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**Steve Bates OBE,**  
CEO, BIA

The next Voluntary Pricing and Access Scheme (VPAS) currently being negotiated is taking place in a significantly changed health policy context to all previous schemes. Not only has the current scheme resulted in a globally unprecedented rebate rate for many firms, this is the first VPAS to be negotiated post-Brexit with the UK having decided to become a sovereign regulatory system for a market that is around 3% of global sales by value.

In the past five years, the costs and friction of undertaking commercial activity in the UK have increased, business taxes have risen and the reputation for being one of the easiest markets in which to do business in Europe has been tarnished. The life sciences sector, like the country, has lived through an extraordinary period of political uncertainty and risk, not something global company boardrooms traditionally associate with the UK. As a result, the country potentially risks losing its status as a ‘first launch’ market for new medical technologies.

The NHS proudly celebrates having the cheapest drug prices in Europe but there is a downside to being known as the life science sector’s toughest customer. Grudging commercial respect for the UK’s negotiating prowess also results in global firms investing the minimum into a market with the thinnest, or even negative margins.

For global players, the combination of low prices and Brexit has made the UK unattractive as a global early launch market in which to invest. With a statutory scheme that can be imposed by the Government, for a market that only has one customer in the NHS, ignoring the UK and focusing on other markets becomes a practical and profitable proposition for companies. There is now a real possibility the UK faces relegation to a second tier of markets for new product launches. The full implications of this have not been factored in by the NHS and Department of Health and Social Care (DHSC) in their initial negotiating positions.

If clinicians cannot participate or lead research in the UK, some will move abroad to health systems where they can. If UK affiliates of global companies are reduced to a basic salesforce, the capacity of the life science ecosystem is diminished. NHS patients could also question their support for a tax funded system where they do not have access to the latest transformative therapies in areas like cancer, sickle

cell disease, cystic fibrosis and rare genetic diseases. If clinical trials are placed outside the UK, both the speed of access to the latest medicines for patients and the UK's clinical research capacity will be severely affected.

The UK faces a stark choice – to be a welcoming market for innovative global industries that create value for the health system, or a commercial environment solely focused on cost saving, resulting in declining life science investment and reduced access to the next generation of innovative treatments for NHS patients.

The NHS cannot tackle the country's disease burden without new products. New drugs, developed by commercial companies, are a core part of the solution, not the problem. Recently we have seen Lilly, an American company and BIA member, unveil trial results for their new Alzheimer's drug showing it can slow the disease by a third. They have been very clear in their concerns about the attractiveness of the UK market by leaving VPAS. They told the Financial Times this month that they are pausing a potential investment in London because of concerns about a "stifling commercial environment" in the UK saying "in the short term, negotiating a new and sustainable pricing deal that unlocks the growth potential of our sector is key to restoring the UK's international competitiveness and attracting future investment," They are currently making future decisions about launch plans for their Alzheimer's drug.

During my lifetime, the NHS has provided significant increases in quality of life expectancy by combining effective public health provisions and the adoption of key pharmaceutical technologies. Cardiovascular health has been improved both by smoking cessation measures and statins. Cancer by early detection and new therapies. It is exciting to see a host of new therapies being developed in the UK's biotech industry and key developmental steps from UK clinical trials. We know that world leading clinicians like to be involved in research and many leading NHS clinicians value this as part of their career.

There is much to commend the UK as the place to develop and pioneer novel therapeutics. A successful VPAS negotiation can lead to a win-win situation for NHS patients with the UK's life science sector as a driver of economic growth. We have a blueprint for success with the UK Vaccine Taskforce adopting a customer-facing strategy – keen to partner, pioneer and adopt the newest products. Not only were we able to roll out a world-class vaccine programme sooner than our global competitors as a result of our significant life science sector capability, but it also led to investment in mRNA and other capabilities from key global players.

The new VPAS needs to capture that spirit of partnership for the long term and prioritise making market entry as simple and welcoming as possible. Other countries are doing this with lower health technology assessment hurdles for the first few years and simple and fast early pricing deals for new products.

An optimistic and positive deal for the future will unlock the potential for the UK to be the global hub for the next generation of life science technologies.

# Introduction



In setting out its vision for making VPAS fit for the future, the BioIndustry Association (BIA) is calling for a reset between government and industry to deliver both taxpayer value and a fair return for innovators. The call is one of several recommendations outlined in this report, presented to the Minister of State for Health and Social Care, Will Quince MP in March 2023 at a meeting with a delegation of BIA member companies.

It contains a balanced and evidence-based assessment for the future of VPAS from the perspective of BIA members, demonstrating that global company perceptions of the UK are shifting as a consequence of VPAS, which is in turn discouraging inward investment and frustrating the launch of new technologies.

The UK has already seen several high-profile companies publicly withdraw from VPAS, and new evidence has emerged showing that the level of terminated drug launches is rapidly increasing. Meanwhile, there has been a shift in companies placing investment in ‘safer’ markets such as China and the US, and in more favourable tax environments, as demonstrated by the recent decision of a large multi-national company investing in the Republic of Ireland instead of the North-West of England.

The report exposes how the DHSC is using outdated economic arguments to justify its approach to VPAS and illustrates how the Scheme has fallen short of many of its original ambitions, accelerating a trend that represents an unsustainable position for the UK’s pharmaceutical industry.

The report makes a series of constructive recommendations which aim to address these concerns and present solutions to secure the future viability of the life sciences industry in the UK.

It was produced following a series of meetings with a reference group comprising BIA members from early-stage biotech firms to large pharmaceutical companies.

# VPAS in principle vs in practice

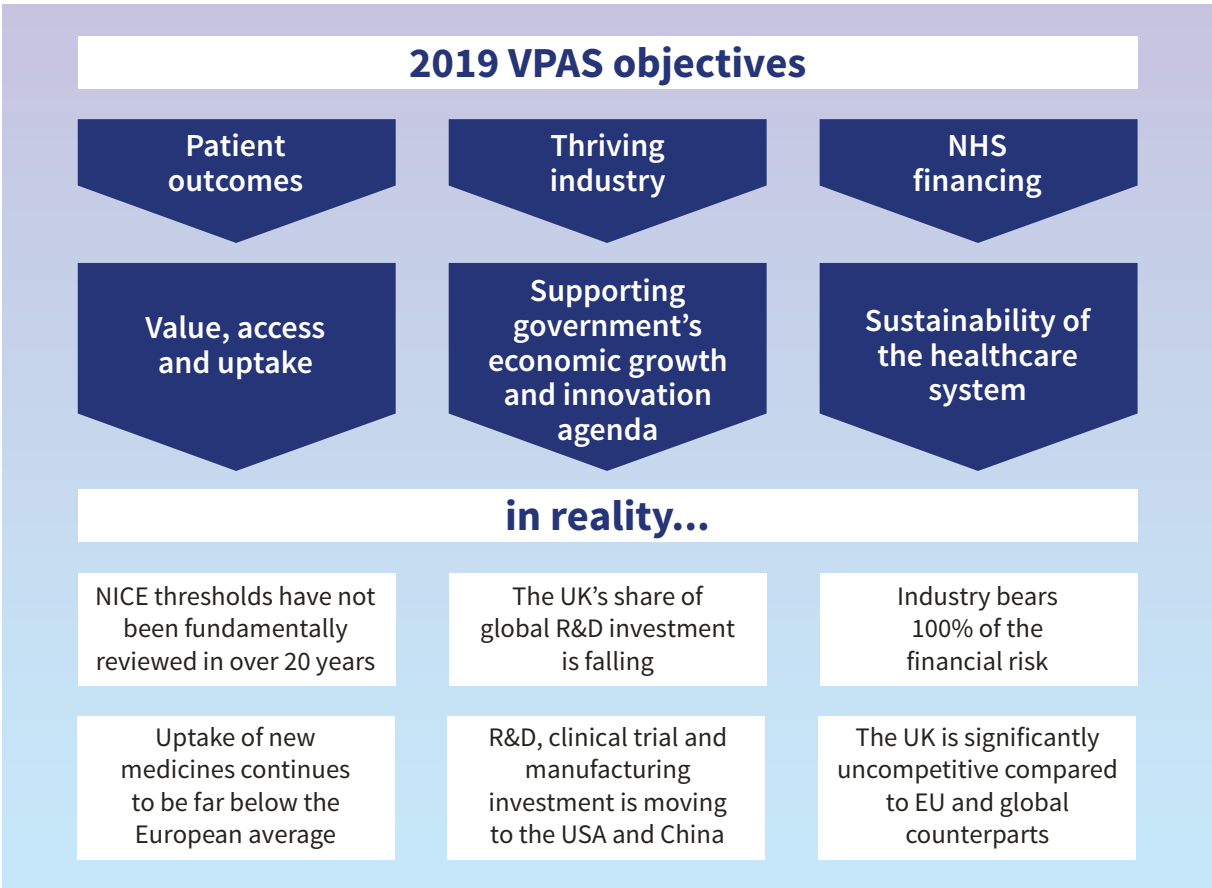


## Review of 2019 VPAS objectives

The 2019 VPAS was intended to deliver three main objectives; to improve patients’ access to cost-effective medicines and streamline routes to market; to support economic growth and the innovation agenda; and to deliver value to the taxpayer through a stable and predictable affordability mechanism, generally referred to as the “rebate”, a ‘clawback’ payment made by industry to the Government.

The Scheme was intended to improve health outcomes by increasing patient access to medicines, both in terms of speed and breadth of new medicine launches, but also by improving the uptake of NICE-recommended medicines in the NHS. This goal included an objective to improve the way NICE evaluates new medicines as a cost-effective use of NHS resources.

The Scheme was also intended to encourage an environment in which to grow the life sciences industry and to position the UK as an attractive destination for investment, particularly post-Brexit. Finally, the Scheme was intended to ensure taxpayer value in the use of branded medicines, and to deliver predictability on spend for the entire branded medicines’ bill for the NHS. Unfortunately, in reality the Scheme has fallen short of many of the original ambitions.

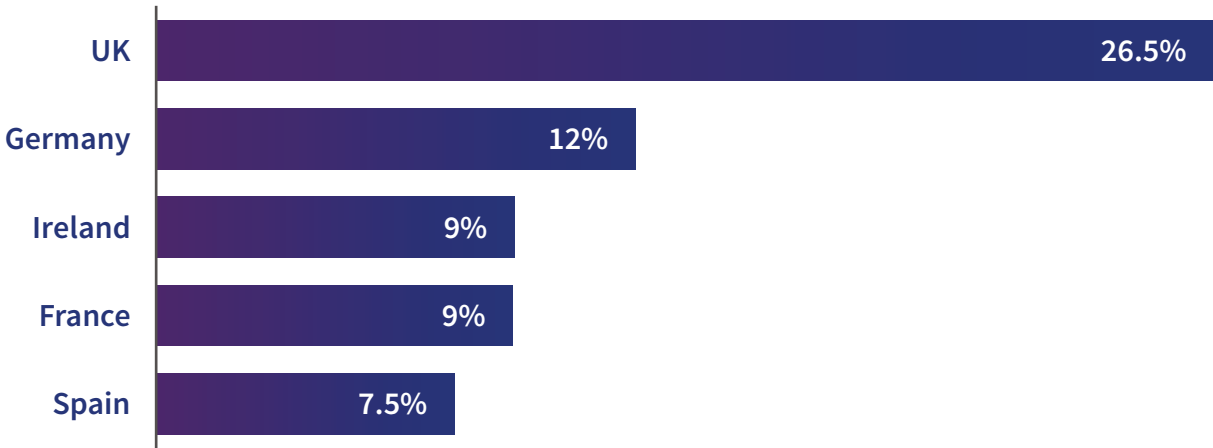


# The inequitable impact of the 2019 VPAS



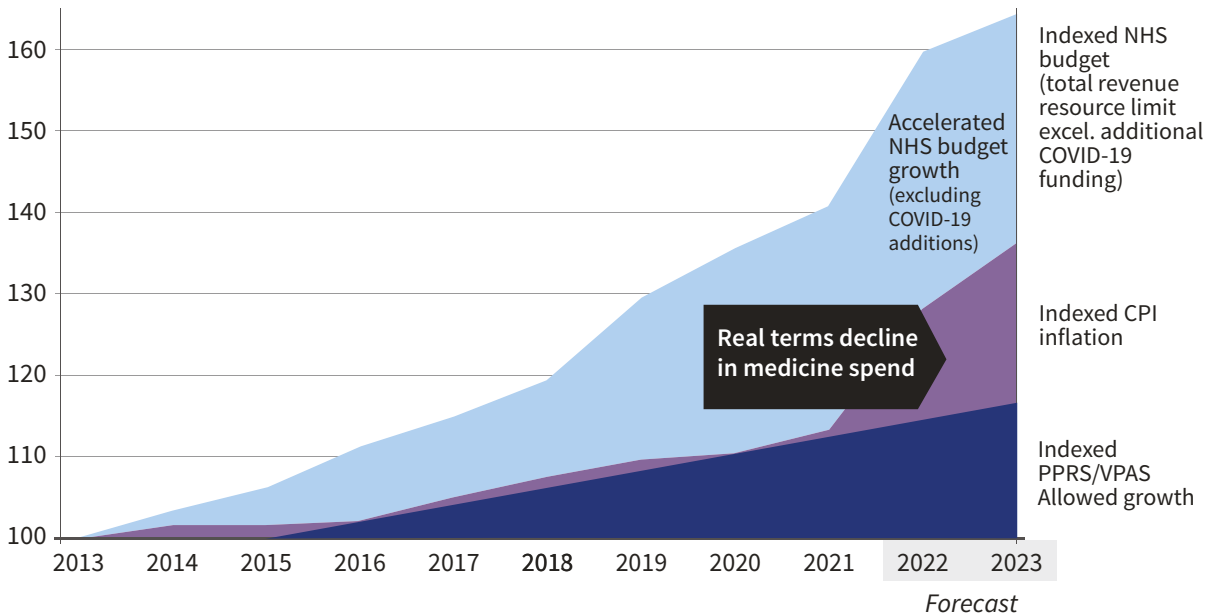
The BIA believes the 2019 Scheme has delivered a highly inequitable outcome for industry despite the significant contribution made by the life sciences sector to supporting COVID-19 recovery. For example, clawback payment rates are higher in the UK than in any other EU country.<sup>1</sup> The DHSC has confirmed that the VPAS payment percentage for 2023 will be set at 26.5%. This is a significant rise from the last year’s rate of 15%<sup>2</sup> and much higher than comparable EU countries, where rates are between 7.5%-12%.<sup>3</sup> In addition, in the UK industry bears 100% of the financial risk for clawback payments, unlike Italy and Spain where risk is shared more proportionally with payers.<sup>4</sup>

### Clawback Payments in 2023 (% of revenues)



Meanwhile, medicines’ spending is declining in real terms due to a combination of the VPAS growth cap, which limits the total market growth for branded medicines, and rising inflation.<sup>5</sup>

### Indexed NHS and medicine expenditure figures over time (2014-2023) in £bn

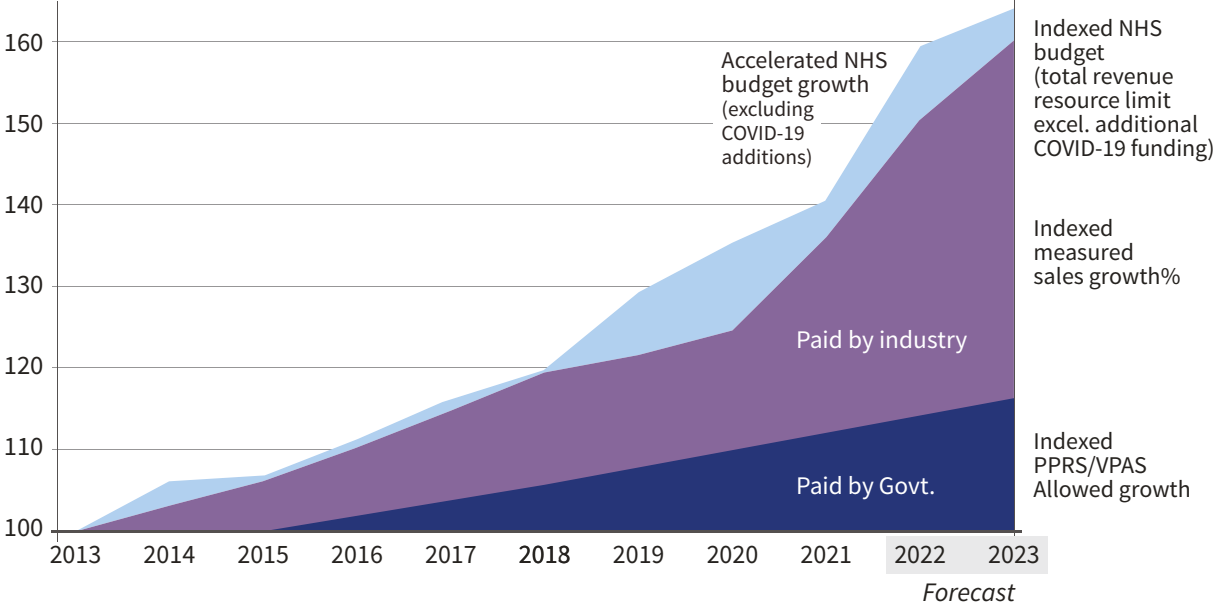




The growth cap has remained the same at 2% allowable growth per year despite the significant increase in inflation, meaning the real terms level of medicine spending has declined.

Furthermore, the compounded impact of the rebate has delivered a highly inequitable outcome for industry.<sup>6</sup>

**Indexed NHS and medicine expenditure figures over time (2014-2023) in £bn**



Until 2018, measured sales rose in line with the overall NHS budget, but an increasing share of growth has been subsidised by VPAS members since the end of 2019. NHS expenditure consistently exceeded the allowed growth cap in the VPAS agreement, placing increasingly unsustainable financial pressure on the pharmaceutical industry to pay more in rebates each year. Together with the 2023 rebate, the DHSC will have received around £10 billion in rebate payments, equivalent to an entire year of free branded medicines since the capped market model was introduced.

It should also be noted that the current fixed growth rate drives a compounding impact year on year. If branded medicines spending grows at a consistent rate annually, the level of rebate owed by industry compounds and increases each year throughout the scheme.

**Illustrative example:**

- If the medicines bill grows at 4% in year 1, and the scheme cap is set at 2% growth, companies must then rebate the 2% difference in year 2.
- If the medicines bill grows at 4% again in year 2, and the cap is maintained at 2% for that year, companies must rebate the 2% difference from year 2 and the 2% difference from year 1.
- This compounding is a result of the scheme not returning to the baseline year on year.

This trend represents an unsustainable position for the UK pharmaceutical industry. Global leaders are now realising how inequitable this construct is since it has been revealed by the exceptional COVID-19 recovery growth.



# Case study evidence: putting the VPAS debate in a wider policy perspective



BIA members firmly believe that global company perceptions of the UK are shifting as a consequence of VPAS, which is discouraging inward investment and frustrating the launch of new technologies. Global boardrooms are now choosing to deprioritise the UK in favour of more ‘pro-innovation’ markets, which is reflected in recent data on levels of medicine launches, R&D investment and clinical trials.

Astra Zeneca’s Chief Executive, Pascal Soriot, recently commented *“If you want to build a thriving life sciences sector, you need more than research and discovery science [...] You need an environment that provides the right incentives: the right tax environment and the right environment to conduct clinical trials.”*

He also noted that the UK has some of the lowest prices for medicines in Europe and “when you add the 26.5% rebate, it becomes rapidly unattractive for companies to operate in the environment and certainly very unattractive to invest. We are hoping to achieve a more favourable environment from a pricing and investment viewpoint.”<sup>7</sup>

The following case studies set out the BIA’s evidence and analysis of these concerning trends.

## ► **CASE STUDY 1**

**BIA members have begun to see the impact of VPAS on commercial operations.**<sup>8</sup>

### **Global boardrooms have become apathetic towards the UK**

*“As a result of the existing cost containment environment and VPAS, the global boardroom has become deeply apathetic towards the UK.*

*“Ipsen UK has been forced to make cost-saving considerations throughout the business, resulting in a company restructure which saw a 15% decrease in our commercial business headcount. Ipsen has also been forced to consider the impact of the commercial environment and VPAS rebate levels on our ability to launch new medicines in the UK, meaning UK patients are at risk of losing out on innovative treatments.”*

UK General Manager – **Ipsen UK**

### **Disinvestment in clinical trials and R&D**

*“Between 2020 and 2022, there was a 22% reduction in the number of clinical trials we conducted in the UK. This is reflective of the growing perception that the UK is a challenging environment to conduct trials and launch new medicines.”*

General Manager Specialty Care – **Sanofi**

### **Limiting patient access and risking the UK's reputation as a first launch country**

*“VPAS has recently become a topic for consideration in launch and launch sequencing decisions. While NAS are exempt for 36 months, the current high rates mean that expected future payments must be factored in to launch decision making. VPAS on top of factors such as low net pricing and concerns about informal HTA referencing mean the UK market is being deprioritised as an early launch market in planning for the next wave of launches to come through the pipeline.”*

General Manager Specialty Care – **Sanofi**

### **UK missing out on pioneering and innovative technologies**

*“From our perspective the single biggest barrier for the company when considering commercialising of ATMPs in the UK first, is the lack of a transparent joined-up process from regulatory approval, NICE assessment and adoption by the NHS.*

*“The hurdles and time needed to navigate this process in the UK is creating a scenario where the company is considering commercialising in the US and Europe ahead of the UK even though it is UK HQ company, with manufacturing capabilities in the UK.”*

Head of Market Access – **Autolus Therapeutics**

### **De-prioritisation of the UK as a destination for investment**

*“Since 2022, Sanofi has made 17 investments to support R&D and manufacturing across Europe, amounting to €1.2BN of investment. The UK was not considered as a suitable market for this investment.”*

General Manager Specialty Care – **Sanofi**

*“VPAS is further decreasing the attractiveness of the UK as a destination for inward investment. The level of support offered by the UK Government falls significantly short of what other countries, with lower rebate rates, have to offer.*

*“Our recent decision to expand our manufacturing facility in Wrexham was a result of global demand for product and should not be mistaken as a positive reflection of the UK environment.”*

UK General Manager – **Ipsen UK**

### **Reduction in UK headcount as a result of VPAS**

*“As a new/young company our lead product has benefited from VPAS exemption for ~18 months, having taken 18 months to get reimbursement from NICE after licence approval. As our lead revenue driving product, the spike in VPAS repayments has caused our revenue to drop drastically in the last 2 years. This has led to less headcount in the UK relative to other European and International markets.”*

UK Country Manager – **American biopharmaceutical company**

▶ **CASE STUDY 2**

**The DHSC is using outdated economic arguments to justify its approach to VPAS negotiations. This is best reflected in the recent public consultation on the Statutory Scheme, which is summarised below.**

**DHSC claim**

There is “little reason to believe that providing favourable market conditions – for example, higher prices – would be a significant determinant of companies’ decisions on where to establish headquarters and undertake research and development.”

“Despite the favourable pricing policy of the Canadian government and agreements with industry to increase research and development investment, pharmaceutical research and development activities have not increased significantly in Canada.”<sup>9</sup>

£15,000 of non-medicines’ spending generates one Quality Adjusted Life Year with a “social value” of £70,000 as per HMT’s Green Book.<sup>10</sup>

**The reality**

This claim is based on a 15-year-old report that fails to reflect the reality of today’s policy environment – Pharmaceutical Pricing Policies in a Global Market’ (2008).<sup>11</sup>

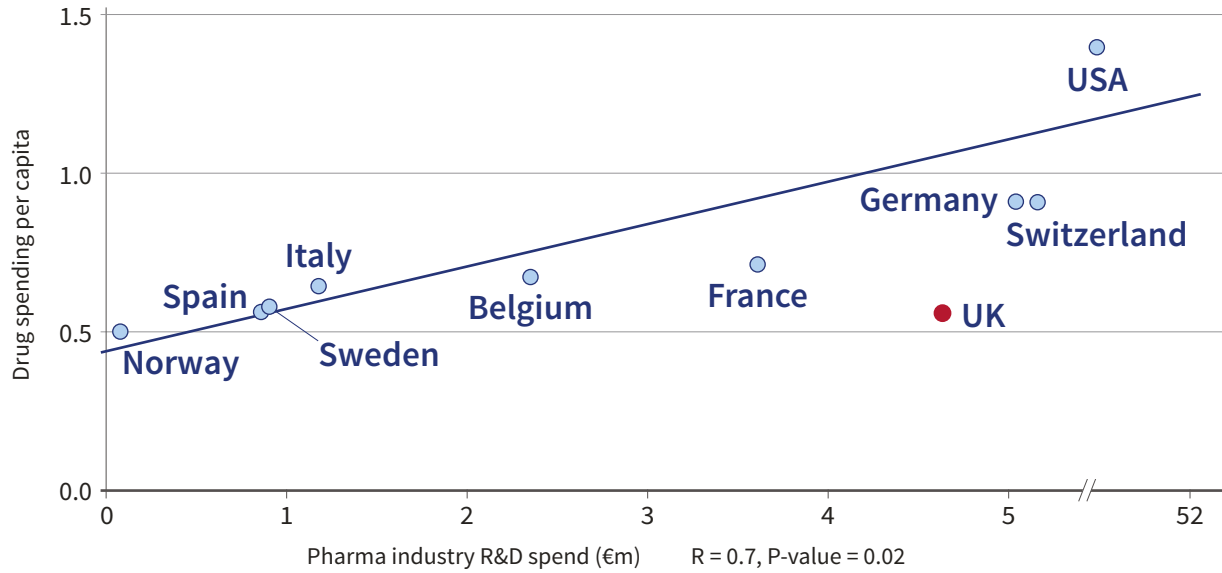
AstraZeneca has recently announced a major expansion of its R&D investment in Canada, creating 500 new jobs. The UK is being outcompeted on a global stage – showing that our scientific heritage alone is not enough to secure life sciences investment.<sup>12</sup>

These claims are based on outdated evidence that has not been reviewed in over 10 years, or updated to reflect the post-Brexit/post-COVID landscape. Medicines should not be viewed as a financial cost to be constrained; they are a scalable investment that can help alleviate pressures on the NHS.

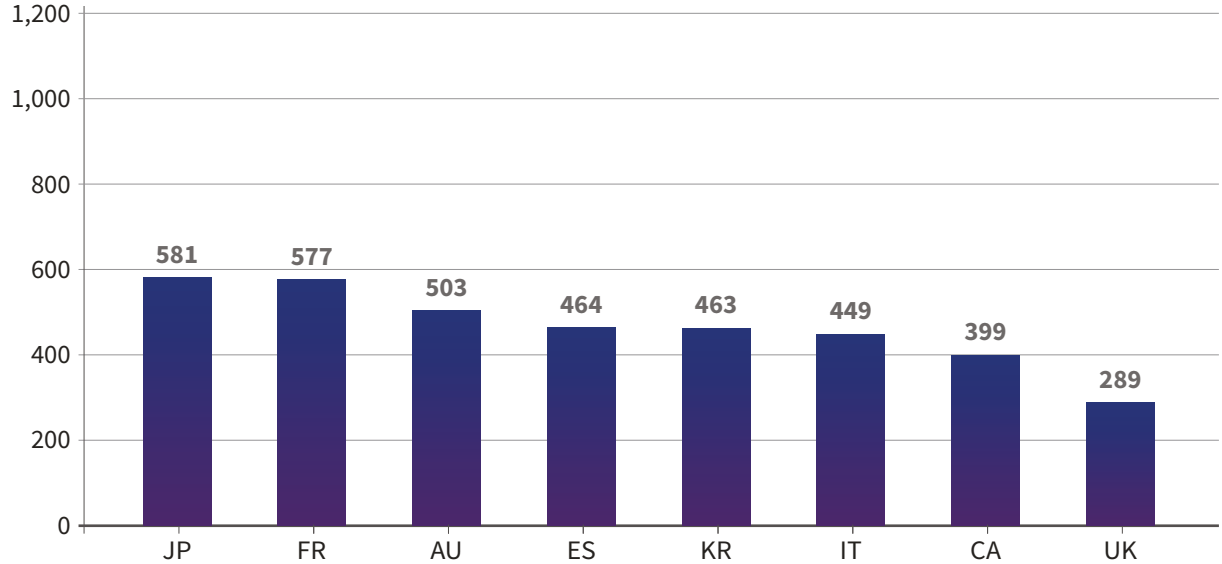
► **CASE STUDY 3**

The UK has traditionally enjoyed high levels of R&D investment relative to very low spending on medicines demonstrating the high level of value offered to the Government from the life sciences sector.

Relationship between medicines spend per capita and industry spend on R&D (€, 2016)<sup>13</sup>



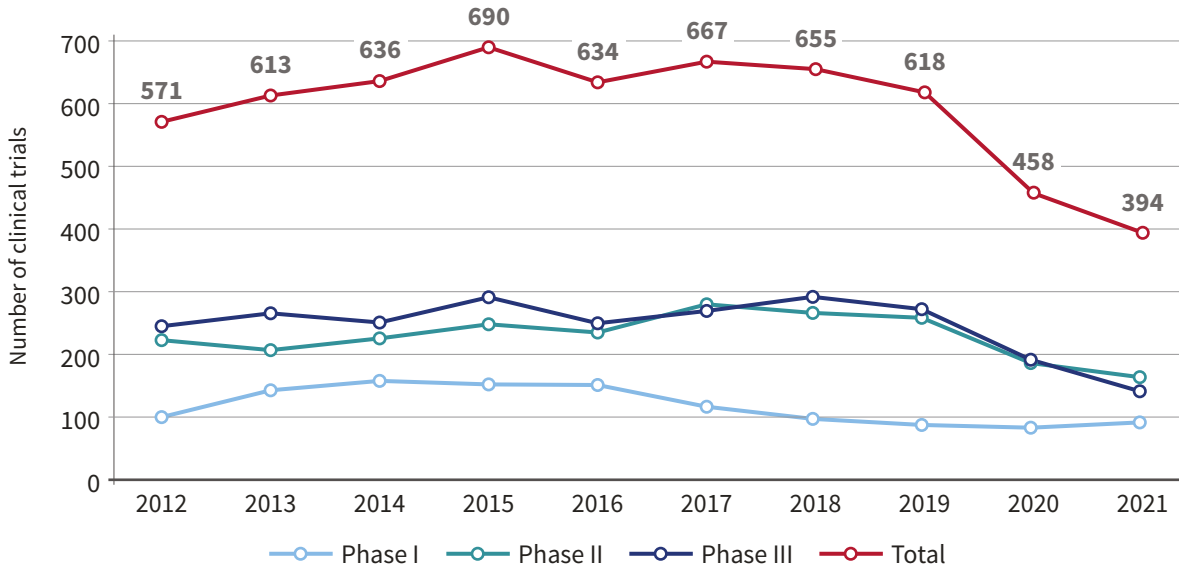
Real net pharmaceutical spend per capita (£, 2018)<sup>14</sup>



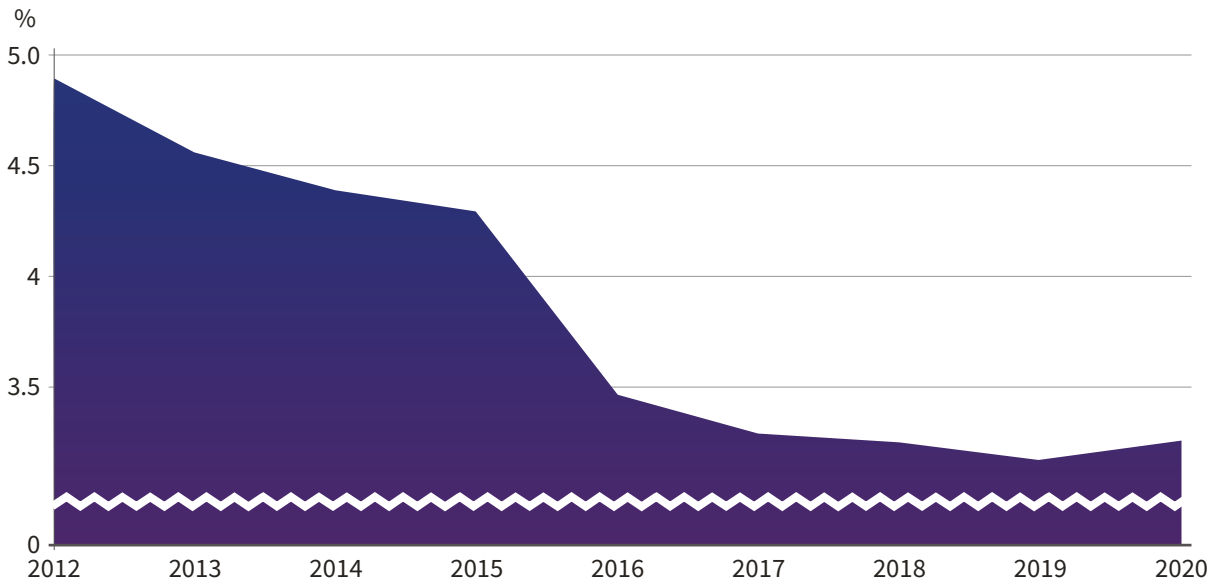
► **CASE STUDY 4**

**Recent data indicates the UK is rapidly losing ground as a life sciences power.**

**The number of industry clinical trials initiated in the UK per year has fallen by 41% between 2017 and 2021<sup>15</sup>**



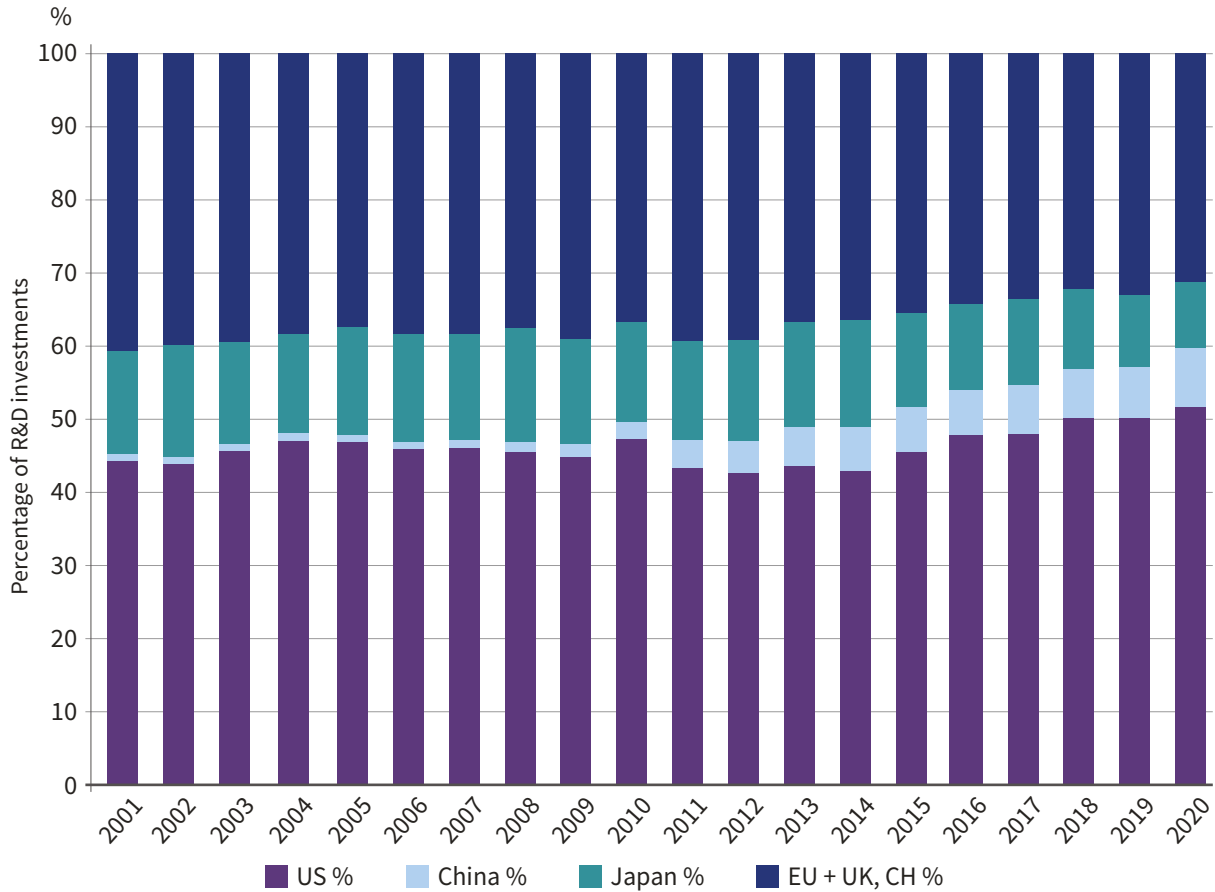
**Meanwhile, the UK's share of global R&D spend has decreased from 4.9% to 3.6% between 2012-2020<sup>16</sup>**



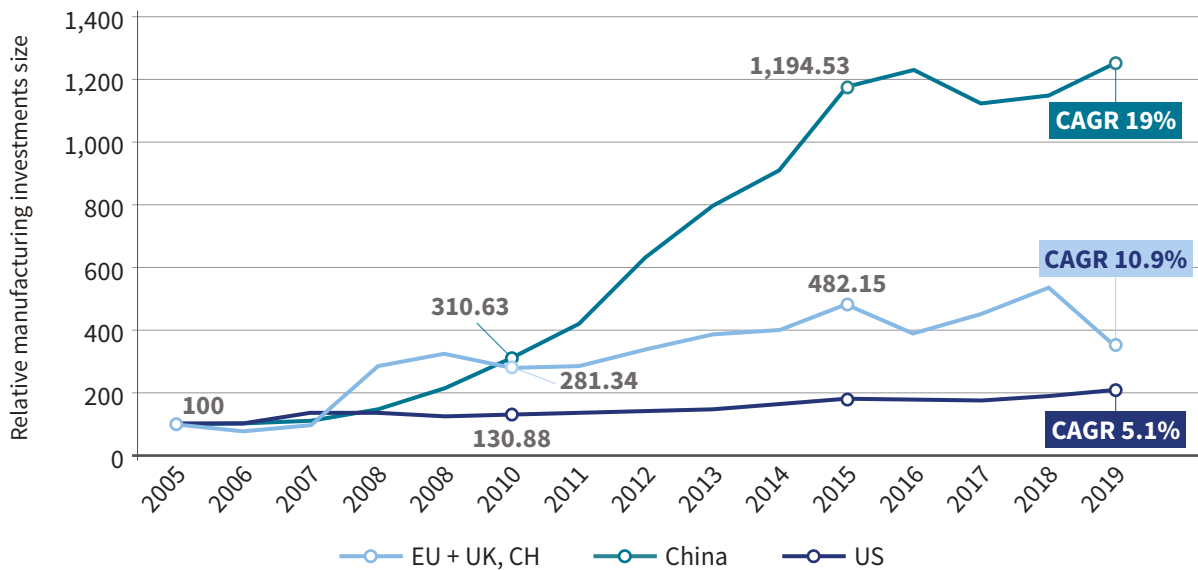
► **CASE STUDY 5**

**Global trends indicate a shift towards China and the USA as preferred locations for investment.**

**China and the USA represent a growing share of biopharmaceutical R&D investments made in major markets<sup>17</sup>**



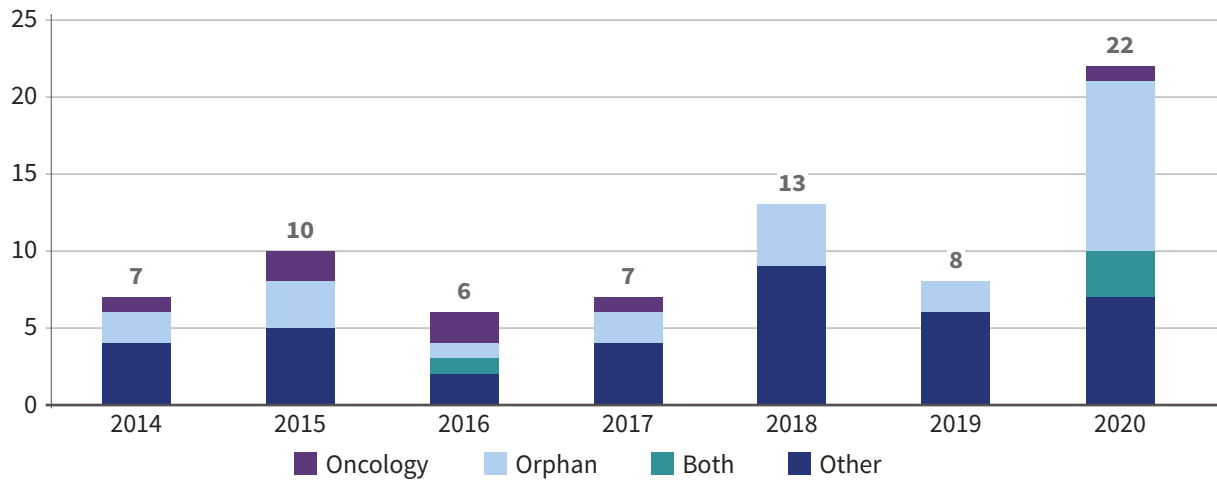
**Pharmaceutical manufacturing investment in China has grown on average 19% each year, a rate significantly higher than that observed in Europe + UK and the US<sup>18</sup>**



► **CASE STUDY 6**

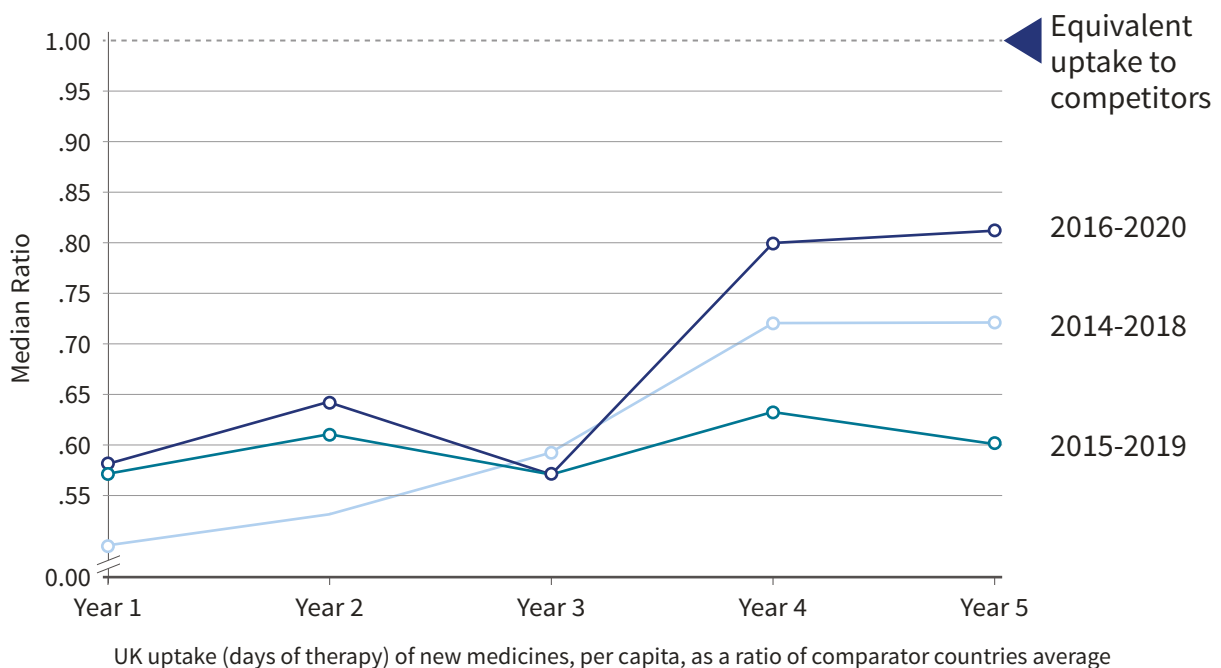
**An increasing number of new medicines are not being launched in the UK and comparative patient access to medicines remains poor.**

The number of European-approved medicines that have not been launch in the UK has drastically increased<sup>19</sup>



- Data shows that the UK has seen the highest rate of decline in new drug launches across EU4+UK as a percentage of global launches.<sup>20</sup>
- The UK has seen a decline of 6.7% in new drug launches.<sup>21</sup>
- In comparison, other EU countries have seen less significant declines at between 2-1%. For instance, Spain has seen a decline on 2%, Italy 1.2% and Germany 1%.<sup>22</sup>
- Meanwhile, France has seen a notable 7.3% increase in new drug launches.<sup>23</sup>

**Uptake of new medicines across the UK also continues to be far below the average of UK comparators<sup>24</sup>**



Recent studies have shown that the UK has lower levels of patient access to new medicines compared to France and Germany, with patients in France and Germany five times more likely to get brand new medicines than patients in the UK.<sup>25</sup>

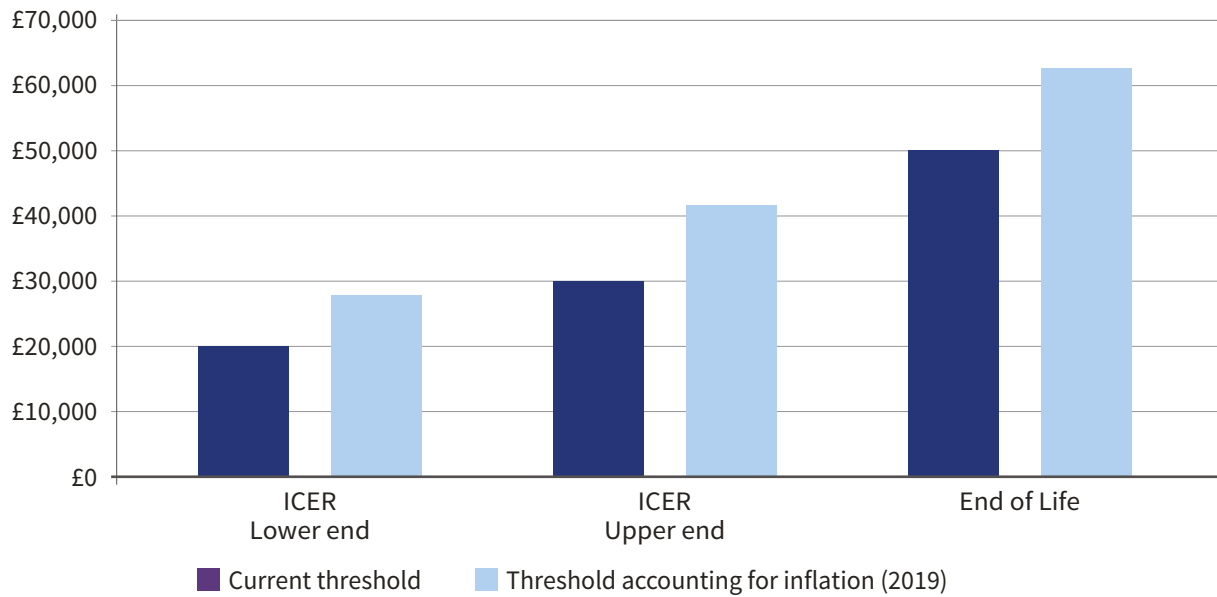


► **CASE STUDY 7**

**The increase in new drug withdrawals is likely due to VPAS devaluing the way patients’ lives are valued by the Government.**

VPAS alongside predecessor policies have effectively devalued the lives of British citizens, as measured by the Quality Adjusted Life Year (QALY), since 1999. The QALY is a health economic measure used by NICE to estimate the years of life remaining for a patient following a particular treatment or intervention and weighting each year with a quality-of-life score. NICE uses a cost-effectiveness threshold in the range of £20,000 to £30,000 per QALY for reimbursing new drugs on the NHS.

**VPAS and predecessor policies have effectively devalued the lives of citizens – as measured by the OALY – since 1999**



The 2019 VPAS committed to reviewing health technology assessment methods. However, NICE announced in 2021 that it was required to conduct the review within a ‘cost neutral envelope’. During a NICE Board meeting in December 2022, VPAS was cited as the reason why QALY thresholds could not be increased. Meanwhile, NICE thresholds have never risen with inflation, further devaluing the lives of patients.<sup>26</sup>

# Recommendation for securing the future viability of the UK life sciences ecosystem



In considering this evidence and the importance of the strategic relationship between government and life sciences sector, the BIA has proposed a series of ‘partnership principles’ for industry-government collaboration to help foster a spirit of problem-solving.

The BIA believes a reset is needed in the relationship between government and industry that delivers both taxpayer value and also a fair return for innovators. The BIA’s proposed principles are as follows:

## 1 Financial controls should be more predictable, equitable and competitive

- It should be acknowledged that the rebate was never meant to set a long-term precedent and that industry should not shoulder all the financial risk.
- Any future financial control mechanism must be a single-digit, stable, predictable rate that is competitive with comparable markets.
- The allowable growth rate for any VPAS cap should be in line with wider healthcare spending increases.

## 2 VPAS should be a mutually beneficial partnership that realises value for both parties

- VPAS negotiations should be conducted in the spirit of collaboration to deliver genuine and binding ‘quid quo pro’ benefits.
- This requires acknowledgement from ministers that the UK industry has genuine and legitimate concerns.
- A shift is needed in DHSC and HM Treasury thinking to consider medicines spending as an investment not just a cost if future iterations of VPAS are to deliver mutual value.

## 3 Health technology assessment methods should be genuinely reviewed

- It should be acknowledged that the fundamental measure of medicines’ value has not been updated for over 20 years.
- Measurable commitments should be adopted to address the UK’s below average use of medicines.
- VPAS should be seen as the primary policy to ensure taxpayer value; Arm’s Length Bodies should not impose measures that cause net prices to fall below levels deemed cost effective by HTA bodies.

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## About BIA



The BioIndustry Association (BIA) is the voice of the innovative life sciences and biotech industry, enabling and connecting the UK ecosystem so that businesses can start, grow and deliver world-changing innovation.

We are an award-winning trade association representing more than 550 member companies including:

- Start-ups, biotechnology and innovative life science companies
- Pharmaceutical and technological companies
- Universities, research centres, tech transfer offices, incubators and accelerators
- A wide range of life science service providers: investors, lawyers, IP consultants and IR agencies

**Explore opportunities to influence, connect and save with the BIA**

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[www.bioindustry.org](http://www.bioindustry.org)

[info@bioindustry.org](mailto:info@bioindustry.org)

+44 (0)20 7630 2180

Upper Ground Floor, Victoria House, Bloomsbury Square

London WC1B 4DA





