Background

Quality & Biologicals

Quality (Chemical & Herbal)

Biologicals

Non-Clinical

Clinical Efficacy & Safety

Multidisciplinary

Scientific Guidelines for Human Medicinal Products

Non-Clinical Guidelines

C = Concept Paper D = Draft Guideline A = Adopted Guideline O = Overview of Comments

Title	C	D	A	O	Reference Number	Publication Date	Effective Date	Other Remarks
Pharmacology								
The nonclinical Evaluation of the potential for delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals (ICH S7B)			u		CPMP/ICH/423/02	May 2005	Nov 2005	
Safety pharmacology studies for human pharmaceuticals (ICH S7A)			u		CPMP/ICH/539/00	Nov 2000		Under revision
Non-Clinical Safety Studies For The Conduct Of Human Clinical Trials For Pharmaceuticals (ICH M3[R2]) modification		u	u		CPMP/ICH/286/95	Released for comments July 2008		Deadline for commens October 2008
Points to Consider on the assessment of the potential for QT interval prolongation by non-cardiovascular medicinal products					CPMP/SWP/986/96	Dec 1997		Replaced by ICH S7A and taken off EMEA website on 18/05/06
Pharmacokinetics								

Toxicokinetics: the assessment of systemic exposure in toxicity studies (ICH S3A)			u		CPMP/ICH/384/95	Nov 1994	Jun 1995
Pharmacokinetics: Guidance for repeated dose tissue distribution studies (ICH S3B)			u		CPMP/ICH/385/95	Nov 1994	Jun 1995
Pharmacokinetics and metabolic studies in the safety evaluation of new medicinal products in animals			u		3BS11A		Apr 1994
Toxicology							
Single-Dose Toxicity							
Single dose/acute toxicity	u				CHMP/ SWP/302413/08	Release for consultation Jun 2008	Deadline for comments Oct 2008
Single dose toxicity			u		3BS1A	Apr 2001	
Repeat-Dose Toxicity							
Repeated dose toxicity		u			CHMP/ SWP/488313/07	Release for consultation Feb 2008	Deadline for comments May 2008
Repeated dose toxicity			u		CPMP/SWP/1042/99	Jul 2000	Oct 2000
Duration of chronic toxicity testing in animals (rodent and non-rodent toxicity testing) (ICHS4A)			u		CPMP/ICH/300/95	Nov 1998	May 1999
Genotoxicity							
Guidance on Genotoxicity Testing and Data Interpretation for Pharmaceuticals intended for Human use (ICH S 2 (R1))		u			CHMP/ ICH/126642/08	Release for consultation Mar 2008	Deadline for comments May 2008

Limits of genotoxic impurities			u		CPMP/SWP/5199/02 CHMP/ QWP/251344/2006	Jun 2006	Jan 2007	Questions and Answers on the guideline
Reflection Paper on the assessment of the Genotoxic Potential of Antisense Oligodeoxynucleotides			u		CHMP/ SWP/199726/04	Jan 2005		
Position Paper on the genotoxic and carcinogenic potential of phenolphthalein			u		CPMP/818/97	Dec 1997		
Genotoxicity: a standard battery for genotoxicity testing of pharmaceuticals (ICHS2B)			u		CPMP/ICH/174/95	Sept 1997	Mar 1998	
Specific aspects of regulatory genotoxicity tests for pharmaceuticals (ICHS2A)			u		CPMP/ICH/141/95	Sept 1995	Apr 1996	
Carcinogenicity								
Carcinogenicity Evaluation of Medicinal Products for the Treatment of HIV Infection		u	u		EMEA/194898/2006	Jan 2008	Jul 2008	
CHMP SWP Conclusions and recommendations on the use of genetically modified animal models for carcinogenicity assessment			u		CPMP/SWP/2592/02 Rev 1	Jun 2004		
Carcinogenic potential			u		CPMP/SWP/2877 /00	Jul 2002	Jan 2003	

Points to consider on the Non-clinical assessment of the carcinogenic potential of human insulin analogues			u		CPMP/SWP/372/01	Nov 2001	
Carcinogenicity: testing for carcinogenicity of pharmaceuticals (ICH SIB)			u		CPMP/ICH/299/95	Sep 1997	Mar 1998
Need for carcinogenicity studies of pharmaceuticals (ICH SIA)			u		CPMP/ICH/140/95	Dec 1995	Jul 1996
Dose selection for carcinogenicity studies of pharmaceuticals (ICH S1 C (R2))			u		CPMP/ICH/383/95	Apr 2008	Oct 2008
Reproductive and Developmental Toxicity							
Risk Assessment of Medicinal Products on Human Reproduction and Lactation: From Data to Labelling		u	u		EMEA/ CHMP/203927/05	Jul 2008	Jan 2009
Need for Non-Clinical Testing in Juvenile Animals on Human Pharmaceuticals for Paediatric Indications		u	u		CHMP/ SWP/169215/05	Mar 2008	Aug 2008
Points to consider on the Need for assessment of reproduction toxicity of human insulin analogues			u		CPMP/SWP/2600/01	Mar 2002	Mar 2002

Reproductive toxicology: Detection of toxicity to reproduction for medicinal products including toxicity to male fertility (ICH S5A)			u		CPMP/ICH/386/95 (ICH S5A)	Sep 1993	Mar 1994	
Local Tolerance								
Non-clinical local tolerance testing of medicinal products			u		CPMP/SWP/2145/00	Feb 2001	Feb 2001	
Other Toxicity								
Non-clinical guideline on drug-induced hepatotoxicity		u			CHMP/ SWP/150115/06	Release for consultation Jan 2008		Deadline for comments Aug 2008
Non-Clinical Investigation of the Dependence Potential of Medicinal Products			u		CHMP/ SWP/94227/04	Mar 2006	Sep 2006	
Immunotoxicity studies for Human Pharmaceuticals (ICH S8)			u		CHMP/ICH/167235/04	Oct 2005	May 2006	
Need for revision of the Note for Guidance on photosafety testing (CPMP/SWP/398/01)	u				CHMP/ SWP/534549/07	Release for consultation Jan 2008		Deadline for comments May 2008
Photosafety testing			u		CPMP/SWP/398/01	Jun 2002	Dec 2002	
Background to the CPMP Position Paper on possible pre-clinical studies to investigate addiction and dependence/ withdrawal related to the use of selective serotonin uptake inhibitors (SSRIs)			u		CPMP/2278/00	Dec 2000		

Background to the CPMP Position Paper on selective serotonin uptake inhibitors (SSRIs) and dependency/ withdrawal reactions			u		EMEA/CPMP/2775/99	Apr 2000		
Replacement of animal studies by in-vitro models			u		CPMP/SWP/728/95	Feb 1997		
In Vitro investigation of mitochondrial toxicity of anti-hiv nucleoside reverse transcriptase inhibitors	u	u			CHMP/SWP/8212/07	Release for consultation Dec 2007		Deadline for comments Jul 2008
General Guidelines								
Medicinal Gases: Pharmaceutical Documentation (including recommendation on non-clinical safety requirements for well established medicinal gases)		u	u		CPMP/QWP/1719/00	Jan 2002 (addition of annex 1 in June 2008)	Aug 2002 (annex 1 from October 2008)	Annex 1 (Recommendation on safety requirements) was added with revision 1 of the guideline published in 2008. No other changes were introduced with revision 1
Strategies to identify and mitigate risks for first-in-human clinical trials with investigational medicinal products		u	u	u	CHMP/SWP/28367/07	Jul 2007	Sep 2007	
Non-clinical studies required before first clinical use of gene therapy medicinal products		u			CHMP/ GTWP/125459/2006	Release for consultation Mar 2007		Deadline for comments Nov 2007

Scientific Requirements for the Environmental Risk Assessment of Gene Therapy Medicinal Products	u	u			CHMP/ GTWP/125491/06	Release for consultation Feb 2007		Deadline for comments Aug 2007
Specification Limits for Residues of Metal Catalysts		u u	u		CPMP/SWP/ QWP/4446/00	Feb 2008	Sep 2008	
Environmental Risk Assessment of Medicinal Products for Human Use			u		CPMP/SWP/4447/00	Jun 2006	Dec 2006	
Development of a CHMP Guideline on the Non-Clinical Requirements to Support Early Phase I Clinical Trials with Pharmaceutical Compounds	u				EMEA/CHMP/ SWP/91850/06	Release for consultation Mar 2006		Deadline for comments Jun 2006
Annex Guideline on Similar Biological Medicinal Products containing Biotechnology-Derived Proteins as Active Substance: Non-Clinical and Clinical Issues - Guidance on Similar Medicinal Products containing Recombinant Erythropoietins			u		EMEA/ CHMP/94526/05	Mar 2006	July 2006	

Quality, Preclinical and Clinical aspects of Gene Transfer Medicinal Products - Annex on Non-Clinical testing for Inadvertent Germline transmission of Gene Transfer Vectors		u			EMEA/273974/05	Release for consultation Nov 2005		Deadline for comments May 2006
Non-Clinical Documentation for Mixed Marketing Authorisation Applications			u		CPMP/SWP/799/95	Oct 2005	Apr 2006	
Non-Clinical Development of Fixed Combinations of Medicinal Products		u	u		CHMP/ SWP/258498/05	Mar 2008	Aug 2008	
Evaluation of Control Samples for Non - clinical Safety Studies: Checking for Contamination with the Test Substance			u		CPMP/SWP/1094/04	Mar 2005	Sep 2005	
Environmental risk assessment for human medicinal products containing or consisting of GMOs			u		3BR1A		Jan 1995	(under revision)
Development of a CHMP Guideline on non-clinical testing for inadvertent germline transmission of Gene Transfer Vectors	u				CPMP/ SWP/110180/04	Nov 2004		
Position Paper on the non-clinical safety studies to support clinical trials with a single micro dose			u		CPMP/SWP/2599/02	Jun 2004	Jun 2004	

Dossier Structure and Content for Pandemic Influenza Vaccine Marketing Authorisation Application			u		CPMP/VEG/4717/03	Mar 2004	Apr 2004
Comparability of medicinal products containing biotechnology-derived proteins as active substance -annex on non-clinical and clinical issues			u		CPMP /3097/02*	Dec 2003	Jun 2004
Impurities in new drug products (Revision)			u		CPMP/ICH/2738/99	Feb 2003	Aug 2003
Maintenance of Note for guidance on impurities: Residual solvents			u		CPMP/ICH/1940/00 corr	Nov 2002	Mar 2003
Impurities testing: impurities in new drug substances (Revision)			u		CPMP/ICH/2737/99	Feb 2002	Mar 2002
Limitations to the use of ethylene oxide in the manufacture of medicinal products			u		CPMP/QWP/159/01	Mar 2001	Apr 2001
Pre-clinical evaluation of anti- cancer medicinal products			u		CPMP/SWP/997/96	Jul 1998	Jan 1999
Pre-clinical pharmacological and toxicological testing of vaccines			u		CPMP/SWP/465/95	Dec 1997	Jun 1998
Preclinical safety evaluation of biotechnology-derived pharmaceuticals (ICH S6)			u		CPMP/ICH/302/95	Sep 1997	Mar 1998
Investigation of chiral active substances			u		3CC29A	Jun 1997	Jan 1998

Impurities: Residual solvents			u		CPMP/ICH/283/95	Sep 1995	Mar 1996	
Herbal medicinal products								
Selection of test materials for genotoxicity testing for Traditional Herbal Medicinal Products/ Herbal Medicinal Products	u				EMEA/ HMPC/315413/08	Release for consultation Jul 2008		Dedline for comments Oct 2008
Assessment of genotoxicity of herbal substances/ preparations	u	u	u	u	EMEA/ HMPC/107079/07	Jun 2008	Dec 2008	
Non-Clinical Documentation for Herbal Medicinal Products in Applications for Marketing Authorization (Bibliographical and Mixed Applications) and in Applications for Simplified Registration			u	u	EMEA/ HMPC/32116/05	Sep 2006	Jul 2006	
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*new guidelines