



BULGARIA

Recent and planned changes in pharmaceutical pricing and reimbursement and overview of the medical devices system

P H A R M A C E U T I C A L S	Changes in pricing	Changes in reimbursement
	<p>Change in the institution- The National Council on Prices and Reimbursement of Medicinal Products started its work in April 2013.</p> <p><u>Recent changes related to:</u></p> <p><i>price changes (e.g. price cuts, price freezes, other price reductions)</i></p> <ul style="list-style-type: none"> Regulating the ceiling prices of the POM medicines, which are not included in the Positive Drug List. Freezing the registered prices of OTC products for 1 year since April 30th, 2013 (Prices increase of OTC products was allowed only by the percentage of the inflation rate until May 1st, 2014) <p><i>price reviews</i></p> <ul style="list-style-type: none"> Price review of reimbursement medicinal products every six months. This requirement has come into force in September 2012. <p><i>margin changes (wholesale, pharmacy)</i></p> <ul style="list-style-type: none"> Wholesale margin reduction from 9%, 8% and 6% (but not more than 15 BGN) to 7%, 6% and 4% (but not more than 10 BGN) in September 2012. Retail margin reduction from 22%, 20% and 18% (but not more than 30 BGN) to 20%, 18% and 16% (but not more than 25 BGN) in September 2012. <p><i>discounts / rebates (out-patient, in-patient), managed-entry agreements, clawback/payback system</i></p> <ul style="list-style-type: none"> Since 2011 the National Health Insurance Fund can negotiate discounts from the reimbursement value of the out-patient medicinal products and in-patient oncology products <p><i>change in VAT on medicines</i></p> <p>There is no change.</p>	<p>Change in the institution- The National Council on Prices and Reimbursement of Medicinal Products started its work in April 2013.</p> <p><u>Recent changes related to:</u></p> <p><i>changes/modifications of reimbursement lists</i></p> <ul style="list-style-type: none"> The National Health Insurance Fund has started to reimburse medicinal products for treating rare diseases, oncology, transplant patients since 2011. Until that period the Ministry of Health had to pay for these products by conducting a tender. The National Health Insurance Fund has started to reimburse medicinal products for eight additional diseases since April 2013. When including a first generic product in the PDL its price must be 80% of the price of the reference product. This requirement has come into force in September 2012. <p><i>changes/modifications of reimbursement rates</i></p> <p>There are no changes.</p> <p><i>changes/modifications of co-payment</i></p> <p>There are no changes.</p> <p><i>other changes/modifications of the reimbursement system</i></p> <ul style="list-style-type: none"> Since January 1st, 2014 the National Health Insurance Fund will have to pay for new molecules or indications for oncology included in the PDL during the current year from the next year. <p><u>Planned changes:</u></p> <p>Change in time of actual payment of medicines by public funds from 6 months to 1 year for all new molecules for out-patient use</p>



	<p>other changes in pricing policies (e.g. change of reference countries in EPR)</p> <ul style="list-style-type: none"> • In September 2012 Italy, Finland, Denmark and Slovenia were added as reference countries in EPR <p><u>Planned changes:</u></p> <ul style="list-style-type: none"> • Change in the period of price review of reimbursement medicinal products from six months to one year • Freezing the registered prices of OTC products for more eight months until December 31st, 2014 	
	<p style="text-align: center;">Other changes related to medicines</p> <p>There are no changes.</p>	
<p style="text-align: center;">M E D . D E V I C E S</p>	<p style="text-align: center;">Pricing and reimbursement system of medical devices</p> <ul style="list-style-type: none"> • <u>Competent authority:</u> The Bulgarian Drug Agency is responsible for classification and clinical trials of medical devices. The Bulgarian Drug Agency supports registration of medical devices by running the platform for registration on its website. • <u>Price regulation:</u> Prices are not regulated in Bulgaria and can be freely set by the manufacturers. • <u>Reimbursement:</u> The National Health Insurance Fund reimburses medical devices for out-patient and in-patient use. The National Health Insurance Fund negotiates the reimbursed price for each class of medical devices. The Ministry of Health had to pay for medical devices by conducting a tender. • <u>Price sources/prices known:</u> Not available. 	