Title: Regulations to enable the Government to require information on health service products **IA No:** **RPC Reference No:** **Lead department or agency:** Department of Health and Social Care **Other departments or agencies:**	**Impact Assessment (IA)** **Date:** 16/02/2018 **Stage:** Final **Source of intervention:** Domestic **Type of measure:** Secondary legislation **Contact for enquiries:**

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**
- £88.3m	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 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. This is the preferred option. Break even analysis demonstrates that approximately £3m of savings to the medicines bill would be required to offset the additional costs of data collection (this is equivalent to less than 0.1% of spend on generic drugs in community pharmacy in 2016/17).

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 (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs.

Signed by the responsible Minister: Lord O'Shaughnessy Date: 5 June 2018

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: NA	**Benefits:** NA	**Net:** NA	NA

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: -£48.2m	**High: -£201.9m**	**Best Estimate: -£88.3m**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	£2.6m	1	£4.9m	**£48.2m**
High	£3.6m		£21.2m	**£201.9m**
Best Estimate	£2.8m		£9.1m	**£88.3m**

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'

The main benefits are to ensure the continuity of the reimbursement system, improve the resilience of the reimbursement system, improve the resilience in the supply chain for medicines, and provide 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. Although these benefits do not stem directly from the proposal, it is important to note that access to information on the medicine supply chain is a vital first step in realising these benefits – without this information, government would lack the evidence required to develop new policies.

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: NA	**Benefits:** NA	**Net:** NA	NA

Executive Summary

1. This Impact Assessment considers proposals to introduce new requirements for 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.

2. Two options are considered – a do nothing option, where the Department continues to rely on voluntary arrangements to gain some limited information on the medicines supply chain, and Option 1, to put in place regulations to require UK suppliers to provide the Department with specific information.

3. The key costs considered in this Impact Assessment are the costs imposed on industry of meeting these requirements, and the costs to the Department in collecting and analysing this information. The benefits of policy are to improve the reimbursement arrangements for medicines and secure greater transparency, value for money, and resilience across the medicine supply chain. Although it has not been possible to fully quantify these benefits (as they will depend significantly on subsequent decisions by the Department on how it makes use of and responds to the information collected), it is clear that the ability to access and gather information across the medicine supply chain is a vital first step in realising these benefits. Without this information, the Department would lack the necessary knowledge to begin identify and tackle potential issues in the supply chain.

4. Following an analysis of the potential costs and benefits of the proposed approach, we estimate that approximately £3m of savings on the drugs bill would be required in order to offset the addition costs of data collection (this is equivalent to less than 0.1% of spend on generic drugs in community pharmacy in 2016/17). As a result, option one is considered to the preferred policy option, as it represents a proportionate approach to collecting the necessary information the Department needs to ensure the continued running of the reimbursement system and to secure greater transparency and assurance across the medicines supply chain.

Background

5. 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.

6. In September 2017, the Government consulted on draft regulations to define the information which would come within the scope of the proposed requirements. The accompanying impact assessment considered the potential costs and benefits of those proposals. This revised impact assessment updates these estimates in light of changes to the proposals since the consultation.

The problem

7. In 2015/16 The NHS in England spent approximately £16.8bn on medicines. 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.

8. 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.

9. 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.

10. 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.

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

Margin survey (community pharmacy)

12. 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 240 independent pharmacies (5 or less outlets) – 20 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.

13. 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

14. 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

15. 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)

16. 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)

17. 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.

18. 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

19. 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.

20. 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

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

22. 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.

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

24. 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

25. In this scenario, we would be reliant, as now, on current voluntary arrangements.

26. 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.

27. 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.

Option 1: Introduce a range of new information requirements

28. The Department is proposing information requirements within five broad areas as summarised in the table below:

Table 1: Description of the proposed information requirements

Requirement	Rationale
Routine (quarterly) information on prices and volumes for generic medicines and special medicinal products at a product level	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 2 business days**	The aim of this collection is to support the setting of concessionary prices (when a medicine is not available at the price listed in the Drug Tariff)
Requirement on manufacturers to notify the Secretary of State of potential **medicine supply issues**, and to provide information on request about available volumes within 2 business days	The aim 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 and issue the necessary communications to the NHS
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**	

29. In order to secure compliance, it is proposed that the Department should be able, if necessary, to impose penalties on any operators in the supply chain that either fails to provide information or continues to provide incomplete or inaccurate information. The proposed penalties are:

Table 2: Penalties chargeable for each proposed requirement

Requirement	Penalty
Routine (quarterly) information	A daily penalty as outlined in Table 3 below.
Price and volume information within 2 business days	A one-off penalty of £1,000
Information about medical supply issues	For notification of supply issues a daily penalty as outlined in Table 3 below. For price and volume information a one-off penalty of £1,000
Non-routine transaction-level information	A daily penalty as outlined in Table 3 below.
Cost information	A daily penalty as outlined in Table 3 below.

Table 3: Daily penalty amounts

	Daily penalty for first 14 days	Daily penalty for subsequent days
Small producer	£250	£500
UK turnover 5 million or more	£500	£1,000
UK turnover 20 million or more	£1,000	£2,000
UK turnover 50 million or more	£2,500	£5,000
UK turnover 100 million or more	£5,000	£10,000

30. 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 options previously considered

31. As part of the Department's consultation on introducing new information requirements, three options were initially considered for the **routine information on prices and volumes** and **on request information related to individual transactions** requirements 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)

32. Following the results of the consultation, Options 2 and 3 have now been ruled out due to concerns about the potential burden that providing transaction level data on a routine basis would place on industry.

33. In addition to these options, the consultation also sought views on a number of variations to these options as follows:

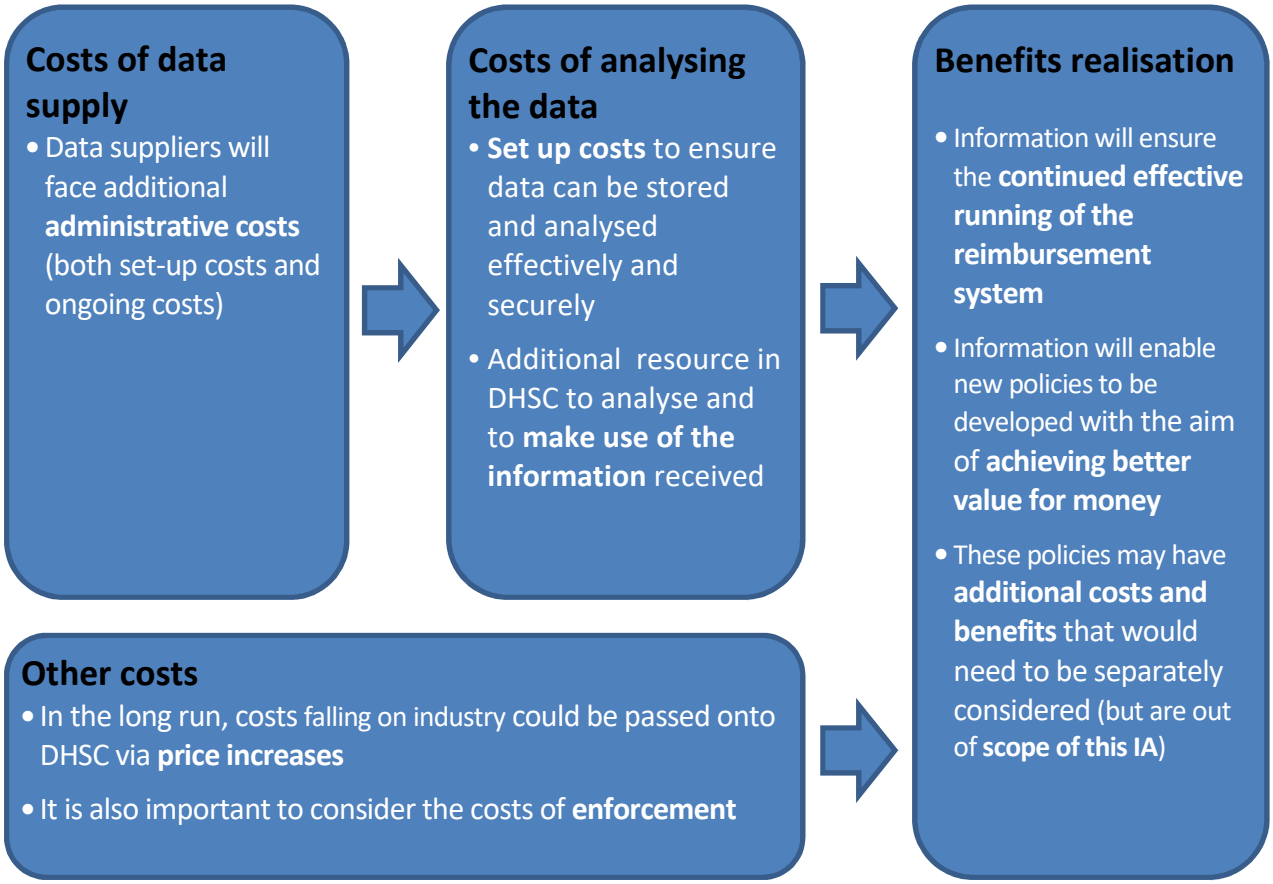
    - Whether, under option 1, there is any value in also continuing with the voluntary arrangements for companies to provide the Department with information on some unbranded generic and unlicensed medicines (schemes M, W and specials). Although some consultation respondents expressed support for the continuation of voluntary agreements, this was not felt to be workable in practice as, in order to ensure consistency of data returns, this would still necessitate alignment of the terms of the voluntary and statutory requirements. Instead, the Department has considered how the statutory data requirements can be revised to better reflect the voluntary schemes in order to minimise burdens.

    - As well as a quarterly routine data collection, the Department sought views on the potential impact of moving to a more regular data collection (e.g. monthly). The results of the consultation indicated that many respondents felt that increasing the frequency of data collections would significantly increase the burden. As such, this option has now been ruled out.

    - Finally, the Department also separately considered a regulatory approach to provision of information about supply shortages. These proposals have now been incorporated into Option 1 above and so will be assessed alongside the other existing proposals.

Estimated impacts

34. 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 requirements described in Table 1 above.



Costs relating to the routine information on prices and volumes requirement

35. Under this requirement, all manufacturers, importers and wholesalers of unbranded generic medicines and special medicinal products (manufactured and imported) to provide information every quarter about the UK sales and purchases of these products including information on any discount and rebates.

Costs of supplying the data

36. 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 approximately 450 products.

37. Although it was previously proposed that the new statutory data collection would extend the existing voluntary data collection by requiring information on all generic medicines and specials medicinal products, during the consultation we received feedback that this approach would not be feasible in practice. As a result, it is now proposed that price and volume information will only be required for products that are currently in the drug tariff, or that the Department is considering adding to the drug tariff. Since this approach now largely mirrors the existing voluntary data collections, we would expect that, for those companies who already provide data under the voluntary arrangements, there would be no additional costs of providing data under the statutory arrangements.

38. However, these companies may still face some **one-off familiarisation costs** to understand the new statutory requirements relative to the voluntary collections. As these companies would already be

familiar with the voluntary data collections, it is not anticipated that these familiarisation costs would be significant. It is estimated that on average, this could require up to 2 days of an analyst's time to review the requirements, and 1 hour of a senior manager's time to sign off any changes required. Based on an hourly wage rate of £17 and £33 respectively[1] and applying a 30% uplift for non-wage costs[2], this would imply an average cost of approximately £390. Summing over all existing providers in the voluntary schemes, this would suggest a total cost of around **£13,700**.

39. For suppliers who are not part of any existing voluntary agreements, they 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:

Table 4: MHRA License holders by company type

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

40. 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.

41. 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[3]. 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)[4].

42. 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 to set up the necessary processes to meet these.

43. As part of the consultation, some respondents suggested that these set up costs could be very high, and range into hundreds of thousands of pounds. However, given the nature of the requirements, this was felt to be excessive. As the vast majority of wholesalers and manufacturers would already have systems in place to monitor sales and stock information, we do not anticipate that there would be significant set up costs to extracting and providing a quarterly report of this information. As stated above, the main tasks required would be to read and understand the data requirements, and to consider how these can be met. For example, we would expect suppliers to spend some time considering how the required information would be best extracted from their existing IT systems, and this may require the setting up of some additional queries. However, we would not expect any suppliers to need to invest in entirely new IT systems in order to store or process this information.

44. Our assessment therefore remains that this could represent the equivalent of 1 week of work for an analyst. 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 1 day of time. Applying the same cost assumptions as above and summing across all suppliers, this equates to a total **one-off set up cost** of approximately **£555,300.**

[1] 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 and Corporate managers and directors

[2] 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

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

[4] 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.

45. In terms of the actual **costs of data supply for new suppliers**, we would anticipate that costs would be similar to those under the existing voluntary collections, since the two collections are now closely aligned. Our previous 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 special medicinal products[5]. Scaling these up for the estimated number of new data suppliers under the statutory requirements gives an estimated total cost of approximately **£1,848,500 p.a.**

46. However, this estimate relies on the assumption that, on average, the costs of data supply for a new supplier would be very similar to the costs currently incurred by those under the voluntary arrangements. In reality, costs could potentially be higher or lower than this for a variety of reasons. For example, based on an examination of the average number of products per supplier listed in Dictionary of Medicines and Devices (dm+d) database, we estimate that on average new data suppliers have about half as many products potentially falling into scope of the routine data collection compared to existing voluntary providers. To the extent that costs would scale in proportion to the size of the data collection, this might mean that the costs of data supply for new providers would be lower than those estimated above (and assuming full scalability of costs – **as low as £924,300 p.a**.).

47. On the other hand, it may be the case that, as new suppliers will not be as familiar with the process of collecting and submitting the data under a routine data collection, their costs would be higher (at least in the initial period). To reflect this potential risk, we remodel the costs by applying the maximum cost estimate derived from the existing voluntary schemes to all new providers (i.e. we no longer make a distinction between costs for manufacturers, wholesalers etc. and instead assume that costs for all new providers are in line with the most costly of the existing voluntary schemes). This gives a **high cost estimate of up to £4,674,900 p.a**.

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 DHSC of developing additional systems to collect, process and analyse the data.

49. 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.

50. The Department is currently exploring options for how such a system could operate and as such, costs have not yet been finalised. However, based on ongoing discussions with potential suppliers, we have been able to further refine and narrow down the range of potential costs since the consultation stage impact assessment.

51. Based on discussions with other NHS organisations with experience in data collection, we believe that it should be possible to adapt one of their existing systems to create a new data collection platform at relatively low cost. We currently anticipate that costs could be in the region of up to £50,000 p.a. with initial set up costs in a similar ballpark.

52. However, 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[6].

    Table 5 below summarises our selection of the most appropriate adjustment levels and rationale for these:

[5] 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.

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

Table 5: Assessment of Optimism Bias

Mitigation factors	Contribution to Optimism Bias	Mitigation	Rationale
Complexity of contract structure	7	0	Unknown at present so no mitigation applied
Late contractor involvement in design	7	0	Unknown at present so no mitigation applied
Poor contractor capabilities	4	0	Unknown at present so no mitigation applied
Information management	5	0	Unknown at present so no mitigation applied
Design complexity	10	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.
Degree of innovation	17	1	
Inadequacy of business case	18	1	
Project management team	5	0	Unknown at present so no mitigation applied
Poor project intelligence	4	0.5	Partially mitigated for as collection will mirror voluntary collections
Legislation	5	0	Unknown at present so no mitigation applied
Technology	18	0	Unknown at present so no mitigation applied
Reduction in optimism bias	47%		
Level of optimism bias	106%		

53. As a result, we have revised our best estimate of the potential IT costs accordingly to £103,000 p.a. (plus similar set up costs).

54. However, these estimates remain based on the assumption that we would adapt an existing NHS data collection platform for our purposes. If this turned out not to be feasible, and we would need to commission a new system from scratch, costs could be considerably higher. As such, we have also included a higher cost estimate of approximately £200,000 p.a. plus £300,000 in set up costs to reflect this risk.

55. Overall, our estimated IT costs are summarised as follows:

Table 6: Summary of IT costs for data collection

	Low	High	Best
Set up costs	£50,000	£300,000	£103,000
Annual running costs	£50,000	£200,000	£103,000

56. In addition, it is likely that additional DHSC 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). Based on an assessment of the number of additional hours of work that this could take, using average DHSC pay scales, it is estimated that this could equate to a cost of approximately **£24,100**.

57. Finally, 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 DHSC pay scales, it is estimated that this could equate to a cost of approximately **£12,300 per year**.

58. 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.

Costs relating to the non-routine price and volume information within 2 business days requirement

59. We propose to introduce a requirement on manufacturers and wholesalers to provide information within 2 business days about available volumes and prices of generic medicines and special medicinal products listed in part VIII of the drug tariff.

60. 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.

61. 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

62. 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.

63. 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.

64. 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.

65. Based on an average hourly wage of just under £17, plus 30% for non-wage costs[7], we therefore anticipate that the **additional cost to suppliers** of meeting the new statutory requirement to be approximately **£17,600 p.a.**

Costs of analysing the data

66. 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.

67. 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

[7] 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

supplier. Overall, the **NHS BSA estimate a time saving** of approximately 25-50%, which would equate to an annual saving of approximately **£8,800 p.a.**

Costs relating to non-routine information relating to medicines supply issues

68. 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.

69. 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.

70. This requirement seeks to put the existing voluntary guidelines for shortages on a statutory footing[8] 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 information at least 6 months prior to the date of interruption or discontinuation, or if not possible as soon as practicable

    - Where there are supply disruptions, require manufacturers and wholesalers to let the Secretary of State know the available volume of the product they hold within 2 business days.

Costs of supplying the data

71. 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.

72. 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 estimate to the 50% of cases above where notifications are currently not received, this implies a total cost to manufacturers of between **£1,100 and £1,600 p.a.** (based on an average hourly wage of just under £17 and 30% non-wage costs).

73. 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.

74. 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 2 days, 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.

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

Costs to the Department

75. 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 2 business days 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.

76. 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.

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

77. 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.

78. We anticipate that the Department would request information to be provided when more transparency is required about transactions in the supply chain. This could be triggered by the assessment of information that has been provided routinely or any other concerns about pricing or costs in the supply chain. We expect that any request would be targeted at specific products and/or parts of the supply chain and so would be limited in scope.

79. In addition, 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.

Costs of supplying the data

80. In terms of the margins survey, it is not anticipated that these new requirements would affect the total cost to pharmacies of supplying data. Although there may be some improvements in enforcement, we do not anticipate that this would affect the number of pharmacies supplying data. 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. Any potential legal costs associated with changes in enforcement are discussed later in this impact assessment.

81. 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. Table 7 below sets out our initial assumptions in this area:

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

Table 7: Cost assumptions for non-routine transactional level data

	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	35	As a starting point, we assume the overall time requirement would be similar to those currently estimated for the voluntary scheme M and scheme W collections. During the consultation, respondents indicated that the maximum time requirements could be up to a week's worth of staff time.
Total costs per year	**£43,600**	**£572,800**	Based on an hourly salary of approximately £17, plus 30% non-wage costs.

Costs of analysing the data

82. 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 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).

83. In the long run, it is possible that the additional resource would also be required for the Department to develop new policy options to address any issues identified and improve the efficiency and value for money of the 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 a separate business case within the Department to ensure that resources are appropriately allocated across competing priorities.

Costs relating to non-routine information about costs

84. 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.

85. 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.

86. 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

Costs of supplying the data

87. The number of times per year where the Department would seek to request information on costs remains uncertain 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.

88. 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 2 and 12 days of staff time. Based on an hourly salary of approximately £17, plus 30% non-wage costs, this would equate to a total cost of approximately **£7,000 and £62,800** per year.

Costs of analysing the data

89. 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 **£64,000 approximately**.

90. 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.**

91. 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 £111,800 per year.**

92. As above, it is possible that the additional resource would also be required for the Department to develop new policy options to address any issues identified from the costs information. These costs are considered to be out of scope of this Impact Assessment, and would be subject to a separate business case within the Department to ensure that resources are appropriately allocated across competing priorities.

Costs of data storage

93. 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 4 years. In the previous Impact Assessment accompanying the consultation, it was anticipated that these requirements to record and store information would not impose any additional costs on suppliers because these requirements were already in line with the existing requirements for tax purposes to keep records. However, respondents to the consultation raised concerns that the nature of the information required to be kept was different to that required for tax purposes. As such, they felt that there would be an additional cost of storing this information.

94. To address this concern, the proposed regulations have been clarified to make it clear that, rather than requiring specific pieces of information to be stored in a specific format, information just needs to be kept so that the information listed in the regulations can be provided when required. This reflects the original policy intention for the requirement to keep information not to impose any additional burdens on suppliers, beyond what is already required for tax purposes.

Costs of enforcement

95. 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.

96. 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.

97. 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.

98. 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.

99. 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 to 3 appeals a year.

100. It is estimated that the **cost of running the tribunal** would be in the region of 4500 per appeal, which in turn suggests a total cost to the tribunal of between **£9,000 and£13,500**.

101. In terms of **legal costs**, an analysis of DHSC 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 **£7,000 and £10,500**.

102. 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

103. Table 8 provides a summary of the costs associated with each of the proposed policy options (relative to the do nothing option):

Table 8: summary of costs

		Low	High	Best
Routine data collection	Set up costs - existing providers			£13,700
	Set up costs - new providers			£555,300
	Ongoing costs - new providers	£924,300	£4,674,900	£1,848,500
	DH costs - IT costs (set up)	£50,000	£300,000	£103,000
	DH costs - IT costs (ongoing)	£50,000	£200,000	£103,000
	DH costs - Preparatory work			£24,100
	DH costs - Processing			£12,300
Non routine data within 2 business days	Costs to suppliers			£17,600
	Savings to BSA			£8,800
Non routine data relating to medicines supply issues	Costs to suppliers	£1,100	£1,600	£1,400
	Costs to DH			£0
Non routine transactional data	Costs to suppliers	£43,600	£572,800	£308,200
	Costs to DH			£96,500
Non routine costs data	Costs to suppliers	£7,000	£62,800	£34,900
	Costs to DH	£95,800	£111,800	£103,800
Enforcement costs	Costs to Tribunal Service	£9,000	£13,500	£11,300
	Legal costs	£7,000	£10,500	£8,700

104. Based on these costs, we calculate that the net present value of the costs of the proposed policy (relative to the do nothing option and using a discount rate of 3.5%) is:

Table 9: Summary of Net Present Value of costs

	NPV	**Business NPV**
Low	£11.4m	£9.2m
High	£50.5m	£46.5m
Best	£22.5m	£19.6m

Ultimate societal value of the costs

105. 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 DHSC 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.

106. 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 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.

107. 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.

108. 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:

Table 10: Summary of Net Present Value of Costs (Ultimate Societal Impacts)

	NPV	Business NPV
Low	£48.2m	£0.01m
High	£201.9m	£0.1m
Best	£88.3m	£0.1m

Impact on small businesses

109. 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 total NHS sales of £5 million or less, as set out in their most recent statutory audited accounts'.

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

[11] BEIS analysis of ONS/BERD data

110. 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.

Benefits

Impact on the reimbursement system

111. The proposed policy 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 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

112. 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.

113. 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. Although these benefits do not directly flow from the policy proposal, it is important to note that access to information across the medicine supply chain remains a vital first step in realising these benefits. Without this information, the Department would lack the evidence it requires to consider potential reimbursement reforms.

Development of new policy options

114. Increased information powers will also allow additional information to be gathered to 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 benefits could 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

[12] Whilst the voluntary Scheme M, Scheme W and Specials data collections enjoy a good level of compliance, the 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

115. 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. As discussed above, although these benefits do not directly flow from the policy proposal, it is important to note that access to information across the medicine supply chain remains a vital first step in realising these benefits. Without this information, the Department would lack the necessary knowledge to begin identify and tackle potential issues in the supply chain.

Illustrative Cost Savings

116. Although it has not been possible to quantify the size of the potential benefits resulting from possible improvements to the reimbursement system or other measures to improve the efficiency and value for money in the medicines supply chain, some illustrative figures are given below as to the size of the potential savings required to offset the estimated costs of the proposal, and a range of possible sources for such savings. 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.

Table 11: Illustrative savings required to outweigh estimated policy costs

Cost scenario	Absolute annual saving required
Best	£3.4m
Low	£1.7m
High	£7.6m

117. Overall, we estimate that a saving of £3.4m p.a. would be required in order to offset the costs of the policy (based on our best estimates of costs). Under the higher cost scenario, a larger saving of £7.6m p.a. would be required to offset the higher costs, whilst in the best case low cost scenario, only a saving of £1.7m would be required.

118. For context Table 12 below sets out the total spend on different categories of drugs, which can be compared to the estimates of the total annual savings required above. From this, we can see that compared to most areas of drug spend, 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, the required annual saving of £7.6m only represents 0.22% of the total annual spend on generics dispensed by pharmacies (£3.4bn total spend), whilst the estimated savings required under our best estimate scenario can be seen to represent 0.10% of spend in this same category (falling to 0.05% under the low cost scenario).

Table 12: Total spend on different categories of drugs*

Total spend on drugs (hospital and pharmacy)	£17.4bn
Spend on drugs (pharmacy)	£9.1bn
Spend on generics (pharmacy)	£3.4bn
Spend on Part VIII drug tariff	£4.9bn
Spend on Cat A Drugs	£0.5bn
Spend on Cat M Drugs	£1.6bn
Spend on Cat C Drugs	£2.7bn
Spend on Special Medicinal products	£81.5m
Spend on Part VIIIB of the drug tariff	£26.8m

* Total drug spend based on 2016/17 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.

119. However, it is important to bear in mind that any new policies developed as a result of the additional information and insights obtained through the proposed information powers may have additional costs or other resource implications, which must be taken into account alongside the potential benefits. As

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

such, we would expect that any new policy proposals would need to undergo a separate impact assessment to properly consider these impacts.

Improved ability to respond to medicine supply issues

120. As previously discussed, the aim of the requirements for information on medicines supply issues 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.

121. 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.

Societal valuation of benefits

122. 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, as previously discussed, it is important to also consider what the ultimate long run effects of any changes are.

123. In terms of the estimated costs of the policy, paragraphs 105 to 108 above illustrated how these costs could have further implications for the NHS, patients and the UK economy, and quantified these ultimate effects. In a similar manner, it is also important to consider whether the benefits described above would also have any additional long run impacts that need to be taken into account in the analysis. In particular, it will be important to note that, as was the case with cost pressures on the NHS discussed previously, cost savings to the NHS can have additional health impacts. The latest available evidence suggests that for every £15,000 cost saving on the NHS, one Quality Adjusted Life Year (QALY) is gained[15]. These health impacts are monetised using their estimated societal value of £60,000.

124. However, when we consider the additional impact on industry, this sort of analysis quickly becomes very complicated as it will depend crucially on the types of new policies that could be developed as a result of the information powers, and how savings (or other benefits) are delivered. For example if financial savings to the NHS arise due to reductions in the prices paid for medicines, then these savings could arguably be accompanied by reduced profits to medicines manufacturers or wholesalers. 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 price reductions through more competitive markets and greater efficiencies, or eliminating other inefficient practices in the reimbursement system, this could also bring some benefits to the sector.

125. In order to provide an illustrative example of how this analysis might change once these wider impacts are taken into account, we have repeated the break-even analysis set out in Table 11 above, this time ensuring that the full wider societal impacts of the potential costs and benefits are taken into account. In order to simplify the analysis, we make the assumption that all financial savings 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.

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

Table 13 below compares the level of annual savings required in the NHS (assuming that they begin in year 3 of the policy) when full societal impacts are considered compared to when only the first order financial impacts are taken into account. Overall the figures are relatively similar, largely due to our assumptions that both costs and benefits are largely passed through to the NHS and patients (for costs, this is largely via price increases in generic medicines – see paragraph 105).

Table 13: Comparison of illustrative savings required under different assumptions

Annual Savings required	Mid	Low	High
Financial Basis	£3.4m	£1.7m	£7.6m
Societal Basis	**£3.0m**	**£1.6m**	**£6.8m**

Risks

126. 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. As part of the consultation we have worked with stakeholders to understand the potential costs of data supply, and we are continuing to explore options for the creation of an IT platform in order to minimise the potential burdens of data supply. The data collections will be kept under continual review to ensure that burdens on suppliers do not become disproportionate or excessive.

127. The second risk is that information is collected and no benefits emerge. For example, if the data collected is not subsequently used in any way, or does not lead to the development of new policy options. 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 benefits required to offset these costs and justify the policy. This in turn means that there will be a greater need to ensure that the information collected is properly made use of and that new policy options are identified as a result. Whilst it is entirely possible that the collection of more routine information would provide more opportunities for issues to be identified and policy options developed, this may not materialise. For example, if resource constraints in DHSC limit the amount of analysis of the data that can be undertaken, or if additional analysis simply fails to identify any further opportunities.

128. 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. 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. The Department will also need to develop a clear work plan to ensure that any new data collected is appropriately used and any insights incorporated into its ongoing policy development work.

129. 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.

130. 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. However, as it is not anticipated that the Department would regularly request large quantities of information from these suppliers, this risk is judged to be relatively small.

Summary and conclusions

131. 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. The

main benefits of the proposals are to ensure the continuity of the reimbursement system, improve the resilience of the reimbursement system, improve resilience in the supply chain for medicines, and provide 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. This illustrative analysis demonstrates that savings of approximately £3m p.a. are required in order for this proposal to be considered value for money. Although these cost savings are reliant on further policies being put in place and do not directly flow from the information powers proposed here, it is important to note that access to information across the medicine supply chain remains a vital first step in realising these benefits. Without this information, the Department would lack the necessary evidence to begin identify and develop new policy options. As such, Option 1 remains the preferred policy option.