



BROADENING THE PERSPECTIVE

RECOMMENDATIONS FOR IMPROVING
PHARMACEUTICAL AFFORDABILITY



COLOPHON

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Citation

Vintura, 2023. Broadening the Perspective.
Recommendations for improving pharmaceutical affordability.

This report was commissioned and financed by EFPIA.

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KEY MESSAGES

With the European population ageing rapidly, health care budgets are under sustained, significant pressure. This pressure is only amplified by a worsening macroeconomic climate.

As a result of this pressure, health care payers across the continent are increasingly reporting that even if an intervention is cost-effective, it may not be affordable within existing budget constraints.

Affordability can by definition only be improved either by reducing costs or improving the ability to pay. However, options related to both of these options appear to be extremely limited in the European context.

This report offers a new perspective on pharmaceutical spending. While it is primarily an investment in better health outcomes for patients, pharmaceutical expenditures can also create efficiencies and cost offsets – net savings – over time and across budgets. The key challenge is for all stakeholders involved to take this broader perspective of time and budget into consideration.

Only by taking a broader perspective of time will sufficient resources be dedicated to investments in health care that pay off over time.

And only by taking a broader perspective on budgets will we be able to solve the ‘wrong pocket’ problem where the primary payer does not receive the primary reward.

In practice, this can be realised with the existing funding through:

- Long-term horizon scanning of net pharmaceutical costs and multi-year budgeting
- Including the societal value perspective in Health Technology Assessment (HTA)
- Innovative reimbursement agreements for pharmaceuticals
- Integrated (pharmaceutical) budgeting

A further avenue to explore is whether new sources of funding can be found to tap into. Social Impact Bonds for identified health care priorities are one such new funding source showing promising results.

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CHAPTER 1

AFFORDABILITY - THE CHALLENGE

European health care budgets are under pressure due to a rapidly aging population and a worsening macroeconomic climate

By 2040 it is estimated that OECD countries will have to dedicate more than 19% of total government spending on health care in order to meet the future needs of ageing populations.¹ Expenditure on pharmaceuticals is also growing, in line with total growth of the health care budget.

At the same time, there is significant downward pressure on government spending in general due to economic performance. GDP growth has

slowed after consistent average growth of 2.2% between 2013 and 2019. OECD member average annual growth is predicted to be just 1.2% until 2040.²

As a result, pricing and reimbursement authorities and payers increasingly struggle to make treatments available, despite proven clinical value and an attractive value story: the affordability challenge.

“We can no longer guarantee that health care will be accessible to all at all times”

Chairman of the board of CZ
(third largest health care insurer in The Netherlands), November 2022³

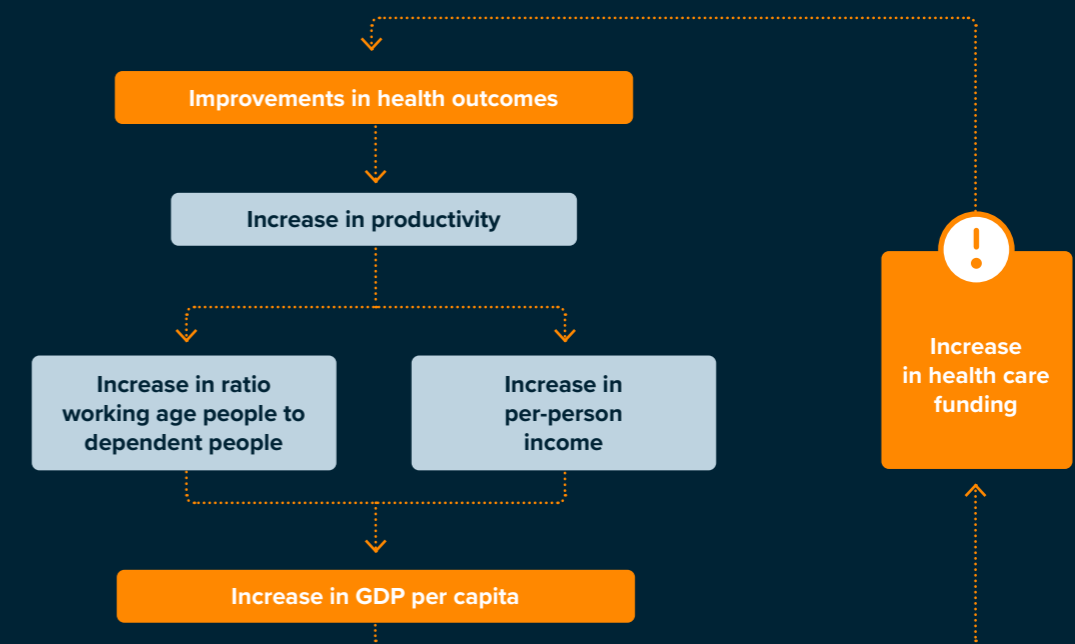
The immediate response to these challenges in some major European markets has been to introduce overall cost-containment measures targeted at innovative pharmaceuticals. Recent examples of this include the *Voluntary Scheme for Branded Medicines Pricing and Access* (VPAS) in the United Kingdom and the *Act for the Financial Stabilization of the German Statutory Health Insurance System* (GKV-FinStG) in Germany.^{4,5}

Nonetheless, the affordability challenge is starting to negatively affect actual patient access: 7 of the 24 advanced therapeutical medical products (ATMPs) approved in Europe have been pulled from the market.⁶ In one recent example, an ATMP was launched in the US market but withdrawn from the European market after failing to agree on a price tag at a ~35% discount to the US price.⁷

Forgoing investments in improving health outcomes may compound the affordability challenge, as a healthy population is a prerequisite for economic growth and further health care funding

In times of slow or negative growth it is tempting for governments to delay or cancel investments across the economy, including in health care. However, it is important to remember that a healthy population – one that maximises the productivity of every individual – is a prerequisite for economic growth. A positive feedback loop exists where improvements in health outcomes are at least partially funded by taxation on the increased productivity that health care improvements bring about. Therefore, it is important to view health – and the ways in which good health can be promoted – as an investment.

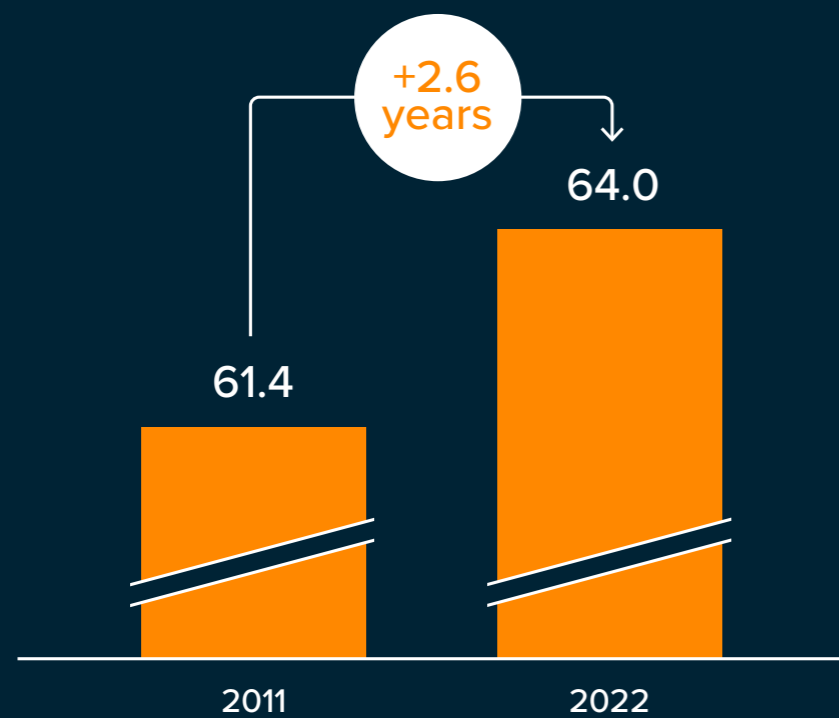
Figure 1
Health as an investment⁸



New approaches, innovations, and interventions in care over the last few decades have helped keep people healthy, or enabled them to return to the workforce faster.

As a result, productivity loss due to cancer decreased by 21% between 1995 and 2018, and on average the healthy life expectancy at birth has increased by 2.6 years in the 10 years up to 2020.^{9,10}

Figure 2
Healthy life years expectancy at birth (EU-27)¹⁰



COST OFFSETS EXAMPLE

BIOLOGICS FOR RHEUMATOID ARTHRITIS

Rheumatoid Arthritis (RA) is a chronic, destructive autoimmune disease for which 32% of patients did not have access to effective treatments before disease-modifying antirheumatic drug biologics (bDMARDs) entered the market and provided these patients with a new treatment option.¹¹

Biologics significantly reduce absenteeism and presenteeism (decreased ability to be productive while at work). A double-blind placebo-controlled trial showed a ~70% decrease from the baseline in terms of number of days missed from work after 12 months, as compared to a mere ~2% decrease for the placebo. Similarly, presenteeism was down 70% compared to ~30% for the placebo.¹²

This is a significant reduction, as indirect costs such as from absenteeism and presenteeism, are estimated to account for 39-86% of total RA costs. These costs are harder to quantify and occur later in time, but are key to understand the full economic impact of RA and hence to understand the full added value of biologics to treat RA.¹³

CHAPTER 2

AFFORDABILITY - THE DILEMMA

By definition, affordability can only be improved by reducing costs or by increasing the ability to pay

The extent to which something is **affordable** is measured by cost relative to the amount the purchaser is able to pay.

There are two levers available to policymakers and purchasers to improve affordability:

1. Reduce cost
2. Increase the ability to pay

Figure 2
Affordability concept



1 LEVER 1: REDUCING COST

Despite the recent popularity of policy measures that reduce pharmaceutical costs (e.g., clawbacks, rebates, windfall taxes, or even de-listing pharmaceuticals from the reimbursement list, etc.), sustainable options for reducing costs related to pharmaceutical interventions are limited due to three main factors:

1. Pharmaceutical expenditures are primarily a necessary investment in better health outcomes

Reducing pharmaceutical expenditures may negatively affect future improvements in health outcomes. It is estimated that, if no new drugs had been launched after 1981, the number of years of life lost before the age of 70 (due to premature mortality) in 2013 would have been 2.45 times as high as it actually was, based on an analysis of 66 diseases in 27 countries.¹⁴

first six months of 2022 and Europe is the only region with more Phase 2 or Phase 3 trials than Phase 1 trials.¹⁶ Ultimately such reductions in R&D may mean that it takes longer to improve outcomes for patients as future medicine development in Europe is delayed or put off entirely.

3. The share of pharmaceutical expenditure as a proportion of total health care expenditure has not increased

Despite significant changes in the composition of pharmaceutical expenditure, type of medicines used, complexity of molecules and number of patients treated, pharmaceutical spending as a share of total health care spending has in Europe stayed mostly stable since 2000 at around 15%. In several countries overall health care expenditure is growing faster than pharmaceutical expenditure.¹⁷

2. The sustainability of the economic model for developing innovative therapies is already under pressure

A long-running study into the forecast internal rate of return on investments for large-cap biopharma companies shows expected returns are falling. Projected return on investment in pharma R&D in 2022 has fallen to 1.2 per cent, the lowest ROI seen in the 13 years since the research began.¹⁵ The effects of this pressure is already visible in Europe: just three new Phase 1 trials for cell and gene therapies were started in the

The stable aggregate notwithstanding, specific budget holders (e.g. for oncology products) have experienced a growth in the share of pharmaceutical spending.

2

LEVER 2: INCREASING THE ABILITY TO PAY

The OECD offers four potential policy options to increase the ability to pay for rising health care costs. The feasibility of all four of these options seems low, as the OECD acknowledges that ‘in the current economic climate, the policy options remain limited’:¹⁸

1. Increasing health spending without changing other government spending so overall government spending rises

Slow economic growth means there is little chance of an increase in overall government revenue which could fund increased spending on pharmaceuticals.

2. Keeping overall government spending constant but increasing the allocation to health within government budgets

Health spending is competing with other public expenditures such as education, defense, and welfare. The opportunity costs of prioritizing health has likely risen, given the war in Ukraine, soaring energy costs and inflationary pressures. As a result, it is unlikely that we see a significant re-prioritization of health care spending within government budgets.

3. Reassessing boundaries between public and private spending

With their principle of universal health care, it is unlikely that there is political appetite to fundamentally change the European social model and shift the financial burden to the private sector.

4. Realising efficiency gains by cutting wasteful spending

It is likely that significant health care resources are expended on care that does not deliver better outcomes.¹⁹

The challenge is to identify such wasteful spending ex-ante: the solution may lie in taking a broader perspective.

COST OFFSETS EXAMPLE COVID-19 VACCINES

Vaccinations against COVID-19 prevented up to 20 million deaths from the virus.²⁰ Full vaccination costs around €40 per person, with an estimated cost of vaccinating around 40% of the world’s population of around €50 billion.²¹

The cost offsets generated by COVID-19 vaccination in terms of health care were estimated at €9 trillion. This represents the expected cost of dealing with severe complications in unvaccinated patients. Beyond health care, it is estimated that the productivity enabled by the vaccination programme led to €1 trillion in extra tax revenue.²²

The challenge for health care systems was to pay the high upfront costs of providing vaccination when cost offsets are mainly realized outside the pharmaceuticals budget. This led to varying timelines between, for example, the US, UK, and EU in making vaccine purchase commitments.²³

For other types of vaccinations (e.g. HPV) the funding challenge is compounded as the added value to society is not as immediately apparent as for COVID-19.

CHAPTER 3

AFFORDABILITY - A BROADER PERSPECTIVE

Pharmaceutical expenditures create cost offsets – net savings – over time and across budgets

Pharmaceutical expenditures are generally assessed through the lens of improving the health and quality of life for patients. However, pharmaceutical expenditures can also create cost offsets: savings or increased productivity for the health care system or even society as a whole. In that regard, pharmaceutical expenditures can at least in part be seen as investments.

The current health care models – siloed, and with a focus on meeting annual budgets – result in discussions on pharmaceutical affordability

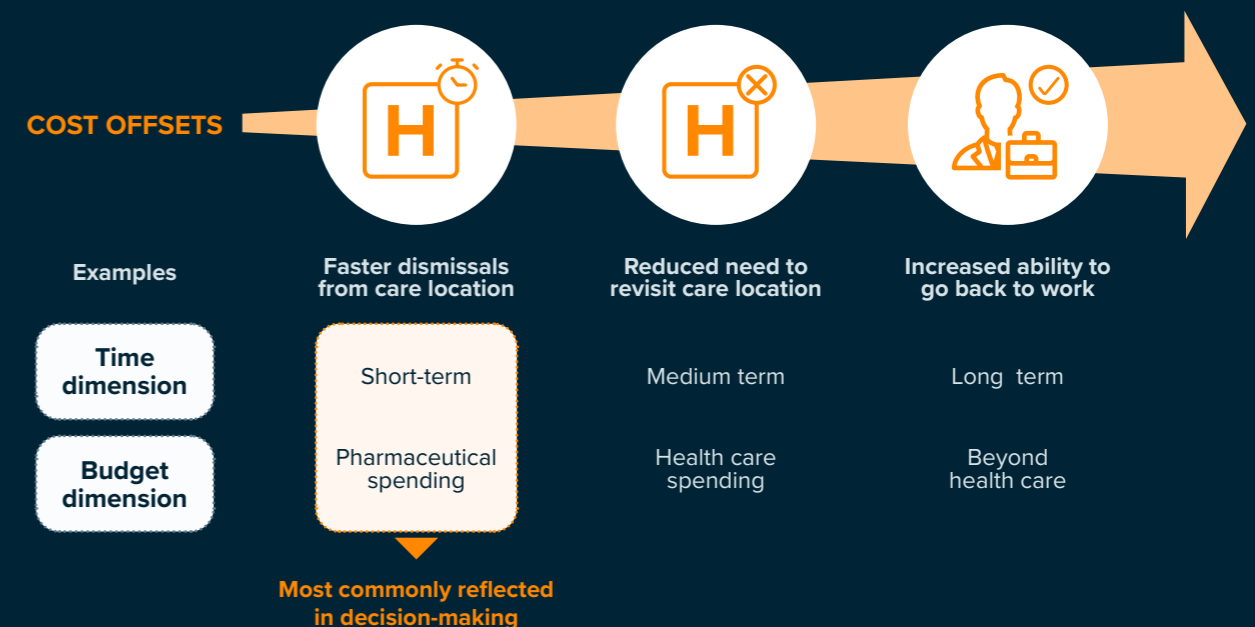
that are primarily focused on the short-term and solely on the pharmaceutical budget. As a consequence, decision-making on affordability most commonly does not sufficiently take into consideration long-term and cross-budget effects.

This approach risks missing the forest for the trees. Accounting for the full cost offsets of pharmaceutical spending requires looking beyond the short-term and beyond siloed pharmaceutical budgets.²⁴

- In the short-term, cost offsets and efficiencies can for example be realized by faster hospital dismissals through improved medication/treatment, forgoing additional costs of having to stay in hospital longer
- In the medium term, cost offsets may be realized by a reduction in readmissions to the hospital or reductions in the the need for (informal) care at home
- In the long-term, cost offsets arise when people are returning to full health and can go back to work again. Improved labour productivity reduces absenteeism and presenteeism, directly contributing to the economic prosperity of a country

It is important to note that all these cost offsets are primarily of benefit to the patient and future patients, as they free up much needed capacity in a health care system constrained by a lack of nurses, doctors, and beds.

Figure 4
Cost offsets across time and budget dimensions



Pharmaceutical spending can generate costs offsets over time. The challenge is to enable upfront capital investment

Affordability is not static: changes over time in costs and ability to pay impact affordability. For pharmaceuticals in particular, affordability is threatened by rising costs (as drug use increases due to aging populations and improved treatment options) without a concurrent rise in the ability to pay. To manage affordability, it is vital to consider the effects of expenditures over time, so that the true value of the expenditure is taken into account.

Affordability WITHOUT consideration of time

Short-sighted cost reduction strategies for pharmaceuticals will decrease costs for the system in the short-term, but may increase future costs. For instance, when cost reductions hamper the use of pharmaceuticals that:

- are preventive or curative
- reduce complications
- slow or stop disease progression
- reduce the need to visit the hospital for treatment, administration, or monitoring

When the negative effects of short-term cost reduction strategies on the long-term are not taken into account, too much short-term cost reduction will take place. In the worst case, this will instead lead to higher costs for the system in the medium/long-term, amplifying the affordability challenge.

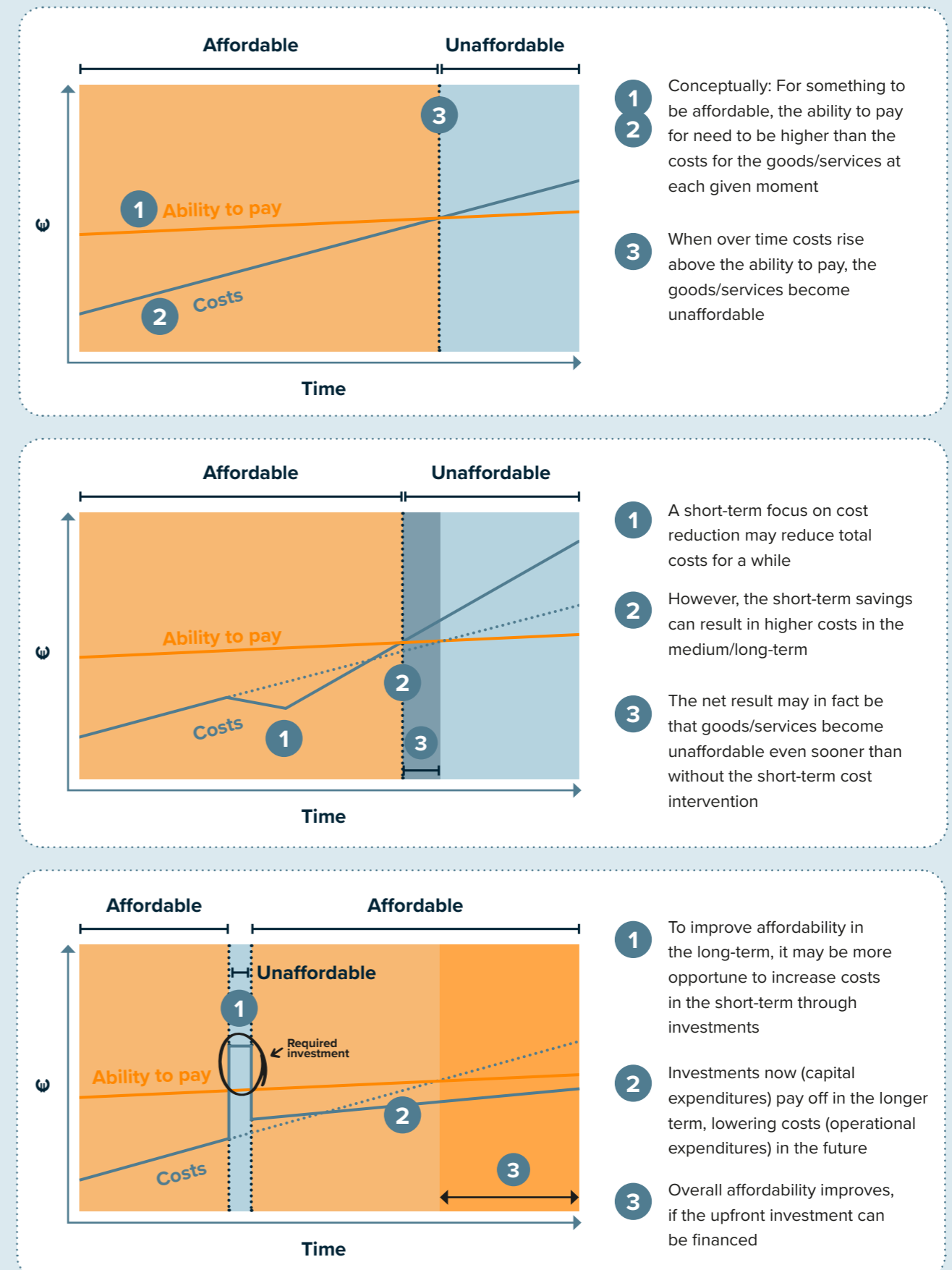
Affordability WITH consideration of time

By including the time dimension in pharmaceutical spending decisions, costs can be conceptually separated into investments (capital expenditures/CAPEX) and 'day-to-day' expenses (operational expenditures/OPEX).

Capital expenditures increase costs in the short-term, but this spending is in fact an investment that can create cost offsets over the medium/long-term by reducing future operational expenditures. Costs rise slower over time, improving overall affordability and sustainability for the long-term. As a second-order effect, ability to pay may increase, through the positive feedback loop of investment in health and ability to pay for health care (see Figure 1).

When the time dimension is taken into consideration, the challenge becomes how to finance the initial investments as these may go above the ability to pay threshold. Here, considering a second dimension can offer a solution: looking across budgets.

Figure 5
Affordability across time



COST OFFSETS EXAMPLE

DIRECT ACTING ANTIVIRALS AGAINST HEPATITIS C

Direct Acting Antivirals (DAAs) against Hepatitis C offer viral eradication in more than 98% of all patients infected with Hepatitis C Virus (HCV). They prevent around 19,000 patients each year across the EU from developing advanced liver disease and prevent the deaths of around 850 people by cirrhosis or liver cancer.²⁵ The median originator price per treatment is €24,000 - €44,000 compared to €1,000 - €2,000 for the standard of care²⁶.

The cost offsets generated by these treatments include savings made in other health care costs, which has in one instance been found to amount to a net saving per patient of €11,000 when compared to costs incurred with patients who do not receive the DAA treatment.²⁷ A study

in four European countries showed that the investment required to expand access to DAAs has a payback period of 6.5 years in England, 5.4 years in Italy, 6.7 years in Romania, and 4.5 years in Spain – all just in medical cost offsets for avoided treatments (e.g., hepatocellular carcinoma, decompensated cirrhosis and liver transplantations).²⁸

The challenge for health care systems is to pay the upfront investment cost of providing access to DAA treatment for all patients with HCV, while the cost offsets are realized gradually and are spread across different health care budgets and the wider economy. This challenge remains unsolved in countries such as Italy, where access to DAAs is restricted.

COST OFFSETS EXAMPLE

HAEMOPHILIA B GENE THERAPY

Even the most expensive drugs can generate cost savings for the overall health care system. In the US, the gene therapy Hemgenix (Etranacogene Dezaparvovec) for Haemophilia B has a list price of \$3.5 million. However, without gene therapy, patients with moderate to severe hemophilia B can cost health care systems more than \$20 million over their lifetimes.²⁹

The independent Institute for Clinical and Economic Review (ICER)* concluded that Hemgenix could have clinical effectiveness for up to 23 years based on their durability models,

and calculated that even in a shared savings model – in which 50% of lifetime health care cost offsets from a new treatment are assigned to the health care system instead of being assigned entirely to the new treatment – Hemgenix would be cost effective at the lowest Willingness to Pay threshold (\$50,000 per QALY gained) at a price of more than \$5 million.³⁰

* ICER is an independent non-profit research organization that evaluates medical evidence and convenes public deliberative bodies to help stakeholders interpret and apply evidence to improve patient outcomes and control costs.

Pharmaceutical spending can generate costs offsets across budgets. The challenge is to avoid the ‘wrong pocket’ problem

Pharmaceutical spending does not take place in isolation. Spending on pharmaceuticals influences spending on health care more broadly and even impacts costs and ability to pay for countries as a whole.

Affordability WITHOUT cross-budget perspective

Pharmaceutical expenditure can generate cost offsets for other budget holders. For example, a treatment which helps a patient avoid a visit to a hospital or a treatment that reduces a debilitating symptom resulting in increased labour productivity.

When budgets are managed in siloes this creates a “wrong pocket” problem: a situation in which the entity which bears the cost of providing a product or service does not receive the primary benefit. This results in underinvestment in that product or service, as well as a reduction in the overall benefit to society which would be generated through its provision.

Affordability WITH cross-budget perspective

If a cross-budget perspective is applied, cost offsets in one budget caused by spending in another can be used (through shared savings) to increase the ability to pay in the other budget.

Budget holders are only incentivized to identify and realise these cost offsets when considering both budgets together, as this enables the budget holders to see the combined benefits and costs..

These cross-budget effects can be very significant compared to the pharmaceutical expenditure. A recent Swiss study showed that ~85% of drug expenditures in 2018 on drugs registered during the period 1990–2011 may have been offset by the reduction in expenditure on inpatient curative and rehabilitative care.³¹

COST OFFSETS EXAMPLE

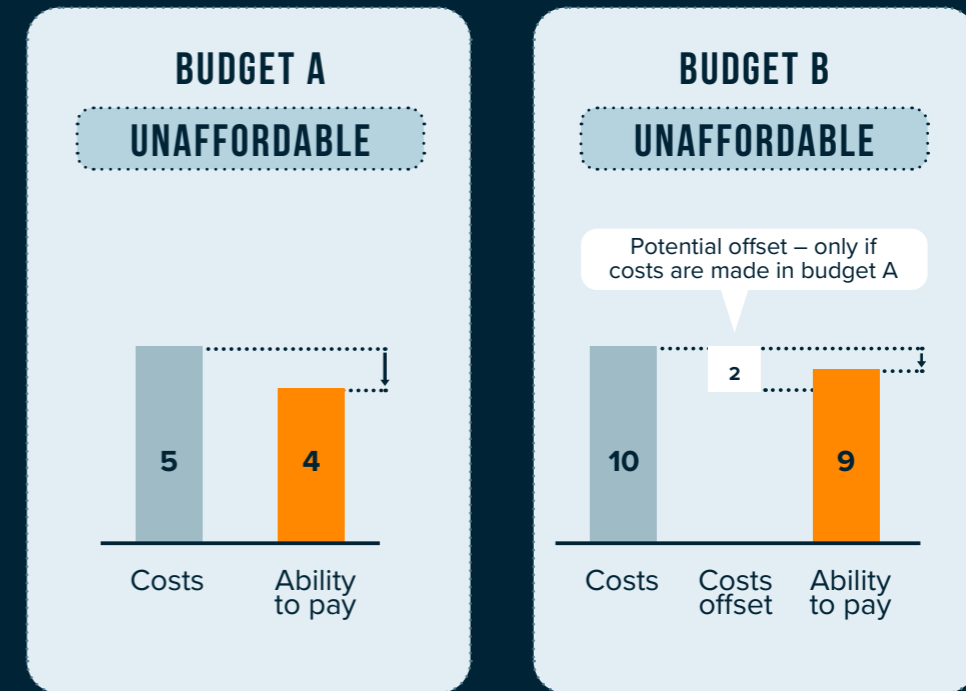
ANTICOAGULANTS FOR ATRIAL FIBRILLATION

The single-payer in England, the National Health Services (NHS), conducted a cost-benefit assessment into antithrombotic therapy for atrial fibrillation (AF). It estimated that, over a lifetime, 0.30 strokes are averted, 0.79 QALYs are gained and net savings of more than £2,400 are generated for the NHS per person with AF treated with warfarin (an anticoagulant).

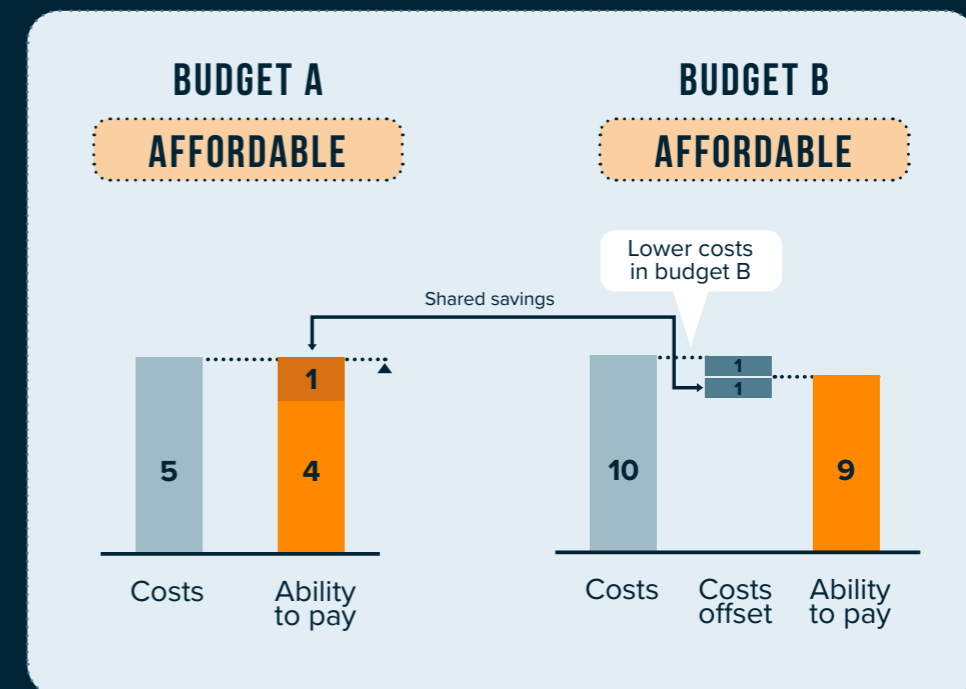
If all patients for whom the guidelines recommend anticoagulants were to receive them, the NHS would save approximately £124 million a year, relative to current patterns of care, and an additional ~£28 million would be saved on social care costs.³²

Figure 6
Affordability across budgets

Affordability **without** cross-budget perspective



Affordability **with** cross-budget perspective



CHAPTER 4

AFFORDABILITY – POTENTIAL SOLUTIONS

Making it happen: a long-term, cross-budget perspective

This report has identified five specific policy solutions that improve pharmaceutical affordability through application of a long-term, cross-budget perspective:

COST OFFSETS EXAMPLE

HPV VACCINATION

Almost all cases of cervical cancer are caused by an infection from human papillomavirus (HPV). Since 2006, several vaccines against HPV are available, providing the opportunity to prevent most cases of cervical cancer. The total costs for two courses of vaccination are estimated at well below €200, whereas the cost of cervical cancer treatment is over €20,000.³³ Consequently, vaccination of girls has been consistently predicted to be cost-effective for reducing the HPV-related disease burden.³⁴

Figure 7
Potential solutions

	TIME DIMENSION	BUDGET DIMENSION	AFFORDABILITY DRIVERS		FUNDING SOURCES	
	based on a long-term perspective on cost offsets	based on a cross-budget perspective on cost offsets	Improve ability to pay	Improve cost assessment	Existing	New
1 LONG-TERM HORIZON SCANNING OF NET PHARMACEUTICAL COSTS AND MULTI-YEAR BUDGETING	✓			✓	✓	
2 INCLUDING THE SOCIETAL VALUE PERSPECTIVE IN HTA		✓		✓	✓	
3 INNOVATIVE REIMBURSEMENT AGREEMENTS FOR PHARMACEUTICALS	✓	✓	✓	✓	✓	
4 INTEGRATED PHARMACEUTICAL BUDGETING		✓	✓		✓	
5 SOCIAL IMPACT BONDS FOR HEALTH CARE PRIORITIES	✓	✓	✓			✓

1 LONG-TERM HORIZON SCANNING OF NET PHARMACEUTICAL COSTS AND MULTI-YEAR BUDGETING

The aim of long-term horizon scanning of net pharmaceutical costs is to improve the quality of information available to payers to help them make a more efficient assessment of a potential intervention and take multi-year budget implications into consideration.

Broadening traditional horizon scanning methods to include assessments of the total impact on pharmaceutical budgets over time, across products and including loss of exclusivity, as well as cost offsets generated by individual pharmaceutical products, ensures a more comprehensive understanding of the total value generated by an intervention.

Cost-offset dimension: Time

Affordability driver: Improve cost assessment

Funding source: Existing

Key actor(s): Government, Payers

Key enabler:

- Long-term horizon scanning can only be successful when combined with a platform for early-dialogue between pharmaceutical companies and payers/policy makers

Key barrier:

- The pressure on payers to meet their short-term annual budgets, and on politicians to focus on the electoral cycle

EXAMPLE

While several European countries have horizon scanning mechanisms, most of these fail in terms of using horizon scanning data for long-term planning (including for budgets) and looking at costs holistically. The Oslo Medicine Initiative from the WHO (World Health Organization) is a new platform that aims to improve dialogue and build transparency and trust between private and public parties to address some of the shortcomings in current horizon scanning mechanisms.³⁵

2 INCLUDING THE SOCIETAL VALUE PERSPECTIVE IN HEALTH TECHNOLOGY ASSESSMENT

Most national health care economic evaluation guidelines stipulate that Health Technology Assessments (HTAs) should be conducted from a narrow ‘payers perspective’. Including the societal value perspective in HTA decisions, through broader ‘accounting’ that takes into consideration societal cost offsets (e.g. productivity gains through secondary prevention or informal care costs), helps ensure resources are allocated more efficiently.

Cost-offset dimension: Budget

Affordability driver: Improve cost assessment

Funding source: Existing

Key actor(s): Government, Payers

Key enabler:

- Multi-sector alignment on HTA guidelines and the sharing of best practices can help to promote the use of the societal value perspective in HTAs

Key barrier:

- Lack of political guidelines and approved approaches to assess future societal savings in a sufficiently robust way

EXAMPLE

The Swedish HTA body (SBU Sweden – Swedish Agency For Health Technology Assessment And Assessment Of Social Services) applies a societal perspective in HTA to show the total costs and effects for society at large, not just for a particular sector.³⁶

3 INNOVATIVE REIMBURSEMENT AGREEMENTS FOR PHARMACEUTICALS

Innovative agreements between payers and pharmaceutical companies, such as multi-year and multi-indication agreements or subscription, installment or shared savings purchase models, can increase the ability of payers to deal with high upfront costs for investments.

To be able to agree on innovative reimbursement agreements, pharmaceutical companies may need to invest in collecting different or additional evidence whilst HTA bodies may need different or additional capabilities to be able to evaluate innovative agreements

Cost-offset dimension: Time, Budget

Affordability driver: Improve ability to pay, Improve cost assessment

Funding source: Existing

Key actor(s): Pharmaceutical companies, Payers

Key enabler:

- A flexible ‘sandbox’ environment to test and model innovative access agreements and facilitate the discussion with HTAs and payers on what kind of deal might best suit the particular access situation

Key barrier:

- The multi-stakeholder process to agree on an innovative reimbursement model is time-consuming and requires trust, mutual respect, and collaboration

EXAMPLE

In the UK, the National Health Services made a ‘Netflix’-style deal with Vertex for unlimited patient access to existing and future cystic fibrosis (CF) therapies.³⁷ The advantages of such a ‘Netflix’ model for the payer is that there is a greater degree of clarity upfront what the total impact of the access agreement will have on the broader pharmaceutical budget. At the same time the pharmaceutical company gets upfront clarity on the income it will receive to recuperate their R&D investment.

4 INTEGRATED (PHARMACEUTICAL) BUDGETING

By merging siloed (pharmaceutical) budgets, governments and payers can allow for optimal distribution of costs as external effects between budgets (i.e. cost offsets) can be fully internalized. This may even go beyond different health care budgets so that finance/treasury departments have visibility on overall cost offsets from pharmaceutical budgets.

Similarly, regional budgets (such as in Sweden) could be merged to increase the budget’s resilience, for instance to cope with regional high costs for certain genetic diseases.

Cost-offset dimension: Budget

Affordability driver: Improve ability to pay

Funding source: Existing

Key actor(s): Government, Payers

Key enabler:

- Accurately measuring cross-pharmaceutical cost offsets increases transparency on the broader benefits that expenditure on pharmaceuticals can bring

Key barrier:

- Siloes are often introduced to make budgets manageable. Integrating these budgets will require adapted governance procedures to still be able to manage the integrated budget effectively

EXAMPLE

Belgium has an integrated budget for inpatient and outpatient pharmaceuticals, whereas the Netherlands has created two separate budget silos. This latter approach impedes a complete analysis of overall pharmaceutical cost dynamics.³⁸

5

SOCIAL IMPACT BONDS FOR IDENTIFIED HEALTH CARE PRIORITIES

Social Impact Bonds are public-private partnerships that fund effective social or health care services through performance-based contracts. Impact investors (e.g., banks, impact funds, or even retail investors) provide the capital to fund the intervention of a social or health care provider. Part of the societal savings realized through the provision of the intervention can be used to repay the investors, creating a quadruple win for the patient, the investor, the service provider, and society.

In health care settings, the payor will reimburse investors if health care expenditures are lower than they would otherwise have been without the intervention, resulting in net lower costs overall.

Cost-offset dimension: Time, Budget

Affordability driver: Improve ability to pay

Funding source: New

Key actor(s): Health care providers, (Private) investors, Payers

Key enabler:

- Social Impact Bonds are a relatively new phenomenon. Guidelines on how to set-up successful projects and showcase examples to make the added value clear to all stakeholders are needed to catalyze use

Key barrier:

- Social Impact Bonds currently still have high transaction cost, due to the large number of different stakeholders, difficulty of measuring outcomes – especially the cost offsets – and the novelty of the approach

EXAMPLE

In Sweden, the Healthmovement project is a Diabetes Type 2 prevention program financed by an insurance company. If a participant develops Type 2 diabetes, the insurer covers part of the cost of treatment, but if the participant is found to have reduced their risk of diabetes, the insurer receives a return. The payer is expected to receive a 100% return on investment as people will either need less expensive care because they remain healthy or the costs for treatment are shared with the insurance company.³⁹

CONCLUSION

To safeguard the affordability of pharmaceuticals in Europe, a new perspective is needed. Without it, we run the risk that our health systems can no longer guarantee timely access to the best treatments. The current narrow focus on reducing costs is unlikely to turn the tide and could inadvertently lead to poorer health outcomes as patient access is delayed.

Instead, taking a broader perspective will help to identify opportunities where pharmaceutical spending generates cost offsets and thus contributes to keeping health systems affordable.

These offsets only become apparent when looking over a longer period of time and across multiple budgets. When pharmaceutical spending reduces health care costs later and allows employees to return to work sooner, society as a whole benefits.

Applying such a long-term, cross-budget perspective to spending decisions allows for a better assessment of net costs and relevant budgets, which creates opportunities for improving pharmaceutical affordability.

As illustrated by the examples and potential solutions in this report, it is possible to optimise upfront investment decisions by adopting a long-term and cross-budget perspective regarding cost offsets.

LIST OF ABBREVIATIONS

AF	Atrial fibrillation
ATMP	Advanced therapy medicinal product
bDMARD	Biological disease-modifying antirheumatic drug
CAPEX	Capital expenditure
CF	Cystic fibrosis
COVID-19	Corona Virus Disease 2019 caused by SARS-CoV-2
DAA	Direct-acting antiviral
EFPIA	European Federation of Pharmaceutical Industry Associations
EU	European Union
GDP	Gross Domestic Product
GKV-FinSt	Gesetzlichen Krankenversicherung Finanzstabilisierungsgesetz, Germany
HCV	Hepatitis C virus
HPV	Human papillomavirus
HTA	Health Technology Assessment
ICER	Institute for Clinical and Economic Review, US
NHS	National Health Service, United Kingdom
OECD	Organisation for Economic Co-operation and Development
OPEX	Operational expenditure
QALY	Quality-adjusted life year
RA	Rheumatoid arthritis
R&D	Research & Development
ROI	Return on investment
SBU	Swedish Agency For Health Technology Assessment And Assessment Of Social Services
VPAS	Voluntary Scheme for Branded Medicines Pricing and Access, United Kingdom
WHO	World Health Organization

LIST OF REFERENCES

1. <https://www.oecd.org/governance/budgeting/sbo-health.htm>
2. <https://data.oecd.org/gdp/real-gdp-long-term-forecast.htm>
3. <https://www.telegraaf.nl/financieel/1190071453/zorgverzekeraar-cz-kunnen-niet-meer-garanderen-dat-zorg-altijd-voor-iedereen-toegankelijk-is>
4. <https://www.ft.com/content/671bfe19-2ef0-4f3c-84e4-a573b8567345>
5. <https://www.insideeulifesciences.com/2022/10/26/germany-significantly-tightens-drug-pricing-and-reimbursement-laws/>
6. Alliance for Regenerative Medicine, Cell & Gene State of the Industry Briefing 2023 (<http://alliancerm.org/wp-content/uploads/2023/01/SOTI-2023-Slides.pdf>)
7. <https://www.ft.com/content/f77cac8c-9c75-4c77-9d63-d3d5c1c3965b>
8. Jamison, Dean T., et al. “Global health 2035: a world converging within a generation.” *The Lancet* 382.9908 (2013): 1898-1955
9. Hofmarcher, T., et al. “Comparator report on cancer in Europe 2019—disease burden, costs and access to medicines.” *IHE Report 7* (2019): 204-209
10. https://ec.europa.eu/eurostat/databrowser/view/hlth_hlye/default/table?lang=en
11. <https://www.efpia.eu/media/676700/allowing-ra-patients-to-live-a-normal-life-with-biologics.pdf>
12. Kavanaugh, Arthur et al. “Effect of certolizumab pegol with methotrexate on home and work place productivity and social activities in patients with active rheumatoid arthritis.” *Arthritis and rheumatism* vol. 61,11 (2009): 1592-600
13. Hsieh, Ping-Hsuan, et al. “Economic burden of rheumatoid arthritis: a systematic review of literature in biologic era.” *Annals of the rheumatic diseases* 79.6 (2020): 771-777
14. Lichtenberg, Frank R. “Contribution of pharmaceutical innovation to longevity growth in Germany and France, 2001–7.” *Pharmacoeconomics* 30 (2012): 197-211; Lichtenberg, Frank R. “The association between pharmaceutical innovation and both premature mortality and hospital utilization in Switzerland, 1996–2019.” *Swiss Journal of Economics and Statistics* 158.1 (2022): 7

15. <https://www2.deloitte.com/uk/en/pages/press-releases/articles/pharma-r-d-return-on-investment-falls-in-post-pandemic-market.html>
16. Alliance for Regenerative Medicine, Regenerative Medicine: The Pipeline Momentum Builds, 2022 (<https://alliancerm.org/sector-report/h1-2022-report/>)
17. Troein, P., M. Newton, and K. Stoddart. "Understanding net pharmaceutical expenditure dynamics in Europe." Durham, NC: IQVIA Institute for Human Data Science (2022)
18. <https://www.oecd.org/health/Health-care-financing-in-times-of-high-inflation.pdf>
19. Gautam, Amy, ed. Tackling wasteful spending on health. OECD, 2017
20. Watson, Oliver J., et al. "Global impact of the first year of COVID-19 vaccination: a mathematical modelling study." *The Lancet Infectious Diseases* 22.9 (2022): 1293-1302
21. <https://www.imf.org/en/News/Articles/2021/06/01/pr21150-new-billion-health-trade-finance-roadmap-end-pandemic-secure-global-recovery>
22. Agarwal, Ruchir, and Ms Gita Gopinath. A proposal to end the COVID-19 pandemic. International Monetary Fund, 2021
23. Kirkegaard, Jacib Funk. "The European Union's Troubled COVID-19 Vaccine Rollout." PIIIE. Mar 15 (2021)
24. Zozaya, Néboa, Bleric Alcalá, and Jhon Galindo. "The offset effect of pharmaceutical innovation: A review study." *Global & Regional Health Technology Assessment* 2019 (2019)
25. <https://efpia.eu/media/676701/efpia-power-of-innovation.pdf>
26. Barber, Melissa J., et al. "Price of a hepatitis C cure: cost of production and current prices for direct-acting antivirals in 50 countries." *Journal of Virus Eradication* 6.3 (2020): 100001
27. <https://pharma.be/sites/default/files/2021-08/value-of-medicines.pdf>
28. Mennini, Francesco S et al. "The impact of direct acting antivirals on hepatitis C virus disease burden and associated costs in four European countries." *Liver international: official journal of the International Association for the Study of the Liver* vol. 41,5 (2021): 934-948
29. <https://www.fiercepharma.com/pharma/csl-and-uniquest-hemophilia-b-gene-therapy-scores-approval-35-million-price-tag>
30. Tice J.A., et al. "Gene Therapy for Hemophilia B and An Update on Gene Therapy for Hemophilia A: Effectiveness and Value.;" Draft Evidence Report. Institute for Clinical and Economic Review (2022)
31. Lichtenberg, Frank R. "The association between pharmaceutical innovation and both premature mortality and hospital utilization in Switzerland, 1996–2019." *Swiss Journal of Economics and Statistics* 158.1 (2022): 7.
32. Kerr, M. "Costs and Benefits of Antithrombotic Therapy in Atrial Fibrillation in England: An Economic Analysis based on GRASP-AF." NHS (https://qna.files.parliament.uk/qna-attachments/449222/original/af_economic_analysis_final.pdf)
33. <https://efpia.eu/media/676701/efpia-power-of-innovation.pdf>
34. Qendri, Venetia, et al. "The cost-effectiveness profile of sex-neutral HPV immunisation in European tender-based settings: a model-based assessment." *The Lancet Public Health* 5.11 (2020): e592-e603
35. <https://www.who.int/europe/initiatives/the-oslo-medicines-initiative>
36. <https://www.sbu.se/en/publications/medical-and-science-newsletter/health-economists-search-for-ways-to-stretch-health-care-budgets/>
37. <https://www.england.nhs.uk/2019/10/nhs-england-concludes-wide-ranging-deal-for-cystic-fibrosis-drugs/>; <https://investors.vrtx.com/news-releases/news-release-details/vertex-announces-agreement-nhs-england-access-all-licensed>
38. European Commission. "Joint Report on Health Care and Long-Term Care Systems and Fiscal Sustainability – Country Documents 2019 Update." European Commission, Brussels (2016)
39. <https://eithealth.eu/news-article/eit-health-drives-plan-to-pay-for-health-not-illness/>

ACKNOWLEDGEMENTS

We would like to thank the following individuals for their valuable input during interviews and/or round table discussions:

- Adrian Pana (Center for Health Outcomes and Evaluation)
- Giovanni Gorgoni (EUREGHA)
- Jaime Espin (Escuela Andaluza de Salud Pública)
- Jacqueline Bowman-Busato (European Association for the Study of Obesity)
- Marcin Czech (Institute of Mother and Child, Warsaw, Poland and Polish Pharmacoeconomic Society)
- Matt Hickey (Value Health Alliance)
- Ruben Koekoek (Social Finance NL)
- Thorsten Wolf (Pronova BKK)