Title: Proposed amendments to The Health Service Products (Provision and Disclosure of Information) Regulations 2018 Impact assessment
IA No:
RPC Reference No:
Lead department or agency: Department of Health and Social Care
Other departments or agencies:

Impact Assessment (IA)

Date: 14/08/2025
Stage: Consultation
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 Social Value	**Business Net Present Value**	**Net cost to business per year**	**Business Impact Target Status**
-£9.4m	NA	NA	Not a regulatory provision

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

The Information Regulations already require suppliers to provide sales and volume data and notification of shortages or discontinuations of medicines to the Department. However

i) In light of developing reimbursement policy and a new type of supplier, the Information Regulations are now misaligned. The Department is seeking to get information on more products, be updated of changes to products including price changes, and receive data from the new type of supplier. Increasing the scope of the regulatory provisions will make the reimbursement arrangements more effective and efficient, paying contractors fairly and provide better taxpayer value for money.

ii) There are gaps in the data the Department is able to access so it does not have a complete market view of the supply of medicines, to identify medicine supply issues. This means the Department is not able to help prevent potential shortages or where they do occur implement cost-effective mitigations, particularly with regard to over the counter (OTC) medicines also used by the NHS and when there is an identified public health risk. Increasing the scope of the regulatory provisions will ensure the Department has a more complete market view of the total supply of medicines, to support better cost-effective planning and help manage supply issues and discontinuations increasing patient access to medicines and provide better taxpayer value for money.

iii) The current compliance regime does not always enable the Department to enforce data reporting under the Information Regulations when suppliers do not comply. Changes to the compliance provision regime will enable the Department to take action when suppliers do not comply, acting as deterrent against non-compliance.

What are the policy objectives of the action or intervention and the intended effects?

The overarching objectives of the Information Regulations, and in turn these amendments, are to improve the effectiveness and efficiency of the reimbursement arrangements, improve patient access to medicines, and in turn both will increase taxpayer value for money. The regulatory amendments will increase the scope of the current regulations in terms of the products on which data is collected, the type of data collected and who is required to provide data. An improved compliance regime will act as a strengthened deterrent for non-compliance.

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

Option 0: 'business as usual' – In this baseline, the Department is reliant, as now, on ad hoc powers and existing legislation to obtain some of the information from suppliers and is not able to operate an efficient compliance regime.

Option 1: to make amendments to the Information Regulations so the Department can:

- obtain information from suppliers such as the stock, sale and purchase of health service products across more products than currently are in scope of requirement under the Information Regulations.
- receive notification from suppliers of new products and changes to products.
- define a new type of supplier ('hubs') that is required to supply data.
- collect more data to have a more complete view of national medicine supply to help prevent medicine shortages and mitigate them in the most cost-effective way when they do occur to. Specifically, this relates to data collected on over the counter products also used in the NHS and when there is an identified public health risk.
- have a more effective compliance regime when suppliers do not submit their data in line with the regulations.

This is the preferred option because it builds on systems and processes already in place while allowing the Department to access data on an increased number of products, new data on products and data from a new type of supplier.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** TBC

Is this measure likely to impact on international trade and investment?		NA		
Are any of these organisations in scope?	**Micro** Yes	**Small** Yes	**Medium** Yes	**Large** Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)		**Traded:** NA	**Non-traded:** NA	

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

Signed by the responsible SELECT SIGNATORY: ..... Date: .....

Summary: Analysis & Evidence

Policy Option 0

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year 2025	PV Base Year 2026	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 Department will continue to rely on the use of the existing legislative provisions. Under the existing legislation there is provisions for the Department to ask for ad hoc data which is not the most efficient way for suppliers to provide us with their data that we might need regularly. It will be unable to require suppliers to provide it with updated product details (including price) and will not be able to get data from the new type of supplier. Also, the department will continue to rely on voluntary arrangements to obtain some data, which, for modelling purposes, is assumed to be fragile and may breakdown due to the lack of formal regulation in Option 0. Finally, the Department will continue not to be able to operate an effective compliance regime when data is not supplied in accordance with the Information Regulations.

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 2025	PV Base Year 2026	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: -£4.1m	**High: -£18.1m**	**Best Estimate: -£9.4m**

COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		£0.5m	**£4.1m**
High	Optional		£2.1m	**£18.1m**
Best Estimate	NA		£1.1m	**£9.4m**

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

The costs will come from two channels. Firstly, costs will fall on medicine suppliers (e.g. manufacturers and wholesalers) to meet the new data requirements. Secondly, the Department will also incur additional costs associated with processing, analysing and storing the information. All costs are recurrent i.e. there are no transitional costs expected. Data is largely already being supplied so we expect that suppliers will already have systems in place to provide the data, but the number of products or number of occasions when they need to provide data might increase. In conclusion, analysis indicates that two thirds of costs fall on the Department whereas one third fall on industry.

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

Certain unpredictable costs arising from any mitigating actions put in place for supply issues due to having access to more supply data have not been quantified.

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 comprehensively monetise benefits. However, for scale, illustrative analysis indicates that two thirds of total annual costs associated with this IA could be recouped by one aspect of a use case relating to one proposed amendment.

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

The main benefits are to ensure the reimbursement arrangements are fairly paying dispensing contractors; to ensure the Department has a more complete market view of the total supply of medicines, to support better cost-effective planning and mitigations for supply issues and discontinuations and to improve the compliance regime to provide a strengthen deterrent for non-compliance. In turn improving patient access to medicines and taxpayer value for money.

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

There is a risk that the proposed amendments could place an inappropriate and disproportionate cost burden on UK suppliers. There is also a risk that the information collected is not used efficiently and fails to support a more effective and efficient reimbursement arrangements, or the successful identification of potential issues in the supply chain. 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 amend existing regulatory provisions, for the collection of information such as the stock, sale and purchase of more health service products from manufacturers and wholesalers.

2. The proposals cover three areas:
   - Increased data to inform the reimbursement arrangements.
   - Increased data to inform the Department's work on supply issues.
   - Updated provisions to support the Department's compliance regime.

3. Two options are considered – a "business as usual'' option, where regulatory amendments are not made, the Department continues to rely on the ad hoc powers in the existing legislation and voluntary arrangements, and Option one, to amend existing regulations.

4. The key costs considered in this Impact Assessment are the costs imposed on industry (UK health service product suppliers) of meeting these requirements, and the costs to the Department in collecting and analysing this information. On these costs, analysis indicates that two thirds of costs fall on the Department whereas one third fall on industry.

5. The main benefits are:
   - that the reimbursement arrangements are fairly paying dispensing contractors.
   - to ensure the Department has a more complete market view of the total supply of medicines, to support better cost-effective planning and mitigations for supply issues and discontinuations.
   - improve the compliance regime to act as a strengthened deterrent for non-compliance.

6. The overarching objectives are to improve the effectiveness and efficiency of the reimbursement arrangements, improve patient access to medicines, and in turn both will increase taxpayer value for money. Although it has not been possible to quantify these objectives (as they will depend significantly on subsequent decisions by the Department on how it responds to the information received), the ability to access and gather further information across the medicine supply chain is an important step in realising these increased objectives.

7. Following an analysis of the potential costs and benefits of option one, the best estimate indicates an annual cost of ~£1.1m, which compounds to ~£9.4m over a 10-year period in Present Value terms. Therefore, these figures represent the benefits necessary to offset the costs associated with the adaptations. Given the relatively small nature of these costs, representing only a tiny fraction of medicine spend (NHS England spend more than £19 billion per year on medicines), and the potentially large scope for benefits, option 1 is the preferred policy option. On the potentially large scope for benefits, illustrative analysis indicates that two thirds of total annual costs associated with this IA could be recouped by one aspect of a use case relating to one proposed amendment.

Background

8. The Health Service Products (Provision and Disclosure of Information) Regulations 2018 ('Information Regulations') entered into force on 1 July 2018. The main purpose of the Information Regulations is to require persons who manufacture, distribute or supply any UK health service products to record, keep and provide information to the Secretary of State about the purchase, supply, price and availability of those products. This is to facilitate effective reimbursement arrangements for primary care. They also require Marketing Authorisation holders and wholesalers to inform the Secretary of State about shortages and discontinuations of medicines to facilitate the Department's market view of the total supply of medicines, to inform cost-effective planning and mitigations for supply issues and discontinuations. They also provide a compliance regime for suppliers that do not comply with the Information Regulations.

9. Reimbursement arrangements are set out in the Drug Tariff, published each month on behalf of the Department. It includes reimbursement prices to be paid to pharmacy contractors for products prescribed generically and dispensed on NHS prescriptions. Generic reimbursement prices listed in Part VIIIA of the Tariff are placed in a category, the categories are A, C, and M. The reimbursement price is established differently depending on the category in which the product is placed.

10. Category C lists products which are not readily available as a generic. The reimbursement price of those products is based on a particular proprietary product, manufacturer or supplier. The reimbursement price of generic products listed in Categories A and M are set using volume and sales data from suppliers submitted under the Information Regulations. For special and imported unlicensed medicines (Drug Tariff Parts VIIIB and VIIID), prices are calculated using average selling prices reported by suppliers under the Information Regulations. Data supplied in accordance with the Information Regulations also support the setting of temporary concessionary prices when pharmacies cannot source medicines at or below the listed Drug Tariff reimbursement price. Overall, the system relies on timely and accurate data from suppliers to ensure fair pricing, and value for money for the NHS.

11. The Department's work to help prevent medicine shortages and to take mitigating actions in the most cost-effective way when they do occur is underpinned by the Information Regulations which require Marketing Authorisation holders to inform the Secretary of State about shortages and discontinuations of medicines. Once a supplier issue notification has been received by the Department the process follows a structured decision-making pathway. The process begins with an initial risk assessment of the potential impact on supply of products from that manufacturer and, if required, develops strategies to manage the supply issue. The initial risk assessment considers factors such as the nature of the problem, duration, market share, alternative products, and clinical need. Once a decision is made as to the severity of the medicines supply issue, it is then assigned one of four clinical escalation tiers, from low to very high patient safety risk. If no significant impact is identified, the process halts. Potential shortages trigger the use of different escalation/ mitigation pathways such as Serious Shortage Protocols (SSP) and Medicine Supply Notifications[1]

[1] Info on MSNs here: NHS England » A guide to the systems and processes for managing medicines supply issues in England

(MSN), which aim to minimise patient impact by determining alternatives and engaging the NHS or, engaging with industry to assess their ability to fill gaps in shortfalls of health products.

The problem

12. The NHS in England spends more than £19 billion per year on medicines, making this the second largest single area of NHS expenditure, after workforce[2]. Therefore, the Department and the NHS need to ensure that best value for money is achieved through the pricing and supply arrangements. The data provided in accordance with the Information Regulations includes supply and purchase data of unbranded generic health service medicines and made and imported special health service medicines, costs incurred by UK producers in connection with the manufacturing, distribution or supply of UK health service products and the price and available quantities of health service medicines. This data substantiates the reimbursement arrangements which underpin significant NHS spending in primary care. It also supports the Department's work identifying medicine supply issues potentially helping prevent them or being able to take mitigating action in the most cost-effective way when they do occur.

13. However, the Information Regulations do not:

i) enable the Department to access all the suppliers' data it needs to operate the reimbursement arrangements as efficiently or effectively as possible including not being able to implement all of the reimbursement reforms which have previously been consulted on[3]; not being able to access data from a new type of supplier (hubs[4]) and not being able to require suppliers to update on new products, prices or pack sizes.

ii) allow the Department to access readily available data to comprehensively help prevent shortages and mitigate them in the most cost-effective way when they do occur. In particular the Department needs to rely on the subjective view of the supplier as to whether a change in their supply will cause a shortage and on voluntary arrangements to access data on the availability of over-the-counter medicines if it becomes aware of a potential public health risk and needs to proactively understand the market supply situation for relevant medicines.

iii) in certain circumstances, the current provisions do not allow for an effective compliance regime and so there is not a suitable deterrent for supplier non-compliance.

The amendments proposed in this IA aim to provide a solution the problems outlined above.

Objectives

14. The overarching objectives are to improve the effectiveness and efficiency of the reimbursement arrangements; increase patient access to medicines and improve taxpayer value for money. The root to achieving these objectives is to amend the Information Regulations to increase the scope of the current regulatory provision in terms of the products

[2] NHS England: NHS England » Medicines Value and Access

[3] See here for more information: Community pharmacy drug reimbursement reform: consultation response - GOV.UK

[4] A hub is a central pharmacy that handles the routine and large-scale aspects of prescription assembly, often using automated processes. It forms the 'hub and spoke' model.

on which data is collected, the type of data collected and who is required to provide data. An improved compliance regime will provide a strengthen deterrent for non-compliance.

15. The intended aims of the amendments are:
    a) To improve the efficiency and effectiveness of the reimbursement arrangements to support more accurate reimbursement price setting.
    b) To ensure the Department has a more complete market view of the total supply of medicines, to support better cost-effective planning and mitigations for supply issues and discontinuations.
    c) To improve the existing compliance regime to provide a strengthen deterrent for non-compliance.

Options

Option 0: "business as usual" option

16. In this baseline, the Department is reliant, as now, on ad hoc powers and existing legislation to obtain some of the information and is not able to operate an efficient compliance regime where suppliers have not complied with the Information Regulations as the Department cannot always enforce compliance measures under the existing provisions.

17. Ad hoc powers have been used to obtain data on potential Cat M, Part VIIIB products and Cat C products. Voluntary arrangements (due to goodwill) have been used to rely on suppliers updating prices and packs; get availability data on over the counter (OTC) products that might also be dispensed in primary care and get availability data when there is a public health concern that may lead or has led to an increased demand for medicines. However, there is no formal regulation to ensure these voluntary arrangements.

18. Not amending the Information Regulations will mean that we will:
    i) continue to rely on the use of the existing ad hoc provisions which is not the most efficient way for suppliers to provide us with their data.
    ii) continue to rely on goodwill where not all suppliers co-operate. There are no repercussions for suppliers that do not provide the data and for those that do, they do not have the same guarantee around the use and sharing of their data that comes with providing information in accordance with the Information Regulations. For modelling purposes, we have assumed that goodwill is fragile and may breakdown due to the lack of formal regulation.
    iii) continue not to be able to operate an effective compliance regime when data is not supplied in accordance with the Information Regulations undermining the ability to operate efficient and effective reimbursement arrangements and the ability to help prevent shortages and to take mitigating action in the most cost-effective way when they do occur.

Option 1: Introduce a range of new information requirements

19. The Department is proposing information requirements within 10 areas as summarised in table 1 below.

Table 1: Description of the proposed information requirements

Requirement	Explanation / Rationale
Adaptations to improve the efficiency and effectiveness of the reimbursement arrangements.	

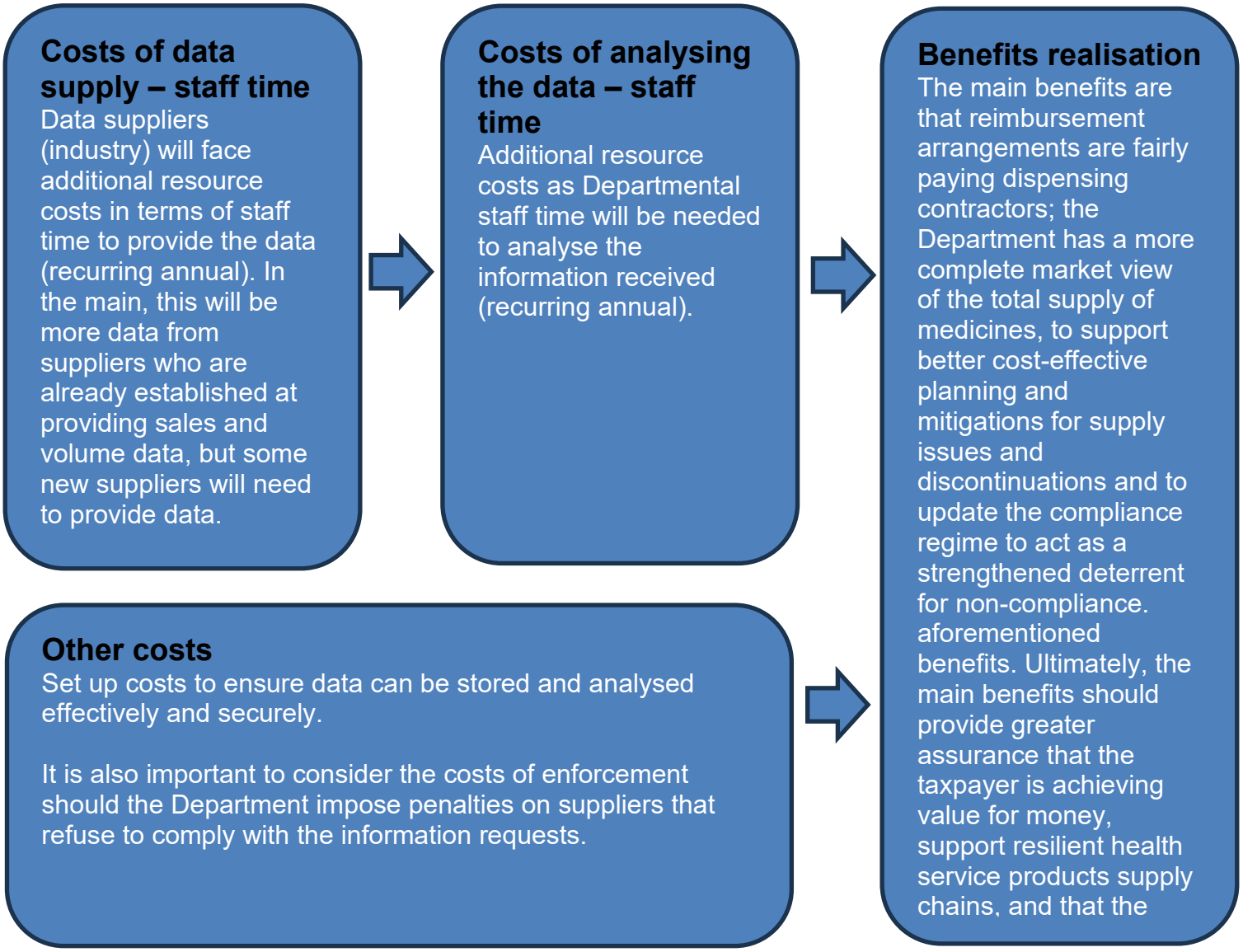
1) Increase the scope of data collection for an increased number of products that are not currently covered by the regulations in order to make a decision about setting a reimbursement price.	The Department would like to increase the scope of the Information Regulations so that it captures those products not currently in Part VIII of the Drug Tariff and hence not currently covered by the legislation, in order to make a decision about whether a reimbursement price should be set using the necessary data obtained through the Information Regulations and put in Part VIII of the Drug Tariff. This formalises data requests which are currently made using ad hoc powers, instead bringing the data collection in line with the existing quarterly collection. Therefore, we will no longer have to issue ad hoc requests.
2) Formalise regular quarterly data collections for medicines listed in Part VIIIA Category C of the Drug Tariff that includes branded medicines.	The Department needs to update the legislation to formalise routine quarterly collections of sales and volume data listed in Part VIIIA Category C of the Drug Tariff, which includes branded medicines. This adaptation formalises the Department's request for data on Cat C products which is currently done using ad hoc powers. Therefore, the Department will no longer have to issue an ad hoc request for information. The information is used to help set accurate reimbursement prices.
3) Notification for all new products being put on the market and updates to pack sizes and prices to ensure that the prices on the dictionary of medicines and medical devices (dm+d) are up to date for reimbursement purposes**.'**	The Department is proposing to introduce a legislative provision which will require all suppliers to notify the NHS BSA when they place a product on the market and keep it updated (i.e. updates to pack sizes and prices) which will be used in the NHS. The NHS BSA can in turn update the dictionary of medicines and medical devices (dm+d) which is a dictionary of descriptions and codes which represent medicines and devices in use across the NHS. This will include the pack size and price and list price of suppliers. This will provide transparency to the Department, prescribers and dispensers as to whether a product is marketed and its price. The information underpins the setting of reimbursement prices. This is already happening for branded medicines through formal legislation (existing powers). It does not happen at all for generic and other products prescribed in primary care.
4) Introduce provisions to require product data returns from hubs to inform reimbursement prices.	Introducing legislation so that hubs are subject to the same data reporting requirements as wholesalers by expanding the definition of wholesalers. Currently, hubs are not operational yet, so the proposed change is not expected to have any short-term impact. The information will inform price setting for

	reimbursement and provide an overview of product availability and value for money.
Adaptations to ensure the Department has a more complete market view of the total supply of medicines, to support better cost-effective planning and mitigations for supply issues.	
5) Removing subjectivity where producers need to give notice on a supply shortage.	The Department is proposing legislation to remove subjectivity on what warrants being reported, ensuring all potential supply issues or discontinuations are reported. This will improve the ability of the Department to understand and react to supply shocks and price rises.
6) Supply data requests for products available on a prescription and as a retail sale to inform a whole market view of supply levels to support Department mitigation of supply issues	Under the current legislation, the Department cannot ask for sales data if the product is used for retail sale, even if there is a supply issue. The Department is proposing that suppliers of products intended for retail sale that can be used in the NHS, are subject to data requests from the Department for information related to their supply. This information will allow the Department to better mitigate and manage supply shortages. The Department currently relies on goodwill from suppliers for this information.
7) Expanding the scope to enquire on a product's supply level where there is an identified public health risk to support the Department to manage any shortage in a cost-effective manner.	Under the current legislation, there is no legal provision for a supplier to provide stock position and anticipated supply details unless they are experiencing a supply issue/have an intention to discontinue. The Department would like to expand the requirement to be able to ask suppliers to report both current stock and future deliveries of identified health service products when there is not necessarily a shortage but there is an identified public health risk that might put an unexpected increase demand on supply of a product or group of products. The information would allow the Department to better manage supply. The Department currently relies on goodwill from suppliers for this information when needed, which means each time there is an identified public health risk the Department has to negotiate data from suppliers and may not get data from all suppliers.
Adaptations to improve compliance regime to further support both of the above.	
8) Amending the reference to "NHS Digital's" portal as the delivery point for submitting data to The Department due to NHS Digital ceasing to exist and the portal now being hosted by the NHS Business Services Authority (BSA). Accordingly, this should now reference NHS BSA.	The portal is now provided by the NHS BSA (no longer NHS Digital as NHS Digital has ceased to exist since its merger with NHS England in February 2023), this needs to be updated so the signposting is accurate and there is no confusion for suppliers.

9) Reporting of supply issues and discontinuations to a specific designated delivery point (currently the Discontinuations and Shortages (DaSH)Portal).	Ensuring information on discontinuations and shortages is reported through the best/official route - currently DaSH. The Department proposes that the Information Regulations now name the DaSH portal, so signposting is accurate and there is no confusion for suppliers.
10) Changes and improvements to arrangements for penalties to suppliers for contraventions.	Introducing the ability to apply a penalty to suppliers immediately without a notice period when they do not send shortage or discontinuation notices. Currently, if the Department sends a data request to a supplier or they do not do as the Information Regulations instruct, they have 7 days to rectify until penalties are applicable. However, if the Department already knows about the shortage or the discontinuation, granting another 7 days to provide the information is futile. Therefore, being able to issue a penalty immediately could act as a deterrent and incentivise companies to report sooner, meaning the Department is aware earlier and able to take proactive measures.

Estimated impacts

20. The diagram below illustrates the main impacts associated with these proposed amendments. 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 adaptation 1)

Expand the scope of data collection to include products that are not currently covered by the regulations in order to make a decision about setting a reimbursement price.

21. The Information Regulations only permit the collection of data to underpin reimbursement prices for products that are already listed within the relevant parts of the Drug Tariff. However, the Department always considers whether to add more products to the relevant parts of the Drug Tariff, in order to set reimbursement prices for more products using supplier's sales and volume data. The Department would like to expand the scope of the data collections to be able to ask for routine quarterly data, on any health service products in order to consider setting a reimbursement price for that product using suppliers' sales and volume data. On average between 2019 and 2024 we asked for 5 products per quarter (VMP[5] level) that are not in the current generic Drug Tariff (Cat M), with the most in a single quarter being 16 products in 2020 Q4.

[5] VMP stands for Virtual Medicinal Product and represents the abstract or generic medicinal product, defined by its active ingredient, strength, and form. It is used in the dm+d to group medicines.

22. This adaptation is already happening through ad hoc powers and hence is included in the “business as usual’’ baseline scenario, although should not be viewed as robust as the proposed terms of this adaption. The Department does not anticipate any costs from this adaptation, because there is minimal change between our “business as usual’’ baseline and the proposed option 1. The adaptation is a formalisation of a process which already occurs and may bring some predictability to the routine and type of information that companies are expected to return.

23. No staff time costs are expected on either the industry or the Department’s side. Data suppliers are already familiar with the process of submitting this data and the Department is already familiar with the process of analysing this data, so no staff time increases are expected.

24. There are also no additional set up costs to ensure the data can be stored and analysed effectively and securely as these processes are already in place in our baseline.

Costs relating to adaptation 2)

Formalise regular quarterly data collections for medicines listed in Part VIIIA Category C of the Drug Tariff that includes branded medicines

25. The Department is proposing to update the legislation to formalise routine quarterly collections of sales and volume data listed in Part VIIIA Category C of the Drug Tariff, which includes branded medicines. On average between March 2023 and September 2024, we asked for 495 Cat C products per quarter (VMP level). This is not expected to change going forward, with the range in this period between around 480 and 510.

26. As with adaptation 1), this already occurs through ad hoc powers and hence is already happening in the “business as usual’’ baseline scenario. Therefore, the Department does not anticipate any costs from this adaptation, because there is minimal change between the “business as usual’’ baseline and the proposed option 1. The adaptation is a formalisation of a process which already occurs. The above comments for adaptation 1) regarding staff time and set up costs are the same for this adaptation.

Costs relating to adaptation 3)

Notification for all new products being put on the market and updates to pack sizes and prices to ensure that the prices on dm+d are up to date for reimbursement purposes

27. Members of the Voluntary Scheme for Pricing, Access and Growth (VPAG) and Statutory Scheme are required to notify the Department of any new presentations of branded medicines including pack size, strength or formulation and to provide timely information on list price. However, outside of this scheme there are no reporting requirements for suppliers to notify the Department of new health service medicines being placed on the market or updates to existing products already on the market.

28. Where a prescription is for a generic medicine not listed in the Part VIII of the Drug Tariff, dispensing contractors are paid the list price of the supplier they endorsed which is typically the supplier's price in dm+d. Therefore, up to date product information such as pack and price is crucial to ensure that the BSA can keep the dm+d up to date, so community pharmacies have transparency and receive accurate payment for products not listed in Part VIII.

29. The Department is proposing to introduce a legislative provision which will require suppliers to notify the NHS BSA when they place a new product classified as a health service medicine and prescribed in primary care on the market and to provide updates on any changes made to existing products including price and pack size. This will ensure that dm+d is kept up to date and ensure dispensing contractors have transparency as to what is marketed by which suppliers at which price to facilitate accurate reimbursement according to the Drug Tariff. Our analysis will focus on the impact of new data being reported for the generic market only, as the branded data would be obtained in our baseline through the existing powers.

Costs of supplying the data

30. The cost to industry of supplying/reporting data depends largely on two factors: time and frequency. Regarding time, the Department estimates the time spent by industry reporting each presentation will be 5 minutes. This is based on how long it currently takes suppliers to report branded presentations and should be no longer for generics. Whilst this has not been included as a formal sensitivity analysis assumption, there is still a degree of uncertainty in the length of time this may take industry which has the potential to increase costs to industry. Regarding frequency, 246 new branded presentations were reported in 2023, and this is deemed representative of what can be expected per annum. As the proportion of the market that are branded is small (our best estimates indicate around 20%), it is estimated that the generic market could result in around 984 new presentations reported per year.

31. Therefore, in terms of cost to suppliers of complying with the data request, our best estimate is that this could take 82 hours of staff time (time multiplied by frequency). Based on an hourly value of staff time (including a 30% uplift for non-wage costs[6]) of £27.27[7] for industry, this would equate to a total estimated cost of **~£2,236** per annum.

Costs of analysing the data

32. The cost to the Department resulting from analysing and processing the new information will again depend on time and frequency. On time, it is expected that the Department will spend approximately 1.3 hours working on each new presentation which is reported. The frequency is still 984 new presentations reported per year, giving a final expected time spent by the Department on new generic presentations of 1,248 hours.

[6] Based on the Better Regulation Executive's Standard Cost Model. Cabinet Office. Available from: [ARCHIVED CONTENT]

[7] Based on the 2024 edition of the dataset 'Earnings and hours worked, all employees: ASHE Table 1'. Office for National Statistics. Available from: Earnings and hours worked, all employees: ASHE Table 1 - Office for National Statistics

33. Based on an average Departmental hourly salary (including on costs) of £38[8], this gives an annual cost to the Department of **~£47,424** resulting from analysing and processing the new information.

Costs relating to adaptation 4)

Introduce provisions to require product data returns from hubs to inform reimbursement prices

34. The final adaptation for reimbursement purposes stipulates that hubs should be subject to the same data reporting requirements as wholesalers, however they won't be wholesalers, as they will not be required to hold a wholesaler dealers' licence. To address this, the Department is proposing to expand the definition of wholesaler to capture hubs and thereby subject hubs to wholesaler record keeping and reporting obligations.

35. The Department has not been able to model any significant costs from this proposed change as there is no impact as things stand. This is because currently hubs are not operational yet (pending Parliamentary approval, due to take effect from October 2025), so the proposed change will have no short-term impact. In addition, with no indication of how many hubs there are likely to be, and more importantly, no indication of the size of their product portfolios, the Department cannot model any costs associated with the proposed change. Finally, the Department only requires a hub's purchase and sales data returns for products that are part of the hub operation (not those that it dispenses in the traditional way), again limiting the impact of these new requirements.

Costs relating to adaptation 5)

Removing subjectivity where producers need to give notice on a supply shortage

36. The Department is proposing legislation to remove subjectivity on what warrants being reported to DaSH, ensuring all potential supply issues, or discontinuations are reported.

37. The Department considers that the current regulations provide a need for producers to make subjective judgements when determining whether to report a shortage or change in supply. There are instances where suppliers are not providing information to the Department which had the Department known, it could have acted on to help manage the risk of a potential supply issue in the most cost-effective way. The Department wants to ensure that all situations that could lead to any supply issues in the market are reported including unexpected delays, non-supply or planned supply reduction and withdrawal.

38. As a result of this adaptation, the number of supply issue notifications is expected to increase from the 1,941 experienced in 2024 (this increase will be a mix of simple and complex notifications).

[8] Provided by THE DEPARTMENT HR for specific use in Impact Assessments. HR provided the average salary and a breakdown by grades.

Costs of supplying the data

39. The Department's best estimate is that the expected uplift in the number of notifications as a result of the proposed change could be around 20%, which equates to ~388 new notifications per year. Based on past trends, it is assumed that 95% (~369) of these are expected to be simple (easier to manage) notifications and 5% (~19) will be complex (harder to manage) notifications.

40. It is expected that it will take industry 7.5 minutes to report a DaSH notification (for both simple and complex notifications). This was calculated by timing how long it takes to report a notification on the DaSH system. Whilst this has not been included as a formal sensitivity analysis, there is still a degree of uncertainty as industry may not have all information to hand, which could increase the cost to them. Under our assumption of 7.5 minutes, industry collectively will spend ~49 hours per annum reporting all the data, which based on an hourly value of staff time (including a 30% uplift for non-wage costs) of £27.27, gives a final cost of **~£1,323**. In conclusion, this is not expected to be costly to industry as reporting each issue is not expected to take a long time, despite the high frequency.

Costs of analysing the data

41. For the Department, the amount of time spent on each notification depends on whether it is a simple or complex notification. For the 369 new simple notifications, it is estimated that the relevant policy team will spend 15 mins on each notification on average, and this work will be done by an SEO grade. Therefore, given an SEO hourly value of staff time (including on costs) of £33.26, it is expected that the annual cost of increase in the Department's resource from simple notifications is ~£3,066.

42. For the 19 new complex notifications, it is estimated that the average time spent managing the supply issue associated with each notification will be 148 G6 hours, 222 G7 hours and 74 SEOs. This is based on estimations made by pharmacists who manage supply issues, but it varies by supply issue and so does contain a degree of uncertainty. Given that the hourly value of staff time (including on costs) is £55.19 for G6, £43.95 for G7 and £33.26 for SEO, it is estimated that the annual cost to the Department in staff time managing the notifications will be ~£395,709. Due to the complex nature of these notifications, they will also likely require some analytical support, which when accounted for, results in an annual cost of increase in Departmental resource for complex notifications of ~£474,851. Overall, it is expected that the increase in notifications resulting from the regulation change will cost the Department **~£477,917** to process and analyse the information on both simple and complex notifications.

Costs relating to adaptation 6)

Supply data requests for products available on a prescription and as a retail sale to inform a whole market view of supply levels to support Department mitigation of supply issues.

43. The Department is proposing legislation requiring suppliers of products that can be used in the NHS, but intended for retail sale, are subject to data requests from the Department for information related to their supply. This data is intended to better inform the cost-effective

decision making of the Department when planning for or taking mitigating action to supply issues.

44. Under the current legislation, the Department cannot ask for sales data if the product is used for retail sale. An inability to access data on the supply of these products is problematic when there may be a supply issue and the Department is reliant on the goodwill of suppliers to provide the required data. Concerns have been expressed with providing this data as there is not currently the governance around the use of the data that comes with providing the data in line with the Information Regulations.

45. For example, previously during a supply issue the Department obtained data from a specific supplier covering the entire NHS and retail market which meant the Department had oversight of availability and could better mitigate and manage the supply issue. This case study shows that data captured in this way is possible and has been deemed representative of a typical use case for this proposed regulation. Despite ultimately receiving this data due to goodwill, there was no legal requirement for the supplier to provide this data, and under our strict "business as usual'' baseline it should not be considered as standard practice to receive this information. Therefore, there will be a change between the "business as usual'' baseline and our proposed option 1. The case study represents what is possible by law under our proposed option 1, so we have derived costs based on this case study. Also, it is worth noting that voluntary compliance here suggests that the costs to industry, at least for similar use cases of this amendment, may not be particularly burdensome.

Costs of supplying the data

46. The Department's best estimate is that the time spent by industry reporting the data for the case study was 6.5 hours. The reason for the low figure, is that only one supplier was involved, and it is believed the data was largely already on hand (i.e. no time was spent creating bespoke data for the Department). Based on an hourly value of staff time (including a 30% uplift for non-wage costs) of £27.27 for industry, this would equate to a total cost to industry of ~£177.

47. As this case study has been deemed representative of a typical use case for this proposed legislation, it is possible to scale up the figures based on how frequently we expect to use the legislation. In this case, the Department estimates there to be one supply issue per year where this regulation could be used. Hence, this case study on its own is representative of annual costs. In conclusion, the annual cost of additional reporting for industry is estimated to be **~£177**.

Costs of analysing the data

48. More significant costs are expected on the Department's side due to the staff time spent analysing and processing the supplier data. The time spent by Departmental officials working on the data was 2 people for 1 working week, which equates to 74 hours. Based on an average salary (including on costs) of £38 per hour, this gives a cost to the Department's resource of ~£2,812 for the case study.

49. As has been discussed, because there is only expected to be a singular use case per year for this legislation, and because the case study is representative of a typical use case, the case study is representative of annual costs. Therefore, the annual cost to the Department's resource resulting from analysing and processing the new information is estimated to be **~£2,812**.

Costs relating to adaptation 7)

Expanding the scope to enquire on a product's supply level where there is an identified public health risk to support the Department manage any shortage in a cost-effective manner

50. The Department would like to expand the requirement to be able to ask suppliers to report both current stock and future deliveries of identified health service products when the Department has concerns that the market may struggle to meet demand because of an identified public health risk but where there is not a current shortage.

51. Under the current legislation, there is no legal provision for a supplier to provide stock position and anticipated supply details unless they are experiencing a supply issue/have an intention to discontinue (this would be reported through DaSH).

52. For example, the Department reached out and obtained data from 51 suppliers for winter monitoring as there was a perceived public health risk. This outreach was vast and came in two waves (October and January). Consequently, it has been deemed representative of a typical use case for this proposed legislation, as this legislation would be used for larger potential issues. This information gathering cannot take place under our "business as usual" baseline (the Department can only obtain data in line with current legislation). Therefore, there will be a change between the "business as usual" baseline and our proposed option 1. The winter monitoring case study represents what is possible by law under our proposed option 1, so costs have been derived from this case study.

Costs of supplying the data

53. For the winter monitoring project, 419 entries (effectively 419 products) in total were reported by suppliers across the two waves, indicating the scale of the project. Secondly, the Department's best estimate based on response times is that 7.1 hours were spent by industry reporting each product for the winter monitoring case study. This figure is large partly due to varying response times, and because in general it took suppliers quite a long time to reply because the request was for bespoke data (predictions on future stocks), which they likely wouldn't have had to hand.

54. Combining time and frequency gives a total industry time spent providing/reporting the data of 2,975 hours. Therefore, given an industry hourly value of staff time (including a 30% uplift for non-wage costs) of £27.27, the cost of additional reporting for industry for the winter monitoring case study is estimated to be ~£81,133.

55. As this case study has been deemed representative of a typical use case for this proposed legislation, it is possible to scale up the figures based on how frequently the Department expects to use the legislation. In this case, the Department expects there could be approximately four use cases per year where this regulation would be used. Therefore, it is expected that the annual cost of additional reporting for industry will be **~£324,532**.

Costs of analysing the data

56. Regarding the time spent by the Department processing and analysing the data, an SEO spent 800 hours on the data for the winter monitoring project spent (or 1.9 hours per entry). Based on an SEO hourly value of staff time (including on costs) of £33.26, the cost of increase in the Department's resource for the winter monitoring case study is estimated at ~£26,606.

57. As has been discussed, because there are expected to be four use cases per year for this legislation, and because the winter monitoring case study is representative of a typical use case, the costs can be scaled up to annual costs. The annual cost to the Department's resource resulting from analysing and processing the new information is estimated to be **~£106,425**.

Costs relating to adaptation 8)

Amending the reference to "NHS Digital's" portal as the delivery point for submitting data to the Department due to NHS Digital ceasing to exist and the portal now being hosted by the NHS Business Services Authority (BSA). Accordingly, this should now reference NHS BSA

58. The Department is proposing to amend the reference in the legislation from "NHS Digital's" portal. The portal is now provided by NHS BSA, and the legislation needs to be updated so the signposting for industry is accurate.

59. The Department does not anticipate any significant costs from this proposed change as it is a name change in the formal regulations. There is no change resulting from this adaptation, and there is no additional staff time expected on either the industry side (to supply the information) or the Department's side (to process and analyse the information).

60. Whilst more data will be reported to the new portal, this is the direct result of other adaptations and as such impacts are discussed in relevant adaptation sections.

Costs relating to adaptation 9)

Reporting of supply issues and discontinuations to a specific designated delivery point (currently the DaSH Portal)

61. The Department is proposing that the Information Regulations are prescriptive in discontinuations and shortages are reported by naming the Discontinuations and Shortages (DaSH) portal as the specific delivery point. Accurate signposting will support industry with

their reporting requirements on potential discontinuations and shortages and align the Information Regulations with current practice.

62. The Department does not anticipate any significant costs from this proposed change as it is just a name change in the formal regulations. The Department currently receives the vast majority of notifications via DaSH with a small volume of email notifications. This change will mean that industry is signposted to report to DaSH. There is no additional staff time expected on either the industry side (to supply the information) or the Department's side (to process and analyse the information).

Costs relating to adaptation 10)

Changes and improvements to arrangements for penalties to suppliers for contraventions

63. The improved compliance adaptation is introducing the ability to apply a penalty to suppliers that do not supply data in accordance with the Information Regulations without issuing a compliance notice. Note this is only related to supplier reported information on discontinuations and shortages, made via DaSH.

64. Currently, if a company does not inform the Department of a shortage, a compliance notice must be issued granting the supplier 7 days to provide the information prior to a penalty being applied. In practice, by the time the Department becomes aware of a supply issue, or a product listing problem, it is often too late to issue a compliance notice and wait the required seven working days for a response. As the Information Regulations stand (and the "business as usual'' baseline), the Department has never issued a 7-day notice or an actual penalty.

65. The proposed change should support more prompt and effective responses to supply risks. There is no cost of additional reporting for industry as they would have to report the discontinuation/shortage anyway. Reporting discontinuations/shortages sooner is not expected to require any more industry staff time than had it been reported at a later date. Therefore, the Department is not expected to experience any cost in terms of staff time resulting from the change, as the Department would be expected to process and analyse the reported data regardless of the timing.

66. There are also no additional set up costs to ensure the data can be stored and analysed effectively and securely. This is because no new data is expected compared to our "business as usual'' baseline.

Costs of data storage (set up costs)

67. Some of the proposed amendments will 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. As per the current regulations, the information would need to be kept for 4 years.

68. As with the previous Information Regulations, the proposed amendments 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. Ultimately, it is anticipated that these requirements to record and store information will not impose any additional costs on suppliers.

Costs of enforcement

69. The proposed amendments would be in line with existing regulation that includes a provision allowing the Department, 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.

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

71. In addition, the appeals regulations provide that either the Secretary of State 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.

72. 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.

Summary of costs

73. Table 2 provides a summary of the costs associated with the proposed policy options (relative to the "business as usual" option). In conclusion, two thirds of costs fall on the Department whereas one third fall on industry.

Table 2: Summary of costs

Cost	As a Result Of…	Associated Proposed Change	Cost Type	Cost Felt By	Annual Value (if Quantifiable)

Industry (suppliers) resource	Suppliers having to report additional information, which takes up staff time and hence industry resource	3), 5), 6), 7)	Industry staff time cost Quantifiable	Industry (suppliers)	~£382,268
Departmental resource	Processing and analysing the additional information provided by suppliers, which takes up staff time and hence the Department's resource	3), 5), 6), 7)	Public sector staff time cost Quantifiable	Department	~£709,819
Total Annual Cost: ~£1,092,087					

74. So far in this Impact Assessment, only our best estimates have been outlined, giving the results above. However, sensitivity analysis has also been conducted by flexing certain assumptions where there is an element of uncertainty on their true value. For these assumptions we took a lower, higher and best estimate.

75. Table 3 outlines all the assumptions which have been used for the sensitivity analysis (and the proposed change they are associated with). Plugging in all the lower estimate assumptions into the model gives our low/optimistic estimate, which represents where costs are limited. Alternatively, plugging in all the high estimate assumptions into the model gives our high/pessimistic estimate, which represents the case where costs are more significant. Our best estimate serves as the central estimate and uses what we believe are the most likely values for the assumptions in question. The costs from all three models are in table 4.

Table 3: Sensitivity analysis assumptions

Proposed Change	Value (Description)	Low Estimate	Best Estimate	High Estimate
3)	Proportion of the market that is branded	0.3[9]	0.2	0.1
5)	Expected uplift in number of notifications after regulation change (%)	10%	20%	30%
6)	Time spent by industry reporting the data (hours) for case study in adaptation 6.	1	6.5	12
6)	Multiplier to account for the number of supply issues per year where this regulation would be used	0.5	1	2

[9] A higher proportion of the market that is branded is in the low estimate because it corresponds to a lower proportion of the market that is generic, and the analysis was conducted on new generics entering the market.

7)	Time spent by industry reporting each product (hours) for the winter monitoring case study	1	7.1	14.2
7)	Multiplier to account for the number of times per year where this regulation would be used	2	4	6

Table 4: Sensitivity analysis results

Model	Total Annual Cost
Low Estimate (optimistic)	~£475,315
Best Estimate	~£1,092,087
High Estimate (pessimistic)	~£2,099,348

76. Based on these costs, we calculated the Net Present Value of the costs of the proposed policy (relative to the "business as usual" option and using a discount rate of 3.5%). The Net Present Value considers a term period of 10 years, from 2026 (Present Value base year) to 2035, see the results in table 5 below.

Table 5: Summary of Net Present Value of costs

Model	Net Present Value
Low Estimate (optimistic)	~ -£4,091,363
Best Estimate	~ -£9,400,341
High Estimate (pessimistic)	~ -£18,070,530

Opportunity cost of departmental resource

77. This IA has estimated ~£710,000 of departmental resource costs in the form of staff time. For these costs, as they fall on the Department, there will be an opportunity cost associated with diverting resources away from other calls on the DHSC budget. Essentially, because some of our resource is being allocated on processing and allocating the information stemming from our proposal, the resource cannot be used elsewhere in the system. Therefore, assuming these costs are not to be funded from additional resource, the ultimate effect of this increased cost pressure for the Department would be felt through a reduction in health elsewhere in the NHS. So, there would be slightly less budget available to fund the NHS, and hence fewer QALYs, valued at their social value.

78. 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 then monetised using their estimated societal value of £70,000[11]. In conclusion, if the DHSC costs

[10] See: Methods for the estimation of the NICE cost effectiveness threshold - York Research Database

[11] Each QALY is monetised using a standard social valuation of a QALY of £70,000. See the official guidance here: The Green Book (2022) - GOV.UK

displace NHS expenditure at the margin, the associated opportunity cost might be greater; and this implies a higher bar for generating any off-setting benefits.

Impact on small businesses

79. 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'.

80. 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.

81. It is hard to gauge the number of small businesses in the market, though it is expected to be relatively small compared to the number of larger businesses. One paper found that in 2020, less than 20% of all human medicines recommended for authorisation were developed by micro, small and medium-sized enterprises (SMEs)[12]. Though this figure uses a broader European definition of SME, which stipulates an annual turnover of not more than 50 million Euro. With our more restrictive definition of NHS sales of £5 million or less, the figure is likely to be significantly below 20%. In addition, small businesses, by their very nature, will have a limited number of products, and thus will have far less products coming under the scope of the information requirements (if they have any at all). Therefore, the burden of reporting in terms of staff time would likely be relatively minor for small businesses. All this is to say that the burden of these amendments will likely fall more so on to bigger companies than smaller companies.

Benefits

82. The main benefits are to improve the reimbursement arrangements ensuring fairly paying dispensing contractors; to further help prevent and be readily available to react to shortages (and to be able to take mitigating action in the most cost-effective way when they do occur) and put an effective compliance regime in place. Ultimately, the main benefits are that the reimbursement arrangements are fairly paying dispensing contractors, and more resilient health service products supply chains are in place ultimately supporting better patient access to medicines, both of which represent taxpayer value for money.

Impact on the reimbursement system

83. The proposed changes would create legal requirements for information from suppliers. This would have several direct benefits for the reimbursement system as follows:
    - Minor and unquantifiable saving to the Department in terms of staff time.
    - Improve the effectiveness and efficiency of the reimbursement arrangements by:
        - Setting more reimbursement prices on supplier sales and volume data with less reliance on suppliers' list prices

[12] Scendea Article on SMEs: Micro, Small and Medium-sized Enterprise Status in the EU and UK — Scendea

- Having up to date information on new products and changes in pack sizes and prices
- Increase the scope of data collection from Hubs, to ensure the whole market is captured by the regulations, this will ensure reimbursement price setting is representative of the market.

84. It is worth noting that there may be additional benefits, though they are already happening in our baseline and are thus not described here.

85. 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 can deliver. 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 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.

86. Ultimately, the reimbursement amendments will ensure that reimbursement prices are timely and more accurate. Meaning that the NHS is less likely to overpay or underpay pharmacies for reimbursement. Both scenarios improve value for money for patients.

Impact on the supply chain

87. The additional information resulting from the changes will also have direct benefits to resilience of the supply chain:
    - Minor and unquantifiable savings to the Department staff time.
    - The Department is aware of supply issues sooner and can take proactive measures in a cost-effective manner.
    - Improve the ability of The Department to understand and react to supply shocks and price rises.
    - The Department will better be able to mitigate and help prevent potential supply shortages cost-effectively.
    - Taken together, these factors will improve the resilience of the supply chain (which helps manage the risk of supply issues of medical products for patients) and ultimately indicate value for money.

88. Although no studies have systematically examined the impacts associated with medicine supply issues using quantitative methods, a UK Parliament Research Briefing[14] highlights that the primary impacts are reduced patient safety and access to medicines, combined with increased pressures on pharmacies and GPs. More specifically, the report highlights how shortages increase patient stress and can lead to a potential deterioration in health and quality of life. In some cases, medicine shortages had negative impacts on patients' work,

[13] The Community Pharmacy Contractual Framework and the retained medicine margin. Available from: The Community Pharmacy Contractual Framework and the retained medicine margin - NAO report

[14] Medicine Shortages Research Briefing. UK Parliament. Available from: Medicines shortages - House of Commons Library

education and relationships. Beyond patients, the report points to the additional workload for pharmacies created by shortages and how medical shortages affect a GP's work and wellbeing.

89. Whilst the lack of systematic empirical evidence in this area means that it is not possible to fully quantify the benefits associated with better management of medicine supply issues, the report discussed does provide an illustration of the potential direct and indirect benefits that might arise, both in terms of time savings for pharmacists and impacts on patients.

90. As an illustrative example, it is possible to determine potential benefits by looking at the winter monitoring case study used for adaptation 7), which had a range of benefits. The information provided for this case study and the analysis of said information allowed the Department to take two significant actions. Firstly, two concentrations of a sugar free antibiotic were reported by a supplier to be out of stock, this allowed the Department to issue both a SSP and an MSN advising the use of the sugared alternatives for patients. This ensured that patients got continued access to medication. Separately, there was a significant rise in demand for a brand of ear drops, which was problematic due to it having a single supplier. Following analysis of demand and the information provided by suppliers, the Department successfully persuaded the supplier to bring stocks forward to avoid a potential outage, ensuring patients were not impacted.

91. These two examples show what has been possible due to the goodwill of suppliers. However, there was no legal requirement for the suppliers to provide this data and so it shouldn't be included under the 'business as usual' baseline as there is no guarantee that the Department will continue to be in receipt of this data. Hence, there is a need to formalise the request for information, in case certain suppliers are not forthcoming with the data.

92. As previously discussed, a comprehensive quantification of benefits has been avoided in this IA, but it is possible to give some figures to illustrate the scale of potential benefits. Again, looking at the winter monitoring case study, one benefit of the information was that it allowed an SSP to be issued to mitigate against any shortage of product.

93. For an SSP, it is not possible to predict the number of shortages that could have arisen or the length of any shortage, but the department can consider potential NHS savings. An SSP enables pharmacists to supply alternative formulations of a product without the need for the patient to revisit the GP to change prescriptions, saving GPs time.

94. Assuming a GP cost per check is 5 minutes and this equates to ~£18 based on GPs unit costs[15], and multiplying this by the number of expected prescriptions, we get to a GP costs saved of ~£155,000.

95. Then, a final figure is derived by looking at the cost per QALY "at the margin". Effectively, for each £15,000[16] of GP time saved we can gain one QALY. Each of these QALYs are each

[15] For GP unit costs: pssru.ac.uk/pub/uc/uc2022/Unit_Costs_of_Health_and_Social_Care_2022.pdf

[16] The £15k is the cost per QALY "at the margin". The £15k is based on an estimate from York University: https://pubmed.ncbi.nlm.nih.gov/25692211/

valued at £70,000[17]. So ~£155,000 of GP time saved can be estimated to equate to ~10.4 QALYs, which when monetised indicates a final saving (benefit) of ~£730,000.

96. This illustrates that up to two thirds of the estimated total annual costs associated with this IA (~£1.1 million) could be recouped by a single use case associated with one proposed amendment. It is also worth noting that what has been quantified here is an indirect benefit stemming from the type of mitigation used (SSP). This illustrative analysis indicates the scale of benefits associated with the proposals set out.

Summary of benefits

97. Table 6 below provides a summary of the direct benefits associated with the proposed changes. It is important to note that these benefits are from the perspective of looking what would change between the "business as usual'' baseline scenario and the proposed option 1. The list is not necessarily exhaustive as there may be indirect benefits stemming from the adaptations. Crucially, it is believed that the changes will ultimately result in value for money, largely due to their improvements in both the reimbursement system and in supply chain resilience.

Table 6: Summary of clear direct benefits

Benefit	As a result of…	Benefit Type	Beneficiary
Minor and unquantifiable saving to the Department's staff time	**Change 1):** The Department no longer has to issue ad hoc requests for information on products not currently in Part VIII of the Drug Tariff. **Change 2):** The Department no longer has to issue ad hoc requests for information on Cat C products. **Change 9):** The Department no longer receive any emails about supply issues, so a minor unquantifiable saving to the Department's staff time.	Public sector staff time saving Unquantifiable (especially minor)	The Department
Price setting for reimbursement for Hub products	**Change 4):** Hubs will be required to record, keep and provide information about the purchase, sale and supply of relevant products (informs price setting for reimbursement).	Public sector efficiency and industry cost saving Unquantifiable	The Department's Reimbursement recipients
Speed up the setting of	**Change 3):** The Department now has extra data on new branded products	Public sector efficiency and	The Department and

[17] Each QALY is monetised using a standard social valuation of a QALY of £70,000. See the official guidance here: The Green Book (2022) - GOV.UK

accurate reimbursement prices for new products entering the market	and generics entering the market, when they change price, or are removed from the market.	industry cost saving Unquantifiable	reimbursement recipients
The Department is aware of supply issues sooner and can take proactive measures	**Change 10):** A robust sanction will act as a deterrent, perhaps causing companies to notify the Department sooner (suppliers would give more notice to prevent receiving a penalty).	Societal - supply resilience Unquantifiable	Society
Improve the ability of the Department to understand and react to supply shocks and price rises	**Change 5):** With more objective regulation, all potential supply instances are reported to the Department via DaSH.	Societal - supply resilience Unquantifiable	Society
The Department will better be able to mitigate and manage actual or potential supply shortages	**Change 4):** Hubs will be required to record, keep and provide information about the purchase, sale and supply of relevant products (providing an overview of product availability. **Change 6):** As the Department can now monitor retail sales of products, it will better be able to mitigate and manage supply shortages. **Change 7):** The Department can get supply data at any point regardless of whether there is a supply issue or not (if there is a public case), allowing the Department to work more proactively and help prevent shortages.	Societal - supply resilience Unquantifiable Unquantifiable	Society

Benefits relative to costs

98. As has been outlined in the costs section, the best estimate indicates an annual cost of ~£1.1m, which compounds to ~£9.4m over a 10-year period in Present Value terms. Therefore, these figures represent the amount of benefit necessary to offset the costs associated with the adaptations. Given the relatively small nature of these costs, representing only a tiny fraction of medicine spend (the NHS in England spends more than £19 billion per year on medicines), and the potentially large scope for benefits, option 1 is considered to be the preferred policy option. On the potentially large scope for benefits, as has been presented above through illustrative analysis, two thirds of total annual costs associated with this IA could be recouped by one aspect of a use case relating to one proposed amendment; indicating the scale of benefits associated with the proposals.

Risks

99. We have identified two main risks associated with the policy adaptations. The first is that there could be an inappropriately high-cost burden placed on suppliers. This will of course depend on the amount, frequency and complexity of information requested. It is worth noting that we have modelled this risk in the sensitivity analysis section, where we have varied select assumptions resulting in a higher cost burden on suppliers. The data collections will be kept under continual review to ensure that burdens on suppliers do not become disproportionate or excessive.

100. The second main risk is that information is collected, and no benefits emerge, for example, if the data collected is not subsequently used in any effective way. This size of this risk rises in line with the anticipated costs of the proposed adaptations – the higher the costs, the greater the benefits required to offset these costs and justify the adaptations. This in turn means that there will be a greater need to ensure that the information collected is properly made use of especially with regard to helping prevent and mitigating supply shortages.

101. To mitigate against risk, it is important that the scope of the information powers is continually kept under review. The Department is required to review the Information regulations annually as stipulated in Regulation 36 to assess the extent to which the Information Regulations are appropriate and are achieving their objectives and whether they can be achieved by less onerous regulatory provisions. We are proposing to reduce the frequency of this review to biannually to reflect current practice and facilitate meaningful evaluation of the Information Regulations and their objectives.

102. If a data collection is found to offer no clear value to the Department, it should be discontinued so it does not burden suppliers. 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.

103. There are also some further minor risks. Firstly, 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 has been discussed previously, 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.

104. Furthermore, another minor risk is that beyond just burdening suppliers, it is possible that they do not feel comfortable with confidential data sharing. Having said this, the legislation outlines the purpose of collecting the data, and what it will be used for, which should mitigate against this risk by providing reassurance that data is being collected only for its outlined purpose.

105. In line with guidance from the Department for Business and Trade, the impact on the internal market needs to be considered for all regulatory IAs. For this IA, the impact on the internal market and hence any risk, is believed to be minimal. To elaborate, the proposed regulatory changes will have minimal to no impact on traders moving goods between Northern Ireland and Great Britain as there is no difference in the regulatory changes between the two nations. Also, the regulations do not impact the ability or willingness of traders to move goods between the two nations.

Summary and conclusions

106. The main costs of the adaptations are the costs to UK suppliers of providing the data to the Department, and the costs to the Department in processing, storing and analysing the information. Our estimates indicate that two thirds of costs fall on the Department whereas one third fall on industry. The main benefits are to improve the reimbursement system; to enhance the Department's oversight of the total supply of medicines, to support better cost-effective planning and help mitigate supply issues and discontinuations and put an effective compliance regime in place. Ultimately, the main benefits should provide greater assurance that the taxpayer is achieving value for money and support better patient access to medicines.

107. Despite benefits not being quantified, there is a particularly large scope for benefits, both direct and indirect, resulting from the adaptations. The main clear direct benefits that this IA has determined are to improve public sector efficiency and improve supply resilience (which reduces the risk of supply issues of medical products for patients).

108. The best estimate indicates an annual cost of ~£1.1m, which compounds to ~£9.4m over a 10-year period in Present Value terms. Therefore, these figures represent the amount of benefits necessary to offset the costs associated with the adaptations. Given the relatively small nature of these costs, representing only a tiny fraction of medicine spend (£19 billion per year), and the potentially large scope for benefits, option 1 is considered to be the preferred policy option. On the potentially large scope for benefits, illustrative analysis indicates that two thirds of total annual costs associated with this IA could be recouped by one aspect of a use case relating to one proposed amendment.