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# VALIDATING PHARMACOVIGILANCE SYSTEM IN INDIA

**[1] Ganga Devi. S, [1] Jino Syam J. S, [1] Soorya. S, [2] Dr. Jayachandran Nair C. V**
**[3] Sanitha. M, [4] Dr. Prasobh G. R**
[1]B. Pharm Student, [2] Professor and Head, Department of Pharmacology
[3] Assistant Professor, [4] Principal
Sree Krishna College of Pharmacy and Research Centre, Parassala
Thiruvananthapuram

## ABSTRACT

This study provides an overview of the pharmacovigilance system in India over the last five years. Pharmacovigilance is the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems.

The study focuses on collecting and analyzing adverse drug reactions (ADRs) reported by healthcare professionals, patients, and other stakeholders. Also PvPI collaborations with various stakeholders such as pharmaceutical companies, regulatory authorities.

Over the past five years, India has witnessed a steady increase in the number of ADR reports, indicating improved awareness and reporting.

The validation of the pharmacovigilance system in India over the last five years demonstrates the country's commitment to ensuring the safety and well-being of its population through effective monitoring and surveillance of drug safety. Continued efforts in strengthening the system, expanding reporting networks, and promoting awareness will further enhance India's pharmacovigilance capabilities.

**KEYWORDS**

Pharmacovigilance programme of India (PvPI), Adverse Drug Reaction (ADR), ADR Monitoring Center (AMC), Marketing Authorization Holders (MAHs), Individual Case Safety Reports (ICSRs)

## 1. INTRODUCTION

Pharmacovigilance (PV) is a pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects, particularly long-term and short-term adverse effects of medicines.[1] Adverse drug reaction (ADR) are highly variable in individuals and are major limiting factors in drug therapy and development.

The purpose of Pharmacovigilance programme of India (PvPI) is to collect, collate and analyze this reported data to arrive at an inference to recommend regulatory interventions for safeguarding the health of the Indian population by ensuring that the benefit outweighs the risks associated with the use of medicines. Under PvPI, the Adverse drug reaction monitoring center (AMC) plays a vital role in the collection and follow-up of ADRs reports from healthcare professionals. To monitor ADRs, AMCs have been set up all over India, which send reports to National Coordination Centre-PvPI(NCC-PvPI), located at Indian Pharmacopoeia Commission (IPC), Ghaziabad. Initially, there were 22 AMCs in the country. At present (up to June 2023) there are 701 AMCs under this programme.[2]

Under-reporting (UR) of adverse drug reactions is widespread and a daunting challenge in Pharmacovigilance. This is because primarily most countries, including India, follow the spontaneous or voluntary system of ADR reporting. There are patient-related reasons for UR like failure to recognize ADR or inability to link the ADR with a drug. The commonest doctor-related reasons are the feeling of guilt, fear of litigation, ignorance, lethargy, inadequate risk perception about newly marketed drugs, insufficient training to identify ADRs, and lack of awareness about PV program.[3]

## 1.1 PHARMACOVIGILANCE PROGRAMME OF INDIA

Pharmacovigilance programme of India (PvPI) was operationalized in July 2010 by Ministry of Health and Family Welfare (MoHFW), Government of India with a mission to reduce the risks associated with the use of medicines in the Indian population. The AIMS, New Delhi was established as National Coordinating Centre for PvPI. Later on, Ministry of Health and Family Welfare (MoHFW), Government of India on 15$^{th}$ April 2011, recasted this programme and shifted the National Coordination Centre from AIIMS, New Delhi to Indian Pharmacopoeia Commission(IPC) Ghaziabad.[4]

## 1.3 EVOLUTION OF PHARMACOVIGILANCE IN INDIA

In early 1980 attempts were made in India towards ADR monitoring. The Drugs Controller General of India established 5 centers in 1982 for nationwide monitoring of ADRs. In 1998, India joined World Health Organization (WHO) International drug monitoring programme. At that time, National Coordination Center for Pharmacovigilance was the department of pharmacology, All India Institute of Medical Sciences (AIIMS), New Delhi.[4]

| YEAR | WHAT HAPPENED |
|---|---|
| 1986 | AMC system for India proposed with 12 regional centre |
| 1997 | India joined WHO-ADR reporting programme |
| 2004 | The National Pharmacovigilance Programme (NPP) officially inaugurated by Central Health Minister of New Delhi |
| 2010 | PvPI initiated with AIIMS, New Delhi as National Coordination Centre for monitoring ADRs |
| 2011 | NCC shifted from AIIMs, New Delhi to IPC, Ghaziabad |

| | |
|---|---|
| 2013 | Jointed with AEFI and National Tuberculosis control Programme |
| 2014 | Collaborated with National AIDS Control Organization |
| 2016 | Collaborated with ICMR Institutions, Indian Medical Association & National Vector-Bone Disease Control Programme |
| 2017 | Jointed with National Accredited Board of Hospitals |
| 2018 | WHO- South- East Asia Regional Office, Collaborating centre for PV in Public Health Programmes&Regulatory Services |

Table 1: Evolution of Pharmacovigilance Programme in India[4]

## 2. AIM AND OBJECTIVE

### 2.1 AIM

To validate Pharmacovigilance Programme in India for the last five years

### 2.2 OBJECTIVE

- Collecting the last five-year Adverse Drug Reaction reporting of all states in India. The data were collected from official website of IPC-PvPI.
- Collecting annual, monthly reports of PvPI in the last five years from various AMCs, Market Authorization Holders(MAHs), Non-AMC and other organizations from the financial year 2017-18 to 2021-22.
- Cumulative data preparation for Individual Case Safety Reporting in the last five years.

## 3. MATERIALS AND METHOD

A review was done through the National Coordination Centre-PvPI (NCC-PvPI) published data sources such as PvPI newsletters, Performance reports of Pharmacovigilance Programme of India, to assess the findings and regulatory status of medicines, ADR reporting in India as well as globally. In this study, ADRs reported between 2017-2022 were analyzed and the impact of PvPI was evaluated

The ADR reporting status from ADR Monitoring Centre, Non-AMCs, Marketing Authorazation Holder (MAHs), National Programmes of the last five annual year was obtained from the Performance report of Pharmacovigilance Programme of India. The study was undertaken to evaluate the extent and reasons of under reporting of ADRs in the AMC and also to evaluate the knowledge and awareness about PvPI. In this study, there are lack of availability of information for April, October, November, December in 2017 and December in 2021.

# 4. REVIEW: PvPI DATA BASE

ADR reporting status in India were collected from the Data available on the website of IPC- PvPI

### 4.1 DURING THE PERIOD 2017-2018

The PvPI is responsible for collection, assessment and detection of risks associated with the use of medicines by Indians. The ADRs collected by the ADR monitoring centers and MAHs are communicated to NCC-PvPI in the form of an Individual Case Safety Report (ICSR). Annual database accounts for more than 50, 000 ICSRs each year.[5] During the year 2017-18 collected ICSRs information were Tabulated (Table 2).

| YEAR | ICSR |
|---|---|
| 2017 | 71586 |
| 2018 | 18612 |

Table 2: Annual ICSRs report 2017-18

4.1.1 REPORTER WISE CONTRIBUTION 2017-18

NCC-PvPI receives ICSRs from various stakeholders such as physicians, pharmacists, other Healthcare professionals (HCPs), consumers, etc. Spontaneous ADR reports from physicians (60%) continue to be the major source of reports received, followed by other HCPs (17%), pharmacist (12%) and consumers/non HCPs(11%) in the financial year 2017-2018.[5] Figure 1 shows the representation.

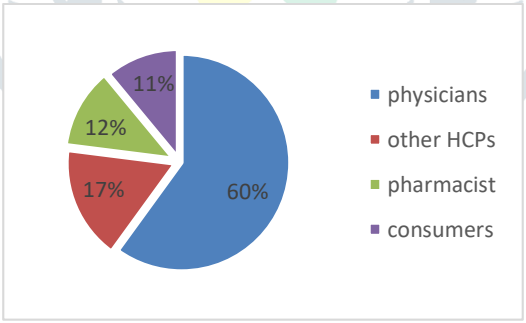


Fig 1: Reporter wise contribution 2017-18

4.1.2 ADR REPORTING THROUGH HELPLINE 2017-18

Following the initiation of the toll-free Helpline ( 1800-180-3024) on October 11, 2013, a steady increase in reporting through this method has been observed. The increase follows efforts by Pharmacovigilance associates posted at AMCs. The Helpline number has also been embossed on In Patient Department (IPD) and Out Patient Department(OPD) prescription slips/cards. Calls are primarily responded to in English and Hindi on all working days

between 09:00 AM and 05:30 PM.[5] Analysis of the ADRs received through PvPI helpline reports during index period shows that 238 cases were reported( Fig.2).

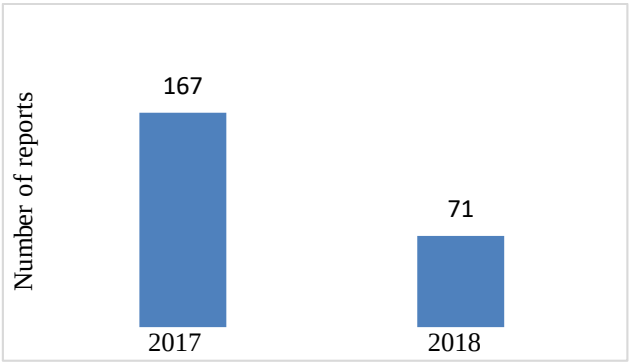


Fig 2: ADR reporting through Helpline 2017-18

**INTEGRATION OF PvPI WITH NATIONAL TUBERCULOSIS CONTROL PROGRAM(NTCP) AND AIDS CONTROL ORGANIZATION**

The cornerstones of Pharmacovigilance apply equally to TB as to many other diseases amenable to medication. Events linked to medication, particularly novel medicines or new combinations; thereof need to be recognized in a timely fashion if the evens are to provide benefit to the individual patient and the public. Appropriate measures need to be put in place to ensure that harm is reduced and symptoms relieved. Healthcare workers need to be informed and trained about the methodology and routes for reporting ADRs. Keeping this in view and to improve patient care and safety concerning the use of anti-tubercular drugs, NTCP formally entered into collaboration with PvPI on October 11, 2013 and renamed to 'National Tuberculosis Elimination Program(NTEP)' on 1st January 2020

To ensure the safety of antiretroviral (ARV) medicines used in the program, IPC, NCC-PvPI, and National AIDS Control Organization formally agreed to collaborate on September 15, 2014, for setting up systems and processes for reporting, analyzing, and monitoring of ADRs due to ARV medicines used in NACP. Currently, PvPI has 20 Anti Retroviral Therapy (ART) and 21 NTEP across the country.[6]

4.1.3 CONTRIBUTION BY NATIONAL HEALTH PROGRAMMES 2017-18

During the index period (April 2017-March18), NCC-PvPI received 1230 cases from NTCP and 476 cases from ART.

4.1.4 ADR REPORTING BY MAHs 2017-18

Marketing Authorization Holders (MAHs) have a crucial role in reporting ADRs to PvPI. The recent amendment to the Drugs and Cosmetics Rules, 1945, has made Pharmacovigilance a legal obligation for MAHs. This has paved the way for collecting product-specific safety data, aimed at optimizing drug-safety and ensuring healthcare for Indian population.[7]

During the index period 2017-18, 74 MAHs were contributed to PvPI. Figure 3 shows the representation.

MAHs-74

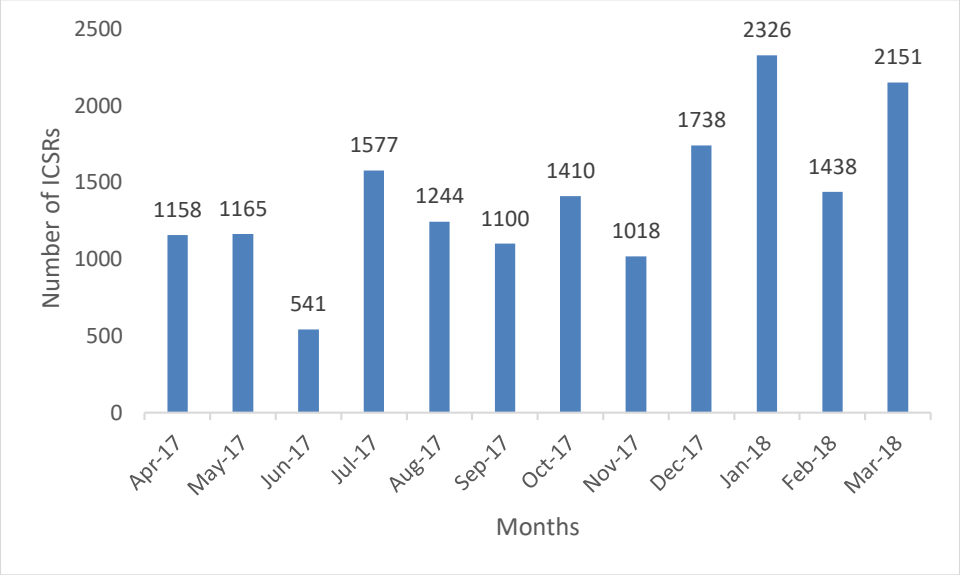


Fig 3: ADR Reporting by MAHs 2017-18

## 4.2 DURING THE PERIOD 2018-2019

The 2018-19 annual database accounts 64,441 ICSRs for this index period. Figure 4 shows the representation.


Fig 4: Annual ICSRs Report 2018-19

4.2.1 ADR REPORTING THROUGH HELPLINE 2018-19

Analysis of the ADRs received through PvPI helpline reports during index period shows that 173 cases were reported( Fig 5).

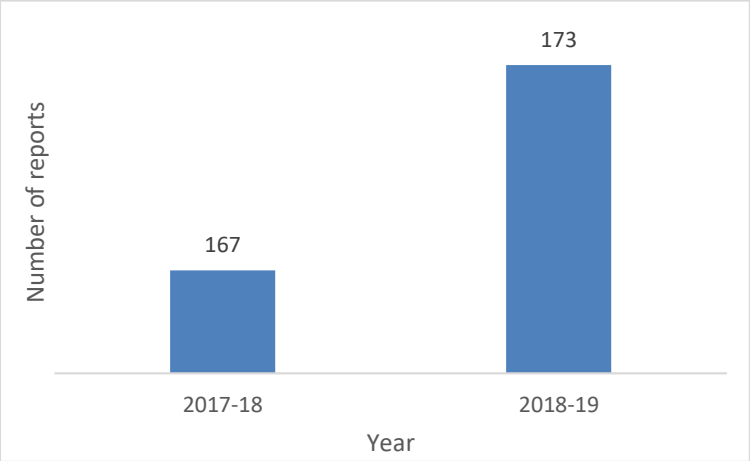


Fig 5: ADR reporting through Helpline 2018-19

4.2.2 REPORTER-WISE CONTRIBUTION 2018-19

NCC-PvPI receives ICSRs from various stakeholders such as physicians, pharmacists, other healthcare professionals(HCPs), consumers, etc. Spontaneous ADR reports from physician (54%) continue to be the major source of reports received, followed by pharmacist (18%), other HCPs (17%) and consumers (11%) in the financial year 2018-2019.[7] Fig 6 shows the representation.

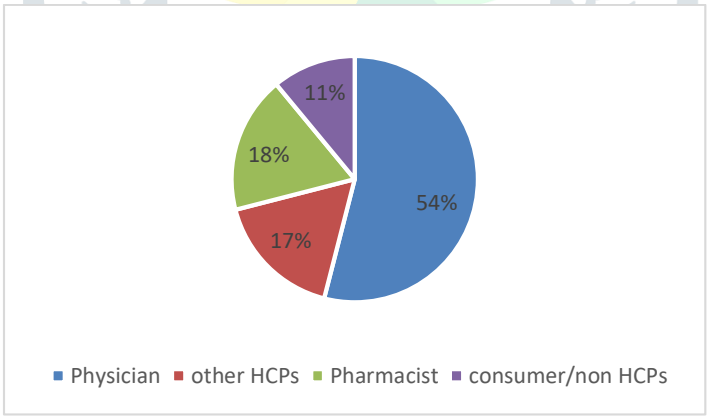


Fig 6: Reporter wise contribution 2018-19

4.2.3 NON-AMCs REPORTING 2018-19

During this index period, as many as 2, 006 ADRs were reported via non AMCs, month-wise distribution of these ADRs is depicted in Fig 7.

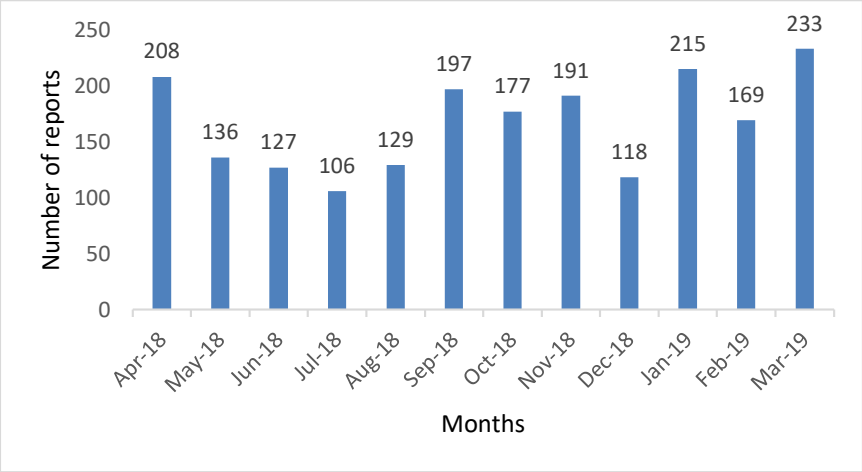


Fig 7: Non-AMC Reporting 2018-19

4.2.4 CONTRIBUTION BY NATIONAL HEALTH PROGRAMMES 2018-19

During the index period (April 2018-March19), NCC-PvPI received 1367 cases from NTCP and 375 cases from ART.

4.2.5 ADR REPORTING BY MAHs 2018-19

Marketing Authorization Holders (MAHs) have played a crucial role in reporting ADRs to PvPI. During the index period 2018-19, 90 MAHs were contributed to PvPI. Figure 8 shows the representation in each month.

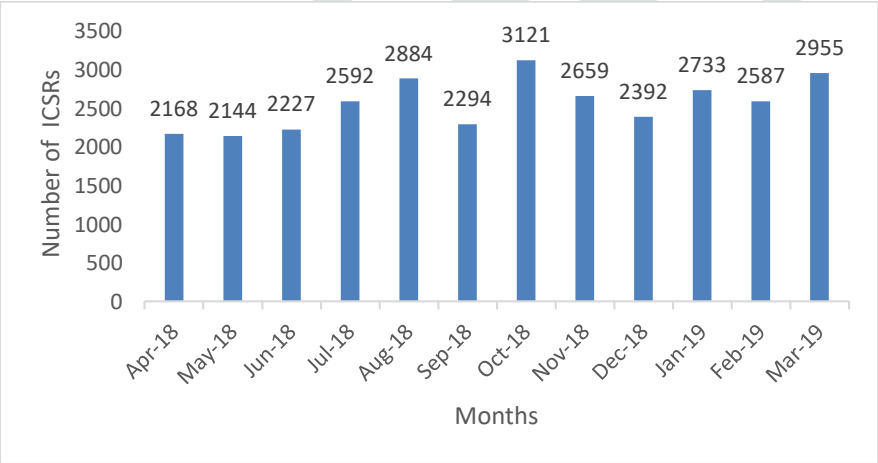


Fig 8: ADR reporting by MAHs 2018-19

### 4.3 DURING THE PERIOD 2019-2020

The 2019-20 annual database accounts 63,384 ICSRs for the index period. Figure 9 shows the representation.

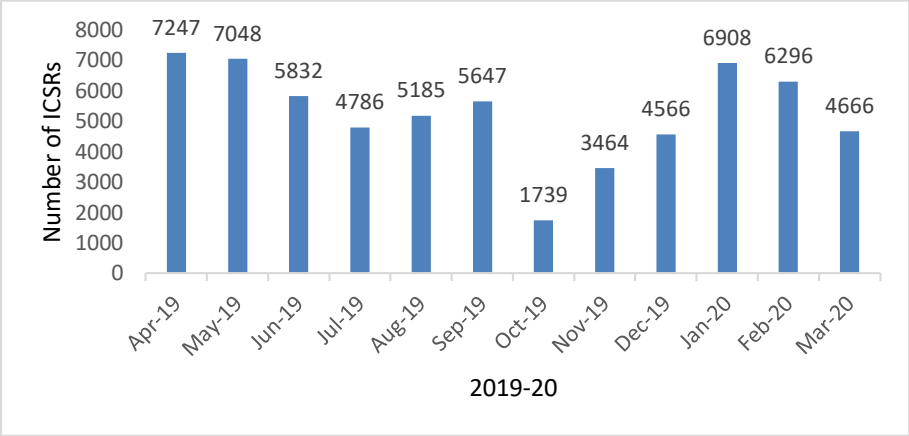


Fig 9: Annual ICSRs Report 2019-20

#### 4.3.1 REPORTER WISE CONTRIBUTION 2019-20

Reporter-wise distribution of ICSRs NCC-PvPI receives from Physicians, Pharmacists, Other Healthcare Professionals and Consumers. Spontaneous reports from physicians (51.2%) continued to be the major source of reports received, followed by pharmacists (14.8%), Other HCPs (17.6%) and consumers/non HCPs(21.5%).[8] Representation given in Figure 10.

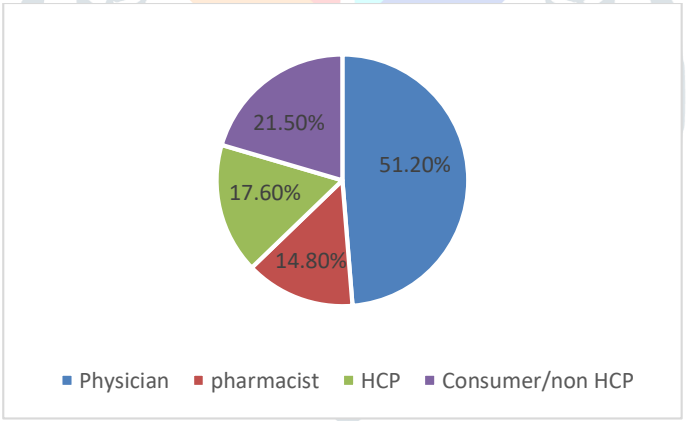


Fig 10:Reporter wise contribution 2019-20

4.3.2 NON-AMCs REPORTING 2019-20

During the index period, 2508 ADRs were reported via non-AMCs, Month-wise distribution of these ADRs is depicted in Figure 11.

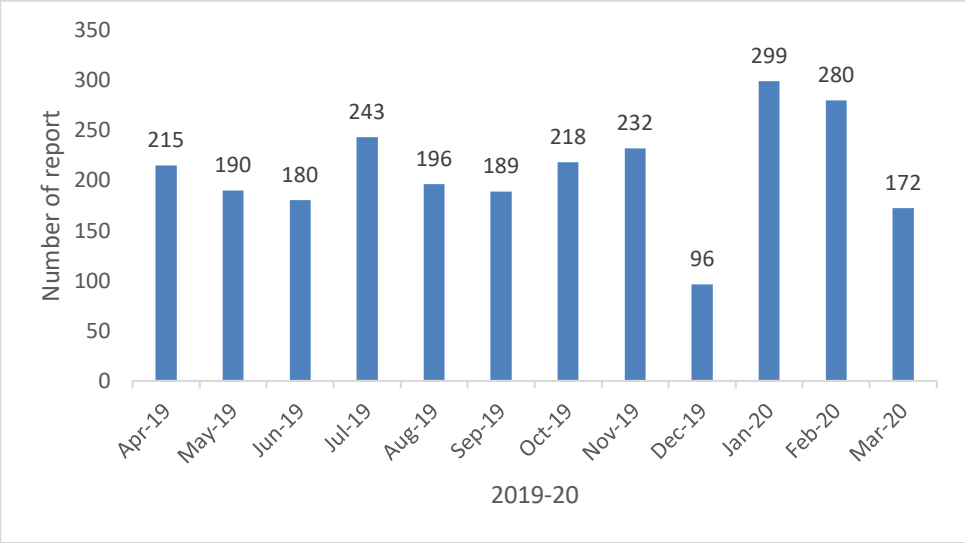


Fig 11: Non-AMC Reporting 2019-20

4.3.3 ADR REPORTING THROUGH HELPLINE 2019-20

ADRs collected through the Helpline were figured in Fig 12.

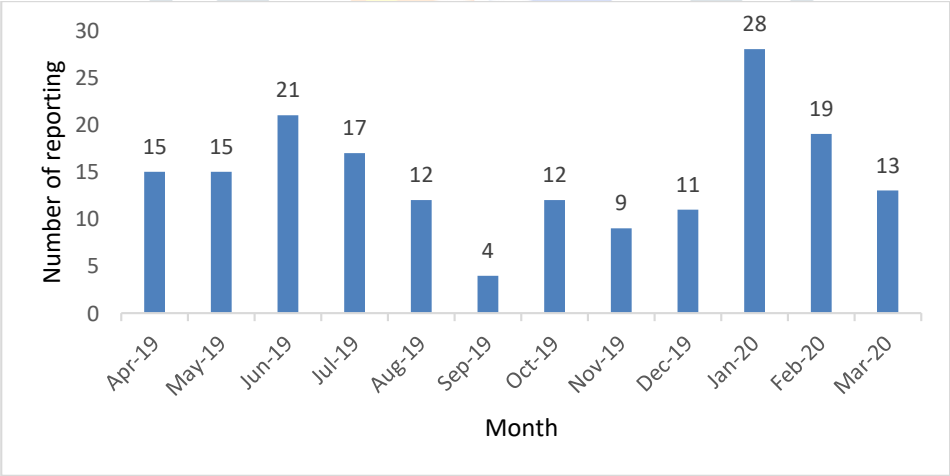


Fig 12: ADR Reporting through Helpline 2019-20

4.3.4 ADR REPORTING THROUGH MOBILE APP 2019-20

Android Mobile App ('ADR PvPI') is a seamless tool developed by PvPI, IPC to provide ease in reporting adverse events. The following graph (Fig 13) illustrates month-wise adverse events reported through the mobile app.

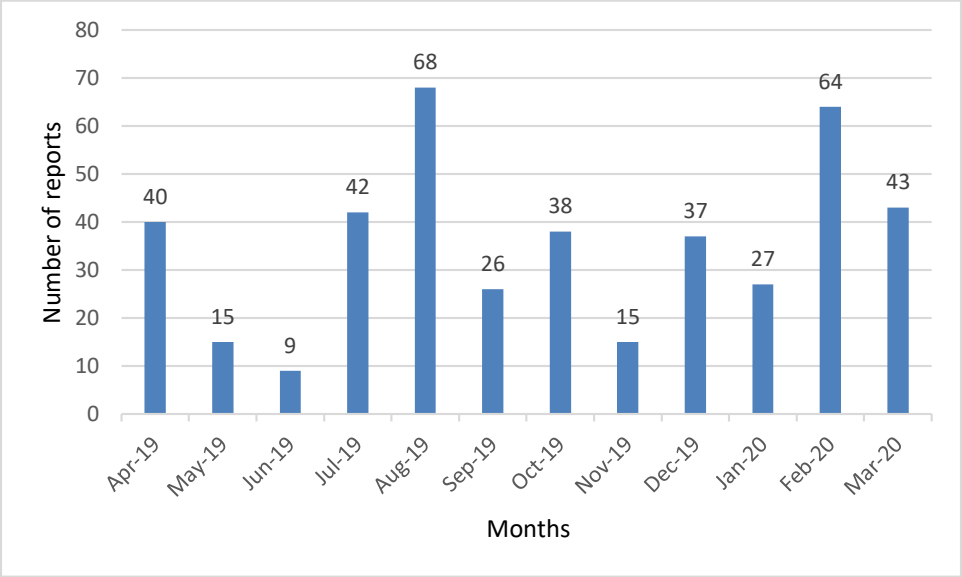


Fig 13: ADR reporting through mobile app 2019-20

4.3.5 CONTRIBUTION BY NATIONAL HEALTH PROGRAMMES 2019-20

During the index period (April 2019-March20), NCC-PvPI received 446 cases from NTEP and 139 cases from ART.

4.3.6 ADR REPORTING BY MAHs 2019-20

During the index period 2019-20, 104 MAHs contributed to PvPI and submitted 35759 ICSRs ( Fig 14).

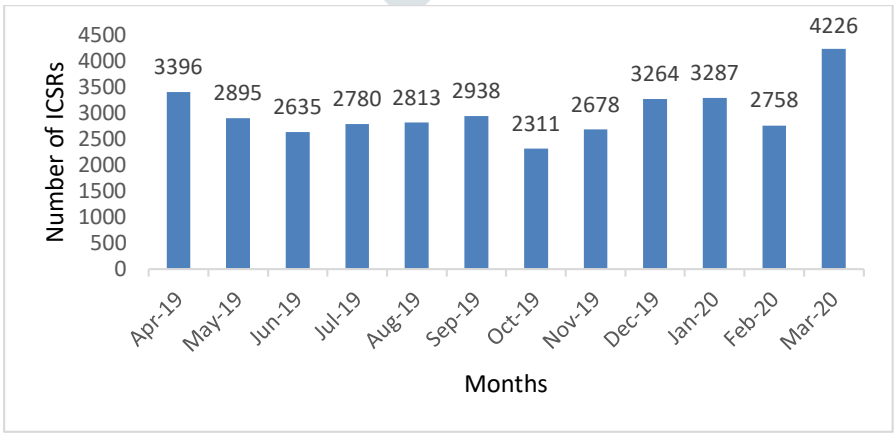


Fig 14: ADR reporting by MAHs 2019-20

## 4.4 DURING THE PERIOD 2020-2021

The annual database accounts for 52, 810 ICSRs for this index period. Figure 15 shows the month-wise representation.

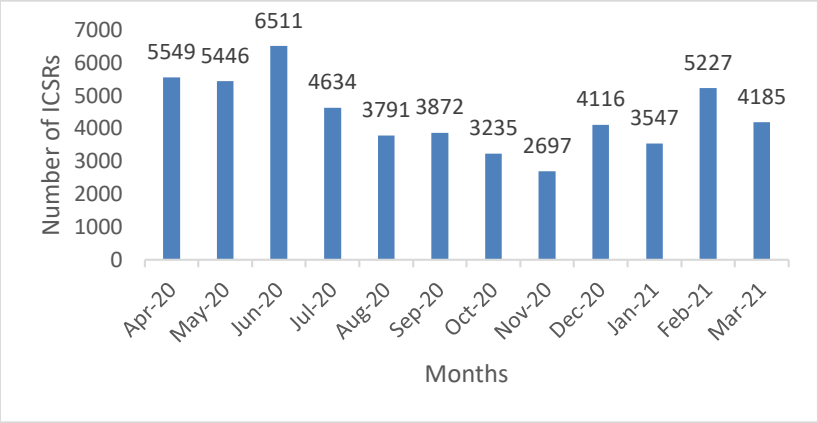


Fig 15: Annual ICSR Report 2020-21

### 4.4.1 REPORTER WISE CONTRIBUTION 2020-21

NCC-PvPI receives ICSRs from stakeholders including Healthcare Professionals (HCPs) such as Physician, Pharmacist, etc. and Consumers. Spontaneous reports from physician (44.10%) continue to be the major source of reports received, followed by consumers/Non-Healthcare professionals (32.50%), Other HCPs (20.50%) and pharmacist (10.5%).[9] Data figured in Fig 16.

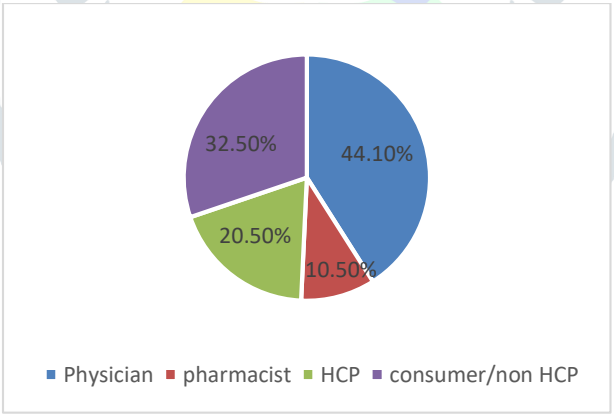


Fig 16: Reporter-wise contribution 2020-21

4.4.2 NON-AMCs REPORTING 2020-21

During the index period 2020-21, as many as 3017 ADRs were reported via non-AMCs, the month-wise distribution of these ADRs were depicted in Fig 17.

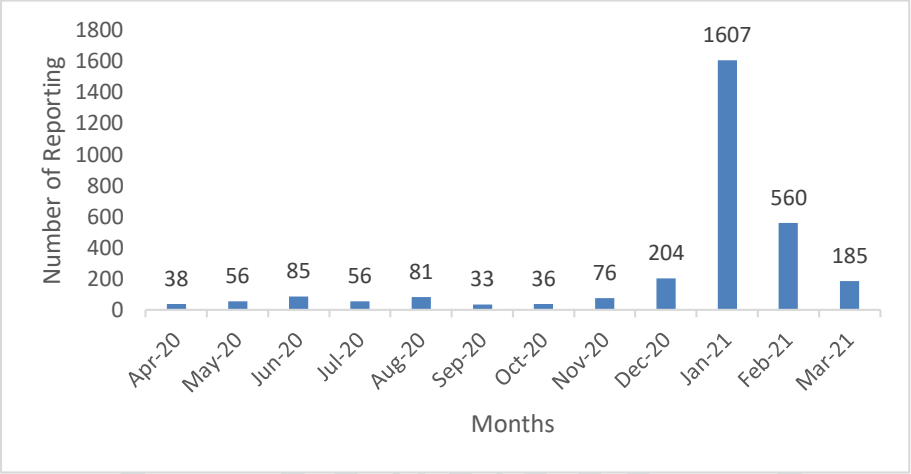


Fig 17: Non-AMCs reporting 2020-21

4.4.3 ADR REPORTING THROUGH HELPLINE 2020-21

Figure 18 shows the month wise ADR reporting through Helpline.

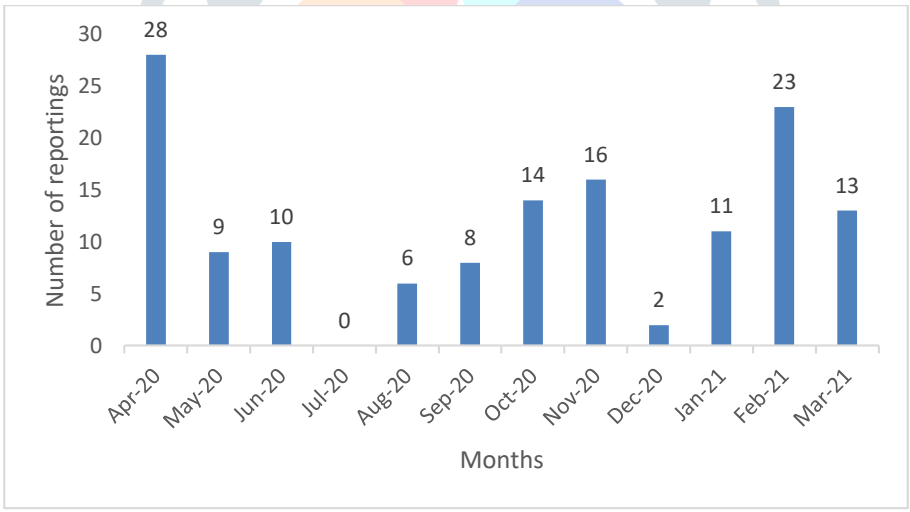


Fig 18: ADR reporting through helpline 2020-21

4.4.4 ADR REPORTING THROUGH MOBILE APP 2020-21

Android mobile app 'ADR PvPI' is a seamless tool developed by PvPI, IPC. The following graph ( Fig 19) shows month-wise adverse events reported by mobile app.

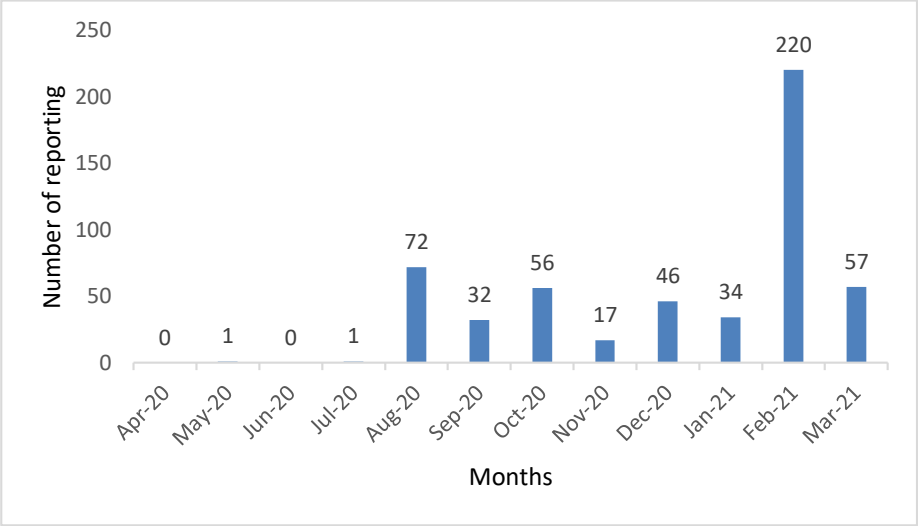


Fig 19: ADR reporting through Helpline 2020-21

4.4.5 CONTRIBUTION BY NATIONAL PROGRAMME 2020-21

During the index period (April 2020-march21), NCC-PvPI received 392 cases from NTEP and 182 cases from ART.

4.4.6 ADR REPORTING BY MAHs 2020-21

During the index period 2020-21, a total of 117 MAHs submitted 44,420 ICSRs. The graphical representation given in Fig 20.

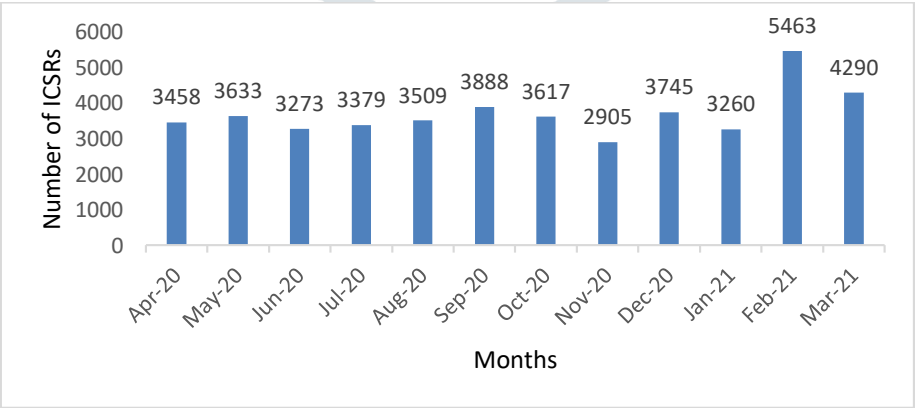


Fig 20: ADR reporting by MAHs 2020-21

## 4.5 DURING THE PERIOD 2021-22

The annual database accounts for 88360 ICSRs for the index period 2021-22. The data presented as a graph ( Fig 21).

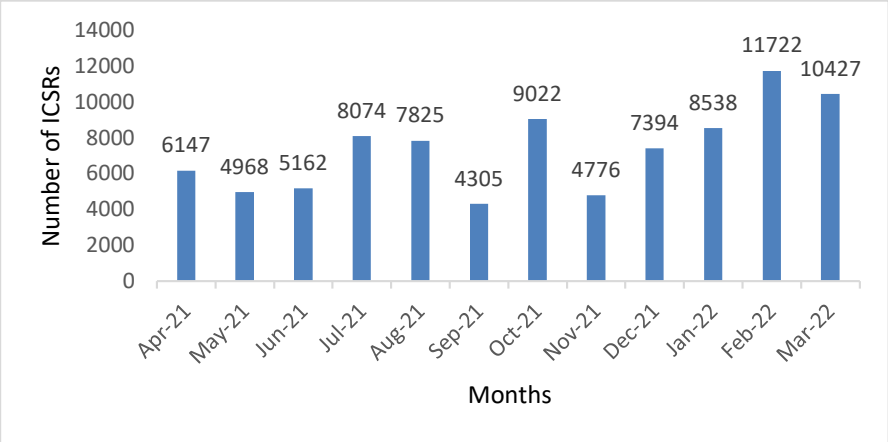


Fig 21: Annual ICSRs report 2021-22

### 4.5.1 REPORTER-WISE CONTRIBUTION 2021-22

The NCC-PvPI has received 36.0% ICSRs from physician, 16.3% from pharmacists, 27.0% from other healthcare professionals, 26.3% from consumers/non-healthcare professionals and 0.01% from lawyers[10].The representation given in Fig 21.

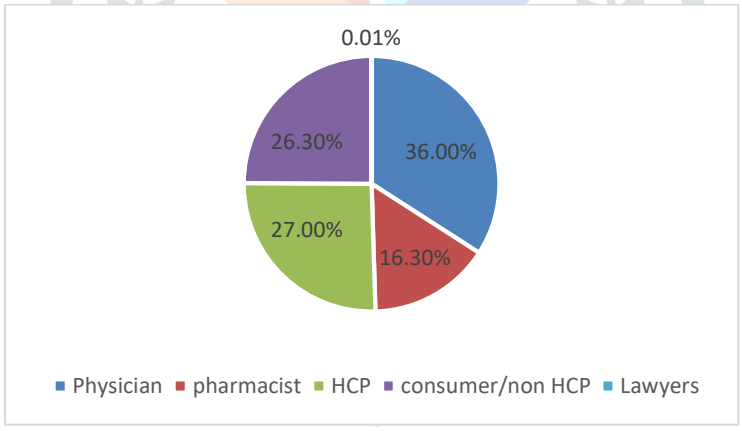


Fig 22: Reporter-wise contribution 2021-22

4.5.2 NON-AMCs REPORTING 2021-22

During the index period, 1061 ADRs were reported via Non-AMCs month-wise distribution of these ADRs are depicted in Fig 23.

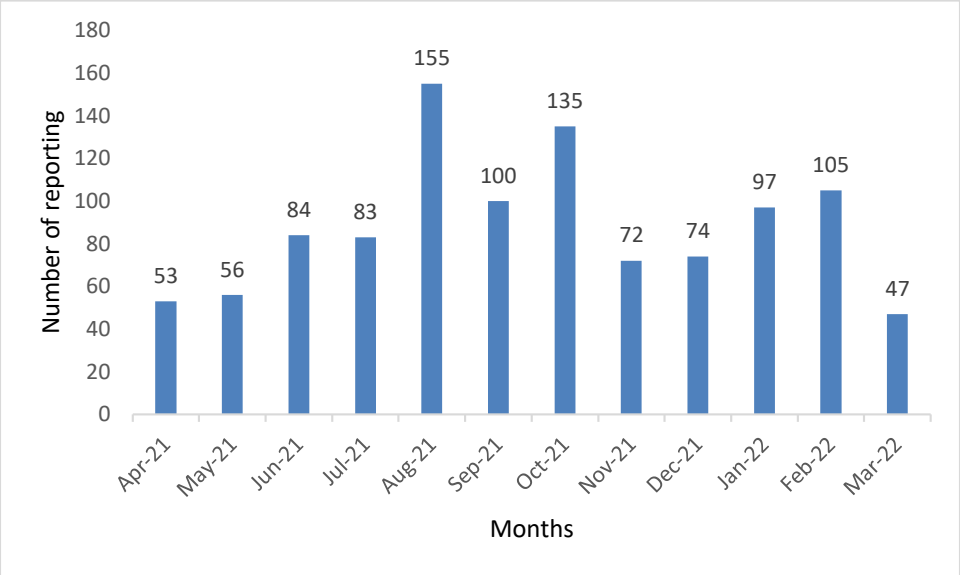


Fig 23: Non-AMCs Reporting 2021-22

4.5.3 ADR REPORTING THROUGH HELPLINE 2021-22

Month-wise reports received during the index period are shown in the graph( Fig 24)

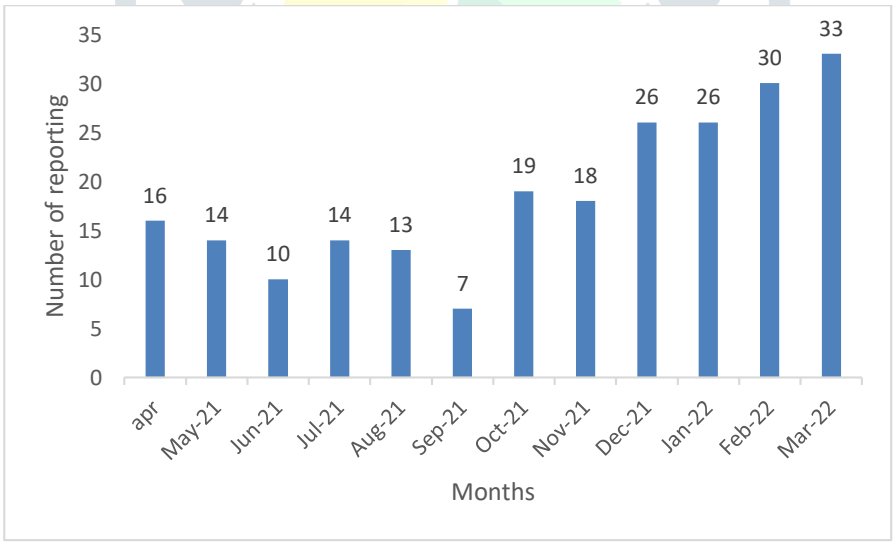


Fig 24: ADR reporting through Helpline 2021-22

**4.6 CUMULATIVE REPORT OF FIVE YEARS**

After reviewing and collecting annual, and monthly reports of PvPI in the last five years from various AMCs, Market Authorization Holders(MAHs), Non-AMC and other organizations from the financial year 2017-18 to 2021-22, the cumulative reports for ICSRs, MAHs and other contributions to PvPI were performed.

4.6.1 CUMULATIVE ICSRs REPORTING STATUS

Annual database accounts for more than 60, 000 ICSRs each year and communicated to WHO-UMC. Reporting patterns are on the increase year-wise and have increased drastically in recent years. The figure ( Fig 25) showed the total cumulative status of ICSRs contribution by PvPI to the global data base.

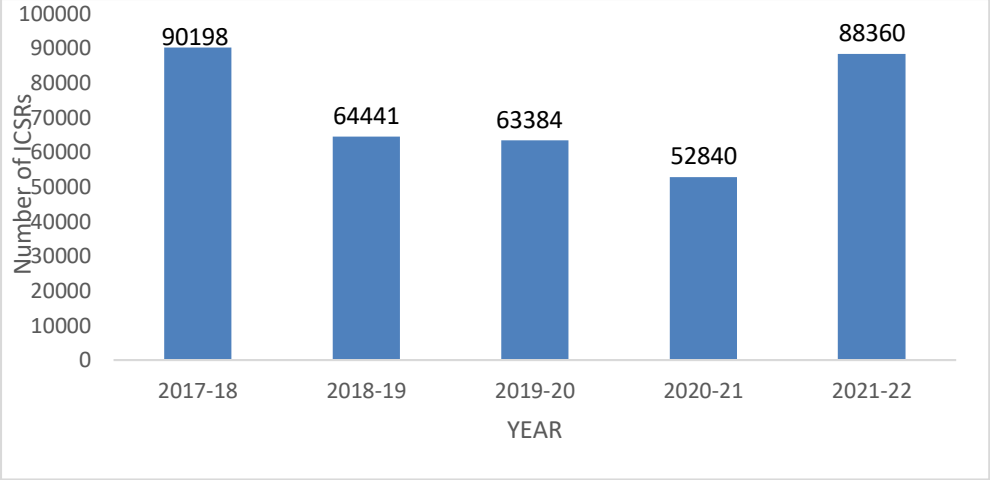


Fig 25: Cumulative ICSRs Reporting status

4.6.2 CUMULATIVE HELPLINE REPORT

The cumulative helpline reporting status of PvPI were shown in Fig 26.

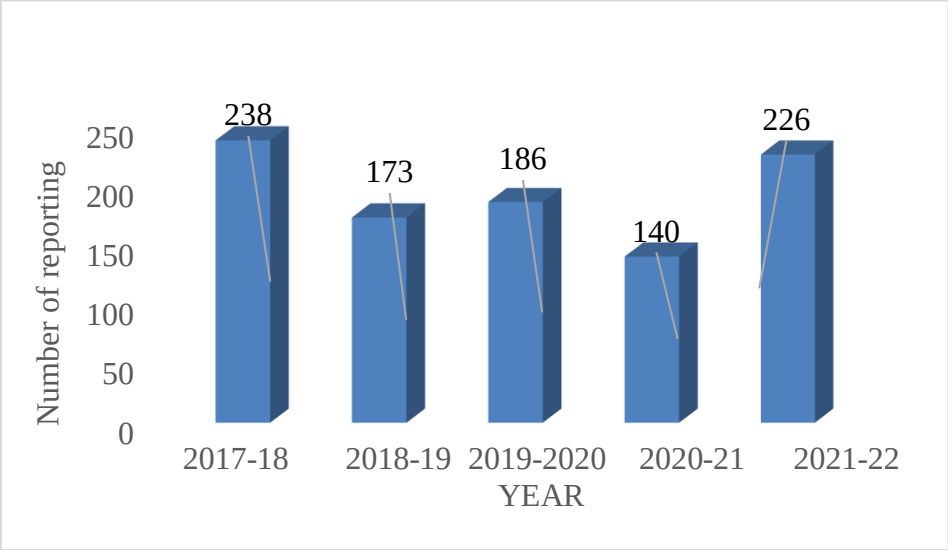


Fig 26: Cumulative Helpline Report

4.6.3 CUMULATIVE NON-AMCS REPORTING

During the index period, as many as 11,151 ADRs were reported via non-AMCs. The reporting in the each year were figured ( Fig 27).

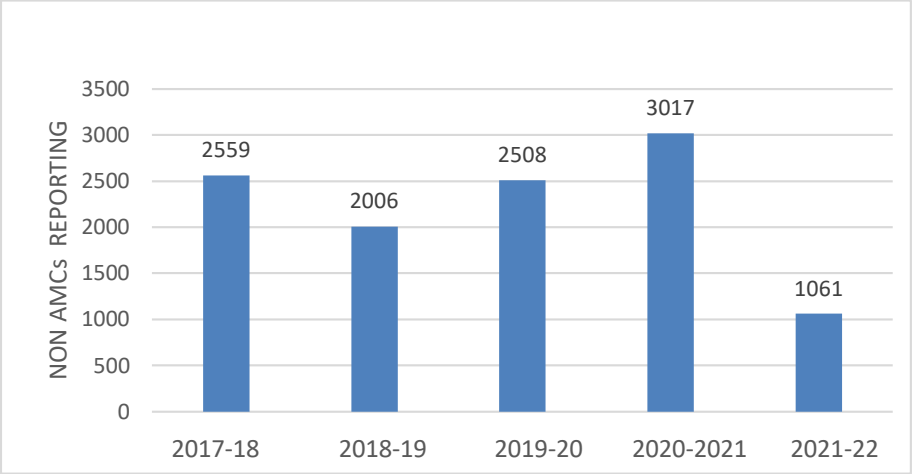


Fig 27: Cumulative Non AMCs reporting

4.6.4 CUMULATIVE REPORTER-WISE CONTRIBUTION

The cumulative reporter-wise contributions showed in Table 3. The results show patient wise reporting needs to be improved.

| Reporter-wise contribution | 2017-18 | 2018-19 | 2019-20 | 2020-21 | 2021-22 |
|---|---|---|---|---|---|
| Physician | 60% | 54% | 51.2% | 44.10% | 36% |
| Pharmacist | 12% | 18% | 14.8% | 10.5% | 16.3% |
| Consumer/Non-HCPs | 11% | 11% | 21.5% | 32.50% | 26.3% |
| HCPs | 17% | 17% | 17.6% | 20.50% | 27% |
| Lawyers | Nil | Nil | Nil | Nil | 0.01% |

Table 3: Cumulative Reporter-wise contribution

4.6.5 CUMULATIVE CONTRIBUTION BY NATIONAL PROGRAMMES

The cumulative contributions by the Nations programme were represented in Table 4.

| Sl.No | Year | ART* (20) | NTEP#(21) |
|---|---|---|---|
| 1 | 2018 | 324 | 1146 |
| 2 | 2019 | 189 | 715 |
| 3 | 2020 | 123 | 227 |
| 4 | 2021 | 241 | 375 |
| 5 | 2022 | 96 | 492 |

Table 4:Cumulative contribution by National Programmes

ART(20)* :Number of ART, NTEP# : Number of NTEP/NPTC

4.6.6 CUMULATIVE MAHs REPORTING

Marketing Authorization Holders(MAHs) have a crucial role in reporting ADRs to PvPI. The recent amendment to the Drugs and Cosmetics Rules, 1945, has made Pharmacovigilance a legal obligation for MAHs. This has paved the way for collecting product-specific safety data, aimed at optimizing drug-safety and ensuring healthcare for the Indian population.[7] The cumulative MAHs reporting showed in Fig 28. The MAHs contribute the reporting through E2Bxml format and their contribution and quality progress the PV growth in India.

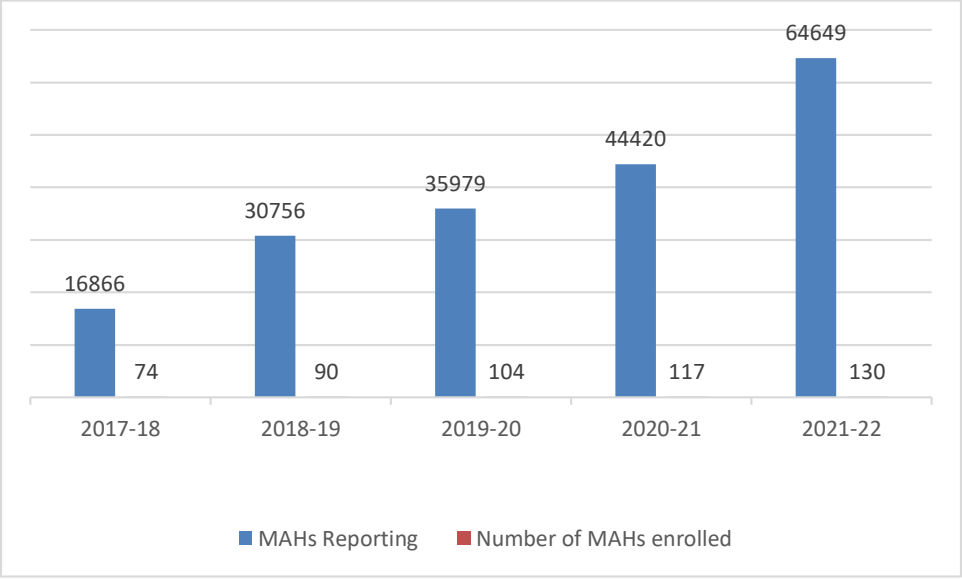


Fig 28: Cumulative MAHs Reporting

The review data shows a progressive growth of ADR reporting under the ages of IPC-PvPI. The safety UMC database contribution by PvPI is growing with the increase in the number of AMCs in each year. The state-wise AMCs under PvPI ( I and II) were represented in Fig 29 and Fig 30. AMCs cover all over India.

## 4.7 CUMULATIVE REPORT OF STATE-WISE AMC UNDER PvPI

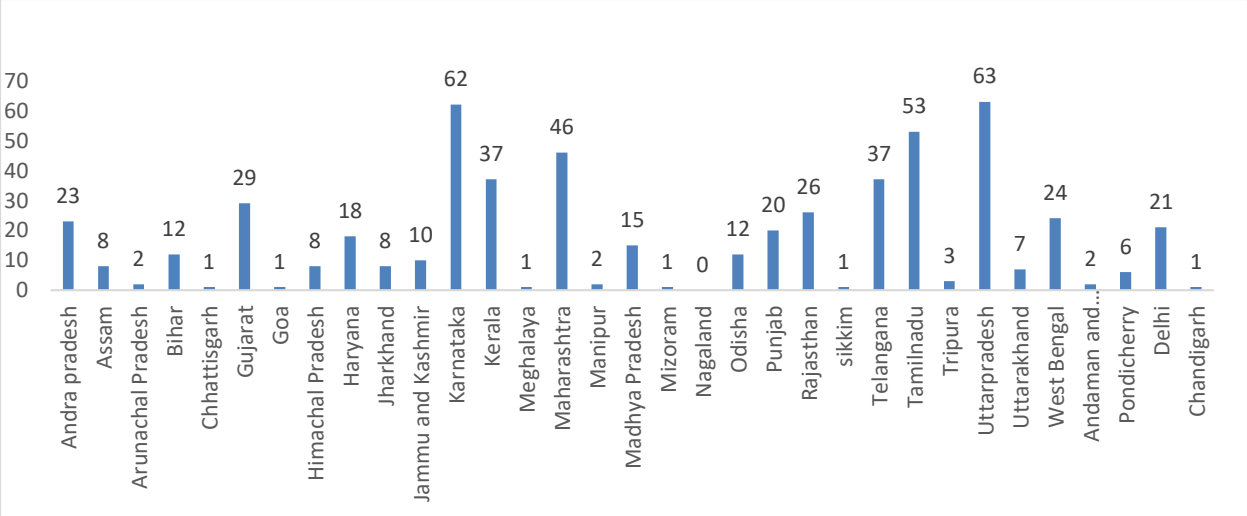


Fig 29: I State-wise AMCs under PvPI*

*The result without the data in April, October, November, December in 2017 and December in 2021

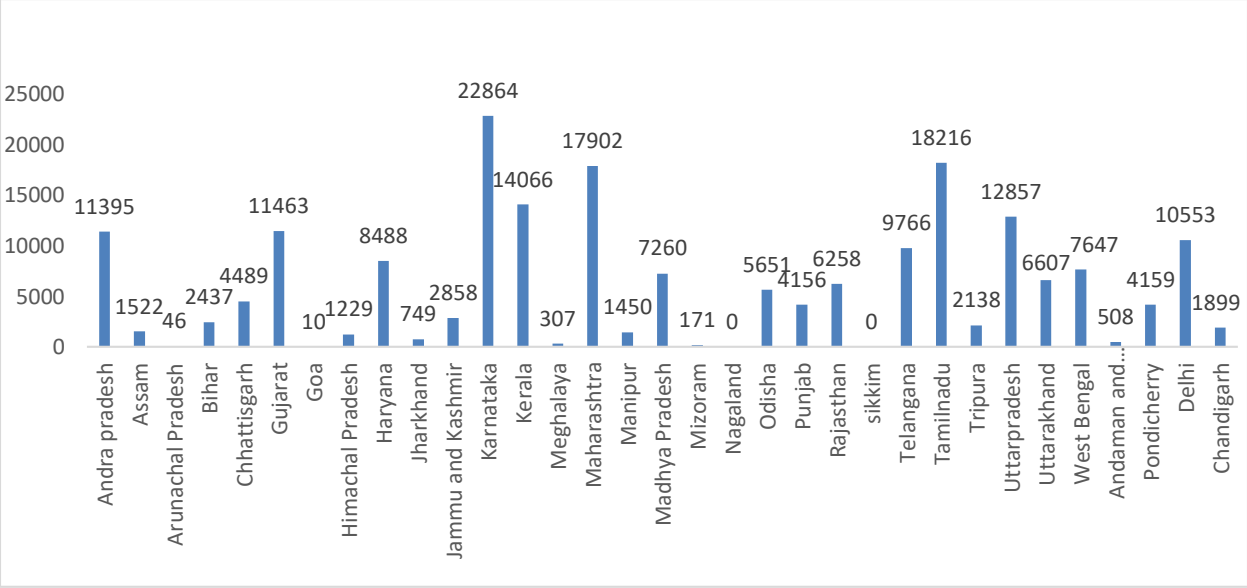


Fig 30: II State-wise reporting to PvPI during the period 2017-2022*

*The result without the data in April, October, November, December in 2017 and December in 2021

### 4.8 GLOBAL ICSRS REPORTING STATUS OF INDIA

Currently, the contribution of India to the WHO global Individual Case Safety Reports (ICSRs) submission is 1.90%. India secured 9th position in global reporting of ICSRs among the top 10 contributing countries.[10] The representation in Fig 31 shows the position of India in the global PV contributions.

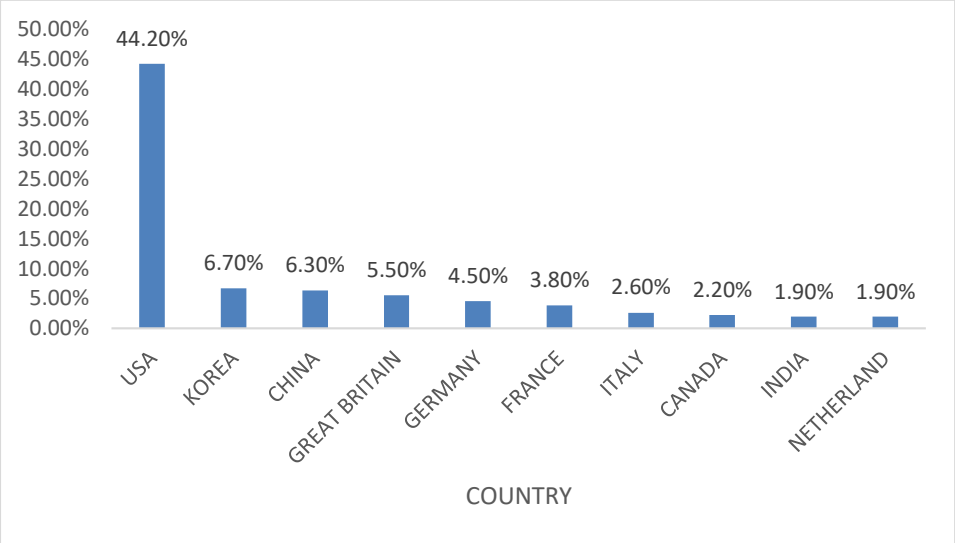


Fig 31: Global ICSRs reporting status of India[10]

## 5. DISCUSSION

The objective of this study was to ascertain the contribution of different stakeholders in reporting of ADRs. All Individual Case Safety Reports (ICSRs) received by the NCC between April 2017 and March 2022, were taken into account for analysis.

Limitation of this study, that PvPI data information was not available for April, October, November, December in 2017 and December in 2021.

Currently, 701 centres have been identified as ADRs Monitoring Centers (AMCs) across the country most of them are National Medical Council-approved teaching hospitals and corporate hospitals. These centers are covered in four zonal offices of the Central Drugs Standard Control Organization (CDSCO) for administrative and logistic purposes. Over five years, the NCC has played a significant role and more than 80,000 ADRs were reported till March 2022.[3]

Analysis of ICSRs data reveals that the majority of ADRs were reported by Karnataka. Relatively lower reporting was done by Sikkim.

Eventhough Uttarpradesh has 63, highest number of AMCs with a total of 12857 reporting, that is relatively lower than Karnataka state that hold 62 centers.

Till now states like Nagaland has no enrolled AMCs. Enrolled AMCs are lower in Sikkim, Goa, Mizoram, Meghalaya.

Data represents, states like Tamilnadu and Kerala holds the second and third position in reporting of ADR.

Presently 20 ART and 21 NTEP are contributing PvPI, with no strategic modulation as the more public programs are most popularized in India.

During the index period of 2017 to 2022, about 130 MAHs were enrolled and contributed a total of 192670 ADR reports through E2Bxml. The progressive growth in this area reflected in all the years.

Following the initiation of toll-free helpline, an increase in reporting through this method has been observed. A total of 963 cases were reported. Yearly progress not found in the ADR reporting tool.

This study also revealed the rate of reporting of ADRs month-wise and it was found that the reporting rates were consistently increased after disseminating the information through PvPI Newsletter, awareness programme, sending circulars to the ADRs monitoring centre, etc.[3]

Analysis of a total number of 88, 360 ICSRs revealed that the majority of ADRs were reported by physicians. Relatively lower reporting was done by the pharmacists. Other HCPs and non-HCPs also contributed the reports. This reveals the studies of Kalaiselvan et al., 2014.[2] The reporting rate of pharmacists was low as compared to physicians because, in India, the system of distribution does not leave much scope for the pharmacists to be a significant source of ADRs reporting.

The results suggest that UR in the Indian market also need to be corrected through consumer awareness programmes. In India after the initiation of sustainable PvPI, AMC functional rate is recorded to be minimal. This indicates that among 701 AMC, more centres yet remain non-functional even after being operational most of the time.[3]

When comparing with the population density and drug market , India’s position of PV contribution suggest more UR. This can overcome through active sensitizational programmes.

## 6. CONCLUSION

In conclusion, awareness of ADR reporting among healthcare providers can improve the rate of reporting across the country. Moreover, developing its national database and sharing information with other regulatory agencies will provide much-needed information from worldwide data to take the correct decision on medicines and products. Change of mindset of sharing good medical information is need of the hour. Input Positive or negative experiences through a medicine by an individual is a right to a citizen and it need to be deliberate in the curriculum.

India as diversified country, regional language hurdles can be removed through preparing mobile app and helpline and make operational in each state to support the PV activities.

Currently available mobile app not supports the Apple iOS software. IPC-PvPI with time working with new software ADRMS- IPC, needs rapid integration with the current working patient medical history software of each state for faster progression of PV, quick corrective measure of regulatory actions.

Currently enrolment of ART and NTEP need more corrective step and PvPI need to join hands with other National Programs.

Similarly, pharmacists can also promote the development, maintenance, and on-going evaluation of a programme to reduce the risks of ADRs by detecting, reporting, and assessing any suspected ADRs. Collaboration with Pharmacy council of India will be another tool as controls the major medical contributor. Therefore, coordination among clinician, pharmacist, and nurse appears vital in contributing each of their respective expertise and experience to promote the rational use of medicines.

It was also observed that the lack of knowledge of where, what and how ADRs should be reported is also affects reporting. The reason for poor reporting may also include financial incentives, ignorance (only serious ADRs are to be reported), apprehension of reporting serious ADRs, and lack of time or overload. Thus, healthcare professionals should be under an obligation to report ADR if detected while clinical practice.

Adding PvPI helpline number or QR codes on medicine labels can improve the ADR reporting.

The public or consumers/non-HCPs should be aware of the importance of ADR reporting, ADR reporting form, PvPI toll-free helpline, and PvPI mobile app. Thereby the underreporting of ADR in the country can be improved.

In addition, extending awareness among healthcare providers, consumers, non-HCPs, and continuing medical education in various medical colleges across the country can improve the rate of reporting.

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