Nagaland	26.3	15.5	21.6	11.6	15.4	9.5	100.0
Odisha	36.3	16.1	22.3	8.8	12.3	4.2	100.0
Punjab	29.2	19.7	22.3	9.5	10.9	8.3	100.0
Rajasthan	34.2	10.6	24.6	12.5	9.7	8.4	100.0
Sikkim	45.9	16.9	10.8	5.7	10.2	10.5	100.0
Tamil Nadu	20.7	27.7	21.3	8.7	13.8	7.8	100.0
Telangana	11.0	34.7	21.9	12.4	11.0	8.9	100.0
Tripura	74.3	4.6	10.3	5.9	3.4	1.6	100.0
Uttarakhand	30.1	15.6	20.8	12.2	13.1	8.2	100.0
Uttar Pradesh	20.5	15.0	30.7	10.8	13.3	9.7	100.0
West Bengal	49.3	21.7	12.0	6.8	6.9	3.3	100.0
A & N Islands	69.0	6.2	11.6	6.5	2.5	4.1	100.0
Chandigarh	0.0	35.9	8.5	14.3	4.9	36.3	100.0
Dadra & Nagar Haveli	0.0	38.4	24.3	14.0	22.8	0.6	100.0
Daman & Diu	4.0	52.7	13.6	11.2	9.3	9.3	100.0
Lakshadweep	48.8	5.6	9.8	4.4	15.3	16.0	100.0
Puduchery	68.9	10.4	9.3	4.0	3.5	4.0	100.0
All-India	24.2	19.8	24.9	10.2	12.3	8.7	100.0

Source: NSSO's 75th Round survey on Social Consumption of Health, 2017-18

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State/UT	Percentage break-up of hospitalization expenses						
	package component	doctor's/ surgeon's fee	medicines	diagnostic tests	bed charges	other	total
Andhra Pradesh	0.0	4.3	53.9	23.9	1.7	16.2	100.0
Arunachal Pradesh	0.8	3.8	60.1	18.0	6.1	11.1	100.0
Assam	13.7	2.3	39.5	20.0	2.9	21.7	100.0
Bihar	19.9	1.6	48.3	16.9	1.7	11.6	100.0
Chhattisgarh	22.2	18.7	37.9	10.4	1.7	9.1	100.0
Delhi	49.5	6.8	25.6	9.9	1.5	6.7	100.0
Goa	17.6	0.0	57.2	4.2	0.0	20.9	100.0
Gujarat	24.3	3.6	47.7	8.6	4.4	11.4	100.0
Haryana	21.7	2.9	37.2	13.4	4.3	20.4	100.0
Himachal Pradesh	10.2	1.1	52.8	19.9	4.2	11.8	100.0
Jammu & Kashmir	0.0	5.5	39.6	16.6	0.7	37.6	100.0
Jharkhand	15.3	10.8	46.7	9.1	4.0	14.0	100.0
Karnataka	8.9	4.7	50.7	19.5	2.8	13.4	100.0
Kerala	4.3	2.8	47.4	23.2	4.6	17.7	100.0
Madhya Pradesh	10.3	3.5	48.9	14.1	2.3	20.9	100.0
Maharashtra	35.4	5.0	35.2	10.9	3.8	9.7	100.0
Manipur	1.0	0.2	70.3	17.7	1.6	9.3	100.0
Meghalaya	20.1	1.4	55.8	11.8	3.4	7.6	100.0
Mizoram	10.3	1.8	63.0	14.1	1.0	9.7	100.0
Nagaland	19.2	7.8	41.3	12.2	4.6	14.9	100.0
Odisha	26.5	1.3	43.9	17.1	2.0	9.2	100.0
Punjab	39.9	2.2	27.2	14.5	2.3	13.8	100.0
Rajasthan	25.8	1.8	42.4	12.8	1.9	15.3	100.0
Sikkim	2.0	0.0	72.9	11.5	0.3	13.3	100.0
Tamil Nadu	0.0	2.0	23.4	38.5	0.3	35.8	100.0
Telangana	0.1	1.6	88.1	5.7	0.8	3.6	100.0
Tripura	12.3	3.0	56.4	19.5	1.6	7.2	100.0
Uttarakhand	0.0	7.7	75.1	8.6	2.9	5.7	100.0
Uttar Pradesh	18.9	5.2	38.7	15.5	4.2	17.4	100.0
West Bengal	10.3	1.0	46.3	20.9	2.6	18.9	100.0
A & N Islands	0.0	42.2	16.2	6.8	5.3	29.5	100.0
Chandigarh	0.0	19.3	32.4	18.5	5.9	23.8	100.0
Dadra & Nagar Haveli	0.0	1.3	4.8	12.7	77.9	3.3	100.0
Daman & Diu	0.0	53.7	0.0	0.0	0.0	46.6	100.0
Lakshadweep	0.0	0.0	70.7	8.0	6.0	15.4	100.0
Puducherry	1.9	4.0	67.5	1.9	4.7	20.1	100.0
All-India	17.9	4.1	43.4	15.9	3.1	15.6	100.0

Source: NSSO's 75th Round survey on Social Consumption of Health, 2017-18

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State/UT	Percentage break-up of hospitalization expenses						total
	package component	doctor's/ surgeon's fee	medicines	diagnostic tests	bed charges	other	
Andhra Pradesh	23.6	23.3	21.8	13.2	12.2	5.8	100.0
Arunachal Pradesh	0.3	18.6	34.7	14.7	18.1	13.7	100.0
Assam	55.2	9.9	13.1	7.1	5.8	8.8	100.0
Bihar	44.4	10.4	21.0	8.9	8.7	6.6	100.0
Chhattisgarh	41.9	9.8	20.1	9.9	12.7	5.6	100.0
Delhi	87.4	3.5	2.5	2.3	2.6	1.7	100.0
Goa	74.3	8.0	6.2	2.7	5.0	3.7	100.0
Gujarat	35.4	18.2	18.5	9.4	10.6	8.1	100.0
Haryana	34.1	17.1	16.9	9.6	13.5	8.7	100.0
Himachal Pradesh	56.4	8.0	17.3	6.5	5.2	6.5	100.0
Jammu & Kashmir	59.7	7.6	16.6	7.0	5.7	3.4	100.0
Jharkhand	46.1	14.3	17.0	8.3	8.9	5.5	100.0
Karnataka	32.2	18.2	21.4	10.2	11.0	6.9	100.0
Kerala	16.7	16.8	23.6	12.1	17.7	13.1	100.0
Madhya Pradesh	28.6	14.5	22.7	11.8	13.5	8.9	100.0
Maharashtra	29.5	22.5	17.4	9.9	14.0	6.7	100.0
Manipur	67.4	9.3	11.5	2.9	7.6	1.2	100.0
Meghalaya	61.6	8.2	11.4	5.1	8.8	5.0	100.0
Mizoram	18.1	17.5	37.0	9.5	12.7	5.2	100.0
Nagaland	42.5	10.4	18.8	7.9	12.7	7.8	100.0
Odisha	31.6	22.7	23.4	9.0	8.8	4.4	100.0
Punjab	48.7	11.8	16.3	7.5	8.4	7.3	100.0
Rajasthan	45.1	9.7	21.7	8.5	8.8	6.2	100.0
Sikkim	34.9	22.4	11.3	9.2	11.1	11.0	100.0
Tamil Nadu	47.9	17.2	16.4	5.9	8.0	4.6	100.0
Telangana	38.5	25.7	13.7	8.6	8.4	5.0	100.0
Tripura	37.6	26.3	15.3	9.9	4.8	6.1	100.0
Uttarakhand	23.1	17.5	26.1	15.4	13.0	4.9	100.0
Uttar Pradesh	38.2	12.4	25.3	8.5	9.4	6.3	100.0
West Bengal	65.5	9.0	8.7	5.6	7.6	3.6	100.0
A & N Islands	45.1	16.7	15.1	7.3	6.0	9.8	100.0
Chandigarh	50.6	11.5	14.6	8.4	6.9	8.0	100.0
Dadra & Nagar Haveli	17.7	38.3	12.8	7.1	14.4	9.6	100.0
Daman & Diu	0.0	42.4	17.9	17.5	15.8	6.4	100.0
Lakshadweep	28.6	10.1	16.0	9.7	19.4	16.1	100.0
Puducherry	23.5	42.7	17.5	4.7	6.1	5.5	100.0
All-India	39.6	16.2	18.1	8.8	10.8	6.6	100.0

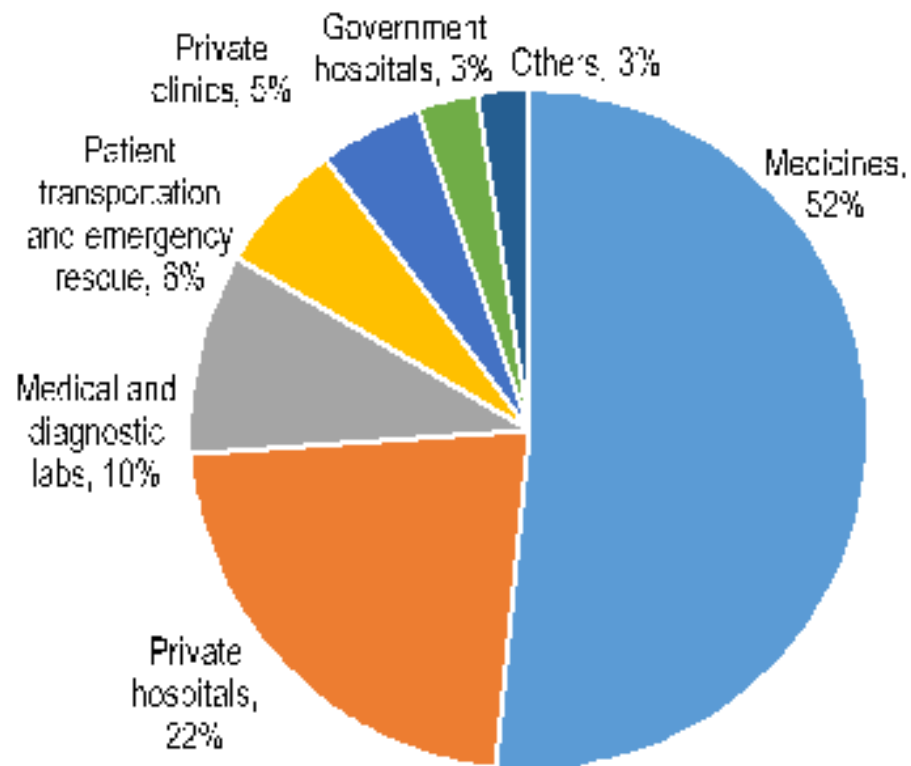
Source: NSSO's 75th Round survey on Social Consumption of Health, 2017-18

What is OOPE?



Out-of-pocket payments are expenditures borne directly by a patient where insurance does not cover the full cost of the health good or service



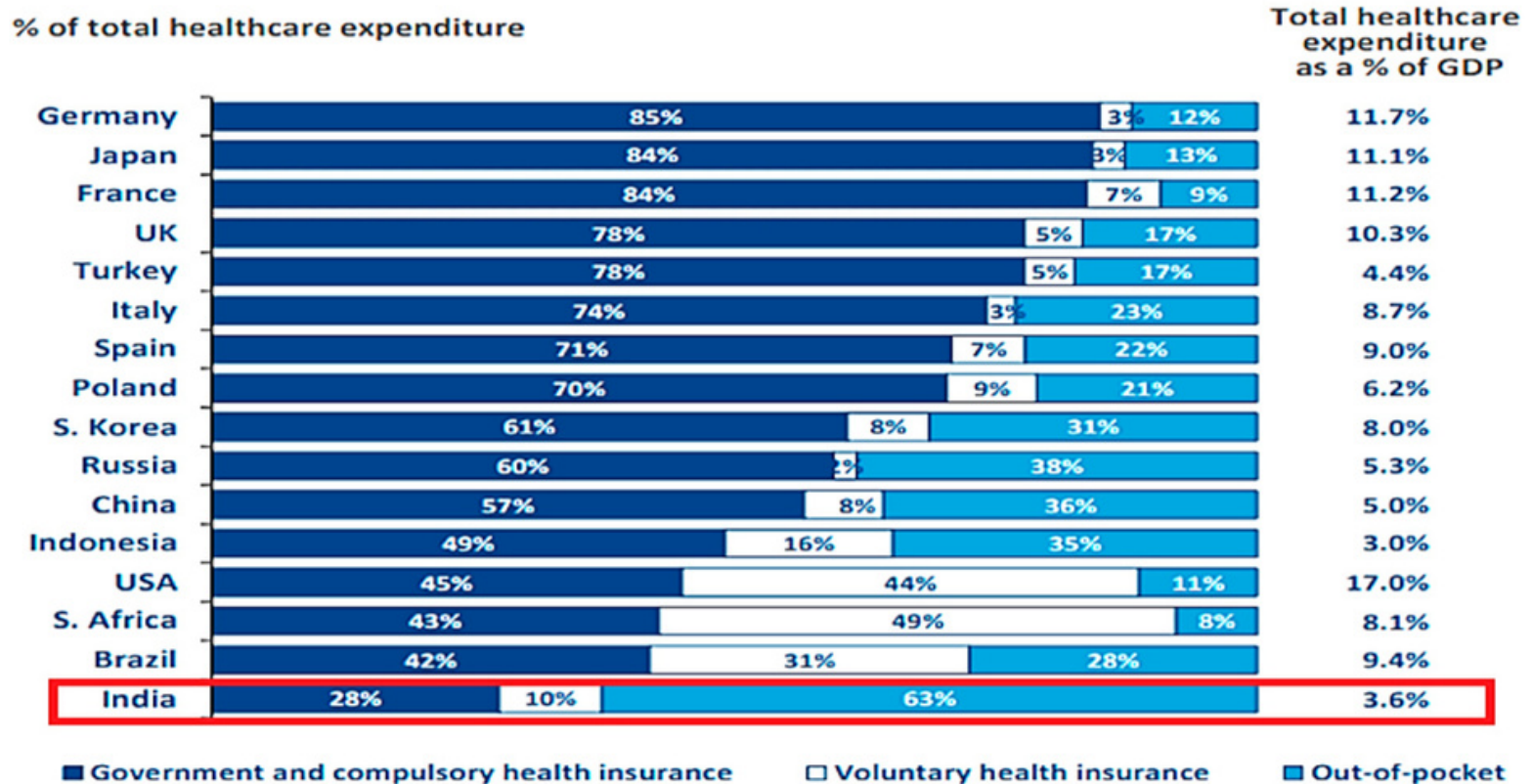


Source: Household Health Expenditures in India (2013-14), December 2016, Ministry of Health and Family Welfare; PRS.

OOPE in India

- The mean out-of-pocket expenditure for India is estimated to be **14,660 INR**. It was higher (**21,564 INR**) for children less than a year old.
- Among the states, Haryana spent more (**27,071 INR**) on the mean OOPE on hospitalized care. This was followed by Goa (**26,423 INR**), Telangana (**24,088 INR**), Punjab (**22,249 INR**), and Lakshadweep (**22,168 INR**).
- However, some states and union territories such as the Andaman and Nicobar Islands (**1,488 INR**), Tripura (**3868 INR**), and Meghalaya (**4,091 INR**) spent less as compared to the ones mentioned above.
- On the other hand, due to high OOPE, nearly **39%** of the households in Tamil Nadu were heavily burdened financially.

Out-Of-Pocket Expenditures (OOPE)



Source: World Bank and OECD databases (March 2021) – Centers for Medicare & Medicaid Services (March 2021) – Smart Pharma Consulting analyses

Out-Of-Pocket Expenditures (OOPE)

- High OOPE is a major barrier to **quality healthcare services and access to appropriate and affordable medicine.**
- Over-reliance on direct payments when people need care is a key barrier in achieving **universal health coverage (UHC).**

Sustainable Development Goals (SDG)

SDG 3 - GOOD HEALTH

Achieve Universal Health Coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all.



“India’s health sector is characterised by low government expenditure on health, high out-of-pocket expenditure (OOPE), and low financial protection for adverse health events.”

– **NITI AYO**G

“High OOPE on health is impoverishing some 55 million Indians annually, with over 17% households incurring catastrophic levels of health expenditures every year.”

– **WHO**

Govt steps to reduce OOPE

Govt steps to reduce OOPE

FREE MEDICINE SCHEME

JAN AUSHADI SCHAME

INSURANCE SCHEMES

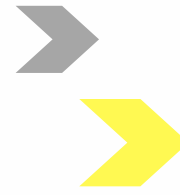
NPPA

GENERIC DRUGS

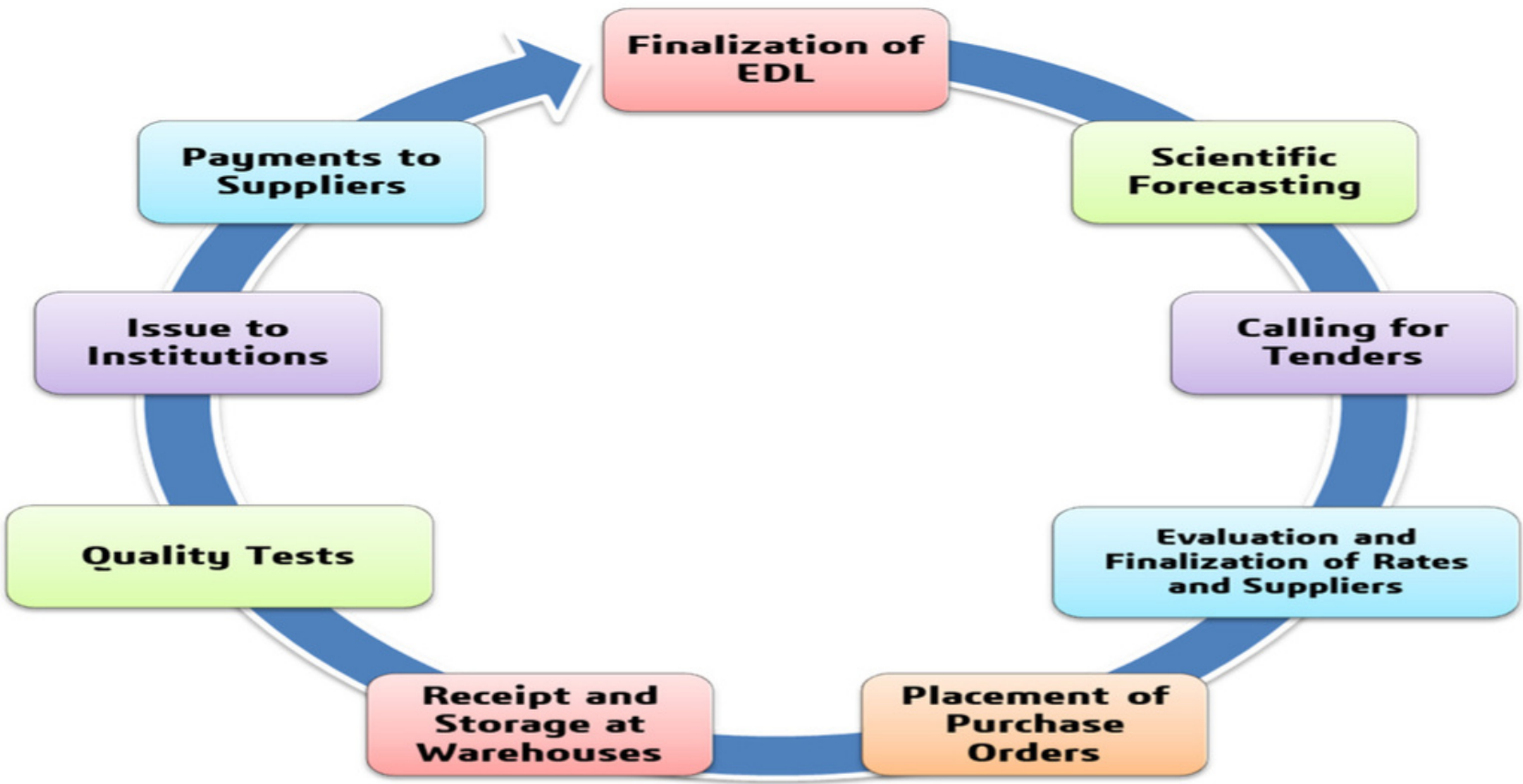
COMPULSORY LICENSING

GOVT FREE MEDICINE SCHEME

- Through Medical Supply Corporations.
- Local Purchase.



Stages of Procurement Process - Medical Supply Corporations



Quality Tests - Medical Supply Corporations

Quality With No Compromise

Samples from Warehouses within 3 days

Eliminating Common Batch at HO

Supplier identification Removed and Separate code given

Sent to empanelled Laboratories

Receipt of Results

If failed, samples are sent to Government Analyst for reconfirmation.

**If Failed
Return to
Supplier**

**If Passed
Distributed to
Institutions**

GOVT FREE MEDICINE SCHEME

Pros:

- Govt free medicine scheme provides timely, reliable and affordable access to necessary medicines for citizens.
- The aim of the scheme is to meet medication and related service needs, so that both optimal health outcomes and economic objectives of the citizens are achieved.

Cons:

- Barriers of access.
- Poor quality medicine – Misconception.
- Availability of limited number of drugs.

JAN AUSHADI SCHEME (PMBJP)

- Jan Aushadi scheme (PMBJP) was launched by the department of pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India in November, 2008 with an objective of making quality medicines available at affordable prices (Generic Medicines) to all.
- Under this scheme, dedicated outlets known as Janaushadi Kendras are functional across the country.
- Product basket of PMBJP comprises 1759 drugs and 280 surgical items.

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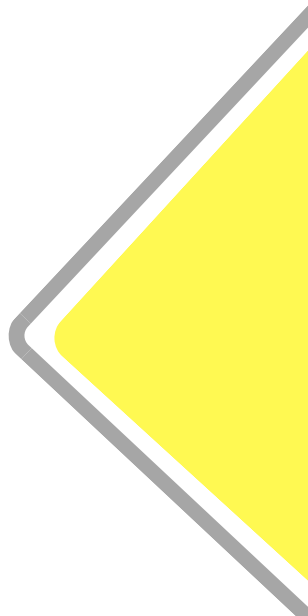
JAN AUSHADI SCHEME (PMBJP)

Pros:

- It ensures access to quality medicines for all sections of the population especially the poor and the deprived ones.
- It creates awareness about generic medicines through education and publicity.
- It generates employment in opening PMBJP Kendra.
- It provides savings on medicines.

Cons:

- Limited number of drugs available.
- Limited number of outlets available.
- No benefit when having prescription of costly branded medicines.



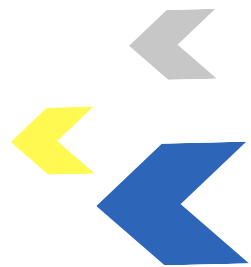
GOVERNMENT HEALTH INSURANCE SCHEMES IN INDIA

- The intention behind the Government Health Insurance Scheme financing system is to ensure that all the citizens have equal access to the same level of healthcare.
- One of the Central government scheme, Ayushman Bharat, which is a flagship scheme of Government of India, was launched as recommended by the National Health Policy 2017, to achieve the vision of Universal Health Coverage (UHC).
- This initiative has been designed to meet Sustainable Development Goals (SDGs) and its underlining commitment, which is to "leave no one behind."
- There are many other public health insurance schemes, some of them are even provided by state governments.



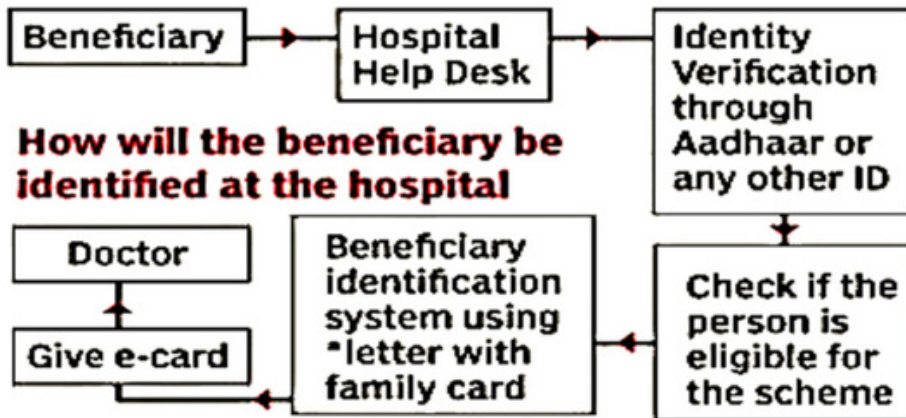
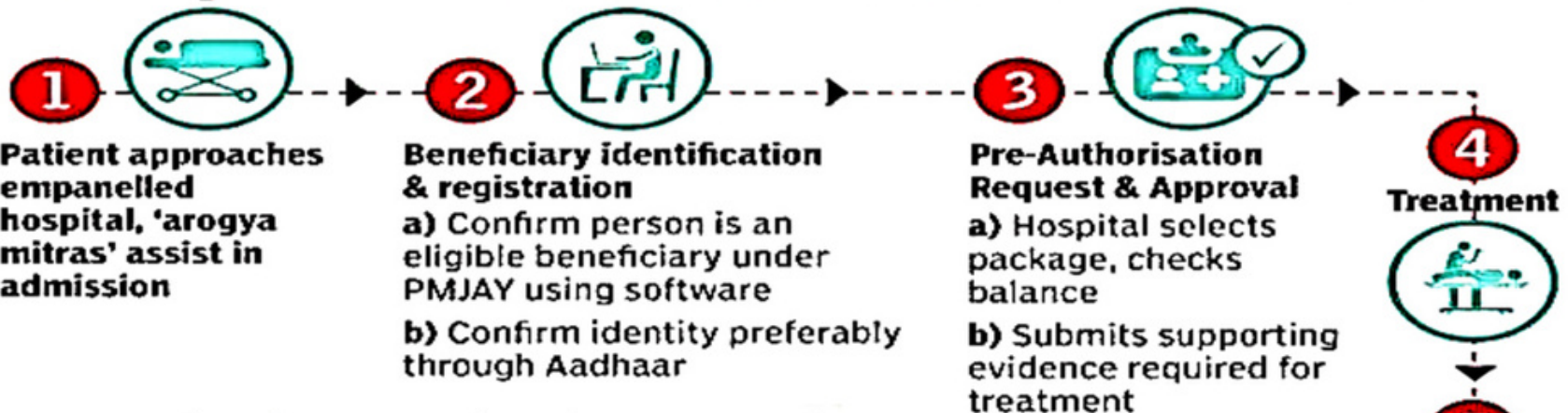
GOVERNMENT HEALTH INSURANCE SCHEMES IN INDIA

- Pradhan Mantri Jan Arogya Yojana under Ayushman Bharat
- Awaz Health Insurance Scheme
- Bhamashah Swasthya Bima Yojana
- Chief Minister's Comprehensive Insurance Scheme
- Aam Aadmi Bima Yojana
- Central Government Health Scheme
- Karunya Health Scheme
- Employees' State Insurance Scheme
- Pradhan Mantri Suraksha Bima Yojana
- Mahatma Jyotiba Phule Jan Arogya Yojana etc



INSURANCE SCHEMES

How a patient can access care under PMJAY



*PM's letter welcoming eligible beneficiaries and identifying family members

GOVERNMENT HEALTH INSURANCE SCHEMES IN INDIA

Pros:

- Lower overall health care costs.
- Removing health-related barriers.
- Promoting equality.
- Stimulating the economy.
- Improving social security.

Cons:


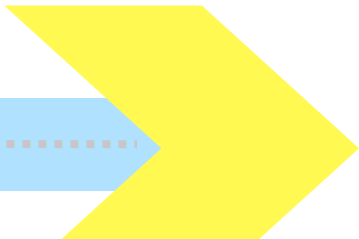
- Less Financial Incentives (Without Co-Payment, people may overuse emergency rooms and doctors).
- Long wait times.
- Decreased quality of care.
- Potential for corruption.

NATIONAL PHARMACEUTICAL PRICING AUTHORITY (NPPA)

- The **NPPA** was set up in 1997 to fix/revise prices of controlled bulk drugs and formulations and to enforce price and availability of the medicines in the country, under the **Drugs Prices Control Order (DPCO)**, 1995-2013.
- The prices of all medicines covered by the **National List of Essential Medicines of India (NLEM)** are regulated. The **NLEM** has a list of scheduled drugs used to treat fever, heart disease, hypertension, anemia etc. as well as commonly used medicines such as paracetamol and azithromycin.

FUNCTIONS OF NPPA



- Under **Essential Commodities Act (ECA)**, Government had issued **Drug Price Control Order**.
 - **NPPA** enforce this Drug Price Control Order.
 - It monitors **Drugs Production, Availability, Import-export Database**.
 - Tries to **prevent** shortage of drugs.
 - Advices Government on **drug policy**.
- 
- 

EFFECT OF DRUG PRICE CONTROL ORDER (DPCO)

- **September 2014:** Government revokes that Paragraph 19 from **Drug Price Control Order**.
- Therefore, **NPPA** automatically lost power to control prices of those 108 drugs which are not in the **NLEM**-list.

Drug	Price Before	After Sep'14
Glivec (Novartis)	8500	1 lakh
Veenat (NATCO)	8500	11,500
Plavix	147	1,615

NATIONAL PHARMACEUTICAL PRICING AUTHORITY (NPPA)

- In the year 2022, NPPA released new NLEM list and **20% price** reduction was enforced on NLEM list of drugs.
 - The price of NLEM list of drugs **should not be over the NPPA cap price**, and it is monitored by NPPA.
 - Also, NPPA regulates the price of Non-NLEM list of drugs from not increased by 10% within a calendar year.
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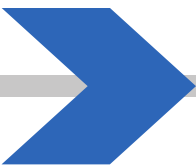
NATIONAL PHARMACEUTICAL PRICING AUTHORITY (NPPA)

Pros:

- Pharma companies could not impose abnormal high price.
- Avoiding monopoly like situations.
- Allowing the government to control the costs.
- Price controls will lead consumers to expect drugs to remain at affordable prices in the future.

Cons:

- NPPA covers only 18% of total drugs (latest NLEM List).
- Too low prices force the pharma companies out of the market.
- The availability of products may be affected.
- Difficulty to judge the efficiency of patent protected drugs.



GENERIC DRUGS

- Generic drugs have secured place in the market due to the “cost factor” and branded drugs due to the “trust factor”.
- A generic medicine is same as a brand name drug in dosage, safety, effectiveness, strength, stability, and quality.
- Most national governments have been encouraging the use of generic medicines worldwide and many healthcare systems have policies of substituting expensive branded original medications with generic medications.
- To make generic medicines available to the population, the Department of Pharmaceuticals, Government of India launched the Jan Aushadi scheme in 2008.

BRANDED VS GENERIC DRUGS

**Brand-
Name**

vs

**Generic
Drugs**



No Difference

Active Ingredient

No Difference

Higher in Cost

Price

Lower in Cost

**Covered if no Generic
Form Exists**

**Insurance
Coverage**

**Normally Always
Covered**

**Tested and Approved
by the FDA**

**Inactive
Ingredients**

**May Differ - But
Proven to be
Acceptable by the FDA**

No Difference

Strength/Dosage

No Difference

**Drugs are Standard in
Size, Color,
Packaging, etc.**

Appearance/Look

**Packaging and the
Drug Itself may Look
Different**

BRANDED VS GENERIC DRUGS

Drug Name	Dosage	Pack	Average Market Price Of Branded Medicine	Generic Medicine At Jan Aushadi Kendra
Ciprofloxacin Tablets	250mg	10	55.00	11.10
Ciprofloxacin Tablets	500mg	10	97.00	21.50
Diclofenac SR Tablets	100mg	10	51.91	3.35
Cetirizine Tablets	10mg	10	37.50	2.75
Paracetamol Tablets	500mg	10	13.56	2.45
Nimusulide Tablets	100mg	10	38.66	2.70
Cough Syrup	110 ml	Bottle	33.00	13.30

GENERIC DRUGS

Pros:

- Lower Individual Costs.
- Lower Industry Costs.
- Bioequivalent and FDA Approved.
- Easy to find the generic alternative.

Cons:

- History of Quality issues.
- Varying inactive Ingredients, may result in some patients with sensitivities or allergies.
- Unavailability.
- No benefit without enforcing Generic prescribing.

COMPULSORY LICENSING

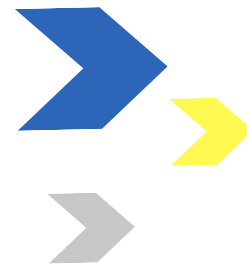
Compulsory licensing is when a government allows someone else to produce a patented product or process without the consent of the patent owner or plans to use the patent-protected invention itself.



COMPULSORY LICENSING



- In India, compulsory license may be issued by the **Controller General of Patents, Designs and Trade Marks under section 84(1) of The Patents Act, 1970**, if:
 - The reasonable requirements of the public with respect to the patented invention have **not been satisfied**, or,
 - The patented invention is **not available** to the public at a reasonably affordable price, or,
 - The patented invention is **not worked** in the territory of India.
- In March 2012, India granted its first compulsory license ever to Indian generic drug manufacturer **Natco Pharma for Sorafenib tosylate, a cancer drug patented by Bayer**.



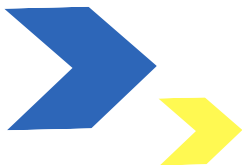
COMPULSORY LICENSING

Pros:

- Compulsory licensing will make the products more accessible to public and it will be beneficial for public welfare.
- Compulsory licensing acts as a remedy to the abuse of IPR.

Cons:

- May deter foreign direct investment in industrial sectors.
- Poor quality management damaging the brand or product reputation may happen from competitors.

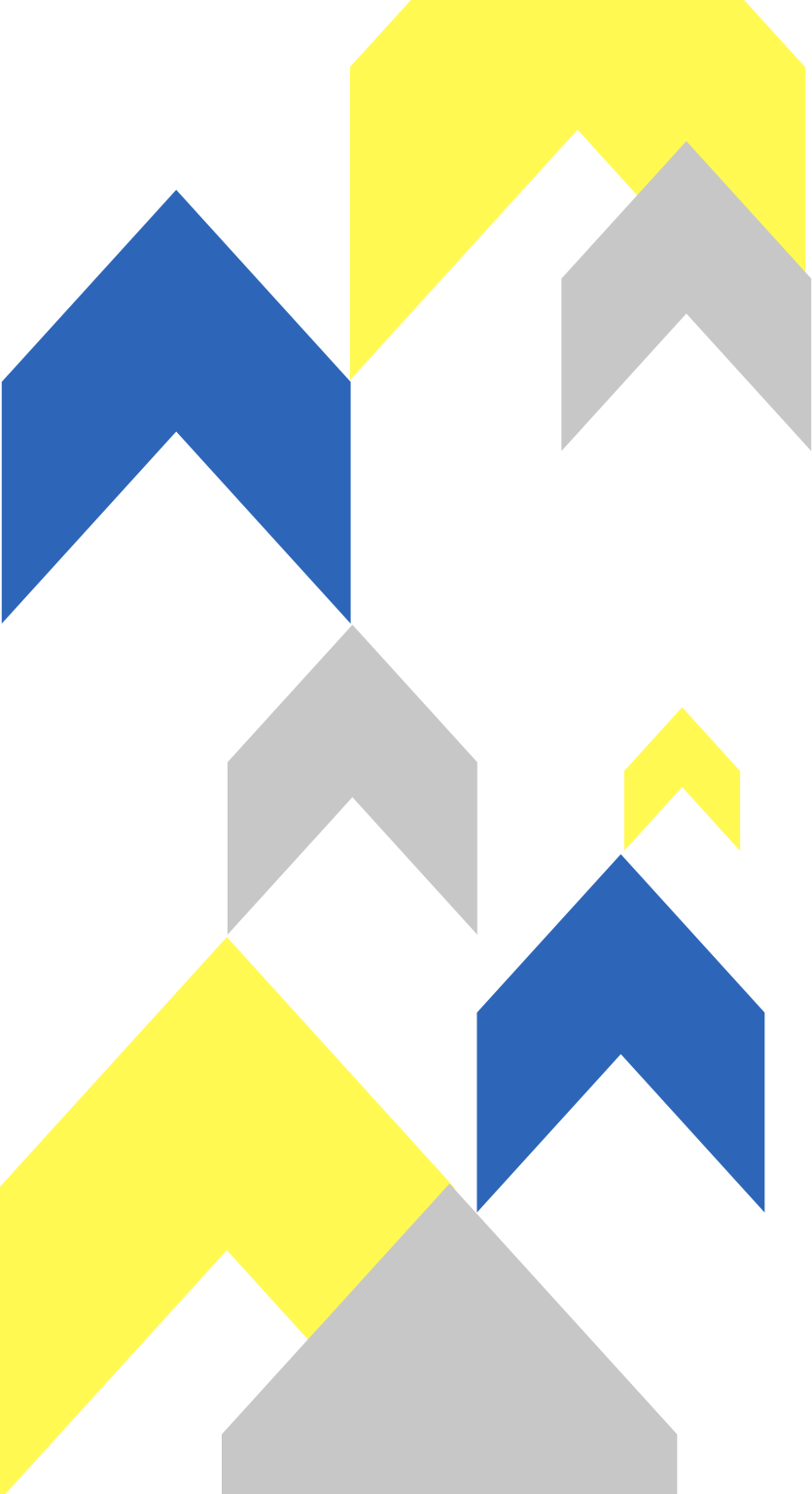


CONCLUSION

- **OOPE** is considered an **key indicator** of the performance of the government's health system.
- Medicines being the **largest component of OOPE**, Government takes many steps in **reducing the OOPE**, irrespective of having PROS & CONS.
- The amount of money spent on **medications and addressing medication-related issues** keeps rising.
- Within the healthcare system, the key issue is the **high occurrence of medication errors and inappropriate prescribing**, which can often contribute to adverse drug events and a huge economic burden with continuing illnesses, many of which are preventable.

CONCLUSION

- There is a huge opportunity for **pharmacists** to have a significant impact on not only reducing healthcare costs but also improving patient outcomes, as they have the competence to **detect, resolve, and prevent medication errors and medication-related problems** and also through **technology and innovation**.
- As pharmacists, we should take responsibility for strengthening the Government's efforts and work with **ethical values with integrity, honesty, discipline, fairness, responsibility and accountability**.



**thank
you!**