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Review of DHSC's Proposal for the Statutory Scheme from 2024

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Executive Summary

In July 2023, The Department of Health and Social Care (DHSC) published a consultation on the design of the Statutory Scheme for Branded Medicines Pricing and Access ("the statutory scheme") from 2024 onwards.[1] NERA Economic Consulting ("NERA") was commissioned by the Association of the British Pharmaceutical Industry (ABPI) to examine the economic reasoning and analysis underpinning DHSC's proposals. This report summarises our findings from that review.

In its consultation, DHSC sets out three policy objectives for the statutory scheme:[2]

- *"To limit the growth in costs of branded health service medicines to safeguard the financial position of the NHS;*
- *To ensure that medicines are available on reasonable terms, accounting for the costs of research and development; and*
- *To deliver the above objectives in a way consistent with supporting both the life sciences sector and the broader economy."*

In delivering these objectives, the design and accompanying Impact Assessment (IA) are **flawed in at least five ways:**

1. The cap mechanism creates uncertainty for investors, which undermines investment conditions;
2. The Life Cycle Adjustment (LCA), which imposes higher rebates on allegedly less competitive drug segments at a later stage of maturity, will likely fail to improve investment conditions;
3. DHSC does not consider alternative policy options, including proposals from industry and international benchmarks, that may better meet the objectives;
4. DHSC's impact assessment lacks transparency; and
5. DHSC has not sought independent scrutiny of the impact on business, which government would typically undertake for decisions of this magnitude.

The result of these flaws is that that proposals do not meet the statutory scheme objectives. They focus only on the first part of the first objective *"to limit the growth in costs of branded health service medicines"* to the detriment of the other two goals.

We explore these flaws in more detail below.

Overview of DHSC Proposal for Design of the Statutory Scheme

The statutory scheme is one of two mechanisms the DHSC uses to control the overall cost of branded medicines to the NHS. The other is the Voluntary Scheme for Branded Medicines

[1] Department of Health & Social Care (18 July 2023), Proposed review of the 2023 scheme to control the cost of branded health service medicines: Open Consultation

[2] Department of Health & Social Care (18 July 2023), Proposed review of the 2023 scheme to control the cost of branded health service medicines: Open Consultation, p.5.

Pricing and Access (VPAS or "the voluntary scheme"). Both schemes require companies to pay a percentage of their NHS branded medicines sales each year to DHSC.

Currently, the majority of pharmaceutical companies in the UK are in the voluntary scheme. However, that is due to expire at the end of 2023 and the negotiations for a successor are ongoing. As such, the statutory scheme could govern all medicines sales from 1 January 2024 if DHSC and ABPI cannot agree a successor to VPAS.

DHSC's latest proposals set out four policy options. All four options share features that would bring the statutory scheme into line with the existing VPAS. These include a cap mechanism, which limits annual growth in branded medicines sales to two per cent in nominal terms, and exemptions for certain products. Two of the four policy proposals include a new mechanism, the "Life Cycle Adjustment" (LCA), whereby newer medicines and medicines that DHSC deems to be in competitive segments would pay back a lower percentage of their sales.

1: The Cap Mechanism Creates Uncertainty for Investors

The cap mechanism is directly motivated by the first part of the first policy objective. It limits the growth in total sales of branded medicines to the NHS to two per cent per year in nominal terms.

However, two per cent is too low to allow for upward pressures on total sales that are driven by factors outside the control of the pharmaceutical industry, such as general inflation and a growing *volume* of demand for branded medicines from the NHS. This has led to volatile and rising payment percentages in recent years.

Volatile and rising payment percentages create uncertainty for the pharmaceutical industry around the value that government places on health benefits obtained through branded medicines and the compensation that government will offer for that value. Such uncertainty is likely to lead companies to launch fewer medicines in the UK market, which is inconsistent with the second policy objective *"to ensure that medicines are available on reasonable terms"*. It may also reduce investment in the UK life sciences sector, for example due to fewer clinical trials or if negative perceptions of the UK regulatory environment become the deciding factor in a close decision between two investment locations. This is inconsistent with the third objective of *"supporting the life sciences sector"*.

2: The LCA Will Likely Fail to Improve Investment Conditions

DHSC itself appears concerned that the headline payment percentages implied by the two per cent cap are too high to be consistent with the second and third policy objectives. As such, in two of its four policy options, it has proposed the LCA, which *reduces* the payment percentages for new medicines with the aim of "enabling innovation".

However, DHSC appears to have overestimated the extent to which the LCA will allow it to reduce payment percentages for new medicines while still maintaining its two per cent cap on sales growth and ensuring continued access to older medicines:

- According to DHSC's own analysis, the payment percentages for older "uncompetitive" medicines must increase every year to meet the two per cent cap. Over the three modelled years, the payment percentage rises from 36 to 40 per cent, a trajectory which is unsustainable;

- DHSC uses a narrow market definition, inconsistent with CMA precedent, which means it likely overstates the share of medicines that are "uncompetitive";
- DHSC fails to recognise that the *threat* of competitive entry can constrain prices, so that margins for supposedly "uncompetitive" medicines may be lower than it assumes.

3: DHSC does not Consider Alternative Policy Options that may Better Meet the Objectives

DHSC takes as given that growth in branded medicines sales should be capped at two per cent per year. It does not assess alternative options that may provide a better balance across the different policy objectives of the scheme, such as:

- A higher cap that accommodates upward pressures on total sales that are outside the control of the pharmaceutical industry, such as general inflation and increased volumes of branded medicines purchased by the NHS;
- A flat payment percentage at a level between 5 and 15 per cent, in line with industry proposals and practice in comparator jurisdictions such as Ireland, the US, and Germany.

4: DHSC's Impact Assessment Lacks Transparency

The accompanying IA compares DHSC's proposed policy options to a Business as Usual (BAU) scenario in which the payment percentage remains at its current level of 27.5 per cent.

DHSC identifies benefits of reducing the payment from pharmaceutical companies to DHSC, including positive industry sentiment towards the UK, support for innovation, and access to novel treatments. It does not quantify these benefits, but implicitly acknowledges that they exceed the net cost of the policy options relative to the BAU (which it estimates to be between £27.3 bn and £27.6 bn), given it recommends the policy options over the BAU.

DHSC's failure to quantify the benefits of reducing the payment from pharmaceutical companies to DHSC makes it impossible to critically appraise DHSC's recommendation or consider the likely impact of alternative options not included in the IA.

DHSC's "indicative" calculations of some of the unquantified benefits are overly simplistic and likely to understate the benefits of reducing the payment from pharmaceutical companies to government. For example, in estimating the impact of the payment percentages on R&D, DHSC makes the unrealistic assumption that companies scale up and down their spending across activities proportionately in response to any revenue changes. In practice, R&D may be more sensitive to changes in revenue than other areas of spending.

Further, the indicative calculations do not account for the long-term health benefits of investment in R&D that leads to the development of new medicines which improve health outcomes. This creates inconsistency in the IA between the treatment of revenues retained by the pharmaceutical industry and revenues transferred by the industry to the NHS. DHSC "scales up" the value of payments to the NHS by a factor of 4.67. This scaling exists because DHSC estimates that the NHS can provide a quality-adjusted life year (QALY) at a cost of £15,000 but that society values the health benefit of a QALY at £70,000. By applying a health benefit scaling factor to payments to the NHS but not to investment in R&D, DHSC systematically biases the IA in favour of transfers to the NHS.

5: DHSC has not Sought Independent Scrutiny of the Impact on Business

Under the Better Regulation Framework (BRF), government departments typically consult with the Regulatory Policy Committee (RPC), a body of independent experts, throughout the development of an impact assessment. We understand that DHSC has not engaged with the RPC in developing its IA, on grounds that the statutory scheme is classified as procurement and therefore there is no requirement for RPC involvement under the BRF.

Whilst the statutory scheme may technically be procurement in nature, it clearly also constitutes a regulatory burden to businesses that will have a significant monetary impact. Under DHSC's proposed policy options, the total payment from industry to DHSC would be between £9.86bn and £11.20bn.[3] Therefore, the statutory scheme arguably merits the same level of scrutiny set out in the BRF. Independent scrutiny would not need to be undertaken by the RPC, but the RPC would be well placed to do so.

Key Conclusions

Our analysis shows that DHSC has likely underestimated the detrimental impact of its proposals on ensuring continued access to medicines for UK patients and supporting the UK life sciences sector, both of which are also policy objectives of the statutory scheme.

Effectively, DHSC has proposed to transfer what it estimates to be approximately £10 billion from the pharmaceutical industry to the NHS, based on a limited impact assessment with no transparent quantitative comparison of costs and benefits. Its proposal and impact assessment would therefore benefit from further independent scrutiny.

[3] Department of Health & Social Care (18 July 2023), Impact Assessment (IA): Statutory Scheme – Branded Medicines Pricing, p. 23

1. Introduction

NERA Economic Consulting ("NERA") was commissioned by the Association of the British Pharmaceutical Industry (ABPI) to examine the economic reasoning and analysis underpinning the Department of Health and Social Care's (DHSC's) proposal for the design of the Statutory Scheme for Branded Medicines Pricing and Access ("the statutory scheme") from 2024 onwards.

The statutory scheme is one of two schemes that DHSC uses to control the overall cost of branded medicines to the NHS (the other is the voluntary scheme for branded medicines pricing and access, or VPAS). Both the current statutory scheme and VPAS will expire at the end of 2023. On 18 July 2023, DHSC opened a consultation on its proposed design of the statutory scheme from 2024 onwards. We have reviewed both DHSC's consultation document and associated Impact Assessment (IA).

We have identified five flaws in the economic reasoning and analysis underpinning either DHSC's proposed design of the statutory scheme or DHSC's IA of its proposals. The consistent theme across all five flaws is a failure by DHSC to fully consider the detrimental impact of its proposals on access to medicines for UK patients and on the UK life sciences sector. This is inconsistent with two of the three policy objectives that DHSC sets out for the statutory scheme.

DHSC's failure to consider the detrimental impact of its proposals on two of its three policy objectives manifests through limited assessment of the proposal's impact on company investment, pricing, and market participation decisions; miscalculation of the costs and benefits of its proposed scheme in the IA; and apparent failure to follow government guidance in developing the IA. We discuss each of these flaws in turn in this report.

The structure of this report is as follows:

- **Chapter 2 provides an overview of DHSC's proposed design** of the statutory scheme from 1 January 2024 onwards, and DHSC's IA of its proposed design of the statutory scheme.
- **Chapter 3 examines DHSC's proposed mechanism of capping growth in total allowed sales of branded medicines at 2 per cent per year** (nominal terms) and requiring pharmaceutical companies to repay a percentage of their total sales to DHSC to cover the cost of any difference between actual and allowed sales. We explain that this approach is likely to result in inefficient allocation of resources across government and uncertainty for manufacturers which, in the long-term, may result in under-investment in the development and launch of medicines in the UK. DHSC does not acknowledge this uncertainty as a cost of the cap mechanism in its IA.
- **Chapter 4 examines DHSC's proposed Life Cycle Adjustment (LCA) mechanism**, whereby the payment percentage would be *lower* for newer medicines or medicines facing more competitive markets and *higher* for other medicines. We explain that the market definition that DHSC uses to assess whether a medicine faces a competitive market is inconsistent with precedent set by the Competition and Markets Authority (CMA) and that DHSC's proposed payment percentages are likely to be miscalibrated.

Both errors mean that DHSC has likely overestimated the extent to which the LCA allows it to reduce payment percentages for newer medicines.

- **Chapter 5 examines the set of options for the design of the statutory scheme that DHSC has considered in its IA.** The IA contains no evidence that DHSC's approach to selecting options for appraisal was in line with government guidance on the development of options. In particular, it appears that DHSC may have focused its attentions on a pre-determined option (transferring the structure of the existing voluntary scheme to the statutory scheme) and failed to consider credible alternatives proposed by industry.
- **Chapter 6 shows that the lack of transparency in DHSC's assessment of the benefits to reducing the payment from pharmaceutical companies to DHSC makes it impossible to critically appraise DHSC's recommendation** or assess alternative policy proposals using a comparable standard. DHSC's "indicative" assessment of these benefits is understated for several reasons, including: that the short three-year time horizon fails to capture the long-term benefits of pharmaceutical R&D; that DHSC has adopted an overly simplistic approach to estimating the impact of payment percentages on R&D investment; and DHSC has failed to quantify the health benefits of R&D, which systematically biases the IA towards policy options that involve transfers to the NHS.
- **Chapter 7 explains that DHSC's proposal would benefit from further independent scrutiny** given the scale of potential impact on business.
- **Chapter 8 concludes**.

2. Overview of DHSC Proposal and Impact Assessment

As explained above, the current VPAS is due to expire at the end of 2023. There is not yet an agreement in place for a successor voluntary scheme. DHSC wants to ensure that the statutory scheme continues to achieve its policy objectives regardless of whether there is a future voluntary scheme. It has therefore set out proposed amendments to the design of the statutory scheme to take effect from 1 January 2024.[4]

In this chapter we provide an overview of DHSC's proposal and accompanying impact assessment.[5] We provide further detail on the regulatory context, including the current statutory scheme, VPAS, and the NICE cost-effectiveness framework, in Appendix A.

2.1. DHSC Proposal

In its proposal for the design of the statutory scheme from 2024 onwards, DHSC sets out three policy objectives for the scheme:[6]

- *"To limit the growth in costs of branded health service medicines to safeguard the financial position of the NHS;*
- *To ensure that medicines are available on reasonable terms, accounting for the costs of research and development; and*
- *To deliver the above objectives in a way consistent with supporting both the life sciences sector and the broader economy."*

DHSC proposes the following amendments to the statutory scheme in its consultation document (discussed in more detail later in this report):[7]

- Increasing the growth cap under the statutory scheme, which determines the payment percentage for pharmaceutical companies, from 1.1 per cent to 2 per cent (i.e., the current allowed growth rate under VPAS).[8]
- Introducing exemptions to the statutory scheme that are already present in VPAS.
- Introducing a Life Cycle Adjustment (LCA) whereby the payment percentage would be *lower* for newer medicines or medicines facing more competition and *higher* for other medicines.

[4] Department of Health & Social Care (18 July 2023), Proposed review of the 2023 scheme to control the cost of branded health service medicines: Open Consultation

[5] Department of Health & Social Care (18 July 2023), Impact Assessment (IA): Statutory Scheme – Branded Medicines Pricing

[6] Department of Health & Social Care (18 July 2023), Proposed review of the 2023 scheme to control the cost of branded health service medicines: Open Consultation, p.5.

[7] Department of Health & Social Care (18 July 2023), Proposed review of the 2023 scheme to control the cost of branded health service medicines: Open Consultation, p.4.

[8] This allowed growth is relative to a 2023 baseline for total sales calculated by uprating the existing 2018 baseline by 1.96 per cent per annum (to approximately reflect a weighted average of the VPAS and statutory scheme allowed growth over 2019-2023). Department of Health & Social Care (18 July 2023), Impact Assessment (IA): Statutory Scheme – Branded Medicines Pricing, p.19-20.

2.2. DHSC Impact Assessment

DHSC has published an impact assessment (IA) alongside its consultation. As part of its IA, DHSC outlines a Business as Usual (BAU) scenario in which the statutory scheme payment percentage remains at its current level of 27.5 per cent for each year from 2024 to 2026.

DHSC's IA evaluates four amendment options for the statutory scheme. Each option has a growth cap of 2 per cent per year and introduces exemptions already present in VPAS. DHSC distinguishes options by whether an option involves the LCA mechanism and whether DHSC includes a 36-month exemption following marketing authorisation for products containing New Active Substances (NAS). We summarise the options in Table 2.1, below.

Table 2.1: Features of Options for Statutory Scheme Amendments

	Without LCA	**With LCA**
Excludes 36-month exemption for NAS	Option 1a	Option 2a
Includes 36-month exemption for NAS	Option 1b	Option 2b

Source: NERA analysis of DHSC IA[9]

DHSC indicates that its preferred option would include the 36-month exemption for NAS, i.e., either Option 1b or 2b. DHSC does not express a preference on the LCA, nor does it outline why it has not established a definitive preferred option.[10]

In its IA, DHSC calibrates all options to obtain a 2 per cent allowed nominal NHS expenditure growth rate per year from the 2023 allowed sales baseline.[11] DHSC analyses each option over the three-year period from 2024-2026; it justifies restricting its analysis to a three-year period because of "*inherent uncertainty surrounding forecasting medicines sales*" and to maintain consistency with the timeframe covered by the 2018 Statutory Scheme IA.[12]

Options 1a-2b all result in lower payment percentages over the three-year evaluation period than the percentages provided for in the BAU case, and therefore reduce the transfer from pharmaceutical companies to the NHS. DHSC estimates that the reduction in the transfer will be between £5.84bn and £6.66bn.[13]

2.2.1. Estimated benefits

The only quantified benefit from lower payment percentages and thus a lower transfer from pharmaceutical companies to the NHS that DHSC includes in its headline IA figures is the increase in revenue for UK-based interests in pharmaceutical companies. It assumes that

9 Department of Health & Social Care (18 July 2023), Impact Assessment (IA): Statutory Scheme – Branded Medicines Pricing, p.1.

10 Department of Health & Social Care (18 July 2023), Impact Assessment (IA): Statutory Scheme – Branded Medicines Pricing, p.14.

11 Department of Health & Social Care (18 July 2023), Impact Assessment (IA): Statutory Scheme – Branded Medicines Pricing, p.15.

12 Department of Health & Social Care (18 July 2023), Impact Assessment (IA): Statutory Scheme – Branded Medicines Pricing, p.11.

13 This range reflects DHSC's low, mid, and high scenario estimates for future branded medicines sales, where the mid forecast is the "*best estimate*", but all three forecasts are "*similarly plausible*". See Department of Health & Social Care (18 July 2023), Impact Assessment (IA): Statutory Scheme – Branded Medicines Pricing, p.11, p. 15, p. 19.

UK-based interests in pharmaceutical companies retain 10 per cent of the benefit that accrues to pharmaceutical companies from lower payment percentages, on grounds that *"the UK is estimated to represent not more than 10% of the global industry"*.[14] This results in a benefit of between £580m-£670m from Options 1a-2b.

DHSC identifies additional benefits that it does not include in its headline IA figures:

- DHSC identifies an indirect benefit to the UK economy from additional R&D investment of £50m plus a further £10m benefit from spillovers due to R&D.[15]
- DHSC also provides commentary on an unquantified benefit associated with setting payment percentages based on a clear and justified methodology, which maintains positive industry sentiment towards the UK.[16]
- DHSC does not quantify the health benefit to NHS users from future availability of medicines funded by additional R&D investment but alludes to it when it writes *"patient benefits in supporting continued access to new and innovative medicines"*.[17]

2.2.2. Estimated costs

The cost that DHSC estimates from applying Option 1a-2b instead of the BAU is equal to the societal GBP value of health lost because of the assumed reduction in NHS expenditure outside of branded medicines. DHSC assumes that since each option results in higher branded medicines expenditure for the NHS, there is a one-for-one reduction in NHS expenditure. DHSC assumes that NHS expenditure outside of branded medicines produces QALYs at a rate of one QALY per £15,000.[18] DHSC assumes that each QALY is worth £70,000 to society.[19] Therefore, DHSC estimates that the cost to society of Options 1a-2b is between £27.25bn and £31.07bn.[20]

In addition, for Options 1b and 2b, DHSC recognises that there may be an additional administrative cost for suppliers in providing the quarterly presentation level data needed to implement the LCA, although DHSC does not quantify the associated cost.[21]

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[14] Department of Health & Social Care (18 July 2023), Impact Assessment (IA): Statutory Scheme – Branded Medicines Pricing, p.33.

[15] DHSC generates these estimates by multiplying the revenue retained by pharmaceutical companies by estimates (from literature review) of: the percentage of pharmaceutical company revenue invested in R&D; the percentage of global pharmaceutical R&D that is UK-based; and the "spillover" impact of R&D investment. See Department of Health & Social Care (18 July 2023), Impact Assessment (IA): Statutory Scheme – Branded Medicines Pricing, pp.33, 41-42.

[16] Department of Health & Social Care (18 July 2023), Impact Assessment (IA): Statutory Scheme – Branded Medicines Pricing, p.18.

[17] Department of Health & Social Care (18 July 2023), Impact Assessment (IA): Statutory Scheme – Branded Medicines Pricing, p.19.

[18] Department of Health & Social Care (18 July 2023), Impact Assessment (IA): Statutory Scheme – Branded Medicines Pricing, p. 43

[19] Department of Health & Social Care (18 July 2023), Impact Assessment (IA): Statutory Scheme – Branded Medicines Pricing, p. 44

[20] For example, £5.84bn / £15,000 = 389,333 QALYs with value equal to 389,333 x £70,000 = £27.25bn. See Department of Health & Social Care (18 July 2023), Impact Assessment (IA): Statutory Scheme – Branded Medicines Pricing, p. 19

[21] Department of Health & Social Care (18 July 2023), Impact Assessment (IA): Statutory Scheme – Branded Medicines Pricing, p.29.

3. The Cap Mechanism Compromises the Statutory Scheme's Objectives

As explained in Chapter 2, DHSC sets the payment percentages for the current VPAS and statutory scheme by reference to a predetermined cap on allowed growth in total sales of branded medicines to the NHS in *nominal* terms ("the cap mechanism"). It proposes to continue this approach for the statutory scheme from 2024 onwards. DHSC proposes to set the cap on allowed growth at 2 per cent per year, which is the current cap under VPAS. DHSC says that this will allow for "*most companies and for the NHS*" to maintain "*broadly the same commercial terms that have operated since 2019*".[22]

In this chapter, we explain that the cap mechanism is inconsistent with the second and third policy objectives of the statutory scheme, as follows:

- Section 3.1 explains that the cap mechanism protects government from uncertainty about required expenditure at the cost of creating uncertainty for pharmaceutical companies about the return on their investment. This may deter investment in the development and launch of new medicines in the UK market, limiting patient access to medicines;
- Section 3.2 explains that the specific cap level of 2 per cent is too low given inflation and upward pressure on total sales from an aging UK population that is likely to require increasing volumes of medication. These factors will erode the real-terms value obtained by pharmaceutical companies for their medicines. Companies may therefore not introduce new low-margin medicines to the UK market (or may even withdraw existing low-margin medicines), again limiting patient access to medicines;
- Section 3.3 explains that the cap mechanism distorts the allocation of funding across government and masks the NHS' need for greater funding to meet increased demand for medicines, which in the long run may be detrimental to all three statutory scheme objectives; and
- Section 3.4 highlights that the cap mechanism and implied payment percentages are out of line with international comparators. This suggests that DHSC is failing in its objective of ensuring that medicines are available on "reasonable" terms because the terms it sets are more onerous than those of comparators.

3.1. The Cap Mechanism Imposes Risk on Companies which may Deter Investment

The cap mechanism protects the government from uncertainty around growth in the cost of expenditure on branded medicines but does so by creating variability in the real-terms value pharmaceutical companies obtain for their medicines. This creates uncertainty and price risk for pharmaceutical companies, which may lead them to reduce their investment in development of new medicines or choose not to launch products in the UK market. Effectively, the mechanism advances the first policy objective of the statutory scheme at the cost of the second and third policy objectives.

[22] Department of Health & Social Care (18 July 2023), Proposed review of the 2023 scheme to control the cost of branded health service medicines: Open Consultation, p.8.

The initial price for a new medicine reflects the outcome of a NICE cost-effectiveness evaluation, described further in Appendix A.2. This evaluation process is intended to ensure that, over the life cycle of a medicine, the price paid for the medicine reflects the value of that medicine to the NHS (and by extension government as a whole). Typically, NICE assesses new medicines against a value threshold of £20,000-£30,000 per QALY.

The payment percentages under VPAS and the statutory scheme mean that the government is paying less for medicines than the price NICE deems to be reflective of the value of the medicine to the NHS. The government is therefore implicitly placing a lower value on medicines than the value used by NICE in its cost-effectiveness assessment.

Pharmaceutical companies require information about the value government places on medicines, and thus the compensation they can expect to receive for providing those medicines, to make investment decisions. If the cost to develop and launch a medicine in the UK market significantly exceeds the value government places on that medicine, companies are unlikely to invest in that medicine.[23]

ABPI estimates that it takes approximately 12.5 years to bring a new medicine from initial research through to commercial launch.[24] Therefore, pharmaceutical companies planning investment for the UK market need an idea of how government will value medicines beyond the 12.5 year horizon, as they will only begin to recoup the cost of their investments after commercial launch (and while the medicine is still under patent).

If the payment percentage were constant, this would imply a government value for branded medicines at a fixed discount relative to the NICE assumed value. Despite setting compensation at a level below the value allowed by NICE, a constant payment percentage would offer a clear planning signal for companies. That is, companies would have forward visibility of the compensation they could expect to receive for new medicines and make decisions about which investments to pursue accordingly. This would be consistent with the second and third policy objectives of the statutory scheme.

However, the cap mechanism introduces uncertainty about the future compensation that government will offer companies for branded medicines. The implied real-terms compensation that companies receive for medicines varies from year to year due to factors that are unlikely to reflect real variation in the value of medicines to government, as follows.

- Changes in the *quantity* of medicines sold to the NHS. This likely reflects changes in demand for medicines. For example, there was "exceptional" high growth in the measured sales of branded medicines in 2021 due to increased demand for certain products during the COVID-19 pandemic.[25]

[23] We understand from ABPI that the UK is perceived by other countries as a leader in cost-effectiveness assessments. UK decisions on whether, and how much, to pay for a medicine can influence other countries' decisions on whether and how much to pay for that medicine. Therefore, the value the UK government places on branded medicines can have a greater influence on company decisions around total R&D investment than would be suggested by its share of the global market.

[24] ABPI, Time to Flourish. Link: https://www.abpi.org.uk/media/h40bcxrq/medicine-development-process.pdf (last accessed 4 September 2023)

[25] Department of Health & Social Care (18 July 2023), Impact Assessment (IA): Statutory Scheme – Branded Medicines Pricing, p.16.

- Changes in the *composition* of medicines sold to the NHS. We understand from ABPI that the recent growth in total nominal measured sales is in part due to a shift in demand towards medicines in high-price therapy classes, such as oncology and immunotherapies.
- General *inflation*. Inflation erodes the real-terms value of prices set in nominal terms.

Changes to the volume and composition of medicines sold to the NHS create upward pressure on total nominal *measured* sales (i.e., sales before the payment percentages are calculated and applied). In these cases, the increased total nominal measured sales are still reflective of the original underlying real-terms value to the NHS of the branded medicine. Therefore, by requiring companies to refund a higher payment percentage of these measured sales, DHSC effectively *reduces* the compensation companies receive for medicines below their actual value to the government in real terms.

Not only does the cap on allowed nominal growth mean that real-terms compensation *declines* over time, it also creates *volatility* in that compensation. This uncertainty is a further deterrent to investment in R&D and new product launches.

DHSC offers no justification in its consultation document or IA for the choice to set payment percentages based on a cap on total allowed sales growth. The approach seems to be a legacy of the 2014 Pharmaceutical Price Regulation Scheme (PPRS, a precursor to VPAS), in which this cap was introduced instead of the previous practice of setting headline payment percentages *"to provide Government with surety on the level of NHS expenditure"* given *"the current state of the global economy"*.[26] However, DHSC has not provided any assessment of whether it continues to be optimal for the pharmaceutical industry to bear the burden of limiting uncertainty for government.

3.2. The 2 Per Cent Cap is Too Low

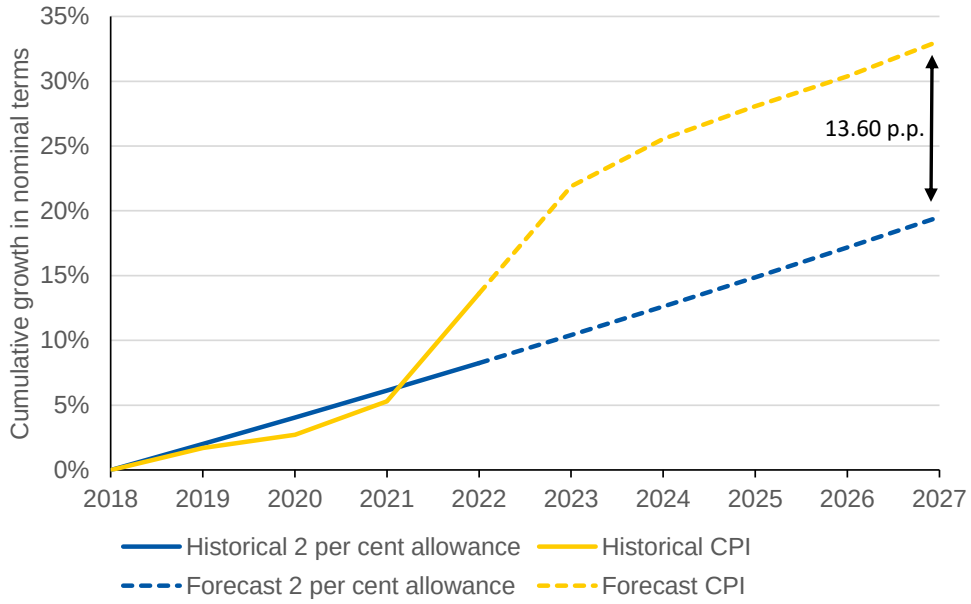
At present the 2 per cent allowed nominal sales growth is well below the prevailing rate of inflation. Even if there were no changes to the quantity or composition of medicines sold to the NHS, the implied real-terms compensation companies receive for their medicines under the payment percentages resulting from the cap would be declining year-on-year.

Figure 3.1 shows the difference between the cumulative growth in sales of branded medicines in nominal terms that would be required to just compensate for inflation (both historical and projected) and the cumulative growth implied by a 2 per cent cap. Both are applied to a 2018 baseline, consistent with the approach proposed by DHSC.[27] The figure shows that, by 2027, DHSC's proposal would undercompensate companies for inflation by 13.60 percentage points (given HMT forecasts of CPI in August 2023).

[26] DHSC and ABPI (December 2013), The Pharmaceutical Price Regulation Scheme 2014, p.33.

[27] Department of Health & Social Care (18 July 2023), Impact Assessment (IA): Statutory Scheme – Branded Medicines Pricing, p.19-20.

Figure 3.1: A 2 Per Cent Growth Allowance Undercompensates for Inflation



Source: NERA analysis of ONS data and HMT forecasts[28]

In addition to the erosion of real-terms compensation through inflation, we also expect erosion of real-term compensation due to growth in the quantity of medicines sold to the NHS over time. We expect growth in the quantity of medicines due to demographic pressures as the population simultaneously increases and grows older.

The 2 per cent allowed growth rate under VPAS has caused payment percentages to more than double since 2019 (see Figure A.1 in Appendix A.1). This suggests that even before the current period of high inflation the 2 per cent cap was not high enough to allow for growth in the volume of medicines demanded and inflationary pressures.

This declining real-terms compensation for branded medicines sends a negative signal to companies considering investment in the development or launch of new medicines in the UK market. This is likely to deter investment in UK product launch, and in some cases development, for medicines with relatively lower margins – even if those medicines would be beneficial for many UK patients. This is inconsistent with the statutory scheme's second objective, to ensure that medicines are available on reasonable terms.

DHSC offers no justification for the specific 2 per cent cap. It is not explicitly linked to any information about NHS budgetary pressures and is not assessed against inflation expectations or demographic pressures that are likely to drive changes in the volume of NHS demand for branded medicines.

[28] (1) Office for National Statistics (16 August 2023), Consumer price inflation time series (MM23). Link: https://www.ons.gov.uk/economy/inflationandpriceindices/timeseries/l55o/mm23 (2) HM Treasury (August 2023), Forecasts for the UK economy: a comparison of independent forecasts, p. 20. We use the independent average of CPI inflation forecasts.

3.3. The Cap Mechanism Distorts Allocation Across Government

The cap mechanism may also create inefficiencies across government insofar as it fails to make explicit the budgetary trade-off between QALYs achieved through purchase of branded medicines, QALYs achieved through other healthcare spending, and benefits achieved through government spending in other departments.

For example, assume that the government previously placed equal monetary value on a QALY achieved through purchase of branded medicine and a QALY achieved through investment in road safety (e.g., new pedestrian crossings). As the cap mechanism erodes the real-terms compensation for branded medicines, this means that the relative value government places on branded medicines and road safety investments has changed with no explicit policy decision to that effect.

This inefficient implicit reallocation of budget across government is particularly likely in the context of high inflation, because government nominal tax receipts and therefore the total nominal budget should rise in line with inflation. Limiting the growth of total spend on branded medicines to a rate below inflation has the effect of reducing the real-terms share of the budget that is spent on branded medicines.

Even before the current period of high inflation, the increasing payment percentages under the existing schemes meant that the pharmaceutical industry has been masking a need for greater funding for branded medicines to meet growing demand from the NHS. This allows government to avoid making difficult decisions about overall budget allocation in the short-term at the potential cost of reduced investment in the development and launch of new medicines in the UK. This is harmful to the second and third policy objectives of the statutory scheme.

In the long term, allowing the pharmaceutical industry to mask a need for increased funding for the NHS is also harmful to the first policy objective of the statutory scheme, to safeguard the financial position of the NHS. On the current trajectory, the scheme will eventually reach a point where the pharmaceutical industry is unable to bear further increases in the payment percentages as revenues will no longer meet even manufacturing costs for existing medicines. The NHS will then face an urgent need to secure additional funding, potentially at a time when the government can ill afford it. DHSC may therefore be creating a future risk to the financial position of the NHS.

3.4. The Cap Means UK Prices are Below those of International Comparators

The cap mechanism and the resulting payment percentages are out of line with international comparators, as shown in Table 3.1. This serves as further evidence that the scheme is failing to provide medicines *"on reasonable terms"* as required under the second policy objective; the UK is imposing more onerous terms on pharmaceutical companies than its comparators.

Of the four comparators we examined, the country with the most similar approach to DHSC's proposed statutory scheme is France, in that it is the only country to also set a cap on total allowed sales. However, the payment percentage in France is limited to a maximum of 10 per cent of total sales.

Both Ireland and Germany set payment percentages, but these appear to be set as headline payment percentages (in line with the approach taken in the UK prior to the 2014 PPRS). The payment percentages used are on the order of 10 per cent.

Only the Medicaid scheme in the US applies a payment percentage above 20 per cent. However, the baseline prices to which the payment percentages are applied are likely to be higher than the baseline prices used in the European comparator countries. The European comparator countries set baseline prices in a similar manner to the UK; they also benchmark these prices to other jurisdictions in Europe (including the UK) and so it is likely that the prices are similar. In contrast, the baseline price for the Medicaid payment percentage is not a centrally negotiated price but an average market price, and therefore is likely to be higher.

Table 3.1: International Comparators Typically Do Not Cap Total Sales and Set Lower Payment Percentages

Comparator	Cap on Total Sales	Payment Percentages
France	Set annually by ONDAM[29]	50-70% of revenue above the cap, but limited to 10% of total revenue[30]
Germany	No evidence of a cap	12%[31]
Ireland	No evidence of a cap	8.25%[32]
US (Medicaid)	No evidence of a cap	23.1%[33]

Source: NERA analysis

A fixed or limited payment percentage under the statutory scheme, in the region of 5-15 per cent, would be more consistent with the approach applied by international comparators.

[29] Légifrance, Code de la sécurité, Article L138-10, URL: https://www.legifrance.gouv.fr/codes/section_lc/LEGITEXT000006073189/LEGISCTA000006172902/#LEGISCTA000041397409. Visited on 21 August 2023.
Légifrance (December 2022), LOI n° 2022-1616 du 23 décembre 2022 de financement de la sécurité sociale pour 2023 (1), Article 18, URL: https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000046791754. Visited on 21 August 2023.

[30] Légifrance, Code de la sécurité sociale, Article L138-12, URL: https://www.legifrance.gouv.fr/codes/section_lc/LEGITEXT000006073189/LEGISCTA000006172902/#LEGISCTA000041397409. Visited on 21 August 2023.

[31] This figure is for 2023.
Covington (October 2022), Germany significantly tightens drug pricing and reimbursement laws, URL: https://www.insideeulifesciences.com/2022/10/26/germany-significantly-tightens-drug-pricing-and-reimbursement-laws/. Visited on 18 August 2023.

[32] This figure is for 2023.
gov.ie website (December 2021), Minister Donnelly announces Framework Agreements on Pricing and Supply of Medicines 2021-2025, URL: https://www.gov.ie/en/press-release/12e24-minister-donnelly-announces-framework-agreements-on-pricing-and-supply-of-medicines-2021-2025/#:~:text=The%20rebate%20to%20the%20HSE%20on%20all%20sales,2023%2C%208.5%25%20in%202024%20and%209%25%20in%202025. Visited on 18 August 2023.

[33] Global Legal Insights (2022), Pricing & Reimbursement Laws and Regulations 2022 | USA, URL: https://www.globallegalinsights.com/practice-areas/pricing-and-reimbursement-laws-and-regulations/usa. Visited on 15 August 2023.

4. The Proposed Life Cycle Adjustment Fails to Improve Investment Conditions

At present, DHSC's statutory scheme applies a "one-size-fits-all" approach, whereby companies subject to the scheme face the same payment percentage on all branded medicine sales. In its consultation, DHSC proposes to introduce a life cycle adjustment (LCA) which would vary the payment percentages based on the age of the product and the degree to which it faces market competition. Specifically, DHSC's proposed LCA would *increase* the payment percentages for older products facing limited competition to create headroom under the allowed 2 per cent nominal growth rate in total sales that would enable it to *reduce* payment percentages for newer products or older products in more competitive markets.[34]

Theoretically, the proposed LCA is consistent with life-cycle pricing of branded medicines. For newer medicines that are still within their patent period, avoiding high payment percentages ensures continued incentives for innovation. For older medicines, targeting the rebate to products that do not experience competitive pressure on prices would in theory result in more efficient outcomes.

However, several aspects of DHSC's proposed approach to implementing the LCA in practice appear to be miscalibrated. In particular, the miscalibration of two aspects of the proposed approach means DHSC has likely overestimated the extent to which it can reduce payment percentages for new medicines to encourage innovation while still maintaining its 2 per cent cap on sales growth. In both cases, the miscalibration means that there may not be headroom in the prices of older medicines to accommodate DHSC's high payment percentages, which would make continued supply unviable at the prevailing price. This contradicts DHSC's second policy objective of ensuring medicines remain available on reasonable terms.

The remainder of this chapter proceeds as follows:

- Section 4.1 explains the theoretical principles underpinning the LCA;
- Section 4.2 summarises DHSC's proposed approach to implementing the LCA;
- Section 4.3 explains that DHSC has defined markets for older medicines too narrowly, such that it is likely to conclude that medicines do not face sufficient competition when in fact they do. High payment percentages imposed on such medicines may be detrimental to continued supply of medicines to UK patients;
- Section 4.4 explains that DHSC's proposed payment percentages for both competitive and uncompetitive older medicines under the LCA are not adequately supported by empirical evidence. Therefore, even if DHSC had correctly identified whether the medicines face market competition or not, there is no guarantee that these payment percentages will have the desired effect of bringing prices in line with costs for these medicine groups. In particular, if they overstate the extent to which prices could be reduced, then companies may either seek price increases; withdraw their medicines from

[34] Department of Health & Social Care (18 July 2023), Proposed review of the 2023 scheme to control the cost of branded health service medicines: Open Consultation, p.13.

the UK market; or be forced to cross-subsidise older medicines with revenues from new ones, reducing the incentive for continued investment in new medicines.

4.1. Theoretical Justification for the LCA

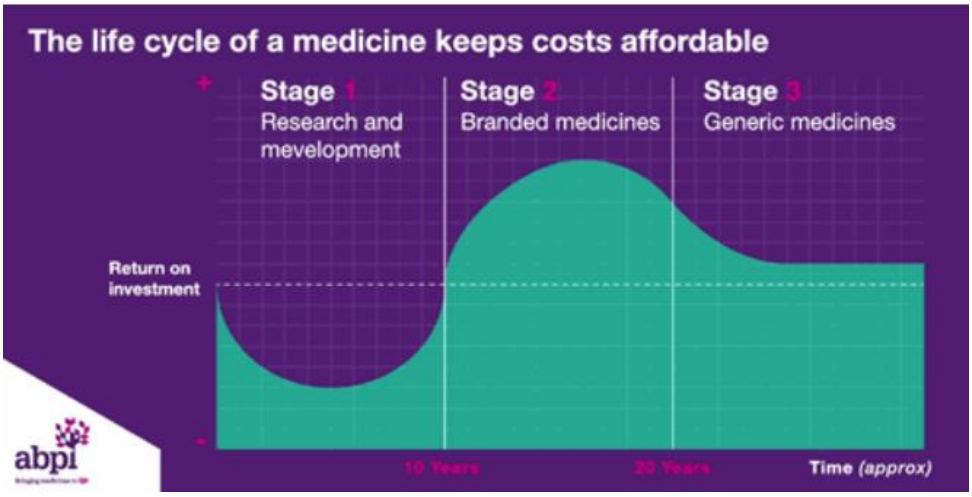
In explaining its rationale for proposing the LCA, DHSC refers to what it calls the "innovation paradigm", whereby:[35]

- New medicines receive time-limited patents that protect manufacturers from competition, allowing them to charge prices above the marginal cost of supply and perhaps above the opportunity cost to the NHS (i.e., the NHS could do more to improve health by using the same funds elsewhere);
- After patent expiry, competition from generics and biosimilars pushes the price down to the marginal cost of supply, which is below the opportunity cost to the NHS.

Under the innovation paradigm, DHSC suggests that the opportunity cost to the NHS should balance out so that the NHS can obtain a "net health gain overall" (improving health at a lower cost than alternative uses of the funds) over the course of a medicine's lifecycle.[36]

DHSC describes this paradigm as "enabling innovation", presumably because the initial period of patent protection and higher prices allows manufacturers to recover the upfront costs of R&D, as shown in Figure 4.1. Absent this initial period of patent protection, manufacturers would have less incentive to engage in R&D.

Figure 4.1: The Life Cycle of a Medicine



Source: ABPI[37]

Since DHSC describes the LCA as motivated by this "innovation paradigm", and one aim of the LCA is to *reduce* the payment percentages for new medicines, it seems likely that DHSC

[35] Department of Health & Social Care (18 July 2023), Proposed review of the 2023 scheme to control the cost of branded health service medicines: Open Consultation, p.13.

[36] Department of Health & Social Care (18 July 2023), Proposed review of the 2023 scheme to control the cost of branded health service medicines: Open Consultation, p.13.

[37] ABPI website, Medicine lifecycle, URL: https://www.abpi.org.uk/value-and-access/uk-medicine-pricing/medicine-lifecycle/. Visited on 18 August 2023.

is concerned that the headline payment percentages implied by its 2 per cent allowed nominal growth rate may be too high to enable innovation. To create the headroom to reduce payment percentages for new medicines while maintaining its 2 per cent cap on sales growth, DHSC must increase payment percentages for another category of medicines.

DHSC posits that some older medicines do not face sufficient competition in the later stage of the medicine lifecycle, allowing the manufacturer to maintain a price above the marginal cost of supply and thus preventing the NHS from recovering the opportunity cost of the medicine over its lifecycle. Under the LCA, DHSC therefore proposes to *increase* payment percentages for older medicines that do not face sufficient competition to keep prices close to marginal costs (under the assumption that it can correctly identify those medicines that do not face adequate competition).[38]

The final proposed element of the LCA relates to older medicines that *do* face sufficient competition. Due to the dynamics of competition, the market price for these medicines should already be at or close to the marginal cost of supply. Therefore, in theory, a high payment percentage for these medicines would make continued supply unviable at the prevailing price, leading to one of three adverse effects:

- Price increases, which would increase total measured sales of branded medicines to the NHS, nullifying the contribution of the high payment percentages to meeting DHSC's 2 per cent cap (i.e., failing to meet DHSC's first policy objective);
- Market exit. This would reduce the availability of medicines to patients (i.e., failing to meet DHSC's second policy objective);
- For suppliers with diverse portfolios, cross-subsidisation of older products, which would reduce returns to newer products and may consequently limit R&D investment (i.e., failing to meet DHSC's third policy objective).

Apparently recognising this, DHSC proposes to set a reduced payment percentage for these older medicines.

Theoretically, the principles underpinning the lifecycle model and LCA are economically sound. First, allowing novel products to earn revenues above marginal cost (e.g., through patent protection) is a well-established means of providing incentives for socially beneficial innovation. Second, intervention by governments or regulators to limit prices in cases where companies do not face adequate competition, or an adequate *threat* of competition, is economically efficient.

4.2. Overview of Proposed Implementation of the LCA

DHSC proposes to implement the LCA as follows:

- DHSC proposes to define an **older medicine** as one where the active substance has been marketed in the UK for at least 12 years. DHSC explains that it selected 12 years because it "*loosely reflects the average length of exclusivity/patent period*".[39] It says that it

[38] Department of Health & Social Care (18 July 2023), Proposed review of the 2023 scheme to control the cost of branded health service medicines: Open Consultation, p.13.

[39] Department of Health & Social Care (18 July 2023), Proposed review of the 2023 scheme to control the cost of branded health service medicines: Open Consultation, p.14.

adopted a "*simple definition of an older product*" rather than using actual product patent durations because "*IP law is complex and multifaceted and that multiple elements of a product might be protected at different points in time*".[40]

- DHSC proposes to define each **market** for older products at the individual generic presentation level (also known as a virtual medicinal product, or VMP). For example, Aspirin 300mg tablets, Aspirin 200mg tablets, and Aspirin 300mg capsules would each be separate markets. We assume that DHSC proposes to include generics and biosimilars as well as branded medicines with the same VMP within a market, although this is not clear from the consultation document.
- DHSC proposes to define an existing market as **uncompetitive** if a company (or group of companies with the same parent company/under a commercial arrangement) controls greater than 80 per cent of sales quantity (by units sold).[41]
- DHSC proposes to set the **payment percentages for older drugs** at pre-determined levels. Where the market is competitive, this level will be 10 per cent. Where the market is uncompetitive this level will be 36, 38, and 40 per cent in each of 2024, 2025, and 2026 respectively. DHSC does not specify what this level will be from 2027 onwards.
- DHSC proposes to calculate the **headline payment percentage** for newer products as the rate required to maintain the 2 per cent overall cap given projected sales volumes for new and older drugs and applying the pre-set payment percentages for older products (under the assumption that prices for those drugs remain constant).[42]

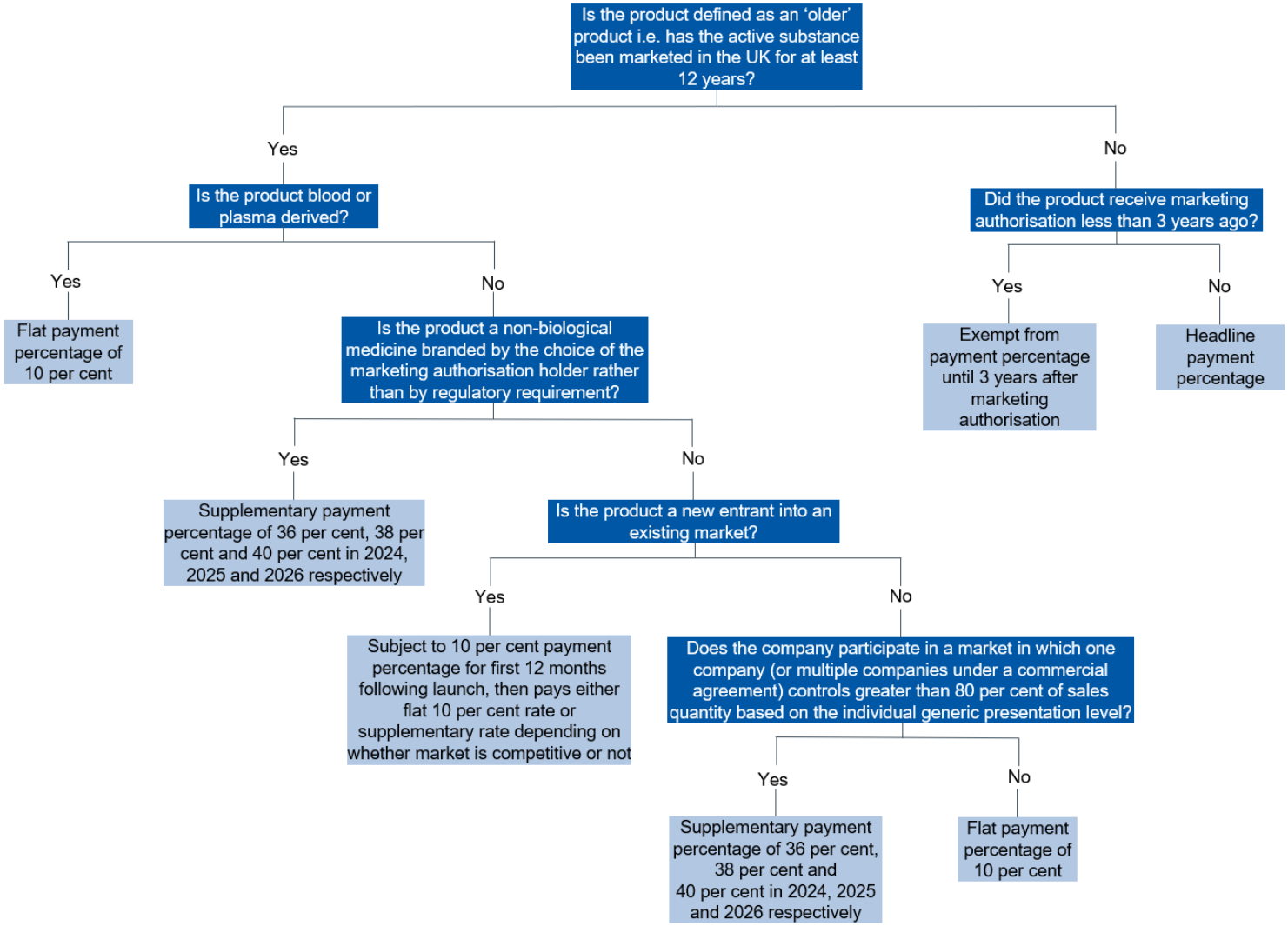
Figure 4.2 illustrates DHSC's approach to determining the payment percentage applicable to a given product.

[40] Department of Health & Social Care (18 July 2023), Proposed review of the 2023 scheme to control the cost of branded health service medicines: Open Consultation, p.15.

[41] DHSC defines an existing market as a market where the originator product has been marketed in the UK for more than 12 years. Department of Health & Social Care (18 July 2023), Proposed review of the 2023 scheme to control the cost of branded health service medicines: Open Consultation, p.19.

[42] Department of Health & Social Care (18 July 2023), Proposed review of the 2023 scheme to control the cost of branded health service medicines: Open Consultation, p.19-20.

Figure 4.2: Flow Diagram of Payment Percentage Applicable to Different Types of Medicinal Product



Source: NERA analysis

4.3. Definition of Market at Presentation Level is Inconsistent with CMA Precedent

As explained above, DHSC proposes to define the market for a product at *"individual generic presentation level (also known as virtual medicinal product or VMP) when measured UK wide."*[43] A VMP represents *"a collection of clinically equivalent pharmaceutical products with the same strength, dose form and the same routes of administration"*.[44] Under this definition, Aspirin 300mg tablets, Aspirin 300mg capsules, Aspirin 200mg tablets and Aspirin 200mg capsules would all constitute separate markets where the form and strength of the latter would be capsule and 200mg respectively.[45]

DHSC offers no clear justification for its choice to define markets at the VMP level. It explains that "*individual presentations of a product may not be fully interchangeable such that price competition does not occur between different presentations of the same medicine*" but does not provide any evidence of a lack of price competition between different presentations of the same medicine.[46]

DHSC does not appear to have referred to CMA guidance or precedent in its approach to defining markets. DHSC's approach to defining markets appears inconsistent with CMA precedent, as we discuss further below.

Our review of CMA precedent suggests that the CMA typically defines a pharmaceutical market at the level of the active substance (sometimes with specific form), not at the VMP level. We searched the CMA's publicly available record of CA98 cases and civil cartel investigations for cases relating to pharmaceutical products and identified ten non-confidential case decisions from either the CMA or its predecessor, the OFT.[47] In eight of these cases, the CMA defined the relevant market at the level of the active substance (sometimes with specific form) without further narrowing down the market to VMP level. We summarise these cases in Table 4.1.

Table 4.1: CMA and OFT Pharmaceutical Market Definition Decisions

Drug	Case Reference	VMPs Considered	Market Definition Decision
Fludrocortisone[48]	50455	Fludrocortisone acetate 0.1mg tablets.	The supply of fludrocortisone acetate tablets in the UK.

[43] Department of Health & Social Care (18 July 2023), Proposed review of the 2023 scheme to control the cost of branded health service medicines: Open Consultation, p.17.

[44] Health Information and Quality Authority (January 2015), Data model for an electronic medicinal product reference catalogue – a National Standard, p. 15

[45] NHS Digital (9 November 2020), dm+d Implementation Guide (Primary Care), p.5.

[46] Department of Health & Social Care (18 July 2023), Proposed review of the 2023 scheme to control the cost of branded health service medicines: Open Consultation, p.17.

[47] CMA website, Competition and Markets Authority cases and projects, URL: https://www.gov.uk/cma-cases?case_type%5B%5D=ca98-and-civil-cartels&market_sector%5B%5D=pharmaceuticals. Visited on 17 August 2023.

[48] CMA (9 July 2020), Anti-competitive agreement with respect to fludrocortisone acetate 0.1mg tablets, para 3.27 and 6.2.

Drug	Case Reference	VMPs Considered	Market Definition Decision
Hydrocortisone[49]	50277	Hydrocortisone 10 and 20mg tablets.	The supply of hydrocortisone tablets in the UK with combined (separate) markets prior to (following) the entry of competing suppliers.
Liothyronine[50]	50395	Liothyronine 20mcg tablets.	The supply of liothyronine tablets in the UK.
Nortriptyline[51]	50507.2	Nortriptyline 10 and 25mg tablets.	The supply of nortriptyline tablets in the UK.
Paroxetine[52]	CE-9531/11	Paroxetine 20 and 30mg tablets.	The supply of paroxetine in the UK.
Phenytoin[53]	50908	Phenytoin sodium 25, 50, 100 and 300mg capsules.	The manufacture and distribution of phenytoin sodium capsules in the UK.
Prochlorperazine[54]	50511-2	Prochlorperazine 3mg tablets.	The supply of Prochlorperazine prescription only medicine (prochlorperazine 3mg tablets) in the UK.
Gaviscon[55]	CE/8931/08	GL (alginate formulation) 150, 300 and 600ml packs and GA (alginate product) 150, 250, 300 and 500ml packs.	The supply of alginates and antacids by prescription in the UK.
Cerezyme[56]	CP/0488-01		The supply of drugs for the treatment of Gaucher disease in the UK (upstream) The delivery of cerezyme to hospitals and sales support in the UK (downstream).

[49] CMA (15 July 2021), Competition and Markets Authority Decision: Hydrocortisone tablets – Excessive and unfair pricing and Anti-competitive agreements, para 4.5 and 4.158.

[50] CMA (29 July 2021), Excessive and unfair pricing with respect to the supply of liothyronine tablets in the UK, para 4.2 and 4.24.

[51] CMA (4 March 2020), Decision of the Competition and Markets Authority: Nortriptyline Tablets, paras 1.3 and 5.3.

[52] CMA (12 February 2016), Decision of the Competition and Markets Authority: Paroxetine – Case CE-9531/11, para 3.22 and 4.2.

[53] CMA (21 July 2022), Unfair pricing in respect of the supply of phenytoin sodium capsules in the UK, p.4, 5 and 134.

[54] CMA (3 February 2022), Decision of the Competition and Markets Authority: Prochlorperazine, para 3.23, 4.3 and 4.4.

[55] GL and GA were the two leading Gaviscon products at the time of the OFT's investigation, both of which contain alginates as an active ingredient. See CMA (12 April 2011), Decision of the Office of Fair Trading: Abuse of a dominant position by Reckitt Benckiser Healthcare (UK) Limited and Reckitt Benckiser Group plc, p.23-26 and 227.

[56] Cerezyme is administered by intravenous infusion. Due to this mode of administration, Genzyme (the manufacturer of Cerezyme) distributes Cerezyme alongside specialised homecare services, allowing patients to receive infusions in their own homes. As a result, the OFT distinguishes the upstream and downstream markets for Cerezyme in its definition.

Drug	Case Reference	VMPs Considered	Market Definition Decision
Morphine[57]	CA98/2/2001	Sustained release morphine 5, 10, 15, 30, 60, 100 and 300mg tablets.	The supply of sustained release morphine tablets and capsules in the UK.

Source: NERA analysis

In addition to the existence of CMA precedent on the definition of specific markets, there is also CMA precedent on the *process* of market definition, which DHSC does not appear to have considered. The CMA follows a standard process in its assessment of the relevant market for a pharmaceutical product in the anti-competitive pricing cases we have reviewed. The CMA evaluates the relevant product market based on the extent to which other products, alleged to form part of the same market, act as a competitive constraint on the conduct of the allegedly dominant firm.[58] This involves the review of both qualitative and quantitative evidence, as follows:[59]

- *Qualitative evidence:* The CMA's qualitative assessment examines whether other products are perceived by prescribers to be therapeutically substitutable for the drug under consideration.[60] Both the CMA and European Commission have previously consulted the Anatomical Therapeutical Chemical (ATC) classification system as a starting point for this evaluation followed by an assessment of factors influencing GP and doctors' tendency to prescribe the given drug.[61] The CMA may also evaluate internal documents of the drug manufacturer as part of this assessment for insight into whether the manufacturer perceives prices or sales as being constrained by the existence or development of other products as well as changes to guidance in the treatment area.[62]
- *Quantitative evidence:* The CMA's quantitative assessment evaluates whether other products exert a significant competitive constraint on the drug under consideration by evaluating actual consumption patterns.[63] This assessment is typically conducted through the analysis of prices and volumes dispensed over an alleged infringement period to

[57] CMA (30 March 2001), Decision of the Director General of Fair Trading: Napp Pharmaceutical Holdings Limited and Subsidiaries (Napp), para 40 and 93.

[58] See for example: CMA (29 July 2021), Decision of the Competition and Markets Authority: Excessive and unfair pricing with respect to the supply of liothyronine tablets in the UK, para 4.3.

[59] See for example: CMA (15 July 2021), Competition and Markets Authority Decision: Hydrocortisone tablets, para 4.18.

[60] CMA (15 July 2021), Competition and Markets Authority Decision: Hydrocortisone tablets – Excessive and unfair pricing and Anti-competitive agreements, para 4.41.

[61] The Anatomical Therapeutic Chemical (ATC) classification system is an internationally recognised system for drug utilisation monitoring and research. It is recognised and employed by the European Pharmaceutical Market Research Association (EPhMRA) and the corresponding system maintained by the World Health Organisation (WHO). CMA (29 July 2021), Excessive and unfair pricing with respect to the supply of liothyronine tablets in the UK, p.91.

[62] See for example: (1) CMA website (29 July 2021), Excessive and unfair pricing with respect to the supply of liothyronine tablets in the UK, p.93. (2) CMA (12 February 2016), Decision of the Competition and Markets Authority: Paroxetine – Case CE-9531/11, p.201-209.

[63] See for example: CMA (29 July 2021), Excessive and unfair pricing with respect to the supply of liothyronine tablets in the UK, para 4.87.

evaluate the extent of switching to proposed substitutes.[64] The CMA has also evaluated the effect of generic supplier entry on prices in previous cases.[65]

It would likely not be feasible for DHSC to conduct a comprehensive assessment of the relevant market for each pharmaceutical product that has been on the UK market for at least 12 years. However, DHSC could conduct such an assessment for a random or representative selection of pharmaceutical products. There is no evidence that DHSC attempted or considered any such analysis.

Overall, DHSC appears to have adopted an overly restrictive approach to market definition. DHSC itself even appears to use a broader market definition when conducting the empirical analysis that it uses to support the specific payment percentages that it sets as part of the LCA (discussed further in Section 4.4). DHSC reports that it sets the higher payment percentages to align with *"expected price decline following competitive market entry"* based on an analysis of historical data on entry by *biosimilars*, rather than medicines with the same VMP.[66]

DHSC's overly narrow market definition means it has likely overstated the proportion of older medicines that face competitive market conditions and has therefore applied the higher payment percentages to too many products in its IA. This in turn means that DHSC has overstated the extent to which it can maintain the 2 per cent cap on allowed growth and avoid imposing high payment percentages on newer products by imposing elevated payment percentages on older, supposedly uncompetitive products. In practice, if these supposedly uncompetitive products do in fact face market competition, then the current market price will be close to cost-reflective. Imposing an elevated payment percentage will therefore lead to one or more of the adverse effects set out in Section 4.1.

4.4. Payment Percentages for Older Medicines Appear Arbitrary

As outlined above, as part of the LCA, DHSC proposes to set payment percentages that differ from the headline rate for specific categories of older medicines. Specifically: [67]

- DHSC proposes to apply a *supplementary* payment percentage for older medicines in markets that it deems "uncompetitive". This payment percentage would be 36 per cent in 2024, 38 per cent in 2025 and 40 per cent in 2026. DHSC does not specify what the percentage would be from 2027 onwards. DHSC proposes to also apply this supplementary percentage to non-biological medicines which brand by choice.
- DHSC proposes to apply a *lower* payment percentage of 10 per cent for older medicines in markets that it deems to be competitive. DHSC also proposes to apply this rate to

64 See for example: CMA (29 July 2021), Excessive and unfair pricing with respect to the supply of liothyronine tablets in the UK, p.117-121.

65 See, for example: (1) CMA (29 July 2021), Excessive and unfair pricing with respect to the supply of liothyronine tablets in the UK, p.122-123. (2) CMA (12 February 2016), Decision of the Competition and Markets Authority: Paroxetine – Case CE-9531/11, p.220-224.

66 Department of Health & Social Care (18 July 2023), Proposed review of the 2023 scheme to control the cost of branded health service medicines: Open Consultation, p.16.

67 Department of Health & Social Care (18 July 2023), Proposed review of the 2023 scheme to control the cost of branded health service medicines: Open Consultation, p.16.

blood and plasma derived products (due to supply chain constraints for these products) and to new entrants into existing product markets.

DHSC provides very limited empirical analysis to justify its choice of payment percentages. DHSC dedicates just over one page of its consultation document to explaining its chosen percentage levels, with no references to external sources or appendices for supporting evidence. There are at least three flaws in DHSC's approach to setting payment percentages for older medicines, which we discuss in turn below. These flaws means that DHSC's payment percentages are likely to be miscalibrated and therefore will not have the intended effects.

4.4.1. The 10 per cent flat payment percentage is not based on analysis of price dynamics for the products to which it applies

DHSC initially proposes the 10 per cent flat payment percentage for older products in markets that DHSC deems to be "competitive". To explain its choice to set the percentage at 10 per cent specifically, DHSC simply states that *"the level of 10% is appropriate, as it is within the range of rates that have been previously set within the statutory and voluntary schemes without causing issues for products operating in competitive markets"*.[68] It is not clear what "issues" DHSC has in mind or what analysis it has done to show that there were no such issues.

DHSC has not examined whether payment percentages applied to older products in competitive markets have historically been passed through in the form of higher prices, as would be expected in theory (see Section 4.1). If DHSC does not have this understanding of how the payment percentages will be passed through to prices, then its estimates of how much payment percentages limit total NHS costs will be inaccurate.

DHSC also applies the same flat payment percentage of 10 per cent to two very different categories of product: new entrants to existing markets (for the first twelve months only), and blood and plasma products. In neither case does DHSC offer any independent evidence to support the 10 per cent level. It simply explains that both categories of product face relatively high cost pressures and so may need a lower percentage rate than the headline rate, then takes the 10 per cent level as given.[69] This further contributes to the impression that the 10 per cent number has been arbitrarily selected and is not calibrated to meet the needs of any of the product categories to which it is assigned.

4.4.2. The historical data used to set supplementary payment percentages may not be relevant to current products

DHSC says that it has set the supplementary payment percentages to reflect the *expected* decline in prices following competitive market entry, based on historical data on *observed* decline in prices following market entry. There are several reasons for which historically observed declines in prices following competitive market entry may not be achievable for medicines that do not currently face competition:

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[68] Department of Health & Social Care (18 July 2023), Proposed review of the 2023 scheme to control the cost of branded health service medicines: Open Consultation, p.16.

[69] Department of Health & Social Care (18 July 2023), Proposed review of the 2023 scheme to control the cost of branded health service medicines: Open Consultation, p.19-20.

- Those products which do not currently face direct competition may still be subject to the *threat* of competitive entry and may have reduced their prices accordingly following the expiry of patent protection. They may therefore already be pricing close to marginal cost;
- We understand from the ABPI that the headroom in baseline prices above marginal cost has fallen in recent years, in part due to stricter application of NICE cost effectiveness tests. DHSC does not describe the historical dataset it uses for its analysis in detail, but to the extent that prices in the historical data were set under a different regime, the historical data may overstate the headroom available in current prices;
- Products which have faced competition following patent expiry may be substantively different to products which did not face this competition, such that there is less headroom in the original price relative to marginal cost for products that did not face competition than for products that did. For example, the product may be one that is complex to produce or for which there is limited demand, and so the manufacturer may have been willing to set a lower price assuming that it would not face competitive entry following patent expiry.

In summary, DHSC's assumption that the price decline observed over some unspecified historical period should be applicable to all products going forward is overly simplistic.

Even if it were reasonable to make this assumption, the range of the decline in prices following market entry that DHSC observes in the historical data is wide: *"between 20 to 50%"*.[70] From this range, DHSC picks three levels for each of the years 2024 to 2026: 36 per cent, 38 per cent, and 40 per cent. DHSC provides no explanation for why it took 36 per cent as the starting level.

Overall, DHSC's simplistic approach of applying a near-midpoint of a wide range of historical values to all current products means that the payment percentages for these products are likely to be miscalibrated. In particular, if payment percentages are too high and exceed the available headroom in baseline prices, the approach may have adverse consequences for the statutory scheme policy objectives as set out in Section 4.1.

4.4.3. Annually increasing supplementary payment percentages create uncertainty for investors

DHSC's approach to setting the supplementary payment percentage rates creates significant uncertainty over the future development of the statutory scheme for market participants.

DHSC appears to have introduced the year-on-year increase to ensure its forecasts continue to meet the 2 per cent allowed growth cap without requiring a high headline payment percentage. It writes, *"the proposed year-on-year increase reflects that according to current forecast sales growth will outstrip allowed sales growth, and therefore that scheme payment percentages will need to increase"*.[71] In other words, the increase is motivated entirely by the need to maintain the 2 per cent cap on allowed sales growth and is not driven by any

[70] Department of Health & Social Care (18 July 2023), Proposed review of the 2023 scheme to control the cost of branded health service medicines: Open Consultation, p.16.

[71] Department of Health & Social Care (18 July 2023), Proposed review of the 2023 scheme to control the cost of branded health service medicines: Open Consultation, p.16.

theoretical or empirical evidence around what is sustainable for a typical product that faces competitive entry.

DHSC has pushed the problem of the unsustainability of the 2 per cent cap on allowed sales growth from the headline percentage rates to the percentage rates on older "uncompetitive" products – at least for the period from 2024 to 2026. This creates substantial uncertainty for market participants about the post-2027 evolution of the scheme, as DHSC may either continue increasing the payment percentage for older "uncompetitive" medicines or may begin to increase the headline rate. This uncertainty may deter investment.

5. The Options Selected for Assessment are Too Narrow

In this chapter, we explain that the set of options included in DHSC's IA may be overly narrow and pre-determined by the existing structure of the VPAS scheme. This would be inconsistent with government guidance on the development of options for policy appraisal and means that DHSC may have failed to consider options that could better meet all three of the policy objectives for the statutory scheme. In particular, there is no evidence that DHSC considered a flat percentage payment at a level below 27.5 per cent, in line with ABPI proposals for the successor to VPAS and international comparators.

As described in Chapter 2, DHSC considers five options in its IA. The first of these is the BAU option. The remaining four options all maintain the cap mechanism of the current statutory scheme with the cap set to 2 per cent per annum. The options vary by whether (a) NAS receive a 36-month exemption and (b) older medicines are subject to a life-cycle adjustment, as summarised in Table 5.1 below.

Table 5.1: Features of Options for Statutory Scheme Amendments

	Without LCA	**With LCA**
Excludes 36-month exemption for NAS	Option 1a	Option 2a
Includes 36-month exemption for NAS	Option 1b	Option 2b

Source: DHSC[72]

When developing options for a regulatory IA to support new secondary legislation, such as the IA at hand, government departments are required to follow the guidance set out in HMT's Green Book.[73] The Green Book advises that government departments should first develop a longlist of policy options and then filter down its longlist of options to an "*optimum viable shortlist*".[74] We assume that the five options set out above constitute this shortlist.

DHSC's inclusion and definition of the BAU option in its shortlist is consistent with Green Book guidance on policy appraisal. The Green Book advises that the shortlist should include a BAU option. It further advises that the BAU option should reflect *"the continuation of current arrangements, as if the proposal under consideration were not to be implemented"*.[75] DHSC explains that it has set a continued payment percentage of 27.5 per cent as the BAU case because *"under the existing regulations, this is the payment percentage that would apply if no further intervention were pursued"*.[76] This is consistent with the Green Book advice on what the BAU option should reflect.

[72] Department of Health & Social Care (18 July 2023), Impact Assessment (IA): Statutory Scheme – Branded Medicines Pricing, p.1.

[73] GOV.UK (2022), The Green Book (2022), Section 3.3, URL: https://www.gov.uk/government/publications/the-green-book-appraisal-and-evaluation-in-central-governent/the-green-book-2020. Visited on 17 August 2023.

[74] GOV.UK (2022), The Green Book (2022), Section 4.5, URL: https://www.gov.uk/government/publications/the-green-book-appraisal-and-evaluation-in-central-governent/the-green-book-2020. Visited on 4 August 2023.

[75] GOV.UK (2022), The Green Book (2022), Section 4.1, URL: https://www.gov.uk/government/publications/the-green-book-appraisal-and-evaluation-in-central-governent/the-green-book-2020. Visited on 18 August 2023.

[76] Department of Health & Social Care (18 July 2023), Impact Assessment (IA): Statutory Scheme – Branded Medicines Pricing, p.12.

However, it is not clear that the remainder of the shortlist (i.e., options 1a, 1b, 2a, and 2b) was developed in line with Green Book guidance on policy appraisal. DHSC provides no information in its consultation or impact assessment about how this shortlist was developed. It also does not provide any information about the initial longlist of options considered and how that longlist was developed (if indeed it was).

All four of the shortlisted options other than BAU are variations on transferring the structure of the existing VPAS to the statutory scheme. As a result, DHSC may have failed to adhere to Green Book guidance that *"when constructing the longlist a predetermined or complete final option should be avoided"*.[77] The Green Book emphasises in several places the importance of considering a wide range of possible options and not restricting appraisal to predetermined solutions.

The Green Book explains that focusing on a predetermined option is *"likely to ignore potentially better alternatives by taking too narrow a view"* and risks failing to recognise implicit assumptions which it describes as *"invariably the seeds of cost escalation, time delays, under delivery and often outright failure, because they have not been considered and tested"*.[78] In the context of the statutory scheme proposal, one such implicit assumption appears to be that the level of growth in expenditure on branded medicines that is affordable to the NHS is equal to 2 per cent per annum (in nominal terms).

Per Green Book guidance, DHSC should have approached the development of the longlist and shortlist as set out below.

1. First, DHSC should have set out SMART (Specific, Measurable, Achievable, Realistic, Time-limited) objectives when making its case for intervention, where these objectives represent outcomes that a given option should achieve.[79] It is likely that in the case of the statutory scheme, these are the three policy objectives set out in Chapter 2.

2. Second, DHSC should have identified the Critical Success Factors (CSFs) for the proposal. CSFs are "*attributes that any successful proposal must have, if it is to achieve successful delivery of its objectives*".[80] The Green Book defines five basic CSFs that apply to all proposals and allows that in some cases one or two more may be added; there is nothing in DHSC's IA to suggest it added further CSFs.

3. Third, DHSC should have used "structured facilitated workshops" to develop its longlist. The Green Book refers to HMT's Business Case guidance as a source for further information on using these workshops to develop a longlist of options. This guidance explains that the workshops should involve *"senior managers and stakeholders (business input), customers (user input) and specialists (technical input) among other interested*

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77 GOV.UK (2022), The Green Book (2022), Section 4.5, URL: https://www.gov.uk/government/publications/the-green-book-appraisal-and-evaluation-in-central-governent/the-green-book-2020. Visited on 4 August 2023.

78 GOV.UK (2022), The Green Book (2022), Sections 4.4 and 4.5, URL: https://www.gov.uk/government/publications/the-green-book-appraisal-and-evaluation-in-central-governent/the-green-book-2020. Visited on 4 August 2023.

79 GOV.UK (2022), The Green Book (2022), Section 4.2, URL: The Green Book (2022) - GOV.UK (www.gov.uk). Visited on 4 August 2023.

80 GOV.UK (2022), The Green Book (2022), Section 4.4, URL: https://www.gov.uk/government/publications/the-green-book-appraisal-and-evaluation-in-central-governent/the-green-book-2020. Visited on 4 August 2023.

parties".[81] It suggests a number of factors that the relevant government department should consider in developing options, including international examples, the full range of available policy instruments, and radical options. There is no evidence in the consultation document or IA that DHSC considered these kinds of departures from the existing VPAS in its development of the proposed statutory scheme.

4. Fourth, DHSC should have assessed each option on the longlist against its outlined CSFs and its SMART objectives to narrow down its longlist into a shortlist, including at least the BAU option, a "do minimum" option, the "preferred way forward", and variations on the preferred way forward that are either more or less ambitious.[82] There is no evidence in the IA or consultation document that DHSC constructed the final shortlist in this way. In particular, there is no evidence that the preferred way forward (presumably option 1b, with options 2b and 1a capturing the more and less ambitious variations respectively) is superior to other substantively different options that appeared in a longlist in terms of either CSFs or DHSC's SMART objectives for the statutory scheme.

Given HMT guidance to consult with business stakeholders and consider international examples, it seems inconsistent with this guidance that DHSC does not consider an option of a flat percentage payment at a lower level than 27.5 per cent. In the context of consultations on a successor to the VPAS, industry stakeholders (through ABPI) have proposed a flat payment percentage of 6.88 per cent.[83] In other countries such as Ireland and the US, a flat payment percentage is used, and the BAU payment percentage level of 27.5 per cent is towards the upper end of the range of percentages set as discussed in Chapter 3.

[81] HM Treasury (2018), Guide to Developing the Project Business Case, p.28.

[82] GOV.UK (2022), The Green Book (2022), Section 4.5, URL: https://www.gov.uk/government/publications/the-green-book-appraisal-and-evaluation-in-central-governent/the-green-book-2020. Visited on 4 August 2023.

[83] ABPI (March 2023), At the crossroads: how a new UK medicines deal can deliver for patients, the NHS and the economy, p.9.

6. DHSC's Assessment of Costs and Benefits is Flawed

In this chapter, we assess DHSC's approach to assessing the costs and benefits of each of the five options set out in its IA. We identify six flaws in DHSC's assessment, each of which we discuss in the relevant subsection as follows:

- Section 6.1 explains that the three-year appraisal period DHSC uses for its IA is shorter than the horizon recommended in the Green Book and fails to capture long-term benefits from R&D investment;
- Section 6.2 highlights the lack of transparency in DHSC's selection between options that results from its failure to quantify key benefits that determine its final recommendation;
- Section 6.3 explains that DHSC's approach to estimating the impact of changes to the statutory scheme on R&D investment is overly simplistic and therefore likely to distort estimates of the impact on R&D;
- Section 6.4 explains that DHSC is incorrect in its assumption that R&D investment does not confer direct economic benefits, leading it to understate the benefits of R&D;
- Section 6.5 highlights that DHSC has adopted an estimate for the spillover benefits of R&D that is not consistent with its own evidence, which in turn suggests that it has relied on predetermined parameters in its IA rather than engaging with recent evidence;
- Section 6.6 explains that, to be consistent in its assessment of the relative benefits of revenues retained by pharmaceutical companies versus revenues transferred to the NHS, DHSC should quantify the long-term health benefits of pharmaceutical R&D.

6.1. Three-Year Appraisal Period is Too Short

The three-year appraisal period that DHSC uses for its IA is shorter than the period recommended as standard practice in the Green Book. By using this short appraisal period, DHSC's IA fails to capture longer-term *economic* benefits of a creating a regulatory environment that supports the life sciences sector (policy objective 3 of the scheme) and *health* benefits from the development of new medicines through investment in R&D (policy objective 2 of the scheme).

The Green Book advises that IAs should assess costs and benefits *"over the lifetime"* of a proposal or intervention.[84] It notes that a ten-year horizon is a standard measure. It further advises that, when evaluating interventions over shorter periods (it gives the example of a five-year commercial contract), then *"it is necessary to understand and plan for service delivery over the longer period"*.[85]

DHSC's three-year appraisal period is therefore out of line with Green Book guidance. Although DHSC suggests that the three-year period *"covers the lifetime of the Regulations proposed"* since it has only calculated payment percentages for years 2024-2026, this

[84] GOV.UK (2022), The Green Book (2022), Section 2.4 and 5.3, URL: https://www.gov.uk/government/publications/the-green-book-appraisal-and-evaluation-in-central-governent/the-green-book-2020. Visited on 31 August 2023.

[85] GOV.UK (2022), The Green Book (2022), Section 2.4, URL: https://www.gov.uk/government/publications/the-green-book-appraisal-and-evaluation-in-central-governent/the-green-book-2020. Visited on 31 August 2023.

statement is inaccurate.[86] If DHSC implements its preferred option via secondary legislation in the manner proposed, then absent any further action by government the proposed regulation will continue to govern payment percentages from 2027 onwards.[87] This is similar to the current situation, whereby the payment percentage set for 2023 will continue to apply going forward if there is no change to policy.

Even if DHSC were correct that the regulations would only have effect for three years, it would still under Green Book guidance need to understand and plan for the development of the scheme from 2027 onwards and account for this in its IA.

DHSC also suggests that it can only assess costs and benefits over a three-year period due to "inherent uncertainty" in forecasting medicine sales over time. However, there is nothing in DHSC's reported methodology for forecasting medicine sales to suggest there should be a significant deterioration in the quality of forecasts produced using the methodology between a third and fourth year.[88] DHSC also does not offer any analysis of the accuracy of its previous forecasts to support its position that the "inherent uncertainty" of forecasts beyond a three-year horizon is too great for the forecasts to be useful.

Some of the impacts of the proposed regulations will occur over a relatively long horizon. For example, there may be long-term impacts on industry perceptions of the UK as a supportive environment for R&D investment, which is likely to slow or even reverse the growth of investment in the UK life sciences sector. This would be contrary to the statutory scheme's third policy objective of supporting the life science sector.

Reduced R&D investment is also likely to slow the development of new medicines that would have health benefits for patients. This contradicts the statutory scheme's second policy objective of ensuring the availability of medicines for patients.

By restricting its analysis to a relatively short time horizon of three years, DHSC excludes the most important benefits that accrue from supporting R&D in the life sciences sector, which are necessarily long-term.

6.2. Non-Monetised Benefits Determine Recommendation and Render Quantitative Impact Assessment Irrelevant

DHSC's recommendation to pursue either option 1b or 2b relies critically on assumptions about the magnitude of non-monetised benefits from each of the policy options. DHSC makes no attempt to quantify these benefits and offers little justification for its assumptions. This makes it impossible to critically appraise DHSC's recommendation or consider the likely impact of alternative options not included in the IA.

[86] Department of Health & Social Care (18 July 2023), Impact Assessment (IA): Statutory Scheme – Branded Medicines Pricing, p. 11

[87] Department of Health & Social Care (18 July 2023), Impact Assessment (IA): Statutory Scheme – Branded Medicines Pricing, p. 14

[88] Department of Health & Social Care (18 July 2023), Impact Assessment (IA): Statutory Scheme – Branded Medicines Pricing, Annex A – Medicine Spend Forecast, pp. 35-38

None of the policy options that DHSC considers have a positive net benefit relative to the BAU option, according to DHSC's estimates. The two preferred options, 1b and 2b, have estimated costs of £27,430 million and £27,460 million respectively, as shown in Table 6.1.

Table 6.1: DHSC Estimates a Net Cost Relative to BAU for all Four Policy Options

	Policy option key features				
	Payment percentage fixed at 2023 level (27.5%)	**Payment percentage set based on 2% allowed growth**	**36-month exemption for NAS**	**Life Cycle Adjustment**	**Monetised net benefit (cost) relative to BAU, £m**
BAU	Y				0
Option 1a		Y			(27,460)
Option 1b		Y	Y		(27,430)
Option 2a		Y		Y	(27,460)
Option 2b		Y	Y	Y	(27,460)

Note: Highlighted rows indicate DHSC preferred options.
Source: NERA analysis of DHSC IA[89]

DHSC's justification for recommending options 1b and 2b therefore relies on an assumption that the non-monetised benefits of these options exceed the monetised costs, such that options 1b and 2b confer more net benefit than the BAU or options 1a and 2a. DHSC provides no clear evidence and very limited argumentation to support this critical assumption in its IA.

DHSC is correct that there are likely to be benefits to its proposed policy options that it has not quantified. These include:

- **More positive industry sentiment regarding the UK:** The headline non-monetised benefit that DHSC identifies in the IA is that setting payment percentages according to a clear methodology *"supports the perceived rationality of the UK market and protects from a potential deterioration in industry sentiment towards the UK"*.[90] More positive industry sentiment towards the UK is likely to mean that more new medicines are launched in the UK and more clinical trials occur in the UK, consistent with the second policy objective of the statutory scheme (to ensure medicines are available). It also is likely to mean more R&D investment occurs in the UK than under BAU, in line with the third policy objective of the scheme (supporting the life sciences sector and broader economy).

- **Development of new medicines:** DHSC also identifies non-monetised benefits specific to the policy features of options 1a, 2a, and 2b, noting that *"Including a New Active Substance exemption may support continued access to these products"* and *"the lower payment percentage for newer products may further support innovation and access to novel treatments"*.[91] This reflects that the policy options may result in more

[89] Department of Health & Social Care (18 July 2023), Impact Assessment (IA): Statutory Scheme – Branded Medicines Pricing, p.1.

[90] Department of Health & Social Care (18 July 2023), Impact Assessment (IA): Statutory Scheme – Branded Medicines Pricing, p. 3

[91] Department of Health & Social Care (18 July 2023), Impact Assessment (IA): Statutory Scheme – Branded Medicines Pricing, p. 4, p. 5

pharmaceutical R&D than the BAU option, which in the long-term means more medicines are available to patients, in line with the second policy objective of the statutory scheme.

DHSC makes no attempt to quantify these substantial non-monetised benefits, even on an indicative basis to understand the likely scale of the benefits. This makes it impossible to understand and critically appraise DHSC's selection between the different options it has considered.

DHSC also provides little argumentation to support its selection between the different options. It simply states that *"the unquantified benefit around supporting access to new and innovative products may be enhanced"* by the proposed exemptions under 1b.[92] It states that option 2a may have *"a more significant unquantified benefit in terms of supporting patient access to new and innovative products compared to the BAU counterfactual and options 1a and 1b"* because of the LCA.[93] DHSC does not explain why it believes the benefit from a LCA (under 2a) exceeds the benefit from the exemptions (under 1b).

From this limited argumentation, the ranking of the options in terms of non-monetised benefits appears to be 2b > 2a > 1b > 1a > BAU. Looking at the monetised costs and benefits, the ranking appears to be BAU > 1b > (1a, 2a, 2b). DHSC's recommendation favours 1b/2b. It is not clear how DHSC concluded that the 2b was superior to 2a (or indeed 1a) in net benefit terms.

Essentially, DHSC's recommendation is determined by the non-monetised benefits. This renders the quantification that DHSC has provided (and thus arguably the entire IA) redundant. Effectively, DHSC has proposed to transfer what it estimates to be approximately £10 billion from the pharmaceutical industry to the NHS without providing any quantitative evidence that the benefits of doing so outweigh the costs.[94] This gives the impression, rightly or wrongly, that DHSC's recommendation simply reflects its predetermined view about what form the future statutory scheme should take, rather than an evidence-based decision.

In the absence of any quantification of the non-monetised benefits, it is also impossible to gauge the potential ranking of any alternative to the proposed policy options. For example, an option with a lower flat payment percentage (in line with ABPI proposals for the voluntary scheme and with international practice) would likely increase the non-monetised benefits as well as increasing the monetised costs to the NHS. Since DHSC has not provided any guidance on the quantification of non-monetised benefits, it is not possible to estimate the net benefits of this alternative option on a consistent basis with DHSC's appraisal of the existing policy options.

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92 Department of Health & Social Care (18 July 2023), Impact Assessment (IA): Statutory Scheme – Branded Medicines Pricing, p. 25

93 Department of Health & Social Care (18 July 2023), Impact Assessment (IA): Statutory Scheme – Branded Medicines Pricing, p. 29

94 DHSC estimates that the "income" it will receive from Option 1b is £10,500 million, or from Option 2b £10,490 million (under the central forecast of measured sales). Department of Health & Social Care (18 July 2023), Impact Assessment (IA): Statutory Scheme – Branded Medicines Pricing, p. 23 and p. 31

6.3. Simplistic Estimate of Impact on R&D Investment

DHSC provides partial estimates of some inputs that would be needed to calculate non-monetised benefits "for illustrative purposes only". This includes an estimate of the impact on both global and UK-specific R&D of changes to revenues obtained by pharmaceutical companies from UK medicine sales. The approach taken to derive these estimates is overly simplistic and so any attempt to quantify non-monetised benefits that relies on these estimates may over- or under-state the true benefit.

6.3.1. DHSC approach and limitations

DHSC assumes that the change to global pharmaceutical sector R&D investment resulting from changes to the statutory scheme is equal to a share of the change in pharmaceutical company revenues. DHSC sets this share based on its estimate of the proportion of pharmaceutical industry revenues that are currently spent on R&D. Specifically, DHSC estimates that the global pharmaceutical industry currently invests 25 per cent of its revenues in R&D.[95] Because DHSC estimates the difference between any of the policy options and the BAU option in revenues retained by the pharmaceutical industry is £6.27 billion, this implies an estimated difference between the options in global R&D investment of £1.57 billion.[96]

DHSC uses a similar logic to estimate the difference in UK pharmaceutical sector R&D between IA options. It assumes that the difference in UK R&D is equal to a share of the difference in global R&D, where that share reflects DHSC's estimate of the proportion of current global pharmaceutical R&D that occurs in the UK. DHSC estimates that the UK share of global pharmaceutical R&D is 3.1 per cent.[97] This implies an estimated difference in UK pharmaceutical R&D between any of the policy options and the BAU option of £48.59 million (i.e., 3.1 per cent of £1.57 billion).

This approach is overly simplistic because it fails to account for the following considerations:

- **The assumption that companies scale up and down their spending across activities proportionately in response to revenue changes is unrealistic.** In practice, companies are likely to prioritise cuts to certain areas of spending when faced with a reduction in revenue. Therefore, the impact of a reduction in UK medicines revenue on R&D depends on how companies prioritise R&D investment. On the one hand, they may protect it from cuts entirely, so there is no change to R&D; on the other, R&D might be seen as an area that can more easily withstand cuts than, say, manufacturing.
- **The assumption that the share of global pharmaceutical R&D investment located in the UK is static is unrealistic.** If pharmaceutical companies perceive changes to the statutory scheme as a signal that the UK is less supportive of life sciences innovation, they may reduce the share of their R&D investment that is located in the UK. This is

[95] Department of Health & Social Care (18 July 2023), Impact Assessment (IA): Statutory Scheme – Branded Medicines Pricing, p. 41

[96] The same £6.27 billion figure is reported for all four policy options. Differences between the policy options are not evident because of rounding and only become apparent once revenues are scaled up to societal value of QALYs. See for example Department of Health & Social Care (18 July 2023), Impact Assessment (IA): Statutory Scheme – Branded Medicines Pricing, p. 24

[97] Department of Health & Social Care (18 July 2023), Impact Assessment (IA): Statutory Scheme – Branded Medicines Pricing, p. 41

consistent with the findings of overview reports by CRA in 2022 and NERA in 2007 into the determinants of R&D investment locations. Both reports are referenced by DHSC as evidence that supply-side factors are of greatest importance in determining investment location.[98] However, both reports find that, while pricing policy is less important in determining the location of R&D investment than supply-side factors such as access to a skilled labour force, there are channels through which pricing can influence investment decisions. For example, companies may not locate clinical trials in countries that that they perceive as unsupportive of innovation, either because they do not expect that the country will be a core market for the medicine in future or because the prevailing standard of care is not up-to-date enough to serve as a robust control.[99] Further, in cases where supply-side factors are similar enough that there are a number of choices for location of investment, "executives' perception of market conditions" may become an important factor in decisions.[100]

6.3.2. Alternatives to DHSC approach

For DHSC to quantify the benefit to the UK of allowing pharmaceutical companies to retain more revenue under policy options 1a-2b (or any alternative option) than under the BAU scenario, it would need to understand how companies are likely to adjust R&D spending (both globally and in the UK) in response to changes to the statutory scheme. It could do this by using information from the ABPI, referring to academic or grey literature, or commissioning further independent analysis.

ABPI surveyed its members in February 2023 to understand how they expect to adjust R&D spending in response to changes to the statutory scheme. The survey asked members to report their total expected R&D spending for 2023 and 2028 under four different payment percentage scenarios: below 10 per cent, 10-15 per cent, 15-20 per cent, and 20-30 per cent. WPI Strategy analysed the survey data and found that by 2028, if DHSC were to set payment percentages of 20-30 per cent, R&D investment in the UK would be 26 per cent lower than if DHSC set payment percentages of less than 10 per cent. WPI Strategy therefore estimates that over the period 2024-2028, if DHSC were to set payment percentages of 20-30 per cent, R&D investment in the UK would be £5.7 billion less than if DHSC set payment percentages of less than 10 per cent.[101]

WPI Strategy's figure is not directly comparable to the estimated change in UK R&D investment of £48.59 million using DHSC's approach, because DHSC uses a shorter time horizon (2024-2026) and looks at a smaller difference in payment percentages. For example, the average difference in payment percentages between option 1b and the BAU is just 3.5 per

[98] See (1) reference to the CRA report in Department of Health & Social Care (18 July 2023), Impact Assessment (IA): Statutory Scheme – Branded Medicines Pricing, pp. 39-41 and (2) reference to the NERA report in DHSC (21 February 2023), Impact Assessment: Spring 2023 update to the Statutory Scheme controlling the costs of branded health service medicines, p. 23.

[99] Charles River Associates (3 October 2022), Factors affecting the location of biopharmaceutical investments and implications for European policy priorities, pp. 87-88

[100] NERA (21 September 2007), Key Factors in Attracting Internationally Mobile Investments by the Research-Based Pharmaceutical Industry, p. 13

[101] WPI Strategy generates this estimate based on linear interpolation between the levels of investment for 2023 and 2028 under each payment percentage scenario as reported in the survey. WPI Strategy (February 2023), False economy? How NHS medicine procurement threatens the UK's Life Sciences growth engine, p. 11

cent. However, if we apply simple linear adjustments to make a rough comparison between the numbers, WPI Strategy's estimate is still more than ten times that of DHSC.[102]

DHSC may be concerned that ABPI members could have reported greater sensitivity of their R&D investment decisions to the statutory scheme in response to this survey than would actually transpire, since the survey involves hypothetical scenarios. Given that, DHSC may instead want to draw on publicly available evidence on how actual investment decisions have responded to changes in price regulation, for example from academic or grey literature.

In assessing the academic literature, DHSC should take care to ensure that the empirical specifications used in the papers it cites are relevant to the question at hand, that is, how changes to the payment percentage level may influence R&D investment in the UK.

For example, the 2020 paper by Shaikh et al. that DHSC cites in the IA answers a different empirical question, specifically, whether companies with a higher ratio of European to US sales invest less of their revenues in R&D.[103] This analysis may capture differences in corporate strategy driven by factors unrelated to price regulation. Further, the assumption that the explanatory variable (ratio of European to US sales) is positively correlated with price regulation may be confounded by the fact that sales are defined on a *value* rather than *volume* basis. A company whose European markets are primarily countries where strict regulation keeps prices very low may in fact have a *lower* share of their sales by value in Europe than a company whose European markets are countries with weaker price regulation, where prices may be higher.

A paper like Koenig and MacGarvie (2011) is more relevant to the question at hand, in that it tests the relationship between a direct measure of country-level pricing policy and R&D investment decisions.[104] However, this specific paper may be less useful to understand the impact of changes to the *level* of the statutory scheme payment percentage because it represents country-level pricing policy decisions in a simplified way using dummy variables.

The 1994 study by the GAO, referenced in NERA's 2007 report on factors affecting pharmaceutical R&D, does attempt to capture the impact of changes to price levels.[105] It estimates the elasticity of company R&D investment in a country to the average pharmaceutical price in that country, finding that a 1 per cent decrease in the pharmaceutical price is related to a 0.68 per cent decrease in the average company's R&D expenditure. The data used in that paper is now over 30 years old and so may not provide a good guide to

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[102] The adjustment process is as follows: First, we multiply the DHSC estimate by 1.67 to adjust for the difference in the number of years (5 years for WPI vs. 3 years for DHSC). Second, we multiply the DHSC estimate by 5.17 to adjust for the difference in payment percentage differences. We assume a payment percentage difference of 3.5 per cent for DHSC. We assume a payment percentage difference 18.1 per cent for WPI Strategy, based on the difference between 25 per cent (the midpoint of 20-30 per cent) and 6.9 per cent, where the latter figure is in line with WPI Strategy's approach to interpretation of payment percentages below 10 per cent; see WPI Strategy (February 2023), False economy? How NHS medicine procurement threatens the UK's Life Sciences growth engine, p. 17. That is, we calculate £48.59 million x 1.67 x 5.17 = £418.82 million. The ratio of £5.7 billion to £418.82 million is 13.61.

[103] Shaikh, M., Del Guidice, P., and Kouroukils, D. (2021), Revisiting the relationship between price regulation and pharmaceutical R&D investment, *Applied Health Economics and Policy 19*, pp. 217-229

[104] Koenig, P. and MacGarvie, M. (2011), Regulatory policy and the location of bio-pharmaceutical foreign direct investment in Europe, *Journal of Health Economics 30*, pp. 950-965

[105] NERA (21 September 2007), Key Factors in Attracting Internationally Mobile Investments by the Research-Based Pharmaceutical Industry, p. 13 cites HEHS (1994), Prescription Drugs: Spending Controls in Four Countries

contemporary responsiveness of R&D to pharmaceutical prices. However, the order of magnitude of the GAO's estimate is more consistent with the results of WPI Strategy's survey of ABPI membership than of DHSC's simplistic analysis.

We have not conducted an exhaustive literature review in developing this paper, and it is likely that more suitable empirical references than the three listed above exist. However, if no suitable empirical references can be found, DHSC or the ABPI may wish to commission independent research on the relationship between R&D investment and price regulation.

6.4. Failure to Account for Direct Benefits of R&D Investment

DHSC argues that any increase in R&D arising from changes to the statutory scheme should not be counted directly as a benefit because *"it represents deployment of resources that would otherwise have found some other use"*; instead, only spillover effects should count as benefits.[106] This fails to consider that alternative deployment of resources may be less efficient, such that those resources would contribute less to UK GDP; and that resources deployed through pharmaceutical R&D investment may not otherwise be in the UK. It therefore understates the benefits from R&D.

DHSC's argument implies an assumption that there is no net gain in terms of UK GDP from R&D investment by pharmaceutical companies, because any resources used for R&D would otherwise find equally gainful employment in another sector.

First, alternative deployment of resources is on average likely to be less efficient than deployment in pharmaceutical R&D. In theory, markets forces should ensure that resources are deployed where they are most valuable (as they will command the highest compensation there). In the absence of pharmaceutical R&D, any alternative employment for those resources should be *at most* equally profitable to employment in pharmaceutical R&D and in some cases is likely to be less profitable. In reality, markets may be imperfect and so some resources engaged in pharmaceutical R&D may be able to find more profitable employment. However, on average, alternative deployment is likely to yield less benefit than deployment in pharmaceutical R&D.

Second, DHSC assumes that all resources currently committed to UK pharmaceutical R&D would be deployed in other UK-based activities if they were not deployed in pharmaceutical R&D. This is unlikely to be true. In particular, much of the skilled and specialised labour force engaged in pharmaceutical R&D may have moved to the UK specifically for that purpose, and would move elsewhere (e.g., the US or Germany) in the absence of pharmaceutical R&D in the UK.

6.5. Arbitrary Percentage for GDP Spillovers of Pharmaceutical R&D

As explained in Section 6.4, DHSC claims that only spillover effects from R&D should be counted as benefits. Spillover benefits from investment are benefits that accrue to other

[106] Department of Health & Social Care (18 July 2023), Impact Assessment (IA): Statutory Scheme – Branded Medicines Pricing, p. 41

entities and are not captured by the investing entity. DHSC gives as examples *"the generation of knowledge and human capital, which generate net societal benefits".*[107]

DHSC assumes that the *net present value* of spillover benefits to UK R&D is 30 per cent of the R&D investment. DHSC reports that it bases this figure on a review of estimates from academic and grey literature. DHSC does not provide the full list of sources to which it refers; however, looking at the two sources which DHSC does explicitly reference, it appears that DHSC has seriously misinterpreted this evidence.

DHSC reports that it examined ten papers on spillover benefits. It explicitly references two of the ten papers that it considers to be of greatest relevance: a 2014 paper by Frontier Economics on UK investment in science and innovation that DHSC claims reports spillovers of 20 per cent and a 2020 paper by researchers at the University of York on returns to UK biomedical investment that DHSC claims reports spillovers of 58 per cent.

In its calculations, DHSC treats the figures from these papers as estimates of the *net present value* of the total spillover benefits. However, upon closer review of the two papers, these figures are not estimates of the net present value of total spillover benefits but rather estimates of *rates of return*, and so cannot be used in the manner adopted by DHSC.

Any spillover benefits that accrue from R&D investment occur over a relatively long time horizon. To take a simple example, imagine that as part of developing a new medicine a company develops an innovative piece of scientific equipment that produces more accurate analysis and is widely adopted by industry; this R&D investment has the spillover benefit of more accurate analysis in perpetuity. To estimate the total benefit of this innovation, it is therefore necessary to estimate the stream of per-year benefits of more accurate analysis across industry, apply a discount rate to those future benefits, and then calculate the sum of those discounted benefits to get a net present value of the total benefit. One could then express this net present value as a percentage of the initial investment.

By adopting the simple calculation that total spillover benefits are equal to 30 per cent multiplied by the initial change in R&D investment, DHSC implicitly assumes that the 30 per cent figure is an expression of the net present value of the stream of spillover benefits as a percentage of the initial investment.[108]

However, neither of the values in papers to which DHSC refers are percentage estimates of the net present value of the spillover benefits to the initial investment:

- The headline 20 per cent figure reported in the 2014 Frontier paper is not actually estimated in that paper but drawn from another paper, Haskel et al. (2014).[109] Haskel et al.'s 20 per cent figure is an estimate of the per-year benefit to total private sector productivity from upfront R&D investment, i.e., the *annual rate of return*.[110]

[107] Department of Health & Social Care (18 July 2023), Impact Assessment (IA): Statutory Scheme – Branded Medicines Pricing, p. 41

[108] Department of Health & Social Care (18 July 2023), Impact Assessment (IA): Statutory Scheme – Branded Medicines Pricing, p. 42

[109] Frontier Economics (July 2014), Rates of return to investment in science and innovation, p. 6 and p. 31

[110] Haskel., J. et al. (March 2014), The Economic Significance of the UK Science Base, pp. 47-48

- The headline 58 per cent figure reported in the 2020 paper by University of York researchers is an estimate of the *internal rate of return* to investment in R&D, which is the discount rate that would be required to make the net present value of the stream of benefits equal to the upfront costs of R&D.[111] This figure also appears to not only capture spillover benefits, but also includes an estimate of the direct long-term health benefit of R&D investment. We discuss the importance of accounting for long-term health benefits of R&D investment further in Section 6.6.

DHSC's incorrect reading of this evidence raises concerns about DHSC's interpretation of evidence elsewhere in the IA, in particular the interpretation of evidence that is not transparently reported (e.g., on the magnitude of non-monetised benefits, as discussed in Section 6.2).

Further, even if the figures DHSC had collected from its literature review were all percentage estimates of the net present value of spillover benefits, the selection of 30 per cent as the final figure appears arbitrary. The midpoint of the numerical values from the papers by Frontier Economics and University of York researchers is 39 per cent.[112] DHSC reports that the mean value from the ten academic papers it reviewed was 34 per cent while the median value was 32 per cent (we cannot validate this as or confirm whether any of these figures is actually an estimate of the net present value in percentage terms, rather than a rate of return, because DHSC does not provide references for eight of the ten papers it consulted).

DHSC choice to use a figure of 30 per cent (rather than 32, 34, or 39 per cent) appears to be a holdover from previous IAs; DHSC writes that it is *"continuing to use"* this assumption, and DHSC used the same 30 per cent figure in its 2020 IA of the statutory scheme.[113]

Overall, DHSC's cursory treatment of the evidence from its literature review suggests that it is relying on predetermined parameters and principles in assessing its options for the future development of the statutory scheme, rather than engaging with the new evidence available to it. This general approach may lead DHSC to erroneous conclusions if applied elsewhere in the analysis, for example, in the selection of options for assessment (Chapter 5) or in the reliance on unquantified benefits to select between options for assessment (Section 6.2).

6.6. Failure to Quantify Health Benefits of Increased R&D

To the extent that DHSC expects changes to the level of R&D to result from changes to the statutory scheme, DHSC should account for the long-term effects of changes to the level of R&D on medicine development and thus on health outcomes. Failure to account for the long-term health benefits of R&D means that there is inconsistency in the IA between the treatment of revenues retained by the pharmaceutical industry and revenues transferred by the industry to the NHS, which systematically biases the IA in favour of transfers to the NHS.

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111 Craig, J., et al. (17 August 2020), Estimating the Economic Value of NIHR Biomedical Research Centres and Units, p. i and p. 125.

112 Department of Health & Social Care (18 July 2023), Impact Assessment (IA): Statutory Scheme – Branded Medicines Pricing, p. 42

113 Department of Health & Social Care (21 January 2020), Impact Assessment (IA): Statutory Scheme to control costs of branded health service medicines, p. 21. Link: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/859212/statutory-scheme-to-control-costs-of-branded-medicines-impact-assessment.pdf (last accessed 31 August 2023)

Throughout the IA, DHSC assumes that changes to the statutory scheme will result in changes to both global and UK-specific pharmaceutical R&D, in proportion to the share of total pharmaceutical revenues that are allocated to each activity (we discuss the limitations of this assumption further in Section 6.3). However, the only benefit that it assumes arises from this R&D is the economic benefit of spillovers to the rest of the economy (discussed further in Section 6.5).

The purpose of pharmaceutical R&D is to develop new medications which provide health benefits to patients. In that sense, allocating revenues to investment in R&D rather than transferring those revenues to the NHS for immediate use reflects a trade-off between health benefits in the future (from new medicines) and health benefits in the present (from NHS services). DHSC's IA does not account for the future health benefits from R&D investment and so understates the benefit from allowing pharmaceutical companies to retain revenues for R&D investment rather than transferring them to the NHS.

To estimate the long-term health benefit from allowing pharmaceutical companies to retain revenues for R&D investment, DHSC would need to proceed as follows:

1. Identify an estimate of the impact of investment in R&D on health outcomes (measured in terms of QALYs). For example, ABPI members may be able to provide an estimate of the average QALYs that can be obtained by investing £100 million in R&D – effectively, a rate of return in terms of QALYs to investment in R&D. Alternatively, DHSC could draw on Medical Research Council estimates of the return to investment in medical research. Another way of thinking about this is that DHSC needs an estimate of the cost of obtaining a QALY through investment in pharmaceutical R&D. In the absence of other evidence, it could use the NICE cost-effectiveness threshold as an upper bound on this cost (insofar as pharmaceutical companies, knowing that this cost-effectiveness threshold exists, should not invest in R&D that achieves a rate of return less than that implied by the threshold).

2. Combine the estimated impact of investment in R&D on QALYs with the estimated total change in R&D investment to generate an estimate of the total QALYs achieved by that investment in each future year.

3. Convert the QALY benefit into a monetised benefit using the same societal value for a QALY as used to estimate the benefit of QALYs obtained through NHS services (in the present IA, this is £70,000 per QALY).[114]

4. Discount the monetised benefits in line with Green Book guidance on discounting to obtain the net present value of the monetised health benefit of R&D investment.

DHSC applies a method like that set out above when estimating the benefit to society of transferring revenue from pharmaceutical companies to the NHS (in the IA, this appears as a *cost* of the policy options 1a-2b relative to the BAU, since the policy options involve smaller transfers to the NHS). It assumes that transfers to the NHS are converted into QALYs at a

[114] We assume that the £70,000 per QALY figure applies for all future years, given that DHSC makes the same assumption in valuing QALYs for 2024-2026.

cost of £15,000 per QALY, and then applies a societal value of £70,000 for each of these QALYs – effectively "scaling up" the value of those transfers by a factor of 4.67.[115]

DHSC's IA scales up the value of transfers to the NHS by converting them into health benefits from NHS services but fails to scale up the value of investment in R&D by converting it into the health benefits of new medicines. This inconsistency overstates the value of transfers from pharmaceutical companies to the NHS relative to the value of investment in long-term health gains through R&D. The overstatement is potentially by a factor of 4.67, depending on the relative cost of QALYs obtained through R&D versus QALYs obtained through other NHS services.

[115] 70,000 / 15,000 = 4.6667

7. DHSC has not Requested Independent Scrutiny of Impact on Business

The Statutory Scheme's objective to be consistent with supporting "*both the life sciences sector and the broader economy"* is in line with the Government's objective to grow the economy and support businesses.[116] To this end, the Better Regulation Executive (BRE), which sits within the Department for Business and Trade, works with government departments to reform regulation on business. The BRE aims to ensure regulatory burden to businesses is measured consistently, regulation is smart, and the costs to businesses of regulation are minimised.[117]

The BRE develops and maintains a Better Regulation Framework which provides guidance for impact assessments that support ministerial decisions to introduce/amend/repeal regulatory legislation. The Better Regulation Framework applies HMT Green Book principles and aims to ensure proportionate scrutiny of regulatory policy.[118]

The Regulatory Policy Committee (RPC) is a body of independent experts, who consistent with the Better Regulations Framework, provide independent scrutiny for regulatory impact assessments. The RPC is typically consulted throughout the development of an impact assessment by a government department, and it publishes opinions on impact assessments alongside the laying of the statutory instruments in parliament. This process typically improves the quality and transparency of the evidence base used for ministerial decisions and the debate of measures laid before parliament to be passed into legislation.

The Better Regulations Framework guidance sets out exemptions for the framework, and thus scrutiny by the RPC, including if the regulatory measure can be classified as a tax/levy, procurement, financial grant or covers a period of less than 12 months.[119] DHSC states that the statutory scheme is out of scope of the better regulation framework due to being classified as procurement.[120]

Whilst the statutory scheme is technically procurement in nature, it also clearly constitutes a regulatory burden to businesses and its impacts therefore arguably merit the same level of scrutiny set out in the Better Regulation Framework.

As we cover in the above chapters of this report, many aspects of the impact assessment lack transparent evidence on the process followed. These include the development of a shortlist of options for IA, the setting of the growth cap at 2 per cent rather than some other level, and the

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116 GOV.UK (2023), The Department for Business and Trade (2023), Who we are, URL: Department for Business and Trade - GOV.UK (www.gov.uk)Visited on 22 August 2023.

117 GOV.UK (2023), The Better Regulations Executive (2023), Who we are, URL: Better Regulation Executive (BRE) - GOV.UK (www.gov.uk)Visited on 22 August 2023.

118 GOV.UK (2023), The Better Regulations Framework, URL: Better regulation framework - GOV.UK (www.gov.uk)Visited on 22 August 2023.

119 GOV.UK (2023), The Better Regulations Framework Guidance, URL: The Better Regulation Framework (publishing.service.gov.uk)), p6. Visited on 22 August 2023.

120 Department of Health & Social Care (18 July 2023), Impact Assessment (IA): Statutory Scheme – Branded Medicines Pricing, p.11.

implementation of the LCA. There are also several other business impacts, that the RPC tends to opine on, and where further scrutiny would be beneficial, including:

- *Administration costs to business:* This typically covers the cost of labour within regulated businesses to gain familiarisation with new/amended regulation and develop and deploy processes to ensure compliance with it. DHSC makes no effort to quantity these costs when it is generally low effort to make some credible assumptions on the required labour. Whilst the administrative burden is likely to not be material in context of the quantified impacts of the policy options (options 1a-2b) relative to the BAU counterfactual, it could be large with respect to the small differences between the impacts of the policy options.
- *Direct and indirect costs to business:* This involves a holistic assessment of the multiple business sectors to ensure both costs to those businesses that are required to comply directly with the regulation and those that are affected indirectly are considered. Analysis of these direct and indirect effects, as well as scrutiny of that analysis, would help draw out the wider impacts of the statutory scheme.
- *Transfers between businesses:* This typically involves assessing the distortionary and anti-distortionary impact of policy on market participants in the affected sectors. This is relevant to the statutory scheme given the variation across the policy options in the treatment of different products, meaning there will be different impacts on market participants with different portfolios of products.

The process of independent scrutiny of the final impact assessment would be beneficial to increase transparency of the evidence based to make ministerial decisions and ease the passage of the legislation through parliament. Independent scrutiny would not need to be undertaken by the RPC, but the RPC would be well placed to do so.

8. Conclusion

Our analysis in the preceding chapters shows that DHSC's proposal is likely to be detrimental to the second and third policy objectives of the statutory scheme. These objectives relate to ensuring continued access to medicines for UK patients and supporting the life sciences sector, respectively. Both objectives are furthered by continued investment by pharmaceutical companies in UK-based R&D that supports initial research into new medicines and clinical trials and launch of those medicines in the UK market.

DHSC's proposal is tailored to achieving only the first policy objective of the statutory scheme, i.e., limiting the growth in costs of branded health service medicines to the NHS. By focusing its attention on this one policy objective in developing its proposal for the statutory scheme from 2024 onwards, DHSC has omitted to consider alternative scheme designs that may provide a better balance across all three policy objectives.

The 2 per cent cap on annual growth in total allowed sales to the NHS in *nominal* terms is too low to allow for upward pressures on total sales that are driven by factors outside the control of the pharmaceutical industry, such as general inflation and a growing *volume* of demand for branded medicines from the NHS. Total sales have grown faster than the allowed 2 per cent each year since 2021, which has driven payment percentages up from 5-10 per cent to over 25 per cent, well above the level of international comparators.

Volatile and rising payment percentages create uncertainty for the pharmaceutical industry around the government's real-terms willingness to pay for health benefits obtained through branded medicines. This uncertainty makes it difficult for the industry to make decisions about which medicines to invest in developing and launching for the UK market. Ultimately, rising and volatile payment percentages are likely to constrain investment.

In its IA, DHSC has compared its policy proposal to a BAU scenario that is likely to be even more damaging to the second and third policy objectives. This creates the impression that DHSC's proposal is the best available option for achieving these two policy objectives. However, other options may better achieve these objectives, including:

- The same cap mechanism, but with a cap higher than DHSC's proposed rate of 2 per cent. A higher cap could accommodate upward pressures on total sales that are outside the control of the pharmaceutical industry.
- A flat payment percentage at a level between 5 and 15 per cent, in line with industry proposals and practice in comparator jurisdictions such as Ireland, the US, and Germany.

The lack of transparency in DHSC's IA makes it impossible to independently assess these or other alternative proposals in line with the standards adopted by DHSC. In its IA, DHSC does not quantify any of the benefits that motivate its decision to recommend its policy options over the BAU scenario. DHSC simply provides a list of unquantified benefits (all improvements to policy objectives 2 and 3) and asserts that these exceed the societal costs of higher NHS expenditure on branded medicines (a cost to policy objective 1).

By failing to provide a quantification of its trade-offs between the three policy objectives, DHSC makes it impossible to critically appraise its recommendation or to assess the merits of alternative proposals on comparable terms.

Appendix A. Further Information on Branded Medicines Pricing

A.1. The Statutory and Voluntary Schemes

The Statutory Scheme for Branded Medicine Pricing ("the statutory scheme") is part of a suite of measures that control the cost of branded medicines to the NHS. The statutory scheme sits alongside the Voluntary Scheme for Branded Medicines Pricing and Access (VPAS, or "the voluntary scheme"). VPAS is a negotiated agreement between DHSC and ABPI that covers the period from 1 January 2019 to 31 December 2023. Any company that supplies eligible branded health service medicines to the NHS is subject to the statutory scheme unless they opt to join VPAS or a future voluntary scheme.[121]

In 2020 and 2021, the voluntary scheme constituted just over 90 per cent of the value of sales of branded medicine, while the statutory scheme constituted just over 3 per cent.[122] However, in January 2023 two large companies (AbbVie and Eli Lilly) resigned from VPAS in protest at the high payment percentages and their sales now covered by the statutory scheme.[123] The statutory scheme is therefore an important backstop to, and reference point in, the negotiation for the voluntary scheme.

The headline price at which the NHS is willing to purchase a medicinal product is called the "list price". Different NHS entities typically negotiate with pharmaceutical companies to obtain confidential further discounts for medicines relative to the list price. The statutory scheme and VPAS further reduce the total cost of branded medicines to the NHS, after any discounts have been applied.

The Department of Health and Social Care (DHSC) defines branded medicines as those medicines *"to which a brand name has been applied that enables the medicine to be identified without reference to the 'common name' (the generic or international non-proprietary name)"*.[124] Branded medicine sales represented c. 71 per cent of total medicines sales to the NHS in 2021.[125]

The current statutory scheme is specified in law by the Branded Health Service Medicines (Costs) Regulations 2018 (amended 2023).[126] This is a statutory instrument which requires companies with total annual sales to the NHS exceeding £5 million to pay back a percentage

[121] Department of Health & Social Care (18 July 2023), Proposed review of the 2023 scheme to control the cost of branded health service medicines: Open Consultation, p.4.

[122] DHSC (21 February 2023), Impact Assessment: Spring 2023 update to the Statutory Scheme controlling the costs of branded health service medicines, p. 10.

[123] ABPI (16 January 2023) Link: https://www.abpi.org.uk/media/news/2023/january/leading-global-pharma-firms-exit-uk-drug-pricing-agreement/#:~:text=AbbVie%20and%20Lilly%20have%20left,the%20foundation%20of%20the%20NHS.

[124] Department of Health & Social Care (18 July 2023), Proposed review of the 2023 scheme to control the cost of branded health service medicines: Open Consultation, p.3.

[125] This figure reflects branded medicine sales as a share of total sales *after* accounting for rebates to the NHS under VPAS and the statutory scheme, as well as additional discounts such as those achieved through commercial access agreements and patient access schemes. See Department of Health & Social Care (8 February 2023), Analysis of UK medicine sales – overview, p.5.

[126] Legislation.gov.uk, The Branded Health Service Medicines (Costs) Regulations 2018, URL: https://www.insideeulifesciences.com/2022/10/26/germany-significantly-tightens-drug-pricing-and-reimbursement-laws/. Visited on 21 August 2023.

of their NHS branded medicine sales each year as a rebate to DHSC. DHSC then distributes the funds to the NHS. The payment percentage is currently 27.5 per cent.

As a matter of policy, DHSC sets the payment percentage every year to ensure "broad commercial equivalence" with VPAS, which means that the government aims to set payment percentages for both schemes that are comparable (but not necessarily identical).[127]

DHSC sets the VPAS and statutory scheme payment percentages with the aim of limiting the annual growth rate in total sales under each scheme relative to a 2018 baseline in *nominal* terms (i.e., DHSC makes no adjustment for inflation) to a predetermined cap. We refer to this as the "cap mechanism". At present, DHSC caps the allowed growth rate at 1.1 per cent each year for the statutory scheme and 2 per cent each year for VPAS.[128] That is, allowed sales under the statutory scheme in 2023 are those implied by a cumulative growth rate of 1.1 per cent per year applied to the 2018 baseline measured sales, rather than those implied by a growth rate of 1.1 per cent applied to 2022 measured sales.[129]

For VPAS, DHSC sets the payment percentage for the year ex ante based on a forecast of measured sales. If actual measured sales exceed the forecast, such that even after applying the payment percentage total NHS expenditure on branded medicines exceeds the level allowed sales, DHSC applies a correction through the payment percentage in subsequent years.[130] There is no explicit provision for a similar mechanism in the statutory scheme. However, since the statutory scheme payment percentages are set to be broadly in line with the VPAS payment percentages they implicitly reflect any such adjustments.

The payment percentages under both schemes have increased substantially in recent years. Figure A.1 shows the evolution of the payment percentages since 2019.

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127 Department of Health & Social Care (18 July 2023), Proposed review of the 2023 scheme to control the cost of branded health service medicines: Open Consultation, p.7.

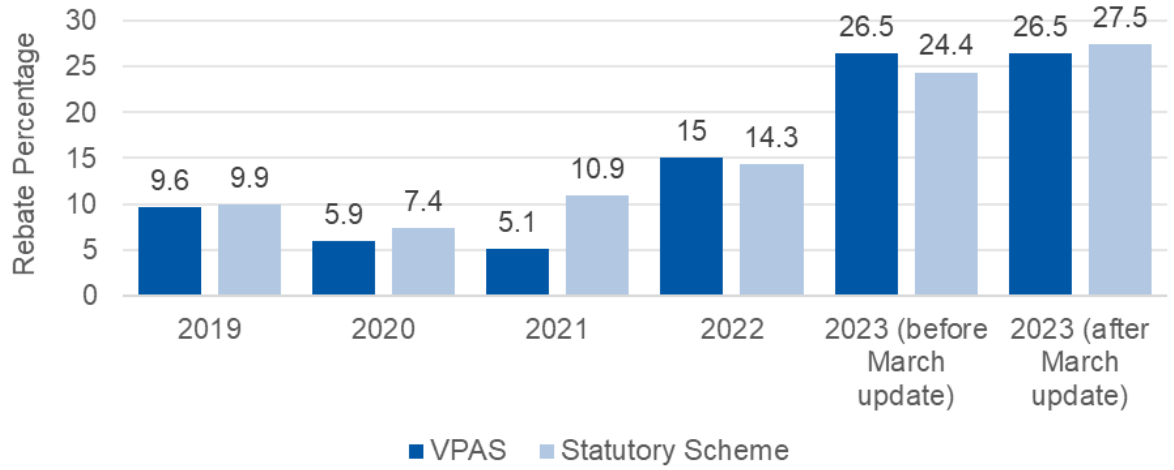
128 Department of Health & Social Care (18 July 2023), Proposed review of the 2023 scheme to control the cost of branded health service medicines: Open Consultation, p.8.

129 "Measured sales" refers to sales of branded medicines to the NHS across VPAS, the statutory scheme, and parallel imports *prior* to the application of VPAS and statutory scheme payments. Although parallel imports are included within measured sales, parallel imports are not eligible for the payment percentage; therefore, the payment percentages on sales under VPAS and the statutory scheme must fully cover the required payment to the NHS.

The UK parallel import licensing scheme allows for a medicinal product authorised in another European Economic Area (EEA) member state to be marketed within the UK, if there is no therapeutic difference between the imported product and the cross-referenced UK product. Source: GOV.UK (14 June 2023), Medicines: apply for a parallel import license, URL: https://www.gov.uk/guidance/medicines-apply-for-a-parallel-import-licence. Visited on 7 August 2023.

130 For the final year of VPAS (2023), there is provision for an end of scheme reconciliation process to ensure that the overall allowed sales target for the five-year period is not exceeded. See DHSC and ABPI (December 2018), The 2019 Voluntary Scheme for Branded Medicines Pricing and Access – Chapters and Glossary, p.32-34.

Figure A.1: Payment Percentages have more than Doubled Since 2019



Source: NERA analysis of DHSC response to SLSC questions[131]

A.2. NICE Evaluation Process

The VPAS and statutory scheme are part of a larger set of measures intended to control NHS expenditure on medicines. In particular, the National Institute for Health and Care Excellence (NICE) assesses the cost-effectiveness of new medicines to determine whether they should be purchased by the NHS.

NICE evaluates whether a medicine is a cost-effective use of NHS resources in a defined patient population. It divides the incremental cost of using the medicine by the difference in benefits it provides compared to standard of care, measured in quality-adjusted life years (QALYs), to determine an incremental cost effectiveness ratio (ICER).[132] NICE recommends a medicine for use by the NHS if the ICER is between £20,000-30,000 per QALY gained. As the ICER increases in this range, NICE will consider factors such as the degree of certainty around the ICER benefits not captured through the ICER calculation in determining whether the medicine is cost-effective.

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[131] Department of Health & Social Care (March 2023), Response to questions from the SLSC, p.3.

[132] National Institute for Health and Care Excellence (31 January 2022), NICE health technology evaluations: The Manual, Chapter 4: Economic evaluation

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