

Table 2: Numbers of similar biotherapeutic products/biosimilars approved by regulatory authorities in 16 countries (July 2020)

The information below provided based on the categorization of similar biotherapeutic products/biosimilars by each national regulatory authority. Thus, similar biotherapeutic products/biosimilars approved in certain countries might not have been approved following as strict a regulatory process as is required by WHO guidelines. Indications also as reported by survey participants; not necessarily representing WHO approval of these.

INN	Brazil	Canada	China	EU	Ghana	India	Iran	Japan	Jordan	Malaysia	Republic of Korea	Russia	Singapore	Thailand	Ukraine	USA
Others*				1		15	1	1								
hCG						2										
Teriparatide				2 (2)		3		1			1					
Somatropin	1	1		2		1		1	1	1	1		1		1	
LMWH	1			2												
Peg-interferon						2	1									
Interferon						6	6					6				
Human insulin	1				8	4	1		1	1		10				
Insulin isophane	1															
Insulin glargine	3	1		3		2		2		1	2	2	2			
Insulin lispro	1	1		1				1				2				
FSH				2	2	5	1								1	
Peg-filgrastim		3		7		7	2			1				1		4
Filgrastim	2	2		9		9	2	3	2	2		4	2	4	2	2
Etanercept	3	2		3		2	1	2			3			1		2
EPO				5	2	11	2	1	1	3	1	3			1	1
Darbepoetin						4		3			1					
Rituximab	4	3	1	7		5	2	2	3	1	1	2	2	3	1	2
Infliximab	3	4		4		2		3	1	1	2	2	1			4
Trastuzumab	5	4	1	6	1	5	1	3	2	3	2	2	2	4	2	5
Ranibizumab						2										
Bevacizumab	2	2	2	3 (1)		5	1	2		1		1		1		2
Adalimumab	3	3	2	11		4	1	1	1	1	1	1	1	1		6
Total	30	26	6	68 (3)	13	96	22	26	12	16	15	35	11	15	8	28

In EU: 1) numbers in brackets indicate biosimilars with positive opinions; 2) nine biosimilars approved then withdrawn (3 adalimumab, 2 filgrastim, 1 insulin glargine, 1 rituximab, 1 somatropin); or ceased (LMWH). *Others: EU (insulin aspart); India (abciximab, becaplermin, denosumab, granulocyte macrophage colony, hepatitis B vaccine, itolizumab, molgramostim, omalizumab, raburicase, reteplase, streptokinase); Iran (eptacog alfa); Japan (agalsidase beta). EPO: erythropoietin; FSH: follicle stimulating hormone; hCG: human chorionic gonadotropin; INN: International Nonproprietary Name; LMWH: low molecular weight heparin; WHO: World Health Organization.