USEFUL ACRONYMS

Acronyms and full terms
ADRs Adverse Drug Reactions
ATMP Advanced Therapy Medicinal Products
BLA Biologic License Application
CAT Committee for Advanced Therapies
CHMP Committee for Human Medicinal Products
COMP Committee for Orphan Medicinal Products
CRO Contract (or Clinical) Research Organisation
CVMP Committee for Medicinal Products for Veterinary Use
DG SANCO Directorate General for Health and Consumers (santé et consommateurs)
DIA Drug Information Association
DSMB Data Safety Monitoring Board
EATG European AIDS Treatment Group
EBM Evidence-Based Medicine
EC European Commission
ECRIN European Clinical Research Infrastructures Network
EFPIA European Federation of Pharmaceutical Industry Associations
EMA European Medicines Agency
Enpr-EMA European Network of Paediatric Research at the European Medicines Agency
EPAR European Public Assessment Report
EU European Union
EUCTR European Clinical Trials Registry
EUNetHTA European network for health technology assessment
EUPATI European Patients' Academy on Therapeutic Innovation
EU-RMP EU Risk Management Plan
EURORDIS European Organisation for Rare Diseases
FDA Food and Drug Administration
FDAAA Food and Drug Administration Amendments Act
GCP Good Clinical Practice
GLP Good Laboratory Practice
GMP Good Manufacturing Practice
HCP HealthCare Professionals
HCPWP HealthCare Professionals Working Party
HIV Human Immunodeficiency Virus
HMPC Committee for Herbal Medicinal Products
HTA Health Technology Assessment
ICH International Conference on Harmonisation
IRB Institutional Review Board
ITF Innovation Task Force

MAA Marketing Authorisation Application
MA Marketing Authorisation
MAH Marketing Authorisation Holder
MS Member State
NBAC National Bioethics Advisory Commission
NCA National Competent Authority
NDA New Drug Application
NEJM New England Journal of Medicine
NME New molecular entity
NORD National Organization for Rare Disorders
PA Protocol Assistance
PAES Post-Authorisation Efficacy Study
PASS Post-Authorisation Safety Study
PCWP Patients and Consumers Working Party
PDCO Paediatric Committee
PDUFA Prescription Drug User Fee Act (1992 USA)
PL Package Leaflet
PO Patient Organisation
PRAC Pharmovigilance Risk Assessment Committee
PSO Public Summary of Opinion
PSUR Periodic Safety Update Report
QoL Quality of Life
RCT Randomised Controlled Trial
REMS Risk Evaluation and Minimisation Strategies
REPROTOX reproductive toxicity
RMP Risk Management Plan
RR Response Rate
SA Scientific Advice
SAG Scientific Advisory Group
SAWP Scientific Advice Working Party
SEED Shaping European Early Dialogues for Health Technologies
SCID Severe combined immunodeficiency
SME Small, micro and medium-sized enterprises
SmPC Summary Product Characteristics
SUSAR Suspected Unexpected Serious Adverse Reaction
TAG Treatment Action Group
TEP Tissue Engineered Product
TOPRA The Organisation for Professionals in Regulatory Affairs
UMN Unmet medical need
US United States