

Supplementary Information

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Supplementary Table 1: Biosimilar Medicines in the EU currently authorized or with a positive opinion up to data cut off (30 May 2026).

Product Class	Active substance	Currently Authorized or Positive Opinion*	Approved indications
Monoclonal Antibodies (mAbs)	Denosumab	29	- Osteoporosis in post menopause - Bone loss associated with hormone ablation in men with prostate cancer - Bone loss associated with glucocorticoid therapy - Cancer-related bone conditions
	Ustekinumab	14	- Crohn's disease - Ulcerative colitis - Plaque psoriasis - Psoriatic arthritis
	Adalimumab	10 (4 withdrawn) ‡	- Rheumatoid arthritis - Crohn's disease - Ulcerative colitis - Plaque psoriasis - Psoriatic arthritis - Juvenile idiopathic arthritis - Axial spondyloarthritis - Hidradenitis suppurativa - Non-infectious uveitis
	Trastuzumab	8 (2 withdrawn) ‡	- HER2-positive breast cancer (early and metastatic) - HER2-positive metastatic gastric cancer
	Bevacizumab	8 (3 withdrawn) ‡	- Breast cancer - Colon cancer - Non-small-cell lung carcinoma - Ovarian, fallopian tube or peritoneum cancer - Cervix cancer - Kidney cancer
	Rituximab	6 (3 withdrawn) ‡	- Rheumatoid arthritis - Non-Hodgkin lymphoma - Chronic lymphocytic leukemia - Granulomatosis with polyangiitis and microscopic polyangiitis - Pemphigus vulgaris
	Ranibizumab	8	- Neovascular (wet) age-related macular degeneration - Visual impairment due to diabetic macular oedema - Proliferative diabetic retinopathy

			• Visual impairment due to macular oedema secondary to retinal vein occlusion • Visual impairment due to choroidal neovascularization
	Infliximab	4	• Rheumatoid arthritis • Crohn's disease • Ulcerative colitis • Plaque psoriasis • Psoriatic arthritis • Ankylosing spondylitis
	Tocilizumab	4	• Rheumatoid arthritis • Systemic Juvenile idiopathic arthritis • Polyarticular juvenile idiopathic arthritis • Giant cell arteritis • Cytokine release syndrome • Coronavirus disease 2019
	Eculizumab	2	• Paroxysmal nocturnal haemoglobinuria • Atypical haemolytic uremic syndrome • Refractory generalized myasthenia gravis in patients who are anti-acetylcholine receptor antibody-positive • Neuromyelitis optica spectrum disorder in patients who are anti-aquaporin-4 antibody-positive
	Golimumab	2	• Rheumatoid arthritis • Ulcerative colitis • Psoriatic arthritis • Ankylosing spondylitis • Polyarticular juvenile idiopathic arthritis
	Pertuzumab	1	• Breast cancer
	Natalizumab	1	• Highly active relapsing remitting multiple sclerosis
	Omalizumab	1	• Asthma • Urticaria
Granulocyte Colony-Stimulating Factors (G-CSFs)	Pegfilgrastim	10 (5 withdrawn) ‡	• Neutropenia in chemotherapy patients
	Filgrastim	8 (2 withdrawn) ‡	• Neutropenia in chemotherapy patients • Mobilization of peripheral blood progenitor cells
VEGF Inhibitors	Aflibercept	7 (1 withdrawn) ‡	• Neovascular (wet) age-related macular degeneration • Visual impairment due to diabetic macular oedema • Proliferative diabetic retinopathy • Visual impairment due to macular oedema secondary to retinal vein occlusion

			Visual impairment due to choroidal neovascularization
Erythropoiesis Stimulating Agents (ESAs)	Epoetin alfa	3 (1 withdrawn) ‡	- Anaemia in chronic kidney disease - Chemotherapy-induced anaemia - Anaemia prior to surgery
	Epoetin zeta	2	- Anaemia in chronic kidney disease - Chemotherapy-induced anaemia - Anaemia prior to surgery
Insulins	Insulin aspart	5(1 withdrawn) ‡	Diabetes mellitus
	Insulin glargine	3 (1 withdrawn) ‡	Diabetes mellitus
	Insulin lispro	2	Diabetes mellitus
	Insulin human	0 (2 withdrawn) ‡, 1 refused)	Diabetes mellitus
Parathyroid Hormone (PTH)	Teriparatide	7 (4 withdrawn) ‡	Osteoporosis in women (postmenopausal and after glucocorticoid therapy) and men (after glucocorticoid therapy) at increased fracture risk
Tumour Necrosis Factor (TNF) Inhibitors	Etanercept	4	- Rheumatoid arthritis - Psoriatic arthritis - Plaque psoriasis - Juvenile idiopathic arthritis - Ankylosing spondylitis
Follicle-Stimulating Hormones (FSHs)	Follitropin alfa	2	- Anovulation - Stimulation of (multi)follicular development - Stimulation of spermatogenesis
Human Growth Hormones (hGHs)	Somatropin	1 (1 withdrawn)	Growth hormone deficiency
Low Molecular Weight Heparin (LMWH)	Enoxaparin sodium	1 (1 lapsed)	Prevention and treatment of thromboembolic disorders
Cytokine/Immunomodulator	Recombinant human interferon alfa-2a	0 (1 refused)	Chronic hepatitis C

*Including duplicates ‡ Withdrawn products have not been distinguished between those withdrawn during review—likely reflecting comparability issues—and those withdrawn post-authorization, more often for commercial reasons.