



COUNTRY HEALTH PROFILE: THE CASE OF ROMANIA



1st Draft

**The impact of Underinvestment on Medicines
and Health Services in Romania**

Turcu-Stiolica A. Ph.D., Yfantopoulos J. (Ph.D.)

September 2022

Health is a value in itself.



- **Health/Wealth** is also a precondition for economic prosperity.
- People's **health** influences **economic outcomes** in terms of **productivity**, labor supply, human capital and public spending.
- **Investing in sustainable health systems** combines **innovative reforms** aimed at improving **cost-efficiency**.
- **Investing in people's health as human capital** helps improve the health of the population in general.
- **Investing in health helps the EU and the CEE** countries rise to the challenges identified in its **Health Strategy Europe 2025**.
- Evidence across the EU and the CEE Member States reveals the significant **underinvestment** in health and the **need for policy intervention to improve access and Health Outcomes**.

Contents

Contents	3
List of Figures.....	5
List of Tables.....	5
1. Summary.....	6
2. Key messages.....	7
3. An Overview of the Healthcare System in Romania.....	11
3.1 Social Health Insurance (SHI).....	12
3.2 National Health Strategy	13
3.2.1 National Health Strategy 2014-2020	13
3.2.2 National Health Strategy 2022-2030	17
4. Health outcome trends in Romania	19
4.1 Life Expectancy at Birth	19
4.1.1 Life expectancy by sex	20
4.2 Infant mortality rate	21
4.3 HEALTHY LIFE YEARS.....	23
4.4 Good and Very Good Health	25
5. GDP per Capita	27
6. Health expenditure in Romania.....	28
6.1 Total Health Expenditure as % of GDP	28
6.1.1 Public Health Expenditure as % of GDP.....	29
6.1.2 Private Health Expenditure as % of GDP	29
6.3 Pharmaceutical expenditure	30
6.3.1 Public Pharmaceutical expenditure.....	31
6.3.2 Private Pharmaceutical expenditure.....	31
7. Health Unmet Needs for Medical care in Romania.....	32
7.1 Total of the unmet needs for medical care in Romania	32
7.1.1 Unmet needs for medical care for females	33
7.1.2 Unmet needs for medical care for males	34
7.3 Unmet Needs for Prescribed Medicines.....	35
8. The Romanian pharmaceutical policies.....	37
8.1 Drug turnover and pricing	39
8.2 Drug reimbursement	41

8.3 The claw-back taxation on medicines	42
8.4 The role of Health Technology Assessment	44
9. References	48
Research Team	54

List of Figures

Figure 1. Demographic and socioeconomic context in Romania [4].....	11
Figure 2. The main causes of the avoidable mortality in Romania vs. EU-27 in 2017(SMR, Standardized Mortality Ratio, deaths observed in a 100.000 population)	14
Figure 3. Total of numbers of deaths according to patient's residence in Romania (2017-2019)(Source: INSP-CNSISP, National Public Health Institute-National Center of Statistics and Informatics in Public Health)	14
Figure 4. Total number of avoidable deaths from acute myocardial infraction	15
Figure 5. Total numbers of avoidable deaths from stroke	15
Figure 6. Total numbers of avoidable deaths from cancer	16
Figure 7. Life expectancy at birth in the EU and Romania (1960-2020).....	19
Figure 8. Male life expectancy in the EU and Romania (1960-2020)	20
Figure 9. Female life expectancy in the EU and Romania (1960-2020).....	21
Figure 10. Infant mortality rate in the EU and Romania	22
Figure 11. Total healthy life years in Romania	23
Figure 12. Male's healthy life years.....	24
Figure 13. Female's healthy life years	24
Figure 14. Good and very good health in Romania	25
Figure 15. Males reporting good and very good health.....	26
Figure 16. GDP per Capita	27
Figure 17. Total health expenditure as % of GDP.....	28
Figure 18. Public Health expenditure as % of GDP.....	29
Figure 19. Private health expenditure as % of GDP	30
Figure 20. Total pharmaceutical expenditure per capita PPS	30
Figure 21. Public pharmaceutical expenditure per capita PPS.....	31
Figure 22. Private pharmaceutical expenditure per capita PPS	32
Figure 23. Total Unmet needs for medical care	33
Figure 24. Females Unmet needs for medical care.....	34
Figure 25. Males unmet need for medical care.....	35
Figure 26. Unmet needs for prescribed medicines	36
Figure 27. Claw-back values (https://cnas.ro/clawback/).....	44

List of Tables

Table 1. Type of prices for medicines.....	40
Table 2 Claw-back taxation.....	42
Table 3. Type of decision after Romanian HTA process	46

1. Summary

The objective of this study was to examine the magnitude of underinvestment on health in Romania and its impact on health outcomes. We focus on time trend analysis in an attempt to assess the causal relationships between health outcomes, expenditures, and unmet medical needs. We establish comparisons between Romania and the European Union average (EU-27) to underline the convergence or divergence of the trends. Romania has joined EU on January 1st, 2007 and our analysis explores the existing gap on health and the socio-economic indicators. Finally some discussion takes place in the last section on the implemented pharmaceutical policies in Romania

Romania has gone through deep political, economic and social transformations over the last 30 years, a fact that had a major impact both in the health of the population and in organization of the current health system. Although the health outcome improvements over the last 20 years, they still remain below the EU-27 and also decreased substantially during COVID-19 pandemic. Life expectancy at birth has increased not only in the EU, but also in Romania, reaching its peak point in 2019. (Romania: 75.61 years, EU: 81.06 years). The big difference between them is that the increase in the EU was continuous, while in Romania a slight increase was observed between 1960-1973, followed by stability for the next 25 years, also as a consequence of the Romanian Revolution in December 1989. From 1997 onwards, life expectancy in Romania increased by 5 years. This may be attributed to the full accession of Romania in the European Union on January 1st, 2007. Romania, is one of the few CEE countries presenting impressive convergence in terms of the economy but not as much as in the health sector. The effects of COVID -19 have been more severe in Romania in comparison to other EU Countries. In 2020, year known for the onset of COVID-19 pandemic, life expectancy at birth decreased in Europe by 0.46 years and in Romania by 1.25 years.

2. Key messages

- In Romania, life expectancy at birth between 2000 and 2019 increased by approximately 4 years. However, this number decreased by 1.4 years after the outbreak of the COVID-19 pandemic. The country has a low ranking compared to the European Union due to the risky habits of citizens, as high rates of smoking and alcohol consumption are reported.
- Women live longer than men in both Romania and the EU. The gender gap averaged 6.09 years in Romania and 6.39 years in the EU. Male life expectancy reached its peak point in 2019, across the EU (78.45 years) and Romania (71.9 years). The highest female life expectancy was marked in 2018 in the EU (83.87 years) and in 2019 in Romania (79.5 years). Divergence of male life expectancy between the EU and Romania was exacerbated from 1978 to 1996. In particular, while the difference was 2.6 years in the beginning of the period, it grew into 7.2 years in 1996 and 8 in 2020. From 1997 to 2002, a converging or diverging trend were described between the EU and Romania. Furthermore, from 2003 onwards, both slopes tend to increase in parallel, without convergence or divergence observed.
- The differences between Romania and EU average in life expectancy at birth for males ranged between 1.2 in 1975 to 8.0 in 2020. Finally, the outbreak of the Covid-19 pandemic led to a significant decrease of 1.4 years in Romania, while EU faced an increase of 0.09 years.
- The same trends were observed for female life expectancy at birth: from 1960 to 1978 both slopes change in parallel, without significant convergence or divergence, followed by divergence during 1979 and 1997. In particular, if the gap was 3 years in 1960, it increased from 4.5 years in 1979 to 6.8 years in 1997. Between 1998 and 2013, both slopes tend to increase in parallel, while from 2014-2019 a convergent trend is observed, with the existing gap ameliorated from 5.1 years to 4.3 years. Same as male life expectancy, female

life expectancy decreased in Romania in 2020 as much as 1.1 years, while the shrink in the EU was only 0.02 years.

- Infant mortality also appears higher in Romania than in the EU. In EU, infant mortality rate decreased from 36 to 3.3 deaths between 1960 and 2020, which translates to a decline of 90.83%. In Romania infant mortality rate decreased from 72.7 deaths to 5.6 deaths, which translates into 92.72%.
- In terms of per capita expenditure on prevention, the country is the second lowest in the EU. That is, even before the pandemic outbreak, public health was not performing at its best. The country's primary health care is considered to be problematic and, as a result, the country's mortality rates are at an alarmingly high level.
- Over the years, Romania has significantly increased its health spending but not to a satisfactory level, leaving it as the second lowest EU country in the health care sector. Regarding inpatient and outpatient care, public funding has increased but out-of-pocket costs are high, especially for medicines. However, COVID-19 treatments as well as the medicines needed are provided free of charge to citizens.
- During the first wave of the pandemic, testing rates were quite below the EU average and the high positivity rates during the pandemic indicate that testing capacity is not keeping pace with the speed of virus transmission. Furthermore, in the second half of 2020, the number of exaggerated deaths was much higher than the number of reported COVID-19 deaths, suggesting that COVID-19 deaths are underestimated.
- The COVID-29 vaccination started with positive prospects but the problems that occurred regarding the supply have set the country back, and the reluctance to use vaccines continues to negatively affect the course of the pandemic, with the result that the vaccination program has lost momentum.
- During 1990 and 2020, the gap between Romania and EU-27 regarding the GDP per capita increased from 13130,95 \$ in 1990 to 33170.4 \$ by 2019. The outbreak of the Covid-19 pandemic led to a slight increase of 15.9 \$ in Romania, while EU faced a decrease of 1306.6 \$.

Total health expenditure is significantly higher in Europe than in Romania during the examined period. The gap between them decreased from 4.1% in 2011 to 2.6% in 2019. From 2011 to 2019 the European health expenditure as percentage remains somewhat stable at 8% and later is decreased from 9.3% in 2009 to 8,4% in a decade. 6, Romania remained stable at approximately 5% reporting a slight increase among the years. From 2013 to 2019, there was an increase in Romania from 5.2% to 5.7%. The gap between Europe average and Romania ranged from 2.6% to 4.1%, having a convergent trend in the last years.

- Public health spending as % of GDP in Romania presented a different trend in relation to the Romanian public health expenditure, observing a convergent trend from 2009 onwards. Public health expenditure decreased in Europe from 7% to 6.2%, whereas it increased from 3.5% to 4.6%, reducing the differences between Romania and Europe average.
- Private health spending decreased in Europe from 2.3% in 2011 to 2.1% in 2019 while Romania also registered a slight decrease of 0.04% in public health expenditure. Europe increased its public health expenditure (% of GDP) from 2.3% to 2.4% (total increase of 0.1%) between 2009-2010 and 2011-2012, but Romania recorded very small variations compared to 1.1%, still remaining lower than the EU average. On the other hand, in Europe from 2009 onward, public health expenditure registered a slight decrease however remained above the average. Overall, especially in period 2009-2012, the gap between EU and Romania expanded at its most.
- The self-reported unmet needs reached both a minimum in 2017 for EU-27 (1.6%) and for Romania (4.7%), whereas the maximum was declared in 2013 for European Union countries (4%), respectively in 2011 for Romania (12.2%).
- People from EU countries reported in median 2.8 times less unmet needs than Romania. Over the eleven years compared, the highest unmet need for medical care for females was found in 2013 (4.6%) for EU countries and in 2012 (13.8%) in Romania. The unmet needs for medical care were in median 3 times higher for Romanian females than for EU females, with the smallest

difference in 2016 (2.5 times) and highest in 2010 (3.2 times). During all examined period, the highest unmet need for medical care for males was found in 2013-2014 (3.3%) for EU countries and in 2011 (11.3%) in Romania. Analyzing the distribution of data on needs for medical care males, the trend is declining till 2017 for both EU countries and Romanian males, when they declared a convergent, almost parallel evolution.

- Unmet needs for prescribed medicines in 2019 were defined as 6%, perhaps due to financial reason or to medicines missing in community pharmacies from Romania. Some medicines were missed because of the parallel trends.

3. An Overview of the Healthcare System in Romania

Public sector characteristics dominate Romania's healthcare, where most of the country's hospitals are housed, and almost all residents are included through the country's health insurance. Health spending in 2019 was around 5% of GDP, much lower than that of the maximum international countries in the European Union, which averages 7%. In the case of Romania, the health spending in GDP increased to 5.5% of GDP in 2020, one of the lowest percentage increases in the EU, where the average for 2020 was 8% of GDP [1]. At the same time, a parallel community of personal healthcare providers is expanding. The ministry has a committed man or woman in the direction of the sufferer and the clinical system, with the belief that sooner or later the individual will not need to be transferred to achieve the best possible result of a better examination, however the aim is also to have the system itself as near as possible to the sufferer, with the brand-new authorities' software. In keeping with the country's personally authorized plans, essential future reforms will include the arrangement and eventual creation of 8 nearby and one treatment authorities, in addition to a preferred quality development inside the best and efficiency of the system [2]. Romania has significant potential for improvement and boom in the market for high-tech clinical systems and equipment, and this is a good way for the country to develop as demand increases, production in the intersection of healthcare in the country increases, and the desire to meet the best European requirements in line with the average resulting from the rest of Europe increases [3].

Figure 1. Demographic and socioeconomic context in Romania [4]

Demographic Factors	ROMANIA	EU
Population size (mid-year estimates)	19 328 838	447 319 916
Share of population over age 65 (%)	18.9	20.6
Fertility rate (2019)	1.8	1.5
Socioeconomic factors		
GDP per capita (EUR PPP)	21 296	29 801
Relative poverty rate(% , 2019)	23.8	16.5
Unemployment rate (%)	5.0	7.1

3.1 Social Health Insurance (SHI)

Romania's social health insurance (SHI) system aims to provide universal health insurance coverage, and the state plays an active role, with the Ministry of Health responsible for overall governance and the National Health Insurance Agency (NHIH) managing and regulating the system as a whole. At the local level, both authorities are represented by the District Public Health Authorities (DPHA) and the District Health Insurance Houses (DHIH). Health-care services are provided in 41 counties and the capital, always in accordance with the rules established by the central government [5]. DHIHs are responsible for purchasing services from health care providers such as general practitioners (GPs), sophisticated specialized dispensaries, hospitals, and home-based benefits for people who are unable to move.

The system is funded by four main sources: national health insurance funds, local and state budgets, and out-of-pocket payments (OOP), and the Voluntary Health Insurance (VHI) contribution is so small that it has almost no impact on the system. Out-of-pocket payments are mostly direct and are provided by private providers, as are co-payments for drugs or other services. Payments that are not typical do not appear in statistics but have a significant impact due to their size. In terms of primary care, family doctors provide services in their individual practices while relying on contracts with DHIHs [6]. Their role is similar to that of a gatekeeper in terms of availability, though access to a specialist doctor is limited to specific conditions and is provided through the previously mentioned contract network of hospital outpatient and polyclinics, specialist health, diagnostic and treatment centers, and individual specialist doctors' offices. In terms of hospital care, there is a network of hospitals that meet certain criteria such as size, responsibilities, and coverage areas. Again, rural areas have less access to specialized care and have fewer financial resources than urban areas.

3.2. National Health Strategy

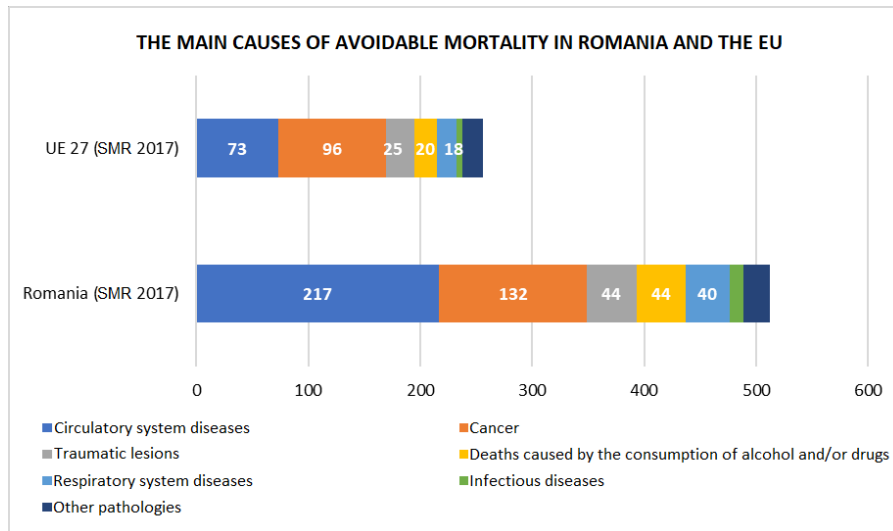
3.2.1 National Health Strategy 2014-2020

The National Health Strategy 2014-2020 wanted to unite the Government and all decision makers (institutional actors and health professionals) to ensure and promote health as a crucial determinant of society development, reducing as much as possible the burden of the diseases for patients, their family and health care system in Romania [2].

Romania has gone through deep political, economic, and social transformations in the last 32 years, after the Revolution from December 1989, a fact that had a major impact both on the health of the population and on organization of the current health system. The transition from a totalitarian political system to a democratic system, the perpetual economic, social and educational reforms, but also the unfinished transition of the health system had a direct and major ambivalent impact in the main demographic and health indicators (low birth rate, increased emigration, increased life expectancy, very slowly declining infant mortality, the changing pattern of morbidity and mortality, high avoidable mortality).

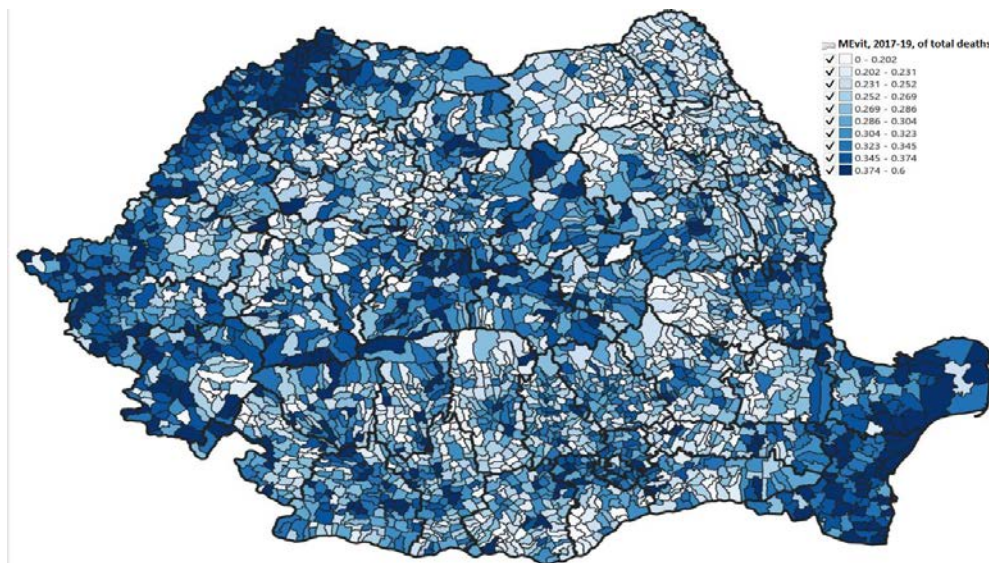
Although the health outcomes improved in Romania in the last 20 years, they still remain under the average from UE. Life expectancy in Romania is one of the lowest in UE, even if it increased with more than 4 years from 71.2 years to 75.6 years in 2019 [1]. The main causes of avoidable mortality in Romania are diseases of the circulatory system, cancer, and traumatic injuries, but the values recorded in our country are 1.5 to 3 times higher than the EU 27 average, as in the Figure 1. The most registered cause of avoidable mortality in Romania are the circulatory system diseases, as 3 times higher than the EU 27 average, but all the infectious or non-communicable diseases are included in the National Health Strategy objectives.

Figure 2. The main causes of the avoidable mortality in Romania vs. EU-27 in 2017(SMR, Standardized Mortality Ratio, deaths observed in a 100.000 population)



The avoidable mortality was higher in Satu Mare (North-West), in Constanta and Tulcea (South-West) or in Timis, Caras Severin (South-West), as in the Figure 2.

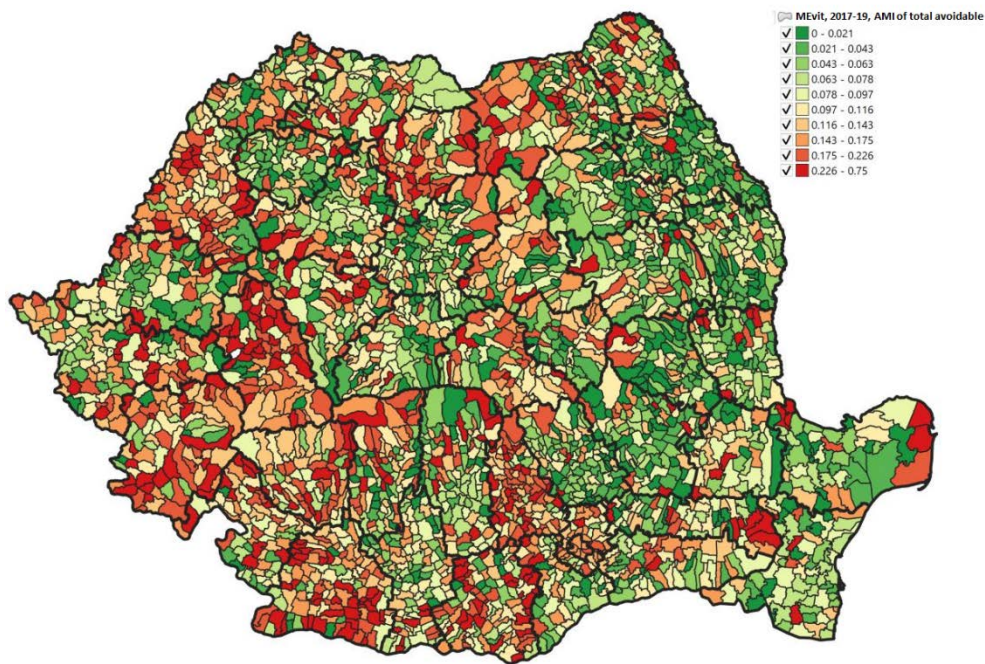
Figure 3. Total of numbers of deaths according to patient's residence in Romania (2017-2019) (Source: INSP-CNSISP, National Public Health Institute-National Center of Statistics and Informatics in Public Health)



Source National Strategy 2022 -2030 Ministry of Health Romania

The acute myocardial infarction (AMI) is one of the non-communicable diseases with major negative impact on public health and the reducing of the AMI burden is one of the national health strategies. The avoidable mortality having AMI as cause is higher in places/cities where AMI are not treated (the biggest number of AMI patients were treated in Bucharest, Cluj, Iasi, Timis, Mures and Dolj) [7].

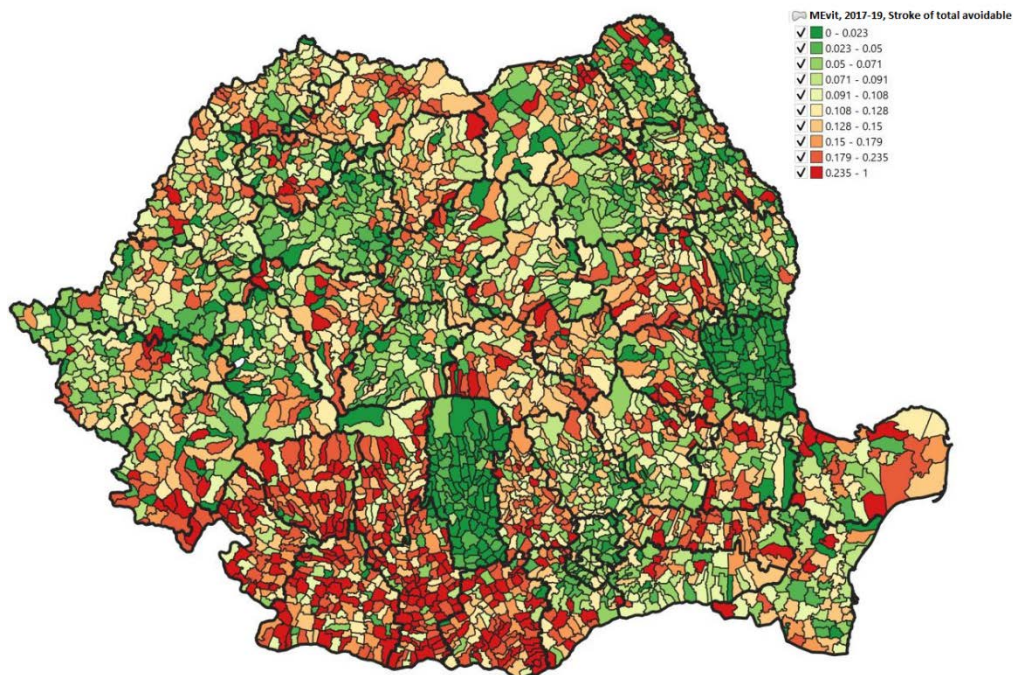
Figure 4. Total number of avoidable deaths from acute myocardial infraction



Source National Strategy 2022 -2030 Ministry of Health Romania

The biggest number of avoidable deaths from stroke were registered in South of the country, as in Figure 4. One of the objective of the National Health Strategy is the expansion of specialized recovery/rehabilitation services offered early after an acute event [7].

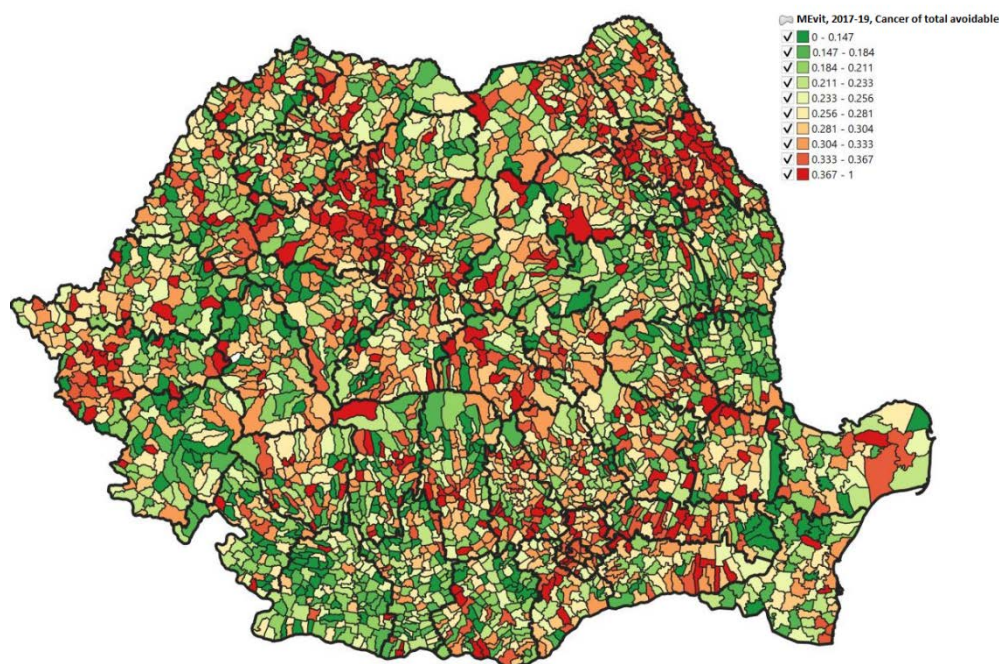
Figure 5. Total numbers of avoidable deaths from stroke



Source National Strategy 2022 -2030 Ministry of Health Romania

A high number of deaths having cancer as cause is higher in places from Romania where the screening and specialized information is not developed. Population screening is underdeveloped, the predominant mode of delivery being the opportunistic one. The only active screening program funded from the budget of the Ministry of Health is for cervical cancer, but with unsatisfied results. In the last years, a series of regional screening programs (for example, colon cancer in Oltenia) are co-financed from EU funds. More screening programs will be offered (breast cancer, viral hepatitis B and C, cardiovascular disease) through the National Health Strategy 2022-2030 [8].

Figure 6. Total numbers of avoidable deaths from cancer



Source National Strategy 2022 -2030 Ministry of Health Romania

Analyzing the results obtained after the National Health Strategy 2014-2020, OG 7 "Health infrastructure" and OG 6 "E-health" achieved the lowest performance. OG 7 was on the "first" place mainly due to the lack of progress in public health infrastructure, infrastructure for ambulatory and hospital. The best performance in OG 7 "Infrastructure" was achieved in the emergency medicine system, in terms of the number of vehicles purchased and the number of operational teams. The results were at or close to the planned values in terms of investment in emergency services and

very low in the case of specialized outpatient clinics. OG 6 "E-health" achieved the second lowest performance and the lowest result. The low performance of the information system was mainly due to delays in the development of national disease registries and the implementation of the electronic referral and electronic sick leave form. Advances in telemedicine were not evaluated due to lack of data, despite regulatory advances [8].

3.2.2 National Health Strategy 2022-2030

In the last year's important investment projects were started (among which large investments for infrastructure and medical equipment), but these were financed from uncoordinated sources and responding to different objectives. The total needs of investments in public health infrastructure have not been determined. An inventory of infrastructure of public hospitals is necessary to establish the needs of endowment and specialist expertise as well as for planning, prioritization and funding investment projects. Synergy between different financial streams and projects should be a continuing concern for the Ministry of Health as the central authority for health.

The objectives of the National Health Strategy 2014-2020 are also valid in the current context, remaining aligned with the international reform trends of the health systems. The new objectives proposed by the National Health Strategy 2022-2030 are as follows [8].

The general objectives OG1-OG3 propose directions for action and measures that redefine the role of the public health system considering the long-term consolidation of essential public health interventions.

OG1: Sustainability and resilience of the public health system

OG2: Reduction of mortality and morbidity associated with communicable diseases with major individual and societal impact

OG3: Healthy life years and enhanced quality of life

The general objectives OG4 propose to transfer the center of gravity of health services from hospital to specialist outpatient and from specialist outpatient to primary care.

OG4: Improving availability, equity access and in useful time in health services and safe and cost-effectiveness health technologies

The general objectives OG5-OG11 want to ensure the governance of the health system through adequate administrative capacity, partnerships with the main public and private actors and a coherent and transparent framework of evidence-based public policies.

OG5: Health system governance

OG6: Ensuring sustainability and financial resilience of the health system

OG 7: Ensuring adequate human resources, retention and the professionalization of it

OG 8: Increasing the objectiveness, transparency and accountability of the health system

OG 9: Coordination of care and integration of health services

OG 10: Proper integration of research and innovation for improvement of health

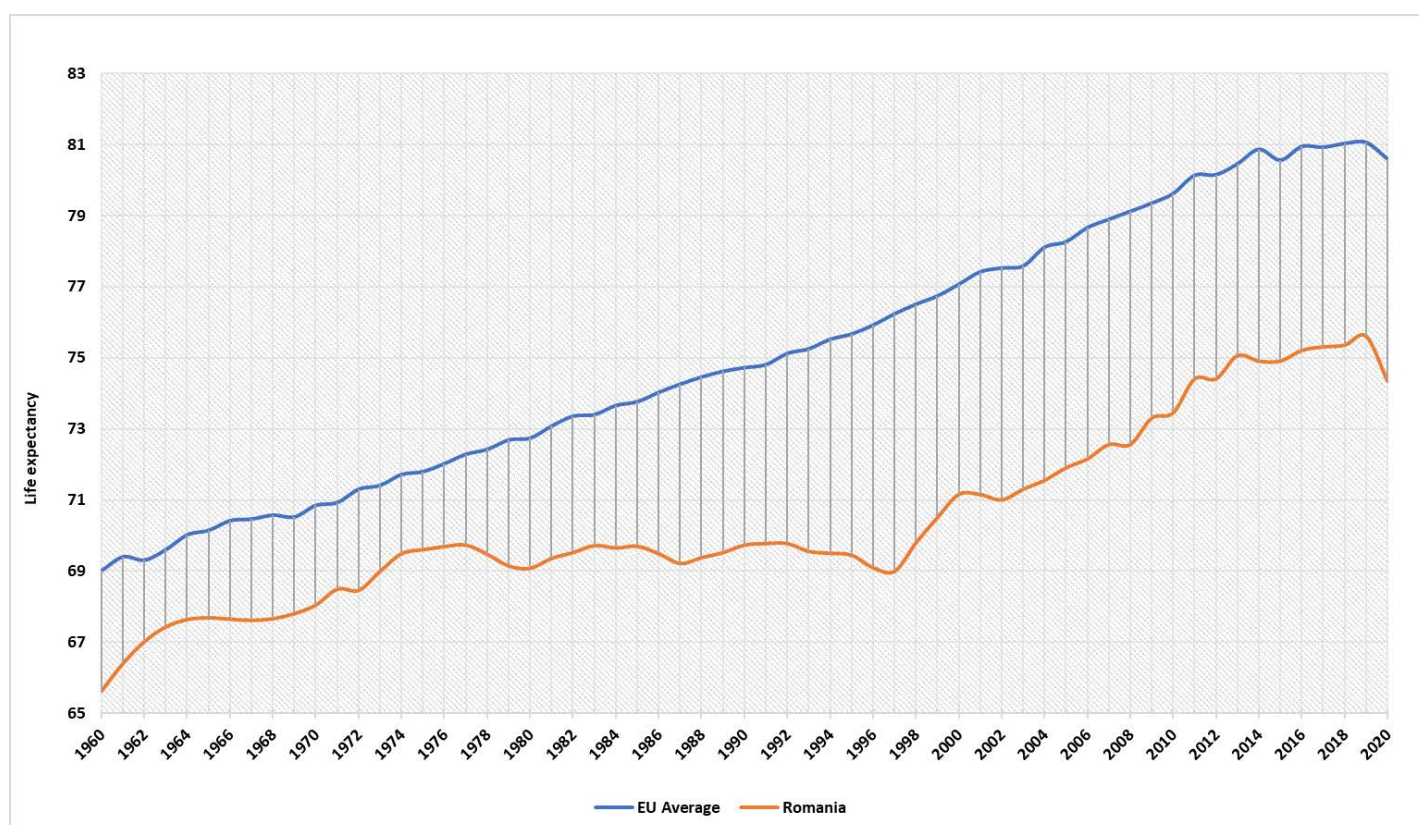
OG 11: Improving the quality of health services through investments in health infrastructure

4. Health outcome trends in Romania

4.1 Life Expectancy at Birth

Figure 7 displays the changes in life expectancy at birth over time in Romania and in Europe overall. Life expectancy has increased not only in the EU, but also in Romania, reaching its peak point in 2019 for both of them (Romania: 75.61 years, EU: 81.06 years). The big difference between them is that the increase in the EU was continuous, while in Romania a slight increase was observed between 1960-1973, followed by stability for the next 25 years, also as a consequence of the Romanian Revolution in December 1989. From 1997 onwards, life expectancy in Romania increased approximately 5 years, maybe as an impact of becoming member state of European Union on January 1st, 2007. The differences between Romania and EU average in life expectancy at birth ranged between 2.2 in 1963 to 7.2 in 1997. In 2020, year known for the onset of COVID-19 pandemic, life expectancy at birth decreased in Europe by 0.46 years and in Romania by 1.25 years.

Figure 7. Life expectancy at birth in the EU and Romania (1960-2020)

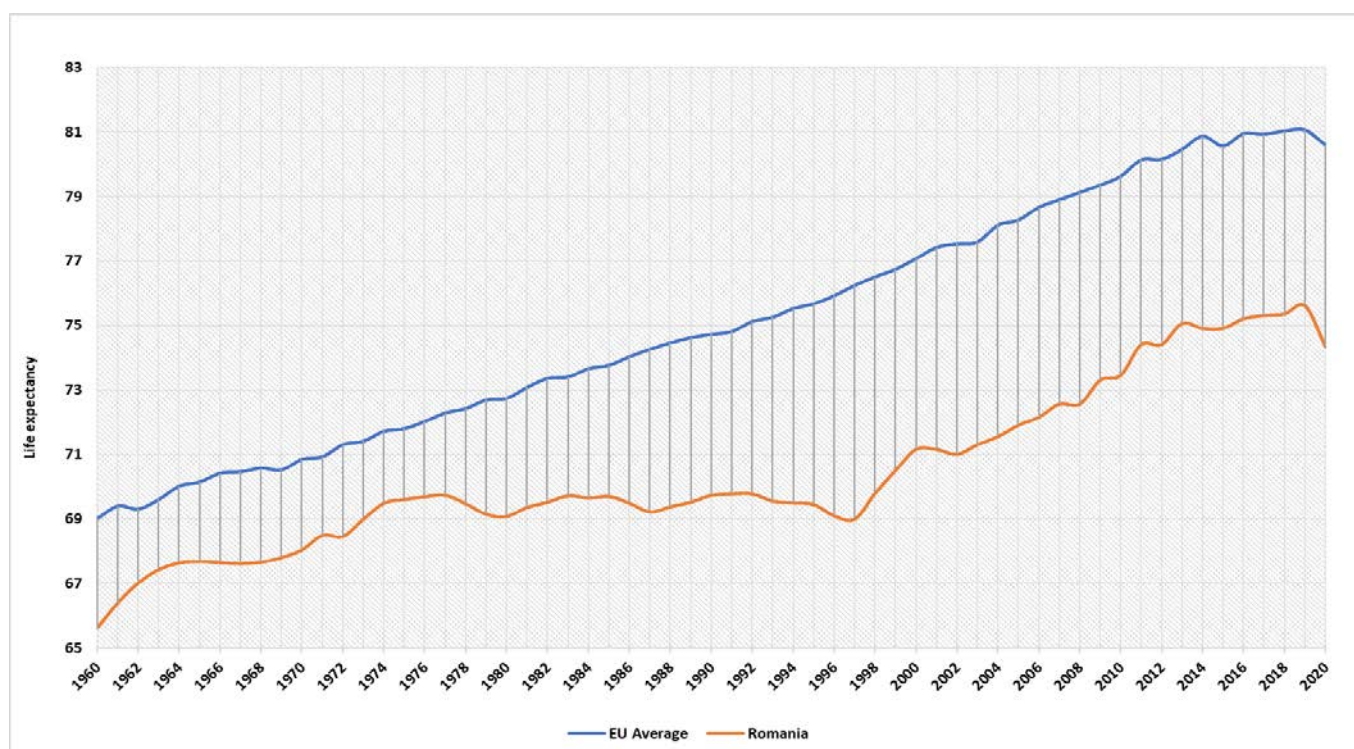


4.1.1 Life expectancy by sex

Women live longer than men in both Romania and the EU. The gender gap averaged 6.09 years in Romania and 6.39 years in the EU. Male life expectancy reached its peak point in 2019, across the EU (78.45 years) and Romania (71.9 years). The highest female life expectancy was marked in 2018 in the EU (83.87 years) and in 2019 in Romania (79.5 years).

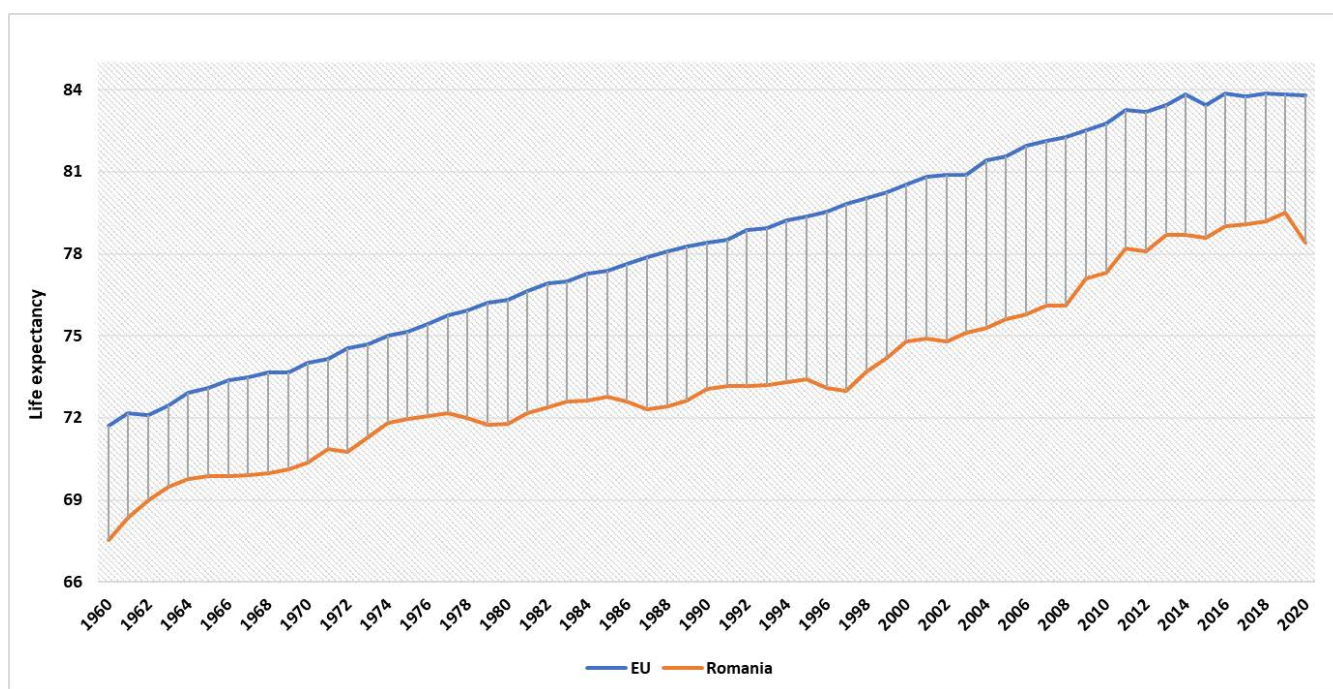
Figure 8 displays the changes happened in male life expectancy in the EU and in Romania. During all the period explored, comparisons are always favorable for the EU, which has steadily higher male life expectancy than the one detected in Romania. Divergence between the EU and Romania was exacerbated from 1978 to 1996. In particular, while the difference was 2.6 years in the beginning of the period, it grew into 7.2 years in 1996 and 8 in 2020. From 1997 to 2002, a converging or diverging trend were described between the EU and Romania. Furthermore, from 2003 onwards, both slopes tend to increase in parallel, without convergence or divergence observed. The differences between Romania and EU average in life expectancy at birth for males ranged between 1.2 in 1975 to 8.0 in 2020. Finally, the outbreak of the Covid-19 pandemic led to a significant decrease of 1.4 years in Romania, while EU faced an increase of 0.09 years.

Figure 8. Male life expectancy in the EU and Romania (1960-2020)



As presented in Figure 9, from 1960 to 1978 both slopes change in parallel, without significant convergence or divergence observed. During 1979 and 1997, divergence is observed between the EU and Romania. In particular, if the gap was 3 years in 1960, it increased from 4.5 years in 1979 to 6.8 years in 1997. Between 1998 and 2013, both slopes tend to increase in parallel, while from 2014-2019 a convergent trend is observed, with the existing gap ameliorated from 5.1 years to 4.3 years. Same as male life expectancy, female life expectancy decreased in Romania in 2020 as much as 1.1 years, while the shrink in the EU was only 0.02 years.

Figure 9. Female life expectancy in the EU and Romania (1960-2020)



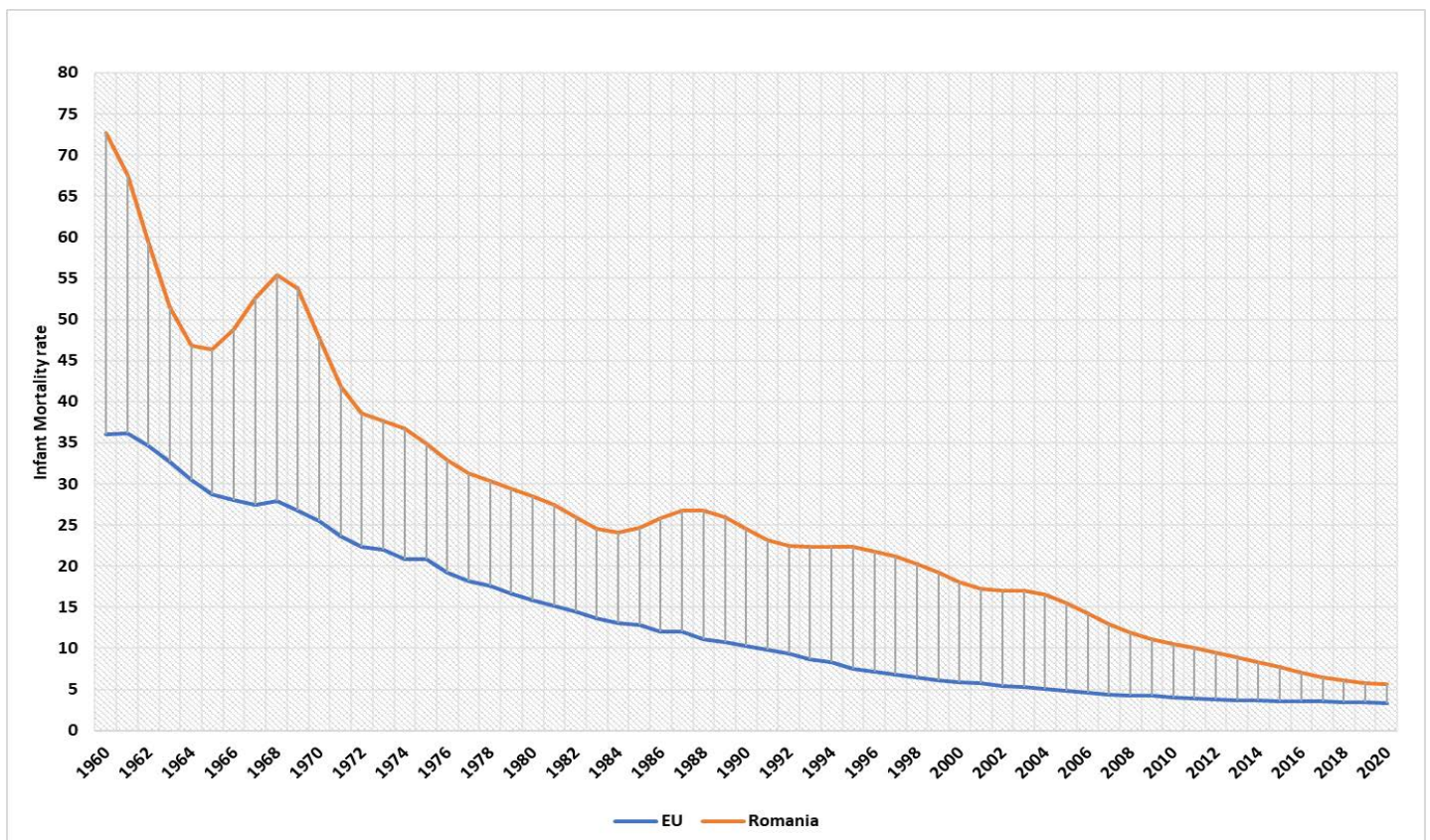
Source: World Bank Health Data

4.2 Infant mortality rate

Infant mortality rate in the EU and Greece showed a decreasing tendency from 1960 to 2020, but the EU and Romania tends to convergence only between 2007-2020. Overall, infant mortality rate decreased from 36 to 3.3 deaths between 1960 and 2020, which translates to a decline of 90.83%. In Romania infant mortality rate decreased from 72.7 deaths to 5.6 deaths, which translates into 92.72%. During all

period examined, infant mortality appears higher in Romania than in the EU. The existing gap between the EU and Romania was higher from 1960 to 1969, reaching its highest point in 1968 when the gap averaged to 27.5 deaths per 1000 live births. This is attributed to the fact that during Ceausescu leadership contraception was banned in 1966 and abortion was also heavily restricted that gave rise to crude birth rates with a pick seen at 1968, followed by a remarkable rise in infant mortality rate in 1968. After this year, a sharp improvement is observed, followed by gradual narrowing of the existing gap. During the last five years (2016-2020), the gap between the EU and Romania is lower than 4 years, while between 2019 and 2020 is less than 2.5 years. Finally, the outbreak of the Covid-19 pandemic led to a significant decrease of 0.2 years in Romania, 0.1 years in EU, respectively.

Figure 10. Infant mortality rate in the EU and Romania

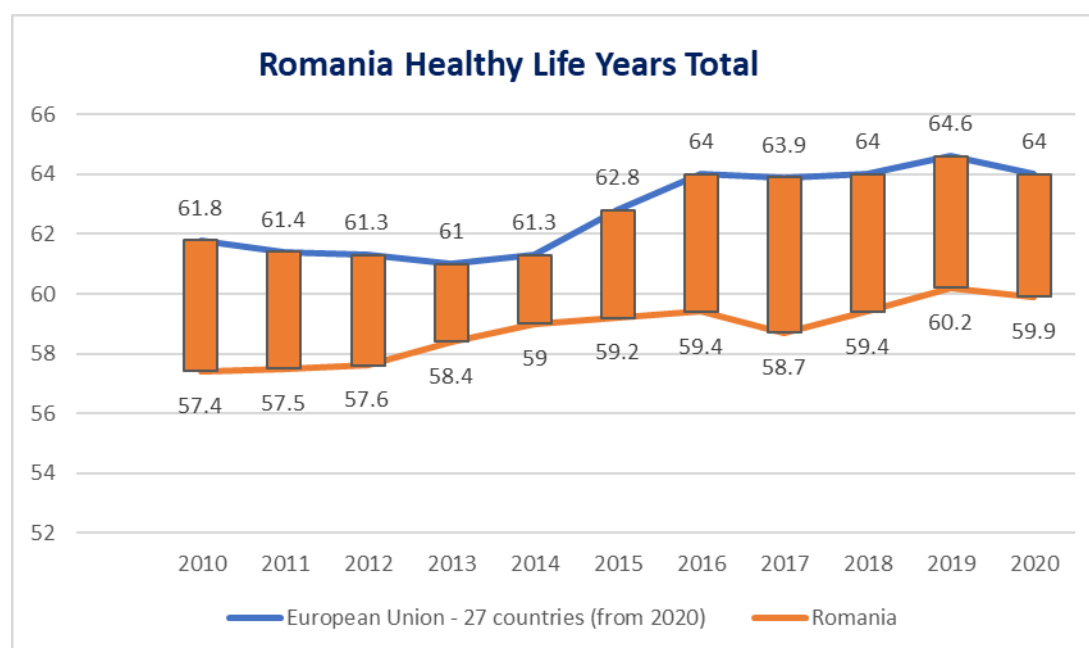


Source: World Bank Health Data

4.3 HEALTHY LIFE YEARS

Figure 11 displays the changes in healthy life years over time in Romania and Europe overall. Healthy life years have increased not only in the EU, but also in Romania, reaching its peak point in both of them in 2019 (Romania:60.2 years, EU: 64.6). The big difference between them is that the increase in Romania was continuous, while the EU was followed by stability from 2010 to 2014. After that time, a slight increase was observed between 2015- 2020 in the EU, at approximately 63 years. In Romania, healthy life years remained stable at 57.5 years and from 2013 to 2016 an increase of 1 year was observed. From 2018 to 2020 a slight increase is observed and healthy life years are about 59.

Figure 11. Total healthy life years in Romania

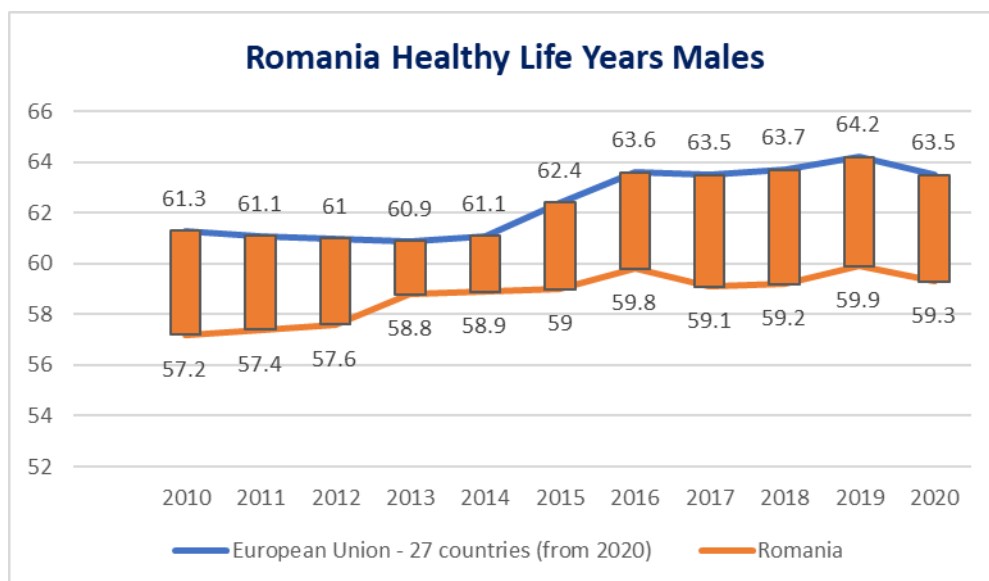


Source: Eurostat Health data

Figure 12 displays the changes happened in male healthy life years in the EU and in Romania. During all period explored, comparisons are always favorable for EU, which has steadily higher healthy life years than those detected in Romania. Divergence between the EU and Romania was exacerbated in 2019 when the gap grew into 4,3 years. Furthermore, from 2016, both slopes tend to increase in parallel, without much convergence or divergence observed. Finally, both Romania increased

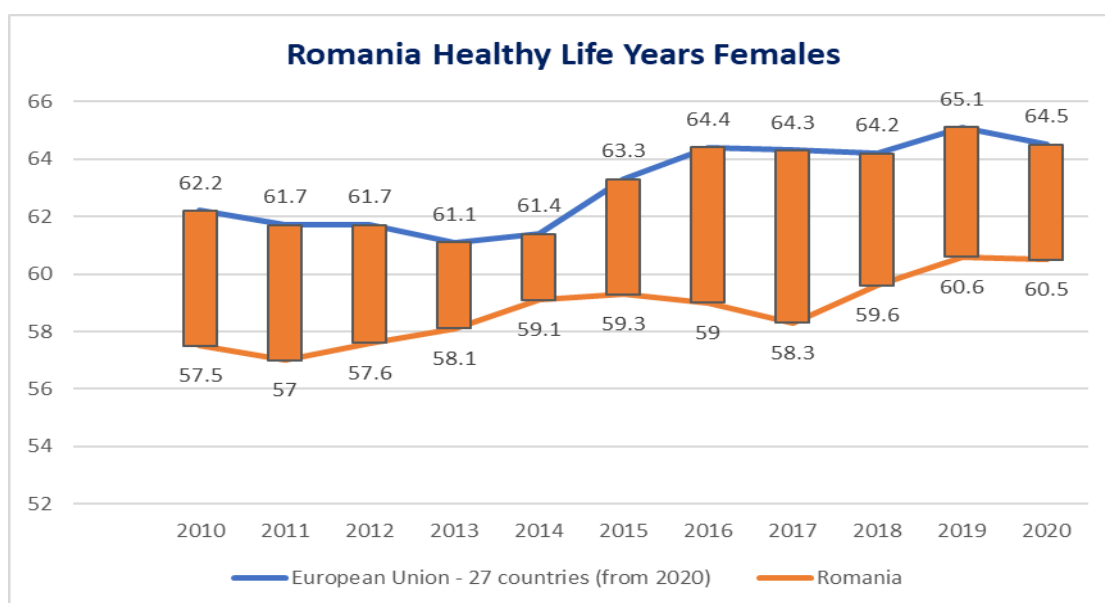
and the European Union increased the healthy life years from 2010 to 2020 (Romania: 57.2 in 2010 and 59.3 in 2020, EU: 61.3 in 2010 and 63.5 in 2020).

Figure 12. Male's healthy life years



Females live longer than men in both Romania and the EU. As presented in figure 13, the healthy life years increased for both the EU and Romania from 2010 to 2020 (EU: 62.2 in 2010 and 64.5 in 2020, Romania: 57.5 in 2010 and 60.5 in 2020). There was a slight increase from 2010 to 2012 in Romania and later from 2016 to 2020, reaching its peak point in 2019 (60.6). In the EU, a stable increase is observed from 2014 to 2020 and one year later, healthy female life years slightly decreased by 0.1.

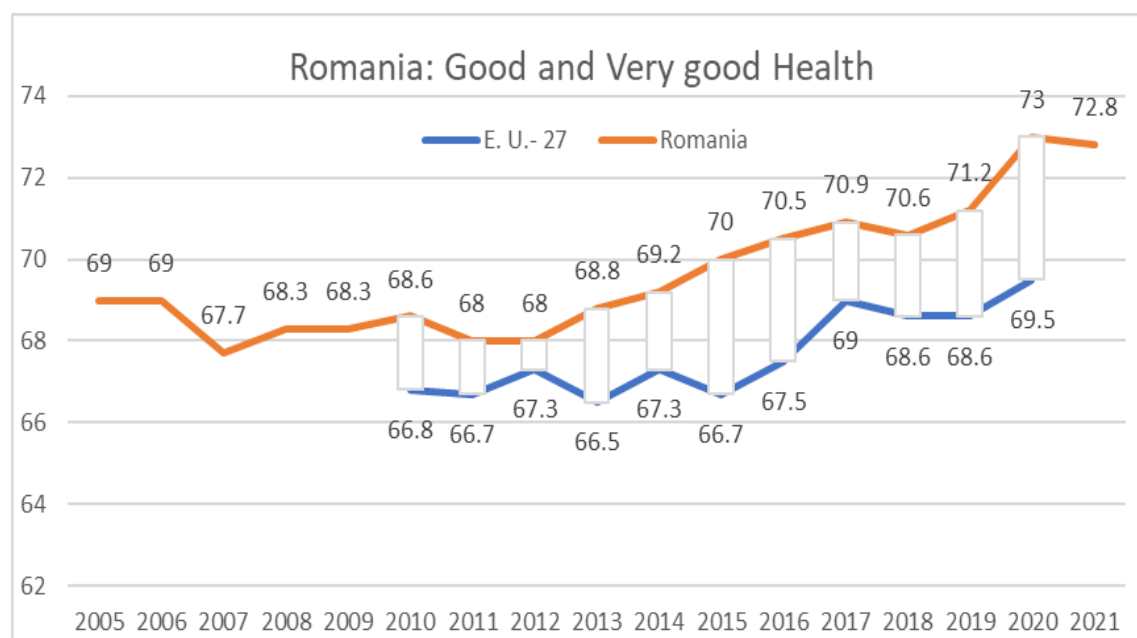
Figure 13. Female's healthy life years



4.4 Good and Very Good Health

Average share of population reporting good and very good perceived health in EU-27 has increased from 66.8 in 2010 to 69.5 in 2020. In Romania, it has also increased in a decade from 68.6 in 2010 to 73 in 2020 and the gap between Romania and the EU has also increased from 1.8 to 3.5 in the same decade. However, it should be noted that Romanians report better health overall throughout all the examined period than the EU-27. (Figure 14)

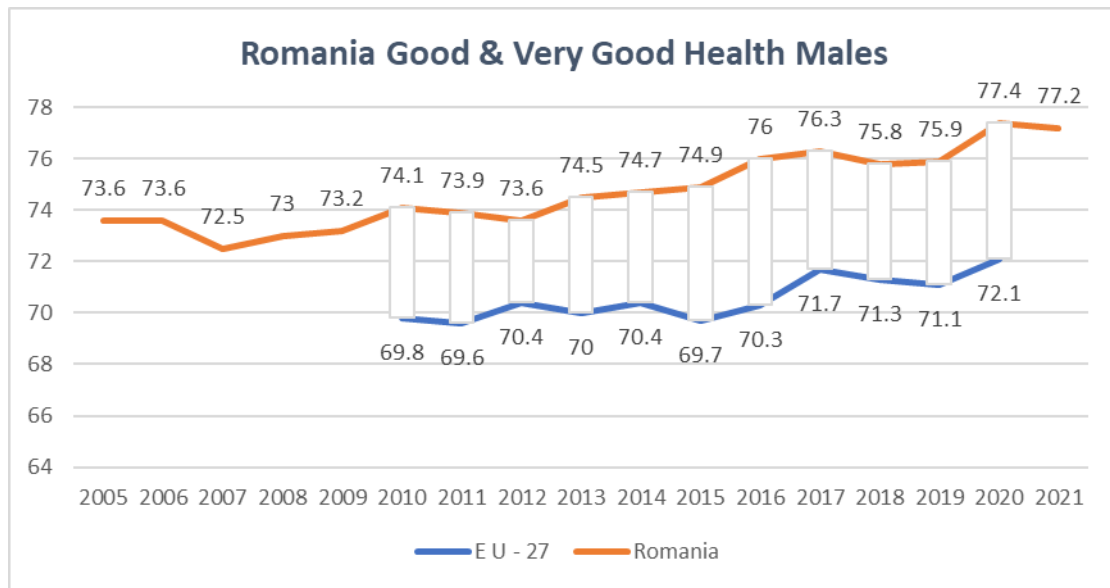
Figure 14. Good and very good health in Romania



Source: Eurostat Health data

Average share of males with good and very good perceived health in EU-27 has increased from 69.8 in 2010 to 72.1 in 2020, while in Romania an increase of approximately 3 years is observed. Due to several changes, the gap between share of males in good and very good health as for EU-27 and Romania has increased since 2010 (4.3 years) to 2020 (5.3 years). (Figure 15)

Figure 15. Males reporting good and very good health

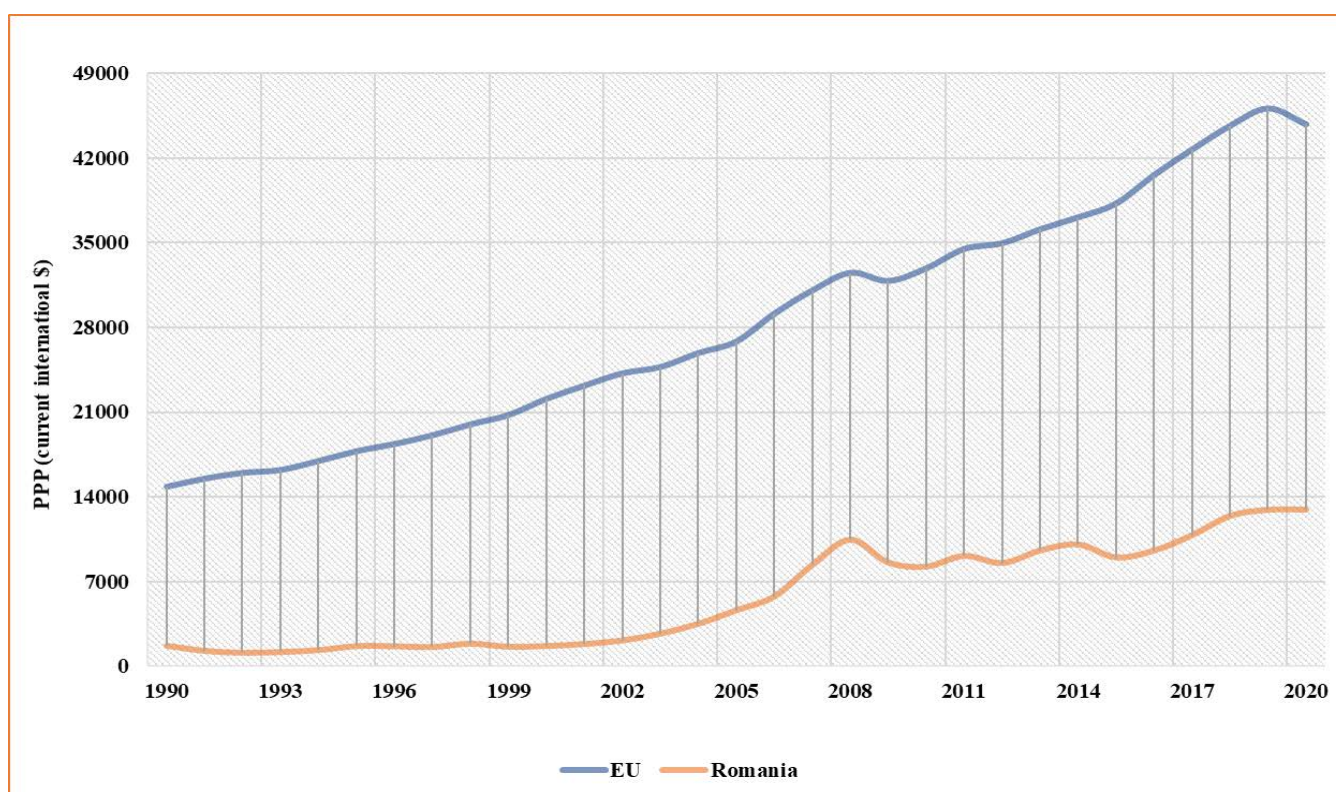


Source: Eurostat Health data

5. GDP per Capita

Figure 16 shows the changes of GDP per capita in the EU and in Romania between 1990 and 2020. During all the period examined, GDP per capita in the EU (14811.7 \$) was significantly higher as that one in Romania (1680.7 \$). The existing gap was as high as 13130,95 \$ in 1990 and it increased at 33170.4 \$ by 2019. Overall, a steady increase of the gap is shown overtime. Finally, the outbreak of the Covid-19 pandemic led to a slight increase of 15.9 \$ in Romania, while EU faced a decrease of 1306.6 \$.

Figure 16. GDP per Capita



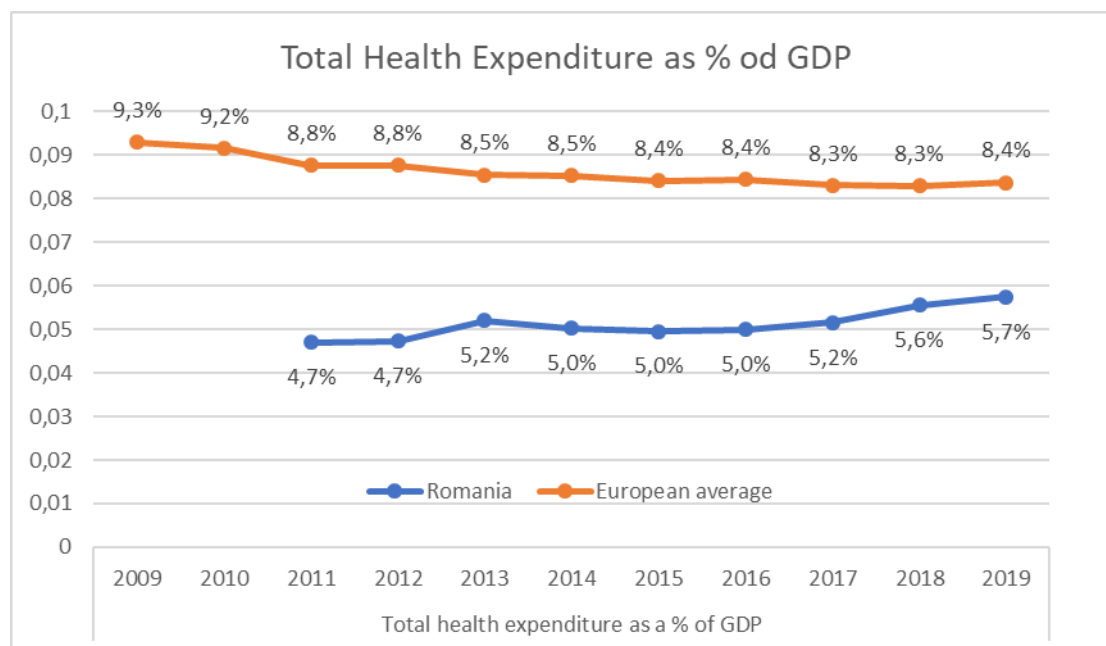
Source: World Bank Health Data

6. Health expenditure in Romania

6.1 Total Health Expenditure as % of GDP

As described on Figure 17, total health expenditure is significantly higher in Europe than in Romania during all the examined period. The gap between them decreased from 4.1% in 2011 to 2.6% in 2019. From 2011 to 2019 the European health expenditure as percentage remains somewhat stable at 8% and later is decreased from 9.3% in 2009 to 8,4% in a decade. As shown in Figure 6, Romania remained stable at approximately 5% reporting a slight increase among the years. From 2013 to 2019, there was an increase in Romania from 5.2% to 5.7%. The gap between Europe average and Romania ranged from 2.6% to 4.1%, having a convergent trend in the last years.

Figure 17. Total health expenditure as % of GDP

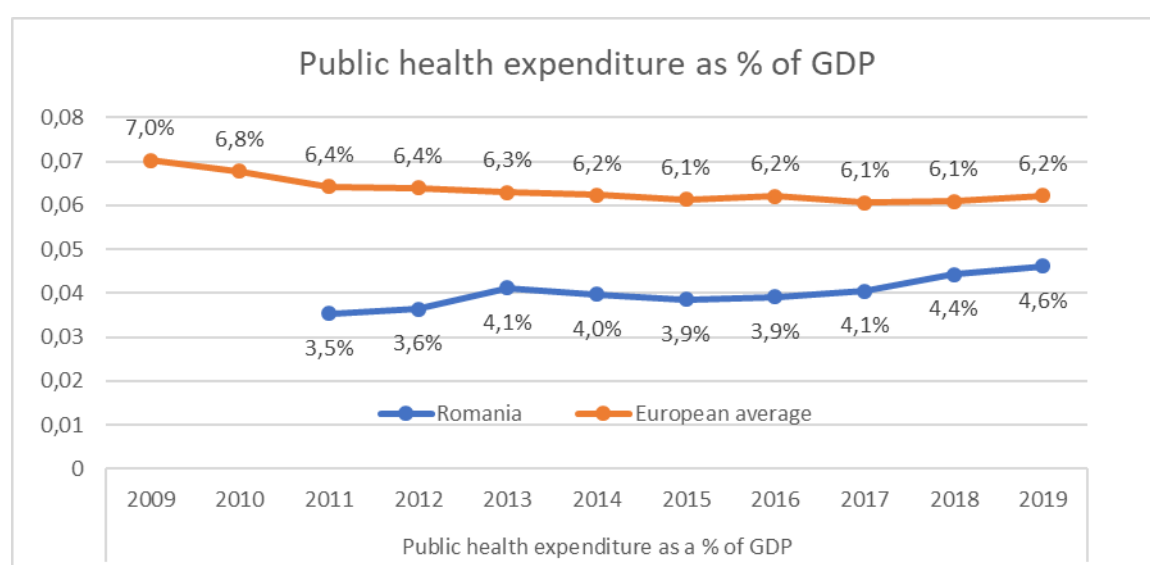


Source: Eurostat Health data

6.1.1 Public Health Expenditure as % of GDP

Public health spending as % of GDP in Romania presented a different trend in relation to the Romanian public health expenditure, observing a convergent trend from 2009 onwards. Public health expenditure decreased in Europe from 7% to 6.2%, whereas it increased from 3.5% to 4.6%, reducing the differences between Romania and Europe average.

Figure 18. Public Health expenditure as % of GDP

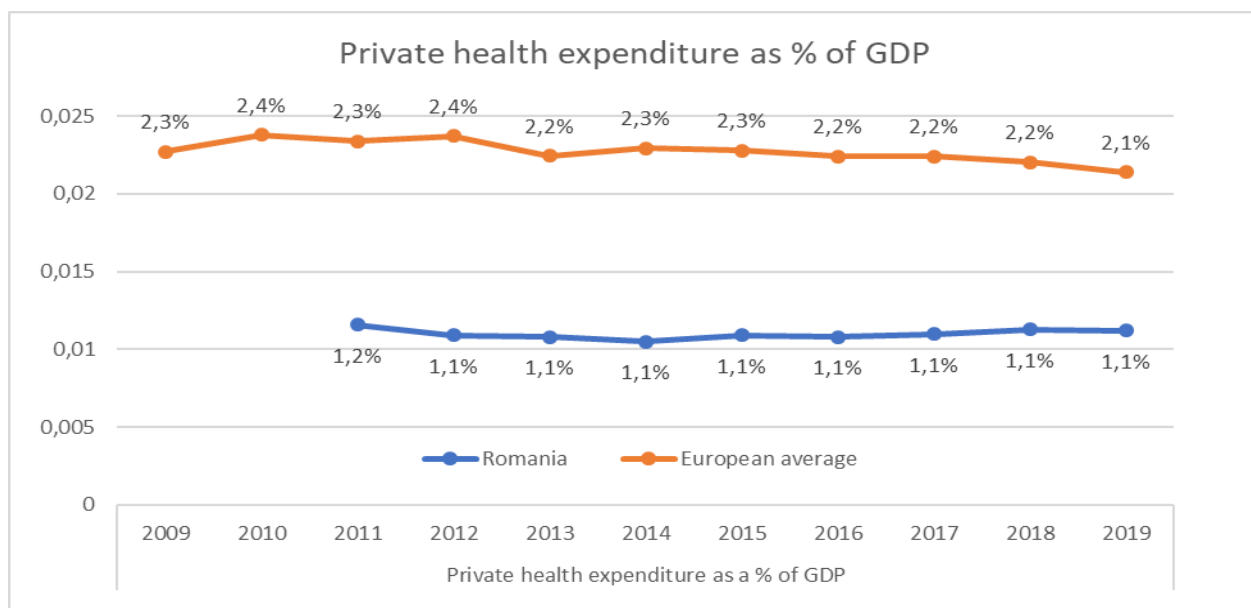


Source: Eurostat Health data

6.1.2 Private Health Expenditure as % of GDP

Private health spending decreased in Europe from 2.3% in 2011 to 2.1% in 2019 while Romania also registered a slight decrease of 0.04% in public health expenditure. As shown in figure 19, Europe increased its public health expenditure (% of GDP) from 2.3% to 2.4% (total increase of 0.1%) between 2009-2010 and 2011-2012, but Romania recorded very small variations compared to 1.1%, still remaining lower than the EU average. On the other hand, in Europe from 2009 onward, public health expenditure registered a slight decrease however remained above the average. Overall, especially in period 2009-2012, the gap between EU and Romania expanded at its most.

Figure 19. Private health expenditure as % of GDP

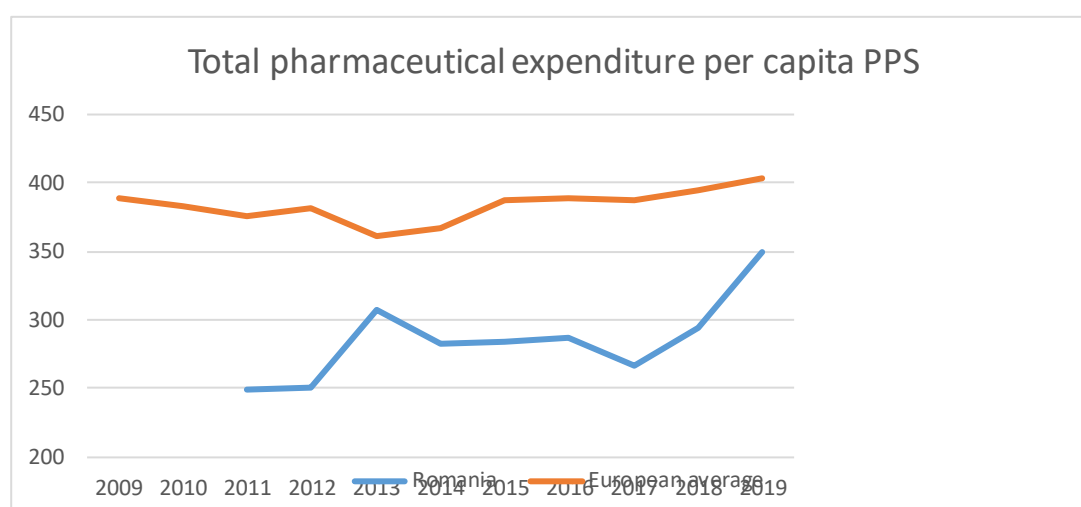


Source: Eurostat Health data

6.3 Pharmaceutical expenditure

Figure 20 display the total pharmaceutical expenditure per capita PPs in Romania and in Europe overall. The European average remains somewhat steady at approximately 400, reaching its highest point in 2019 (402) and its lowest in 2013 (361). On the other hand, Romania has a slight increase in 2013 reaching 306 and then it is followed by stability for the next 5 years until 2019 were it reaches its highest point 349.

Figure 20. Total pharmaceutical expenditure per capita PPS

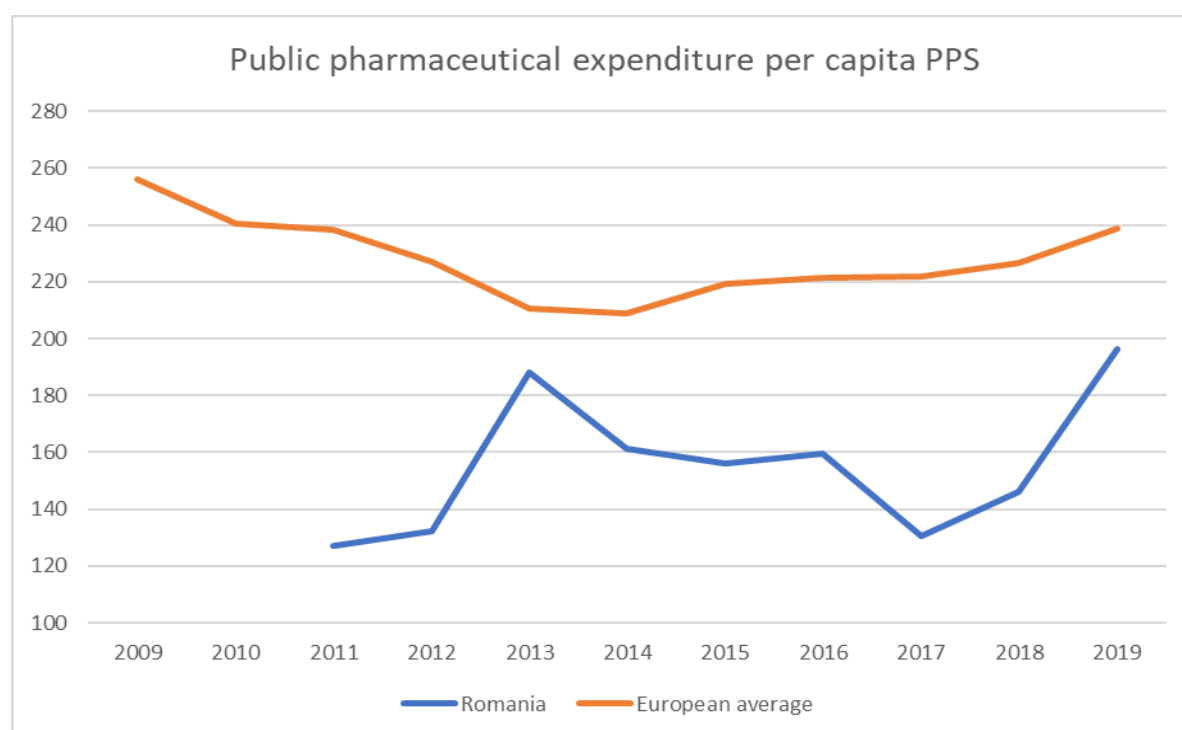


Source: Eurostat Health data

6.3.1 Public Pharmaceutical expenditure

As shown in figure 21, Public pharmaceutical expenditure is higher in the EU than in Romania. In particular, the gap reached its highest point in 2017 (130 in Romania, 221 in the EU). From 2014 to 2016, both slopes tend to increase in parallel, without significant convergent or divergence observed. On the other hand, Romania decreased from 159 in 2016 to 130 in 2017 and then again increased rapidly to 196 in 2019. The EU average remained somewhat steady at approximately 230-260.

Figure 21. Public pharmaceutical expenditure per capita PPS

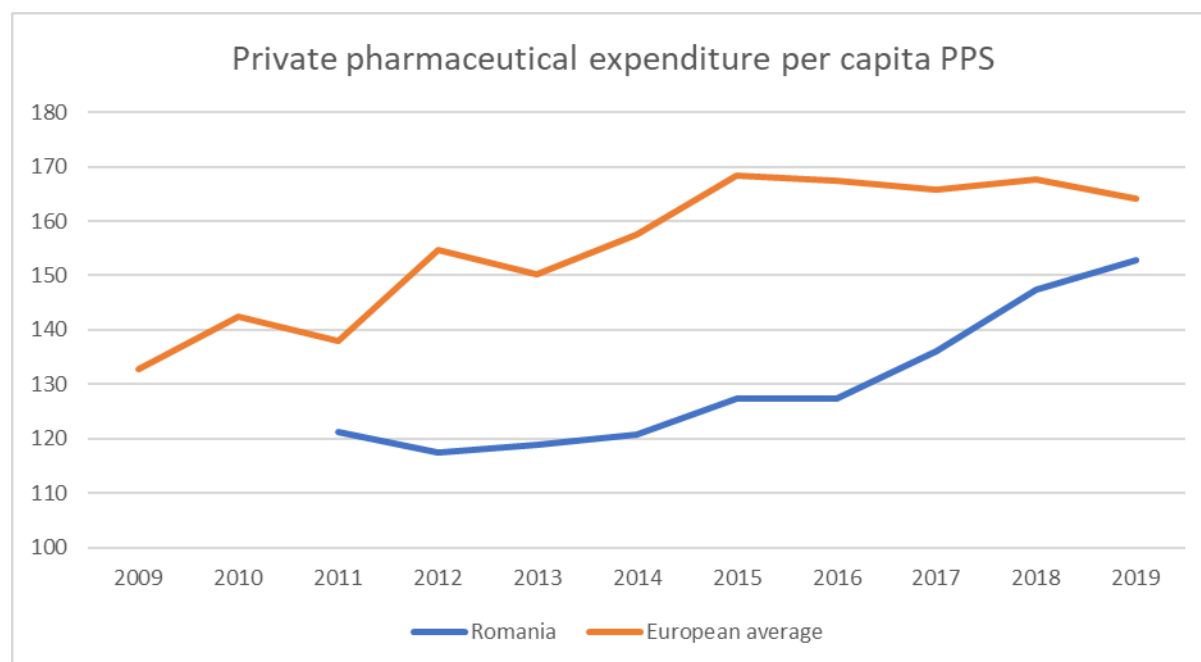


Source: Eurostat Health data

6.3.2 Private Pharmaceutical expenditure

Private pharmaceutical expenditure per capita PPs showed an increasing tendency from 2015 to 2019 in Romania and from 2013 to 2015 in the EU. During all period examined, private expenditure appears higher in the European Union reaching its highest point in 2015 (168). On the other hand, Romania has a slight increase in 2015 reaching 127 which is then followed by a decrease. From 2017 to 2019, Romania reached its highest point which is approximately 152.

Figure 22. Private pharmaceutical expenditure per capita PPS



Source: Eurostat Health data

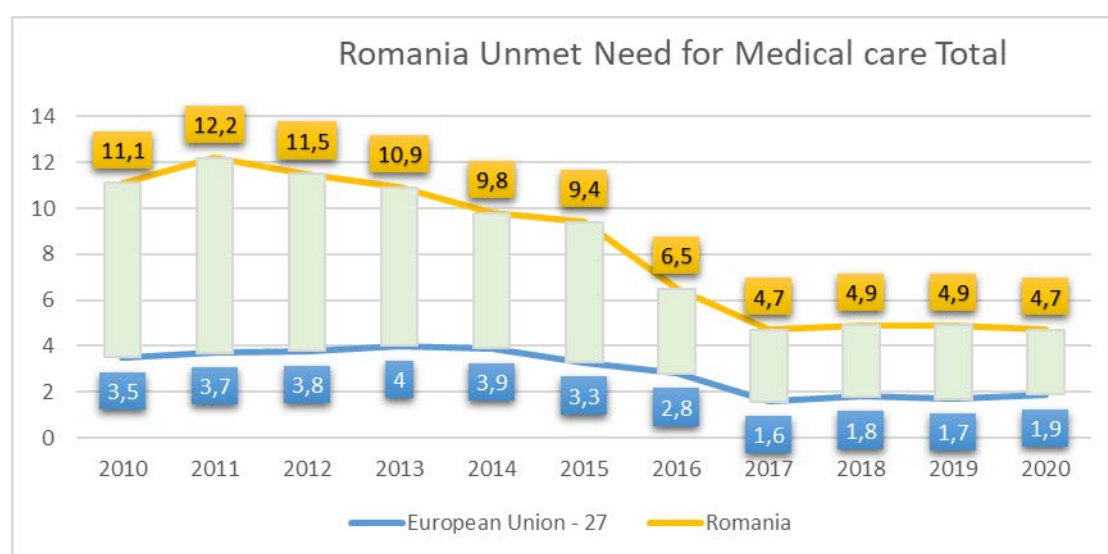
7. Health Unmet Needs for Medical care in Romania

7.1 Total of the unmet needs for medical care in Romania

The Eurostat collects data on unmet needs for medical care across the EU-27 Member States. Medical care refers to individual healthcare services (medical examination or treatment excluding dental care) provided by or under direct supervision of medical doctors or equivalent professions according to national healthcare systems. Data are collected from the European Statistics of Income and Living Condition survey and refer to such needs during the previous 12 months. Data are expressed as percentages within the population aged 16 years old and over living in private households. According to Eurostat guidelines self-reported data are collected from the European Statistics of Income and Living Condition (EU-SILC) survey and refer to such needs during the previous 12 months [9]. Data are expressed as percentages within the population aged 16 years old and over living in private households. Figure 23 presents the unmet needs for medical care in Romania.

People from EU countries reported in median 2.8 times less unmet needs than Romania. The gap between Europe Union countries and Romania was higher till 2017, when they tended to remain constant in parallel. Analyzing the period 2010-2020, the maximum unmet need for medical care was declared in 2013 for European Union countries (4%), respectively in 2011 for Romania (12.2%). At the same time, the minimum unmet need for medical care was declared both in 2017 for European Union countries (1.6%), and for Romania 4.7%), respectively.

Figure 23. Total Unmet needs for medical care



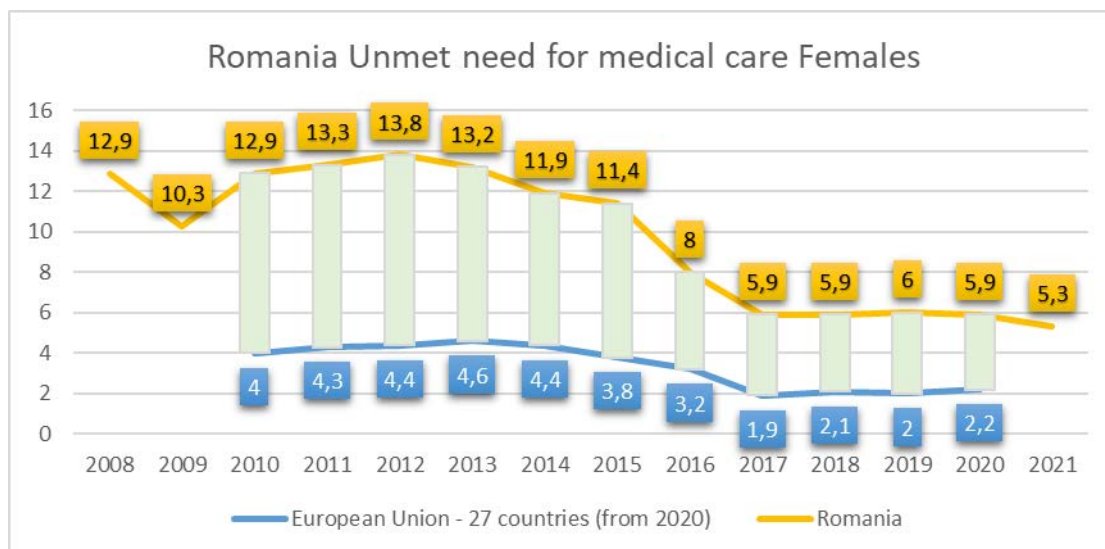
Source: Eurostat Health data

7.1.1 Unmet needs for medical care for females

Over the eleven years compared, the highest unmet need for medical care for females was found in 2013 (4.6%) for EU countries and in 2012 (13.8%) in Romania. The unmet needs for medical care were in median 3 times higher for Romanian females than for EU females, with the smallest difference in 2016 (2.5 times) and highest in 2010 (3.2 times). We observed a reduction of 45% from 2010 to 2020 in UE and of 54% in Romania. In UE countries, the decreasing was continuously till 2017 when it stopped, remaining constant as 2% for the overcomes years. In Romania, after becoming EU member in 2007, we observed a reduction of 20% till 2009, when the unmet needs for medical care for females started to increase till 2012

and after that to constantly decrease till 2021. From 2017 to 2020, both females from EU and Romania reported a constant level of 2%, respectively 6%.

Figure 24. Females' Unmet needs for medical care

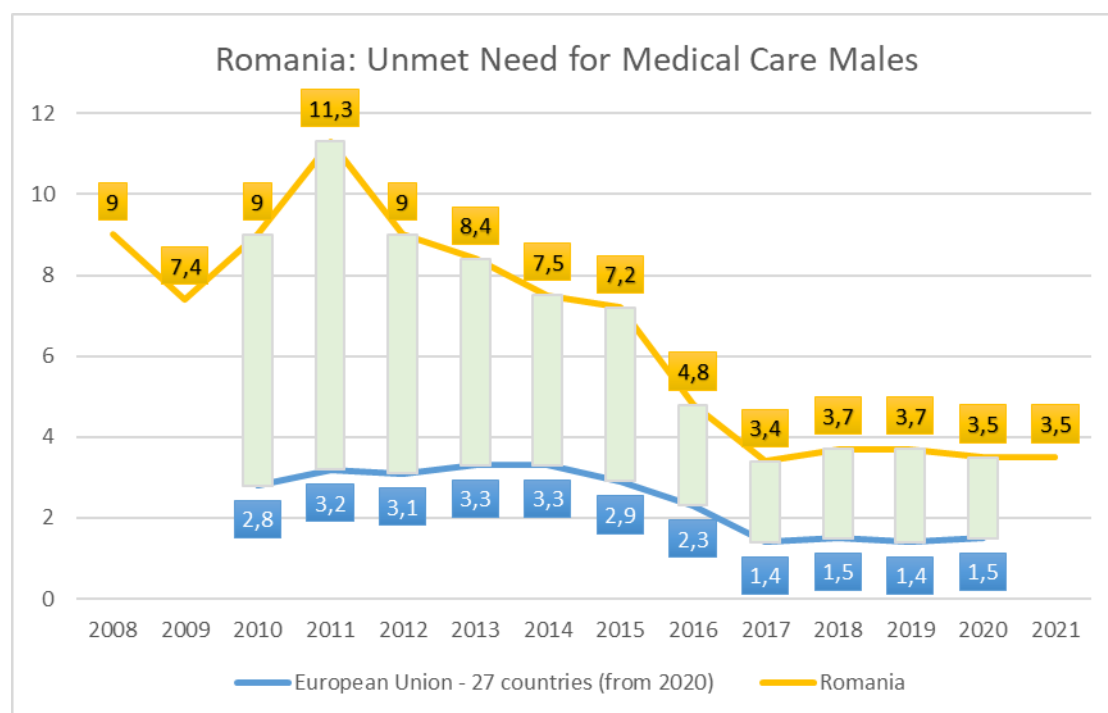


Source: Eurostat Health data

7.1.2 Unmet needs for medical care for males

During all examined period, the highest unmet need for medical care for males was found in 2013-2014 (3.3%) for EU countries and in 2011 (11.3%) in Romania. Analyzing the distribution of data on needs for medical care males, the trend is declining till 2017 for both EU countries and Romanian males, when they declared a convergent, almost parallel evolution.

Figure 25. Males unmet need for medical care



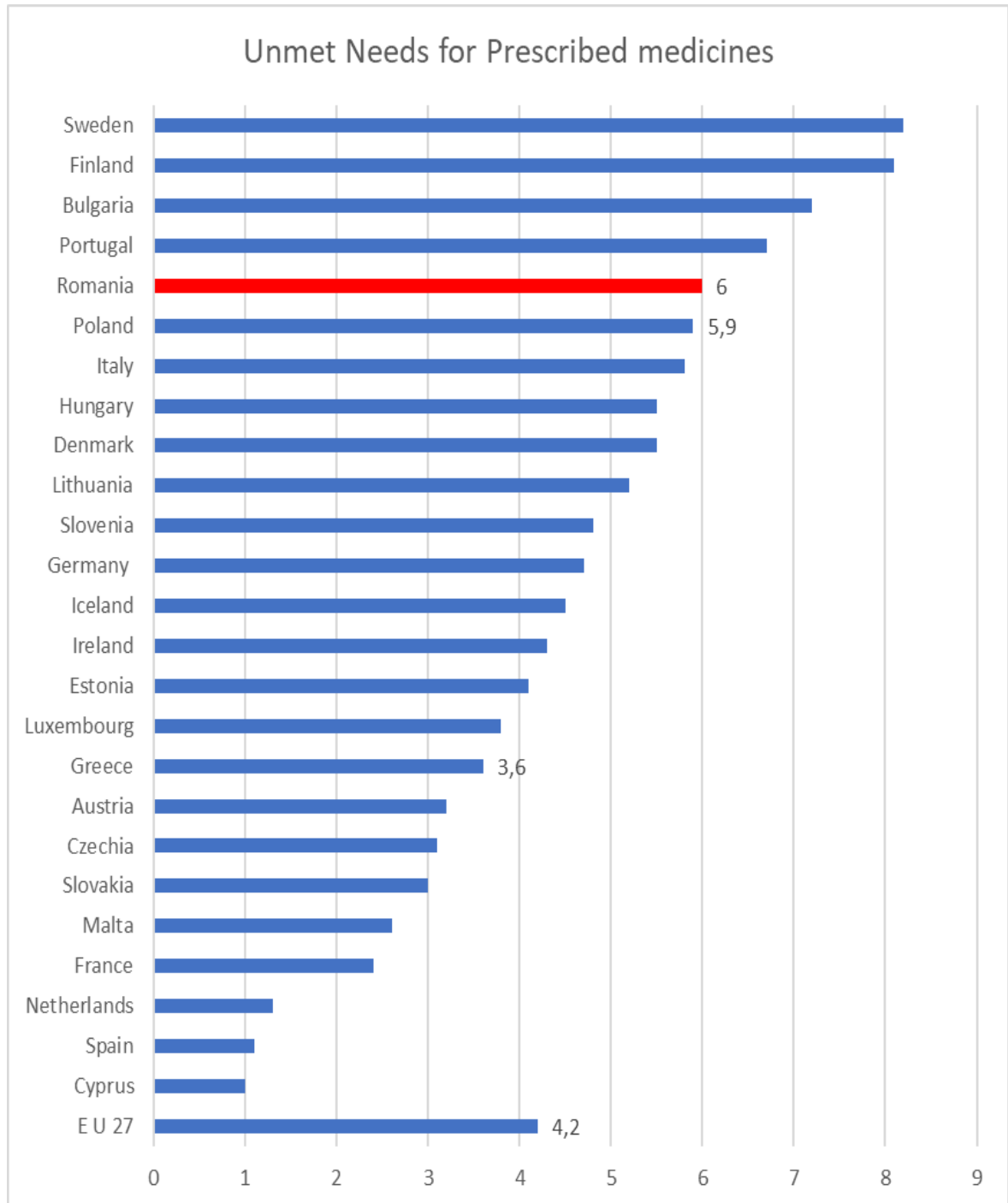
Source: Eurostat Health data

7.3 Unmet Needs for Prescribed Medicines

Unmet needs for prescribed medicines in 2019 were defined as 6%, perhaps due to financial reason or to medicines missing in community pharmacies from Romania. Some medicines were missed because of the parallel trends. In 2018, Romania, Poland and Slovakia have been investigated by the European Commission for restrictions placed on the parallel trade in medicines. However, no sanction has been applied and the current document showed that the EC is aware that the parallel export of medicines can affect patients' access to treatment. Parallel imports and exports of medicines represent a legal form of trade within the single market. However, Member States may, in certain cases, restrict parallel trade, as long as the measures they take are justified, reasonable and proportionate to guarantee a legitimate public interest. For example, it could be about measures aimed at ensuring an adequate and continuous supply of medicines to the population. The fact that pharmacies are not properly and permanently supplied with medicines for human use is a serious and growing problem which, in recent years, has affected several Member States and which has a significant negative impact on patients [10,11]. The EC

recognizes that one of the reasons that led to the emergence of the shortage of supply of certain medicines for human use could be exactly parallel trade.

Figure 26. Unmet needs for prescribed medicines



Source: Eurostat Health data

8. The Romanian pharmaceutical policies

National Strategy for Health 2014-2020 configured public health objectives, including national pharmaceutical policies for ensuring all patients equitable access to medicines, with emphasis on preventive services and interventions. The health reform law no. 95/2006 was amended more than 50 times till now, mainly through secondary legislation, ad hoc, that limited reaching consensus that is necessary to ensure the successful implementation of health reforms [5].

Furthermore, technical assistance has been provided under a project financed by World Bank for setting up a transparent frame for using HTA in policy decision-making. Particular emphasis was being placed on designing an effective institutional framework, developing and applying rigorous HTA methodologies, and establishing robust governance standards and operating procedures that enable the effective application of HTA to support evidence-informed policy decision-making across the healthcare sector. This project intended to propose comprehensive methods according to Romanian specificity and guide the design and implementation of appropriate and effective governance arrangements and operating procedures for a redesigned HTA process for medicines and, also, for vaccines. This project outcomes (four models of Romanian HTA process) were not implemented yet, one of the reasons could be the high number of the ministers at the MoH in the last years [8].

The implementation of the National Strategy for health 2014-2020 was evaluated and the lowest performance scores was obtained for OG 7 “Infrastructure in health” and OG 6 “E-health”, followed by OG 4 “Access on services”, OG 3 “Policies regarding the non-communicable disease” [8].

National Strategy for Health 2022-2030 is in the public consultation and the National Agency for the Evaluation of Health Technologies and Services will be established, as a public institution under the coordination of the Ministry of Health, financed from its own revenues, with attributions in the evaluation process of health technologies, the foundation, establishing and monitoring the rates of health services financed from public funds and support in the realization/adaptation in the local context of clinical management tools (e.g. guidelines, protocols, clinical algorithms) [8].

Some important strategies are related to the development of patient registries. If there is a willingness for patients' drugs availability, real-world data must not be lacking, and the national plans must stimulate the creation of registries as scientific real-world data.

Population screening is underdeveloped, the predominant mode of provided being the opportunistic one. The only active screening program financed from the budget of the Ministry of Health is the one for cervical cancer, but it has unsatisfied results. Currently, a series of regional screening programs co-financed by EU funds are underway, organized according to international good practices in the field, which will constitute models for the reform, diversification and expansion at national level of population screening (breast cancer, cervical cancer, colon cancer, viral hepatitis B and C, cardiovascular disease). A systematic literature review of rare disease policies in some EU countries and Romania was performed, focusing on orphan drug reimbursement systems, newborn screening, patient registries, legislation, guidelines and the access to orphan medicinal products. Despite the lack of homogeneity between newborn screening, the number of screened disorders was the main differences: if Romania had only 2 newborn screening disorders for phenylketonuria and congenital hypothyroidism, Poland screened for 28 rare diseases or The Netherland for 20 rare diseases [12, 13].

The problem of avoidable mortality is even more urgent, as the demographic profile of the Romanian population is unfavorable, and that of morbidity is mixed, marked by the coexistence of non-communicable and communicable diseases. A special attention was given to cancer, cardiovascular diseases, and tuberculosis. In order to evaluate these diseases control strategies, it is essential to trace their incidence, prevalence and mortality, but also to comprehend treatment outcomes [14]. For example, in 2018, in Dolj county (with more than 50% of the tuberculosis cases from Romania), the prevalence of tuberculosis was 1.01% and the treatment outcomes were: 22.6% cured, 78.9% completed treatment, 0.4% died, 0.7% failed and 2.6% interrupted, which is a good indicator compared with the 85% World Health Organization target of tuberculosis treatment success [15].

OG 5 "The control of infectious diseases", respectively the control of tuberculosis, had reduced performance, and the new National Strategy for health

propose reducing the infectious diseases burden as tuberculosis, HIV/AIDS, and viral hepatitis [16].

8.1 Drug turnover and pricing

The system of External Reference Pricing (ERP), known also as International Reference Pricing, was introduced in Romania in 2009 for the first time. After establishing the price for a prescription drug with marketing authorization, it is published on a public catalog named CaNaMed (the National Catalogue of Medicines prices) that includes the maximum prices of medicinal products for human use, and it is updated by the Medicine and Medical Devices Policy Department – Ministry of Health [17].

A numerous number of Ministry of Health Orders regarding the norms for drugs prices were approved over the time, the last one was published in 2021 [18]. According to this legislation, the basket used for ERP consists in 12 EU countries (Austria, Belgium, Bulgaria, Czech Republic, Germany, Greece, Hungary, Italy, Lithuania, Poland, Slovakia, and Spain). The Marketing Authorization Holder (MAH) of the medicine will submit a dossier proposing as price for its medicine equal to the lowest price from these basket countries. If, following the comparative checks, it is found that the medicine has no price registered in the basket countries, the proposed price is approved, which, in the case of generic/biosimilar medicines, cannot exceed the generic/biosimilar reference price. In the situation where the producer price in the basket countries is registered for another form of packaging, the form of packaging closest to the one requested for price approval in Romania will be taken into consideration [19].

Special rules were approved for the first generic or biosimilar drug: the maximum price is 65% of the existing innovative drug, respectively, 80% of the existing innovative biologic drug. The generic/biosimilar/innovative reference prices in RON are updated annually in February, by applying the average RON/EURO exchange rate of the National Bank of Romania, related to the third quarter of the previous year in which the update is carried out [20].

These prescription drugs can be released/sold exclusively by community pharmacies, local distribution offices or hospital pharmacies.

Table 1. Type of prices for medicines

Type of price	Method	Comments
CaNaMed price (Producer price)	ERP based on 12 EU countries	Minimum price from the 12 EU countries
Wholesaler price [21]	Maximal margins are applied from Producer price	14% for Producer price \leq RON 50
		12% for Producer price $>$ RON 50 and \leq RON 100
		10% for Producer price $>$ RON 100 and \leq RON 300
		RON 30 for Producer price $>$ RON 300
Pharmacy price [21]	Maximal margins are applied from Wholesaler price	24% for Wholesaler price \leq RON 25
		20% for Wholesaler price $>$ RON 25 and \leq RON 50
		16% for Wholesaler price $>$ RON 50 and \leq RON 100
		12% for Wholesaler price $>$ RON 100 and \leq RON 300
		RON 35 for Wholesaler price $>$ RON 300
Reference price	Cluster model	For the medicines from A, B and D lists, it is calculated at ATC 3 level classification, and it is equal with the first quartile For the medicines from C list, it is calculated at ATC 5 level classification, and it is the minimum price of the same INN
Reimbursed price paid by NHIH	Four lists with different percentage of reimbursement	A list (90% from the reference price) B list (50% from the reference price) C list (100% from the reference price) D list (20% from the reference price)
Net price	Claw-back	It is a inconstant quarterly adjusted percentage calculated as the report between the over-expenditures above the threshold (quarterly approved budget for drugs) and the total expenditures

ERP, External Reference Pricing. NHIH, National Health Insurance House.

8.2 Drug reimbursement

Starting with 2015, the list with reimbursed drugs is updated at list one time/year, according with the budgetary policies of the Government and with the national priorities established by Ministry of Health. At this moment, Romania has four lists with reimbursed medicines, every list with a different percentage of reimbursement: A list (90% of the reference price), B list (50% of the reference price), C list (100% of the reference price) and D list (20% of the reference price).

The reference price is not the same with the medicine price. It is computed according with the MoH Order no. 1030/2021, using the methodology as follows:

- For the drugs included in lists A, B, or D: a cluster models that groups the drugs from the same therapeutic area, at first quartile (25%)
- For the drugs included in list C, sublists C1, C2, and C3: the reference price is the minimum price of the group of drugs with the same International Nonproprietary Name (INN) and the same concentration.

Depending on the sublist the medicine is included, the co-payment for drugs could be 0 RON or higher. Even for a drug included in C list (100% of the reference price), the patient can have a co-payment because the patient pays the difference between the medicine price and the medicine reference price. The highest co-payment is in the case of a medicine from D list because the patient pays 80% of the medicine reference price plus the difference between the medicine price and the medicine reference price.

It does not exist any co-payment of the medicines dispensed in hospitals.

8.3 The claw-back taxation on medicines

Being a tool to hold drug prices under control, the claw-back (payback) taxation on drugs was first entered in 2009 in Romania [22]. This tax was introduced as an emergency legislative intervention, considering the high consumption of medicines that led to exceeding the health budget allocated in 2009, to ensure uninterrupted access of the population to medicines with and without personal contribution granted in outpatients, within the national health programs, as well as in health units with beds. The quarterly contribution is paid by MAHs and was first ranged between 5% and 11% from the total sales, as in the below table.

Table 2 Claw-back taxation

Quarterly Sales of MAHs (thousands RON)	Claw-back taxation in 2009
> 75,000	11%
50,001 – 75,000	10%
25,001 – 50,000	9%
12,501 – 25,000	8%
6,251 – 12,500	7%
1,250 – 6,250	6%
< 1,250	5%

By now, there were several changes in the claw-back legislations, three more MoH orders were approved:

- Ministry of Health Order no. 928/591/June 2010 regarding the update of the reform in healthcare domain Law no. 95/2006, published in Romanian Official Gazette no. 429/2010

This MoH order clarified the definition and utility of the claw-back tax:

- The quarterly sales consist in the volume of sales within a quarter, meaning the entire number of medicines from the national health programs, of medicines that benefit the insured in ambulatory treatment, with or without personal contribution, on the basis of medical prescription, and of medicines that benefit the insured in hospital treatment, sold in the system of social health insurance to

providers of medicines in outpatient treatment and to health units with beds.

- Total quarterly revenues obtained represent the value resulting from the commercialization of the entire quantity of medicines included in the national health programs, of medicines that the insured patients benefit from in outpatient treatment, with or without personal contribution, based on medical prescription, in the social health insurance system, and of medicines that the insured benefit from in hospital treatment, collected by MAHs within a quarter, after deduction of VAT.
- The revenues realized as a result of the application of the contribution of claw-back is owed and collected quarterly and constitutes the Ministry of Health's own income, which is used for:
 - investments in infrastructure and equipment in the public health system;
 - financing of national health programs;
 - reserve of the Ministry of Health for special situations;
 - other destinations.

- Ministry of Health Order no. 351/464/April 2011 regarding the update of the reform in healthcare domain Law no. 95/2006, published in Romanian Official Gazette no. 295/2011 and NHIH Order no. 212/April 2015 regarding the methodology of reporting the medicines included in the claw-back.

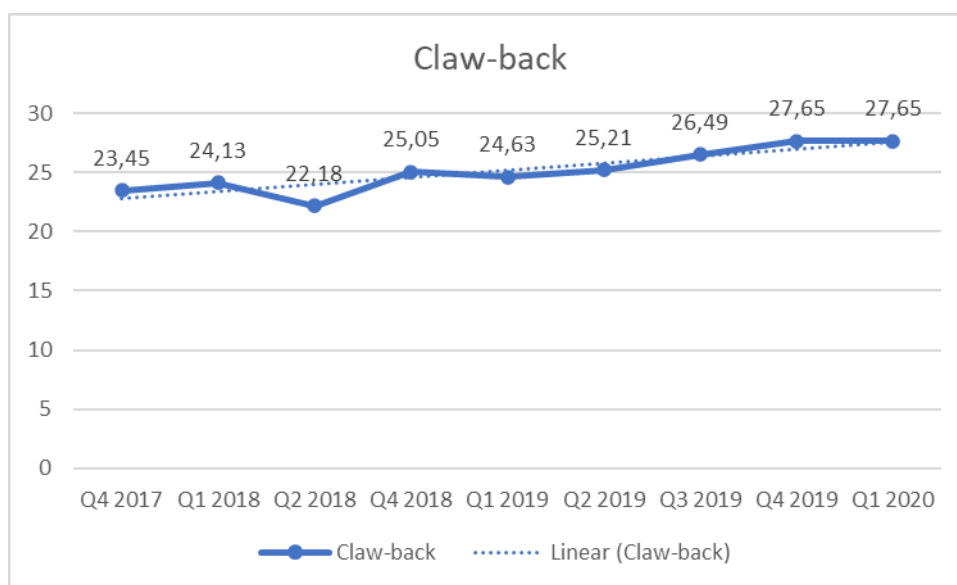
This MoH and NHIH orders consist in the payment methodology of claw-back (examples of documents).

The claw-back is computed without including vaccines and the drugs from cost-volume/cost-volume-outcome agreements.

Also, from 2011, MAHs must cover through claw-back all NHIH medicines expenditures over the threshold of RON 1515 billion (around €303 billions) and this new formula changed the fixed percentage to a variable percentage. According to NHIH, the claw-back in the last quarter of 2017 reached the level of 23.45%. Starting with the first quarter of 2019, this threshold was increased from RON 1515 billion to RON 1595 billion, which had the effect of increasing the claw-back to approx. 27%,

as in the Figure 27. The claw-back tax in first quarter of 2020 was maintain the same as in the last quarter of 2019, through Emergency Government Ordinance no. 31/March 26, 2020, even if it was calculated at the value of 33.86% [23].

Figure 27. Claw-back values (<https://cnas.ro/clawback/>)



Even it was seen with advantages from the financial perspective, the claw-back tax has also negative effects on drugs availability, with simulation of over-prescription or lack of drugs on the pharmaceutical market [24]. A lot of voices ask the elimination of the claw-back tax in the case of generics [25].

8.4 The role of Health Technology Assessment

EU countries pharmaceutical policies differ considerably, even if the resources are limited in healthcare for all EU countries and it is essential to determine the priority to be assigned to a drug, a device, or a service a patient need. There is no perfect step in the right direction, but Romania must consider 3 principles that should guide any decision-making process and subsequent framework: transparency, predictability, and clarity [26]. One of the big challenges is establishing a formal or

informal rule for the cost-effectiveness threshold (CET). From the World Bank data, Romania appears to have had in 2021 a GDP (Gross Domestic Product) per capita of \$14,861.9 and is having one the fastest economic growth of the countries in EU. Taking into account the formal or informal rules for the neighboring countries around Romania for their CET, a value of 3 x GDP/capita can be considered a reasonable limit for Romanian CET [27].

A real first step toward HTA harmonization between Romania and EU member states was done in 2014 (Order of Ministry of Health no. 861/2014) when it was approved the criteria and methodology of evaluation of medical technologies, of the documentation to be submitted by applicants, the methodological tools used in the evaluation process on inclusion, extension of indications, non-inclusion or exclusion of medicines in/from the List containing the corresponding international common names medicines covered by the insured, with or without a personal contribution, on the basis of a medical prescription, in the social health insurance system. The order has undergone changes over time, the last one, in 2020, provided only an information about the evaluation request.

The actual HTA in Romania is based on a score, without making cost effectiveness and budget impact analysis mandatory for reimbursement of pharmaceuticals, as other UE countries do. There is not an established threshold (CET, cost-effectiveness threshold) for Romania, highest priority could be considered in the case of products with ICER less than CET. The public health priorities from the national healthcare strategy could be underlined taking into account the medical conditions and the national health programs from the C1 and C2 lists.

The HTA process consists in assessing some criteria for which a number of points is admitted:

- Assessment of therapeutical benefit in France: 0 points (BT3 classification), 7 points (BT2 classification) or 15 points (BT1 classification)
- Cost-effectiveness from NICE UK: 0 points (non-approval), 7 points (approval with restrictions) or 15 points (approval without restrictions)
- Cost-effectiveness from IQWiG/G-BA Germany: 0 points (non-approval), 7 points (approval with restrictions) or 15 points (approval without restrictions)

- The drug is reimbursed in other countries from UE or UK: 25 points (minimum 14 countries), 20 points (8-13 countries), 10 points (3-7 countries) or 0 points (less than 3 countries)
- 45 points are admitted if MAH demonstrates one of these activities:
 - o A clinical trial of the drug was started in Romania, on patients with the disease from the dossier
 - o EUnetHTA evaluation for the disease from the dossier
 - o A noninterventional study that was notified at NADMD
- The costs of the therapy: maximum 30 points

Regarding the HTA of orphan drugs, the evaluation of the therapy costs is replaced with evolutionary stage of the disease (maximum 30 points).

The HTA Department from the National Agency of Medicine and Medical Devices (NAMMD) could recommend two types of reimbursement: unconditional inclusion decision (if the score is greater than or equal to 80 points) or conditional inclusion decision (if the score is between 60 and 79 points inclusive), meaning products are only reimbursed if they close a cost-volume/cost-volume-outcome agreement. Special criteria were adopted for orphan drugs because usually orphan drugs (prevalence of the disease is lower than 5 patients/10.000 inhabitants) have higher prices and, also, higher ICERs.

The HTA comparator is an already reimbursed drug in Romania for the same disease and the same type of patients. A product already reimbursed on the basis of cost-volume or cost-volume-outcome contracts can be considered a comparator exclusively by comparing the prices available in CANAMED at the time of submission of the evaluation file. If the comparator is a product reimbursed on the basis of a cost-volume or cost-volume-outcome contract, the drug subject to evaluation will be able to benefit from conditional compensation at most, even if the final score obtained as a result of the evaluation process would allow unconditional inclusion, with its score greater than 80 points.

Table 3. Type of decision after Romanian HTA process

Type of decision	Criteria for issuing the decision
Unconditional	a) obtaining a score greater than or equal to 80 points

inclusion	b) the cost of the combination less than or equal to the sum of the components in the case of fixed combinations whose components are already offset.
Conditional inclusion	a) obtaining a score between 60 and 79 points, in which case the medicine is granted under the social health insurance system only on the basis of the following documents, as appropriate: cost-volume agreement or cost-volume-outcome agreement b) the decision of conditional inclusion is valid for the period of time.
Not inclusion	a) DCIs (other than those in sub-list C) that are intended for hospital treatment b) over-the-counter (OTC) medicines, except for those with a specific indication in a rare serious illness and those given to children up to the age of 18, young people from the age of 18 to the age of 26, if are pupils, including high school graduates, until the beginning of the academic year, but not more than 3 months, apprentices or students and if they do not earn income from work, as well as pregnant women and women c) DCIs that obtain a score of less than 60 points following the health technology assessment process.

The evaluation of the HTA dossiers are done by a small team, but a lot of reimbursement dossiers were evaluated by the HTA department of NAMMD in January 2022, for example: Ramucirumabum (unconditional inclusion), Dapagliflozinum (non-inclusion), Secukinumab (updated therapeutical protocol), Ropeginterferon Alfa-2B (unconditional inclusion), Cabozantinib (conditional inclusion), Carfilzomib (updated therapeutical protocol), Emicizumab (updated therapeutical protocol), Fedratinib (conditional inclusion), Enzalutamida (unconditional inclusion). Nine dossiers were evaluated in February 2022: Atezolizumab (conditional inclusion), Avelumab (conditional inclusion), Olaparib (unconditional inclusion), Baricitinib (conditional inclusion), Canakinumabum (non-inclusion), Apalutamida (unconditional inclusion), Lanadelumab (unconditional inclusion) and Naproxen (move between lists). As compared to the other EU countries, the reimbursed medicines number is almost the same in Romania as in other countries [28-36], but some programs are at the beginning [37-48].

9. References

1. E.C. europa.eu/eurostat
2. Government Decision no. 1028/2014 regarding the approval of National Health Strategy and the Action Plan for the period 2014-2020, Romanian Official Gazette no. 891/08.12.2014.
3. Vladescu C, Scintee SG, Olsavszky V, et al. Romania: health system review. *Health Syst Trans* 2016; 18: 1-170.
4. European Commission. 2021. State of Health in the EU, Romania. [online] Available at: <[http://file:///C:/Users/konst/AppData/Local/Packages/microsoft.windowscommunicationsapps_8wekyb3d8bbwe/LocalState/Files/S0/355/Attachments/74ad9999-en\[643\].pdf](http://file:///C:/Users/konst/AppData/Local/Packages/microsoft.windowscommunicationsapps_8wekyb3d8bbwe/LocalState/Files/S0/355/Attachments/74ad9999-en[643].pdf)> [Accessed 7 July 2022].
5. The Law no. 95/2006 regarding the reform in healthcare domain
6. Ministry of Health Order No. 2642/578/2022 for the modification and completion of the Methodological Norms of application in 2021 of Government Decision no. 696/2021 for the approval of service packages and a The framework contract that regulates the conditions for the provision of medical assistance, a medicines and medical devices within the social insurance system of health for the years 2021 - 2022, approved by the Order of the Minister of Health and the president of the National Health Insurance House no. 1.068/627/2021
7. INSP-CNSISP, National Public Health Institute-National Center of Statistics and Informatics in Public Health
8. Public consultation on the next national health strategy on Ministry of Health site https://www.ms.ro/wp-content/uploads/2022/04/SNS_consultare-public%C4%83.pdf
9. Eurostat data
<https://ec.europa.eu/eurostat/databrowser/view/tespm110/default/table?lang=en>
(accessed 7.09.2022)
10. Adriana-Elena Taerel, Adina Turcu-Stiolica. Study on the range of drugs authorized in Romania – a determinant element for the accessibility and availability of drugs. *Farmacia*. 2009;57(2):254-259
11. Vončina L, Strbad T, Fürst J, Dimitrova M, Kamusheva M, Vila M, Mardare I, Hristova K, Harsanyi A, Atanasijević D, Banović I, Bobinac A. Pricing and Reimbursement of Patent-Protected Medicines: Challenges and Lessons from South-Eastern Europe. *Appl Health Econ Health Policy*. 2021 Nov;19(6):915-927. doi: 10.1007/s40258-021-00678-w.
12. Czech M, Baran-Kooiker A, Atikeler K, Demirtshyan M, Gaitova K, Holownia-Voloshova, Turcu-Stiolica A, Kooiker C, Piniashko O, Kostandyan N, Zaliska O, Sykut-Cegielska J. A review of rare disease

- policies and orphan drug reimbursement systems in 12 Eurasian countries. *Frontiers in Public Health*. 2020. 7:416. doi: 10.3389/fpubh.2019.00416.
13. Lungulescu, C.; Croitoru, V.M.; Volovat, S.R.; Cazacu, I.M.; Turcu-Stiolica, A.; Gheonea, D.I.; Sur, D.; Lungulescu, C.V. An Insight into Deficient Mismatch Repair Colorectal Cancer Screening in a Romanian Population—A Bi-Institutional Pilot Study. *Medicina* 2021, 57, 847. <https://doi.org/10.3390/medicina57080847>
 14. Ghimpau V, Sur D, Volovat SR, Cazacu IM, Croitoru VM, Turcu-Stiolica A, Gheonea DI, Taerel AE, Subtirelu MS, Lungulescu CV. The direct costs burden of bevacizumab in South-West Romania. *Farmacia* 2022, 70(1), 164-170. <https://doi.org/10.31925/farmacia.2022.1.24>.
 15. Meca AD, Subtirelu MS, Turcu-Stiolica A, Nitu FM, Bogdan M, Matei M, Cioboata R, Stanoiu BP, Pisoschi CG. Prevalence of tuberculosis in South-West Romania and the direct costs burden. *Farmacia* 2021, 69(1). <https://doi.org/10.31925/farmacia.2021.1.24>.
 16. Subtirelu MS, Meca AD, Pisoschi CG, Bogdan M, Nitu FM, Matei M, Turcu-Stiolica A. The economic burden assessment of tuberculosis in Dolj county, Romania: a retrospective analysis. *Value in Health*. 2020; 23(1): S184
 17. <http://preturi.ms.ro/interogare.php>
 18. Ministry of Health Order no. 1030/25.06.2021 regarding the approval of maximum prices for drugs used within the social health insurance system.
 19. Ministry of health Order no. 368/2017 regarding the approval of the Norms from March 28, 2017, used in calculation the prices of drugs in Romania, published in Romanian Official Gazette no. 215/2017
 20. Ministry of Health Order No. 861/2014 regarding the approval of criteria for evaluation of medical technologies, the documents to be submitted by solicitants, the process and the methodology used to assess the drugs and the new indications to be included on the list, and the criteria for exclusion of drugs from the list, published in Romanian Official Gazette No. 557/28.07.2014.
 21. Ministry of health Order no. 368/2017 regarding the approval of the Norms from March 28, 2017, used in calculation the prices of drugs in Romania, published in Romanian Official Gazette no. 215/2017
 22. Emergency Government Ordinance no. 104/2009 regarding the update of the reform in healthcare domain Law no. 95/2006, published in Romanian Official Gazette no. 669/2009
 23. http://www.casan.ro//theme/cnas/js/ckeditor/filemanager/userfiles/ATC3_consum_clawback_T1_2020.pdf
 24. Radu PC, Chiriac ND, Pravat MA. Romanian Claw-Back Taxation: From A Financial Solution to A Challenge for Patients Access to Drugs. *Value in*

25. Boboia A, Florea LS, Turcu-Stiolica A, Taerel AE, Rais C, Revnic C, Florea A, Vedeanu NS, Nastasa C, Oniga O. Decision analysis of antibiotic use. *Farmacia*. 2020. 68(4): 757-765. doi: 10.31925/farmacia.2020.4.24
26. Radu CP, Pana BC, Furtunescu FL. Drug Policy in Romania. *Value in Health Regional Issues* 2018; 16:28-32.
<https://doi.org/10.1016/j.vhri.2017.11.003>.
27. Kawalec P, Tesar T, Vostalova L, Draganic P, Manova M, Savova A, Petrova P, Rugaja Z, Mannik A, Sowada C, Stawowczyk E, Harsanyi A, Inotai A, Turcu-Stiolica A, Gulbinovic J, Pilc A. Pharmaceutical regulation in Central and Eastern European countries: a current review. *Frontiers in Pharmacology, section Pharmaceutical Medicine and Outcomes Research*. 2017; 8:892. doi: 10.3389/fphar.2017.00892
28. Kamusheva M, Turcu-Stiolica A, Gierczyński J, Subtirelu M-S, Czech M and Petrova G (2021) Do Advanced Therapies Have a Future in the Low- and Middle-Income Countries - The Case of Bulgaria, Romania, and Poland. *Front. Public Health* 9:729847. doi: 10.3389/fpubh.2021.729847
29. Kawalec P, Stawowczyk E, Tesar T, Skoupa J, Turcu-Stiolica A, Dimitrova M, Petrova G, Rugaja Z, Mannik A, Harsanyi A, Draganic P. Pricing and Reimbursement of Biosimilars in Central and Eastern European Countries. *Frontiers in Pharmacology*. 2017; 8:288. doi:10.3389/fphar.2017.00288
30. Godman B, Simoens S, Kurdi A, Selke G, Yfantopoulos J. et al. Variation in the prices of oncology medicines across Europe and the implications for the future. *GaBI Journal*. 2021;10(2):72-82. DOI: 10.5639/gabij.2021.1002.008
31. Godman B, Hill A, Simoens S, Selke G, Selke Krulichová I, Zampirolli Dias C, Martin AP, Oortwijn W, Timoney A, Gustafsson LL, Voncina L, Kwon HY, Gulbinovic J, Gotham D, Wale J, Cristina Da Silva W, Bochenek T, Allocati E, Kurdi A, Ogunleye OO, Meyer JC, Hoxha I, Malaj A, Hierländer C, Sauermann R, Hamelinck W, Petrova G, Laius O, Langner I, Yfantopoulos J, Joppi R, Jakupi A, Greiciute-Kuprijanov I, Vella Bonanno P, Piepenbrink JH, de Valk V, Wladysiuk M, Marković-Peković V, Mardare I, Fürst J, Tomek D, Obach Cortadellas M, Zara C, Pontes C, McTaggart S, Laba TL, Melien Ø, Wong-Rieger D, Bae S, Hill R. Potential approaches for the pricing of cancer medicines across Europe to enhance the sustainability of healthcare systems and the implications. *Expert Rev Pharmacoecon Outcomes Res*. 2021 Aug;21(4):527-540. doi: 10.1080/14737167.2021.1884546.
32. Moorkens E, Godman B, Huys I, Hoxha I, Malaj A, Keuerleber S, Stockinger S, Mörtenhuber S, Dimitrova M, Tachkov K, Vončina L, Palčevski VV, Achnotou G, Slabý J, Popelková L, Kohoutová K, Bartels D, Laius O, Martikainen JE, Selke GW, Kourafalos V, Magnússon E, Einarsdóttir R,

- Adams R, Joppi R, Allocati E, Jakupi A, Viksna A, Greičiūtė-Kuprijanov I, Vella Bonanno P, Suttorp V, Melien Ø, Plisko R, Mardare I, Meshkov D, Novakovic T, Fürst J, Zara C, Marković-Peković V, Grubiša N, Befrits G, Puckett R and Vulto AG (2021) The Expiry of Humira® Market Exclusivity and the Entry of Adalimumab Biosimilars in Europe: An Overview of Pricing and National Policy Measures. *Front. Pharmacol.* 11:591134. doi: 10.3389/fphar.2020.591134.
33. Brian Godman, Holly McCabe, Trudy D Leong, Debjani Mueller, Antony P. Martin, Iris Hoxha, Julius C. Mwita, Godfrey Mutashambara Rwegerera, Amos Masele, Juliana de Oliveira Costa, Renata Cristina Rezende Macedo do Nascimento, Livia Lovato Pires de Lemos, Konstantin Tachkov, Petya Milushewa, Okwen Patrick, Loveline Lum Niba, Ott Laius, Israel Sefah, Suhaj Abdulsalim, Fatemeh Soleymani, Anastasia N Guantai, Loice Achieng, Margaret Oluka, Arianit Jakupi, Konstantīns Logviss, Mohamed Azmi Hassali, Dan Kibuule, Francis Kalemeera, Mwangana Mubita, Joseph Fadare, Olayinka O. Ogunleye, Zikria Saleem, Shazhad Hussain, Tomasz Bochenek, Ileana Mardare, Alian A. Alrasheedy, Jurij Furst, Dominik Tomek, Vanda Markovic-Pekovic, Enos M. Rampamba, Abubakr Alfadl, Adefolarin A Amu, Zinhle Matsebula, Thuy Nguyen Thi Phuong, Binh Nguyen Thanh, Aubrey Chichonyi Kalungia, Trust Zaranyika, Nyasha Masuka, Ioana D. Olaru, Janney Wale, Ruaraidh Hill, Amanj Kurdi, Angela Timoney, Stephen Campbell & Johanna C. Meyer (2020) Fixed dose drug combinations – are they pharmaco-economically sound? Findings and implications especially for lower- and middle-income countries, *Expert Review of Pharmacoeconomics & Outcomes Research*, 20:1, 1-26, DOI: 10.1080/14737167.2020.1734456.
34. Godman B, Hill A, Simoens S, Kurdi A, Gulbinovic J. et al. Pricing of oral generic cancer medicines in 25 European countries; findings and implications. *GaBI Journal*. 2019;8(2):49-70. DOI: 10.5639/gabij.2019.0802.007.
35. Patricia Vella Bonanno, Anna Bucsics, Steven Simoens, Antony P Martin, Wija Oortwijn, Jolanta Gulbinovič, Celia Rothe, Angela Timoney, Alessandra Ferrario, Mohamed Gad, Ahmed Salem, Iris Hoxha, Robert Sauermann, Maria Kamusheva, Maria Dimitrova, Guenka Petrova, Ott Laius, Gisbert Selke, Vasilios Kourafalos, John Yfantopoulos, Einar Magnusson, Roberta Joppi, Arianit Jakupi, Tomasz Bochenek, Magdalene Wladysiuk, Claudia Furtado, Vanda Marković-Peković, Ileana Mardare, Dmitry Meshkov, Jurij Fürst, Dominik Tomek, Merce Obach Cortadellas, Corrine Zara, Alan Haycox, Stephen Campbell & Brian Godman (2019) Proposal for a regulation on health technology assessment in Europe – opinions of policy makers, payers and academics from the field of HTA, *Expert Review of Pharmacoeconomics & Outcomes Research*, 19:3, 251-261, DOI: 10.1080/14737167.2019.1575730.

36. Ferrario, A., Arāja, D., Bochenek, T. et al. The Implementation of Managed Entry Agreements in Central and Eastern Europe: Findings and Implications. *PharmacoEconomics* 35, 1271–1285 (2017).
<https://doi.org/10.1007/s40273-017-0559-4>.
37. Lacosta TB, Vulto AG, Turcu-Stiolica A, Huys I, Simoens S. Qualitative Analysis of the Design and Implementation of Benefit-Sharing Programs for Biologics Across Europe. *BioDrugs* 2022.
<https://doi.org/10.1007/s40259-022-00523-z>.
38. Baran-Kooiker A, Kagan A, Gaitova k, Holownia-Voloskova M, Turcu-Stiolica A, Kooiker C, Piniashko O, Czech M. Applicability of the evidem multi-criteria decision analysis framework for orphan drugs - results from a study in 7 eurasian countries. *Acta Poloniae Pharmaceutica* 2019;76(3). DOI: 10.32383/appdr/102681
39. Pisana A, Wettermark B, Kurdi A, Tubic B, Pontes C, Zara C, Van Ganse E, Petrova G, Mardare I, Fürst J, Roig-Izquierdo M, Melien O, Bonanno PV, Banzi R, Marković-Peković V, Mitkova Z and Godman B (2022). Challenges and Opportunities With Routinely Collected Data on the Utilization of Cancer Medicines. Perspectives From Health Authority Personnel Across 18 European Countries. *Front. Pharmacol.* 13:873556. doi: 10.3389/fphar.2022.873556.
40. Godman B, Tubic B, Allocati E, Wladysiuk M, McTaggart S, Kurdi A, Haque M, MacBride-Stewart S, Kameera F, Masele A, Hoxha I, Markovic Pekovic V, Petrova G, Tachkov K, Laius O, Harsanyi A, Inotai A, Jakupi A, Henkuzens S, Garuolienė K, Vella Bonanno P, Rutkowski J, Mardare I, Fürst J, Pontes C, Zara C, Pedrola MT, Akter F, Kwon HY, Martin AP, Banzi R, Wale J, Gulbinovič J. Biosimilars are essential for sustainable healthcare systems; however, key challenges remain as seen with long-acting insulin analogues. *J Appl Pharm Sci*, 2022; 12(03):055–072.
41. Godman B, Wladysiuk M, McTaggart S, Kurdi A, Allocati E, Jakovljevic M, Kameera F, Hoxha I, Nachtnebel A, Sauermann R, Hinteregger M, Marković-Peković V, Tubic B, Petrova G, Tachkov K, Slabý J, Nejezchlebova R, Krulichová IS, Laius O, Selke G, Langner I, Harsanyi A, Inotai A, Jakupi A, Henkuzens S, Garuolienė K, Gulbinovič J, Bonanno PV, Rutkowski J, Ingeberg S, Melien Ø, Mardare I, Fürst J, MacBride-Stewart S, Holmes C, Pontes C, Zara C, Pedrola MT, Hoffmann M, Kourafalos V, Pisana A, Banzi R, Campbell S, Wettermark B. Utilisation Trend of Long-Acting Insulin Analogues including Biosimilars across Europe: Findings and Implications. *Biomed Res Int.* 2021 Oct 11; 2021:9996193. doi: 10.1155/2021/9996193.
42. Godman B, Fadare J, Kwon HY, Dias CZ, Kurdi A, Dias Godói IP, Kibuule D, Hoxha I, Opanga S, Saleem Z, Bochenek T, Marković-Peković V, Mardare I, Kalungia AC, Campbell S, Allocati E, Pisana A, Martin AP,

Meyer JC. Evidence-based public policy making for medicines across countries: findings and implications for the future. *J Comp Eff Res*. 2021 Aug;10(12):1019-1052. doi: 10.2217/ce-2020-0273.

43. OECD/European Observatory on Health Systems and Policies (2021), Romania: Country Health Profile 2021, State of Health in the EU, OECD Publishing, Paris/European Observatory on Health Systems and Policies, Brussels.
44. Eurofound (2021), Living, working and COVID-19 survey, third round (February-March 2021).
45. European Commission (2020), A pharmaceutical strategy for Europe.
46. European Commission (2021a), Europe's Beating Cancer Plan.
47. European Commission (2021b), The European Health Data Space.
48. WHO Regional Office for Europe, European Commission, European Observatory on Health Systems and Policies (2021), COVID-19 Health Systems Response Monitor – Romania.

Research Team



Professor Adina Turcu-Stiolica, Ph.D.

Adina Turcu-Stiolica is Professor of Pharmacoeconomics at the University of Medicine and Pharmacy of Craiova, Romania. She graduated the Faculty of Pharmacy and the Faculty of Computer Science in Craiova, Romania. Her education background is also in Applied data science and artificial intelligence (MIT, Massachusetts, USA) and Applied methods on cost-effectiveness analysis (University of Oxford, Nuffield Department of Population Health, UK). She was a member in the HTA Task Force of the project of Romanian Ministry of Health and Mondial Bank for setting up a transparent frame for using HTA in Romanian policy decision-making. She is member of ISPOR from 2010 and, now, she is the Chair of the ISPOR Medication Adherence and Persistence Special Interest Group. She is an author of over 100 peer-reviewed articles, including those on cost-effectiveness, MCDA, health-related quality of life, medication adherence and interventional/observatory studies.



PROFESSOR JOHN YFANTOPOULOS D.Phil. University of York

President of IPOKE Research Institute (www.ipoke.gr)

John Yfantopoulos is Emeritus Professor of Health Economics at the University of Athens, President of IPOKE Research Institute, President of the ISPOR the Greek Chapter, former President of the National Centre for Social Research and an elected member of the Senate of the University of Athens, He was a keynote Speaker in several European meetings during the 2014th Greek Presidency in the European Commission and the European Parliament. He received his Doctor of Philosophy in Health Economics from the University of York, UK. Professor Yfantopoulos has extensive teaching and research experience in Health Economics, Health Technology Assessment (HTA) and Pharmaco-economics in Europe and the USA. He collaborated with several Universities in Europe, and the USA He has been working and advising the European Commission, (Eurostat), the World Health Organization, the International Labor Office, and the World Bank. He was the elected Rapporteur of the 23rd WHO Regional Office for Europe and the elected Chair of the 11th European Congress of ISPOR. In November 2008, he was awarded the ISPOR Distinguished Service Award. He has extensive experience with the Eurostat data sources (HBS, LFS, ECHP, SILC, EHIS) as well as with the EU Research Projects like SHARE and the (European Social Survey, (ESS)). In 2005 in the evaluation of the Greek research centers from an international peer review committee, he received the highest grade (excellent (5)) for his scientific work, commitment to international collaboration and research networking. Recent activities in a number of Eastern European countries, Russia, Bulgaria, Romania, Poland, Moldova, Albania include studies in the evaluation of economic efficiency, health technology assessment, pharmaco-economics, and implementing effective health reforms. He has published 39 books, as well as more than 300 articles in international refereed journals.