

Table 1. Total number of UK direct spontaneous suspected ADR reports received each year between 2012 and 2022

| | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 | 2021 | 2022 |
|------------------------------|--------|--------|--------|--------|--------|--------|--------|--------|--------|---------|--------|
| Number of ADR reports | 13,608 | 16,753 | 18,181 | 23,242 | 26,826 | 29,869 | 29,328 | 21,509 | 31,509 | 440,036 | 79,352 |

Table 2. Total number of UK direct spontaneous suspected ADR reports received by seriousness each year between 2012 and 2022 ¹

| | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 | 2021 | 2022 |
|--------------------|-------|--------|--------|--------|--------|--------|--------|--------|--------|---------|--------|
| Non-serious | 4,237 | 5,258 | 5,437 | 7,372 | 8,748 | 10,243 | 10,165 | 1,142 | 12,482 | 113,073 | 25,602 |
| Serious | 9,371 | 11,495 | 12,744 | 15,870 | 18,078 | 19,626 | 19,163 | 20,367 | 19,027 | 326,963 | 53,750 |

¹ The seriousness criteria for ADR reporting were determined by a working group of the Council for International Organizations of Medical Sciences (CIOMS) and are defined as 6 possible categories which are documented on the Yellow Card. Reporters can select one or more of the following criteria by ticking the appropriate box on the Yellow Card. The criteria are: (1) patient died due to reaction (2) life threatening (3) resulted in hospitalisation or prolonged inpatient hospitalisation (4) congenital abnormality and (5) involved persistent or significant disability or incapacity or (6) if the reaction was deemed medically significant.

Table 3. Total number of UK direct spontaneous suspected ADR reports received by reporter type each year between 2012 and 2022

| | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 | 2021 | 2022 |
|--|-------|-------|-------|-------|-------|-------|-------|-------|-------|---------|--------|
| Physician* | 5,650 | 6,474 | 7,003 | 8,367 | 8,479 | 8,889 | 8,338 | 8,766 | 7,192 | 27,623 | 9,878 |
| Nurse* | 2,354 | 2,985 | 2,791 | 3,364 | 3,763 | 3,977 | 3,843 | 3,870 | 3,674 | 15,540 | 3,862 |
| Pharmacist* | 2,591 | 3,221 | 3,346 | 4,512 | 6,083 | 6,776 | 6,463 | 6,973 | 6,720 | 13,419 | 6,812 |
| Consumer or other non health professional | 1,735 | 2,680 | 3,659 | 5,281 | 6,505 | 7,499 | 7,926 | 8,251 | 8,760 | 355,307 | 52,808 |
| Other healthcare professional* | 1,584 | 1,564 | 1,521 | 1,904 | 2,309 | 2,941 | 2,995 | 3,869 | 3,893 | 28,598 | 6,117 |
| Not known | 1 | 1 | 2 | 0 | 0 | 1 | 2 | 2 | 0 | 17 | 3 |

*Aggregated group. Physician: Hospital doctor, Physician, GP. Nurse: Hospital nurse, Nurse. Pharmacist: Community pharmacist, Pharmacist, Hospital pharmacist. Other healthcare professional: Carer, Chiropodist, Dentist, Healthcare assistant, Hospital Healthcare Professional, Medical Student, Midwife, Optometrist, Other healthcare professional, Paramedic, Radiographer.

Table 4. Number of UK spontaneous suspected ADR reports with the fifteen most frequently reported medicines included received each year between 2012 and 2022

| 2012 | | 2013 | | 2014 | | 2015 | | 2016 | | 2017 | | 2018 | | 2019 | | 2020 | | 2021 | | 2022 | |
|-------------------------|--------|-------------------------|--------|-------------------------|--------|-------------------------------|--------|----------------------------------|--------|----------------------------------|--------|-------------------------------|--------|-------------------------|--------|---|--------|---|--------|---|--------|
| Substance | Number | Substance | Number | Substance | Number | Substance | Number | Substance | Number | Substance | Number | Substance | Number | Substance | Number | Substance | Number | Substance | Number | Substance | Number |
| HUMAN PAPILLOMA VIRUS | 678 | HUMAN PAPILLOMA VIRUS | 796 | RIVAROXABAN | 530 | RIVAROXABAN | 870 | MENINGOCOCCAL GROUP B VACCINE | 856 | PHENOXYMETHYLPENICILLIN | 765 | INFLUENZA VIRUS | 1314 | ADALIMUMAB | 1092 | MONOVALENT COVID-19 VACCINE PRIZER/BIONTECH | 2705 | COVID-19 VACCINE ASTRAZENECA | 236036 | MONOVALENT COVID-19 VACCINE PRIZER/BIONTECH | 19448 |
| VARENICLINE | 657 | VARENICLINE | 580 | INFLUENZA VIRUS | 418 | INFLUENZA VIRUS | 518 | RIVAROXABAN | 846 | RIVAROXABAN | 754 | PHENOXYMETHYLPENICILLIN | 678 | INFLUENZA VIRUS | 1083 | INFLUENZA VIRUS | 1268 | MONOVALENT COVID-19 VACCINE PFIZER/BIONTECH | 145560 | MONOVALENT COVID-19 VACCINE MODERNA | 11152 |
| SIMVASTATIN | 280 | INFLUENZA VIRUS | 412 | LIVE INFLUENZA VIRUS | 411 | PHENOXYMETHYLPENICILLIN | 485 | PHENOXYMETHYLPENICILLIN | 646 | INFLUENZA VIRUS | 743 | APIXABAN | 596 | PHENOXYMETHYLPENICILLIN | 685 | ADALIMUMAB | 615 | ELASOMERAN | 30701 | COVID-19 VACCINE | 5183 |
| INFLUENZA VIRUS | 258 | RIVAROXABAN | 369 | HUMAN PAPILLOMA VIRUS | 377 | LIVE INFLUENZA VIRUS | 456 | INFLUENZA VIRUS | 483 | MENINGOCOCCAL GROUP B VACCINE | 640 | RIVAROXABAN | 570 | APIXABAN | 599 | PHENOXYMETHYLPENICILLIN | 584 | INFLUENZA VIRUS | 2256 | COVID-19 BIVALENT SPIKEVAX | 4790 |
| ETONOGESTREL | 203 | LIVE INFLUENZA VIRUS | 341 | VARICELLA ZOSTER VIRUS | 348 | HUMAN PAPILLOMA VIRUS | 409 | APIXABAN | 464 | MENINGOCOCCAL A,C,W135,Y VACCINE | 639 | AMOXICYLLIN | 534 | AMOXICYLLIN | 586 | NITROFURANTOIN | 565 | SARS-COV-2 VIRUS | 1349 | COVID-19 BIVALENT COMIRNATY | 3554 |
| PHENOXYMETHYLPENICILLIN | 193 | DABIGATRAN | 257 | VARENICLINE | 303 | VARENICLINE | 350 | MENINGOCOCCAL A,C,W135,Y VACCINE | 454 | APIXABAN | 599 | NITROFURANTOIN | 477 | NITROFURANTOIN | 581 | SERTRALINE | 488 | NITROFURANTOIN | 586 | INFLUENZA VIRUS | 1814 |
| RAMIPRIL | 191 | SIMVASTATIN | 236 | SIMVASTATIN | 286 | APIXABAN | 343 | AMOXICYLLIN | 436 | AMOXICYLLIN | 507 | SERTRALINE | 465 | SERTRALINE | 505 | AMOXICYLLIN | 451 | PHENOXYMETHYLPENICILLIN | 541 | NIRMATRELVIR AND RITONAVIR | 1184 |
| DABIGATRAN | 187 | RAMIPRIL | 227 | PHENOXYMETHYLPENICILLIN | 246 | MENINGOCOCCAL GROUP B VACCINE | 336 | IBUPROFEN | 379 | DT IPV VACCINE | 449 | MENINGOCOCCAL GROUP B VACCINE | 403 | FLUCLOXACILLIN | 441 | FLUCLOXACILLIN | 443 | AMOXICYLLIN | 529 | PHENOXYMETHYLPENICILLIN | 867 |
| CITALOPRAM | 173 | ETONOGESTREL | 209 | ATORVASTATIN | 242 | ATORVASTATIN | 331 | ATORVASTATIN | 356 | FLUCLOXACILLIN | 433 | FLUCLOXACILLIN | 395 | RIVAROXABAN | 417 | APIXABAN | 436 | SERTRALINE | 520 | NITROFURANTOIN | 730 |
| AMLODIPINE | 164 | VARICELLA ZOSTER VIRUS | 208 | RAMIPRIL | 239 | TRIMETHOPRIM | 320 | TRIMETHOPRIM | 383 | SERTRALINE | 418 | MMR VACCINE | 384 | AMLODIPINE | 417 | RIVAROXABAN | 377 | FLUCLOXACILLIN | 443 | SARS-COV-2 VIRUS | 679 |
| ADALIMUMAB | 162 | MMR VACCINE | 203 | TRIMETHOPRIM | 238 | AMOXICYLLIN | 307 | SERTRALINE | 352 | CLARITHROMYCIN | 408 | RAMIPRIL | 383 | MMR VACCINE | 416 | CLARITHROMYCIN | 363 | AMLODIPINE | 373 | ATORVASTATIN | 646 |
| AMOXICYLLIN | 148 | AMLODIPINE | 187 | AMLODIPINE | 232 | CLARITHROMYCIN | 299 | AMLODIPINE | 336 | ATORVASTATIN | 402 | AMLODIPINE | 381 | RAMIPRIL | 404 | AMLODIPINE | 358 | DOXYCYCLINE | 361 | SERTRALINE | 643 |
| TRIMETHOPRIM | 146 | AMOXICYLLIN | 186 | AMOXICYLLIN | 231 | SERTRALINE | 297 | FLUCLOXACILLIN | 333 | RAMIPRIL | 399 | ATORVASTATIN | 374 | LIVE INFLUENZA VIRUS | 391 | STREPTOCOCCUS PNEUMONIAE | 338 | CLARITHROMYCIN | 357 | DOXYCYCLINE | 633 |
| RIVAROXABAN | 136 | SERTRALINE | 182 | SERTRALINE | 203 | RAMIPRIL | 290 | CLARITHROMYCIN | 330 | AMLODIPINE | 396 | CLARITHROMYCIN | 371 | CLARITHROMYCIN | 389 | ATORVASTATIN | 331 | ESTRADIOL | 349 | AMOXICYLLIN | 627 |
| SITAGLIPTIN | 126 | PHENOXYMETHYLPENICILLIN | 171 | ROTAVIRUS | 194 | AMLODIPINE | 283 | RAMIPRIL | 306 | TRIMETHOPRIM AND LIVE INFLUENZA | 354 | LIVE INFLUENZA VIRUS | 344 | ATORVASTATIN | 357 | EDOXABAN | 329 | ATORVASTATIN | 339 | FLUCLOXACILLIN | 613 |