

Popis novih lijekova za koje je odobrenje dala Europska komisija od 1.12.2018. do 31.12.2018. godine/The list of new medicinal products authorised by the European Commission in December 2018

Redni broj/No.	Naziv lijeka/Name	Naziv djelatne tvari/Active Substance	Broj odobrenja EK/EC Authorisation number	ATK/ATC
1.	Bevespi Aerosphere	glycopyrronium / formoterol fumarate dihydrate	EU/1/18/1339	R03AL07
2.	Dengvaxia	chimeric yellow fever dengue virus serotype 1 (live, attenuated) / chimeric yellow fever dengue virus serotype 2 (live, attenuated) / chimeric yellow fever dengue virus serotype 3 (live, attenuated) / chimeric yellow fever dengue virus serotype 4 (live, attenuated)	EU/1/18/1338	J07BX
3.	Flucelvax Tetra	Influenza virus surface antigens (haemagglutinin and neuraminidase)* , inactivated, of the following strains: A/xxxxx (H3N2)-like strain (reassortant used)/ A/xxxxx (H1N1)-like strain (reassortant used)/ B/xxxxx (Yamagata Lineage)-like strain (reassortant used)/ B/xxxxx (Victoria Lineage)-like strain (reassortant used)	EU/1/18/1326	J07BB02
4.	Namuscla *	mexiletine	EU/1/18/1325	C01BB02
5.	Ogivri	trastuzumab	EU/1/18/1341	L01XC03

* lijek u EU ima "orphan" status/medicinal product with "orphan" designation