Title: Community pharmacy reimbursement reforms **IA No:** **RPC Reference No:** Not applicable **Lead department or agency:** Department of Health and Social Care **Other departments or agencies:** Not applicable	Impact Assessment (IA) **Date:** 22/07/2019 **Stage: Consultation** **Source of intervention:** Domestic **Type of measure:** Other **Contact for enquiries:** sandor.beukers@dhsc.gov.uk

Summary: Intervention and Options

RPC Opinion: Not Applicable

Cost of Preferred (or more likely) Option (in 2016 prices)			
Total Net Present Social Value	**Business Net Present Value**	**Net cost to business per year**	**Business Impact Target Status**
£1,650m	n/a	n/a	Not a regulatory provision

What is the problem under consideration? Why is government intervention necessary?

In 2018, 1.1 billion prescription items (drugs, appliances and other items) were dispensed in the community with a total value of £8.8 billion. The Department wants to ensure that the money spent on those items represents value for money to the NHS and tax payer 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 we would like to consult on.

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 tax payer
- 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 – 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 introduce together 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	**Large** 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 **Discount rate (%)** 3.5

As consistent with IA convention, the costs and benefits of the business as usual option are set to zero

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 2018	PV Base Year 2016	Time Period Years 5	Net Benefit (Present Value (PV)) (£m)		
			Low: 925	**High:** 2,265	**Best Estimate:** 1,650

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	0.4		200	**935**
High	0.6		295	**1,370**
Best Estimate	0.5		245	**1,150**

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 there will also be winners and losers withing the pharmacy sector and across CCGs 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 Price)	Total Benefit (Present Value)
Low	0		490	**2,380**
High	0		670	**3,255**
Best Estimate	0		580	**2,815**

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 in to health benefits).

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

Key assumptions/sensitivities/risks **Discount rate (%)**

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 Committmee (PSNC).
It is difficult to establish a robust counterfactual for later years given the fast-moving nature of the market.
There is uncertainty around the second-order market impacts of the proposals: the above costs and benefits assume no major structural impacts on the sector.

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	

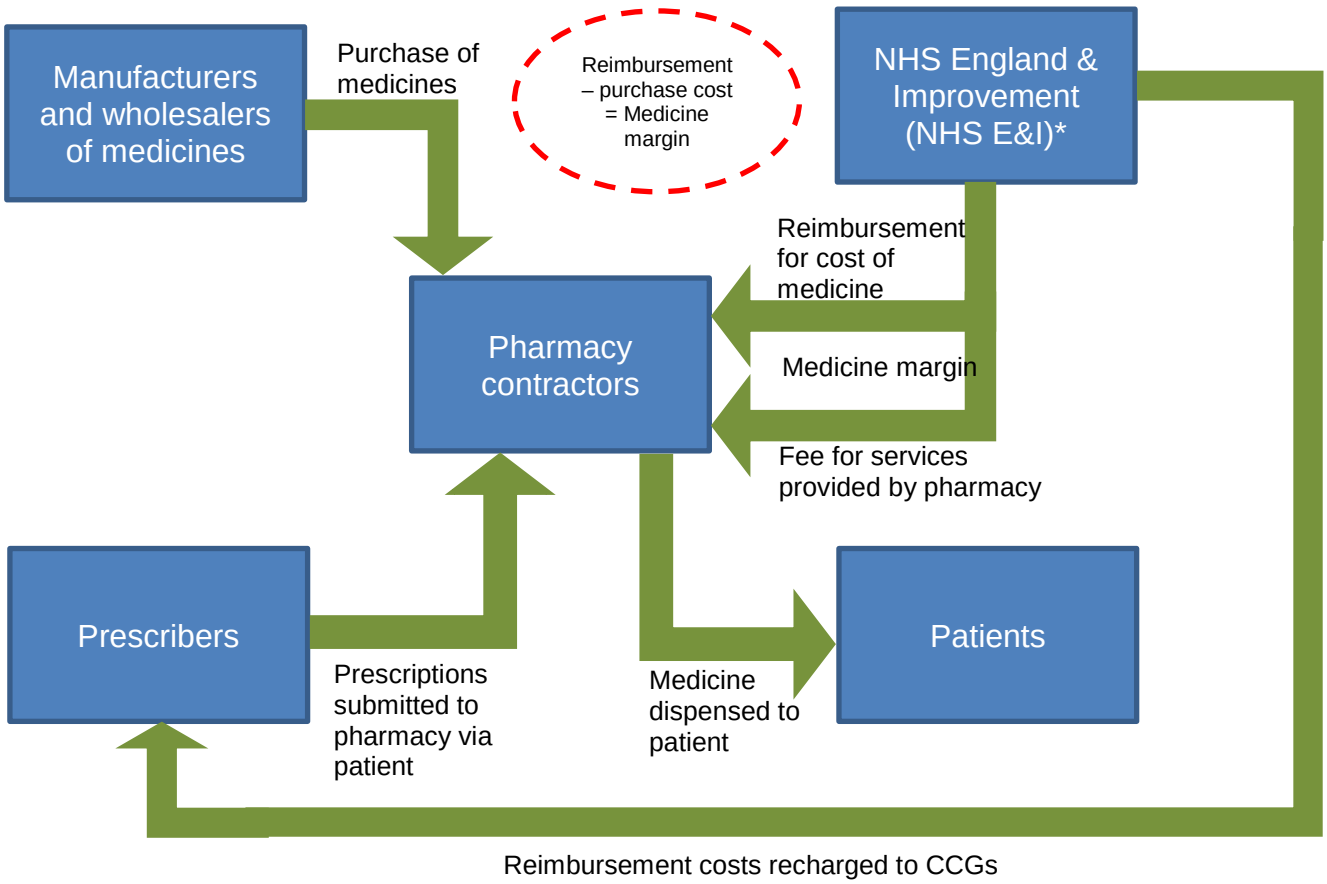
Evidence Base (for summary sheets)

Background

1. Data from the NHS Business Services Authority (NHSBSA) shows that in 2018, 1.1 billion prescription items (drugs, appliances and other items) were dispensed in the community with a total value of £8.8 billion. 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 (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 contractors are reimbursed monthly for the items they dispense in a given month, minus an assumed amount of discount.

4. This discount is also known as the ‘deduction scale’. This is an assumed amount of discount received to avoid pharmacies having to calculate and declare discount received on each item dispensed. 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 medicines (including some drugs) in three Categories (M, A and C):

   - Category M are generic medicines that are readily available from at least two manufacturers and have an associated minimum spend and volume supplied annually. Reimbursement prices are based on quarterly information from manufacturers with an addition of medicine margin.

   - 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).

   - 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 unlicenced medicines, whilst Part IX of the Drug Tariff lists reimbursement prices for appliances. Prescription items not listed in the Drug Tariff are reimbursed at the supplier’s list price.

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. Under the CPCF pharmacy contractors are paid for NHS pharmaceutical services in medicine margin set at £800m per annum. 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 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 tax payer;

- 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 tax payers 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. However, for medicines not listed in the Drug Tariff and without a reimbursement price, this incentive mechanism does not operate as effectively, as pharmacy contractors are reimbursed based on the actual cost of the medicine that they endorse on the prescription. As a result, there is no incentive for pharmacy contractors to seek to source these products at the lowest possible cost.

11. The Department is considering a number of options to address this lack of incentive, including:

    a. Where possible, adding more of these products to the Drug Tariff

    b. 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

    c. 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

12. 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.

13. Improving pharmacy contractors' cash flow and medicine margin distribution 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 make adjustments to 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 the pharmacy contractors who benefited most from previous over-delivery of medicine margin are not those who are most affected by any subsequent downwards adjustment to reimbursement prices. Pharmacies dispensing below average Category M products will be least affected by any such changes despite potentially having benefitted from over-delivery of medicine margin.

14. 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 possible, in order to minimise the need for subsequent adjustments to correct for over or under delivery of medicine margin. As such, the Department wishes to consult on a series of options to:

    a. 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

    b. 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.

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

15. Some suppliers of branded medicines, including branded generics, price their stock below the Category M reimbursement price. This can have a distortive effect on prescribing decisions. Because the branded version appears cheaper, CCGs and prescribers are encouraged to prescribe the product by brand rather than generically.

16. 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.

17. 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 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 - to the ultimate detriment of CCGs.

18. 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.

19. 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 to avoid pharmacies having to calculate and declare discount received on each item dispensed.

20. 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. As a consequence 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.

21. To address these issues the Department is proposing to consult on two measures to:

    a. 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

    b. Split the deduction scale into one for generic medicines and one for branded medicines

Rationale for intervention

22. 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).

23. As a result, government intervention is considered to be the only option to bring about the improvements in the reimbursement system identified above.

Description of the Options

24. 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.

25. Under option 2, the Department proposes to consult on a range of proposals to improve the current reimbursement arrangements. 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

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

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

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

d. 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

e. Changes to the determination of reimbursement prices for non-Part VIIIA drugs

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

Other changes to reimbursement arrangements

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

h. Changes to the deduction scale

26. Table 1 overleaf 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	• Improve value for money for the NHS and the tax payer
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 medicines do not look more expensive than branded versions and to better reflect the actual purchase price	• Ensure that the addition of medicine margin to reimbursement prices does not create distorting effects • Ensure that contractors have equitable access to medicine margin • Reduce cash flow issues created by medicine margin adjustments to the Tariff
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.	• Improve value for money for the NHS and the tax payer • Reduce cash flow issues created by medicine margin adjustments to the Tariff
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: • 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+d[1] 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	• Improve value for money for the NHS and the tax payer
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.	• Improve value for money for the NHS and the tax payer
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 on possible solutions: • Require pharmacies to obtain three quotes for non-Part VIIIB specials ('quotes')	• Improve value for money for the NHS and the tax payer

[1] 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.

	• 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')	

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. Additionally the special is much 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. For a generically written prescription, if the contractor has the choice of whether to dispense a drug or special, generally the special is much more expensive. To help limit costs to the NHS, we would propose to move to reimbursement of at the drug price even when a special has been dispensed.	• Improve value for money for the NHS and the tax payer
Changes to the deduction scale to reflect different levels of discount for branded and generic medicines	To address the current perverse incentives for prescribers and to improve medicine margin distribution, we propose to change the deduction scale to split it into two separate ones; one for generic medicines and one for branded medicines	• Ensure that the addition of medicine margin to reimbursement prices does not create distorting effects • Ensure that contractors have equitable access to medicine margin • Reduce cash flow issues created by medicine margin adjustments to the Tariff

27. The purpose of the public consultation is to consult widely on the high level principles of the proposed changes. The detail and the mechanics of how we reimburse pharmacy contractors, for example the formulas used to calculate reimbursement prices, will be subject to a follow-up consultation with the Pharmaceutical Services Negotiating Committee (PSNC) only.

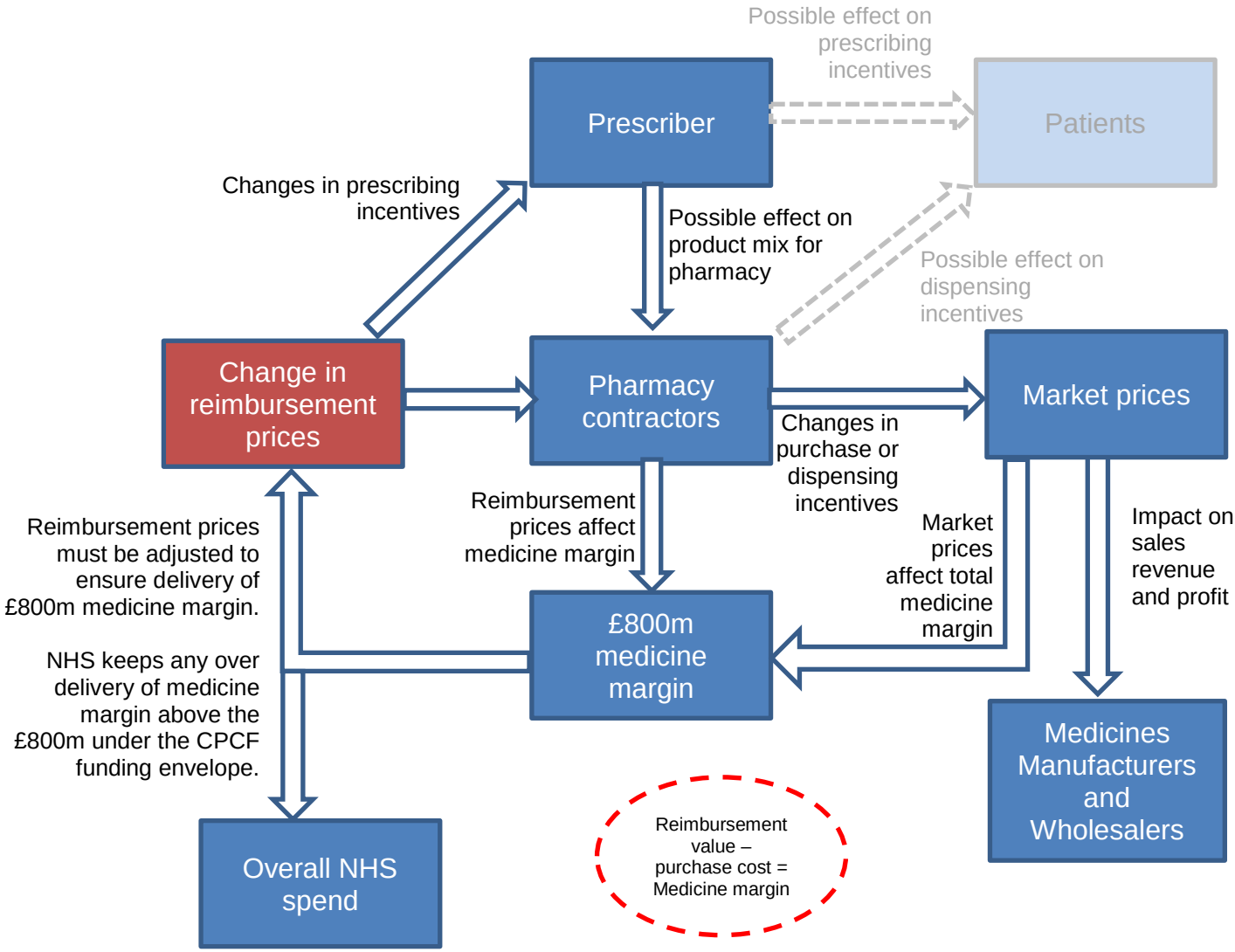
28. Because the details will be determined following this consultation, it is not possible at this stage to present finalised proposed reimbursement prices against each of these measures. The remainder of this assessment instead focuses on providing a high level summary of the likely costs and benefits 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

29. 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.

30. 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



31. 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).

32. 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 may 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.

33. 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.

34. 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 OI3O status” section for further details of how we count this.

35. 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 have to 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.

36. 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.

37. 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.

38. 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.

39. 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 identied above.

Table 2: summary of impacts of proposals

Proposal	Expected key impacts	Initial central estimate present value costs	Initial central estimate present value benefits	Initial central estimate net present value
Changes to the determination of reimbursement prices of generic medicines in Category A	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 are also considered	£825m revenue cost to industry	£2,335m (saving to the NHS translated into health benefits valued at £60k/QALY)	£1,510m
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.	£15m revenue cost to industry	Unquantified benefits - reduced perverse price signals enabling £800m medicine margin delivery at lower cost & more equitable access to medicine margin for pharmacies.	-£15m vs 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 likely to be much lower as £800m medicine margin is maintained under the CPCF funding envelope. However, there are likely to be savings for the NHS if having reimbursement prices that are more representative of the market incentivises better purchasing decisions. The impact on industry of these changes is also considered. Unquantified benefits include perhaps reducing the size of future medicine margin adjustments (improving pharmacy cashflow) & potentially driving further competition in the market for these products.	£175m revenue cost to industry.	£415m (saving to the NHS translated into health benefits valued at £60k/QALY).	£240m plus unquantified potential benefit of improving pharmacy cash flow
Inclusion of products treated as drugs (i.e. products other than	Reimbursement prices likely to fall initially reducing NHS spend on these medicines. But savings			

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 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/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 in to 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 determination of reimbursement prices for non-Part VIIIA 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 in to 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.	£28m cost to industry. £0.6m - £2m cost to industry and £0 - £14m to public sector (option dependent).	£66m (saving to the NHS translated into health benefits valued at £60k/QALY). Unquantified benefits of reducing variation in prices and of pharmacies purchasing at lower prices expected to cover costs.	£39m. Various depending on option selected.
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 the NHS. The impact on industry is also considered. 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.	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. 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.		
Changes to the deduction scale to reflect different levels of discount for	Differentiating the deduction scale applied to brands vs generics is expected to allow for	£108m cost to industry.	Unquantified benefits of increased access	-£108m vs unquantified benefits.

branded and generic medicines	fairer access to medicine margin for pharmacies and help ensure CCGs pay their fair share towards medicine margin.		to medicine margin and ensuring CCGs pay their fair share towards medicine margin.	

Risks and sensitivities

40. The Department has identified 3 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; and
- How we value the health benefits against the costs to industry.

Each of these issues is considered in more detail below.

High level nature of the policy proposals

41. The consultation this impact assessment accompanies is seeking views on high-level policy proposals as opposed to detailed interventions. The reponses to the public consultation will then be fed in to a second period of engagement between DHSC and the PSNC at which point details around implementation will be determined.

42. 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 consultation with the PSNC, utilising responses received to this consultation, as policy detail emerges from these discussions.

43. 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

44. 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 2017/18, 2018, or 2018/19) will be representative of future years in order to calculate impacts. 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 central estimates (more details are provided at the end of this section).

45. Finally, we present forecasts over a 5-year period only as the likelihood of resemblance to future years will decrease over time.

Value of health benefits versus costs to industry

46. We have considered that the financial savings to the NHS equal the revenue costs to industry of the proposals. Because NHS savings can then be converted into health benefits, and the best available evidence suggests society generally values these health benefits at a level greater than the cost of generating them, the result will be a net benefit overall.

47. However, 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 on the basis of the current NHS reimbursement arrangements.

- Secondly, the pharmaceutical industry is global and revenue from the UK represents just 3%[2] of world sales. 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.

- 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 implies UK price levels may not affect a large proportion of the UK industry as the medicines produced are exported anyway.

48. 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.

49. Companies will locate manufacturing sites and/or research facilities where they can find the best science base at reasonable cost, taking into account other factors such as research infrastructure, tax, flexible labour markets and economic stability. We would expect UK prices to be secondary to these factors.

50. 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

[2] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/761064/impact-assessment-2018-statutory-scheme-branded-medicines-pricing.pdf

company shareholders that are non-UK (see subsequent “impact on business and OI3O” section for detail).

Applying optimism bias to mitigate these uncertainties

51. 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 impact scenarios. The average of these is then presented as the central estimate of each proposal’s impact.

52. 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 scalers for different project types				
	Works duration		Capital expenditure	
Spending type	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%

Table 7 annex A5 at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/685903/The_Green_Book.pdf

53. 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 our central estimates are a simple average of the two.

Overall NPV

54. The overall NPV of the proposals remains positive even in the most pessimistic scenario albeit the initial, uncertain nature of the values should be borne in mind. The NPV ranges from a low estimate of £0.9bn to a high of £2.3bn, with a central estimate around £1.7bn. Whilst, as explained above, the values will be subject to change and refinement throughout the ongoing stages of policy development and consultation, it seems reasonable to be confident that an overall net benefit could be generated by these measures.

Impact on business and OI3O status

55. As the proposals are only concerned with how the NHS reimburses pharmacy contractors for their NHS prescriptions, they are considered to be out of scope of the One in Three Out and the Business Impact Target as they concern procurement arrangements for NHS services.

56. 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.

57. 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 to be an indirect impact.

58. 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.

59. 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 it:

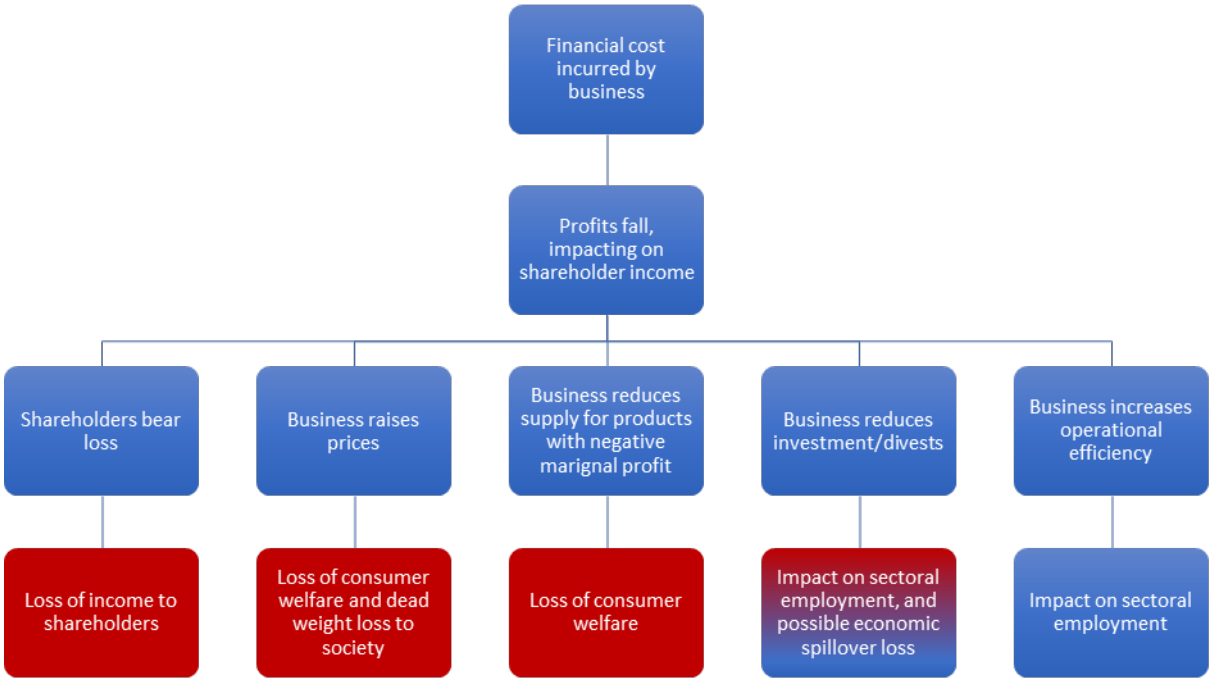
    - Is expected to increase suppliers' incentive to compete vigorously;
    - Is expected to generate a net increase in competition/to improve competition overall;
    - Has promoting competition as a core purpose; and
    - Is estimated to generate societal benefits that will outweigh the costs.

60. As a result, any impacts are not expected to count towards the government's Business Impact Target.

61. 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 net present value of around £1bn over 5 years.

62. 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



63. 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. But not all shareholders are UK based and therefore not all of this impact will accrue to UK society. Previous analysis undertaken by BEIS suggests only around 10% of pharmaceutical industry shareholders are UK shareholders on average.

64. 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. 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 as discussed previously in paragraph 50.

65. In reacting to the first order impact, different companies may 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. Only those impacts shaded in red are counted as impacts on UK society for the purpose of IAs.

66. We can therefore see that, even when accounting for second order impacts, not all the the impacts of financial costs should be counted within IAs. For example, any such costs businesses compensate for by increasing operational efficiency are 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&D[3] respectively.Therefore, it is possible that the ultimate UK societal impact arising from the £1bn revenue costs to industry would be over stated even if secondary impacts are fully accounted for. 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 this factor.

67. 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.

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

68. 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 wholesalers[4]. 2 principal issues with this have been identified:

    a. List prices are unlikely to accurately reflect selling prices; and

    b. The small sample is unlikely to be representative of the whole sector.

69. 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, NHS finances, patients and manufacturers and wholesalers (denoted industry) as the key identified groups.

Impact on pharmacies

70. 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.

71. That said, if the distribution of medicine margin across different products changed it could generate winners and losers in the pharmacy sector if:

- Selling prices for Category A products do not fall to the same extent as reimbursement prices, reducing medicine margin earned on Category A products and feeding through

[3] 13% for R&D calculated as a 30% uplift to the original to account for estimated economic spillover 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 wich equals £0.13 or 13% of the original £1.

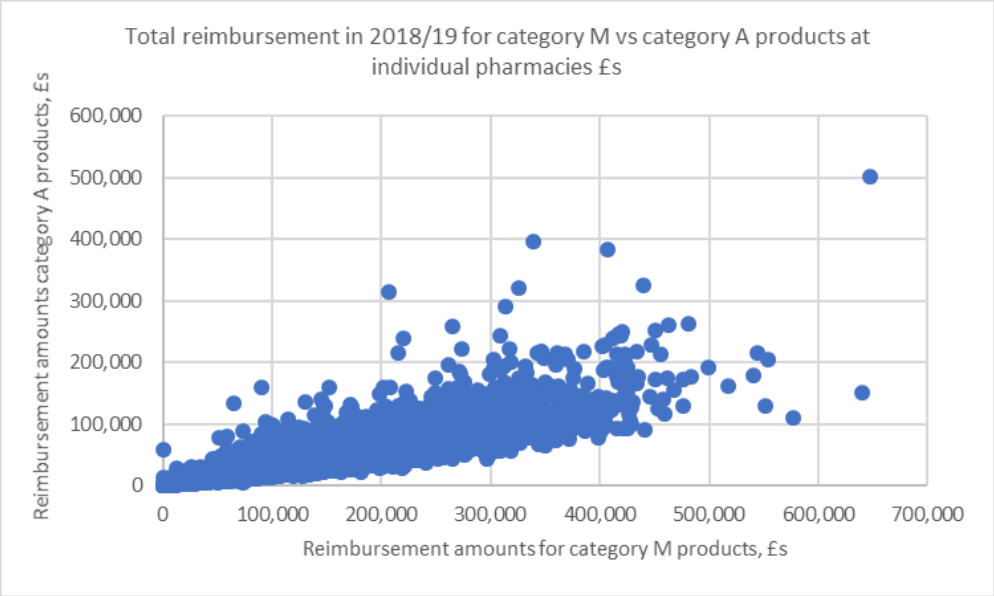
[4] This could in practice just be two wholesalers as a total weight of 4 is required and wholesalers are weighted 2 and manufacturers are weighted 1. So, the sample could be comprised of 2 wholesalers or 1 wholesaler and 2 manufacturers.

to a rise in Category M reimbursement prices benefitting those that dispense more Category M than Category A at the expense of those dispensing more A; or

- Selling prices for Category A products fell further than reimbursement prices, increasing medicine margin earned on Category A products and feeding through to a fall in Category M reimbursent pices, benefitting those that dispense more Category A than Category M at the expense of those dispensing more M.

72. We can check if this is likely using data from the NHS BSA on the distribution of reimbursement amounts across Category A and M products at individual pharmacy level. Figure 4 plots total annual reimbursement at Tariff price for Category A versus Category M at individual pharmacy level to assess whether a potential future change in margin distribution across these products could generate a large number of winners and losers.

Figure 4: Individual pharmacy level Category A Net Ingredient Cost (NIC)[5] versus Category M NIC (NHS BSA bespoke data)



73. We can see that for the majority of pharmacy contractors total annual reimbursement at Tariff price for Category A products maintains a rough ratio of circa 1:3 compared to that for Category M (subject to certain tolerance ranges as the total level of reimbursement increases). There are however a small number of outliers where Category A reimbursement was higher than Category M. Of the 40 pharmacies (0.3% of the total) where this was the case, 16 had total reimbursement for Category A and Category M products estimated at less than £5k in 2018.

74. 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

[5]NIC 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.

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.

Impact on NHS finances

75. More accurately reflected market prices in reimbursement prices could incentivise smarter shopping by pharmacies and efficiency gains in manufacturers/wholesalers, leading to increased competition and reductions in selling prices.

76. 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.

77. 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.

78. 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 this initial, high-level estimate we assume 50% is a reasonable adjustment (i.e. that calculated savings are reduced by 50%) and more work will be needed to investigate this further.

79. We looked at monthly data on reimbursement prices running from Q1 2015 to Q4 2018. Over this period, we identified 67 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.

80. Converting the monthly weighted average into an annual scaler and applying it aggregate Category A NIC in 2018 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.

81. 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.

82. This significantly prudent approach overall seems reasonable given that we know the reimbursement amount will contain an element of medicine margin that will need to be added back in to the system to maintain the £800m under the CPCF. Additionally, on the

whole, Category A reimbursement prices tend to be more static versus Category M, suggesting that shifts in underlying selling prices at the scale we might see for Category M products may be less likely. The results are set out below in table 4 and discussed in the following paragraphs.

Table 4: Initial estimates of potential savings through increased competition in Category A products adjusted for optimism bias

Central 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 (2016 prices discounted at 3.5%) £m	145	180	195	175	130	825
Benefits to society (2016 prices discounted at 1.5%) £m	395	500	555	510	375	2,335
Overall net present value (NPV)	250	320	360	335	245	1,510

83. The central estimate for revenue costs to industry is between £130m and £195m per annum in 2016 prices, discounted at 3.5%. The resulting cumulative, present value, revenue costs to industry are £825m over the full f.

84. This assesment 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.

85. 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 £15,000[6]. 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.

86. In addition, standard IA methodology entails monetising impacts in order to represent their value to society. The Department's best estimate is that society values a QALY at £60,000[7]. Applying this methodology to estimate the value to society of QALYs generated and discounting at 1.5% in line with the Government's Green Book guidancegives a . Finally, row a) of table 4 presents the overall net present value of the policy proposal calculated by subtracting the estimates in row e) from row b). Overall, the cumulative net present value of the proposal is estimated at circa £1.5bn over 5 years.

87. 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.

[6] https://www.york.ac.uk/che/research/teehta/thresholds/

[7] 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.

Impact on Industry

88. As discussed above, more accurately reflected market prices in reimbursement prices could incentivise pharmacies to search out the best prices available and manufacturers/wholesalers to make efficiency gains, leading to increased competition and reduced selling prices. The latter could translate into real savings for the NHS via lower reimbursement prices being needed to support the £800m of medicine margin under the CPCF funding envelope. However this would also affect manufacturers and wholesalers via reduced revenues.

89. The revenue cost to business will equal the benefit to NHS finances before it is converted into health benefits and discounted. Table 4 includes full details of the revenue cost to industry estimates which are not repeated here other than the central estimate cumulative present value revenue cost to industry ofcirca £825m. Note that this is significantly lower than the value of health benefits generated.

90. Overall, as described in page 19, 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

91. 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).

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

92. 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 to the CCG.

93. 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. 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).

94. 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 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 M1 products and all other Category M products are denoted Category M2 products.

95. 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 48.

Potential number of products affected

96. 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. For example, if thresholds were to be used to allow for some margin of error. As the number of products on the market, and reimbursement prices move around, the total number of products affected is likely to change.

97. 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 20% to 30%.

98. Using a very prudent definition of brands with a cheaper reimbursement price (this included the use of a 10% threshold, 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.

99. 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

100. At the aggregate level we expect a net zero impact on the pharmacy sector as the policy 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.

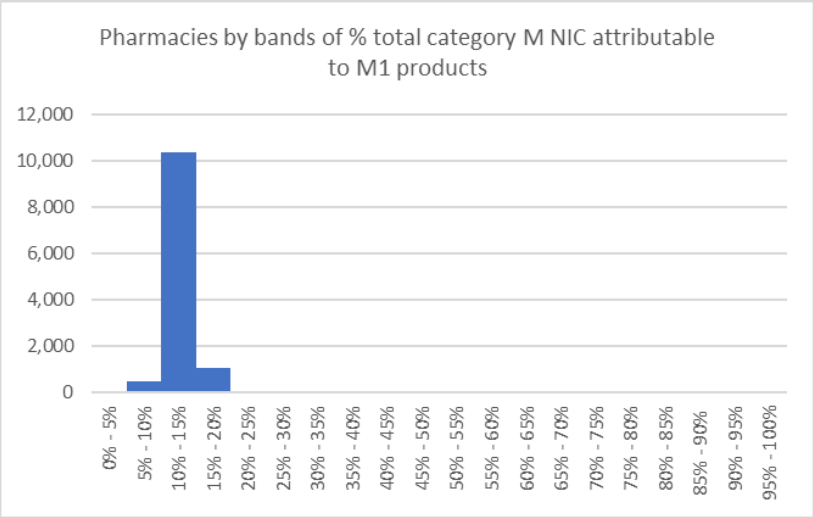
101. Bespoke data provided by the BSA detailing NIC for drugs in Category M in 2018 at individual pharmacy level was used to assess the potential for winners and losers. NIC associated with products that would come under the prudent definition of Category M1 was split out and the implied M2 NIC per pharmacy calculated. The proportion of all Category M NIC attributable to M1 products is used as a proxy for reliance on Category

M1 products (new lower medicine margin products) and therefore to identify potential losers.

102. The data showed only 32 out of almost 12,000 pharmacies had greater than 20% of their total Category M NIC attributable to M1 products. Furthermore, the average NIC across these pharmacies in 2018 was less than £10k compared to an average of over £130k[8] for the rest of the sample.

103. The vast majority of pharmacies (87%) had M1 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 5:

Figure 5: Individual pharmacy level reimbursement for M1 products as a % of total Category M reimbursement (see footnote 5 page 22 for definition of NIC), NHS BSA bespoke data



104. 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.

105. 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 would have made.

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

Impact on industry

106. 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 for prescribers to prescribe branded products instead of generics, this proposal is expected to lead to a shift in prescribing away from brand to generics. This is likely to lead to a fall in revenue associated with branded products and a gain in revenue for generic products.

107. 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.

    - 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 take into account the revenue gained by the suppliers of the generic products.

108. 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 actually be realised. Adjusting for optimism bias implies a net present value central estimate revenue cost to industry of circa £3m per annum could result.

109. The total amount reimbursed for the product list generated by applying the widest possible definition of M1 products (see paragraph 97 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 a central estimate present value revenue cost to industry of around £15m to £17m per annum.

110. 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.

111. The approach used drug names taken from the 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.

112. 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% did they account for >50%.

113. It therefore seems unlikely that reducing the medicine margin added to some products in Category M would impact the industry sufficiently to jeopardise supply or the feasibility of businesses not at the extreme.

Impact on patients

114. 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

115. The Category C reimbursement price is based, in the main, on the brand originator's list price and mostly relate to branded medicines. Reimbursement prices of products without Part VIII reimbursement prices are based on the list price of the supplier the pharmacy contractor has sourced the medicine from, which can be the manufacturer or wholesaler.

116. The reimbursement arrangements for edicines 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.

117. 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 is 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.

118. 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 13. 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.

Number of products affected

119. As the number of suppliers of a particular product may change over time, as firms enter or exit the market, or products are discontinued, it is not possible to provide a definitive picture at any one time of the exact number of products where there are multiple suppliers available.

120. However we have conducted an initial survey of products that were in Category C of the Drug Tariff over the financial years 2017/18 and 2018/19, using the Dictionary of Medicines and Devices (dm+d), the electronic Medicines Compendium (eMC), and information from the Medicines and Healthcare products Regulatory Agency (MHRA). This analysis suggests that approximately a quarter to a third of Category C products may have multiple suppliers or around 600 products.

Potential reduction in reimbursement prices

121. Whilst at this stage it has not been possible to examine the full list of circa 600 products to examine the impact of a revised reimbursement price, analysis has been conducted on a selection of 34 products for which data was available to hand. Based on information provided by the NHS Business Service Authority (NHSBSA) on the list prices held in their Dictionary of Medicines and Devices (dm+d) covering the period 2017-18, indicative reimbursement prices were constructed by taking a weighted average of the manufacturers' list prices available within dm+d, weighted by the number of prescription items dispensed within 2017/18 for each of the listed products.

122. A total NIC (see footnote 5) was calculated based on these indicative reimbursement prices and dispensing volumes over the period 2017/18 and compared to the actual reimbursement NICs for these products over the same period.

123. Over just these 34 products, the results of the analysis suggested that total NHS reimbursement spend in 2017/18 could have been in the region of £30m lower, equating to around a 24% reduction in spend. However this latter figure should be treated with caution as it is not clear how representative the 34 products used to generate this figure are of other products within Category C with multiple suppliers. Our choice of these products was driven by the availability of data, rather than any representative or random sampling across products.

Wider impact on pharmacy contractors and NHS spend

124. As previously discussed, since the medicine margin is targetted at £800m under the CPCF funding envelope, it is not expected that this reduction in 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 a further adjustment to reimbursement prices to address this.

125. 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.

126. For example, by avoiding potential risks that reimbursement prices need to be adjusted downwards to account for previous overdelivery 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.

127. 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.

128. 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. However, we invite views as part of the consultion as to whether this distribution effect is likely to be significant.

Impact on pharmacy purchasing decisions

129. Changing reimbursement prices to make them more reflective of actual market selling prices is expected to improve incentives for pharmacies to source medicines at the lowest possible cost to the NHS. This in turn is expected to help drive competition within the market, leading to a reduction in the selling price of medicines. Any reduction in selling prices would result in real savings for the NHS as lower reimbursement prices would be 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.

130. However, it is difficult to estimate to what extent this might occur as it was not possible to identify a suitable proxy for the changes in reimbursement prices that are proposed here. The previous section calculated that reimbursement spend across a sample of 34 of the potentially affected 600 products may be £30m lower per annum in the five years after this measure was implemented.

131. To the extent that pharmacies would seek to reflect the changes in reimbursement prices in their purchasing decisions (in order to maintain their share of medicines margin), this figure represents the best starting point we currently have for estimating potential NHS savings. However, it may be the case that if pharmacies are unable to push selling prices

down to the same extent (or are otherwise not incentivised to do so), the overall impact on selling prices would be less than the initial impact on reimbursement prices estimated above.

132. We therefore assume that the reduction in reimbursement prices for the sample of 34 products could be a proxy for the subsequent reduction in sales prices of all potentially affected 600 products. This equates to assuming that the impact on reimbursement prices we calculated in relation to just over one-twentieth of all Category C products (albeit these may account for a higher than average proportion of NIC) might be a reasonable proxy for the impact on selling prices across the whole of Category C. We consider this to represent a prudent estimate of the potential savings and will continue to seek evidence as part of the consultation on how this estimate can be improved.

133. Adjusting for optimism bias and converting this figure into the estimated value to society of the health benefits reinvesting the savings in the frontline could generate this suggests a potential cumulative present value benefit of £415m.

Impact on Industry

134. Any reduction in NHS reimbursement spend driven by this policy (before it is converted in to health benefits) will be matched by a revenue loss for the pharmaceutical industry. The circa £30m per annum fall in spend estimate derived above could, if it occurred in five consecutive years, generate cumulative revenue costs to industry with a present value of around £140m, rising to £175m once adjusted for optimism bias. Note that this will be outweighed by the value of the health benefits this revenue loss would generate if reinvested in the frontline calculated in paragraph 132.

Impact on patients

135. 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.

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

136. 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.

137. Where drug reimbursement prices are based on the list price of the supplier (manufacturer or wholesaler), pharmacy contractors will source drugs (excluding licensed and unlicensed medicines) 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.

138. 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 VIIIA 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.

Impact on pharmacies

139. For drugs newly listed in Part VIII, we would expect these products to be in Category A or Category C of the Drug Tariff. Since we have previously discussed in this IA, the impact

of proposals to change the reimbursement prices for Category A and Category C medicines, we do not repeat this analysis again specifically for drugs that are not medicines.

140. For drugs currently not listed in the Drug Tariff, dispensing pharmacies are reimbursed the price they purchased the product at. Products not currently listed in the Drug Tariff are therefore not expected to contribute to pharmacy medicine margin and there is little or no incentive to shop around for the best price.

141. When these products are added to the Drug Tariff, there may be potential for pharmacies purchasing at the lowest available rates to maximise their share of the £800m medicine margin if the Tariff price is calculated as an average of manufacturer/wholesaler selling prices. Because pharmacy medicine margin is targeted at £800m, any extra medicine margin earned from this measure will be netted off by reduction in medicine margin elsewhere. There is therefore a zero net aggregate impact on the pharmacy sector but winners and losers could be created.

142. For drugs that remain outside of Part VIII, the proposed changes in the reimbursement rules are expected to generate very similar effects to those described above. However, as the weighted average prices on dm+d will not be knowable in advance, there is a risk that pharmacy contractors may have less certainty over reimbursement prices than under current arrangements. 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 NHS finances

143. As previously discussed, the existence of medicine margin helps to create value for money for tax payers by encouraging 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. However, for medicines not listed in the Drug Tariff, this incentive mechanism does not operate as effectively, as pharmacy contractors have been reimbursed based on the actual cost of the medicine that they endorse on the prescription. 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.

144. We looked at reimbursement report data from the NHS BSA to see what happened to the average reimbursement prices of products that entered Category C as a proxy for how prices of non-medicines might change on being added in to Part VIII. The data showed an average price fall of 6% per annum, suggesting it's reasonable to expect that bringing non-medicines in to Part VIII of the Drug Tariff should drive a fall in reimbursement prices.

145. However, without a list of non-medicines that might be moved in to the Drug Tariff we cannot reliably quantify the scale of the potential savings. We have therefore chosen to

take the prudent option and not quantify the potential savings from bringing non-medicines in to Part VIII of the Drug Tariff at this time, although we are confident some benefits will arise. Similarly for drugs in non-Part VIII, we do not believe that the Category C proxy can reliably be used as these products would remain outside of the Drug Tariff.

146. As previously described above, by changing the reimbursement prices to better reflect the wider range of suppliers' prices in the market, this may result in some additional competitive pressure arising in the market for these products, which would also help to drive savings for the NHS.

Impact on Industry

147. 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

148. 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.

149. For drugs in non Part VIII, the lack of published reimbursement prices (as described in paragraph 141 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')

150. There are two separate proposals in relation to unlicenced medicines. These are assessed in turn below.

A. Bringing unlicensed tablets and capsules into Part VIIIB of the Drug Tariff

151. Part VIIIB of the Drug Tariff does not currently set out reimbursement prices for unlicensed tablets and capsules. Because pharmacists are reimbursed the purchase price for non-Part VIIIB 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.

152. This policy proposal is to include all possible unlicensed tablets and capsules with a reimbursement price in Part VIIIB of the Drug Tariff. The reimbursement prices would be based on data manufacturers and wholesalers are already providing on around 100 tablets and capsules (covering 95% of our spend on these products).

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

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

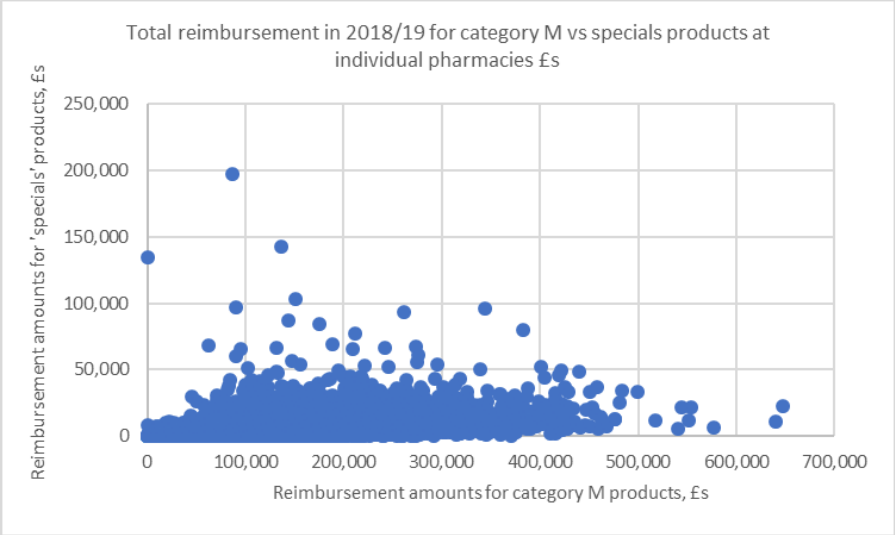
Impacts on pharmacies

154. Starting with the pharmacy sector, because these products are not currently listed in the Drug Tariff, dispensing pharmacies will currently be reimbursed the price they purchased the product at. Specials 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.

155. Conversely, reimbursement prices for Part VIIIB products include an element of medicine margin. Bringing unlicensed tablets and capsules (UT&Cs) in to 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 will likely trigger a downwards adjustment to Category M reimbursement prices to maintain medicine margin at the £800m under the CPCF funding envelope.

156. 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. To test this, we have used bespoke BSA data to look at the distribution of Category M and specials dispensing across pharmacy types. This is shown below in figure 6:

Figure 6: Individual pharmacy level amounts reimbursed for 'specials' versus Category M products, NHS BSA bespoke data



157. 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 MTtariff prices would be diluted across a large amount of reimbursement and a large number of pharmacies. And therefore the risk of significant scale losers should be minimal.

Impact on NHS finances

158. To assess whether there might be an impact on NHS finances, we can look at what happened to selling prices for products that have already been added in to the Part VIIIB specials Tariff, compared to products that remained outside of the Tariff. Because specials are reimbursed at the price they were sold at, we can use ePACT data to look at this.

159. Our analysis finds that on average, products that were added to Part VIIIB of the Drug Tariff fell in price, whilst prices rose for non-Tariff specials. We are not aware of anything else that would have driven price falls in the Part VIIIB specials and price rises in the non-Part VIIIB. Therefore, it seems reasonable to attribute most of the Part VIIIB 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.

160. We applied the smallest fall in average annual price per unit for Part VIIIB specials in the data which equalled -7% 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.

161. Applying this reduction to the UT&Cs NIC (for definition see footnote 5) in 2018 gives us the 5 year savings forecast set out below in Table 5. Note, we have again assumed the volume of UT&Cs would remain constant at 2018 levels to maintain prudence.

Table 5: Estimated potential savings through increased competition in unlicenced tablets and capsules

Aggregate NIC, fixed at 2018 volumes, with prices fixed vs adjusted down to account for addition to the tariff £m					
	Year 1	Year 2	Year 3	Year 4	Year 5
Implied aggregate savings £m	2	3	5	7	8
Implied UT&Cs NIC adj. down for addition to tariff, £m	24	22	20	19	18
UT&Cs NIC fixed 2018 price & volume £m	25	25	25	25	25

162. 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.

163. 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 £15,000[9]. 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.

164. In addition, standard IA methodology entails monetising impacts in order to represent their value to society. The Department's best estimate is that society values a QALY at £60,000[10]. Putting these two valuations together, the ultimate value to patients of the NHS savings of this magnitude could generate rises from circa £7m in year 1 to just under £31m in year 5, as shown below in table 6:

Table 6: Estimated potential QALY value of savings in unlicensed tablets and capsules

Number of QALYs generated by saving and value of these to society					
	Year 1	Year 2	Year 3	Year 4	Year 5
Value of QALYs to society £m	7	14	20	26	31
Number of QALY savings generate	121	233	337	434	524

165. Adjusting these estimates for optimism bias in line with the approach described previously gave the central estimates shown below in table 7:

Table 7: Central estimate net present value – adjusted for optimism bias

Present value costs and benefits of adding UT&Cs into tariff - central estimate						
	Year 1	Year 2	Year 3	Year 4	Year 5	Cumulative
Net present value overall, 2016 prices - central estimate £m	3	5	8	10	12	39
Value QALYs to society 2016 prices discounted 1.5% - central estimate £m	5	10	14	17	21	66
Lost revenue to business 2016 prices discounted 3.5% - central estimate £m	2	4	6	7	8	28

[9] https://www.york.ac.uk/che/research/teehta/thresholds/

[10] 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.

Impact on Industry

166. As discussed above, more accurately reflected market prices in reimbursement price could incentivise smarter shopping by pharmacies and efficiency gains in manufacturers/wholesalers, leading to increased competition and reductions to selling prices. The latter could translate into real savings for the NHS via lower reimbursement prices being needed to support the £800m of medicine margin under the CPCF funding envelope. However this would also affect manufacturers and wholesalers via reduced revenues.

167. The revenue cost to business will equal the benefit to NHS finances (before it is converted into health benefits) calculated previously. The central estimate for the present value revenue cost to industry in 2016 can be found in table 7 and result in a cumulative cost of circa £28m over 5 years. Note that this is significantly lower than the value of health benefits generated.

168. Overall, as described in page 19, 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

169. 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 treatment decisions, availability or outcomes).

B. Introducing alternative arrangements for non-Tariff specials

170. 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 it is not feasible to add 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.

171. There are 4 options being considered to address this problem for products it is not feasible practical to add into Part VIIIB of the Drug Tariff:

- Require pharmacies 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

172. Requiring pharmacies 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 pharmacists can select lower priced products.

173. The quotes option is expected to generate additional costs to pharmacies 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.

174. 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.

175. We start estimating potential costs by calculating a notional average paybill[11] 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 18% uplift to account for employer pension and national insurance contributions. Additionally, an average 2% pay uplift per annum is applied to earnings data from pre-2019.

176. Our baseline scenario assumes that quotes are sought by pharmacy technicians and provided by individuals with average earnings equivalent to those in the 10th percentile[12] 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.

177. We then estimatied how many additional quotes may need to be produced and sought per annum and the associated staff time requirement. ePACT data shows circa 87,000 items were dispensed in 2018 that were specials and not listed in the Drug Tariff or within the tablets and capsules definition (denoted from here as non-amended Part VIIIB specials). We further assume each quote would take an average of 5 minutes to produce and obtain a quote.

178. This suggests an aggregate cost to business per annum from introducing a quotes system could be circa £310k before adjusting for optimism bias, split almost evenly across pharmacies and manufacturers/wholesalers, if number of items dispensed

[11] Earnings plus employer national insurance and pension contributions.
[12] Assume lower percentile due to administrative as opposed to technical or expert role.

remained constant. Inflating to account for optimism bias suggests a central estimate of £395k is not unreasonable. This would translate to a present value aggregate cost to business of around £1.8m over the full 5 year period.

179. 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.

180. Savings of ~2% on the £20m NIC associated with these products in 2018 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

181. 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 VIIIB products.

182. Instead, it 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. The service would use this knowledge to approve or otherwise the reimbursement prices sourced by dispensing pharmacies to fill a prescription and thereby help to reduce the variation in prices paid for equivalent products.

183. 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.

184. 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.

185. ePACT data shows around 87k specials items were dispensed in 2018 that would not come under the amended Part VIIIB 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 8. Combining these assumptions with the 87k items dispensed estimate and some rough estimates on hours worked per annum allowed us to calculate the implied number of FTEs needed in Table 9.

Table 8: 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 9: estimated FTEs required to provide approvals

Estimating FTEs required to provide approvals	
Implied number of FTEs required to provide approvals	11
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	18,561

*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.

186. 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 10.

Table 10: 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 £	
***Pharmacist**	20%	43.83	
***Pharmacy technician**	40%	11.27	
Combined office administration service activities (lower percentile assumed general admin)	30%	10.74	25th percentile assumed representative
administration service activities (higher percentile assumed managerial type	10%	22.64	75th percentile assumed representative

187. Setting the necessary assumptions to these levels suggests introducing a central approvals service may have an aggregate cost in the region of £600k per annum. Note, this includes the cost of pharmacy staff time seeking approvals. There could also be in the region of £30k recruitment costs and £225k familiarisation costs (assuming 1 hour per pharmacy technician to get up to speed) in year 1. Annual cost forecasts are set out below in Table 11. There may in addition be some requirements for additional IT set up costs to support the service. However, these remain unquantified at this stage.

Table 11: Estimated total costs of approval service

	Year 1	Year 2	Year 3	Year 4	Year 5
Aggregate cost of introducing a central approvals service £000's	**870**	**610**	**610**	**610**	**610**
Cost to pharmacy sector £000's	435	210	210	210	210
ost to public sector (set-up and running approvals service) £000's	435	400	400	400	400

Estimates rounded to nearest £5,000

188. Adjusting these initial estimates for optimism bias provides a central estimate for the present value aggregate cost to the pharmacy sector over the full 5 year period of circa £1.5m. The central estimate cost to the public sector is just over £9.5m once we apply the 4:1 rate of return on investment in frontline NHS services under the standard QALY methodology.

189. Taking the cost to the pharmacy and public sectors together suggests an 11 FTE approval service would need to generate savings equivalent to ~11% of 2018 NIC for non-Part VIIIB, non-tablets and capsules per annum (14% in year 1 given transition costs) for a net zero economic impact.

Procurement solutions

190. 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 VIIIB 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.

191. 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.

192. We do not expect there to be any additional cost impacts of introducing a central procurement service on pharmacies, 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.

193. Pharmacies 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.

194. 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 ongoing costs. This equates to a paybill estimate of over £520k per annum or around £575k once office space and equipment costs are also included, before we adjust for optimism bias and the 4:1 rate of return on spending on the frontline.

195. Our central 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 £3m per annum.

196. The central procurement service would consequently need to generate ~15% savings versus the 2018 NIC on non-amended Part VIIIB specials per annum (18% in year 1 given the 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 VIIIB 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.

197. As above, we anticipate the only impact of this policy on the pharmacy sector would be a reduction in administrative burden of sourcing non-amended Part VIIIB specials.

198. The impact on manufacturers/wholesalers supplying non-amended Part VIIIB 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.

199. The cost of the contract awarded would not exceed the expected expenditure on non-amended Part VIIIB specials in the counterfactual. But any company undertaking the

contract is likely to require compensation for the risk associated with such an uncertain undertaking. If, for example, quantities demanded increased, they could be exposed to making a loss albeit the opposite might happen instead.

200. 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).

201. To generate savings, the cost of the contract and associated contract management must be smaller than expected spend on non-amended Part VIIIB specials in the counterfactual. If we take 2018 NIC as our estimate of the size of the pot, it would need to be <£20m. We would need more time and details 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'

202. There are instances where a pharmacy contractor has the choice to dispense either an appliance or an unlicensed medicine (special) against a generically written prescription. 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.

203. 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. Prescribing in a way that allows for dispensing either an appliance or a medicine is therefore inherently problematic in terms of patient welfare.

204. The cost of dispensing a special is considerably 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 costs the NHS more. This means that the NHS is not getting good value for money from its spend on these products.

205. 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 generically written prescription that could be fulfilled by a special or an appliance, regardless of whether they dispensed an appliance or a special. As this policy has clear parallels with the next policy proposal, the impacts of the two proposals are considered jointly below.

Drugs vs 'specials'

206. Similarly, in some instances, a generic prescription can be filled by contractors dispensing either an unlicensed medicine or a drug that is not also a medicine. As above,

there is also a higher cost associated with dispensing a special versus a drug that is not a medicine. This policy seeks to 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 medicine to the cost of the available drug.

207. 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

208. In considering how contractors may be affected by this proposal, and because we are assessing the 2 measures together given their similarity, we assume that the speicals and drugs this change relates to are not listed in the Drug Tariff. This means that pharmacies will be reimbursed the price endorsed on the prescription and therefore not make any medicine margin (appliances can only be dispensed if they are listed in the Drug Tariff).

209. We assume limiting the amount that will be reimbursed to the price of the drug/appliance will mean that pharmacies no longer choose to make purchases above this price, in the knowledge that they would doing so at a loss. Therefore, we do not expect there to be an impact on pharmacies.

210. 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 in order to avoid dispensing at a loss. 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

211. Instead, by incentivising pharmacies to purchase the lower cost alternative, we anticipate savings will accrue to the NHS. To assess the potential extent of these savings we have considered data for a small sample of 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 NHSBSA.

212. We calculated NIC per item and NIC per quantity[13] 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 12, 13 and 14 respectively. Note that the special order products identified in the appliances versus specials sample have been discontinued. They are still noted here to highlight the type of products that have been an issue in the past.

[13] 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, milllitres or grams.

Table 12: Estimated NIC/quantity for special versus drug alternatives of the same VMP

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 13: Estimated NIC/quantity for special versus drug alternatives of the same VMP

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%

Table 14: Estimated NIC/quantity or item for special versus appliance

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%

213. In each case for drugs the special has a higher associated NIC per item or quantity compared to the drug alternative. Additionally, there would be no £20 SP fee payable for dispensing a drug which could feed through to increase the single service fee and thereby provide a small benefit across the pharmacy sector.

214. For appliances, NIC per item is lower for both the appliances versus the specials and NIC per quantity is lower for the appliance in the case of hypromellose 0.3% eye drops preservative free but higher for sodium chloride 5% eye drops.

215. On balance, it seems reasonable to conclude that the result of restricting reimbursement prices to those for the drug or appliance where there is a special alternative is most likely to be a fall in reimbursement costs.

Impact on Industry

216. There will be a cost to industry as companies who had been selling their products above the proposed price ceiling will lose out. This lost revenue should equate to the estimated savings to the NHS. But this will always be outweighed by the value of the patient benefits as these are in effect a function of the cost to industry. Until the detail of the products that would come under this definition is confirmed, we cannot quantify what the aggregate impact may be.

Impact on patients

217. We do not anticipate that there will be any impact on patients. This proposal would only apply where a generic prescription is issued, giving the pharmacy the choice whether to dispense the special or a drug/appliance. If there were a clinical reason for one type of product being preferred over another, it is likely that the prescriber would have issued a more specific prescription specifying the required product, and thus these proposals would not apply.

218. 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 administrative or time costs over and above the conversations that would already need to take place to establish this requirement.

Changes to the deduction scale

219. 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.

220. 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% deduced from the total monthly reimbursement.

221. 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.

222. Currently, the deduction scale does not take into account whether a pharmacy contractor dispenses brands or generics.

223. 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.

Impact on pharmacies and CCGs

224. 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.

225. However, it is likely that there would be significant distributional effect. 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.

226. The reverse is 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.

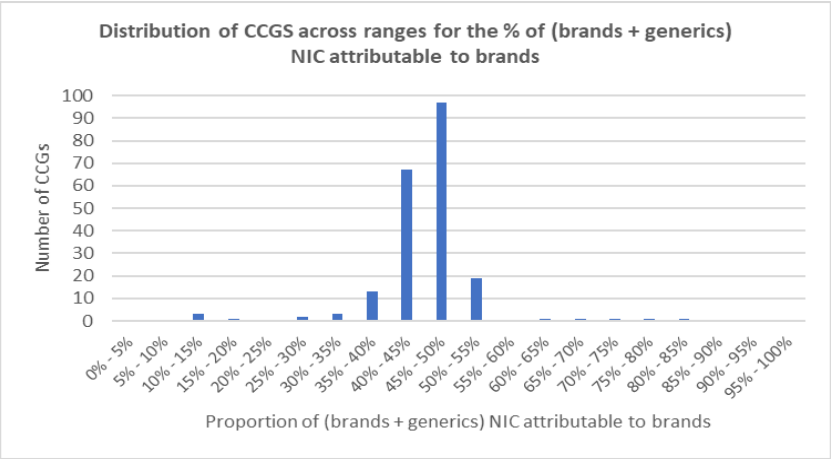
227. Overall this effect rises because the changes to the design of the discount scale have been done with revenue neutrality in mind from the aggregate point of view of the government, pharmacies and CCGs. As a result, the expected smaller discount deduction for pharmacies' dispensing of branded items (where currently less medicine margin is earned) is financed by a 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 CCGSs prescription of generics.

228. 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 generic[14] NIC that is attributable to branded products for CCGs and generic products for pharmacies[15]. Figure 7 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.

[14] Class 1 and class 3 definitions used to proxy brands and generics respectively.

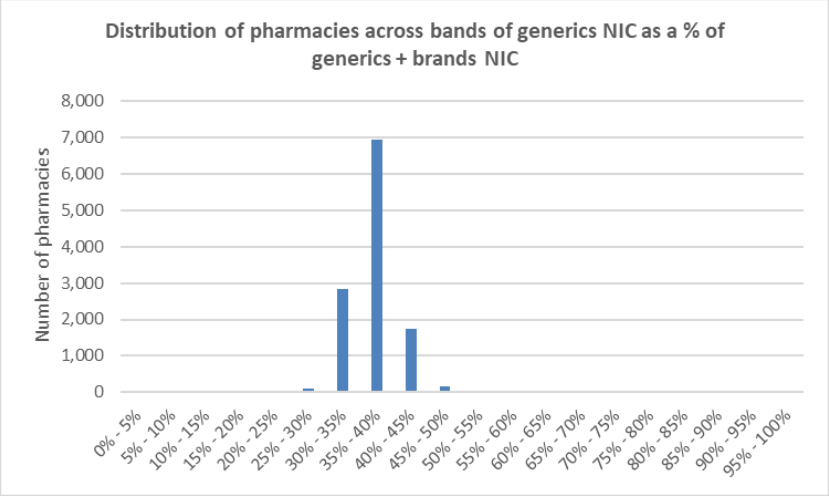
[15] See paragraphs 217 and 218 for details on opposite distributional effects.

Figure 7: Class 1 NIC as a % of class 1 + class 3 NIC split by CCG



229. Similarly bespoke data sourced from the NHSBSA on amounts reimbursed for brands versus generics at individual pharmacy level showed that circa 97% of pharmacies fell within the bounds of generics accounting for 30% - 45% of amount reimbursed. This is shown below in figure 8. Overall, the scale of clustering suggests it is unlikely that a significant number of winners and losers will be generated by this policy.

Figure 8: Class 1 NIC as a % of class 1 + class 3 NIC split by pharmacy type



Impact on industry

230. 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.

231. If prices are different, the lost revenue from branded manufacturers is not compensated for by generic manufacturers but we are not able to quantify/assess this. Instead we have

taken a prudent approach to assessing the potential cost to industry on the assumption that the cost to industry is full value of any reduction in branded prescribing.

232. We start with a bespoke dataset provided by the NHS BSA detailing NIC and items dispensed for preparation class I (proxy for generics) and preparation class III (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.

233. 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.

234. Applying the optimism bias adjustments set out in the introductory sections suggests a central estimate for the potential revenue cost to industry of circa £22m per annum on average.

Impact on patients

235. 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.

Conclusion

236. Taking all the proposed reforms together, the overall NPV of the proposals remains positive even when the most prudent approach is taken to the analysis albeit the initial, uncertain nature of the specific values should be borne in mind.

237. The NPV ranges from a low estimate of £0.9bn to a high of £2.3bn implying a central estimate around £1.7bn. Whilst, as explained above, the values will be subject to change and refinement throughout the ongoing stages of policy development and consultation, it seems reasonable to be confident that a net benefit could be generated overall by these measures.