The Economist INTELLIGENCE UNIT

HEALTHCARE

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

Introduction: 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. The positive economic effects of investment in healthcare are apparent at both an individual and a macro-economic level[1]. While a country's health outcomes and economic performance are clearly interlinked, proving the direction of causality is complex.[2] Clearly wealth is a factor in improved health. Higher incomes stimulate better living standards, nutrition, sanitation and greater access to healthcare services, and, cumulatively, improve national health indicators;[3] Wealthier countries have healthier populations, but they also spend more on health – both in per capita terms and as a proportion of GDP[4].

However, there is a growing body of evidence revealing that good health is a cause, as well as a consequence, of higher income[5]. Good health boosts labour productivity and improves returns on investment in education. Improved access to healthcare and medicines leads to longer life expectancy.[6] 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.[7]

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.

The health of a population and the economic returns from investment in health do not depend just on general standards of living, or just on total national expenditure on healthcare, but also on the actual design and performance of the health systems themselves. These systems need to be comprehensive, reliable and capable of ensuring high standards. However, they also need to be efficient and cost-effective so that they provide a good return on health investment.

Key aims in healthcare

Against this backdrop, Europe's national policy makers have broadly targeted universal access to healthcare, efficient distribution of resources, high-quality healthcare services and optimal treatment efficacy as fundamental objectives for their countries' health systems. National governments aim to

1. 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.

2. Esteban Ortiz-Ospina and Max Roser (2018) - "Financing Healthcare". *Published online at OurWorldInData.org*. Retrieved from: 'https://ourworldindata.org/financing-healthcare'

3. 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.

4. Esteban Ortiz-Ospina and Max Roser (2018) - "Financing Healthcare". *Published online at OurWorldInData.org*. Retrieved from: 'https://ourworldindata.org/financing-healthcare'

5. Economic growth and healthy populations in developing countries: A summary of recent literature, EIU 2016

6. 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.

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

strike the right balance between demand, costs and available funds. However, there is broad consensus that timely access to effective medicines is critical to improving a population's health and for optimising return on investment in all other health resources.[8]

Despite the consensus over these objectives, European countries have adopted diverse approaches to healthcare financing, health system organization and spending priorities. There is a broad spectrum of strategies for funding, selecting, purchasing, pricing and distributing national supplies of essential, generic and innovative pharmaceuticals and biologics. Governments also have different policy responses to immediate cost pressures in all these areas. [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.[10] 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.[11]

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)[12]. Compulsory expenditure (mostly via the national health insurance system) accounts for 78% of total spending, with 22% coming from private expenditure. As a result a considerable proportion of health spending is swallowed by a population with comparatively low incomes.

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). 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.[13]

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 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[14], out of a total population of 19.71m, according to CNAS statistics. This equates to 87% of the population. Access to health care is especially poor in rural areas, often exacerbated by gaps in

8. Pharmaceutical Financing Strategies. In World Health Organisation (2012). MDS-3: Managing Access to Medicines and Health Technologies, Chapter 11.

9. Saltman, R., Rico, A., & Boerma, W. (2004). Social health insurance systems in western Europe. McGraw-Hill Education (UK).

10. The Economist Intelligence Unit

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

12. The Economist Intelligence Unit

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

14. http://www.cnas.ro/theme/cnas/js/ckeditor/filemanager/userfiles/Rap_act/RAPORT_ACTIVITATE_2016_.pdf

population monitoring and reporting[15]. 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 included in this report. Despite its considerable progress over the past two decades, Romania also has the lowest life expectancy in the group.

The aims of this report

All of these issues are explored in more detail in this report, which 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.

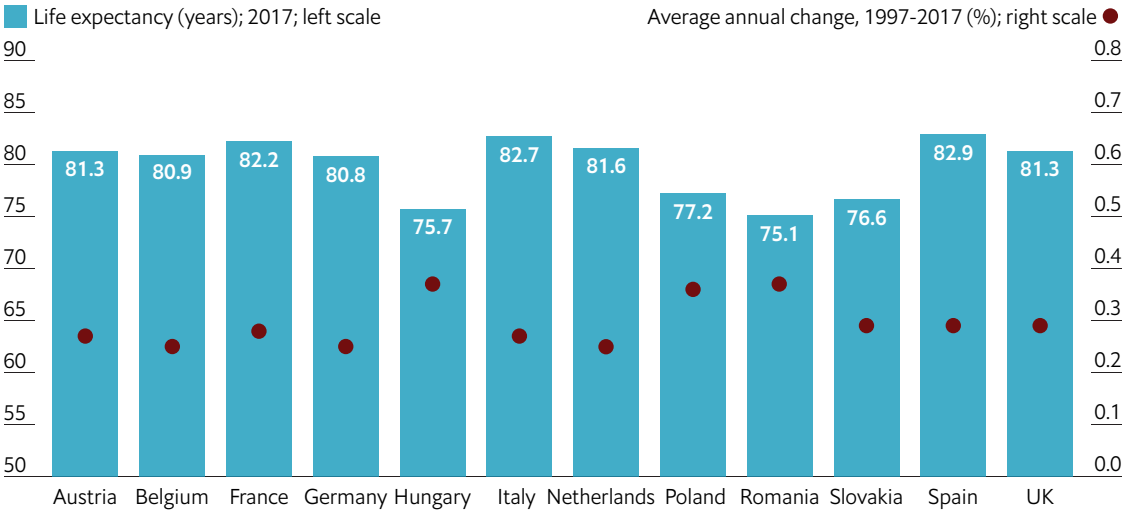
The final section of this report focuses on ways that European governments try to improve access to medicines that may have a direct impact on health outcomes, including survival rates from cancer and other life-threatening diseases. Although Romania has improved access to treatments, particularly for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

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.

15. https://ec.europa.eu/health/sites/health/files/state/docs/chp_romania_english.pdf

Health and wealth: How the two are related

Figure 1: Average life expectancy in 2017



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

While average life expectancy across Europe has continued to rise in the past 20 years, the rate of improvement has slowed in recent years (2015-17) in several countries. In Austria and France, for example, the number of extra months gained each year has slowed from nearly four a decade ago to less than two in the most recent data.

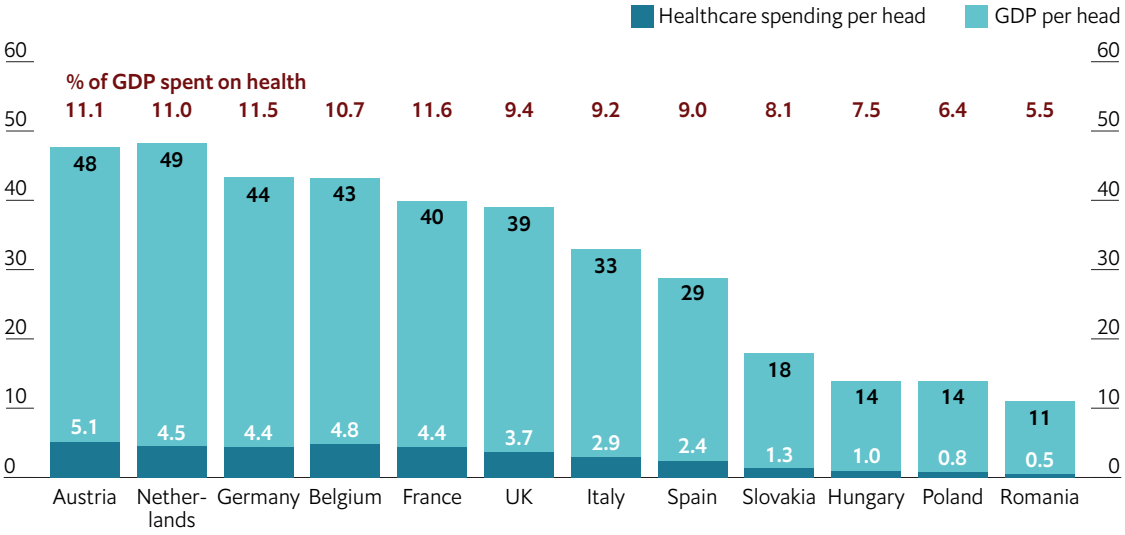
Life expectancy in Eastern Europe has risen rapidly over the past two decades, with Romania among the countries benefiting from a significant improvement in population outcomes. However, there remains a gap in average life expectancy between the new EU member states covered in this report – Hungary, Poland, Romania and Slovakia – and the eight older EU member states under review. This gap is in line with a vast East-West disparity in per capita healthcare expenditure in US dollar terms.

Some of this slowdown reflects the increasing difficulty of improving health at older ages, when people require far more care. However, literature on the relationship between economy and healthcare indicate the likelihood of a 'lag' in the health effects of economic downturns and policy changes. This means that in many countries, including Romania, the effect of real-terms cuts in health expenditure in 2009-10 are only now starting to be felt in terms of life expectancy.

Across the 12 European countries included in this report, expenditure on health (both nominally per head and as a share of GDP) is clearly linked to wealth, measured here in GDP per head in US dollar terms *(Figure 2)*. Levels of health spending vary from less than US$600 per year per capita in Romania to over US$5,000 in Austria, or from 5.5% of GDP to 11.6% in France. Overall, Eastern European countries have lower GDP per capita (less than US$20,000) and spend less on healthcare.

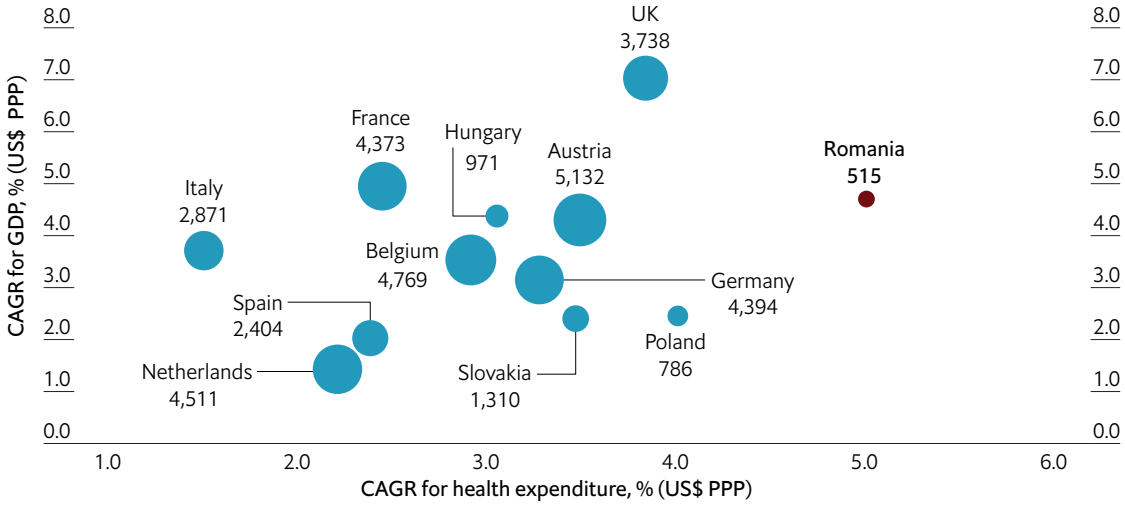
Growth in health spending, although it is also driven by factors such as population, is also clearly related to economic growth, as tax revenues and social insurance payments rise along with

Figure 2: Health expenditure and GDP per head in 2016
(US$ at PPP)



Sources: World Health Organisation; The Economist Intelligence Unit.

Figure 3: Five-year growth rates: health v GDP (2012-16)



Sources: World Health Organisation (WHO); The Economist Intelligence Unit

employment and wages. This chart *(Figure 3)* shows growth in health spending in purchasing power parity (PPP), which takes into account differing living costs, against GDP growth in PPP terms.

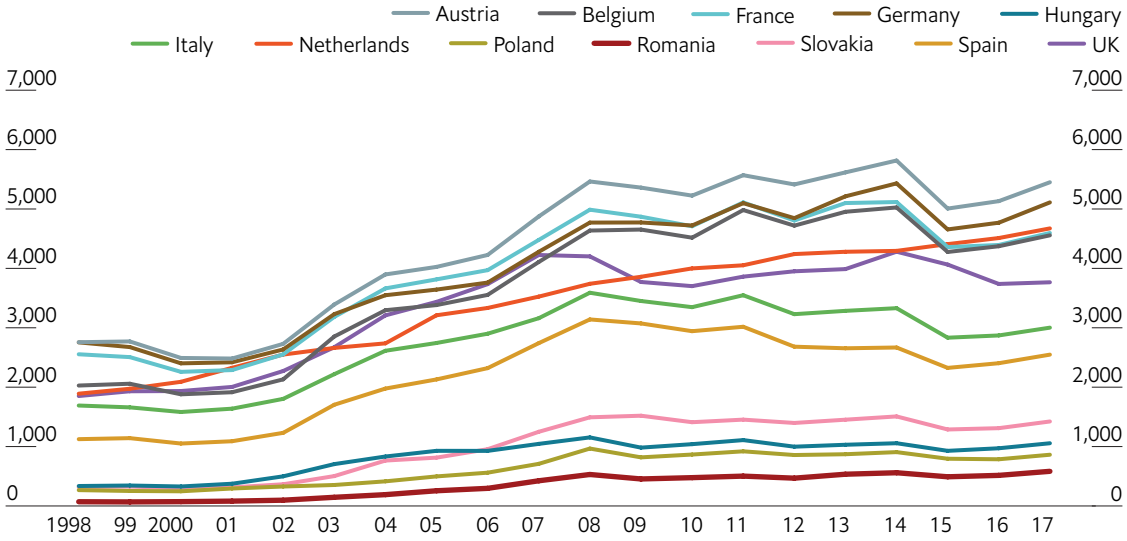
It demonstrates that countries such as Italy and Spain, which saw slow economic growth on average in 2012-16, were forced to constrain health spending, while countries such as Poland and the UK took advantage of an economic expansion to invest in their healthcare systems. Indeed, the compound annual growth rate (CAGR) for UK health expenditure, in PPP terms, was nearly twice as high as that for GDP. Overall, however, seven of the 12 countries saw health spending grow faster than the economy.

Romania, however, is among the five countries where GDP growth, at a CAGR of 5%, has outstripped health spending, with a CAGR of 4.7%. Although Romania's health spending growth has

been rapid, moreover, it has not been as rapid as in some countries starting from a far higher base, such as France and the UK. This may reflect Romania's comparatively young population, but it also points to continuing financial constraints.

Financial resources are identified by health professionals as the most important factor affecting the quality of healthcare. Dramatic fluctuations in health spending, or a long-term trend of inadequate financing, can both impact negatively on planning and services. Health financing systems are key to determining how healthcare systems weather economic pressures and how well equity and quality are protected.

Figure 4: Healthcare spending total
(US$ PPP)



Source: The Ecconomist Intelligence Unit, based on WHO data.

The lingering effect of the 2009-10 economic crisis

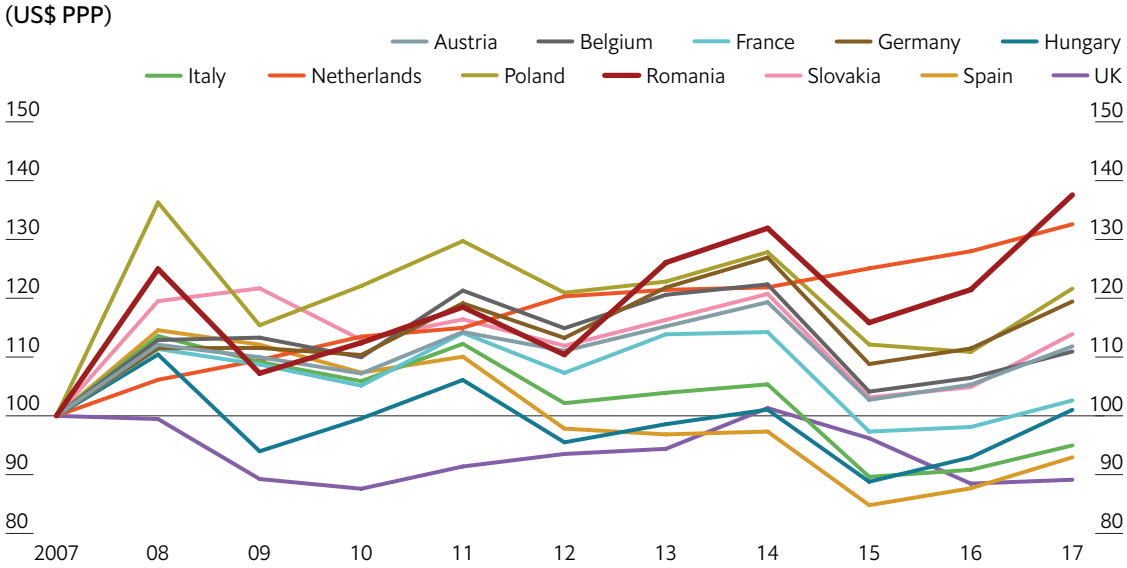
As described in the previous section, there is a large gap between the newer and older EU member states in terms of how much they spend on health per head in PPP terms. This gap has not noticeably narrowed over the past two decades, even though Romania, along with Hungary, Poland and Slovakia, has seen more rapid growth in health spending than its Western neighbours. This higher growth rate largely reflects their low starting point as well as pressures such as rising wages.

However, when we rebase the data over a 10-year trend to give a uniform starting point *(Figure 5)*, it becomes clear that Romania saw relatively slow growth in its total health expenditure to 2015. This is despite Romania's strong economic growth from a low base. Only Italy and Hungary have seen slower growth in these terms.

The impact of inadequate healthcare

To demonstrate how inadequate financing affects health it is useful to compare outcomes. Romania performs poorly on several of the indicators commonly used to assess population health, including life expectancy at birth *(see Figure 20)*, infant mortality *(Figure 22)* and maternal mortality. In all these

Figure 5: Healthcare spending rebased, 2007=100
(US$ PPP)

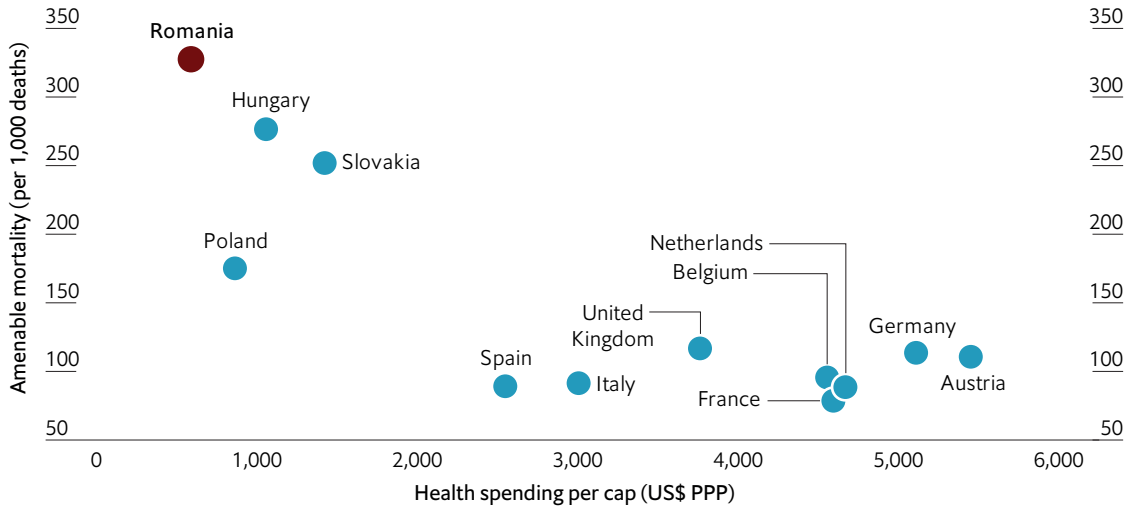


Source: The Ecconomist Intelligence Unit, based on WHO data.

cases, Romania's outcomes are the worst of the 12 countries compared in this report. However, while Romania's poor performance on these indicators is undoubtedly partly a reflection of inadequate healthcare, including vaccinations, they are also closely linked to living standards, public health risks and the country's wealth levels – factors that are outside the remit of this report.

A more useful indicator of the direct harm done by healthcare systems, however, is provided by amenable mortality rates[16], which measure the proportion of deaths that would have been avoided if patients had better access to optimal quality healthcare and medicines. These vary widely in the 12 European countries under review, but correlate strongly with levels of per capita healthcare spending as shown in *Figure* 2. Romania, which spends the least, has the highest average amenable mortality rate of the 12 countries, at 319 deaths per 100,000 inhabitants, compared with an EU average of 126.

Figure 6: Amenable mortality v health expenditure, 2017



Sources: Eurostat, The Economist Intelligence Unit.

16. http://ec.europa.eu/eurostat/statistics-explained/index.php/Amenable_and_preventable_deaths_statistics

Romania, along with Hungary, also performs poorly on a related measurement – preventable deaths – which is a broader indicator of those deaths that could have been avoided. In total, Eurostat concludes that across the EU, over 562 000 deaths could have been avoided in 2014 (latest data) if healthcare systems had offered more timely and effective medical treatments (amenable deaths). Meanwhile, close to 1m deaths could have been prevented through better public health interventions (preventable deaths).

The leading cause of amenable deaths in the EU is ischaemic heart disease, followed by cerebrovascular diseases, colorectal cancers, and breast cancer, according to the Eurostat data. Other leading causes include hypertensive diseases and pneumonia. In all these cases there are well-recognised and effective treatments that could be offered to patients, while many cases could also have been prevented through better health interventions. Research by pharmaceutical companies into all these areas also promises further breakthroughs, as long as patients are able to access the resulting new treatments.

Health funding systems: The European way

In all 12 countries covered in this report, public funding accounts for the lion's share of total health expenditure. This is in line with a Europe-wide tradition that began in the first half of the twentieth century[17] and took hold with a political shift to the left after the 2nd World War as governments answered popular demands for universal access to healthcare regardless of ability to pay or health status.[18] Three main forms of public health systems, both entailing compulsory financing, developed:

The first are **Bismarck systems**, such as those in Belgium, France, The Netherlands and Germany, which are based on social insurance. These are generally organised through not-for-profit public insurance funds, or 'sick-funds' - and financed mainly by employer-employee contributions through payroll deductions.[19] Doctors and hospitals tend to be private operators, but a tradition of tight regulation affords the government much of the cost-control power that is seen in the single-payer Beveridge model.[20]

The second group consists of **Beveridge systems**, such as those in the UK, Spain, Italy and some Nordic states. Here, public health financing is organised through single tax-financed structure, such as the UK's National Health Service (NHS), much like other public services such as police forces. Under this system, many hospitals and clinics are government-owned and some doctors are government employees. However, there are also private doctors who collect fees from the government and are government-regulated. As the sole-payer, the government tightly controls what doctors treating NHS patients can do and charge. While most services are free at the point of service, co-payments are generally charged for medicines and some services such as dentistry.[21]

The third group contains the **Semashko systems** generally adopted in the former Eastern Bloc. In line with the bloc's nationalised economies, the Semashko system was based on state financing, central planning and management, state control over health services and free access at the point of delivery.[22] As part of their transitions to market economies, the newer EU member states have mostly undergone a transition from the Semashko model towards the Bismarck social insurance model. However, some (notably Slovakia) have incorporated aspects of the single-payer Beveridge model.[23] The development of a new healthcare system in Romania has been particularly difficult due to the severe and enduring underfunding of the healthcare system under the Ceausescu regime, which left the country with an extremely low quality of infrastructure and medical equipment.

Regardless of the model, healthcare systems in all the European countries covered by this report have deep roots in the primary principals of universality, equity and solidarity. By sharing funding obligations amid the whole population, they aim to provide care to all citizens when needed and reduce the financial risks associated with ill-health or old age. In these terms they have largely been successful, with some caveats.

Although health systems are in theory universal, coverage may not be complete. In Romania, 13% of the population was not covered by the health insurance system in 2016, according to CNAS data. This makes Romania one of just a handful of EU members (others include Bulgaria, Cyprus and Greece) where more than 10% of the population was still not consistently covered for healthcare costs that year.

17. Financing Healthcare: https://ourworldindata.org/financing-healthcare

18. Saltman, R., Rico, A., & Boerma, W. (2004). Social health insurance systems in western Europe. McGraw-Hill Education (UK).

19. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4570753/

20. http://www.pnhp.org/single_payer_resources/health_care_systems_four_basic_models.php

21. http://www.pnhp.org/single_payer_resources/health_care_systems_four_basic_models.php

22. http://neuron.mefst.hr/docs/CMJ/issues/2002/43/4/12187523.pdf

23. http://www.bmj.com/content/316/7142/1468.2

Moreover, while universal coverage is a key indicator of access to healthcare it is not a guarantee of equity. Even in some supposedly universal systems coverage may be shallow or uneven, leaving some patients facing out-of-pocket (OOP) charges or needing to take out private insurance to cover their unmet healthcare needs. In some countries, such as France, health policies are designed to encourage and enable this, with private insurance incorporated as a key element of the public system.

Fighting funding constraints

Moreover all European countries are finding that adhering to these underlying principles inevitably leads to rising expenditure as populations grow and age, quality expectations rise, and more advanced medical treatments are developed. In the face of these trends, national policy-makers in all 12 countries have had to address the long-term tension between the need to provide quality healthcare equitably and the need to keep healthcare spending sustainable for the rest of the economy. Moreover, policy-makers have also faced short-term challenges, notably economic downturns, public outcries or changes of government, that have forced them to introduce measures that may adversely affect health provision in the longer term.

In all 12 countries under review, the trend in recent years has been towards cuts in core services and treatments, and rises in OOP payments. In many countries, reimbursement rates have fallen, while user charges and co-payments have risen. Policy-makers have generally tried to mitigate the adverse effect of such measures on population health by including exemptions or subsidies for economically vulnerable sections of the population and / or those suffering with chronic and long-term illnesses. Many also impose caps on the maximum annual OOP payments for public health services and products.

In those countries that operate healthcare systems based on the Bismarck health insurance model, there have also been efforts to diversify revenue streams. Taxes or central government transfers are often used to supplement social insurance funding; the aim is to render public health insurance revenue base less vulnerable to the impact of wage and employment fluctuations. This trend has been especially noticeable in Germany.

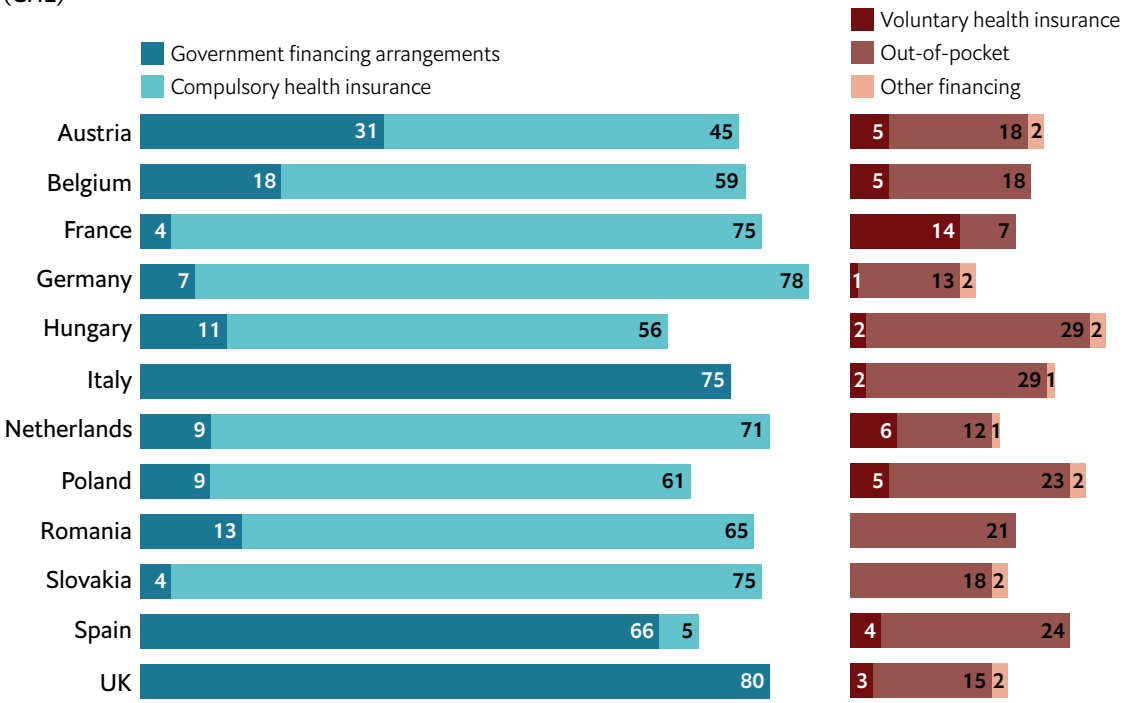
Health system	Countries covered in this report
Bismarck (insurance based)	Austria, Belgium, France, Germany, Netherlands
Beveridge (tax-based)	Italy, Spain, UK
Previously Semashko (now transitioning to)	Hungary (mixed), Poland (Bismarck), Slovakia (mixed), Romania (Bismarck)

Devil in the detail: How European funding systems vary

In order to assess the benefits and drawbacks of the different funding systems used in Europe, it is useful to look in more detail at how the region's healthcare systems operate. As noted above, general government expenditure dominates funding of healthcare in all 12 countries covered in this report. Compulsory financing – a term encompassing both government financing from taxation and compulsory health insurance schemes – accounts for around 80% of healthcare spending across the 12 countries *(see Figure 7.)*

Healthcare systems in most countries are based on social health insurance schemes that are dependent on payroll-based social security contributions from employers and employees and subsidised by government funding that is raised from general taxation. The exceptions to this broad pattern are Italy, Spain and the UK, where universal coverage is provided by a national health service funded mainly from general taxation.

Figure 7: Financing sources as % of current health expenditure (CHE)



Source: WHO.

OOP payments, mainly for co-payments and user-charges that are levied for pharmaceuticals and for treatment provided in the public health system, dominate private expenditure. The share of voluntary health insurance (VHI) in Romania and Slovakia is negligible, but is highest in France where more than 90% of the population pays for complementary VHI, which covers co-payments and provides for medical goods and services that are not fully covered by the statutory health insurance (SHI) package. Consequently, at just 7% of total health expenditure, the share of OOP is lowest in France.

Romania, by contrast, has little or no VHI, with private prepaid plans accounting for less than 1% of total healthcare spending in 2014. As a result there is little way for patients to offset their OOP spending. However, Romania's OOP share of spending is not the highest of the 12 comparator countries. That distinction belongs to Hungary, where the combined government/compulsory share is, by contrast, the lowest in the region.

Austria

Public health financing schemes and sources of revenue

Public financing is based on a social health insurance system (sickness funds) under The General Social Security Act (ASVG). Twenty-two social insurance funds provide cover for health, pension and accidents, of which 19 offer health insurance. A regional health insurance fund provides cover for residents in each of the country's nine states. In addition, there are six company insurers that provide cover for their employees and four specialist insurance funds for farmers, for the self-employed, for civil servants and for railway and mining employees.

The revenues of social health insurance funds come mainly from income-related contributions, but also from tax-financed federal budget contributions for pensioners and the unemployed. General government funds are also channelled into the Health Insurer's Structural Fund, which is distributed to health insurers to shrink their structural deficits. Regional health funds pool resources from social security health insurers, states, local authorities and the federal government for hospital financing. Finances at a regional level are distributed via a financial equalisation mechanism. Taxes that are directed towards healthcare include value added tax, tobacco tax and income tax.

Coverage / enrolment

Health insurance is compulsory and covers more than 99% of the population. Cover extends to co-insured dependants – children, spouses and partners – as well as the self-employed, apprentices, pensioners and the unemployed.

Insurance contributions

Social insurance contributions are fixed as a percentage of income. The rates are 1.3% for accident insurance, which is paid by employers; 22.8% for pension insurance, which divided into 10.25 % from the employee and 12.55% from the employer; and 7.65% for the health insurance, which is split 3.87% paid by the employee and 3.78% paid by the employer.

Core services covered

Legislation states that cover must be provided in cases of illness, pregnancy and incapacity to work. The basket of care for all sickness funds must include: ambulatory care, travel costs, hospital care, treatment by physicians, dental care, midwifery, physiotherapy, occupational therapy, speech therapy and psychotherapy, clinical psychology, therapeutic masseurs, dentistry, home-based nursing care, sickness and maternity benefit, medical rehabilitation, certain health promotion provisions, some health consolidation and illness prevention, early identification of diseases, assistance and therapeutic aids for physical infirmity and pharmaceutical products.

Co-payments

Coverage is comprehensive, but patients make small co-payments for prescriptions, consultations and hospital stays, while cost-sharing can also be imposed for services such as transportation costs or dental treatments. For every prescription included in the Reimbursement Codex, a standard prescription fee of €5.85 is applied as a patient co-payment (as of 2017). The level of user charges is high compared to other EU countries, but access is ensured by numerous exemptions, such as a prescription fee cap set at 2% of net income.

Co-payments and exemptions vary from fund to fund. In general, exemptions are given to patients with infectious diseases that warrant reporting to the authorities, dialysis or preventive health check-ups; pensioners with a minimum pension; children; civil servants; people in receipt of social protection benefits; and people whose monthly net income falls below a certain minimum threshold (this threshold increases depending on the number of dependents).

Belgium

Public health financing schemes and sources of revenue

Funding is based on a social insurance system, with payments and benefits for healthcare administered by mutual insurance funds (or sickness funds; private non-profit bodies). Compulsory health insurance is managed by the National Institute for Health and Disability Insurance (NIHDI), which allocates a budget to the sickness funds to finance healthcare. Income-related social security insurance contributions accounts for 73% of the system's expenditure. The remainder comes from state subsidies, indirect tax revenue and from diverse receipts, such as solidarity contributions, value-added taxes and tobacco taxes. The sick funds are financially accountable for a proportion of any overspend.

The sickness funds offer two additional kinds of insurance beyond the compulsory cover: "complementary" and "voluntary" insurance (VHI). Both are available for an additional premium.

Population coverage/enrolment

Membership of a health insurance fund is compulsory for all residents registered on the Belgian National Registry. Around 99% of the population is covered, including economically active and non-active people and their dependents. There are two main schemes: a scheme for the self-employed and a scheme for the whole population, including the unemployed, retirees, students and orphans. Sickness funds are generally organised in line with political or religious affiliation, but The Auxiliary Fund exists for those not wanting to affiliate with such groups. People are free to choose their own fund, except for railway workers, who are automatically enrolled in the Belgian railway company's health insurance fund.

Insurance contributions

Social insurance is payable by the employer and the employee. For employed persons total social insurance contributions amount to 13.07% of gross income for the employee and 24.77% of gross income for the employer (with contributions not paid for annual holidays). These contributions cover pensions, unemployment, occupational diseases, accidents at work, and incapacity benefits, as well as healthcare. The share specifically for healthcare amounts to 3.55% of income for the employee and 3.8% for the employer.

The self-employed pay quarterly social security contributions directly to their social insurance fund. The total contribution for social security is €699.32 per quarter for salaries up to €13,010.66, 21.5% of income for salaries between €13,010.66 and €56,182.50 and 14.16% for salaries between €56,182.45 and €82,795.16 and €0 on any income over €82,795.16.

Core services covered

Compulsory health insurance covers a very comprehensive benefits package listed in detail in a nationally established fee schedule – about 8,000 items in total. For each one, a contractual fee and reimbursement rate are identified.

Services covered by complementary insurance are decided by individual sickness funds, but generally include orthodontics, homeopathy and extra hospital benefits such as a double room. VHI, which can also be provided by private for-profit insurance firms, covers healthcare costs not covered by either compulsory or complementary health insurance.

Co-payments

User charges and co-payments apply for out-patient care, in-patient care and pharmaceuticals. Some are regulated by law and others are supplementary and charged on top of the regulated official user charges. Patients are, in principal, expected to pay full fees upfront and then make reimbursement claims to their sickness funds.

Charges are applied at the same rate for everyone, except those qualifying for preferential reimbursement status – which includes those earning less than a minimum income threshold (including pensioners, the disabled, widowers/widows, orphans, and the long-term unemployed over 50 years of age). Standard co-payment rates are approximately 25% for GP consultations, 35% for GP home visits and 40% for specialist consultations, speech therapy, and physiotherapy. Examples of preferential reimbursement rates are around 10% for GP consultations and 15% for specialist consultations.

For in-patient care and medicines purchased in pharmacies, patients only pay user charges or co-payments. About 2,500 pharmaceuticals are reimbursable. For medicines from a pharmacy, patients are charged a fixed portion of the cost, with insurers covering the remainder. The percentage charged is determined by its category according to assessed social importance. These range from category A drugs such as insulin, cancer drugs or antiretrovirals, which are 100% reimbursable, to Category C drugs for systematic treatment such as antiemetics, which carry a co-payment fee of 50% with a maximum threshold of €13.50 (or €8.90 for preferential reimbursement). Means tested annual OOP payments are applied at a household level for vulnerable groups and for children irrespective of family income. For children it is set at around €650, and at the household level maximums range from €450 to €1,800.

France

Public health financing schemes and sources of revenue

Healthcare provision is based on a social health insurance system dependent on contributions the Central Social Security Agency (ACOSS), which are raised through employer and employee payroll payments from gross earnings as well as an earmarked tax on all sources of income. Although a social health insurance system, healthcare financing is highly centralised through a single public payer and also dependent on additional tax-based revenue. More than 90% of population pays for complementary VHI, which covers co-payments and provides for medical goods and services that are poorly covered by the Statutory Health Insurance (SHI). Government subsidies to this complimentary health insurance - via contributions to the Universal Health Coverage Fund (CMU) – cover complementary universal health coverage (couverture maladie universelle complémentaire; CMU-C) for those on lower incomes; this covers 7% of the population. Statutory health insurance (SHI) is funded by allocations from the Central Security Agency (ACOSS), from the CMU (which receives funds from taxes levied on tobacco and alcohol), from an earmarked premium tax on VHI contracts and from the Agency for Funding Social Security Debt, which is itself funded by a dedicated tax. Additional revenue comes from taxes on pharmaceutical companies. The system is also funded by co-insurance payments and other OOP charges, although these upfront payments are usually covered by enrolment in VHI.

Coverage / enrolment

SHI is mandatory and provides near universal coverage (an estimated 99.9% of the population). Residents are usually covered by an obligatory SHI scheme on an employment basis, but the CMU provides statutory health cover for those residing in France legitimately, but are not covered by an employment scheme and / or have low household income. Prisoners and their families are covered by the SHI general scheme. In January 2016 the government introduced a new healthcare system for permanent foreign residents, called Protection universelle maladie (PUMA), which covers 70% of health costs. The reform equalised rights for EU and non-EU citizens, with both categories requiring three months residence before being able to access health services. Reforms implemented in January 2016 also mandate employers to ensure that their employees are covered by supplementary VHI insurance and that they pay at least 50% of the premiums.

Insurance contributions

The CMU provides statutory health cover free of charge for those with low household income up to a certain ceiling, while others not covered by an obligatory SHI schemes on an employment basis pay an annual premium of 8% on revenue above the set CMU ceiling for free cover. Contribution rates for SHI have risen steadily to cover higher healthcare spending. The employer payroll contribution rate is about 13.1% of gross earnings.

Since 1998, employees' payroll contributions have been gradually replaced by an earmarked tax for social security on all sources of income. The employee payroll element has consequently fallen to around 0.75% of gross earnings. The replacement dedicated tax - the 'general social contribution' (CSG) - rate is 7.5% on earned income (of which 5.29% goes to SHI), 8.2% on capital (5.95% to SHI), up to 12% on gambling winnings, 6.6% on pensions (4.35% to SHI) and 6.2% on benefits such as unemployment and sick leave allowances (3.95% SHI). For people on lower incomes, the rate is 3.8% of earned income, which account for almost half of French households.

Consequently, the SHI revenue base has been and is less vulnerable to the impact of wage and employment fluctuations. Around 70% of CSG revenues is directed to SHI schemes; this accounts for some 35% of their finance. The pharmaceutical companies are mandated to contribute a 1.6% tax on their turnover and tax on drug retailing and on advertising; they are also charged a tax if their revenue exceeds a certain limit as set by the Social Security Finance Act.

Core services covered

The core services covered by statutory health insurance (SHI) span a broad package of services that encompasses hospital care and treatment in public or private healthcare institutions, rehabilitation or physiotherapy, outpatient care, dentists and diagnostic services. Preventative treatments are also covered, but cosmetic and spa treatments are not. Medical goods covered include pharmaceuticals, medical appliances and prostheses that are prescribed and included in the positive lists for reimbursement. Prescribed health-related transport is also included.

The SHI package is provided in benefits in-kind and in-cash. The benefit package in-kind for outpatient services and goods are itemised in positive lists of reimbursable treatments, pharmaceuticals and devices. There is also a negative list. For hospital in-patient care, there is a specific list of pharmaceuticals covered by SHI.

Hospitals are paid on a Diagnosis-Related Group (DRG) system of classifying any inpatient stays. Expensive and innovative drugs and devices are paid in addition to the DRG tariffs and practitioners can decide what care and drugs to prescribe, as long as products have marketing authorisation.

Co-payments

Co-payments required to cover non-reimbursable parts of costs under the SHI are generally covered by the supplementary VHI. As long as they are registered with a fund, patients are reimbursed for medical treatment, usually at a rate of 70% of doctor and dentist fees, 80% of hospital costs and 60% for medical auxiliaries and laboratory tests. In cases of long-term chronic disease, 100% reimbursement is applied. The rate of reimbursement coverage for medicines varies according to the seriousness of the pathology and a product's medical benefit (SMR) evaluation. Those categorised as major or considerable are reimbursed at a rate of 65% for serious illness, or 30% for less serious or benign illness, at 30% for drugs categorised as SMR moderate and at 15% for Low SMR rating. The vast majority of drugs are covered at a 65% rate. A flat fee of €18 is applied for in-patient or out-patient treatments or tests with a tariff of more than €120. This flat fee is also applied if the cumulative cost of a single visit exceeds €120. Flat rate deductibles / co-payments are applied for drugs at €0.50.Nominal flat rate charges are levied for physician visits, ancillary care, laboratory tests and diagnostic imaging up to an annual ceiling of €50. Co-payments and non-reimbursable parts of treatment costs are generally covered by VHI.

Germany

Public health financing schemes and sources of revenue

Public healthcare provision is based on a model of universal healthcare insurance through non-profit quasi-public health insurance funds / sickness funds. This Statutory Health Insurance (SHI) - Gesetzliche Krankenversicherung (GKV) – is primarily financed by employer and employee contributions as deductions from wages. Since 1 January 2009, the SHI contributions have been transferred by the sickness funds on the day of receipt to a Central Reallocation Pool, which redistributes the contributions among the sickness funds after making adjustments for risk. The other main contributions to revenue for statutory insurance provisions come from other components of social security - statutory retirement insurance, statutory insurance for occupational accidents and disease with and statutory long-term care insurance and governmental sources. The proportion of public healthcare financed through taxes has declined over the past decade, aided by the introduction of the long-term care insurance.

Coverage / enrolment

Since 2009 it has been mandatory for all residents to have either state or private health insurance. At the end of 2016 about 72.3m people (87% of the population) were covered by statutory health insurance, which is compulsory for all residents with a gross annual income of less than €57,600 (as of March 2017). Civil servants, the self-employed and employees earning above this threshold have the option of joining one of the public health insurance funds, taking out private health insurance, or combining the two. Students, the unemployed and pensioners are required to obtain SHI coverage. Those in self-employment can choose SHI coverage if they were members of a sickness fund at the time of embarking of self-employment, or they can take out private insurance. Spouses with no independent earnings and children are covered without any surcharges.

Insurance contributions

SHI contributions are based on income not risk. Contributions are based entirely on income from employment, pensions or unemployment benefits. Savings, capital gains and other forms of unearned income are excluded. The contributions rise proportionally with income up to a threshold of around €4050 per month. The total contribution rate of 15.5% (including a 0.9% "general contribution"). The insured person pays 7.3% + 0.9% gross earned and the employer pays 7.3% in addition to wages. People with monthly earnings below €450, only employers make contributions – at 13% (or 5% for employment in private households). Students pay a standard per capita premium of around €65 per month. Fore retired and the unemployed, the institutions administering the statutory scheme for old-age and disability insurance, or the Federal Employment Agency, pay the 'employer' portion of the contribution. Pensioners must pay contributions from company and other non-statutory pensions.

Core services covered

Although sickness funds are responsible for negotiating prices and quantities, they no longer have the right to determine their own contribution rates for services. Standard services covered are usually available to everybody and do not require prior authorization from individual sickness funds. The benefit package usually includes services that fall under the following categories - prevention of disease; health promotion; disease screening; treatment of disease, which includes ambulatory medical care, dental care, pharmaceuticals, medical devices, care by allied health professionals, inpatient care, nursing care in the home, and some areas of rehabilitative care. Also included are dental prostheses and orthodontics, emergency and rescue care and other services such as supporting self-help groups. The Federal Joint Committee has considerable autonomy in defining the details pf the benefits package for curative diagnostic and therapeutic procedures. The range of procedures covered is wide, ranging from basic examinations to surgical care, antenatal care, terminal care, laboratory tests and imaging procedures. Prior authorization from sickness funds is necessary for preventive spa treatments, rehabilitative services and short-term nursing care at home.

Co-payments

Germany does not have a positive list of reimbursable drugs, but so-called lifestyle medicines and over-the-counter (OTC) medicines are excluded from the standard benefit basket. Patients generally pay co-payments for pharmaceuticals of €5–10. Around 29% of prescriptions are exempted from co-payments. OOP payments relating to co-payments for benefits partly covered by SHI or not reimbursed by a person's prepaid scheme have increased in recent years. Co-payments are charged for various services including physician visits and dental treatment. Co-payments are standardized at around €10 per inpatient day and €5–€10 for services and products in ambulatory care. SHI-covered patients are eligible for exemption from user charges for benefits in the SHI package once more than 2% of the gross household income has been spent on co-payments annually. The rate for those with a serious chronic illness is 1% of gross annual income.

Hungary

Public health financing schemes and sources of revenue

The public health system is based on a combination of social health insurance contributions, tax revenue transfers and direct payments from pharmaceutical companies to the national social health insurance fund (OEP), a compulsory insurance scheme covering citizens. The national government is the dominant regulator of healthcare services and also provides direct grant funding to local governments for capital costs and to help finance the services for which they are responsible. The national government also provides public health and some tertiary services directly. A small share of the public health system comes from EU funding.

Coverage / enrolment

According to OECD statistics, public healthcare cover reached 95% of the population in 2013. All nationals are entitled to cover regardless of employment status, with the state paying health insurance contributions for certain groups such as the unemployed and pensioners. Non-nationals without insurance cover through employment are entitled only to essential health services free of charge in cases of emergency or an acute condition. Expatriates employed by Hungarian companies can access public healthcare in the same way as Hungarian nationals.

Insurance contributions

Contributions to the OEP are set by the national parliament and collected by the national tax office. It is therefore separate from the government budget, but the government must cover any deficits, although it cannot use any surpluses. Total social security contributions for an employee (covering health, pensions and unemployment benefits) was 18.5% in 2017. These contributions are made up of 7% health insurance contribution, 10% pension contribution and 1.5% unemployment contribution.). Additionally, employers pay a total of 22% in social security payments. A separate health tax is also levied separately on taxed income, which is not subject to social security payment; this includes dividend income, income from borrowing and lending securities, and income from capital gains. This is payable by the individual up to a contribution cap of HUF450,000 (€1,445) a year.

Core services covered

The OEP covers most in-patient and out-patient treatments and services, including pharmaceutical costs (including around three-quarters of the latter). It also provides some health-related benefits, such as sick pay. The number of fertility treatments covered by the health insurance fund for each couple is limited. Exemptions include medical examinations for fitness to drive or hold firearms certification, treatments for aesthetic or recreational purposes, treatments not proved effective in improving health (such as services excluded in the WHO's International Classification of Procedures in Medicine. Other services not covered by the public health insurance system include massage, cosmetic surgery, abortion and sterilization without medical indication, treatment for injuries due to extreme sports and injuries from vaccinations not included in the state's compulsory immunization programme.

Co-payments

Co-insurance and co-payments are levied for products and services including pharmaceuticals, medical aids and prostheses, dental prostheses, long-term chronic care and some 'hotel services' in hospitals. Co-payments will also be charged if non-emergency specialist services are sought without referral from a physician, and for treatments and services not covered under the public health insurance package. There are key types of reimbursement for medicines - indication-related and fixed. The indication for a certain substance must be confirmed by a specialist, with drugs for less severe chronic conditions covered by insurance for up to 90%, 70% or 50% of the agreed retail price and medicines for the more severe, life-threatening diseases covered at 100% In most cases a small minimum patient co-payment – the 'package fee', equivalent to about €1 must be paid. In the fixed category all indications for which the medication is licensed are covered, either up to a fixed amount through the reference pricing system (for products with generic equivalents or with similar therapeutic effects) or on a percentage basis (80%, 55% or 25% of the agreed price). Exemptions for social service beneficiaries exist from user co-payments on drugs, medical aids and prostheses, and rehabilitation services. Exemptions also exist for chronic diseases. Eligible patients are granted a monthly personal budget to cover user charges and co-payments. Other exemptions include those for abandoned children and for low-income households on a means-tested basis. Despite the comprehensive exemptions the share of public spending is expected to continue to decline slowly over the forecast period as co-payments and other OOP expenses increase.

Italy

Public health financing schemes and sources of revenue

Italy has a universal national health service, the Servizio Sanitorio Nazionale (SSN), which is financed from general national taxes, regional taxes and patient co-payments for pharmaceuticals and outpatient care. Previously a proportion of income tax revenues were earmarked for the health system. However, this proportion has been cut in recent years, in particular under the 2016 Stability Law, which instead extended tax exemption for private or company health insurance premiums. Pooling of funds is managed at the national level.

Coverage / enrolment

The national health system automatically covers all citizens and resident foreign nationals. Undocumented migrants are granted access to basic services. Temporary visitors from outside the EU can pay for treatment, while EU citizens can access free cross-border care from the SSN.

Insurance contributions

None. The national health system is funded from general taxation.

Core services covered

Italy's public healthcare provides a comprehensive package of core services and treatments, outlined in both positive and negative lists. Coverage includes primary care and emergency care, ambulatory and home care, residential and semi-residential care, pharmaceuticals, specialist outpatient care, integrated care, prosthesis care, thermal therapy, hospital services and public health and occupational health services (Torbica & Fattore, 2005). A list exists for the preventive services covered; these include hygiene and immunization and early diagnosis services. Dental care, particularly orthodontics and dental prostheses, is generally not covered. Negative lists also exist and include services deemed as ineffective services, treatments that are covered only on a case-by-case basis. Some mental health services are excluded from the core benefit package. Long-term care services and vaccination programmes are generally excluded, but limited is afforded to certain groups dependent on age and clinical conditions. The basic package of guaranteed health services was last updated in January 2017, when a National Commission was set up to monitor compliance[24].

Co-payments

Primary and inpatient services are universally free at the point of use. Co-payments are charged for diagnostic procedures, such as laboratory tests and imaging, as well as for specialist consultations, pharmaceuticals, and non-urgent interventions in hospital emergency departments. Pharmaceuticals co-payments are regulated at the national and regional levels; In 15 of the regions they are applied as a flat rate or percentage of the price. Specific levels of co-payment differ from region to region. Exemptions from co-payments exist for the elderly, children under 6, the unemployed, people in households with an income below a certain threshold, people with severe disabilities and prisoners. Those with chronic or rare conditions, HIV, and pregnant women are exempt from co-payments for treatments related to their condition.

[24] https://mapbiopharma.com/blog/news/news-italy/2016/new-benefits-package-developed-after-15-years/

Netherlands

Public health financing schemes and sources of revenue

The Netherlands has a social health insurance system, which operates through a dual income stream. Firstly, all residents are mandated to take out health insurance and make monthly payments; they pay a flat community-rated premium directly to an insurer of their choice Secondly, funding also comes from a direct taxation stream, in the form of an income-related "a social welfare tax", paid by employers. This finance is pooled in the Health Insurance Fund. Health insurance companies have to accept all applicants at a standard premium. A risk-equalisation system pools some of the premium income of the insurers according to the risk profile of their insured persons. Direct contributions are also made from the Ministry of Health (MoH), mainly for tax-funded subsidies and healthcare allowances for certain groups including children under 18, as well as for hospital financing, for social care and for health promotion and for medical training.

Coverage / enrolment

Health insurance is compulsory for all Dutch residents, with coverage for a core set of services through the public health system reaching virtually 100%. The government covers insurance premiums for children, but they must be included on their parents' plan. A system of "allowances" exists for certain vulnerable groups. Undocumented migrants cannot purchase health insurance and have to pay OOP. However, for those unable to pay, medically necessary care must be provided and healthcare providers can sometimes receive a refund from the government.

Insurance contributions

The flat community premium for an individual is around €2,000, depending on the insurer chosen. The income related employer contribution is charged at around 8% of annual income, capped at a certain level. The government's exceptional medical expenses scheme pays for expensive and/or uninsurable medical treatment. To ensure access, a "healthcare allowance" fund has been created from general taxation to protect lower-income groups.

Core services covered

The Health Insurance Act provides a basic benefit package; this includes all care considered to be essential, efficient and unaffordable by individual citizens. Virtually all GP-care, maternity care, hospital care, mental care and home nursing care, are included. Dental care is provided for children under 18 and for the elderly. All medical aids, devices and pharmaceuticals are covered. Medical transportation. Other treatments, such as speech therapy are included, as is physiotherapy for people with a chronic medical condition. Cover for additional costs accrued for arthritis and cancer care have also recently been added in response to the ageing population.

Co-payments

For all adult citizens, a mandatory deductible is applicable whereby the first €385 (as of 2016) of yearly healthcare expenses must be paid-of-pocket (with the exception of GP-consultations, maternity and home nursing care). After that amount is spent, insurance takes over. Reimbursement for pharmaceuticals is based on a reference pricing system. Pharmaceuticals are categorised in groups of therapeutic equivalents. Health insurers can list preferred medicines meaning that patients who use other similar medicines may have to pay the difference in costs or the total amount. Care not insured under the basic insurance package can be covered by Voluntary Health Insurance. Most insurers offer free complementary VHI for children with a parent's complementary VHI policy.

Poland

Public health financing schemes and sources of revenue

Poland operates a social insurance health system with a single payer structure, which is subsidised by taxes. Mandatory health insurance payments are paid through the Social Insurance Institution or the Agricultural Social Insurance Institution, and transferred to the National Health Fund (NHF). Income-based health insurance contributions are borne entirely by employees, pooled by the NHF and distributed between the 16 regional NHF branches. The system also receives funds, raised from general taxation, from central and territorial government budgets. The NHF is responsible for contracts with public and non-public healthcare providers. The MoH is the key policy-maker and regulator and is supported by a number of advisory bodies, some recently established.

Coverage / enrolment

Social health insurance (SHI) is compulsory for the vast majority of citizens and legal residents. A list of all groups subject to mandatory cover is detailed in law and includes employees, the self-employed, business owners, farmers, pensioners and some students. Cover extends to dependents such as spouses, children under 18 (or 26 if students), and to grandchildren, parents and grandparents resident in the same home. People with certain conditions such as HIV, tuberculosis and mental health disorders, get automatic cover. Although universal in principal, the OECD estimates population coverage at 91% in 2015. The cause of non-cover is largely casual or atypical work contracts, although the state covers contributions for most unemployed people.

Insurance contributions

Compulsory health insurance contributions are payable by the employee at 9% of gainful income. However, 7.75% is deductible from tax as a credit, meaning that, in practice, the net cost for individuals is 1.25%. Social security tax payments for pension, disability, accident, and sickness and maternity insurance are also payable and, unlike health insurance, these are split with employer. For people on old-age or disability pension, the SHI contribution is based on gross benefits. For the self-employed, SHI contribution is based on their gross profit, or 75% of the average Polish salary if the latter is greater. For those receiving unemployment benefits, contributions are based on the total amount of benefits. However, the majority of people without work (i.e. 86% of the unemployed in 2007) are not eligible for unemployment benefits. For this group, contributions are covered by the state budget. The state pays the health insurance premiums of all farmers who own less than 6 ha of land. All other farmers pay health insurance premiums according to the amount of land that they own.

Core services covered

The mandatory health insurance scheme covers a broad range of healthcare services and treatments. These include primary healthcare, ambulatory specialist care, hospital treatment, nursing and long-term care, psychiatric care, therapeutic rehabilitation, dental treatment, health resort treatment, addiction treatment, orthopaedic and auxiliary medical devices, medical rescue services, palliative care, highly specialised medical procedures and pharmaceuticals. Although most conventional procedures and services are formally covered, however, the NHF's limited financial capacity means that access to core treatments and care is not guaranteed.

Co-payments and user-charges

SHI formally guarantees fully covered access to a broad package of healthcare services and treatment. However, there are co-payments for pharmaceuticals, auxiliary medical devices, health resort treatments and certain dental procedures and materials. Most conventional medical procedures are included, but the list of reimbursable drugs is narrow and determined by a positive reimbursement list. Separate reimbursement lists and rules exist for people with chronic, infectious and psychiatric diseases and disabilities. There are also co-payment exemptions for certain groups including veterans with disabilities and their dependent spouses, servicemen and their families and for blood and organ donors.

Most OOP expense is for outpatient medicinal products, including pharmaceuticals and other non-durables. Inpatient drugs are fully covered by the NHF, but lump sums or co-payments are charged for most outpatient medicines patient drugs, depending on patient category and indication. Reimbursement and co-payment levels are set centrally. For medicines, the levels are based on the lowest wholesale prices per daily dose of a drug, contributing to Poland's high OOP payments. There are no co-payment caps for medical goods or services, although some disadvantaged groups can claim social assistance to help with co-payment costs. Informal payments are commonplace. Gratitude payments, particularly to underfunded or indebted hospitals, are frequent, as are bribery payments to physicians in order to reduce typically long waiting times.

Romania

Public health financing schemes and sources of revenue

Romania has an insurance-based health system revolving around the National Health Insurance Fund (CNAS), which is funded by compulsory income-based contributions from employees. Some health programmes, including preventative health campaigns, are also funded through the MoH budget, using revenues raised through national and local taxation, including revenues from tobacco and alcohol taxes. Additionally, OOP payments and rebates from pharmaceutical companies play a significant role in funding medicines prescribed through the state health system.

Funds are distributed by the CNAS to district level health insurances branches, to purchase services from public and private providers. Primary care doctors own their practices and receive payments for services provided.

Coverage / enrolment

Although membership is compulsory, the state healthcare insurance system only covered 87% of the population in 2016, according to CNAS data, with the proportion of those covered higher in urban areas. Uninsured people include some of those working in agriculture, in casual private sector work, self-employment and those that are unemployed but not registered for unemployment and other social security benefits. Lack of insurance cover is high amongst the Roma population. The uninsured can only access a minimum benefits package covering emergency care, treatment of communicable diseases and pregnancy care. Officially, cover extends to the unemployed, people on parental leave, pensioners, refugees during a period of status clearance, children, people under the age of 26 if they are still in education or come from a child protection institution and have no income, war veterans and war veteran widows.

Insurance contributions

As of January 2018, compulsory health insurance contributions are set at 10% of the gross wage for employees and the self-employed. People on sick leave due to a work accident or occupational illness are covered by a separate work accident and occupational disease insurance fund. Those excused from payment of contributions include: children, dependent spouses; students; pensioners; the unemployed; refugees; prisoners; those with chronic diseases or who are on medical leave; war veterans; and people with disabilities. Their entitlement to healthcare services and treatments is financed by the health insurance contributions of the general paying population, or by government funding used to cover any deficit at CNAS.

Core services covered

The insured population is entitled to a standard benefits package, which includes healthcare services, pharmaceuticals and medical devices. The CNAS will also pay cash benefits to cover sickness leave in certain circumstances. Healthcare services include preventive, hospital care, ambulatory care, dental services, medical emergencies and medical rehabilitation, maternity and birth and home nursing care. Excluded services include services covered by the insurance fund for work accidents and professional diseases, as well as services requiring very expensive technology or services that are considered not to have a medical justification such as aesthetic corrections and in vitro fertilization. Decisions on services and goods covered are taken by the CNAS and the MoH based on consultations with interested parties. For pharmaceuticals, a positive list is elaborated by the ministry, with input from the HTA department of the National Agency for Medicines and Medical Devices (ANMDM). Access to covered services is often hampered by lack of knowledge regarding benefits, the uneven distribution of service providers (especially in rural areas), and scarcity of financial resources in the health system, meaning that entitlement does not guarantee access.

Co-payments and user-charges

Co-payments apply mainly to pharmaceuticals and rehabilitation services. There are four reimbursement lists (A, B, C and D) and patients must pay between 0% and 80% of the reference price, depending on the reimbursement category that the product falls into. Medicines for chronic diseases and those included in national programmes are 100% reimbursed at the reference price. Where generics are available, patients must pay extra if they wish to access an equivalent but more expensive product. These copayments, as well as parallel trade in Romania, lead to a high share of OOP spending on pharmaceuticals.

The co-payment rates are adjusted to some extent, depending on the age, income and condition of the patient. Certain groups, such as children, students and pregnant women, are entitled to full reimbursement of drugs in categories that normally carry a co-payment fee. Private providers that have signed contracts to provide services and treatment under the statutory health insurance scheme are reimbursed at the same level as public providers but, unlike public providers, they can charge patients additional fees for services not included in the care package. Informal, or 'under the counter' payments have traditionally been commonplace, making the actual level of OOP payments hard to ascertain. However, additionally penalties for accepting such payments were introduced in 2014.

Slovakia

Public health financing schemes and sources of revenue

Slovakia has an insurance-based system of healthcare financing, involving mandatory employer and employee contributions to both state-owned and private insurers. Those classed as 'voluntarily unemployed' also pay contributions to social health insurance system. Dividend contributions are also made from domestic or foreign activities. Direct contributions are made by the state, from general tax revenue, for economically inactive people. The central government budget also finances the activities of the MoH. The health ministry also funds several health agencies, including the Public Health Authority and the Slovak Health University and it covers capital investments in some state hospitals directly. Self-governing regions and municipalities also fund capital investment in their outpatient facilities and hospitals, but the contribution of funds from this level is small. Patient co-payments for pharmaceuticals and medical devices have risen steadily since 2010. It is estimated that contributions paid to the three main health insurance companies, which are responsible for providing statutory cover and contracting providers to deliver a core package of services, account for 69.6% of total public expenditure on healthcare.

Coverage / enrolment

Health insurance is mandatory and, in theory, all residents in Slovakia are entitled to social health insurance. In practice, it is estimated that around 4% of residents remain uninsured for a core set of services. The role of the voluntary health insurance (VHI) market remains marginal. All residents, with the exception of those with a health insurance cover in another country, are entitled to social health insurance cover. This includes asylum seekers and foreigners employed, studying or involved in business in Slovakia and it applies to economically inactive groups who are 'state-insured', such as children, the elderly, those looking after children under the age of three and the unemployed.

Insurance contributions

Mandatory social health insurance is set at 14% of gross monthly income, with employees contributing 4% and employers paying 10%. The self-employed pay the full 14%, but some discounts can apply. Voluntarily unemployed people also pay the full 14%. In 2017 the government insurance contribution for state-insured people was raised to 5.67% of the minimum wage. Caps on mandatory health insurance contributions have been abolished. In 2014 the government introduced a scheme exempting those on the lowest wages (under €380 a month) from health insurance contributions, and reducing contributions for those on slightly higher but still low wages. Disabled employees and their employers are entitled to discounts of up to 50%.

Core services covered

The social health insurance system has a benefit package that all insurance companies must provide. Health insurance companies (HIC) are free to contract providers and to negotiate quality, prices and volumes. The social health insurance market is shared between one large publicly owned HIC, and two smaller private companies. A redistribution formula partly mitigates risk differences across the three companies. The same core basket of health services is provided to all insured. There is a list of free preventive care examinations, a list of essential pharmaceuticals exempt from co-payment, and a list of conditions eligible for free spa treatment and a list of priority diagnoses, for which all health procedures are free of charge. Many non-priority disease treatments are also provided free of cost-sharing. Services upon request, not based on medical need, or those resulting from drug or alcohol abuse are not officially covered. HICs often offer additional benefits such as medicine discounts, or shorter surgery waiting times to attract more people.

Co-payments / user-charges

Co-payments are charged for prescribed pharmaceuticals. Decisions on inclusion in the benefits package, along with reimbursement, co-payment and conditions for reimbursement, are set by the MoH and based on a reference pricing system, with drugs categorised according to active substance. There is also a user-charge of € 0.17 per prescription. Small user charges are levied for certain health services such as emergency care, dental care, ophthalmology care, ambulance transportation and spa treatment. Service providers are limited in their ability to charge additional fees with the exception of some premium services, such as the option of choosing a surgeon. Informal payments to providers and practitioners continue to play a role in the public health system, but the value of such payments is difficult to ascertain.

Spain

Public health financing schemes and sources of revenue

Spain's public health system, the Sistema Nacional de Salud (SNS), is funded almost entirely from general taxation. Public healthcare (except for pharmaceuticals) has traditionally been free at the point of use for all except the wealthy self-employed. However, a new system of cost-sharing was introduced by a new law in 2012. In addition to the general SNS scheme, there are three mutual funds - Mutual Fund for State Civil Servants (MUFACE), General Justice Mutual Company (MUGEJU) and Social Institute for the Armed Forces (ISFAS) specifically for employees in these areas and their beneficiaries (about 5% of the population). These funds are financed from payroll contributions and taxation. In 2002, health primary jurisdiction over the organisation and delivery of health services was devolved to 17 regional health ministries.

Coverage / enrolment

Spain's public national health service covers nearly 99.9% of the population. However, after the 2008 financial crisis, a new law redefined eligibility criteria, moving from universal entitlement based on residency to coverage in-line with social insurance entitlement – meaning workers affiliated with the Social Security, as well as pensioners and recipients of social benefits, and their dependents. As a result, non-registered immigrants were excluded from entitlement to SNS services, except emergency services and maternal and child care. There is no agreement on the exact number of people who lost their entitlement to health services, as some regions did not follow this restrictive policy.

Insurance contributions

None. The national health system is funded from general taxation.

Core services covered

Core services covered by the national health system are defined by a common package and a complementary package. The common package comprises three categories of services; firstly, it includes 'basic services', which encompass prevention, diagnostic, treatment and rehabilitation services and emergency transport, which are all fully publicly financed at 100%. Secondly, the common package includes 'supplementary services' – including pharmaceuticals, orthopaedic services and non-urgent transport, which are subject to some level of cost sharing. Thirdly, the common package includes 'ancillary services', which is yet to be fully defined. The complementary package encompasses medical products and services defined by the regions and paid for with regional funds. Dental care is generally limited to emergency cases and treatment for children, but this can vary from region to region.

Co-payments

A new law introduced in 2012 redefined core services provided by the national health system and increased user-charges in the system. Cost-sharing is used for orthopaedic services, dietetic products and non-urgent transport. Co-payments for pharmaceuticals were increased, although medicines for chronic diseases such as cancer remain fully reimbursable. There are also exemptions for some groups including the long-term unemployed. People with an income of more than €18,000 a year now pay a co-payment of 50%. Those with income below €18,000 pay up to 40%. Pensioners with an income under €18,000 pay 10% with a maximum capped at €8 per month. Pensioners with an income of more than €18,000 pay 10% with a €18 per month cap.

UK

Public health financing schemes and sources of revenue

The UK's National Health Service (NHS) is funded mainly through general taxation and supplemented by national insurance contributions. Healthcare is generally free at the point of delivery, but some user-charges, co-payments and direct payments are applied. Most NHS funding and commissioning is controlled by the four regions - England, Scotland, Wales and Northern Ireland.

Coverage / enrolment

Access to NHS care is universal for people ordinarily resident in the UK. With the exception of European visitors, those not 'ordinarily resident' are charged the full cost of any care and treatments provided. Since 2015, non-European Economic Area migrants have had to obtain 'indefinite leave to remain' before accessing free hospital care. Asylum seekers and refugees can register with a GP and access free NHS hospital care. Cover for irregular migrants differs in various parts of the UK.

Insurance contributions

Although most NHS funding comes from general taxation, the NHS budget is supplemented by some funding from payroll-based employer and employee national insurance contributions. Around 19% of funds raised through national insurance goes to the NHS, and the remainder is used to fund various state benefits including pensions, disability and unemployment allowances. For employees earning £680 to £3,750 per month (gross), the rate is 12%. For any earnings over this amount, 2% is levied. Employers pay a rate of 13.8%. For self-employed people, the rate is 9% on profits of £8,164 and £45,000 and 2% on profits over £45,000.

Core services covered

The NHS provides comprehensive care, but there is no defined list of services and treatments. The overarching principle of NHS benefits coverage is that coverage should be comprehensive. However, this is not a guarantee that everything will be covered, with the term allowing for significant discretion by decision-makers in determining which services will be provided. The scope of NHS cover has been reduced in the area of long-term care, with the introduction of means-testing for personal care. In certain instances and areas of care, devolved administrations and local authorities can make decisions about what services to provide in view of budgetary constraints. Local rationing has seen services such as in vitro fertilisation or elective surgery restricted in some locations. Most inpatient medication is covered, but outpatient pharmaceuticals are subject to prescription charges (copayments) for most working adults (see below).

Co-payments

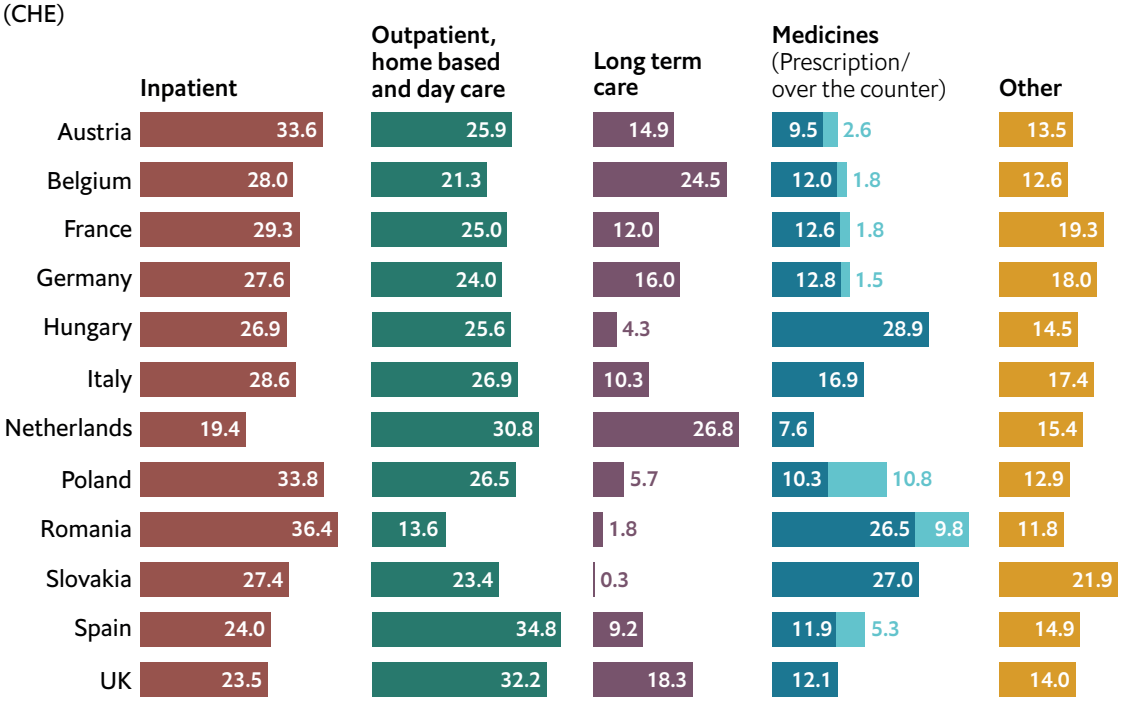
Most NHS care is free at the point of delivery and OOP payments remain low in the UK. However, there are fixed co-payment charges for the cost of glasses, dental care and prescription pharmaceuticals. In 2017, the fixed charge for prescription medication was raised to £8.60 (US$11.50) per item, although prepayment certificates are available to cap the cost for those requiring more than three prescriptions per month. Charges are waived for certain groups, including those aged over 60 or under 16, and many do not apply in Scotland, Wales or Northern Ireland. Long-term care is provided on a means-tested basis, with patient savings and other assets (including housing) taken into account in determining the level of state support.

Setting priorities: How the money is spent

Health systems differ in how they allocate money to different service providers in the system. Reforms tend to focus on ways to drive spending towards primary and preventative care, in order to reduce costs and improve responsiveness. Militating against this is systemic inertia, the rising price of specialist health technologies and population ageing, which combine to drive up inpatient care. Issues within the health workforce, as well as public pressure over hospital closures, can add to this trend.

In eight of the 12 countries covered, curative and rehabilitative care accounts for the greatest share of health spending, followed by medical goods. However, there are three exceptions to this—the Netherlands, Spain and the UK—where outpatient care is a bigger priority than either. In Netherlands and, to a lesser extent, the UK, long-term care also accounts for a high share of spending. Germany's spending on long-term and inpatient care is surprisingly moderate, given it has the oldest population in Europe and is third only to Japan and South Korea in the world.

Figure 8: Financing sources as % of current health expenditure
(CHE)



Source: WHO.

The share of spending on medicines is highest in Slovakia, Hungary, Poland and particularly Romania, although spending is low in nominal terms *(see Figure 9)*. The high share spent on medicines largely reflects lower wages in these countries, which deflate spending in areas that are more heavily dependent on workforce costs, notably outpatient or in-home care. Additionally, these countries have lower old-age dependency ratios than in West European countries, reducing the share of spending needed for curative care.

However, there are also other reasons why these Romania spends a higher proportion of their budget on medicines. One reason is the high proportion of spending on over-the-counter (OTC) medicines in Romania, at 9.82% of total current health expenditure (CHE). Although Romania's OTC spending is low in nominal terms, its share is second only to that of Poland among the countries where data is available for this item. Prescribed medicines account for 26.5% of total CHE in Romania, compared with 27% in Slovakia, 28.9% in Hungary and 10.34% in Poland.

Lessons from the comparison of health funding

The preceding section of this report highlighted the importance of overall health funding in terms of overall health outcomes. It is no coincidence that, of the 12 countries compared, Romania is the lowest spender on healthcare per capita in nominal terms, and is also the worst performer in terms of amenable mortality. Even as a percentage of GDP, Romania's health funding lags behind that of the other European countries, although it has risen rapidly in the past five years. Public spending increased in Romania from 3.7% of GDP in 2010 to 4.2% of GDP in 2017, with most of the new funding going to pay salary rises and, to a lesser extent, improve access to medicines.

Nonetheless, Romania struggles to provide the comprehensive universal healthcare system that its residents are implicitly promised. Although membership is compulsory, the state healthcare insurance system only covers around 87% of the population and unmet care needs are the highest in the comparator group. There are widespread exemptions from the health insurance system and from co-payments, which help to keep down the share of OOP spending on healthcare to around the average of the comparator average. However, these are poorly monitored and targeted, meaning that those on low incomes may have difficulties accessing healthcare and that the pool of those paying contributions is relatively small. The lack of a significant VHI scheme contributes to these difficulties, particularly (as we shall see in the following section) for pharmaceuticals. Around 70.8% of Romania's OOP spending goes on pharmaceuticals, compared with an EU average of 44.2%.

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	9% (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

Medicines funding overview

Access to health treatment is heavily dependent on the availability of affordable medicines.[25] 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[26]. 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. [27]

In this section, 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.[28] The results have a direct impact on patients and their access to affordable medicines.

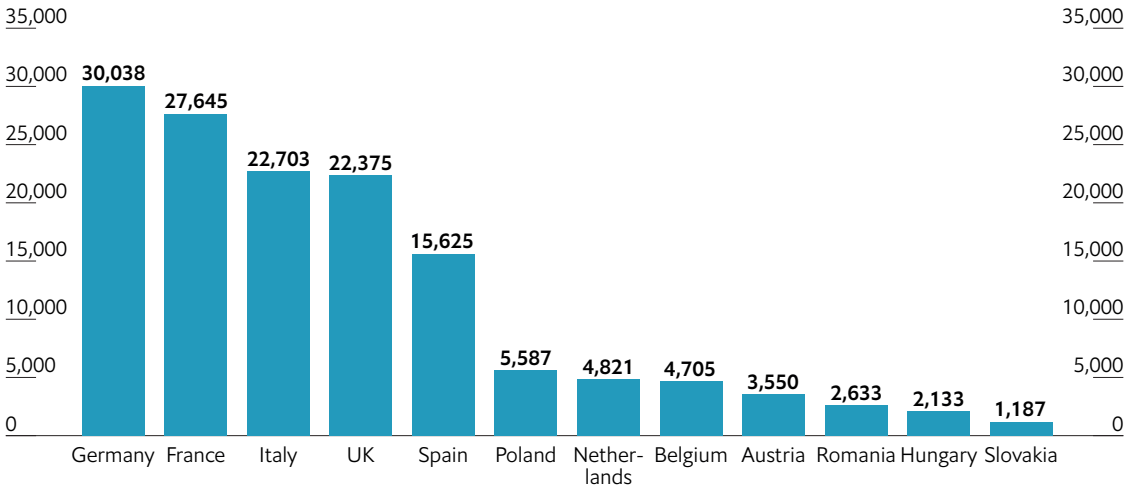
Europe's pharmaceuticals markets

Pharmaceuticals represent the third largest expenditure item of total healthcare spending after in-patient and out-patient care in the EU, accounting for approximately one-sixth of all health spending. As a result the EU's total expenditure on medicines reached an estimated €4bn in 2017.

The ranking of the 12 countries by total pharmaceutical market value falls roughly in-line with that of total healthcare spending, with Germany spending the most and Slovakia the least. The only significant disparity is that Poland is the ninth highest spender on total healthcare, but sixth highest spender on pharmaceuticals in nominal terms. This is consistent with a higher proportion of healthcare spending channelled to pharmaceuticals in Poland (21.5%), than in the Netherlands (7.6%), Belgium (13.9), and Austria (12.3%) where total healthcare spending is higher in nominal terms.

Figure 9: Pharmaceutical market value 2015

(€ m)



Notes: (a) Data is for pharmaceutical sales, at ex-factory prices, through all distribution channels (including hospitals), whether dispensed on prescription or OTC. Veterinary medicines are excluded. (b) Figures for Belgium, France, Germany, Italy, Spain & the UK are estimates.
Source: European Federation of Pharmaceutical Industries and Associations (EFPIA).

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

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

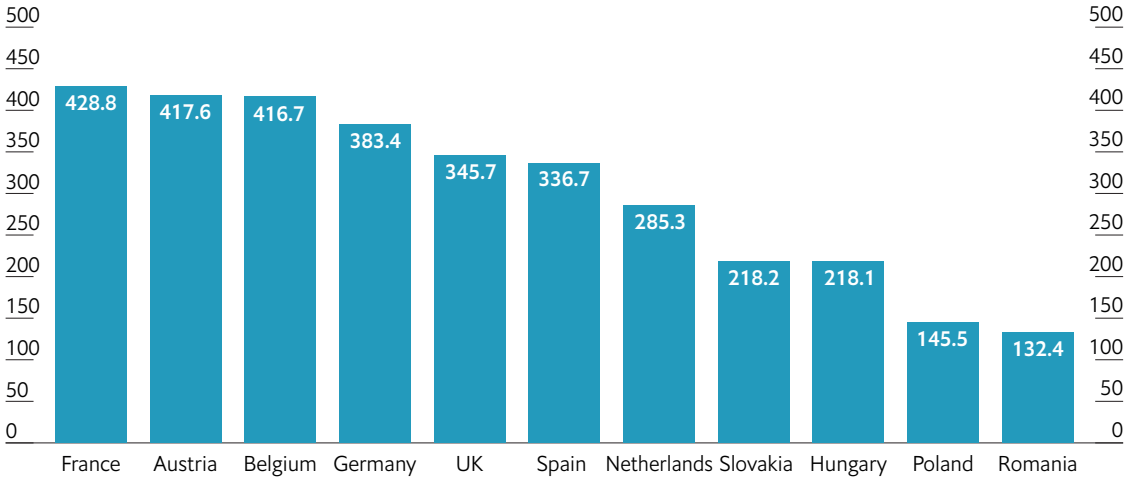
27. Karampli, E., Souliotis, K., Polyzos, N., Kyriopoulos, J. and Chatzaki, E., 2014. Pharmaceutical innovation: impact on expenditure and outcomes and subsequent challenges for pharmaceutical policy, with a special reference to Greece. *Hippokratia*, *18*(2), p.100.

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

However, while the value of Poland's pharmaceutical market is marginally higher than those of Netherlands, Belgium and Austria, drug sales in this East European market cover a far larger population of 38.3m, compared with 17.1m the Netherlands, 11.43m in Belgium and 8.6m in Austria (EIU estimates, 2017). As a result, per capita expenditure on pharmaceuticals in far lower in Poland, with Romania's the lowest of all in 2015. However, Romania's market has seen significant growth from this low base since then.

Figure 10: Pharmaceutical sales per capita 2015

(€)



Notes: Actual per capita expenditure on medicines, all channels including hospitals, EIU estimate based on EFPIA market value data and EIU population

Source: European Federation of Pharmaceutical Industries and Associations (EFPIA).

Different per capita spending on medicines among EU countries can be attributed to different consumption rates and patterns, due to factors such as burden of disease, patient attitudes, variations in prices[29], as well as by affordability and access. Affordability and access in turn is determined by several factors including pricing, reimbursement rates, and levels of co-payment charges relative to income levels. Romania ranks as the lowest spender on medicines in per capita terms; this reflects the combination of low public coverage, the absence of an established VHI market and the high burden of OOP spending for medicines.

The relatively low level of spending on pharmaceuticals in the Netherlands, one of the region's wealthier countries, is also noticeable. It is largely attributable to restraint on the part of prescribing doctors and patients, as well as agreements between manufacturers and the government, which have lowered prices. Although low levels of unmet need for prescription drugs have been reported for the Netherlands up to 2014 (Eurostat data), price pressures have discouraged manufacturers from producing certain essential medicines, leading to shortages.[30]

Under restraint: Pharmaceutical spending growth

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. [31]

29. http://eprints.lse.ac.uk/68290/7/Wouters_Pharmaceutical_regulation.pdf

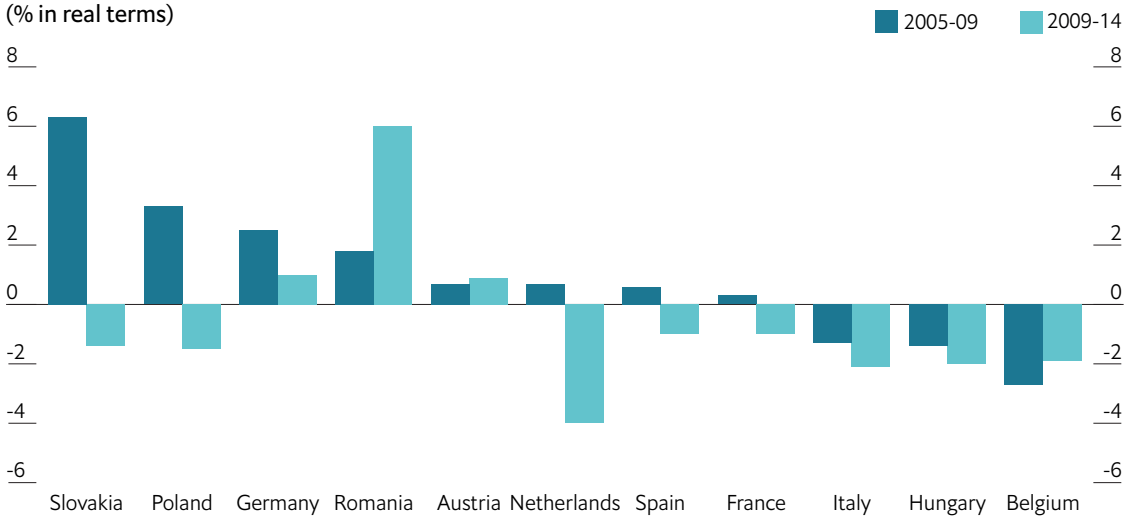
30. Economist Intelligence Unit.

31. OECD, Health at a Glance, Europe, 2016.

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. [32]

Policy measures adopted to rein in pharmaceutical spending in the EU have included the exclusion of products from reimbursement lists, reductions in pharmacy and wholesale margins, cuts to manufacturers' prices, increased user charges for retail prescription medicines and the implementation of pro-generic prescribing policies. Since 2014, pharmaceutical spending, in real terms, has rebounded in most countries, largely due to sharp increases in spending on a new generation of antiviral, hepatitis C drugs and oncology medicines.

Figure 11: Average annual growth in pharmaceutical expenditure per capita
(% in real terms)



Note: Net spending in outpatient settings on prescription and over-the-counter drugs, including taxes and rebates. In some countries, other medical non-durable goods are included. Spending on inpatient pharmaceuticals is excluded. UK data are not available.

Source: OECD, reproduced from *Health at a Glance: Europe 2016.*

Romania bucks the trend

Romania's trajectory has bucked this trend, with pharmaceutical spending gathering pace in the 2009-17 period, but growth has been from a very low base. Pharmaceutical spending per capita, in real terms, grew at an average annual rate of 6% in Romania 2009-14[33]. This growth was recorded despite the list of reimbursed drugs not being updated between 2008 and 2015, which denied most patients access to new medicines in this period.[34] Growth since 2014 has also been extremely rapid, with the result that per capita expenditure topped €200 in 2017.

The rise in expenditure has been driven by an increase in both the volume and the value of pharmaceuticals consumed, owing to population ageing, growing morbidity and rising incomes in urban areas[35], as well as the increased use of drugs for chronic conditions[36]. However, Romania's higher pharmaceutical expenditure growth masks a high level of OOP spending on medicines, low public coverage for pharmaceuticals, a high level of income inequality[37], and a high level of self-reported unmet needs for prescribed medicines due to financial reasons—a strong indicator of insufficient access.[38]

32. https://ec.europa.eu/health/sites/health/files/state/docs/health_glance_2016_rep_en.pdf

33. https://ec.europa.eu/health/sites/health/files/state/docs/health_glance_2016_rep_en.pdf

34. http://www.euro.who.int/__data/assets/pdf_file/0017/317240/Hit-Romania.pdf?ua=1

35. The Economist Intelligence Unit.

36. http://www.euro.who.int/__data/assets/pdf_file/0017/317240/Hit-Romania.pdf?ua=1

37. https://ec.europa.eu/health/sites/health/files/state/docs/chp_romania_english.pdf

38. Eurostat http://appsso.eurostat.ec.europa.eu/nui/submitViewTableAction.do

Slovakia records the sharpest change

Slovakia recorded the sharpest change in real per capita expenditure growth pattern in the latter part of the decade. The health system has long suffered from poor gatekeeping, over-utilisation of services and over-prescription of medication. Since the 2008 financial crash, cost-containment has taken priority. A new reference pricing system with very narrow definitions of reference groups, along with an agenda of generic prescribing, have reduced expenditure on medication.

However, other measures have also been introduced to improve the efficiency, effectiveness and coverage of the public health insurance system. Compulsory health insurance contributions are collected and are re-distributed to health insurance companies using a risk-adjustment scheme, which since 2012, has included an element that accounts for 'pharmaceutical cost groups', which classifies the insured into groups according to their annual use and need of medicines. Patient fees for prescriptions in Slovakia are low and the share of public spending on pharmaceuticals (71%) is considerably higher than in Romania (60%), Hungary (49%) and Poland (33%).[39]

Deep cuts in the Netherlands

The steepest decline in pharmaceutical expenditure, in real per capita terms, has been in the Netherlands. This reflects the impact of cost-containment measures and budget cuts, which have focused on shifting expenditure from public to private sources.[40] One such measure is the "preferred medicine policy", which most Dutch health insurers now follow. Health insurers select one specific brand from a group of products with the same active ingredients, and this is usually the cheapest available. Pharmacists must deliver the preferred brand to the patient or the patient must pay the difference in cost or the full cost. [41]

The resulting decline in per capita expenditure on drugs is also the result of several expensive specialist medicines being shifted from the out-patient drug reimbursement system budget to the hospital budget in 2012, with patients having to go to hospital to obtain these drugs, rather than to the local pharmacy; these include TNF inhibitors, growth hormones and expensive cancer drugs, fertility hormones, and, since 2015, all other cancer medicines.[42]

Pharmaceutical spending in PPP terms

Disparities between spending on medicines in part reflect pricing in the different markets, with most pharmaceutical companies offering tiered pricing that takes into account affordability within a particular country. Healthcare payers use affordability as a negotiating tool to drive down prices. Romania and Poland benefit from these policies, in that they appear to pay lower prices. As a result, when measured in purchasing power parity (PPP), the gap in terms of medicines spending is narrower than it is in nominal terms.

Nevertheless, there is still a spending gap that affects access to medicines. Payers often argue that this suggests that pricing concessions for poorer countries are not generous enough. However, driving down prices still further may result in particular markets becoming unprofitable for pharmaceutical companies, forcing them to withdraw or limit supplies. Tiers are also generally applied at a national level, which means that they do not take into account income inequalities within countries.

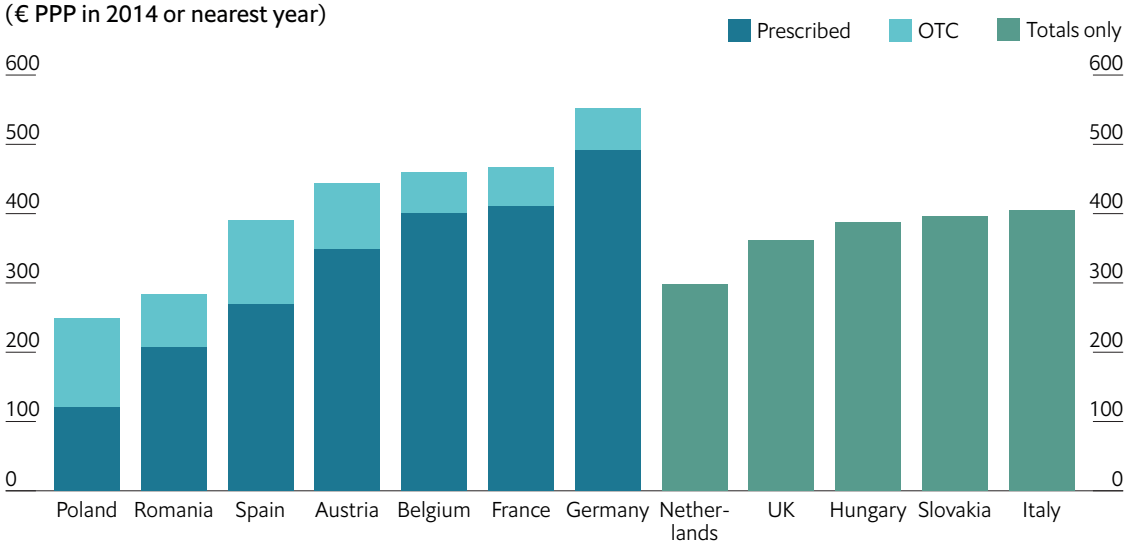
39. http://www.euro.who.int/__data/assets/pdf_file/0011/325784/HiT-Slovakia.pdf?ua=1

40. https://ec.europa.eu/health/sites/health/files/state/docs/chp_nl_english.pdf

41. http://www.euro.who.int/__data/assets/pdf_file/0016/314404/HIT_Netherlands.pdf?ua=1

42. http://www.euro.who.int/__data/assets/pdf_file/0016/314404/HIT_Netherlands.pdf?ua=1

Figure 12: Expenditure on pharmaceuticals per capita
(€ PPP in 2014 or nearest year)



Note: Totals given where breakdown is unavailable. Hungary excludes OTC.
Source: OECD, reproduced from Health at a Glance: Europe 2016.

Moreover the room for manoeuvre for pharmaceutical companies is limited owing to two factors. One is the widespread use of international reference pricing systems. Although these are intended to increase the bargaining power of payers, they also mean that price reductions in one market may have unintentional effects in other countries. This may deter companies from offering discounts to ease affordability. Another is the existence of a thriving parallel trade in Europe, whereby medicines are bought at lower prices in poorer countries for use in a wealthier country. This further complicates companies' pricing policies.

There are also other factors that may affect affordability, including inefficient coverage of drugs by health systems, inefficient distribution systems, and the unintended consequences of pricing regulations. Nevertheless, the data suggest that Romania's overall spending on pharmaceuticals per capita is low in PPP as well as nominal terms.

Cost-containment efforts

Overall Poland once again has the lowest spending per head on medicines, even taking into account purchasing power parity. This partly reflects poor affordability as well as an absence of policy interventions to protect against high OOP spending for vulnerable groups[43]. However, it is also the result of a host of other regulatory interventions in Poland's pharmaceutical sector that affect supply. For example, the government has imposed penalties for pharmaceutical companies when budgets are exceeded.[44] Romania, for its part, has imposed a "clawback tax" that requires all manufacturers of reimbursed medicines to pay a proportion of their revenues towards the health financing system.

Similar policy interventions, involving various types of discounts and paybacks, have been implemented in other countries in the comparator group, such as the UK, France and Germany.[45] The precise design and application of these schemes varies. For example, while rebate requirements in Romania are applied to all manufacturers of reimbursed prescription drugs, the UK's PPRS encompasses only manufacturers of on-patent drugs. The Netherland's "preferred medicine policy"

43. Economist Intelligence Unit

44. Economist Intelligence Unit.

45. http://eprints.lse.ac.uk/68290/7/Wouters_Pharmaceutical_regulation.pdf

was introduced by a number of health insurers in 2005, with others adopting the system later. By 2011, the policy had induced an average reduction of 85% in generic drug prices.[46]

Many of these cost-containment measures were introduced in the wake of the eurozone economic crisis, in order to reduce pharmaceutical spending. They have been effective in that respect, but the possible impact on patient outcomes is less clear. Much depends on how regulatory mechanisms are applied and the knock-on effects for the wider healthcare system. The following table lists some of the most common strategies adopted:

Snapshot of pricing strategies

Rate-of-return mechanisms: a method of indirect price control; the manufacturer's contribution to pharmaceutical development are taken into account. This is used in Belgium, France, Hungary and the UK (PPRS considers contribution to development).

External reference pricing (ERP); benchmarking prices for new drugs against prices paid by payers in other countries; cost-plus pricing; the production cost of a medicine is taken into account when establishing retail prices. ERP is used extensively by countries in the comparator group. The UK is the only country in the comparator group that does not use ERP in any way. However, it is applied differently in all countries, which in-turn affects the impact on drug prices and access to medicines.

- The number of countries referenced, and the average that is applied to establish a reference price, varies widely. For example, Austria uses 27 reference countries and the reference price is set at the average of all countries. Poland references 30 countries, but the method of calculating the reference price from these countries is not fixed. France references four countries, but the method of calculating the reference price from these countries is not specified. In Romania, the reference price is the lowest among 12 selected EU countries.
- In some comparator countries ERP is applied as a main criterion (Austria), while in others it is a main criterion along with internal price referencing (IRP) or therapeutic reference pricing (France, Netherlands, Slovakia, Hungary, Romania). Some countries use ERP as a secondary criterion with IRP (Spain, Italy, Poland, Belgium and Germany).
- In some comparator countries, ERP is used to help determine the prices of reimbursable out-patient medicines (such as Austria, Belgium, Germany and Spain) in others it is used for pricing both in-patient and out-patient medicines (such as France, Italy, Romania, and Poland).
- Cost-plus pricing: considers the production cost of a given drug when setting the price. It is usually only applied to help determine the price of locally produced drugs and is used in combination with ERP. It is used in Slovakia.

Clinical and cost–effectiveness pricing: this covers methods of assessing value when setting prices and considering the worthiness of a drug for premium pricing – for instance, above ERP and IRP set prices – by assessing a drug's cost and clinical effectiveness compared to other treatment. The differences in application of this method in the 12 comparator countries, underscores the subjectivity of a product's value, particularly in context of different economic environments. Some elements of value-based assessment are used for price negotiations in Belgium, France, Germany, Italy, the UK (for some products, in patient access schemes).

Value-based pricing (VBP): considers a wider range of criteria than clinical and cost–effectiveness pricing. Wider criteria might include the disease prevalence and the longer-term benefits in the health sector and beyond. This is often the approach taken when considering premium prices for orphan drugs.

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

46. http://www.gabionline.net/Country-Focus/The-Netherlands/Policies-and-Legislation

Pro-generic policies on the rise, but penetration varies

For many countries, one way of holding down spending on medicines has been to encourage the use of generic drugs. The global patent cliff, which saw many blockbuster medicines come off patent, has allowed a vast expansion in the number of generics available, as has the development of sizeable pharmaceutical industries in developing markets such as India. However, generics can only replace older products, not the newest and most innovative products being brought to market.[47] Moreover, in some markets there is resistance to their use from healthcare staff and patients, who often see them as less effective than the original products. Market mechanisms, including resistance from the pharmaceutical industry, may also block their uptake.

Despite these concerns, several countries in the comparator group have extended efforts to increase uptake of generic medicines since 2008, including France, Slovakia and Spain. However, the use of generics and their impact on costs varies considerably depending on different policy settings. This is partly reflected in differing market shares for generics – in both value and volume terms – as a proportion of national pharmaceutical markets. In 2014, these lower-cost drugs accounted for more than 70% of the volume of reimbursable drugs sold in the UK, Germany, the Netherlands and Slovakia, but less than 50% of the reimbursable market in Spain, Belgium and Italy.

Prescribing using generic, rather than brand names, is permitted in all of the comparator countries except for Austria[48]. In Spain it has been mandatory since 2011 and France since 2015.[49] The penetration of generics is also impacted by pricing regulations. In Germany, manufacturers are free to set the prices of generics, and in the Netherlands, there is free pricing, but with some parameters. For the remainder of the comparator group, prices are set at a certain percentage below the originator price – ranging from 60% below the originator price in France, to 20% below in Italy and 25% below in Poland. This explains the higher value share of generics in these latter countries' drug markets. External reference pricing is also applied to generic medicines in Slovakia, Poland and Romania.[50]

	Share of generics as % of total pharmaceutical market, volume, 2014	Share of generics as % of total reimbursable drug market, volume, 2014	Share of generics, value at ex-factory prices, 2015
Austria	38	52	37 (share of generics in reimbursable pharmacy market sales)
Belgium	39	33	16 (share of generics in reimbursable pharmacy market sales)
France	52	30	18.7 (share of generics in reimbursable, officially listed pharmacy market sales)
Germany	73	81	30.9 (share of generics in reimbursable pharmacy market sales)
Hungary	53	Unavailable	38 (share of generics in pharmacy market sales.)

47. http://eprints.lse.ac.uk/68290/7/Wouters_Pharmaceutical_regulation.pdf

48. http://www.medicinesforeurope.com/wp-content/uploads/2016/11/Market-Review-2016-Generic-medicines-policies.pdf

49. https://ec.europa.eu/health/sites/health/files/state/docs/health_glance_2016_rep_en.pdf

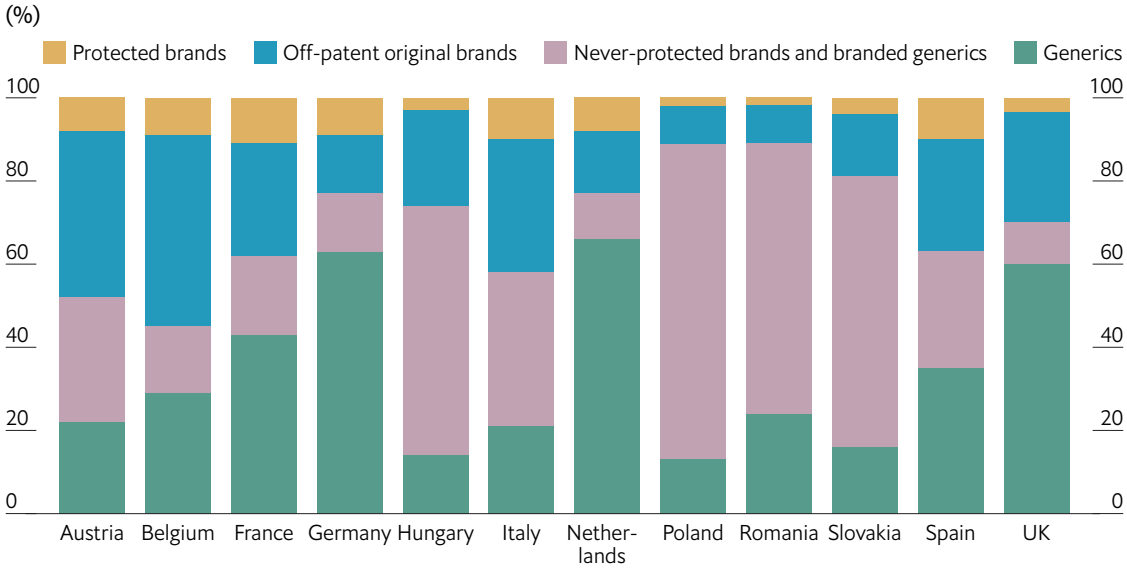
50. http://www.medicinesforeurope.com/wp-content/uploads/2016/11/Market-Review-2016-Generic-medicines-policies.pdf

	Share of generics as % of total pharmaceutical market, volume, 2014	Share of generics as % of total reimbursable drug market, volume, 2014	Share of generics, value at ex-factory prices, 2015
Italy	41	18	54.2 (share of generics in reimbursable pharmacy market sales)
Netherlands	66	71	16.7 (share of generics in reimbursable pharmacy market sales).
Poland	69	Unavailable	61.8 (share of generics in total market sales.)
Romania	59% (2017)	Unavailable	28.1 (share of generics in total market sales.)
Slovakia	57	71	22 (share of generics in total market sales.)
Spain	51	48	22.3 (share of generics in reimbursable pharmacy market sales)
UK	66	84	31 (share of generics in pharmacy market sales.)
Source: OECD Albrecht M, Chen X, Höer A, de Millas C, Ochmann R, Seidlitz C, Zimmermann A (2015). Value of Generic Medicines: Health Economics Study. Study Report for the European Generic Medicines Association. Berlin: IGES Institute. Based on data derived from the IMS Health MIDAS database	OECD Health Statistics 2016; OECD National Accounts; Eurostat Database.	Source: European Federation of Pharmaceutical Industries and Associations.	

Truly comparable data on generic market shares (either in value or volume terms) is hard to obtain. However, the available data suggest that generic penetration in Romania is around the average for the 12 countries compared. In both volume and value terms, it is higher than in Slovakia but lower than in Poland. However, data from Medicines for Europe/IMS Quintiles for mid-2015 *(see figure 13)* also suggest that the volume share of patented/protected medicines in Romania is extremely low in a European context.[51]

51. http://www.medicinesforeurope.com/wp-content/uploads/2017/05/20170220-Medicines-for-Europe-recommendationsv1.0_FINAL.pdf

Figure 13: 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.

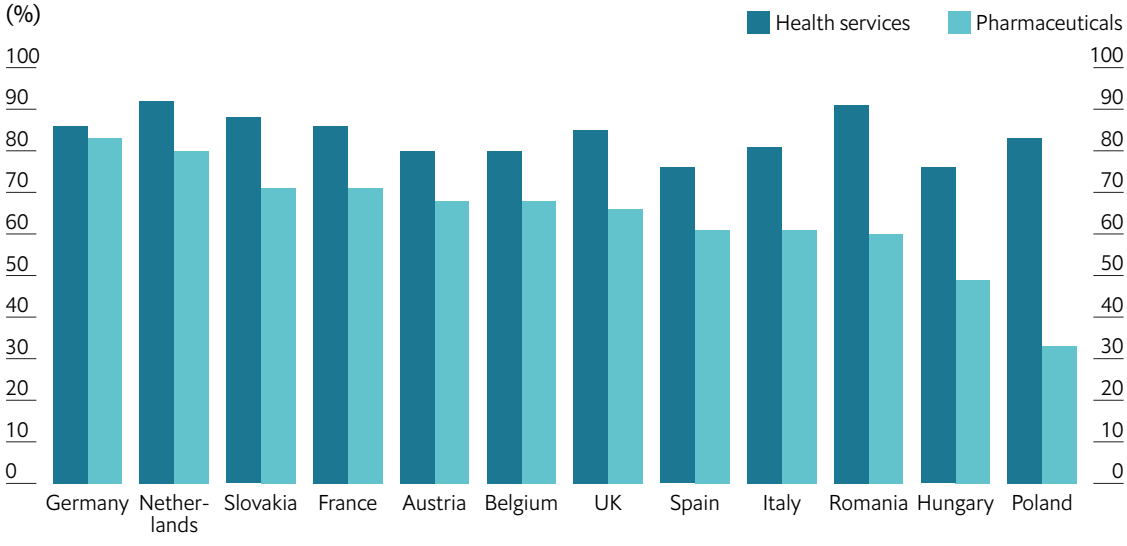
Pharmaceuticals coverage: poor protection

Disparities in pharmaceutical spending across the 12 comparator countries in part reflect how generous healthcare systems are in covering the cost of medicines for patients. Across the 12 countries, the proportion of national pharmaceutical costs covered by public schemes varies dramatically – from 83% (Germany) to 33% (Poland) *(see Figure 14)*. This contrasts with a more even pattern of public coverage for healthcare services, with proportions across the 12 countries ranging from 92% (Netherlands) to 76% (Spain).

In many countries, reimbursement lists have been pruned in recent years, sometimes through de-listings or by decisions to turn prescription drugs into over-the-counter ones. In France, for example, re-imbursement de-listings have been executed on the basis of scientific evidence of insufficient or low medical benefit[52]. In Germany, de-listings have focused on so-called lifestyle drugs and OTC medicines, rather than prescription medicines. [53]

Overall, however, public schemes in the 12 comparator countries now cover a higher proportion of healthcare services than pharmaceuticals, meaning that the proportion of OOP payment for drugs is higher than for healthcare services. This reflects trends in the EU as a whole, where public schemes covered, on average, 83% of healthcare services costs and 64% of pharmaceutical costs in 2014. The public protection available for disadvantaged or high-need groups – through residence-based entitlement schemes, exemptions or discounts, or through compulsory private insurance – is also less developed for pharmaceuticals than for other healthcare services such as in-patient and outpatient care. [54]

Figure 14: Public share of health services and pharma spending in 2014



Note: Pharmaceuticals includes medical non-durables in some countries.
Source: OECD Health Statistics 2016.

The widest disparities between public coverage of healthcare services and public coverage of pharmaceuticals are recorded in Poland and Romania, and the most even shares of expenditure are recorded in Germany and the Netherlands. Public coverage for pharmaceuticals was also highest in

52. http://www.euro.who.int/__data/assets/pdf_file/0011/297938/France-HiT.pdf?ua=1

53. http://www.euro.who.int/__data/assets/pdf_file/0008/255932/HiT-Germany.pdf?ua=1

54. https://ec.europa.eu/health/sites/health/files/state/docs/health_glance_2016_rep_en.pdf, p. 120

Germany and the Netherlands.[55] In Poland and Hungary, private expenditure on medicines accounts for more than 50% of the national pharmaceutical bill, most of which is accounted for by household OOP payments. In Romania the public share of medicine costs is the third lowest in the comparator group – at 60%, while the public share of healthcare services costs is the second highest at 91%.

Burden on the sick: OOP payments for pharmaceuticals

The result of limited public coverage for pharmaceuticals is that the share of OOP spending in overall pharmaceuticals sales also varies markedly, although the two measures do not correlate exactly. As noted above, Germany and France fare best in this respect. This reflects high coverage of pharmaceutical costs, through either compulsory or voluntary insurance schemes. In the wake of the financial crisis, both countries also implemented further reforms to shift some of the burden of drug spending away from the public purse to private payers, partly by raising copayments and partly by recategorising some prescription drugs as OTC.

In France, more than 90% of population pays for complementary VHI, which covers co-payments for medical goods and services not fully covered by Statutory Health Insurance (SHI). Reforms implemented in January 2016 mandate employers to ensure that their employees are covered by supplementary insurance and that they pay at least 50% of the premiums[56]. In Germany, sickness fund membership is mandatory for employees whose gross income does not exceed the opt-out threshold of €4,462.50 gross income per month (2014)[57], with those choosing to opt out now mandated to enrol in other private insurance schemes.[58] Reforms since the financial crisis have included the de-listing of some drugs from reimbursement, but this has been done on the basis of assessments finding insufficient or low medical benefit[59].

Although patients usually pay co-payments of €5–10 for medicines, exemption mechanisms to protect low-income and vulnerable groups from prohibitive OOP costs remain a persistent feature in German health care system, despite rising public expenditure pressures. Although a general exemption linked to poverty was abolished in 2004, exemption measures are still proportionately linked to income and patient ability to pay. SHI-covered patients are now eligible for exemption from user charges for

OOP spending on pharmaceuticals as a % of total expenditure on pharmaceuticals

	2011	2015
Austria	31	31
Belgium	32	31
France	29	17
Germany	18	16
Hungary	41	45
Italy	Unavailable	40
Netherlands	25	34
Poland	Unavailable	66
Romania	46	39
Spain	29	41

Source: Eurostat http://appsso.eurostat.ec.europa.eu/nui/submitViewTableAction.do

Data for the UK and Slovakia are not available

55. https://ec.europa.eu/health/sites/health/files/state/docs/health_glance_2016_rep_en.pdf, p. 120

56. Economist Intelligence Unit.

57. http://www.euro.who.int/__data/assets/pdf_file/0008/255932/HiT-Germany.pdf?ua=1

58. Economist Intelligence Unit

59. http://www.euro.who.int/__data/assets/pdf_file/0011/297938/France-HiT.pdf?ua=1

benefits in the SHI package once more than 2% of the gross household income has been spent on co-payments annually. The rate for those with a serious chronic illness is 1% of gross annual income.[60]

However, not all wealthy countries have low levels of OOP spending for pharmaceuticals. In Belgium, around one-third of drug spending is OOP. However, in 2016 the country introduced reduced reimbursement rates for patented drugs. Pro-generic policies and measures to lessen the impact of co-payments for vulnerable groups[61] also helped contain overall OOP expenditure between 2011 and 2015.

Poland has the highest OOP burden

In the new EU member states covered by this data (Hungary, Poland and Romania), the share of OOP spending in pharmaceuticals is comparatively high. This partly reflects patient demand for pharmaceuticals not included in the reimbursement system, but it may also reflect parallel trade in pharmaceuticals. In Romania such trade accounted for 22% of the pharmaceutical market in 2014, according to the ANMDM.

Poland's low per capita expenditure on pharmaceuticals and restrictive reimbursement system correlates with high OOP spending on pharmaceuticals. Although most conventional medical procedures are included, the list of reimbursable drugs is narrow. Limited public coverage of pharmaceuticals, combined with an undeveloped private health insurance market, has resulted in a heavy cost burden for patients; OOP expenditure on medicines as a proportion of total expenditure on medicines is the highest of the 12 comparator countries – at around 66%, according to Eurostat data. Around 60% of all medical OOP payments in Poland are dedicated to pharmaceuticals.[62]

In 2012, a new act sought to cut Poland's pharmaceutical bill with tough new reimbursement regulations. It set a ceiling of 17% on the proportion of public health expenditure devoted to the reimbursement of medicines. As well as fixing prices and margins for reimbursed medicines, imposing penalties for pharmaceutical companies when budgets are exceeded,[63] and granting reimbursement listings for a limited time of 2-5 years[64], the act also raised patient co-payments. As the burden of drug expenditure was shifted further towards households, sales in the reimbursement segment of the market fell[65]. Lump-sum co-payments for prescription drugs on the positive reimbursement list vary depending on the type of medicine.

Although separate reimbursement lists and rules apply for chronic, infectious and psychiatric diseases and disabilities, there is no cap on co-payments for medicines and income-related protection mechanisms are weak. An avenue exists only for the most disadvantaged to claim social assistance to cover co-payment costs. Co-payment exemptions are also extended to a handful of groups, such as servicemen and veterans with disabilities regardless of wealth or income.[66]

Romania offers weak protection

Most OOP healthcare spending in Romania is dedicated to pharmaceuticals; at 70.8% compared with an EU average of 44.2%. OOP expenditure accounts for 39% of total national expenditure on medicines. Although this is a slightly lower share than in Spain and Italy, as well as in Hungary, it partly reflects the high share of parallel trade in Romania.

60. http://www.euro.who.int/__data/assets/pdf_file/0008/255932/HiT-Germany.pdf?ua=1

61. OECD / European Commission Country Profile Belgium, 2017. https://ec.europa.eu/health/sites/health/files/state/docs/chp_be_english.pdf

62. https://ec.europa.eu/health/sites/health/files/state/docs/chp_poland_english.pdf

63. The Economist Intelligence Unit.

64. http://apps.who.int/medicinedocs/documents/s19046en/s19046en.pdf p. 27

65. Economist Intelligence Unit.

66. http://www.euro.who.int/__data/assets/pdf_file/0018/163053/e96443.pdf?ua=1

However, the impact of access to medicines in Romania is exacerbated by the country's higher relative poverty rate - at 19.8%, compared with 9% in Hungary, 13.4% in Italy and 15.9% in Spain.[67] Income-linked protection against high OOP expenditure on drugs is extremely weak in Romania. There are four reimbursement lists (A, B, C and D) and patients must pay between 0% and 80% of the reference price, depending on the reimbursement category that the product falls into.

The co-payment rates are adjusted to some extent, depending on the age, income and condition of the patient. Certain groups, such as children, students and pregnant women, are entitled to full reimbursement of drugs in categories that normally carry a co-payment fee. However, the income-linked protection mechanisms are weak and there are no personal expenditure caps against high OOP expenditure on drugs, other than for the most disadvantaged pensioners.[68]

OOP expenditure on pharmaceuticals as a proportion of total expenditure on pharmaceuticals fell in Romania between 2011 and 2015. This is most likely due to faster growth in public spending on medicines due to greater consumption of medicines falling into categories A and C of the reimbursement list; these drugs, which are deemed to be essential and cost-effective (A), speciality drugs for chronic diseases (C1), used in national treatment programmes (C2), or disbursed through hospital pharmacies (C3), are reimbursed at a higher rate than other pharmaceutical products. Nevertheless, OOP spending in Romania continued to grow in actual monetary terms – from €1.16bn in 2011 to €1.18bn in 2015.[69]

67. https://ec.europa.eu/health/state/country_profiles_en

68. http://www.euro.who.int/__data/assets/pdf_file/0017/317240/Hit-Romania.pdf?ua=1 p. 61

69. http://www.euro.who.int/__data/assets/pdf_file/0017/317240/Hit-Romania.pdf?ua=1

Access to medicines

Cost-containment measures have allowed many European countries to slow the pace of pharmaceutical spending, which is now slower than that of overall healthcare expenditure in most of the 12 comparator countries. However, while policy-makers and pharmaceuticals companies debate pricing policies, patients remain single-minded in their need to ensure that their access to medicines is impeded as little as possible by financial constraints, whether their own limited incomes or the funding available to health systems. Unfortunately, there is little doubt that the level of spending on pharmaceuticals directly affects patients' access to medicines in the 12 comparator countries, although other factors also play a role.

Unmet needs highest in countries with low spending

One way to look at whether pharmaceuticals markets are for the benefit of patients is to look at unmet needs for medicines. According to data available from Medicines for Europe, an association for generics producers, unmet needs for prescribed medicines are highest in Poland (9.4%), Italy (7.2%), Romania (6.7%) and Hungary (5.9%). The public share of medicine costs covered is also lowest in these four countries.

Poland records both the lowest share of public scheme coverage of pharmaceuticals and the highest rate of unmet needs for prescribed medicines. Italy has the next highest rate of unmet needs for prescribed medicines, although public schemes cover a higher share of pharmaceutical costs than in Hungary, which has the fourth highest level of unmet prescribed drug needs. This may be due to the latter having more extensive protection mechanisms against prohibitive pharmaceutical co-payments – according to indication and severity of condition, as well as exemptions from co-payments for social services beneficiaries and low-income households.

Self-reported unmet needs due to financial reasons (% of population, 2014)

	All health-related services	Prescribed medicine
Austria	9.8	2.2
Germany	13.4	3.7
Hungary	13.8	5.9
Italy	17.2	7.2
Netherlands	5.7	1.9
Poland	17	9.4
Romania	14.8	6.7
Slovakia	7.2	4.3
Spain	17.2	3.2
UK	6.6	1.3
EU (28 countries)	15.2	5.1

Source: Medicines for Europe. Data for Belgium and France are not available

Italy's poor performance in the Index can be accounted for by the adverse impact of reforms introduced in 2012, via the government's Balduzzi Decree, which included measures revising co-payment levels and the list of reimbursable pharmaceuticals, as part of a cost-containment package.[70] Low penetration of generics and delayed access to new medicines have threatened the sustainability of the healthcare system in recent years, with drug makers threatening to leave the market and regional health authorities falling into the red.[71] The central government continued to cut its healthcare budget in 2016, but is starting to look more seriously at access problems.

Romania has the third highest rate of unmet needs for prescribed medicines in the comparator group, and public coverage of pharmaceutical costs is the third lowest. A similar 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.

By contrast rates of unmet medical care needs (according to the OECD/Eurostat data) are lowest in Austria, The Netherlands, Germany and Spain. Only around 2% of the Austrian population report problems accessing services and only a very small proportion of this group make reference to difficulties due to costs. [72] However, overall, the data show that the share of the population reporting unmet care needs because of affordability problems has increased in several countries since 2009, with the lowest-income households disproportionately affected. [73]

Comparatively poor access to appropriate medicines in Romania is the result of weak protection for vulnerable groups against a high burden of OOP expenditure on medicines[74]. While certain groups are exempt from prescription co-payments, exemptions relating to income are set at very low thresholds, leaving many low-income people exposed to high OOP costs. Access to medicines has also been impeded by the slow process of updating the reimbursement lists for medicines.

Efforts to overcome these problems have resulted in 85 new innovative medicines being included in the lists since 2014, including tuberculosis and HIV drugs that can be included without HTA and orphan drugs that are included unconditionally regardless of the cost. All this flexibility is driving costs up and needs additional funding to make it sustainable. Otherwise Romania's clawback tax will increase to unaffordable levels.

UK records lowest unmet need

Crucially, however, rates of unmet needs for prescribed drugs do not directly reflect the level of per capita expenditure on medicines. According to Medicines for Europe, the UK has the lowest level of unmet needs for prescribed medicines, while per capita expenditure is the lowest amongst West European countries in the comparator group, with the exception of the Netherlands. Despite the effect of cost-containment measures, the unmet needs rate for prescribed medicines in Slovakia in 2014 (4.3%), was the lowest recorded amongst the East European countries in the comparator group.

The UK's positive showing comes despite reforms that have shifted costs towards pharmaceutical companies (through the PPRS rebate system) and towards patients (through an increase in the fixed fee for prescriptions). Public funds cover just 66% of the cost of drugs in the UK, lower than in all other West European nations, except Italy and Spain. However, over-the-counter (OTC) medicines are also accounted for in the 34% of pharmaceutical costs not covered by public expenditure. The high

70. https://ec.europa.eu/health/sites/health/files/state/docs/chp_it_english.pdf

71. https://www.politico.eu/article/troubled-italian-health-system-frustrates-doctors-drugmakers-2/

72. https://ec.europa.eu/health/sites/health/files/state/docs/chp_romania_english.pdf

73. https://ec.europa.eu/health/sites/health/files/state/docs/health_glance_2016_rep_en.pdf

74. http://www.medicinesforeurope.com/docs/20170927_Positionpaper_medicines%20shortages.pdf https://www.frontiersin.org/articles/10.3389/fphar.2017.00892/full?utm_source=S-TWT&utm_medium=SNET&utm_campaign=ECO_FPHAR_XXXXXXXX_auto-dlvrit%0A

penetration of generic drugs, by volume, in the reimbursement market is also a key contributing factor to the UK's low unmet drug need rates.[75]

Furthermore while out-patient prescription charges are high at £8.60 (€9.69) per item, in reality, they only apply to a minority of people in the UK. Prescription fees have been abolished in Scotland, Wales and Northern Ireland, and exemptions in the UK are extensive – including children, the elderly, pregnant women, people aged over 60, the unemployed, those qualifying for income support, those with specific serious medical conditions including epilepsy, diabetes and cancer, along with people with a physical disability.[76] This indicates that public expenditure is directed appropriately in proportion with scales of need.

The Euro Health Consumer Index: Romania ranks lowest

For a broader look at how markets are functioning, it is also useful to look at The Health Consumer Powerhouse Euro Health Consumer Index (EHCI). This 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

	Score / 1,000	Ranking / 34
Netherlands	924	1
Germany	836	7
Belgium	832	8
France	825	10
Austria	816	11
Slovakia	749	13
UK	735	15
Spain	695	18
Italy	673	21
Poland	584	29
Hungary	584	30
Romania	439	34

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

75. http://www.medicinesforeurope.com/docs/20170927_Positionpaper_medicines%20shortages.pdf

76. Boyle, S. United Kingdom (England): Health system review. Health systems in transition. 2011, 13(1):1-486. Available from: http://www.euro.who.int/__data/assets/pdf_file/0004/135148/e94836.pdf . NHS Choices. NHS in England - help with health costs. London: Department of Health, 2016. Available from: http://www.nhs.uk/NHSEngland/Healthcosts/Pages/Prescriptioncosts.aspx

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

The EHCI's pharmaceuticals assessment

The index's pharmaceutical use category assesses access to and effective and appropriate use of medicines in European countries, using six key indicators as detailed below:

Rx subsidy			
Rx subsidy: this is based on the percentage of total drug sales (including OTC medicines) that are paid by public subsidy, such as through social insurance reimbursement mechanisms. It therefore serves as a measure of relative affordability of medicines for a population and of equity in access to medicines. The indicator is based on data from European Federation of Pharmaceutical Industries and Associations as well as on WHO Health for All *(HFA)* values.			
Score key	> 70%	69.9-50%	< 50%

Novel cancer drugs			
Novel cancer drugs deployment rate: This indicator measures the use monoclonal antibodies in cancer patients in each country. It determines whether a health system is under-using late generation cancer drugs, and therefore serves as a measure of the availability of innovative medicines. It is based on IMS Health MIDAS and CUTS data. Use is measured in MUSD p.m.p. (US$ m per m population). Measures in DDD (Defined Daily Doses) would have been preferable, but unavailable.			
Score key	> 15	15-10	< 10

Access to new drugs			
Access to new drugs: The indicator measures the time between registration of a new medicine and that product being included in the country's national subsidy system, and therefore available to patients via public health systems. This indicator is based on EFPIA data.			
Score key	< 150 days	< 300 days	> 300 days

Arthritis drugs			
Arthritis drugs: This measures the consumption of TNF-α inhibitors, which are highly effective in arthritis patients, as Standard Units per 1,000 prevalent population. The measure highlights relative effective or restrictive deployment of these medicines, with the results found to be not tightly correlated with GDP per capita. The sources used for this indicator are: IMS MIDAS database, eumusc.net: Report v5.0 Musculoskeletal Health in Europe (2012), Special Eurobarometer 272 (2007).			
Score key	> 300	300-500	< 100

Statins use			
Statin use: Measures the sales units per capita 50+ (prevalence adjusted) of statins, which are the primary therapy for the prevention of cardiovascular events. Statins are 'essential drugs'; consequently, this indicator provides a sample insight into the effective provision of essential medicines in national healthcare systems. This indicator uses IMS MIDAS data.			
Score key	> 150	149-150	< 49

Antibiotics consumption:			
Antibiotics consumption: This measures the consumption of antibiotics by antibiotic group, in order to assess their appropriate use and highlight over-usage, which stokes resistant infection rates. It is measured in defined daily dose (DDD) per 1000 inhabitants per day. This indicator uses European Centre for Disease Prevention and Control (ECDC) data.			
Score key	< 17	17-22	>22

EHCI Index, 2017 – Pharmaceuticals, subcategory performance

	Rx subsidy	Novel cancer drugs	Access to new drugs	Arthritis drugs	Statin Use	Antibiotics consumption	Final weighted score / max 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

It may seem surprisingly that the Netherlands, which ranks poorly for unmet prescription drug needs, ranks top in the EHCI for overall pharmaceutical sector performance. However, this does correlate with its relatively high public coverage of prescription drug spending and its relatively low level of OOP spending on drugs. The same is also true of Germany and France, where insurance is available to cover co-payments where they exist. Germany, however, only performs moderately well in its deployment of TNF-α inhibitors and statins, which is likely to be linked to per-patient budgets that are imposed on physicians in Germany.[77] If physicians exceeding target volumes, paybacks may be required. [78]

In the area of Rx subsidy (the public financing of drugs), Austria and Belgium do less well than other West European countries. In Austria, cost-containment priorities saw the introduction of annual prescription co-payment increases in 2010[79]. However, Austria ensures protection from excessive expenditure through numerous exemptions from cost-sharing requirements. As a result, the overall lower subsidised cover of total pharmaceutical sales does not translate into high unmet needs for prescription pharmaceuticals. [80]

Prescription co-payments have been raised in Belgium since the eurozone financial crisis, and there have been cuts in reimbursement rates, shifting a higher burden of costs on to patients. The Belgian government intends to introduce further restrictions on the number of drugs that are reimbursed.[81] Nevertheless, the Belgian government has introduced measures to reduce the impact of OOP payments for vulnerable groups[82]. Although data are not available for this country, unmet needs for prescription drugs are unlikely to be significant. As in Austria, Belgium's generic penetration is also relatively low as a share of the total pharmaceutical market in volume terms compared with countries that score better in the Rx indicator – the Netherlands, Germany, UK and France. Non-reimbursable costs are generally higher in countries with lower generic penetration.

77. https://www.medscape.com/viewarticle/810296

78. http://eprints.lse.ac.uk/68290/7/Wouters_Pharmaceutical_regulation.pdf

79. http://apps.who.int/medicinedocs/documents/s19046en/s19046en.pdf

80. https://ec.europa.eu/health/sites/health/files/state/docs/chp_at_english.pdf

81. Economist Intelligence Unit.

82. https://ec.europa.eu/health/sites/health/files/state/docs/chp_be_english.pdf

The four East European countries, as well as Italy, all perform badly in the area of public subsidy for prescription medicines. Pharmaceutical provision in Poland, Romania and Hungary are all characterised by narrow and shallow reimbursement and high levels of co-payment. As noted above, protection for vulnerable groups against the barrier of high OOP charges is especially weak in Poland and Romania.[83]

The considerable disparity between the OECD's relatively high measure of the proportion of total pharmaceutical costs covered by public schemes in Slovakia, and this country's poor scoring on the 2017 EHCI Index's indicator for prescription drug subsidies, can be accounted for by the time lag between the two data sets and the gradual impact of cuts to the number of reimbursable drugs and increases in co-payments between 2011 and 2013.

83. https://ec.europa.eu/health/sites/health/files/state/docs/chp_romania_english.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. Drug-makers have come under increasing pressure to prove the long-term benefits of their products. They have also encountered more mundane barriers in terms of slow administrative access to markets.

A study of access to innovative cancer medicines, conducted by the Swedish Institute for Health Economics [84] found that delays in patient access to innovative new treatments can range from five months to up to four years across Europe. Uptake of these treatments in Europe was closely linked to the GDP per capita of the countries surveyed, with Central and Eastern Europe noticeably slower in providing access to these medicines. The research also found a link between uptake of innovative medicines and cancer survival rates.

Although affordability is one reason for slow uptake of innovative medicines, the study 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. In most of the 12 comparator countries, for example, marketing authorisation, which requires proof of product safety and efficacy, has to be obtained with relevant national authorities before decisions on pricing and reimbursement are taken. Pricing and reimbursement decisions involve assessments of patient benefit, added therapeutic benefit, cost-effectiveness and budget impact.

Although new products are, in theory, available once authorisation has been granted, patients in countries may have to wait for reimbursement decisions to be finalised before they can access medicines. Germany and the UK present exceptions to this general rule, with new products usually reimbursed before post-marketing evaluation.[85] This correlates with these countries' high scores on the access to new medicines indicator in the EHCI Index, 2017.

By contrast, Belgium and Austria, which perform less well in terms of the EHCI's new medicines index, take on average between 150 to 300 days from marketing authorisation before new drugs are accessible to patients through public health systems. [86] However, the EFPIA indicator, which the EHCI Index uses, does not consider the time taken for availability in the inpatient sector. Because medicines deployed in Austrian hospitals are not subject to the same price controls as those administered in the outpatient setting, some manufacturers do not apply for reimbursement in the outpatient setting[87]. This could explain Austria's lower ranking.

Regardless of variations in methodology for measuring time from authorisation to reimbursed patient access, Austria and Belgium still fare considerably better than Italy. However, this assessment ignores regional variations; in some areas of Italy, provisional agreements can be made between marketing authorisation holders and regional administrations, allowing access to a new medicine

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

85. http://eprints.lse.ac.uk/68290/7/Wouters_Pharmaceutical_regulation.pdf

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

87. http://eprints.lse.ac.uk/68290/7/Wouters_Pharmaceutical_regulation.pdf

before pricing and reimbursement terms are finalised by the national authorities. Despite its strong showing in the EHCI index, the Netherlands also performs only moderately well in its deployment of effective novel cancer drugs and in speed of reimbursable access to new medicines.

Romania's approach to innovation

The poorest performers in the comparator group in terms of new medicines are the East European countries, where patient access often takes more than 300 days. [88] In Romania, funding for innovative and speciality medicines is based on assessments of their cost and effectiveness, with co-payments fees reflecting the availability of alternative treatments. Significant improvements have been made in terms of access to innovative treatments in recent years, including more regular updates to reimbursement lists. However, the process of obtaining reimbursement listings for new medicines is still lengthy.[89]

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 finalisation of cost-volume/ cost-volume-result negotiations for some drugs, 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, which allow 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 health outcomes.

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

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

Improving access to innovative medicines

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. In France, regulations allow for highly innovative drugs to be reimbursed prior to post-marketing evaluation, and in the case of highly innovative drugs without any therapeutic alternatives on the market can be made available through public reimbursement, before marketing authorisation is even granted. Prices are set freely until an agreement on price is reached with the manufacturer after the post-marketing evaluation process.

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:.

These schemes can facilitate nominative and / or cohort early access:

Nominative EAPs: These are named-patient early access schemes, which can be initiated by doctors and administered under their responsibility to patients in urgent need of a medicine.

Cohort EAPs: Typically, these are defined programmes initiated by a manufacturer to facilitate early access for a group of patients.

These schemes benefit patients with life-threatening or serious conditions for which no other approved treatments are available. They give regulatory agencies and public healthcare payers the chance to evaluate real-world effectiveness and safety for cost-effectiveness analysis, and better inform pricing and reimbursement decisions, as well as provide greater certainty on target populations and therapeutic benefits. Data from EAPs also aids pharmaceutical companies' preparations for full product launch and can benefit subsequent pricing and reimbursement negotiations. [90]

Early access programmes in Europe

Austria: Compassionate Use Programme
Austria's Compassionate Use Programme also covers nominative and cohort schemes, with a clear process set out in law with comprehensive guidelines and a relatively easy implementation. Reimbursement is possible, but conditional.
Belgium: Compassionate Use Programme
Belgium's EAP is also newer than the majority of other European Schemes (2014). It provides nominative and cohort early access pathways. Legislation governing cohort intervention is not comprehensive. Steep fees act as a barrier to implementation, but reimbursement is possible under certain conditions.
France: Autorisation Temporaire d'Utilisation
The ATU offers pharmaceutical companies an exceptional and temporary authorisation to allow patients to use their products without waiting for marketing authorisation. Permission must be granted by the French National Agency for Medicines and Health Products Safety (ANSM), in combination with a Therapeutic Use Protocol, and the drug must meet three criteria: • It must be a treatment for serious or rare pathologies, • There must be no suitable therapeutic alternative available in France, • The benefit-risk assessment must be strongly presumed to be positive. In addition, the ATU are only granted if a continuous and reliable supply of the drug can be guaranteed. The ATU is not a clinical trial and must not jeopardise the clinical development of the drug. There are two types of ATU: nominative and cohort. Free pricing and reimbursement are allowed under this scheme.

90. Heathfield, A., Lebiecki, J., Young, K. E., Urbinati, D., Soussi, I., & Toumi, M. (2015). The Evolving Landscape of Early Access Programmes: Comparisons and Implications for Market Access. *Value in Health*, *18*(7), A519.

Germany: Compassionate Use Programme
Germany's EAP is also covers nominative and cohort early access. Legislation is reportedly not clear and it fails to precisely differentiate between the two pathways. However, implementation is relatively free of barriers. Reimbursement is conditional.
Italy: Special Use (law 648/96)
This covers nominative and cohort early access, with a clear process set out in law with comprehensive guidelines. Free pricing and full reimbursement are possible. However, bureaucracy entailed in facilitating early access through this scheme is reportedly burdensome and a barrier to implementation. An unauthorized drug can qualify for this scheme if it targets a disease with no therapeutic choice. Access can be facilitated under three main categories: innovative medicines with marketing authorisation in other countries, unauthorised drugs that have undergone clinical trials, authorised drugs for use under a different therapeutic indication.
Poland: Import Docelowy
Poland's EAP provides a nominative scheme. There is no official compassionate use programme (CUP) policy; processes and guidelines are therefore unclear, which acts as a barrier to implementation. The innovative medicine needs marketing authorisation from the country of import. Reimbursement is possible, but conditional.
Romania: Early Access Programme
Romania offers a cohort EAP that is fully funded by the manufacturer, with no reimbursement available. After drug approval, but before reimbursement is agreed, manufacturers can offer a named patient programme once they have secured approval from the ANMDM. However the EAP is hard to access owing to a complicated legislative framework and delays in the system.
Spain: Individual Access Authorisation / Temporary Use Authorisation
Spain's EAP is also a nominative and cohort scheme, with a clear process set out in law with comprehensive guidelines. Reimbursement is possible, but conditional; negotiations take place with the Spanish Agency of Medicines and Health Products (AEMPS).
UK: Early Access to Medicine Scheme (EAMS)
This is a relatively new EAP (2014) facilitating nominative early access under clear legislation. Guidelines are clear and implementation is straightforward. Reimbursement is not possible. Instead, a company provides the product to the NHS free of charge during the EAP period until marketing authorisation is granted.

Sources: Heathfield, A., Lebiecki, J., Young, K. E., Urbinati, D., Soussi, I., & Toumi, M. (2015). The Evolving Landscape of Early Access Programmes: Comparisons and Implications for Market Access. Value in Health, 18(7), A519;

UK government: https://www.gov.uk/government/publications/early-access-to-medicines-scheme-eams-how-the-scheme-works/early-access-to-medicines-scheme-eams-task-group-and-principles Canadian government:

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. A sample of possible risk-sharing agreements is listed in the following table. 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

There are several examples of MEA implemented in Europe.

Spain has a Central Purchasing System under which the Ministry of Health, through a specialised agency, negotiates with companies to secure a "initial tender price" for several high-value molecules, based on the information from the regions on actual prices. Regions covered by the purchasing system accept this price and forego their right to do a second tendering round. Companies can choose to accept the price – and sell to the regions – or not. There is one winner per tender, but since tenders are done by molecule, there will be several competitors in the market.

For Hepatitis C, for example, a national plan was set up under which the MoH negotiated a price-volume scheme with each company. Final prices were based on national and regional volumes, with several competitors present in the market. This price-volume agreement has been discontinued. However, Spain is now discussing the implementation of value caps for HCV products, with regions paying paid the full amount until they reach the sales cap, after which companies will supply the product free of charge.

In **Italy** a specific fund is allocated for each therapeutic area, with no cap per molecule. Once the potential group of patients has been identified, the authorities negotiate with various companies to obtain a therapy cost that allows these patients to be treated within the fund limits. If the budget is overshot, then part of the treatment costs will be repaid by the companies providing the drug (through a payback mechanism based on market shares) as well as other pharmaceutical companies.

The system relies on the traceability of medicines by Italy's medicines agency, the AIFA, so that it can calculate the cost of treatment at the year end. In addition there is a web monitoring system where all patients are recorded to ensure that the right patient profile, with the agreed characteristics agreed, is treated.

In **Poland**, the MEA system involves supply agreements with two or more companies in each therapy area. A value cap is imposed, with any excess paid in full by the industry.

Europe's Innovative Medicines Initiative (IMI)

The IMI is a public-private partnership (PPP) between the pharmaceutical industry in Europe (EFPIA) and the EU that aims to accelerate and improve access to innovative medicines, partly by facilitating collaboration between those involved in healthcare research such as universities, research institutions and the pharmaceutical industry in order to accelerate the development of treatments[91].

The IMI has a total budget of €5bn. It has had two programmes: IMI-1 which ran from 2008-13 with a budget of €2bn and IMI-2 which is currently operating with a budget of €3.276bn. In the IMI-2 programme, half the budget comes from the EU – from the Health, Demographic Change and Wellbeing Societal Challenge of Horizon 2020, and the other half is committed to the programme by EFPIA partners. EFPIA companies and associated partners do not receive any funding from IMI but contribute to projects 'in kind'.

The IMI-2 projects aim to focus on the following priority disease areas for the European healthcare system and pharmaceutical industry:

- Antimicrobial resistance
- Osteoarthritis
- Cardiovascular disease
- Diabetes
- Neurodegenerative diseases
- Psychiatric disease
- Respiratory disease
- Autoimmune disease
- Ageing-associated diseases
- Cancer
- Orphan diseases

Romania currently receives €163,655 of funding from IMI which has been given to one small and medium-sized enterprise. The project, *Aetionomy*, has a total pan-European budget of nearly €18m and is involved in organising knowledge about neurodegenerative diseases for the improvement of drug development and therapy.

Hungary and Poland have received substantially more funding from the IMI. Hungary receives a total of €2,776,686 for six projects, including four at Semmelweis University. Poland receives a total of €1,799,530 IMI funding for 5 university projects.

91. http://www.imi.europa.eu/

The rollout of innovation funds

As seen above, Italy's performance is mediocre in terms of access to medicines[92]. Additionally, health technology assessment (HTA) activity – the process that assesses information on a drug's benefits and cost-effectiveness – is fragmented and under-developed in Italy, which can also hamper efficient access to the most effective medicines.[93] However, the need to improve access to innovative medicines has been acknowledged by Italian policy makers and initiatives to address the shortfalls are gathering pace.

Since 2017 €4bn of the annual government budget has been set aside for the purchase of new medicines over three years, with €1.5bn to be spent on oncology drugs, €1.5bn on other innovative drugs, €400m on vaccines and €600m on general increases in national medicines funding.[94] Then in February 2018 the government took further steps to address this problem by introducing a new Innovative Drug Fund, acknowledging an urgent need to channel financial resources specifically into funding for advanced new medicines.

The Italian Medicines Agency also introduced new processes for assessing products' levels of innovation, providing clearer definition of what constitutes innovation, as well as more flexibility for regulators to use scientific discretion on a case-by-case basis. Assessment of innovation will now be based on three criteria – unmet therapeutic need, added therapeutic value and quality of evidence.

The aim is to rectify a rigid regulatory environment that lacked transparency and thereby failed to optimise health and cost-efficiency gains through access to the most advanced new medicines

Consequently, the new fund not only dedicates funds specifically for new medicines, but also sets out an explicit framework for manufacturers seeking market entry in Italy. The innovation assessment for funding through this new channel is undertaken independently of the country's marketing authorisation and reimbursement processes, although it is largely dependent on the same evidence required by those processes. The Innovative Drug Fund is therefore expected to accelerate market access for new medicines, with those deemed to meet the innovation criteria being instantly granted inclusion in reimbursement.[95]

Spain's new financing model for rare diseases

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. Spinraza costs about €400,000 (US$500,000) a year for a single patient, but Biogen has agreed to halve the cost to the Spanish healthcare system after the first year of treatment. Biogen has also committed to pay for some treatment as part of its clinical trials.[96]

The MoH says that the agreed discounts will make treatment sustainable. Along with Italy, Spain is now one of the first countries to finance the treatment for the rare disease under its National Health Scheme. Apart from financing, the new model also involves setting up clinical protocols and

92. https://ec.europa.eu/health/sites/health/files/state/docs/chp_it_english.pdf

93. http://www.euro.who.int/__data/assets/pdf_file/0003/263253/HiT-Italy.pdf

94. Economist Intelligence Unit.

95. https://www.pharmaceuticalonline.com/doc/what-is-pharmaceutical-innovation-anyway-italy-s-new-algorithm-the-global-trend-0001

96. http://www.prioritis.com/2018/02/26/spain-a-new-financing-model-for-high-economic-impact-medicines/

monitoring the efficacy of treatments for the diseases that are covered. Medicines will be withdrawn from the scheme if proven ineffective although patient care will continue to be funded as needed. Although initially devoted solely to Spinraza, the new programme will eventually be extended to new drugs and treatments for other rare conditions that come with a high financial impact.

UK cancer conundrum exposes regulatory anomaly

The UK's poor performance in the access to novel cancer drugs indicator comes despite an impressive score for speedy access to new medicines generally, and despite a dedicated fund to improve and accelerate access to clinically-effective and cost-effective innovative new cancer drugs.[97] The Cancer Drug Fund (CDF) was set up in 2011 as a temporary solution to complaints about poor access to cancer medicines through the national health system (NHS). Operating via a managed access arrangement, the CDF fund selected new oncology medicines until more information on their effectiveness can be considered for routine commissioning.[98]

The CDF was originally supposed to end in 2014, when the UK was due to introduce value-based pricing. However, the promised rollout of value-based pricing was shelved amid industry disagreements. After consistently overspending on its original budget, the CDF was brought under the control of the National Institute for Health and Care Excellence (NICE), the UK's HTA agency, in 2016. Guidelines for CDF funding were also overhauled to introduce new cost-effectiveness criteria. Although the CDF continues to offer funding for selected oncology drugs ahead of their routine reimbursement, there are complaints from patient groups that access to newer drugs has deteriorated since the changes.[99]

In November 2017 the UK government unveiled another strategy to improve access to new medicines[100]. Under the mechanism, a panel of healthcare experts, headed by Sir Andrew Witty, the former chief executive officer of GlaxoSmithKline, will select five drugs each year from those currently being developed. The chosen drugs will get "breakthrough" status, triggering a support package that will help speed their way through clinical development and the NHS approval processes. In return the drugmakers involved will have to promise to offer them at cost-effective prices.

The government believes that the accelerated access plan will bring relevant medicines to the NHS up to four years earlier than usual. The initiative is also expected to allay concerns that the UK's exit from the EU in 2019 could hinder access to innovative medicines and undermine the life sciences industry. Simultaneously the government allotted £86m in funding to help smaller healthcare and pharmaceutical companies adopt digital platforms and encourage the uptake of medical technologies.

97. https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/cancer-drugs-fund

98. https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/cancer-drugs-fund

99. https://www.theguardian.com/society/2016/aug/15/nhs-cancer-patients-innovative-drugs-breast-prostate-uk

100. http://www.bbc.co.uk/news/health-41843320

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 still 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 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 EIU's proposals

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[101]. 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.[102]

● 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[103], 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.

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

101. http://ec.europa.eu/eurostat/statistics-explained/index.php/Government_expenditure_on_health

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

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

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 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.

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 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 that Romania's HTA agency needs at least 20 staff, not the six currently employed.[104]

- 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.

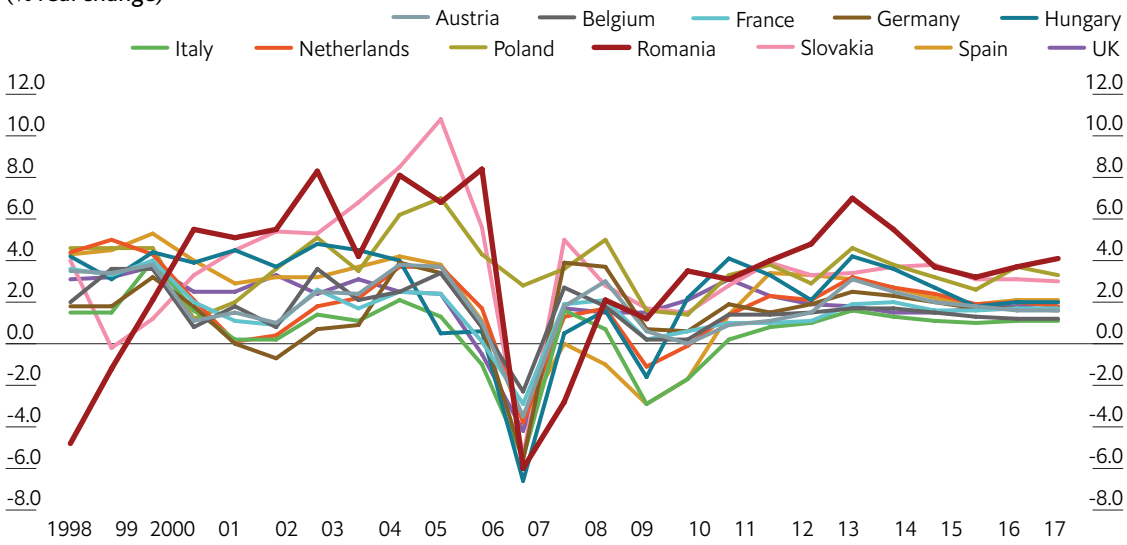
- The rollout of MEAs in Romania has improved access to medicines. However, after two year of implementation, the cost-volume legislation has arguably reached its limits. Romania is one of the few countries in EU that has implemented only two types of MEA (cost-volume and cost-volume results) despite 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.

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 the country's funding approaches.

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

Figure 16: GDP growth 1998-2017
(% real change)



Soure: The Economist Intelligence Unit, as of April 2018.

Healthcare spending as % of GDP (ten-year trend)

	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	Change
Austria	10.6	11.2	11.2	10.9	11.2	11.1	11.2	11.2	11.3	11.2	+0.6
Belgium	9.6	10.4	10.2	10.4	10.5	10.6	10.6	10.6	10.6	10.6	+1
France	10.6	11.3	11.2	11.3	11.4	11.6	11.5	11.5	11.5	11.6	+1
Germany	10.4	11.4	11.3	10.9	11.0	11.2	11.3	11.3	11.3	11.5	+1.1
Hungary	7.3	7.5	7.9	7.8	7.7	7.5	7.4	7.4	7.5	7.5	+0.2
Italy	8.5	8.9	9.4	9.4	9.3	9.3	9.2	9.2	9.2	9.2	+0.7
Netherlands	9.4	9.6	10.3	10.5	10.5	11.0	11.0	10.9	10.9	10.9	+1.5
Poland	6.9	7.1	6.9	6.7	6.6	6.4	6.4	6.4	6.4	6.4	-0.5
Romania	5.3	5.6	5.8	5.5	5.5	5.6	5.6	5.5	5.5	5.4	+0.1
Slovakia	8.0	9.2	8.5	8.0	8.1	8.0	8.1	8.0	7.9	8.0	Flat
Spain	8.8	9.5	9.6	9.5	9.4	9.1	9.0	9.0	9.0	9.0	+0.2
UK	8.9	9.8	9.5	9.3	9.4	9.3	9.1	9.1	9.2	9.4	+0.5

Source: The Economist Intelligence Unit, as of January 2017

Healthcare spending in nominal US$ bn (ten-year trend)

	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Austria	45.6	44.9	44	47	45.9	47.7	49.6	42.8	44	46.9
Belgium	50	50.5	49.4	54.9	52.3	55.2	56.4	48.3	49.7	52.1
France	310.9	305.3	296.8	323.7	305.9	326	328.4	280.9	284.4	300.1
Germany	391.3	390.5	386	409.5	390.2	421.2	441	382.6	393.9	424.8
Hungary	11.5	9.8	10.3	11	9.9	10.1	10.4	9.1	9.5	10.3
Italy	213.6	205.8	200	212	192.9	196	198.4	168.6	170.6	178.2
Netherlands	90.2	88.6	88	93.9	91.2	95.4	96	82.7	84.7	90
Poland	36.8	31.2	33.1	35.4	33	33.6	34.9	30.5	30.1	33
Romania	11	9.4	9.7	10.2	9.4	10.7	11.2	9.8	10186	11479
Slovakia	5.5	6	5.7	5.7	5.9	5.9	6.2	6.3	6.4	6.8
Spain	144.5	142.8	137.7	141.5	125.7	124	124.1	107.9	111.4	118.1
UK	140	150	150.1	152.1	158.4	163	167.2	172.1	179.6	191.4

Source: The Economist Intelligence Unit, as of January 2017

Public and private health financing in 2015 (% of CHE)

	General government health expenditure as % CHE	Private health expenditure % CHE	Health as % of general government expenditure
Austria	76	24	15
Belgium	82	18	16
France	79	21	15
Germany	84	16	16
Hungary	67	33	10
Italy	75	25	13
Netherlands	81	19	19
Poland	70	30	11
Romania	78	22	11
Slovakia	80	20	12
Spain	71	29	15
UK	80	20	19

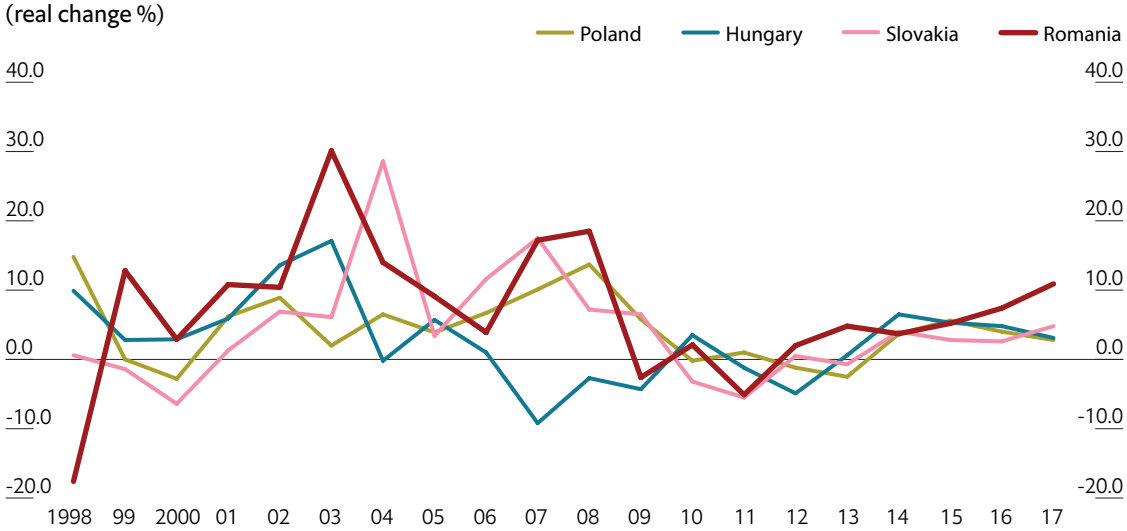
Source: WHO Global Health Expenditure Database.

Financing sources breakdown in 2015 (% of CHE)

	Compulsory financing arrangements	Government financing arrangements	Compulsory health insurance	Social health insurance	Voluntary financing arrangements	VHI	OOP	Other financing
Austria	76	31	45	45	24	5	18	2
Belgium	77	18	59	59	23	5	18	-
France	79	4	75	75	21	14	7	-
Germany	84	7	78	78	16	1	13	2
Hungary	67	11	56	56	33	2	29	2
Italy	75	75	-	-	25	2	23	1
Netherland	81	9	71	19	19	6	12	1
Poland	70	9	61	60	30	5	23	2
Romania	78	13	65	65	22	-	21	-
Slovakia	80	4	75	75	20	-	18	2
Spain	71	66	5	5	29	4	24	-
UK	80	80	-	-	20	3	15	2

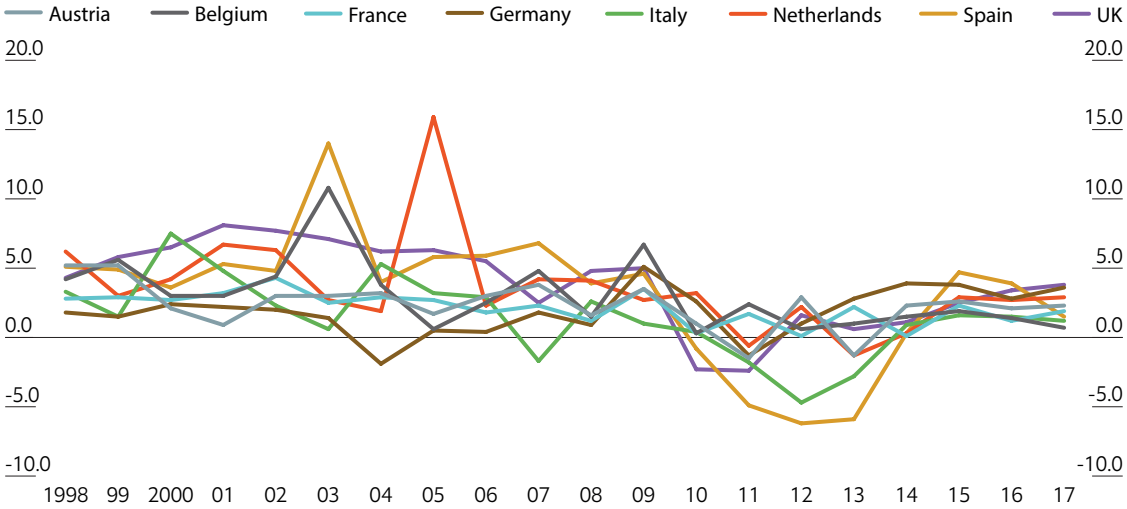
Source: WHO Global Health Expenditure Database.

Figure 17: Eastern Europe health expenditure growth
(real change %)



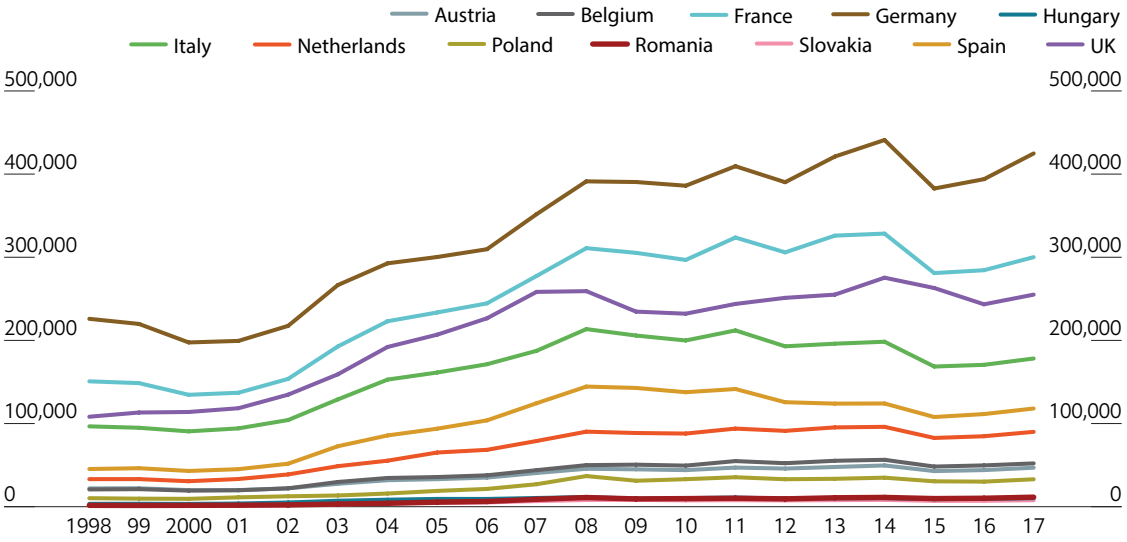
Source: The Economist Intelligence Unit; World Health Organisation

Figure 18: Western Europe health expenditure growth
(real change %)



Sources: The Economist Intelligence Unit; World Health Organisation.

Figure 19: Current health expenditure
(nominal US$m)



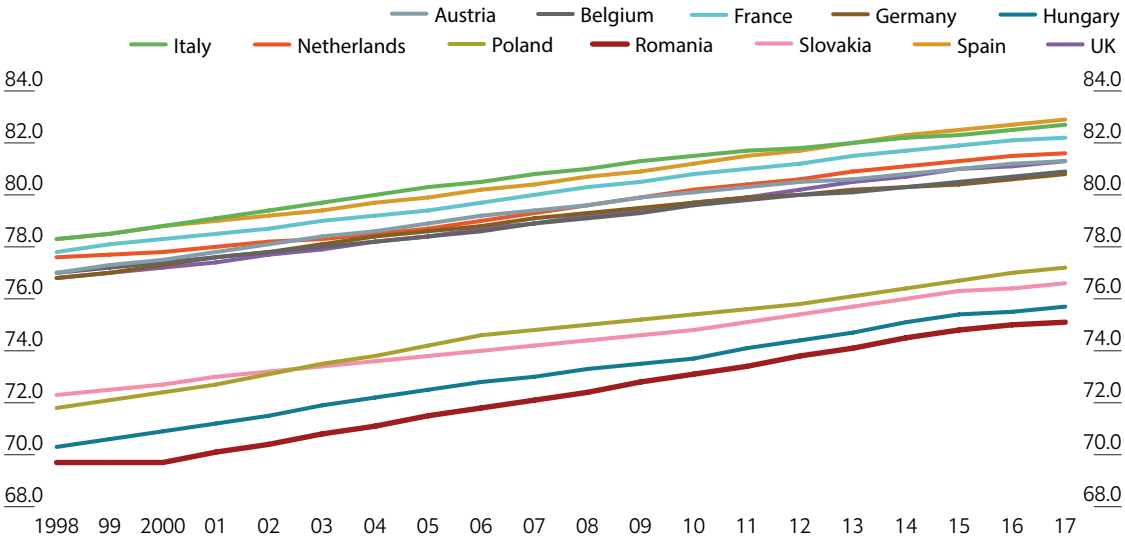
Source: The Economist Intelligence Unit.

Pharmaceutical market, 2015

Countries	Market value €m * (at ex-factory prices)	Market value per capita € **	CAGR 10 years to 2017
Austria	3,550	417.64	3.6
Belgium	4,705	416.74	3.4
France	27,645	428.80	2.6
Germany	30,038	365.55	4.2
Hungary	2,133	218.10	3.6
Italy	22,703	383.37	1.1
Netherlands	4,821	285.27	0.78
Poland	5,587	145.49	4.2
Romania	2,633	132.44	5.2
Slovakia	1,187	218.20	3.4
Spain	15,625	336.74	2.7
UK	22,375	345.72	-1.62

Source:
*European Federation of Pharmaceutical Industries and Associations (EFPIA).
** EIU estimate based on EFPIA market value data and EIU population data.

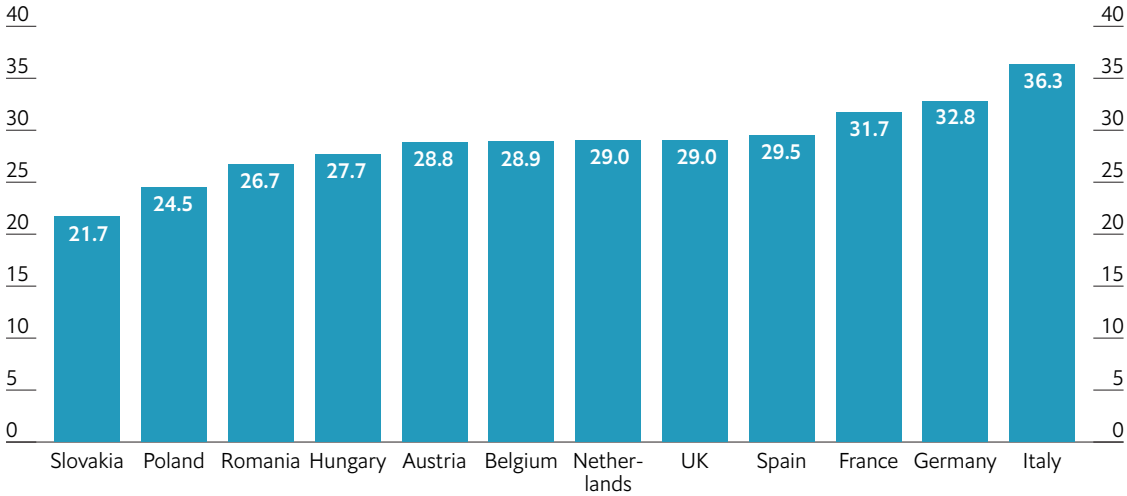
Figure 20: Average life expectancy at birth
(years)



Source: UN Bureau of Census; The Economist Intelligence Unit.

Figure 21: Old-age dependency ratio

(%)

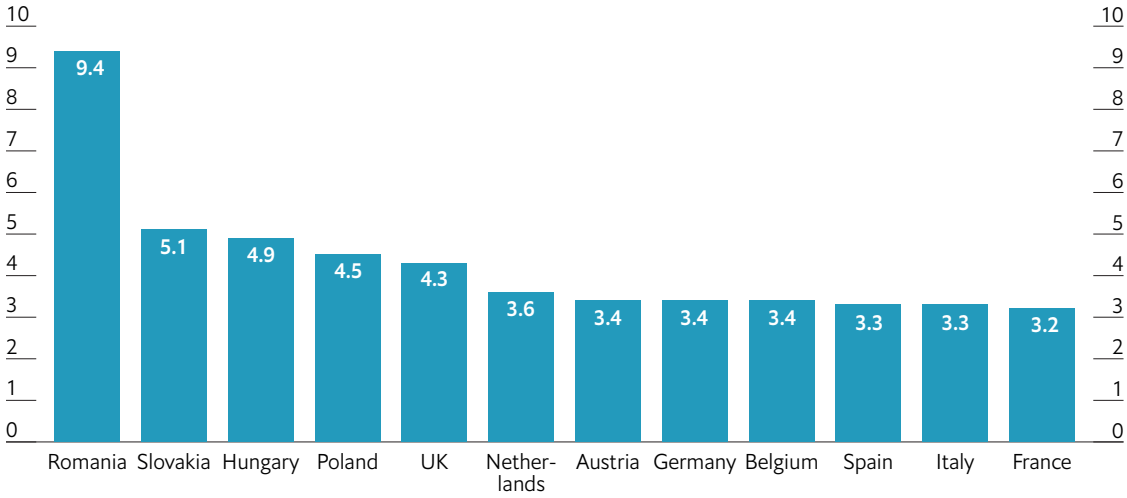


Note: Estimated ratio of those people older than 64 to those aged 15-64 in 2017.

Source: The Economist Intelligence Unit.

Figure 22: Infant mortality rate in 2017

(estimated deaths per 1,000 live births)



Source: The Economist Intelligence Unit.

About EIU Healthcare

EIU Healthcare is a business of The Economist Intelligence Unit (EIU). It delivers world-renowned analytical and strategic advisory services, providing businesses and institutions with market-leading intelligence on all areas of the healthcare market.

Our services combine the specialist skills of the Health Policy and Clinical Evidence practice with the extensive global reach required when accessing leading market consultancy and intelligence across the world.

We share the principles of independence and intellectual rigour with our sister company, The Economist. Our research is based on empirical evidence, giving clients the assurance that our findings are honest and impartial.

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