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BIOSIMILAR GUIDELINES

Country	Agency Name	Biosimilar Regulatory Pathway	Links to Biosimilar Guidelines
Australia	Therapeutic Goods Administration (TGA)	No specific regulatory pathway, the process follows an assessment of category 1 or 2 applications	Adopted the following **EMA guidelines:** **CHMP/437/04 Rev1** (Guideline on similar biological medicinal products **EMA/CHPM/BWP247713/2012** (Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: quality issues (revision 1) **EMEA/CHMP/BMWP/42832/2005 Rev1** (Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substances: Non-clinical and clinical issues)
Argentina	National Administration of Drugs, Foods and Medical Devices (ANMAT)	Legislation numbers **7075** and **7729**	**Regulation 7075** (Registration and registry modification of biological medicinal products)
Brazil	The National Health Surveillance Agency (ANVISA)	**RDC no. 55/2010** Comparability development pathway	Documents not available in English
Canada	Health Canada	**Part C division 8** of Food and Drugs Act	**Information and Submission Requirements for Biosimilar Biologic Drugs**
China	China Food and Drug Administration (CFDA)	Subject to the new drug approval pathway with customized technical review criteria (no separate pathway)	Documents not available in English

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Europe	European Medicines Agency (EMA)	**Article 10(4) of Directive 2001/83/EC**	**CHMP/437/04 Rev1** (Guideline on similar biological medicinal products **EMA/CHPM/BWP247713/2012** (Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: quality issues (revision 1) **EMEA/CHMP/BMWP/42832/2005 Rev1** (Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substances: Non-clinical and clinical issues)
India	The Central Drugs Standard Control Organisation (CDSCO)	**Drug and Cosmetics Act,** active from 1940. Biosimilars are considered new drugs. This pathway can be abbreviated on a case by case basis	**Guidelines on Similar Biologic: Regulatory Requirements for Marketing Authorisation in India**
Israel	Ministry of Health (MoH)	**Procedure No. 127**	Documents not available in English
Japan	The Pharmaceuticals and Medical Devices Agency (PMDA)	**Section 2.(7) of part 1 of the notification from the Pharmaceutical and Food Safety Bureau, MHLW (PFSD Notification No. 0304004)**	**PFSB/ELD Notification No. 0304007** (Guideline on the Quality, Safety and Efficacy Assurance of Follow-on Biologics)
Mexico	Mexico Ministry of Health (COFEPRIS)	**Article 222** of the Mexican Health Law	**Biologics and Biosimilars Guideline**
New Zealand	New Zealand Medicines and Medical Devices Safety Authority (Medsafe)	**Medicines Act 1981**	**EMA/CHPM/BWP247713/2012** (Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: quality issues (revision 1) **EMEA/CHMP/BMWP/42832/2005 Rev1** (Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substances: Non-clinical and clinical issues)

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Saudi Arabia	Saudi Food and Drug Authority (sFDA)	**Guidelines on Biosimilars**	**Guideline on Biosimilar Products: Quality Considerations**
Singapore	Health Sciences Authority (HAS)	Abridged evaluation route	**Guidance on Therapeutic Product Registration in Singapore** **Appendix 15: Guidance on registration of biosimilar products**
South Africa	South African Health Products Regulatory Authority (SAHPRA)	**Medicines and Related Substances Act, 1965 (Act 101 of 1965)**	**Biosimilar medicines: Quality, Non-clinical and Clinical Requirements**
South Korea	Ministry of Food and Drug Safety (MFDS)	**Guideline on the Evaluation of Biosimilar Products** issued in 2009	Documents not available in English
Switzerland	Swissmedic	**Article 12, paragraph 5 or Ordinance of the Swiss Agency for Therapeutic Products of 22 June 2006 on the Simplified Licensing of Therapeutic Products and the Authorisation of Therapeutic Products by the Notification Procedure**	**Guidance Document: Authorisation Biosimilar** **Federal Act on Medicinal Products and Medical Devices**
Thailand	Thai Food and Drug Administration (TFDA)	**The Drug Act of B.E. 2510 (1967)**	Documents not available in English
Turkey	Turkish Medicines and Medical Devices Agency (TMMDA)	**Regulation on the Registration of Medicinal Products for Human Use (2005 / Issue No. 25705)**	Documents not available in English
United Kingdom	Medicines and Healthcare Products Regulatory Agency (MHRA)	Same as EMA	Same as EMA currently, MHRA specific approach post Brexit to be confirmed

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United States of America	Food and Drug Administration (FDA)	**Section 351(k) of the Public Health Service act**	**Scientific Considerations in Demonstrating Biosimilarity to a Reference Product** **Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product** **Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product**
Various	World Health Organisation (WHO)	N/A	**Guidelines on Evaluation of Similar Biotherapeutic Products (SBPs)** **Guidelines on Evaluation of Monoclonal Antibodies as Similar Biotherapeutic Products (SBPs)**