

ANALYSIS OF HTA PROCESSES IN EUROPE AND BULGARIA UNDER CONDITIONS OF DYNAMIC ECONOMY

S. Georgiev ¹, A. Yanakieva ¹

¹Department of Health Technology Assessment, Faculty of Public Health, Medical University - Sofia, Bulgaria, Address: "Bialo more" str., №8, 1527 Sofia; email: svetlinggeorgiev@gmail.com

¹Department of Health Technology Assessment, Faculty of Public Health, Medical University - Sofia, Bulgaria, Address: "Bialo more" str., №8, 1527 Sofia; email: a.yanakieva@foz.mu-sofia.bg

Abstract: Objectives: The purpose of the study is to analyze the relationship between the socio-economic characteristics and the availability of HTA agencies across Europe as well as conducting comparison with the process in Bulgaria. The World Bank database is used in order to take in to consideration different indicators and demographic characteristics of the countries. **Methods:** The subject of this study is the HTA institution. A sociological survey method has been used to divide participants from countries with HTAs and without HTAs agencies. Through a documentary method, 175 countries of different regions classified by the World Bank were analyzed based on socio-economic indicators. Moreover, the necessary information was extracted from the HTA agencies' protocols and official documents. **Results:** The relationship between the demographic and economic indicators in the various World Bank Group's revenues was analyzed. A question regarding World Bank grouping based on income and population, life expectancy, health costs per capita, and GNI was asked in order to investigate the correlation between socio-economic characteristics and the implementing of the process of HTA. 38.3% of all countries in the world that are subject to analysis have an HTA agency. In countries with low average income, the distribution of HTAs is 21.4% with HTA against 78.6% without HTA activities. **Conclusion:** Understanding the processes at the HTA institutions while approaching by adapting the world experience is a safe formula for success while considering good HTA practices. From the presented we can conclude that for each group there is a statistically significant relationship.

Keywords: HTA, Social Indicators, Economic Indicators, Bulgaria

1. Introduction

Background

HTA applies scientific knowledge and evidence in the field of health, aiming at strengthening the link between science and decision-making [1]. Studying and analyzing the medical, social, ethical and economic implications of the development, dissemination, and use of health technologies [2, 3]. Strategic goals for HTA are related to achieving solidarity, security, and well-being corresponding with the WHO basic definition of health [4].

In this context, the conditions and level of development of HTA policies in Bulgaria require coordination with global practices. As part of the EU and the European Economic Community (EEC), the country's government should consider the EU politics regarding HTA.

Within the EU, HTA cooperation is a trend that follows the pace of socio-economic development of countries globally. The European Commission proposes to strengthen the relationship between the parties in this area. Since 2006, Member States have been working on a joint HTA on the European Health Technology Assessment Network (EUnetHTA) to support

on a voluntary basis while identifying the collaboration between regulators and HTA authorities as necessary for decision-making [5].

The European Medicines Agency (EMA) has been working closely with HTA authorities since 2008. The evaluation criteria used by the HTA authorities differ between member states in accordance with regional and national legislation as well as with the socio-economic parameters of the countries on a global scale.

HTA in Bulgaria and in the other part of Europe

Since 2010, Italy has a voluntary system for HTA - The Italian National Agency for Regional Healthcare Services (AGENAS) [6], which includes representatives of 13 of 21 regions. *Agenas* coordinates the *RIHTA* network, and the regions participate in the system in different ways depending on their capacity [7]. By 2019, Italy ranks 8th in the world on GDP [8]. Italy is a high-income country, according to the World Bank, belonging to the Europe and Asia region, with a population of 2017 of 60.55 mils. people and a slice of - 0.1%. The country's GDP amounted to 1.988 trillion US dollars.

Spain is among the high-income countries, according to the World Bank, belonging to the Europe region, with a population of 2017 from 46.57 milions and a 0.2% increase. The country's GDP amounted to 1.397 trillion US dollars and for 2019 occupies the 13th place in the World Bank ranking system [8]. The Spanish national network of HTA agencies is a collaboration between eight HTA agencies (seven regional and one national) working together to develop national HTA health technology reports in Spain. Agencies work together to develop guidelines and tools to support their procedures. Regional representatives are usually the most active in HTA process with interest in the subject of evaluation [9].

The Netherlands is a high-income country, according to the World Bank, belonging to the Europe region, with a population of 2017 from 17.13 million people and a turn of 0.6%. The data refer to five-year periods from 1 July 2015 to 30 June 2020 [10]. The country's GDP amounted to 902.355 million US dollars and occupies 17th place in the World Bank classification. The most significant number of estimates made by the Dutch HTA *Zorginstituut Nederland* (ZIN) is corresponding to outpatient drug technologies. All medicinal products designed for outpatient treatment require company initiations of an assessment when applying for reimbursement. However, all non-medical health technologies requires evaluation which can be provided by a number of stakeholders (including patients, payers, manufacturers), and ZIN assesses whether a request for evaluation is appropriate before taking action.

The Care Knowledge Center (KCE) is a semi-governmental institution that conducts research independent of the Belgian government established by a law of 24 December 2002. KCE is a member of INAHTA [11]. It provides reports on HTA and rapid assessments as well as other scientific reports on health topics. Another essential objective of the Commission is to promote the integration of HTA into the Belgian health system to efficiently exploit resources and reduce healthcare costs while providing the best health services to Belgian citizens. The Belgium population has a population of 11.35 million citizens in 2018, with an average life span of 79.4 years. The GDP value in 2018 is 517.609 million US dollars, with which Belgium ranked 24th in the World Bank rankings.

In recent years, Bulgaria has faced two mutually related challenges: increasing the needs for health services and solving the problems related to the rapid demographic changes in the country [12]. The state of public health in Bulgaria is due in addition to socio-economic determinants (low incomes, poverty, social exclusion) and the fact that the population of the country is "laden" with many health risk factors. There are about 3 million smokers in the country, with Bulgaria as the number one smoker in Europe [13]. More than 3 million

Bulgarians are overweight [14], over 300 000 people are dependent on alcohol [15], 2/3 of the population has low motor activity [16], over 2 million suffer from hypertension. In Bulgaria, 28.4% of the population aged 15 and over were insufficiently active (men 24.6% and women 31.8%), according to WHO estimates [17, 18]. The average life expectancy in Bulgaria is 72.7 on average, and this position is ranked 79th in the UN ranking.

Significant problems exist in the health financing system. By this indicator, Bulgaria continues to be the last of the 27 EU Member States, which account for an average of 6.7% of GDP for health, at 66,250 million. \$. GDP for 2019 [19]. Public expenditure on healthcare increased from BGN 810 million in 1998 to BGN 4.3 billion in 2017. Accordingly, their share in GDP is from 3.1% to 4.6%. In 2008, public health expenditure in Bulgaria amounted to only 4.2% of GDP. This also reflects the health technology market and HTA. According to a World Bank report in Bulgaria, the share of payments by own funds is the highest percentage of total healthcare expenditure [20]. This fact, as well as the meager incomes of the population, poses severe problems for the citizens' access to health services.

2. Aims, materials and methods

The subject of this study are HTA agencies. The focus is economic and social indicators of the countries in which they operate. The aim is to investigate the available HTA agencies in different economic conditions, based on a worldwide analysis based on data from the World Bank.

A sociological survey method has been used to divide participants from countries with HTAs and without HTA agencies. In total, 175 countries from different regions, classified by World Bank income, with whom a communication link has been established through a questionnaire and for which HTA reports have been examined. They are selected by sufficient information, confirmed by various sources in terms of social and economic aspects. Of these, 67 countries are potential respondents because of an HTA agency.

The actual study has complied with the algorithm for sending information from official sources. A documentary method has been used to collect primary data from the database of HTA agencies in different countries, showing the principles and ways of functioning [21].

The selected socio-economic factors are population, life expectancy, per-capita healthcare costs measured in USD, World Bank Group by revenue, Gross National Income (GNI) per capita population and country division according to the UN.

Statistical methods of data processing are used. Comparison of statistical data across countries concerning life expectancy and whether the presence of an HTA institution influences it was compared. Descriptive and analytical statistical methods are applied in this study.

3. Results

The results of this study clearly outline the current situation, based on the implementation of HTA approaches in countries around the world. In the study are included population, life expectancy, health care per capita and GNI. The other factors are measured in categorical expressions.

The World Bank classifies countries by income [22]:

- Low-income economies;
- Lower-middle-income economies;
- Upper-middle-income economies;
- High-income economies;

The current classification has been in use since 1989. The dividing line between the groups is fixed by real indicators and is updated every year, taking into account the value of inflation [23].

Table 1 shows normal or close to normal distribution of mean life expectancy of the population of the different countries and for the two groups under consideration (with and without an agency).

Table 1. Average life expectancy.

<i>Indication</i>	<i>Number</i>	<i>Median</i>	<i>Standard deviation</i>	<i>Standard error of sample mean</i>
<i>Without HTA</i>	108	67,62	8,602	0,828
<i>Available HTA</i>	67	76,60	5,371	0,656

It is clear from the results that in the absence of HTA, the average life expectancy (67.62 years) is less nine years than in the countries with an HTA agency (76.60 years). The performance of the test showed a statistically significant difference in mean life expectancy in the absence of HTA, which was between 7 and 11 years higher than life expectancy in countries without HTA. Such a difference in life expectancy is considered statistically significant, on the one hand, and as socially substantial, on the other. Life expectancy of 9 years (between 7 and 11) is more a goal that any health system would take as a priority if the decision to do this is to implement the HTA processes and agency in the country concerned.

Statistical analysis was carried out to establish a supposed link between the presence and absence of an HTA agency and the economic indicators: population, health expenditure per capita, measured in US dollars, and GNI.

The results show a statistical link between the availability of an agency and the World Bank's income level: $\chi^2 (2) = 54.253$, with a significance level $p = 0.01$ and a strong link strength of Cramer $V = 0.557 > 0.35$. The results obtained are summarized in table 2.

Table 2. Comparison of the absence and presence of HTA in different income groups, according to the World Bank.

	<i>World Bank revenue group</i>				<i>Total:</i>
	<i>Low-income</i>	<i>Lower-middle-income</i>	<i>Upper-middle-income</i>	<i>High-income</i>	
<i>Without HTA</i>	34	32	29	13	108
	100,00%	80,00%	56,90%	26,00%	61,70%
<i>Available HTA</i>	0	8	22	37	67
	0,00%	20,00%	43,10%	74,00%	38,30%
<i>Total:</i>	34	40	51	50	175
	100,00%	100,00%	100,00%	100,00%	100,0%

All countries classified as low-income are without an HTA agency. At the same time, the percentage of countries with low average income without HTA is also high - 80%. Contrary to the data provided, high-income countries handle CPT in 74% of cases, which exceeds three times those without CPT.

Figure 1 shows the distribution of the four categories of World Bank groups by revenue.

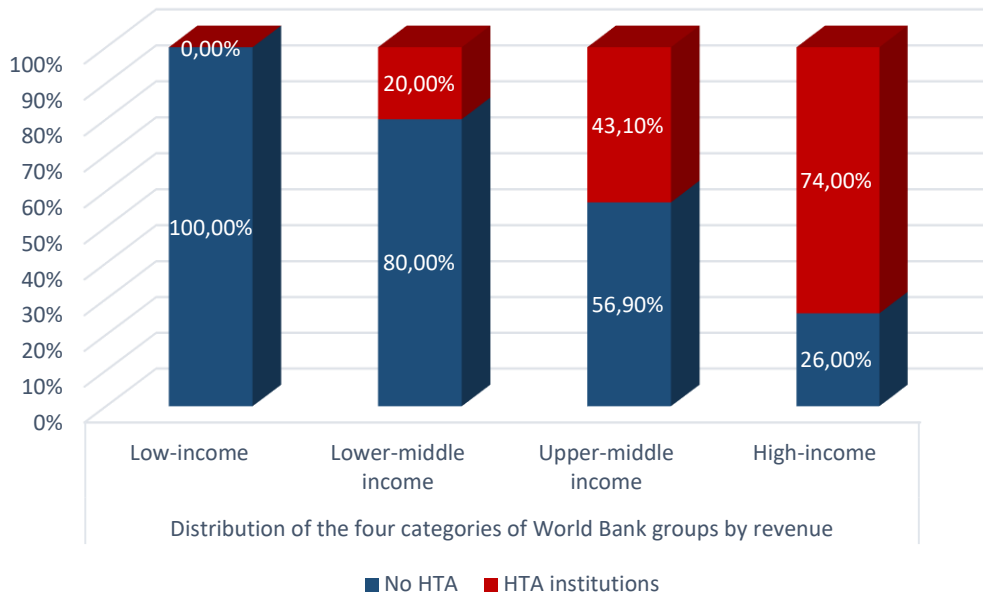


Fig. 1. Distribution of the presence and absence of the HTA Agency in the various revenue groups, according to the World Bank.

The relationship between the economic and social indicators in the different World Bank Groups is analyzed. The Kolmogorov-Smirnov test demonstrates a normal or near normal distribution in terms of the per capita health expenditure indicator.

Of the 175 countries surveyed, 108 have not implemented procedures and no official HTA institution. 38.3% of all countries in the world that are subject to analysis have an HTA agency. The remaining 61.7% of countries have no HTA. For them, the development of an HTA policy is not a priority, or they do not have the necessary resources and capacities for its implementation (Figure 2).

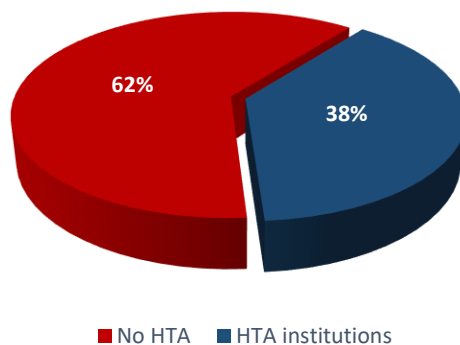


Fig. 2. Percentage distribution of the presence of HTA in the world.

Interest in the survey is the distribution of countries by income and solvency of the population. This is an essential socio-economic factor in the implementation of HTA (Figure 3). High and high average income categories account for approximately the same number of countries, which is 29% for each group, with countries numbering 50 and 51 respectively. The Lower-middle income category includes 23% (40 of the surveyed countries) and with low income - 19%.

■ Low-income ■ Lower-middle income ■ Upper-middle income ■ High-income

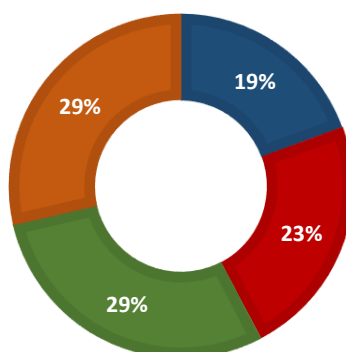


Fig. 3. Ranking of countries surveyed versus World Bank income grouping.

The United Nations currently has 194 countries [24]. Of all internationally recognized states, only the Vatican is not a member of the United Nations. The WHO maintains a detailed list of the member countries and, respectively, the regions in which they are represented. These countries fall into one of the six areas - Oceania, the Middle East, Europe, Asia, America, and Africa. The largest share of the countries surveyed in Africa - 28%, followed by Europe - 24.6%, 18.9% - America, 17.1% in Asia. The smallest share is in the Middle East - 4.6%, and in Oceania - 6.9%.

The values presented in Fig. 3 shows the number of countries holding HTA agencies and the number of states with no HTAs. From the analysis, we can see how regions a large number of HTA units around the world are concentrated. The leading share belongs to Europe - 32 countries with an official HTA institution. In America, 13 states are located with available HTA agencies. In Asia and Africa, the number of HTA countries is as follows - 11 countries in Asia and 5 in Africa. Countries with an available HTA agency in the Middle East are 4, and in Oceania - 2.

The most significant number of countries without HTA agencies is in Africa - 44. For Asia and America, 19 and 20 states do not have agencies, followed by Europe - 11, Oceania - 10, and the Middle East - 4.

For countries in the region of Africa, a total of 49 countries are considered, of which 10.2% have an agency. In the area under consideration, the division of individual smaller regions has a substantial impact on economic and social aspects. 51% of African countries are in the low-income category, 29% in low average income and 20% in high income. There is no country in Africa to fall into a high-income category.

The distribution of HTAs in African countries by the income grouping criteria shows the highest share of HTA shortages in low-income countries - 100%. In countries with low average income, the distribution of HTAs is 21.4% with HTA against and without - 78.6%. In countries with high average income, there is a tendency for agencies to be lacking, only 20% of the analyzed countries have one, the remaining 80% missing.

In Africa are concentrated a large number of countries, referring to the low and middle-income level, according to the World Bank. The economic factor is indicative of the development and distribution of HTA agencies globally. In this case, no meaningful conclusion can be drawn regarding the locations of the TABs according to the economic growth of the given country, because the analyzed region is specified in the socio-economic aspect.

For countries in the region of America, 39.4% of all 43 countries surveyed have an HTA agency. 52% of the countries are in the high middle-income category, 27% too high income,

18% to low average income, and 3% to low-income countries. The data shows that the economic factor is decisive for the region. Institutions in America are localized mainly in high-income countries. Of this category, 53% have HTA.

For the Asian region, 33 countries came to the survey. Of these, 63.3% do not have an HTA agency. The remaining 36.7% have one. 40% of countries are in the low, middle-income category, 27% low income, 20% high average income and 13% high income. Asia's agencies are localized mainly in high-income countries. Of this category 75% have an agency, 25% no.

In Europe, where the majority of HTA agencies are concentrated globally, only 25.6% of countries do not have a functioning one. The total number of countries participating in the survey for Europe is 43. The income of the population is different according to the division of the countries of Europe. The World Bank ranks 72% of countries as high-income, 23% medium-high, and only 5% low-middle-income. No country in Europe refers to the category of low-income countries. High-income countries in Europe have HTA in 80.6% of cases.

In Middle East countries, HTA agencies have approximately 50% of the countries examined. The total number of countries surveyed is 8, of which four have, 4 have no. The World Bank ranks 50% of Middle East countries as high-income, 38% medium-high, and 12% low-middle-income. It is interesting to note that, like the countries of Europe and here, no country falls into the category of low-income countries. Middle East agencies are localized mainly in high-income countries, which are 50% of those analyzed.

Of the examined 12 countries in Oceania, 3 of them have an HTA agency. The other nine are missing as a percentage ratio of 16.7% has an agency compared to the remaining 83.3%, which is missing. The highest percentage share in Oceania is in countries with a high average income - 42%, low average income - 41%, and high-income countries - 17%. Here too, one can notice that no countries are falling under the low-income category. High-income countries in Oceania, which account for 17% of the total, have 100% of HTA agencies.

4. Discussion

Bulgaria is part of the Europe and Central Asia region and is in the middle of the country with high incomes, which in Europe is 23%. The neighboring countries of Bulgaria - Serbia, Romania, Albania, Turkey - are also filled in the high average income category, which is well-known for the level of correspondence to HTA activities and needs for the adoption of good practices in the field of social and social policy. Economic Indicators. Countries in Europe in the high-income category with 80.6% available.

However, all HTA policies globally, the real cost share of the process remains low - 38% are available for evaluation, with the most significant percentage being observed in Europe (74%), small in Africa (10.2%). There are statistically significant differences concerning social indicators.

In the case of HTA, the average life expectancy (76.60 years) is nine years higher than in the absence of HTA (67.26 years). There is a difference between the per capita healthcare costs measured in US dollars for countries where there is an HTA agency (average rang 124,22) and countries with a lack of such (average rang 64,5).

It can be summed up that 100% of the World Bank low-income countries do not have an HTA, while 74% of those with high income apply the method, which is indicative of the level of economic development of a given country and respectively the activities that are carried out in the sphere of HTA. The implementation of HTA processes and good practices in the area would have a beneficial effect on the socio-economic and demographic situation in Bulgaria. According to the World Bank, the average life expectancy in Bulgaria is 74.47 years, and the implementation of HTAs at a national level in the future should be seen as a priority for a positive demographic response.

5. Conclusions

It is worth noting that there is a clear need to institutionalize a national HTA structure and that its priorities, objectives, and tasks should be aligned with the needs and needs of the health system in which they operate.

In Bulgaria, this is entirely possible and applicable in the conditions of globalization in which we live, as world experience in the sphere could be an exceptional asset for rapid development, in line with the recommendations of the International Bank for Reconstruction and Development.

The introduction of HTA procedures in a small country like Bulgaria requires the establishment and maintenance of active links and communication with all stakeholders and partners on an individual, national and international level. Bulgaria has its place on the world health and political scene. In an environment characterized by a national consensus achieved, assessments of high-quality evidence carried out in a timely and transparent manner, will lead to the implementation of the HTA goal - efficient allocation of resources in healthcare. Understanding the processes in HTA institutions and approaching by adapting the world experience is a safe formula for success in building good HTA practices.

Reference

1. Battista RN, Peckham M, Smith R. The scientific basis of health services. BMJ Publishing Group; 1996.
2. Chen Y, Banta D, Tang Z. Health technology assessment development in China. *Int J Technol Assess Health Care*. 2009;25(SUPPL.S1):202–9.
3. Hernández-Quevedo C, Masseria C, Mossialos E. Analysing the socioeconomic determinants of health in Europe: new evidence from the EU-SILC [Интернет]. European Union; 2010 [цитиран 09 Ноември 2018]. Available at: <http://epp.eurostat.ec.europa.eu/portal/page/portal/eurostat/home/>
4. World Health Organization (WHO); Constitution of the World Health Organization; New York, 1948, 1.
5. By A, Hta THE. EUROPEAN COMMISSION DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY Health systems, medical products and innovation Medical products: quality, safety, innovation HTA NETWORK REFLECTION PAPER ON " SYNERGIES BETWEEN REGULATORY AND HTA ISSUES ON PHARMACE. 2016;(November):1–8. Available at: https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/ev_20161110_co06_en.pdf
6. <http://www.agenas.it/contenuto-inglese>; Data Accessed: 13.03.2019.
7. Favaretti C, Cicchetti A, Guarrera G, Marchetti M, Ricciardi W. Health technology assessment in Italy. *Int J Technol Assess Health Care*. 2009;25(Suppl 1):127–33. doi:10.1017/S0266462309090539.
8. GDP (current USD). // World Development Indicators. World Bank. Посетен на 31 December 2018.
9. Patient T. 10th anniversary of the Spanish Network of Health Technology Assessment (HTA) Agencies : Towards Patient and public engagement in HTA. 2017;15–7.
10. The World Bank IBRD - IDA [Интернет]. [цитиран 03 Януари 2019]. Available at: <https://databank.worldbank.org/data/reports.aspx?source=2&country=NLD>
11. INAHTA; KCE – Belgian Health Care Knowledge Centre; <http://www.inahta.org/members/kce/> 17.01.2019.
12. The World Bank [Интернет]. World Bank in Bulgaria. [цитиран 11 Май 2018]. Available at: <http://www.worldbank.org/bg/country/bulgaria/overv>
13. Smoking of tobacco products by sex , age and degree of urbanisation Source of data :

- Eurostat TIME : 2014 DEG _ URB : Total SEX : Total AGE : Total UNIT : Percentage. 2014;2014.
14. Obesity rate by body mass index (BMI). 2018;2018.
 15. HICP - food , alcohol and tobacco. 2018;2017.
 16. Union E, Republic C. Time spent on health-enhancing (non-work- related) aerobic physical activity by sex , age and educational attainment level Source of data : Eurostat UNIT : Percentage TIME : 2014 ISCED11 : All ISCED 2011 levels SEX : Total AGE : Total. 2014;75–6.
 17. Nutrition, Physical Activity and Obesity Bulgaria [Интернет]. World Health Organization 2013. 2013 [цитиран 03 Ноември 2018]. Available at: https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=2ahUKEwiD2tmW39PeAhVIIIsKHS3VDU8QFjAAegQIAhAC&url=http%3A%2F%2Fwww.euro.who.int%2F__data%2Fassets%2Fpdf_file%2F0020%2F243290%2FBulgaria-WHO-Country-Profile.pdf&usg=AOvVaw02
 18. WHO Global Health Observatory Data Repository [Интернет]. Geneva, World Health Organization, 2013. [цитиран 23 Октомври 2018]. Available at: <http://apps.who.int/gho/data/view.main>
 19. Financing and management of healthcare [Интернет]. Ministry of Finance, Department of Microeconomic Analysis, Directorate „Budgets“. [цитиран 13 Октомври 2018]. с 299. Available at: https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=2ahUKEwi_uNmQ5NPeAhVvoYsKHeeECJEQFjAAegQICBAC&url=https%3A%2F%2Fwww.minfin.bg%2Fupload%2F2891%2FHealth%2Bsector%2Banalysis%2Bfinal.pdf&usg=AOvVaw1xLL2miiBfJ9bGbDyVSVVG
 20. Asia C. Republic of Bulgaria Bulgaria Health Financing RAS Final Report on Health Financing Diagnostic and Review of Envisaged Reforms. 2015;(May). Available at: <http://www.copyright.com/>.
 21. Learning Curve - Business Dictionary [Интернет]. [цитиран 12 Септември 2018]. Available at: <http://www.businessdictionary.com/definition/learning-curve.html>
 22. The World Bank Group. World development Indicators 2017 [Интернет]. International Bank for Reconstruction and Development/The World Bank. 2017 [цитиран 06 Ноември 2018]. с 10. Available at: <https://openknowledge.worldbank.org/handle/10986/2135>
 23. Fantom N, Serajuddin U. The World Bank ' s Classification of Countries by Income. World bank [Интернет]. 2016;(January):1–52. Available at: <http://www.worldbank.org>
 24. Member States [Интернет]. United Nations. [цитиран 10 Юни 2018]. Available at: <https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=12&cad=rja&uact=8&ved=2ahUKEwiZ8JWG69PeAhUsxosKHT0rBvgQFjALegQIDxAB&url=http%3A%2F%2Fwww.un.org%2Fen%2Fmember-states%2F&usg=AOvVaw1iC9taszRxfU8VenfTcEvY>