The Economist INTELLIGENCE UNIT | HEALTHCARE

Executive summary

Learning from Europe:

The options for health and medicines financing in Romania

A report by The Economist Intelligence Unit

Sponsored by LAWG local american working group

Contents

The aims of this report

This report aims to present a broad overview of access to healthcare and medicines in 12 European countries. The countries surveyed – Austria, Belgium, France, Germany, Hungary, Italy, the Netherlands, Poland, Romania, Slovakia, Spain and the UK – were chosen as representing major trends in EU health funding for both wealthy and less wealthy parts of the EU, as well as their geographical spread from east to west.

The objective is to highlight differences and commonalities in healthcare financing trends and policy approaches, as governments rise to the challenge of managing the interlinked dynamics of population health and economic growth. The report also aims to benchmark Romania's healthcare services and medicine supply system against these findings, laying the foundation for a realistic discussion about how to enhance healthcare and medicines funding in Romania.

The final section of this report focuses on ways that European governments try to improve access to medicines that may have a direct impact on health outcomes, including survival rates from cancer and other life-threatening diseases. Although Romania has improved access to treatments, particularly for innovative medicines, it still suffers from both financial barriers and administrative barriers. This report aims to identify these barriers and to suggest possible solution.

The report is intended to form a basis for further discussion with key officials and experts from Romania and beyond. Although the issues outlined in this report may be particularly acute for Romania, it is far from being the only country that needs to tackle them. The proposed solutions therefore need to be multi-faceted and adaptable, in order that countries can select and implement those best-suited to their particular socio-economic conditions and their political priorities.

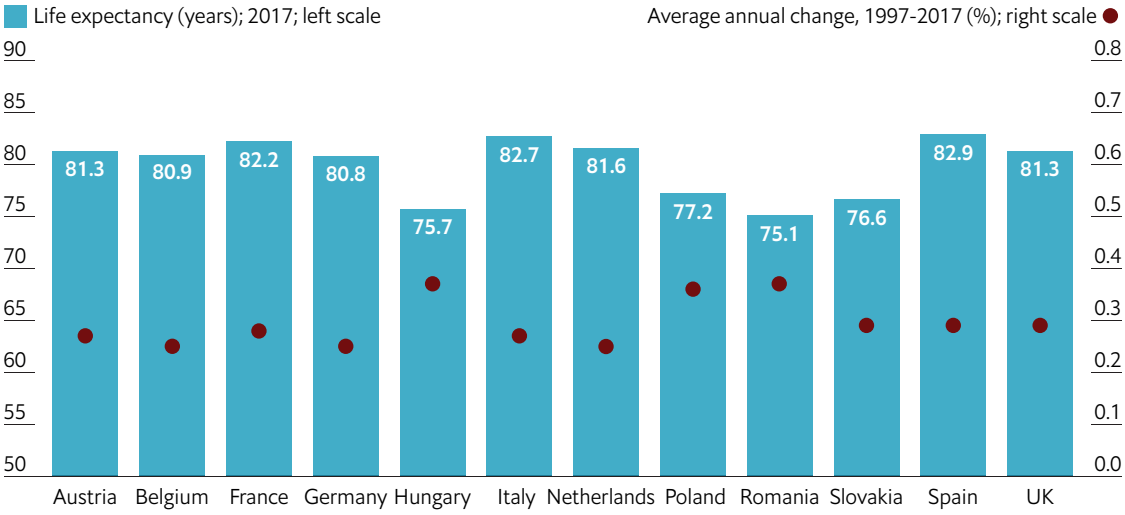
The case for health investment

Investment in healthcare is a critical tool for improving human welfare: it is also a key mechanism for raising national income and prosperity. There is a growing body of evidence revealing that good health is a cause, as well as a consequence, of higher income[1]. Good health boosts labour productivity and improves returns on investment in education. Improved access to healthcare and medicines leads to longer life expectancy.[2] Moreover investment in healthcare systems and in life sciences industries offers opportunities for higher employment, output and exports, developing skills that can sustain national economies for decades.

By contrast, poor population health hinders institutional performance and employment prospects. Lower life expectancy or general ill-health is a disincentive for adult training and damages national productivity, as well as having knock-on effects for dependents who may in turn suffer from lower health outcomes. Infectious diseases impede the development of sectors such as tourism and business travel, while a high prevalence of non-communicable diseases such as diabetes, cancer and cardiovascular disease dampen national workforce capabilities.[3]

While investment in health is therefore crucial, cost-pressures in healthcare systems in Europe and elsewhere have grown due to a combination of factors. These include ageing populations and shifting dependency ratios, the increasing prevalence of long-term chronic diseases, and the availability of expensive-to-develop, sophisticated and increasingly effective health technologies. These pressures accentuate the importance of addressing the relationship between health and the economy when approaching policy-making.

Average life expectancy in 2017



Source: Economist Intelligence Unit, based on data from the US Bureau of Census.

[1] Economic growth and healthy populations in developing countries: A summary of recent literature, EIU 2016

[2] Bloom D and Canning D (2008). Population health and economic growth. *Background paper for the Commission on Growth and Development*. Washington, DC, USA: World Bank.

[3] Frenk, J. (2004). Health and the economy: A vital relationship. *Organisation for Economic Cooperation and Development. The OECD Observer*, (243), 9.

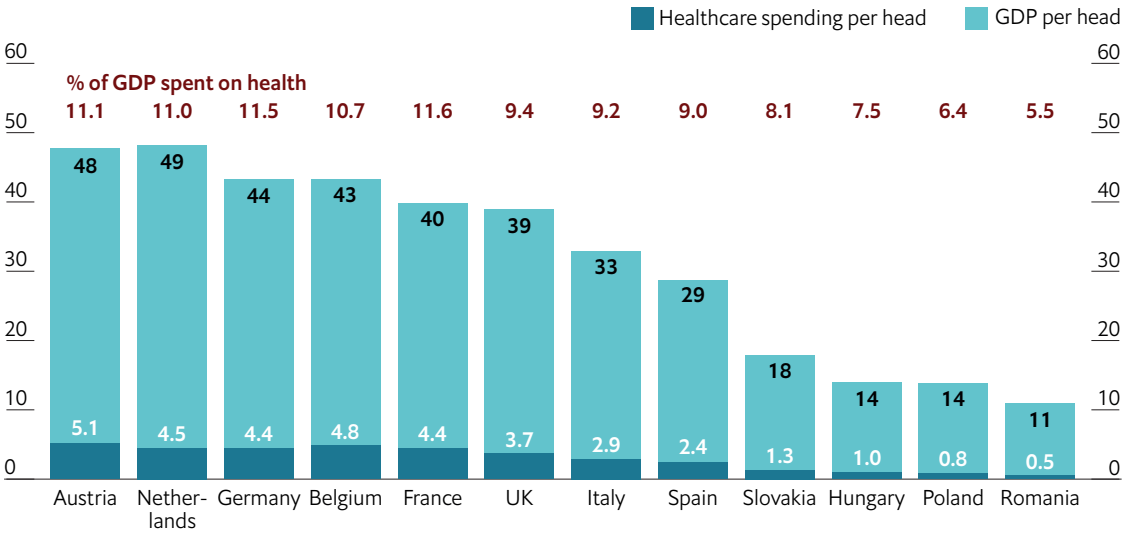
Romania in context

Romania's healthcare system has seen considerable improvements since the country introduced an insurance-based health system involving the National Health Insurance Fund (CNAS) in 1998. Life expectancy at birth has risen by 5.5 years since then, while the infant mortality rate has more than halved, from 20.6 deaths per 1,000 live births in 1998 to an estimated 9.3 deaths in 2017. More recently, the government has raised budgetary healthcare spending, improved the sustainability of the funding system and increased the wages of health workers. It has also tried to improve access to medicines, including increases to funding and more regular updating of reimbursement lists.

Romania's total expenditure (public and private) on healthcare amounted to an estimated 5.5% of GDP in 2016, according to The Economist Intelligence Unit. Despite rapid spending growth in recent years, this remains lower than the average of about 7% for new EU members and among the lowest share of any EU state. On a purchasing power parity basis, health spending per head is about half the level of the ten EU accession states (regional average) and 25% of the EU average.[4]

In US dollars per head, Romania also spends considerably less on health per head (an estimated US$583 in 2017) than countries with comparable GDP per head, such as Brazil (US$847) and Russia (US$733)[5]. The picture is similar when it come to pharmaceutical spending. At an estimated US$200 in 2016, drug consumption per head is among the lowest in Europe (the west European average is about US$450, and the central and east European average is about US$220).

Health expenditure and GDP per head in 2016
(US$ at PPP)



Sources: World Health Organisation; The Economist Intelligence Unit.

Despite this relatively limited spending, Romania is determined to fund a comprehensive universal healthcare system, based on compulsory insurance that covers all residents and offers good protection for vulnerable groups. Government reforms focus on efficiency gains and shifting expenditure away

[4] http://ec.europa.eu/eurostat/statistics-explained/index.php/Healthcare_expenditure_statistics

[5] Economist Intelligence Unit data

from inpatient care and towards primary care. The country has also raised health wages sharply to reverse a brain drain as doctors and health workers move to other EU countries.

However, the country continues to face challenges in terms of access to healthcare and access to medicines. Although the health system is, in theory, universal, coverage extended to just 17.13m people in 2016 , out of a total population of 19.71m, according to the National Health Insurance Fund (CNAS). This equates to 87% of the population. Access to health care is especially poor in rural areas, often exacerbated by gaps in population monitoring and reporting[6]. Moreover, the system of exemptions from health insurance contributions means that the burden for funding the system falls disproportionately on a relatively small share of the population.

A survey conducted by the OECD/EU shows that in 2015 9.4% of Romanians reported unmet medical care needs because of cost, geographical barriers or waiting lists, compared to an average of 3.2% in the EU. This is the highest level of any of the 12 countries covered in this report. Other surveys suggest that unmet needs for medicines are the third-highest in the comparator group.

This all has an effect on the country's health outcomes. It is unlikely to be a coincidence that Romania, which spends the least on healthcare in both per capita and percentage of GDP terms, has the highest average amenable death rate (men and women) of the 12 countries. Despite its considerable progress over the past two decades, it also has the lowest life expectancy in the group.

Summary of insurance contributions, as % of income

	Employee	Employer	Self-employed	Exceptions
Health insurance only				
Austria	3.87%	3.78%	7.65%	Allowances for low-income groups
Belgium	3.55%	3.8%		Allowances for low-income groups
France	0.95% plus dedicated tax of 6.2% to 12%	13.1%	As for employee + 4% entrepreneurial contribution	Allowances for low-income groups
Germany	8.2% (with income cap)	7.3%	15.5%	Funds cover employer portion for low-income groups.
Netherlands	€2,000 (flat rate)	8%	As for employee	Allowance for low-income groups
Poland	7.75% (tax-deductible)	0%	As for employee	Discounts/exemptions for low-income and disabled people
Romania	10%		10%	Widespread exemptions
Combined social insurance system				
Hungary	18.5% (7% for health), plus health tax	22%	As for employee	Allowances for low-income groups
Slovakia	4%	10%	14%	5.67% of the minimum wage
UK	12-14%	13.8%	up to 9%	Health also covered by general taxation

Spain and Italy have tax-funded systems

[6] https://ec.europa.eu/health/sites/health/files/state/docs/chp_romania_english.pdf

Romania's access to medicines

Access to health treatment is heavily dependent on the availability of affordable medicines.[7] Pharmaceuticals play a crucial role in the health system and medicine innovation can lead to cost savings through the reduced use of health services, particularly expensive in-patient care[8]. Efficient deployment of pharmaceuticals can improve employment rates and boost economic productivity. With healthcare budgets under strain, securing access to the right effective medicines at an affordable cost is a policy task that contributes to the overall success or failure of a nation's healthcare system. [9]

Our analysis of 12 of Europe's pharmaceutical markets reveals wide disparities in the availability of essential and innovative medicines. This is the result not just of differences in national wealth, but of regulatory practices affecting pricing, reimbursement systems, and time periods for market entry. At an estimated US$200 in 2016, Romania's drug consumption per head is among the lowest in Europe (the west European average is about US$450, and the central and east European average is about US$220). The total Romanian pharmaceutical market, at an estimated US$4bn in 2016, is a similar size to that of Hungary, which has half the population of Romania.[10]

Across the EU pharmaceutical spending growth has remained below total health spending growth over the past decade, according to the OECD. This lag is due largely to policy responses to the eurozone financial crisis, which targeted national pharmaceutical bills. A range of these measures were implemented in the 12 comparator countries in the early months of the financial crisis. [11]

As a result, average annual growth rates in 2009-14 were significantly lower than those in the pre-financial crisis years. On average across EU member states, pharmaceutical spending increased by 1.4% a year on average in real terms in 2005-09, but dropped by 1.1% between 2009 and 2014, according to OECD data. [12] Romania's trajectory has bucked this trend, with pharmaceutical spending per capita, in real terms, growing at an average annual rate of 6% in Romania 2009-14. Growth since 2014 has also been extremely rapid, with the result that per capita expenditure topped €200 in 2017.

Nevertheless, access to medicines in Romania continues to compare poorly to that in the other 11 EU countries. Moreover, data from Medicines for Europe/IMS Quintiles for mid-2015 also suggest that the share of patented/protected medicines in Romania is extremely low in a European context.

The Euro Health Consumer Index: Romania ranks lowest

The Health Consumer Powerhouse Euro Health Consumer Index (EHCI) analyses 34 national healthcare systems in Europe using 46 indicators in the areas covering six key categories - patient rights and information, accessibility (waiting times for treatment), outcomes (eg infant deaths, MRSA infections; cancer survival rates), range and reach of services (equity; and available services), prevention, pharmaceuticals (effective and appropriate use of medicines). Countries are given a weighted score in each of these six categories, with the maximum total score reaching 1,000. Our 12 comparator countries are listed below in order of final score and ranking.

[7] http://www.europarl.europa.eu/RegData/etudes/STUD/2016/587304/IPOL_STU(2016)587304_EN.pdf

[8] Lichtenberg, F. R. (2016). *The Benefits of Pharmaceutical Innovation: Health, Longevity, and Savings.* Montreal Economic Institute. pp. 5-6

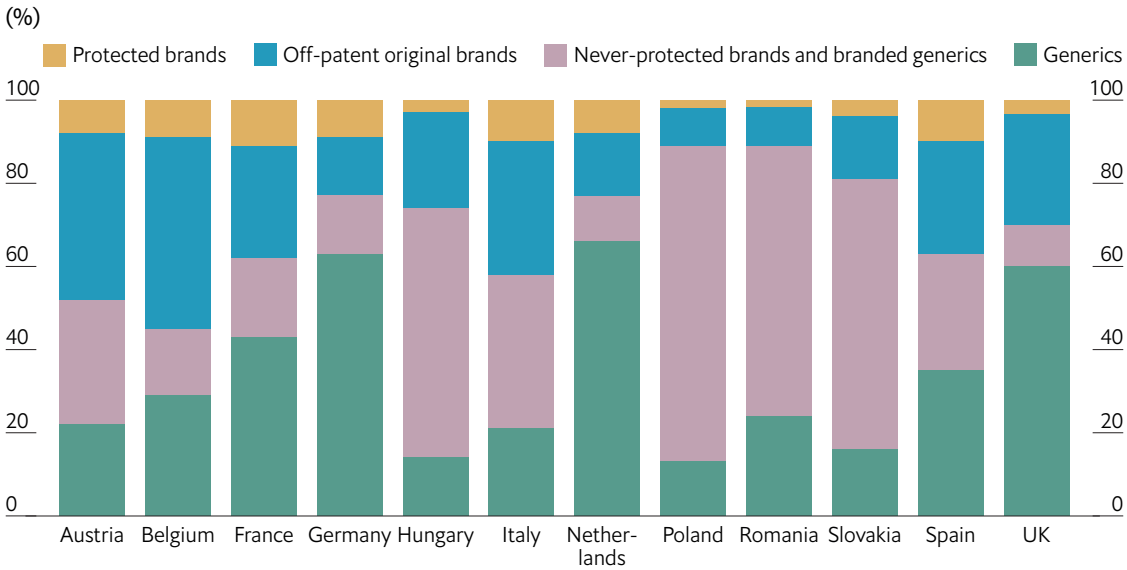
[9] Karampli, E., Souliotis, K., Polyzos, N., Kyriopoulos, J. and Chatzaki, E., 2014. Pharmaceutical innovation: impact on expenditure and outcomes and subsequent challenges for pharmaceutical policy, with a special reference to Greece. *Hippokratia*, *18*(2), p.100.

[10] http://www.eiu.com/industry/Healthcare/europe/romania/article/716060855/pharma-and-biotech/2017-10-30

[11] OECD, Health at a Glance, Europe, 2016.

[12] https://ec.europa.eu/health/sites/health/files/state/docs/health_glance_2016_rep_en.pdf

Protected and off-patent market shares (volume) by country, June 2015



Notes: Sales through retail and hospital channels; non-original brands and branded generics include copy products in some countries; generics include INN branded and company branded.

Source: Medicines for Europe, based on data from QuintilesIMS Health, MIDAS, Q2 2015.

The Index finds that, in healthcare as a whole and in the area of pharmaceutical care specifically, the Netherlands tops the board for performance – scoring the highest number of points in the both the comparator group and in the full list of 34 countries. In the pharmaceutical category, Netherland's shares the top spot with Germany. Romania records the lowest scores for both healthcare and pharmaceutical care, in both the comparator group and the full Index of countries.

EHCI Index, 2017 – performance of national health systems in the category of pharmaceuticals

	Weighted score / maximum 100
Netherlands	89
Germany	89
France	83
Austria	78
UK	78
Belgium	72
Spain	72
Slovakia	67
Poland	56
Italy	50
Hungary	44
Romania	33

Source: https://healthpowerhouse.com/files/EHCI-2017/EHCI-2017-report.pdf

Improving access to innovation

Whereas European policy-makers have focused on improving patient access to generic medicines over the past few years, their attitude to innovative medicines has been more complex. On the one hand, patient pressure has increased. Difficulties in gaining access to innovative medicines often hit newspaper headlines, while particularly patient groups (notably for rare diseases) have considerable advocacy power. On the other hand, policy-makers have been under pressure to reduce pharmaceutical spending, and high-priced innovative medicines are an obvious target.

However, a study of access to innovative cancer medicines, conducted by the Swedish Institute for Health Economics [13] found a strong link between uptake of new cancer medicines and cancer survival rates. The study also found that uptake can differ sharply even between countries with similar levels of spending on cancer. One reason for these differences is bureaucratic delays in the processes required to get products to patients. Another is the availability of mechanisms to fund the rollout of new medicines.

In many EU countries, average times before new medicines are readily available at affordable cost through public health reimbursement schemes are reduced by various mechanisms in some countries, including early access programmes. Eight of the 12 countries in the comparator group—Austria, Belgium, France, Germany, Italy, Poland, Romania and Spain—now offer patients a chance to gain early publicly reimbursable access to medicines before these products gain marketing authorisation and post-marketing evaluation. Prices are set freely until an agreement on price is reached with the manufacturer after the post-marketing evaluation process.

Many countries, including Austria, Belgium, France, Germany, the Netherlands, the UK and Romania, also offer Managed Entry Agreements, often individually negotiated with pharmaceutical companies. These use a variety of mechanisms, with varying success, to encourage the makers of new drugs to take on some of the financial risks of an early rollout. In the best cases, these allow patients to get access to medicines that may not otherwise be available, while allowing companies to gather data on their effectiveness that may eventually be used to persuade payers to fund a more lucrative agreement.

In addition, several countries have introduced specific mechanisms to ease access to innovative medicines that would otherwise have a high impact on health financing. These mechanisms include Italy's Innovative Drug Fund, introduced in 2017, the UK's Cancer Drugs Fund, introduced in 2011 and revised in 2016, and Spain's new financing model for rare diseases, introduced in early 2018. The rollout of such funds has gathered pace in recent months, acknowledging an urgent need to channel financial resources specifically into funding for advanced new medicines.

[13] http://portal.research.lu.se/ws/files/11713673/IHE_Report_2016_4_.pdf

Romania's approach to innovation

In Romania, funding for innovative and speciality medicines is based an assessment of their cost and effectiveness, with co-payments fees reflecting the availability of alternative treatments. However, the process of obtaining reimbursement listings for new medicines is still lengthy.[14] An health technology assessment (HTA) dossier is obligatory for reimbursement, and new products are not available to patients via the statutory national health insurance scheme until all legislative steps are fulfilled, including finalization of cost-volume/ cost-volume-result negotiations, publication of the government decision and therapeutically prescription protocols are completed.

Romania does not have a separate fund for innovative medicines. It does have an early access programme and provision for managed entry agreements, (MEAs) which allows new drugs to be included in the reimbursement list on the basis of a negotiated deal over pricing and access. Such agreements, which are usually done on cost-volume or cost-volume-result basis, face several barriers, however. The therapies must address diseases without therapeutic alternatives and the supplier needs to offer very large discounts for eligible patients. Meanwhile, the application process is often hampered by the lack of staff in the negotiation committee.

The combination of these barriers clearly contributes to Romania's low ranking in terms of access to medicines, and particularly in terms of access to innovative medicines. Rapid growth in healthcare spending and pharmaceutical spending has failed to ease this problem, partly because such increases have been from a low base but also because, owing to the clawback tax, the net increase in spending is less rapid than the gross figures would suggest. The effect of these barriers to treatment can again be seen in Romania's comparatively poor outcomes.

[14] http://health-observatory.ro/wp-content/uploads/2017/11/ORS_TB_report_2017_eng.pdf

Conclusion

The findings of this report demonstrate that investment in healthcare and access to medicines is clearly linked to health outcomes, and also to national economic growth. The rapid development of new medicines, particularly those to treat longer-term chronic diseases, offers hope for patients and for governments seeking cost-effective ways of tackling disease burdens. However, there are wide disparities in the effectiveness and success of these efforts in different countries. Processes to identify and reward clinical and societal value in individual country contexts are necessary to optimise and accelerate the entry of new medicines and to harness the benefits of therapeutic innovation.

In Romania, although much progress has been made in recent years, healthcare and pharmaceutical policies struggle to effectively balance access, expenditure and cost-effectiveness. Overall expenditure on health compares poorly not only in comparison with richer European countries but also in comparison with many countries with equivalent GDP per head. As a result, although Romania ostensibly offers a universal health system to its residents, coverage is poor. The result is that the countries underperforms in terms of health outcomes, most noticeably life expectancy.

The country is also the lowest scoring performer in the EHCI Index's pharmaceutical sub-category, suggesting imbalances in its approach to both generic and patented medicines. A high level of OOP spending in the pharmaceuticals market transfers the burden of payment to patients, with few protection mechanisms in place for those with high needs. The blunt tool of the clawback mechanism, meanwhile, sometimes leads to drug shortages. There are also barriers in terms of administration, which results in delay in approval and reimbursement. Meanwhile, the few mechanisms in place to encourage the adoption of innovative drugs, which could improve health outcomes, fail to operate as needed.

Identifying the problems, however, is the easy part. Far more difficult is the task of identifying firm solutions that are affordable for a country with Romania's level of economic development, that will adapt to changes in economic growth, and that are suitable for both its healthcare system and wider societal values. Such policies need to take into account several complex factors:

- Access: Would patients get the treatment and medicines they need?
- Efficiency: Do policies deliver the most value from the resources invested?
- Equity: Who benefits and who has to pay for services?
- Sustainability: Are policies sustainable over time?
- Implementation: Are the mechanisms viable in a real-world context?
- Incentives: Are the rewards for implementation appropriate, or are there perverse incentives?
- Acceptability: Are key stakeholders and the wider community supportive and supported?
- Transparency: Can policies be scrutinised and corrected as needed?
- Flexibility: Will policies respond to changing social, disease, economic and fiscal factors?
- Impact: How will the success of the policies be measured?

The policy debate

Our analysis of the available data for Romania and 11 other European countries does, however, point to several possible directions for policy that would answer some of these questions.

Healthcare spending

- Given rapid growth in health spending, it is perhaps unsurprising that the debate over healthcare in Romania tends to focus on cost-containment. While efficient use of funds is important, the case for seeing health spending as an investment, rather than a cost, needs to be made more strongly. In this regard Romania has to consider ways to harness all four sources of funding: compulsory health insurance, VHI, government funding and OOP spending.
- A public commitment to a comprehensive package of care, combined with long-term targets for the healthcare system, would serve to frame the annual debate over budgets and deficits. Such targets could include a commitment to raise government health spending as a percentage of GDP to 7%, the average for other new EU member states[16]. In October 2017, Poland adopted just such an approach, when its cabinet promised to raise public health spending to 6% of GDP by 2025, from 4.7% currently.[17]
- There may be opportunities to improve the earmarking of taxes towards healthcare, an approach that the UK is now contemplating. For example, revenue from alcohol or tobacco taxes – which also help reduce public health risks – is supposed to be directed towards healthcare in Romania but the MoH does not always receive the full amount. General improvements in tax collection, aided by recent changes in EU regulations over taxation for online businesses[18], would also release more funds.
- Romania's health insurance system is in theory universal, but in practice covered only 87% of the population in 2016 (latest data). There are inequities in access to services between the rural and urban populations, and underrepresentation for some vulnerable populations including the Roma. Efforts to reduce these gaps need to continue in order to improve inequalities in health outcomes, while efforts to improve the training and retention of doctors and other health workers need to continue.
- The health funding system is overly reliant from contributions from a comparatively small group of people. Reigning back exemptions and ensuring that all taxes are collected would ensure a more equitable sharing of the burden, and make funding more sustainable. Although the contribution system has recently been overhauled, this process is far from complete and the system of exemptions needs to be further refined. Better monitoring of exempt persons and their eligibility criteria would also ensure that contributions are more closely linked to the ability to pay.

[16] http://ec.europa.eu/eurostat/statistics-explained/index.php/Government_expenditure_on_health

[17] http://thenews.pl/1/9/Artykul/331251,Poland-to-increase-health-spending-to-6-percent-of-GDP-by-2025-official

[18] https://ec.europa.eu/taxation_customs/business/company-tax/fair-taxation-digital-economy_en

The balance between public and private

- Like most European health systems, that of Romania is dominated by the state sector. In theory this should help to ensure more consistent access to care, on a more equitable basis. However, in practice, the share of OOP spending in health is very high. Reducing copayments is unlikely to be a sustainable answer to this problem; indeed, there may be areas of the system where small increases in copayments would improve efficiency, while reducing the scope for informal payments that skew incentives within the system.
- Given political realities, however, there is an argument for Romania to expand its voluntary health insurance (VHI) system in a way that is complementary to, rather than destructive of, the public healthcare system. In France, for example, VHI is used to cover copayments as well as additional services. Additional tax exemptions or subsidies could be used to support the rollout of VHI in Romania, while the legal basis to support the sector could be improved.
- Support from private providers could also be enlisted to support expanded access to health, through more flexible provider payment mechanisms that encourage efficiency and excellence. It would be crucial to ensure that a public-private mix in either funding or provision does not increase administrative costs or the opportunities for corruption, however.

Funding for medicines

- One area where Romania clearly needs to improve access is in its pharmaceuticals market. At present it scores particularly poorly in this area in the EHIC assessment, with low rankings in all six areas measure. Pricing and reimbursement policies in Romania are largely geared towards the provision of generic medicines. Although these may offer the lowest list prices, they may not actually be the most cost-effective or appropriate treatments in every case.
- In many cases innovative medicines offer an opportunity not only to improve patient outcomes but also to reduce future healthcare costs. Elsewhere in Europe there has been a steady stream of new mechanisms, including the Innovative Fund in Italy or the Cancer Drug Fund in the UK, that offer examples of how funding for innovative medicines can be made affordable and sustainable, by side-stepping annual budgetary limits.
- Romania has also improved access to new innovative medicines since 2014, with an increase in funding and updates of its reimbursement lists. However, the challenge is to sustain this funding, and to continue to improve and develop the HTA system. At present Romania largely adopts HTA decisions made in other countries, such as the UK.
- In future such efforts could include a commitment to shift towards value-based assessment, where the true value of medicines to the Romanian population is reflected in reimbursement decisions. A relaxation of reference pricing systems in the wider region could also allow more scope for differential pricing, balancing affordability with access while taking into account different income levels in Romania.

Administrative barriers to treatment

- As well as financial barriers, delays in the system often act as a disincentive for the launch of medicines. In Romania, for example, the delay between registration of a new medicine and that product being included in the reimbursement system is more than 300 days, according to the EHIC.
- In many cases these delays reflect cumbersome regulations or administrative processes. In others it reflects poor staffing levels in key organisations, including the MoH and the ANMDM. A 2017 technical assistance report by Oxford Policy Management UK, Imperial College London and Management Sciences for Health concluded that Romania's HTA agency needs at least 20 staff, not the six currently employed.[19]
- The unpredictability of decisions also acts as a deterrent for pharmaceutical companies. Sporadic updating of reimbursement lists, complex budgeting rules, or inconsistent application of funding principles effectively impose costs on suppliers, making it difficult for them to plan and cost the rollout of treatments.
- The rollout of MEAs in Romania has improved access to medicines. However, after two year of implementation, the cost-volume legislation has arguably reached its limits. Romania is one of the few countries in EU that has implemented only two types of MEA (cost-volume and cost-volume results) despite an increase in unmet needs.

Any effort to increase funding in one area will inevitably result in opportunity costs elsewhere, and it is up to Romania to decide on its own health funding priorities. However, there are lessons to be learnt from this comparison of 11 other European countries, many of which face similar challenges to Romania in terms of ensuring universal access while containing rising healthcare costs. The biggest is that there is a direct link between investment in health and national productivity, as well as national wellbeing.

[19] http://www.ms.ro/wp-content/uploads/2017/05/Inception-Report-en.pdf

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