





WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

National Council on Prices and Reimbursement of Medicinal Products

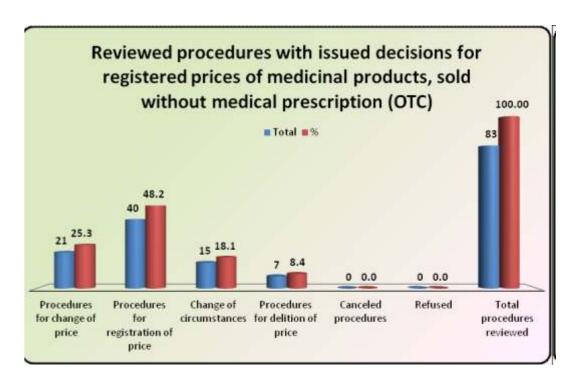
BULGARIA

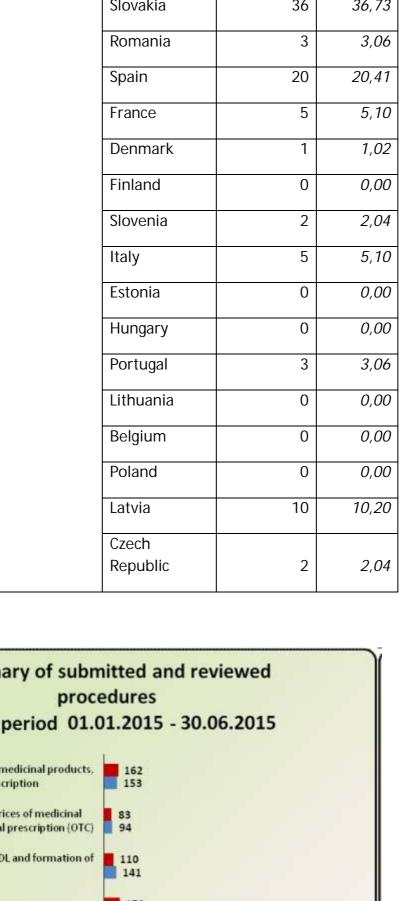
Recent and planned developments in pharmaceutical policies 2015

	Changes in pricing	Changes in reimbursement	EX OF OR NO
	Changes in the Ordinance on the terms, rules and procedure for regulation and registration of prices for medicinal products in 2014 – in August and November.	Changes in the Ordinance on the terms, rules and procedure for regulation and registration of prices for medicinal products in 201 4 – in August and November	Checke
	Recent changes related to:	Recent changes related to:	produ refei mer
	price changes (e.g. price cuts, price freezes, other price reductions)	changes/modifications of reimbursement lists	cour
	 ✓ Freezing the registered prices of OTC products in August 201 4 for another eight months until December 31 st, 2015 (Prices increase of OTC products was allowed only by the percentage of the inflation rate) 	✓ For the purposes of determining the value of payment for medicinal products included in the PDL for which there is a difference in the indications for treatment, the reference value can be calculated for vario us indications in the summary of product characteristics.	
	<i>price reviews</i>✓ Price review of reimbursement medicinal	changes/modifications of reimbursement rates	
	 products every six months (single product in the international non-proprietary name). ✓ Change in the period of price review of reimbursement medicinal products from six months to one year (for others). 	There are no changes.	
D	 ✓ This requirement has come into force in August, 2014. 	changes/modifications of co-payment	
E V	margin changes (wholesale, pharmacy)	There are no changes.	
E	There are no changes.	other changes/modifications of the	
L O P M E N T	 ✓ Wholesale margins are 7%, 6% and 4% (but not more than 10 BGN) of the ex- factory price. ✓ Retail margins are 20%, 18% and 16% (but not more than 25 BGN) of the ex- factory price. <i>discounts / rebates (out-patient, in- patient), managed-entry agreements, clawback/payback system</i> 	 Since January 1st, 2015 the National Health Insurance Fund will have to pay for new molecules or indications for oncology included in the PDL in 2014. This payment process shall commence in the b eginning of very new year and shall cover the new molecules or indications for oncology included in the PDL in the previous year. 	
S	✓ Since 2011 the National Health Insurance Fund can negotiates discounts from the	Planned changes:	L
	reimbursement value of the out -patient medicinal products and in-patient oncology products	1. New regulation HTA (draft).	-
	change in VAT on medicines	2. New regulation diagnosis reimbursement (draft).	
	There is no change. The VAT in Bulgaria is 20 %.	3. Pay back and clow back (draft).	
	other changes in pricing policies (e.g.		Procedures
	<u>change of reference countries in EPR)</u>		Procedu products,
	 ✓ Reference countries – 17 (10 Basic and 7 additional) Basic countries - RO, FR, LV, EL, SK, LT, PT, IT, SI, ES; 		Procedur
	 Additional countries – BE, CZ, PL, HU, DK, FI, EE. ✓ In November 2014, Finland and Denmark were included as additional countries for the purposes of ERP. ✓ Estonia as a basic country for ERP was 		Proce
	replaced by Latvia as an additional country.		Declaration
	Othe	er changes	
	✓ There are no changes.		

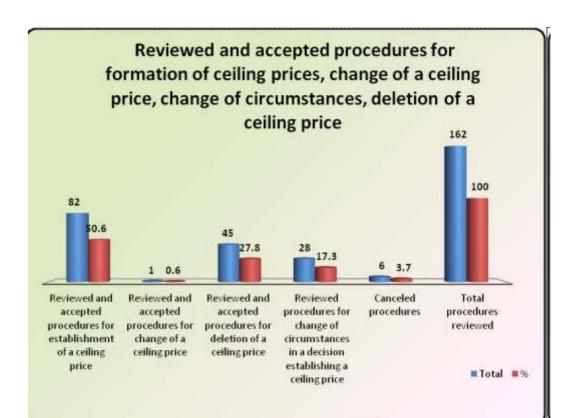
EX OFFICIO CHECKS MADE FOR ESTABLISHMENT OF CHANGE OR NO CHANGE OF PRICE FROM ALL CHECKS OVER THE LAST SIX MONTHS

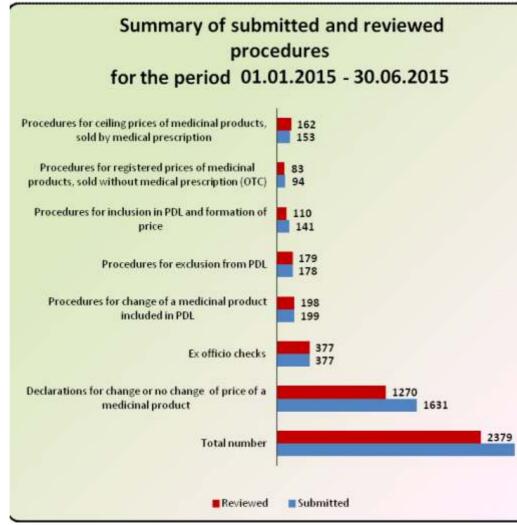
Checked prices of medicinal products in reference member countries	Found a lower price than manufacturing price in Bulgaria	Reference country	Found lowest price/pcs	%
		Greece	11	11,22
		Slovakia	36	36,73



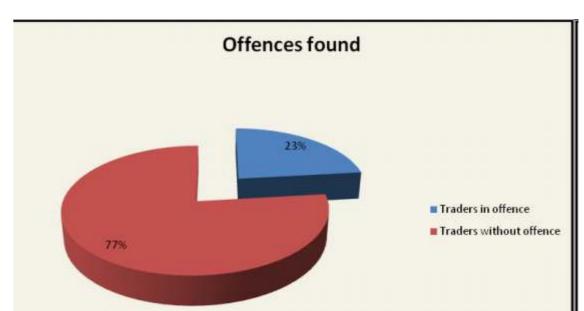


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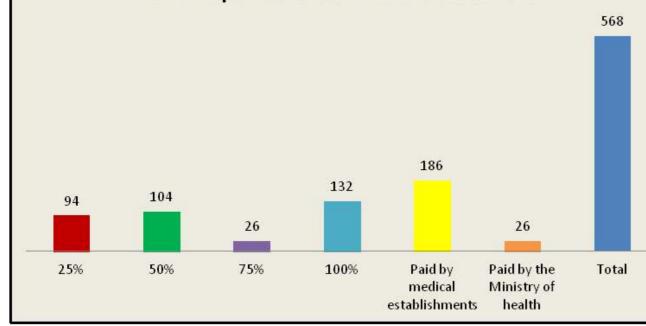




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Medicinal products with decisions that have come into force for decrease of price by level of reimbursement for the period 01.01.2015-30.06.2015



Medicinal products with decisions that have come into force for decrease of price and percentage of decrease for the period 01.01.2015 - 30.06.2015



