Title: Regulations to enable the Government to require information on health service products **IA No:** 3137 **RPC Reference No: n/a** **Lead department or agency:** Department of Health **Other departments or agencies:**	**Impact Assessment (IA)** **Date:** 15/08/2017 **Stage:** Consultation **Source of intervention:** Domestic **Type of measure:** Secondary legislation **Contact for enquiries:** Sandor Beukers 02079721152

Summary: Intervention and Options

RPC Opinion: Not Applicable

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANDCB in 2014 prices)	**One-In, Three-Out**	**Business Impact Target Status**
- £66.6m	NA	NA	Not in scope	Not a regulatory provision

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

The Government does not have sufficient powers to collect information on the sale and purchase of health service products by manufacturers, wholesalers, and dispensers in order to provide transparency for the Government on the cost of drugs used by the health service. This leads to an asymmetry of information which can enable actors in the supply chain to inappropriately increase NHS costs. In addition, the Government currently relies on a number of voluntary agreements to obtain the information it needs to run the drug reimbursement system for dispensers. There is a risk that, should compliance with these schemes fall, this would severely impact the continued effective running of the reimbursement system.

What are the policy objectives and the intended effects?

The objective is to collect information on the sale and purchase of health service products by manufacturers, wholesalers, and dispensers. The intended effects are

a) to eliminate the risk of non-compliance with current voluntary arrangements for collecting information to ensure the continued effective running of the reimbursement system for dispensers and

b) to provide greater transparency for the Government on the cost of drugs used by the health service.

The ultimate objective is to achieve best value for money in terms of the supply of medicines (and other helath service products) to the health service.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in evidence base)

Option 0: Do nothing - continue to utilise voluntary arrangements to collect information

Option 1: Introduce a range of powers to collect information on the sale and purchase of health service products - including a requirement for routine product level information on the sales and purchase of generic medicines to be submitted to the Department. (Preferred option)

Option 2: Require routine transaction level data on the sales and purchase of generic medicines to be submitted to the Department. In addition continue to require non-routine information as in Option 1

Option 3: Require transaction level data to be routinely returned on all medicines, medical supplies and other related products from the whole of the supply chain. In addition, there will be some non-routine information requirements as in options 1 and 2.

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		
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 DH Chief Economist: C. Mun Date: 15 August 2017

Summary: Analysis & Evidence

Policy Option 0

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year 2017	PV Base Year 2018	Time Period Years 10	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'

NA

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

NA

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'

NA

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

NA

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

Under this option, the Government would continue to rely on current voluntary arrangements to collect the information necessary to run the reimbursement system for dispensers effectively and to provide transparency for the Government on the cost of drugs used by the health service. The voluntary arrangements do not encompass all of the market which would perpetuate the asymmetry of information and inappropriate NHS costs referred to above.

BUSINESS ASSESSMENT (Option 0)

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

Summary: Analysis & Evidence

Policy Option 1

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year 2017	PV Base Year 2018	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: -£54.1m	High: -£100.9m	Best Estimate: -

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	£3.8m	1	£5.4m	**£54.1m**
High	£14.3m		£9.2m	**£100.9m**
Best Estimate	£6.4m		£6.4m	**£66.6m**

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

The main costs will be on manufacturers, wholesalers and dispensers to meet the new data requirements. DH will also incur additional costs associated with processing, analysing and storing the information.

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

Analysis of the new data could lead to new policy options being developed. This may result in additional costs for different groups. However, these costs are not quantified as they would depend on the nature of the new policy options identified, which would in turn be subject to a separate decision making process, including further consultation and an impact assessment.

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				

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

It has not been possible to monetise any benefits

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

There will be benefits in terms of ensuring the continuity of the reimbursement system, improving the resilience of the reimbursement system, improving resilience in the supply chain for medicines, and providing greater assurance that the NHS is achieving value for money. There could also be financial savings for the NHS resulting from the development of new policies based on the information received under these powers. However, it is not possible to quantify these at this stage.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

There is a risk that the information requirements could place an inappropriate and disproportionate cost burden on UK suppliers. There is also a risk that the information collected fails to support the identification of potential issues in the supply chain and aid the development of new policy options to address these. The higher the burden placed on suppliers to return data, the larger the size of the benefits that must be realised to justify these.

BUSINESS ASSESSMENT (Option 1)

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

Summary: Analysis & Evidence

Policy Option 2

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year 2017	PV Base Year 2018	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: -£62.3m	High: -£159.4m	Best Estimate: -£90.3m

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	£3.8m	1	£6.2m	**£62.3m**
High	£32.7m		£13.5m	**£159.4m**
Best Estimate	£14.1m		£8.1m	**£90.3m**

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

The main costs will be on manufacturers, wholesalers and dispensers to meet the new data requirements. DH will also incur additional costs associated with processing, analysing and storing the information.

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

Analysis of the new data could lead to new policy options being developed. This may result in additional costs for different groups. However, these costs are not quantified as they would depend on the nature of the new policy options identified, which would in turn be subject to a separate decision making process, including further consultation and an impact assessment.

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				

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

It has not been possible to monetise any benefits

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

There will be benefits in terms of ensuring the continuity of the reimbursement system, improving the resilience of the reimbursement system, improving resilience in the supply chain for medicines, and providing greater assurance that the NHS is achieving value for money. There could also be financial savings for the NHS resulting from the development of new policies based on the information received under these powers. However, it is not possible to quantify these at this stage.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

There is a risk that the information requirements could place an inappropriate and disproportionate cost burden on UK suppliers. There is also a risk that the information collected fails to support the identification of potential issues in the supply chain and aid the development of new policy options to address these. The higher the burden placed on suppliers to return data, the larger the size of the benefits that must be realised to justify these.

BUSINESS ASSESSMENT (Option 2)

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

Summary: Analysis & Evidence

Policy Option 3

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year 2017	PV Base Year 2018	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: -£322.6m	High: -£550.9m	Best Estimate: -£406.6m

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	£16.6m	1	£32.8m	**£322.6m**
High	£143.9m		£43.6m	**£550.9m**
Best Estimate	£75m		£35.5m	**£406.6m**

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

The main costs will be on manufacturers, wholesalers and dispensers to meet the new data requirements. DH will also incur additional costs associated with processing, analysing and storing the information.

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

Analysis of the new data could lead to new policy options being developed. This may result in additional costs for different groups. However, these costs are not quantified as they would depend on the nature of the new policy options identified, which would in turn be subject to a separate decision making process, including further consultation and an impact assessment.

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				

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

It has not been possible to monetise any benefits

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

There will be benefits in terms of ensuring the continuity of the reimbursement system, improving the resilience of the reimbursement system, improving resilience in the supply chain for medicines, and providing greater assurance that the NHS is achieving value for money. There could also be financial savings for the NHS resulting from the development of new policies based on the information received under these powers. However, it is not possible to quantify these at this stage.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

There is a risk that the information requirements could place an inappropriate and disproportionate cost burden on UK suppliers. There is also a risk that the information collected fails to support the identification of potential issues in the supply chain and aid the development of new policy options to address these. The higher the burden placed on suppliers to return data, the larger the size of the benefits that must be realised to justify these.

BUSINESS ASSESSMENT (Option 3)

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

Background

1. The Health Service Medical Supplies (Costs) Act 2017 provides the Secretary of State for Health with the powers to make regulations to require anyone involved in the manufacture, distribution and supply of health service products (a 'UK producer') to record, keep and provide certain information about the products including about supplies, costs, prices, discounts and revenues. UK health service products are defined in section 264A of the 2006 NHS Act and are medicines, medical supplies and other related products used for the purposes of the health services in the United Kingdom. The draft regulations define the products which would come within the scope of the proposed requirements. This impact assessment considers how these information powers should be implemented.

2. In 2015/16 The NHS in England spent approximately £16.8bn on medicines per year[1]. This is the second largest block of NHS expenditure (after pay costs). The Department and the NHS needs to ensure that best value is achieved through the pricing and supply arrangements.

3. In primary care, the NHS does not directly buy medicines; rather dispensers act as the 'agent' for the NHS (the NHS being 'the principal'). Pharmacies (or GP practices when they dispense or supply medicines) buy the medicines and the NHS reimburses the cost of these medicines. The system relies on competition throughout the supply chain – dispensers seek out the best prices, wholesalers compete on price and service, and manufacturers (where there is competition, mainly in the generics sector) compete on price.

The problem

4. The Government does not have sufficient powers to collect information on the sale and purchase of health service products by manufacturers, wholesalers or dispensers in order to provide transparency for the Government on the cost of drugs used by the health service. In addition, the Government currently relies on a number of voluntary agreements to obtain the information it needs to run the drug reimbursement system for dispensers. There is a risk that, should compliance with these schemes fall, this would severely impact the continued effective running of the reimbursement system.

5. The principal-agent relationship (as described above), relies on alignment of incentives across the principal and the various parties acting as agents. In the main this can be expected to work well, as dispensers, wholesalers and manufacturers have incentives to purchase and supply at lowest cost driven by competition. However, even where this is the case, the principal may not benefit fully if there is asymmetry of information – i.e. actors in the supply chain may be able to appropriate some of the benefit that should in fact accrue to the principal. This could occur because of:

    - Gaming/manipulation of the pricing and reimbursement system in order to retain cost benefits that should be passed on to the principal.

    - Tacit collusion between players in the supply chain – e.g. between some suppliers and purchasers.

    - Inefficiencies in the supply chain, where government intervention may result in better value for money for tax payers.

6. Currently the Department receives information on the supply of medicines through a limited number of voluntary agreements with the industry, as set out below.

<u>Margin survey (community pharmacy)</u>

7. Monitors the difference between invoice prices compared to reimbursement prices of a sample of around 330 drugs (150 brands, 150 generics and 30 'specials'), for a sample of 120 independent

[1] See http://www.content.digital.nhs.uk/catalogue/PUB22302/hosp-pres-eng-201516-report.pdf

pharmacies (5 or less outlets) – 10 per month. The results of the margin survey are used in negotiations with the Pharmaceutical Services Negotiation Committee to inform adjustments to reimbursement to deliver the agreed funding as part of the contractual framework for community pharmacy.

8. Although compliance is generally good, not all companies comply (the compliance rate of community pharmacies in 2015/16 is 91%) and full disclosure (e.g. of all statements) is not always provided, which may raise some concerns regarding the accuracy of the information.

Scheme M

9. Under scheme M participating manufacturers (currently 19) provide sales value and volume information for a limited number (though generally the most commonly used) generic medicines – just under 1,000 product lines. Not all companies choose to be members of scheme M, therefore there is incomplete coverage. Scheme M data is used as the basis for the setting of category M drug reimbursement prices.

Scheme W

10. Scheme W participating wholesalers (currently 7) provide purchase and sales value and volume information for a limited number (though generally the most commonly used) generic medicines – just under 1,000 product lines. Not all companies choose to be members of scheme W, therefore there is incomplete coverage. Scheme W data is used as supporting / cross reference information for category M drug pricing.

Unlicensed medicines (specials)

11. A similar voluntary arrangement to scheme M exists for suppliers of unlicensed medicines (commonly known as 'specials'). There are currently 8 specials manufacturers supplying data.

Pharmaceutical Price Regulation Scheme (PPRS)

12. Under the PPRS, certain sales information is gathered to enable the Department to operate the scheme. For companies with sales of £5 million or more, this includes quarterly unaudited high level information and an annual audited version of this information. The Department uses this to ascertain, amongst other things, total net sales of PPRS products and sales covered by the PPRS payment. It also identifies various exclusions from the PPRS payment. In addition, unaudited annual presentation level data is required from scheme members on an annual basis. This provides information on net sales and volumes and levels of discounts and breaks the information down into various sales channels, including primary care; homecare; and other customers.

13. Other aspects of the PPRS require different forms of information to be provided. For example, sales information to monitor price reductions under the rules on modulation; annual financial return information to enable the Department to measure a company's profits from it sales of branded medicines to the health service; information about the launch of new medicines.

Statutory branded medicines pricing scheme

14. Currently the Health Service Medicines (Information Relating to Sales of Branded Medicines etc.) Regulations 2007 (as amended) allow the Department to gather sales information from manufacturers and suppliers that are not members of the voluntary PPRS. The regulations, which apply to any manufacturer or supplier of branded health service medicines with sales to the health service of £5 million or more, stipulate that the information, which includes net sales and volumes and levels of discounts, to be provided at presentation level and broken into various sales channels (e.g. retail pharmacies; health service hospitals). Where the information has been audited, an audited copy of it should be provided to the Department.

15. Though these arrangements help generate some information with respect to the operation of subsets of the supply chain, as noted above, coverage is not comprehensive in terms of the range of products supplied, nor suppliers to the market. The type of information requested under the statutory scheme is

specific to the purposes of the statutory scheme and therefore would not necessarily provide the Department with information to analyse whether there is manipulation to hide cost benefits, tacit collusion or inefficiencies which mean that the principal is not accruing the cost benefit it should on behalf of the tax payer.

Objectives

16. The objective is to collect information on the sale and purchase of health service products by manufacturers, wholesalers and dispensers.

17. The intended effects are:

    - to eliminate the risk of non-compliance with current voluntary arrangements for collecting information to ensure the continued effective running of the reimbursement system for dispensers; and

    - to provide greater transparency for the Government on the cost of drugs used by the health service.

18. The ultimate objective is to achieve best value for money in terms of the supply of medicines to the health service.

19. By improving the reimbursement arrangements and securing greater transparency, this may allow the Government to satisfy itself that the market for medicines is functioning effectively. For example, in the area of generic reimbursement, without having adequate data to inform reimbursement prices the only option for the Government may be to have a scheme that limits the prices of generic medicines. The ability to obtain information on costs and prices/revenues from any supplier of health service products will help identify where problems are occurring more generally, and would feed into policy options that may address these problems in a way that could achieve better value for money.

Options

'Do nothing' option

20. In this scenario, we would be reliant, as now, on current voluntary arrangements. Voluntary arrangements have been reasonably successful in obtaining valuable information on, for example, independent pharmacy purchase prices, and ex-factory/ex-wholesaler prices for some of the larger volume generic medicines. However, as noted elsewhere, this does not give comprehensive coverage and there is no reserve power to require the players in the supply chain to provide the information required both to ensure the continued effective running of the reimbursement system for dispensers and to identify and tackle problems with the system.

Overview of information requirements considered

21. The Department is currently considering information requirements within four broad areas as summarised in the table below:

Requirement	Rationale
Routine information on prices and volumes	The primary aim of this collection is to ensure the continued effective running of the drug reimbursement system. The Department would also be able to use this information to better understand the supply chain for medicines and ensure value for money in the supply chain.
On request provision of price and volume information within 24 hours	The aim of this collection is to support the setting of concessionary prices (an important part of the drug reimbursement system)

Requirement	Rationale
On request provision of information related to individual transactions in connection with any health service product (transaction-level information).	Where the Department has concerns over a part of the medicine supply chain, it will be able to request further information to better understand what is happening. Ultimately this will enable the Secretary of State to secure greater efficiency and effectiveness in the supply chain for health service medicines.
On request provision of cost information	

22. The three options considered in this impact assessment only concern differences in the requirements for **routine information on prices and volumes** and **on request information related to individual transactions** as follows:

    - **Option 1**: make regulations that require (i) routine provision of information about generic medicines and special medicinal products at **product-level** and (ii) non-routine information provision about any health service product at transaction-level

    - **Option 2**: make regulations that require (i) routine provision of information about generic medicines and special medicinal products at **transaction-level** and (ii) non-routine information provision about any health service product at transaction-level

    - **Option 3**: make regulation that require routine provision of information about **all health service products at transaction-level** (non-routine information provision would not be required under this option)

    Annex C further summarises these key differences between the options.

23. Under all the options we have assumed we would in addition require:
    - On request provision of cost information,
    - On request provision of price and volume information within 24 hours

Enforcement

24. In order to secure compliance, it is also proposed that, under any of the options above, the Department should be able, if necessary, to impose penalties on any operators in the supply chain that refuse to comply. The proposed penalties are:

    - If the total UK sales turnover is less than £100m: £2,500 per day for the first 14 days, and £5,000 per day thereafter.

    - If the total UK sales turnover is over £100m: £5,000 per day for the first 14 days, and £10,000 per day thereafter.

25. Where a penalty enforcement notice is issued, suppliers would have the right to appeal to a tribunal established in accordance with regulations made under section 265(5) of the 2006 Act: the Health Service Medicines (Price Control Appeals) Regulations 2000, as amended.

Other considerations

26. In addition to the options outlined above, the consultation document also seeks views on a number of variations to these options as follows:

27. Whether, under option 1, there is any value in also continuing with the voluntary arrangements for companies to provide the Department with information on some unbranded generic and unlicensed medicines (schemes M, W and specials). This is not examined as a standalone option in this impact assessment as it is not anticipated that the use of voluntary agreements alongside the statutory scheme would materially affect any of the anticipated costs and benefits associated with this option (since the same data requirements would need to apply to both the voluntary and statutory scheme).

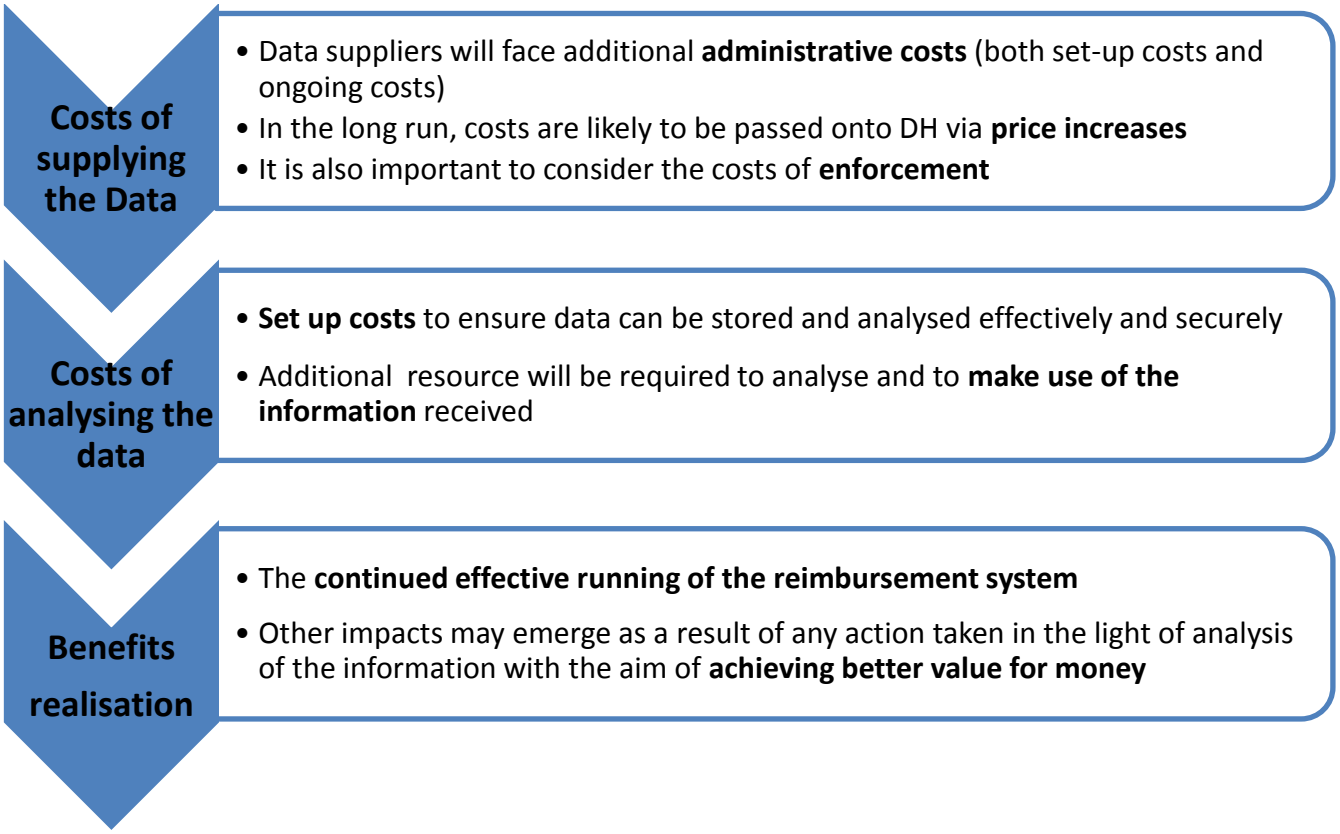
As part of the consultation, the Department is seeking views as to whether there are any significant differences in costs or benefits from continuing to run a voluntary scheme.

28. The frequency of the routine collections is currently proposed to be quarterly in order to reflect the timing of the existing voluntary scheme M and scheme W collections. However, the Department would also like to understand what the potential impacts might be of moving to a more regular data collection (e.g. monthly). Annex A of this impact assessment briefly considers the potential impact of such a scheme. However, further information will be sought as part of the consultation.

29. The Department is also considering a regulatory approach to provision of information about supply shortages. Annex B of this impact assessment separately considers the likely costs and benefits of this option.

Estimated impacts

30. The diagram below illustrates the main impacts associated with these proposals. The remainder of this section examines the likely size of these impacts for each of the options described above.



31. In addition, the proposed regulations will also require certain information to be kept and recorded by all actors in the supply chain for health service medicines, medical supplies and other related products. The information would need to be kept for 6 years. It is not anticipated that these requirements to record and store information would impose any additional costs on suppliers. This is because these requirements are already in line with the existing requirements for tax purposes to keep records for 6 years.

Routine information on prices and volumes – costs of supplying the data

Option 1: Routine price and volume information about unbranded generic medicines and unlicensed medicines (specials) at product level

32. Currently, under the voluntary scheme M and scheme W arrangements, there are 19 manufacturers and 7 wholesalers who provide quarterly data to the Department on up to approximately 1000 products. Similarly under the voluntary specials collection, 8 specials manufacturers provide data on a

maximum of approximately 450 products. Under the new proposal it is anticipated that the existing voluntary suppliers would need to return data on a larger number of products.

33. In addition, suppliers who are not part of any existing voluntary agreements would now also be required to provide data. Based on data from the Medicines and Healthcare products Regulatory Agency (MHRA) on the number of license holders, this would potentially equate to:

Type of Company	**License-holders in UK**
Medicines Manufacturers	772
Wholesalers	2155
Specials	282

34. However, although the total number of license holders is known, it is not known how many of these companies would actively be engaged in the supply of the products within scope of this requirement. Where companies are not engaged in the supply of these products, they would not be required to return any information under these regulations.

35. Following further discussions with MHRA, it is estimated that it is likely that less than 100 wholesalers might regularly wholesale generic medicines. In addition, based on an examination of the number of suppliers registered in the Dictionary of Medicines and Devices (dm+d) database, this suggests that there may be a further 100 or so manufacturers of generic medicines[2]. With no further information about the number of specials manufacturers, we continue to use the full 282 figure. Finally, we estimate that there will be approximately 55 importers of unlicensed medicines (specials)[3].

36. In terms of the additional costs for existing voluntary suppliers, our analysis of the costs associated with the existing voluntary agreements suggested that this amounts to approximately £40,000 per year for members of scheme M, £65,000 per year for members of scheme W and £20,000 per year for companies providing information for specials[4]. Under the new proposals, it is anticipated that the total number of products for which information would be required would increase to approximately 3320 for generics and to 2500 for specials, and so at first glance, it might be reasonable to assume that the total cost to these suppliers would similarly scale up in proportion to the increase in the number of products.

    However, a more detailed examination of the process of data supply suggests that only a handful of the steps might increase in proportion to the size of the data collection, whilst other steps are likely to require a fixed amount of time irrespective of the size of the collection. Our initial assessment of the stages most likely to be affected is as follows:

Stage	**Impact of more product lines?**	**Rationale**
Refresh and review of requirements	Fixed	Review of previous submissions and creation of working folders unlikely to be affected by size of collection
Preparation of the data	Fixed	We assume that the initial data extract of the sales data would be largely automated.
Data gathering	Possible scaling up	There may be some increased time required to match company and DH product codes to ensure the correct products are selected.
Data cleansing	Most likely to scale up	The larger the data collection, the more errors to be queried and checked
Data validation	Most likely to scale up	The larger the data collection, the more errors to be queried and checked
Final sign off	Possible scaling up	The sign off process may be slightly extended as there will be a larger number of products to review
Responding to queries from DH	Most likely to scale up	The larger the data collection, the more errors to be queried and checked

[2] However, as the list of suppliers on the dm+d database is incomplete, this figure should be treated with caution.

[3] Based on the MHRA Report on the Import of Unlicensed Medicines, which found that a total of 15545 notifications were received from 88 importers for the period 01 Jul 2016 to 30 Sep 2016. Of these, it is estimated that approximately 60% will hold a wholesaler license, whilst the remaining 40% will hold a manufacturing license.

[4] Note that these figures differ from those in the impact assessment accompanying the primary legislation. This is due to further refinement of the methodology used.

37. Based on this assessment, we estimate that the total additional cost for all existing voluntary providers would be approximately £211,000 per year[5].

38. In addition, it is likely that there would be some initial one-off set up costs for these providers – for example, to familiarise themselves with the new data requirements, and to reconfigure their systems in order to match up the DH product codes with their company product codes. Previous feedback from scheme M members has suggested that this latter exercise could represent a substantial undertaking. In the absence of further evidence on the likely cost of this exercise, our initial starting assumption is that this could represent the equivalent of 16 hours (2 days) of work for an analyst to set up. Summed across all suppliers, this would equate to a total one-off costs of approximately £48,900 (using the same hourly wage assumptions as above and including non-wage costs of 30%[6]).

39. For suppliers who are not part of any existing voluntary agreement, we anticipate that the set up costs are likely to be much higher to reflect the increased time required to familiarise themselves with the requirements and set up their systems to accommodate the request. Our initial starting assumption is that this could represent the equivalent of 35 hours (1 week) of work for an analyst to set up. In addition, it is likely that some senior input is likely to be required in order to sign off the arrangements, and we assume that this would equate to about 5 hours' worth of time or a total one-off cost across all new suppliers of £491,000 (using the same hourly wage assumptions as above and including 30% non-wage costs).

40. Finally, in terms of the ongoing costs of data supply, we apply the assumption that these costs will be driven by the size of the data collection. An analysis of the Dictionary of Medicines and Devices (dm+d) database suggests that on average, manufacturers who are not part of any existing arrangements would on average be likely to return data for just over 20 products under the new proposals (the corresponding figure for wholesalers is just over 230). Comparing this to the existing voluntary scheme costs (where on average, manufacturers return data for an average of 100 products each and wholesalers 780), and using our above assessment of how costs might change with the size of the data collection, we estimate that the total cost across all new data suppliers is likely to be in the region of £778,000 per year (using a the same methodology to scale the cost estimates for the average number of products in the data collection as discussed above).

41. Adding up the different cost estimates above, this suggests that the total annual cost across all suppliers in scope of this requirement could be in the region of **£989,000.** In addition, there may be total one-off set up costs of approximately **£540,000**.

Option 2: Routine price and volume information about unbranded generic medicines and unlicensed medicines (specials) at transaction level

42. For those required to supply transaction level data on a routine basis, there are likely to be set up costs associated with developing new processes and configuring their systems in order to be able to meet the new data request. Initial discussions with suppliers have suggested that these costs could vary hugely for different organisations – whilst some suppliers may already have very sophisticated systems set up that could generate the requested data with minimal modifications required, others may need to undergo much more substantial adjustments in order to be able to provide such data on a regular basis.

43. As part of the consultation we intend to seek further information to understand the costs of routinely providing transaction level data. To provide a starting point for these discussions, we have made an initial assumption that these set up costs would equate to additional staff time of between 35 and 70 hours, with additional financial costs (e.g. to develop new IT solutions) of between £0 and £5,000. Overall, this would suggest an initial total cost estimate of between **£410,000 and £3,510,000** across all affected suppliers (with a mid-point estimate of £1,960,000).

[5] Calculated by scaling our estimates of costs of data provision under the existing scheme M agreement, using the assumptions outlined above and an estimated hourly wage rate of approximately £17 (based on figures from the Annual Survey of Hours and Earnings 2016), plus 30% non-wage costs.

[6] Based on the Better Regulation Executive's Standard Cost Model – see: http://webarchive.nationalarchives.gov.uk/20121106104725/http://www.bis.gov.uk/files/file44505.pdf

44. In terms of the ongoing costs of data supply, it is not known how these would be affected compared to the product level data requirement outlined in option 1. It is possible that the larger size of the data at transaction level would increase the time required to supply the data by increasing data processing times and increasing the amount of data cleaning required. However, on the other hand, it is also possible that processing times may in fact reduce as the provision of transaction level data would mean that companies would no longer need to manually process the data in order to calculate figures such as product level totals. In the absence of further information at this stage about these potential costs, we make the simplifying assumption that the ongoing costs of providing transaction level data would be similar to the costs associated with providing product level data (approximately **£989,000** per year).

Option 3: Routine price and volume information at transaction level for all health service products

45. Under this option, routine transaction level information would be required from all UK suppliers, not just those related to the supply of generic or unlicensed medicines. As a result, we anticipate that this proposal would impose costs on organisations as follows*:

Medicines manufacturers	772
Appliances	9156
Parallel Importers	57
Wholesalers	2155
Specials	282
Community pharmacies (England only)	11800
GP practices that dispense medicines (England only)	1000
Total	**25222**

*Whilst the above list encapsulates the main types of suppliers of health service products, it is important to recognise that this list may not be complete. There are others who supply healthcare products to patients such as hospital pharmacies, home care companies, ambulances, prisons etc. who could also potentially be considered to be UK suppliers and so may be caught by the requirements (both for non-routine information provision as described below, and routine information provision in option 3).

46. As in option 2, we will seek further information as part of the consultation in order to better understand the costs associated with routinely providing transaction level data. As a starting point, we have used the same cost assumptions as in option 2. Applied to the larger number of organisations potentially within scope of the regulations under option 3, this suggests that:

    - Set up costs could be in the region of **£19,300,000 to £165,000,000** with a middle estimate of £91,900,000

    - Ongoing costs of data supply could be in the region of **£39,100,000** per year.

47. However, as discussed in the consultation document the Department will explore options to introduce more automation into the process of data submission, with the aim of minimising the costs of supplying data to the Department. Further work will be required with suppliers to understand the existing data systems that they use and the feasibility of putting in place more automated systems for data collection. However, it is hoped that this will help to reduce the burden on suppliers under all of the options discussed in this impact assessment.

Routine information on prices and volumes – costs of analysing the data

48. As the quantity of data that the Department receives, it is anticipated that this will also increase the costs to DH of developing additional systems to collect, process and analyse the data. The cost of setting up such a system is discussed below.

49. In addition, it is anticipated that additional staff time would be required to run the drug reimbursement model in order to properly make use of the larger quantity of data that will be available. For example, where manual reconciliation of the model is required, this is likely to involve the investigation of a larger quantity of data. Based on an assessment of the number of additional hours of work that this could

take, using average DH pay scales, it is estimated that this could equate to a cost of approximately **£12,300** per year.

50. In terms of the different options for the routine data collection, it is not known if additional time would be required to run the drug reimbursement model using transaction-level data. This would depend on the nature of the new methodology and the degree of automation that could be built into the model. As a starting point, we therefore assume that these costs would be the same under all of the options.

51. In the long run, it is possible that the increased quantity of information on generic medicine prices and volumes could enable further refinements to the methodology for setting the drug tariff or further reimbursement reforms. This would in turn have further resource implications for the Department, both in terms of developing these policy options and in terms of the day to day running a modified reimbursement system. However, these costs are considered to be second order effects, and are not further quantified in this impact assessment. Any such proposals would be subject to a separate decision making process, including the need for substantial further consultation with stakeholders, and a new impact assessment to be developed.

Cost to DH of setting up a new routine data collection

52. The Department current manually collates and checks the data submissions for the voluntary scheme M, scheme W and specials data collections. As the number of organisations and size of the data returns grows, this will no longer be practical. As such, it will become necessary to develop a data collection platform in order to handle the collection and processing of the routine data returns.

53. The Department is currently exploring options for how such a system could operate, and as such, the costs of such a system remain highly uncertain. Based on initial discussions with a number of organisations, the following approaches have been explored:

    - **A low cost approach** – an existing web platform would be used to collect data returns in a spreadsheet format. The platform would then attempt to automatically collate these returns into a larger database for further analysis using the Department's existing software packages. It is anticipated that such a simple system would cost less than £100,000 to set up. However, we have been advised that such a system would also incur significant administrative costs as, where the system fails to automatically collate a return, this would have be manually investigated. Past experience from other data collections have shown that the failure rate could be as high as 50%. Due to the risk of very high administrative costs, this approach has been ruled out.

    - **Adaption of existing data collection systems** – we are working with other NHS organisations with experience in data collection to explore the feasibility of adapting one of their existing systems to create a new data collection platform. Based on discussions so far, it is anticipated that costs are likely to be in the hundreds of thousands and potentially reaching several millions of pounds under option 3. This is likely to be our preferred approach; however this would be subject to ongoing work to fully explore and understand the feasibility and cost of this option.

    - **Commissioning a new bespoke data collection system** – this is considered to be the highest cost option as it would involve building a new system from scratch. Although our preferred approach would be to make as much use of existing systems as possible, this approach remains on the table as we continue to explore the feasibility and cost of all options. At present, our understanding is that this option could cost up to £2m.

Optimism bias

54. As based on standard HM Treasury Green Book guidance, it is recognised that there is a demonstrated systematic tendency for IT costs to be underestimated. To address this tendency, HM Treasury recommend that explicit adjustments are made to project costs. For equipment/development projects, HM Treasury recommend that an upper bound adjustment of 200% is made to the estimated

capital expenditure. This figure can then be adjusted downwards towards the lower bound estimate based on a number of mitigation factors as set out in the guidance[7].

55. The table below summarises our selection of the most appropriate adjustment levels for each of the options:

Mitigation factors	Contribution to Optimism Bias	Option 1	Option 2	Option 3	Rationale
Complexity of contract structure	7	0	0	0	Unknown at present so mitigation applied
Late contractor involvement in design	7	0	0	0	Unknown at present so mitigation applied
Poor contractor capabilities	4	0	0	0	Unknown at present so mitigation applied
Information management	5	0	0	0	Unknown at present so mitigation applied
Design complexity	10	1	0.5	0	Option 1 closely mirrors other routine data collections in the NHS so design complexity or innovation is not felt to be an issue and the scope of the project is expected to be well defined. Under option 2, the larger size of the data collection means that these risks are only partially mitigated.
Degree of innovation	17	1	0.5	0	
Inadequacy of business case	18	1	0.5	0	
Project management team	5	0	0	0	Unknown at present so mitigation applied
Poor project intelligence	4	0.5	0	0	Partially mitigated for as option 1 collection will mirror voluntary collections
Legislation	5	0	0	0	Unknown at present so mitigation applied
Technology	18	0	0	0	Unknown at present so mitigation applied
Reduction in optimism bias		47%	23%	0%	
Level of optimism bias		106%	155%	200%	

Overall estimates

56. The table below summarises our final estimates of the potential IT costs associated with option. In line with HM Treasury guidance, set up costs are explicitly adjusted for optimism bias. The low cost estimate is based on our best understanding of the likely costs of the adaption of an existing data platform approach outlined above, whilst our high estimate is based on our best understanding of the likely costs of the commissioning a bespoke system approach. Our best estimate is constructed by taking a weighted average of the estimated costs of these two scenarios – based on an internal assessment of the relative likelihood of the two scenarios.

		Option 1	Option 2	Option 3
Set up costs	Low	£391k	£484k	£570k
	High	£3m	£4.6m	£5.9m
	Best estimate	**£1.1m**	**£1.5m**	**£1.9m**
Ongoing annual costs	Low	£30k	£30k	£30k
	High	£0.9m	£1.8m	£2.7m
	Best estimate	**£0.3m**	**£0.5m**	**£0.7m**

[7] See https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/191507/Optimism_bias.pdf

Other costs

57. In addition to the costs of setting up and running a new data platform, it is anticipated that regular administrative support will be required in order to manage the data collection process (e.g. responding to queries from suppliers) and to undertake data cleaning. The larger the size of the data collection, the more resource that will be required to undertake this task.

58. In addition, it is likely that significant DH resource will be required to manage the process of procuring the new data collection platform, as well as undertaking other preparatory work to support the new data collection (for example to work with suppliers to clarify the products that are within scope and to update the drug reimbursement methodology for use with the new data available). As above, it is expected that the larger the data collection, the increasing complexity of this work, and thus the greater the resource requirement.

59. The following table sets out our initial assessment of the number of people required to undertake these tasks under the different options:

		Option 1	Option 2	Option 3
Administering the data collection	Number of people	2	4	8
	Total cost (per year)	**£62,900**	**£140,000**	**£295,000**
Initial 0preparatory work	Number of people	1	2	3
	Duration	6 months	6 months	6 months
	Total cost	**£24,100**	**£48,200**	**£72,300**

Costs relating to non-routine price and volume information within 24 hours requirement

60. We propose to introduce a requirement on manufacturers and wholesalers to provide information within 24 hours about available volumes and prices of generic medicines and special medicinal products listed in part VIII of the drug tariff.

61. Currently, when the Department is considering setting a concessionary price following a request from the PSNC, it instructs the NHS BSA to seek information from suppliers on a voluntary basis about the available volumes and prices. The Department then uses this information to decide whether a concessionary price needs to be set and what that price should be which is then agreed with the PSNC.

62. Not all suppliers provide the NHS BSA with information and therefore concessionary prices are based on information from only a part of the market. The requirement to provide information on available volumes and prices of generic medicines and special medicinal products would help make the concessionary price setting process more robust with more information to base decisions on.

Costs of supplying the data

63. In order to determine whether a generic medicine should be granted a price concession and 'No Cheaper Stock Obtainable' (NCSO) status, the NHS Business Service Authority (NHS BSA) currently contact approximately 40 suppliers each month to seek information about prices and volumes for those drugs under consideration.

64. At present, it is estimated that approximately one third to a half of those surveyed fail to provide the required information to the NHS BSA. Under these new proposals, these arrangements will be put on a statutory footing and so it is expected that all suppliers would now need to provide the required information.

65. Overall, it is not anticipated that this data request would place a significant burden on those providers affected since the information requested (on price and volumes) is expected to be readily available to companies and the number of products is not expected to be large. At present, NHS BSA estimate that the time requirement for companies would fall between the region of a matter of minutes to 2 days – depending on whether the information is requested via a formal data request or through a phone call.

66. Based on an average hourly wage of just under £17, plus 30% for non-wage costs[8], we therefore anticipate that the additional cost to suppliers of meeting the new statutory requirement to be approximately **£17,600**.

Costs of analysing the data

67. It is not anticipated that there would be any significant change in the costs of processing and analysing the data in order to set price concessions and NCSO status.

68. Instead, NHS BSA have indicated that these proposals could result in a cost saving if the regulations were to reduce the amount of follow up and chasing required to obtain the information from each supplier. Overall, the NHS BSA estimate a time saving of approximately 25-50%, which would equate to an annual saving of approximately **£8,770**.

Costs relating to the non-routine information about price and volume requirement

Costs of supplying the data – option 1

69. Under these requirements, any UK supplier of health service medicines, medical supplies or other related products could potentially be required to supply transaction level information about prices and volumes.

70. The Department already collects transaction-level information on an on-routine basis from a sample of pharmacies every month for the margins survey. The margins survey identifies the buying margin in community pharmacy i.e. the profit pharmacies earn on dispensing drugs through cost effective purchasing. The arrangements for conducting the margins survey are agreed with the Pharmaceutical Services Negotiating Committee (PSNC). There are existing requirements on community pharmacies in the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013[9] that require community pharmacies to provide this information. However, the regulations would provide us with a stronger legal basis for enforcing the provision of information.

71. The potential legal costs associated with changes in enforcement are discussed later in this impact assessment. It is not anticipated that changes in enforcement would affect the total cost to pharmacies of supplying data for the margins survey. This is because the total number of pharmacies surveyed each month is fixed - where a pharmacy fails to comply with the requirement, a new pharmacy would be contacted instead. The main effect of improved enforcement would instead be to improve confidence in the quality of the data, potentially reduce administrative costs associated with running the survey (if fewer pharmacies need to be contacted) and help to ensure the continuity of the reimbursement system and mitigating the risk of pharmacies choosing not to cooperate in the future.

72. To support the Department in understanding and identifying potential issues in the supply chain for medicines, it is anticipated that other UK suppliers will also be required to return information on a non-routine basis. The overall cost associated with meeting these requests will depend on the nature of the data requested, the frequency of the requests, and the number of suppliers affected. The table below sets out our initial assumptions in this area:

	Low	**High**	**Rationale**
Number of requests per year	25	75	DH's initial assessment of the potential number of requests (excluding requests to Pharmacies under the margins survey – see below)
Number of suppliers in scope per request	5	10	The dm+d database suggests an average of just under 5 suppliers per product, however, this does not include the potential for other organisations such as dispensers to also be in scope
Time required to collect information (hours)	16	16	As a starting point, we assume the overall time requirement would be similar to those currently estimated for the voluntary scheme M and scheme

[8] Based on data from the Annual Survey of Hours and Earnings 2016 on the gross median hourly wage for the Pharmaceutical Manufacturing and Wholesale industries

[9] http://www.legislation.gov.uk/uksi/2013/349/contents/made

	Low	High	Rationale
			W collections. In reality, costs could be higher due to the high familiarisation costs associated with non-routine data collections. On the other hand, as these non-routine requests are likely to focus on a much smaller number of products, they could be less costly to put together.
Total costs	**£43,600**	**£262,000**	Based on an hourly salary of approximately £17, plus 30% non-wage costs.

Costs of supplying the data – options 2 and 3

73. Under **option 2**, non-routine information requests for transaction-level data would only need to be made in respect of branded medicines and other medical suppliers (since information on generic medicines would be received on a routine basis). Based on a very rough split of the spend on unbranded vs branded medicines, this suggests that the number of requests could fall to approximately between 18 and 55 compared to under option 1. The corresponding cost to suppliers of meeting these requests would be approximately **£32,200 to £193,000**.

74. Under **option 3**, no non-routine information requests for transaction-level data would be required since transaction-level information would be required from all suppliers on a routine basis. As a result, the cost to suppliers of non-routine transaction-level requests would be **zero**.

Costs of analysing the data

75. It is anticipated that non-routine transaction level data requests would be used to support the Department in understanding and identifying potential issues in the supply chain for medicines. This would in turn allow the Department to begin to develop policy options to address these issues and improve the efficiency and value for money of the system. In order to undertake these tasks, we estimate that:

    - Under **option 1** this might require a team of 2 people working full time, at an approximately cost of **£96,500** per year (including 30% non-wage costs).

    - Under **option 2**, although the number of non-routine transaction-level data requests would be smaller, the overall level of transaction-level data would increase through the routine data collection. To fully analyse all of this data, it is anticipated that the resource required to do this would increase to a team of 5 people, at a total annual cost of approximately **£241,000** (including non-wage costs).

      Under **option 3**, although no non-routine requests for transaction-level data would occur, the Department would still require additional resource to properly analyse the information received through the routine collection in order to understand whether there are issues in the supply chain and consider options to address these. It is anticipated that the resource required to do this would increase to a team of 12 people, at a total annual cost of approximately **£579,000** (including non-wage costs).

Costs relating to non-routine information about costs

Costs of supplying the data

76. Under this proposal, the Department could require any UK supplier to provide information about costs incurred in connection with the manufacturing, distribution or supply of a health service product. These costs would include for example the costs of manufacturing a product, the costs of research and development and the costs of distributing a product.

77. In order make such a request, the Health Service Medical Supplies (Costs) Act 2017 requires the Secretary of State to issue an information notice. A UK producer would be able to appeal against the information notice (see chapter on enforcement) if they believe the information requested is beyond the scope of the legislation. These legal costs are considered later on in this impact assessment.

78. It is anticipated that the Department may choose to request information on costs for a number of reasons including:

    - if the Department has concerns about the high price of an unbranded generic medicine and it wanted the manufacturer to demonstrate that the costs related to making and marketing the product are proportionate to the price charged before

    - where companies in the statutory scheme ask for a price increase for a particular product and the Department wants to assess whether this is justified. This would however be part of the statutory scheme regulations that we are separately consulting on

    - where the Department has no visibility over costs in the supply chain and wants to assure itself that the market is working effectively

79. However, the number of times per year where the Department would seek to request information on costs is highly uncertain and difficult to predict as it will depend on a number of different factors including the number of cases where the Department might have a concern about the price of a generic medicine (which in turn depends on company pricing behaviour) and the Department's resourcing decisions. Based on these considerations, the Department's best estimate at present is that there could be between 20 and 30 requests for information on costs per year. However, whilst this figure represents an average annual figure, it is possible that the actual number of requests in a particular year could vary significantly. For example, if the Department chose to conduct an exercise to understand the drivers of price increases of generic medicines across recent years, this might require a larger one off data collection to occur. However, at this stage, it is not possible to anticipate to what extent these larger one off exercises might occur and it is also possible that substantially fewer requests could take place in a given year.

80. In terms of the cost to suppliers of complying with the data request, our initial assumption is that this could take the equivalent of between 16 and 48 hours of staff time (i.e. 2 to 6 days). Based on an hourly salary of approximately £17, plus 30% non-wage costs, this would equate to a total cost of approximately **£6,980 and £31,400** per year.

Costs of analysing the data

81. It is anticipated that it would be necessary for the Department to employ 1 additional person in order to manage the process of issuing information notices, process the information that is returned, and to consider the Department's response to the information. It is anticipated that the total annual cost of this would be **approximately £63,800**.

82. Due to the complexity of the cost information, it is also likely that specialist advice from an accountant would be required in order to analyse the information. Based on an hourly charge of £100 per hour, and an assumed time requirement of 16 hours of work per case, this equates to a cost of approximately between **£32,000 and £48,000 per year.**

83. In summary, we therefore estimate that the total cost to the Department of analysing and processing information in relation to costs would be between **£95,800 and £112,000.**

Costs of enforcement

84. The proposed regulations would also include a provision that the Department should be able, if necessary, to impose penalties on any operators in the supply chain that refuse to comply with the information requests. Where a penalty enforcement notice is issued, suppliers would have the right to appeal to a tribunal established in accordance with regulations made under section 265(5) of the 2006 Act: the Health Service Medicines (Price Control Appeals) Regulations 2000, as amended.

85. These proposals could potentially result in additional legal costs to both UK suppliers and the Department of Health. Under current arrangements with the Ministry of Justice, any tribunal costs would also be funded by the Department of Health.

86. In addition, the appeals regulations provide that either the SofS or the appellant may after the tribunal's decision bring a further appeal to the High Court. We are proposing that the implementing regulations should provide explicitly for recovery of penalties or recoverable sums not paid by the manufacturer or supplier as a civil debt due to the Secretary of State. Any such claim would be pursued through the county court or the high court depending on the amount. This could potentially also result in additional legal and court costs that would need to be taken into account.

87. However, it is not anticipated that the Department would need to impose penalties, and as a result the number of appeals (and cases to the high court) is also expected to be zero. This assessment is based on the experience of existing information requirements that have applied to manufacturers of branded medicines since 2007. Here the same maximum penalty levels applied and compliance has been very good. The Department has not had to impose any penalties or had any case appear before the tribunal.

88. Although we have initially applied this assessment across all three options, it is important to note that, under option 3, the risk of non-compliance and thus the need for enforcement activity may be higher due to the larger number of organisations within scope of the routine information requirement. This is an issue we intend to explore further as part of the public consultation.

89. Finally, UK suppliers who are issued with an information notice to provide non-routine cost data to the Department also have a right to appeal the information notice to the tribunal. There is a potential risk that some providers may choose to appeal such notices. However, it is difficult to estimate how often this might occur. On the one hand it could be argued that requests for cost information would be viewed similarly by suppliers as requests for other data included in this impact assessment. In this case, we would assume that compliance with requests would be similarly high and so there would be very few appeals of the information notices. On the other hand, there is a risk that suppliers may view requests for costs information differently, and this may in turn result in a higher number of appeals for information notices. Based on an initial internal assessment, we estimate that there could be between 2-3 appeals a year. This figure would apply to all of the options, since the requirement for non-routine cost data remains the same across all options.

90. It is estimated that the cost of running the tribunal would be in the region of £4,500 per appeal, which in turn suggests a total cost to the tribunal of between **£9,000 and £13,500**.

91. In terms of legal costs, an analysis of DH costs of hiring Counsel for the PPRS Dispute Resolution Panel suggested that on average cost per case was approximately £1,700. Assuming that the Department would incur similar costs for information notice appeals, the total costs are estimated to be in the region of **£3,500 and £5,200**.

92. Finally, companies who choose to appeal an information notice will also incur legal costs associated with doing so. In the absence of further information, it is assumed that these costs are similar to those incurred by the Department. Where companies are successful at tribunal, the Department may be obliged to cover the company's legal costs. The likelihood of success is not currently known. Whilst the Department's view is that the 2017 Act clearly defines the scope of the information that can be requested, as a prudent assumption, this impact assessment considers the worst case, maximum cost scenario, whereby all legal costs fall on the Department.

Summary of costs

93. The following tables provide a summary of the costs associated with each of the proposed policy options (relative to the do nothing option):

Option 1		High	Low	Mid
Routine information on prices and volumes	Ongoing costs - existing providers			£211,000
	Set up costs - existing providers			£48,900
	Ongoing costs - new providers			£778,000

Option 1		High	Low	Mid
	Set up costs - new providers			£491,000
	DH costs - IT costs (set up)	£3,030,000	£391,000	£1,050,000
	DH costs - IT costs (ongoing)	£910,000	£30,000	£250,000
	DH costs - administering the data collection			£62,900
	DH costs - preparatory work			£24,100
	DH costs - processing			£12,300
Information within 24 hours	Costs to suppliers			£17,600
	Savings to BSA			£8,770
Non-routine information on prices and volumes	Costs to suppliers	£262,000	£43,600	£153,000
	Costs to DH			£96,500
Non-routine information on costs	Costs to suppliers	£31,400	£6,980	£19,200
	Costs to DH	£112,000	£95,800	£104,000
Enforcement costs	Costs to tribunal service	£13,500	£9,000	£11,300
	Legal costs	£10,500	£6,980	£8,730

Option 2		High	Low	Mid
Routine information on prices and volumes	Data supply - Ongoing costs			£989,000
	Data supply - Set up costs	£3,510,000	£410,000	£1,960,000
	DH costs - IT costs (set up)	£4,630,000	£485,000	£1,520,000
	DH costs - IT costs (ongoing)	£1,780,000	£30,000	£468,000
	DH costs - administering the data collection			£140,000
	DH costs - preparatory work			£48,200
	DH costs - processing			£12,300
Information within 24 hours	Costs to suppliers			£17,600
	Savings to BSA			£8,770
Non-routine information on prices and volumes	Costs to suppliers	£194,000	£32,300	£113,000
	Costs to DH			£241,000
Non-routine information on costs	Costs to suppliers	£31,400	£6,980	£19,200
	Costs to DH	£112,000	£95,800	£104,000
Enforcement costs	Costs to tribunal service	£13,500	£9,000	£11,300
	Legal costs	£10,500	£6,980	£8,730

Option 3		High	Low	Mid
Routine information on prices and volumes	Data supply - Ongoing costs			£39,100,000
	Data supply - Set up costs	£165,000,000	£19,300,000	£91,900,000
	DH costs - IT costs (set up)	£5,870,000	£570,000	£1,890,000
	DH costs - IT costs (ongoing)	£2,680,000	£30,000	£693,000
	DH costs - administering the data collection			£295,000
	DH costs - preparatory work			£72,300
	DH costs - processing			£12,300
Information within 24 hours	Costs to suppliers			£17,600
	Savings to BSA			£8,770
Non-routine information on prices and volumes	Costs to suppliers	£0	£0	£0
	Costs to DH			£579,000

Option 3		High	Low	Mid
Non-routine information on costs	Costs to suppliers	£31,400	£6,980	£19,200
	Costs to DH	£112,000	£95,800	£104,000
Enforcement costs	Costs to tribunal service	£13,500	£9,000	£11,300
	Legal costs	£10,500	£6,980	£8,730

94. Based on these costs, we calculate that the net present value of the costs of each policy option (relative to the do nothing option) are as follows:

	High	Low	Mid
Option 1	£25.3m	£12.8m	£16.5m
Option 2	£38.7m	£14.6m	£21.9m
Option 3	£539.2m	£365.3m	£445.2m

95. Option 1 is the lowest cost option as this option involves the smallest increase in the number of data collections compared to the do nothing option. On the other hand, option 3 represents the highest cost option due to the large number of suppliers who would be required to provide data routinely to the Department.

96. In terms of the cost to industry, the following table sets out the net present value of costs falling on business associated with each option:

	High	Low	Mid
Option 1	£11.8m	£9.7m	£10.7m
Option 2	£14.1m	£9.4m	£11.8m
Option 3	£501.4m	£355.8m	£428.6m

97. Option 1 is estimated to impose the lowest cost on industry in the high and mid cost scenarios. In the low cost scenario the lower cost to industry of option 2 is driven by the assumption that the routine transaction-level data collection does not involve any additional costs for industry compared to the product level collection, coupled with the reduced need for non-routine transaction-level data requests in option 2.

Ultimate societal value of the costs

98. Finally, it is important to note that although the initial costs of supplying the data will fall upon UK suppliers, in the long run it is possible that suppliers of generic medicines would respond to the increase in their running costs by putting up their prices. As the ultimate purchaser of health service products will be the NHS and Department of Health, we would expect that the ultimate effect of these cost increases to be increased expenditure on generic medicines. As the NHS budget is limited, an increase in expenditure in one part of the system can be expected to reduce the amount of funding available elsewhere to spend on health. Thus, the ultimate effect of this increased cost pressure for DH would be felt through a reduction in health elsewhere in the NHS. The latest available evidence suggests that for every £15,000 increased cost pressure on the NHS, one Quality Adjusted Life Year (QALY) is lost[10]. These health impacts are monetised using their estimated societal value of £60,000.

99. For branded products, cost pass through is less likely as the prices of branded medicines are less likely to be linked directly to costs. In the short run, increased costs are likely to result in reduced profits

[10] See https://www.york.ac.uk/media/che/documents/papers/researchpapers/CHERP81_methods_estimation_NICE_costeffectiveness_threshold_(Nov2013).pdf

for shareholders in these companies. In the long run, economic theory would suggest that these effects would disappear as market forces work to return profits back in line with the market rate of return. Although the exact duration of these transitional effects is unknown, it is assumed that they persist for the duration of this impact assessment.

100. On this basis, any increase in costs on branded products are assumed to affect the UK economy as follows:

- It is estimated that 30% of changes in cost would flow through into changes in profits (based on a similar assessment by the Department for Business, Energy & Industrial Strategy (BEIS) on the proportion of pharmaceutical revenue taken as profits). As the pharmaceutical industry is global, the majority of this change in profits will accrue to overseas interests. BEIS estimate that around 10% of drug spend is on domestic production. This suggests that only 3% of the change in costs would directly affect the UK economy via changes in profits. As shareholders are likely to have higher than average wealth, a distributional weight is applied to their loss of profit. Based on HM Treasury Green book guidance, and assuming that shareholders are on average in the fourth quintile of income, this gives a weighting of 0.7 to be applied to profits.

- Changes in costs may further have an impact on R&D expenditure. Applying the estimate that 36% of pharmaceutical company revenues are devoted to R&D[11] to our changes in cost and using the estimate that 10% of drug spend is on domestic production, this implies a 3.6% effect on R&D expenditure. Investment in R&D is not, of itself, a net benefit (as it represents deployment of resources that would otherwise have found some other use). However, there may be spill-over effects which generate net societal benefits compared with other uses. BEIS estimate the value of these additional benefits to be 30% of the value of the investment. Overall this implies that just over 1% of the increase in costs would be felt through reductions in R&D spill-overs.

101. Applying these considerations to our estimates of financial costs above, it is estimated that the ultimate societal cost impacts associated with these policy proposals are as follows:

	High	Low	Mid
Option 1	£100.9m	£54.1m	£66.6m
Option 2	£159.4m	£62.3m	£90.3m
Option 3	£550.9m	£322.6m	£406.6m

Impact on small businesses

102. In order to mitigate the burden of non-routine data requests on smaller businesses, it is proposed that small producers as well as GP practices may provide the requested information in the form of pre-existing documentation, including invoices. In the draft regulations a small producer has been defined as 'a UK producer with a total United Kingdom turnover of £5 million or less, as set out in their most recent statutory audited accounts'.

103. The processing and analysis of pre-existing documentation is likely to impose additional costs to the Department, however, these costs are unquantified as it is not known to what extent small producers may be called upon to provide non-routine information. However, the biggest risk is likely arise under option 3, as the wide scope of the organisations covered under this option would mean that a large number of small and medium enterprises could potentially be asked to provide information on a routine basis. In particular, the medical devices and diagnostics industry is recognised to comprise of a large number of SMEs.

Benefits

Impact on the reimbursement system

[11] BEIS analysis of ONS/BERD data

104. The proposed policy options would create a statutory replacement for many of the existing voluntary arrangements. This would have a number of benefits for the reimbursement system as follows:

- It ensures the continuity of the reimbursement system and mitigates the risk of companies choosing not to cooperate with the voluntary agreements in the future[12].
- The increased information flows proposed under each of the options will ensure that the reimbursement prices set are fully reflective of the market.
- Taken together, these two factors will improve the resilience of the reimbursement system

105. It is difficult to quantify the benefits associated with a continued and robust reimbursement system. However, existing evidence does provide some indication of the size of the benefits that the reimbursement system has delivered. A 2010 NAO report[13] examined the financial impact of the introduction of the Community Pharmacy Contractual Framework in April 2005 and concluded that, between 2005/06 and 2008/09, there had been a cost saving to the NHS of £1.8bn compared to the counterfactual scenario of retaining pre-Framework remuneration and medicines pricing arrangements. In addition, the report found that the productivity of pharmacies, with respect to core dispensing work, had increased by 8% over the four years examined. Whilst it is not clear whether these benefits would still be applicable in more recent times (especially as the counterfactual would now be argued to be very different), the report can still be argued to provide a useful indication of the potential scale of the benefits associated with a robust and well-functioning reimbursement system.

106. As well as improving the resilience of the reimbursement system, increased information flows may also reveal areas opportunities to reform or expand the reimbursement system. This could result in further improvements to the functioning and resilience of the reimbursement system, and potentially also lead to financial savings to the NHS. However, it is not possible to quantify these at this stage as it is not possible to anticipate what these reforms might be. The nature and extent of these opportunities would depend on what the new information collection reveals, and would also be subject to a full consultation process with stakeholders.

107. However, to put these potential benefits into context we have conducted further modelling to examine what level of annual savings the drug tariff would need to deliver in order to offset the estimated costs of each policy options. As it is likely that there would be a delay before any savings would be realised[14], we have conducted this modelling based on the assumption that savings would begin to accrue in year 3 of the policy.

Annual saving required (starting from year 3)		
Mid	Option 1	£2.5m
	Option 2	£3.3m
	Option 3	£67m
High	Option 1	£3.8m
	Option 2	£5.8m
	Option 3	£81.2m
Low	Option 1	£1.9m
	Option 2	£2.2m
	Option 3	£55m

108. Whilst options 1 and 2 require only modest annual benefits of up to approximately £2.5m - £3.3m per year to be realised in order for the policy as a whole to be considered value for money, the minimum required benefits associated with option 3 are much higher.

[12] Whilst the voluntary Scheme M, Scheme W and Specials data collections enjoy a good level of compliance, NHS BSA have reported more difficulties with obtaining the necessary information to set Concessionary Prices.

[13] The Community Pharmacy Contractual Framework and the retained medicine margin

[14] For example, due to the need to develop new policy options and consult on these

109. To provide further context for these figures, the table below presents these figures as a proportion of current spend on various elements of the drug tariff:

		Spend on Total Drug Tariff*	Spend on Category A	Spend on Category M	Spend on Category C	Spend on Unlicensed Medicines
		£4.82bn	£530m	£1.64bn	£2.66bn	£60m
Mid	Option 1	0.05%	0.47%	0.15%	0.09%	3.94%
	Option 2	0.07%	0.63%	0.20%	0.12%	5.22%
	Option 3	1.39%	12.74%	4.09%	2.52%	106.24%
High	Option 1	0.08%	0.72%	0.23%	0.14%	6.04%
	Option 2	0.12%	1.11%	0.36%	0.22%	9.24%
	Option 3	1.68%	15.43%	4.96%	3.05%	128.66%
Low	Option 1	0.04%	0.37%	0.12%	0.07%	3.06%
	Option 2	0.05%	0.42%	0.13%	0.08%	3.49%
	Option 3	1.14%	10.45%	3.36%	2.07%	87.17%

*Drug tariff spend based on figures for 2016-17 from the NHS BSA

110. Overall, this analysis highlights how the size of the required benefits grows as the expected costs of the policy increase. In our best estimate scenario, option 3 would require approximately 25 times the benefits as under options 1 and 2.

111. However, across the board, our analysis suggests that, relative to the total annual spend on the drug tariff, only very moderate annual savings would be required in order to offset the potential costs associated with each policy option. Even under the high cost scenario for option 3, annual savings equivalent to only 1.68% of the total annual spend on the drug tariff or 4.96% of spend on category M drugs would be required.

Development of new policy options

112. The other main benefit associated with these proposals will be that the increased information powers will allow additional information to be gathered, which will help to assure the Department that the supply chain for health service products provides value-for-money to the NHS and the tax payer. Following analysis of the data, this could result in new policies being developed to address any problems that are identified in the supply chain and ensure greater value for money for all. The potential may comprise:

- Financial savings to the NHS
- Greater resilience in the reimbursement system
- Greater resilience in the supply chain
- Reassurance that NHS is achieving value for money

113. However, as above, it is difficult at this stage to quantify these benefits as it is not yet known what policy options could be developed as a result of the analysis of the data. Any such changes would require further consultation with stakeholders and a further full impact assessment.

114. As a result, this impact assessment is unable to quantify these benefits. However, as above, some illustrative figures are given below to demonstrate the minimum size of the annual benefits that would be required in order to offset the estimated costs associated with each policy option. As before, we have assumed that benefits would not be realised until year 3.

		Annual saving required (starting from year 3)	Spend on all drugs (primary and secondary care)	Spend on all drugs (primary care)	Spend on generics (primary care)
			£16.8bn	£8.56bn	£3.21bn
Mid	Option 1	£2.5m	0.01%	0.03%	0.08%
	Option 2	£3.3m	0.02%	0.04%	0.10%
	Option 3	£67m	0.40%	0.78%	2.09%
High	Option 1	£3.8m	0.02%	0.04%	0.12%
	Option 2	£5.8m	0.03%	0.07%	0.18%
	Option 3	£81.2m	0.48%	0.95%	2.53%
Low	Option 1	£1.9m	0.01%	0.02%	0.06%
	Option 2	£2.2m	0.01%	0.03%	0.07%
	Option 3	£55m	0.33%	0.64%	1.72%

* Total drug spend based on 2015/16 figures from the Prescribing Costs in Hospitals and the Community Report published by NHS Digital. Other figures are for 2016/17 from the Prescription Cost Analysis dataset.

115. The table shows that, relative to the total annual drugs bill, the total annual savings required to offset the estimated costs associated with the different policy options considered appears to be very modest. Even under the high cost scenario, only an annual reduction equivalent to 2.53% of the total annual cost of generics dispensed by pharmacies would be required in order to offset the costs, whilst under Option 1, only a 0.12% saving would be required.

Societal valuation of benefits

116. It is important to note that this modelling has been conducted based on a consideration of financial value of costs and benefits rather than the social value. However, it is perhaps more instructive to re-consider this analysis using the ultimate societal valuation of the costs and benefits. The ultimate social impacts associated with the estimated costs of this policy have previously been discussed.

117. In terms of the ultimate social impact of benefits, the analysis becomes very complicated. For example, if financial benefits to the NHS are accompanied by losses to the sectors affected, the social value of the losses to shareholders in the sectors affected would need to be balanced against the social value of savings to the NHS budget. On the other hand, to the extent that any policies bring about more competitive markets and greater efficiencies, this could also bring some benefits to the sector.

118. In order to simplify the analysis, we make the simplifying assumption that all financial benefits to the NHS accrue via commensurate reductions in revenue for drug companies. To the extent that policy changes arising from the information gathered can also generate benefits for the pharmaceutical sector (e.g. by encouraging greater efficiency), the required level of societal benefits identified in our break even analysis below will be overstated.

119. The table below shows the new level of annual savings required in the NHS (assuming that they begin in year 3 of the policy) when full societal impacts are considered. Whilst the figures for options 1 and 2 are largely unchanged, there is a large drop in the required level of annual savings needed under option 3. This is because a significant proportion of costs under option 3 accrue to suppliers of branded products. As previously discussed, the societal impacts of these costs are heavily discounted as it is estimated that the large majority of these impacts will accrue to overseas interests.

Annual saving required (starting from year Costs to suppliers)		Financial basis	Societal basis
Mid	Option 1	£2.5m	£2.2m
	Option 2	£3.3m	£3m
	Option 3	£67m	£13.6m
High	Option 1	£3.8m	£3.4m
	Option 2	£5.8m	£5.4m
	Option 3	£81.2m	£18.5m
Low	Option 1	£1.9m	£1.8m
	Option 2	£2.2m	£2.1m
	Option 3	£55m	£10.8m

Risks

120. We have identified two main risks associated with the policy proposals. The first is that there could be inappropriately high cost burden on suppliers. This will of course depend on the amount and complexity of information requested. At present, option 3 represents the most costly option in terms of the complexity and quantity of the information required. However, there remains a risk that under any of the options, the burden of information collection is higher than anticipated. As part of the consultation we will continue to explore these costs with suppliers and also explore options around the mechanisms for transfer of data etc. in order to minimise costs, and ensure proportionality.

121. The second risk is that information is collected and no policy options emerge – i.e. the cost has been incurred when no subsequent (beneficial) government intervention is identified. This size of this risk rises in line with the anticipated costs of the proposal – the higher the costs of the policy, the greater the need to identify policy options in order realise benefits in order to offset these costs. Whilst it is entirely possible that the collection of more routine information under the higher cost policy options would provide more opportunities for issues to be identified and policy options developed, this may not materialise for a number of reasons. For example, resource constraints in DH could limit the amount of analysis of the data that can be undertaken, or it may be that more analysis simply fails to identify any further opportunities.

122. To mitigate this risk, it is important that the scope of the information powers is continually kept under review. If a data collection is found to offer no clear value to the Department, it should be discontinued. To this extent, option 1 appears to mitigate this risk most effectively as the collection of transaction-level data would be on a non-routine basis, meaning that there would be more pressure on the Department to be able to articulate a clear rationale for requiring the data. Similarly, it will be important that the Department continues to keep its resource requirements under review, to ensure that the level of resource devoted to data processing and analysis is appropriate and proportionate.

123. However, it is important to remember that there are also other important benefits associated with these policy proposals that are not contingent on the development of further policy proposals. For example, the regulations provide a statutory back-up to ensure the continuity of the current reimbursement system. It is also an intangible benefit to have reassurance across the NHS that value for money is being achieved.

124. Finally there is a risk that costs could be higher than anticipated if the exemption for small businesses to provide the requested information in the form of pre-existing documentation creates a large burden for the Department to process it. In particular, there is a high risk associated with Option 3, due to the wide scope of organisations require to routinely provide information under this proposal.

Choosing between the options

125. So far our break even analysis has indicated that only modest savings relative to the size of the drugs bill would be required for any of the options under consideration to deliver value for money. However, in order to make a judgement about which of the options might represent the best value for money, further information is required about the *relative* size of the benefits of each option. For example, would the additional information collected under option 3 generate sufficient additional benefits compared to option 1 in order to justify the additional costs?

126. At this stage, it is not possible to make such a judgement about the likely size of the relative benefits of each option as we do not know what the analysis of the information might reveal, and therefore what policy options could be developed as a result. On the one hand, it seems reasonable that the greater the amount of data that the Department collects, the more potential there is for analysis to be conducted and the deeper the understanding gained about issues the medicines supply chain. In turn, it could therefore be expected that this would lead to a wider range of (and perhaps improved) policy options to be developed. On the other hand, there is a risk that if benefits do not scale up in this way, this could place an inappropriately high cost burden on UK suppliers. This could occur due to factors such as:

- A lack of resource in DH to conduct analysis or take forward policy options (e.g. if further legislative changes are required, parliamentary time would be a constraint)
- DH might lack expertise to properly interrogate such large datasets
- The additional information collected may not indicate that are any further issues in the supply chain (i.e. a smaller data collection would have similarly identified the key issues)
- Data cleaning issues – the larger the size of the data collection, the longer the process of data cleaning. This could potentially result in significant delays in processing the data, meaning that there is a trade-off between the quantity and timeliness (and therefore relevance) of data.

127. Although it is not possible to determine at this stage which option might deliver the highest benefits relative to cost, the following table provides an indication of the size of the *additional* annual benefits that would be required for each of the higher cost options to deliver a benefit to cost ratio that is at least as good as the previous lower cost options.

		vs Option 1	vs Option 2
Option 2	Mid	£0.81m	
	High	£2.02m	
	Low	£0.27m	
Option 3	Mid	£64.5m	£63.7m
	High	£77.4m	£75.4m
	Low	£53.1m	£52.8m

128. When this exercise is repeated using the ultimate societal cost and benefit estimates, the corresponding figures are:

		vs Option 1	vs Option 2
Option 2	Mid	£0.8m	
	High	£1.97m	
	Low	£0.27m	
Option 3	Mid	£11.4m	£10.6m
	High	£15.1m	£13.1m
	Low	£9m	£8.7m

129. As was the case previously, the figures for options 1 and 2 remain largely unchanged whilst there is a large reduction in the incremental benefits required for option 3. As previously discussed, this is because a significant proportion of costs under option 3 accrue to suppliers of branded products. The societal impacts of these costs are heavily discounted as it is estimated that the large majority of these impacts will accrue to overseas interests.

Summary and conclusions

130. The main costs of the policy proposals are the costs to UK suppliers of providing the data to the Department, and the costs of the Department in processing, storing and analysing the information. Our initial cost estimates suggest that option 1 is the lowest cost option, whilst option 3 has significantly higher costs.

131. The proposed policy options all offer benefits in terms of ensuring the continuity of the reimbursement system, improving the resilience of the reimbursement system, improving resilience in the supply chain for medicines, and providing greater assurance that the NHS is achieving value for money. In addition, it is possible that there could be financial savings for the NHS resulting from the development of new policies based on the information received under these powers. Although it has not been possible to quantify these potential benefits, we have conducted some modelling to demonstrate the potential size of the benefits required, relative to current spend on the drug bill.

132. Overall, the analysis suggests that any of the proposed policy options could potentially represent value for money. However, under options 2 and 3, larger benefits would need to be realised in order to offset the greater estimated costs of these options. At this stage, it is not possible to make any further judgements about the likely size of the relative benefits of each of the options. On the one hand, the collection of more routine information under the higher cost policy options would provide more opportunities for issues to be identified and policy options developed, and therefore generate larger benefits (relative to cost). On the other hand, there are significant risks that if benefits do not scale up in this way, these policies could place an inappropriately high cost burden on UK suppliers. Based on this assessment, option 1 is considered to be lowest risk option that is most likely to deliver value for money. As such, it is recommended as the preferred option.

Annex A – consequences of moving to a monthly routine collection

A1. Throughout this impact assessment, we have assumed that all routine data collections could be on a quarterly basis, in line with the existing voluntary collections for scheme M, scheme W and the specials data collection. However, the consultation will also consult on the option of moving to a monthly data collection.

A2. The table below illustrates the potential net present value of the costs associated with such a move. However, at present, this remains a crude illustration of the possible costs as we have simply assumed that all of the ongoing costs associated with the policy options would be multiplied by 3. We have assumed that all one-off costs would be unchanged.

A3. However, in reality, this may not be the case. Instead, it may be that there are some efficiencies associated with running a monthly collection that mean that the additional cost is less than 3 times the cost of the quarterly costs. On the other hand, costs may increase by more than three times to reflect the additional investments in infrastructure that would be needed to supply data on such a regular basis. As part of the consultation, we will seek further information to better understand the consequences of such a move.

	High	Low	Mid
Option 1	£59.1m	£31.5m	£39m
Option 2	£88.8m	£34.7m	£49.4m
Option 3	£1262.9m	£1043.5m	£1134.8m

A4. The higher anticipated costs of a monthly collection would also require larger benefits to be realised. The table below illustrates the potential size of these benefits, relative to current expenditure on medicines. As before, relative to the size of the drugs bill as a whole, these benefits appear to be modest. However, in order for a monthly collection to be preferred over a quarterly collection, it must be further demonstrated that the monthly collection would offer substantial benefits over and above those that can be derived from a quarterly collection in order to justify the additional cost.

A5. In addition, it is worth bearing in mind that a monthly collection may have other drawbacks compared to a quarterly collection, for example, in terms of the accuracy of the data. This would need to be traded off against the benefits of increased timeliness of the data.

		Spend on all drugs (pharmacy)	Spend on all drugs (pharmacy)	Spend on generics (pharmacy)	Spend on Total Drug Tariff	Spend on Category A	Spend on Category M	Spend on Category C	Spend on Unlicensed Medicines
		£16.8bn	£8.56bn	£3.21bn	£4.82bn	£530m	£1.64bn	£2.66bn	£60m
Mid	Option 1	0.03%	0.05%	0.14%	0.09%	0.86%	0.28%	0.17%	7.18%
	Option 2	0.04%	0.07%	0.18%	0.12%	1.09%	0.35%	0.22%	9.10%
	Option 3	0.87%	1.54%	4.11%	2.73%	25.06%	8.05%	4.96%	208.94%
High	Option 1	0.05%	0.08%	0.21%	0.14%	1.30%	0.42%	0.26%	10.88%
	Option 2	0.07%	0.12%	0.32%	0.21%	1.96%	0.63%	0.39%	16.35%
	Option 3	0.97%	1.71%	4.57%	3.04%	27.89%	8.96%	5.52%	232.53%
Low	Option 1	0.02%	0.04%	0.11%	0.08%	0.70%	0.22%	0.14%	5.80%
	Option 2	0.03%	0.05%	0.13%	0.08%	0.77%	0.25%	0.15%	6.38%
	Option 3	0.80%	1.42%	3.78%	2.51%	23.04%	7.40%	4.56%	192.13%

Annex B – impact of requirement to provide information about supply shortages

1. The Department monitors shortages of medicines and works with the supply chain to manage shortages and put in place contingency arrangements where necessary. To prevent or mitigate any impact on patients it is important that the Department is made aware of any shortages that could impact on patient care.

2. The Department has agreed best practice guidelines for the notification and management of medicines shortages with the Association of the British Pharmaceutical Industry (ABPI) and the British Generic Manufacturers Association (BGMA). We estimate that under these guidelines manufacturers notify the Department about half of the shortages that impact on patient care. It is notable that in many instances the Department is informed about supply shortages from other parts of the supply chain when there is already an impact on patients and the costs of medicines.

3. This requirement seeks to put the existing voluntary guidelines for shortages on a statutory footing[1] and so would involve:

    - Requiring manufacturers to notify the Secretary of State of an interruption of the manufacture of a UK health service medicine that is likely to lead to a supply disruption with a direct impact on patients in the UK or any permanent discontinuation in the manufacture of a UK health service medicine. Manufactures would be required to provide the following information at least 6 months prior to the date of interruption or discontinuation, or if not possible as soon as practicable:

        i. Product name and presentation
        ii. Licensed/ unlicensed uses
        iii. Reason for shortage
        iv. Expected duration of shortage
        v. Quantity of remaining stock is left; both at manufacturer level and at the wholesale level, if known
        vi. Date for next delivery of new stock and quantity expected
        vii. Company's market share for this product
        viii. Steps taken/ planned to address shortage including communication plans
        ix. Point of contact within company who can provide regular updates and respond to any ongoing queries from DH on the product in question.

    - Require manufacturers and wholesalers to let the Secretary of State know in case of supply disruptions the available volume of the product they hold within 24 hours.

4. The aim of the first of these requirements is to ensure that the Department is notified earlier of any potential medicines supplies issues. This would allow the Department to better plan its response to potential supply issues and issue the necessary communications to the NHS in order to mitigate the impact on patients and the NHS. At present, it is estimated that there are between 200-300 significant medicines supply issues per year, of which the Department receives advanced notification in approximately 50% of cases. This means that in many cases, the Department does not become aware of a medicine supply issue until it is already taking place, thereby missing opportunities to try to prevent the issue from materialising in the first place.

Costs of supplying the data

5. It is not anticipated that the process of notifying the Department of potential medicines supply issues would place a significant burden on manufacturers as the information required by the Department is relatively straightforward. We anticipate that, at most, 30 minutes of staff time might be required in order to gather the necessary information and send it to the Department (most likely via email). Applying this figure to the 50% of cases above where notifications are currently not received, implies a

[1] The guidelines can be found here www.abpi.org.uk/our-work/library/guidelines/Documents/NMMS.pdf.

total cost to manufacturers of between **£1,090 and £1,640** (based on an average hourly wage of just under £17 and 30% non-wage costs).

6. Turning to the second of these requirements, as part of the process of managing and responding to medicine supply issues, the Department will often contact manufacturers and wholesalers in order to understand the level of stock available. The aim of the second requirement is to improve the speed and reliability of these information flows. At present, there can be significant delays in the Department receiving the necessary information, meaning that the Department has to spend significant resources following up with suppliers. As a result of this, the information received is often incomplete.

7. It is not anticipated that this requirement would place any new data burden on suppliers as the Department already requests this information from suppliers. However, by making it a legal requirement that information is provided within 24 hours, this is expected to improve the timeliness of information provision, thereby ensuring that the Department has access to more timely and complete information about medicines volumes. Given the very simple nature of the information required, it is not anticipated that this time requirement would place any additional burdens on suppliers. However, this is something that we aim to test at consultation.

Costs to the Department

8. These requirements are not anticipated to impose any additional costs on the Department. Whilst the requirement to notify the Department of potential medicine supply issues might result in an increase in the amount of information that the Department receives and processes, this information will also enable the Department to better plan its response to potential supply issues, which could result in a resource saving. In addition, the requirement to provide volumes information within 24 hours may save the Department resources by reducing the amount of follow up required to obtain the information from suppliers. Ultimately, it is anticipated that earlier notification and more timely information would also allow the Department to focus its resources on seeking to prevent medicine supply issues rather than the active management of ongoing issues, but this would not necessarily affect the total level of resource required.

9. However, there is a risk that, if manufacturers misinterpret the requirement as a need to notify the Department for very minor supply issues, this would increase both the resource costs for manufacturers and the Department. This risk would need to be mitigated through clear guidance to manufactures on what constitutes a significant supply disruption.

Benefits of allowing the Department to better manage medicines supply issues

10. As previously discussed, the aim of requirement iii is to enable the Department to ensure value for money in the supply chain by allowing the government to better plan its response to potential supply issues in order to mitigate the impact on patients and the NHS.

11. Although no studies have systematically examined the impacts associated with medicine supply issues, the report of the All Party Pharmacy Group Inquiry into Medicines Shortages highlighted these potential impacts through its evidence sessions. The report cites a survey by Chemist & Druggist magazine in 2011 which found that 43% of pharmacists who responded were spending on average between two and five hours a week sourcing out-of-stock medicines, and 18% were spending more than that. In addition the report highlighted a number of reports to the inquiry about vulnerable patients who were not able to access the medicines that they needed, potentially causing stress, anxiety and adverse health consequences. Whilst the lack of systematic evidence in this area means that it is not possible to fully quantify the benefits associated with better management of medicine supply issues, they do provide an illustration of the potential benefits that might arise, both in terms of time savings for pharmacists and impacts on patients.

Annex C – further information on difference between options

		Option 0	Option 1	Option 2	Option 3
Routine information provision	**Products**	Unbranded generic medicines Special medicinal products	Unbranded generic medicines Special medicinal products	Unbranded generic medicines Special medicinal products	All health service medicines Medical supplies Other related products
	Impact	Manufacturers and wholesalers in voluntary schemes	All manufacturers/ importers/ wholesalers of generic and special medicinal products	All manufacturers/ importers/ wholesalers of generic and special medicinal products	All manufacturers, importers, wholesalers and those supplying patients (including pharmacies and GPs)
	Type of information	Product-level	Product-level	Transaction-level	Transaction-level
Information on request	**Products**	None	All health service medicines Medical supplies Other related products	All health service medicines Medical supplies Other related products	None
	Impact	None	All manufacturers, importers, wholesalers and those supplying patients (including pharmacies and GPs)	All manufacturers, importers, wholesalers and those supplying patients (including pharmacies and GPs)	None
	Type of information	None	Transaction-level	Transaction-level	None

Product-level vs Transaction-level information

Product-level information (Aggregate information about sale and purchases)	Transaction-level information (Information about individual transactions)
• the category of purchaser for each product (e.g. pharmacy, hospitals, wholesalers etc.); • the quantity of each product that is sold or bought; • the sales income received for each product, being the income from the sale of the product after deduction of any discounts or rebates or other payments given that can be attributed to the sale of the product; • the amount that is paid for each product after deduction of any discounts or rebates or other payments received for the amount paid; and • the discounts, rebates or other payments given or received for each presentation which cannot be attributed to that product.	• the invoices which relate to the sale or purchase of any products; • the name of the purchaser or seller of any products; • the category of purchaser for any medical products (e.g. pharmacy, hospitals, wholesalers etc.); • the quantity of any products that are sold or bought; • the sales income received for any products, being the income received from the sale of the supplies or products after deduction of any discounts or rebates or other payments given that can be attributed to that sale; • the amount that is paid for any products after deduction of any discounts or rebates or other payments received for the amount paid; • the discounts, rebates or other payments given or received by the producer which cannot be attributed to a particular product; • the terms which applied to any discounts or rebates or other payments mentioned; • the name of any person who received the discounts or rebates or other payments; and • whether the product is an English health service product, Welsh health service product, Scottish health service product or Northern Ireland health service product.