

Title: Community pharmacy reimbursement reforms	<h2>Impact Assessment (IA)</h2>
IA No: 9571	
RPC Reference No: Not applicable	
Lead department or agency: Department of Health and Social Care	
Other departments or agencies: Not applicable	
	Date: 8 th November 2021
	Stage: Consultation Response
	Source of intervention: Domestic
	Type of measure: Other
	Contact for enquiries: Salma.Jalil@dhsc.gov.uk
Summary: Intervention and Options	RPC Opinion: Not Applicable

Cost of Preferred (or more likely) Option (in 2018 prices)			
Total Net Present Social Value	Business Net Present Value	Net cost to business per year	Business Impact Target Status
£127m	n/a	n/a	Not a regulatory provision

What is the problem under consideration? Why is government intervention necessary?
 In 2020/21 1.1 billion prescription items (drugs, appliances, and other items) were dispensed in the community with a total value of £9.6 billion. The Department wants to ensure that the money spent on those items represents value for money to the NHS and taxpayer, and that pharmacy contractors are paid appropriately and fairly for the items they dispense. Whilst in general the arrangements for reimbursing pharmacy contractors for the prescription items they dispense works well, the Department has identified a number of technical adjustments to fine tune the system.

What are the policy objectives and the intended effects?
 The policy objective is to ensure that the rules for reimbursing pharmacy contractors for the prescription items that they dispense are fair and appropriate, ensuring that:

- Pharmacy contractors are fairly reimbursed for the prescription items that they dispense
- The overall NHS spend on these items represents value for money for the taxpayer
- There are no perverse incentives for purchasing at above lowest overall cost within the system
- Patients have access to the medicines that they need in a timely manner

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)
Option 1: Business as usual – Under this option, the system for reimbursing pharmacy contractors for the prescription items that they dispense would remain unchanged.
Option 2: Preferred option – Continue to consult on introducing a package of measures to improve reimbursement arrangements. Under this option, the Department has identified a number of different measures to improve the current reimbursement system. Note that each individual proposal is assessed separately, albeit the preferred option is to agree the package as a whole to minimise uncertainty for affected sectors and administrative burden.

Will the policy be reviewed? It will be reviewed. If applicable, set review date: Month/Year				
Does implementation go beyond minimum EU requirements?		N/A		
Is this measure likely to impact on trade and investment?		N/A		
Are any of these organisations in scope?		Micro Yes	Small Yes	Medium Yes
What is the CO ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent)		Traded: NA	Non-traded: NA	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits, and impact of the leading options.

Signed by the responsible **SELECT SIGNATORY**: _____ Date: _____

Summary: Analysis & Evidence

Policy Option 1

Description: Business as usual

FULL ECONOMIC ASSESSMENT

Price Base Year	PV Base Year	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate: 0
COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)		Total Cost (Present Value)
Low	Optional		Optional		Optional
High	Optional		Optional		Optional
Best Estimate	0		0		0
Description and scale of key monetised costs by 'main affected groups' As consistent with IA convention, the costs and benefits of the business as usual option are set to zero.					
Other key non-monetised costs by 'main affected groups' As consistent with IA convention, the costs and benefits of the business as usual option are set to zero					
BENEFITS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)		Total Benefit (Present Value)
Low	Optional		Optional		Optional
High	Optional		Optional		Optional
Best Estimate	0		0		0
Description and scale of key monetised benefits by 'main affected groups' As consistent with IA convention, the costs and benefits of the business as usual option are set to zero					
Other key non-monetised benefits by 'main affected groups' As consistent with IA convention, the costs and benefits of the business as usual option are set to zero					
Key assumptions/sensitivities/risks As consistent with IA convention, the costs and benefits of the business as usual option are set to zero					Discount rate
					n/a

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m: Out of scope
Costs: n/a	Benefits: n/a	Net: n/a	

Summary: Analysis & Evidence

Policy Option 2

Description: Introduce a series of reimbursement reforms

FULL ECONOMIC ASSESSMENT

Price Base Year 2020	PV Base Year 2018	Time Period Years 5	Net Benefit (Present Value (PV)) (£m)		
			Low: 72	High: 182	Best Estimate: 127

COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	4	1	17	86
High	4		24	120
Best Estimate	4		21	103

Description and scale of key monetised costs by 'main affected groups'

The monetised costs are comprised almost entirely of revenue costs to pharmaceutical manufacturers and wholesalers that would accrue if selling prices fall as a result of increased competition driven by the measures in this IA. Because of the uncertainty we have not adjusted these down to reflect the proportion that would accrue to UK shareholders (typically 10% of the total) as opposed to overseas to ensure prudence.

Note that, although the proposals in large do not affect the aggregate finances of pharmacies and CCGs, there will also be winners and losers within these groups which is also considered.

Other key non-monetised costs by 'main affected groups'

BENEFITS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant	Total Benefit (Present Value)
Low	0		39	196
High	0		54	272
Best Estimate	0		47	234

Description and scale of key monetised benefits by 'main affected groups'

The monetised benefits are the value to UK society of the health benefits that could be generated from the reduced NHS expenditure identified in this IA (equal to the revenue costs described above before translating into health benefits).

Other key non-monetised benefits by 'main affected groups'

Improving pharmacy cashflow by making reimbursement prices more reflective of market prices. This is done with a view to reduce the need for significant retrospective adjustments, improve the fairness of pharmacy access to medicine margin and increase the extent to which CCGs pay their fair share towards medicine margin.

Key assumptions/sensitivities/risks	Discount rate (%)	3.5% and 1.5%
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The detail of the proposals will be developed with regard to responses received to this consultation during a subsequent engagement with the Pharmaceutical Services Negotiating Committee (PSNC) only.

It is difficult to establish a robust counterfactual for later years given the fast-moving nature of the market so we have assumed the net benefits estimated per annum do not increase in years after year 2. Furthermore, there is uncertainty around the second-order market impacts of the proposals and the above costs and benefits assume no major structural impacts on the sector. This IA therefore inflates estimated costs and deflates estimated benefits in accordance with high, low, and average optimism bias scenarios.

Additionally, the IA assumes that any savings that arise from implementation of the reforms will accrue to CCG budgets and, as such, will be spent elsewhere in the NHS at the marginal cost per QALY.

BUSINESS ASSESSMENT (Option 2)

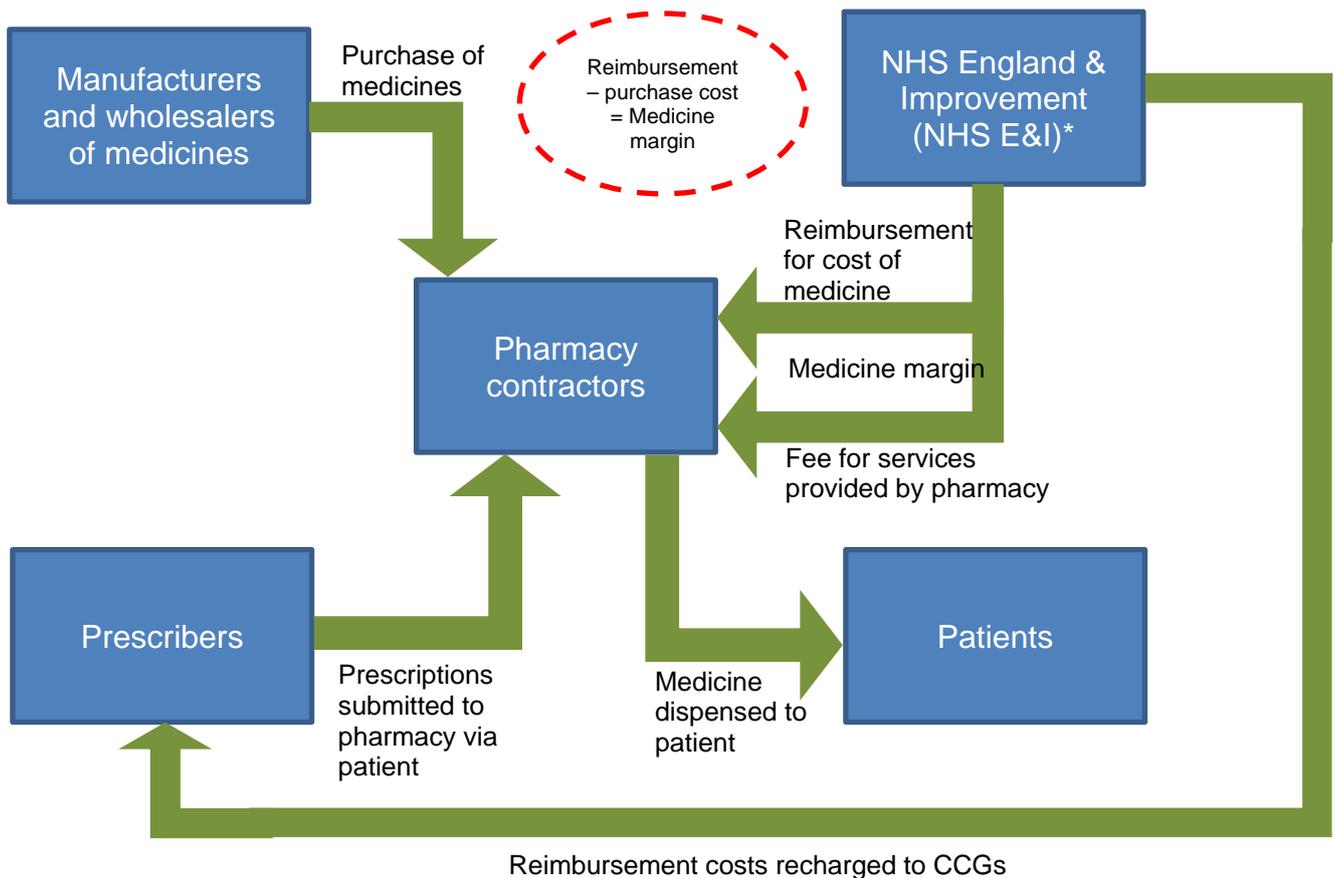
Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m: n/a
Costs: n/a	Benefits: n/a	Net: n/a	

Evidence Base (for summary sheets)

Background

1. Data from the NHS Business Services Authority (NHS BSA) shows that in 2020/21, 1.11 billion prescription items (drugs, appliances and other items) were dispensed in the community with a total value of £9.61 billion.¹ Figure 1 illustrates the broad mechanism by which the costs of these prescription items are funded by the NHS.
2. Pharmacy contractors are private businesses that provide NHS pharmaceutical services under the community pharmacy contractual framework (CPCF). Under the CPCF they are remunerated for the services they provide and reimbursed for the products they dispense. Pharmacy contractors purchase their own stocks of medicines (and other prescription items) from manufacturers and wholesalers, directly negotiating the prices that they pay, including any discounts and rebates.

Figure 1: Stylised schematic illustrating high level arrangements for medicines dispensed in the community



*Note that in reality funding may flow through the NHS Business Services Authority (NHS BSA)

3. Alongside the fees for services paid to pharmacy contractors, reimbursement prices for medicines, appliances and other products dispensed are published monthly in the Drug Tariff or determined in accordance with the provisions of the Drug Tariff. Pharmacy

1. NHS BSA. 2021. https://nhsbsa-opensource.s3.eu-west-2.amazonaws.com/pca/pca_summary_narrative_2020_21_v001.html

contractors are reimbursed monthly for the items they dispense in each month, minus an assumed amount of discount.

4. This discount is also known as the 'deduction scale'. This is an assumed amount of discount that pharmacy contractors are able to access on their purchases from suppliers including an assumption that pharmacy contractors with higher NIC will be able to negotiate larger discounts. The assumption based approach is necessary to avoid pharmacies having to calculate and declare discount received on each item dispensed and the prohibitive administrative burden this would generate. Currently, the deduction scale is based on the monthly total value of prescriptions dispensed (calculated based on reimbursement prices) with a minimum of 5.65% and a maximum of 11.5% deducted from the total monthly reimbursement. When CCGs are recharged reimbursement costs, this is less an average level of deduction rate.
5. Part VIIIA of the Drug Tariff lists the reimbursement prices for many, but not all, generic medicines in three Categories (M, A and C). Generic medicines are proposed to enter, exit, or move between categories in line with the criteria outlined below. However, any proposals must be agreed with the PSNC and so products may not necessarily fulfil the category criteria.
 - Products listed in Category M are generic medicines that are readily available from at least two manufacturers and meet minimum spend and volume supplied annual criteria. Reimbursement prices are based on quarterly information from manufacturers on their actual sales prices with an addition of medicine margin.
 - Products listed in Category A are generic medicines that are readily available but do not meet the criteria for Category M. Reimbursement prices are based on the weighted average from price lists submitted by four suppliers (two wholesalers and two manufacturers).
 - Products listed in Category C are branded medicines or single source generic medicines. Reimbursement prices are based on the reference product which in the main is the branded originator or the supplier's list price.
6. Additionally, Part VIIIB of the Drug Tariff lists the reimbursement prices for the most commonly prescribed special order or unlicensed medicines, whilst Part IX of the Drug Tariff lists reimbursement prices for appliances. Products not listed in the Drug Tariff are reimbursed at the list price of the manufacturer, wholesaler, or supplier from which the dispensing contractor sourced the medicine.
7. Pharmacy contractors can earn medicine margin by sourcing as cheaply as possible. Medicine margin is the difference between the price reimbursed by the NHS for the products dispensed and the price at which pharmacies buy them. Funding for the CCPF is £2.592 billion, some of which is paid in fees and allowances and some (currently £800million) through medicine margin. An additional benefit of this system is that it encourages pharmacy contractors to source as cheaply as possible which leads to competition, putting downward pressure on selling prices which in turn leads to lower reimbursement prices.

8. The medicine margin achieved by pharmacy contractors is assessed in the medicine margin survey, which is based on invoices from a sample of independent pharmacy contractors. Any over or under delivery of medicine margin is adjusted, generally but not exclusively, by amending Category M reimbursement prices.

Description of the problem and rationale for intervention

9. The pharmacy contractor reimbursement arrangements described above generally work well but the Department believes that some improvements can be made to better ensure that the following principles are adhered to, in so far as is possible and practicable:
 - the arrangements provide value-for-money to the NHS and taxpayer;
 - reimbursement prices better reflect market prices to improve pharmacy contractors' cash flow;
 - pharmacy contractors have equitable access to medicine margin; and
 - the addition of medicine margin to reimbursement prices does not make medicines look unduly expensive and thereby influence prescribing patterns.

These are described in turn below.

Value for money

10. The existence of medicine margin helps to create value for money for taxpayers by encouraging pharmacy contractors to source products as cheaply as possible which leads to competition, putting downward pressure on selling prices, which in turn leads to lower NHS reimbursement prices.
11. However, for medicines not listed in the Drug Tariff and without a reimbursement price², this incentive mechanism does not operate as effectively, as pharmacy contractors are reimbursed based on list price of the manufacturer, wholesaler or supplier from which the dispensing contractor sourced the medicine. As a result, pharmacy contractors may be incentivised to source the medicine with the biggest margin against the list reimbursement price and not the medicine that has the lowest suppliers' list price.
12. Whilst ultimately this would be picked up via the margin survey and so not generate costs to the NHS, pharmacy contractors may have reduced incentives to purchase at the lowest available list price. This in turn may preclude the virtuous circle described above from manifesting, and costs of medicines may not decrease through this mechanism.
13. Similarly, for unlicensed items dispensed pharmacies are reimbursed the amount they paid, net of any discount negotiated with the supplier, and so do not retain any medicine margin and are not incentivised to source at the cheapest price. The ultimate

² Excluding unlicensed products – see paragraph 13 for a description of reimbursement for unlicensed items.

consequence may therefore be that the amount the NHS/CCGs pays for these products does not decrease despite there being supplier competition.

14. The Department is considering a number of options to address this, including:
 - Where possible, adding more of these products to the Drug Tariff;
 - Where this is not practical, introducing other rules to make the reimbursement prices of these products more reflective of the market and create incentives for better purchasing by pharmacy contractors; and
 - For specials and unlicensed medicines not listed in the Drug Tariff, considering alternative mechanisms outside of the normal Drug Tariff mechanisms to incentivise better purchasing.
15. For products that are already in the Drug Tariff, it is recognised that these existing incentive mechanisms are most likely to be effective when the reimbursement prices listed in the Drug Tariff are reflective of the actual selling/purchase prices in the market. As a result, the Department also wishes to consult on a number of measures designed to change the methodology for setting listed reimbursement prices to make greater use of market data.

Improving pharmacy contractors' cash flow and medicine margin distribution

16. Although the current medicine margin system, described in paragraph 7, is designed to deliver the right level of funding to pharmacy contractors overall, there are disadvantages to the need to adjust reimbursement prices:
 - There will inevitably be a delay between when medicine margin is earned, when it is measured in the survey and when appropriate adjustments to reimbursement prices are made. There is a very real risk that this delay can mean that reimbursement prices need to be adjusted downwards to account for previous over-delivery of medicine margin at a time when market conditions have worsened. This may have significant negative effects on pharmacy cashflow.
 - Subsequent adjustments to correct for over or under delivery of medicine margin will generally be made by adjusting Category M reimbursement prices. This creates a risk that if the over delivery of medicine margin was through medicines not in Category M, pharmacy contractors who benefited most from this over-delivery of medicine margin are not those who are most affected by any subsequent downwards adjustment to reimbursement prices.
17. As a result, the Department's preferred position is that reimbursement prices should be set in a way that is most accurate and as reflective of the market as near to the time as possible. This will minimise the need for subsequent adjustments to correct for over or under delivery of medicine margin. As such, between 23 July and 17 September the Department consulted on a series of options to:

- Change the methodology for setting reimbursement prices to make greater use of market data to ensure that reimbursement prices are as reflective of the market as possible; and
 - Propose changes to the methodology for setting reimbursement prices for specific products where issues have been identified that mean that reimbursement prices are not reflective of market prices.
18. This impact assessment reflects the latest data and assumptions, following feedback received during the consultation and as a result of further informal engagement with stakeholders.

Distorting effect of medicine margin on prescribing and ensuring contractors have equitable access to medicine margin

19. Some suppliers of branded medicines, including branded generics, price their stock below the Category M reimbursement price, which is inclusive of added medicine margin. This can have a distortive effect on prescribing decisions. Because the branded version appears cheaper, CCGs and prescribers may be encouraged to prescribe the product by brand rather than generically.
20. To take the simplest example of how this might work in practice, when a GP prescribes a medicine, the software that they use generally informs them of the Drug Tariff reimbursement price of the medicine. It will also generally inform them of branded versions of the medicine that are available and their prices. It may therefore look to the GP that a branded version represents good value to the NHS because its list price is significantly below the Drug Tariff reimbursement price.
21. In reality however, the branded medicine may well be more expensive to the NHS because it does not contribute (or contributes very little) to the £800m medicine margin under the CPCF. This is because pharmacies generally do not earn medicine margin (especially when the discount deduction is made) when they dispense a branded product against a prescription written by brand. This, in turn, leads to a shortfall in medicine margin that will need to be factored into reimbursement prices elsewhere. This also leads to an unequal distribution of medicine margin amongst pharmacy contractors and means that the NHS overall will lose money because some reimbursement prices will have to be set higher than they would have been otherwise. This is ultimately to the detriment of CCGs.
22. In addition, where CCGs recommend prescribing the branded product, pharmacy contractors in the CCG's catchment area do not have equitable access to medicine margin as they do not generally retain medicine margin on brands. This also means that not all CCGs contribute equally to the £800m medicine margin under the CPCF. So, an individual CCG may benefit from the amount apportioned to it in relation to a particular transaction, but CCGs as a cohort and the NHS overall will lose out.
23. These issues are also exacerbated by the application of a single discount scale to cover brands and generics. When pharmacy contractors are reimbursed for the medicines and

appliances they have dispensed, a deduction is made to their payments, based on what is known as 'deduction scale'. This is an assumed amount of discount received by the pharmacy from their supplier to avoid pharmacies having to calculate and declare discount received on each item dispensed.

24. Currently, the deduction scale does not take into account whether a pharmacy contractor dispenses brands or generics. However, branded medicines do not attract as much discount as generic medicines. Pharmacy contractors, on average, dispense branded medicines at a loss. Because of this, pharmacy contractors that dispense more branded medicines than average do not have equitable access to medicine margin. Additionally, CCGs in areas where more branded medicines are prescribed are not paying their fair share of medicine margin.
25. To address these issues the Department has consulted on two measures to:
 - Change the distribution of medicine margin added to generic medicines in Category M to ensure that the generic medicine does not look more expensive than the branded version and better reflect the actual purchase price
 - Split the deduction scale into one for generic medicines and one for branded medicines

Rationale for intervention

26. Under section 164 of the NHS Act 2006 the Secretary of State for Health and Social Care is responsible for determining the remuneration to be paid to persons who provide pharmaceutical services, whilst under regulation 89 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 the Secretary of State for Health and Social Care is responsible for publishing the Drug Tariff which contains all determinations of remuneration by the Secretary of State or another determining authority (the only other determining authority at present is NHS England & Improvement (NHS E&I), but it only has powers in respect of service remuneration).
27. As a result, government intervention is considered the only option to bring about the improvements in the reimbursement system identified above.

Description of the Options

28. This Impact Assessment considers two options. Option 1 is the business as usual option. Under this option, the rules for reimbursing pharmacy contractors for prescription items dispensed would not change, and the set of potential improvements identified above would not be made.
29. Under option 2, the Department proposes to carry out a follow-up consultation with the Pharmaceutical Services Negotiating Committee (PSNC) to identify the details and

mechanics behind the range of proposals to improve the current reimbursement arrangements identified in the initial consultation. These are listed below and their impacts assessed separately in subsequent sections of this IA. Whilst any combination of these individual measures could in theory be introduced at any one time, our preferred option is to progress the reforms in one package, albeit with staged implementation dates and transitional measures, to avoid prolonging uncertainty and unnecessary administrative burden.

Changes to setting reimbursement prices for specific groups of products

- Changes to the determination of reimbursement prices of generic medicines in Category A
- Changes to the distribution of margin added to generic medicines in Category M
- Changes to the determination of reimbursement prices of branded medicines with multiple suppliers in Category C
- Inclusion of more products treated as drugs (i.e. products other than licensed and unlicensed medicines that are treated as “drugs” for the purposes of NHS pharmaceutical services) in Part VIII of the Drug Tariff with a listed reimbursement price
- Changes to the determination of reimbursement prices for non-Part VIIIA drugs
- Changes to the arrangements for reimbursing and procuring unlicensed medicines (specials)

Other changes to reimbursement arrangements

- Changes to the reimbursement of generically prescribed appliances and drugs dispensed as ‘specials’
- Changes to the deduction scale

30. Table 1 summarises each of these measures in turn:

Table 1: Description of key measures to be consulted on

Changes in the rules for setting reimbursement prices for specific groups of products		
Measure	Description	Rationale
Changes to the determination of reimbursement prices of generic medicines in Category A	To help to encourage better purchasing by pharmacy contractors, we propose to make reimbursement prices more reflective of actual selling/purchase prices in the market by changing the methodology on which Drug Tariff prices are determined	<ul style="list-style-type: none"> • Improve value for money for the NHS and the taxpayer • Reduce cash flow issues created by medicine margin adjustments to the Tariff
Changes to the distribution of margin added to generic medicines in Category M	To address the current perverse incentives for prescribers, we propose to change the distribution of medicine margin added to generic medicines in Category M to ensure that generic	<ul style="list-style-type: none"> • Ensure that the addition of medicine margin to reimbursement prices

	medicines do not look more expensive than branded versions and to better reflect the actual purchase price	<p>does not create distorting effects</p> <ul style="list-style-type: none"> • Ensure that contractors have equitable access to medicine margin • Ensure CCGs are paying their fair share of medicine margin •
Changes to the determination of reimbursement prices of branded medicines with multiple suppliers in Category C	To ensure reimbursement prices are more reflective of the market, for medicines in Category C with multiple suppliers, we propose to determine the reimbursement price by using the weighted average of all suppliers' prices (either list prices or actual selling prices). Currently the reimbursement price is based on a single supplier's list price.	<ul style="list-style-type: none"> • Reduce cash flow issues created by medicine margin adjustments to the Tariff • Ensure reimbursement prices do not create distorting effects
Inclusion of products treated as drugs (i.e. products other than licensed and unlicensed medicines that are treated as "drugs" for the purposes of NHS pharmaceutical services) in Part VIII of the Drug Tariff with a listed reimbursement price	To help incentivise better purchasing decisions by contractors, we propose: <ul style="list-style-type: none"> • For drugs (excluding licensed and unlicensed medicines) in Part VIII of the Drug Tariff, set reimbursement prices based on either a weighted average of suppliers' dm+d³ list prices, or a weighted average of their actual selling prices • Add as many drugs into the Part VIII of the Drug Tariff as possible 	<ul style="list-style-type: none"> • Improve value for money for the NHS and the taxpayer
Changes to the determination of reimbursement prices for non-Part VIIIA drugs	Similarly to the above, for non-Part VIII drugs we also propose to set reimbursement prices based on average weighted list prices of suppliers as published on dm+d. Where there is only a single supplier of the product, the weighted average list price will be equivalent to the list price of the single supplier.	<ul style="list-style-type: none"> • Improve value for money for the NHS and the taxpayer
Changes to the arrangements for reimbursing and procuring unlicensed medicines ('specials')	Where possible, we propose to include tablets and capsules with a reimbursement price in Part VIIIB of the Drug Tariff For those specials for which we cannot introduce a reimbursement price listed in Part VIIIB we are seeking views from the PSNC on possible solutions: <ul style="list-style-type: none"> • Require pharmacies to obtain three quotes for non-Part VIIIB specials ('quotes') • Set up or procure a central approvals service for non-Part VIIIB specials ('central approvals service') • Procure the central supply of non-Part VIIIB specials to pharmacies ('central supply') 	<ul style="list-style-type: none"> • Improve value for money for the NHS and the taxpayer
Other changes in reimbursement rules		
Measure	Description	Rationale
Changes to the reimbursement of generically prescribed appliances and drugs that could be dispensed as a special	For a generically written prescription, the dispenser in some instances may choose to dispense a special instead of an appliance. However, if the product is listed as an appliance in Part IX of the Drug Tariff, this should not be taking place. It reduces the transparency for patients and prescribers regarding what will be	<ul style="list-style-type: none"> • Increase transparency and clarity for prescribers and patients, regarding what will be dispensed against a prescription, and for pharmacies, who

³ dm+d is the Dictionary of Medicines and Devices. The dm+d is a dictionary of descriptions and codes which represent medicines and devices in use across the NHS. It is delivered through a partnership between NHS Digital and the NHS Business Services Authority and provides the recognised NHS Standard for uniquely identifying medicines and medical devices used in patient care.

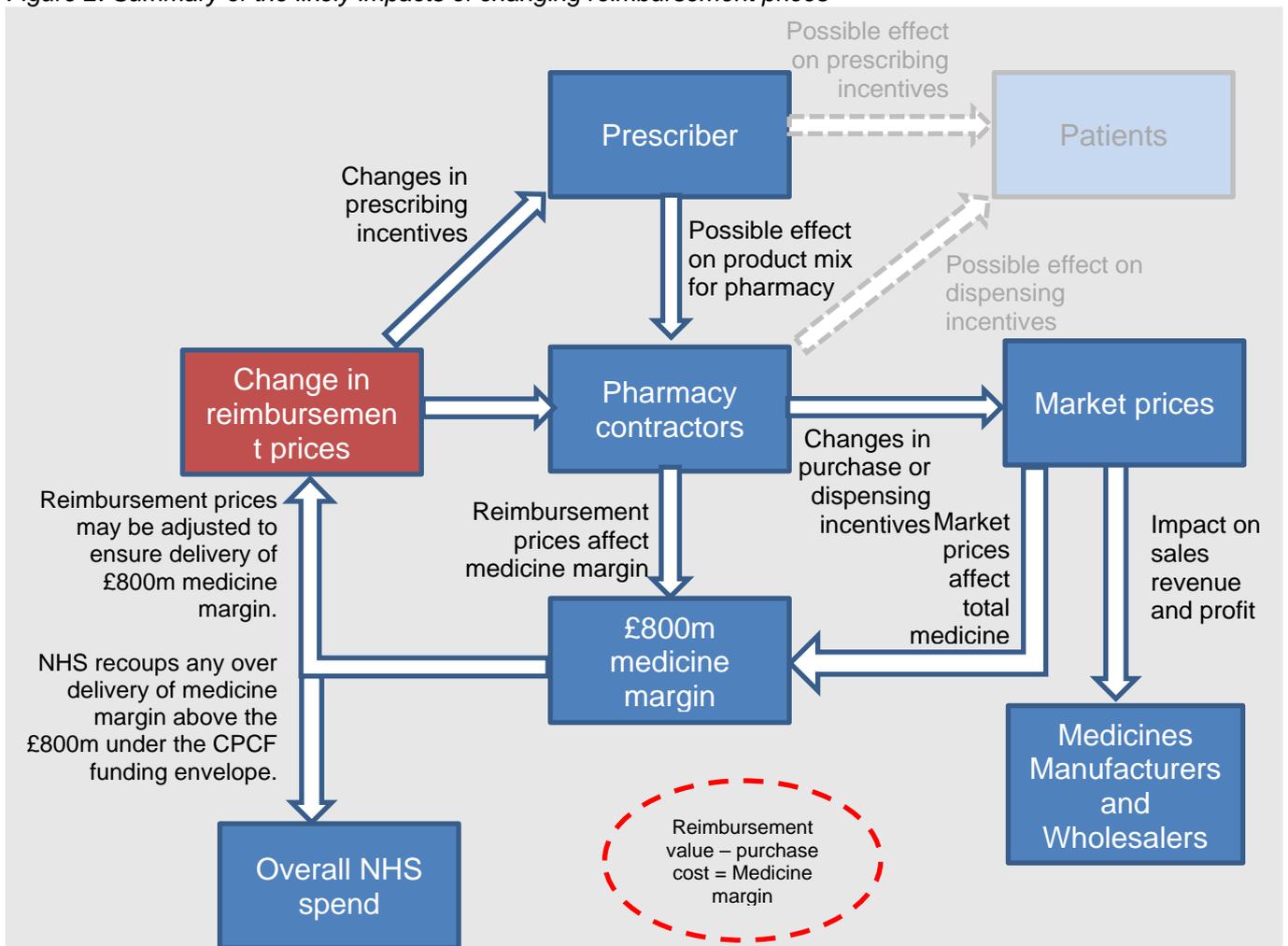
	<p>dispensed against a prescription. Additionally, specials in the main tend to be more expensive. To disincentivise this activity, we propose moving to reimbursement at the list price of the appliance that could be dispensed, even when a special has been dispensed, against a generically written prescription.</p> <p>For a generically written prescription, if the contractor has the choice of whether to dispense a drug or special, the same transparency and potentially value for money issues as set out above may apply. To help address these, we would propose to move to reimbursement at the drug price even when a special has been dispensed.</p>	<p>will be clear what they will be reimbursed for</p> <ul style="list-style-type: none"> • May also improve value for money for the NHS and the taxpayer
<p>Changes to the deduction scale to reflect different levels of discount for branded and generic medicines</p>	<p>To address the current perverse incentives for prescribers and to improve medicine margin distribution, we propose to change the deduction scale by splitting it into one scale for generic medicines and one scale for branded medicines. Separately, we are consulting NHSE&I about amending the recharge of reimbursement costs to CCGs to reflect their generic prescribing levels.</p>	<ul style="list-style-type: none"> • Ensure that the addition of medicine margin to reimbursement prices does not create distorting effects • Ensure that contractors have equitable access to medicine margin • Ensure CCGs are paying their fair share of medicine margin • Reduce cash flow issues created by medicine margin adjustments to the Tariff

31. The purpose of the public consultation was to consult widely on the high level principles of the proposed changes giving all the pharmaceutical supply chain and the NHS (especially CCGs and prescribers) the opportunity to comment. The detail and the mechanics of how we reimburse pharmacy contractors, for example the formulas used to calculate reimbursement prices, the transition from current arrangements to new arrangements and timing of introduction will now be subject to a follow-up consultation with the Pharmaceutical Services Negotiating Committee (PSNC) only.
32. Because the details will be determined following this subsequent consultation, and will depend on changes in underlying prices at the point of implementation, it is not possible at this stage to present finalised proposed reimbursement prices against each of these measures. The remainder of this assessment instead focuses on providing a high level summary of the likely costs and benefits of each proposal. Where possible, indicative figures have been provided, however it is important to note that the exact size of any costs and benefits cannot be determined until the final detailed methodology has been agreed. As such, these estimates will be subject to change and refinement going forward and their initial, approximate nature should be borne in mind.

Summary Narrative of Impacts

33. The large majority of our proposals involve making changes to the reimbursement prices paid to contractors for the prescription items that they dispense. Figure 2 below illustrates the general high level impacts that could potentially arise due to a change in reimbursement prices.
34. Note that the impact on patients of changes in prescribing and dispensing decisions are greyed out. This is to signify that there is no expectation that prescribing or dispensing decisions will cease to be made on a clinical basis and in accordance with patients' needs even if relative prices change.

Figure 2: Summary of the likely impacts of changing reimbursement prices



35. In the first instance, changing reimbursement prices will directly affect the total amount that pharmacy contractors are reimbursed for the prescription items that they dispense. This in turn may have a direct effect on the amount of medicine margin that pharmacy contractors earn (assuming for now that there is no change in pharmacy purchasing decisions).
36. If this change in reimbursement prices leads to significant under or over delivery of medicine margin, compared to the figure of £800m under the CPCF funding envelope,

further adjustments will be required to reimbursement prices (usually made through Category M reimbursement prices) in order to correct for this over or under delivery. This further adjustment to reimbursement prices is intended to lead to distributional effects between pharmacies, depending on the mix of products that they dispense, however the overall impact on NHS spend is unlikely to be affected since reimbursement prices must subsequently be adjusted to ensure delivery of the £800m medicine margin under the CPCF funding envelope.

37. However, once the impact on pharmacy purchasing decisions is taken into account, this picture becomes different. Where changes in reimbursement price also generate incentives for pharmacies to make different purchasing or dispensing decisions, these changes to purchasing decisions can drive additional changes to the medicine margin. For example, by making reimbursement prices more reflective of actual market prices, it is anticipated that this will strengthen incentives for contractors to seek the lowest price from the market, which in turn will further drive competition in the market and help to lower the price of medicines. Lower purchase prices would in turn benefit the NHS by supporting the ability of the system to deliver the £800m medicine margin under the CPCF funding envelope whilst also lowering reimbursement prices, and thus reducing NHS total spend on medicines reimbursement.
38. Any changes to actual market prices, or other purchasing decisions made by pharmacies, may in turn affect the sales revenue and ultimately profits of medicines manufacturers and wholesalers. Please see the subsequent “Impact on Business and regulatory burden” section for further details of how we count this.
39. Additionally, changes to reimbursement prices may also affect prescribing incentives with a possible subsequent impact on pharmacy contractors through changes in the mix of products that pharmacies must dispense. Assuming that the amount of medicine margin that can be earned on these products differs, this may flow through to an impact on the total amount of medicine margin earned, and therefore to an ultimate impact on NHS finances. These impacts are most relevant for the proposed changes to Category M reimbursement prices and the deduction scale.
40. We assume that any savings generated for the NHS will be recycled back into CCGs budgets for spending on frontline services. This will ultimately benefit NHS patients as the recipients of the additional care the savings will be translated into.
41. Whilst we consider the risk of there being impacts on patient health outcomes due to these changes to be minimal, it is important to note that these could in theory arise from:
 - Changes to prescribing decisions; or
 - Changes in dispensing decisions made by pharmacy contractors.
42. However, prescribers still retain a responsibility to prescribe appropriately and in accordance with the clinical need of the patient, whilst dispensers are required to dispense in accordance with what is specified on the prescription, hence our assessment that the risks to patient health outcomes are minimal.

43. Following this general overview of the high level impacts of our proposals, Table 2 summarises our assessment of each of the policy proposals against the key impacts identified above.

Table 2: summary of impacts of proposals

Proposal	Expected key impacts	Initial “average bias” estimate present value costs over 5 years	Initial “average bias” estimate present value benefits over 5 years	Initial “average bias” estimate net present value over 5 years
Changes to the determination of reimbursement prices of generic medicines in Category A	Improve pharmacy cashflow by making reimbursement more reflective of market prices and reducing the need for significant retrospective adjustments. Incentivise & drive competition in the generics medicine market, leading to lower purchase prices for Category A medicines, thereby driving savings to the NHS & patient benefits. The impact on industry of additional competition is also considered	£78m costs arising due to loss of industry revenue	£226m (saving to the NHS translated into health benefits valued at £60k/QALY) plus the unquantified benefit of improving pharmacy cashflow	£148m
Changes to the distribution of margin added to generic medicines in Category M	Increase prescribing of generics versus brands to drive more equitable access to medicine margin for individual pharmacies & generate savings for the NHS if the need to compensate pharmacies for low medicine margin on branded products reduces. The impact on industry of shifting demand away from branded products is also considered, as well as the loss of NHS income from the voluntary and statutory schemes for branded medicine spend. The illustrative example in this section use 2018 data.	£15m costs arising due to lost industry revenue plus NHS lost income from voluntary and statutory schemes for branded medicine spend	Unquantified benefits - reduced perverse price signals enabling £800m medicine margin delivery at lower cost & more equitable access to medicine margin for pharmacies.	-£15m plus unquantified benefits
Changes to the determination of reimbursement prices of medicines with multiple suppliers in Category C	Reimbursement prices likely to fall initially reducing NHS spend on these medicines. But savings to the NHS are likely to be much lower, as £800m medicine margin is maintained under the CPCF funding envelope. Changes to reimbursement prices may also drive changes in purchasing decisions which will affect both NHS and industry finances. Unquantified benefits include perhaps reducing the size of	Unquantified – if these changes result in pharmacies making better purchasing decisions then this may drive savings for the NHS and costs to industry, but these cannot be quantified. There are also unquantified benefits from having reimbursement prices better aligned to market prices, reducing the need for future margin adjustments, and improving pharmacy cashflow.		

⁴ For explanation of the terminology please see the subsequent section on applying optimism bias.

	future medicine margin adjustments (improving pharmacy cashflow) & potentially driving further competition in the market for these products.			
Inclusion of products treated as drugs (i.e. products other than licensed and unlicensed medicines that are treated as “drugs” for the purposes of NHS pharmaceutical services) in Part VIII of the Drug Tariff with a listed reimbursement price.	Reimbursement prices likely to fall initially reducing NHS spend on these medicines. But savings to the NHS likely to be much lower as £800m medicine margin is maintained under the CPCF funding envelope. Although evidence suggests that adding additional products into the Drug Tariff can drive reductions in selling or reimbursement prices through increased pharmacy incentives to get the best deal on these products, these effects remain unquantified.	Unquantified – we would like to explore the options for adding as many products as possible into the Drug Tariff. Similarly, during further discussions with PSNC we would like to explore the options for basing prices on actual selling prices as opposed to published list prices.		
Changes to the determination of reimbursement prices for non-Part VIII A drugs.	As above initial falls in reimbursement prices will not result in any savings to the NHS as we need to maintain £800m medicine margin. However, the new reimbursement rules are expected to increase incentives for pharmacies to look for the best deal on these products, potentially leading to NHS savings, these effects remain unquantified.	Unquantified – linked to above we would like to explore the options for adding as many products as possible into the Drug Tariff. Similarly, we would like to explore the options for basing prices on actual selling prices as opposed to published list prices.		
Changes to the arrangements for reimbursing and procuring unlicensed medicines ('specials')	The first part of this proposal is expected to incentivise & drive competition in the specials medicine market, leading to lower purchase prices for unlicensed medicines & thereby driving savings to the NHS and patient benefits. The impact on industry of additional competition is also considered. The second part of this proposal is to directly incentivise better pharmacy purchasing decisions. It does not affect reimbursement prices and the analysis focuses on weighing up the administrative costs of different options versus savings required to cover these.	£3m cost to industry.	£8m (saving to the NHS translated into health benefits valued at £60k/QALY).	£4m.
		~£1m - £9m cost to industry and public sector (option dependent).	Unquantified benefits of reducing variation in prices and of pharmacies purchasing at lower prices expected to cover costs.	Unquantified - analysis estimates the proportion of NIC associated with these products required for a new system to breakeven.
Changes to reimbursement of generically prescribed appliances and drugs that could be dispensed as a special	Limiting reimbursement prices to that of the appliance will shift dispensing away from specials on to lower cost appliances therefore generating savings for	Unquantified at aggregate level due to ongoing work to identify the whole sample. Examples of products that historically fit the definition showed appliances had a lower cost than the specials in 3 of 4 measures.		

	<p>the NHS. The impact on industry is also considered.</p> <p>Limiting reimbursement prices to that of the drug will shift dispensing away from specials on to lower cost appliances therefore generating savings for the NHS. The impact on industry is also considered.</p>	<p>Unquantified at aggregate level due to ongoing work to identify the whole sample. Examples included for a sample of products that do fit the definition find that drugs have a lower cost than the specials.</p>
<p>Changes to the deduction scale to reflect different levels of discount for branded and generic medicines</p>	<p>Differentiating the deduction scale applied to brands vs generics is expected to allow for fairer access to medicine margin for pharmacies and help ensure CCGs pay their fair share towards medicine margin.</p>	<p>The proposed deduction scale will be designed with cost neutrality in mind from an aggregate point of view, but individual pharmacies will gain or lose to achieve fairer access to medicine margin. The illustrative example in this section use 2018 data.</p> <p>If prescribing behaviour changes then there may be further impacts for NHS and industry finances.</p>

Impact on Business and regulatory burden

44. As the proposals are only concerned with how the NHS reimburses pharmacy contractors for their NHS prescriptions, they are not expected to increase the regulatory burden as they concern procurement arrangements for NHS services.
45. The measures are not regulatory in nature as under section 164 of the NHS Act 2006 the Secretary of State for Health and Social Care (alongside NHS E&I) already has responsibility for determining the remuneration to be paid to persons who provide pharmaceutical services.
46. The main impact on business will arise from pharmacy contractors changing their purchasing decisions, or from prescribers making decisions to prescribe different products. Any impact on manufacturers or wholesalers of medicines would therefore be considered an indirect impact.
47. Finally, the policy intention behind the large majority of these proposals is to make reimbursement prices more reflective of the market and therefore incentivise and encourage better purchasing decisions by pharmacies. This in turn is intended to encourage more competition in the medicines market.
48. As detailed in annex 1 section D of the Better Regulation Framework manual we consider this measure to meet the pro-competition administrative exclusion criteria in that it⁵:
 - Is expected to increase suppliers' incentive to compete vigorously;
 - Is expected to generate a net increase in effective competition/to improve competition overall;

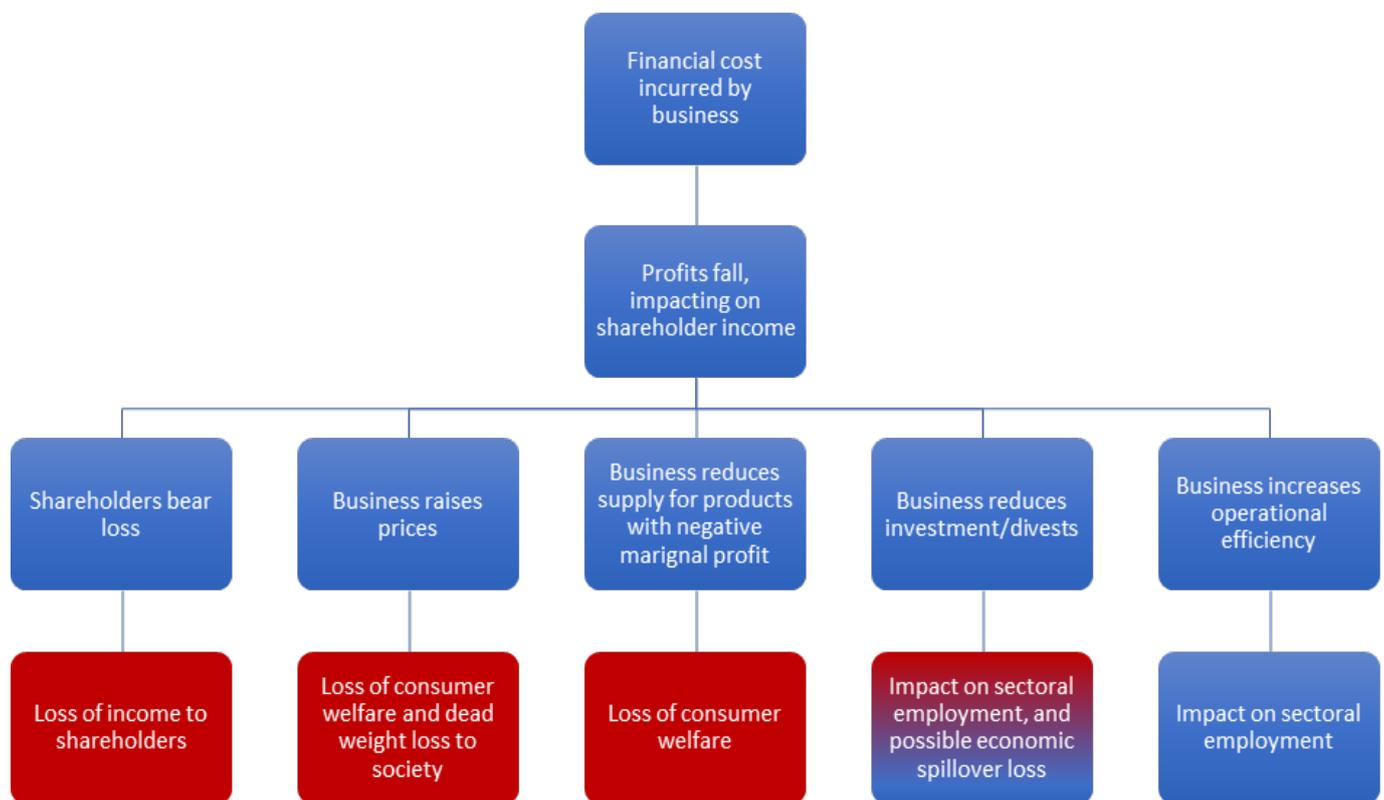
⁵ The Better Regulation Framework. March 2020.

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/916918/better-regulation-guidance.pdf.

- Has promoting competition as a core purpose; and
- Is estimated to generate societal benefits that will outweigh the costs.

49. That said we have quantified the potential impacts on business wherever possible given the high-level nature of the proposals being consulted on. Overall, we estimate the proposals currently quantified in this IA could generate revenue costs to businesses with a cumulative present value of between £83m and £115m over 5 years, depending on the optimism bias scenario.
50. But the resulting UK societal impact of a revenue cost to pharmaceutical businesses depends on both the proportion of shareholders that are UK and the industry response. Figure 3 summarises the potential first and second order business responses and the associated economic impacts. Due to difficulties in determining the second order business responses, this IA only seeks to quantify the first order business impacts.

Figure 3: Business responses and economic impacts from a financial cost incurred



51. As we can see in Figure 3, the first order impact of a revenue cost to pharmaceutical firms will be a reduction in profit and an associated fall in shareholder income. In reacting to the first order impact, different companies may then choose different combinations of second order responses depending on the specific features of the market they are operating in. These would result in different UK societal impacts, as presented in the fourth tier of Figure 3 above.
52. Only those impacts shaded in red are counted as impacts on UK society for the purpose of IAs. For example, if businesses compensate for reduced revenue by increasing

operational efficiency, this is assumed to feed through to temporary sectoral employment effects and therefore should not be counted in an IA. Similarly, if the first order impact of the cost drives a second order response of reducing investment we should only count between 0% and 13% of this within the IA depending on whether the fall in investment impacts sectoral employment or R&D⁶ respectively.

53. Therefore, it is very difficult to fully determine the ultimate UK societal impact arising from the potential just under £100m revenue costs to industry (which is the central estimate). Because we have no evidence on which to base an assessment of the secondary impacts, we have taken the prudent approach of not adjusting our cost estimates for these secondary effects.
54. Instead, we take the first order revenue impacts (unadjusted for the proportion of pharmaceutical company shareholders that are UK for further prudence) as a starting point for possible costs falling on UK society and then inflate these further to account for optimism bias.
55. This represents an extremely prudent approach as previous analysis undertaken by the Department for Business, Energy & Industrial Strategy (BEIS) suggests only around 10% of pharmaceutical industry shareholders are UK shareholders on average. On that basis it would be reasonable to estimate the first order present value of the revenue costs to business developed in this IA as 10% of those quoted in the summary sections.
56. However, as explained in more detail below, the second order impacts of the costs vary depending on how companies respond to the cost. As it is not possible to quantify these second order responses, we have taken a prudent approach of not adjusting the estimated NPV to account for only 10% of shareholders being UK shareholders. This prudent approach allows for the possibility that there are additional second order impacts that we have been unable to account for. These risks are discussed in more detail in the subsequent “Impact of further industry responses” section.

Impact on dispensing doctors

57. In addition to the impacts on community pharmacies described earlier, these proposals will also affect dispensing doctors. Other than the fact that dispensing doctors (DDs) both prescribe and dispense items, they are reimbursed in the same way as pharmacy contractors except for the following 3 points:
 - DDs have their own deduction scale;
 - DDs deduction scale applies to all products (i.e. none are discount not deducted (DND) products); and

⁶ 13% for R&D calculated as a 30% uplift to the original to account for estimated economic spill over effects of pharmaceutical R&D, then adjusted down because only 10% of investment is in the UK. So, a second order impact of a £1 fall in R&D investment should be counted as $£1 * 1.3 * 0.1$ which equals £0.13 or 13% of the original £1.

- DDs medicine margin is not measured and does not count towards the £800m medicine margin set out in the CPCF.
58. The first two points simply mean that the proposal to amend the deduction scale will not affect dispensing doctors at all. They will continue to have their own deduction scale applied to amounts they're reimbursed as currently.
59. The latter point is somewhat more complicated and will have a wide-ranging impact across different proposals. As such, the following sections set out whether and how the impact of each proposal on dispensing doctors may differ to that on pharmacy contractors.

Risks and sensitivities

60. The Department has identified four principal drivers of uncertainty associated with the analysis in this assessment:
- The high-level nature of the policy proposals being consulted on;
 - The difficulty with establishing a counterfactual in a fast-changing market;
 - The impact of further industry responses; and
 - The scope of interdependencies between the proposed reforms.

Each of these issues is considered in more detail below.

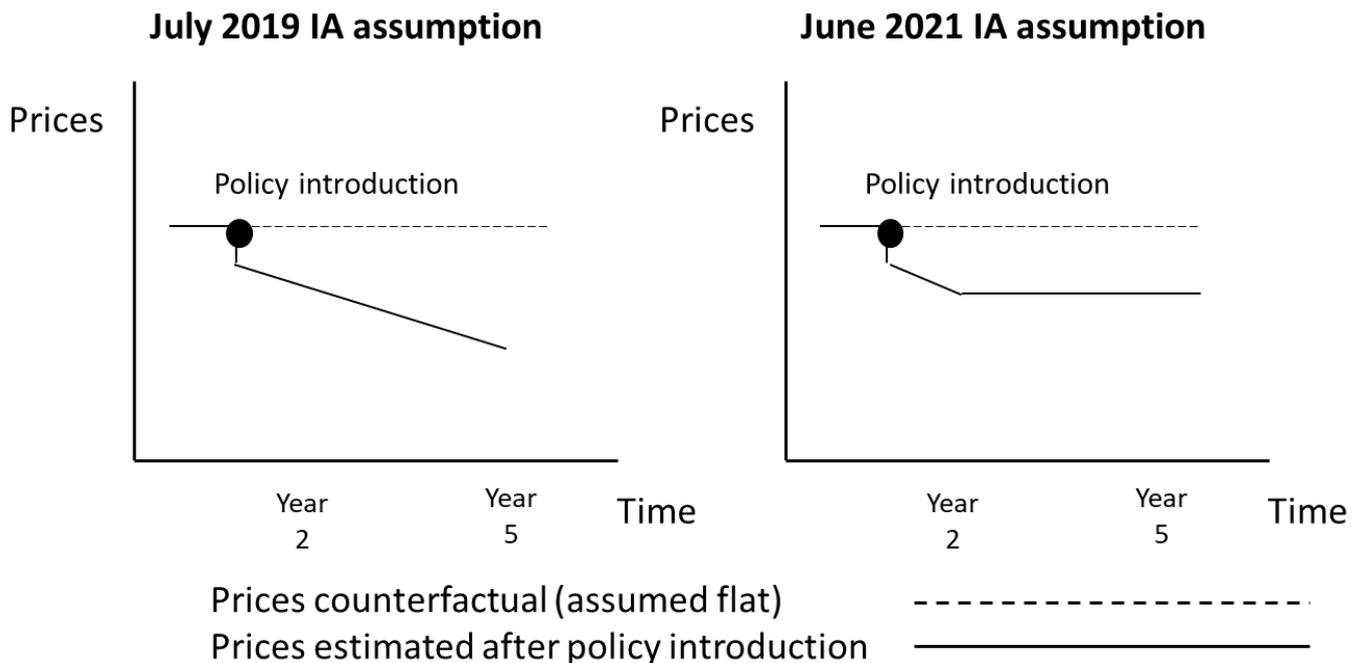
High level nature of the policy proposals

61. The consultation response which this impact assessment accompanies details responses received to the public consultation which sought views on high-level policy proposals as opposed to detailed interventions. The responses to the public consultation will then be fed in to a second period of engagement between DHSC and the PSNC only, at which point details around implementation will be determined.
62. The impact of proposals could vary depending on the detail of how they are implemented which, as noted above, will be agreed later with the PSNC. Therefore, this analysis is an initial assessment of potential impacts on a high-level principles basis and should be treated as such. It will be subject to change and refinement during the private consultation with the PSNC, utilising responses received to the public consultation, as policy detail emerges from these discussions.
63. Additionally, the implementation of measures may be staggered or impacts temporarily mitigated by transition arrangements. Any such proposals will be discussed and agreed with the PSNC during the second, more limited consultation exercise. These could significantly affect the short-term impact of policy proposals but have not been factored into this impact assessment as they will be designed later.

Difficulty in establishing a robust counterfactual

- 64. The pharmaceutical market is global in nature and can be fast-changing. It is difficult to establish a business-as-usual forecast for key variables such as prices and demand. Throughout this IA we assume that the latest available data (depending on the measure in question and data availability 2018, 2019 or 2020) will be representative of future years to calculate impacts.
- 65. It is not expected that COVID-19 will have decreased the relevance of 2020 data because, although prescribing and dispensing shifted around during the year, types, numbers, and total cost of prescriptions were similar to previous years. We then utilise an optimism bias approach loosely based on adjustments set out in the Government’s Green Book to generate high and low impact scenarios and take the average as our “average bias estimates” (more details are provided at the end of this section).
- 66. Finally, this update differs from the initial IA published July 2019 in that we have capped any forecast reductions in medicine spend as a result of these proposals so that they do not exceed the level achieved by year 2 in any subsequent years. This is shown below in figure 4.

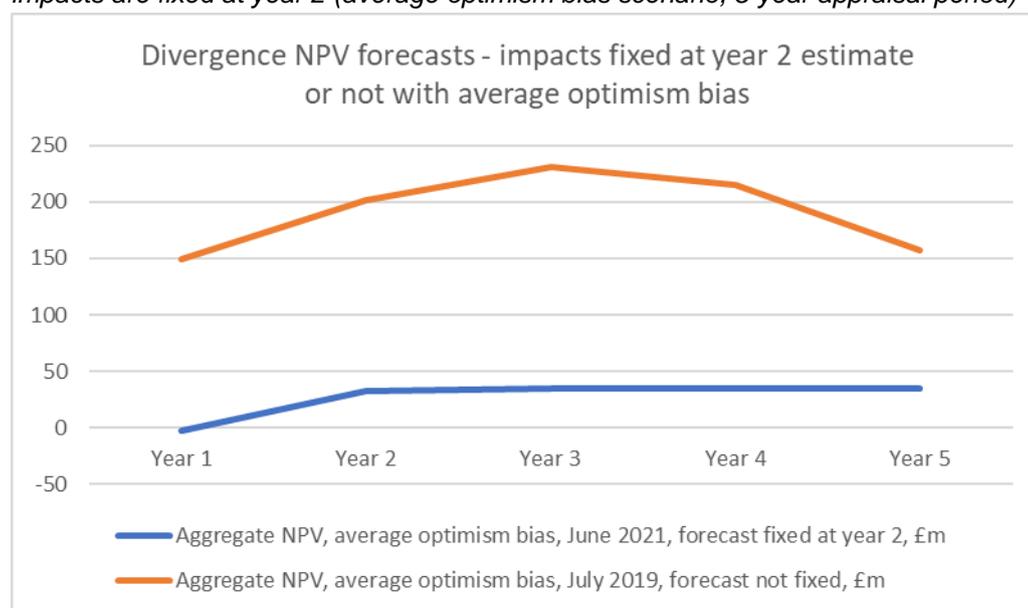
Figure 4: Comparison of price reduction assumptions July 2019 versus June 2021 IA versions



- 67. As shown above, this approach is designed to act as a most prudent estimate and mitigate the risk of over-estimating the size of potential savings due to the difficulties involved of projecting future medicines prices. In reality, we have observed that previous changes to reimbursement arrangements have been successful in achieving sustained year-on-year reductions in the cost of medicines for the NHS.
- 68. To indicate the scale of impact this assumption has, the estimated NPV in the IA is adjusted to account for changes made to the treatment of costs and benefits within specific proposals and netted off from the NPV assuming impacts are fixed at year two levels.

69. The result is shown below in figure 5 for the average optimism bias scenario. The chart shows that, although the difference between the forecast NPVs where the forecast is fixed at year 2 vs not fixed initially increases, the difference decreases in later years. Additionally, much of this difference can be explained by the introduction of a more specific method of calculating the impact of changing the method of determining reimbursement prices of generic medicines in Category A. Furthermore, the basket of products used to estimate the impact of the reforms was updated between the 2019 and 2021 IAs and variation in prices is to be expected as a result.

Figure 5: Annual NPV estimate 2019 IA where impacts increase in all years vs NPV estimate from 2021 where impacts are fixed at year 2 (average optimism bias scenario, 5-year appraisal period)



Impact of further industry responses

70. As previously discussed, this IA only seeks to quantify the initial cost to industry associated with any NHS savings from medicines spend. This assumes no major knock-on impact of reduced revenue costs on the industry or how firms may respond to this. This section considers this and concludes the risks are likely to be minimal for the three principal reasons set out below:

- Firstly, the reforms aim to make reimbursement prices more accurately and consistently reflective of market prices to stimulate competition. The policy is not intended to push market prices below the level at which companies can viably sell. So, we anticipate any risk to medicine supply or the viability of firms producing medicines in the UK should be minimal, unless they are particularly reliant on making excessive profits based on the current NHS reimbursement arrangements.
- Secondly, the pharmaceutical industry is global and revenue from the UK represented just 2.4%⁷ of world sales in 2016. It is assumed unlikely that changes to UK prices would strongly influence prices elsewhere or have a significant impact on the viability of multi-national companies.

⁷ <https://www.abpi.org.uk/facts-and-figures/global-pharmaceutical-market/shares-of-the-global-pharmaceutical-markets/>

- Thirdly, ONS data indicates that 94% of medicine by value consumed in UK is imported, with a similar percentage of medicines manufactured in the UK exported. This further demonstrates the global nature of the industry and implies UK price levels may not affect a large proportion of the UK industry as the medicines produced are exported anyway.
71. A final concern relates to whether lower price levels may reduce investment and R&D spend by pharmaceutical companies in the UK. Though it is difficult to absolutely disprove that investment is linked to spend through analysis of actual investment decisions taken, there is no theoretical economic case for such a link.
 72. Companies will locate manufacturing sites and/or research facilities where they can find the best science base at reasonable cost, considering other factors such as research infrastructure, tax, flexible labour markets and economic stability. We would expect UK prices to be secondary to these factors.
 73. Although our analysis above suggests the likelihood of significant second-order effects will be minimal, we have continued to adopt a prudent approach in this IA by deliberately not scaling down industry costs to account for the percentage of pharmaceutical company shareholders that are non-UK (see previous Impact on Business and regulatory burden section for detail).

Interdependencies between proposed reforms

74. There are a number of possible interdependencies between the proposed reforms to the Community Pharmacy Reimbursement system laid out in the proposed package. These are discussed in further detail in the relevant sections. The impact of the interactions between reforms is dependent on the detail of the proposals and implementation strategy, which will be finalised following discussions between DHSC and PSNC.
75. Interdependency may occur through interactions of the following reforms:
 - If the proposed change to the distribution of margin added to generic medicines in Category M results in a rise in generic prescribing versus brands this may reduce the potential benefits of splitting the deduction scale applied to brands versus generics. As the deduction scale is not quantified, the scale of the interaction is also unquantifiable and will, by definition, not impact the NPV presented in this IA.
 - Inclusion of more products in Part VIII A of the Drug Tariff with a listed reimbursement price could reduce the impact of changes to the determination of reimbursement prices for non-Part VIII A drugs. Again, because the impacts of these proposals are not quantified, there will be no effect on the estimated NPV.
 - Within the Changes to the arrangements for reimbursing and procuring unlicensed medicines ('specials'), if during discussions with PSNC greater numbers of products are included in Part VIII B this will increase savings for this part of the reform, and reduce possible savings from the proposed changes to the procurement of non-part VIII B unlicensed medicines.

- Changes to reimbursement of generically prescribed appliances and drugs that could be dispensed as a special may reduce the number of products which are covered under the changes to the arrangements for reimbursing and procuring unlicensed medicines reform, leading to a fall in impact of the latter. Because it was not possible to quantify the impact of the former reform within this high-level assessment, the extent of this interaction cannot be quantified either.

Applying optimism bias to mitigate these uncertainties

76. To acknowledge the level of uncertainty and the high-level nature of the proposals at this stage of their development, adjustments have been applied to generate low and high optimism bias scenarios. The average of these is then presented as the average bias estimate of each proposal's impact.
77. The Government's Green Book sets out a range of optimism bias adjustments to adjust expected spending estimates for different types of projects. These are shown below in table 3. However, the reimbursement reform policy proposals do not fit within any of these project type definitions. Furthermore, the adjustments in this assessment are applied to estimated costs and benefits that accrue to different groups as opposed to just forecast government spending.

Table 3: Green Book optimism bias adjustments

Generic lower and upper range optimism bias scalars for different project types				
Spending type	Works duration		Capital expenditure	
	Lower	Upper	Lower	Upper
Standard buildings	1%	4%	2%	24%
Non-standard buildings	2%	39%	4%	51%
Standard civil engineering	1%	20%	3%	44%
Non-standard civil engineering	3%	25%	6%	66%
Equipment/development	10%	54%	10%	200%
Outsourcing	n/a	n/a	0%	41%

Supplementary Green Book Guidance, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/191507/Optimism_bias.pdf

78. As such, using the Green Book optimism bias adjustments as a loose guide, we have inflated the cost estimates in this assessment by 5% and 50% for the low and high optimism bias scenarios respectively. Similarly, the benefits have been deflated by 5% and 50% in the low and high optimism bias scenarios respectively and average bias estimates are a simple average of the two to reflect the lack of parity between these proposals and the types of spending set out in the Green Book.
79. From this point on the three varying levels of optimism bias are described as the average, high and low optimism bias scenarios. Please note, no scenario is considered particularly more likely than the others.

Overall NPV

80. The impact of each individual reform on the overall NPV in the average optimism bias scenario is shown in table 4 below:

Table 4: Present value of central optimism bias scenarios for costs and benefits per measure, £m

Benefits and costs		Year 1	Year 2	Year 3	Year 4	Year 5	Average annual	Cumulative
All proposals	Benefits £m	2	56	59	59	58	47	234
	Costs £m	6	24	25	24	23	21	103
	NPV £m	-4	32	34	34	34	26	131
Category A	Benefits £m	1	54	58	57	56	45	226
	Costs £m	0	19	20	20	19	16	78
	NPV £m	1	35	38	38	37	30	148
Generic medicine margin (M1/M2)	Benefits £m	0	0	0	0	0	0	0
	Costs £m	3	3	3	3	3	3	15
	NPV £m	-3	-3	-3	-3	-3	-3	-15
Non-tariff, not tablet/capsule procurement	Benefits £m	0	0	0	0	0	0	0
	Costs £m	2	1	1	1	1	1	6
	NPV £m	-2	-1	-1	-1	-1	-1	-6
Unlicensed tablets and capsules	Benefits £m	2	2	2	2	1	2	8
	Costs £m	1	1	1	1	1	1	3
	NPV £m	1	1	1	1	1	1	4

Excluding transition costs of £4m

81. Summing the NPV of individual proposals presented in Table 4 gives an overall NPV of £131m in our average optimism bias scenario, with high and low optimism bias estimates of £76m and £186m, respectively and the uncertain nature of these values should be borne in mind. Whilst, as explained above, these values will be subject to change and refinement throughout the ongoing stages of policy development and consultation with the PSNC, it seems reasonable to be confident that an overall net benefit will be generated by these measures.
82. We have undertaken one further test on this overall expectation by considering the extent to which costs would have to rise or benefits would have to fall in order for the proposals to generate a net neutral impact ("breakeven analysis").

Breakeven analysis

83. The amount by which costs would need to rise or benefits would need to fall to produce a net zero impact of these measures differs across scenarios is estimated below. Tables 5 and 6 present, for each year, the required change in benefits and costs to drive an estimated NPV of zero in each optimism bias scenario.

84. In year 1 only, costs would need to fall, or benefits would need to rise in order to reach an NPV of zero. This is driven by the estimated savings of changing the determination of reimbursement prices of generic medicines in Category A taking time to develop and by the benefits of some of the proposals remaining unquantified at this stage.
85. The tables also show that in the high optimism bias (i.e. worst case) scenario, a fall in benefits of 40% or more would be required in years 2-5 to drive an NPV of zero. From the alternative perspective, costs would need to increase by over 65% in years 2-5 before the NPV would reach zero.
86. When assessing the average bias scenario, benefits would need to fall by approaching 60%, or costs increase by more than 130% in years 2-5, for the proposals to have a net zero impact.

Table 5: Percentage by which benefits would have to change to drive an estimated net zero impact of the proposals

% by which benefits would have to change to result in a net zero impact of the proposals			Year 1	Year 2	Year 3	Year 4	Year 5
Sum all proposals	Average bias	% change in benefits required for neutral	143%	-57%	-58%	-59%	-60%
	High optimism bias	% change in benefits required for neutral	284%	-40%	-42%	-43%	-44%
	Low optimism bias	% change in benefits required for neutral	59%	-69%	-70%	-70%	-71%

Table 6: Percentage by which costs would have to change to drive an estimated net zero impact of the proposals

% by which costs would have to change to result in a net zero impact of the proposals			Year 1	Year 2	Year 3	Year 4	Year 5
Sum all proposals	Average bias	% change in costs required for neutral impact	-59%	130%	138%	143%	147%
	High optimism bias	% change in costs required for neutral impact	-74%	66%	71%	75%	78%
	Low optimism bias	% change in costs required for neutral impact	-37%	220%	231%	237%	243%

87. On the basis of the estimates in tables 5 and 6 it seems reasonable to conclude that breakeven analysis shows a significant deviation from the estimated, quantified impacts would be required in order for these measures to have a zero NPV.
88. The remainder of this IA sets out the detailed assessment of costs and benefits for each proposal in turn.

Changes to the determination of reimbursement prices of generic medicines in Category A

89. The reimbursement prices for drugs listed in Category A of Part VIII A of the Drug Tariff are currently set based on list prices provided by a small sample of manufacturers and wholesalers⁸. Two principal issues with this have been identified:
- List prices are unlikely to accurately reflect selling prices; and
 - The small sample is unlikely to be representative of the whole sector.
90. Like the process already used for Category M products, we propose to use market data to inform reimbursement prices for Category A products. It is expected that this method will produce a Tariff more reflective of the market price for Category A drugs. We have considered the impact this change may have on pharmacies, dispensing doctors, NHS finances, patients and manufacturers and wholesalers (denoted industry) as the key identified groups.

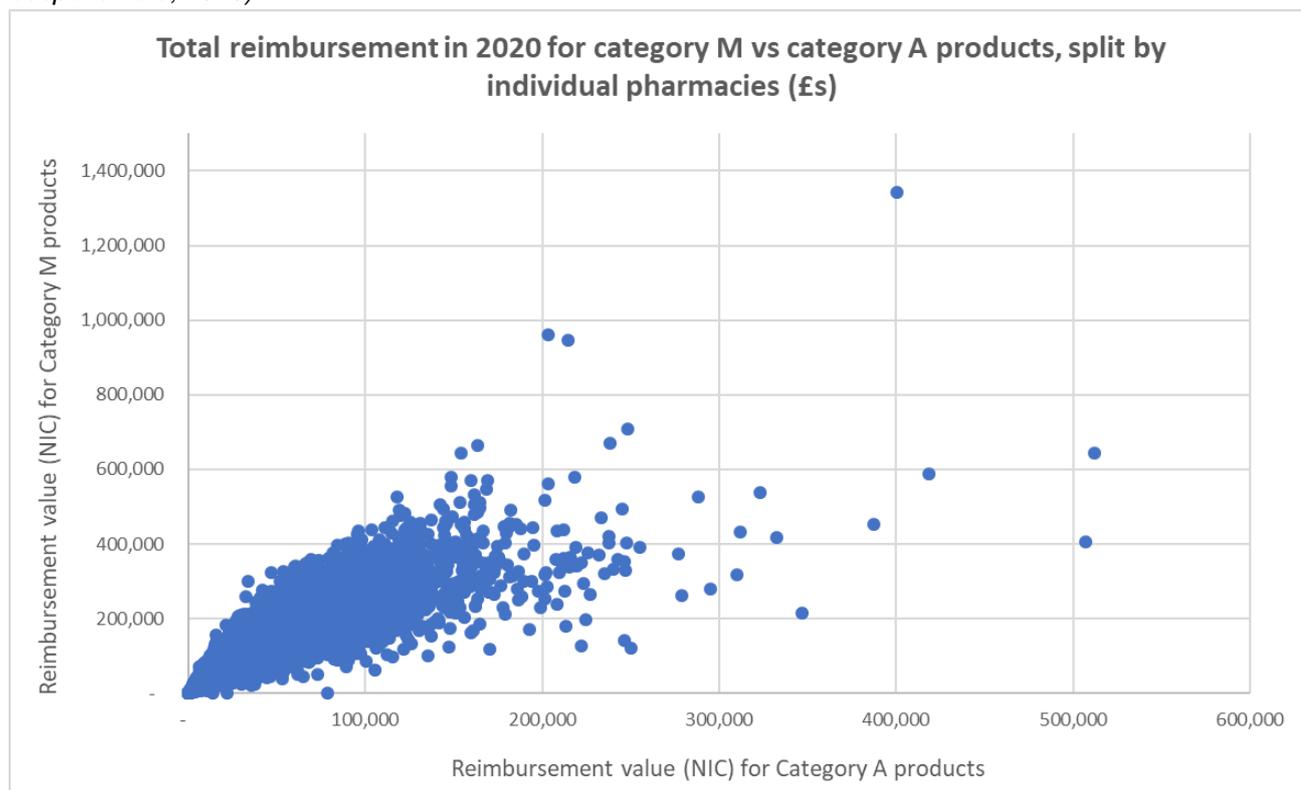
Impact on pharmacies

91. Changes to reimbursement prices can affect the amount of medicine margin made by pharmacies. At the aggregate level pharmacy medicine margin is set at £800m per annum under the CPCF funding envelope so there will be no net impact. Any shift in medicine margin away from £800m would generally be mitigated via adjustments to the Category M Tariff prices.
92. That said, if the distribution of medicine margin across different products changed it could generate winners and losers in the pharmacy sector if:
- Changes in reimbursement prices were to cause medicine margin earned on Category A products to reduce, then medicine margin for Category M products may be increased to deliver the £800m. This would benefit pharmacies that dispense relatively more Category M products, whilst disadvantaging pharmacies that dispense relatively more Category A products; or
 - Changes in reimbursement prices were to cause medicine margin earned on Category A products to rise, then medicine margin earned on Category M products may be decreased to deliver the £800m, this would benefit pharmacies that dispense relatively more Category A products, whilst disadvantaging pharmacies that dispense relatively more Category M products.
93. We can check if this is likely using data from the NHS Business Services Authority (NHS BSA) on the distribution of reimbursement amounts across Category A and M products at individual pharmacy level. Figure 6 plots individual contractors' total annual reimbursement at Tariff price for Category A versus Category M products to assess

⁸ This could in practice just be two wholesalers as a total weight of 4 is required and wholesalers are weighted 2 and manufacturers are weighted 1. So, the sample could be comprised of 2 wholesalers or 1 wholesaler and 2 manufacturers.

whether a potential future change in margin distribution across these products could generate a large number of winners and losers.

Figure 6: Individual pharmacy level Category A Net Ingredient Cost (NIC)⁹ versus Category M NIC (NHS BSA bespoke data, 2020)



94. For the majority of pharmacy contractors, total annual reimbursement at Tariff price for Category A products maintains a rough ratio of around 1:3 compared to that for Category M (subject to certain tolerance ranges as the total level of reimbursement increases). There is considerable variation within the group. There are however a small number of outliers where Category A reimbursement was higher than Category M. Of the 59 pharmacies (0.5% of the total) where this was the case, 18 had total reimbursement for Category A and Category M products estimated at less than £5k in 2020.
95. On this basis the data does not seem to indicate that there is a high risk of significant winners or losers. Overall, the likelihood of there being significant distributional effects between pharmacies will depend on the relative distribution of medicine margin between Category M and Category A. This risk can be managed by ensuring that careful consideration is given to any potential distributional impacts when we consult with PSNC on the detail of how these reimbursement prices are to be determined.

⁹NIC is defined by the NHS BSA [here](#) as the basic cost of a drug as used in primary care. This is the cost at list price excluding VAT, i.e. the price listed in the national Drug Tariff or in standard price lists and is not necessarily the price the NHS paid. It does not take into account of any contract prices or discounts, dispensing costs, fees, or prescription charge income, so the amount the NHS paid will be different. NIC is used in Prescription Services reports and other analyses, as it standardises cost throughout prescribing nationally, and allows comparisons of data from different sources.

Impact on NHS finances and Industry

96. More accurately reflected market prices in reimbursement prices could incentivise better purchasing decisions by pharmacies, leading to increased competition and reductions in selling prices.
97. The latter could translate into real savings for the NHS. Lower selling prices would translate into lower reimbursement prices being needed to support the delivery of £800m of medicine margin under the CPCF funding envelope. This would also affect manufacturers and wholesalers via reduced revenues.
98. To investigate, we examined reimbursement price data for products that have moved from Category A to M. We expect this to be a solid proxy for our proposed policy because, under current arrangements, Category M reimbursement prices are set using market data whilst Category A reimbursement prices are based on list prices.
99. We looked at monthly data on reimbursement prices running from Q1 2018 to Q4 2020. Over this period, we identified 46 products in total that moved from Category A to Category M and looked at changes in the Drug Tariff price for each in every month after they moved to Category M. We then combined the monthly changes to estimate a weighted (for total reimbursement amounts) average change 1 month, 2 months, 3 months and so on after entrance to Category M.
100. Converting the monthly weighted average into an annual scaler and applying it aggregate Category A NIC in 2020 completed the first step to estimating the aggregate impact of this measure. This initial figure then needed to be adjusted down to account for:
 - Category A products having less competition than Category M as their lower volume means fewer manufacturers to compete; and
 - Optimism bias.
101. A key limitation of this approach is that Category A products may have a lower level of competition compared to Category M products. Because the driver for expected savings is increased competition, we need to make a downwards adjustment to account for relatively less competition in Category A versus Category M. In the initial July 2019 IA an assumed 50% adjustment was applied to account for lower competition in Category A versus Category M.
102. This update adjusts the estimates down even further on the basis that around 200 products in Category A only have one manufacturer. Although single manufacturer does not equate to no competition, given there may be multiple wholesalers selling the product, for prudence we assume no additional competition savings on single source products for the purposes of this IA's estimates. This equates to scaling down total impacts by 67% in the 2021 IA.
103. We also applied an average adjustment to remove any impacts on Category M prices generated by previous medicine margin adjustments from our estimation of the impacts. This should contribute to increasing the suitability of reimbursement prices as a proxy for selling prices.

104. As noted previously, this update assumes that estimated savings will not increase past the level forecast by year 2 following policy implementation, due to the difficulty of determining longer term trends in medicines prices (both in the counterfactual scenario and as a result of these policy proposals). In reality, we have however observed that previous changes to reimbursement rules have resulted in continued year on year reductions in the costs of medicines to the NHS.
105. The impact on NHS finances will be determined by the estimated revenue costs to business. Under this revised approach the “average bias” estimate for revenue costs to industry increase from around £0m in year one to £19m in year five when converted to 2018 prices and discounted at 3.5%. The resulting cumulative, present value, revenue costs to industry are just under £80m over the full five year forecast period. As described in page 17, any impacts on medicines manufacturers or wholesalers are not considered to form part of the EANDCB as they are both indirect impacts and relate to measures designed to promote competition.
106. This assessment assumes that any savings generated for the NHS will ultimately accrue as health benefits to NHS patients, by more money being spent on general NHS care versus in the counterfactual. We can quantify the benefit to patients using the standard cost of a Quality Adjusted Life Year (QALY) methodology.
107. The standard unit for measuring health benefits is the Quality-Adjusted Life Year (QALY). While it is not possible to know the specific use to which any individual amount of additional funding provided to the NHS will be put, evidence is available of the average number of QALYs expected to be gained for any given amount of additional NHS funding – by whatever means these gains are achieved. This evidence is expressed as an estimate of the cost per QALY gained “at the margin” in the NHS of £15,000¹⁰. In other words, the best available evidence indicates that additional health benefits of 1 QALY are generated for every £15,000 of additional funding provided to the NHS. Similarly, a reduction in funding of £15,000 for frontline NHS services is expected to lead to a reduction in health benefits of 1 QALY.
108. In addition, standard IA methodology entails monetising impacts in order to represent their value to society. As set out in HM Treasury’s Green Book¹¹, the best estimate is that society values a QALY at £60,000¹². Applying this methodology to estimate the value to society of QALYs generated suggests this starts at £1m in year one, increasing to £56m by year five when converted to 2018 prices and discounted at 1.5% (rounded to the nearest million). The resulting cumulative, present value of these QALYs is circa £226m over the full five year forecast period. These figures are summarised below in table 7.

¹⁰ <https://www.york.ac.uk/che/research/teehta/thresholds/>

¹¹ https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/685903/The_Green_Book.pdf

¹² It is important to note that the value society puts on a QALY is not necessarily the same as the cost at which the NHS can generate additional QALYs due to budget constraints and other factors.

Table 7: NPV estimate changing the determination of reimbursement prices of generic medicines in Category A, 2020

Average bias estimate impacts of changes to determination of reimbursement prices of generic medicines in Category A						
	Year 1	Year 2	Year 3	Year 4	Year 5	Cumulative
Revenue cost to industry (2018 prices discounted at 3.5%) £m	0	19	20	20	19	78
Benefits to society (2018 prices discounted at 1.5%) £m	1	54	58	57	56	226
Overall net present value (NPV) £m	1	35	38	38	37	148

Rounded to nearest £m

109. Note that this is subject to a high degree of uncertainty and has been developed on the basis of high-level policy principles as opposed to a detailed methodological proposal. As more detail becomes available the estimates will be refined, using the responses to this consultation, as part of the subsequent consultation process with the PSNC only.

Impact on patients

110. The key impact on patients of this proposal are the impacts arising due to the potential to recycle NHS savings into additional frontline care. No other patient impacts have been identified (this proposal should not materially impact upon treatment decisions, availability, or outcomes).

Impact on dispensing doctors

111. As discussed above, changes to reimbursement prices can affect the amount of medicine margin made by dispensers. For pharmacy contractors, their medicine margin is set at the £800m per annum set-out in the CPCF and as such the aggregate impact is expected to be net zero. Any margin adjustments made (in particular via the Category M Drug Tariff) to maintain pharmacy contractor margin at £800m per annum will affect dispensing doctors too. So, if the distribution of dispensing doctor NIC across Category A and Category M products is like that exhibited in pharmacy contractors, the overall impact should be too.

112. To consider this, data was extracted from the ePACT2 portal showing aggregate NIC and items dispensed across Category A and Category M in dispensing doctors and pharmacies. As ePACT2 excludes hospital prescriptions 'English Pharmacies' is assumed to refer to community pharmacy prescriptions only. The results are summarised below in table 8:

Table 8: Distribution of items and NIC across categories A and M for dispensing doctors and pharmacies, 2020

Distribution of items and NIC across Categories A and M, Jan-Dec 2020			
		% A+M items	% A+M NIC
Category A	Dispensing doctors	4%	18%
	English Pharmacies	4%	22%
Category M	Dispensing doctors	96%	82%
	English Pharmacies	96%	78%

113. Based on the latest 12 months of data available, there is no observable difference in the distribution of items dispensed across the two categories between dispensing doctors and pharmacies. When looking at the relative value of these two drug tariff categories (as measured by NIC), Category A products form a slightly lower proportion of total dispensing value for dispensing doctors compared to pharmacies.
114. As explained above, if the proposed reform were to reduce medicine margin earned by pharmacies for Category A medicines this will be compensated for, likely via a margin adjustment made to Category M prices. Because dispensing doctors NIC is slightly more skewed to Category M compared to pharmacies it is reasonable to expect the overall impact on this group to be neutral or potentially a small rise in medicine margin, although it is not possible to quantify this as the medicine margin for dispensing doctors is not measured.
115. On the other hand, if the medicine margin earned by pharmacies for Category A medicines were to increase, the effect would be in the opposite direction. Finally, if medicine margin were instead to stay the same, then we would expect there to be no net impact.

Changes to the distribution of margin added to generic medicines in Category M

116. Reimbursement arrangements are significantly undermined when brands with a cheaper reimbursement price than the Category M reimbursement price of their generic counterparts are prescribed solely on the grounds of the cost by the CCG.
117. The Category M reimbursement price can appear to the CCGs on the surface to be more costly than some brands because the listed reimbursement price includes an element of medicine margin. The amount of medicine margin varies by product. Pharmacy contractors on average do not earn medicine margin on brands, but they are able to retain some medicine margin on generics, which contributes to the payment for pharmaceutical services under the Community Pharmacy Contractual Framework (CPCF).
118. The above issue can be addressed by decreasing the amount of medicine margin included in the listed reimbursement price of the affected products, i.e. by lowering their reimbursement price to either below the brand's price or closer to the brand's price. Where there is a branded alternative that appears cheaper than the generic we denote these Category M2 products and all other Category M products are denoted Category M1 products.
119. To complement this, we also propose to apply differential discount scales to branded and generic products to account for the fact that brands typically have little or no associated medicine margin. This policy is described in more detail on page 58.

Potential number of products affected

120. The number of products affected will depend on the exact rules used to determine the definition of a brand with a cheaper reimbursement price than the equivalent Category M generic. As the number of products on the market, and reimbursement prices move around, the total number of products affected is likely to change.
121. However, based on various separate pieces of internal DHSC analysis conducted using data covering the period 2012 to 2018, the proportion of total Category M products with an equivalent branded product with a lower reimbursement price appears to lie in the region of 10% to 30%.
122. Using a very prudent definition of brands with a cheaper reimbursement price (this included requiring the corresponding branded product to be 10% cheaper and requiring the product to be cheaper across the year as a whole), we have identified 72 products that appeared to have brands with cheaper reimbursement prices over the calendar year 2018. All subsequent analysis has been based on this sample of products.
123. We also undertook sensitivity testing to see how many products could potentially come into scope of the policy if we used as wide a definition as possible. Looking for products that had a branded alternative cheaper than or equal to the generic price during 1 or more months in 2018 yielded a list of 181 products. As noted above, the number of products ultimately affected will depend on the exact rules implemented, the number of products available and reimbursement price levels in the future.

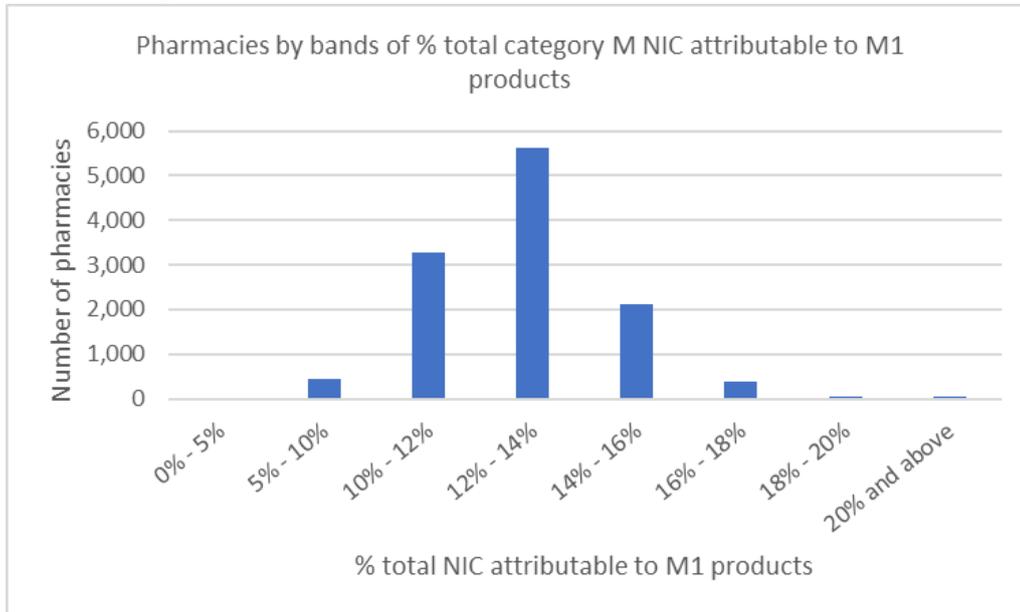
Impact on pharmacies and NHS finances

124. At the aggregate level we expect a net zero impact on the pharmacy sector as the policy proposal is to redistribute medicine margin across Category M products in a cost neutral manner. However, this could generate winners and losers at individual pharmacy level if propensity to dispense these products is uneven. Some pharmacies who dispense a higher proportion of the new higher medicine margin products will gain, whilst those who dispense a higher proportion of the new lower medicine margin products may lose out.
125. Bespoke data provided by the NHS BSA detailing NIC for drugs in Category M in 2018 at individual pharmacy level was used to assess the potential for winners and losers. NIC associated with products that would come under the prudent definition of Category M2 was split out and the implied M1 NIC per pharmacy calculated. The proportion of all Category M NIC attributable to M2 products is used as a proxy for reliance on Category M2 products (new lower medicine margin products) and therefore to identify potential losers.
126. The data showed only 32 out of almost 12,000 pharmacies had greater than 20% of their total Category M NIC attributable to M2 products. Furthermore, the average NIC across these pharmacies in 2018 was less than £10k compared to an average of over £130k¹³ for the rest of the sample.

¹³ Not adjusted to account for very low NIC (definition at footnote 5 page 22) at the opposite end of the distribution.

127. The clear majority of pharmacies (87%) had M2 NIC as a proportion of all category M NIC between 10% and 15%, whilst 99.6% of pharmacies fell within 5% to 25%. It therefore seems unlikely that there will be many significant winners or losers as relatively small scale losses would be spread across the majority of pharmacies. The distribution is shown in figure 7 below:

Figure 7: Individual pharmacy level reimbursement for M2 products as a % of total Category M reimbursement (see footnote 5 page 22 for definition of NIC), NHS BSA bespoke data



128. In addition, correcting incentives for prescribers to prescribe the brand instead of the generic could help increase access to medicine margin for pharmacies previously dispensing more brands because of this issue. This in turn is expected to lead to an improvement in the ability of the system to deliver the £800m medicine margin under the CPCF funding envelope with no upwards pressure in reimbursement prices. Therefore, both pharmacies, who gain more equitable access to medicine margin and the NHS, by no longer having to compensate pharmacies for lower medicine margin earned on brands by adjusting reimbursement prices upwards to meet the £800m under the CPCF funding envelope, benefit.

129. It is not possible to quantify this saving as it is not possible to break down past movements in measured medicine margin to estimate the contribution that this perverse incentive could have made.

130. Finally, it is important to note the interaction between this proposal and the proposal to amend the deduction scale, as this could help to mitigate the impact on pharmacies of any reduction in medicine margin on M2 products.

131. For example, if M2 products were to be included in the branded discount scale, they would be expected to be subject to a lower discount rate, which would help to offset the reduction in medicine margin on these products. It is important to note that as both the proposals on M1 M2 and the discount scale are to be designed with cost neutrality in mind, individual pharmacies may gain or lose but the overall income for the sector would not change.

Impact on dispensing doctors

132. Dispensing doctors are reimbursed the same prices as pharmacies for dispensing Category M products as set out in the Drug Tariff. As the proposed policy is to redistribute medicine margin across Category M products in a cost neutral manner for community pharmacy contractors in aggregate, switching margin between M1 and M2 products would be expected to lead to a similar cost neutral impact on dispensing doctors providing the distribution of NIC across M1 and M2 products is similar across the two groups.
133. On the other hand, if dispensing doctors dispensing was disproportionately skewed towards M2 products, compared to community pharmacy, then the aggregate effect could be a reduction in their medicine margin earned. Alternatively, if dispensing were skewed towards M1 products, then the aggregate effect could be an increase in medicine margin earned.
134. BNF presentation level Category M items and NIC data is available to extract from the ePACT2 portal for English dispensing doctors and English pharmacy. This shows a similar distribution of Category M NIC and items across products initially identified as M2 or M1 in the previous analysis undertaken June 2019 for dispensing doctors and pharmacy as shown in table 9:

Table 9: Distribution of NIC and items across Category M1 and M2 products for dispensing doctors and pharmacies

Distribution of NIC and items across Cat M1 and M2 dispensing doctors vs pharmacy			
		% Cat M NIC	% Cat M items
Estimated M1 Nov18 - Oct19	Dispensing doctors	87%	93%
	English pharmacy	86%	91%
Implied M2 Nov18 - Oct19	Dispensing doctors	13%	7%
	English pharmacy	14%	9%

135. The data suggests there is very little variation between the distribution of Category M NIC across products initially identified as M1 or M2 for dispensing doctors compared to pharmacy. As such, it seems reasonable to expect the aggregate impact on dispensing doctors medicine margin will be in line with that for pharmacy.
136. It is not possible to assess the potential scale of the impact without a measure of dispensing doctors medicine margin. This will be kept in mind as the detail of the potential reform proposal is developed.
137. Finally, there may be additional cashflow implications for dispensing doctors as, unlike for pharmacies, this package of reforms does not include amending the deduction scale applied to reimbursement for dispensing doctors. As discussed above, if M2 products were to be included in the branded discount scale, they would be expected to be subject to a lower discount, which would help to offset the reduction in medicine margin on these products. As there is no proposal to change the deduction scale for dispensing doctors, they would not benefit from this same cashflow mitigation.

Impact on industry

138. We have also considered what the impact might be of reducing reimbursement prices for Category M1 products on the manufacturers who produce the branded alternatives. As the aim of the proposal is to correct perverse incentives that encourage prescribers to prescribe branded products instead of generics, this proposal is expected to lead to a shift in prescribing away from brands to generics. This is likely to lead to a fall in revenue associated with branded products and a gain in revenue for generic products.
139. It is difficult to quantify this figure, as we do not currently know the size of the potential shift in prescribing that might result from this proposal. However, looking at the 72 products identified in our prudent scenario, the total value of NHS reimbursement in 2018 was just under £5.5m. We would judge this to be the maximum value of any potential lost revenue for businesses since:
- This figure would assume 100% switching between brands and generics for these products, in reality the figure is likely to be lower as not all prescribers would necessarily be price sensitive. In some cases, it may be more clinically appropriate to continue to prescribe the branded product. This would depend on the needs of the patient which will not be compromised.
 - This figure assumes that the selling price of the products are equivalent to the NHS reimbursement prices paid. In reality, suppliers may offer additional discounts on their products. This would mean that the actual loss in revenue is less than the NHS reimbursement price, which for brands, is likely to be based on suppliers' list prices.
 - This figure also does not consider the revenue gained by the suppliers of the generic products.
140. As a result of these considerations, we assume for the purposes of this IA that approximately 50% of this maximum potential lost revenue would actually be realised. Adjusting for optimism bias implies a net present value average bias estimate revenue cost to industry of circa £3m per annum could result.
141. The total amount reimbursed for the product list generated by applying the widest possible definition of M2 products (see paragraph 123 for detail) was around £28m in 2018. Assuming this will be representative of future years, applying the assumed 50% scaler and adjusting for optimism bias suggests an average bias estimate present value revenue cost to industry of around £81m across the whole five year forecast period.
142. In addition to the changes in revenue for suppliers, we recognise that some businesses may face disproportionately higher costs, if a higher proportion of their products are more affected by these changes. To provide an initial view of this, we looked up the number of market authorisations held by manufacturers of the branded alternatives to proxy their reliance on the types of products likely to be affected by this proposal.
143. The approach used drug names taken from the dictionary of medicines and devices (dm+d) to establish sellers of each brand identified as having a more expensive generic alternative, then looked these up against a list provided by MHRA which had all Market

Authorisation Holders so that we could understand how many Market Authorisations each firm has.

144. The data suggests that 33 manufacturers could be affected by the policy and for over three quarters of these the branded alternatives represent less than 10% of their total Marketing Authorisations. Branded alternatives accounted for between 10% and 50% of all Marketing Authorisations for 18% of the identified manufacturers while for only 6% of manufacturers did they account for >50%.
145. It therefore seems unlikely that, for the most part, reducing the medicine margin added to some products in Category M would impact the industry sufficiently to jeopardise supply or the feasibility of businesses.

Impact on income under the Voluntary Scheme for Branded Medicines Pricing and Access

146. If this proposal leads to a shift away from prescribing branded products this will also feed through to the income accrued through the voluntary and statutory schemes¹⁴ used in the UK to control the cost of branded health service medicines. Details of the schemes may be found at the reference provided and in short:
- The 2019 Voluntary scheme for branded medicines pricing and access (VPAS) is a voluntary scheme agreed between DHSC and the branded pharmaceutical industry. VPAS introduced a limit on growth in the overall cost of branded health service medicines. Eligible scheme members make payments based on the difference between allowed growth and actual growth in NHS expenditure on branded medicines. This is achieved through the calculation of a payment percentage, where companies make payments of a particular percentage of their eligible sales in order to bring expected growth in line with allowed growth.
 - In conjunction with the VPAS a set of Regulations ensure that there are similar limits on the cost of branded health service medicines supplied by those companies that choose not to join the VPAS. These Regulations are referred to as the “statutory scheme”. The terms of the current statutory scheme provide for the application of payment percentages in a similar fashion to the VPAS.
147. If sales of branded medicines were to fall this could reduce the income generated by these schemes, assuming branded medicines sales had otherwise exceeded the allowed growth. We have undertaken initial, high-level analysis looking at the potential range of impact on income from the VPAS (only) that the potential fall in sales of branded medicines could drive.
148. The analysis is limited to VPAS only as only circa 3% - 4% of sales are anticipated to be made by companies sitting in the statutory scheme. It was therefore deemed proportionate and appropriate to exclude the statutory scheme impact in this initial, high-level assessment.

¹⁴ Voluntary Scheme: <https://www.gov.uk/government/publications/voluntary-scheme-for-branded-medicines-pricing-and-access>
Statutory Scheme: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/761015/consultation-response-statutory-scheme-to-control-costs-of-branded-health-service-medicines.pdf

149. The central estimate for potential impact on VPAS income in our prudent scenario is less than £200k and the equivalent under the widest possible definition of M2 products is just less than £1m. The full range of estimates depending on definition of M2 applied and average, high or low optimism bias scenario covers from a minimum of ~£100k to a maximum of just over £1m. On this basis, initial analysis suggests the impact on 2019VS income should be minimal.

Impact on patients

150. We do not anticipate that there will be significant impacts on patients. Where there are clinical reasons for a patient to be prescribed a branded product, we assume that clinicians will continue to prescribe by brand, in accordance with the needs of the patient.

Changes to the determination of reimbursement prices of medicines with multiple suppliers in Category C

Introduction

151. The Category C reimbursement price is based, in the main, on the brand originator's list price and mostly relate to branded medicines.

152. The reimbursement arrangements for medicines in Category C generally assume that they are branded medicines with no competition. However, in reality there are multiple suppliers of some Category C products.

153. The current reimbursement prices for medicines with competition in Category C do not reflect actual selling/purchase prices and, as a consequence, more medicine margin than intended may be retained. Pharmacy contractors will source the medicine with the biggest margin against the list reimbursement price and not the medicine that has the lowest suppliers' list price. As a consequence, the NHS/CCGs pay more for Category C medicines where there is competition, resulting in poor value for money.

154. The Department relies on the medicine margin survey to ensure that the £800m of medicine margin under the CPCF funding envelope is delivered to contractors, as described in paragraph 8. But it is preferable to ensure reimbursement prices are set in a way that is most accurate and as reflective of the market as possible, to minimise the need for subsequent adjustments to correct for over or under delivery of medicine margin.

Wider impact on pharmacy contractors and NHS spend

155. As previously discussed, since the medicine margin is targeted at £800m under the CPCF funding envelope, it is not expected that changing reimbursement prices would necessarily translate directly into any changes in the overall amount of funding paid for

pharmacy contractors, and hence any savings for the NHS. This is because any reduction in reimbursement prices that resulted in the measured medicine margin falling below the £800m under the CPCF funding envelope would result in further adjustments to address this. Instead, we expect that reimbursement prices that better reflect market prices will reduce the need for margin adjustments.

156. However, as previously noted, there still remain significant benefits of setting reimbursement prices that are more reflective of market prices, and so avoiding the risk of more medicine margin being retained than intended and the need for subsequent adjustments to reimbursement prices to correct for this.
157. For example, by avoiding potential risks that reimbursement prices need to be adjusted downwards to account for previous over delivery of medicine margin at a time when market conditions have worsened, which may have significant negative effects on pharmacy cashflow. As it is not possible to predict the timing of future medicine margin adjustments, and likely associated market conditions, it has not been possible to quantify this benefit any further.
158. There may in addition be distributional effects across pharmacy contractors as changes in reimbursement prices may have the largest impact on those contractors who dispense the highest proportion of Category C products where there are multiple suppliers. On the other hand, contractors who dispense a relatively smaller proportion of these products may benefit, if general reimbursement prices no longer have to be adjusted to account for any over-delivery of medicine margin driven by these Category C products.
159. Due to the difficulties in extracting product level dispensing data at an individual contractor level, no further assessment of these distributional effects has been conducted.

Impact on dispensing doctors

160. As discussed above, changes to reimbursement prices can affect the amount of medicine margin made by dispensers. For pharmacy contractors, their medicine margin is set at the £800m per annum set-out in the CPCF and as such the aggregate impact is expected to be net zero. Any margin adjustments made (in particular via the Category M Drug Tariff) to maintain pharmacy contractor margin at £800m per annum will also affect dispensing doctors. So, if the distribution of dispensing doctor NIC across Category C and Category M products is like that exhibited in pharmacy contractors, the overall impact should be too.
161. To consider this, data was extracted from the ePACT2 portal showing aggregate NIC and items dispensed across Category C and Category M in dispensing doctors and pharmacies in 2020. The results are summarised below in table 10:

Table 10: Distribution of items and NIC across Categories C and M for dispensing doctors and pharmacies, 2020

Distribution of items and NIC across Categories C and M, Jan-Dec 2020			
		% C+M items	% C+M NIC
Category C	Dispensing doctors	13%	54%
	Pharmacies	14%	53%
Category M	Dispensing doctors	87%	46%
	Pharmacies	86%	47%

- 162. The latest 12 months of data suggests that there is barely any difference in the distribution of dispensing doctors NIC across Categories C and M when compared to the equivalent for pharmacies.
- 163. It therefore seems reasonable to expect the impact on dispensing doctor margin is likely to be largely neutral given the 1 percentage point difference in reliance on Category C versus pharmacies.

Impact on Industry

- 164. The main impacts of this proposed policy are to create a fairer distribution of margin for dispensers and ensure reimbursement prices do not create distorting effects. It may be the case that having reimbursement prices that are more reflective of the market may help to improve competition in the medicines market, which may help to drive down selling prices and therefore would have implications for both NHS finances and industry. However, it is not possible to quantify these effects as it is not possible to determine the likely size of these competition effects. For any branded products within Category C, any change in the selling prices may also have implications for the income accrued through the voluntary and statutory schemes used in the UK to control the cost of branded health service medicines, as described in paragraph 146 above.

Impact on patients

- 165. To the extent that patients are still able to access the medicines that they need, there is no expected impact on patient health outcomes. There may be a risk that if reimbursement prices are set below the market price of the product, this would create supply issues for patients as pharmacy contractors would be unwilling to supply the medicine at a loss. However, as the proposal is to set reimbursement prices based on a weighted average of suppliers' list prices, weighted by the relative volumes and therefore availability of each supplier, this risk is likely to be low. Additionally, contractors are required to dispense patient prescriptions under the 2013 Pharmaceutical and local pharmaceutical services regulations, even if the cost of doing so is higher than the NHS reimbursement. This further decreases the risk of adverse impacts on patient health outcomes.

Inclusion of products treated as drugs (i.e. products other than licensed and unlicensed medicines that are treated as “drugs” for the purposes of NHS pharmaceutical services) in Part VIII of the Drug Tariff with a listed reimbursement price and changes to the determination of reimbursement prices for non-Part VIIIA drugs.

Introduction

166. This single section covers 2 policy proposals given their similarity and inter-dependence:

- Inclusion of products treated as drugs (i.e. products other than licensed and unlicensed medicines that are treated as “drugs” for the purposes of NHS pharmaceutical services, such as some medical foods, food supplements and dermatological products) in Part VIII of the Drug Tariff with a listed reimbursement price; and
- Changes to the determination of reimbursement prices for non-Part VIIIA drugs.

167. There are products treated as "drugs" that are not medicines but that have been prescribed for medical purposes such as medical foods, commercially available food supplements and some dermatological products. Some of these products have been included with a reimbursement price in Category A or C in Part VIIIA of the Drug Tariff. Drugs not listed with a reimbursement price are reimbursed under the non-Part VIII arrangements i.e. the list price of the manufacturer, wholesaler, or supplier from which the dispensing contractor sourced the medicine.

168. Not many drugs which are not medicines are currently listed with a reimbursement price in Part VIIIA of the Drug Tariff. Because most of these products are currently reimbursed under the non-Part VIII arrangements i.e. the list price of the supplier (manufacturer or wholesaler), pharmacy contractors will source products with the biggest discount and not the drug that has the lowest list price. As a consequence, the NHS/CCGs pay more for those products than is necessary. Because of the disparity in reimbursement, the amount paid for essentially the same products varies across and within CCGs.

169. To address the problem outlined above we are proposing:

- a. To list as many drugs that are not medicines in Part VIII of the Drug Tariff as possible. For these drugs newly listed in Part VIII that are not medicines, we would determine the reimbursement price of these products in Part VIII by using the weighted average of the supplier's list prices as published on dm+d. We would also like to explore the option of basing these prices on actual selling prices, and to include as many drugs in Part VIII as possible.
- b. Where it is not possible or practical to include these drugs in Part VIII, the reimbursement rules would be changed to:
 - Single source non-Part VIIIA reimbursement prices will be based on manufacturer's list price as published on dm+d.

- Multi source non-Part VIII A reimbursement prices will be based on average weighted list prices of suppliers as published on dm+d. The weighted average of the supplier's list prices from the previous month as published on dm+d will be published to provide an indicative reimbursement price to pharmacy contractors.
- Please note that the impact of the proposed reforms to reimbursement rules for non-part VIII A products will be dependent on the number of drugs that are not medicines that are added to part VIII A of the Drug Tariff in the reform outlined above.

Impact on pharmacies

170. For drugs newly listed in Part VIII, pharmacies will now be reimbursed based on a weighted average of supplier's list prices. This could affect the amount of margin that the contractor earns on that product, however this is not possible to quantify as we lack visibility of contractor margin at an individual product level. In aggregate, pharmacy medicine margin is fixed at £800m per annum under the CPCF agreement, and so any increase or reduction in medicine margin earned on the products in scope of this proposal would result in further adjustments to reimbursement prices elsewhere to maintain medicine margin at £800m, as measured in the margin survey.
171. For drugs remaining outside Part VIII, the proposed change to reimbursement rules are expected to generate effects akin to those described above. However, as weighted average prices on dm+d will not be knowable in advance, there is a risk that pharmacy contractors' certainty over reimbursement prices may fall versus current arrangements.
172. There is a risk that this may make it harder for pharmacies to manage and forecast their cashflow, which could also affect their purchasing decisions. To mitigate this risk, it is proposed that the weighted average of suppliers' list prices from the previous month are published in order to provide an indicative reimbursement price to pharmacy contractors.

Impact on dispensing doctors

173. As the same reimbursement rules will apply to dispensing doctors, they will be affected in a similar way to community pharmacies as described above. However, as dispensing doctors' medicine margin is not measured and does not contribute to the agreed £800m medicine margin for pharmacy contractors, it is not possible to determine what the aggregate impact on dispensing doctors' medicine margin is. As discussed in other sections, if dispensing doctors share a similar pattern of dispensing to community pharmacy, then we would expect a broadly similar net zero impact. However, if their pattern of dispensing differs significantly, then the aggregate impact on the amount of medicine margin they earn could be very different. As we do not have visibility of margin earned for specific products, it is not possible at this stage to further quantify this.

Impact on NHS finances

174. As previously discussed, because most of these products discussed in this section are currently reimbursed under the non-Part VIII arrangements i.e. the list price of the supplier (manufacturer or wholesaler), pharmacy contractors will source products with the biggest discount and not the drug that has the lowest list price. As a consequence, the NHS/CCGs pay more for those products than is necessary, and because of the disparity in reimbursement, the amount paid for essentially the same products varies across and within CCGs. As a result, adding a greater number of products to the Drug Tariff, and changing reimbursement rules for non-Part VIII drugs is expected to improve incentives for pharmacy contractors to source these products at the lowest possible cost, ultimately resulting in savings for the NHS.
175. Without a list of non-medicines that might be moved into the Drug Tariff we cannot reliably quantify the scale of the potential savings. However, it is worth noting that even where products moved from outside the Part VIII into Category C of the Drug Tariff, the data showed an average fall in reimbursement prices of 6% per annum, despite the fact that the reimbursement price for Category C products is still currently based on the list price of a single supplier¹⁵. We anticipate that our proposal to base reimbursement prices on a weighted average of all suppliers list price could perhaps drive even higher savings.

Impact on Industry

176. By changing the reimbursement prices to better reflect the wider range of suppliers' prices in the market, and by adding more products into the Drug Tariff, this may result in some additional competitive pressure arising in the market for these products. Any reduction in pharmacy purchase prices due to increased competition would be expected to feed into savings to the NHS via lower reimbursement prices needed to support the £800m of medicine margin under the CPCF funding envelope, but also affect manufacturers and wholesalers via reduced revenues. As we have not been able to quantify the potential NHS savings of associated with these measures, it is also not possible to quantify the potential impact on industry.

Impact on patients

177. To the extent that patients are still able to access the medicines that they need, there is no expected impact on patient health outcomes. There may be a risk that if reimbursement prices are set below the market price of the product, this would create supply issues for patients as pharmacy contractors would be unwilling to supply the medicine at a loss. However, as the proposal is to set reimbursement prices based on a weighted average of suppliers' list prices, weighted by the relative volumes and therefore availability of each supplier, this risk is likely to be low. Additionally, pharmacy contractors are obliged to dispense requested items under the 2013 Pharmaceutical and local

¹⁵ Note that this differs from non-Part VIII arrangements, where the reimbursement price is the list price of the manufacturer, wholesaler, or supplier from which the dispensing contractor sourced the medicine

pharmaceutical services regulations, even if the cost of doing so is higher than the NHS reimbursement.

178. For drugs in non-Part VIII, the lack of published reimbursement prices (as described in paragraph 171) may create additional uncertainties that exacerbate this issue. As discussed above, this would be mitigated by publishing previous month's weighted average list prices.

Changes to the arrangements for reimbursing and procuring unlicensed medicines ('specials')

179. There are two separate proposals in relation to unlicensed medicines. These are assessed in turn below.

Bringing unlicensed tablets and capsules into Part VIII B of the Drug Tariff

Introduction

180. Part VIII B of the Drug Tariff does not currently set out reimbursement prices for unlicensed tablets and capsules. Because pharmacists are reimbursed the invoice price (less any discounts or rebates) for non-Part VIII B specials, they have no incentive to seek out the cheapest products available. This has driven significant variation across prices paid for comparable products and, in some instances, pharmacies paying prices that seem significantly above a level the manufacturing cost would suggest.

181. This policy proposal is to include all possible unlicensed tablets and capsules with a reimbursement price in Part VIII B of the Drug Tariff. The definition of unlicensed tablets and capsules used in this analysis is any product with 'tablets, capsules or tabs' in the BNF presentation name. Note that the actual list of products that may be added to the tariff and associated entry and exit criteria will be determined via detailed consultation with the PSNC. The Department proposes to set the reimbursement prices based on market data as is already the case for unlicensed medicines listed in Part VIII B of the Drug Tariff currently.

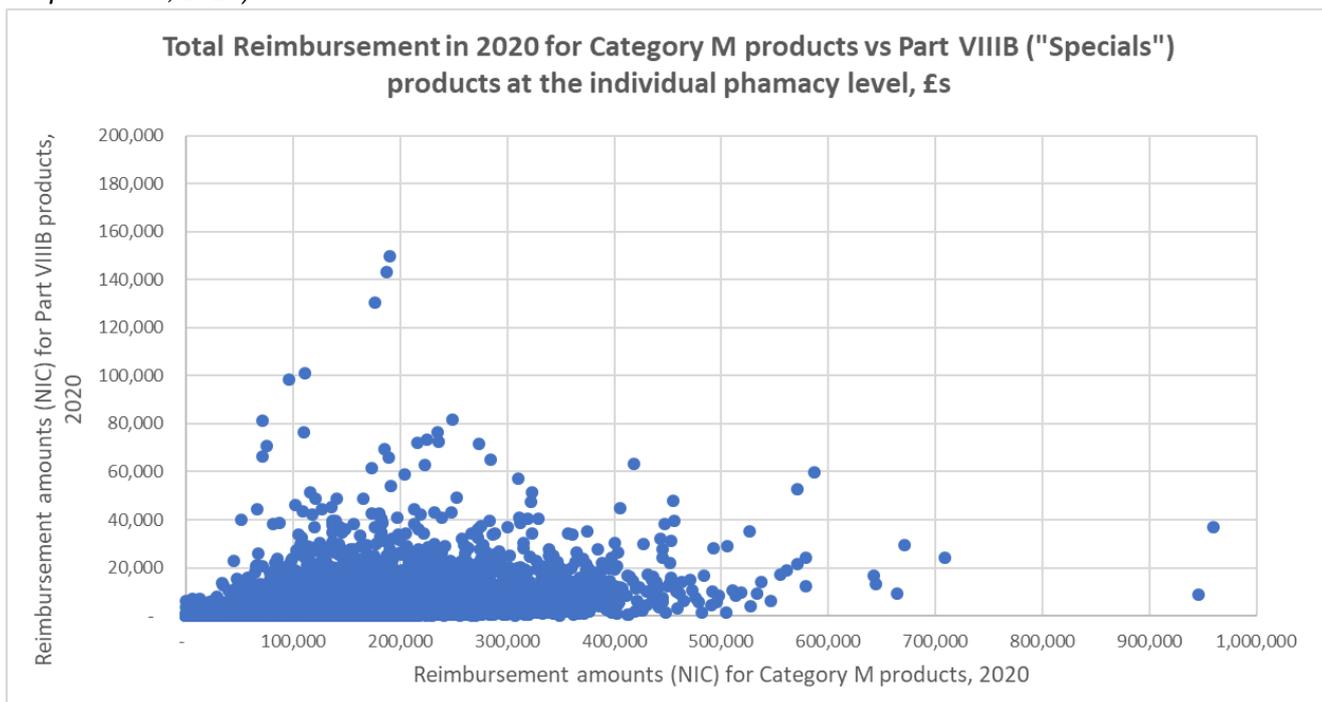
182. We have considered the impact this change may have on:

- The pharmacy sector;
- Dispensing doctors;
- NHS finances;
- Patients; and
- Specials tablets and capsules manufacturers and wholesalers.

Impacts on pharmacies

- 183. Because these products are not currently listed in the Drug Tariff, pharmacies will currently be reimbursed the invoice price (less any discounts or rebates). Unlicensed tablets and capsules are therefore not expected to contribute to pharmacy medicine margin at present and there is little or no incentive to shop around for the best price.
- 184. Conversely, reimbursement prices for Part VIII B products include an element of medicine margin. Bringing unlicensed tablets and capsules (UT&Cs) into the Drug Tariff will therefore increase medicine margin earned on these products. Medicine margin is capped at £800m per annum. So, the addition of “new” medicine margin from UT&Cs may result in a downwards adjustment (most likely to Category M reimbursement prices) to maintain medicine margin at the £800m under the CPCF funding envelope.
- 185. The aggregate impact of this on the pharmacy sector will be zero as the £800m medicine margin will be maintained. However, the shift in medicine margin away from Category M products on to unlicensed tablets and capsules could create winners and losers within the sector. We tested this using bespoke NHS BSA data to look at the distribution of Category M and specials dispensing across pharmacies as shown in figure 8:

Figure 8: Individual pharmacy level amounts reimbursed for ‘specials’ versus Category M products (NHS BSA bespoke data, 2020)



- 186. The data shows that the amounts reimbursed across pharmacies are skewed strongly towards Category M products. As a result, we expect that any impact of a downwards adjustment to Category M tariff prices would be diluted across a large reimbursement value and a large number of pharmacies. And, therefore, the risk of significant scale losers should be minimal.

Impact on dispensing doctors

187. For community pharmacy no aggregate impact is expected as their medicine margin is maintained at £800m per annum as set out in the CPCF. However, any margin adjustments made (in particular, via the Category M Drug Tariff) to maintain pharmacy contractor margin at £800m per annum will also affect dispensing doctors. So, if the distribution of dispensing doctor NIC across unlicensed tablets and capsules and Category M products is like that exhibited in pharmacy contractors, the overall impact should also be very similar.
188. To consider this, data was extracted from the ePACT2 portal showing aggregate NIC and items dispensed across non-part VIII B specials and Category M medicines for dispensing doctors and pharmacies. The results are summarised below in table 11:

Table 11: Distribution of items and NIC across Category M and non-part VIII B specials for dispensing doctors and pharmacies

Distribution of items and NIC across Category M and non-part VIII B specials Jan-Dec 2020			
		% non-VIII B + Cat M items	% non-VIII B + Cat M NIC
Non-part VIII B specials	Dispensing doctors	0%	1%
	Pharmacies	0%	2%
Category M	Dispensing doctors	100%	99%
	Pharmacies	100%	98%

189. The latest 12 months of data suggests that the proportion of dispensing doctors' non-part VIII B specials and Category M NIC attributable to non-part VIII B specials is around half that observed for pharmacies. Please note that this is in the context of very low proportions (1% and 2% for dispensing doctors and pharmacies respectively).
190. If dispensing doctors dispensing is skewed more towards Category M, as suggested here albeit very slightly, the rise in margin earned on unlicensed tablets and capsules for dispensing doctors may be more than offset in aggregate by any subsequent reductions made to Category M reimbursement prices to maintain community pharmacy margin at £800m. Because dispensing doctors' margin is not measured, we are unable to assess the extent to which this might occur.

Impact on NHS finances and industry

191. To assess whether there might be an impact on NHS finances, we can look at what happened to reimbursement prices for products that have already been added into the Part VIII B Tariff, compared to products that remained outside of the Tariff.
192. Our analysis finds that on average, products that were added to Part VIII B of the Drug Tariff fell in price, whilst prices rose for non-part VIII B specials. We are not aware of anything else that would have driven price falls in the Part VIII B specials and price rises in the non-Part VIII B. Therefore, it seems reasonable to attribute most of the Part VIII B price reductions to the products' inclusion in the Tariff and so to expect that adding UT&Cs into the Tariff should generate real savings for the NHS.

193. We applied the smallest fall in average annual price per unit for Part VIII B specials in the data which equalled -3% rather than, for example, taking an average of the changes shown by the data. Furthermore, we assume as a counterfactual that the prices of these products would have remained static, rather than rising in price as suggested by our analysis. As such, this represents an extremely prudent approach.
194. Applying this reduction to the UT&Cs NIC (for definition see footnote 5) in 2020, and adjusting for optimism bias, gives us an average bias estimate of savings of just under £1m per annum or £4m cumulatively across the five year forecast period. Note, we have again assumed the volume of UT&Cs would remain constant at 2020 levels to maintain prudence.
195. We assume that any savings generated for the NHS will be recycled back into CCGs budgets for spending on frontline services. This will ultimately benefit patients as the recipients of the additional care the savings will translate to. We can quantify the benefit to patients using the standard cost of a Quality Adjusted Life Year (QALY) methodology described previously. This suggests the ultimate value to patients of NHS savings of this magnitude could be around £2m per annum.
196. Adjusting these estimates for optimism bias in line with the approach described previously gave an average bias estimate for lost revenue to business of ~£1m, value of QALYs gained to society of ~£2m and therefore a net present value of £1m per annum. This implies a cumulative net present value of £4m over the five year forecast period.
197. As described on page 17, any impacts on medicines manufacturers or wholesalers are not considered to form part of the EANDCB, as they are both indirect impacts, and relate to measures designed to promote competition.

Impact on patients

198. The key impact on patients of this proposal are the impacts arising due to the potential to recycle NHS savings into additional frontline care. No other patient impacts have been identified (these proposals should not materially impact upon prescribing decisions, availability of medicines or patient outcomes).

Introducing alternative arrangements for non-Tariff specials

199. Under the current system pharmacies are reimbursed the invoice price for specials that are not in the Drug Tariff. This does not incentivise pharmacies to shop around for the best deals or manufacturers and wholesalers to compete on price. For those products where it is not feasible to add them to the Drug Tariff, this policy proposes introducing rules with a view to stimulating price competition and thereby ensure VfM and generate savings for the NHS.
200. There are 4 options being considered for discussion with PSNC which will address this problem for products where it is not feasible or practical to add them into Part VIII B of the Drug Tariff:

- Require dispensers to obtain three quotes for non-Part VIII specials ('quotes');
- Set up or procure a central approvals service for non-Part VIII ('central approvals service');
- Set up a central procurement service; or
- Procure the central supply of non-Part VIII specials to pharmacies ('central supply').

Quotes

201. Requiring dispensers to source 3 quotes before making a purchasing decision is expected to reduce the variation across prices paid for equivalent products by improving pharmacists' knowledge of market prices. This should increase the probability of relatively low cost purchasing as awareness of the range of prices available grows and dispensers can select lower priced products.
202. The quotes option is expected to generate additional costs to dispensers in the form of the staff time taken to obtain the additional 2 quotes. Additionally, we expect equivalent costs to accrue to manufacturers and wholesalers as staff time will have to be dedicated to producing extra quotes.
203. Note that these costs to business do not bring the policy in to the scope of the Better Regulation Framework as they will only be generated by activity undertaken for the NHS, which businesses are not obligated to provide.
204. We start estimating potential costs by calculating a notional average paybill¹⁶ per hour for those providing quotes and those seeking them. To approximate paybill, we combine internal and published earnings data from the Annual Survey of Hours and Earnings (ASHE) with an assumed 30% uplift to account for employer pension and national insurance contributions, as well as holiday and sick pay. This is a larger adjustment compared to the equivalent applied in the consultation stage IA, as the previous figure was intended to approximate employer pension and NI contributions only. Additionally, an assumed average 2% pay uplift per annum is applied to earnings data from pre-2020. A different earnings estimate is used for dispensing doctors as it would be the doctor seeking the quotes.
205. Our baseline scenario assumes that quotes are sought by pharmacy technicians and provided by individuals with average earnings equivalent to those in the 10th percentile¹⁷ of several relevant occupations. Examples include:
- Manufacture of basic pharmaceutical products and pharmaceutical preparations;
 - Wholesale of pharmaceutical goods; and
 - Office administrative, office support and other business support activities.
206. We then estimated how many additional quotes may need to be produced and sought per annum and the associated staff time requirement. ePACT2 data shows circa 48,000 specials items were dispensed in 2020 that were not listed in the Drug Tariff or within the

¹⁶ Earnings plus employer national insurance and pension contributions.

¹⁷ Assume lower percentile due to administrative as opposed to technical or expert role.

tablets and capsules definition (denoted from here as non-amended Part VIII B specials). We further assume each quote would take an average of 5 minutes to produce and obtain a quote.

207. For dispensing doctors, the Annual Survey of Hours and Earnings only provides data for employees and many GPs are not employees. So, earnings data was sourced from NHS Digital's GP earnings publication¹⁸ for annual GP income, before tax, in England and converted into an hourly equivalent via the application of basic assumptions around days and hours worked per annum. Calculating a weighted average across contract types and combining this with the number of non-tariff, non-tablets and capsules unlicensed items dispensed gave us an estimated cost of quotes to dispensing doctors of between £15k-£20k.
208. This suggests an aggregate cost to business per annum from introducing a quotes system could be circa £215k before adjusting for optimism bias, split almost evenly across pharmacies and manufacturers/wholesalers with a small amount attributable to dispensing doctors, if number of items dispensed remained constant. Inflating to account for optimism bias suggests an average optimism bias estimate in the region of £275k per annum is not unreasonable. This suggests a cumulative net present cost of just under £1.2m over five years.
209. However, we do not anticipate that the quotes option would achieve the objectives of reducing price variation and improving VfM for the NHS because there is no way of ensuring the cheapest quote is taken up. Pharmacies would still be reimbursed at the invoice cost for items dispensed and there may be other factors affecting purchasing decisions. Similarly, there would be no mechanism for monitoring compliance with the quotes system and so implementation and engagement rates could vary.
210. Savings of ~1%-2% on the £16m NIC associated with these products in 2020 would be necessary just to break even on the costs. It's unclear whether this is likely to be achieved given the lack of incentive for purchasing behaviour change. As a result, this is not currently considered to be the preferred option.

Central approval service

211. An alternative is to introduce a "central approvals service" for purchases of non-Tariff specials. The service would not mandate or restrict who pharmacies can purchase from. Rather, approval from the service would be required for a pharmacy to be reimbursed for purchases of non-Part VIII B products.
212. The service will act as a central source of knowledge about the various non-Tariff special products available and their relative prices, possibly including a database of prices paid previously. We would require pharmacy contractors to seek approval from the central approvals service for every quote for a non-Part VIII B special. The central approval service then either approves or declines the quote. If the quote is declined, then the service would provide the pharmacy contractor with an indication of what would be an

¹⁸<https://digital.nhs.uk/data-and-information/publications/statistical/gp-earnings-and-expenses-estimates/2018-19>

acceptable price. We believe that the majority of quotes could be dealt with relatively easily based on historic purchase prices.

213. The exact nature and role of the approvals service under consideration is yet to be determined. Possibilities range from an automated in all but the most uncertain cases approval system to an in-depth advisory and support body to help guide pharmacies to optimal purchasing decisions and to liaise with prescribers where needed.
214. The cost of providing an approvals service would be comprised of staff, accommodation, and IT costs. The costs will ultimately depend on the role of the service and the resources required to fulfil this, so we have provided an illustrative worked example below. Note we assume throughout that equipment costs relate to ongoing maintenance, upgrade and similar and so feature in the ongoing as opposed to transition cost estimates.
215. ePACT data shows around 48,000 specials items were dispensed in 2020 that would not come under the amended Part VIII B Drug Tariff criteria. We then assumed a distribution of approvals across complexity criteria and assigned an average time taken to approve for each criteria as shown in Table 12. Combining these assumptions with the 48,000 items dispensed estimate and some rough estimates on hours worked per annum allowed us to calculate the implied number of Full Time Equivalents (FTEs) needed in Table 13.

Table 12: assumptions about the types of approvals and time requirements

Various assumptions for approvals with varying levels of complexity			
	% total items	Minutes to approve	% of an hour
Approved automatically	30%	0	0%
Very simple to approve	10%	2.5	4%
Quite simple to approve	10%	5	8%
Neither simple or complex	20%	10	17%
Quite complex to approve	10%	20	33%
Very complex to approve	20%	40	67%

Table 13: estimated FTEs required to provide approvals

Estimating FTEs required to provide approvals	
Implied number of FTEs required to provide approvals	6
Implied average hours worked p/a per FTE	1,702
Assumed average hours worked per week per FTE	37
*Assumed number working weeks p/a	46
**Implied total person time required to approve (hours) p/a	10,308
*52 weeks in a year less 4 weeks A/L plus bank holidays and a few days sick leave.	
**Dependent on assumptions re distribution of approvals by complexity and average time to approve.	

216. The final step in our cost estimates was to think about the type of staff that would be providing and seeking quotes, what proportion of total staff each group might equate to and their associated paybill, as set out in Table 14.

Table 14: Distribution of FTEs by staff type at central approval service

Distribution of FTEs by staff type at central approver service		
	Assumed % FTEs	Avg. hourly paybill, 2020 £
*Pharmacist	20%	49.25
*Pharmacy technician	40%	12.66
Combined office administration service activities (lower percentile assumed general admin)	30%	12.60
Combined office administration service activities (higher percentile assumed managerial type role)	10%	25.22

25th percentile assumed representative of wages for individuals in this occupation

75th percentile assumed representative of wages for individuals in this occupation

217. Setting the necessary assumptions to these levels suggests introducing a central approvals service may have an aggregate ongoing cost in the region of £395k per annum. Note, this includes the cost of pharmacy and dispensing doctor staff time seeking approvals as well as the running of the service. There could also be in the region of £20k recruitment costs, £255k familiarisation costs for pharmacy technicians and £385k familiarisation costs for dispensing doctors (assuming 1 hour required for familiarisation) in year 1. There may in addition be some requirements for additional IT set up costs to support the service. However, these remain unquantified at this stage.
218. Adjusting these initial estimates for optimism bias provides a central estimate for the present value aggregate cost to dispensers of just over £1.5m over the full five year forecast period. The equivalent cumulative central estimate cost to the public sector is just over £5.5m once we apply the standard QALY methodology as described in paragraph 107.
219. Taking the cost to the pharmacy and public sectors together suggests a 6 FTE approval service would need to generate savings equivalent to 15% of 2020 NIC for non-Part VIIB, non-tablets and capsules in year 1 for a net zero economic impact. In subsequent years this falls to 9% as we assume transition costs are limited to year 1 only.

Procurement solutions

220. There are 2 options being considered under the procurement heading which are considered in turn below.

- **Option P1** – central procurement service
 - DHSC or NHS E&I would procure a central procurement service for non-Part VIIB specials.
 - The contract would be for a service that sources specials at the cheapest possible price from across the industry (but the service does not supply or pay for the special). NHS E&I/CCGs would pay the company supplying the special directly.

- Pharmacy contractors would be required to contact the central service for each prescription for a special. The central supply service would then seek the cheapest supplier who will provide the special to the pharmacy.
 - Pharmacy contractors would not be reimbursed but they would still be remunerated the standard £20 specials (SP) fee to cover the additional costs associated with dispensing a special.
221. We expect that a central procurement service would build up a level of knowledge and expertise around the specials market, and relative prices available within it over time, that it might not be feasible or efficient to exist at individual practice level. As such they may be more successful at procuring the lowest cost option for pharmacies to dispense. Additionally, with a specific remit to achieve VfM for the NHS, a central procurement service could be better incentivised to identify the lowest price products available.
222. We do not expect there to be any additional cost impacts of introducing a central procurement service on pharmacies or dispensing doctors. Instead, the administrative burden of sourcing specials should be reduced. The savings resulting from this are not expected to be greater than the cost of a central procurement service undertaking the same task but would offset at least part of this.
223. Pharmacies and dispensing doctors would no longer pay or be reimbursed for specials as NHS E&I/CCGs would transact directly with suppliers, however they would still receive the £20 SP fee.
224. We anticipate a central procurement service could have similar set-up costs but larger ongoing costs versus the central approval service given its role in ordering specials and lower potential for automation. That said, both bodies could have a similar role in building and disseminating expertise about the specials market and relative prices charged. We have therefore scaled the ongoing costs estimated for a central approvals service by a factor of 1.5 as a rough estimate for a central procurement service's ongoing costs.
225. This equates to a paybill estimate of just under £330k per annum or around £360k once office space and equipment costs are also included, before we adjust for optimism bias and apply the standard QALY methodology as set out in paragraph 107.
226. Our average bias estimate for the opportunity cost of public funding for a central procurement service once we adjust for these factors (assuming this money would otherwise have been spent of the frontline) is around £2m per annum.
227. The central procurement service would consequently need to generate ~11% savings versus the 2020 NIC on non-amended Part VIII B specials per annum (although in year 1 the required proportion of NIC to breakeven is 19% as a result of transition costs) to cover its economic costs. It's currently unclear whether it is reasonable to expect savings of this magnitude could be exceeded, i.e. whether there would be a net benefit from the policy.
- **Option P2** – central supply

- DHSC or NHS E&I would procure the central supply of non-Part VIII B specials to pharmacies. This could be one or multiple (regional) contracts and the contractor may sub-contract some supply that it could not fulfil itself.
 - Pharmacy contractors would be required to contact the central service for each prescription for a special.
 - The central supply service then provides the pharmacy with the special, either directly or via a sub-contractor. Pharmacy contractors would not be reimbursed but they would be remunerated the £20 SP fee.
228. As above, we anticipate the only impact of this policy on the pharmacy sector and dispensing doctors would be a reduction in administrative burden of sourcing non-amended Part VIII B specials.
229. The impact on manufacturers/wholesalers supplying non-amended Part VIII B specials would ultimately depend on the nature of the contract awarded and the level of sub-contracting undertaken. If the firm awarded the contract chose to manufacture or import and supply all products itself, we would expect a negative impact on the rest of the industry as they would be shut out of the market. Conversely, if significant sub-contracting was undertaken then there could be a minimal impact.
230. The cost of the contract awarded would not exceed the expected expenditure on non-amended Part VIII B specials in the counterfactual. But any company undertaking the contract is likely to require compensation for the risk associated with such an uncertain undertaking.
231. Such a complicated contract would also be likely to require a large amount of administrative resource to manage, the cost of which would fall on the public sector (DHSC or NHS E&I).
232. To generate savings, the cost of the contract and associated contract management must be smaller than expected spend on non-amended Part VIII B specials in the counterfactual. If we take 2020 NIC as our estimate of the size of the pot, it would need to be <£16m. There is currently not sufficient detail available to assess whether this might be feasible and therefore whether a net benefit or cost may result.

Changes to the reimbursement of generically prescribed appliances and drugs dispensed as a ‘specials’

Appliances vs ‘specials’

233. If a product is listed as an appliance in Part IX of the Drug Tariff it should not also be a medicine and therefore supplied as a special. However, there are instances where pharmacy contractors dispense an unlicensed medicine (special) against a generically written prescription instead of an appliance. This practice creates a lack of transparency

in the current system for prescribers and patients around what will be dispensed against a prescription.

234. For the appliance, the pharmacy contractor will be reimbursed the reimbursement price listed in Part IX of the Drug Tariff. For the special, the pharmacy contractor will be reimbursed the invoice price (less any discount and rebate) and will be remunerated the £20 SP fee.
235. The cost of dispensing a special tends to be higher than dispensing an appliance. In the main, specials are more expensive than appliances and in addition pharmacy contractors are paid a fee of £20 every time they dispense a special. Every time a pharmacy contractor chooses to dispense a special instead of an appliance this may cost the NHS more, and thereby not maximise value for money from its spend on these products.
236. To address the problem outlined we propose that pharmacy contractors are reimbursed the price of the appliance in Part IX of the Drug Tariff for a prescription that could be fulfilled by a special or an appliance, regardless of whether they dispensed an appliance or a special. If the pharmacy dispenses a special they will not be remunerated the £20 SP fee. As this policy has clear parallels with the next policy proposal, the impacts of the two proposals are considered jointly below.

Drugs vs 'specials'

237. Similarly, in some instances, a prescription can be filled by contractors dispensing either an unlicensed medicine or a drug that is not also a licensed medicine. As above, there tends to be a higher cost associated with dispensing a special versus a drug that is not a licensed medicine. This policy seeks to increase transparency in the system by increasing clarity for prescribers and patients regarding what will be dispensed against a prescription and for pharmacies who will be clear what they will be reimbursed for. In addition, the proposal may secure greater value for money for the NHS by restricting reimbursement prices for generic prescriptions that could be fulfilled by a special or a drug that is not a licensed medicine to the cost of the available drug.
238. The impact of limiting reimbursement to the price of the appliance or drug, rather than a special, are considered together in the following sub-sections given the similarity of the proposals.

Impact on pharmacies

239. The main impact for pharmacy contractors will arise due to any difference in margin that they would earn due to the change in reimbursement rules. Where contractors currently dispense an appliance against the prescription, they will continue to be paid the reimbursement price for the appliance and so there will be no change in the medicine margin that they can earn.
240. If on the other hand the contractor was dispensing a special and continues to do so in the event this reform was introduced, then under this proposal, the contractor would now be

reimbursed the price of the appliance in Part IX of the Drug Tariff instead of the reimbursement price for the special. To the extent that reimbursement prices for specials tend to be higher than for appliances, this may result in contractors seeing a reduction in the amount of medicine margin earned. This effect could be partially offset if contractors are able to change their purchasing behaviour and switch to dispensing a lower cost alternative, i.e. the appliance, in order to mitigate the negative effect on their medicine margin.

241. As we do not have robust estimates of margin earned at a specific product level (and appliances are completely excluded from the survey), it is not possible to assess the size of any potential reduction in medicine margin, nor the potential opportunity that pharmacies would have for offsetting any reduction in medicine margin. However, it is important to note that, as the margin earned on appliances is not measured and therefore does not count towards the agreed £800m for pharmacy contractors, any change in the amount of medicine margin earned (either negative or positive) would not result in any further adjustments to bring the medicine margin to the agreed £800m.
242. For drugs vs specials, a similar logic would apply as for the case of appliances vs specials described above. The only difference is that the medicine margin earned on drugs is measured in the margin survey and would count towards the agreed £800m medicine margin for pharmacy contractors. Therefore, any changes (either positive or negative) to measured medicine margin as a result of these proposals may result in the need for further adjustments to medicine margin to be made.
243. In both cases, we would not expect contractors to dispense at a loss: if there is a specific reason why a special should be dispensed contractors would need to contact the prescriber and ask them to reissue a prescription specifically for the special. Then the reimbursement price for the special would continue to apply. Any potential minor delay this could generate is not expected to be noticeable given the longer dispensing time associated with specials anyway.

Impact on NHS finances

244. By incentivising pharmacies to dispense appliances or drugs instead of specials, we anticipate savings will accrue to the NHS. The extent to which these savings will arise will depend on the extent to which pharmacies are able to shift to dispensing a cheaper alternative and the resultant impact that this shift has on their measured medicine margin relative to the agreed £800m.
245. Although it is not possible to fully assess this, some illustrative examples are provided for January to December 2018 below of specific products that have been manually confirmed as fitting this definition via checking their details on dm+d from a list of potentials provided by the NHS BSA.

246. We calculated NIC per item and NIC per quantity¹⁹ for each of these products (with a special or drug/appliance alternative that could be dispensed to fill a generic prescription). The difference in NIC/quantity and NIC/item are shown below in Table 15, 16 and 17 respectively. Note that the special order products identified in the appliances versus specials sample have since been discontinued. However, we continue to present them here to highlight the type of products that have been an issue in the past.

Table 15: Estimated NIC/quantity for special versus drug alternatives of the same VMP, 2018

VMP_ID	VMP_NAME	NIC/qty specials	NIC/qty not specials	% change NIC/qty specials vs NIC/qty not specials
7929	Acetylcysteine 600mg capsules	2.33	1.12	108%
9543	Sodium chloride 1.46g/5ml (5mmol/ml) oral solution	1.05	0.20	438%
19560	Magnesium glycerophosphate (magnesium 121.25mg/5ml (5mmol/5ml)) oral solution	0.32	0.19	68%

Table 16: Estimated NIC/item for special versus drug alternatives of the same VMP, 2018

VMP_ID	VMP_NAME	NIC/items specials	NIC/items not specials	% change NIC/items specials vs NIC/items not specials
7929	Acetylcysteine 600mg capsules	227.77	78.27	191%
9543	Sodium chloride 1.46g/5ml (5mmol/ml) oral solution	657.63	60.84	981%
19560	Magnesium glycerophosphate (magnesium 121.25mg/5ml (5mmol/5ml)) oral solution	302.11	95.37	217%

247. In each case for drugs the special has a higher associated NIC per item and NIC per quantity compared to the corresponding drug. Additionally, there would be no £20 SP fee payable for dispensing a drug. As the total CPCF funding envelope is current fixed at £2.592bn per annum, any reduction in SP fees would feed through to an increase in fees elsewhere, thereby providing a small benefit across the pharmacy sector.

Table 17: Estimated NIC/quantity or item for special versus appliance, 2018

VMP	VMP_NAME	NIC/item special £	NIC/item not special £	% change NIC/item special vs not special	NIC/quantity special £	NIC/quantity not special £	% change NIC/quantity special vs not special
10239	Hypromellose 0.3% eye drops preservative free	94.20	6.52	1345%	9.42	1.32	613%
10200	Sodium chloride 5% eye drops	101.00	32.55	210%	5.05	18.46	-73%

¹⁹ A prescription item refers to a single medicine prescribed by a doctor (or dentist/nurse/etc.) on a prescription form. This is different to quantity i.e. if salbutamol inhaler x 2 is prescribed. This is one item with a quantity of two. The quantity of a drug dispensed is measured in units depending on the formulation of the product. This could include number of tablets, millilitres or grams.

248. For appliances, the NIC per item and NIC per quantity are lower for both the appliances compared to the corresponding specials, with the exception of the NIC per quantity for sodium chloride 5% eye drops, where the special appears to be cheaper.

Impact on Industry

249. By incentivising pharmacies to dispense appliances or drugs instead of specials, it is likely that suppliers of special medicinal products will see a reduction in revenue whilst suppliers of drugs and appliances will see an increase in revenue. Ultimately, we would expect that any net loss in revenue should equate to the estimated savings to the NHS.

Impact on patients

250. We do not anticipate that there will be any impact on patients. If there were a clinical reason why a special should be dispensed instead of a drug or appliance, it is likely that the prescriber would have issued a more specific prescription specifying the required product, and thus these proposals would not apply.

251. Where conversations are already taking place between prescriber and dispenser to clarify whether there is a specific reason a special should be dispensed against a generic prescription, we could expect these to continue taking place under the new proposals. The only potential difference would be if a new prescription needs to be issued specifying the special to prevent the contractor dispensing at a loss. We do not believe that this would result in significant additional time or administrative costs above the conversations that would already need to take place to establish this requirement.

Impact on dispensing doctors

252. Dispensing doctors differ from pharmacy contractors in that they both prescribe and dispense items. If there is a clinical reason to prescribe a special, they will be able to continue prescribing and dispensing a special, as they can currently, and be reimbursed the amount endorsed on the prescription. They therefore can dispense the corresponding drug or appliance against this.

253. If there is no clinical reason why a special is required dispensing doctors will not have to specify that a special is required by annotating the prescription. They therefore can dispense the corresponding drug or appliance against this.

254. There should be no negative impact on dispensing doctors because they both prescribe and dispense items, and so can simply ensure the correct specifications are made in the prescription.

Changes to the deduction scale

255. When pharmacy contractors are reimbursed for the medicines and appliances they have dispensed, a deduction is made to their payments, known as 'deduction scale'. This is an assumed amount of discount received to avoid pharmacies having to calculate and declare discount received on each item dispensed.
256. Currently, the deduction scale is based on the monthly total of reimbursement prices with a minimum of 5.63% and a maximum of 11.5% deducted from the total monthly reimbursement.
257. However, branded medicines do not attract as much discount as generic medicines. Pharmacy contractors, on average, dispense branded medicines at a loss overall. As a consequence, pharmacy contractors that dispense more branded medicines than average do not have equitable access to medicine margin. And, CCGs in areas where more branded medicines are prescribed are not paying their fair share of medicine margin.
258. Currently, the deduction scale does not take into account whether a pharmacy contractor dispenses brands or generics.
259. To address the problem outlined above we propose that the deduction scale is split into two separate scales, one for generic medicines and one for branded medicines. This will on average improve access to the medicine margin for community pharmacists and it will improve the deduction scale apportionment to CCGs. Separately, we are consulting NHS E&I about amending the CCG apportionment.
260. Additionally, to complement this measure we are proposing to decrease the medicine margin included in the Drug Tariff reimbursement price of Category M products where a branded alternative appears less expensive than the Category M product (M2 products). The changes to the deduction scale outlined in this reform could mitigate any impacts on pharmacy cashflow driven by a reduction in the medicine margin added to these products if the proposed brands deduction scale were also applied to M2 products. As noted previously the detail of the proposals and implementation will be discussed during a subsequent consultation process between DHSC and PSNC only.

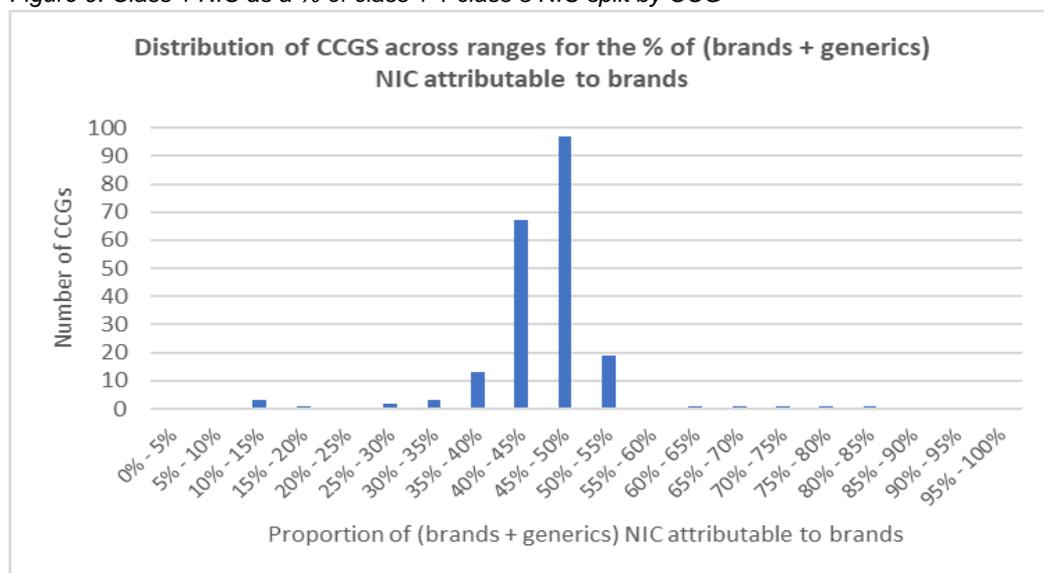
Impact on pharmacies and CCGs

261. Under this option two new discount scales are required. In thinking about how they should be designed, the new discount scale must better reflect the difference between the discounts obtained for branded and generic medicines. The design of the new discount scale will determine the magnitude of the costs and benefits for pharmacies and CCGs.
262. However, it is likely that there would be significant distributional effect if the proposal were to achieve its aim of improving access to medicine margin. It is likely that the higher a pharmacy's share of brands dispensed, the more they would benefit from the change.

At the same time, the larger the proportion of generics dispensed the larger the losses from these new reimbursement arrangements.

263. If CCG apportionment is also changed, then the reverse would be true for the corresponding CCGs. Those CCGs prescribing a higher share of brands will see an increase to the apportionment taken from them. On the other hand, the higher the share of generics prescribed the lower the apportionment to a CCG under this option.
264. Overall, this effect arises because any changes to the design of the discount scale would be done with cost neutrality in mind from the aggregate point of view of the government, pharmacies, and CCGs. As a result, the expected smaller discount deduction for pharmacies' dispensing of branded items (where currently less medicine margin is earned) is mitigated by a larger discount deduction on the generics dispensed (where currently relatively more medicine margin is earned). Similarly, the higher apportionment taken from CCGs prescription of branded is balanced out by a lower apportionment taken from CCGs prescription of generics.
265. We have taken an initial view on whether changes to the deduction scale are likely to generate significant winners and losers across CCGs and pharmacies by looking at the proportion of branded plus generic²⁰ NIC that is attributable to branded products for CCGs and generic products for pharmacies²¹. Figure 9 shows this for all CCGs, and we can see that the majority (almost 80%) are clustered at roughly 40% to 50%. Whilst only around 10% of CCGs are above or below this range respectively. We therefore do not expect this policy to generate a significant number of large winners or losers at CCG level. It is important to note that this change would only arise if CCG apportionment were changed, which is subject to a separate decision from NHS E&I.

Figure 9: Class 1 NIC as a % of class 1 + class 3 NIC split by CCG



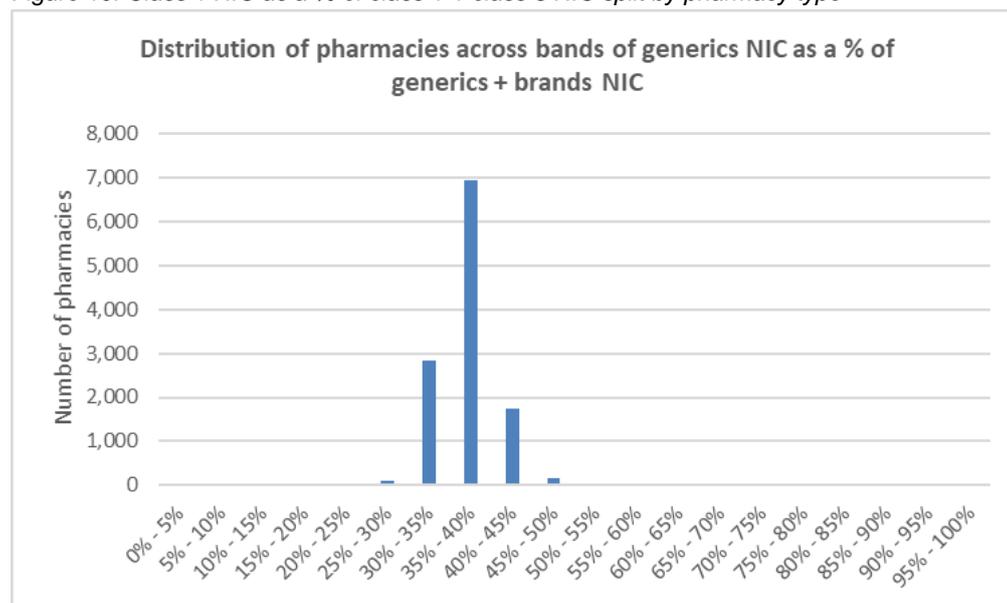
266. Similarly, bespoke data sourced from the NHS BSA on amounts reimbursed for brands versus generics at individual pharmacy level showed that circa 97% of pharmacies fell

²⁰ Class 1 and class 3 definitions used to proxy brands and generics respectively. <https://www.nhsbsa.nhs.uk/sites/default/files/2019-04/PCA%20Glossary%20V3%20-%2002-04-19.docx>

²¹ See paragraph 264 for details on opposite distributional effects.

within the bounds of generics accounting for 30% - 45% of amount reimbursed. This is shown below in figure 10. Overall, the scale of clustering suggests it is unlikely that a significant number of winners and losers will be generated by this policy.

Figure 10: Class 1 NIC as a % of class 1 + class 3 NIC split by pharmacy type



Impact on NHS finances and industry

267. In general, if this policy shifts prescribing away from brands, then branded manufacturers will lose out at the expense of generics manufacturers. To the extent that branded and generic prices are similar, there is only a distributional effect.
268. If, on the other hand, branded prices are higher than the corresponding generic product prices, the lost revenue from branded manufacturers is not compensated for by generic manufacturers. Any net reduction in revenue received by industry would also translate into a saving to the NHS. It is not possible to fully quantify this impact as we are not able to assess the extent to which prescribing may be incentivised to switch from branded to generic prescribing as a result of this policy. In particular, it is important to note that any change to prescribing incentives would most likely arise due to the change in CCG apportionment since this affects CCG finances more directly, whilst the initial change to the deduction scale is focused on improving the distribution of funding for community pharmacy.
269. However, to provide some illustrative figures on the potential size of this impact, we start with a bespoke dataset provided by the NHS BSA detailing NIC and items dispensed for NHS BSA preparation class 1 (proxy for generics) and preparation class 3 (proxy for brands) products in 2018. The data is at individual CCG level, allowing us to calculate the proportion of branded NIC relative to total NIC in each CCG.
270. After ranking each CCGs by the proportion of their NIC attributable to branded medicines, we looked up the proportion of total NIC attributable to brands at the 80th percentile. We then applied the 80th percentile as a cap to calculate the impact if the 20% of CCGs with the highest proportions of branded NIC reduced this to the same proportion as the CCG at the 80th percentile.

271. Applying the optimism bias adjustments set out in the introductory sections suggests an average bias estimate for the potential revenue cost to the branded industry of circa £22m per annum, with low and high bias estimates of £18m and £26m respectively. This suggests cumulative present value costs of ~£110m over the full forecast period in the average bias scenario. It has not been possible to estimate corresponding changes in revenue for generic medicine suppliers.
272. Please note the estimated impacts above have not been included in the NPV estimate for these reforms as the change in prescribing habits that would generate them are considered a possible impact of a future change to CCG apportionment, as opposed to an impact of splitting the deduction scale.

Impact on patients

273. We do not anticipate that there will be significant impacts on patients. Where there are clinical reasons for a patient to be prescribed a branded product, we assume that clinicians will continue to prescribe by brand, in accordance with the needs of the patient.

Impact on dispensing doctors

274. Dispensing doctors have their own separate deduction scale. The reimbursement reform around the deduction scale will not apply to the dispensing doctors' deduction scale and so this group will not be affected by the proposal.

Conclusion

275. Taking all the proposed reforms together, the overall NPV of the proposals is positive in all scenarios including the most prudent approach. However, the uncertain nature of the specific values should be borne in mind.
276. As such, the reimbursement reforms outlined in this document will support good value-for-money to the taxpayer and the NHS and reduce the possibility of inadvertently influence prescribing patterns by distorting the market price. Additionally, the reforms package will increase equitable access to medicine margin for pharmacy contractors and improve pharmacy contractor's cash flow.
277. The NPV ranges from a low estimate of £72m to a high of £182m with the average bias estimate around £127m. Whilst, as explained above, the values will be subject to change and refinement throughout the ongoing stages of policy development and consultation with the PSNC, it seems reasonable to be confident that a net benefit, or minor net cost, could be generated overall by these measures, particularly in light of further testing undertaken in the overall NPV section.