

ABPI submission: Autumn Budget 2024

The ABPI exists to make the UK the best place in the world to research, develop and access medicines and vaccines to improve patient care.

We represent companies of all sizes that invest in making and discovering medicines and vaccines to enhance and save the lives of millions of people around the world. In England, Scotland, Wales and Northern Ireland, we work in partnership with governments and the NHS so that patients can get new treatments faster and the NHS can plan how much it spends on medicines. Every day, our members partner with healthcare professionals, academics and patient organisations to find new solutions to unmet health needs.

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Summary of recommendations

Incentivising investment and boosting UK competitiveness

- Formally launch the pre-agreed, £520 million Life Sciences Manufacturing Capital Grants Facility, with a longer-term ambition to increase the quantum of funding in the event of oversubscription.
- Maintain the current structure of R&D tax credits as per Labour's Business Tax Plan, and extend the scope to include capital expenditure.
- Maintain a globally competitive 'patent box' incentive that rewards and incentivises the commercialisation of UK innovations.
- Reduce UK visa costs and speed up processing times in line with other leading economies.
- Prevent people from leaving the labour market by delivering on the outcome of the occupational health tax incentives consultation with an ambitious expansion of non-taxable health support.

Improving UK attractiveness for industry R&D

- Maintain public R&D spending at current levels with an index-linked increase for FY25/26, with a longer-term ambition to commit the UK to achieving the highest level of public R&D investment in the G7.
- Target government investment towards a major cross-sector initiative to develop pre-clinical models that better replicate human disease.
- Restore the UK's reputation as a destination of choice for industry clinical trials.
- Establish an internationally competitive dedicated health data research service.

Realising the full benefit of innovative medicines and vaccines

- Support NICE to immediately review the severity modifier in England to adjust downwards the cut-off levels used to determine the degree of severity. NICE should replace the opportunity-cost-neutral approach to implementing the modifier.
- Enable NHS England (NHSE) to update the NHS Commercial Framework to ensure better patient access to innovative products.

- Provide adequate funding for the national immunisation programme.
- Announce a formalised, system-wide approach to horizon scanning for vaccines.
- The application of VAT rules to advanced therapy medicinal products should be reviewed to ensure consistent rules and guidance are applied.

Deliver a globally competitive regulatory system that supports innovation and enhances patient access to new medicines

- Sufficiently resource the MHRA to enable the UK to develop a world-leading regulatory offer.
- Enhance and ring-fence resourcing for a refreshed and relaunched Innovative Licensing and Access Pathway (ILAP).

Introduction

The pharmaceutical industry is already the largest investor in UK research and development (R&D), investing £9 billion into UK R&D in 2022ⁱ, delivering £17.6 billionⁱⁱ in direct economic value and providing 126,000 highly skilled jobs across the UKⁱⁱⁱ.

Much more is possible, and through collaboration and partnership, the pharmaceutical industry can play a key role in delivering the goals outlined in the Life Sciences Sector Plan and the missions for government.

The new Voluntary Scheme for Pricing, Access and Growth ([VPAG](#)) agreement provides strong platform to achieve this, through its explicit focus on ‘growth’ for the first time in its history. To echo the new health and social care secretary, the health of the nation and that of the economy are inextricably linked^{iv}.

By working together to create the right levers and infrastructure for growth, we can:

- drive a 40 per cent decrease in the total UK burden of disease^v
- generate £16.3 billion in gross domestic product (GDP) and 85,000 new jobs in total from increased pharmaceutical exports (if the UK were to increase its share of global exports by 4 per cent)^{vi}.
- attract an additional £1.2 billion and 7,230 high-quality jobs annually from greater life sciences foreign direct investment^{vii}.

Unlocked benefits will be seen in all parts of the UK, as demonstrated by the [ABPI Pharma Impact Map](#), which shows the significant contribution industry already makes to local and regional economies in all four UK nations, as well the benefits gained through partnerships with the NHS, local research and manufacturing sites.

Central to achieving this growth will be recognising the value of medicines and vaccines as a healthcare investment that can prevent disease progression, ease the burden on the NHS, and drive socioeconomic outcomes such as increased productivity. Doing so successfully requires end-to-end action from investment in the R&D ecosystem through to competitive fiscal incentives and improved adoption and uptake of innovation.

In Labour's manifesto the government committed to investment and fundamental reform, and our proposals set out below are part of that agenda. This submission sets out four key areas which directly support two of the government's core missions:

- a) kickstarting economic growth – securing the highest growth in the G7
- b) building an NHS fit for the future

For the life sciences sector (one of the government's named growth sectors) both missions are interdependent. Sector growth strongly relies on the NHS's ability to seed and adopt innovation and leverage its potential as an incubator for world-class research. The adoption of clinically effective and cost-effective medicines, alongside improvements to the NHS's data environment and capacity to host commercial clinical research, is equally important in relieving pressure on front-line services, improving patient outcomes, and tackling economic inactivity. As such, the recommendations set out in this response should be seen as complementary and addressed in parallel.

1. Incentivising investment and boosting UK competitiveness

Following the pandemic, international competition to attract life sciences investment is at an all-time high, with many countries launching targeted strategies to capture globally mobile investment. This has resulted in the UK seeing a declining share of global pharmaceutical R&D investment, falling from 4.9 per cent in 2012 to 3.3 per cent in 2020^{viii}.

To compete with other countries also vying for investment, the UK must ensure that it offers an attractive and sustainable operating and business environment for Life Sciences companies to invest in the (early) launch of medicines, research and development, and manufacturing. In addition to an internationally competitive tax offer, high-quality skills and infrastructure, and a commitment to global free trade and open supply chains, an important element of this is fair recognition of the value of medicines. This is demonstrated through access, pricing and financial arrangements which are competitive with (or at least comparable to) other developed healthcare markets.

The government must ensure that the UK continues to enhance its competitive edge and attracts the necessary inward investment to kickstart economic growth. As part of this, it is critical that the UK lays the foundations for advanced manufacturing and cutting-edge research to thrive and delivers stability for prospective investors by maintaining an internationally competitive tax and fiscal incentives environment for R&D and capital investment. Both are in line with the Labour Party's Life Sciences Plan^{ix} and subsequent manifesto commitments.

Recommendations for the 2024 Autumn Budget:

- 1.1. Formally launch the pre-agreed, £520 million Life Sciences Manufacturing Capital Grants Facility, with a longer-term ambition to increase the quantum of funding in the event of oversubscription.**

- The government's previously stated commitment^x to delivering this programme is welcome. Optimising the operation of the fund will be key to maximising growth, supporting health resilience, and leveraging the UK's potential to be a leader in net-zero medicines manufacturing.
- Early response to the Facility indicates that it will be a highly effective investment lever, therefore the government should consider expanding it in line with demand at a future fiscal event if it becomes oversubscribed, as is currently forecast. The preceding Life Sciences Manufacturing Innovation Fund (LSIMF) has attracted £400 million worth of investment from £32 million grant distribution^{xi}. The scale and longevity of this programme gives the chance to compete and secure a far larger quantum of internationally mobile investment.
- The government should ensure early prioritisation of investments greater than £100 million and support companies through the programme to invest in late-stage manufacturing R&D which can anchor commercial and clinical manufacturing capabilities for years to come. Work with trade associations to effectively market the fund to the widest pool of potential investors, and offer greater clarity on the application process and assessment criteria for grant distribution.
- Ensure assessment criteria builds in the flexibility to support internationally competitive grant offers, recognising that automation, new modalities and flexible manufacturing requirements are changing the way investments are made. This should consider the full suite of economic drivers, including GVA, productivity gains, export value and volumes, and employment, and ensure that flexible weighting can be given. This should include recognition that not all desirable investments for the UK economy and health resilience will result in significant direct employment increases – but where spillover benefits will be felt in the supply chain and associated R&D roles.
- Ongoing assessment of the UK's underpinning Green Book rules is needed to ensure grant assessment criteria are responsive to the pace of technological change and keep pace with the offer from competitor markets. Additionally, the reporting requirements on grant recipients must be reviewed to ensure they are both proportionate in terms of administrative burden and allow sufficient flexibility for reasonable adjustments to be made in the implementation of an investment project without penalties or grant reduction being incurred.
- Fiscal incentives are critical but not sufficient alone to attract internationally mobile investment in an era of fierce competition. The Medicines Manufacturing Industry Partnership^{xii} (MMIP) has produced a detailed report that highlights the key policies needed to support growth, with analysis outlining the opportunity for the UK to attract investment and provide global leadership in attracting innovative, and environmentally sustainable medicines manufacturing. Leadership in sustainability can be achieved by:

- investing in the UK's innovation strengths – including maximising the potential of the £78 million industry-funded Sustainable Medicines Manufacturing Innovation Fund, agreed as part of the most recent VPAG agreement
- demonstrating international leadership via the ongoing collaborative work with the British Standards Institute, industry and NHS to define product-level sustainability measurement frameworks.
- public investment in, and incentives for businesses to invest in clean and renewable energy sources, such as biomethane and green hydrogen which can power medicines manufacturing facilities.

1.2. Maintain the current structure of R&D tax credits as per Labour's Business Tax Plan^{xiii}, and extend the scope to include capital expenditure.

- In line with the government's commitments to bring stability to the UK tax environment, the government should ensure that the current structure of the new Merged R&D tax credit regime is retained, including retention of the existing rates of relief for large companies.
- A key enhancement which could be made to the regime would be the inclusion of capital expenditure eligibility, with the scheme in its current form lacking an incentive for "sticky" capital and infrastructure investments which are commonplace in equivalent regimes globally. If the UK can anchor businesses' activity in the UK, both the R&D and downstream benefits are more likely to remain here as the company scales up to commercial manufacture and the UK economy will accumulate more of the value arising from the tax reliefs UK businesses receive throughout their life cycle.
- Under current arrangements, the R&D allowance (which is a welcome component of the UK's tax incentives environment) simply provides accelerated tax relief for R&D-related capital investments, but no absolute benefit or cash payments that are key for incentivising investment from loss-making businesses, including pre-revenue R&D-intensive SMEs. This is of particular relevance in the life sciences industry where R&D is at the core of what we do, and innovation requires significant upfront investment. This often leads to the generation of in-year tax losses which will continue as the company moves along the lengthy timeline required to develop and bring a pharmaceutical product to market.
- In a 2023 CBI survey^{xiv}, 19 per cent of firms said including capital into R&D tax credits would have the greatest impact on their innovation investment in the UK, increasing to 30 per cent among manufacturers. Firms would raise capital investment on average £1.03 million this tax year, £1.3 million per year by 2025 and £2.2 million per year by 2032.

1.3. **Maintain a globally competitive ‘patent box’ incentive that rewards and incentivises the commercialisation of UK innovations.**

- The patent box is a vital underpinning of the UK’s fiscal incentives for R&D investment. For global investors in innovation, it is a key competitive feature and underlying assumption in business plans. This is important to the UK’s ability to retain and attract R&D investment and the jobs associated with it.
- The patent box has been shown to increase investment by around 10 per cent. The introduction of the UK patent box in 2013 was the key driver behind the decision of one of our members to centralise ownership of their pharmaceutical intellectual property (‘IP’) (i.e. the economic rights to commercialised and pipeline pharmaceutical products) in the UK.
- The patent box helps to ensure that UK companies are not attracted to relocate to overseas territories as the location of choice to exploit their IP rights. It remains a significant component in shoring up the UK’s competitiveness and creating the right fiscal environment for scaling up the multitude of high-potential UK companies coming from its world-leading R&D base.
- The most notable benefits that this operating model continues to bring to the UK include:
 - Many key business decision-makers are operating in the UK, meaning that they have a deep understanding of the UK R&D and wider business environment and are therefore more readily available to engage with current and potential strategic partners in the UK, removing a barrier to further UK collaboration and investment.
 - Specialised and highly skilled pharmaceutical R&D jobs are maintained in the UK (as are jobs relating to associated commercial and support activities).
 - Ensures that the UK is at the forefront of conversations when considering where IP rights acquired externally should be held long-term. In relation to the example cited above, recent examples include commercialised and pipeline oncology assets migrated to the UK from Switzerland and Bermuda following acquisition of a US Biotech company.
 - Recent analysis (available on request)^{xv} outlines that the patent box supported £14.9 billion of economic activity in 2021 and 2022. Between 15 to 25 per cent of this is estimated to be additional and as a result, the economy is £2.2 billion to £3.7 billion a year larger than it would have been without the patent box.
 - Patent boxes are now an established part of countries’ incentives for R&D. As of mid-2024, 13 out of 27 EU Member States have a patent box regime. Looking across advanced economies, 19 out of 37 OECD countries have one. Canada is the latest G20 country to consider introducing one. This demonstrates the vital importance of this incentive to UK competitiveness and its growth goals.

OECD's Pillar 2 proposals – a new global minimum tax rate

The introduction of the new global minimum tax rate is expected to strengthen (rather than dilute) the impact of the UK patent box in incentivising UK investment. Existing UK patent box claimants should be encouraged to relocate activities outside of the scope of the patent box to the UK, allowing them to benefit from the effect of blending profits taxed at relatively higher and lower rates to an overall rate closer to the global minimum tax rate of 15 per cent. It is also thought that multinational corporations that are not currently invested in the UK may be further encouraged to migrate assets and activities to the UK to enjoy that same blending effect.

- 1.4. **Reduce UK visa costs and speed up processing times in line with other leading economies** to ensure the UK can attract the highly skilled international talent who perform groundbreaking discovery science and power growth in the life sciences sector. A 2024 analysis of visa costs undertaken by the Royal Society found that UK costs are now up to 17 times higher than an average of 17 other leading science nations including Australia, Canada, France, Germany, Japan, Sweden and the US. When the same analysis was carried out in 2021, UK costs were up to 10 times higher^{xvi}. This has been identified as a significant weakness in the UK's attractiveness to foreign talent by the Futures Group – an expert advisory group of the UK's Life Sciences Council.
- 1.5. **Prevent people from leaving the labour market by delivering on the outcome of the occupational health tax incentives consultation with an ambitious expansion of non-taxable health support.**

The CBI has shown that action on tax incentives for employee health support would ease labour market pressures and boost the economy by £2.65 billion over the next four years.^{xvii} This should include making employee assistance programmes a fully tax-free benefit, allowing more employees to access mental health support, relaxing tax rules to enable early occupational health referrals, enabling employees to claim eye tests on expenses, allowing an exemption for adult vaccinations to prepare for future pandemics, removing the cap for health screening and medical check-ups, and allowing tax-free private GP consultations and private medical insurance. This would radically simplify the tax system, incentivise employers to invest in the health of their workforce and stem the flow of economic inactivity.

2. Improving UK attractiveness for industry R&D

The R&D of new medicines and vaccines is a powerful contributor to economic growth. In the UK, life sciences represent the top-spending private R&D sector, driving medical progress and bringing new treatments to patients that can transform their quality of life.

However, this impressive performance has seen some decline, notably in the number of UK clinical trials taking place, which dropped rapidly during the pandemic, and has not recovered as fast as other countries (although there are now some early signs of recovery). Clinical research accounts for around half of global pharmaceutical R&D investment^{xviii}, so it is important that the UK restores its reputation as a destination of choice of industry clinical trials.

In addition, UK data infrastructure is heavily fragmented and in need of reform.

To address these issues, the UK must target public funding towards creating the cutting-edge assets and expertise needed to attract inward investment. It must also focus on creating the right infrastructure to take innovation from laboratories through clinical trials and all the way to becoming approved medicines used by the NHS.

Recommendations for the 2024 Autumn Budget:

2.1. Maintain public R&D spending at current levels with an index-linked increase for FY25/26, with a longer-term ambition to commit the UK to achieving the highest level of public R&D investment in the G7. This would require an uplift in annual R&D budgets from an estimated £20 billion (2024/25)^{xix} to around £24 billion over the course of this parliament. This equates to around 1 per cent of GDP spent on public R&D budgets. Combined with private and third sector spending on R&D, this would likely take UK net expenditure on R&D to around 3.5 per cent of GDP, placing the UK above the US (3.45 per cent, 2021–22) and in first place among G7 nations.^{xx}

Ambitious, long-term and sustainable investment in R&D is the foundation upon which the UK's economic prosperity and global competitiveness rest: it will build confidence in the UK as a place to do business, leverage inward industry and cement the UK's role as a life sciences powerhouse.

2.2. This funding should be directed into research that would support the government's missions, including kickstarting economic growth and building an NHS fit for the future. For instance, targeted government investment in a major cross-sector initiative to **develop pre-clinical models that better replicate human disease** would make the UK a global leader in models to study disease and test new medicines. The lack of scientifically robust laboratory models that resemble human biology is a major barrier to predicting the likely success of a new treatment. It is the reason why over a quarter of new medicines fail when they enter clinical development^{xxi}. Delivering on Labour's manifesto commitment to accelerate the creation of robust laboratory models is too great a challenge for any one organisation or company to overcome. Solving this problem requires a coordinated programme of models development, which will lead to faster development of safe and effective medicines. There is consensus amongst research funders, academics and industry, that with government backing, the UK is uniquely placed to collaboratively tackle this challenge and become a beacon for attracting

pharmaceutical industry investment in medicines discovery in the UK. We are seeking government commitment to fund a cross-sector initiative that will catalyse pharmaceutical industry investment and propel the UK into a global leader in medicines discovery.

- 2.3. Restore the UK’s reputation as a destination of choice for industry clinical trials.** In recent years, the number of industry trials placed in the UK has been in sharp decline. Yet in 2022, industry clinical trials supported 65,000 UK jobs, including 13,000 in the NHS, and created £6.5 billion GVA, including £1.2 billion revenue for the NHS.^{xxii} *The value of industry clinical trials to the UK*^{xxiii} shows that restoring the proportion of global trials run in the UK to 2017 levels could generate an additional £3 billion of GVA per year, and 26,000 new jobs, including 5,000 jobs in the NHS. Clear government commitment to supporting industry trials will lead to more trials being run in the UK, with higher numbers of UK patients benefiting from cutting-edge treatments and increased economic growth.

To deliver on this potential, the government should bring clinical trials legislation that has been outstanding since the UK left the EU into law and accelerate delivery of O’Shaughnessy Review recommendations. This should be done by investing at least an additional £60 million per year in workforce capacity and stimulating industry clinical research in primary care, alongside the £300 million that industry will contribute to boosting delivery of trials through the VPAG investment programme.

- 2.4. Establish an internationally competitive dedicated health data research service that consolidates and expands on existing government services to finally realise the promise of NHS data to improve UK health and wealth.** The government’s Clinical Practice Research Datalink (CPRD), which encompasses 30 per cent coverage of UK GP data linked to a range of nationally collected secondary care datasets, is extensively used for research by the global pharmaceutical industry, medicines regulators including the MHRA, FDA and Health Canada, and academia.^{xxiv} The CPRD operates on a fully cost-recovery basis, the only UK health data research service to do so. The CPRD’s annual income in 2023/24 was £16.4 million,^{xxv} demonstrating that with the right expertise and user-centred services, it is possible to cover operational costs and generate revenue from research using NHS data. To fully realise the opportunity offered by NHS data, the government should establish a single dedicated health data research service in England that expands the CPRD’s services and combines these with centrally collected national datasets from NHS England. The service should focus on delivering research services, providing a return on government investment and delivering profits to the NHS, and it will be essential for the government to gain the trust of the GP profession, patients and the public at the outset. Through more effective deployment of government funding to create an internationally competitive health data research service, there

are significant opportunities to attract additional inward investment, which will benefit the NHS and lead to improved patient outcomes.

3. Realising the full benefit of innovative medicines and vaccines

Medicines and vaccines are a valuable healthcare investment. With research from the IPPR and others showing that economic inactivity due to sickness is at a record high, they should be seen as playing a critical role in delivering growth.^{xxvi}

Analysis by the OBR found that the rise in economic inactivity due to sickness, combined with in-work sickness, was already associated with an £8.9 billion annual tax loss in 2023/24^{xxvii}.

Recent research by the TBI has found that a 20 per cent reduction in the incidence of six major diseases could raise GDP by £26.3 billion annually within 10 years, with medicines and vaccines having a key role in doing so^{xxviii}.

Research by PwC has found that if the UK were to increase the use of just four classes of medicines to NICE-recommended levels, it would deliver 429,000 additional years of life in good health for patients and £17.9 billion in productivity gains for the UK.^{xxix}

However, UK patients are missing out on some of the best standard of care treatments, with high levels of variation in access and adoption across the country and in some cases some of the lowest use of new medicines in the developed world.^{xxx, xxxi}

The new government must take a long-term approach, that recognises the need to prepare the NHS for the new innovations in the pipeline and invest in medicines and vaccines that have the potential to transform patient outcomes and drive economic growth.

Recommendations for the 2024 Autumn Budget:

3.1. **NICE should immediately review the severity modifier in England to adjust downwards the cut-off levels used to determine the degree of severity, so that more patients can benefit from innovative medicines – a measure that will not increase cost to the NHS because of the cap provided by the 2024 VPAG.**

Following an extensive review in England in 2022, NICE updated the methods and processes it follows to evaluate new medicines and replaced the ‘end-of-life modifier’ algorithm with a new ‘severity modifier’. This was intended to give extra weighting to a broader range of medicines that treat severe diseases, and also impacts the systems used in Wales and Northern Ireland.

The concept of the severity modifier was welcomed as a positive development because it had the potential to benefit patients with a wider range of conditions, for example musculoskeletal, inflammatory and mental health, in addition to cancer.

However, when it was introduced, NICE stated the change to the severity modifier should be ‘opportunity cost-neutral,’ meaning that, all else being equal, the total

value across the board from the severity modifier would be equal to the previous end-of-life modifier.

The ABPI was clear that the opportunity cost neutral requirement could risk a situation where some patients with severe conditions could miss out on late-stage treatments that they would have otherwise benefited from.

Since then, the ABPI has been monitoring the impact of NICE's changes by gathering evidence from our members. Our data indicates that the severity modifier is so far being applied on a more conservative basis than is needed even to deliver opportunity cost neutrality.^{xxxii} As such, some medicines have not secured a positive recommendation that might have been approved using previous criteria.

- 3.2. NICE should replace the opportunity cost-neutral approach to implementing the modifier.** Instead, NICE should use an approach that is evidence-based and better reflects societal preferences for helping people with severe disease to access innovative treatment.
- 3.3. Enable NHSE to update the NHS Commercial Framework to ensure better patient access to innovative products, including those for rare diseases and cancer, and re-invigorate the UK's appeal as a launch market.**

The NHS Commercial Framework sets out how companies can work with NHSE on medicines access and commercial arrangements.

An update to the framework was agreed as part of the VPAG, with the review currently live, and this is currently the highest priority for industry. An ambitious approach will ensure better patient access to many products, including those for HIV, rare diseases and cancer, and will re-invigorate the UK's appeal as a launch market.

Most importantly, the industry wants to see an ambitious approach to indication-based pricing and a removal of the requirement to provide additional value beyond the cost-effective price established by NICE.

This would send a positive signal about the ambitions of the government to stimulate investment in the UK and would better future-proof the NHS for the innovation in the pipeline. It would also help to overcome the growing challenge companies face bringing medicines to the UK. Our data shows that between 2019/20 and 2022/23, more than 60 medicines/indications were either not launched or had a delayed launch in the UK, impacting more than 300,000 patients. Nearly 70 per cent of these decisions were made due to limitations in NICE's methods/decision-making framework or lack of NHSE commercial flexibility.

Again, this measure will not increase cost to the NHS because of the cap provided by the 2024 VPAG.

3.4. Provide adequate funding for the national immunisation programme, and review and respond to outstanding recommendations made for the programme by the Joint Committee on Vaccination and Immunisation.

This would allow swift implementation of new cost-effective vaccination programmes, which would deliver immediate public health benefits. Data shows clearly that adult vaccines can return up to 19 times their initial investment to society, when their significant benefits beyond the healthcare system – such as productivity impact - are monetised.^{xxxiii} In fact, many UK immunisation programmes are directly cost-saving for the NHS.^{xxxiv}

3.5. Announce a formalised, system-wide approach to horizon scanning for vaccines. This would improve the time to population access for new preventative vaccines, and enable the Department of Health and Social Care (DHSC) to better forecast immunisation budgets over a longer-term. Unanticipated pressures risk difficult reprioritisations or calls for HMT Reserve Claims, refusal of which could cause the system visibly to fail to implement JCVI recommendations that would reduce the burden of vaccine preventable disease.

3.6. The application of VAT rules to Advanced Therapy Medicinal Products (in particular cell and gene Therapies) should be reviewed to ensure consistent rules and guidance are applied. Inconsistencies have been identified in how these products are classified and therefore the application of VAT varies. To ensure consistent treatment for manufacturers, and to provide greater certainty and clarity for procurers (including the NHS) and bodies like NICE which assess the clinical effectiveness and cost-effectiveness of medicines, these rules and the associated guidance should be assessed.

4. Deliver a globally competitive regulatory system that supports innovation and enhances patient access to new medicines

A predictable, well-resourced and reliable regulatory environment is key to unlocking growth, attracting, and retaining inward investment to the UK. In an increasingly competitive global life sciences market, national regulatory frameworks are a key consideration when companies make decisions on where and when to locate their activity.

It is vital for the UK to provide a globally competitive approval system that is both proportionate and committed to ensuring patient safety, while also being attractive to inward investment and industry research and development.

To support the attractiveness of the life science ecosystem, the ABPI will shortly come forward with a new report on the future of the UK regulatory framework with a focus on access pathways, offering evidence-based recommendations to help unlock the innovative

potential of the pharmaceutical industry and develop a distinctive globally competitive regulatory offer for the UK that will promote confidence and growth in the sector.

Recommendations for the 2024 Autumn Budget:

- 4.1. Sufficiently resource the MHRA to enable the UK to develop a world leading regulatory offer.** Current capacity and reliability challenges are issues that place limitations on the regulator's ability to offer a predictable and quality service. The MHRA must be appropriately resourced and have access to the right expertise if it is to offer innovative regulation that is attractive in a globally competitive market. This must include funding the agency's new IT system RegulatoryConnect to completion so that it can deliver benefits to industry, driving efficiencies and easing regulatory burden.
- 4.2. Enhance and ring fence resourcing for a refreshed and relaunched Innovative Licensing and Access Pathway (ILAP).** ILAP was introduced to help deliver rapid approval for the most innovative new medicines through a synergised path from regulation, Health Technology Assessment and subsequent NHS adoption. Yet its potential remains largely unrealised due to a lack of sustainable strategic direction and sufficient resource. These fundamentals need to be addressed so that novel medicines get to UK patients as quickly as possible.

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- ⁱ ONS, 'Business Enterprise Research and Development statistics 2022' available at <https://www.ons.gov.uk/economy/governmentpublicsectorandtaxes/researchanddevelopmentexpenditure/bulletins/businessenterpriseresearchanddevelopment>
- ⁱⁱ ONS, 'Regional gross value added (balanced) by industry: all ITL regions', 2021. Methodology available at: <https://staging.sector-insights-map.abpi.org.uk/sources/>
- ⁱⁱⁱ ONS, 'Industry Census Data 2021', available at: www.ons.gov.uk/datasets/TS060/editions/2021/versions/1 (methodology available at <https://staging.sector-insights-map.abpi.org.uk/sources/>)
- ^{iv} Gov.UK, 'Secretary of State makes economic growth a priority', July 2024, available at <https://www.gov.uk/government/news/secretary-of-state-makes-economic-growth-a-priority>
- ^v ABPI, 'Life Sciences Superpower report', June 2022, <https://www.abpi.org.uk/publications/abpi-life-sciences-superpower-report/>
- ^{vi} *ibid.*
- ^{vii} *ibid.*
- ^{viii} ABPI, 'Life Sciences Superpower', June 2022, available at <https://www.abpi.org.uk/publications/abpi-life-sciences-superpower-report/>
- ^{ix} Labour Party, 'A prescription for growth', 2024, available at <https://www.bioindustry.org/static/6d6bb7a2-d7e5-4abc-bad4ee8fc02c1c17/Labours-plan-for-the-life-science-sector.pdf>
- ^x *Ibid.*
- ^{xi} Office for Life Sciences analysis <https://www.gov.uk/government/publications/life-sciences-innovative-manufacturing-fund-lsimf>
- ^{xii} Medicines Manufacturing Industry Partnership, 'Follow the green high-tech road', June 2023, available at <https://www.abpi.org.uk/media/he0p1ojq/mmip-2023-report.pdf>

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- xiii Labour's Business Tax Plan (1 February 2024)
- xiv CBI, 'Delivering for business: the CBI's impact in 2023', December 2023, available at <https://www.cbi.org.uk/articles/delivering-for-business-the-cbi-s-impact-in-2023/>
- xv Analysis undertaken by Flint Global and commissioned by GSK – available on request
- xvi The Royal Society, 'Summary of visa costs analysis (2024)', August 2024, available at <https://royalsociety.org/news-resources/publications/2024/summary-visa-costs-analysis-2024/>
- xvii CBI, 'Government can boost economy by £2.65bn with employee health tax incentives', August 2024, available at <https://www.cbi.org.uk/media-centre/articles/government-can-boost-economy-by-265bn-with-employee-health-tax-incentives/>
- xviii PhRMA, '2023 PhRMA Annual Membership Survey', available at [PhRMA_membership-survey_single-page_70523_es_digital.pdf](https://www.phrma.org.uk/media-centre/articles/2023-phrma-annual-membership-survey)
- xix UK Parliament, 'Research and development funding policy', April 2023, available at <https://commonslibrary.parliament.uk/research-briefings/cbp-7237/>
- xx OECD, 'Gross domestic spending on R&D', 2021, available at: <https://www.oecd.org/en/data/indicators/gross-domestic-spending-on-r-d.html?oecdcontrol=8027380c62-var3=2021>
- xxi Scannell, J.W., Bosley, J., Hickman, J.A., Dawson, G.R., Truebel, H., Ferreira, G.S., Richards, D., Treherne, J.M., 'Predictive validity in drug discovery: what it is, why it matters and how to improve it', *Nature Reviews Drug Discovery*, 2022, 21(12), pp. 915–31
- xxii ABPI, 'Getting back on track: Restoring the UK's global position in industry clinical trials', November 2023, available at <https://www.abpi.org.uk/publications/getting-back-on-track-restoring-the-uk-s-global-position-in-industry-clinical-trials/>
- xxiii ABPI, 'The value of industry clinical trials to the UK', September 2024, available at: <https://www.abpi.org.uk/publications/the-value-of-industry-clinical-trials-to-the-uk/>
- xxiv MHRA, 'Bibliography', available at <https://www.cprd.com/bibliography>
- xxv MHRA, 'MHRA Annual Report and Accounts 2023–2024', July 2024, available at [MHRA Annual Report 2024 low res.pdf \(publishing.service.gov.uk\)](https://www.mhra.gov.uk/publications/mhra-annual-report-and-accounts-2023-2024)
- xxvi *Economic inactivity due to long-term sickness stands at 2.83 million, while the number not participating in the labour market due to long-term and short-term illness combined has broken 3 million*
- xxvii OBR, 'Fiscal risks and sustainability – July 2023', July 2023, available at <https://obr.uk/frs/fiscal-risks-and-sustainability-july-2023/>
- xxviii TBI, 'Prosperity Through Health: The Macroeconomic Case for Investing in Preventative Health Care in the UK', July 2024, available at <https://www.institute.global/insights/economic-prosperity/the-macroeconomic-case-for-investing-in-preventative-health-care-UK>
- xxix ABPI, PwC, 'Transforming lives, raising productivity', May 2022, available at <https://www.abpi.org.uk/publications/pwc-transforming-lives-raising-productivity/>
- xxx The King's Fund, 'How does the NHS compare to the health care systems of other countries?', June 2023, available at https://assets.kingsfund.org.uk/f/256914/x/7cdf5ad1de/how_nhs_compares_other_countries_abpi_2023.pdf
- xxxi Gov.UK, 'Ministerial foreword, section 2: domestic market', July 2023, available at <https://www.gov.uk/government/publications/life-sciences-sector-data-2023/life-sciences-competitiveness-indicators-2023#section-2-domestic-market>
- xxxii ABPI, 'Reviewing implementation in practice of the NICE Health Technology Evaluation Manual – CONNIE August 2024', August 2024, available at <https://www.abpi.org.uk/publications/reviewing-implementation-in-practice-of-the-nice-health-technology-evaluation-manual-connie-august-2024/>
- xxxiii El Banhawi H., Chowdhury S., Neri M., Radu P., Besley S., Bell E., Brassel S., Steuten L., 2024. The Socioeconomic Value of Adult Immunisation Programmes. OHE Contract Research Report: Office of Health Economics. Available at: <https://www.ohe.org/publications/the-socio-economic-value-of-adult-immunisation-programmes/>
- xxxiv UK Health Security Agency. UKHSA Advisory Board Enclosure AB/24/026. May 2024. Available at [AB-24-026 Immunisation Schedule.pdf \(publishing.service.gov.uk\)](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/123456/AB-24-026_Immunisation_Schedule.pdf)