



REPUBLIC OF MACEDONIA

Recent and planned developments in pharmaceutical policies 2014

Policies related to high cost medicines

D E V E L O P M E N T S	Changes in pricing	Changes in reimbursement
	<ul style="list-style-type: none"> ✓ The HIFM established the Reference price system for Positive Drug List in 2008 ✓ A new comparative drugs RP methodology was adopted in 2009 and implemented through the new drug RP's in May 2010: <ul style="list-style-type: none"> - Reference price of the medicine is determined by comparative analysis of wholesale prices of medicines in the Republic of Macedonia, as well as in the reference countries. According to the Health Insurance Law, reference countries are Slovenia, Croatia, Bulgaria and Serbia - Reference price is a maximum price by drug's INN (incl. pharmaceutical form and strength) - Reference prices are reviewed at least once a year. ✓ The basic criteria for determining drug reference prices are the following: <ul style="list-style-type: none"> - Drug's reference prices in reference countries, - Average comparative price of the medicine (average of two lowest prices), - Comparative price level in accordance with the GDP ratio. ✓ VAT for medicine is changed from 18% to 5% in 2007. <p>Results:</p> <ul style="list-style-type: none"> ✓ With introducing of the new comparative methodology the achievements are as follows: <ul style="list-style-type: none"> - The percentage of medicines by INN (generic name) without co-payment, additional payment, (due to eventual price alteration from different producers) is increased from 20% in 2009 up to 75% in 2014, growth by 55%. - For the period 2008-2013, the number of prescriptions for dispensed medicines increased for approximately 73%, with tendency for further growth. These prescriptions concerns only medicines that are on the Positive Drug List (PLD) that is covered by HIF. - All Medicines by INN for in-patients in hospitals are purchased provided with public procurement procedure that excludes the price difference (without the above mentioned co-payment). 	<ul style="list-style-type: none"> ✓ Since 2002, PLD is defined by generic names of medicines ✓ In 2012 a new Methodology of expanding the PLD was adopted and approved by the Government ✓ In accordance with the latest Amendments of the Health Insurance Law, for each ATC drug group should be established and appointed by the Government. The newly established 14 Government Committees will decide on the expansions of PDL, namely, which new medicine would be included or replaced on the PLD (covered by the HIF). ✓ Implementation of the pharmacoeconomic based evaluation when deciding for expansion of PDL.
	Other changes	
	<ul style="list-style-type: none"> ✓ As of 2009 all general practitioners (that have contract with the HIF) are obliged to prescribe medicine by generic name (medicine listed on PDL). In addition to this, the HIF enhanced its electronic system controls on drugs prescription and distribution. The result of these major changes is strong control on consumption of reimbursed medicines, financially covered by the HIFM. 	



Health Insurance Fund of the
Republic of Macedonia



S P E C I A L T O P I C	High cost medicines
	<ul style="list-style-type: none">✓ In Republic of Macedonia there are no specific pricing policies for high cost medicines.✓ In order to provide for the insured people high cost medicine, that is included in the PDL, the Health Insurance Fund of Macedonia doesn't financially limit the pharmacies.✓ The List of high cost medicines from the primary PLD is defined by the average monthly costs for therapy with the particular medicine:<ul style="list-style-type: none">- Average costs are calculated by multiplying the required number of packages for monthly treatment (according to the WHO/DDD) and reference price.✓ There are <i>Conditional budgets</i> for some hospitals and clinics in order to have better supplying system for high cost medicines from hospital PDL. These budgets are foreseen for medicines used in treatment of multiple sclerosis, targeted therapy for schizophrenia, rheumatoid arthritis, cystic fibrosis, transplantations, interferon's, coagulation factors, hormones, etc. <ul style="list-style-type: none">• <u>Key challenges and solutions:</u><ul style="list-style-type: none">- Reducing the costs boundary for definition of high cost medicines for primary PDL;- Expansion of the List of medicines, which are defined as high cost medicines;- Improving the PDL, both for primary and hospital health care.- Termination of the financial limits for pharmacies;- Better rational use of medicines.