White Paper

# Understanding Net Pharmaceutical Expenditure Dynamics in Europe

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# Overview

The level of pharmaceutical expenditure is closely watched and often commented upon, but the composition of that expenditure and its dynamics are not as well understood. Healthcare systems require information on the future of their budgets, as well as an understanding of what a sustainable approach to healthcare budgeting could be, as drivers of budgets change over time due to demographic change, epidemiology, and innovative technologies. Typically, official statistics such as OECD data on pharmaceutical spending only includes medicines dispensed in pharmacies and do not include those used in the hospital setting, an issue which raises questions about their representativeness of total spending. In this report, for the first time across Europe, we have generated estimates of total pharmaceutical spending for the past 20-years including hospital spending, as well as discounts and rebates, for 15 countries. These estimates have been based on official statistics from government agencies in the countries (where available).

The findings relating to total pharmaceutical expenditure raise important questions when they defy expectations. The past 20-years have seen dramatic changes in the composition of pharmaceutical expenditure, as well as the type of medicines used, complexity of molecules, and number of patients treated.

This would suggest that total pharmaceutical spending should be rising dramatically, but pharmaceutical spending as a share of healthcare spending has changed to a lesser degree and has represented greater stability than expected.

In this report, we address the misconceptions surrounding pharmaceutical expenditure, affordability, and budget impact of medicines. The analyses describe the magnitude of change in pharmaceutical expenditure during the period 2000 to 2020 and disaggregate the total into segments that help explain the drivers of change over time. We use specific therapy classes or country case studies to illustrate the dynamic changes in more detail.

The study focusses on European countries with a strong foundation of public data. A comprehensive appendix detailing the methodology is provided as well as further detail on the findings in report.

*Thank you to those who supported the development of this document: Orlaith Brennan, Raja Shankar, Daniella Palazzo, Sai Bandaru, and contributors from the IQVIA Institute: Bernie Gardocki, Urvashi Porwal, Michael Kleinrock, and Murray Aitken.*

# Glossary of terms

| | |
|---|---|
| **List price** | The published price level including rebates and discounts, most commonly available price level across Europe. Also commonly referred to as the ex-manufacturer price (or ex-man) |
| **Net price** | The price-level for a single product after the removal of rebates and discounts, often estimated due to clawbacks, and complex discounts |
| **Net pharmaceutical expenditure** | The total cost of all medicines to a country's health system (also referred to as net [payer] expenditure, or net payer cost) |
| **Net manufacturer revenue** | Total revenue generated by the industry after rebates, discounts, supply chain fees, and VAT |
| **Healthcare expenditure** | Total expenditure on all healthcare, and includes all expenditures for the provision of health services, family planning activities, nutrition activities and emergency aid designated for health, but it excludes the provision of drinking water and sanitation |
| **Pharmaceutical expenditure** | All expenditure on prescription medicines and self-medication, often referred to as over-the-counter products |
| **Pharmaceutical expenditure (OECD definition)** | Expenditure on prescription medicines and self-medication, often referred to as over-the-counter products. In some countries, other medical non-durable goods are also included. Pharmaceuticals consumed in hospitals and other health care settings are excluded. Final expenditure on pharmaceuticals includes wholesale and retail margins and value-added tax. Total pharmaceutical spending refers in most countries to "net" spending, i.e., adjusted for possible rebates payable by manufacturers, wholesalers or pharmacies |
| **Purchasing Power Parity** | Purchasing power parities (PPPs) are the rates of currency conversion that try to equalise the purchasing power of different currencies, by eliminating the differences in price levels between countries |
| **GDP-deflation** | GDP deflator is a more comprehensive inflation measure than the CPI index because it isn't based on a fixed basket of goods and helps economists compare the levels of real economic activity from year to year |
| **Real values** | Real values are the reported nominal values adjusted for GDP deflation to report in 2020$ (constant) |
| **International dollar (Int.$)** | A theoretical currency that would buy a comparable amount of goods and services a U.S. dollar would buy in the United States across countries. This term is often used in conjunction with Purchasing Power Parity (PPP) data |
| **Per capita** | Per capita means the average per person and is often used in place of "per person" in statistical observances to normalise for different market sizes |
| **Direct costs** | The cost that the healthcare system incurs directly from medical management of the disease, the treatments provided, admissions, complementary tests and other care to affected patients |
| **Indirect costs** | Indirect costs extend beyond the direct cost of purchasing, in this case, medicines, and are incurred to society from the impact of a disease |

# Section 1: Understanding the components of pharmaceutical and healthcare expenditure

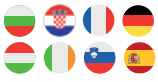
**The total pharmaceutical expenditure in Europe is not easy to calculate. Public sources completed by countries in Europe are updated on an annual basis but often lag 2-3 years behind. Major components of expenditure were not included for historic reasons, and while efforts are being made to improve the information, current policy should be determined based on a complete understanding of the missing pieces. This section discusses the availability of public information, as well as the relevance, and aims to dispel commonly held misconceptions around the total cost of pharmaceuticals in European countries.**

### EUROPEAN PAYERS HAVE INCOMPLETE DATA ON THEIR NET EXPENDITURE AT PRESENT

There are no official, consistent statistics measuring total drug spending across countries. Historically the only consistent measure of drug spending was produced by the OECD and covered 'retail' drugs measured at a total system net spending level. This measures the net amount paid by a country's health system, including that paid by patients, insurers and governments through retail pharmacies, and deducts any discounts and rebates they receive known by governments, who then submit the results to OECD.

Critiques of these measures centre around the lack of inclusion of non-retail drugs, which are presumed to be some of the largest growth drivers in total drug spending. This segment can range from 15% to 70% of the market value.[1] Countries also differ in what comprises retail and hospital pharmaceutical expenditure. OECD has attempted to address this situation in a newer method of reporting total drug spending (stats.oecd.org) but has faced significant issues with countries' inconsistent and incompatible data submissions, as noted in their methodology appendices. Publications and academic institutions often cite this source of information without understanding the limitations or considering the broader impact of pharmaceuticals to patients and their indirect savings to the healthcare system.

**Exhibit 1: Segmentation of European countries based on their availability of net expenditure data**

| | | |
|---|---|---|
| **Tier 1: Reliable public data**<br>High quality OECD data, that has been sense-checked by 3rd party data and information from publicly available sources or national associations | Belgium, Czechia, Denmark, Norway, Slovakia*, Spain (post - 2018), Sweden |  |
| **Tier 2: Established methodologies**<br>Data that is able to be shared via non-OECD public sources (e.g. AIFA reports in Italy, or ABPI methodology in UK), or through national associations with high visibility to sources | Italy, United Kingdom |  |
| **Tier 3: Augmented data**<br>Partial OECD data, that is able to be augmented by 3rd party data and/or information from publicly available sources or national associations | Bulgaria, Croatia, France, Germany, Hungary, Ireland, Slovenia, Spain (pre-2018) |  |
| **Tier 4: Incomplete public data**<br>Partial or non-existent OECD data, that is unable to be augmented by 3rd party data and/or information from publicly available sources or national associations due to visibility or unavailability | Austria, Finland, Greece, Lithuania, Netherlands, Poland, Portugal, Romania, Switzerland |  |

Notes: Methods for estimating total drug spending on a net basis are detailed in the methodology appendix.
* Denotes market with quality OECD data on pharmaceutical expenditure but no submission on total healthcare expenditure to compare over time.

To understand the total pharmaceutical expenditure, analyses were undertaken to determine what information was provided by European countries to the OECD, and which components of spending (e.g., hospital medicines, OTC medicines) were included, in order to then fill-in the gaps with 3rd-party data. The analyses concluded that only 7 countries in Europe provide accurate information to the OECD, and a great many provide unclear or unreliable data that was unable to be validated.

**TRANSPARENCY OF NET EXPENDITURE AT A NATIONAL LEVEL IS SUPERIOR TO A FOCUS ON THE NET PRICE OF SINGLE MEDICINES**

Information on pharmaceutical expenditure should be made transparent to support decision-making. However, the concept of net price is highly misunderstood and only sometimes calculated accurately.

The list price is currently the most transparent price level across Europe, with published prices available throughout countries. This price level varies, with lower prices available in less affluent countries. International Reference Pricing (IRP) and parallel trade limit variability by referencing to other similar countries, and by reallocating cheaper medicines across borders. Both have their benefits to the wider system, but lead to price convergence across countries.

The 'net price to the manufacturer' therefore should represent the price of a single product, determined through negotiation with a payer and the pharmaceutical company after rebates and discounts. However, some payers implement additional clawbacks to cap the growth of pharmaceutical expenditure at a certain level, and as such further rebates are then paid by industry to countries 1–3 years after the price setting. This rebate is not calculated at the product-level but rather by relevant company sales and/or market share. Hospital rebates can be increasingly complex with a maximum cost per patient threshold, and a total cap on the budget allocated to a therapy area.

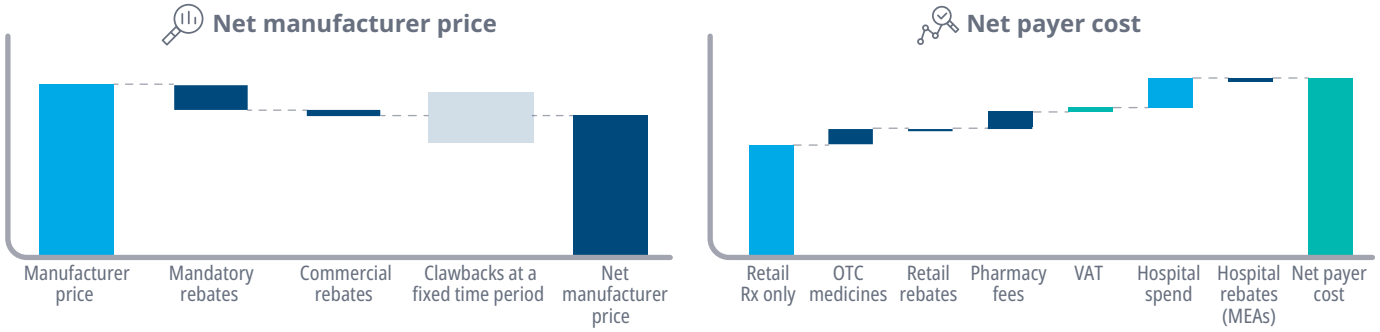
As such, it is not always possible to determine the net price for every product, even if all information was made available. Transparency of net prices does therefore not automatically result in transparency of net expenditure. According to a recent study on pricing policies, only 1 in 16 payer representatives surveyed agrees that net price transparency will improve patient access to medicines.[2]

By aggregating all the rebates and discounts reported, a figure known as the 'net payer expenditure' is generated. This is the net [payer] expenditure of all pharmaceuticals paid by a country and provides a system-wide understanding of the spend on pharmaceuticals. Single products with higher prices for unique conditions can exist, alongside low-cost generic products for other conditions. This supports the ability for payers to negotiate commercial discounts for medicines with pharmaceutical companies based on their ability to pay, and the variable need for the medicine in each country.

In the political debate, the focus is overwhelmingly on list prices of single products which provokes public outcry. At the same time, payers and academics understand the difference between net price and the net expenditure, and there is a problematic and misleading focus of the political debate on a few single product list prices, rather than total net expenditure. This report uses a variety of sources to provide an accurate estimation of the net payer expenditure for 15 countries in Europe.

*Information on pharmaceutical expenditure should be made transparent to support decision-making. However, the concept of net price is highly misunderstood and only sometimes calculated accurately.*

**Exhibit 2: A comparison of net manufacturer price and net payer cost**



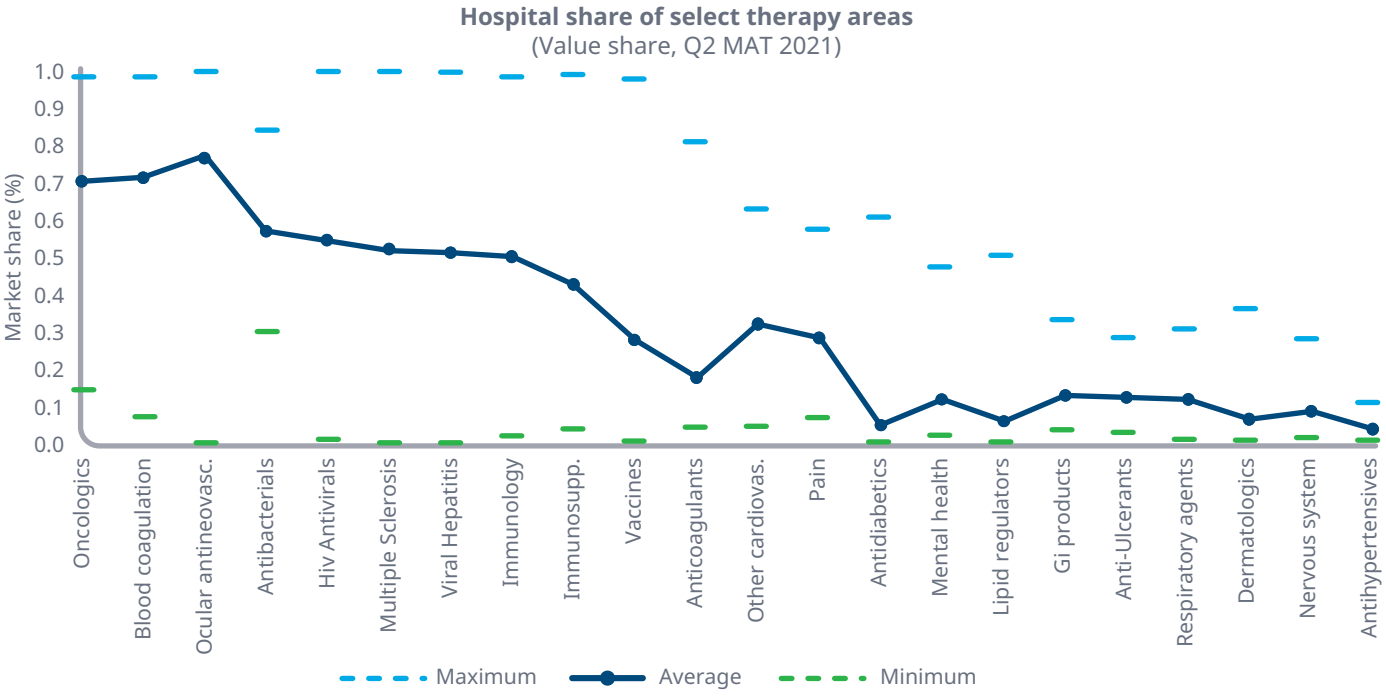

| | | |
|---|---|---|
| **Coverage** | Single medicine(s) | Total healthcare system |
| **Definition** | The price paid by a payer for a single medicine after rebates and discounts | The total cost of medicines paid by the system after rebates and discounts |
| **Pros** | • A small number of low volume products will have lower prices as countries see prices internationally | • Permits system-wide understanding of pharmaceutical costs |
| **Cons** | • Reduces the ability to have lower prices across European markets | • Poorly understood by payers and academics |
| | • Limits the ability to have term-based contracts | • Limited data transparency in 2021 |
| | • Net prices are not available until months / years after the price has been agreed due to payer clawbacks | • Permits confidential rebates that allow countries to generate with pharma companies |
| | • Companies total spend, not products, are subject to clawbacks which means that net price cannot be determined at a product level | |

## INCLUDING THE HOSPITAL SEGMENT MEANS COUNTRIES ARE REPOSITIONED RELATIVE TO EACH OTHER

It could be argued that the major missing segment within OECD information (the hospital segment) is the area that is growing fastest and contributing most to the perception that pharmaceutical expenditure is increasing rapidly. However, this oversimplifies the situation for two reasons.

Firstly, data on hospital medicines is published at list prices and are more likely to have rebates and

**Exhibit 3: Hospital share of select therapy areas in Europe**




Source: MIDAS sales data at list price (extracted October 2021)
Notes: Excludes countries such as Greece, and Slovenia where IQVIA Hospital panels are not available within MIDAS™

discounts applied than the retail setting. This means that published figures will overstate the growth and size of this segment.

Secondly, medicines that are dispensed in the hospital setting in one country are not always dispensed through the hospital setting in another country. To simplify, the same product can be paid for (and therefore visible in published figures) by the retail channel in Ireland, but would be dispensed via the hospital channel in France. This creates a problem in simplifying the issue and is a key concept to understand.

As a result, when analysing European countries, adjustment should be made for the dispensing setting, to ensure an accurate picture of the cost of medicines across countries. It is important to make policy decisions based on robust data that accurately represents country spending.

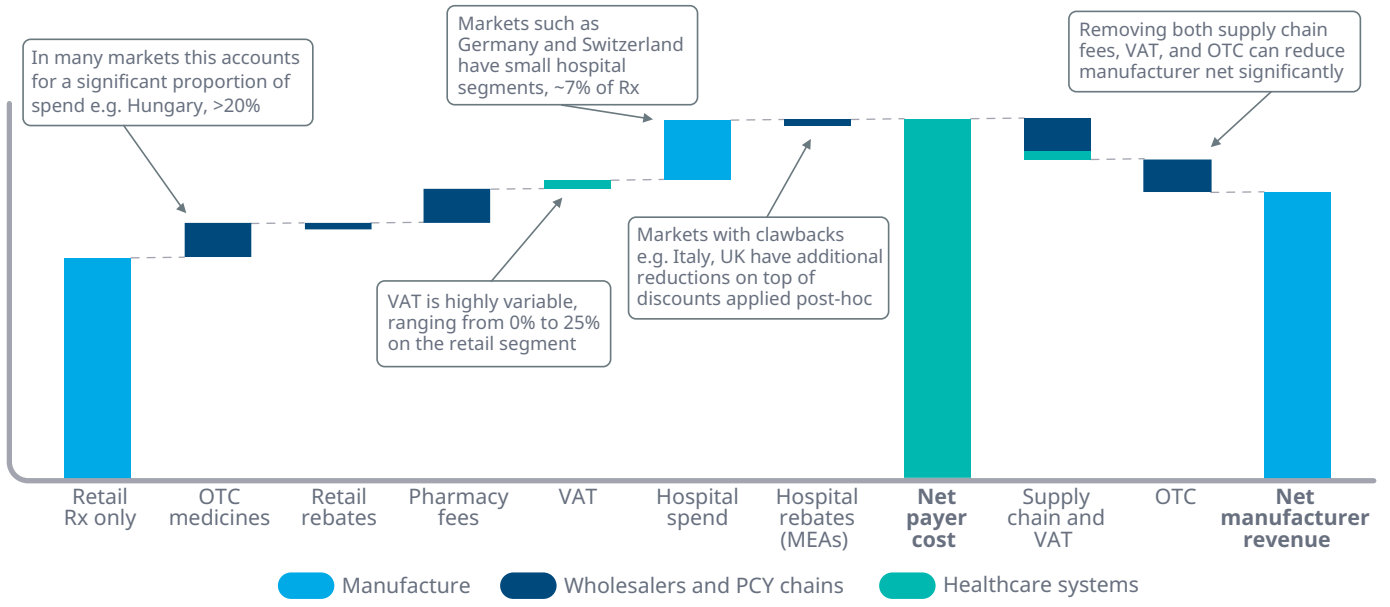
**PHARMACEUTICAL EXPENDITURE INCLUDES TAX, AND SUPPLY CHAIN COSTS BASED ON COUNTRY POLICIES**

Countries have different approaches to dispensing medicines. Dispensing medicines in the hospital or retail setting generates different costs. Dispensing through the retail channel generates supply chain costs for the transportation of the medicine from wholesalers to retail pharmacies, and includes a margin for the pharmacy. In the hospital setting this cost is not present, but is counteracted by the higher healthcare costs associated with specialist care. Prescribing 30-day versus 90-day prescriptions results in higher prescription costs due to increased regulation, as well as increased interaction with healthcare professionals, which is a trade-off considered by many countries. Therefore, what is reported as 'net pharmaceutical expenditure' represents more than the revenue generated by pharmaceutical companies.

Large sections of cost are attributed to the supply of medicines, which is a critical component of the European medicine's infrastructure. 2–3% of the total cost can be attributed to supply chain costs. More significantly, the accounts submitted by countries include the highly variable amount of VAT paid by manufacturers, depending on the country. This figure can range from 20% in Bulgaria to 2.4% in France.

This paper includes a number of analyses that demonstrate the growth rate of this figure net of rebates, discounts, and clawbacks. This net payer expenditure, or total pharmaceutical expenditure, is not yet able to separate the additional fees to supply chain players within the pharmaceutical value-chain. It therefore acts as an over-estimate for the total cost attributable to pharmaceutical companies directly.

**Exhibit 4: Components of net payer cost and net manufacturer revenue**



# Section 2: Real budget impact

**Analyses within this section study the impact of pharmaceutical expenditure in the broader context of the total expenditure on health, at a net cost level. This means that the information included is net of discounts, rebates, and clawbacks and is the most accurate perspective on the total country expenditure published to date for these European countries.**

### THE NET PHARMACEUTICAL EXPENDITURE IS AN IMPORTANT, BUT SMALLER PART OF THE TOTAL HEALTHCARE COSTS

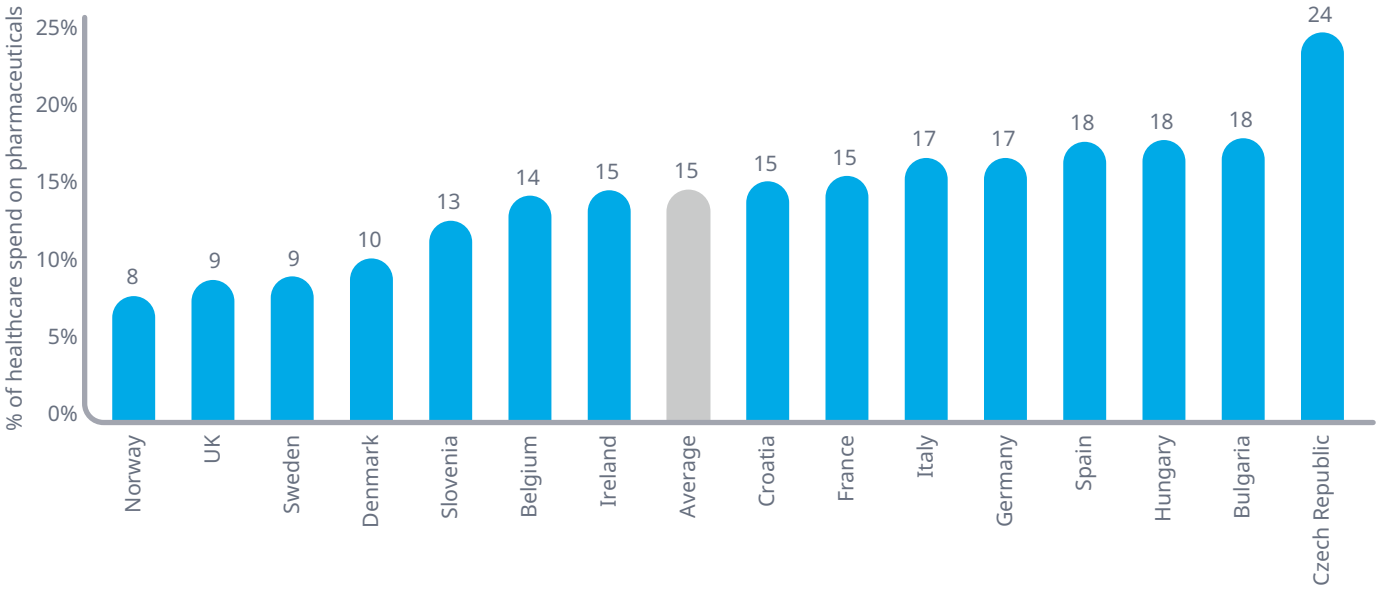
Spending on all pharmaceuticals represents between 8% and 24% of the healthcare budget in 2018 for the available European countries at a net level (including the impact of rebates and discounts from manufacturers to payers). Nordic countries such as Norway, Sweden, and Denmark had the lowest average spend of pharmaceuticals, reaching 9% of their total spend on all healthcare.

This trend extends across Europe to less economically developed countries. Central and Eastern European countries studied, such as Hungary, Croatia, and Bulgaria, also spend a low share of their total healthcare spend on pharmaceuticals. This figure considers the purchasing power of different countries by converting the data into International Dollars (Int$), and using OECD purchasing power parity calculations. The higher expenditure in these countries is explained further by showing examples of inefficiencies in prescribing generic medicines, and historic underinvestment in healthcare in section 3.

Higher drug spending shares are normally associated with countries where healthcare spending is lower overall, such as Spain and Czechia, in which the total healthcare expenditure is below other countries. Pharmaceutical costs therefore appear to represent a higher proportion of the total, rather than being higher by any other metric (e.g., on a per capita basis, or in absolute terms).

Comparing this figure to a recent global study using the same methodology by the IQVIA Institute for Human Data Science[3], European countries have a lower net pharmaceutical expenditure as a percentage of healthcare than major countries like Japan (17%), S. Korea (20%), and often more than less developed countries like Brazil (13%).

**Exhibit 5: Net pharmaceutical expenditure as a percentage of healthcare, 2018**




Source: World Health Organization (WHO), 2018 (extracted on 18 November 2021), WHO SHE 1.0 data (extracted on 18 November 2021); OECD, 2019 (extracted on 18 November 2021).

Notes: Drug spending includes medicines dispensed in both retail and non-retail sectors. Methods for estimating total drug spending on a net basis are detailed in the methodology appendix. Health spending from WHO database. Both the drug and health spend data were adjusted for population, Purchasing Power Parity (PPP) and GDP growth to represent in 2020 values. Czech Republic has low healthcare spend, contributing to the high % pharmaceutical spend.

**PHARMACEUTICAL EXPENDITURE HAS REMAINED ~15% OF HEALTHCARE EXPENDITURE SINCE 2000**

The perception of the pharmaceutical budget in most countries is one of increasing burden. However, understanding the net cost of medicines over a long period of time provides a clear example that pharmaceutical expenditure should not be causing budgetary concerns for payers and policymakers, and that further escalation beyond the current restrictions will have more negative impact than positive.

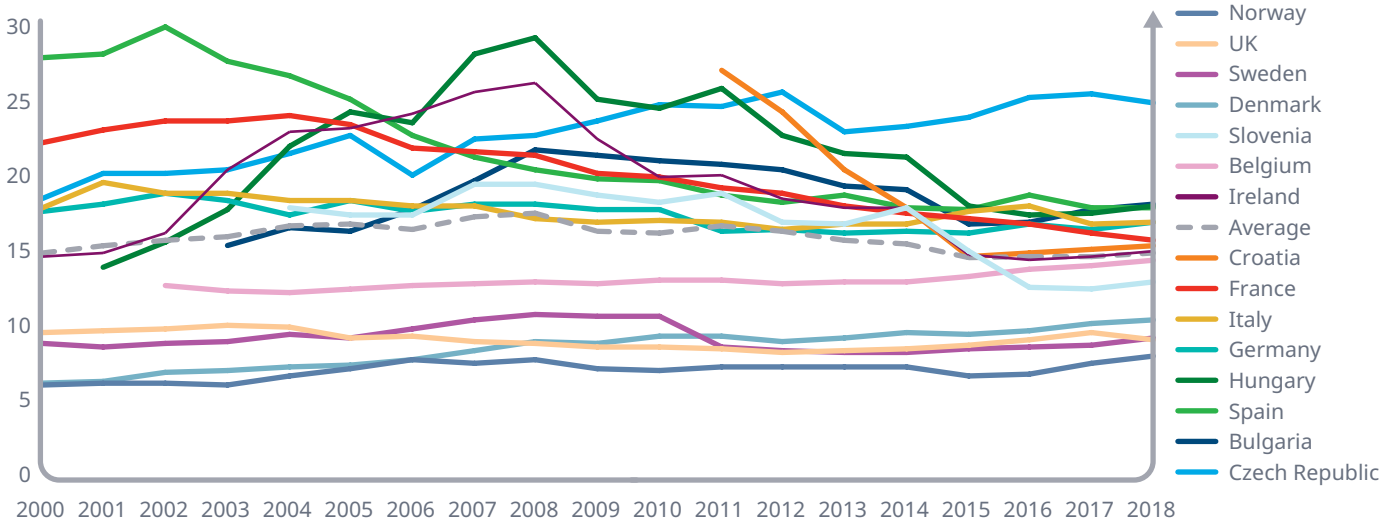
Viewing pharmaceutical expenditure as a proportion of healthcare expenditure over time provides an important insight: the proportion that it represents has remained either flat or reduced in most countries since 2000. Countries' pharmaceutical spending share of healthcare has been converging, with countries ranging from 6–27% in 2008 and 8–17% in 2018 (excluding Czechia). Those countries with the lowest pharmaceutical share of healthcare uniformly have the highest overall health expenditure, such as Norway, Denmark, and Sweden, which all spend more than $6,000 per capita on healthcare, and 8%–10% on pharmaceutical expenditure.

The budget impact of Sovaldi (sofosbuvir) to treat hepatitis C has been regularly misinterpreted by stakeholders across Europe. Following its launch in 2015, there is no noticeable change in the pharmaceutical expenditure at a country-level. This highlights a critical point that viewing single medicines, and even classes of medicines without seeing the wider context can lead to restrictions in access to innovative medicines, and perceptions of affordability without budgetary necessity.

**THE GROWTH RATE FOR PHARMACEUTICAL EXPENDITURE HAS FALLEN SIGNIFICANTLY SINCE 2000, AND REMAINS LOW**

Healthcare expenditure generally fluctuate over time, representing public health emergencies or increased investment in new facilities. In comparison, growth in pharmaceutical expenditure across the European countries studied has remained in the low single digits for the past 10 years, and consistently been under pressure. Critics would consider any growth in this segment above that of the total healthcare expenditure as negative, however it represents a small proportion of the total cost of all healthcare in countries. In addition, it has provided vast value

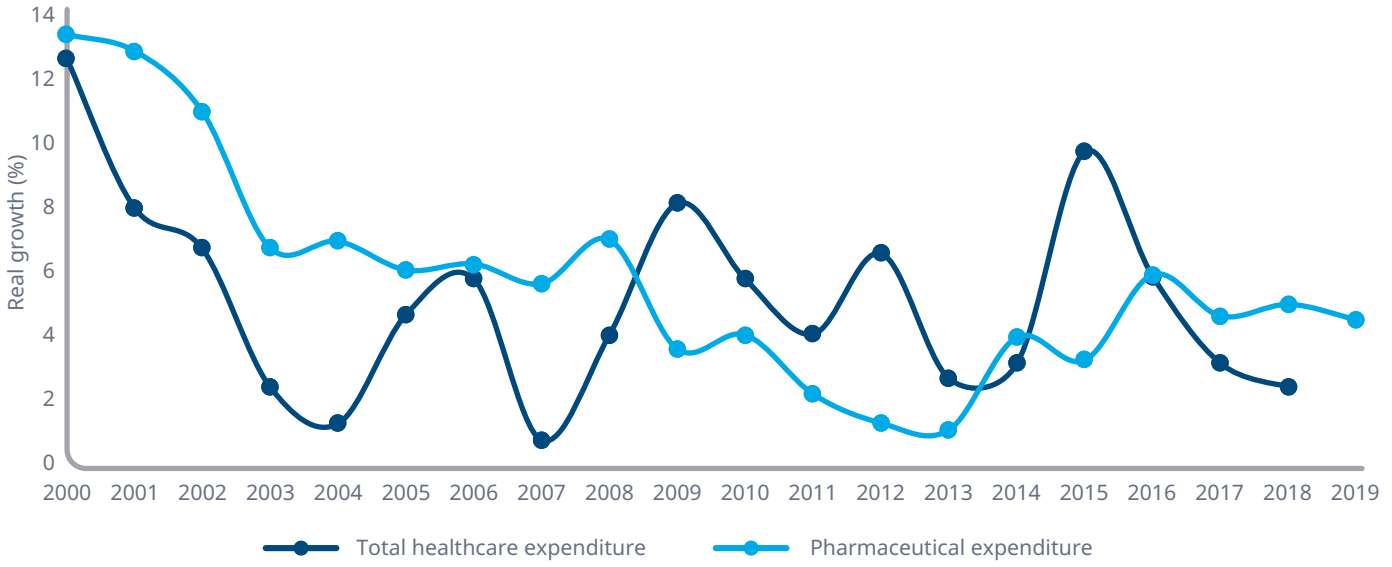
**Exhibit 6: Net pharmaceutical expenditure as a percentage of healthcare, 2000-2018**




Source: World Health Organization (WHO), 2018 (extracted on 18 November 2021), WHO SHE 1.0 data (extracted on 18 November 2021); OECD, 2019 (extracted on 18 November 2021).

Notes: Drug spending includes medicines dispensed in both retail and non-retail sectors. Methods for estimating total drug spending on a net basis are detailed in the methodology appendix. Health spending from WHO database. Both the drug and health spend data were adjusted for population, Purchasing Power Parity (PPP) and GDP growth to represent in 2020 values.

**Exhibit 7: Average expenditure growth in Europe, 2000-2019**




Source: World Health Organization (WHO), 2018 (extracted on 18 November 2021), WHO SHE 1.0 data (extracted on 18 November 2021); OECD, 2019 (extracted on 18 November 2021).
Notes: Average expenditure growth across the 15 markets studied.

to patients and to the wider healthcare system through innovations in cardiovascular disease, cancer, COVID-19, and other debilitating diseases.

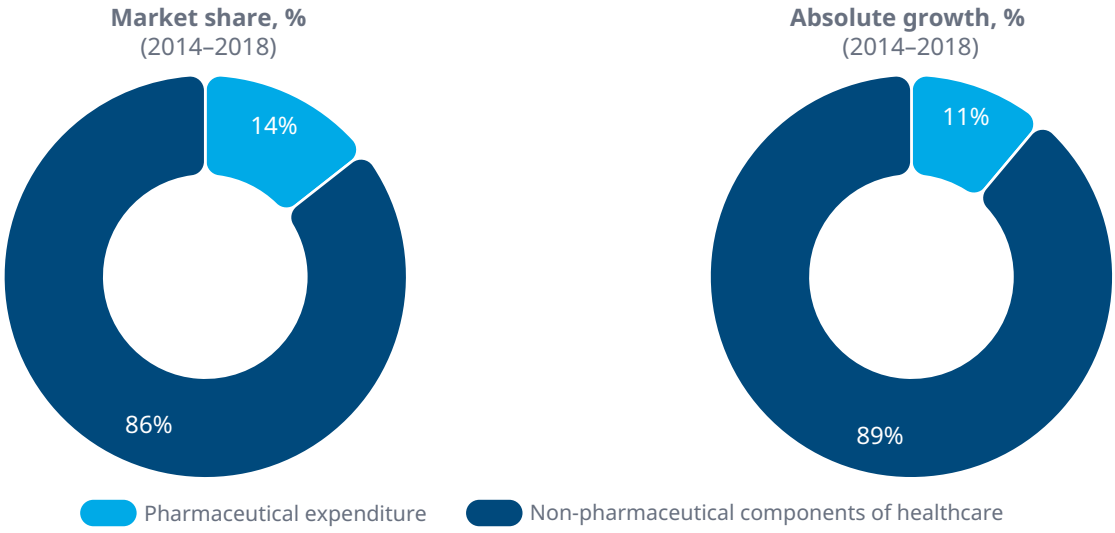
While this figure has increased over time at a rate of 5–6% in most countries on an annual basis, the amount of non-pharmaceutical expenditure has kept pace and even outgrown pharmaceuticals. Non-pharmaceutical elements of spending include a broad spectrum of important items such as inpatient and outpatient care, laboratory services, and home-based patient services. However, isolated focus on the pharmaceutical segment ignores the role of pharmaceuticals in the context of health care and their wider benefits. Pharmaceuticals ultimately reduce the requirement for patients to enter long-term care in the inpatient setting, and act as both disease prevention and treatment for patients that would otherwise enter the system with worse outcomes leading to significant direct and indirect costs.

The period of decline between 2008–2014 can be attributed to a slowing in public funding and budget available after the financial crisis across Europe. The overall growth rate remains low versus the demographic changes that are occurring across Europe, with an aging population who require greater levels of pharmaceutical treatment and other elements of care. In addition, taking into consideration the rate of inflation across Europe since 2000, which has averaged 1.9% from 2000 until 2021[4], reaching an all-time high of 5.3% in December of 2021, the real growth rate is in the low single-digits.

## PHARMACEUTICAL EXPENDITURE GROWTH IS REPRESENTATIVE OF ITS SIZE IN THE TOTAL HEALTHCARE EXPENDITURE OF EUROPEAN COUNTRIES

The topic of growth in pharmaceutical expenditure is regularly cited as the largest area of concern for European payers. The previous exhibit shows the net pharmaceutical expenditure growth rate has remained relatively low over a long period of time, with a nominal inflection in recent years. Absolute growth from pharmaceutical expenditure in the most recent 5-year period prior to the pandemic (2014 - 2018) represents just 11% of the absolute growth in healthcare expenditure across the same period. This is less than the proportion that pharmaceuticals contribute to the total healthcare expenditure. It means that the share of pharmaceutical expenditure has been shrinking over this period.

## Exhibit 8: Pharmaceutical and non-pharmaceutical share of expenditure and absolute growth, 2014-2018

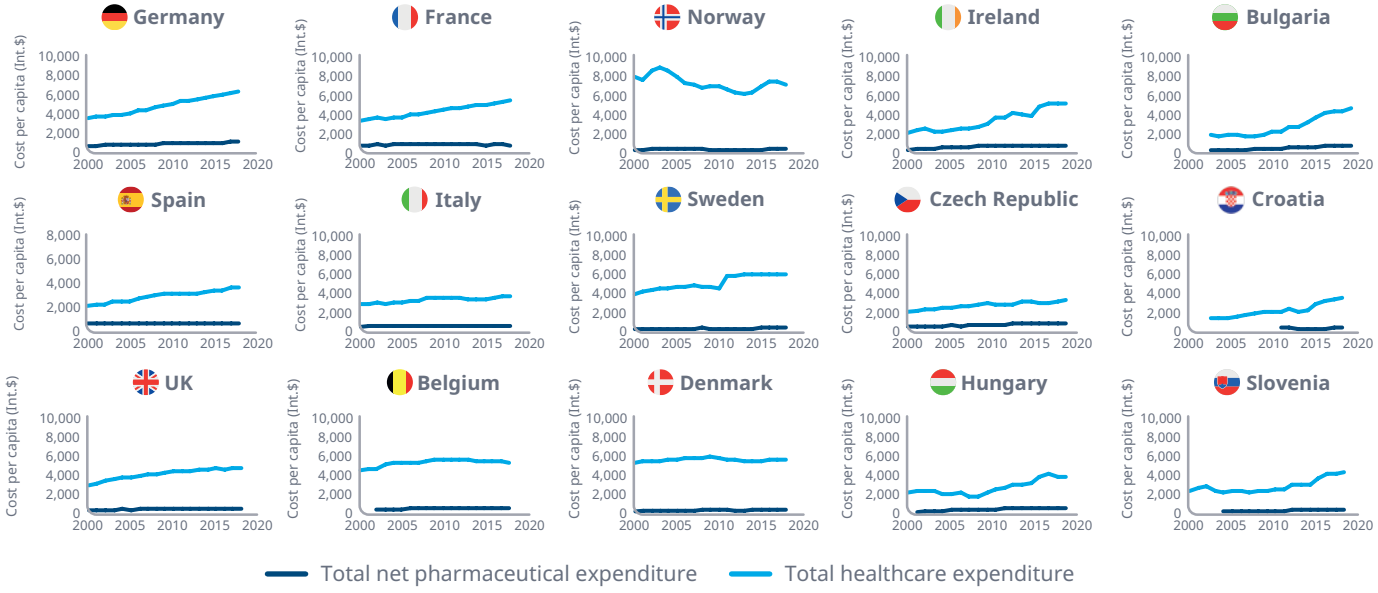



Source: World Health Organization (WHO), 2018 (extracted on 18 November 2021), WHO SHE 1.0 data (extracted on 18 November 2021); OECD, 2019 (extracted on 18 November 2021); Market share and absolute growth share calculated across a multi-year period (2014 – 2018) to reduce variability.
Notes: Average expenditure share and growth across the 15 markets studied.

**HEALTH SPENDING GENERALLY FLUCTUATES BUT HAS RISEN MORE THAN PHARMACEUTICAL SPENDING IN ALMOST ALL COUNTRIES SINCE 2000**

Across the 15 countries studied, total healthcare spending has risen more than pharmaceutical spending over 20 years. Medicines by contrast have been a relatively more stable expenditure and are inclusive of significant volumes of generic drugs at very low costs. Many countries are below current European standards for healthcare expenditure, and have been for long periods.

## Exhibit 9: Total net pharmaceutical and total healthcare expenditure, 2000-2018




Source: World Health Organization (WHO), 2018 (extracted on 18 Aug 2021), WHO SHE 1.0 data (extracted on 18 Aug 2021); OECD, 2019 (extracted on 18 Aug 2021).
Notes: Drug spending includes medicines dispensed in both retail and non-retail sectors. Methods for estimating total drug spending on a net basis are detailed in the methodology appendix. Health spending from WHO database. Both the drug and health spend data were adjusted for population, Purchasing Power Parity (PPP) and GDP growth to represent in 2020 values.

# Section 3: Budgeting for innovation

**Within this section, analyses are shown at list price-level and as a proportion of the total pharmaceutical market to explain the expenditure dynamics. Analyses on a product level are not available at net prices due to the reasons discussed in section 1. This supports the continued usage and appropriate management of the budget for the future.**

### THERAPY AREAS CURRENTLY EXPERIENCING INNOVATION WILL DECREASE OVER TIME

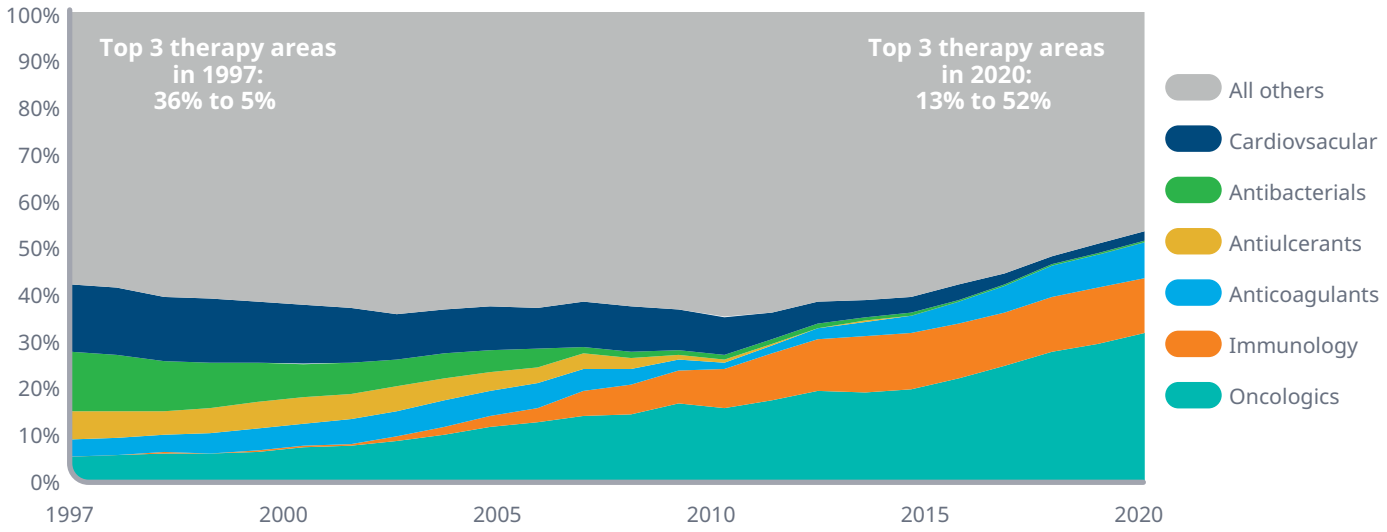
Across the European countries, spending has shifted between therapy classes based on the changing focus of biopharmaceutical innovation and unmet medical need. Therapy areas currently experiencing innovation will decrease over time as a proportion of the total spend. Viewing the composition of pharmaceutical spending over a long-term period (e.g., 20+ years) demonstrates how the focus of innovation changes, as not only new innovations are developed, but diseases are treated, and generic competition enters the market in older classes. We have seen therapeutic areas with historically high numbers of innovative treatments taking an increased share of the pharmaceutical spend as they mature, and despite volume increases it can become a low share of total cost for this reason.

The classes that comprise the largest amounts of spending have shifted over the last 20+ years, from more traditional (small-molecule, GP-driven) therapies to newer specialty (biologic, specialist-led) classes. The top-3 leading classes of drugs in 1997 were cardiovascular, antibacterial, and antiulcerants, accounting for 36% of total pharmaceutical expenditure. In recent periods their contribution declined to less than 2% due to losses of exclusivity, genericization, and limited entry of new products.

The figures we are using are an overestimate as list prices presented are regularly discounted by manufacturers and are trigger clawbacks.

Oncology has seen the largest growth in the past two decades compared to other major drug classes in the European countries. It should be noted that during this period there was an estimated 50% increase in

**Exhibit 10: EEA* (+CH & UK) comparison of protected brand LC$ spend by drug class, 1997–2020**




Source: IQVIA Institute 25-year dataset.

Notes: EEA countries included: Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden. LC: Local currency.

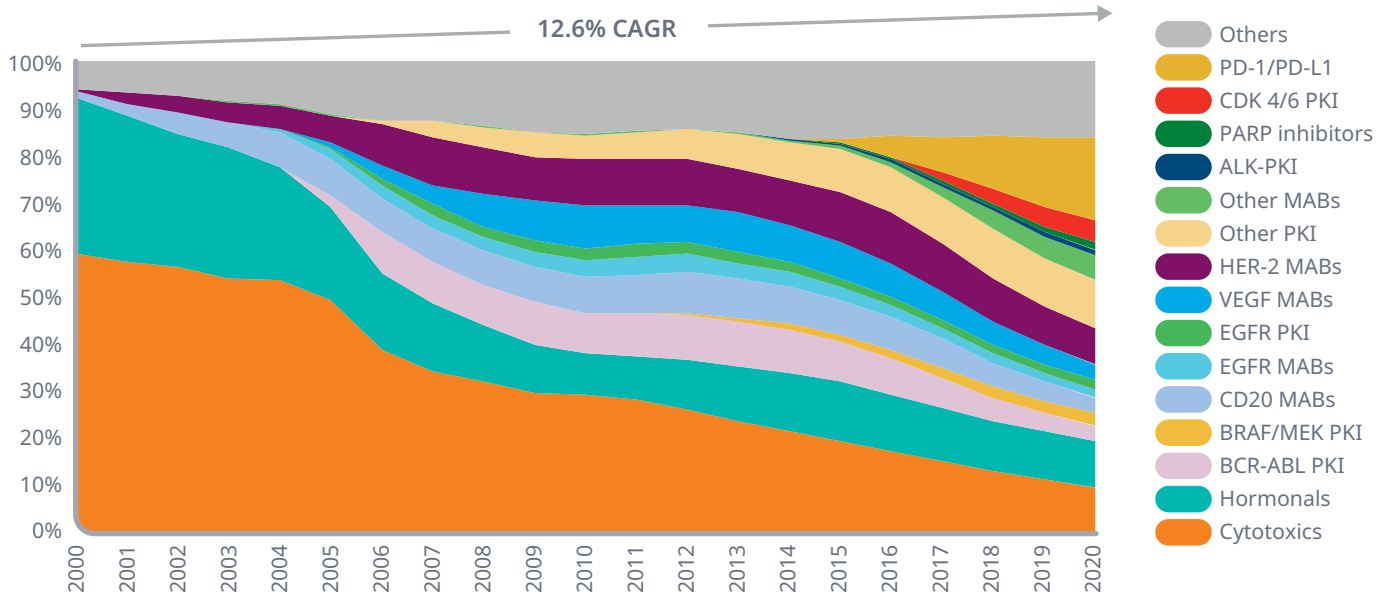
new cancer cases in Europe (from 2.6 million in 1995 to 4 million in 2020), driven by population growth, aging, and the introduction of screening programs for common cancers.[5-7] As a matter of comparison, cardiovascular mortality rates have fallen over the past decade and are projected to be surpassed by cancer mortality rates.[8]

Oncology spending therefore is driven by increased need, as well as unmet need, which drove significant R&D and the continuous adoption of newer treatments. In recent years, the number of major mechanisms of action have increased from 3 to 15, including CDK 4/6, PARP inhibitors, HER-2 monoclonal antibodies, and BRAF inhibitors. Furthermore, a 2020 analysis found that compared with other chronic diseases (CVD, neurological/mental health, and diabetes) cancer was responsible for the highest disease burden but was the second lowest in health expenditure levels in Europe.[9]

Over this period, age-adjusted death rates have been decreasing due to a number of factors including earlier detection of cancers, significant improvement in treatments, and in some countries specific social policies (e.g., discouraging smoking).[3] Importantly, cancer survival (which is considered a better measure of health system effectiveness in dealing with cancer) is improving.[10] Five-year-survival for the most common cancers has been continuously increasing, attributable to both earlier detection (through screening) and timely access to effective treatment.[5,11]

The proportion of the budget allocated to newer medicines is therefore representative of the levels of innovation seen in new therapeutic areas, with older therapeutic areas benefiting from the increased competition and prices seen upon entry of generic medicines and biosimilars. Launches in new treatment areas also increase competition between medicines while they are still on-patent, and result in best-in-class therapies improving patient care. Due to long development timelines and regulatory requirements, therapeutic areas develop slowly, emerge over a longer time period, and are subsequently replaced in cycles. Forecasting methodologies and horizon scanning are required to determine when the current phase (oncology) will begin its decline, and what the next growth area will be.

**Exhibit 11: EU4 + UK oncology real LC$ share of spending by mechanism, 2000–2020**




Source: IQVIA Institute MIDAS 25-year data view.
Notes: CAGRs (Compound annual growth rates) for 2000-2020.

**BUDGET HOLDERS WHO VIEW SPEND IN SILOS WILL RESTRICT ACCESS WHEN SAVINGS ARE BEING MADE ELSEWHERE**

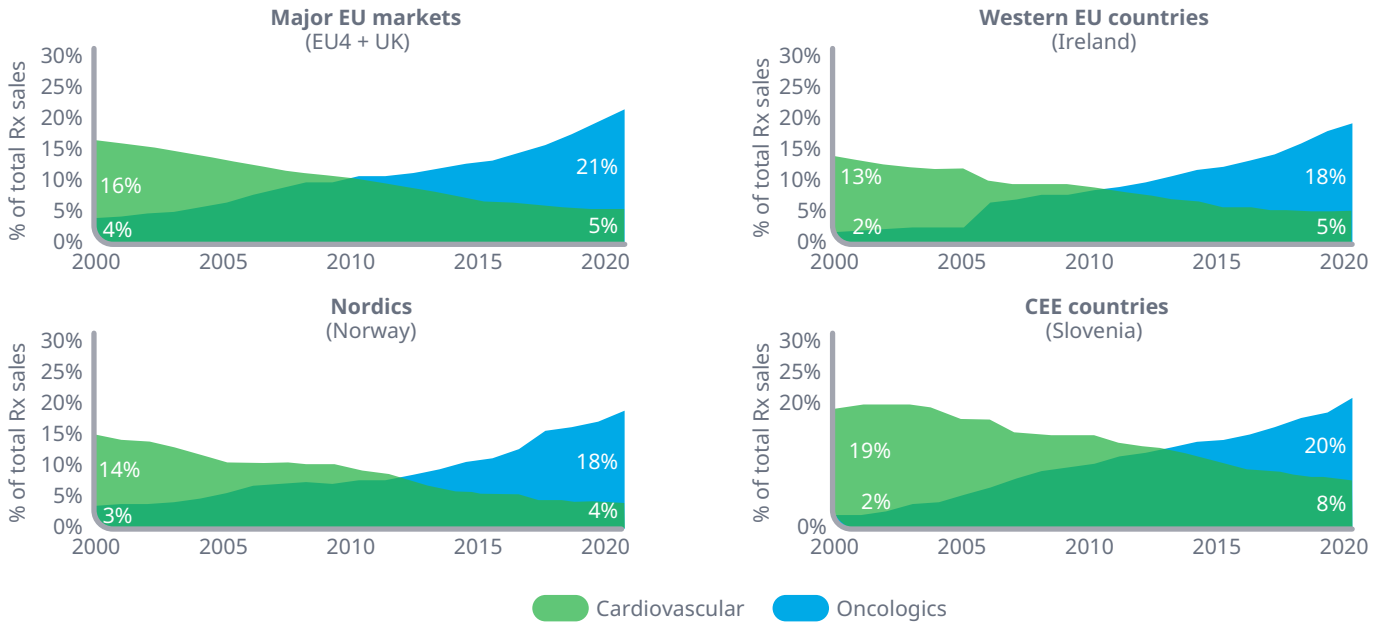
Spending in one area can be directly counteracted by a decline in another. The overall budget impact of key diseases should not be viewed without seeing the full picture as it can distort perceptions of the reality. Payers and budget holders often focus specifically on therapy areas that are increasing, without realizing the extent to which other therapy areas and/or healthcare costs are declining; a mechanism within the healthcare system to fund innovative treatments.

In many Eastern European countries, there are examples of when this has not worked effectively. Historically lower spending on healthcare and growth of their healthcare expenditure is not coping with the expectations of patients in these countries. Low spending on original protected brands over the past 20 years has resulted in an inability to make savings on these medicines. Prices within these markets are naturally lower than others in Europe, due to the presence of confidential discounts and rebates, however using out-of-date medicines that have been superseded generates a viscous cycle in which funding newer medicines is not more difficult.

*Payers and budget holders often focus specifically on therapy areas that are increasing, without realizing the extent to which other therapy areas and/or healthcare costs are declining; a mechanism within the healthcare system to fund innovative treatments.*

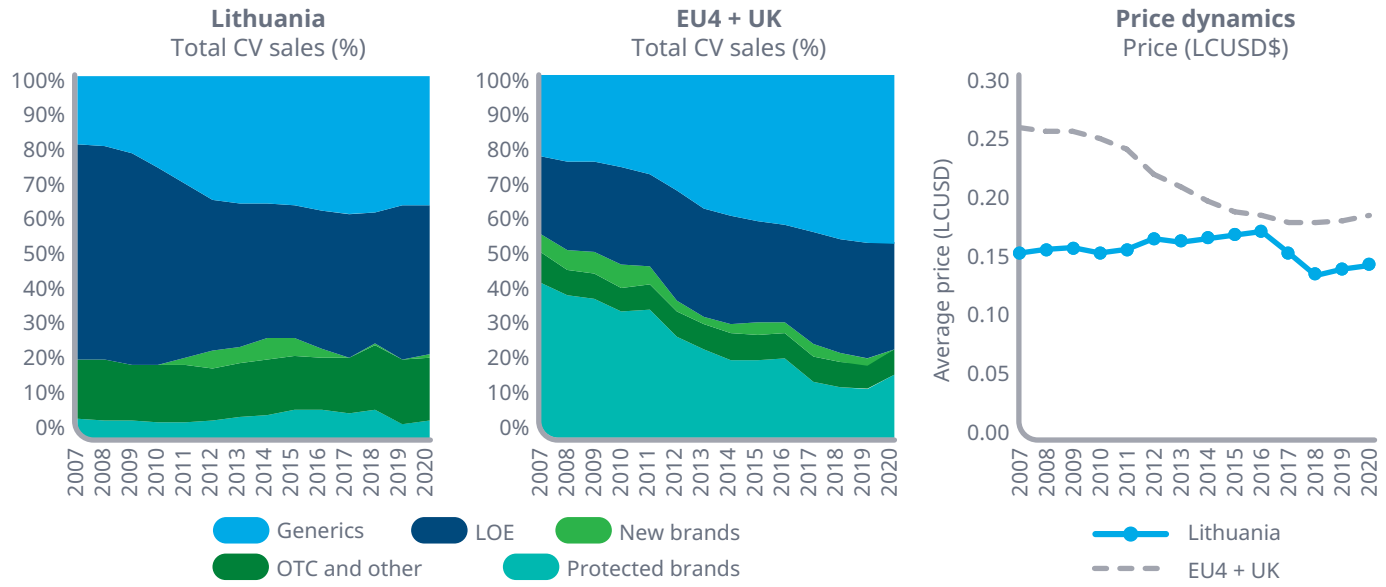
Lithuania has one of the highest cardiovascular death rates in Europe. However, the healthcare system has been historically unable to make savings on the historically protected medicines, as they represented only 6% of the total sales over 10-years ago versus 40% in the major European countries (EU4 + UK).
The price paid for these medicines is consistently lower than in the rest of Europe, but freeing up budget, and generating further savings is limited through this approach and limited by the low healthcare

**Exhibit 12: Comparison of cardiovascular and oncologics real LC$ spend, 2000–2020**




Source: IQVIA Institute MIDAS 25-year data view.

**Exhibit 13: Lithuania and EU4+UK cardiovascular real LC$ spend by product type and average price LC$, 2007-2020**




Source: IQVIA Institute MIDAS 25-year data view.
Notes: *Weighted average based on product sales as a % of total sales.

expenditure. EU4 + UK markets were able to support generic competition which now represents 40% of the market by sales and an even larger proportion of the market by treatment volume.

**PHARMACEUTICAL EXPENDITURE IS OFTEN SMALL IN COMPARISON TO SOCIETAL COST OF DISEASES**

The debate around pharmaceutical prices has only focussed on single medicines in isolation, without viewing the savings to the total healthcare system of the diseases that they aim to treat or prevent.

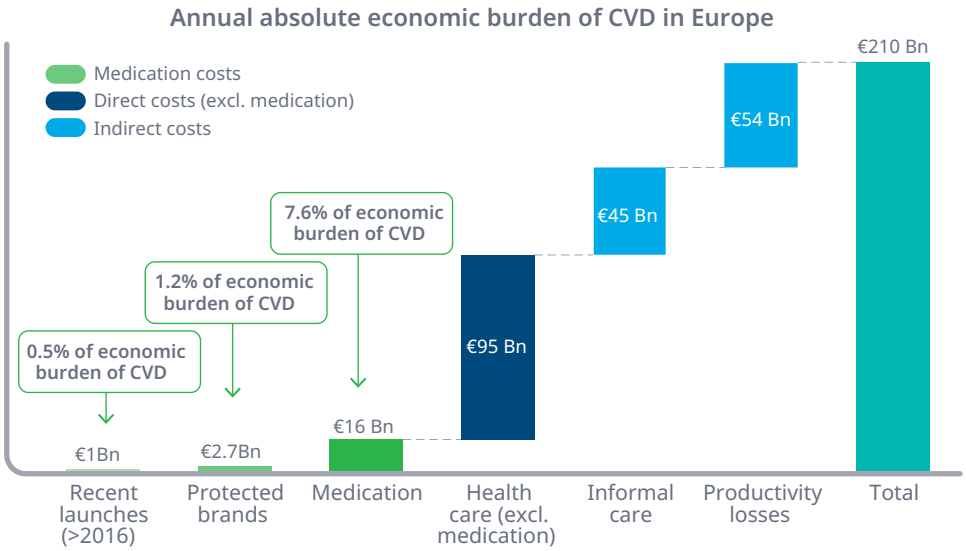
Value-based decision making is increasing in prominence, but many payers also focus on reducing prices across the board regardless of what value new therapies bring to patients and societies. The two approaches are at opposite ends of the spectrum, and demonstrating value across a healthcare system

**Exhibit 14: Understanding the economic burden of cardiovascular disease in Europe**

**CARDIOVASCULAR DISEASE**

"Overall CVD is estimated to cost the EU economy **€210 billion a year**. Of the total cost of CVD in the EU, around 53% (€111 billion) is due to health care costs, 26% (€54 billion) to productivity losses and 21% (€45 billion) to the informal care of people with CVD."

*European Health Network (2017)*




Source: European Heart Network, 2017 report on European Cardiovascular Disease statistics : https://ehnheart.org/cvd-statistics.html#:~:text=Overall%20CVD%20is%20estimated%20to,care%20of%20people%20with%20CVD. (last accessed November 2021); https://knowledge4policy.ec.europa.eu/health-promotion-knowledge-gateway/cost-non-communicable-diseases-healthcare-1_en (last accessed November 2021); IQVIA MIDAS data for ATC-3 Cardiovascular treatments.

*The debate around pharmaceutical prices has only focussed on single medicines in isolation, without viewing the savings to the total healthcare system of the diseases that they aim to treat or prevent.*

is more challenging than simple price reductions as indirect costs associated with diseases are rarely well characterised. Confounding factors, interdependent variables, and poor system-wide data on disease make this complex to prove, but there is a growing body of evidence. A number of the well-researched examples are available below, each of which highlights the small cost of the pharmaceutical component while delivering high value to patients.

Overall CVD is estimated to cost the EU economy €210 billion per year. Of the total cost of CVD in the EU, around 53% (€111 billion) is due to health care costs, 26% (€54 billion) to productivity losses and 21% (€45 billion) to the informal care of people with CVD.[12] Models have been used to explain CVD mortality trends[13] and estimates suggest that approximately 47% of the decline in CVD mortality rate from that period was attributable to evidence-based medical and surgical treatments, while reductions in major risk factors contributed about 44%.

To fully understand the proportional cost of medication, we must also understand the indirect economic costs. According to the International Diabetes Federation, health expenditure for diabetes was estimated at $105.5 billion (€93 billion) in the European Region in 2010: the equivalent of 10% of the total. By 2030, this expenditure is expected to reach US$ 124.6 billion (€110 billion)[14], and would be even higher without the available treatments.

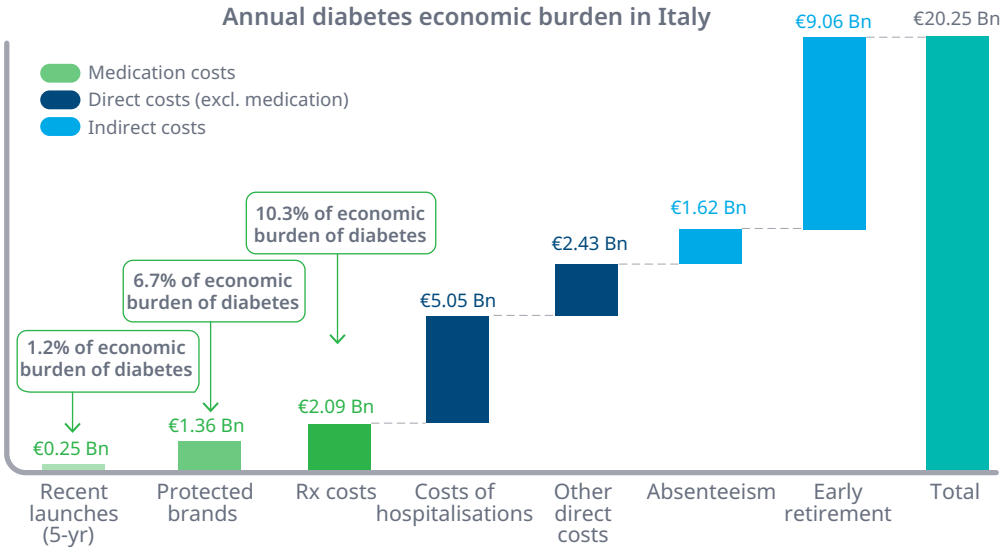
In Italy, direct and indirect costs have been estimated, demonstrating the size of the pharmaceutical component compared to the total disease burden. Innovative medicines launched in the past 5-years account for 1.2% of the total cost of the disease in this market, with the total cost of all medicines representing just 10% of the total cost. Life-saving insulin treatments, and preventative treatments save healthcare systems further costs by avoiding expensive treatment of diabetic complications and co-morbidities, as well as the informal care and productivity losses associated.

**Exhibit 15: Understanding the economic burden of diabetes in Italy**

**DIABETES**

"Health expenditure for diabetes was estimasted at US$ **105.5 billion in the European Region in 2010**: the equivalent of **10% of the total**. By 2030, this expenditure is expected to reach US$ 124.6 billion."

*International Diabetes Federation*




Source: Marcellusi A. et al, The direct and indirect cost of diabetes in Italy: a prevalence probabilistic approach, Eur J Health Econ. 2016 Mar;17(2):139-47. doi: 10.1007/s10198-014-0660-y. Epub 2014 Nov 27.

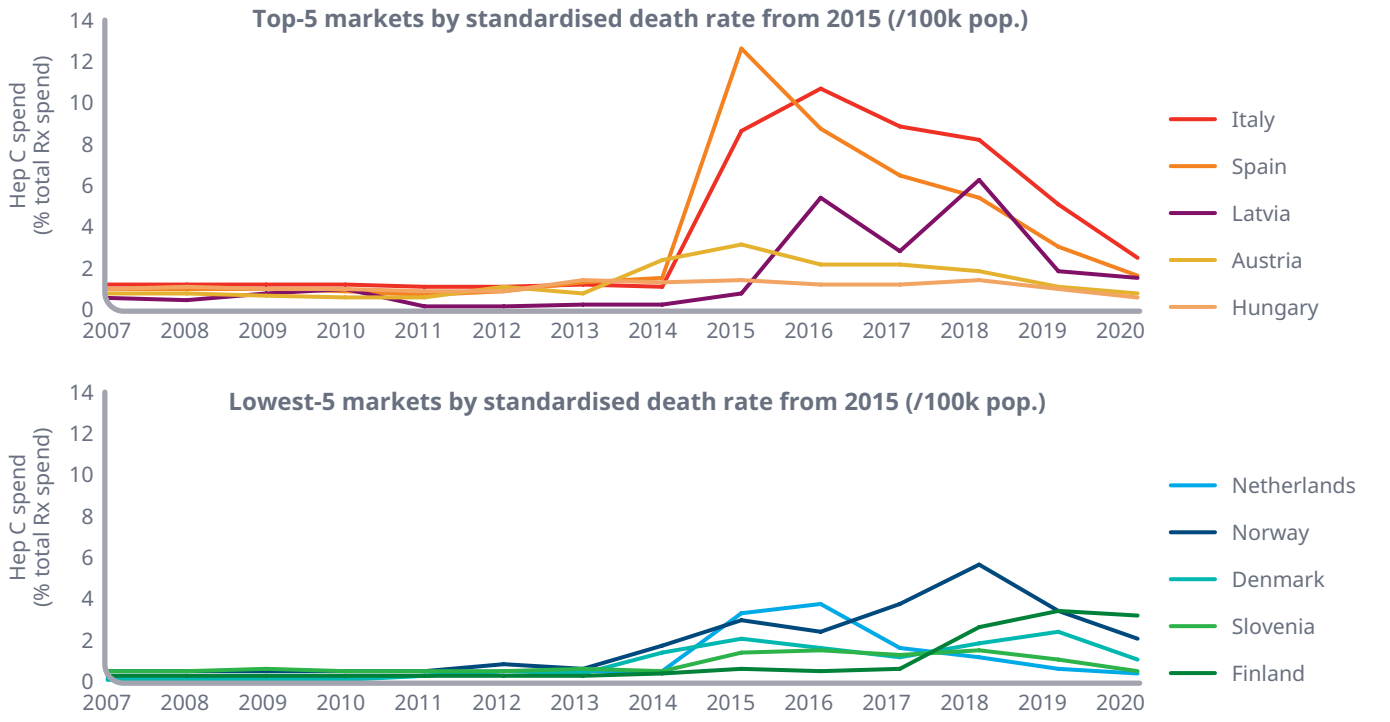
**PERCEIVED 'BUDGET BUSTERS' HAD A SHORT-LIVED IMPACT WHICH WAS OUTWEIGHED BY SOCIETAL COST**

Pre-2014, spending on treatments for hepatitis-C represented <1% of total pharmaceutical spend before the launch of the paradigm-changing, curative medicines, while the indirect impact on healthcare costs through hospital admissions was overwhelming. Upon launch, this figure grew to over 10% in heavily affected markets, but returned to a similar pre-launch level just 5-years later.

These medicines are often highlighted in discussions with the pharmaceutical industry. However, these figures (and those illustrated above) are at list prices these rebates at a single-product level are confidential. The reality is that significant discounts were applied, and that price-volume agreements were in place in markets with high burden (e.g., Italy and Spain), where patients were provided the treatment for longer than the 8-weeks paid for by countries at zero cost to the payer, or the price of the medicine falling based on the number of patients treated. The real net expenditure of this therapy area is therefore significantly lower than shown in the exhibit. Spending has reduced after the peaks in most countries as usage has slowed after countries cleared the 'warehoused' patients, and competition has resulted in lower prices. The significant clinical benefits and tolerability of these newer therapies resulted in millions of patients being treated and cured.

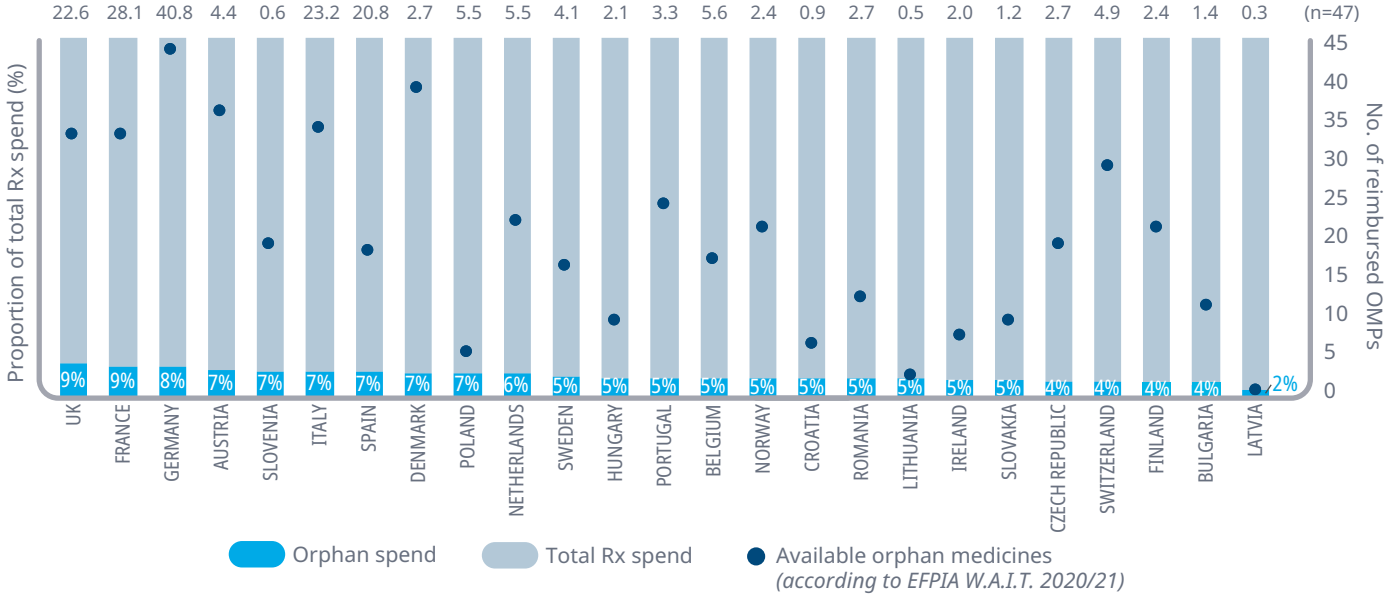
Orphan medicines are also perceived to be a budget buster provide novel treatments to patients with rare diseases. The impact of these medicines on total pharmaceutical expenditure is an average of 6% at list prices, in an area subject to significant rebates and discounts. These treatments focus on areas of significant unmet medical need, and treat often only a few thousand patients across Europe.

**Exhibit 16: Hep C real LC$ spend by standardised death rate, 2007–2020**




Source: IQVIA Institute MIDAS 25-year data view; https://appsso.eurostat.ec.europa.eu/nui/submitViewTableAction.do; Causes of death – standarised death rate by NUTS 2 region of residence - Viral hepatitis and sequalae of viral hepatitis.

**Exhibit 17: Orphan drug spend as a percentage of total pharmaceutical spend and availability of orphan medicines, 2020**



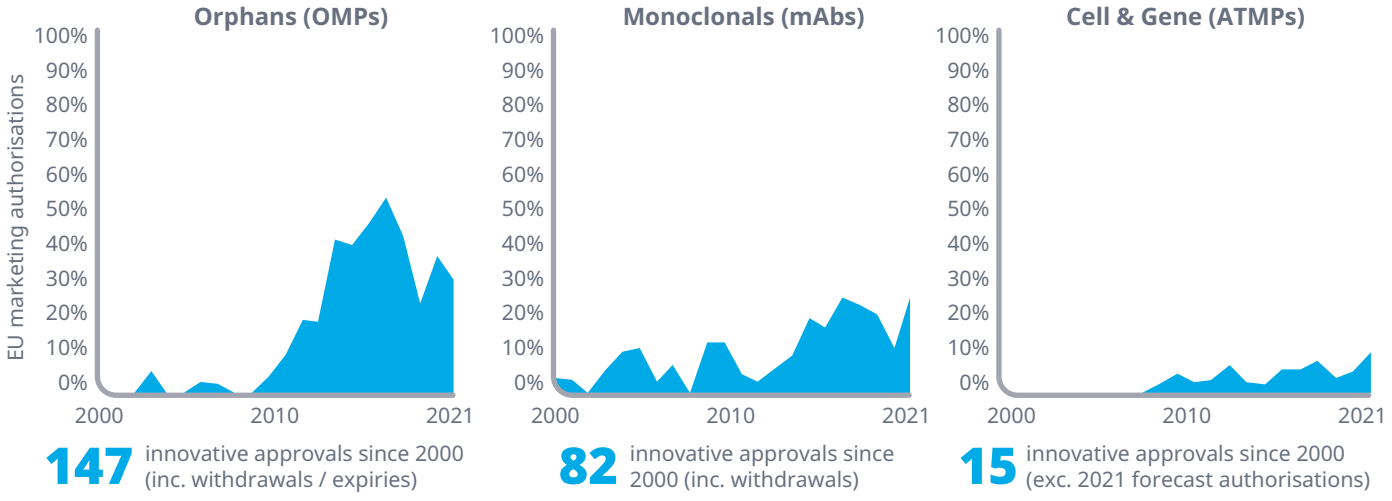

* Excludes expired and withdrawn orphans.

Source: IQVIA MIDAS MAT Q4 2020; EMA EPAR list; Orphanet Lists of medicinal products for rare diseases in Europe, March 2021; Country scope is 28 European countries (EU plus UK, Denmark, Norway and Switzerland); Excludes Estonia, Greece and Luxembourg as IQVIA only has retail panels for these markets.

**THE PACE OF INNOVATION HAS INCREASED FOR THE BENEFIT OF PATIENTS, AND CONTINUES FORWARD**

Complex medicines play a larger role, and require different approaches from payers in the long-term. However, the growth in these treatments has not broken the budget. While 10-years ago there were no formal orphan medicine products to treat rare conditions approved, they now represent ~50% of innovative medicines authorisations, and are focussed on paediatric indications.

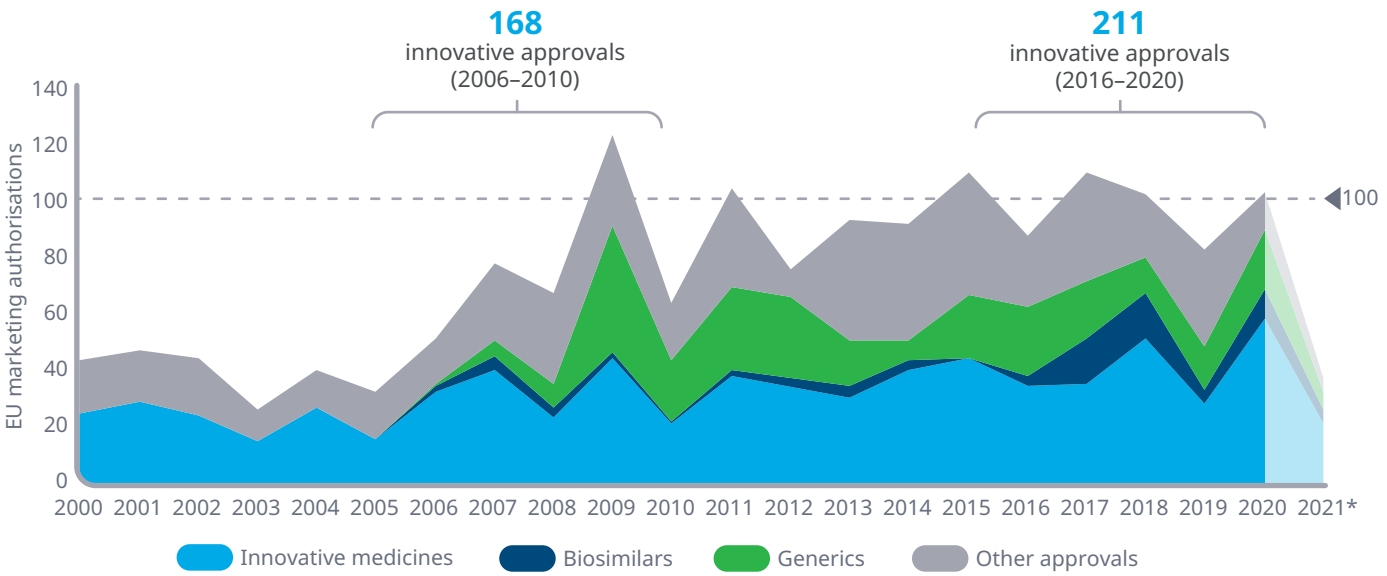
**Exhibit 18: Orphans, monoclonals and cell & gene therapies as a percentage of EU marketing authorisations, 2000–2021**




Source: EMA EPAR list (last accessed January 2022).

Notes: Segments are not mutually exclusive; orphan medicines can be a biologic medicine and/or a cell therapy; Historic data collected from EMA's EPAR list using marketing authorization date removing products with a prior authorization to highlight only truly innovative medicines rather than all authorisations.

**Exhibit 19: Profile of innovative medicines since 2000 by EMA approval year**




Source: IQVIA whitepaper Perspectives on Innovative Medicines (published in June 2021).
Notes: EMA EPAR list of authorised medicines (includes withdrawn medicines within historic data); Human medicines approvals only, vaccines included. Innovative medicines is based on previous approval for the active substance, multiple indications only included upon initial submission, includes orphan medicinal products regardless of prior approval status. Key: * = Analysis accurate as of April 2021.

The pharma industry is launching more new active substances than ever before, with the majority of new medicines being launched for smaller disease classes with significant unmet need. The annual number of innovative medicines approved is at an all-time high, but growth has not been sudden, occurring over a 20-year period as long-term investment from research and development produces new insights. Significant biosimilar and generic approvals balance-out expenditure on innovative medicines. Providing access to previous innovations drives the next innovation wave, bringing cures to previously untreatable diseases. Continued success depends on improving upon current polices and understanding of the dynamics of pharmaceutical expenditure. Viewing the total in context is critical to the success of policy decisions.

*Continued success depends on improving upon current polices and understanding of the dynamics of pharmaceutical expenditure. Viewing the total in context is critical to the success of policy decisions.*

# Methodology

There are no official, consistent statistics measuring total pharmaceutical spending across countries. Historically the only consistent measure of pharmaceutical spending was produced by the OECD and covered 'retail' drugs measured at a total system net spending level. This measures the net amount paid by a country's health system, including that paid by patients and insurers and governments through retail pharmacies, and deducts any discounts and rebates they receive known by the governments submitting the results to OECD.

Critiques of these measures centre around the lack of inclusion of non-retail drugs, which are presumed to be some of the largest growth drivers in total pharmaceutical spending. Countries also differ in what comprises retail and hospital. OECD has attempted to address this situation in a newer method of reporting total pharmaceutical spending (stats.oecd.org) but has faced significant issues with countries' inconsistent and incompatible data submissions as noted in their methodology appendices. Notably Belgium, Czechia, Denmark, Norway, Slovakia, Spain (post-2018), Sweden submitted valid total pharmaceutical spending on a net basis to OECD, while other countries submissions varied significantly making comparisons unreliable.

In section 2 of this report, total pharmaceutical spending has been collated across 15 countries and represents net of discounts and rebates for the first time. This has been accomplished through a variety of methods depending on the availability of necessary public information. In some cases, the information to be collated is official but only published locally and must be identified and translated from local languages. In some cases, the relevant data were submitted to OECD's new total pharmaceutical expenditure process. In other cases, the information is not provided by any source and requires the application of assumptions or inferences (see Methods of estimating total net pharmaceutical spending in 15 European countries). While the findings demonstrate a more consistent and similar view across countries, the diversity of methods and the lack of official attribution leaves room for improvement.

The notes below apply to pages where analysis is sourced from IQVIA data, which does not reflect off-invoice discounts and rebates. Pricing source/type and currency measures have been reported in either constant U.S.$ or in local currencies on a nominal or real 2020 basis, and on a per capita basis using GDP deflation based on published GDP and population information. International comparisons use constant U.S.$ using Q4 2020 average exchange rates.

Product segmentations are based on currently marketed products. Products which are no longer marketed but were included in the archive datasets and which have brand names (most commonly over the counter -OTC, non-original or branded generics) may not be able to be segmented consistently and have been categorized as "other" in segmentations.

Pharmaceutical spending using IQVIA data (in section 3) is measured at ex-manufacturer price levels to provide consistency across countries and does not reflect the amounts payers and /or patients pay for medicines. This differs from the total net spending at a country level used in the initial analyses in this report. In some countries, off-invoice discounts and rebates are significant and result in lower pharmaceutical expenditures and growth and their impact has been increasing over time.

While the magnitude of these items and their impact on growth can be estimated at the total country level and for some large segments of the market, it cannot be applied to small segments or specific medicines. Analyses in this report relating to IQVIA data do not reflect these off-invoice discounts and rebates. Price levels used in calculation of sales are not necessarily the net sales received by manufacturers and therefore will overstate sales from manufacturer perspective. While all of the countries in this study allow or mandate some forms of off-invoice discounts and rebates, no countries explicitly discourage them. All countries in the study have some level of discounts and rebates from mandated rules or negotiations by public insurers or private (or both). Data from IQVIA audits does not reflect these discounts and rebates.

**Exhibit 21: Methods of estimating total net drug spending in 16 European markets**

| COUNTRY | SOURCE OF TOTAL MARKET | SOURCE OF RETAIL | SOURCE OF NON-RETAIL | PERIODS OF 'REAL' DATA | BACK PROJECTION METHOD |
|---|---|---|---|---|---|
| Belgium | OECD | data.OECD.org | stats.OECD.org - retail | 2003 - 2018 | n/a |
| Czechia | OECD | data.OECD.org | stats.OECD.org - retail | 2000 - 2018 | n/a |
| Denmark | OECD | data.OECD.org | stats.OECD.org - retail | 2000 - 2018 | n/a |
| Norway | OECD | data.OECD.org | stats.OECD.org - retail | 2000 - 2018 | n/a |
| Slovakia | OECD | data.OECD.org | stats.OECD.org - retail | 2000 – 2018; however, no total HC data available | n/a |
| Spain | OECD | data.OECD.org | stats.OECD.org - retail | 2018, 2019 | Only last 2 periods were usable to calculate the non-retail due to trend break in 2017. Therefore, average share of 2018 and 2019 was used to back project the non-retail |
| Sweden | OECD | data.OECD.org | stats.OECD.org - retail | 2000 - 2018 | n/a |
| Italy | AIFA reports | Conventional share of net calculated using AIFA report | Total minus retail | 2015 - 2020 | Additional AIFA and academic reports for estimates of hospital gross and net for earlier periods |
| United Kingdom | ABPI/MOH/IQVIA methodology, plus OTC, hospital solutions (ATC=K), diagnostics (ATC=T), and dispensing fees other excluded by industry estimates | data.oecd.org | IQVIA non-retail share | Industry & Ministry of Health method for measuring drug spending net of various discount/ rebate / chargeback programs. Only for 2015, 2016, 2017, 2018, 2019 | OHE papers for 2007-2011 and industry estimates for 2012, 2013. Back projection of average 2007-2011 gross to net ratio for earlier periods |
| Bulgaria | OECD plus IQVIA | data.OECD.org | IQVIA non-retail share | 2003 - 2018 | n/a |
| Croatia | OECD plus IQVIA | data.OECD.org | IQVIA non-retail share | 2011 - 2018 | n/a |
| France | OECD plus IQVIA | data.OECD.org | IQVIA non-retail share | 2000 - 2018 | n/a |
| Germany | OECD plus IQVIA | data.OECD.org | IQVIA non-retail share | 2000 - 2018 | n/a |
| Hungary | OECD plus IQVIA | data.OECD.org | IQVIA non-retail share | 2001 - 2018 | n/a |
| Ireland | OECD plus IQVIA | data.OECD.org | IQVIA non-retail share | 2000 – 2018 | n/a |
| Slovenia | OECD plus IQVIA | data.OECD.org | IQVIA non-retail share | 2004 - 2018 | n/a |

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