EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Scientific guidelines with SmPC recommendations

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Note: the tables below only include adopted scientific guidelines which refer specifically to the SmPC. For complete information on scientific guidelines, please refer to the European Medicines Agency website (https://www.ema.europa.eu/en/human-regulatory-overview/research-development/scientific-guidelines).

Guidelines under review are marked with an *

General guidance on product-information requirements can be found here and includes information on excipients labelling.

1. Clinical efficacy and safety

Guidelines	Reference to specific SmPC section(s)
Wording of therapeutic indication A Guide for Assessors of Centralised Applications	4.1
When is it relevant to include a bodyweight limit in the wording of a paediatric indication?	4.1
Guideline on the investigation of subgroups in confirmatory clinical trials	4.1, 4.3, 4.4, 5.1

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Guidelines	Reference to specific SmPC section(s)
Advanced therapies	
Guideline on xenogeneic cell-based medicinal products	
Guideline on core SmPC, Labelling and Package Leaflet for advanced therapy medicinal products (ATMPs) containing genetically modified cells.	Core SmPC
Anti-infectives for systemic use	
CHMP position paper on thiomersal implementation of the warning statement relating to sensitisation	4.3, 4.4, 4.8
Guideline on clinical evaluation of vaccines	4, 5.1
Guideline on the clinical development of medicinal products for the treatment of HIV infection	4.1, 4.4, 4.5, 5.1
Guideline on the evaluation of medicinal products indicated for treatment of bacterial infections	4.1, 4.2, 4.4, 5.1
Addendum to the guideline on the evaluation of medicinal products indicated for treatment of bacterial infections	4.1, 4.2, 4.4, 5.1
Guideline on the clinical evaluation of antifungal agents for the treatment and prophylaxis of invasive fungal disease	4.1, 4.2, 4.5, 4.4, 5.1, 5.3
*Points to consider on pharmacokinetics and pharmacodynamics in the development of antibacterial medicinal products	5.1
Cardiovascular system	
ICH E14 The Clinical Evaluation of QT/QTs Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs	
Guideline on clinical investigation of medicinal products in the treatment of lipid disorders	
Position paper on the regulatory requirements for the Authorisation of low-dose modified release ASA formulations in the secondary prevention of cardiovascular event	4.1, 5.1
Guideline on clinical investigation of medicinal products in the treatment of hypertension	4.1, 4.2
Nervous system	
* Guideline on clinical investigation of medicinal products in the treatment of epileptic disorders	
Background to the CPMP position paper on selective serotonin uptake inhibitors (SSRIs) and dependency/withdrawal reactions	4.2, 4.8
Guideline on medicinal products for the treatment of insomnia	5.1
Guideline on clinical investigation of medicinal products for the treatment of Multiple Sclerosis	5.1
Guideline on the clinical development of medicinal products intended for the treatment of pain	
Guideline on clinical investigation of medicinal products, including depot preparations, in the treatment of schizophrenia	

Guidelines	Reference to specific SmPC section(s)
Respiratory system	
Guideline on the clinical development of medicinal products for the treatment of cystic fibrosis	4.1, 5.1
*Requirements for clinical documentation for orally inhaled products (OIP) including the requirements for demonstration of therapeutic equivalence between two inhaled products for use in the treatment of asthma and chronic obstructive pulmonary disease …	4.2
Miscellaneous	
Investigation of drug interactions	4.3, 4.4, 4.5, 5.1, 5.2
Evaluation of the pharmacokinetics of medicinal products in patients with impaired hepatic function	4.2, 4.3, 4.4, 4.5, 5.2
Evaluation of the pharmacokinetics of medicinal products in patients with decreased renal function	4.2, 4.3, 4.4, 5.2
Reflection paper on investigation of pharmacokinetics in the obese population	4.2, 5.2
Guideline on the pharmacokinetic and clinical evaluation of modified release dosage forms	
Guideline on the use of pharmacogenetic methodologies in the pharmacokinetic evaluation of medicinal products	4.2, 5.1, 5.2
Guideline on key aspects for the use of pharmacogenomics in the pharmacovigilance of medicinal products	
Guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus	
Clinical investigation of immunosuppressants for solid organ transplantation	4.1, 4.2,4.4, 5.1
Guideline on the evaluation of anticancer medicinal products in man and its Appendix 3 (SmPC for an Anticancer medicinal product – mock-up of 4.8)	4.8
Appendix 2 to the guideline on the evaluation of anticancer medicinal products in man - The use of patient-reported outcome (PRO) measures in oncology studies	5.1
Reflection paper on Immune Tolerance Induction in haemophilia A patients with inhibitors	Section 5.1
Guideline on pharmaceutical development of medicines for paediatric use	
Guideline on the clinical investigation of medicinal products to prevent development/slow progression of chronic renal insufficiency	5.1
Clinical investigation of medicinal products for treatment of rheumatoid arthritis	4.1
Radiopharmaceuticals	
Guideline on core summary of product characteristics of radiopharmaceuticals	Core SmPC
Guideline on core summary of product characteristics and package leaflet for fludeoxyglucose (18F)	Core SmPC

Guidelines	Reference to specific SmPC section(s)
Guideline on core summary of product characteristics and package leaflet for technetium (99mTc) sestamibi	Core SmPC
Core summary of product characteristics (SmPC) and package leaflet for technetium (99mTc) macrosalb	Core SmPC
Guideline on core SmPC and package leaflet for (99Mo/99mTc) generator	Core SmPC
Guideline on core SmPC and Package Leaflet for sodium fluoride (18F)	Core SmPC
Guideline on core SmPC and package leaflet for nanocolloidal technetium (99mTc) albumin	Core SmPC
Guideline on core SmPC and Package Leaflet for (68Ge/68Ga) generator	Core SmPC
Core SmPC and package leaflet for sodium iodide (131 I) for therapeutic use	Core SmPC
Core summary of product characteristics (SmPC) and package leaflet for iopamidol 300	Core SmPC
Core summary of product characteristics (SmPC) and package leaflet for iopamidol 370	Core SmPC
Core summary of product characteristics (SmPC) and package leaflet for gadoteric acid	Core SmPC
Core summary of product characteristics and package leaflet for gadopentetate dimeglumine	Core SmPC
Core summary of product characteristics (SmPC) and package leaflet for fluorodopa (18F)	Core SmPC
Blood Products - Core SmPCs	
Core SmPC for human fibrinogen products	
Core SPC for hepatitis B for intramuscular use	
Core SPC for hepatitis B for intravenous use	
Guideline on the core SmPC for human Anti-D immunoglobulin for intravenous use	
Guideline on the core SmPC for human Anti-D immunoglobulin for intramuscular use	
Clinical investigation of human plasma derived von Willebrand factor products	
Core SPC for human plasma derived von Willebrand factor	
Core SPC for human varicella immunoglobulin for intramuscular use	
Core SPC for human rabies immunoglobulin for intramuscular use	
Core SPC for human tetanus immunoglobulin for intramuscular use	
Core SPC for human tick-borne encephalitis immunoglobulin for intramuscular use	
Core SPC for human albumin solution	
Core SPC for human prothrombin complex products	
Core SPC for human plasma coagulation factor VII products	
Core SPC for plasma-derived fibrin sealant/haemostatic products	

Guidelines	Reference to specific SmPC section(s)
Guideline on the clinical investigation of human normal immunoglobulin for intravenous administration (IVIg)	
Core SmPC for human normal immunoglobulin for intravenous administration (IVIg)	
Core SPC for human plasma derived antithrombin	
Core SPC for human normal immunoglobulin for subcutaneous and intramuscular use	
Core SmPC for human plasma derived and recombinant coagulation factor VIII products	
* Core SmPC for human plasma derived and recombinant coagulation factor IX products	

2. Quality and biological

Guidelines	Reference to specific SmPC section(s)
Quality (chemical and herbal)	
Maximum shelf-life for sterile products for human use after first opening or following reconstitution	
* Guideline on the pharmaceutical quality of inhalation and nasal products	2, 4.2, 6.4
Q and A on specific types of product - graduation of measuring devices for liquid dosage forms	4.2
Guideline on declaration of storage conditions: A: in the product information of medicinal products B: for active substances	
Guideline on quality of transdermal patches	
Quality of medicines questions and answers: • Administration of oral immediate release medicinal products through enteral feeding tubes • Specific type of products – Dry product inhalers • Specific types of product - Needle safety systems • Specific types of product - Eye drops • Storage • Particles originated from the container closure system	4.2, 6.6 6.1 3, 4, 6, 6.5, 6.6
Biologicals	
Warning on transmissible agents in summary of product characteristics (SPCs) and package leaflets for plasma derived medicinal products	4.4, 4.8
Description of composition of pegylated (conjugated) proteins in the SPC	2, 5.1, 5.2
Guideline on potency labelling for insulin analogue containing products with particular reference to the use of "international units" or "units"	4.2, 4.4, 5.1
Guideline on quality aspects included in the product information for vaccines for human use	1, 2, 3, 4, 6.1, 6.2, 6.3, 6.4, 6.5, 6.6

Guidelines	Reference to specific SmPC section(s)
Guideline on the declaration of the quantitative composition / potency labelling of biological medicinal products that contain modified proteins as active substance	

3. Non-clinical

Scientific guidelines	Reference to specific SmPC Section(s)
Guideline on the carcinogenicity evaluation of medicinal products for the treatment of HIV infection	5.3
* Risk assessment of medicinal products on human reproduction and lactation: from data to labelling	4.3, 4.6, 5.3
SWP/NcWP recommendations on the duration of contraception following the end of treatment with a genotoxic drug	4.6
Environmental risk assessment of medicinal products for human use	