



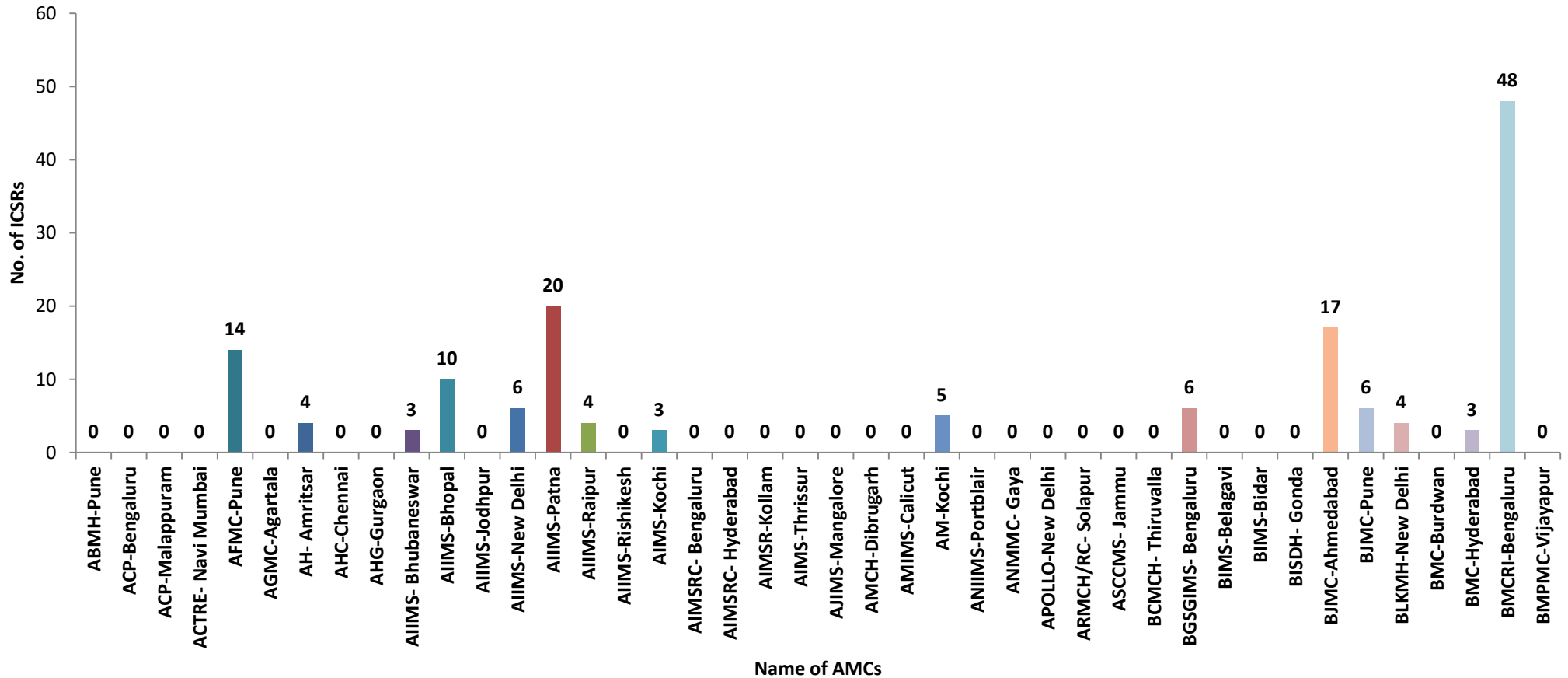
**INDIAN PHARMACOPOEIA COMMISSION**  
**National Coordination Centre - Pharmacovigilance Programme of India (PvPI)**  
**Ministry of Health & Family Welfare, Government of India**

**ADRs Reporting Status May, 2020**

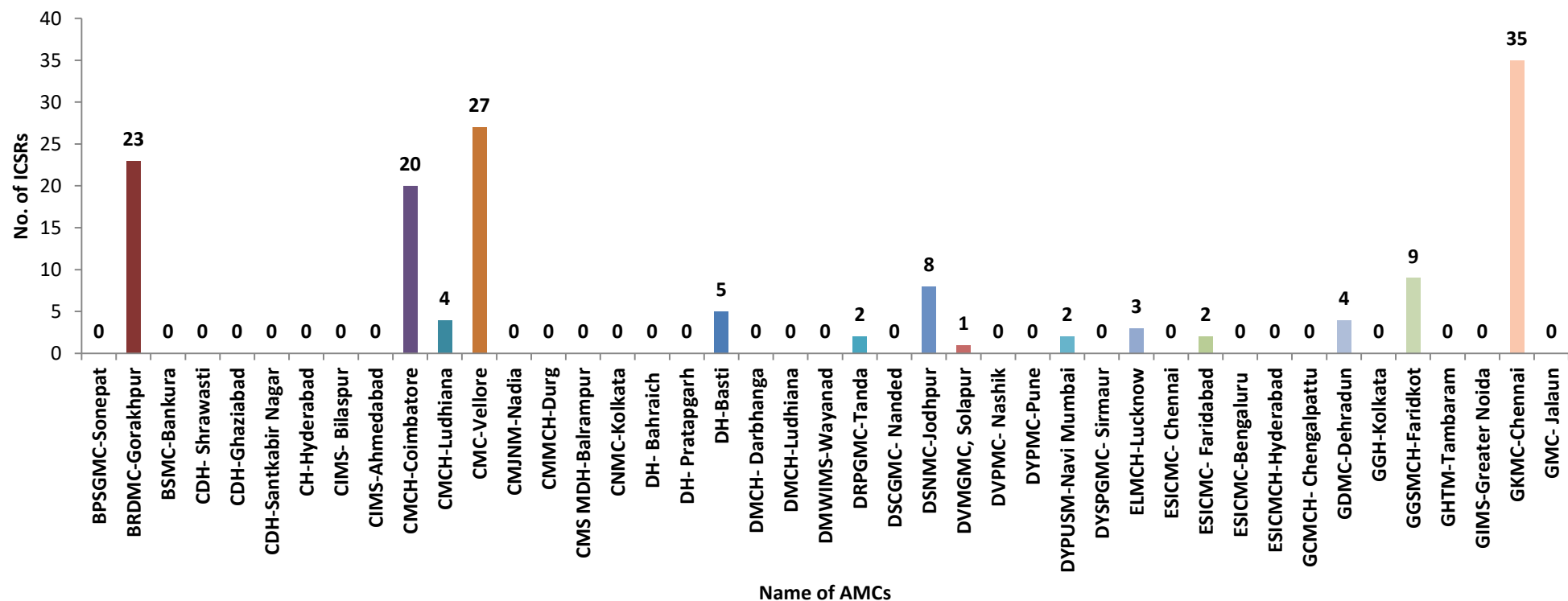
The spontaneous ADRs reporting by the ADR Monitoring Centres (AMCs) under Pharmacovigilance Programme of India (PvPI), Revised National Tuberculosis Control Programme (RNTCP) & Anti-Retroviral Therapy (ART) centres under National Health Programmes, and Pharmaceutical industries to National Coordination Centre-PvPI for the month of May-2020 has been compiled. During the month total **4979 ICSRs (including 1439 Follow-up ICSRs received from Pharmaceutical Industries)** were reported to NCC-PvPI. The detail is given below-

**(I) Spontaneous ADRs reported by the AMCs , ART and RNTCP Centres as follows:**

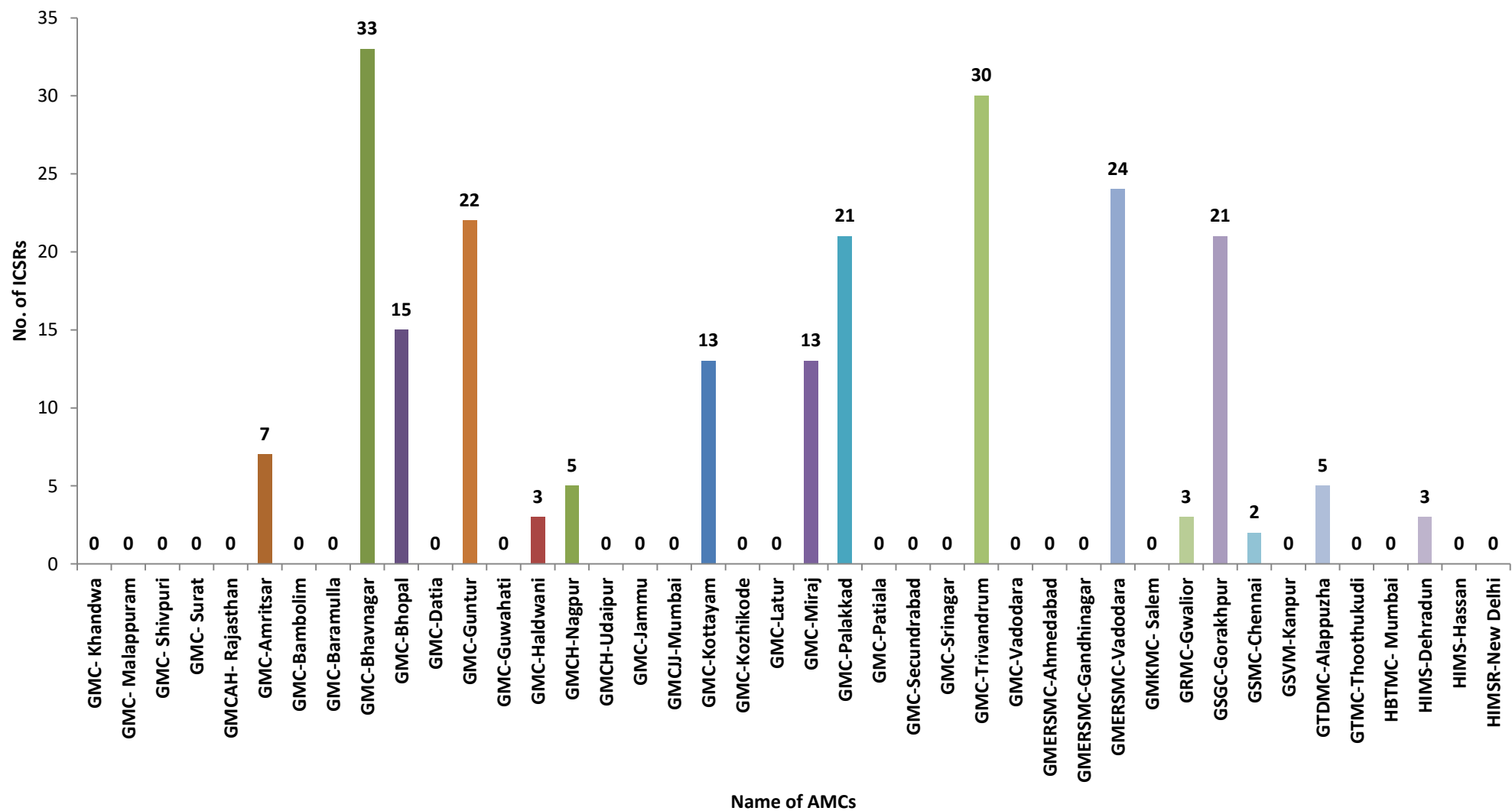
## No. of ICSRs recieved from AMCs in the month of May 2020



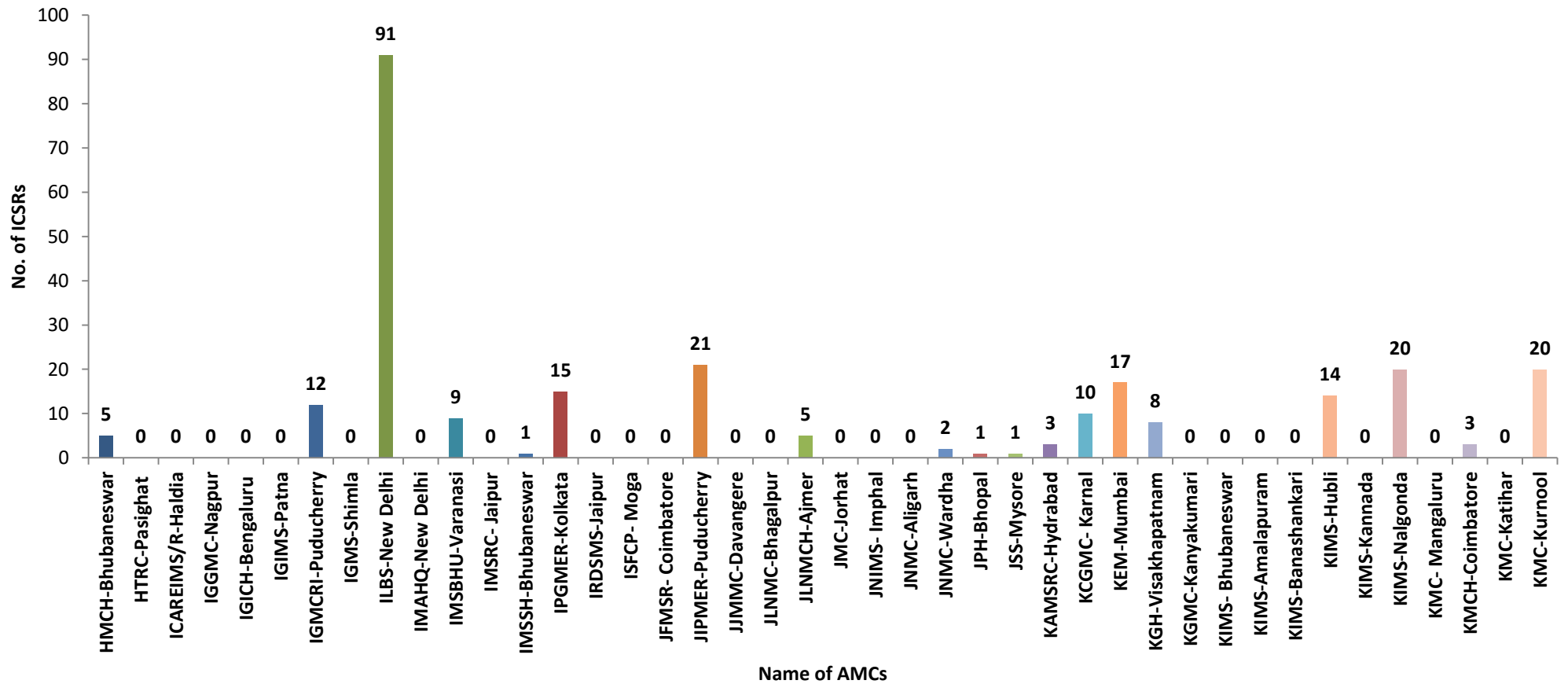
## No. of ICSRs recieved from AMCs in the Month of May 2020



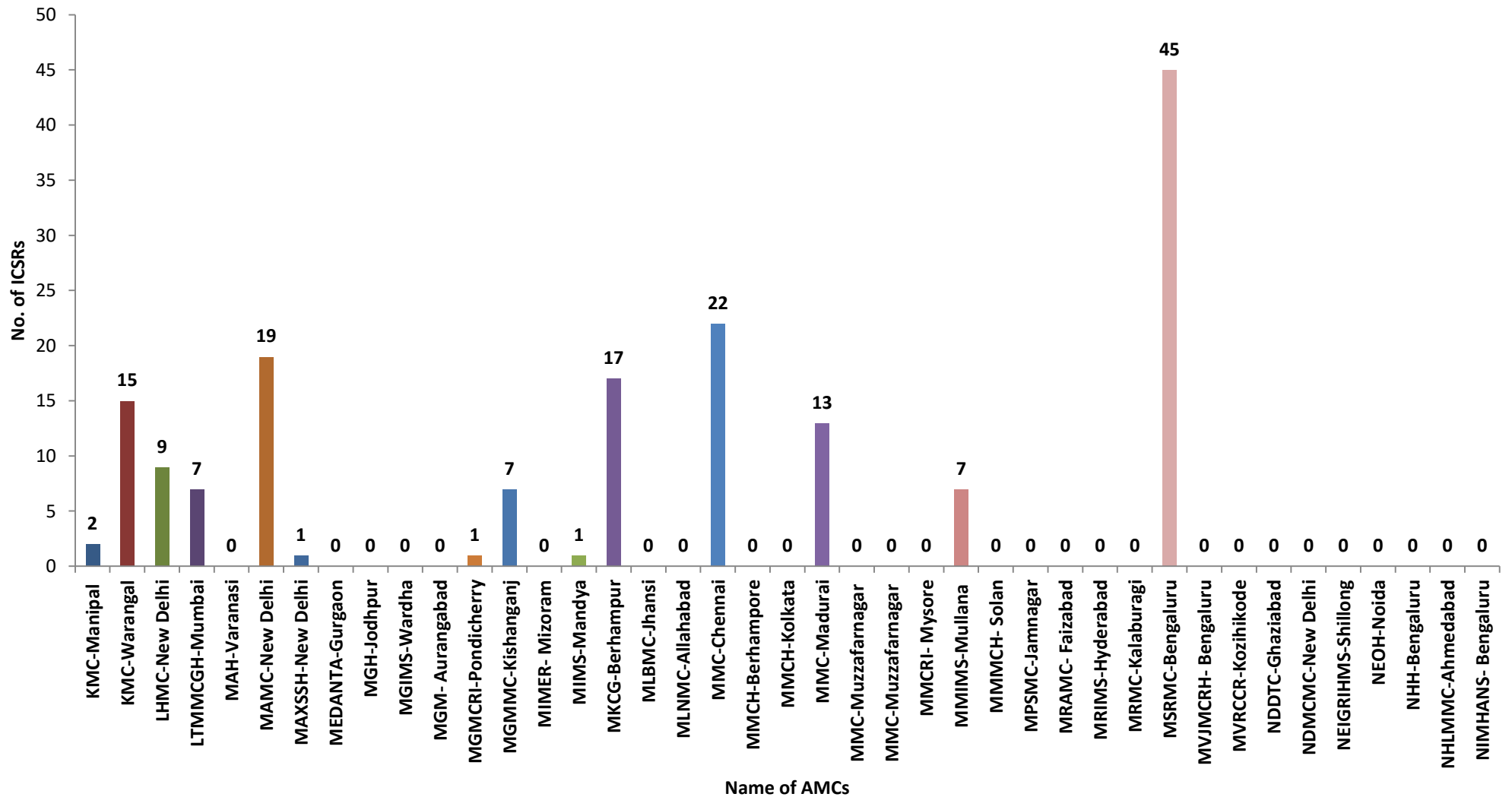
## No. of ICSRs recieved from AMC s in the month of May2020



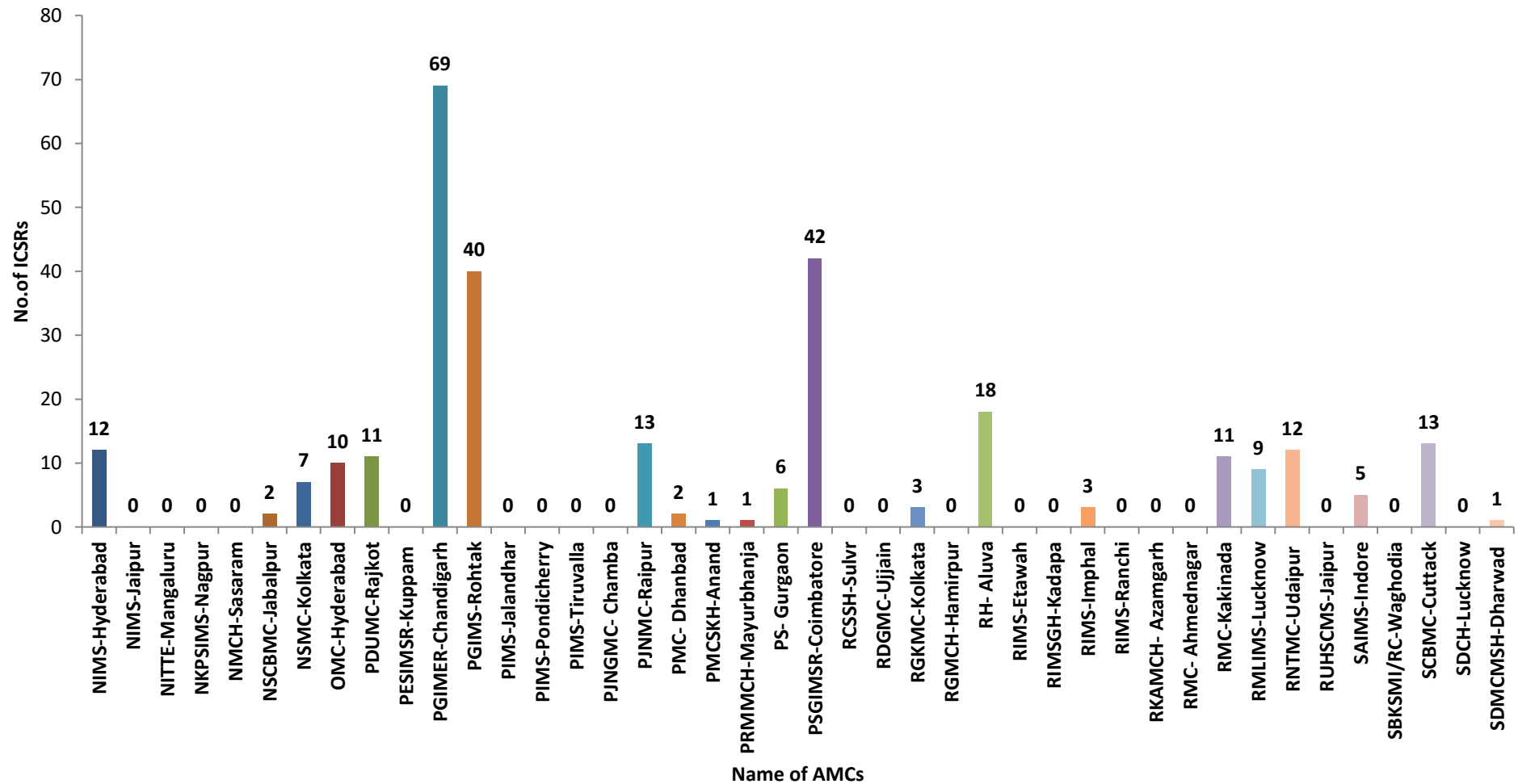
## No. of ICSRs recieved from AMC s in the month of May 2020



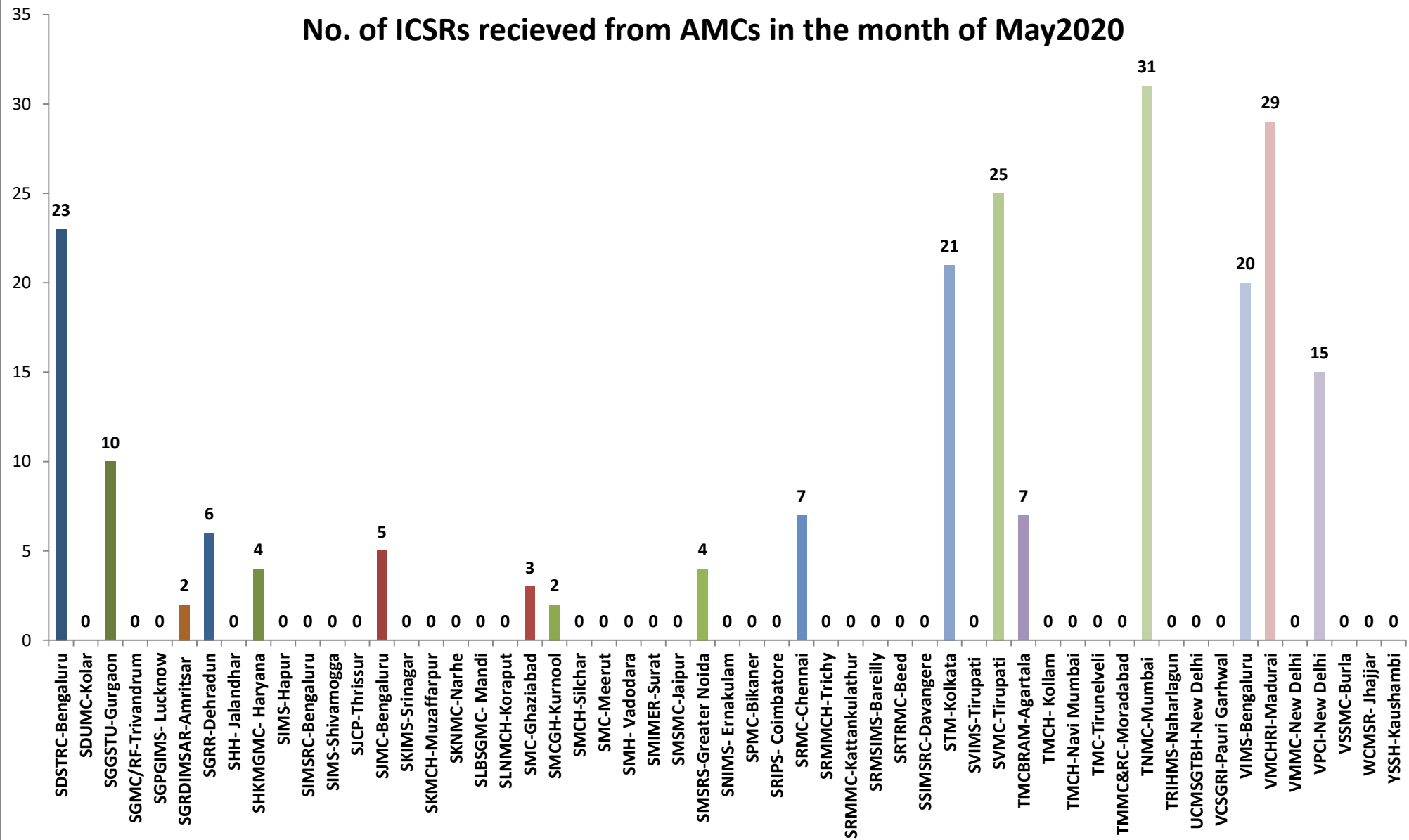
## No. of ICSRs recieved from AMC s in the month of May 2020



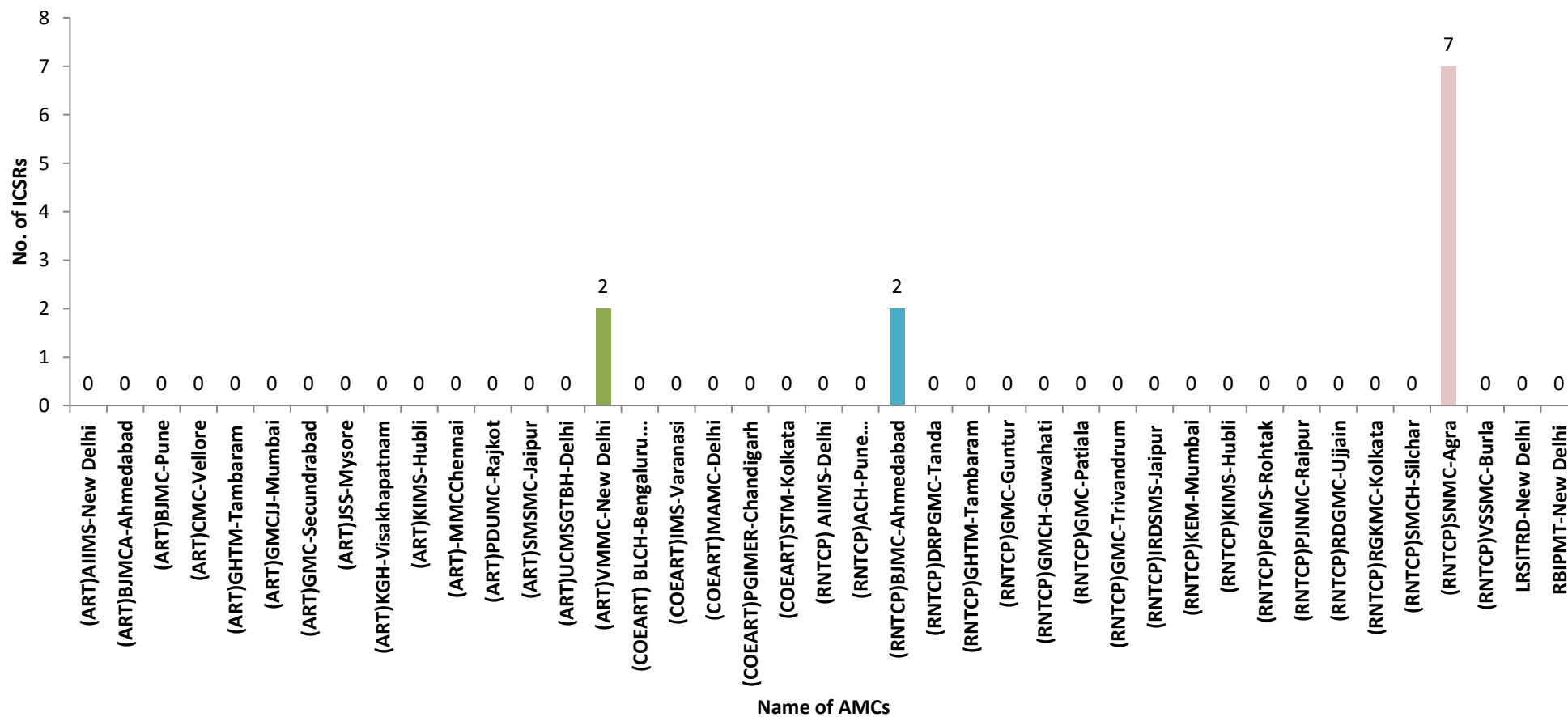
## No. of ICSRs recieved from AMCs in the month of May 2020



## No. of ICSRs recieved from AMCs in the month of May2020



## No. of ICSRs recieved from ART and RNTCP Centres in the month of May2020



**(II) Spontaneous ADRs reported by the Pharmaceutical Industries as follows:**

| <b>S. No.</b> | <b>Industry Name</b>                           | <b>Total</b> | <b>Initial</b> | <b>Follow-up</b> |
|---------------|------------------------------------------------|--------------|----------------|------------------|
| 1             | Abbott India Limited                           | 4            | 2              | 2                |
| 2             | Akums Drugs & Pharmaceuticals Limited          | 1            | 0              | 1                |
| 3             | Astellas Pharma India Private Limited          | 5            | 3              | 2                |
| 4             | AstraZeneca Pharma India Limited               | 57           | 57             | 0                |
| 5             | Aurobindo Pharma Limited                       | 5            | 1              | 4                |
| 6             | Amgen India                                    | 5            | 2              | 3                |
| 7             | Baxalta                                        | 4            | 2              | 2                |
| 8             | Bayer Healthcare Limited                       | 10           | 6              | 4                |
| 9             | Boehringer Ingelheim India Private Limited     | 17           | 14             | 3                |
| 10            | Bristol-Myers Squibb India                     | 24           | 20             | 4                |
| 11            | Dr.Reddy's Laboratories                        | 23           | 19             | 4                |
| 12            | EISAI Pharmaceuticals India Pvt. Ltd           | 53           | 52             | 1                |
| 13            | Eli Lilly & Company (India) Private Limited    | 107          | 96             | 11               |
| 14            | Emcure Pharmaceuticals Limited                 | 10           | 8              | 2                |
| 15            | FDC Limited                                    | 6            | 6              | 0                |
| 16            | Fresenius Kabi India Private Limited           | 9            | 7              | 2                |
| 17            | Glaxo Smithkline Pharmaceuticals Limited       | 37           | 32             | 5                |
| 18            | Grifols India Healthcare Private Limited       | 1            | 1              | 0                |
| 19            | Hetero Drugs Limited                           | 24           | 21             | 3                |
| 20            | Intas Pharmaceuticals Limited (Lambda CRO)     | 2            | 2              | 0                |
| 21            | IPCA Laboratories Limited                      | 4            | 4              | 0                |
| 22            | Johnsons & Johnsons Private Limited            | 29           | 21             | 8                |
| 23            | Kedrion Bio Pharma                             | 1            | 0              | 1                |
| 24            | Lupin Limited                                  | 16           | 14             | 2                |
| 25            | MERCK Limited                                  | 83           | 62             | 21               |
| 26            | MSN Labs                                       | 25           | 24             | 1                |
| 27            | Mylan Laboratories Private Limited             | 34           | 30             | 4                |
| 28            | Novartis India Limited                         | 2015         | 1004           | 1011             |
| 29            | Pavious Pharmaceuticals                        | 2            | 0              | 2                |
| 30            | Pfizer Limited                                 | 234          | 114            | 120              |
| 31            | Panacea Biotec Limited                         | 11           | 10             | 1                |
| 32            | Reckitt Benkiser                               | 5            | 5              | 0                |
| 33            | Sun Pharmaceuticals Industries Limited         | 51           | 32             | 19               |
| 34            | Serum Institute of India Limited. (Lambda CRO) | 2            | 2              | 0                |
| 35            | Torrent Pharmaceuticals Limited                | 27           | 18             | 9                |
| 36            | TFS Trial Form Support                         | 2            | 2              | 0                |
| 37            | USV Private Limited                            | 10           | 9              | 1                |
| 38            | Zydus Cadila                                   | 103          | 100            | 3                |

|    |                                        |             |             |             |
|----|----------------------------------------|-------------|-------------|-------------|
| 39 | Allergan India Pvt. Ltd.               | 4           | 3           | 1           |
| 40 | Baxter (India) Private Limited         | 130         | 36          | 94          |
| 41 | Biocon Limited                         | 11          | 7           | 4           |
| 42 | Roche Products (India) Private Limited | 166         | 143         | 23          |
| 43 | Sanofi India Limited                   | 152         | 91          | 61          |
|    | <b>Total</b>                           | <b>3521</b> | <b>2082</b> | <b>1439</b> |

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