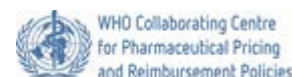


## BULGARIA

### Recent and planned developments in pharmaceutical policies 2014

#### Policies related to high cost medicines

<b>D E V E L O P M E N T S</b>	<b>Changes in pricing</b>	<b>Changes in reimbursement</b>
	<p>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</p> <p><b><u>Recent changes related to:</u></b></p> <p><b><i>price changes (e.g. price cuts, price freezes, other price reductions)</i></b></p> <ul style="list-style-type: none"> <li>Freezing the registered prices of OTC products in August 2014 for another eight months until December 31<sup>st</sup>, 2014 (Prices increase of OTC products was allowed only by the percentage of the inflation rate)</li> </ul> <p><b><i>price reviews</i></b></p> <ul style="list-style-type: none"> <li>Price review of reimbursement medicinal products every six months (<i>single product in the international non-proprietary name</i>).</li> <li>Change in the period of price review of reimbursement medicinal products from six months to one year (<i>for others</i>).</li> <li>This requirement has come into force in August, 2014.</li> </ul> <p><b><i>margin changes (wholesale, pharmacy)</i></b></p> <p>There are no changes.</p> <ul style="list-style-type: none"> <li>Wholesale margins are 7%, 6% and 4% (but not more than 10 BGN) of the ex-factory price.</li> <li>Retail margins are 20%, 18% and 16% (but not more than 25 BGN) of the ex-factory price.</li> </ul> <p><b><i>discounts / rebates (out-patient, in-patient), managed-entry agreements, clawback/payback system</i></b></p> <ul style="list-style-type: none"> <li>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</li> </ul> <p><b><i>change in VAT on medicines</i></b></p> <p>There is no change. The VAT in Bulgaria is 20 %.</p>	<p>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</p> <p><b><u>Recent changes related to:</u></b></p> <p><b><i>changes/modifications of reimbursement lists</i></b></p> <ul style="list-style-type: none"> <li>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 various indications in the summary of product characteristics.</li> </ul> <p><b><i>changes/modifications of reimbursement rates</i></b></p> <p>There are no changes.</p> <p><b><i>changes/modifications of co-payment</i></b></p> <p>There are no changes.</p> <p><b><i>other changes/modifications of the reimbursement system</i></b></p> <ul style="list-style-type: none"> <li>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 beginning of every new year and shall cover the new molecules or indications for oncology included in the PDL in the previous year.</li> </ul> <p><b><u>Planned changes:</u></b></p> <p>There are no planned changes.</p>



	<p><b><u>other changes in pricing policies (e.g. change of reference countries in EPR)</u></b></p> <ul style="list-style-type: none"> <li>Reference countries – 17 (10 Basic and 7 additional) Basic countries - <b>RO, FR, LV, EL, SK, LT, PT, IT, SI, ES;</b> Additional countries – <b>BE, CZ, PL, HU, DK, FI, EE.</b></li> <li>In November 2014, Finland and Denmark were included as additional countries for the purposes of ERP.</li> <li>Estonia as a basic country for ERP was replaced by Latvia as an additional country.</li> </ul>	
	<p><b>Other changes</b></p> <ul style="list-style-type: none"> <li><i>There are no changes.</i></li> </ul>	
<p><b>S P E C I A L  T O P I C</b></p>	<p style="text-align: center;"><b>High cost medicines</b></p> <p><i>Please explain the situation regarding the following aspects in your country:</i></p> <ul style="list-style-type: none"> <li><u>Special pricing policies:</u> There is no special pricing policy. High cost medicines are subject to assessment and can be included in the PDL following a similar procedure applicable for other medicinal products.</li> <li><u>Special reimbursement/funding policies:</u> Commission for assessment of high cost medicines application for every single patient at the National Health Insurance Fund. National Health Insurance Fund can negotiate discounts from the reimbursement value of the high cost medicines.</li> <li><u>High cost medicines at the interface of out-patient and in-patient sectors:</u> In the out-patient sector high cost medicines are included in the PDL. In the in-patient sector high cost medicines are paid separately from the amount of the clinical pathway.</li> <li><u>Key challenges and solutions:</u> Implementation of Management Entry agreements.  Manuals of Pharmacotherapy, recommendations for algorithms for treatment with high cost medicinal products.</li> </ul>	