



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

ADRs Reporting Status February-2024

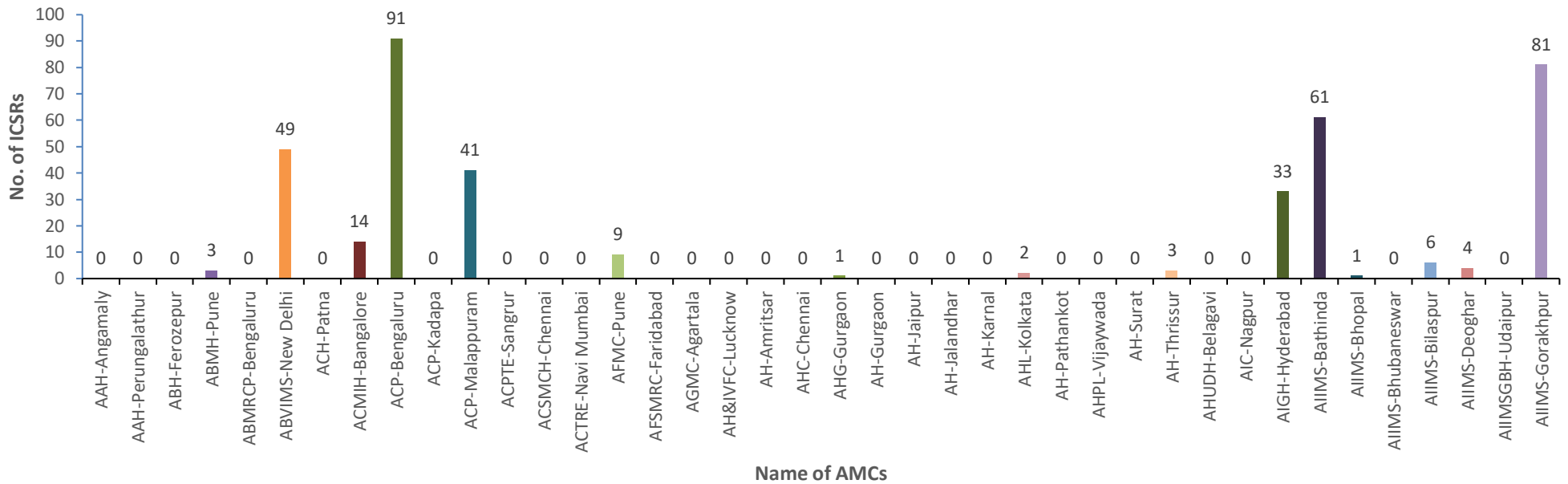
The spontaneous ADRs reporting by the ADR Monitoring Centres (AMCs) under Pharmacovigilance Programme of India (PvPI), National Tuberculosis Elimination Programme (NTEP) & Anti-Retroviral Therapy (ART) centres under National Health Programmes, and Pharmaceutical Industries to National Coordination Centre-PvPI for the month of **February-2024** has been compiled. During the month total **14648 ICSRs** including follow-up ICSRs were reported to NCC-PvPI. The detail is given below-

Source

| | | |
|--|-------------------------------|---------------------------------|
| AMC/ ART/RNTCP/NTEP | 9455 | |
| MAH (Marketing Authorisation Holders) | 5193 | |
| | Initial 3088 | Follow-up 2015 |

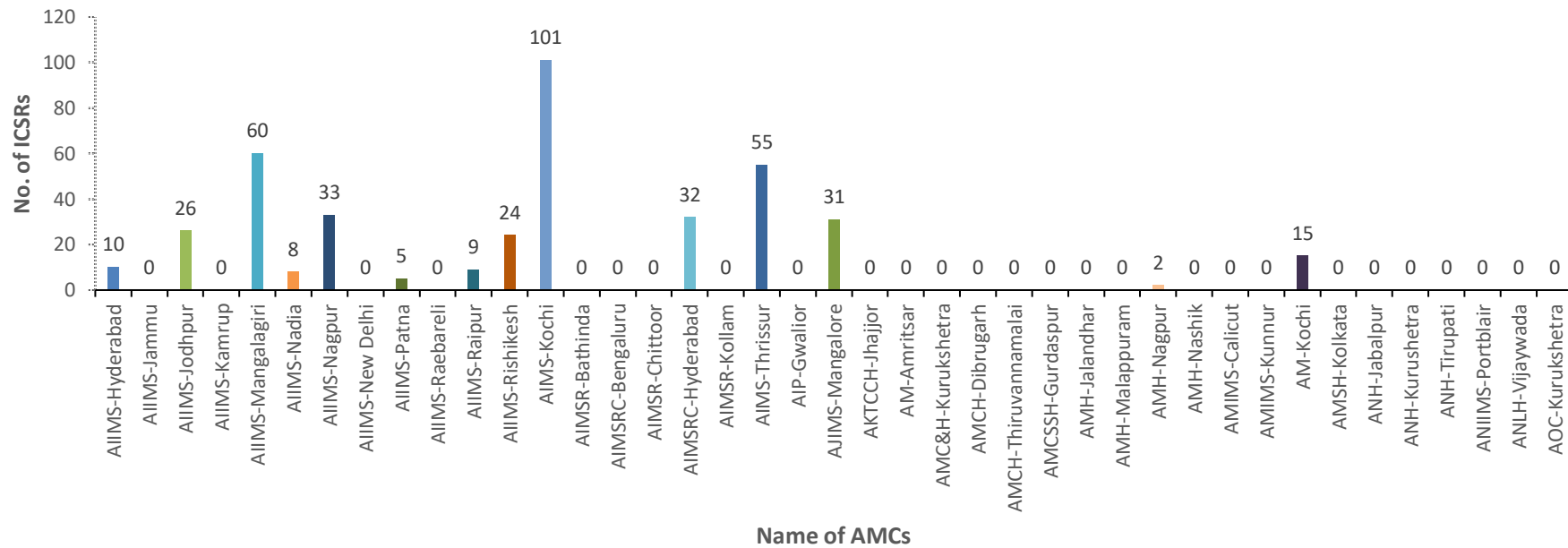
(I) The details are as follows:

No. of ICSRs recieved from AMCs in the month of February-2024



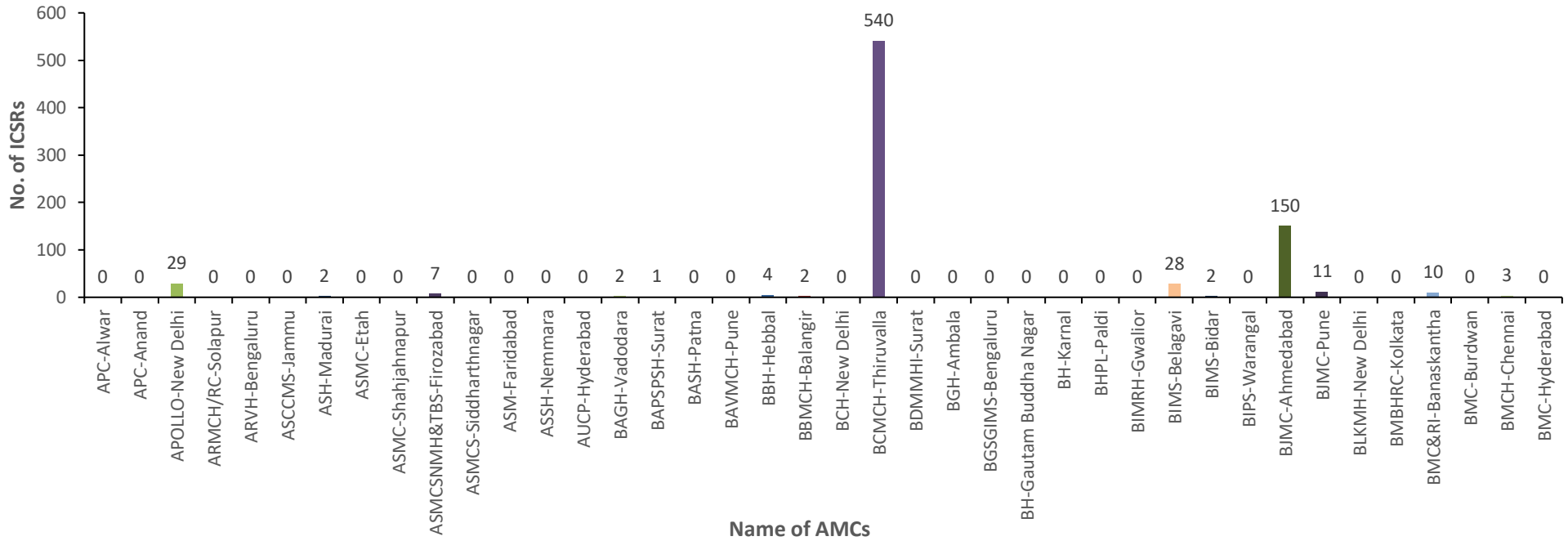
FOR PVI

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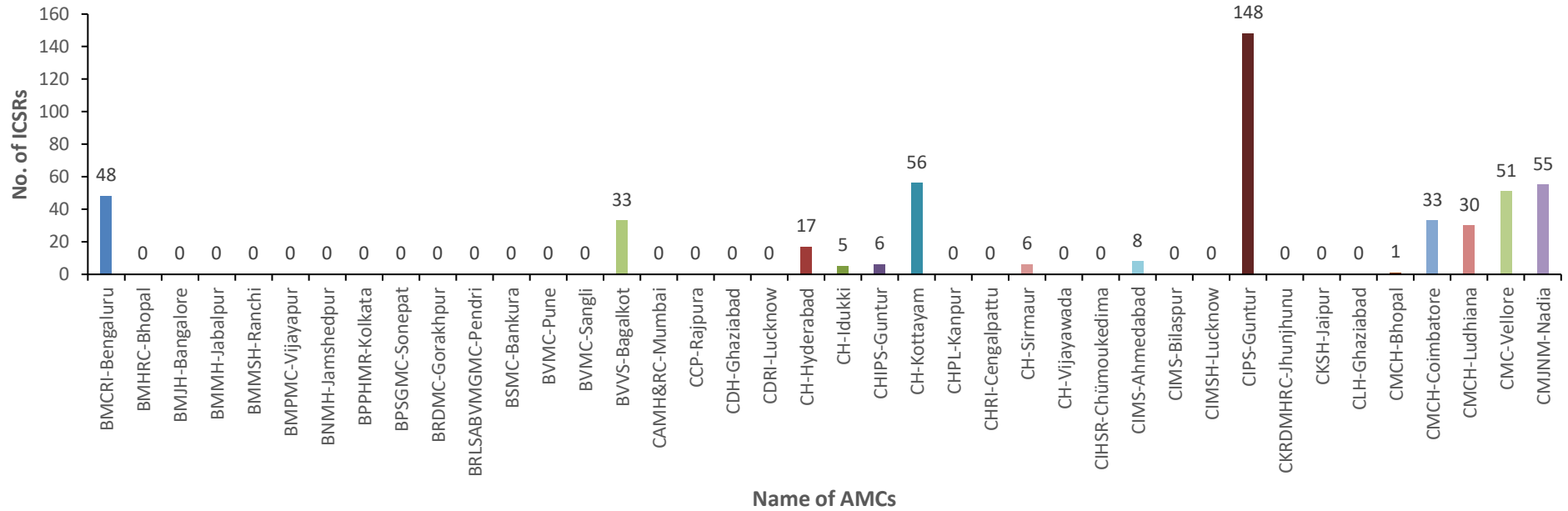


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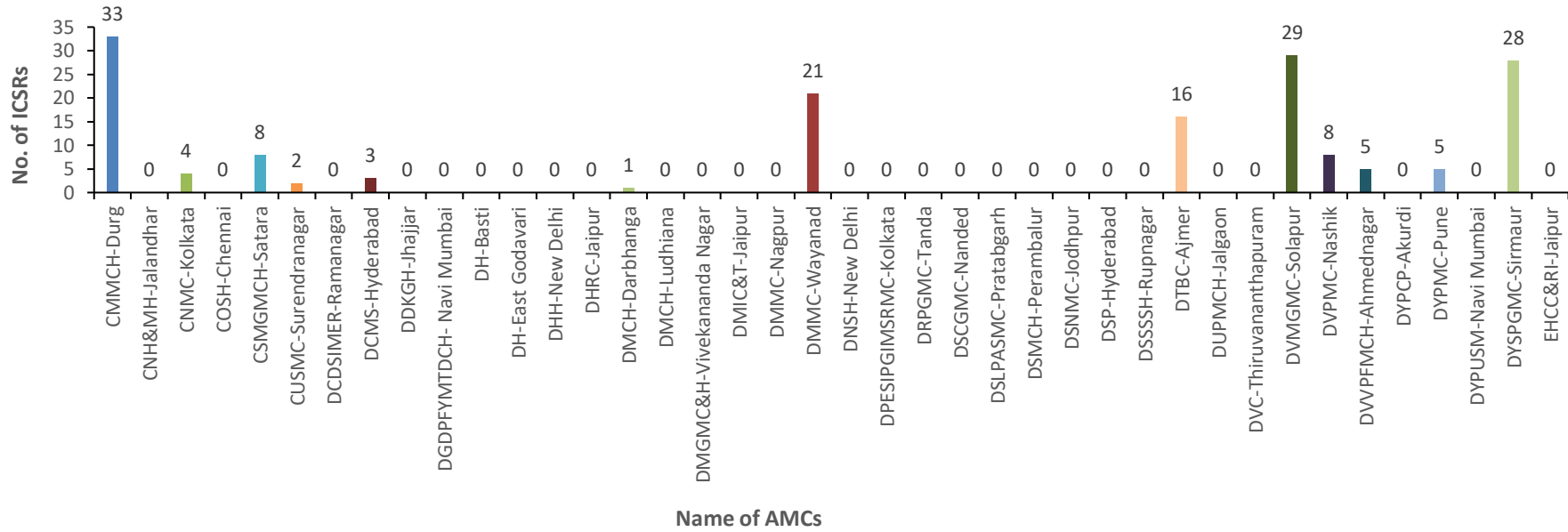
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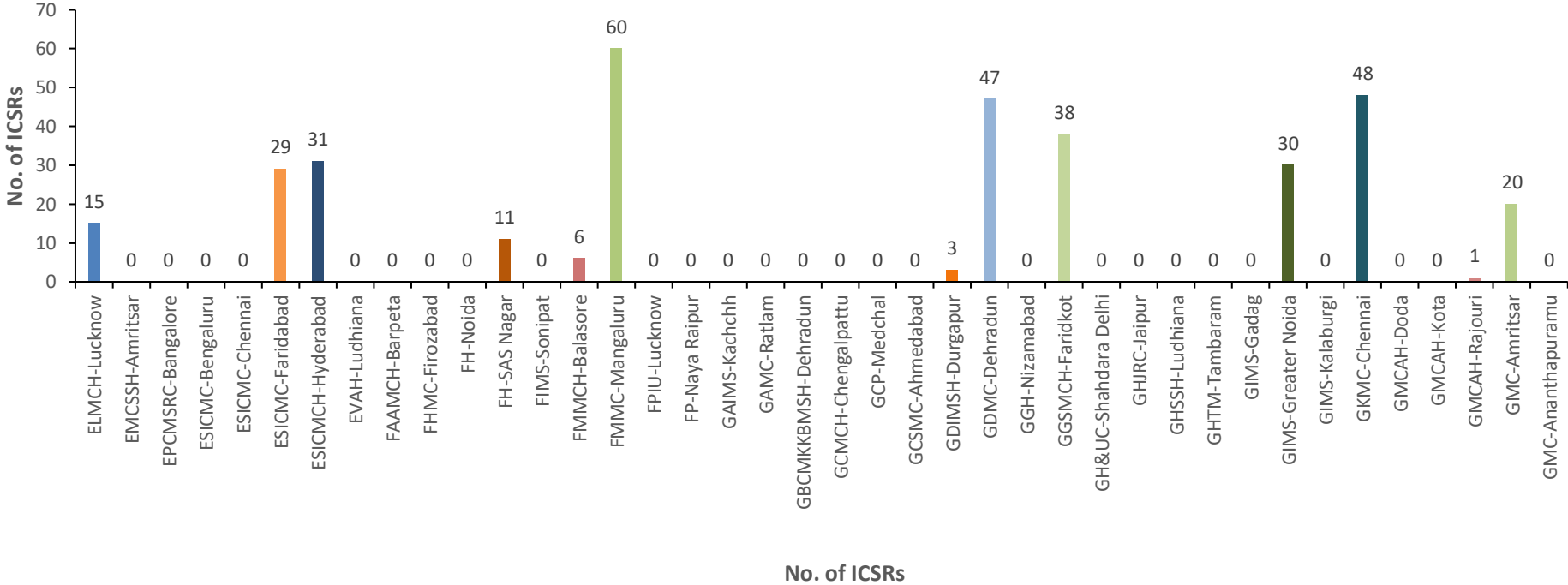
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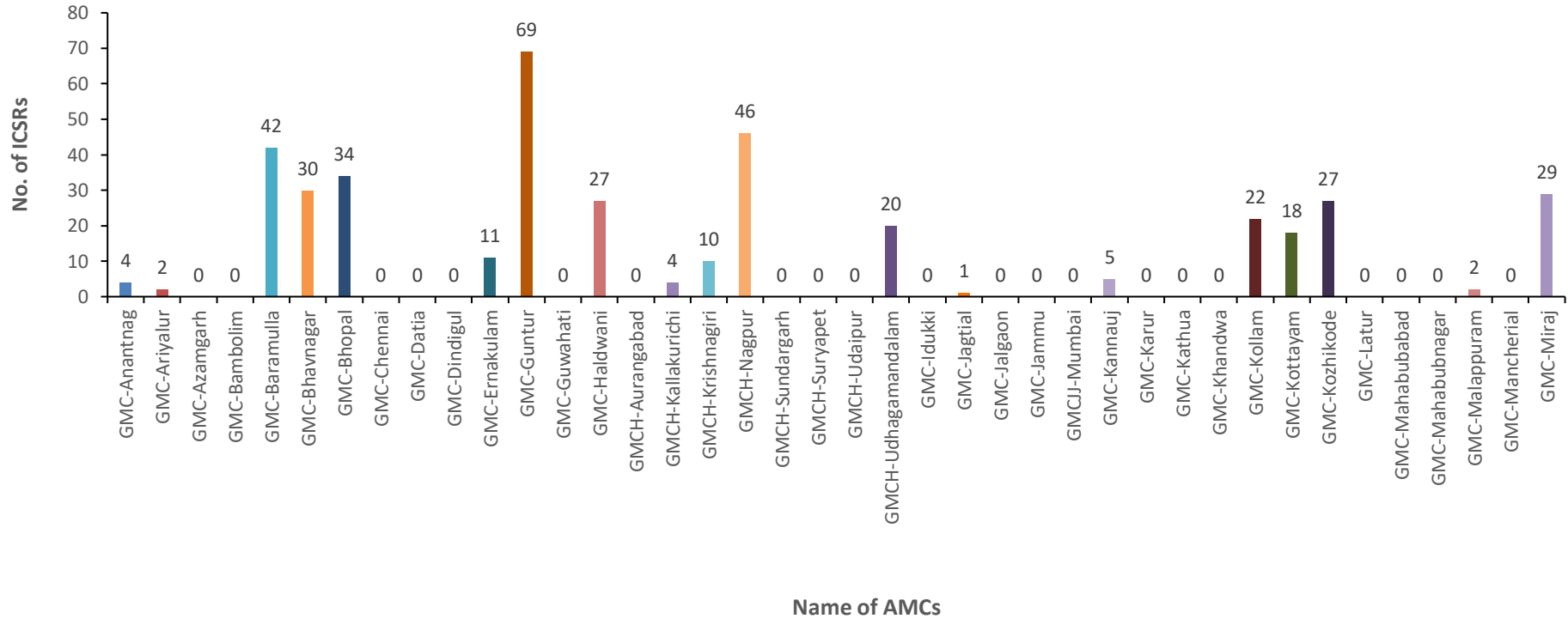
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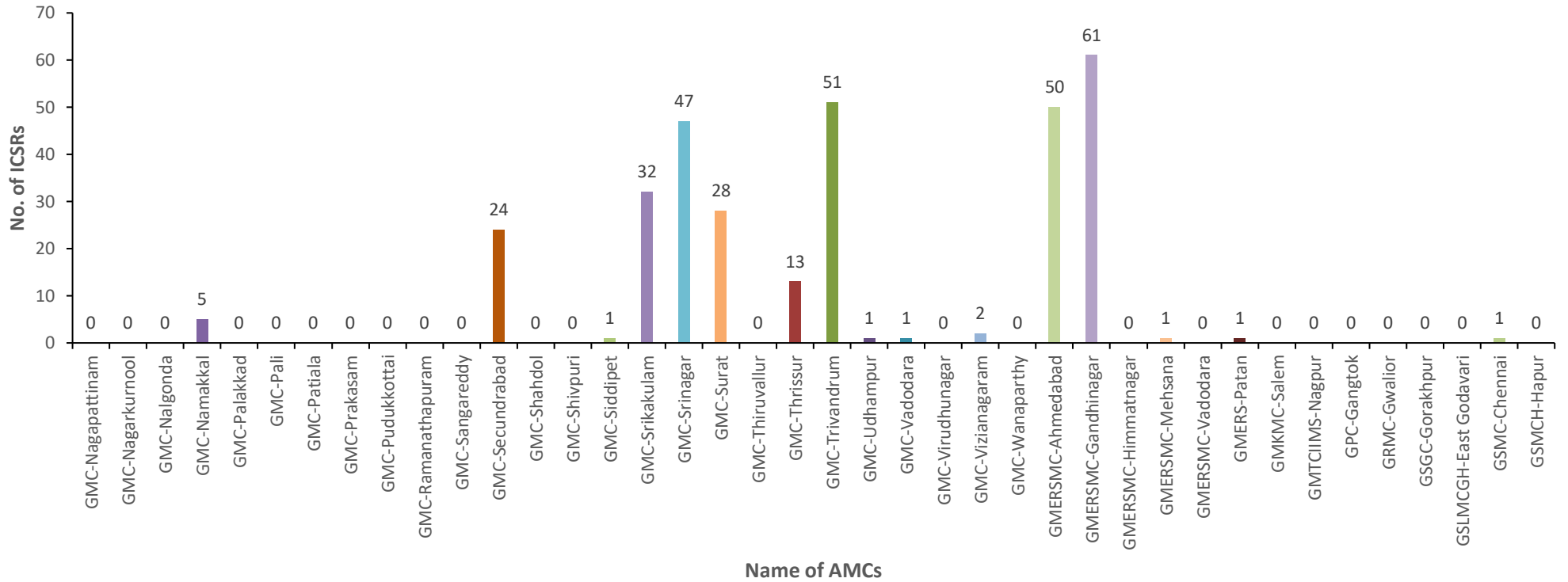
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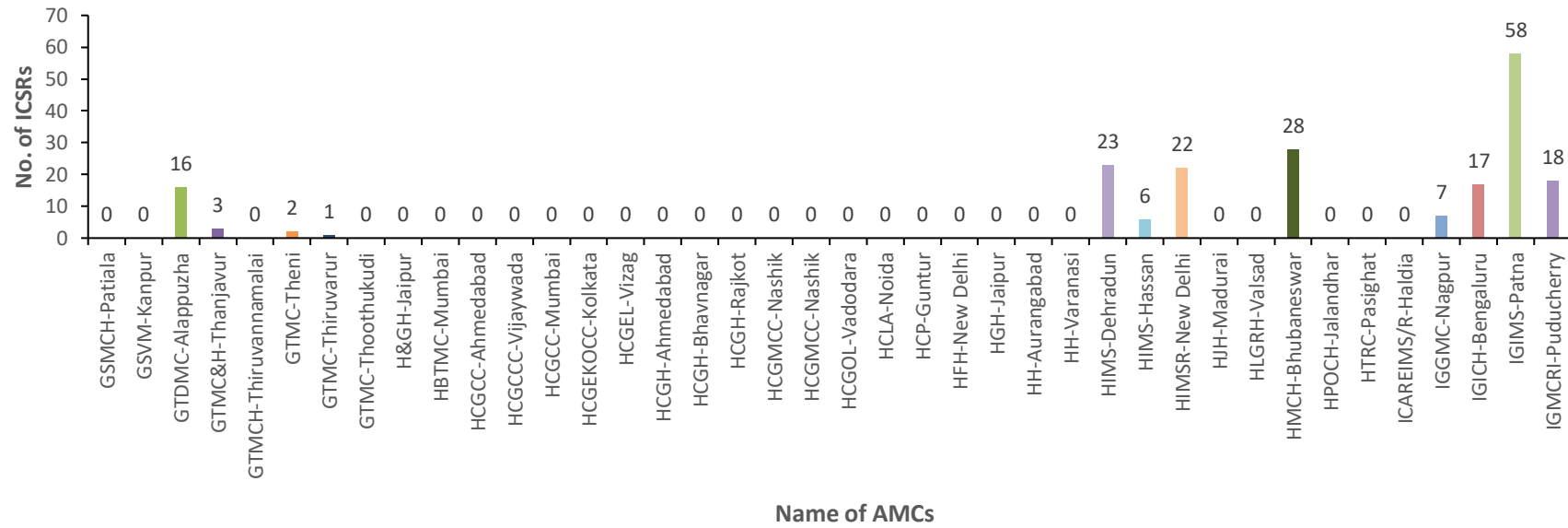


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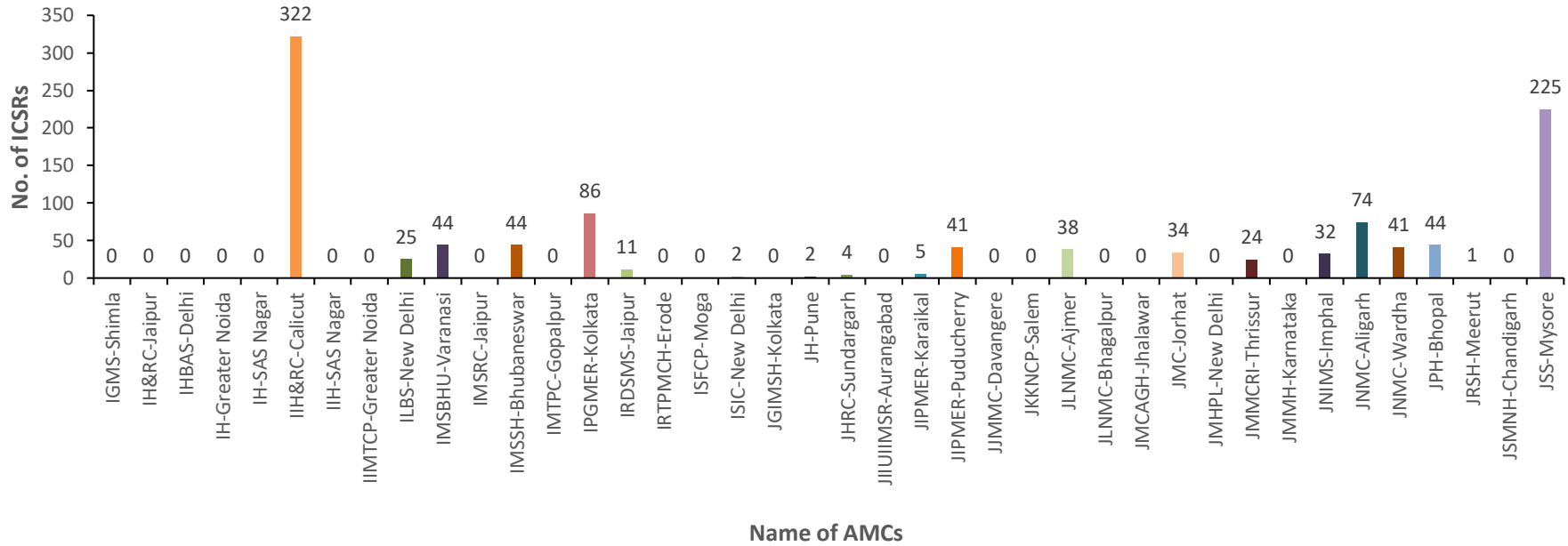


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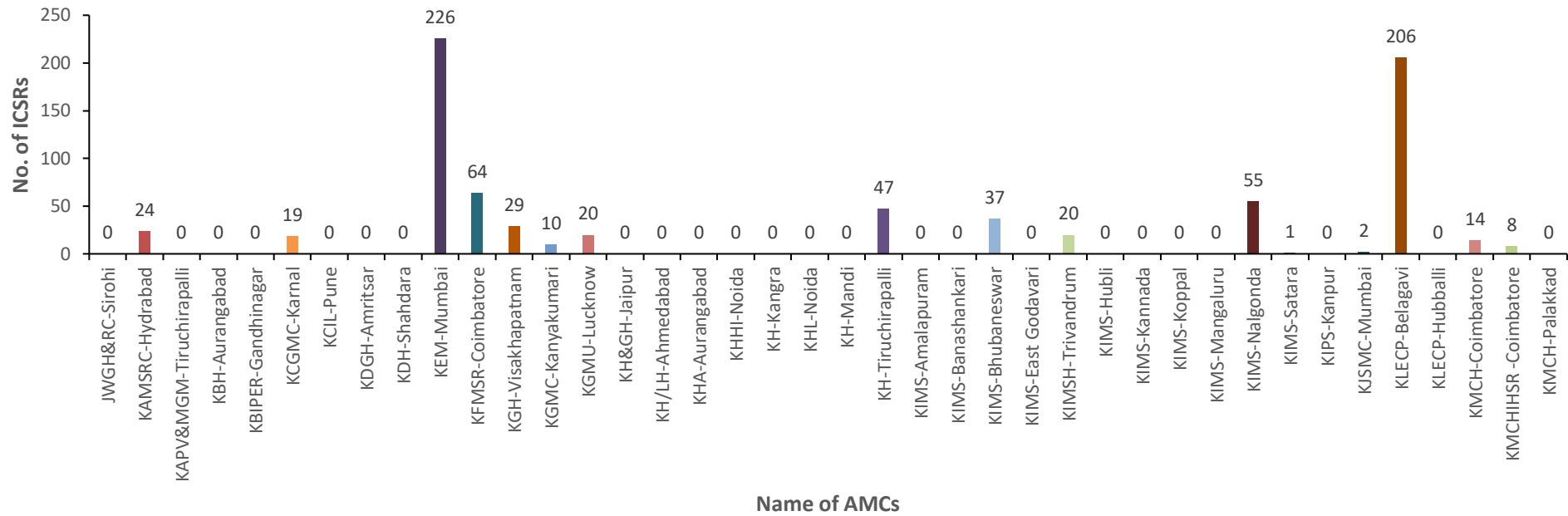


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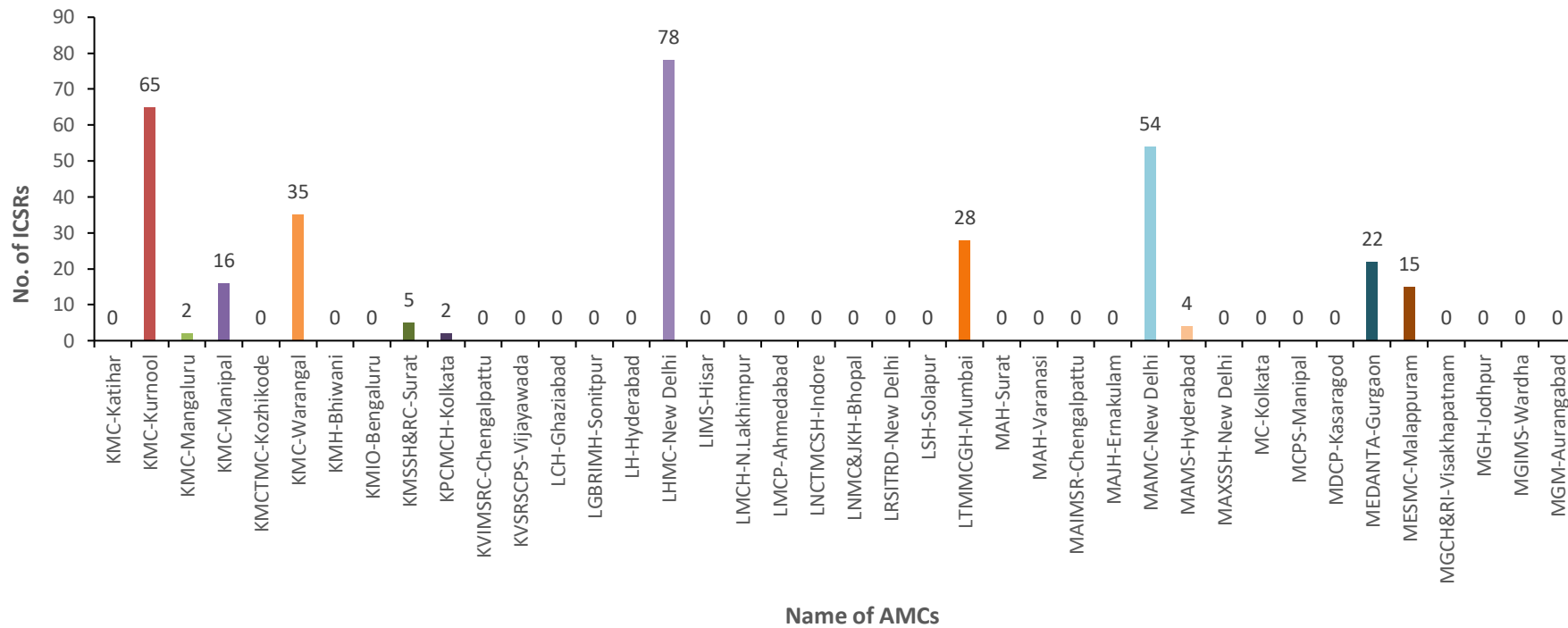
FOR PVI

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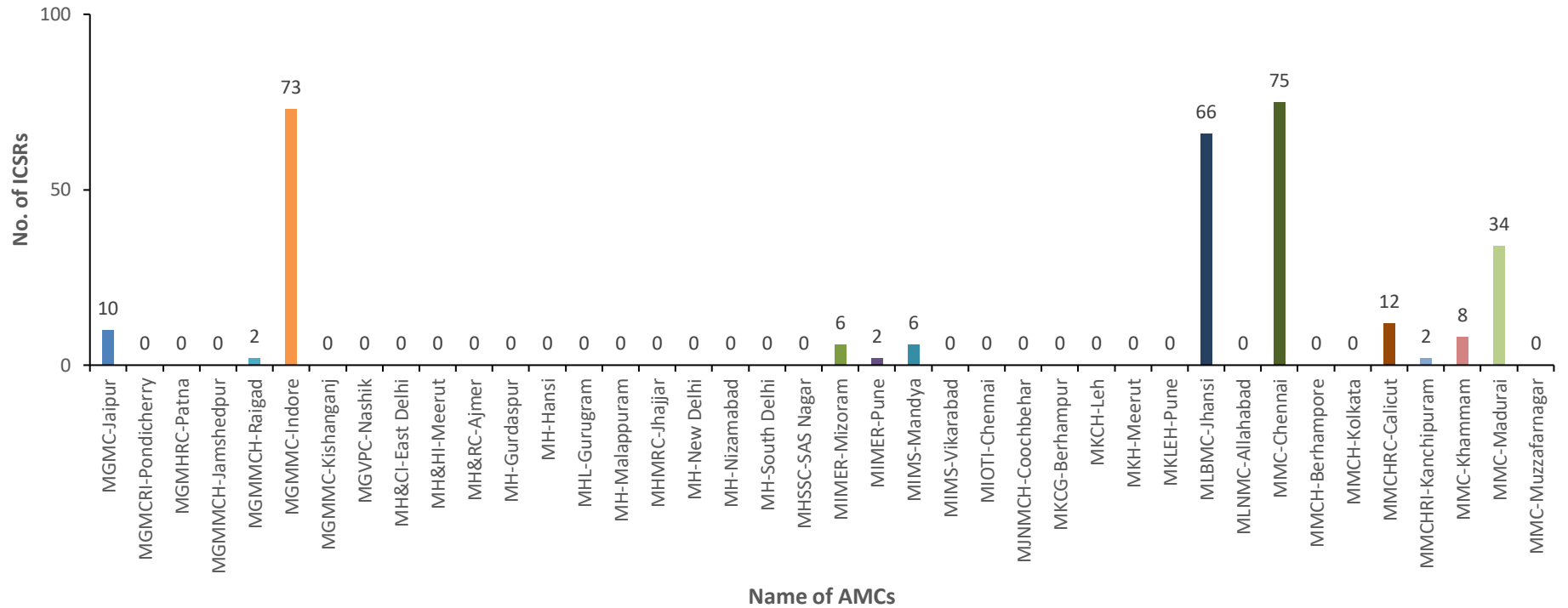


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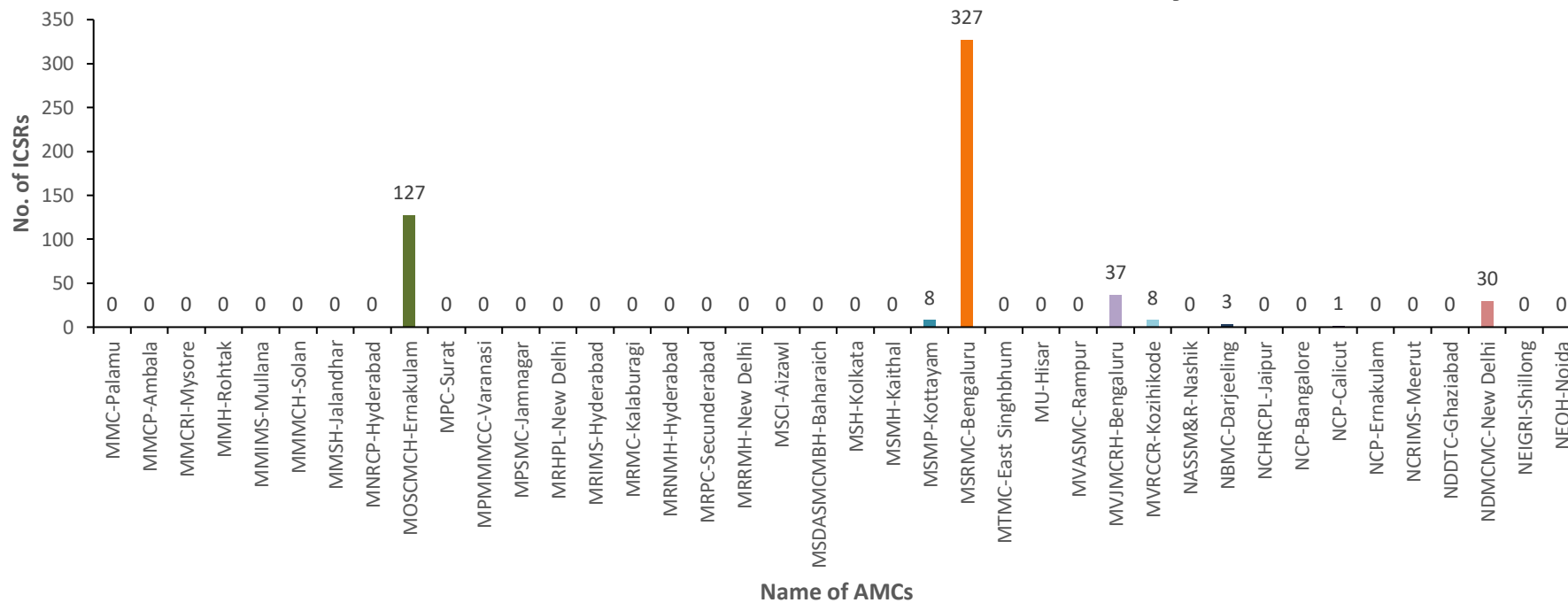
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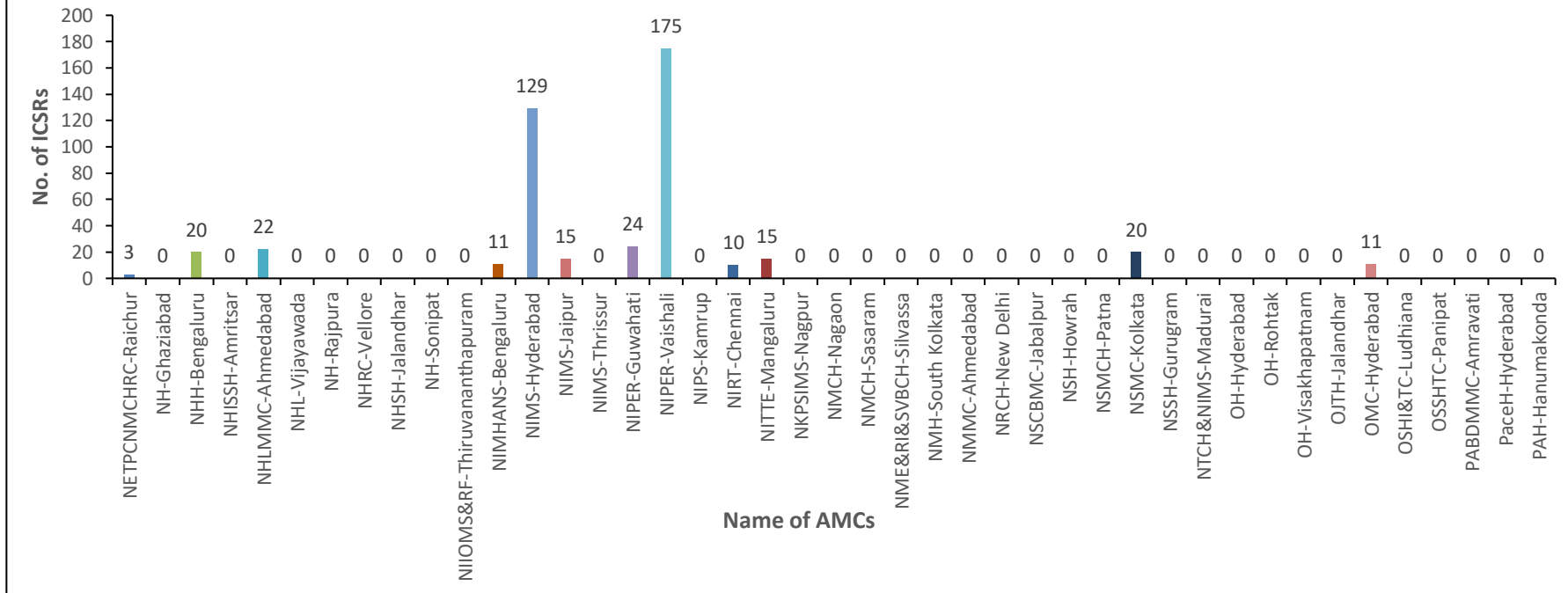
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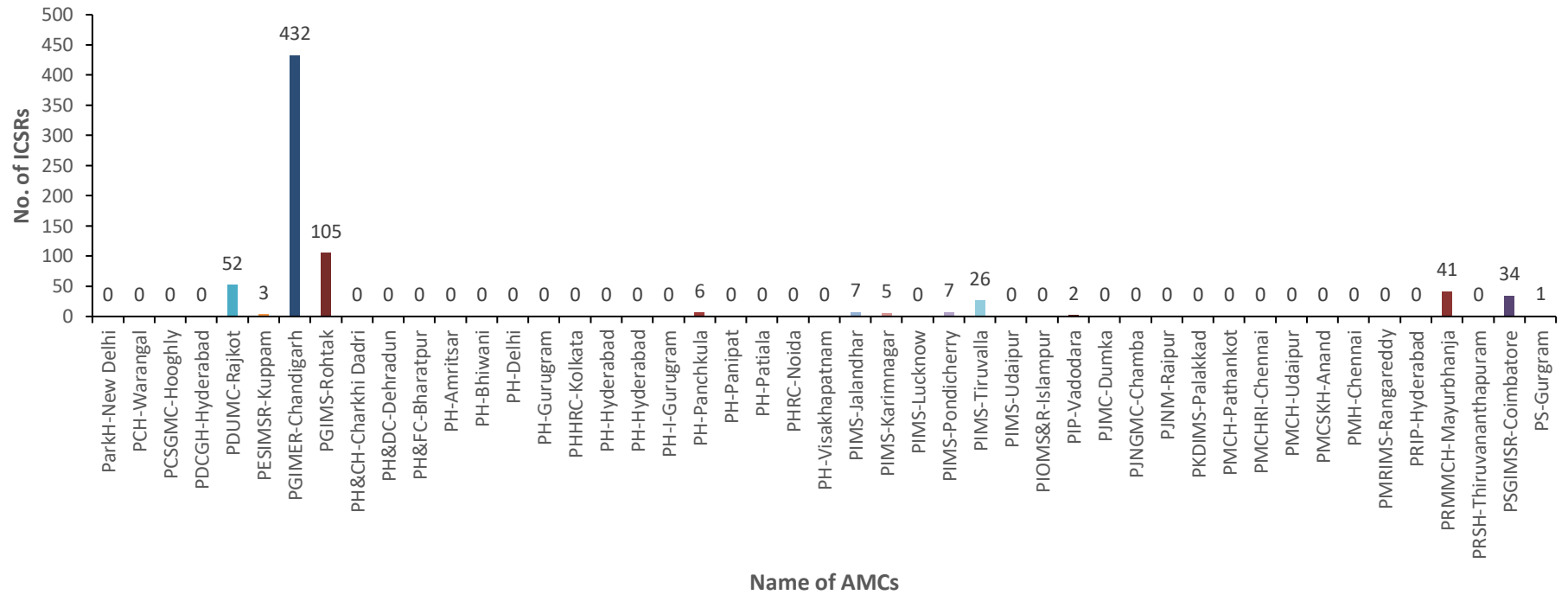
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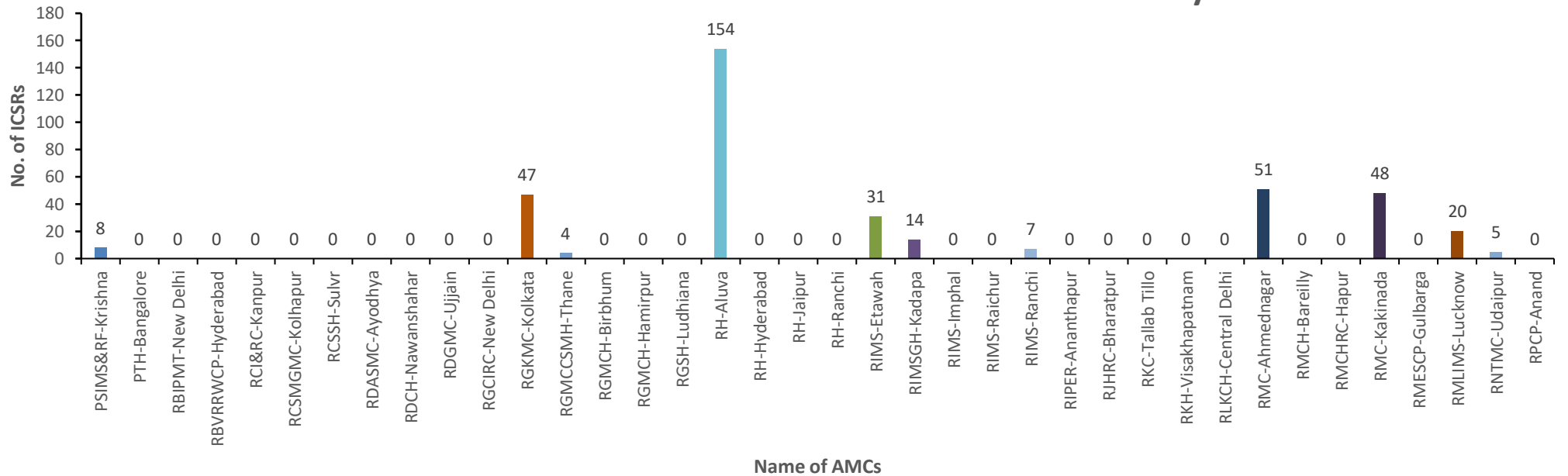
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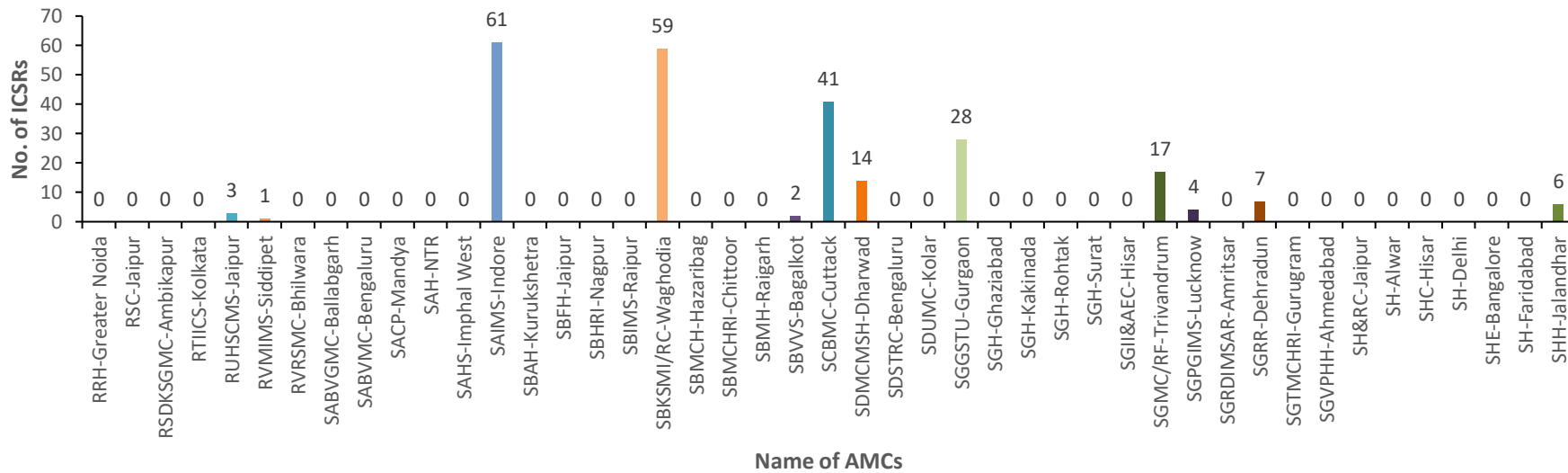
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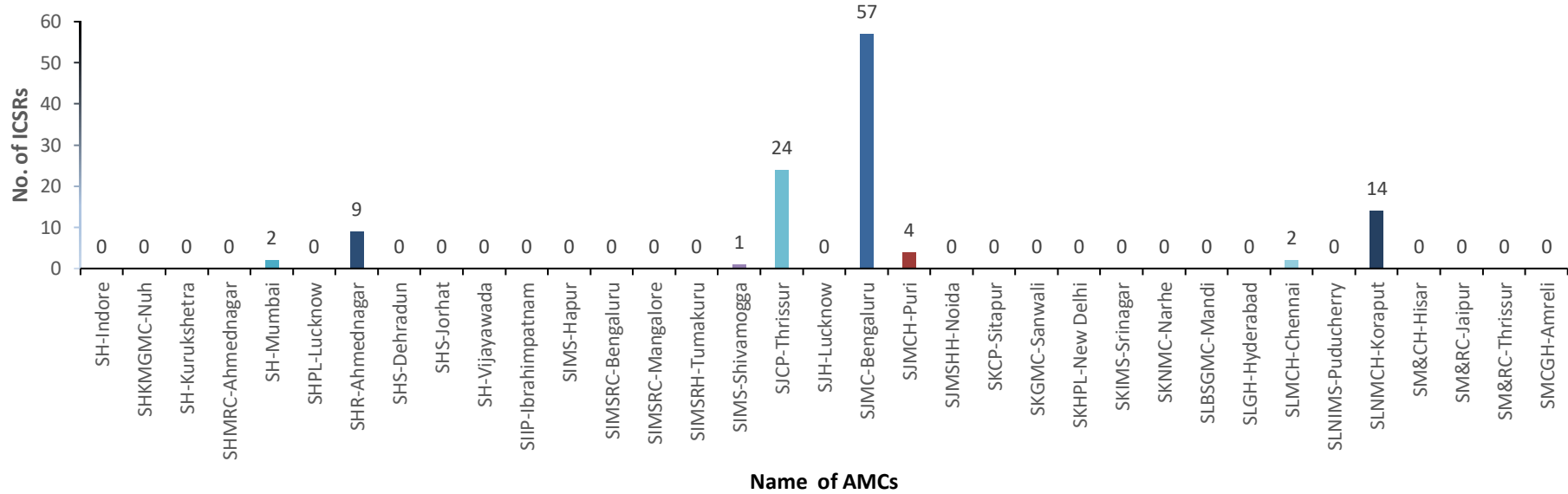


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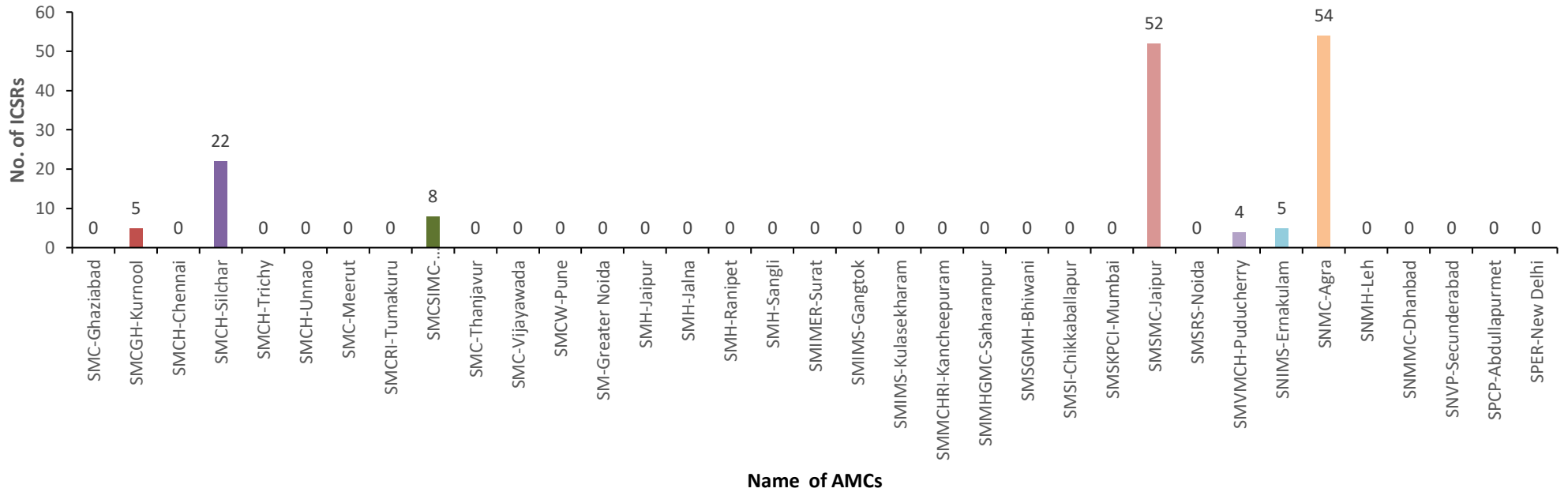
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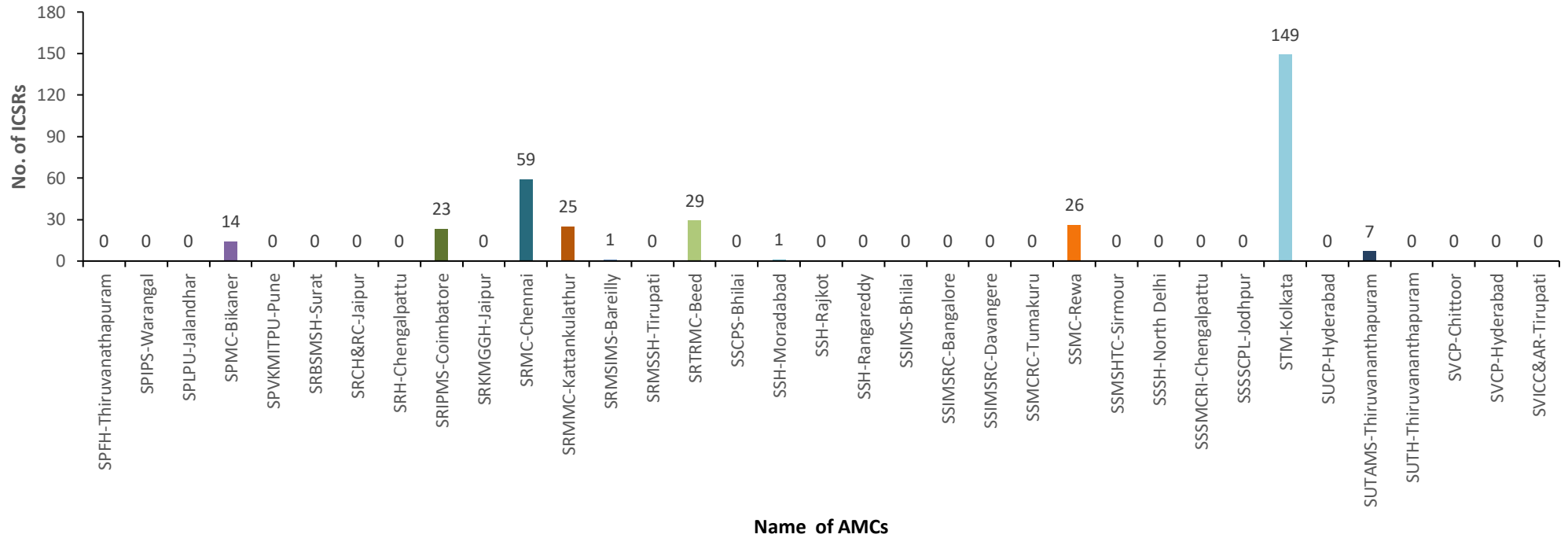


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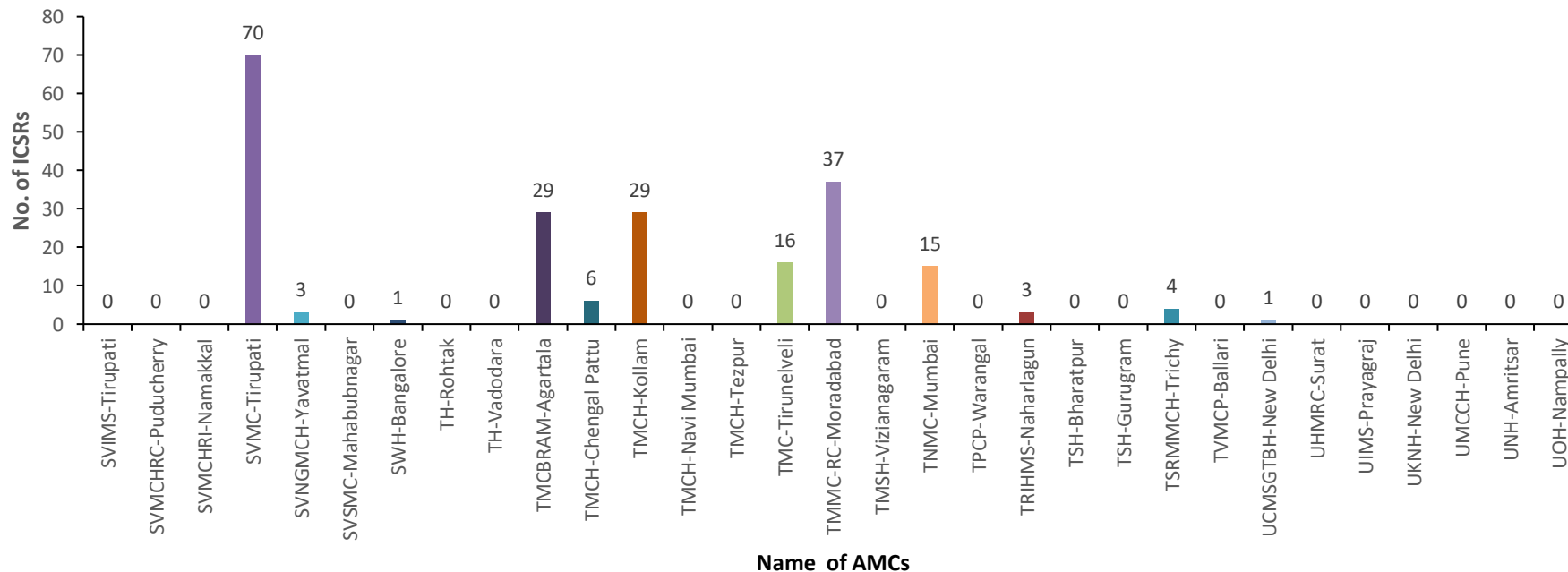


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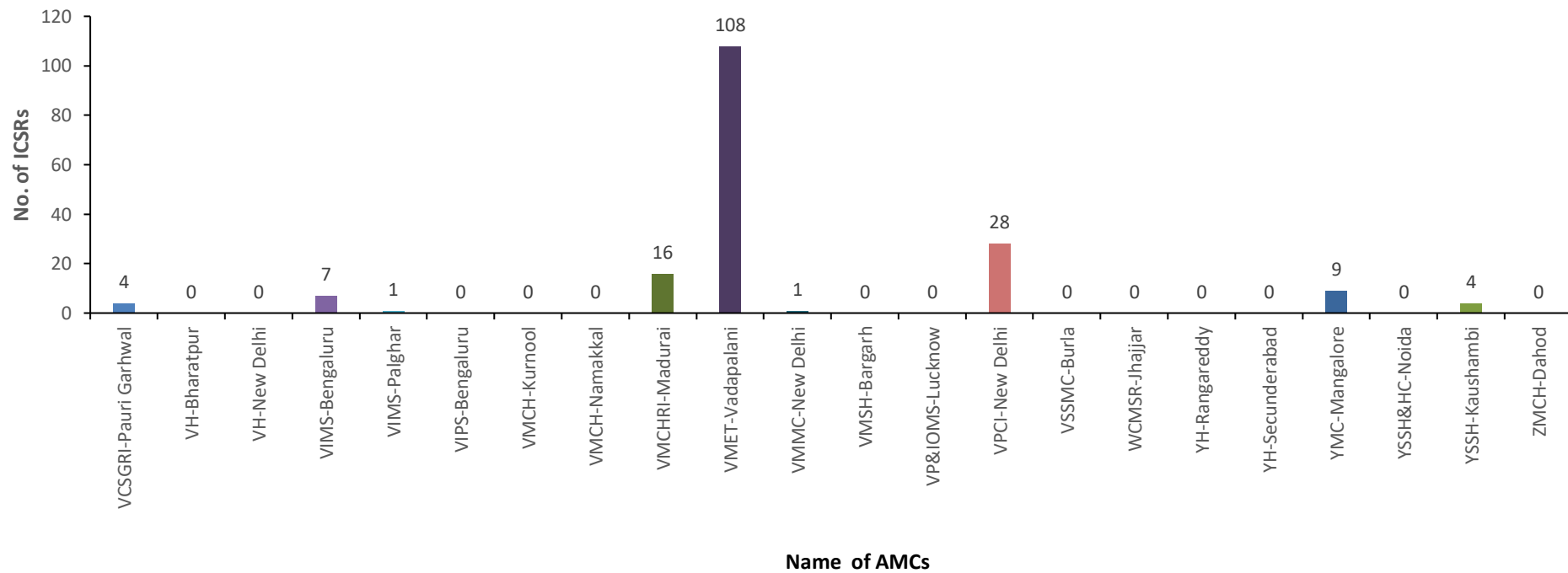
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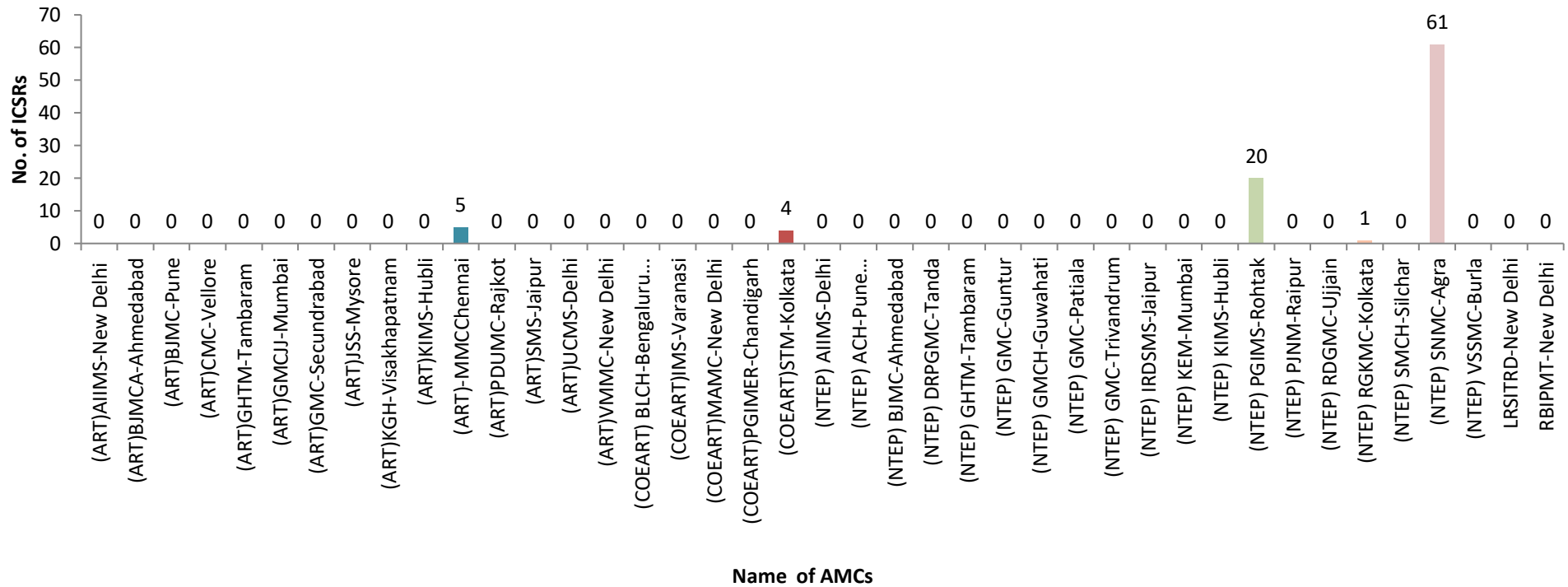


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No. of ICSRs recieved from AMCs in the month of February-2024



No. of ICSRs recieved from ART and NTEP Centres in the month of February-2024



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

| S. No. | Industry Name | Total | Initial | Follow-up |
|--------|---|-------|---------|-----------|
| 1 | Abbott India Limited | 36 | 28 | 8 |
| 2 | Akums Drugs & Pharmaceuticals Limited | 31 | 26 | 5 |
| 3 | Alkem Laboratories Limited | 24 | 20 | 4 |
| 4 | AbbVie Therapeutics India Private Limited | 58 | 31 | 27 |
| 5 | Amgen India | 10 | 7 | 3 |
| 6 | Aristo Pharmaceuticals Private Limited | 1 | 1 | |
| 7 | Astellas Pharma India Private Limited | 61 | 53 | 8 |
| 8 | AstraZeneca Pharma India Limited | 235 | 208 | 27 |
| 9 | Aurobindo Pharma Limited | 141 | 133 | 8 |
| 10 | Baxter (India) Private Limited | 249 | 249 | |
| 11 | Bayer Pharmaceuticals Pvt Ltd | 56 | 34 | 22 |
| 12 | BE pharmaceuticals private limited | 1 | 1 | |
| 13 | Bharat Biotech International Limited | 5 | 5 | |
| 14 | Biocon Biologics Limited | 6 | 5 | 1 |
| 15 | Boehringer Ingelheim India Private Limited | 5 | 5 | |
| 16 | Bristol-Myers Squibb India | 161 | 68 | 93 |
| 17 | Biological E Limited | 2 | 2 | |
| 18 | Blue Cross Laboratories Pvt Ltd. | 2 | 2 | |
| 19 | Cadila Pharmaceuticals Ltd. | 4 | 4 | |
| 20 | Cipla Limited | 126 | 93 | 33 |
| 21 | Dr.Reddy's Laboratories | 43 | 42 | 1 |
| 22 | EISAI Pharmaceuticals India Pvt. Ltd | 73 | 69 | 4 |
| 23 | Eli Lilly & Company (India) Private Limited | 169 | 140 | 29 |
| 24 | Emcure Pharmaceuticals Limited | 24 | 23 | 1 |
| 25 | Eris Lifesciences Limited | 8 | 8 | |
| 26 | Eusa Pharma | 1 | | 1 |
| 27 | Exemed Pharmaceutical Ltd. | 2 | 2 | |
| 28 | FDC Limited | 4 | 4 | |
| 29 | Ferring Pharmaceuticals Pvt Ltd | 3 | 3 | |
| 30 | Fresenius Kabi Oncology limited | 6 | 6 | |
| 31 | Glaxo Smithkline Pharmaceuticals Limited | 86 | 40 | 46 |
| 32 | GlaxoSmithKline Asia Private Limited | 4 | 4 | |
| 33 | GlaxoSmithKline Consumer Private Limited | 13 | 10 | 3 |
| 34 | Glenmark Pharmaceuticals Limited | 91 | 50 | 41 |
| 35 | Galderma India Pvt. Ltd. | 42 | 40 | 2 |
| 36 | Grifols India Healthcare Private Limited | 1 | 1 | |
| 37 | Guerbet India Pvt Ltd. | 1 | 1 | |
| 38 | Gilead | 4 | 3 | 1 |
| 39 | Gufic Biosciences Ltd | 6 | 6 | |
| 40 | Hetero Labs Limited | 39 | 33 | 6 |
| 41 | Imaging Products India Pvt. Ltd. | 3 | | 3 |
| 42 | Inventia Healthcare Ltd | 2 | 2 | |

| | | | | |
|----|--|-------------|-------------|-------------|
| 43 | IPCA Laboratories Limited | 23 | 21 | 2 |
| 44 | J. B. chemicals and Pharmaceuticals | 1 | 1 | |
| 45 | Johnsons & Johnsons Private Limited | 18 | 17 | 1 |
| 46 | LG Chem Life Sciences India Pvt. Ltd | 1 | 1 | |
| 47 | Lupin Limited | 93 | 49 | 44 |
| 48 | Macleods Pharmaceuticals Limited | 19 | 14 | 5 |
| 49 | MERCK Limited | 40 | 27 | 13 |
| 50 | MSD Pharmaceuticals Private Limited | 92 | 86 | 6 |
| 51 | MSN Laboratories Private Limited | 3 | 3 | |
| 52 | Mylan Laboratories Private Limited/Viatrix | 66 | 55 | 11 |
| 53 | Novartis India Limited | 1311 | 431 | 880 |
| 54 | Novo Nordisk India | 7 | 7 | |
| 55 | Organon India Private Limited | 3 | 3 | |
| 56 | Otsuka Pharmaceutical India Pvt. Ltd. | 4 | 1 | 3 |
| 57 | Pfizer Limited | 619 | 132 | 487 |
| 58 | Piramal Pharma Limited | 2 | 2 | |
| 59 | The Procter & Gamble Company | 101 | 100 | 1 |
| 60 | Roche Products (India) Private Limited | 353 | 226 | 127 |
| 61 | Reliance Life Sciences Pvt. Ltd. | 1 | 1 | |
| 62 | Reckitt Benckiser (India) Pvt. Ltd. | 8 | 8 | |
| 63 | Sandoz | 66 | 61 | 5 |
| 64 | Samrudh Pharmaceuticals Pvt. Ltd | 1 | 1 | |
| 65 | Sanofi India Limited | 72 | 39 | 33 |
| 66 | Servier India Private Limited | 31 | 26 | 5 |
| 67 | Shilpa Medicare Limited | 4 | 4 | |
| 68 | Sun Pharmaceutical Industries Limited | 206 | 117 | 89 |
| 69 | Serum Institute of India Limited | 19 | 19 | |
| 70 | Swiss Garniers Genexiaa Sciences Private | 2 | 2 | |
| 71 | Takeda | 68 | 68 | |
| 72 | Torrent Pharmaceuticals Limited | 40 | 28 | 12 |
| 73 | USV Private Limited | 3 | 3 | |
| 74 | Venus remedies ltd. | 1 | 1 | |
| 75 | Windlas Biotech Limited | 3 | 2 | 1 |
| 76 | Win-Medicare Pvt. Limited | 4 | 4 | |
| 77 | Wipro GE Healthcare Pvt. Ltd | 21 | 21 | |
| 78 | Wockhardt Pharmaceutical Limited | 1 | 1 | |
| 79 | Zydus Lifesciences Limited | 47 | 44 | 3 |
| | Total | 5193 | 3088 | 2105 |
| | | | | |