

Investing in healthcare:

Options for alternative financing of healthcare in Romania

A report by The Economist Intelligence Unit



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Introduction

In January 2018, The Economist Intelligence Unit (EIU) began a project, sponsored by the Local American Working Group (LAWG) in Bucharest, the association of research-based pharmaceutical companies, looking at the Romanian healthcare system. Our joint aim was to identify ways that Romania could improve access to care and medicines for its citizens, by drawing on lessons from other European healthcare systems.

The project was a complex one, designed to provide robust evidence that could underpin future reforms in Romania. We began with a systematic and detailed review of how 12 European countries currently structure and manage their healthcare funding. The countries surveyed – Austria, Belgium, France, Germany, Hungary, Italy, the Netherlands, Poland, Slovakia, Spain, the UK and, of course, Romania – 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.

Our task was to highlight the differences and commonalities in their approaches to healthcare financing and policy, in order to identify best practices that were worth exploring or copying elsewhere. We also aimed to benchmark Romania's healthcare services and medicine supply system against these findings, in order to discover where it performs well and where the gaps in its healthcare system lie.

Following four months' research, we produced an in-depth report outlining our research, as well as an executive summary outlining 16 policy directions that Romania could take. Bearing these, we then invited a number of experts, politicians and senior healthcare policy-makers to a technical consultation in Bucharest to discuss our recommendations, in order to determine their benefits, their drawbacks and their feasibility. In this way, we could have a realistic discussion about how to enhance healthcare and medicines funding in Romania.

This document reflects both our original research and the discussion at the expert meeting. It therefore contains:

- An executive summary of the research contained in our in-depth report, a copy of which is available on request. See pages 5 to 13.
- Our 16 original proposals, which were used as the basis for our expert discussion. See pages 15 to 18.
- The experts' responses to these proposals, as well as their additional thoughts. See pages 15 to 18

Key areas for discussion

Both the report and the discussion in Bucharest focused on four policy areas, which together determine how well Romania's healthcare system delivers treatment to its citizens.

- **Healthcare spending.** As our research confirmed, Romania's healthcare spending is low, both in absolute terms and as a share of GDP, compared with that of its European neighbours. Although spending is rising rapidly, this gap has a direct impact on Romania's healthcare outcomes. Our expert panel therefore discussed whether Romania could bolster its national health insurance system by

setting long-term spending targets, as well as how it could best improve the sustainability of the system in a way that balances Romania's limited income against its growing expenditures. This debate encompassed questions about the level of insurance contributions and the number of exemptions from these payments.

- **Balance between public and private.** Romania's healthcare system is dominated by the public sector, with private spending mostly coming from out-of-pocket payments that are high in comparison to national incomes. Our experts debated whether encouraging a voluntary health insurance system to develop that complements, rather than competes with, the public system would improve access to care. They also explored ways that private providers could take the strain off public facilities and whether co-payments could be usefully raised in some areas, by looking at examples from other countries that have this experience.
- **Funding for medicines.** Data suggest that Romania's access to innovative medicines lags behind that of other European countries, affecting health outcomes, particularly for non-communicable diseases. Efforts made by authorities during the last years in order to increase patients' access to innovation and to narrow the gap between Romania and other EU member states are visible. Therefore, the experts debated ways of increasing funding, as well as methods of shifting the focus away from price and towards value.
- **Administrative barriers.** Access to medicines and treatment in Romania is currently hampered by administrative barriers, including delays in the reimbursement system and unpredictable updating of drug lists, as well as policy changes and uncertainties. The experts debated how such barriers could be reduced and investment in the system encouraged.

The discussion in Bucharest was an extremely fruitful one, but it is not yet at an end. Identifying the problems and possible solutions is useless unless they can be refined and implemented in a way that really does enhance Romanians' access to care and treatments. Moreover, 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. Some of the proposed solutions are multi-faceted and adaptable, and our hope is that other countries can also learn from this research as they try to find answers to their own healthcare challenges.

The experts at our meeting are directly involved in these ongoing debates, but we also welcome comments from all those reading this report. Please contact us at: uiuhealthcare@economist.com

Acknowledgements

We would like to express our gratitude to the 13 experts who joined our expert meeting in Bucharest on April 26th. In order to facilitate discussion, it was agreed that their names and job titles, as well as those of the numerous observers at that meeting, would be kept confidential. However, their energy, enthusiasm and expertise have contributed significantly to this report and, we hope, have furthered a debate that will eventually deliver better care and treatment to Romanian citizens. These experts' roles spanned institutions including: the Senate; the Chamber of Deputies; the Ministry of Public Finances; the Fiscal Council; the National Health Insurance Fund; the National Medicines Agency; the Academy of Economic Sciences; the University of Medicines and Pharmacy, other technical experts and LAWG.

Executive summary of the EIU extensive research report

A full copy of this report is available on request

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 income¹. Good health boosts labour productivity and improves returns on investment in education. Improved access to healthcare and medicines leads to longer life expectancy². 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

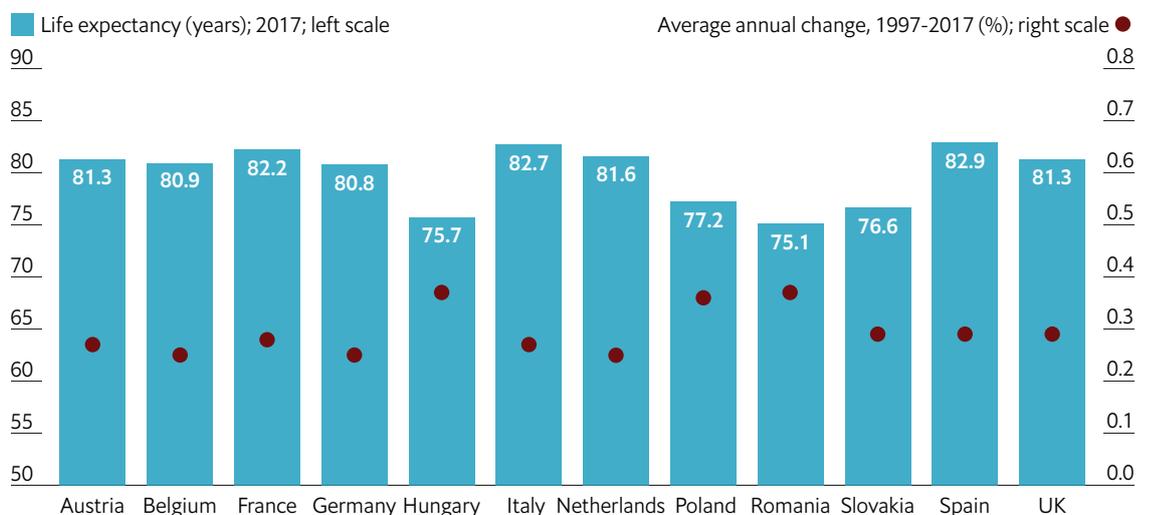
While investment in health is therefore crucial, cost-pressures in healthcare systems in Europe and elsewhere have grown due to a combination of factors. These include ageing populations and shifting

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.

Average life expectancy in 2017



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

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.

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.

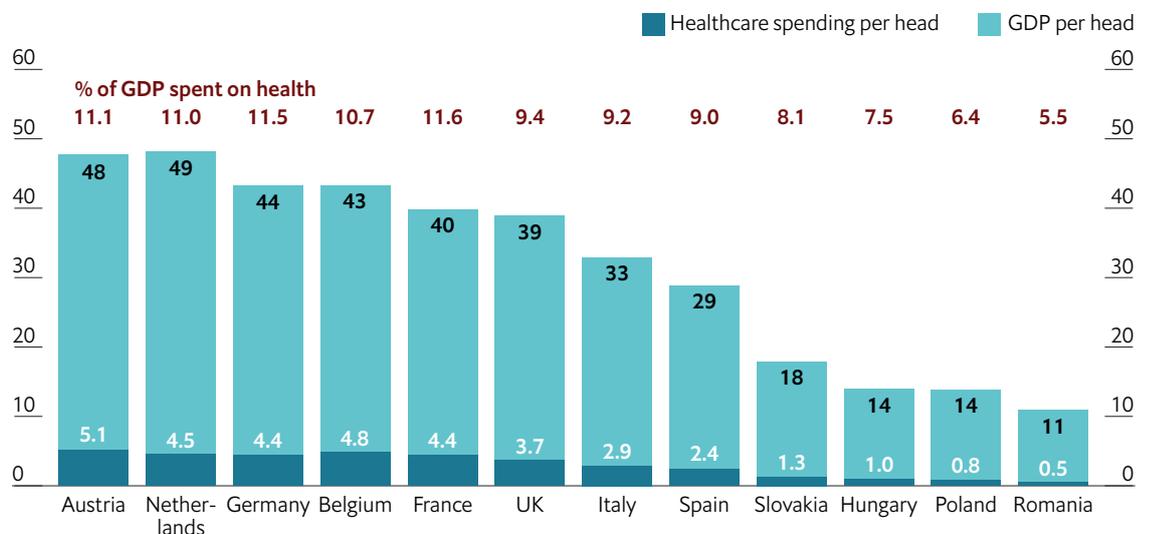
Romania's total expenditure (public and private) on healthcare amounted to an estimated 5.5% of GDP in 2016, according to The Economist Intelligence Unit. Despite rapid spending growth in recent years, this remains lower than the average of 8.1% for EU members and among the lowest share of any EU state. 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 comes 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).

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

GDP per country and healthcare budgets 2016

(US\$ at PPP)



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

⁵ Economist Intelligence Unit data

Sources: World Health Organisation; The Economist Intelligence Unit.

for vulnerable groups. Government reforms focus on efficiency gains and shifting expenditure away 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 reporting⁶. 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.

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

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 of the 12 countries, at 319 deaths per 100,000 inhabitants,

compared with an EU average of 126. Despite its considerable progress over the past two decades, it also has the lowest life expectancy in the group.

Romania's access to medicines

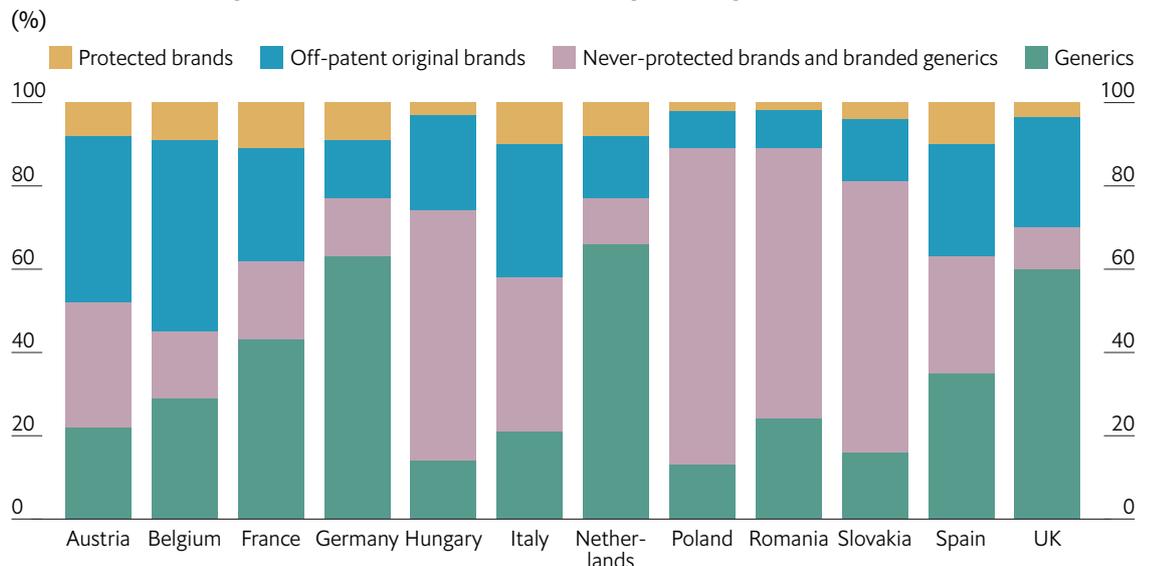
Access to health treatment is heavily dependent on the availability of affordable medicines.⁷ Pharmaceuticals play a crucial role in the health system and medicine innovation can lead to cost savings through the reduced use of health services, particularly expensive in-patient care⁸. Efficient deployment 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

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.

⁷ [http://www.europarl.europa.eu/RegData/etudes/STUD/2016/587304/IPOL_STU\(2016\)587304_EN.pdf](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. https://ec.europa.eu/health/sites/health/files/state/docs/health_glance_2016_rep_en.pdf

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 volume 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.

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 Economics¹³ 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 (to some extent) 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.

Snapshot of Managed Entry Agreements

Managed Entry Agreements and risk-sharing schemes for new and expensive medicines are expanding. These include:

- **Price–volume agreements (PVAs):** a spending threshold is set, and a rebate is paid on the price of additional doses when the threshold is exceeded; these are the most common managed entry agreements, with various such schemes adopted in Belgium, Germany, Hungary, Poland, France, Italy and the UK.
- **Discounts and rebates;** the list price is paid in full and then an agreed rebate is paid by the manufacturer; there are examples of this approach in Italy and the UK.
- **Capping schemes:** set a cap on total treatment cost, or the number of doses or patients that are funded, or on the duration of treatment that will be covered by the public payer. Belgium and Italy operate managed entry agreements that limit the number of patients that can access a new treatment through public funding. Some patient and cost-cap agreements also take place in Belgium and England. As well as controlling the impact of budgets, this approach is intended to target patients with the most need and to minimise the potential impact of any adverse reactions to new medicines.
- **Health outcome-based agreements:** these can be payment by the results achieved by a medicine according to set thresholds that define success. These are relatively new, but some schemes exist in Italy and the UK.
- **Public coverage with evidence development:** where provisional reimbursement is granted, despite more evidence being required by authorities to make final reimbursement decisions. The manufacturer is required to collect additional specific evidence. This approach is often used for managed entry agreements in the Netherlands.

Sources:

<http://apps.who.int/medicinedocs/documents/s21793en/s21793en.pdf>
http://eprints.lse.ac.uk/68290/7/Wouters_Pharmaceutical_regulation.pdf
WHO Health System Reviews (HiTs), country reports.
The Economist Intelligence Unit

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

The rollout of innovation funds

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.

In Italy, since 2017 €1bn of the annual government budget has been set aside for the purchase of new medicines, with half spent on oncology drugs and half on other innovative drugs. Then in February 2018 the government introduced a new Innovative Drug Fund in 2017, acknowledging an urgent need to channel financial resources specifically into funding for advanced new medicines.

In February 2018 the Spanish MoH launched a new financial model to fund treatments for rare diseases and conditions, as previously announced by the Interterritorial Council in June 2017. The model was initially developed for just one drug: Biogen's Spinraza, the only treatment currently available for spinal muscular atrophy, a rare condition of which there are around 300 to 400 patients in the country. However, the new programme will eventually be extended to new drugs and treatments for other rare conditions that come with a high financial impact.

The UK, under pressure from the public, introduced a specialist Cancer Drugs Fund in 2010. Originally intended to be temporary, it was formally brought under the control of the National Institute for Health and Care Excellence (NICE) in 2016. The fund aims to provide access to recommended new medicines not ordinarily available through the national health system (NHS), via a managed access arrangement. The CDF will fund a new oncology medicine until more information on its effectiveness can be considered for routine commissioning.

Romania's approach to innovation

In Romania, funding for innovative and speciality medicines is based on 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 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. Additionally, Romania's current HTA guidelines do not facilitate comprehensive evaluation of new medicines, as they focus on cost-saving elements and side-line efficacy and safety.¹⁵

Romania does not have a separate fund for innovative medicines. It does have an early access programme and provision for managed entry agreements, 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.

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

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.

Conclusions of the EIU report

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 country under-performs 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?

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.

All this points to the need for Romania to find new sources of funding that are politically and economically feasible in order to increase its overall investment in healthcare and treatments and make its universal healthcare system truly universal and sustainable. However, in order to maximise the benefits from such investment, it also needs to ensure that funding is directed towards interventions that really make a difference to people's health, including innovative treatments. It also needs to allow more choice within the system to ensure that public support and solidarity remains strong. That requires more real world data, better analysis of that data, and more flexibility in its funding approaches.

The EIU proposals and the experts' response

Our analysis of the available data for 12 European healthcare systems points to several possible directions for policy that would help Romania to improve access to care and treatment for its citizens. The original proposals drafted by the EIU and LAWG are outlined here, along with our experts' responses to them at the debate in Bucharest on April 26th 2018. Please note that there was not time to debate all the proposals in full.

Healthcare spending

Outcomes of the EIU report

- 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 businesses¹⁸, would also release more funds.
- Romania's health insurance system is in theory universal, but in practice covered only 86% of the population in 2015 (according to the OECD). 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. Reining 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

Feedback from the experts

The experts generally agreed that Romania's healthcare spending is too low, and that this is one of the most important issues the country faces. They agreed that a rise in healthy life expectancy has a direct impact on both living standards and on the country's economic growth. Some experts suggested that Romania should **target total expenditure of 6% of GDP on healthcare**, and that the government should focus on allocating the funds necessary for this priority sector in Romania.

However, they pointed to several difficulties with raising expenditure. One is the need for Romania to spend heavily on other areas connected with its development strategy and geopolitical situation. Another is the challenge of ensuring the sustainability of the health insurance system in the context of falling birth rates, ageing populations and the emigration of many working-age Romanians. Furthermore, the trend in recent years has been to reduce contribution rates to healthcare.

The experts suggested that one option is to **tackle the high levels of tax avoidance** within Romania, as well as the widespread exemptions from CNAS contributions. Together, these mean that the collection base for the national healthcare system is too narrow. Some experts also felt that **the government should match the general contribution rate** when covering vulnerable groups, rather than simply covering the current cost of treatment. This would reduce the regular transfers CNAS needs from the government budget to underpin its finances. They also pointed out that there is often a huge gap between the official insurance coverage for treatment and the real cost of such treatment.

The balance between public and private

Outcomes of the EIU report

- 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 co-payments is unlikely to be a sustainable answer to this problem; indeed, there may be areas of the system where small increases in co-payments 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.

Feedback from the experts

The idea of encouraging the expansion of a **complementary VHI system** was perhaps the most popular of the EIU's original proposals. Experts pointed out that the private share of total health expenditure in Romania has already increased by two percentage points over the past five years (from 20% to 22%), and there is still room for growth.

Private insurance would help to reduce the level of OOP payments; it could, for example, be used to cover co-payments, as it is in France. However, additional mechanisms would be needed to ensure that the expansion in private health insurance does not create inequalities in the system or increase administration costs.

A two-pillar system, with more efficient packages involving both the public health insurance system and a complementary private one, was one option discussed, based on the best practice of other EU countries. Other suggestions included following the model in the Netherlands, whereby obligatory health insurance is provided by private insurers, under state oversight and regulation.

Some experts also felt that private care providers who deliver public healthcare services are filling important gaps in delivery and quality of health services in Romania. Around one-third of

hospitals in Romania are already privately owned and many of them provide services reimbursed by the public system.

Even so, most of the experts agree that the priority should be a **refocusing of the public care system towards primary and preventative care**, reducing its current reliance on tertiary care. This may include encouraging general practitioners to be more pro-active in identifying the real need for specialised healthcare services. There was also considerable support for provider payments being distributed on the basis of diagnosis-related groups. They should also be more closely aligned to regional needs, with the District Public Health Authority determining on how funds are shared across the country.

Funding for medicines

Outcomes of the EIU report

- 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 EHCI 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.

Feedback from the experts

Presented with the European comparison, the experts agreed that improving access to innovative medicines is desirable, and felt that an overall increase in health expenditure would be the best way to address this problem. However, they were concerned about how best to prioritise resourcing so that outcomes are maximised. They pointed to significant progress in the development of the HTA system in Romania, the allocation of funds for managed entry agreements and mentioned a new methodology of per programme budgeting that is due to begin in 2019.

The experts also wondered how the UK's exit from the EU in 2019 (Brexit) would affect the EU drug market. They then briefly debated the effects of Romania's clawback tax, whereby all pharmaceutical

companies have to pay a proportion of their sales back into the healthcare system. Originally introduced as a method of cost control during the economic downturn, this is increasingly seen as a blunt instrument with some unwanted side-effects.

They also pointed to issues related to the reimbursement methodology used by Romania. The HTA system only compares the prices of medicines and it does not assess the impact of a treatment on the system costs. The experts instead advocated for a shift towards value-based assessment, whereby the true value of medicines to the Romanian population is reflected in reimbursement decisions. In this way, the high cost of research-based pharmaceuticals could be seen in the context of how they add value rather than costs to a system.

Administrative barriers to treatment

Outcomes of the EIU report

- 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 EHCI.
- 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 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.

Feedback from the experts

The experts conceded that there have been considerable delays in the approval and reimbursement systems for new medicines in Romania. Although HTA efforts started in 2008 in Romania, policies were only fully implemented in 2015. Drug lists were also not updated during the 2008-2015 period. However, they pointed to considerable improvements in recent months, when 118 molecules were approved by the National Agency for Medicines and Medical Devices (ANMDM).

In terms of policy-making, they pointed out that the National Healthcare Strategy 2020 does provide an overarching framework. However, they agreed that Romania's healthcare system does suffer from inconsistencies. To tackle this, and to underpin a more value-driven approach to care, there needs to be better coordination, and better analysis of healthcare data, so that policies and spending can both be geared towards improving overall outcomes.

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

Final remarks from the EIU

The issues presented in this report are complex ones. Like their European colleagues, Romania's policy-makers see universal access to healthcare, efficient distribution of resources, high-quality services and optimal treatment efficacy as fundamental objectives for their country's healthcare system. They have introduced numerous measures over the past few years to move towards these objectives, with considerable success. Average life expectancy has increased by three years over the past decade, while the infant mortality rate has dropped by nearly one-third. Moreover, Romania has achieved this despite facing far greater funding constraints than any of the other 11 countries covered in this report.

Yet our comparison of these countries still shows that there is more that could be done. As part of their own efforts to balance access to care against cost constraints, EU countries have adopted diverse approaches to healthcare financing, health system organization and spending priorities. They have also introduced several different strategies for funding, selecting, purchasing, pricing and distributing pharmaceuticals. Gradually a consensus is emerging about which of these approaches are the most cost-effective.

Not all of these lessons will be applicable to Romania. 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 priorities. The country also faces its own set of political, economic, demographic and social challenges. Nevertheless, as it looks for extra sources of healthcare funding and new approaches to care, there are plenty of lessons that Romania can learn from the successes and the failures of its European neighbours.

About EIU Healthcare

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