

# Regulations and Guidelines

## 1. Biosimilars Regulations

Country	Regulation	Date	Language	Link
EU	• Regulation (EC) No 726/2004	2012	English	<a href="https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2004_726/reg_2004_726_en.pdf">https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2004_726/reg_2004_726_en.pdf</a>
	• Directive 2001/83/EC	2012	English	<a href="https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2001_83_consol_2012/dir_2001_83_cons_2012_en.pdf">https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2001_83_consol_2012/dir_2001_83_cons_2012_en.pdf</a>
US	• Federal Food, Drug, and Cosmetic Act (FD&C Act)	2015	English	<a href="https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/FederalFoodDrugandCosmeticActFDCA/default.htm">https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/FederalFoodDrugandCosmeticActFDCA/default.htm</a>
	• Public Health Service Act (PHS Act)	2018	English	<a href="https://legcounsel.house.gov/Comps/PHSA-merged.pdf">https://legcounsel.house.gov/Comps/PHSA-merged.pdf</a>
	• The Biologics Price Competition and Innovation Act (BPCI Act)	2009	English	<a href="http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/ucm216146.pdf">http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/ucm216146.pdf</a>
	• 21 of the Code of Federal Regulations (CFR)	2018	English	<a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/cfrsearch.cfm">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/cfrsearch.cfm</a>
Canada	• Food and Drugs Act	2017	English	<a href="https://laws-lois.justice.gc.ca/eng/acts/f-27/">https://laws-lois.justice.gc.ca/eng/acts/f-27/</a>
	• Part C of Food and Drug Regulations	2017	English	<a href="https://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._870/rpdc.html">https://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._870/rpdc.html</a>
Korea	• Pharmaceutical Affairs ACT	2016	English	<a href="http://www.law.go.kr/LSW/eng/engLsSc.do?menuId=2&amp;section=lawNm&amp;query=pharmaceutical+affairs+act&amp;x=0&amp;y=0#liBgcolor13">http://www.law.go.kr/LSW/eng/engLsSc.do?menuId=2&amp;section=lawNm&amp;query=pharmaceutical+affairs+act&amp;x=0&amp;y=0#liBgcolor13</a>
	• Pharmaceutical Affairs ACT	2019	Korean	<a href="http://www.law.go.kr/LSW/lsInfoP.do?lsiSeq=205635&amp;efYd=20190612#0000">http://www.law.go.kr/LSW/lsInfoP.do?lsiSeq=205635&amp;efYd=20190612#0000</a>
	• Regulation on Approval and Review of Biological Products	2016	English	<a href="https://www.mfds.go.kr/eng/brd/m_27/list.do?multi_itm_seq=0&amp;srchTp=7&amp;srchWord=Biological+">https://www.mfds.go.kr/eng/brd/m_27/list.do?multi_itm_seq=0&amp;srchTp=7&amp;srchWord=Biological+</a>

	<ul style="list-style-type: none"> <li>Regulation on Approval and Review of Biological Products</li> </ul>	2018	Korean	<a href="https://www.mfds.go.kr/brd/m_211/view.do?seq=14189&amp;srchFr=&amp;srchTo=&amp;srchWord=%EC%83%9D%EB%AC%BC%ED%95%99%EC%A0%81%EC%A0%9C%EC%A0%9C&amp;srchTp=0&amp;itm_seq_2=0&amp;multi_itm_seq=0&amp;company_cd=&amp;company_nm=&amp;page=1">https://www.mfds.go.kr/brd/m_211/view.do?seq=14189&amp;srchFr=&amp;srchTo=&amp;srchWord=%EC%83%9D%EB%AC%BC%ED%95%99%EC%A0%81%EC%A0%9C%EC%A0%9C&amp;srchTp=0&amp;itm_seq_2=0&amp;multi_itm_seq=0&amp;company_cd=&amp;company_nm=&amp;page=1</a>
Japan	<ul style="list-style-type: none"> <li>Act on Securing the Quality, Efficacy, and Safety of Drugs, Medical Devices and Other Products</li> </ul>	2014	Japanese	<a href="https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000045726.html">https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000045726.html</a>
Switzerland	<ul style="list-style-type: none"> <li>AMZV</li> </ul>	2001	German	<a href="https://www.admin.ch/opc/de/classified-compilation/20011693/index.html">https://www.admin.ch/opc/de/classified-compilation/20011693/index.html</a>
	<ul style="list-style-type: none"> <li>VAZV</li> </ul>	2006	German	<a href="https://www.admin.ch/opc/de/classified-compilation/20051634/index.html">https://www.admin.ch/opc/de/classified-compilation/20051634/index.html</a>
Australia	<ul style="list-style-type: none"> <li>Biosimilar medicines regulation</li> </ul>	2018	English	<a href="https://www.tga.gov.au/sites/default/files/biosimilar-medicines-regulation.pdf">https://www.tga.gov.au/sites/default/files/biosimilar-medicines-regulation.pdf</a>

## 2. Biosimilars Guidelines

Country	Agency	Guidelines	Year	Link
EU	EMA	Multidisciplinary: biosimilar		<a href="https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-guidelines/multidisciplinary/multidisciplinary-biosimilar">https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-guidelines/multidisciplinary/multidisciplinary-biosimilar</a>
US	FDA	All Guidances for Drugs (Filtering ; Biosimilars)		<a href="https://www.fda.gov/drugs/guidances-drugs/all-guidances-drugs">https://www.fda.gov/drugs/guidances-drugs/all-guidances-drugs</a>
Canada	Health Canada	Biosimilar biologic drugs		<a href="https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/biosimilar-biologic-drugs.html">https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/biosimilar-biologic-drugs.html</a>
Korea	MFDS	Guidelines on the Evaluation of Biosimilar Products	2015	<a href="http://www.mfds.go.kr/eng/wpge/m_37/de0110241001.do">http://www.mfds.go.kr/eng/wpge/m_37/de0110241001.do</a>
Japan	PMDA	Guideline for the Quality, Safety, and Efficacy Assurance of Follow-on Biologics	2013	<a href="https://www.pmda.go.jp/files/000153851.pdf">https://www.pmda.go.jp/files/000153851.pdf</a>
Switzerland	Swissmedic	Guidance document Authorisation Biosimilar	2018	<a href="https://www.swissmedic.ch/swissmedic/en/home/humanarzneimittel/authorisations/information/aktualisierung_wegleitung_und_faq-Dokument_zulassung_biosimilar.html">https://www.swissmedic.ch/swissmedic/en/home/humanarzneimittel/authorisations/information/aktualisierung_wegleitung_und_faq-Dokument_zulassung_biosimilar.html</a>
WHO	WHO	Similar biotherapeutic products		<a href="https://www.who.int/biologicals/biotherapeutics/similar_biotherapeutic_products/en/">https://www.who.int/biologicals/biotherapeutics/similar_biotherapeutic_products/en/</a>

