



The impact of the innovative medicines on the Romanian economy

The summary of the study of the innovative medicines sector aims to provide a quantitative dimension of the impact that such producers active in Romania have on the local economy. The first part of the study provides an overview of the Romanian health and pharmaceutical market and a comparison with other European countries, in the broader context of the health system. The second part of the study estimates the socio-economic impact of innovative drug companies present in Romania.



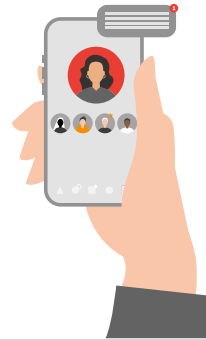
State of health



The ageing phenomenon of the Romanian population became more pronounced in the last years, witnessing a decrease in the working age population, while the number of people aged 65 and above is increasing (from 16.5% in 2014 to 18.5% in 2019). As a consequence, the old-age dependency ratio (28.1% in 2019 compared to 31.4% in the EU-27) has risen by about 3.8 percentage points in the last 6 years (from 24.3% in 2014).

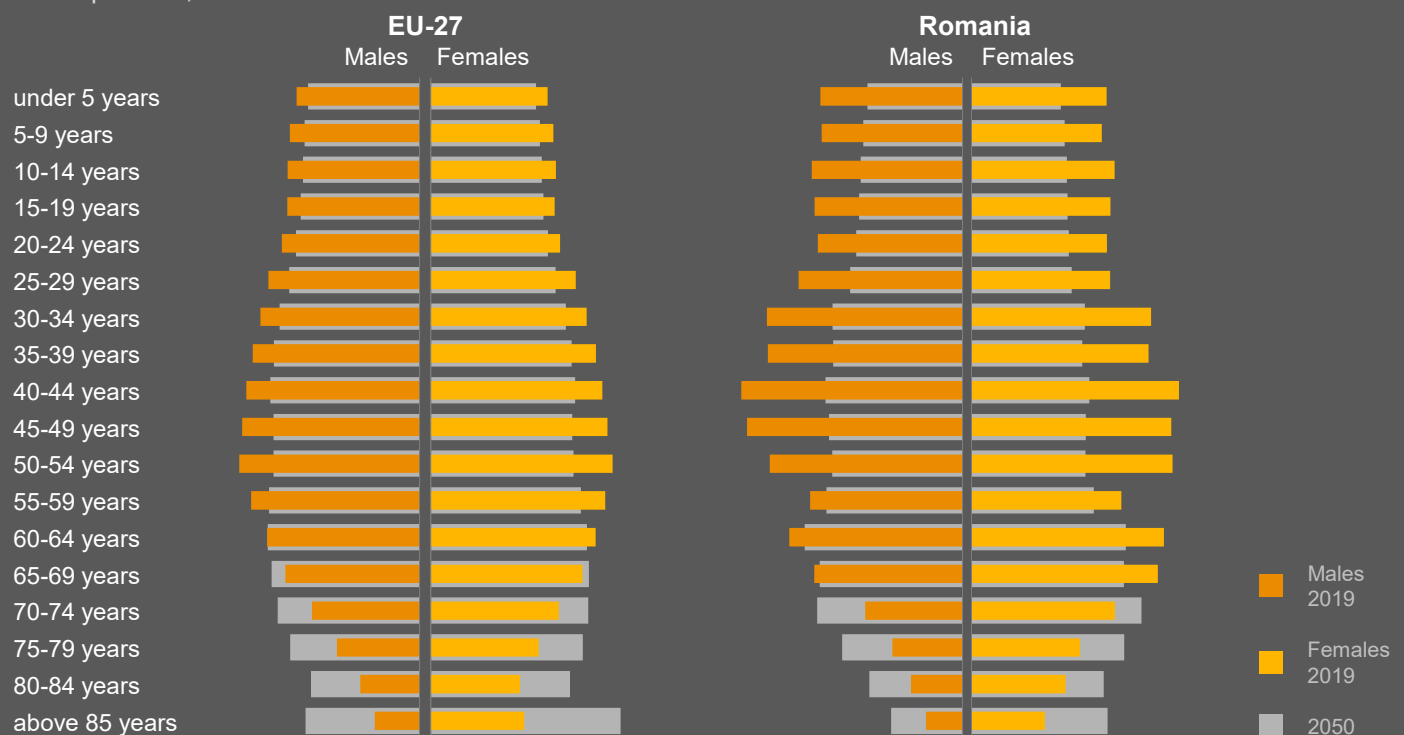


Moreover, according to the latest Eurostat population projections, the age structure of the Romanian population is expected to experience a transition to an elder population structure, with the population aged over 65 being estimated to represent more than 30% of the total population in 2025.



Population structure by age groups

million persons, %



Sources: Eurostat

The demographic aging process has both economic and social implications, amplifying the needs for medical and social care, but also for new specific medical and social services. As a result, health and social security systems are among the most affected by the consequences of changing population age structures.

The health of the population is a reflection of the standard of living, in all its components, which correlated with the GDP per capita (11,520 euros per capita in 2019 compared to the EU average of 31,310 euros per capita), can summarize the relationship between the socio-economic development and population health.

Romania has made progress in terms of average life expectancy (or life expectancy at birth) reaching 75.6 years, up +0.6 years compared to 2014, but continues to be in the group of countries with the lowest life expectancy in the European Union. Regarding healthy life years, the gap between Romania and the EU average has almost doubled from 2.3 years in 2014 to 4.4 years in 2019.



Life expectancy at birth

2019, years



▲ EU-27 average: 81.3 years

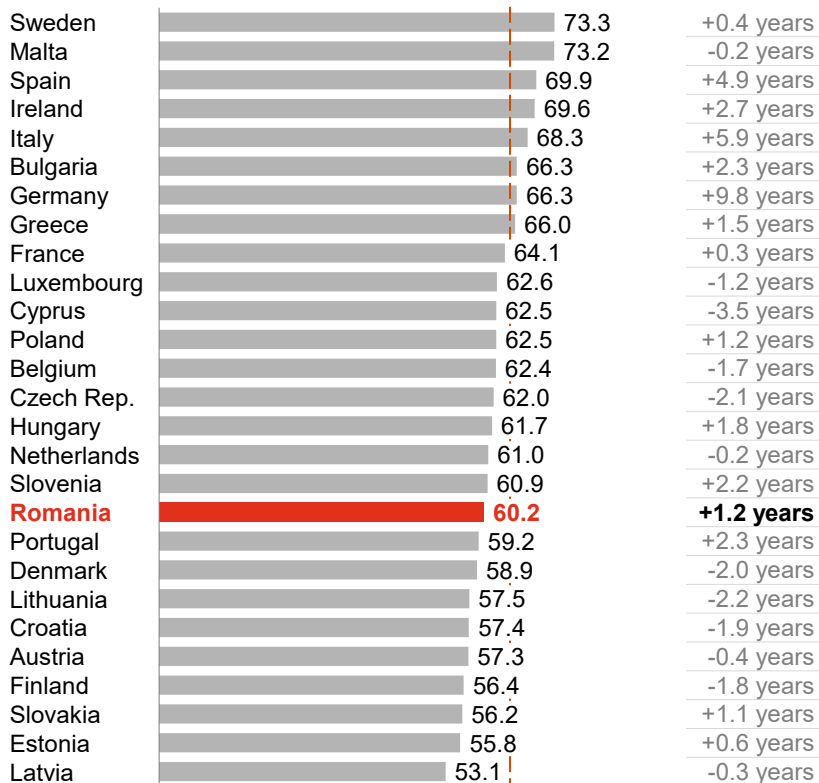


Healthy life expectancy

2019, years, 2019 vs. 2014 expressed in years



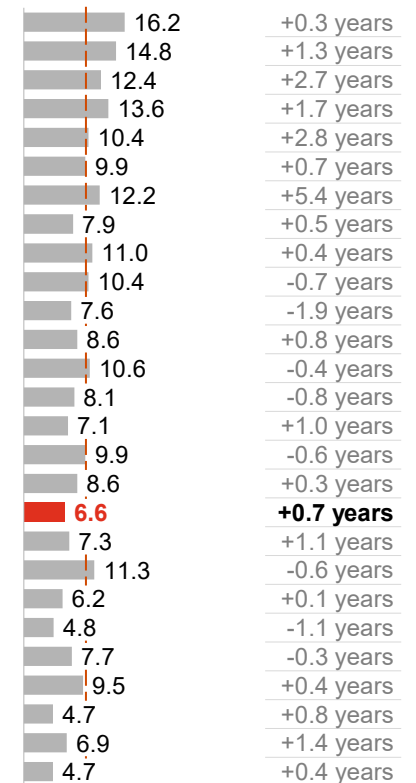
At birth



▲ UE-27 average: 64.6 years



At age 65



▲ UE-27 average: 10.3 years

Sources: Eurostat

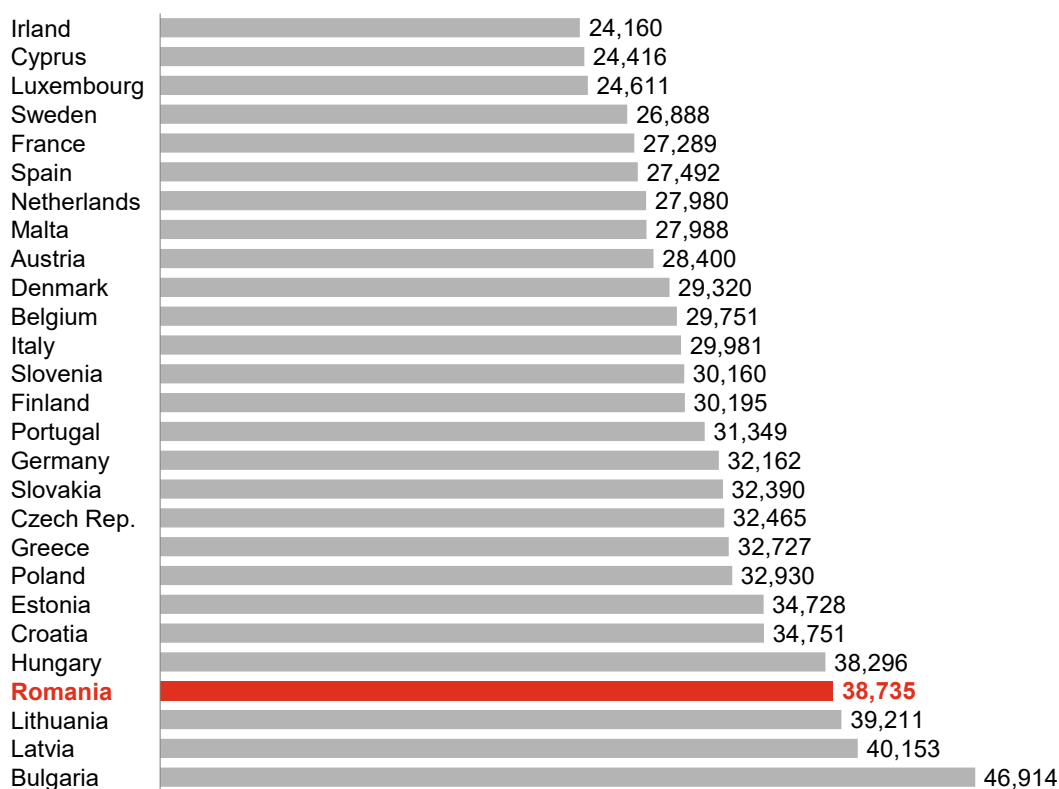
Also, from the perspective of the overall disease burden, Romania occupies the last places. There can be observed a high discrepancy between more developed countries, which generally have a disability-adjusted life year (DALY) rate of less than 30,000 per 100,000 inhabitants (except Germany) and those of Central and Eastern Europe, with significantly higher rates than the EU average. In the case of Romania, cardiovascular and oncological diseases represent the main causes with a share of over 50% of the total.

Main causes in Romania

Cardiovascular diseases	12,763	32.9%
Malignant tumors	6,581	17.0%
Digestive diseases	2,305	5.9%
Musculoskeletal disorders	2,203	5.7%
Leziuni fără intenție Unintentional injuries	2,177	5.6%
Neurological disorders	1,793	4.6%
Mental disorders	1,553	4.0%
Non-communicable diseases	1,492	3.9%
Diabetes and chronic kidney disease	1,346	3.5%
Chronic respiratory diseases	1,161	3.0%
Respiratory infections and tuberculosis	1,140	2.9%
Sense organ disease	1,040	2.7%
Other causes	3,182	8.2%

Overall burden of disease at all ages

2019, DALY⁽¹⁾ expressed per 100,000 population



Notă: (1) DALY – Disability Adjusted Life Years – represents the loss of the equivalent of one year of full health. DALYs for a disease or health condition are the sum of the years of life lost due to premature mortality and the years lived with a disability due to prevalent cases of the disease or health condition in a population.

Sources: GBD Results tool, National Institute of Public Health - Health status of the population in Romania 2019



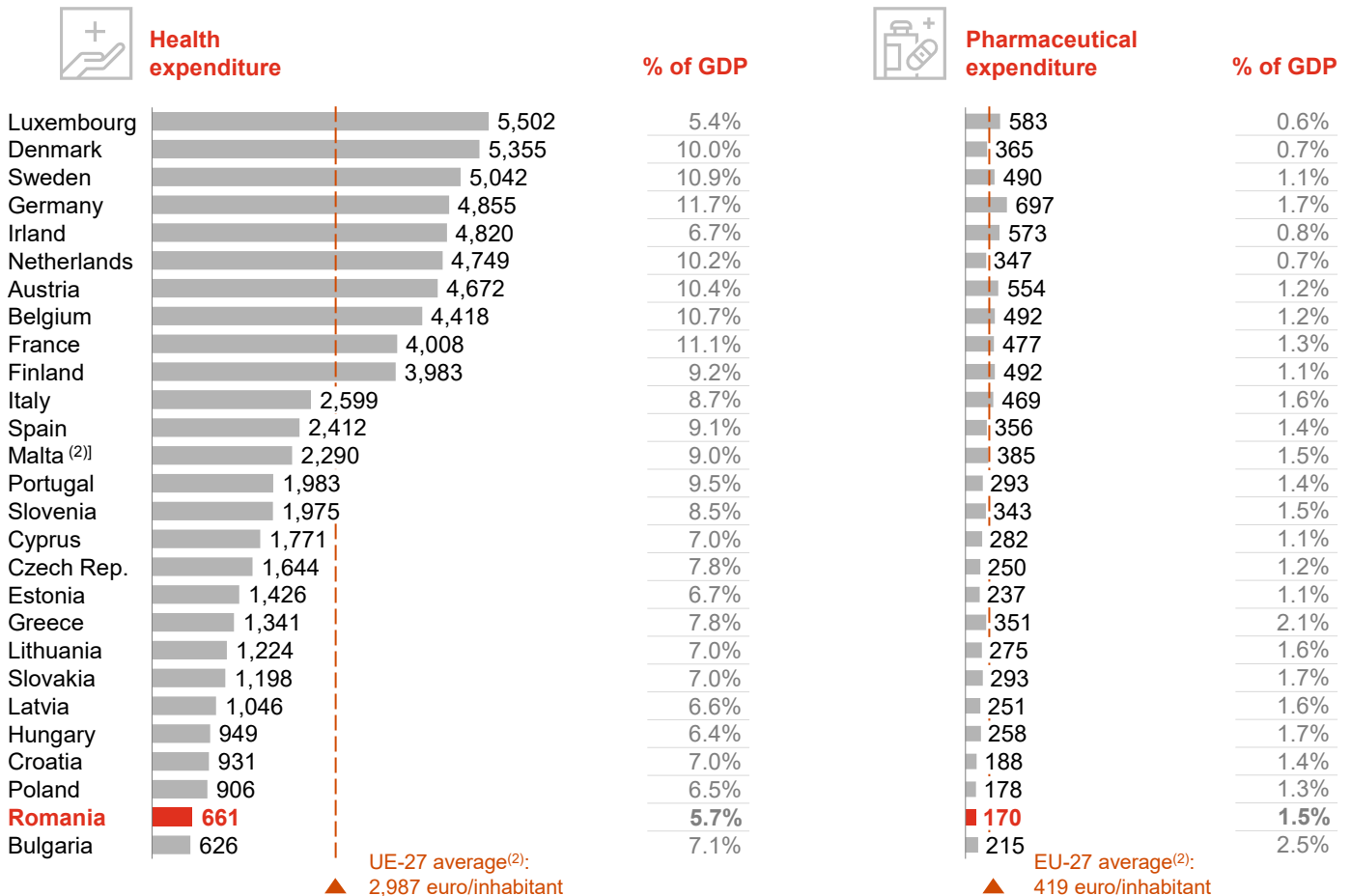
The same two medical causes contribute to another negative record, Romania having one of the highest preventable mortality rates in the European Union (ranked third, followed only by Latvia and Hungary), down one position from 2014 (when it was on the fourth place). While, in the case of the treatable mortality rates Romania registered the highest value in the EU, with 211 deaths per 100,000 inhabitants.



A population in poor health dramatically increases the resources that the society has to devote to health and social care to the detriment of other needs of society. Furthermore, the Romanian health system is underfunded to a considerable extent, recording some of the lowest health expenditures per capita (661 euros, the EU average being 2,987 euros) and as a percentage of GDP (5.7% compared to 9.9% in the EU), while pharmaceutical spending in Romania represents 1.5% of GDP.

Health and pharmaceutical expenditure per capita

2019⁽¹⁾, euro per inhabitant, % of GDP



Note: (1) Health expenditure include expenditure on medical services, medicines and medical equipment. Pharmaceuticals and other medical non-durable goods (non-specified by function), which means pharmaceutical products and non-durable medical goods intended for use in the diagnosis, cure, mitigation or treatment of disease, including prescribed medicines and over-the-counter drugs, where the function and mode of provision are not specified. (2) Statistical data for 2018.

Sources: Eurostat

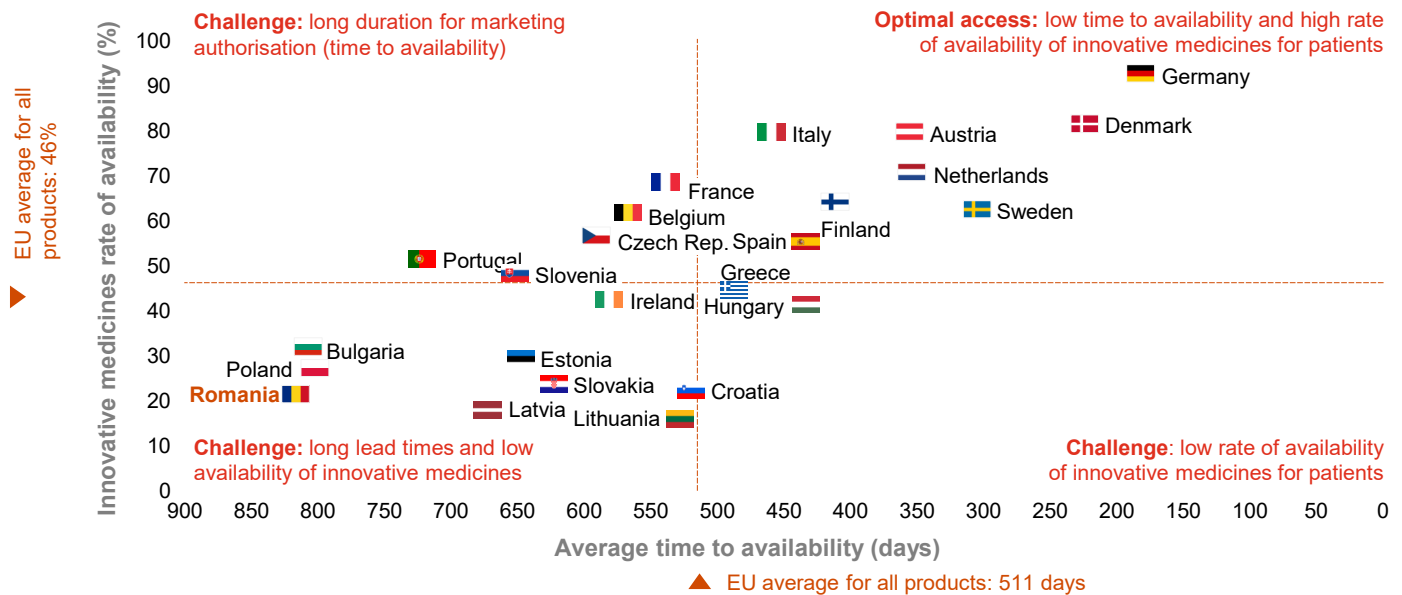
Most European countries use a mix of public and private financing for health spending, with public funds as the main source of financing.

The latest statistics from the EFPIA Patients WAIT Indicator 2021 study indicate that Romanian patients can wait up to almost 30 months (an average of 899 days) between marketing authorisation and availability of new medicines, the average time increasing from the previous report, thus placing Romania on the last place among EU members, with 388 days (more than one year, circa 13 months) above the EU average.





Average time to availability of innovative medicines and rate of availability



Sources: EFPIA Patients W.A.I.T. Indicator 2021 Survey, ARPIM press releases

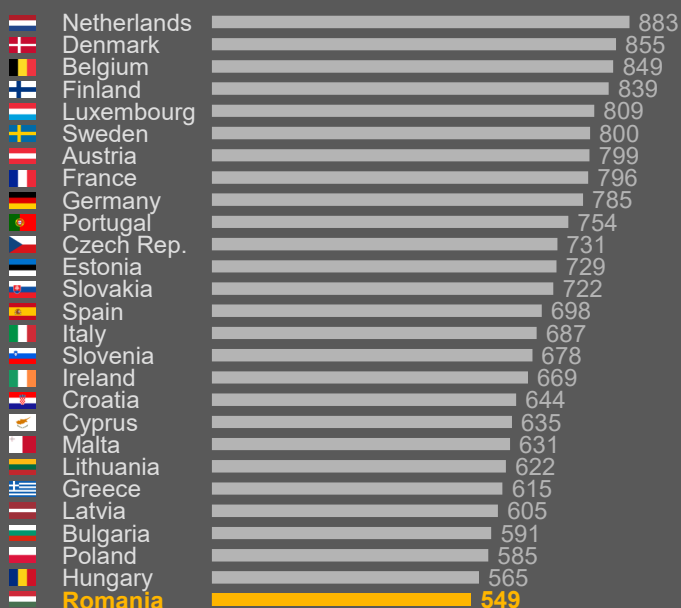
Moreover, out of 160 innovative medicines with central-marketing authorisation in the period 2017-2020, only 38 (less than 1 in 3) were included in the list of reimbursed medicines in Romania.

The Euro Health Consumer Index (EHCI) report places Romania on the 34th place out of 35 countries evaluated (EU-28 and other Central and Eastern European countries), being only 5 points from the last place, with a very large gap in areas such as waiting times for treatment, patients' rights and the general level of information, as well as the general health of the population, thus strengthening the urgent need for support measures of the health system. In terms of access to pharmaceuticals, Romania has a score of only 39 points out of a maximum of 100 points, being the lowest of all the areas evaluated.

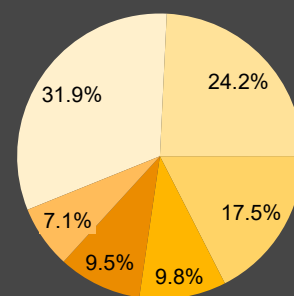


Euro Health Consumer Index⁽¹⁾

2018, EHCI score – 1,000 point scale



Romania score



	Romania score	Maximum score Σ 1,000
Accessibility (waiting times for treatment)	175	225
Outcome (health status of the population)	133	300
Patient rights and information	96	125
Prevention	54	125
Range and reach of services provided	52	125
Pharmaceuticals	39	100

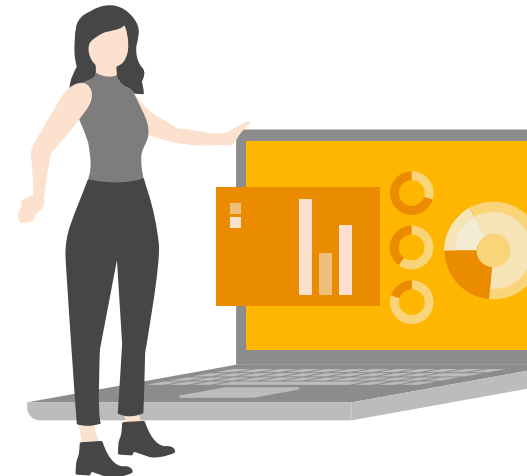
Note: (1) According to the measurement methodology, the maximum theoretical score for a national health system is 1,000, and the lowest possible score is 333. The EHCI index compares and classifies national health systems from the point of view of the consumer / patient, based on a set of approximately 46 indicators, calculated annually at EU level since 2005. The indicators reflect the level of performance achieved in various areas of the health system, such as patient orientation or quality of care.

Sources: Health Consumer Powerhouse – Euro Health Consumer Index Report 2018

Demographic challenges, poor health status of the population and lack of financial resources as well as the low access to medicines are threatening the sustainability of the health system and to some extent the economy as a whole, as in a population with major health problems the degree of participation in economic activities is affected, leading to a certain incompatibility between health and increased labour productivity.

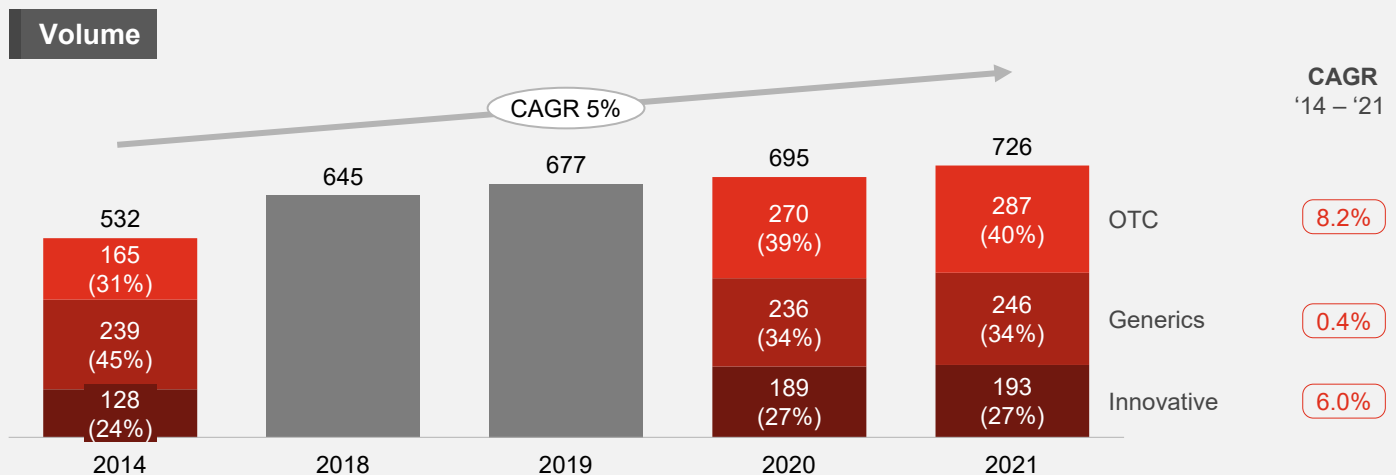
Innovation in medicine in general and next-generation medicines, in particular, bring major benefits to the health of the population, society and thus the national health budget.

In 2020, innovative medicines accounted for 27% of the total volume of pharmaceutical consumption in Romania and 56% of the value of the pharmaceutical market expressed in final consumers prices.

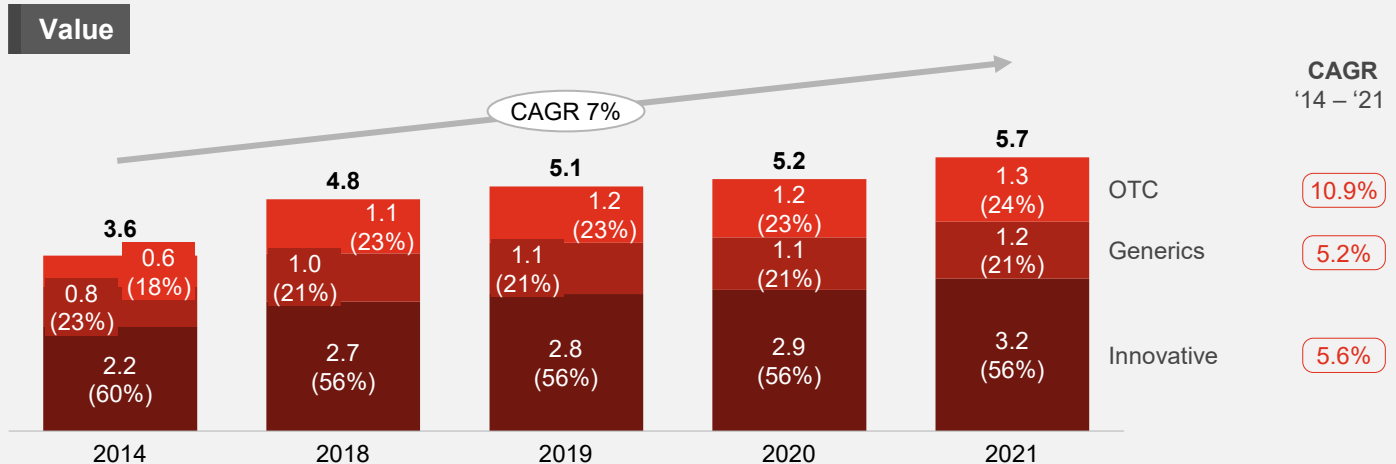


Evolution of the pharmaceutical market in Romania, by type of medicines

million units sold



billion euro⁽¹⁾



Note: (1) Market value is computed based on end consumer prices

Sources: ARPIM, PwC analysis



Socio-economic impact of the innovative medicines sector

The contribution of the innovative medicines sector amounts to over 1 billion euro, with sector-specific payments attaining a significant contribution of more than 0.6-0.7 billion euro.

Total contribution of the innovative pharmaceutical sector to the Romanian economy

Total contribution in 2019: 1.31 miliarde euro

1,099 million euro in gross value added and sector-specific payments, of which:

> **421** million euro gross value added (equivalent to 0.2% of GDP), of which 197 million euro direct contribution

> **678** million sector-specific payments (328 million euro for the clawback tax and 351 million euro cost-volume and cost-volume-result contracts)

214 million euro revenue to the state budget, consisting of non-specific taxes

about **11,200** jobs, of which 2,750 directly supported jobs

Total contribution in 2020: 1.26 miliarde euro

1,026 million euro in gross value added and sector-specific payments, of which:

> **444** million euro gross value added (equivalent to 0.2% of GDP), of which 207 million euro direct contribution

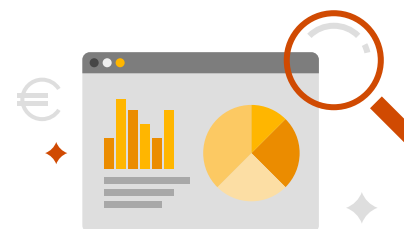
> **582** million sector-specific payments (313 million euro for the clawback tax and 269 million euro cost-volume and cost-volume-result contracts)

229 million euro revenue to the state budget, consisting of non-specific taxes

about **11,600** jobs, of which 2,800 directly supported jobs

Sources: PwC questionnaire (data collected from ARPIM members between October 2021 and April 2022), PwC analysis

The contribution of the sector of innovative medicines to the formation of the Romanian gross domestic product was estimated at 421 million euros in 2019, of which 197 million euros direct contribution through the activities of the companies present on the Romanian market, and another 224 million euros indirectly through the value chain of local suppliers of innovative drug companies. In 2020, a positive evolution of the contribution to the economy has been noted, the total contribution of the sector for the year 2020 amounting to 444 million euro, an increase of 23 million euro, of which 207 million euros gross value added directly created.

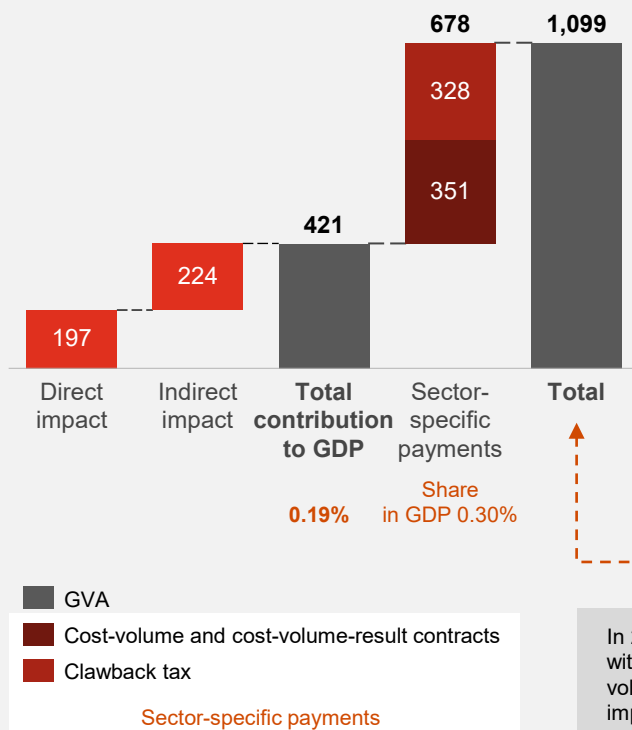




Contribution of the innovative pharmaceutical sector

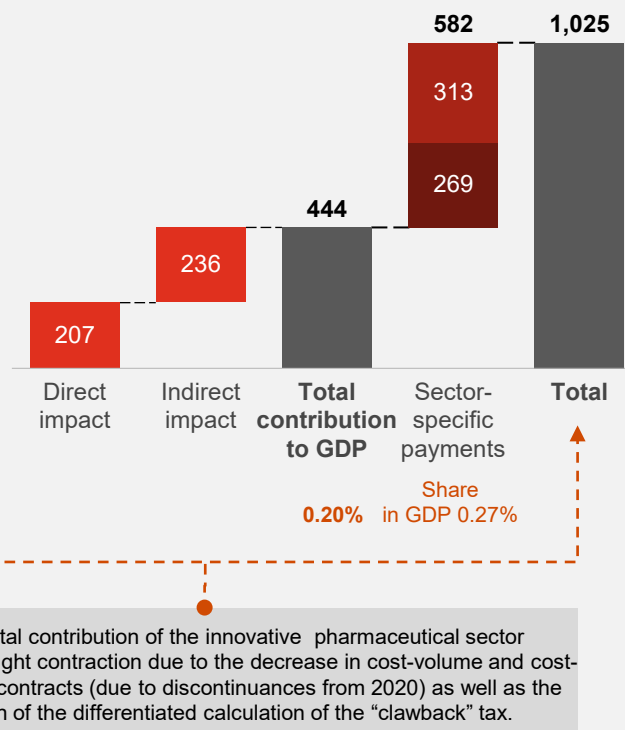
Estimated contribution to GDP and other sector-specific payments

2019, million euro



Estimated contribution to GDP and other sector-specific payments

2020, million euro



In 2020, the total contribution of the innovative pharmaceutical sector witnessed a slight contraction due to the decrease in cost-volume and cost-volume-result contracts (due to discontinuances from 2020) as well as the implementation of the differentiated calculation of the "clawback" tax.

Activities of the innovative medicines sector (direct impact)

1 euro direct contribution to GDP

Propagated effect on the economy (indirect impact)

1.14 euro additional indirect contribution

Note: Contributions are calculated based on the answers to the PwC questionnaire, extrapolated to the total market value.
Sources: PwC questionnaire (data collected from ARPIM members between October 2021 and April 2022), PwC analysis

In addition to the gross value added and the contribution to the formation of the gross domestic product, an important contribution is represented by the sector-specific payments – through the "clawback" tax and the cost-volume / cost-volume-result contracts - which constitute revenues to the budget of the National Health Insurance Fund, the amounts being used to finance the treatment needs of the Romanian patients. Thus, in 2019, the value of contributions through sector-specific payments amounted to 678 million euro, 2020 witnessing a slight contraction due to the decrease in cost-volume / cost-volume-result contracts, due to discontinuances in 2020 contracts as well as the implementation of the differentiated calculation of the "clawback" tax. Thus, in 2020, sector-specific payments amounted to 582 million euro.

In addition to the contribution to the formation of the gross domestic product and the contribution to the National Health Insurance Fund budget through sector-specific payments, the companies from the innovative medicine sector also contribute to Romania's national budget through taxes, represented for the most part by income tax and value added tax, as well as contributions to health and social insurance. Thus, in 2019 the contribution of innovative drug manufacturers to the state budget accounted to more than 200 million euros, with a slight increase of about 7% in 2020 as compared to the previous year.

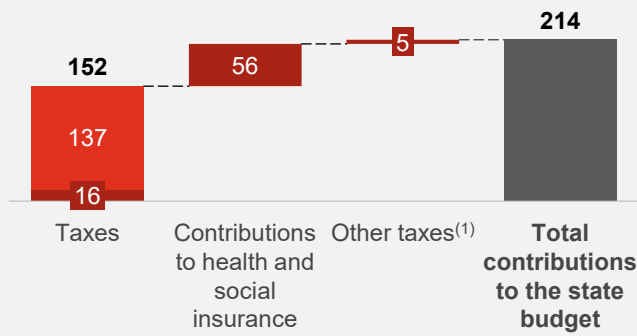




Contribution to the state budget

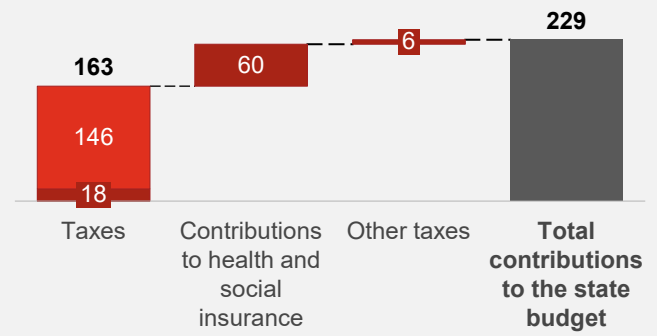
Estimated impact to state budget revenues

2019, million euro



Estimated impact to state budget revenues

2020, million euro



In 2020, the amount of contributions to the state budget increased slightly by about 7.1%.

Note: (1) Other taxes include payments to the Registration Office (including for clinical trials), other payments (property, real estate excise) and others. Contributions are calculated based on the answers to the PwC questionnaire and are extrapolated to the total market value.

Sources: PwC questionnaire (data collected from ARPIM members between October 2021 and April 2022), PwC analysis



From an employment perspective, the innovative medicines sector supports more than 11 thousand jobs, of which over 2.7 thousand jobs being directly supported by the manufacturers of innovative medicines present on the Romanian market, while another 8,000 jobs are indirectly supported by companies that supply goods and services to manufacturers of innovative medicines, in 2020, the number of jobs maintained or newly created in the value chain increasing by about 400.



In addition to the direct and indirect contribution to the Romanian economy, innovative pharma companies made investments in research and development activities, medical education activities and initiatives with social impact, with a focus on prevention, and other continuous medical education campaigns. Thus, in the 2019-2020 period, innovative pharma companies have invested over 67 million euros⁽¹⁾, of which 33 million euros in research and development (i.e. clinical trials) and over 30 million euros in continuing medical education, prevention, and information in support of the medical and patient's community in Romania, while another approximately 4 million euros represented investments in fixed assets.

Investments in research and development have taken place despite significant administrative delays in the approval of clinical trials, reducing these delays potentially leading to an increased number of clinical trials, thus leading to more opportunities for early access to innovative treatments. In addition to clinical trials, innovative pharma companies have carried out also research and development activities, such as studies on the burden of preventable diseases, use of innovative contracting agreements in the EU, etc.

In addition, innovative pharma companies fund medical education both among health professionals and across society, while funding a number of specialized prevention programs that facilitate patients' access to early diagnosis and testing of certain diseases, but also to more effective treatment schemes. According to the information provided in 2019, no less than 28 such programs were carried out ⁽¹⁾.

By joining professional organizations, innovative pharma companies aim for the improvement of the dialogue between authorities and other stakeholders on healthcare topics (for example, the regulatory framework, healthcare financing), promoting the use of digital solutions and services (for example, telemedicine, electronic registers), raising awareness as well as aiming at improving patients' access to medicines and innovation.



Note: (1) Not all participant members provided information on investments made, such as research and development, health education and patient support programs, and other types of investments (for example, investments in fixed assets, social impact initiatives). As such, when these results are presented, they are presented only for the subgroup of participating members that submitted such information.

About this summary of the study (report)

This document is a summary of the study (report) on the socio-economic footprint of the innovative medicines sector in Romania, prepared exclusively for the use of The Romanian Association of International Drug Manufacturers („ARPIM”) under our engagement contract with ARPIM. We do not assume any liability or responsibility to anyone except ARPIM in respect of this summary or the related study and report.

The study of the innovative medicines sector aims to provide a quantitative dimension of the impact that such producers active in Romania have on the local economy.

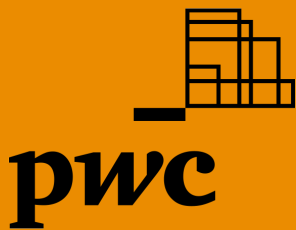
The first part of the study provides an overview of the Romanian health and pharmaceutical market and a comparison with other European countries, in the broader context of the health system. The information presented was taken from various sources, as specified for each analysis.

The second part of the study estimates the socio-economic impact of innovative drug companies present in Romania. The information was collected through a questionnaire completed by 17 ARPIM members between October 2021 - April 2022, and the results of the data collection process were extrapolated to the total market of innovative medicines in Romania.

The socio-economic footprint of the innovative medicines on the national economy was prepared using the Leontief methodology and the input-output tables published by the Romanian National Institute of Statistics, quantified by summarizing the direct impact (as a result of the sector's own contributions) and the indirect impact (as a result of the procurement of goods and services in the innovative medicines sector and respectively the procurement of suppliers of goods and services throughout the supply chain). Thus, the economic impact is measured by three indicators, namely gross value added, employment and contributions to the state budget. In addition, sector-specific taxes, which constitute revenues to the budget of the National Health Insurance Fund, were highlighted separately in the study.

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