Abbreviations and Acronyms

A list of abbreviations and acronyms found in the field of, or connected with, pharmacovigilance.

| ACSoMP | Advisory Committee on Safety of Medicinal Products (WHO) |
|--------|--|
| ACT | Artemisinin-based combination therapy |
| ADE | Adverse drug event/effect |
| ADR | Adverse drug reaction |
| AEFI | Adverse event following immunisation |
| AEMPS | Agencia Española de Medicamentos y Productos Sanitarios (Spanish Medicines and Healthcare Products Agency) |
| ANSM | Agence nationale de sécurité du médicament et des produits de santé, France (<i>has replaced AFSSAPS</i>) |
| API | Active pharmaceutical ingredient (WHO) |
| ART | Antiretroviral therapy |
| ARV | Antiretrovirals |
| ATC | Anatomical, Therapeutic, Chemical classification |
| BCPNN | Bayesian Confidence Propagation Neural Network |
| BfArM | Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Drugs and Medical Devices in Germany) |
| BMA | British Medical Association |
| CDC | Centers for Disease Control and Prevention |
| CEM | Cohort Event Monitoring |
| CEN | Centre Européen de Normalisation (the European Committee for Standardization) |
| СНМР | Committee on Medicinal Products for Human use (EU), previously CPMP |
| CIOMS | Council for International Organizations of Medical Sciences |
| CRO | Contract research organisation (often responsible for clinical trials) |
| DDD | Defined Daily Dose |
| DIA | Drug Information Association |
| DSRU | Drug Safety Research Unit, Southampton, UK |
| DTC | Direct to consumer |
| DTP | Direct to patient |
| EEA | European Economic Area |
| EMA | European Medicines Agency |
| ENCePP | European Network of Centres for Pharmacoepidemiology and Pharmacovigilance |
| EU | European Union |
| E2B | The current international standard for ADR reporting developed by ICH |
| FDA | Food and Drug Administration (USA regulatory body) |

| FIC | (WHO) Family of International Classifications |
|-------|--|
| FIP | International Pharmaceutical Federation |
| FOI | Freedom of information |
| FTP | File transfer protocol |
| GACVS | Global Advisory Committee on Vaccine Safety (WHO) |
| GCP | Good clinical practice. |
| GF | Gates Foundation <i>(full name Bill and Melinda Gates Foundation)</i> or Global Fund <i>(see also GFTAM)</i> |
| GFATM | Global Fund to Fight AIDS, Tuberculosis and Malaria |
| GLP | Good laboratory practice For example: |
| | www.oecd.org/chemicalsafety/testing/goodlaboratorypracticeglp.htm |
| GMP | Good manufacturing practice For example: |
| | www.who.int/medicines/organization/qsm/activities/qualityassurance/gmp/orggmp.shtml |
| GVSI | WHO Global Vaccine Safety Initiative www.who.int/vaccine_safety/initiative/en |
| GxP | generic term for good practice requirements in the pharmaceutical industry |
| HAI | Health Action International www.haiweb.org |
| HATC | Herbal ATC |
| HIC | High income countries |
| HSA | Health Sciences Authority, Singapore |
| IC | Information Component (used in BCPNN) - Informed consent |
| ICD | International Classification of Diseases |
| ICDRA | International Conference for Drug Regulatory Authorities |
| ICH | International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use |
| ICSR | Individual case safety report |
| IMB | Irish Medicines Board |
| IMMP | The Intensive Medicines Monitoring Programme, New Zealand |
| IMS | Not an acronym. Company providing statistics and information in the health care sector |
| INN | International non-proprietary names (for pharmaceutical substances) |
| IPCS | International Programme on Chemical Safety www.who.int/pcs |
| ISO | International Organization for Standardization www.iso.org |
| ISoP | International Society of Pharmacovigilance www.isoponline.org |
| ISPE | International Society for Pharmacoepidemiology www.pharmacoepi.org |
| JPMA | Japan Pharmaceutical Manufacturer's Association |
| Lareb | Netherlands Pharmacovigilance Foundation <i>(Landelijke Registratie en Evaluatie van Bijwerkingen)</i> |
| LMIC | Low- and middle income countries |
| MAH | Market authorisation holder |

| MedDRA | Medical Dictionary for Drug Regulatory Affairs |
|---------|--|
| MHRA | Medicines and Healthcare products Regulatory Agency (UK) |
| MSH | Management Sciences for Health |
| MSSO | Maintenance and Support Services Organization (for MedDRA) |
| MSF | Médecins Sans Frontières |
| NC | National centre (for pharmacovigilance) |
| NCE | New chemical entity |
| NDA | New Drug Application |
| NGO | Non-governmental organisation |
| NME | New molecular entity |
| NRA | National regulatory authority |
| NSAID | Non-steroidal anti-inflammatory drug |
| отс | Over-the-counter |
| PCC | Poison Control Centre |
| PDR | Physician's Desk Reference |
| PDS | Pharmacoepidemiology and Drug Safety (journal) |
| PEM | Prescription event monitoring |
| PEPFAR | US President's Emergency Plan for AIDS Relief |
| PHRMA | Pharmaceutical Research and Manufacturers Association |
| PIL | Package insert leaflet |
| PMDA | Pharmaceuticals and Medical Devices Agency, Japan |
| PMS | Post-marketing surveillance |
| POM | Prescription only medicine |
| PPI | Proton Pump Inhibitor |
| PRAC | Pharmacovigilance Risk Assessment Committee (EMA) |
| PSM | Procurement and supply management |
| PSUR | Periodic safety update report |
| PV | Pharmacovigilance |
| QA | Quality Assurance |
| QSM-WHO | Quality Assurance and Safety of Medicines (WHO) |
| RCA | Root-cause analysis |
| SFDA | State Food and Drug Administration, China |
| SMQ | Standardized MedDRA Query |
| SOC | System organ class |
| SOP | Standard operating procedure |
| SPC | Summary of product characteristics (in the EU) |
| SSFFC | Substandard/Spurious/Falsely-Labelled/Falsified/Counterfeit (SSFFC) Medical Products (WHO) |
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| SSRI | Selective Serotonin Reuptake Inhibitor (group of anti-depressants) |
|---------|--|
| TGA | Therapeutic Goods Administration, Australia |
| THIN | The Health Improvement Network, UK. A medical research database of anonymized patient records from general practitioners |
| TSR | Targeted spontaneous reporting |
| UMC | the Uppsala Monitoring Centre www.who-umc.org |
| UNITAID | <i>Not an acronym.</i> Organization cooperating with WHO and others on the WHO millennium goals |
| VAERS | Vaccine adverse event reporting system |
| WAHO | West African Health Organization |
| WHO | World Health Organization www.who.int |
| WHO-ART | WHO Adverse Reaction Terminology |
| WHO-CC | WHO Collaborating Centre |
| WHO-DD | WHO Drug Dictionary |
| WHO-DDE | WHO Drug Dictionary Enhanced |
| XML | Extensible Mark-up Language |