ABPI Briefing

10th March 2023

Secondary Legislation Scrutiny Committee Submission: The Branded Health Services Medicines (Costs) (Amendment) Regulations 2023

Executive Summary

Government has laid a Statutory Instrument[i] before the House which will increase the rebate charged on branded medicines in the UK under the Statutory Scheme for Branded Medicines Pricing and Access (known as the 'Statutory Scheme') to 27.5% of companies' revenues.

ABPI believe that the update to the Statutory Scheme is of interest to the Committee, in line with its terms of reference because:

a. **It gives rise to issues of public policy** – as it will have a significant unintended negative impact on R&D investment from Life Sciences companies in the UK, as well as the launch and sustainability of medicines.
b. **It may imperfectly achieve its policy objective** – Government has stated that the Statutory Scheme - and an associated Voluntary Scheme - should "create an environment where medicines are supplied at an affordable price, in a way consistent with supporting both the life sciences sector and the broader economy". These amendments may support the affordability of medicines expenditure, however, will do so whilst negatively impacting the sector and economy.
c. **There were inadequacies in the consultation process** – which was short and failed to fully consider the evidence on the entire Life Sciences sector and patient access to medicines.

Background to the Statutory Scheme

- The Statutory Scheme is one of two Schemes in the UK - alongside the 2019 Voluntary Scheme for Branded Medicines Pricing and Access (known the 'Voluntary Scheme') - which control the prices of branded medicines to the NHS.
- The Schemes operate through rebate mechanisms, where companies pay a percentage of their net revenue back to Government.
- As of 2023, rates in the Voluntary Scheme are 26.5% and the SI sets out that rates in the Statutory Scheme will rise to 27.5%.
- ABPI responded to the consultation on this SI on behalf of our members and highlighted that this is a rapid escalation from historic norms. The average payment rate in the Statutory Scheme across the last four years was 10.6%, and this increase is having a demonstrably harmful impact on the life science industry.[ii]
- *N.B. More information on the background to the Statutory and Voluntary Scheme can be found in the Appendix.*

Inadequacies in the consultation process

Timing

The consultation timeframe was very short, running for only 6 weeks over the Christmas period (from 16th December 2022 to 26th January 2023). This made it difficult for companies to undertake the necessary analysis about the impact of the rate and to make the evidence base for their submissions as comprehensive as possible.

This also meant there was very limited time for the ABPI to collate and interpret the necessary data from our member companies.

Impact Assessment

The ABPI and our members do not agree with the methodology used in the economic Impact Assessment (IA) to assess the benefit of the proposal, with many points requiring clarification and further consideration.

- **Narrow focus of the IA**: The Government response to the consultation only looks at the incremental impact of increasing rates from 24.4% to 27.5% and relies on the impact of the policy decision being confined to those companies directly in the Statutory Scheme (and not the Voluntary Scheme), and only impacting within 2023.
- ABPI disagrees with this because:
    a. The Statutory Scheme rates have been set to apply indefinitely, meaning the 2023 rate will likely be used in company planning assumptions in 2023 and beyond. Instead, the ABPI proposed that these should be sun-setted at the end of 2023;
    b. Given that the current Voluntary Scheme is set to expire at the end of 2023, should there not be a successor to the current Voluntary Scheme, the Statutory Scheme payment rates will by the default rates applied across the whole branded medicine industry;
- **Research and Development**: The Government impact assessment, and final response did not recognise a link between payment rates and investment in the UK.
- The ABPI and individual companies provided evidence to demonstrate the impact that such payment rates are already having on company investment decisions.
- The Government response stated that *"our view remains that supply-side factors are of greatest impact compared to demand-side factors in company decisions about where to locate globally mobile investments".*
- In making this assessment Government cited several sources, predominantly published before 2010. Further analysis demonstrates that this is a misinterpretation of the evidence as follows:
    a. **Key evidence referenced (published 2007) in the IA pre-dates the establishment of the UK clawback mechanism**, and not factoring in the magnitude of clawback rates which are historically unprecedented.
    b. **Oversimplification of conclusions made in the IA**, asserting that reduced R&D investment will be distributed evenly across global markets. Contrariwise, the source

data referenced in Government's own response states that "*executives' perception of market conditions is an additional variable that can become an important factor in the overall choice [of where internationally-mobile investment is located]*".

c. **Lack of consideration for how commercial environment factors can themselves affect the supply-side.** For instance, the IA highlights expert scientific knowledge and skills as a key determinant of where R&D expenditure is directed. Yet there is no discussion of how reduced revenues from higher payment rates will affect the investment needed to develop the skills base in the UK.

- **Access to Medicines**: The IA sets out that the Government considered the risk that the payment rates would delay or pause the launch of new medicines in the UK to be 'remote'. This is despite the ABPI and companies sharing examples of the impact on launches of new medicines and indications when payment rates were only 15% or lower.
- This IA further contradicts a previous statement by the Government in 2020, that were payment rates to become 'too high' this could affect supply and innovation. In that statement Government concluded that would happen if the rates were set at 20.5% in the Statutory Scheme (and 14.7% in the Voluntary Scheme).

Consideration of the Consultation Responses

- The Government consultation response acknowledges that the majority of respondents disagreed with the proposed rebate rate (32 out of 33).
- The ABPI has shared tangible examples of the negative impact on the UK due to the increasing Statutory and Voluntary Payment rates, which is supported by the worsening Life Sciences indicators across a broad set of metrics[iii]:
    - The UK has already fallen down the global rankings across all phases of industry clinical trial delivery between 2018-2020;
    - UK manufacturing production volumes have fallen by 29% since 2009;
    - The UK's share of global pharmaceutical R&D has **fallen by over one-third** 2012 to 2020;
    - Compared to other leading EU countries (Italy, Spain, Germany, France), the UK has experienced the largest decline in its global share of new medicine launches between 2016-2021.
- More generally, the ABPI believe that the Government should engage with the evidence presented in a series of Statutory Scheme consultation responses from ABPI and industry respondents more generally.

Impact of proposed changes – issues of public policy and imperfect measures to achieve the aim of the legislation.

- The Government states that the purpose of the Statutory Scheme (and Voluntary Scheme) is to "create an environment where medicines are supplied at an affordable price, in a way consistent with supporting both the life sciences sector and the broader economy."[iv]
- This is underpinned by the Parent Act to the Statutory Scheme, which requires the Government consult on; the economic consequences for the life sciences industry; the consequences for the economy; and the consequences for patients.[v]
- However, the increased rate of 27.5%, will have a negative impact on the life sciences sector and broader economy, as well as harm the quality of health services, outcomes, and research within the UK. Responses to the Statutory Scheme consultation from companies and ABPI evidenced this negative impact.
- This is also contrary to the Government's stated aim to grow the life sciences industry, as set out in the Life Sciences Vision and as recently articulated by the Chancellor, who identified the life sciences as one of three key growth sectors. [vi]

Impact on life sciences sector and the economy

- Currently, the life sciences industry is one of the most valuable sectors to the economy, investing more in R&D than any other private sector in the UK, worth £4.7 billion in 2019 and contributing 584,000 jobs across a diverse geographic presence. [vii]
- However, global CEOs have stated the relationship between payment rates and the level and location of investment in R&D. The proposed rate of 27.5% will place the UK as a global outlier. In countries that do operate similar clawback mechanisms, current rates include 12% in Germany, 7.5% in Spain and 9% in Ireland.
- The link between payment rates and investment exists for several reasons. Amongst the most important, is that placement of clinical research takes into consideration subsequent expected patient uptake and medicine sales in that country. Early clinical experience through trials results in increased clinical awareness and preparedness - especially where a medicine will require complicated pathway change.
- A comprehensive and up to date look at the literature review found that 44 of the 49 studies reviewed showed a significant negative relationship between drug price controls and investment in pharmaceutical R&D or access to innovative drugs" (Labrie, 2020).
- This connection is further evidenced by analysis commissioned by the ABPI, which found continued high payment rates in both the Statutory and Voluntary Scheme would cost the UK £50 billion in GDP and 17.9 billion in tax revenues, as a result of lost R&D investment of £5.7 billion by 2028.[viii]
- Due to company planning cycles, disinvestment decisions at a global level are difficult to reverse, and the long-term implications for the UK have yet to be seen.
- Two case studies are provided below:
  - **AstraZeneca** recently announced a major expansion of its research footprint in Canada, creating over 500 new highly skilled jobs and a new research and development hub.

AstraZeneca commented: *"We're pleased to see the steps that governments at both the provincial and federal level have taken to create a more supportive environment for the biopharmaceutical industry".*

Prime Minister Justin Trudeau commented: "*To deliver better healthcare, it's important to invest in our public, universal system – and it's also important to continue rebuilding our biomanufacturing capacity and investing in research and development. That's exactly why we're here today: we're positioning Canada as a world leader in the sector, delivering better health outcomes for Canadians, and creating good jobs now and into the future*."

- **AbbVie** – who have recently moved into the Statutory Scheme – have undertaken difficult decisions to manage their organisation's operations in the UK sustainably, which has regrettably included disinvestment from certain R&D activities to manage the high repayment rates seen in 2022/23. This includes a meaningful reduction in our UK headcount. Examples of disinvestment include but are not limited to:
  - Four UK data and real-world evidence studies have been halted, some of which are continuing in other countries. These types of research and registries seek to improve patient care and advance NHS clinical practice.
  - Two investigator-initiated studies have not been funded. These studies provide patients with access to innovation and would have provided additional revenue streams to the NHS if they had gone ahead as initially planned.
  - Discontinuation of an initiative to support promising UK biotech companies by providing free laboratory space to facilitate technology advancement and company scale-up. This lost opportunity is of critical focus of successive Government life sciences initiatives, during a time when there is wide recognition that lack of lab space is holding back innovative start-ups in the UK.
  - Medical resource reprioritisation has reduced AbbVie's ability to engage in clinical education and training in the NHS across all therapeutic areas. These programmes support new healthcare standards and clinical techniques being adopted throughout the NHS, and are also supportive of the Secretary of State's statutory duty to enable continuous medical education for NHS staff.
  - Further programmes to support NHS recovery through system transformation are either not proceeding or are under review.

Impacts on patients and the NHS

- The ABPI is further concerned that the proposed rates in the Statutory Scheme could impact on the supply and launch of medicines in the UK.
- There are several factors that impact on the availability of drugs in a country, and price regulation, and the overall level of net prices, is one of those.
- This is consistent with statements by the Department of Health and Social Care in 2020, who noted that lowering the payment rate would "help to ensure the continued availability of medicines to patients".
- With key innovations coming down the Life Sciences pipeline, targeted to address the UK's key health missions such as dementia, cancer and cardiovascular, including

obesity, any delay in access to medicines will have a detrimental impact on patient outcomes and loss of productivity in the economy.

Further reading

1. ABPI's response to the Statutory Scheme consultation (executive summary only – full response redacted due to commercial sensitivity) https://www.abpi.org.uk/media/htnlhdlm/abpi-stat-scheme-consultation-response-executive-summary-31-january-2023.pdf

Appendix: Background to the Statutory Scheme

- The Statutory Scheme is one of two Schemes in the UK - alongside the 2019 Voluntary Scheme for Branded Medicines Pricing and Access (known the 'Voluntary Scheme'), which control the prices of branded medicines to the NHS.
- A Voluntary Scheme has existed in some form or another in the UK for over 65 years, and there is no direct equivalent in any other country. Whilst Government policy is to seek 'broad commercial equivalence', the Statutory Scheme has historically had less favourable terms than the Voluntary Scheme (VPAS), acting as a 'back-stop' and discouraging companies from leaving the VPAS.
- The current Schemes operate through rebate mechanisms, where companies pay a percentage of their net revenue back to Government.
- Currently, the majority of pharmaceutical companies operating in the UK are within the Voluntary Scheme. However, the escalating payment rates have led some companies to withdraw from the Voluntary Scheme and move into the Statutory Scheme.[ix]
- Although the Statutory Scheme is currently even more punitive, certain companies have decided they cannot be seen to consent to such high rates, concerned about the signal this sends to healthcare payers and healthcare systems globally.
- It is possible that a new Voluntary Scheme will not be in place by the time the current one expires on 31 December 2023 and negotiations for a successor scheme have yet to begin. This increases the impact and therefore importance of the Statutory Scheme rates published, effective from 1st April 2023. Companies have to make short- and medium-term plans based on the policy direction signalled, in the knowledge that the entire branded medicine market might be subject to such policy direction from 1st January 2024.

About ABPI

The ABPI exists to make the UK the best place in the world to research, develop and use new medicines and vaccines. We represent companies of all sizes who invest in discovering the medicines of the future.

Our members supply cutting edge treatments that improve and save the lives of millions of people. We work in partnership with Government and the NHS so patients can get new treatments faster and the NHS can plan how much it spends on medicines.

Every day, we partner with organisations in the life sciences community and beyond to transform lives across the UK.

[i] https://www.legislation.gov.uk/uksi/2023/239/made?view=plain
[ii] https://www.abpi.org.uk/publications/abpi-statutory-scheme-consultation-response-executive-summary-31-january-2023/
[iii] https://www.abpi.org.uk/r-d-manufacturing/building-a-thriving-environment-for-medicine-discovery/life-sciences-superpower-growing-the-leading-global-hub-in-the-uk/
[iv] https://www.gov.uk/government/consultations/proposed-update-to-the-2023-statutory-scheme-to-control-the-costs-of-branded-health-service-medicines/outcome/proposed-changes-to-the-statutory-scheme-to-control-the-costs-of-branded-health-service-medicines-consultation-response
[v] https://www.legislation.gov.uk/ukpga/2006/41/contents
[vi] https://www.gov.uk/government/news/chancellor-sets-out-long-term-vision-to-grow-the-economy
[vii] https://www.abpi.org.uk/r-d-manufacturing/building-a-thriving-environment-for-medicine-discovery/life-sciences-superpower-growing-the-leading-global-hub-in-the-uk/
[viii] https://www.abpi.org.uk/media/ofrnfc3d/wpi-false-economy-report-20230220-2.pdf
[ix] https://pharmaphorum.com/news/abbvie-lilly-pull-out-of-uk-voluntary-drug-pricing-agreement

Response from Department of Health on Social Care

March 2023

Background:

Medicines make up a significant proportion of the NHS budget – circa £17.8bn of spend in England (21/22), the majority of which (£13.6bn) is spent on branded medicines. By controlling growth in the cost of medicines we ensure value for money for the taxpayer and enable the NHS to continue investing in patient access to new medicines. We have two main mechanisms to control the branded medicines spend:

- The Voluntary Scheme for Branded Medicines Pricing and Access (VPAS) - an agreement between DHSC, NHSE and industry, under which we receive payments from pharmaceutical companies if sales exceed an agreed cap. The majority (>90%) of companies supplying eligible health service medicines to the NHS are members of VPAS

- The statutory scheme for branded medicine pricing – which sets out in Regulations the terms that apply to any company that supplies eligible branded health service medicines that chooses not to join VPAS.

It is intended that both schemes work together cohesively and in a complementary fashion to create an environment where medicines are supplied at an affordable price, in a way consistent with supporting both the life sciences sector and the broader economy. To this end, our longstanding policy is to maintain broad commercial equivalence between the two schemes. The update to the statutory scheme therefore largely reflects the recent increases in the payment percentages within VPAS. If left unchanged, the statutory scheme payment percentage would be meaningfully lower than that in VPAS in 2023. Given that 94% of payment companies are members of VPAS compared to 6% in the statutory scheme, it is likely that much of the opposition to the statutory scheme consultation originates from recent changes to VPAS.

The pharmaceutical industry, represented by the Association of the British Pharmaceutical Industry (ABPI), negotiated and signed the current VPAS in 2019, describing it as a "pro-innovation deal". Recent higher VPAS payment percentages are below those projected when VPAS was agreed in 2019 and reflect the scheme working as intended to adjust for increased sales of branded medicines to the NHS.

Annex A provides an explanation of the medicine pricing schemes.

SLSC Question	Departmental response
1. ABPI state that the increase of the rebate to 27.5% will have a significant negative impact on R&D investment from Life Sciences companies in the UK because: the average payment rate in the statutory scheme across the last four years was 10.6%, and this rapid escalation to 27.5% is having a demonstrably harmful impact on the life science industry.	
HoL Secondary Legislation Scrutiny Committee comment: *Please can you explain clearly the DHSC's rationale for increasing the rate in such large steps - from 10.9% to 14.3% in 2022 and by a further 10% to 24.4% in 2023.*	**Summary:** Maintaining medicines affordability is a key aim of the statutory scheme and of VPAS. The government aims to maintain the affordability of branded medicines spend across the NHS. By controlling growth in the cost of medicines, we deliver value for money for the taxpayer, enabling NHS patients to access new medicines and providing the resources needed to deliver the Life Sciences Vision. Growth in sales of branded medicines to the NHS increased rapidly from 2021 onwards and this has led to increases in the payment percentages in the statutory scheme. • Since it was established in its current form, the statutory scheme has been managed to ensure that the payment percentage in the scheme is broadly commercially equivalent to that in VPAS. The policy of broad commercial equivalence is widely understood and has been supported in previous consultations. • Increasing sales of branded medicines from 2021 has led to an increase in the payment percentage in both schemes. • The 2023 payment percentage also increased due to a request from ABPI, that DHSC agreed to, that in effect deferred part of the increased payment percentage due in 2022 to 2023. This amendment was mirrored, and had a similar effect, in the statutory scheme. • Accordingly, we have updated the statutory scheme to maintain broad commercial equivalence with VPAS • Failing to maintain our stated policy would see loss in revenues for the NHS; undermine the policy basis on which the schemes operate; and would be unfair for companies who chose to join/remain in VPAS on the basis that the government would uphold its stated policy in respect of the scheme. **Detailed response** The rationale for the payment percentages in the branded medicines pricing schemes is to control growth in sales of branded medicines to the NHS to manageable levels. Since the statutory scheme was established in its current form in 2018, we have maintained a policy of broad commercial equivalence between the statutory scheme and VPAS. This required increasing or decreasing the statutory scheme payment percentage through secondary legislation in each of 2018, 2020, 2022 and 2023 in response to

equivalent changes to VPAS payment percentages. In practice, this is achieved by controlling growth in expenditure under the scheme at 1.1% per year (2% in VPAS) and rates in the statutory scheme have been set by the outcome of this calculation to maintain broad equivalence with VPAS.

Table 1: comparison of payment percentages

Year	Payment percentage	
	VPAS payment %	Statutory scheme %
2019	9.6%	9.9%
2020	5.9%	7.4%
2021	5.1%	10.9%
2022	15%	14.3%
2023	26.5%	27.5% following this Statutory Instrument (24.4% prior to this Statutory Instrument)

The principle of broad commercial equivalence has been supported by respondents to recent consultations, even where they opposed increases in the payment percentage. The government is currently preparing to begin negotiations on a successor scheme to VPAS, which expires at the end of 2023.

VPAS payment percentages are in line with or below those forecast and shared with industry when the scheme was agreed with industry in 2018. Given the policy of broad commercial equivalence, the rates in the statutory scheme are within the range of reasonable expectations from when the statutory scheme was first established in 2018.

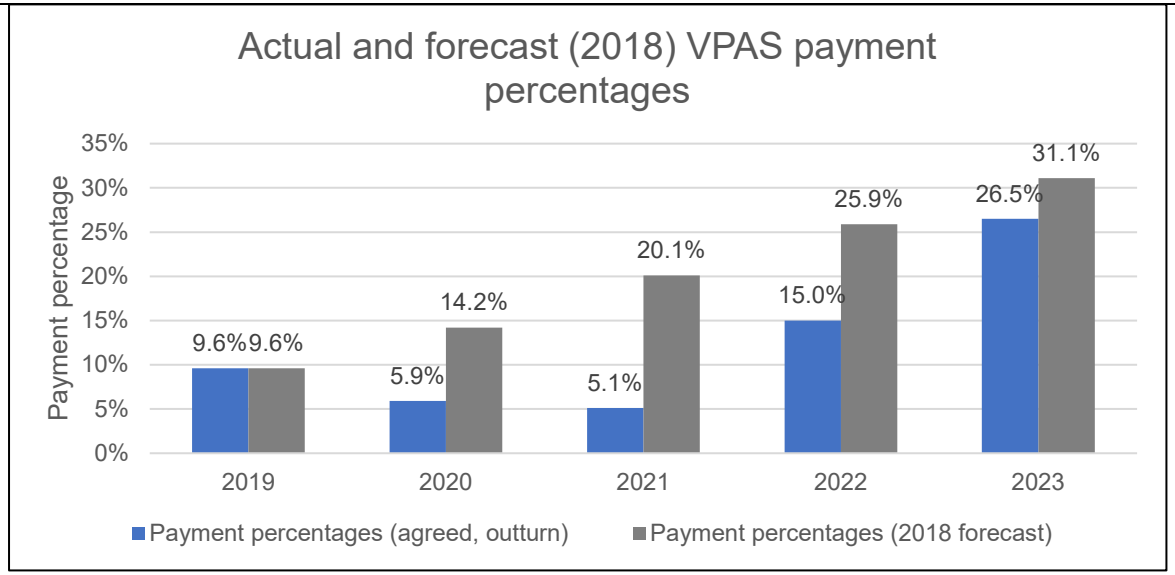

Figure 1: Actual ('agreed, outturn') VPAS payment percentages compared to those forecast when VPAS was agreed

If left unchanged, the statutory scheme payment percentage would be meaningfully lower than that in VPAS in 2023. This would have a number of impacts:

- we would see a reduction in revenue from the scheme for the NHS of £17m-£19m to 2023;
- we consider this would destabilise the medicine pricing schemes by allowing growth to exceed 1.1% within the statutory scheme and undermining the principle of broad commercial equivalence;
- moreover, our stated intention to continue to maintain broad commercial equivalence between the schemes was likely to be a significant factor behind the decision of many companies to remain in VPAS in 2023. As companies chose to join or remain in VPAS for 2023 did so on the basis that the government would uphold is stated policy in respect of the schemes, these companies may also be unfairly disadvantaged should the government subsequently fail to do so.

The rise in the payment percentage in VPAS from 2022 to 2023 is due to two main factors. Firstly, high growth in medicines sales in 2021 and 2022 meant the payment percentage increased to control growth in the schemes to the agreed levels. Secondly, the increase in the VPAS payment percentage between 2022 and 2023 is also in part due to the impact of the amendment agreed with the ABPI in January 2022 to in effect defer part of the payment calculated

	to be owed in 2022 to 2023, an amendment which industry welcomed at the time. Had this amendment not been agreed, the 2023 VPAS payment percentage would have been 22.6% rather than 26.5%. In order to maintain broad commercial equivalence, and to avoid significant financial loss to the NHS from companies benefitting from the lower rate in VPAS 2022 in and then avoiding making payments on their 2023 commitments, a near identical adjustment was made to the statutory scheme to lower the payment percentage in the scheme from 18.4% to 14.3%, with payments foregone by the Department in 2022 in effect deferred to 2023.

HoL Secondary Legislation Scrutiny Committee comment: *Please explain how restricting the increase in the cost of NHS medicines to 1.1% is not also restricting potential jobs and growth in an industry the IA describes as "one of the most important pillars of the UK economy".*	• By controlling growth in the cost of medicines we ensure value for money for the taxpayer and enable the NHS to continue investing in patient access to new medicines. UK medicines policy aims to ensure patients have access to the most innovative and cost-effective medicines they need, whilst ensuring the cost to the NHS is sustainable in the long term, and allowing the pharmaceutical industry to earn the money it needs to fund research and development into new and improved medicine.
	• The majority of companies supplying branded medicines to the NHS are members of VPAS which has higher allowed growth (2%) and contains additional exemptions for medium sized companies and innovative medicines containing a new active substance. All companies supplying branded medicines to the NHS are free to join VPAS and most have chosen to do so.
	• The question is premised on the assumption that the pharmaceutical industry in the UK develops, manufactures and sells medicines predominantly in the UK, whereas in fact the UK accounts for a small fraction (<5%) of global medicine sales and pharmaceutical investments are globally mobile, with the outputs of UK R&D and manufacture sold worldwide. This means that:
	  ○ investment decisions are made based on assessment of anticipated global returns, of which the UK share of sales is a small fraction and it is not therefore clear to what extent investment would fall.
	  ○ even if reduced pharmaceutical revenues lead to reduced investment, it is unclear how much of this reduction would occur in the UK. However, given the global nature of such investments, it is likely that only a fraction of that investment would have otherwise occurred in the UK.
	• While commercial factors will no doubt have some bearing on investment location decisions, available evidence[1] suggests that supply side factors - such as availability of expert scientific labour and favourable tax conditions - are

[1] Specifically used are:

- "Key Factors in Attracting Internationally Mobile Investments by the Research Based Pharmaceutical Industry", NERA Consulting for UK Trade and Investment, and the Association of the British Pharmaceutical Industry, September 2007.

	of greatest significance in the decision of where to locate such globally mobile investments. Most pharmaceutical decision makers will base decisions on economic considerations, and as such, will locate research and development and other investments more on cost and quality than local pricing arrangements. This is developed in detail in our responses to the question below, and in our response to the consultation. • It is also important to consider the opportunity cost of devoting an increased proportion of the NHS spend to medicines: The NICE standard threshold of £30,000 per quality-adjusted life year (QALY- i.e. one unit of 'health' gained) is substantially higher than the opportunity cost of £15,000 per QALY elsewhere in the NHS. This means that increasing spending on medicines at the expense of other healthcare spending may lead to worse patient outcomes. This is discussed in detail in our response to the consultation. • With regard to the wider economic benefit of spending on medicines, while it is true that spending on medicines has economic benefits, the same is true of wider healthcare spending. Given that the majority of revenues from the sales of medicines to the NHS will accrue to global pharma companies and global shareholders, the benefits of this spending are unlikely to be retained in the UK.
HoL Secondary Legislation Scrutiny Committee comment: *How does the increase proposed take into account the potential distortions of the medicines market from the effects of the pandemic?*	Such a line of argument assumes that growth is now artificially high as a result of the pandemic. The Department does not agree that this is the case: growth in medicine sales has been than, or in line with, the forecast made when the VPAS was agreed in 2018 (figure 1 above). COVID-19 vaccines and therapeutics were exempt from VPAS and sales of these products did not generate payments and did not have any impact on the payments made on products covered by the scheme. Moreover, DHSC addressed pandemic-related fluctuations by agreeing with industry to amend the 2022 payment percentage and in effect defer part of the rise due in 2022 to 2023.

- OECD. "Pharmaceutical Pricing Policies in a Global Market", OECD Health Policy Studies, OECD Publishing (2008).
- CRA EFPIA Investment Location - Final Report 031022 https://www.efpia.eu/media/676753/cra-efpia-investment-location-final-report.pdf (accessed 15/3/23)
- https://www.england.nhs.uk/2021/07/nhs-england-announces-new-innovative-medicines-fund-to-fast-track-promising-new-drugs/
- Revisiting the Relationship Between Price Regulation and Pharmaceutical R&D Investment | SpringerLink
- Biomed Alliance, Europabio & Johnson & Johnson (2022) Attracting Life Science Investments in Europe (accessed 15/3/23)
- The 2021 EU industrial R&D investment scoreboard - Publications Office of the EU (europa.eu)
- Global Startup Ecosystem Index 2022 by StartupBlink

<table>
<tr><td colspan="2">2. Evidence submitted by the ABPI to the consultation found continued high payment rates in both the Statutory and Voluntary Scheme would cost the UK £50 billion in GDP and £17.9 billion in tax revenues, as a result of lost R&D investment of £5.7 billion by 2028. wpi-false-economy-report-20230220-2.pdf (abpi.org.uk) This contrasts with an estimate of £1 million per annum lost R&D in the IA:
- The APBI submission gave evidence of various firms disinvesting from the UK including AstraZeneca setting up a research hub resulting in 500 jobs to Canada</td></tr>
<tr><td>HoL Secondary Legislation Scrutiny Committee comment: What is DHSC's response to the difference in those estimates?</td><td>Summary:
The ABPI report considers, primarily, the impact of a hypothetical successor voluntary scheme to VPAS over its lifetime, not an assessment of the current statutory scheme to 2023.
The report provides little economic evidence for the claimed impact on inward investment, relying instead on a survey of ABPI members who will have an inherent interest in demonstrating a link between medicine price controls and R&D investment.
The estimate provided by the report cannot be compared with the impact assessment, nor do we consider the conclusions of the ABPI report to be credible.
The ABPI report aims to quantify the hypothetical impact of the current rate if it is sustained over the lifetime of a successor scheme to VPAS (to 2028). However, such a scheme has not been agreed and is hypothetical at present. In line with HM Treasury’s Green Book guidance, the impact assessment compares the proposed option of a 27.5% payment percentage in the 2023 statutory scheme to the counterfactual of the previous rate of 24.4%. The appraisal period is one year only, reflecting the expectation that a consultation will be held later in 2023 regarding a new statutory scheme to apply from 2024.
Comparability:
The ABPI report considers the impact of the current payment percentages continuing over the period of a successor scheme to VPAS. However, the successor scheme to VPAS is yet to be negotiated. The cited report describes a hypothetical future system of medicine pricing encompassing both a statutory and voluntary scheme that do not exist.
Government has been consistently clear that it is open to ideas about how a successor to VPAS should operate from 2024 onwards and that it looks forward to working with industry to agree a mutually beneficial successor that supports better patient outcomes; ensures the sustainability of NHS spend on branded medicines; and enables a strong UK life sciences industry.
We have also set out that we consider a further consultation is likely to be necessary later in 2023 to define the terms of the statutory scheme from 2024
Moreover, the current payment percentage in both schemes results in part from the 2022 scheme amendment. This will not be a relevant factor in 2024.</td></tr>
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	Claims made • The report provides little economic evidence for the claimed impact on inward investment, relying instead on a survey of ABPI members who will have an inherent interest in demonstrating a link between medicine price controls and R&D investment. • Decisions regarding the location of pharmaceutical investment are complex and multi-factorial. While increased payment percentages will no doubt have some bearing on overall choices, available evidence suggests that supply side factors, such as availability of expert scientific labour and favourable tax conditions are of greatest significance in the decision of where to locate R&D activity (see the Impact Assessment of this SI pp22-26 and footnote 1 above for sources considered). • ABPI's report provides little additional economic evidence of pricing policy influencing inward investment decisions. We have considered the research they cite and remain of the view that supply side factors will be of greatest significance. • Even if such a link exists, the impact on UK GDP and tax revenues would be a fraction of that claimed in the report, as the vast majority of the returns generated by the R&D accrue to global pharmaceutical companies and global shareholders, and are not retained in the UK[2]. • Furthermore, the report compared Voluntary Scheme income over a 5-year time period to loss of tax revenue over a 30-year time period.
3. ABPI assert that the increase of the rebate to 27.5% will have a significant negative impact on the launch and sustainability of medicines, delaying the development and trials of a number of headline medicines.	
HoL Secondary Legislation Scrutiny Committee comment: *Please state DHSC's view*	The vast majority of companies are members of VPAS, which includes strong commercial incentives to launch new products in the form of freedom of list pricing and exemptions from payments (i.e. a payment percentage of 0% for 3 years) for innovative medicines containing a new active substance. Moreover, companies in both schemes benefit from the UK commercial environment, such as the high degree of flexibility in the approach to commercial dealmaking and access to the NHS, which is one of the largest single purchasers of medicines worldwide.
The APBI states that a Government statement in 2020 said that were payment rates to become 'too high' this could affect supply and innovation and referenced the tipping point as rates were set at 20.5% in the statutory scheme (and 14.7% in the Voluntary Scheme).	

[2] Including the following:

- DBT analysis of ONS/Business Enterprise Research and Development data
- Research and Development in the Pharmaceutical Industry | Congressional Budget Office (cbo.gov)
- OLS analysis of Business Population Estimates data and Business enterprise research and development data, provided in correspondence

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<tr><td>HoL Secondary Legislation Scrutiny Committee comment: This seems inconsistent with the current policy, please explain</td><td>This is a mischaracterisation of the position set out in the 2020 consultation. We would refer to the position set out in our consultation response which notes that:

“DHSC does not agree with the characterisation of its 2020 consultation response on the statutory scheme around the impact of higher payment percentages on research and development investment. While the 2020 consultation response noted that a proportion of the resulting increased revenue may be spent on research and development, a proportion of which would be felt as benefit in the UK, the aim of the 2020 reduction was to set a payment percentage that was justified by the level of sales growth in the scheme. By controlling growth in medicines sales at a certain level, we aim to balance the need to control the cost of medicines to the NHS while providing an adequate return to industry, part of which would be invested in research and development.”</td></tr>
<tr><td colspan="2">4.International comparators: The ABPI lists a number of detriments to the UK’s position in the world rankings and attributes them to the disincentive from the high clawback rates:
• The UK has already fallen down the global rankings across all phases of industry clinical trial delivery between 2018-2020;
• UK manufacturing production volumes have fallen by 29% since 2009;
• The UK’s share of global pharmaceutical R&D has fallen by over one-third 2012 to 2020;
• Compared to other leading EU countries (Italy, Spain, Germany, France), the UK has experienced the largest decline in its global share of new medicine launches between 2016-2021.</td></tr>
<tr><td>HoL Secondary Legislation Scrutiny Committee comment: Is that correct? How does DHSC respond?</td><td>Firstly, we do not consider it is credible to attribute the data cited by ABPI to the impact of payment percentages as it refers to a period in which payment percentages (clawback rates) in VPAS or the predecessor scheme (the 2014 pharmaceutical pricing regulation scheme, ‘PPRS’) were low:
<table>
<tr><th>Year</th><th>VS payment percentage (PPRS & VPAS)</th></tr>
<tr><td>2014</td><td>3.74%</td></tr>
<tr><td>2015</td><td>10.36%</td></tr>
<tr><td>2016</td><td>7.80%</td></tr>
<tr><td>2017</td><td>4.75%</td></tr>
<tr><td>2018</td><td>7.80%</td></tr>
<tr><td>2019</td><td>9.60%</td></tr>
<tr><td>2020</td><td>5.90%</td></tr>
<tr><td>2021</td><td>5.10%</td></tr>
</table></td></tr>
</table>

	With regard to trial investment, the same ABPI report attributes this to "Consistently slow and variable study set-up timelines'" and not pricing arrangements[3]. Similarly, with regard to manufacturing investment, this is stated by ABPI, in the report in question to be attributed to factors other than pricing schemes[4]. Issues related to R&D investment are covered in responses above. Secondly, with regard to the data presented on access and launch of new medicines there are several compelling benefits to the UK commercial environment, including: • freedom of list pricing • a flexible approach to commercial dealmaking, in part due to commitments agreed in VPAS which resulted in a new commercial framework and the establishment of a Commercial Medicines Directorate in NHSE • access to one of the largest single purchasers worldwide • the positive signal to global markets of a positive NICE recommendation NHSE identifies a number of recent examples that demonstrate the UK remains a positive environment for the launch of new medicines: • As described above, NHS England has created the Commercial Medicines Directorate and enhanced its commercial capabilities around market access for new medicines to ensure more rapid approval and adoption. The NHS Commercial Framework for new branded medicines, published in February 2021, outlined the range of commercial flexibilities available to companies to support access. • The NHS in England is internationally competitive in adopting innovative medicines and industry data shows that there are five treatments available in England for every four in Europe, as well as almost a third more cancer drugs, with the Cancer Drugs Fund providing fast-track access to cutting-edge treatments for patients.

[3] https://www.abpi.org.uk/media/fjhnjz34/resc

[4] Specifically 'competition, with many similar countries, including Ireland, France and Germany, also focussing on boosting manufacturing productivity, output and exports' https://www.abpi.org.uk/media/news/2023/january/medicines-manufacturing-has-the-potential-to-drive-uk-growth-over-the-next-10-years/

	• The development and deployment of the NHS' commercial and adoption capabilities is clearly demonstrated in the pharmaceutical industry's own data. A review of 222 new medicines showed the UK was 3rd globally in the number of medicines commercialised within one year of their first approval[5]. • In the past five years, NHS England has delivered a record number of medicines access deals – including many world and European-first agreements. The NHS has also used its commercial capabilities to help take international leadership on Hepatitis C elimination, ending HIV transmissions, and incentivising antibiotic development, working in collaboration with industry partners on all these initiatives. • The health service has delivered world-leading rollout of medicines like cystic fibrosis triple-therapy, Kaftrio® and '5-min' breast cancer combination PHESGO® as well as delivering expected levels of uptake on all Cancer Drugs Fund (CDF) treatments. • Since July 2016, the reformed CDF has continued to deliver substantial patient benefit, enabling 88,000 patients to gain faster access to more than 100 cancer treatments for just over 240 different indications. Around 18,000 patients were registered to receive a CDF funded treatment in 2022 alone. • The Innovative Medicines Fund was launched in 2022 and builds on the successful Cancer Drugs Fund and will support patient access to the most promising new medicines while further evidence is collected on their use to address clinical uncertainty. £340 million is available through the Fund for the NHS to fund early access for NHS patients to the most promising treatments while additional data is collected that will inform a future NICE assessment of whether the medicine is cost effective. • Average NICE appraisal timelines have been reduced from 10.2 months (2017/18) to 3.3 months (2020/21). The proportion of positive NICE appraisals increased to 87% in 2021/22 from 79% in 2017/18.
4.a APBI assert that rates in other countries that operate similar clawback mechanisms, current rates are much lower: 12% in Germany, 7.5% in Spain and 9% in Ireland and this is more attractive to R&D investment	
HoL Secondary Legislation Scrutiny Committee comment: *Is that correct? how does DHSC respond?*	While many countries use a rebate mechanism to control spending on medicines, direct comparison of the percentages can be misleading as it will not account for differences in the scope and coverage of the rebate, the initial selling price of medicines within that health system, and the relative weight of this form of cost control compared to other national or regional cost control mechanisms.

[5] Figures from Patented Medicine Prices Review Board, Canada. National Prescription Drug Utilization Information System (NPDUIS). Meds Entry Watch. 6th Edition. April 2022

	Such comparisons can be misleading as the context of the rates differs and all countries have different systems. For example, France has low payment rates, but only because some companies are exempt from the cap if they make a separate commercial arrangement (these were worth >€3bn in payments in 2020). The Department refers to the analysis in its response to the 2022-3 consultation which notes: "International comparisons are complex and fraught with difficulties owing to a range of factors such as difference in systems, disease incidence, demographics, clinical practice, patient choice, the availability of alternative treatment options, and wider health system factors." The data cited by ABPI, for example, may not reflect the extent of confidential discounting that takes place in each country and may make comparisons between countries using a variety of data sources that may not actually be directly comparable.
5. There were inadequacies in the consultation process	
HoL Secondary Legislation Scrutiny Committee comment: *when the increase was bound to be controversial why was the consultation so short and held over Christmas, contrary to good practice recommendations?*	The Department does not agree that the timing was contrary to good practice recommendations. The timing of the consultation was driven by efforts to ensure that, subject to the consultation, the change could be made in time for Q2 2023. The driver being that the scheme works in complete quarters and it was considered preferable for companies to spread the rise over as many quarters as possible. Since the medicine sales data from Q3 2022 did not become available until close to the consultation launch, it was not possible to hold the consultation earlier while being certain that we would be setting a that would be broadly equivalent payment percentage to that in VPAS. We reviewed the 2018 Consultation Principles, with particular attention to principles E,F,G and concluded the timing of the consultation was justifiable because: • The consultation was very likely to be expected by the key respondents (since their expectation of it will have informed choices they made earlier in the year), and the format and content will be familiar to them; • The consultation ran for longer than a previous consultation making similar changes, even excluding the week of Christmas from the overall length of the consultation; and • We did not close the consultation until well into the new year, beyond the end of the holiday period. Moreover, all representative trade associations and scheme members received:

	• Direct communication at launch advising them of the consultation, with communications to trade associations asking them to promote the consultation to their members; • A reminder of the closing date on 26 of January, sent on 13 January.

Annex A: explanation of schemes

Government has two main mechanisms to control the branded medicines spend:

- The Voluntary Scheme for Branded Medicines Pricing and Access (VPAS) - an agreement between DHSC, NHSE and industry, under which we receive payments from pharmaceutical companies if sales exceed an agreed cap. The majority (>90%) of companies supplying eligible health service medicines to the NHS are members of VPAS
- The statutory scheme for branded medicine pricing – which sets out in Regulations the terms that apply to any company that supplies eligible branded health service medicines that chooses not to join VPAS.

The Voluntary Scheme for Branded Medicines Pricing and Access (VPAS)

VPAS sets a cap on the total combined sales value of branded medicines each year. This cap grows at an agreed rate of 2% per year. Sales above the cap are paid back to the Department. This is achieved by requiring companies pay back a set percentage of their eligible sales that year to make up the expected difference between projected sales and the cap. To encourage innovation, certain types of sales are exempt from VPAS payments. This includes a 3-year exemption for drugs containing a new active substance. VPAS also includes a number of commitments from NHSE and NICE related to supporting the access and uptake of the most clinically and cost-effective new medicines.

VPAS also includes a number of commitments from NHSE and NICE related to supporting the access and uptake of new medicines. Broadly these seek to simplify and improve uptake, pricing, and access arrangements for cost effective medicines, and to deliver faster adoption of the most clinically and cost effective medicines.

In general, VPAS requires that companies agree the public list price of branded medicines with the Department, though companies often agree confidential discounts with the NHS on prices actually paid. One way VPAS encourages innovation is to allow companies to freely set the price of any medicine containing a new active substance.

A successor Voluntary Scheme will need to be negotiated to take effect from 2024.

The Statutory Scheme

Companies that do not join VPAS are automatically subject to statutory price control regulations, also known as the Statutory Scheme. As with VPAS, the Statutory Scheme requires that companies pay back a percentage of their eligible sales each year. This percentage is set directly by the Department following consultation. It is not based on a specific sales cap but rather is intended to maintain broad commercial equivalence with the Voluntary Scheme.