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PPRI
Pharmaceutical Pricing and Reimbursement Information

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

SLOVENIA
Recent and planned developments in pharmaceutical policies 2016

Special topic: Pricing and reimbursement policies for biosimilars

DEVELOPMENTS	**CHANGES IN PRICING** No changes	**CHANGES IN REIMBURSEMENT** No changes
	OTHER CHANGES Therapeutic reference pricing system for therapeutic groups of drugs (new groups: for inhaled glucocorticoids for the treatment of allergic rhinitis, somatropin and long acting insulins).	
SPECIAL TOPIC SPECIAL TOPIC	**POLICIES FOR BIOSIMILARS**	
	Pricing procedure for biosimilars External reference pricing system: the price for biosimilars is set on the same procedure as for generics. Maximum allowed price is set for prescription medicinal products (originators and generics or biosimilars), financed or intending for financing from public funds – List of highest recognised values. Ministry of Health has announced first tender for biologicals/ biosimilars (infliksimab 40/60 %). Poor prescribing of biosimilars in 2015 (in DDDs): epoetins 18 %, somatropin 4 %, filgrastim 7 %, infliksimab only 2 % (Table 1).	**The reimbursement procedure** is the same as for all other medicines. A pharmaceutical company applies for inclusion of its medicine. Reimbursement committee takes a decision based on a pharmacological, medical-therapeutic and health-economic evaluation and rules of classification of medicinal products for human use on the list (the same measures for all drugs). **Demand-side measures related to biosimilars** • no direct substitution of generics and biosimilars, • doctors are advised to switch from original to biosimilars (mostly for new patients) • biosimilar substitution is not allowed in pharmacies **Further measures and discussions** • approaches for rational prescribing • therapeutic reference pricing system for therapeutic groups of drugs (new groups: for somatropin and long acting insulins) • education • audits focused mostly on prescribing restrictions

Tab. 1. Consumption of biosimilars and original medicines in DDDs between 2012 and 2015 with respective shares in (%):

	2012		2013		2014		2015	
Medicine	**Consumption**	**Share**	**Consumption**	**Share**	**Consumption**	**Share**	**Consumption**	**Share**
epoetin alfa – original	155.378	23	131.202	19	92.748	14	82.572	12
epoetin alfa – biosimilar	93.478	14	111.893	16	117.952	18	127.566	18
other epoetins	415.845	63	439.966	64	461.811	69	486.199	70
epoetins together	**664.701**	**100**	**683.061**	**100**	**672.511**	**100**	**696.337**	**100**
somatropin – original	109.719	96	112.449	97	114.821	99	122.345	96
somatropin - biosimilar	4.448	4	3.893	3	1.318	1	5.048	4
somatropins together	**114.167**	**100**	**116.342**	**100**	**116.139**	**100**	**127.392**	**100**
filgrastim – original	5.656	10	7.299	11	6.289	7	6.411	7
filgrastim - biosimilar	5.568	10	6.739	10	6.997	8	6.081	7
pegfilgrastim	46.520	81	50.280	78	66.260	74	55.620	61
lipegfilgrastim	-	-	-	-	9.540	11	22.960	25
filgrastims together	57.744	100	64.318	100	89.086	100	91.072	100
infliksimab - original	-	-	-	-	-	-	382.784	98
infliksimab – biosimilar	-	-	-	-	-	-	7.552	2
infliksimabs together	**-**	**-**	**-**	**-**	**-**	**-**	**390.336**	**100**