

# Pharmaceutical expenditure dynamics in the Balkan countries

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EDITORIAL

## Pharmaceutical expenditure dynamics in the Balkan countries

### Peculiarity of Balkan region

Extending to the south from central Europe into the Mediterranean Sea, the region of the Balkans includes the countries of Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Greece, Romania, Serbia, Slovenia, The Former Yugoslav Republic of Macedonia (FYR Macedonia), Montenegro, and the geographical/political region of European Turkey<sup>1</sup>. Most Balkan states are middle-income countries, with the exception of Greece, Croatia, and Slovenia, which are all high-income countries<sup>2</sup>. In addition, some of these countries are Member States of the European Union (EU): Greece since 1981, Slovenia since 2004, Bulgaria and Romania since 2007 and Croatia since 2013<sup>3</sup>. All other Balkan countries are EU candidate countries, with the exception of Bosnia and Herzegovina, which is a potential candidate for EU membership<sup>3</sup>. There are also differences in the performance of health systems among them<sup>4</sup>. All countries in the past 20 years have been faced with different problems in financing healthcare and trying to implement different reforms in order to assure a sustainable and efficient healthcare system<sup>5,6</sup>. During two and a half decades of health reform processes, the formerly massive hospital-centered system of the Post-Semashko countries (Albania, Bulgaria, Romania) and former Yugoslavia republics (Bosnia and Herzegovina, Croatia, Montenegro, Serbia, Slovenia and FYR Macedonia) have clearly been reshaped towards more preventive and efficient primary care, whereas, among the prior-free-market countries (Greece, Turkey) physician density increased the most<sup>4</sup>. Among all Western Balkan countries, Bosnia and Herzegovina, consisting of the Federation of Bosnia and Herzegovina with its 10 cantons, Republic of Srpska and Brcko District, has the most complicated organization of health system financing and medicines reimbursement<sup>6</sup>, leading to inequity in access to medicines among different administrative regions, which are covered by 12 different health insurance funds<sup>7</sup>. Total health expenditure expressed as a percentage of gross domestic product and total expenditure on health per capita in terms of current purchase power parity in international \$ showed an obvious increase in most of the Balkan countries during 1995–2012<sup>8</sup>.

### Expenditure on pharmaceuticals in the Balkan countries

In recent years, a lot of attention has been devoted to pharmaceuticals, which have become one of the largest and fastest growing components of health spending<sup>9</sup>. Although pharmaceutical expenditure is a standard indicator, for some low- and middle-income countries no recent internationally

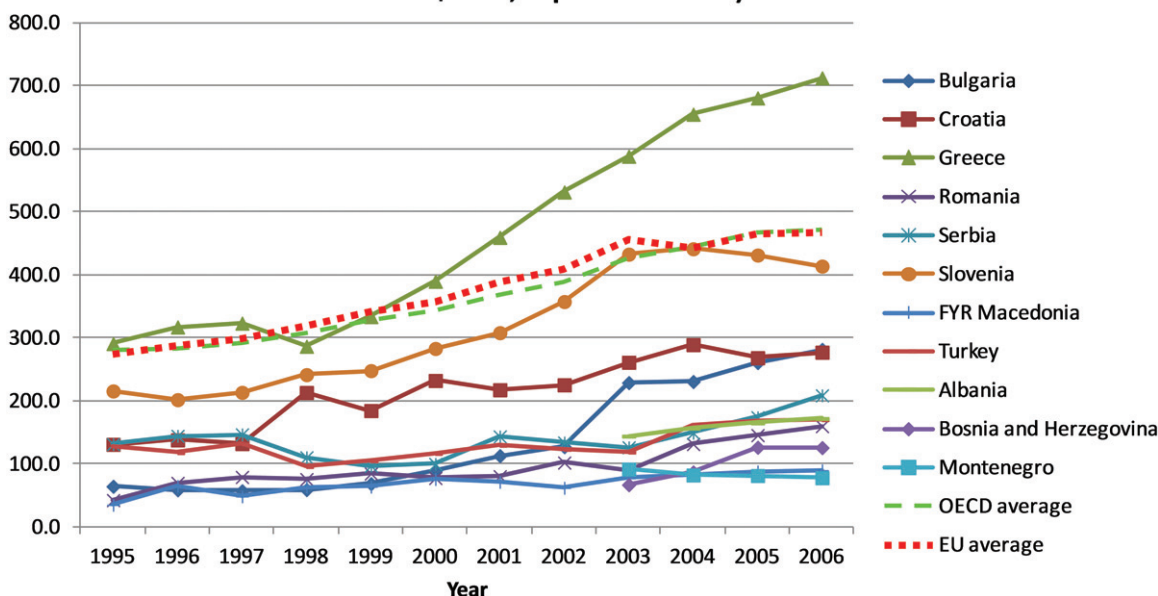
comparable data is available<sup>10,11</sup>. In order to elucidate the trend of pharmaceutical expenditure in the Balkan countries, as the majority of them are middle-income countries, we must refer to the National Health Accounts (NHA) data published as an annex to “The World Medicines Situation Report 2011” by the World Health Organization (WHO), which contains the most comprehensive up-to-date internationally comparable publicly available data on pharmaceutical expenditure for the majority of countries in the world, but only until 2005 and 2006<sup>10,12,13</sup>.

Figure 1 shows dynamics of total pharmaceutical expenditure per capita in terms of purchase power parity (PPP) in constant US\$2005 during the 1995–2006 time span for Balkan countries, along with the OECD (Organization for Economic Co-operation and Development) and EU average values. We can notice that Greece, Slovenia, and Croatia form the top tier, with the largest pharmaceutical spending with mostly increasing tendency, along with Greece being the only Balkan country which had a higher level of pharmaceutical expenditure than the OECD and EU average. This comes as no surprise, as these countries belong to the high-income countries group. All other Balkan countries had a similar level of total pharmaceutical expenditure, with a slight increase since 2002, which was particularly prominent in Bulgaria, where total pharmaceutical expenditure reached the level of Croatia.

The financial crisis, which manifested in late 2007, resulted in a Europe-wide economic crisis by 2009<sup>14</sup>. The economic recession has had mixed effects on pharmaceutical consumption, expenditure, and prices, with substantial variability in the response to recession among different countries<sup>15,16</sup>. Internationally comparable publicly available data on total pharmaceutical expenditure after 2006 are unavailable for the majority of Balkan countries, but some journal articles and national reports may shed light on what happened with pharmaceutical expenditure after this year on a national level.

During 2007–2012, pharmaceutical expenditure in per capita terms recorded 25% growth in Serbia, whereas a marginal decrease (0.4%) was noticed in Greece<sup>17</sup>. Greece recorded much more intense recession effects in the pharmaceutical sector: in 2007 the pharmaceutical expenditure per capita in Greece was 2.22-times the pharmaceutical expenditure per capita in Serbia, whereas in 2012 it reduced to 1.76-times<sup>17</sup>. The Greek government enacted a number of fiscal policies in order to deal with the dramatic economic fluctuations caused by the global financial crisis, including the lowering of pharmaceutical prices, as well as setting the budget for pharmaceuticals to a fixed share of the gross domestic product<sup>18</sup>. It was projected that these restrictions would result in a

### Total pharmaceutical expenditure per capita (in constant US\$2005, expressed in PPP)



**Figure 1.** Total pharmaceutical expenditure per capita in terms of purchase power parity (PPP) in constant US\$2005 in the Balkan countries in 1995–2006. Source: WHO<sup>13</sup>. OECD and EU average are calculated based on a list of countries with active membership in each given year.

considerable share (35–47%) of the outcome of pharmaceutical spending cutback becoming counterbalanced by the yielded loss in public revenues<sup>18</sup>. An increase of pharmaceutical spending in Serbia coincided with the increasing trend in public debt which doubled during 2004–2012, and shortages of pharmaceuticals occurred more frequently compared to the period before 2008, due to substantial public debt towards pharmaceutical companies supplying the Eastern European market<sup>17,19</sup>. Healthcare authorities in Serbia were trying to contain growing pharmaceutical expenditure by cutting prices of medicines—in May 2015, the Ministry of Health announced that the prices of ~930 drugs were set to become up to 30% cheaper<sup>6</sup>.

According to the national reports of agencies for medicines and medical devices, expenditure on pharmaceuticals expressed in absolute terms in national currency increased in: Bosnia and Herzegovina from BAM 467 million in 2009 to BAM 597 million in 2015<sup>20,21</sup>, Croatia from HRK 3.9 billion in 2007 to HRK 5.3 billion in 2015<sup>22,23</sup>, and Montenegro from EUR 53.6 million in 2009 to EUR 66.2 million in 2015<sup>24,25</sup>. In fact, Montenegro is considered to be the smallest pharmaceutical market in the Balkans, with an increasing trend in total pharmaceutical expenditure, despite government recommendations on cost savings<sup>6</sup>.

In Slovenia, pharmaceutical spending slowed down in 2010 and fell by ~1% in real terms in 2011, before rising again by 2.6% in 2012<sup>26</sup>. A series of measures were taken in 2009 in order to control growth on spending on pharmaceuticals, which included a revision of the reimbursement list of the national health insurance fund and agreements with the pharmaceutical industry for discounts on drug prices<sup>26,27</sup>. All these led to a fall in the share devoted by the Health Insurance Institute of Slovenia to pharmaceuticals from 18.2% in 2006 to 14.4% in 2014<sup>27</sup>. A similar occurrence was

noted in Croatia, where the share of expenditure of the Croatian Health Insurance Fund (CHIF) on prescription drugs had fallen from 17.08% in 2007 to 14.61% in 2012, but still represented the second largest proportion of CHIF's expenditure after inpatient care<sup>28</sup>. Croatia introduced a number of reforms in 2013 in order to reduce debt levels, add new medicines to the reimbursement list, and improve quality of care<sup>29</sup>. These reforms included changes in the reference pricing system, including order of reference price countries, lowering the prices of successive generics, and strict control of pharmaceutical company activities<sup>29</sup>.

Turkey experienced a substantial rise in total pharmaceutical sales from USD 2.5 billion in 2002 to USD 8.0 billion in 2012, as a result of improved access to healthcare after implementation of the Turkish Health Transformation Program, which began in 2003<sup>30</sup>. If the pricing mechanism of pharmaceuticals had not been changed during the implementation of the Health Transformation Program, expenditure on pharmaceuticals would be even larger<sup>30</sup>. In Albania, annual expenditures on reimbursed drugs increased from ALL 3.5 billion in 2007 to ALL 8.4 billion in 2013, due to a variety of reasons: expansion of the health insurance scheme, reimbursement of innovative drugs, the tendency of the physicians to prescribe expensive therapies, lack of rules and regulations controlling this sector, and lack of significant policy for using generic drugs as substitutes for expensive products with the same active substances<sup>31</sup>. Pharmaceutical expenditure is a significant area of the health sector in Albania, which demands better regulation in order to assure that expenditure growth stays within the limits of the budget<sup>31</sup>.

The Bulgarian pharmaceutical market has been growing since 1999, with a continuing trend, despite the economic crisis, and in 2009 the value of the total pharmaceutical

market reached BGN 1,553 million (~EUR 800 million), which represented an increase of 27% compared to 2004<sup>32</sup>. Total pharmaceutical expenditure of the National Health Insurance Fund (NHIF) of Bulgaria was EUR 268 million in 2011, which continued to increase in the subsequent years due to the expansion of the NHIF's coverage<sup>33</sup>. This prompted Bulgarian authorities to adopt a new policy framework regarding drug pricing and reimbursement, which seemed successful at first in 2012 and 2013, but deficit spending was a problem again in 2014<sup>33</sup>. The NHIF was experiencing a budget deficit, which was expected to be ~26.6% in 2014: EUR 488 million was projected to be spent on drug therapies, although initially EUR 386 million was allocated<sup>33</sup>. In Romania, pharmaceutical expenditure increased from EUR 1.287 billion in 2012 to EUR 1.380 billion in 2013<sup>34</sup>. Despite the increasing value of the pharmaceutical market and public pharmaceutical expenditure, there have been calls for increasing the public budget for pharmaceuticals<sup>34</sup>. There are concerns regarding underutilization of generics, and health authorities continue to try to improve price-setting procedures, drug reimbursement, and the use of health technology assessment to get better value for money<sup>34</sup>.

## Concluding remarks

It seems that the majority of Balkan countries exhibit a trend of increasing pharmaceutical expenditure which they try to contain more or less successfully by introducing new policy measures. Unfortunately, cross-country comparison of pharmaceutical expenditure in the Balkan countries after 2006 is infeasible due to the lack of internationally comparable data. Evolution of pharmaceutical expenditure has been better characterized for most high-income and few middle-income countries due to the launch of major repositories of data: OECD Health Data and Eurostat Health database for member countries of OECD and the EU<sup>10</sup>. Despite clear definitions and sound methodologies<sup>11</sup>, even these repositories have gaps in time series and missing data for some of the countries<sup>35,36</sup>. The European Health for all database (HFA-DB) also contains some data on pharmaceutical expenditure, but again with inconsistent time periods and unavailable data for the majority of Balkan countries<sup>37</sup>. For many low- and middle-income countries no comprehensive data on retail sales and executed budget on pharmaceuticals are usually available beyond what the Ministry of Health or other interested agencies can collect<sup>12</sup>. That is why the annex to "The World Medicines Situation Report 2011" following a WHO study is still considered to be the most comprehensive source of data on pharmaceutical expenditure worldwide<sup>10,12,13</sup>. Investment in improvement of quantity and quality of internationally comparable data on pharmaceutical expenditure would provide the basis for analyzing the impact of different policies in various settings, which is particularly needed in low- and middle-income countries with scarce financial resources.

Of course, analyzing pharmaceutical expenditure provides only one part of the perspective of the overall drug utilization—the economic one. Pharmaceutical expenditure is

essentially influenced by both prices of drugs and volumes<sup>10</sup>. Therefore, expenditure data is sensitive to changes in ex-factory, wholesale, or retail prices, as well as variations in utilizations and the product mix of drugs<sup>10</sup>. Capturing these changes would further clarify underlying drivers of pharmaceutical expenditure. Comprehensive databases may be used to analyze changes in pharmaceutical expenditure by separating it into three components: relative price of drugs, quantity, and a residual (a measure of impact of changes in drug treatment patterns on pharmaceutical expenditure which if bigger (smaller) than 1 indicates that there is higher usage of more expensive (cheaper) drugs)<sup>38,39</sup>. For example, Lambrelli and O'Donnel<sup>40</sup> used this methodology to decompose pharmaceutical expenditure data from the largest social insurance fund in Greece for 1991-2006, and showed that the dramatic increase in expenditure during this period was mostly attributable to a switch to more innovative and more expensive pharmaceuticals. The increase in the volume of prescribed drugs also contributed to the increase in pharmaceutical expenditure of the fund, but to a lesser extent<sup>40</sup>. Other aspects of pharmaceutical utilization, such as rational prescribing and generic utilization, cannot be evaluated when only expenditure is observed. Rational prescribing and rational use of drugs, regarded as an appropriate way of utilization of limited available public resources, could affect pharmaceutical expenditure without reductions of the rights of insured persons for medical products<sup>41</sup>. In parallel with generic drug competition, opening the market to biosimilar competition could also lead to significant savings for health-care systems<sup>42</sup>. It should be noted that evolution of pharmaceutical spending is influenced by a vast range of drivers which affect both the supply and demand for pharmaceuticals, as well as demographic factors<sup>43</sup>. The inevitable demographic change caused by population ageing will certainly be shaping growing needs for pharmaceuticals and the landscape of their consumption in the years to come<sup>44-46</sup>.

## Transparency



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