Transforming lives, raising productivity

Is the UK missing out on the full potential of innovative medicines?

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In collaboration with

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Bringing medicines to life

Foreword from ABPI

Dr Richard Torbett
ABPI Chief Executive

The ABPI exists to make the UK the best place in the world to research, develop and use the medicines of the future. We are hugely proud of that mission and rightly so, the pipeline has never been more exciting. From cutting edge vaccines that have shown us the way out of the pandemic, to personalised treatments and ground-breaking cell and gene therapies, we are seeing a step change in medicine that promises to transform the lives of patients.

The Life Sciences Vision, published last year, was an ambitious blueprint for how the UK can build on our strengths and cement ourselves as a life sciences superpower.

We have already seen progress delivering on this ambition, from the focus on tackling the healthcare missions to new incentives for manufacturing investment.

There has also been a concerted effort in the NHS to improve access to new medicines – through initiatives like the Accelerated Access Collaborative (AAC).

But this report shows where there is an opportunity for us to go further. By radically improving access to new treatments, we can not only transform patient outcomes but deliver a huge productivity boost for the economy.

Throughout the pandemic, we have seen what we can achieve if we work together, and we must take that spirit of collaboration forward as we work to rebuild the NHS after the pandemic and deliver world class treatments to UK patients.

We thank ABPI members and stakeholders for their involvement in interviews and workshops to support the development of this report. PwC interviewed and surveyed over 30 industry respondents across 13 ABPI member companies and the ABPI itself. Respondents held a variety of roles at their respective organisations, including UK Managing Directors and General Managers and decision-makers across value and access, R&D, commercial and medical teams.

The findings in this report reflect to the best of PwC's ability the sentiment and recommendations made by the following contributors:

- Alexion
- Amgen
- AstraZeneca
- Boehringer Ingelheim
- Bristol Myers Squibb
- GlaxoSmithKline
- Janssen
- Merck
- MSD
- Novartis
- Pfizer
- Roche
- Sanofi

Foreword from PwC

Thalita Marinho
PwC Strategy&,
Pharmaceuticals Partner

PwC's purpose is to build trust in society and solve important problems. One of the ways in which we do this is by helping organisations understand the economic and social impacts of their strategies, activities and products. With the COVID-19 pandemic highlighting the link between the health of citizens and the wealth of economies, the need to recognise these wider impacts is clear.

This report looks at the value of innovative medicines in the UK. Our findings, which were informed by independent desk-based research and interviews from industry representatives, look at some of the challenges around medicine access, impacts of COVID-19 on patient outcomes and potential impacts of patient uptake of innovative medicines in terms of health and productivity. We hope our findings shed a helpful light on how industry and governments can work together to support overall health outcomes.

My thanks to the PwC Strategy& team for approaching this topic with steadfast rigour, and the Association of the British Pharmaceutical Industry for funding this report.

Contents

Executive summary

Innovative medicines transform individual patient lives. But they also bring significant broader benefits to the UK economy and to society as a whole – through greater patient and carer productivity, NHS productivity, and more.

This report has been produced to understand the benefits of increased investment in clinically-and cost-effective innovative medicines to patients, society and the economy. There has been a concerted NHS effort to improve uptake of and access to new medicines through initiatives like the Accelerated Access Collaborative (AAC) and the introduction of the Innovative Licensing and Access Pathway (ILAP). This report demonstrates that building on momentum in this area, and further improving access to and uptake of innovative medicines – that is, branded medicines that offer greater health and other benefits than the existing standard of care – can not only transform individual patient lives, but also provide much wider social and economic gains.

In quantifying these broader benefits, this report reveals the true value of innovative medicines to the UK. And it demonstrates the importance of increasing investment, to realise the UK government's Life Sciences Vision, to support a thriving life sciences ecosystem and transform patients' lives.

The case for investing in innovative medicines is clear. However, at present the UK's investment in pharmaceuticals is less per capita than other high income countries. At net prices, for every £100 in GDP, the UK spends an estimated 81p on pharmaceuticals.[1] This compares to £2.35, £1.94 and £1.84 spent by the US, Germany and Japan, respectively.[2]

Additionally, for some disease areas, UK patients have less rapid and consistent access to these medicines than people in most developed countries.[3,4] Lower and more variable patient uptake in the UK is one driver of poorer health outcomes. For example, both Finland and Sweden have substantially higher uptake than the UK in the leading medicines for lung cancer treatment and it has been shown that increased spending on cancer care and access to medicines is positively associated with improved outcomes.[5]

In this report, we demonstrate the value of innovative medicines to UK patients and the UK economy. We do this by analysing the potential benefits that would come from increasing the uptake from the current number of patients using a given medicine, to the total NICE recommended eligible patient populations. We estimate the benefits for 13 medicines in four different innovative and competitive classes and disease areas: coagulation, type 2 diabetes, severe asthma, and autosomal dominant polycystic kidney disease. See infographic below.

Importantly, these incremental productivity gains would more than offset the incremental costs of increased uptake. Even at the lower end of the range used in our analysis, tax receipts could cover at least 42 per cent of the incremental costs, or at the higher end of the range, potentially all of the incremental costs.

Investing in these medicines also brings broader benefits to patients, carers and families, and the NHS. It can support greater health equity and the levelling up agenda, improving health outcomes for those who are currently disproportionately impacted by disease.

And it creates a virtuous cycle of investment in the life sciences ecosystem, stimulating future waves of innovation and attracting an increased share of global investment to the UK.

As the country begins to emerge from the pandemic, this is an ideal moment to supercharge the execution of the Life Sciences Vision. Improved access to and uptake of innovative medicines will play an important role in that process, supporting the NHS to navigate its vital evolution into a more preventative and efficient system. To make this happen, industry, the NHS, governments and other stakeholders will need to come together and solve three key challenges: increasing the breadth of access, speed of access, and extent and rate of uptake.

The next VPAS in 2024 should be seen as a key component in creating a holistic plan for the UK life sciences ecosystem. The result will be healthier, more productive patients, and a healthier, more productive economy.

For these four medicine classes alone, we found:

1.2 million
patients in the UK are missing out on innovative treatments.

429,000
QALYs (quality-adjusted life years) could be gained from increased uptake.

£17.9 billion
in productivity gains would accrue to the UK as a whole.

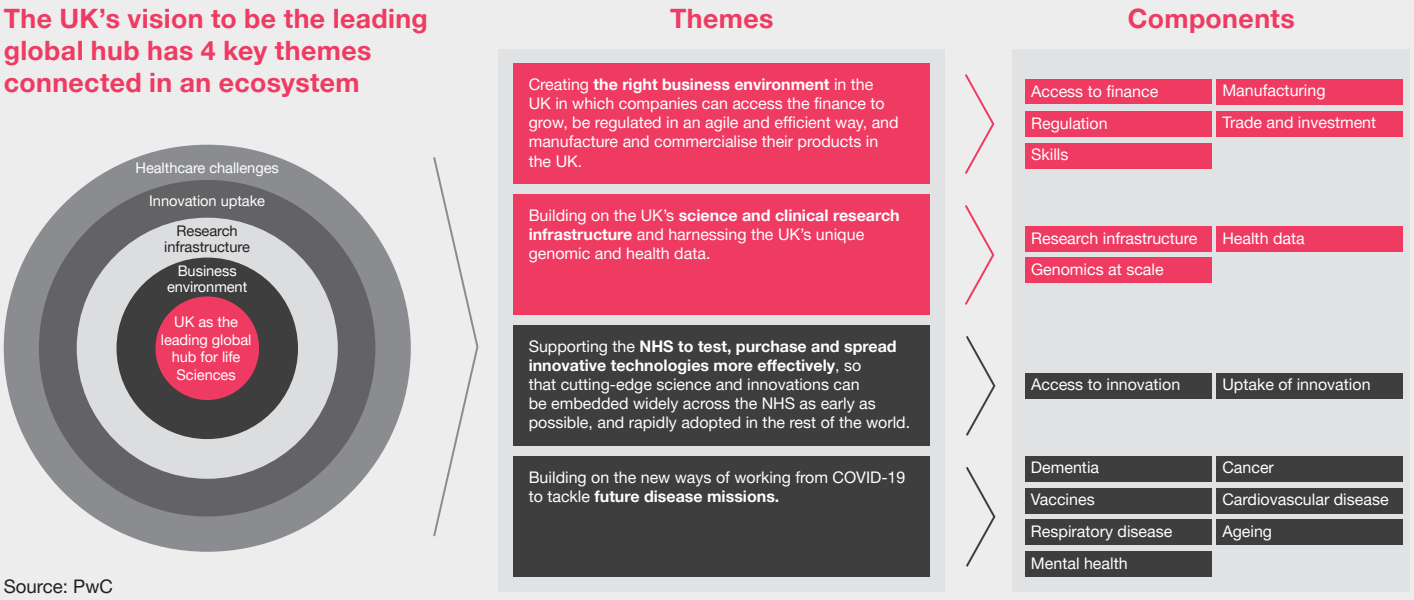
£5.5 billion
of which would be paid back to the Exchequer through taxes.

[1] PwC analysis of data from IQVIA (2021). 'Drug Expenditure Dynamics 1995–2020', October 2021, Exhibit 1; OECD, Health Spending dataset; and OECD, GDP dataset. Estimates based on 2018 figures.
[2] PwC analysis of data from IQVIA (2021). 'Drug Expenditure Dynamics 1995–2020', October 2021, Exhibit 1; OECD, Health Spending dataset; and OECD, GDP dataset. Estimates based on 2018 figures.
[3] Access refers to the availability of innovative medicines on the NHS, e.g. the medicines are licensed for use and have received a positive recommendation by NICE for the NHS to prescribe them to patients.
[4] ABPI (2022). Improving access to medicines in the UK.
[5] IHE (2020). 'Comparator Report on Cancer in Europe 2019 – Disease burden, costs and access to medicines', 2020, p. 154, Figure 65.

1. Why innovation matters

Supporting access to and uptake of innovative medicines delivers better patient outcomes. It is also essential to creating a thriving life sciences ecosystem and are key components of the UK Life Sciences Vision.

Figure 1: Key components in the life sciences ecosystem



Source: PwC

Innovation is a key ingredient of a leading life sciences ecosystem

The UK government's Life Sciences Vision (see **Figure 1**) aims to make the UK the leading global hub for life sciences. It recognises the value of both the sector and the innovative medicines it produces. And it emphasises the benefits that come from true collaboration between governments, the NHS, and industry.[6]

As the Vision articulates, being the leading global hub for life sciences means having an ecosystem firing on all cylinders. That entails not only creating the right business environment, but also building world-leading research infrastructure, tackling major healthcare missions, and supporting access to and uptake of innovative medicines across the NHS.

Innovation saves and improves lives and livelihoods

The last two years have shown why pharmaceutical innovation and collaboration matters – and have demonstrated how critical the UK life sciences sector and the NHS are to the health and wealth of the nation. Over the course of the pandemic, the Oxford/AstraZeneca and Pfizer-BioNTech vaccines were discovered and developed. For example, 2 billion doses of the Oxford/AstraZeneca vaccine were supplied globally.[7] In the UK specifically, there were over 100 million doses of the Pfizer-BioNTech vaccine supplied over the course of 2020 to the end of 2021.[8] Clinical trials for vaccines and therapeutics were facilitated across the NHS.

The supply of critical medicines for COVID and non-COVID patients was maintained. And Dexamethasone was identified as an effective treatment, saving as many as 1 million lives globally.[9,10] Overall, this collaboration has enabled an unprecedented response to an unprecedented challenge.

Partnership working to support existing innovation and foster new innovation will be key to the future health and wellbeing of UK citizens. However, it needs to be considered in the context of the NHS budget where trade-offs between costs and benefits are inevitable. The good news is that innovation in medicine and managing the NHS budget need not be mutually exclusive.

[6] UK Government (2021). 'UK Life Sciences industry sees nearly half billion investment as PM convenes Biopharmaceutical Industry leaders to strengthen future pandemic response', 2 December 2021.
[7] AstraZeneca. COVID-19 vaccine supply news release, 16 November 2021.
[8] DHSC. UK secures extra 60 million Pfizer/BioNTech COVID-19 vaccines – GOV.UK (www.gov.uk).
[9] NHS England (2021). 'COVID treatment developed in the NHS saves a million lives', 23 March 2021.
[10] NHS England (see above article).

2. Access and uptake in the UK

Despite recent progress in some therapy areas and a focus on ensuring patients can access new medicines as close to their licensing as possible, uptake remains lower and more variable than overseas. Patients in the UK often have more restricted access to innovative medicines than do their counterparts in similar countries.

Access to innovative medicines is managed within the NHS budget

In England, medicines spending represents about 9.5 per cent of the NHS budget, totalling around £16.7 billion annually (including generic medicines, at net prices after discounts).[11,12,13] Operating within a defined budget means the NHS must make difficult trade-offs, assessing its investments in medicines in terms of cost-effectiveness as well as other factors like safety and efficacy (see **Box 1** for further detail on access determination and cost control and affordability mechanisms in England). It cannot simply pursue better patient outcomes at any cost.

There have been a number of recent successes in bringing value to the NHS within the service's financial constraints. Companies are working with NICE and NHS England (NHSE) to agree terms that ensure patients can access new medicines as early as possible, including through the use of managed access agreements which support this ambition whilst further evidence is generated. But it is also important to look at how the UK performs on investment in medicines in an international context, in comparison to equivalent countries.

The UK from a macroeconomic perspective

Higher-income countries, including the UK, spend more on pharmaceuticals per capita than non-high-income countries.[15] However, relative to nine of its high-income peers, the UK spends considerably less (see **Figure 2**).

Box 1: How England[14] determines access to medicines and medicines spend

MHRA regulatory approval	The Medicines and Healthcare products Regulatory Agency (MHRA) determines whether a new medicine is **safe, efficacious and of high quality**.
NICE HTA	The National Institute for Health and Care Excellence (NICE) assesses whether innovative medicines are **cost-effective** when compared to the current standard of care; in practice only medicines that meet the cost-effectiveness thresholds will be reimbursed in the NHS.
Budget impact test	A budget impact test is conducted to **understand whether the impact will be significant**; when medicines are expected to have a net budget impact of £20m of more in any of the first three years post-launch, there may be further commercial negotiations.
VPAS	The 2019 VPAS caps the levels of NHS branded medicines spending growth to a maximum of 2% per year; all NHS purchases beyond the cap are **provided free of charge** by the industry.

See **Appendix A.1** for more detail.

For every £100 in GDP, the UK spends 81p on pharmaceuticals. This compares to £2.35, £1.94 and £1.84 spent by the US, Germany and Japan, respectively. Industry stakeholders suggest this is driven by limited access and uptake and the relatively high discounts offered in the UK compared to other high-income countries.[16] See **Appendix A.2** for further detail on our methodology.

[11] NHS Business Services Authority (NHSBSA) Statistics (2021). 'Prescribing Costs in Hospitals and the Community – England 2020/21', 11 November 2021: 'The total expenditure on medicines in England by the NHS in 2020/21 was estimated to be £16.7 billion.

[12] The King's Fund (2021). 'The NHS budget and how it has changed', 24 March 2021.

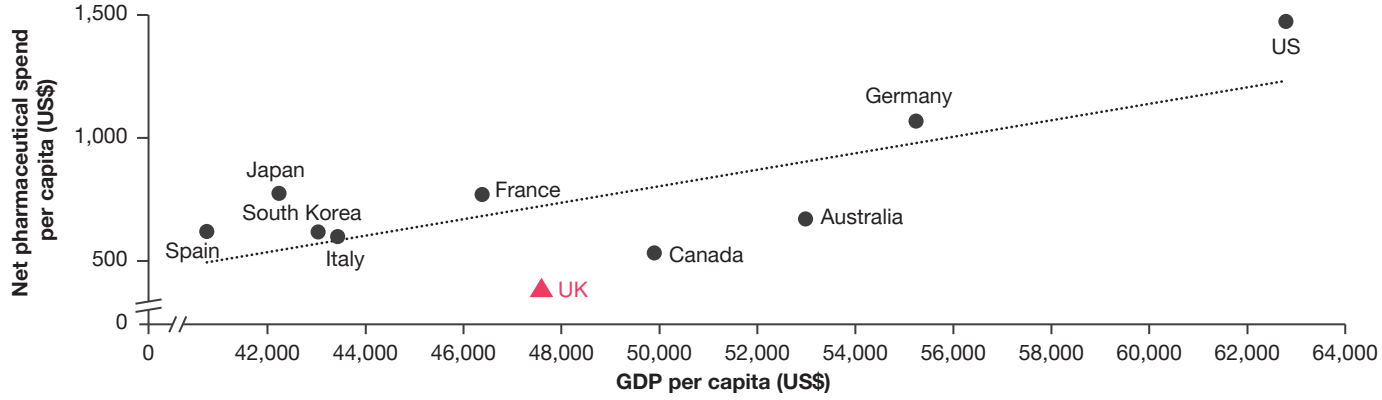
[13] DHSC and ABPI (2019). 'Analysis of UK medicine sales 2019'.

[14] Note that this figure reflects how decisions around medicine access are adopted in England, with the devolved nations of Northern Ireland, Scotland and Wales taking part in some of the steps.

[15] PwC analysis of data from IQVIA (2021), 'Global Medicine Spending and Usage Trends', April 2021; and OECD population and GDP per capita indicators, accessed 1 December 2021.

[16] PwC interviews with ABPI member companies.

Figure 2: Relationship between net pharmaceutical spend per capita and GDP per capita[17]

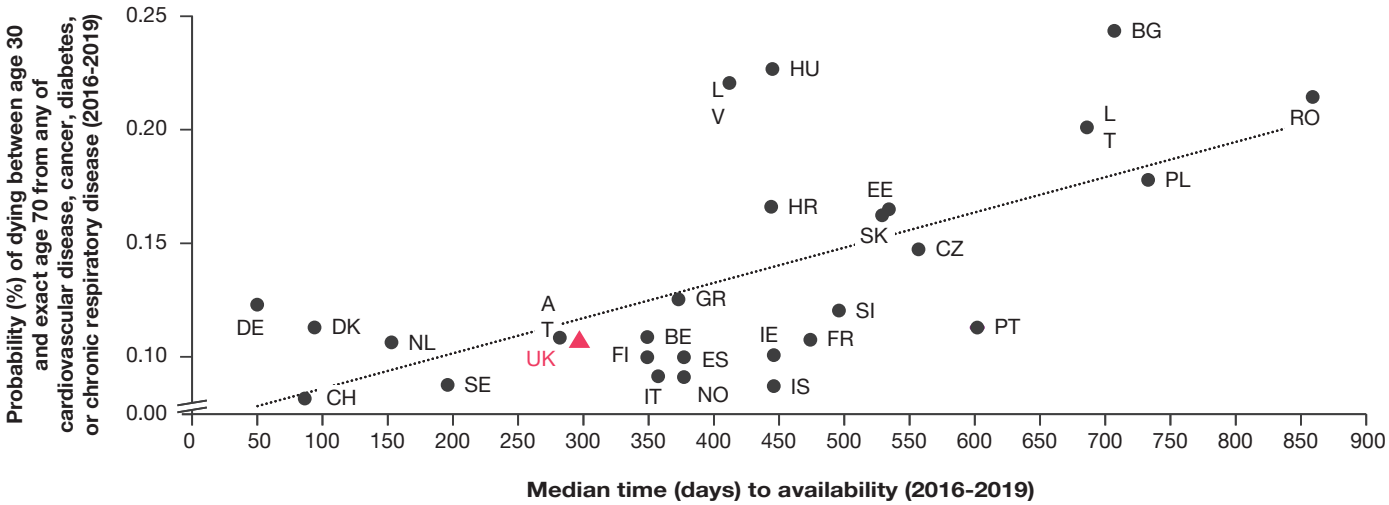


Source: PwC analysis of data from IQVIA (2021). 'Drug Expenditure Dynamics 1995–2020: Understanding medicine spending in context', 14 October 2021; and OECD healthcare spending and GDP per capita indicators.

In addition, longer time to reimbursement is associated with poorer health outcomes. Looking at healthcare in general, long wait times 'have been shown to be associated with patient dissatisfaction, delayed access to treatments, poorer clinical outcomes, increased costs, inequality, and patient anxiety.'[18] For patients with chronic health conditions, this burden may be cumulative.[19]

The correlation between time to availability of innovative medicines and health outcomes is similar. Across Europe, longer wait times for medicine availability are associated with higher mortality (see **Figure 3**).

Figure 3: Relationship between mortality and medicine availability[20]



Source: PwC analysis of time to medicine availability data from EFPIA, 'EFPIA Patients W.A.I.T. Indicator 2020 Survey', April 2021; and WHO Global Health Observatory.

[17] This relationship is found to be statistically significant: t-statistic = 0.777, df = 9, $p < 0.004$.

[18] McIntyre and Chow (2018). 'Waiting Time as an Indicator for Health Services Under Strain: A Narrative Review', Inquiry. 2020 Jan-Dec; 57: 0046958020910305. Published online 2020 Apr 30.

[19] McIntyre and Chow (2018). 'Waiting Time as an Indicator for Health Services Under Strain: A Narrative Review', Inquiry. 2020 Jan-Dec; 57: 0046958020910305. Published online 2020 Apr 30.

[20] Using data from EFPIA, 'EFPIA Patients W.A.I.T. Indicator 2020 Survey', April 2021; and the WHO, 'Probability of dying between the exact ages 30 and 70 years from cardiovascular diseases, cancer, diabetes, or chronic respiratory diseases (SDG 3.4.1)', there is a moderate yet statistically significant, positive correlation between the median time to medicine availability and the probability of dying between ages 30-70 from any of cardiovascular disease, cancer, diabetes or chronic respiratory disease (SDG 3.4.1): $r(26) = 0.637$, $p<0.0001$. In other words, faster access to medicines is moderately, positively associated with progressing against the UN's Sustainable Development Goal regarding 'Good Health and Well-being'.

Access to and uptake of innovative medicines in the UK

Compared with other major pharmaceutical markets, the UK is perceived by industry to place less value on innovative medicines.[21] It is also perceived to have slower access and has lower and more variable uptake.[22] This corresponds with poorer outcomes for many conditions, as innovative medicines are often the best intervention for many conditions. In 2016, for example, England had significantly greater premature mortality across numerous diseases than the best performing countries: [23,24]

1. ~50 per cent more years lost to ischaemic heart disease than France or Spain.
2. ~60 per cent more years lost to lung cancer than Finland or Sweden.
3. ~50 per cent more years lost to stroke than Austria.
4. More than double the years of life lost to chronic obstructive pulmonary disease than Finland or France.

In cancer specifically, although survival rates have risen across the board thanks to improvements in planning, diagnosis and treatment, the UK lags significantly behind other countries for some cancer types,[25] especially in its five-year net survival rates:[26]

- NHS patients are **5.1 per cent less likely to survive** for five years after a breast cancer diagnosis than are patients in the US (the best performing country), with the UK ranked 14th out of 18 developed countries.[27]
- NHS patients are **10.6 per cent less likely to survive** for five years after a cervical cancer diagnosis than are patients in Japan (the best performing country), with the UK ranked 15th out of 18 developed countries.[28]
- NHS patients are **15.1 per cent less likely to survive** for five years after a colon cancer diagnosis than are patients in Australia (the best performing country), with the UK ranked last out of 18 developed countries.[29]

Lower and more variable patient uptake in the UK is one driver of these poor outcomes. For example, both Finland and Sweden have substantially higher uptake than the UK of the leading medicines for lung cancer treatment.[30] And a study has shown that across Europe, while spend on cancer care has remained relatively stable, the share of this spend on cancer medicines has increased and those countries that spend more on cancer care have improved cancer outcomes.[31]

Additionally, Public Health England has acknowledged that ''there remain significant opportunities for the prevention of both cardiovascular disease and cancer through [...] maximising the uptake of known effective care'' among other interventions.[32]

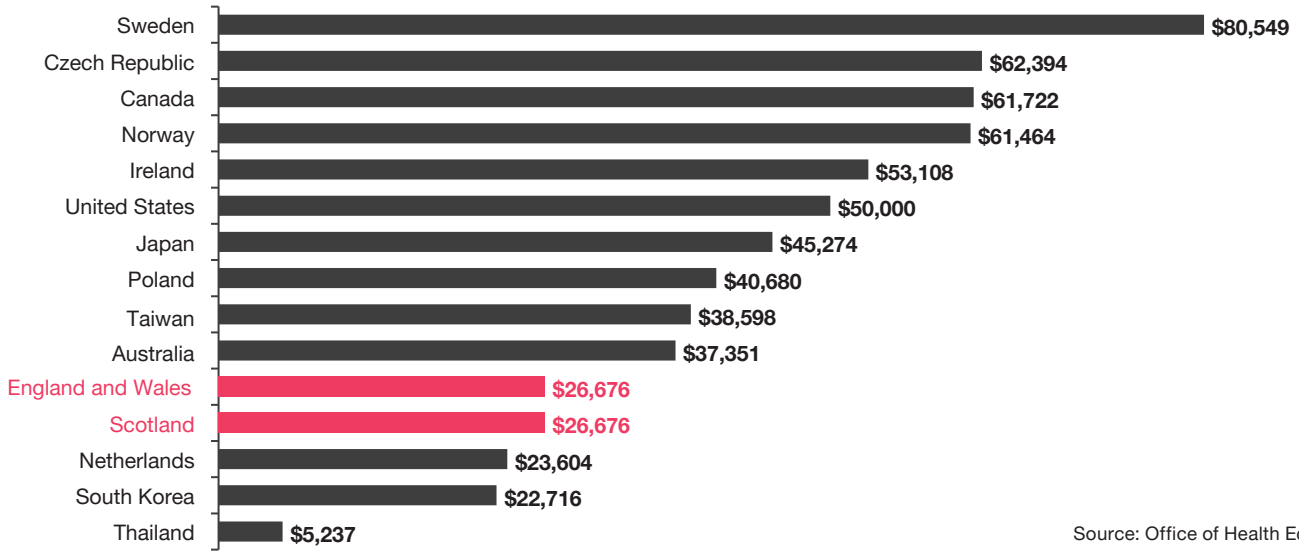
While access and uptake decisions are not typically made at a UK-wide level, although there is limited data availability, the industry perspective is that there is generally no marked difference between the UK's four devolved nations in access, uptake and outcomes, relative to other pharmaceutical markets.[33]

However, the UK has an advantage over some countries with the single-payer system of the NHS, which provides healthcare for everyone, free at point of care. While the NHS operates within a finite budget, and needs to demonstrate value for taxpayer money, this system has all the right ingredients – including vast patient data – to face some of these challenges head on, with industry and government support.

And the UK and devolved nations have made steps to improve their access to and uptake of innovative medicines through a number of targeted interventions, including the Early Access to Medicines Scheme (2014), the Accelerated Access Collaborative (2016), the Voluntary Scheme for Branded Medicines Pricing and Access (2019), the Welsh Government's New Treatment Fund (2020), the NHS England Commercial Framework (2021), the Innovative Licensing and Access Pathway (2021), the Innovative Medicines Fund (2022) and the NICE Methods and Process Review (2022).

[21] PwC interviews with ABPI member companies
[22] PwC interviews with ABPI member companies
[23] Compares the UK's YLLs (age standardised rate per 100,000) against 22 peer countries; countries listed are the top-performing countries in the pool
[24] Public Health England (2020). 'The Burden of Disease in England compared with 22 peer countries – A report for NHS England', January 2020, p. 31.
[25] Cancer Research UK. 'UK improves cancer survival, but is still behind other high-income countries', 2019
[26] Nuffield Trust. 'Cancer survival rates', updated 25 May 2021
[27] Nuffield Trust. 'Cancer survival rates', updated 25 May 2021
[28] Nuffield Trust. 'Cancer survival rates', updated 25 May 2021
[29] Nuffield Trust. 'Cancer survival rates', updated 25 May 2021
[30] IHE (2020). 'Comparator Report on Cancer in Europe 2019 – Disease burden, costs and access to medicines', 2020, p. 154, Figure 65.
[31] IHE (2020). 'Comparator Report on Cancer in Europe 2019 – Disease burden, costs and access to medicines', 2020, p. 154, Figure 65.
[32] Public Health England (2020). 'The Burden of Disease in England compared with 22 peer countries – A report for NHS England', January 2020, p. 31.
[33] PwC interviews with ABPI company members

Figure 4: Lowest or most quoted cost-effectiveness thresholds by country, US$, 2018 prices



Source: Office of Health Economics[40]

As a result of this progress, there are specific examples where highly innovative medicines have been available in the UK. NHS patients became some of the first patients to gain access to a CAR T-cell treatment for lymphoma and a revolutionary lung cancer treatment in 2021.[34,35] 2021 also saw NHS patients gain access to the first oral therapy for spinal muscular atrophy and the first new treatment for sickle cell disease in 20 years.[36,37]

Although the examples above represent good progress in specific cases, challenges remain in providing early access to innovative medicines across many disease areas. And this itself may be compounding the problem. Industry stakeholders have stated that there are already medicines and indications in the pipeline that will not be launched in the UK due to its pricing, uptake and access challenges.[38]

Three challenges for the UK

The key challenges for the UK are breadth of access, speed of access and extent and rate of uptake.

Breadth of access

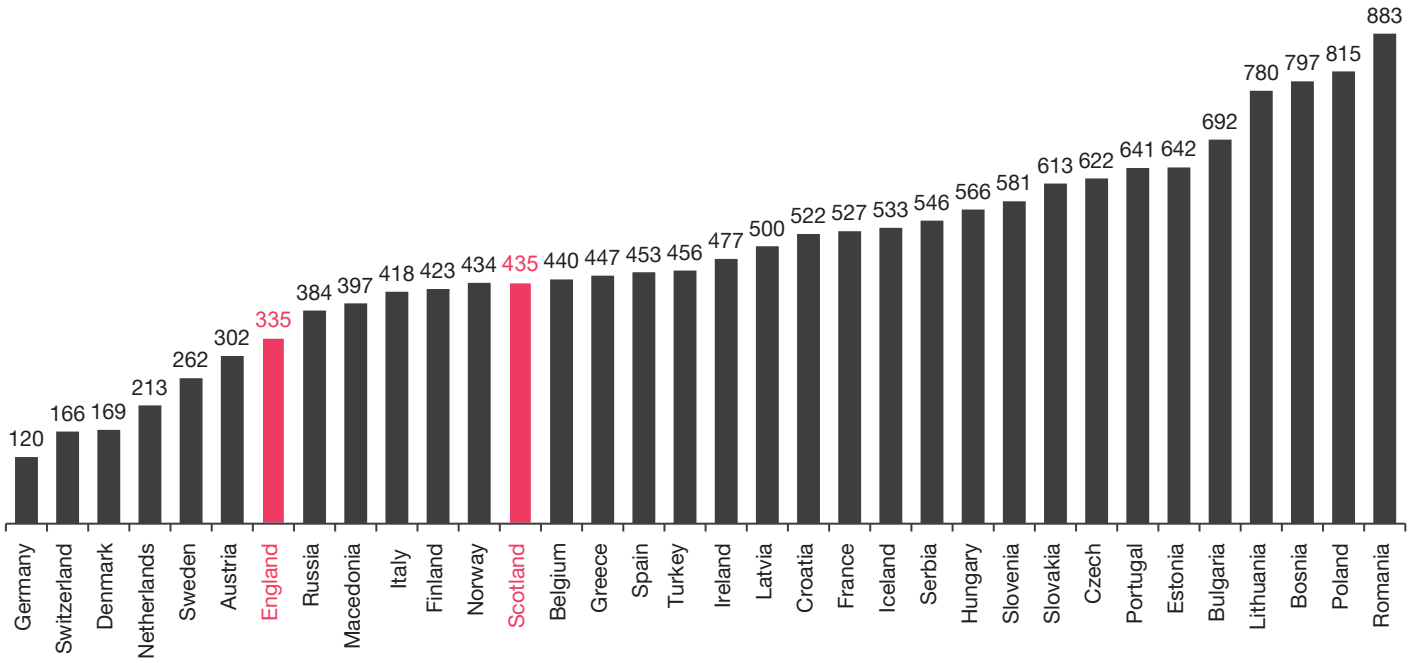
In recent years, of the positive recommendations that NICE has made, a significant number have been for narrower populations than those approved by the EMA or MHRA. Industry stakeholders comment that these restrictions are largely due to the UK applying amongst the lowest willingness-to-pay thresholds for health gains of any developed country (**see Figure 4**).[39]

For industry, the fundamental access challenge in the UK is meeting the NICE willingness-to-pay threshold.[41] The baseline threshold has remained unchanged since NICE was established in 1999, despite the subsequent years seeing an increase in average prices of 2.8 per cent per year and a doubling of the costs of development.[42,43] As a consequence, to meet NICE thresholds, the eligible population is often narrowed to a level below that for which the medicine is approved, and companies offer significantly larger discounts than those offered in other countries.[44]

Between 2015 and 2019, 43 per cent of positive NICE recommendations were 'optimised' (recommended for a smaller patient population than that for which the medicine has been approved by the EMA or MHRA) due to the UK's relatively low willingness to pay by international standards. Of these optimised recommendations, around two-thirds (65 per cent) recommended treatment in less than half the approved population, and over a third (35 per cent) recommended use in less than a quarter of patients.[45] The effect is that a restricted number of patients can benefit from the innovation.

[34] Cancer Research UK (2021). 'NHS patients among first to access new CAR T cell therapy for lymphoma', 20 January 2021.
[35] NHS (2022). 'Hundreds of patients to benefit from revolutionary lung cancer drug on the NHS', 3 March 2022.
[36] NHS (2021). 'NHS deal on spinal muscular atrophy at home treatment', 19 November 2021.
[37] NHS (2021). 'NHS announces deal for life changing sickle cell treatment', 5 October 2021.
[38] PwC interviews with ABPI member companies.
[39] Office for Life Sciences (2021). 'Life Science Competitiveness Indicators 2021', 30 July 2021.
[40] Office of Health Economics (2020). 'Incremental Cost-Effectiveness Thresholds and Modifiers for HTA Decision Making', May 2020.
[41] PwC interviews with ABPI company members.
[42] PwC analysis of data from the Bank of England Inflation Calculator (1999-2021).
[43] EFPIA (2020). 'The Pharmaceutical Industry in Figures – Key data 2020', 2020, p. 9.
[44] PwC interviews with ABPI company members.
[45] Office of Health Economics (2020). 'NICE 'Optimised' Recommendations: What Do They Mean for Patient Access?', 30 July 2020.

Figure 5: Mean wait time for innovative medicine availability, by country (days, 2016-2019)[47]



Source: EFPIA[48]

Speed of access

In terms of average days between approval and reimbursement, England is ranked 7th in Europe, with an average of 335 days. Germany has the fastest access (120 days), followed by Switzerland, Denmark, the Netherlands, Sweden and Austria (see **Figure 5**).[46]

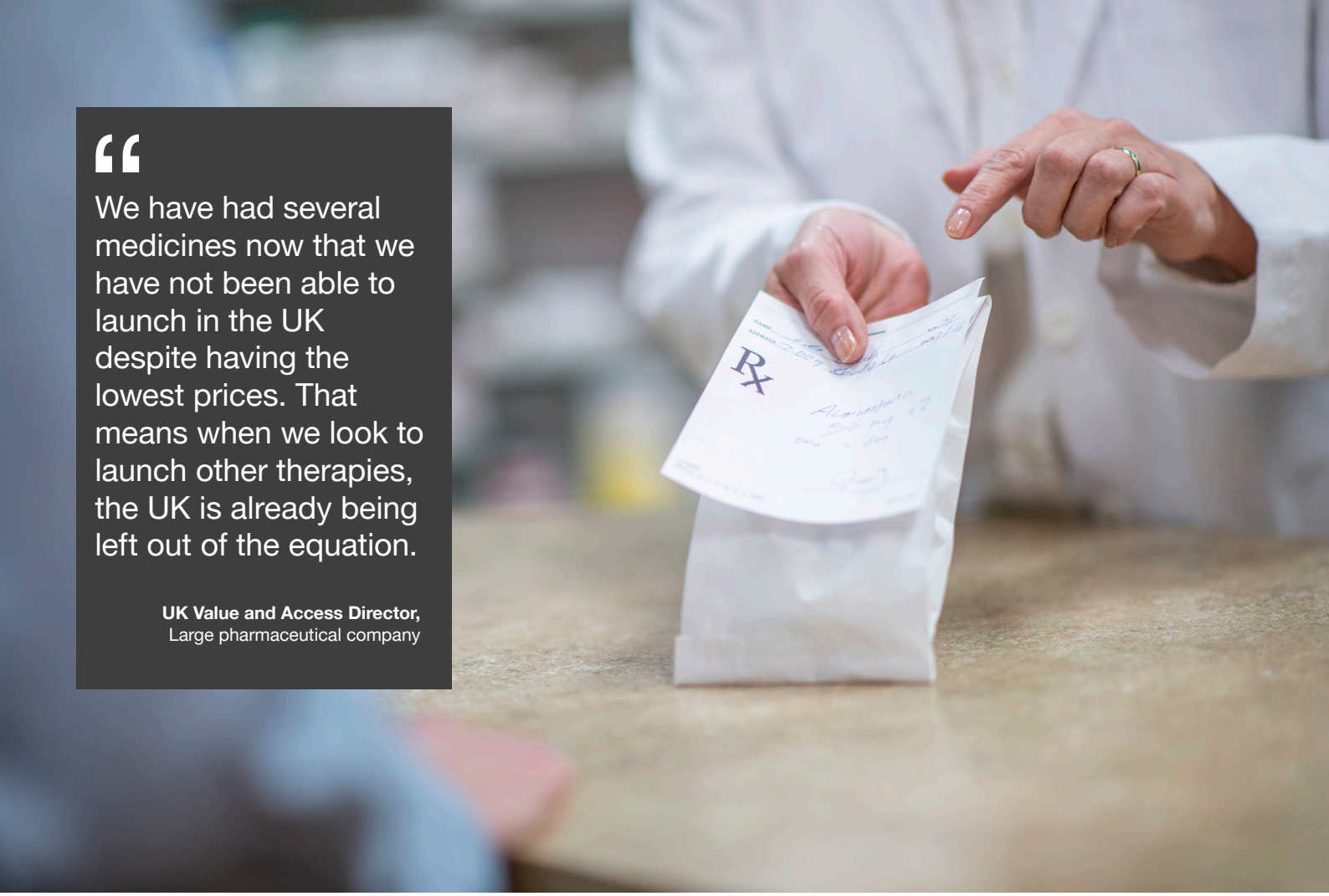
While NICE has made improvements in its speed of access for cancer medicines in 2020/21 and there are positive government interventions in this area (such as the Welsh Government's New Treatment Fund), there remains room for improvement in the UK's speed of access, particularly for rare disease medicines which often take longer to review.

Extent and rate of uptake

ABPI analysis for a recent Office for Life Sciences publication shows that, for over 75 innovative medicines recommended by NICE and launched between 2013 and 2019, the UK per-capita utilisation in the first three years post-reimbursement was around 64 per cent of the average in 15 comparator countries.[49]

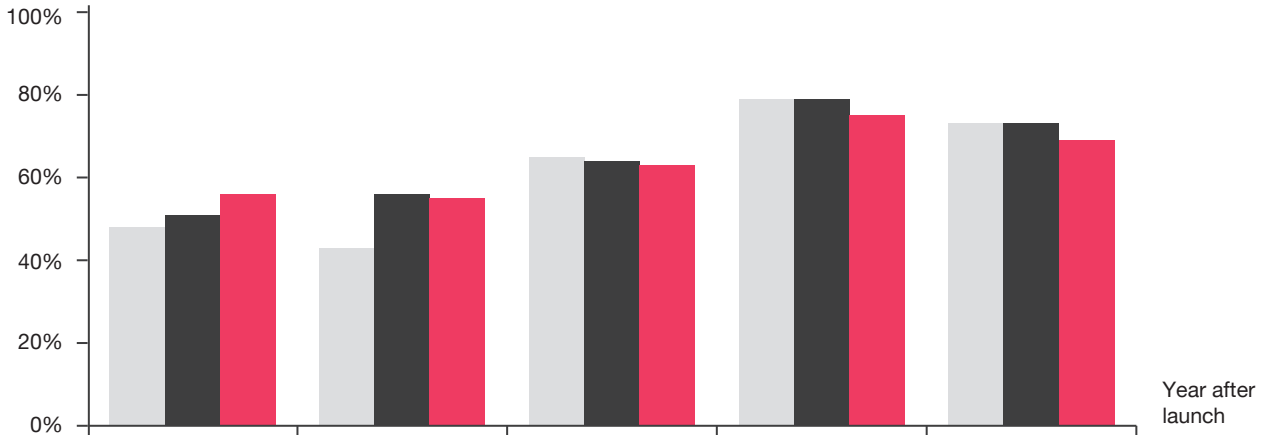
Indeed, industry stakeholders surveyed and interviewed for this report were unanimous in their belief that the UK had lower and slower uptake of innovative medicines than most other developed countries (see **Figure 6**).[50] This is despite the 2019 VPAS, which was intended to stimulate faster adoption of the most clinically- and cost-effective medicines.[51]

[46] EFPIA, 'EFPIA Patients W.A.I.T. Indicator 2020 Survey', April 2021.
[47] Note that in the UK, the MHRA's Early Access to Medicines Scheme provides access prior to marketing authorisation but is not included within this analysis, and would reduce the overall days for a small subset of medicines.
[48] EFPIA, 'EFPIA Patients W.A.I.T. Indicator 2020 Survey', April 2021, p. 9. Note: In the UK, MHRA's Early Access to Medicines Scheme is not included, and would reduce the overall days for a small subset of medicines
[49] Office for Life Sciences (2021). 'Life Science Competitiveness Indicators 2021', 30 July 2021.
[50] PwC interviews and surveys of ABPI member companies
[51] DHSC, 'The 2019 Voluntary Scheme for Branded Medicines Pricing and Access – Chapters and Glossary', 2019.



> We have had several medicines now that we have not been able to launch in the UK despite having the lowest prices. That means when we look to launch other therapies, the UK is already being left out of the equation.
>
> **UK Value and Access Director,**
> Large pharmaceutical company

Figure 6: Relative uptake of NICE approved new medicines (UK per capita uptake per cent of average comparator uptake, 2013-2019)[52]



	Year 1	Year 2	Year 3	Year 4	Year 5
2013-17	48%	43%	65%	79%	73%
2014-18	51%	56%	64%	79%	73%
2015-19	56%	55%	63%	75%	69%

Source: PwC, OLS

[52] Shows UK median uptake as a percentage of average uptake in the comparator countries (e.g. for medicines launched during 2013-17, in the first year after launch the UK median uptake was 48% of average uptake in comparator countries). Comparator countries: Australia, Austria, Belgium, Canada, Finland, France, Germany, Ireland, Italy, Japan, Netherlands, Spain, Switzerland, Sweden, USA.
Source: ABPI analysis of IQVIA data, from Life Sciences Competitiveness Indicator Report 2021

3. The ground lost to COVID-19

COVID-19 had a devastating impact on the health and wealth of the UK. The NHS and the pharmaceutical sector have been critical in tackling the pandemic. They will have an equally significant role in making up lost ground on patient outcomes beyond COVID.

Tackling unprecedented challenges with unprecedented collaboration

COVID-19 has wrought a terrible impact on lives and livelihoods around the world. More than 5.2 million lives have been officially lost to the disease,[53] while total excess deaths are estimated to have reached around 17.5 million globally.[54] The economic impact has been equally shattering. US$2.86 trillion was lost in global GDP in 2020 alone.[55] UK GDP declined by 9.7% in 2020, equal to the decline experienced during the Great Depression in 1921 on unofficial estimates.[56]

While the UK economy as a whole is on track to regain its pre-pandemic performance in early 2022, the recovery is not evenly spread. Indeed, COVID-19 has exacerbated inequalities 'result[ing] in the most severe regional disparity in output in the past 50 years,' with the West Midlands and the South East the slowest to recover.[57]

The pandemic shows why the world needs a thriving life sciences sector

Governments, academia, industry, and others have come together to develop safe and effective vaccines and therapeutics and bring them to patients at record pace. Collaboration has been central to this effort.

Rapidly developing vaccines and therapeutics has been critical to tackling the pandemic. This relied on having a global R&D pipeline that has continually advanced over decades, enabling investors to see a return on innovation. For example, although mRNA vaccines were rapidly made available to patients, the technology had been in development since the 1980s.[58]

There is no doubt that, without a thriving global life sciences sector, the world would be significantly further away from normality than it is today. But COVID-19 also emphasised the importance of local factors, such as scientific expertise, industrial infrastructure and being able to hedge against the risk of global pharmaceutical supply chain disruption.

COVID-19 has also been a challenge for the pharmaceutical industry. Only a small minority of companies have successfully brought vaccines and therapeutics to market so far.

Many more invested in R&D related to COVID-19, which has yet to result in commercial success. The challenges faced by the industry include halts to clinical trials and poor recovery of clinical trial recruitment and enrolment, delays to healthcare appointments and diagnoses leading to a backlog of patients in need of treatment, and low uptake across the board. This is particularly true of specialised medicines, including cancer and multiple sclerosis, as well as non-COVID-19 vaccinations. Despite the challenges, the UK pharmaceutical industry has remained relatively resilient with our research indicating that over 90 per cent of industry stakeholders in the UK perceive the operational and financial impact of COVID-19 on their UK business to be neutral (58 per cent) or negative (33 per cent).[59]

[53] The Economist, 'The pandemic's true death toll'.
[54] The Economist, 'The pandemic's true death toll'.
[55] PwC analysis of data from the World Bank (GDP, current US$), accessed 1 December 2021.
[56] House of Commons (2021). 'Coronavirus: Economics impact', 17 December 2021.
[57] PwC, 'UK Economic Outlook', December 2021.
[58] Dolgin, E. (2021). 'The tangled history of mRNA vaccines', Nature, 22 October 2021.
[59] PwC interviews with ABPI company members; based on responses from 24 stakeholders

COVID-19 continues to affect patient outcomes, the NHS and economic recovery in less direct ways

Beyond the devastating loss of life and ongoing morbidity, COVID-19 is negatively impacting patient outcomes in other disease areas. This is evident in three primary pathways.

First, delays in diagnosis and screening. This is especially important in cancer where earlier diagnosis is directly related to better outcomes. Around 22,000 cancer patients in the UK are currently waiting for surgery, chemotherapy or radiotherapy.[60, 61] And over 2 million screenings have been missed with between 240,000 and 740,000 'missing' urgent GP referrals for suspected cancer[62] and an estimated 50,000 missing diagnoses[63, 64] resulting in between 35,000 and 60,000 'missing' first treatments for cancer from March 2020 up to September 2021 (see **Box 2**).[65]

Second, delays in access to medicines. Patients have been unable to access new or more appropriate medicines due to fewer healthcare professional appointments, whether in hospitals, in general practice, or through other services such as pharmacies (see **Box 3** for a case study on how this has impacted multiple sclerosis patients).

Third, delays to clinical trials. Globally, around 12,000 clinical trials were suspended during 2020, some by more than three months. This will inevitably slow innovation and delay access to future treatments for patients.[66.67]

> "While COVID-19 has not disrupted all business, it has certainly derailed future health outcomes. What will happen to cancer patients in the UK as a result of this time will be truly horrifying.
>
> **UK General Manager,**
> Large pharmaceutical company

Box 2: The impact on cancer patients

Industry experts fear that the COVID-19 pandemic will have an alarming impact on cancer patients.[68] Firstly, there is the direct threat of the disease itself. While studies are ongoing, patients with cancer appear to be more vulnerable to COVID-19, evident in their greater need for ventilator support and elevated mortality rates.

But the pandemic presents other kinds of challenges to cancer patients, too. Many screening programs and services were reduced or suspended globally, creating backlogs that limit the opportunity for vital early diagnosis. In addition, healthcare systems saw a decrease in the number of patients attending appointments, wary of exposing themselves to the risk of infection.[69]

This significant decline in both demand for and supply of oncology services is likely to contribute to substantial excess mortality among people with cancer and multimorbidity.[70] It also starkly illustrates the need for system-wide collaboration to make up the lost ground in patient outcomes.

Addressing the backlog will not be easy. If cancer care services can deliver 105 per cent of 2019 activity levels, it will take until 2028 and 2033 to make up for missed chemotherapy and radiotherapy treatment, respectively. It would take considerably longer to recover missed diagnostic investigations such as endoscopies and MRI scans.[71]

[60] Cancer Research UK (2020). 'Over 2 million people in backlog for cancer care', 1 June 2020.
[61] MacMillan (2020). 'The Forgotten 'C'? The impact of Covid-19 on cancer care', October 2020.
[62] National Audit Office. 'NHS backlogs and waiting times in England', 1 December 2021
[63] Cancer Research UK (2020). 'Over 2 million people in backlog for cancer care', 1 June 2020.
[64] MacMillan (2020). 'The Forgotten 'C'? The impact of Covid-19 on cancer care', October 2020.
[65] National Audit Office (see above)
[66] Evaluate Vantage (2021). 'The pandemic releases its grip on clinical trials', 19 January 2021.
[67] Xue et al. (2020). 'Clinical trial recovery from COVID-19 disruption', Nature, 10 September 2020.
[68] PwC interviews with ABPI company members
[69] Richards, M., Anderson, M., Carter, P. et al. 'The impact of the COVID-19 pandemic on cancer care', Nature Cancer, 20 May 2020
[70] Lai AG, Pasea L, Banerjee A, et al. 'Estimated impact of the COVID-19 pandemic on cancer services and excess 1-year mortality in people with cancer and multimorbidity', BMJ Open 2020
[71] Institute for Public Policy Research (2021). 'Building back cancer services in England', September 2021.

Making up the lost ground requires a system-wide effort

Restoring patient outcomes requires a concerted effort between healthcare systems and industry to ensure diagnosed patients get the treatment they need, undiagnosed patients are rapidly diagnosed, and clinical development is restarted.

The NHS currently faces workforce challenges that are difficult to tackle in the short term. Innovative medicines can be readily procured and could play an important role as scalable tools to tackle healthcare delivery challenges and increase NHS productivity while workforce challenges persist. For example, innovative medicines could help the NHS to circumvent some of its current constraints (including ongoing staff shortages) and deliver improved patient outcomes by switching patients to medicines that avoid hospitalisations or require less intensive monitoring by healthcare professionals.

Box 3: The impact on multiple sclerosis patients

Multiple sclerosis (MS) patients in the UK have benefited from breakthrough medicines for the treatment of primary progressive multiple sclerosis (PPMS) and 'active' relapsing multiple sclerosis.[72]

However, the pandemic has had negative consequences for patient uptake. Many patients did not attend infusion appointments at hospitals for fear of catching COVID-19.[73] Hospital Episode Statistics (HES) data suggests that, by July 2020, admissions to hospital for the primary diagnosis of MS were still 24 per cent lower than pre-pandemic figures.[74] And pharmaceutical companies reported virtually no use of biologics for the treatment of MS during the first four months of the pandemic.[75]

This stall in treatment will have a potentially dire effect on long-term patient outcomes. An August 2021 survey found 53 per cent of people living with MS who thought 'a reduction in specialist support contributed to their symptoms getting worse to some or a great extent'.[76] And a quarter of respondents said they needed to see an MS nurse or neurologist in the past 12 months but were not able to do so.[77]

With a 17 per cent decrease in the number of people starting a disease modifying treatment in 2020 relative to 2019, the majority of neurology healthcare professionals agree that the pandemic will have a long-lasting impact on the physical and mental health of people with neurological conditions.[78]

COVID-19 may also have changed the cost-effectiveness calculation. Traditional methods may assume a steady state healthcare system without the dynamic changes to constraints on the supply of staff, consumables, space, and so on. However, in today's exceptional environment, these resources may not be available, or may be more expensive than previously assumed. Scalable interventions, including innovative medicines and digital solutions, should be considered to create productivity efficiencies for the NHS.

[72] Roche, Ocrevus (ocrelizumab).
[73] PwC interviews with ABPI company members
[74] DICE (2021). 'The impact of COVID-19 on Multiple Sclerosis (MS) patient activity in hospitals', 30 October 2021.
[75] PwC interviews with ABPI company members
[76] MS Society (2021). 'Neurology now – The case for a new approach to neurology services', October 2021.
[77] MS Society (2021). 'Neurology now – The case for a new approach to neurology services', October 2021.
[78] MS Society (2021). 'Neurology now – The case for a new approach to neurology services', October 2021.

4. Pharmaceutical innovation, from bench to bedside

Pharmaceutical innovation continues to bring major advances in healthcare and patient outcomes. But bringing a medicine through research, development and approval remains complex and challenging.

For over a century, innovative medicines have played a pivotal role in reshaping the potential of human life. Pharmaceutical innovation is thought to have been responsible for around 35 per cent of the increase in global life expectancy between 1990 and 2015.[79] What is more, 37 per cent of the difference in life expectancy between high-income and low-income countries has been shown to be due to the availability of medicines.[80]

A challenging future

The UK faces a number of healthcare-related challenges in the coming decades.[81] Demand for NHS services and social care support continues to increase due to a growing and ageing population. Over the next two decades, England's population is expected to expand by around 10 per cent, while the number of citizens aged over 75 is expected to grow by as much as 60 per cent. Poor health is also expected to rise. By 2035, the proportion of people aged 65+ with four or more diseases is set to almost double, with mental health a particular challenge.

These pressures increase the need for safe, efficacious and cost-effective innovative medicines. The NHS has identified several major disease challenges where new innovative medicines will be imperative, including dementia, cancer, ischaemic heart disease and stroke, and chronic obstructive pulmonary disease (COPD).[82,83]

A global pipeline of innovation

The next wave of innovative medicines is already in the global pipeline.[84] Between 2015 and 2020, almost 30,000 new clinical trials were started. Of these, 4,789 were started between January and November 2020 alone.[85]

These have the potential to result in healthcare advances, bringing about improvements in health outcomes over the next few years. In oncology, for example, we could see innovations in CAR-T cell therapy for haematologic cancers and solid tumours (see **Box 4**), mRNA vaccines, antibody-drug conjugates (ADCs), and oncolytic viruses.

In infectious disease, we may see therapeutic vaccines, capsid and core inhibitors for Hepatitis B, and further long-acting antiretroviral therapies for HIV. And in neurology, we may expect new senolytics to degrade amyloid plaques in Alzheimer's disease, as well as remyelinating treatments and stem cell transplantation for multiple sclerosis.

It is possible that, in leading health systems, this wave of pharmaceutical innovation may take up a steadily increasing share of the healthcare resource mix. Indeed, this would be a natural development as we move to more efficient and effective, mid-21st century healthcare.

[79] Buxbaum et al. (2020). 'Contributions of Public Health, Pharmaceuticals, And Other Medical Care to US Life Expectancy Changes, 1990-2015', Health Affairs, Vol. 39, No. 9, September 2020.

[80] Lichtenberg, F. (2014). 'Pharmaceutical innovation and longevity growth in 30 developing and high-income countries, 2000-2009', Health Policy and Technology, Vol. 3, pp. 36-58. 12 October 2013. Doi: 10.1016/j.hlpt.2013.09.005.

[81] Department of Health and Social Care. 'Integration and innovation: working together to improve health and social care for all', 11 February 2021.

[82] NHS England. 'The Burden of Disease in England compared with 22 peer countries', 2020.

[83] NHS Confederation (2019). 'Innovative Medicines Initiative', 9 May 2019.

[84] IQVIA. 'EFPIA Pipeline Review 2021 Update', February 2021. Note: Data for 2020 is only available for up to November 2020.

[85] Number of trials for infectious diseases may be skewed by number of COVID-19 related trials.

Long, challenging, risky and high cost: the path to pharmaceutical innovation

Discovering, developing, and bringing new medicines to patients is complex, risky, and costly. On average, developing a new medicine takes 8 to 12 years from initial discovery to launch (as shown in **Figure 7** below).[92]

Development is also highly uncertain. Only around 1 in 10,000 synthesised compounds make it to approval. Even for medicines that get to clinical development, the chances of getting to approval are only around 7.9 per cent.[93,94] And then there's the cost. The overall R&D cost of making a single medicine available to patients is estimated to be about £1.9 billion on average (including the costs of failure due to assets that don't make it).[95] However, this varies significantly across assets, therapeutic areas and companies.

Box 4: CAR T-cell therapy in the treatment of haematological and solid tumours

Chimeric antigen receptor T-cell (CAR T-cell) therapy involves modifying a patient's T-cells to recognise and attack cancer cells. It works by extracting T-cells from a patient, genetically modifying them so they're more effective at targeting a specific tumour antigen, and then injecting them back into the patient.

Up to now, CAR T-cell therapy has been one of the most promising new therapies for haematological cancers. Indeed the UK has enabled NHS patients to be some of the first to access such a therapy for lymphoma.[86] However, it also has the potential to treat solid tumours if several remaining hurdles can be overcome, namely 'finding, entering and surviving the tumour'.[87] Recent studies have examined the potential for treating cancers like lung cancer, breast cancer, prostate cancer, and more.[88]

CAR T-cell therapy promises significant benefits, both at an individual and a societal level:[89]

- A life-saving therapy for patients, reducing the number of deaths and lessening the burden on families and carers.[90]
- Lower relapse rates would be expected to reduce hospitalisation costs (for example, from shorter stays in hospital and fewer clinician attendances).
- Expenditure on current targeted therapy could decline between 55 and 100 per cent following the replacement of high-cost treatment paradigms in the relapsed/refractory setting.
- Healthcare systems would be able to refocus on other disease areas as resources are freed up.
- Reduced incidence of disease means more people remain economically productive – in the EU, for example, there is an estimated additional annual contribution of around €5.0 billion to nominal GDP for patients diagnosed in 2020.[91]

[86] https://news.cancerresearchuk.org/2021/01/20/nhs-patients-among-first-to-access-new-car-t-cell-therapy-for-lymphoma/.
[87] Martinez M., Kyung Moon E.. 'CAR T Cells for Solid Tumors: New Strategies for Finding, Infiltrating, and Surviving in the Tumor Microenvironment', Frontiers in Immunology, 05 February 2019.
[88] Marofi, F., Motavalli, R., Safonov, V.A. et al. 'CAR T cells in solid tumors: challenges and opportunities', Stem Cell Res Ther 12, 81 (2021).
[89] IQVIA. 'EFPIA Pipeline Review 2021 Update'. (see above).
[90] See 'The transformative impact of innovative medicines on patients' lives and the economy' section of the report for more detail on benefits of innovative medicines.
[91] Based on IQVIA impact analysis.
[92] EFPIA (2021). 'The Pharmaceutical Industry in Figures – Key Data 2021', 2021.
[93] EFPIA (2021). 'The Pharmaceutical Industry in Figures – Key Data 2021', 2021.
[94] PharmaIntelligence (2021). 'Clinical Development Success Rates and Contributing Factors 2011-2020'.
[95] Converted from US dollars to pound sterling using 2021 average annual foreign exchange rate from the Bank of England.

What's more, these estimated costs have increased significantly over the decades. From 1980 to the early 1990s, bringing a medicine to the market cost around £250 million.[96] From 1990 to the early 2000s, this rose to over £600 million.[97,98] And when it comes to advanced therapy medicinal products (ATMPs), the costs are even higher: as much as £3.5 billion to develop a single new medicine.[99,100]

Valuing innovation

Given these costs, it's important that patients gain access to innovative medicines at a price that reflects their value. Currently, about 20 per cent of pharmaceutical revenues are reinvested in R&D.[101] But to keep that investment flowing into pharmaceutical innovation, there must be potential for a fair financial return. And that requires sufficient uptake of innovative medicines at a price that reflects their value to society.

Companies spend on R&D to discover the best innovation possible, and reinvest a proportion of the financial returns from that discovery into future R&D. However, as our understanding of disease improves and technology advances, disease indications are being divided into ever smaller patient groups, leaving companies targeting smaller, more specialised patient populations. This has meant that, over the last decade, the return on investment for pharmaceutical innovators has been decreasing.[102] While some assets in development become innovative medicines, greater than 90% of assets in clinical development do not, highlighting the level of financial risk involved.[103,104]

Innovative medicines have a limited patent period that allows the innovator to manufacture, distribute and receive a return on an innovative medicine without competition – but this period does not eliminate all price pressures on the innovator. Competitors are still able to develop other branded medicines in the same drug class, which can happen quickly: time to second approval in the same class can often be as little as weeks or months (for example, checkpoint inhibitors).[105] The rapid introduction of multiple medicines in the same class leads to price-lowering competition and the triggering of additional commercial deals.[106]

Beyond the list price of medicines, there are often discounts applied to branded medicines when products go through the National Institute for Health and Care Excellence, the Scottish Medicines Consortium (SMC) and the All Wales Medicine Strategy Group (AWMSG) health technology appraisal (HTA) processes. These include the patient access scheme (PAS) and additional commercial agreements nationally or locally, in addition to repayments by industry to maintain the overall spending cap on branded medicines through VPAS.

Although there are examples of products which have had extended patent periods, most products have ~8 years of patent protection remaining at the time of launch.[107] When the patented period ends, multiple generic or biosimilar manufacturers are likely to enter the market with low-cost alternatives.

This may result in a rapid decline in revenues for the pharmaceutical innovator, while giving healthcare systems low-cost access to the innovation indefinitely.

Impact of post-patent price on the value of innovative medicines

Current UK assessments of the value that innovative medicines bring do not consider the future price decreases of medicines and, therefore, potentially undervalue innovative medicines.

The current NICE assessment takes a static view of price and does not consider the potential significant price reductions following expiration of the product's patent. Manufacturers of innovative medicines must show that an innovative medicine meets the ICER – which is the Incremental Cost-Effectiveness Ratio or £/QALY (cost per quality-adjusted life year) – threshold at its launch price. However, the average cost per QALY over the useful lifetime of the medicine may be significantly lower when the post-patent expiry price erosion is factored in.

[96] Converted from US dollars to pound sterling using 1980-1992 period average annual foreign exchange rate from the Bank of England.
[97] EFPIA (2021). 'The Pharmaceutical Industry in Figures – Key Data 2021', 2021.
[98] Converted from US dollars to pound sterling using 1990-2002 period average annual foreign exchange rate from the Bank of England.
[99] Raconteur (2021). 'Rare Diseases', 2021.
[100] Converted from US dollars to pound sterling using 2021 average annual foreign exchange rate from the Bank of England.
[101] PhRMA (2020). '2020 PhRMA Annual Membership Survey', 2020.
[102] Harvard Business Review. 'How Pharma Can Fix Its Reputation and Its Business at the Same Time', 2017.
[103] Torjesen, I. (2015). 'Drug development: the journey of a medicine from lab to shelf', **Pharmaceutical Journal**, 12 May 2015.
[104] PharmaIntelligence (2021). 'Clinical Development Success Rates and Contributing Factors 2011-2020'.
[105] Zhang et al. (2018). 'Cancer Immunotherapy in Diffuse Large B-Cell Lymphoma', **Frontiers in Oncology**, Vol. 8. September 2018.
[106] Grabowski et al. (2015). 'The Roles Of Patents And Research And Development Incentives In Biopharmaceutical Innovation', **Biomedical Innovation**, Vol. 34, No. 2, February 2015. Doi: 10.1377/hlthaff.2014.1047.
[107] EFPIA (2021). 'The Pharmaceutical Industry in Figures – Key Data 2021', 2021.

The impact of this becomes even more apparent if the QALY gain is discounted at 1.5 per cent, as per Green Book guidance on health effects, rather than the current 3.5 per cent. This is acknowledged by NICE's own evaluation of its current methods[108] and a worked example of this dynamic is provided in **Appendix A.4**. This example, which looks at an innovative oncology product, shows that when an estimate of the post-patent period price is considered over the useful lifetime of the medicine, the ICER (cost per additional QALY) could be around 22% lower than the cost per QALY assumed in the original NICE assessment. Moreover, this impact will be even greater for medicines where more significant post-patent period price decreases are expected.[109]

The upshot is that the additional value that innovative medicines create for the UK may not be fully captured in NICE's current valuation methods. In particular, the value of innovative medicines to both the NHS and future generations (in the form of generic versions of branded medicines post-patent expiry) may be underestimated.

[108] NICE (2020). 'The NICE methods of health technology evaluation: the case for change', 2020, p. 31, paragraph 16.
[109] UK Government, (2021). 'Government investment programmes: the 'green book'", 17 March 2021.

Source: PwC[110]

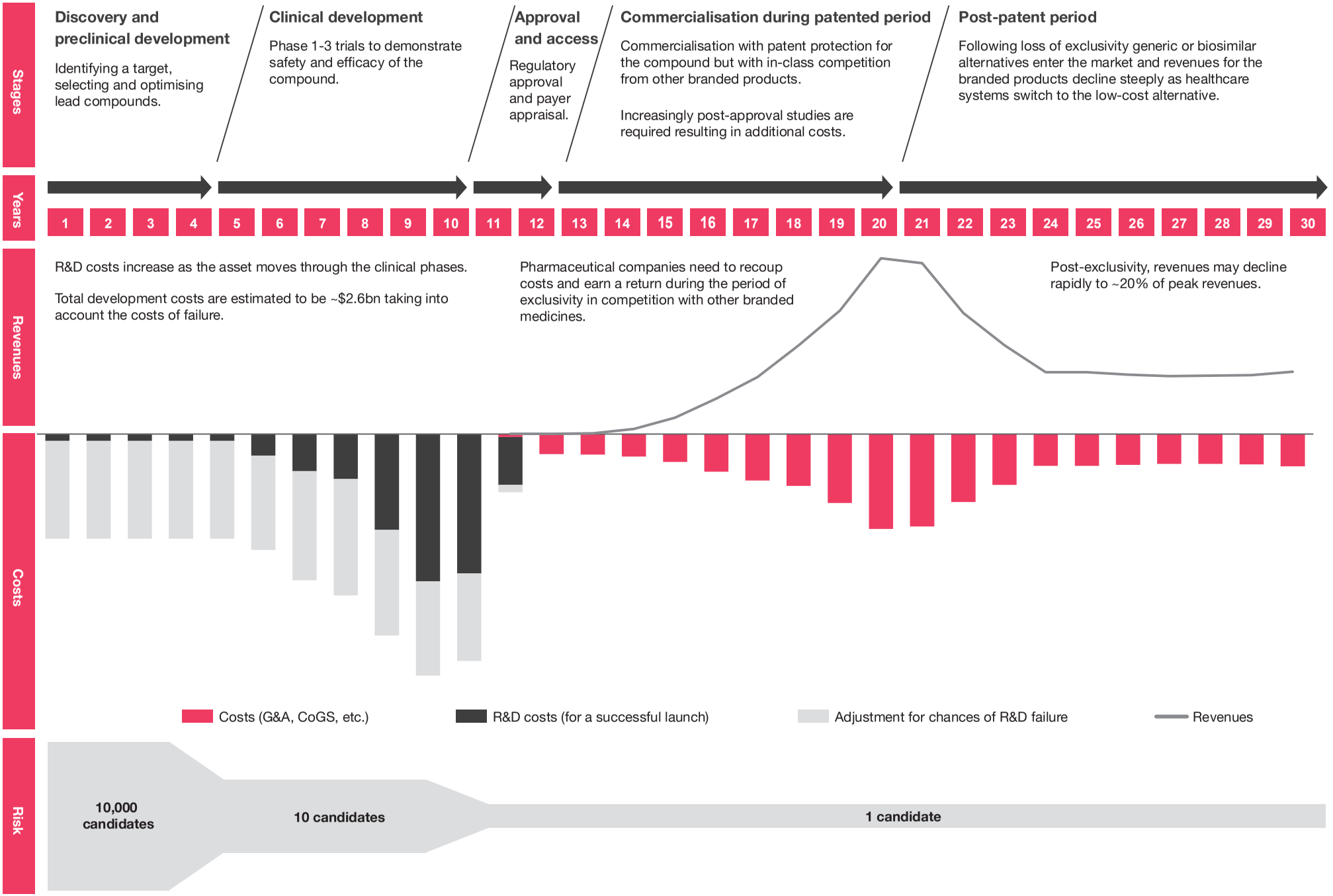


Figure 7: Pharmaceutical R&D process

[110] Revenues and costs based on Towse et al. (2017). 'Time for a change in how new antibiotics are reimbursed: development of an insurance framework for funding new antibiotics based on a policy of risk mitigation', **Health Policy, Vol. 121, issue 10, October 2017, pp. 1025-1030. Doi**: 10.1016/j.healthpol.2017.07.011.

5. The transformative impact of innovative medicines on patients' lives and productivity

Innovative medicines transform patient lives. They also create significant non-health value, including productivity gains and other social and economic benefits.

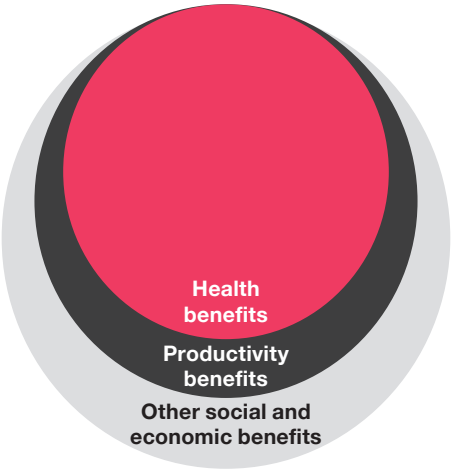
The benefits of innovation extend beyond the patient

In the UK, the value of an innovative medicine is determined by the health benefits it brings to an individual patient. It is true that this is the primary value of a medicine. But there are also numerous secondary benefits. For example, healthier people are typically more productive and can work more for longer, whether in paid or unpaid work (such as caring for others). These benefits are challenging to quantify and not fully captured by current health technology appraisal processes. This could mean that the true value of medicines are currently understated.

Other benefits not currently captured include increased economic productivity of carers, improved mental health and wellbeing of family members, and the investment that is stimulated to bring future waves of innovation. Some of these benefits are external to health benefits to patients, so therefore they may not be outcomes for which the NHS is directly responsible.

Given these benefits, increasing the access to and uptake of innovative medicines could be seen as an investment in the UK's economy and society, not merely a cost.

Figure 8: The broader benefits of innovative medicines



Source: PwC

The case for broader and earlier access and greater uptake

In the following analysis, we set out a case for better access to and uptake of innovative medicines by quantifying, where possible, the broader impacts that could result from increasing the uptake from the current number of patients using a given medicine to the total NICE recommended eligible patient populations.[111] In doing so, we look at 13 innovative and competitive medicines grouped into four classes. We analyse two primary care medicines (medicines prescribed by GPs) and two secondary care medicines (medicines prescribed in hospitals). For each, we examine the potential health and productivity gains and other benefits that could come from increasing uptake, offset against the incremental costs. See **Box 6** for definitions and **Box 7** for further detail on our methodology.

Box 6: Definitions

Health benefits

The health benefits of a new medicine are quantified in quality-adjusted life years (QALYs), measured against the quantity and quality of life provided by the standard of care. QALYs reflect a person's ability to carry out the normal activities of daily life, as well as their freedom from pain and mental disturbance. One QALY represents one year in perfect health.[112]

Productivity benefits

Paid labour productivity is the value associated with individuals being able to work more hours per week or month, more days per year, or more years in a lifetime. Unpaid labour productivity is the value of unpaid time spent on activities like informal caring, volunteering, housework, and so on. Wider economic productivity is the value associated with indirect and induced productivity gains by patients.

Wider social benefits

These include a range of potential broader benefits that arise from the use of new medicines, such as wellbeing benefits, carer productivity, environmental benefits, and so on.

[111] To provide a more conservative view, for SGLT2 inhibitors the total eligible patient population used was midway between the current patient population and the total eligible patient population.

[112] This could be concentrated in one year or spread out over a longer time. For example, one QALY can represent two years living with a severe illness which reduces quality of life by 0.5. See NICE glossary page for more information.

Box 7: Methodology

The health benefits are measured in terms of incremental quality-adjusted life years (QALYs) gained. **Figure 9** presents the key inputs to this estimation.

Figure 9: Estimation of additional health gains from greater uptake of innovative medicines

Source: PwC

Where available, figures from the Estimates Report within the NHS Innovation Scorecard have been used to estimate the potential and current patient volumes.[113] Where these are not available, ABPI member companies have been consulted for reasonable estimates or comparable benchmarks given the total NICE recommended eligible patient populations.

Company submissions within NICE HTA guidance have been used to identify QALY and ICER ranges. **Table 1** below summarises the innovative medicines and standards of care considered in the analysis, as well as the QALY and ICER ranges used.

Table 1: Summary of innovative medicines and standards of care considered in the analysis

Medicine class	Indications	Innovative medicines	Standard(s) of care	HTA files reviewed	Median incremental QALYs	ICERs
DOACs	Venous thrombo-emolism (VTE) and atrial fibrillation	apixaban dabigatran, etexilate edoxaban rivaroxaban	warfarin	NICE: TA 249, TA 256, TA 261, TA 275, TA 287, TA 327, TA 341, TA 354, TA 355	0.119	Range from £4,332 to £17,780
SGLT2 inhibitors[114]	Type 2 diabetes	canagliflozin dapagliflozin empagliflozin ertugliflozin	dipeptidyl peptidase-4 inhibitor pioglitazone sulfonylureas	NICE: TA 288, TA 315, TA 336, TA 390, NG 28[115]	0.284	Range from £14,373 to £30,678
Biologics	Severe asthma	benralizumab mepolizumab omalizumab reslizumab	inhaled corticosteroids and long-acting beta 2 agonists	NICE: TA 278, TA 565	1.880	Range from £25,192 to £32,076
V2-receptor antagonists	Autosomal dominant polycystic kidney disease (ADPKD) in adults with CKD 1-4[116]	tolvaptan	Symptomatic treatments, no pharmacological treatments[117]	NICE: TA 358	0.920	£34,733[118,119,120]

Source: PwC

[113] NHS Digital, 'NICE Technology Appraisals in the NHS in England (Innovation Scorecard) To June 2021'.

[114] We understand from ABPI member company input that around 95% of Type II Diabetes patients are at high risk of cardiovascular disease. We have therefore apportioned the clinical evidence for the treatment of Type II Diabetes by SGLT2 inhibitors across NG28 and older NICE documents. Specifically, a 5% weighting is applied to the evidence from historic TAs and a 95% weighting is applied to the recent NG28 evidence.

[115] Latest NG28 evidence sourced from NG28 Evidence review B, Table 12 (February 2022) and NG28 Health economic model report, Table HE032 (February 2022).

[116] Note that NICE has documented the following restriction: Autosomal Dominant Polycystic Kidney Disease in adults with CKD 2 and 3 at initiation and rapidly progressing disease.

[117] Evidence Review Group notes that 'the standard care was not defined' and committee noted that no pharmacological treatments are available for treating ADPKD with the current standard of care only managing the symptoms (Sections 3.19 and 4.3; TA 358).

[118] There is a single company base case figure provided in NICE published company submission, so range has not been used.

[119] Note that the published ICER range is: £23,503 – £50,524.

[120] Company base case values were used for total population (CKD stages 1 – 4) and CKD stages 2 and 3 subpopulations. Incremental QALY gain reflected from the company base case following model code error correction.

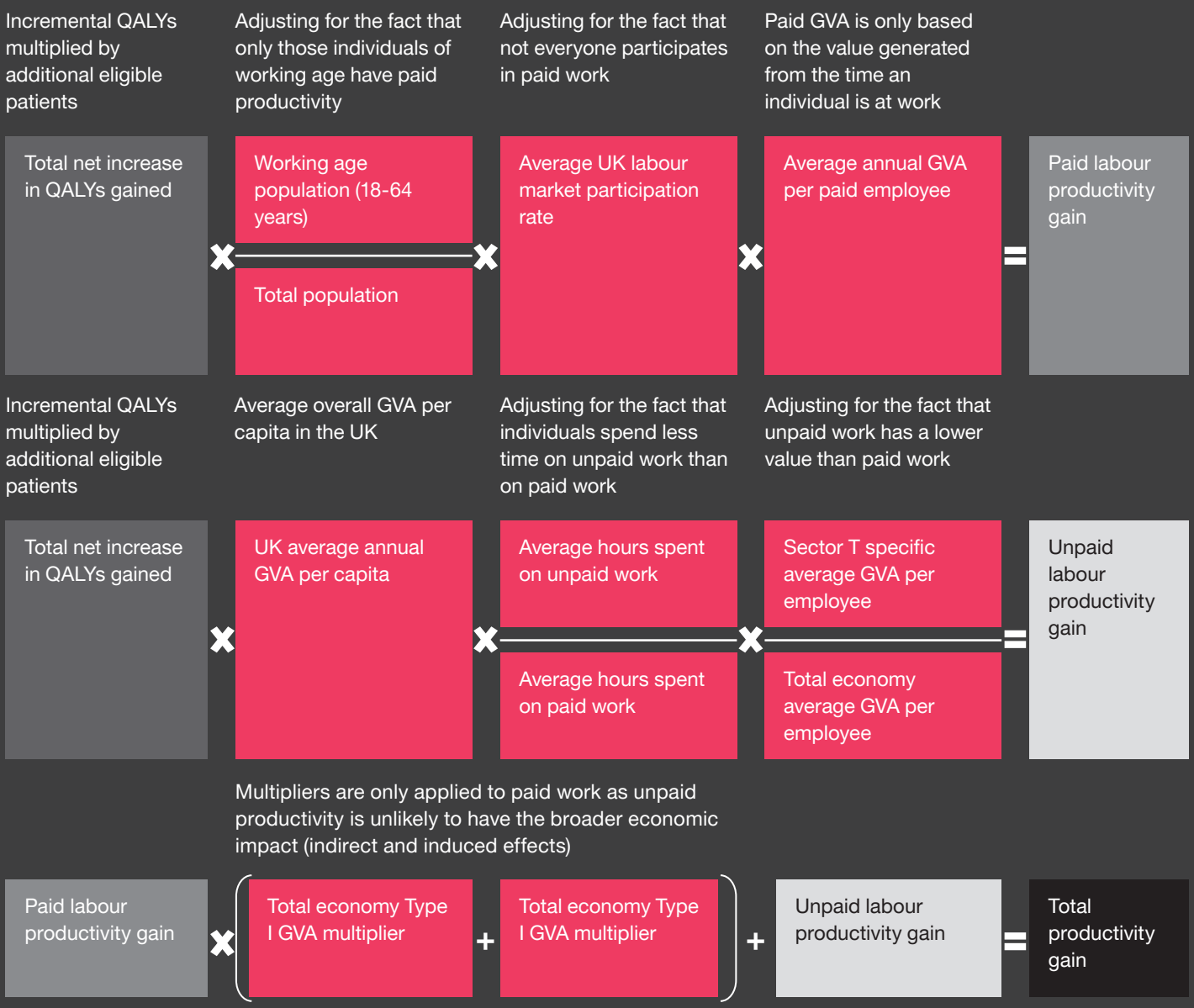
Productivity benefits are measured in terms of the additional direct productivity gains from healthier patients as well as the additional indirect and induced contributions in the wider economy of those productivity gains. This includes, for example, the productivity benefits of the businesses on which healthier patients spend, such as restaurants and hairdressers.

Data on GVA, population and average hours spent on different types of work is sourced from the ONS and OBR. Total economy Type I and Type II GVA multipliers are sourced from a recent Novartis report.[121]

The figures used are extrapolated to capture a 15-year time horizon[122] to account for the time it may take for these additional eligible patients' treatment to be switched to an innovative medicine.

Figure 10 presents the key inputs to the productivity benefit estimation.

Figure 10: Estimation of additional productivity benefits of greater uptake of innovative medicines



Source: PwC
Further detail is provided in **Appendix A.5.**

[121] Novartis and Europe Economics (2020). 'The Economic, Social and Innovation Value Novartis Brings to the UK' 14 January 2020.
[122] Discounted to net present value at a 3.5% discount rate.

The 13 medicines analysed have been selected on the basis of available data and represent only a small sample of the total available innovative medicines, with 173 active substances approved by the EMA over the past five years alone.[123,124] Where an innovative medicine has a QALY benefit over the standard of care, increased uptake will result in increased quality and/or quantity of life.

If the cost per QALY is less than the current NICE thresholds, and a significant proportion of the eligible patient population are of working age, then there will be significant productivity benefits and returns to the Exchequer.

It's also important to note that, although the four classes have each been considered in aggregate (see **Figure 11**), individual medicines within them have different clinical profiles.

There will be individual patients for whom one medicine in a class may be more suitable than another. The final clinical decision on which medicine a patient should receive should always be made by a prescriber and the patient.

Figure 11: Indications and health benefits of direct oral anticoagulants (DOACs), severe asthma biologics, sodium-glucose cotransporter-2 (SGLT2) inhibitors and vasopressin V2-receptor antagonists (VPAs)

Class	**DOACs** (direct oral anticoagulants)	**SGLT2 inhibitors** (sodium-glucose cotransporter-2)	**Severe asthma biologics**	**VPAs** (vasopressin V2-receptor antagonists)
Indication	Treatment and prevention of deep vein thrombosis and pulmonary embolism and prevention of stroke in atrial fibrillation	Type 2 diabetes mellitus	Severe allergic asthma and severe eosinophilic asthma	Autosomal dominant polycystic kidney disease (ADPKD) in adult with chronic kidney disease stage 2-3
Health benefits	Save lives through prevention of deep vein thrombosis, pulmonary embolism and stroke. Prevent the long-term impacts including physical impairment, communication challenges and fatigue.	Reduce major cardiovascular and renal outcomes. Prevent hospitalisations and end stage kidney disease in addition to helping patients keep their diabetes under control.	Reduce the of asthma exacerbations for patients, saving lives, keeping patients out of hospital, reducing anxiety and supporting patients to live normal lives. Reduce reliance on oral corticosteroids thereby reducing significant adverse effects of long-term corticosteroid use.	Helps slow the progression of cyst development and progression to end-stage renal disease. Reduces pain for patients and improves quality of life.

Source: PwC

[123] EMA 2016-2020

[124] It is important to note that this exercise is inherently difficult due to challenges with data availability on current patient uptake and eligible patient populations for medicines generally, but especially secondary care medicines. Both the industry and the NHS would benefit from this data being made available for all medicines to enable the quantification and measurement of the broader value of medicines going forward.

How many patients are missing out on improved health outcomes?

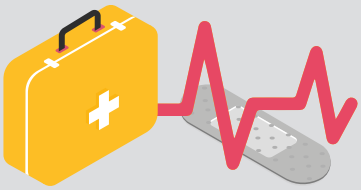
Looking at DOACs (direct oral anticoagulants), sodium-glucose cotransporter-2 (SGLT2) inhibitors, severe asthma biologics, and vasopressin V2-receptor antagonists, there are an estimated 1.2 million patients in the UK deemed eligible by HTA bodies (as proxied by NICE) who are missing out on the potential benefits of a more innovative treatment. This is a population greater than the combined populations of Glasgow, Swansea and Sunderland.

In aggregate, if the UK were to increase uptake across these four classes of innovative medicine to cover the total additional NICE-recommended eligible patient populations,[125] it would see an estimated 429,000 additional QALYs. In other words, treating this group of patients with the latest innovative medicines would afford them 429,000 additional or better-quality years living in perfect health. 1 QALY is equal to 1.5 years in 66% of perfect health, 2 years in 50% of perfect health, and so on. Therefore, greater uptake of just these four innovative medicine classes could provide patients with healthier, more productive[126,127] and fulfilling days or even longer time with their loved ones, totalling more than 429,000 patient years.

This is a significant finding, especially considering the technology is readily available within the UK's healthcare system and has been deemed cost-effective by NICE.

1.2 million

patients missing out on just four innovative medicine classes



429,000

additional quality-adjusted life years afforded with greater uptake across these innovative medicine classes

What productivity gains could the UK see?

Increasing the uptake of these four innovative medicine classes would result in an estimated £17.9 billion productivity gain for the UK overall. This is equivalent to more than doubling the GVA contribution of the UK's sport sector.[128]

This figure includes increases in both paid and unpaid labour productivity from the incremental QALYs gained by healthier patients (including reduced absenteeism or presenteeism). It also includes the indirect and induced multiplier effects of patient productivity gains in the wider economy.[129] For example, for each extra £1 generated by a healthier patient, additional economic value is created through the revenues of the businesses on which that £1 is spent and, by extension, the wages of the employees of those businesses. Indirect and induced effects would also include, for example, the economic value of the work done by paid carers.

These productivity gains are conservative compared to the aggregate willingness to pay (WTP), as stipulated by the Green Book.[130]

The aggregate WTP value is around £30.0 billion,[131] which is £12.1 billion greater than the £17.9 billion figure estimated. This represents the inferred value of the aggregate healthy life years gained from additional uptake of these innovative medicines, from the amount that respondents to surveys conducted by the Department of Health and Social Care are willing to pay to acquire one healthy year of life.

Considering the costs of increased uptake of these 13 innovative medicines against the estimated £17.9 billion productivity gains suggests the UK could see an average net gain of £7.6 billion, but that this gain could be as large as £13.8 billion.[132] We estimate that greater uptake of these medicines yields a benefit-to-cost ratio (BCR) of between 1.36 and 4.45.[133,134]

£17.9 billion

in additional productivity gains

[125] Note that the eligible patient populations are defined by the NHS Digital Estimates Report for 9 of the 13 medicines for which it is available. The eligible patient populations for the remaining 4 medicines are sourced from IQVIA, NICE guidance and analysis from ABPI member companies. Industry sources have confirmed in each case that these are the appropriate figures to use.

[126] Fouad et al. (2017). 'Effect of Chronic Diseases on Work Productivity: A Propensity Score Analysis', Journal of occupational and environmental medicine, May 2017, 59(5):480-485, Doi: 10.1097/JOM.0000000000000981. PMID: 28486344.

[127] Madsen et al. (2019). 'Willingness to pay for flexibility at the workplace for people with diabetes and chronic disease: a discrete choice experiment in a population of workers in Denmark', BMC Public Health 19, 584 (2019). https://doi.org/10.1186/s12889-019-6919-6.

[128] DCMS (2021). 'DCMS Economic Estimates 2019 (provisional): Gross Value Added', 19 February 2021.

[129] The total economy multipliers set out in Novartis and Europe Economics (2020). 'The Economic, Social and Innovation Value Novartis Brings to the UK', 14 January 2020. are applied. These reflect the average economic impact resulting from an injection of extra income (in this case, the additional economic value resulting from healthier patients participating in the economy) to the economy.

[130] PwC analysis using the current monetary willingness to pay value for a QALY of £70,000 in 2020/21 prices from HM Treasury (2022), 'The Green Book – Central Government Guidance on Appraisal and Evaluation', 2022, p. 87.

[131] Note this figure is indicative and has not been discounted to net present value.

[132] This range is based on the lower bound and upper bound of the ICERs published by NICE in company submissions.

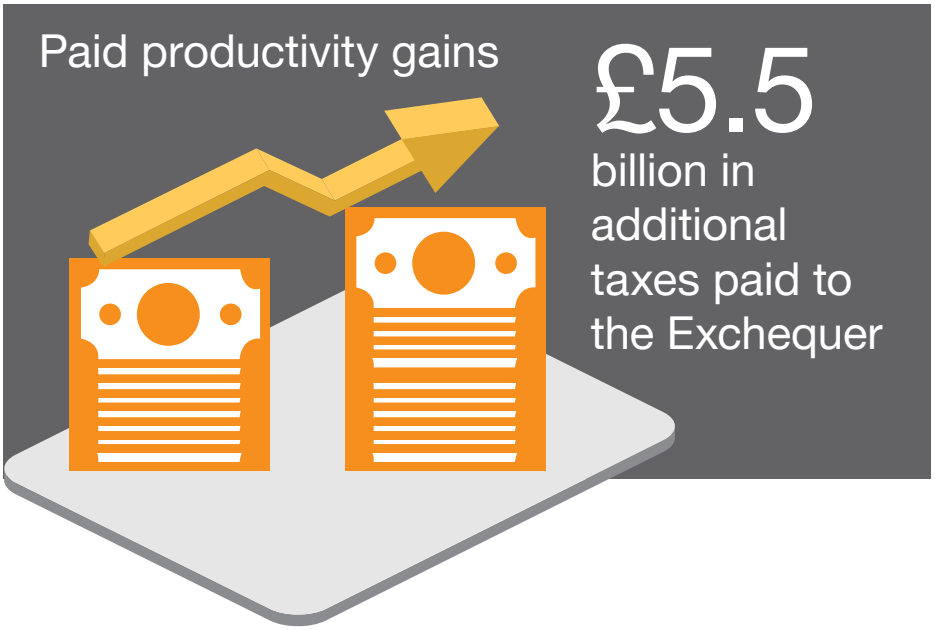
[133] Assuming all costs are incurred today and benefits accrue over a 15-year horizon.

[134] Note that this estimate will be conservative as only productivity gains are considered in our analysis.

What return on investment can the Exchequer expect?

£16.7 billion of the estimated total £17.9 billion productivity gains are from paid labour productivity. This is expected to create around £5.5 billion in additional tax payments to the Exchequer (which is derived by applying the UK's 33 per cent national tax-to-GDP ratio[135] to these paid labour productivity gains).

Importantly, this would more than offset (by about 1.4 times) the total incremental costs associated with the greater uptake of innovative medicines, based on the lower end of the published ICER range for these medicines. Even at the higher end of the ICER range, these estimated additional tax revenues would offset about 42 per cent of the total incremental costs, representing a considerable recuperation of investment.



The implication is clear. Greater uptake of clinically- and cost-effective innovative medicines has the potential to not only transform patients' lives, but also contribute net economic value to the UK economy, with a direct return on investment to the Exchequer. These benefits are not currently factored into NICE appraisals.

Figure 12: Potential benefits of increased uptake across four innovative medicine classes

Aggregate benefits across DOACs, SGLT2 inhibitors, severe asthma biologics and VPAs	DOACs	SGLT2 inhibitors	Severe asthma biologics	VPA
429,000 incremental QALYs	31,400 incremental QALYs	241,100 incremental QALYs	153,900 incremental QALYs	2,600 incremental QALYs
£17.9 billion in productivity gains	£85 million productivity gains	£8.0 billion productivity gains	£9.6 billion productivity gains	£220 million productivity gains
Up to a £13.8 billion net gain	Up to a £58 million net gain	Up to a £7.9 billion net gain	Up to a £5.7 billion net gain	Up to a £130 million net gain

Source: PwC analysis; Figures subject to rounding; Net gain potential equals the productivity gains less the lower bound of the potential incremental costs[136]

[135] OECD, 'Revenue Statistics 2020 – the United Kingdom'

[136] Analysis may be conservative estimations due to data availability and ongoing debate on various areas. For example, the severe asthma biologics eligible patient population is much debated, and workings represent an England population. SGLT2s eligible treatment population is based on draft NG28 and there is significant new opportunity if NICE guidelines are aligned with global views.

What other benefits might the UK see?

There are several other social, healthcare and environmental benefits that may be realised through increasing uptake of these medicine classes. These broader benefits have not been quantified but do hold potential value for the UK.

Patients themselves

By preventing strokes, DOACs can reduce the impact on family relationships, financial problems, social life and sexual function.[137] Kernan et al. (2021) finds that 'approximately 60 per cent of stroke survivors have some neurological symptoms, and 5 to 50 per cent have moderate disability, requiring some assistance with basic activities of daily living.'[138] Communication challenges are common, with 'around one-third of stroke survivors [having difficulty] speaking, reading, writing and understanding what other people say to them.'[139]

In the case of severe asthma biologics, better management of symptoms and fewer attacks can help alleviate patient anxiety and depression (which are reported by 38 per cent and 25 per cent respectively of severe asthma patients).[140]

While some of these broader healthcare benefits to patients may be at least partially considered in quality of life measurements as part of the NICE process, these still represent important benefits associated with increased use of innovative medicines.

Carers and families

Preventing strokes can reduce anxiety and depression in family members and carers. This, in turn, may significantly improve the recovery rate of stroke patients, and have knock-on effects on their quality of life.[141] Zhao et al. (2021) finds that the prevalence of anxiety symptoms and depressive symptoms for main carers of patients with stroke have been reported in 30 to 45 per cent and 20 to 50 per cent of carers, respectively.[142]

Majellano et al. (2021) finds that 'carers of severe asthma patients experience increased levels of emotional distress during sudden severe attacks and have unmet needs relating to informational, biopsychosocial and carer involvement supports.'[143]

Better management of type 2 diabetes with SGLT2 inhibitors can potentially reduce the risk of stroke, kidney failure, or visual impairment, and ultimately reduce patient dependence on carers.
This has been found to have a significant impact on the health, wellbeing, and finances of the carer, particularly if they are caring in an informal capacity (as a family member or friend).[144] In the case of autosomal dominant polycystic kidney disease (ADPKD), the disease is inherited and therefore affects familial generations to a large extent. It may often be the case that 'multiple members of a family across several generations are affected by the disease and often patients with ADPKD also function as carers for other family members.'[145]

Studies on the carer burden have reported impacts on emotional, social, work/employment, financial, and physical aspects of their daily lives.[146]

The NHS

A greater uptake of innovative medicines can free up NHS staff and other resources to deliver more healthcare for patients. This is particularly important while staff shortages persist and there are limited mechanisms for acquiring short-term additional staff.

For example, DOACs can prevent hospitalisations for deep vein thrombosis and pulmonary embolism as well as reduce the acute and long-term care required for stroke patients. It would also reduce the need for the many outpatient anticoagulant clinics across the UK. This would free up the time of doctors, nurses, physiotherapists and others that would otherwise be involved in their care, as well as the NHS budget spent on anticoagulant clinical facilities.

Similarly, severe asthma biologics can halve the number of exacerbations for patients and therefore significantly reduce the number of emergency admissions for respiratory care.

The potential for NHS cost savings are assessed as part of the NICE process, but as discussed in **Section 3** above, in the current context of workforce challenges means that the potential to improve NHS productivity is increasingly important.

[137] Daniel K, Wolfe CD, Busch MA, McKevitt C. 'What are the social consequences of stroke for working-aged adults?'. 40(6) June 2009

[138] Kernan et al. (2021). 'Primary Care of Adult Patients After Stroke: A Scientific Statement From the American Heart Association/American Stroke Association', Stroke, 2021; 52 e558-e571

[139] Stroke Association, 'Communication Problems'.

[140] Severe Asthma Toolkit (2019). 'Anxiety and Depression', 19 September 2019.

[141] Zhao, J., Zeng, Z., Yu, J. et al. 'Effect of main family caregiver's anxiety and depression on mortality of patients with moderate-severe stroke'. Sci Rep 11, 2021.

[142] Zhao, J., Zeng, Z., Yu, J. et al. 'Effect of main family caregiver's anxiety and depression on mortality of patients with moderate-severe stroke'. Sci Rep 11, 2021.

[143] Majellano et al. (2021). ''It's like being on a roller coaster': the burden of caring for people with severe asthma', ERJ Open Research, 2021, 7: 00812-2020. Doi: 10.1183/23120541.00812-2020.

[144] Alves Costa MS, Pereira MG. 'Predictors and moderators of quality of life in caregivers of amputee patients by type 2 diabetes'. Scand J Caring Sci. 32(2):933-942, June 2018

[145] Oberdhan D, Cole JC, Palsgrove A. 'Impact of Autosomal Dominant Polycystic Kidney Disease (ADPKD) on Caregivers and Families', Value in Health/ISPOR, Vol:21, September 2018.

[146] Oberdhan D, Cole JC, Palsgrove A. 'Impact of Autosomal Dominant Polycystic Kidney Disease (ADPKD) on Caregivers and Families', Value in Health/ISPOR, Vol:21, September 2018.

Figure 13: Broader benefits of increased uptake of innovative medicines

Source: PwC

The environment

Home-administered innovative medicines can also have secondary environmental benefits. Fewer hospitalisations and GP visits can remove some of the need to travel (whether by private car or other forms of transport) and thereby reduce the associated carbon impact that would otherwise result. Even in the treatment of severe asthma by biologics, which in many cases can be self-administered at home, any travel required for medicine administration can be offset against less frequent accident and emergency visits and hospitalisations.[147]

Health equity and levelling up

There is also potential to support the health equity and levelling up agenda through greater access to and uptake of innovative medicines. Many major causes of morbidity and mortality disproportionately impact people from lower socioeconomic backgrounds. For example, 86 per cent of northern local authorities have a lower population life expectancy than the England-wide average.[148] The gap in male life expectancy at birth between Westminster (83.9 years) and Blackpool (74.5 years) is 9.4 years.[149] Additionally, conditions like diabetes and asthma are more prevalent in areas with greater deprivation.[150,151]

Therefore, increased access to and uptake of medicines will disproportionately benefit these groups.[152]

86%

of northern local authorities have a lower population life expectancy than the England-wide average

[147] American Academy of Allergy Asthma and Immunology, 'Biologics for the Management of Severe Asthma'.
[148] University of York (2019). 'Researchers to tackle worsening North-South health divide', 18 July 2019.
[149] ONS (2019). 'Health state life expectancies, UK: 2016 to 2018', 11 November 2019.
[150] Connolly V, Unwin N, Sheriff P, et al (2000). 'Diabetes prevalence and socioeconomic status: a population based study showing increased prevalence of type 2 diabetes mellitus in deprived areas', Journal of Epidemiology and Community Health 2000; 54:173-177.
[151] Asthma UK (2018). 'On the edge: How inequality affects people with asthma', 2018.
[152] PwC (2019). 'Action required – The urgency of addressing social determinants of health – A PwC Health Research Institute report', 2019.

6. Investing in system-wide benefits

The UK and devolved nation governments, the NHS and industry have an opportunity to derive system-wide value as well as better health outcomes from innovative medicines. With greater collaboration, they can invest in access to and uptake of innovative medicines and realise the Government's Life Sciences Vision.

Creating a virtuous cycle of innovation

As articulated in **Section 5**, greater access to and uptake of innovative medicines has significant social value, including health, productivity and broader benefits. However, even this is only part of the system-wide benefits that innovative medicines bring. The life sciences sector is a large and interconnected ecosystem. Ensuring a sufficient financial return for innovators is a critical part of that ecosystem, acting to stimulate each next wave of innovation. That means ensuring access to and uptake of medicines, on fair commercial terms.

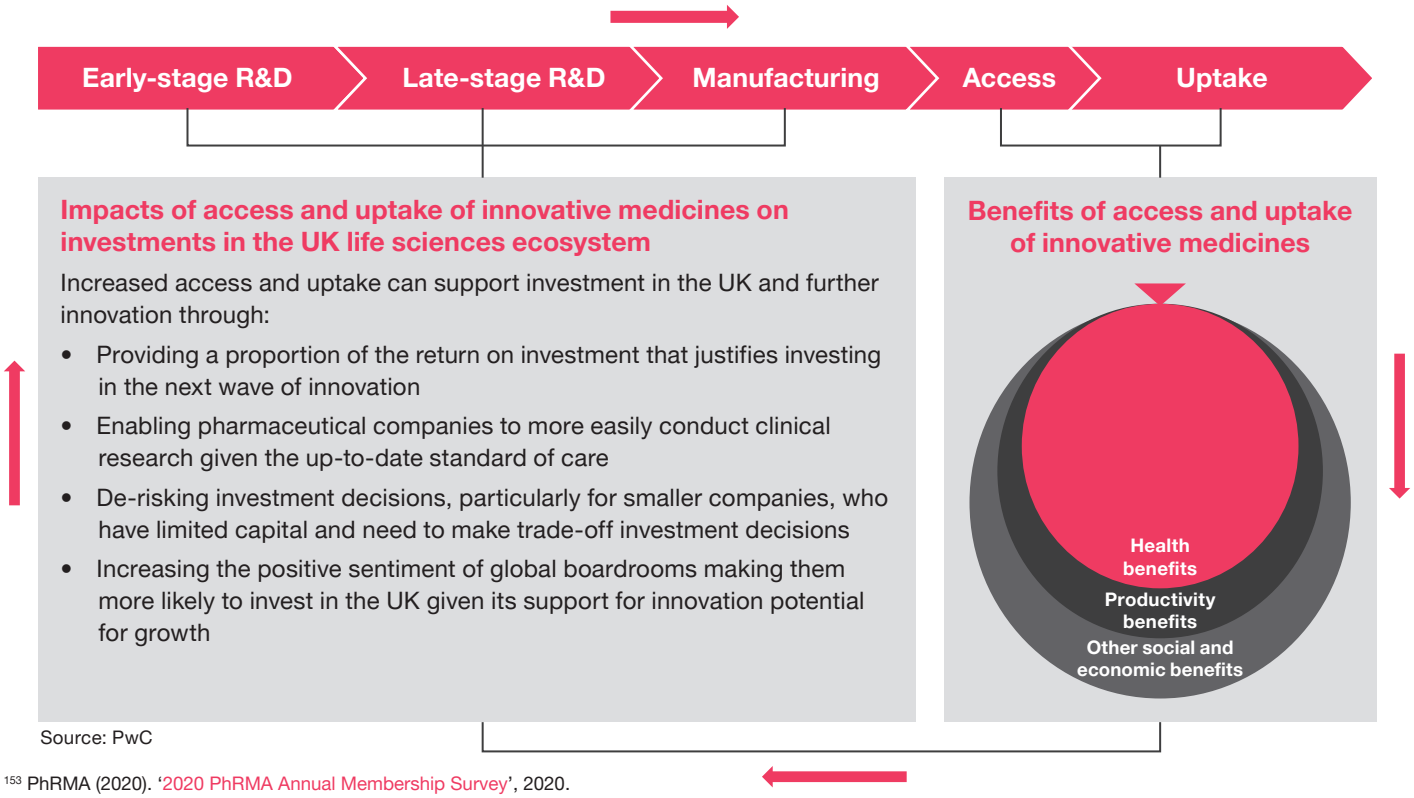
On average, major pharmaceutical companies reinvest about 20 per cent of their revenue back into R&D.[153] This is in addition to the investment provided by venture capital, private equity and public markets. These finances then support early-stage research, clinical development and manufacturing scale-up, creating jobs and bringing significant economic benefits to the UK. This, in turn, brings the next wave of innovation to patients.

The broader view: collaborating to take patient access and uptake to the next level

To realise the system-wide benefits of innovative medicines, many stakeholders will need to work together, including the UK and devolved nation governments, the NHS, the MHRA, NICE and other HTA bodies, and the pharmaceutical industry. As set out in **Section 2**, the UK has three key challenges to solve: breadth of access, speed of access, and extent and rate of uptake.

This also needs to be seen in the context of international competitiveness. The UK has historically been a priority market for launching innovative medicines. But industry stakeholders believe that addressing access and uptake is critical if the UK is to retain its priority status among global boardrooms.[154] Other countries, including France, have recently acknowledged this challenge and are making progress to improve access and uptake.[155]

Figure 14: The virtuous cycle of the UK life sciences sector



Source: PwC

[153] PhRMA (2020). '2020 PhRMA Annual Membership Survey', 2020.
[154] PwC interviews with ABPI company members.
[155] France Healthcare Innovation 2030.

Conclusion

As the Life Sciences Vision makes clear, maintaining alignment and momentum requires effective execution. Moving forward, a mutually beneficial accord between the NHS, Government and industry should be sought that improves patient lives, supports a virtuous cycle of investment in the life sciences ecosystem, and enables the UK and devolved nation governments to address its priorities.

As the country begins to emerge from the pandemic, these priorities include addressing the NHS backlog, navigating resourcing constraints and kick-starting economic growth. This is therefore an opportune moment to supercharge the execution of the Life Sciences Vision. Specifically, to execute on the Vision, it is imperative that the UK creates the right environment which is seen to clearly and demonstrably value and reward innovation in life sciences so that patients can benefit from the innovative medicines that they deserve and demand. For the reasons set out in **Section 5**, that should include making a step-change in access to and uptake of innovative medicines, using the levers described above to address the UK's breadth of access, speed of access, and extent and rate of uptake.

The health, economic and broader social benefits in doing so are clear. In the four classes of medicine analysed, we found that 1.2 million patients could gain a total of over 429,000 QALYs and contribute £17.9 billion to the UK economy (including at least £5.5 billion to the Exchequer), potentially fully offsetting the incremental costs associated with greater uptake. This is especially true under the current VPAS, as the pharmaceutical industry has underwritten any increase in uptake by capping the growth in branded medicines spend until 2024.

> "The UK needs to demonstrate that it is supportive of accelerating access and uptake of medicines. It needs to see medicines as an innovation that should be invested in.
>
> **Policy and Value Director,**
> Large pharmaceutical company

Realising the Life Sciences Vision will require a holistic plan for the UK life sciences ecosystem, supported by a cross-government approach to investing in innovative medicines.

That should take a broader view beyond access and uptake and consider what the industry has to offer the UK in terms of investment across the life sciences ecosystem, such as jobs and R&D. Doing so may pave an easier path to a mutually beneficial agreement.

Collaboration will be critical to execution. And recent history is encouraging. Industry and government can consider applying lessons from the COVID-19 response to other major healthcare challenges. It is exactly this type of partnering that will be required to realise the Life Sciences Vision.[156] But it will need to quickly move beyond discussion and be translated into action from all stakeholders.

[156] UK Government, 'UK Life Sciences industry sees nearly half billion investment as PM convenes Biopharmaceutical Industry leaders to strengthen future pandemic response', 2 December 2021.

Appendix

A.1. Additional information on how the UK[157] determines access to medicines and medicines spend

Before a new medicine can be considered for use in the UK, the innovator must show that it is efficacious, safe and of high quality. This approval is given by the MHRA (previously, it was assessed by the European Medicines Agency (EMA)).

In parallel, medicines will undergo a health technology assessment (HTA), conducted by NICE, to determine its cost-effectiveness and eligibility for reimbursed use in the NHS. This process compares the new medicine to the current standard of care (SoC) and considers:

- the additional benefits associated with the innovation versus the SoC in QALYs (one QALY is equivalent to one year in perfect health).
- the healthcare costs (product acquisition cost and other healthcare costs) associated with using the innovative medicine rather than the SoC.

For a new medicine to be considered cost-effective it must have an incremental cost per incremental QALY (known as the incremental cost-effectiveness ratio, or ICER) of no more than £20,000 to £30,000, £36,000 for some medicines for severe diseases or £50,000 for some end-of-life treatments.[158] A patient access scheme or commercial access agreement may be agreed to enable a positive NICE recommendation.

A budget impact test is also conducted on new medicines. If the effect of introducing the new medicine will be greater than £20 million in any one of its first three years of availability, NHS England and Improvement will engage in commercial discussions with the innovator to negotiate a commercial agreement to manage the budget impact.

Following the NICE appraisal and budget impact test, if the medicine receives a positive recommendation from NICE, it is to be made available in the NHS 90 calendar days after the guidance is published (30 calendar days for Early Access to Medicines Scheme (EAMS) products and products appraised via the Fast Track Appraisal process).

For some specialised medicines which are delivered to patients through a specialised service, availability may be limited to a small number of prescribing centres.

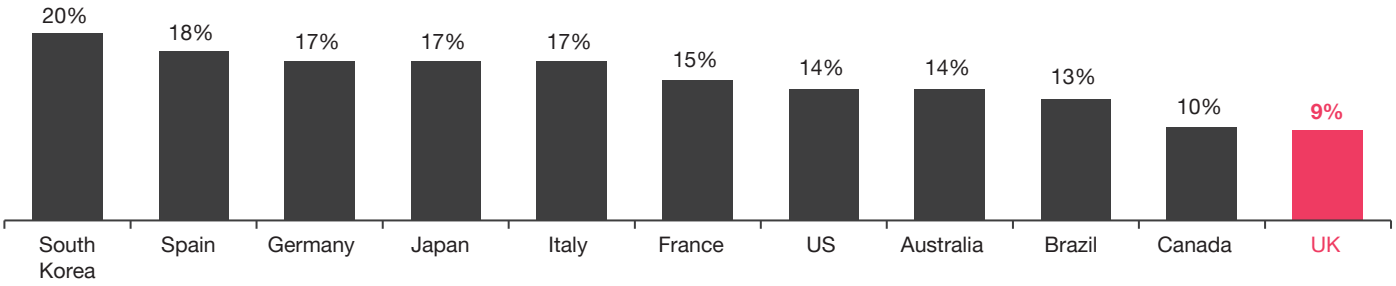
In addition, the 2019 Voluntary Scheme for Branded Medicines Pricing and Access (VPAS) caps NHS branded medicines spending, with the cap growing 2 per cent per year. All NHS purchases beyond the cap are provided free of charge by industry, through a system of rebates paid to the Department of Health and Social Care.

[157] Note that NICE decisions are adopted in England, Wales and Northern Ireland while Scotland has its own HTA body, the Scottish Medicines Consortium (SMC).
[158] Note this is the threshold for end-of-life treatments at the time of writing but that NICE has proposed to replace this threshold with a severity modifier in 2022.

A.2. Methodology for calculating net pharma spending by country

We start with IQVIA data on the net pharmaceutical spending as a share of total healthcare spending, taken from the replicated **Figure 15** below.

Figure 15: Real net drug percentage of healthcare spending, 2018



Source: PwC recreation of IQVIA chart[159]

We then use data from the OECD on health spending per capita to calculate the net pharmaceutical spending in US dollars.[160] We also source data from the OECD on GDP per capita for the same year.[161] We convert these values to pound sterling using the 2018 annual average USD/GBP exchange rate (1.335) from the Bank of England spot exchange rate database.[162]

Finally, we calculate the following equation to get the net pharma spend for every £100 GDP (on a per capita basis):

$$\frac{\textbf{Real net pharmaceutical spend per capita}}{\textbf{GDP per capita}} \times \textbf{100}$$

The data and calculations are summarised in **Table 2** below.

Table 2: Summary of net pharmaceutical spending calculations

Country	Real net pharmaceutical spend as a share of total healthcare spending (%, 2018)	Total health expenditure per capita (US$, 2018)	Real net pharmaceutical spend per capita (US$, 2018)	GDP per capita (US$, 2018)	Real net pharmacuetical spend per capita (£, 2018)	GDP per capita (£, 2018)	Net pharmaceutical spend per capita for every £100 GDP per capita
US	14%	$10,528.48	$1,473.99	$62,783.98	£1,104.11	£47,029.20	£2.35
Germany	17%	$6,291.04	$1,069.48	$55,235.25	£801.11	£41,374.72	£1.94
Japan	17%	$4,558.67	$774.97	$42,231.44	£580.50	£31,633.81	£1.84
France	15%	$5,136.20	$770.43	$46,375.44	£577.10	£34,738.16	£1.66
Spain	18%	$3,443.66	$619.86	$40,756.45	£464.31	£30,529.18	£1.52
South Korea	20%	$3,091.83	$618.37	$43,025.99	£463.19	£32,229.21	£1.44
Italy	17%	$3,522.08	$598.75	$43,427.66	£448.50	£32,530.08	£1.38
Australia	14%	$4,793.46	$671.08	$52,980.73	£502.68	£39,685.94	£1.27
Brazil	13%	$1,454.76	$189.12	$15,090.64	£141.66	£11,303.85	£1.25
Canada	10%	$5,330.85	$533.08	$49,891.90	£399.31	£37,372.21	£1.07
UK	**9%**	**$4,288.65**	**$385.98**	**$47,590.89**	**£289.12**	**£35,648.61**	**£0.81**

Source: PwC

[159] IQVIA (2021). 'Drug ExpenditureDynamics 1995–2020', October 2021, Exhibit 1, p. 5.
[160] OECD, Health resources – Health spending.
[161] OECD, GDP and spending – Gross domestic product (GDP).
[162] Bank of England, GBP exchange rates.

A.3. The development of COVID-19 vaccines

Through unprecedented collaboration, investing at risk, innovative ways of working, and building on research that was decades in the making,[163] COVID-19 vaccines were brought to patients in record time.

COVID-19 vaccines show development can be accelerated but most innovation relies on decades of research, as shown in **Figure 16**.

Figure 16: COVID-19 vaccine development timeline

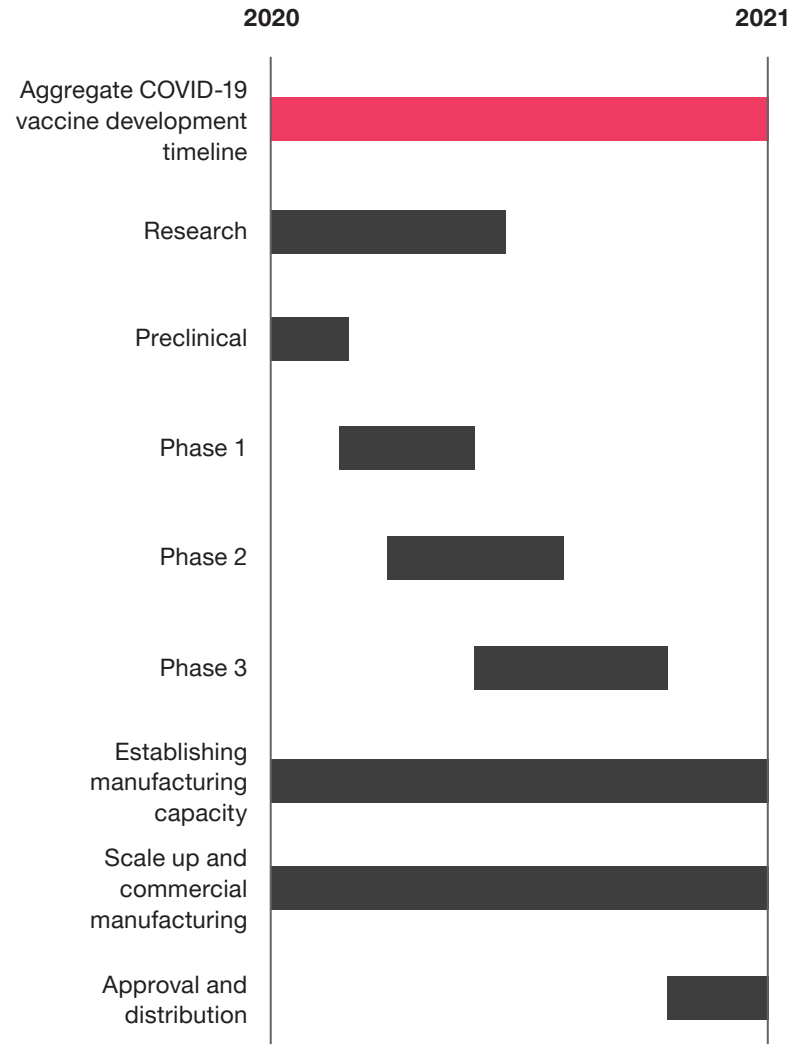
Vaccines typically take ~10 years to reach the market, but a COVID-19 vaccine was developed and approved by the end of 2021

Vaccine candidates were built on technology that had been decades in the making (e.g. mRNA technology) and leveraged research from other coronavirus vaccines such as SARS and MERS

By combining trial phases and rapidly scaling up enrolment globally, researchers were able to move through phases more quickly while maintaining scientific rigour

Private and public funding enabled at-risk establishment of facilities and scale-up of manufacturing processes in order to manufacture the vaccine at risk ahead of clinical trial read-outs

Regulators established an emergency approval process for COVID-19 vaccines and conducted rolling reviews to enable rapid approval without compromising on the robustness of the review



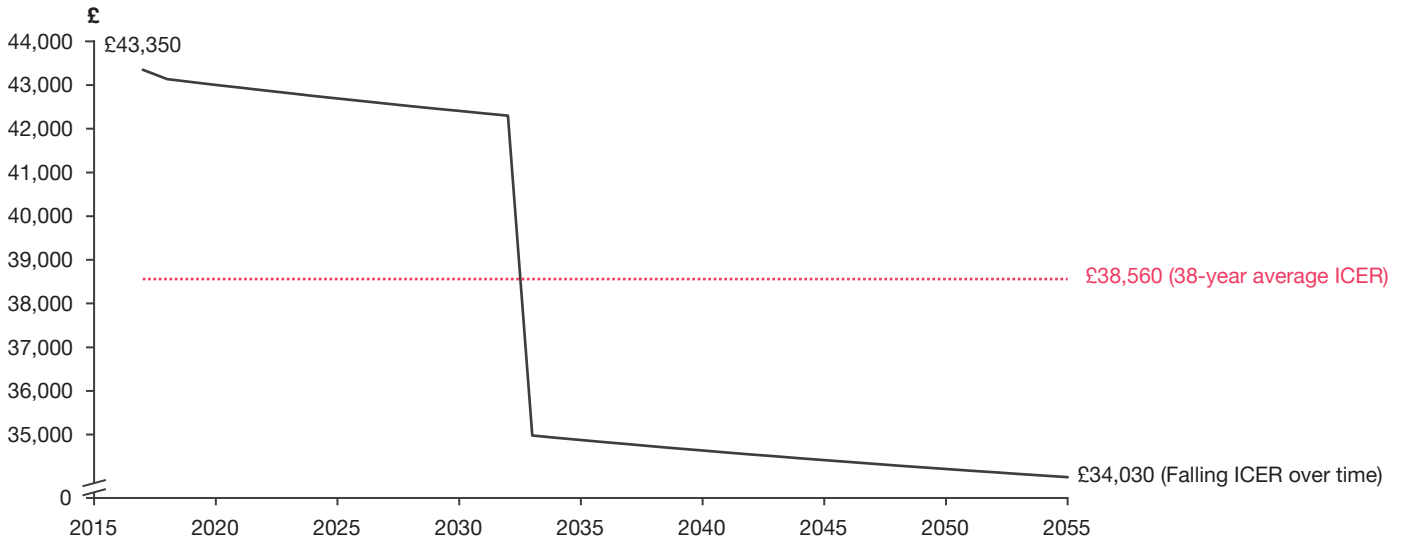
Source: PwC

[163] Dolgin, E. (2021). 'The tangled history of mRNA vaccines', Nature, 22 October 2021.

A.4. Cost per QALY over the useful lifetime of an innovative medicine

Following loss of exclusivity, the entrance of generic or biosimilar medicines to the market enables healthcare systems to access innovative medicines at a lower cost for years to come. The decline in cost per QALY over the lifetime of an innovative medicine driven by potential post-patent expiry price decreases can be seen in the case of a leading oncology drug approved for use in 2017 for treating lung cancer, shown in **Figure 17**.

Figure 17: Falling cost per QALY over the useful lifetime of an innovative cancer medicine



Source: PwC

Relative to the standard of care, the present cost per QALY of this innovative medicine falls from a £43,350 list price considered in the NICE health technology appraisal (HTA)[164] to a £34,030 ICER by the end of the product's lifetime, which is 21.5% lower than indicated in the NICE HTA.[165] We estimate that this product will have an average ICER of £38,560 over its useful lifetime, representing a decrease in the average present cost of the innovative medicine of 11 per cent, primarily due to post-patent expiry price decreases. The analysis reflects a 1.5 per cent discount rate on future incremental QALY gains, a 1.5 per cent discount rate on future incremental costs,[166] a 1.72 per cent annual productivity improvement on other healthcare costs,[167] and a post-patent discount of around 18 per cent for oncology medicines.[168]

[164] NICE submission.

[165] A 38-year useful lifetime is considered following evidence from an NBER report which finds the average generic drug age is about 25 years and evidence from Rome et al. (2020) which finds a median market exclusivity period of branded drugs of about 12.5 years: NBER (2019). 'Four facts concerning competition in U.S. generic prescription drug markets', August 2019. Rome et al. (2020). 'Market Exclusivity Length for Drugs with New Generic or Biosimilar Competition, 2012-2018', American Society for Clinical Pharmacology and Therapeutics, 12 July 2020. Doi: 10.1002/cpt.1983.

[166] Discount rates from HM Treasury (2020). 'The Green Book – Central Government Guidance on Appraisal and Evaluation', 2020.

[167] PwC analysis of ONS output per hour data from 1972-2021.

[168] Average 18.5% discount of biosimilar oncology treatment applied to as SoC is off patent; calculated from data from EU Biosimilar Impact Report (2020): https://ec.europa.eu/health/sites/default/files/human-use/docs/biosimilar_competition_en.pdf.

A.5. Additional information on value of medicines methodology

For every additional day that a patient gets in terms of QALYs, they will be able to be productive both in terms of paid and unpaid productivity. Below we provide a worked example of how a QALY can be distributed over different types of activities.

For individuals that participate in work, an average day is divided between work and non-work productive activities and a variety of other activities.

If we assume a working individual works, on average, 8 hours a day, this would equate to roughly one third of their day.

Data from Our World in Data's Time Use Survey 2020[169] suggests that, on average, a person living in the UK would do about 3 hours of unpaid productive work each day (or about 13 per cent of their day). The remaining 13 hours of their day (~54 per cent) is spent on personal time, sleep or other activities.

Our analysis of GVA data from the ONS indicates that 8 hours of paid work over 5 days in each week is worth, on average, £54,472 in GVA per year.

Our analysis of GVA data from the ONS and the 0.400 time-use ratio of unpaid to paid work time (3 hours unpaid to 8 hours paid) derived from the Time Use Survey 2020 indicates that three hours of unpaid work per day is worth about £6,789 per year, on average. Note that we have valued and discounted these activities over a 15-year time horizon to allow for sufficient time for incremental QALYs from the innovative medicine to accrue.

If we assume an innovative medicine enables a working patient to live 1 extra day pre-retirement, this would be worth about 0.002 QALYs. The value of this extra day would be

(0.002 × £54,472) + (0.002 × £6,789) = £122.52

of £122.52 in additional productivity gains. This is because the paid and unpaid productivity gains are only gained from portions of the additional time that a patient is afforded in QALYs, respectively.

[169] Our World in Data. 'Time Use Survey 2020'.

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