



Department  
of Health &  
Social Care

# Legal requirements to provide information about health service products

Consultation response

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# Executive summary

Between 26 August 2016 and 14 November 2016 the Department consulted on the 'Health Service Products (Provision of Information and Disclosure) Regulations' ('the Regulations').

The Regulations bring together, expand and improve retention and collection of information on a legal basis, implementing the information powers in section 264 of the NHS Act 2006<sup>1</sup> (as amended), in order to:

- help tackle the issue of excessive price hikes of single source generic medicines;
- improve the robustness of the arrangements for reimbursing community pharmacies for health service products dispensed; and
- ensure value-for-money and availability of adequate supplies of health service products.

Information can only be collected and used for limited, specified purposes which are connected with the statutory purposes in section 264A(3) of the 2006 Act:

- to facilitate the determination of remuneration/payment of community pharmacies and GP practices;
- to help ensure the availability of adequate supplies of health service products and value for money; and
- to support the cost control provisions in sections 260 to 265 of the NHS Act 2006.

The consultation contained the following proposals:

- Proposals for quarterly provision of aggregated transaction information about unbranded generic medicines and special medicinal products (manufactured and imported) by manufacturers, importers and wholesalers.
- Proposals for recording, keeping, and providing on request, transaction information about any health service product (medicines, medical supplies or other related products) impacting on all actors in the supply chain (from manufacturers, importers and wholesalers across the UK to pharmacies and dispensing doctors in England).
- Proposals for the provision of information on request about the costs in connection with the manufacture, distribution or supply of health service products, or other aggregated business costs, impacting on manufacturers and wholesalers
- Proposals for the provision of information within 24 hours about volumes and prices about unbranded generic medicines and special medicinal products from manufacturers and wholesalers (concessionary prices).
- Proposals for the notification of discontinuations and supply disruptions of health service medicines by marketing authorisation holders/manufacturers/importers, requiring the provisions of information with six months' notice where this is possible, and proposals for urgent provision of information within 24 hours on request.

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<sup>1</sup> <https://www.legislation.gov.uk/ukpga/2006/41/contents>

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- Proposals for disclosure of information, enforcement and appeals and review of the regulations.

None of the proposals would require companies to set up new systems to record and keep information as the information is already kept by companies for example for tax purposes.

A total of 60 responses were received mostly from industry and industry representative bodies.

This response outlines for each group of proposals what respondents said and what we did with the concerns and comments received.

# 1. Routine information provision

## Voluntary agreements

- 1.1. We proposed to end the three existing voluntary agreements<sup>2</sup> for quarterly information provision and introduce regulations requiring all manufacturers, importers and wholesalers of unbranded generic medicines and special medicinal products (manufactured and imported) to provide certain information every quarter about their sales and purchases.
- 1.2. 48 percent of respondents agreed with this proposal whilst 52 percent disagreed. Those companies currently providing information under the voluntary agreements and their trade bodies thought that the voluntary agreements had worked well and that the Regulations should only apply to those companies that choose not to be part of the voluntary arrangements. In addition, the trade bodies expressed a willingness to update the voluntary agreement to align them with the Regulations so that, for example, the same use could be made of the information and it could be disclosed further.
- 1.3. Although the voluntary agreements have worked well, we have concluded that there would be no benefit in having both Regulations in place covering a range of information provisions and voluntary agreements that only cover the quarterly information provision. It would be burdensome to have to maintain both. Therefore, the Department will terminate the voluntary agreements for information provision.
- 1.4. Transitional provisions have been included in the Regulations to enable those companies currently providing information under the voluntary agreements to choose to continue to provide quarterly information under the schemes voluntarily until the end of the notice periods.
- 1.5. The Department has given notice to end the voluntary arrangements but will nevertheless continue to liaise with the relevant trade bodies i.e. the British Generic Manufacturers Association (BGMA), the Healthcare Distribution Association UK (HDA) and the Association of Pharmaceutical Specials Manufacturers (APSM) about matters related to the quarterly information provision and wider information provision.

## Products that information is required to be provided about

- 1.6. We proposed that every quarter manufacturers, wholesalers and importers would provide us with information about all unbranded generic medicines and special medicinal products sold (manufacturers and suppliers including wholesalers) and bought (wholesalers and importers of special medicinal products). In paragraph 5.17 of the consultation document it was wrongly suggested that we would also require information about purchases from importers of unbranded generic medicines. Importers would only need to provide us with information about their sales unlike importers of special medicinal products who have a role in the supply chain that is more similar to that of wholesalers. Where a wholesaler imports an unbranded generic medicine (i.e. a parallel

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<sup>2</sup> Scheme M between the Department and the British Generic Manufacturers Association (BGMA); Scheme W between the Department and the Healthcare Distribution Association UK (HDA); Memorandum of understanding for manufactured specials between the Department and the Association of Pharmaceutical Specials Manufacturers (APSM)

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imported unbranded generic medicine) we would expect both purchase and sales information.

- 1.7. For unbranded generic medicines 47 percent of respondent said that they had concerns about this whilst 53 percent had no concerns. For special medicinal products, 53 percent had concerns and 47 percent had no concerns. From the responses it has become clear, especially for special medicinal products, that requiring the provision of information about all such products would put an excessive burden on companies. As special medicinal products are bespoke their number is infinite unlike for authorised medicines. Most respondents thought it would be preferable for the Department to work with a list of products for which information is required that would also ensure consistent naming and coding of products. Concerns were also expressed about the proposal for routine provision of information about sales to secondary care as the Department would have no immediate use for that information: unlike primary care sales information, it would not be used to inform reimbursement arrangements for community pharmacies.
- 1.8. Rather than prescribing a list of products in legislation that would quickly become out of date, under the quarterly information provisions (in Part 2 and Part 3 of the Regulations) manufacturers, wholesalers and importers will be required, each month, to record and keep specified information about each available pack size of a presentation of unbranded generic medicine and special medicinal product listed with a price in that month's Drug Tariff for England/Wales, Scotland and Northern Ireland and to provide the information to the Department each quarter. There are no quarterly information requirements in relation to pack sizes above 120 capsules/tablets or 500ml for liquids or topical creams. We will use the "information on request" provisions in Part 4 of the Regulations to require information about any unbranded generic medicines and special medicinal products that we are considering including in any of the Drug Tariffs. In practice, to facilitate information provision, the Department will provide a spreadsheet each quarter listing the products for which companies must provide information. Working with this list will ensure that the same product names and coding are used by all companies providing information. The spreadsheet will be available to be downloaded before the end of the quarter for which information has to be provided. No information will be required about sales to secondary care.
- 1.9. Some respondents thought that the Department should require the provision of quarterly information about all health service medicines instead of only unbranded generic medicines and special medicinal products. However, quarterly information about unbranded generic medicines and special medicinal products is used to inform reimbursement arrangements for community pharmacies. Prices of branded medicines (including branded generic medicines) are controlled by the Pharmaceutical Price Regulation Scheme (PPRS) and statutory scheme for branded medicines and therefore we would have no direct use for quarterly information about such medicines as it is not used to set reimbursement prices for community pharmacies. Ministers committed in Parliament to only requiring the provision of information for which we would have a use.

## Information that is required to be provided

- 1.10. We proposed that every quarter the following information would need to be provided for each presentation:
  - whether the category of purchaser for each presentation is category A, B, C or D;
  - the quantity of each presentation that is sold or bought;



## Routine information provision

- the sales income received for each presentation, being the income from the sale of the presentation after deduction of any discounts or rebates or other payments given that can be attributed to the sale of the presentation;
  - the amount that is paid for each presentation after deduction of any discounts or rebates or other payments received for the amount paid; and
  - the discounts, rebates or other payments given or received for each presentation which cannot be attributed to that presentation.
- 1.11. 72 percent had views on the information whilst 28 percent had no views. 60 percent had concerns in particular about attributing their sales to categories of purchasers. Current IT systems are not designed for this. Concerns were also expressed that information about discount, rebates and other payments are often estimates as they can build up over the duration of a year depending on the supplier's terms and the amount of products bought or sold. For special medicinal products concerns were expressed that the proposed information provision does not match the information that is provided by some manufacturers under the voluntary agreements. Many respondents also said that it was not clear who is required to provide information about sales and who about purchases.
- 1.12. We have dropped the proposed requirement to provide us with information about the different categories of purchasers. For special medicinal product we have had to distinguish between made special health service medicines (i.e. manufactured in the UK) and imported special health service medicines to reflect that, as outlined in the consultation document, we require both purchase and sales information about imported specials from importers/medicines wholesalers. Following comments from consultees and to reflect current practice under the voluntary arrangements, for made special medicines we have included the requirement to provide information about the type of manufacture i.e. whether the product was made in a batch or individually and the excipient formulation i.e. whether the product is, for example, sugar or alcohol free.
- 1.13. Every quarter manufacturers and import-suppliers of unbranded generic medicines will be required to provide information about their sales to primary care service provider, NHS chemists and wholesalers. Wholesalers of unbranded generic medicines will be required to report information about their purchases and their sales to primary care service providers and NHS chemists. Manufacturers of made special medicines will be required to provide information about their sales to primary care service provider, NHS chemists and wholesalers. Wholesalers of made and imported special medicines and importers of imported special medicines will be required to report information about their purchases and their sales to primary care service providers and NHS chemists.
- 1.14. Following concerns raised by respondents, companies will be able to provide a reasonable estimate of their net sales income and/or the net purchase amount paid to reflect that for discounts, including rebates and other payments it may not be possible to provide actual amounts. All discounts including rebates and payments will therefore have to be included by companies when submitting their net sales income and/or net purchase amount. The Regulations enable the Secretary of State to ask a company that has provided a reasonable estimate to give the reasons for which an estimate was provided rather than the actual amount and the method used to calculate the estimate.

## Timelines

- 1.15. We proposed that the quarterly information would have to be provided by the 28th of the month following the end of a quarter.

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- 1.16. 68 percent of respondents had views on the timelines whilst 32 had no views. Most respondent said that if information was required about all unbranded generic medicines and special medicinal products including the categories of purchasers then more time would be required to provide the information.
- 1.17. We have reduced the amount of information that companies are required to provide and we no longer require sales to be attributed to different categories of purchasers. The requirements to provide information by the 28th of the month following the end of the quarter remains.

## Monthly versus quarterly provision

- 1.18. Because the different Drug Tariffs are published monthly we sought views about the impact of requiring the provision of information every month rather than every quarter.
- 1.19. Respondents favoured quarterly provision of information because the burden would increase significantly with monthly provision. Any discounts, rebates and other payments would also be more difficult to estimate on a monthly basis. Some respondents suggested that monthly provision would be possible and that this could potentially negate the need to set concessionary prices.
- 1.20. We do not want to further increase the burden on companies by introducing a monthly requirement and therefore, the requirement to provide information will be for every quarter rather than for every month.

## Parallel imports

- 1.21. The requirement to provide sales and purchase information about unbranded generic medicines applies equally to wholesalers providing these medicines under a parallel import licence or parallel distribution notice. The immediate purpose of the quarterly information is to inform reimbursement arrangements for community pharmacies. If parallel imported products are sold to NHS chemists then it is appropriate to take account of those sales for the reimbursement arrangements.

## Reimbursement arrangements

- 1.22. Some respondents queried what impact the Regulations would have on the reimbursement arrangements for community pharmacies and dispensing doctors. The Regulations will improve the provision of information and enable the Department to use it for any of the statutory purposes set out in section 264A(3) of the NHS Act 2006 (summarised in the executive summary). Any changes to the reimbursement arrangements would have to be agreed with Pharmaceutical Services Negotiating Committee (PSNC) for community pharmacies and the British Medical Association (BMA) for dispensing doctors in England. Similar arrangements are in place in Scotland, Northern Ireland and Wales and any changes there would also need to be consulted on separately.

## 2. Information provision on request

### Branded medicines

- 2.1. The industry for branded medicines thought that they should be entirely excluded from the Regulations as the prices of branded medicines are controlled either by the Pharmaceutical Price Regulation Scheme (PPRS) or by the statutory scheme Regulations for branded medicines. Both schemes contain requirements for information provision. The sector argued that the Regulations were never intended to cover branded medicines. It has however been the intention from the start to apply the on request information provisions to any UK health service product. The illustrative regulations published during the passage of the Health Service Medical Supplies (Costs) Bill 2017 contained such provisions.
- 2.2. The previous statutory scheme Regulations for branded medicines were supported by the Health Service Medicines (Information Relating to Sales of Branded Medicines etc.) Regulations 2007. Both sets of Regulations have been revoked. The 2007 Regulations contained requirements to retain sales income information and provide it when requested. Although the new statutory scheme Regulations contain their own information requirements to support the payment scheme, they rely on the Information Regulations for the retention and provision of information about net sales income. This will enable the Department when necessary to confirm whether or not a breach of the maximum price (Part 2 of the statutory scheme Regulations) has occurred and to calculate accurately the amount that the manufacturer or supplier actually received in order to improve the Department's ability to determine the recoverable sum or to apply a statutory scheme penalty.

### Medical supplies and other related products

- 2.3. We consulted on a definition of medical supplies and other related products that included appliances, foods and dermatological products that are listed in the Drug Tariff, foods and dermatological products that are not listed but are supplied on NHS prescription and appliances, food and dermatological products that are prescribed or directed in hospitals or are available under an NHS framework agreement for supply to patients.
- 2.4. 42 percent of respondents said that they had views on the definition whilst 58 percent had not. 25 percent had suggestions for an alternative definition whilst 75 percent had not. The concerns raised by the appliances industry focused on the lack of clarity of the definition which they argued would lead to uncertainty for producers as to whether their products would be caught by the Regulations or not. In particular, the use of the terminology 'prescribing' and 'directing' in a hospital setting were considered not to be sufficiently clear as this terminology is not necessarily used in a hospital setting. Few responses were received from the foods and dermatological products industry.
- 2.5. To ensure that industry has certainty about which products are caught by the Regulations we have decided to limit the scope of the requested information to appliances and chemical reagents listed in Part IX of the Drug Tariff for England and Wales and equivalent lists in the Drug Tariffs for Scotland and Northern Ireland. We have decided not to include food and dermatological products as we have concluded that we did not consult the appropriate industry bodies. Many foods listed in the Drug Tariff can be supplied by a supermarket, for example, and we did not consult that sector

on the proposed requirements. We have, however, retained the requirement for anyone supplying patients to record and keep information about food and dermatological products which are, when they are supplied, listed in a Drug Tariff. This has been done to reflect that as part of the margins survey<sup>3</sup> the Department requires information about these products.

### Information that is to be recorded, kept and provided

- 2.6. We proposed that every quarter the following information would need to be recorded, kept and provided on request by any actor in the supply chain (except NHS chemists and primary medical service providers in Scotland, Northern Ireland or Wales):
- the invoices which relate to the sale or purchase of each presentation/ any products;
  - the name of the purchaser or seller of each presentation/ any products;
  - the category of purchaser for each presentation/ any products (category A, B, C or D);
  - the quantity of each presentation/ any products that is/are sold or bought;
  - the sales income received for each presentation/ any products, being the income received from the sale of the presentation/products after deduction of any discounts or rebates or other payments given that can be attributed to that sale;
  - the amount that is paid for each presentation/ any products after deduction of any discounts or rebates or other payments received for the amount paid;
  - the discounts, rebates or other payments given or received by the producer which cannot be attributed to a particular presentation/product;
  - the terms which applied to any discounts or rebates or other payments;
  - the name of any person who received the discounts or rebates or other payments; and
  - whether the presentation/products is/are an English health service product(s), Welsh health service product(s), Scottish health service product(s) or Northern Ireland health service product(s).
- 2.7. 85 percent of respondents said they had views on the information that was proposed to be recorded, kept and provided on request. The concerns raised were:
- The burden of putting systems in place to record the information listed.
  - Whilst the information that is required to be recorded and kept is included in the information that companies are already required to keep for tax purposes, much of the information is not easily extracted from systems and companies may have to obtain the information from invoices when they are requested to provide the information.
  - It is not clear how often the Department will request information.
  - It would be difficult, and in some cases impossible, to provide the category of purchaser for each presentation (see also quarterly information) and whether a product is an English, Welsh, Scottish or Northern Ireland product.
  - Information about discounts, rebates and other payments is often an estimate as they can build up over the duration of a year depending on the amount of products bought or sold (see also quarterly information).

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<sup>3</sup> <https://psnc.org.uk/funding-and-statistics/pharmacy-funding/margins-survey/>

## Information provision on request

- It is not clear who can be requested to provide information about sales and who about purchases.
- Producers should be able to appeal any request for information.
- The Department should always provide a reason for requesting information and should allow for a reasonable timeline for any information to be provided.
- Information that is subject to non-UK confidentiality obligations.

## Extraction of information from systems

- 2.8. Some respondents thought that they would be required to put systems in place to record the information listed in the Regulations in a particular way. That is not the intention. The information can be recorded in any way the producer sees fit and as the information is already required to be kept for tax purposes, there should be no need to put new systems in place. However, we recognise that how easy it is to extract information from systems will vary per producer depending on the IT systems they have in place. Depending on the information request, it may be necessary for some producers to extract certain information from individual invoices.

## Number of requests

- 2.9. Some respondents asked how often the Department would request information. Whilst the Regulations do not put a limit on the number of requests, in the accompanying Impact Assessment we have estimated that the number of requests per year would be between 25 and 75 requests which may be addressed to one or multiple producers. We believe this is a realistic estimate. These figures do not include any ad-hoc requests for information about any unbranded generic medicines or special medicinal products that we are considering including in any of the Drug Tariffs or the requests for community pharmacies to provide their invoices for the purpose of the Margins Survey.

## Changes to the information to be recorded, kept and provided

- 2.10. In response to requests to make clear who can be asked to provide specific information, we have listed the requirements for each actor in the supply chain separately. Part 4 is therefore longer than the consultation draft regulations but essentially only small changes have been made to the information that is to be recorded, kept and provided on request. These include that companies will be able to provide a reasonable estimate of their net sales income and net purchase amount paid when it is not possible to provide actual amounts. The Regulations enable the Secretary of State to ask a company that has provided a reasonable estimate to give the reasons for this and the method used to calculate the estimate.
- 2.11. We have also ensured that the information to be recorded, kept and provided on request is accurate for special medicines which are slightly different products from other medicines.
- 2.12. We have clarified that whilst we can ask for information about the categories of purchasers and whether a product is an English, Welsh, Scottish or Northern Ireland product, this information only has to be provided if known to the producer.
- 2.13. As noted in the consultation paper, we expect that most requests under these provisions would be targeted at specific products and/or parts of the supply chain where more transparency is required about transactions. Therefore a company would be unlikely to have to provide all of the information that they are required to record and keep under these provisions.



## Appeal of request

- 2.14. Some respondents felt that a producer should be able to appeal a request for information, including when they think the request is too onerous. The Regulations provide a right of appeal against an information notice (issued under Part 5) or a compliance notice which the Secretary of State may issue if a producer fails to provide other information required under the Regulations or provides incorrect or incomplete information. There is also a right of appeal against any penalty demand issued by the Secretary of State (see Chapter 7).

## Timeline for providing information

- 2.15. To ensure consistency across the Regulations, information requested under these provisions must also be provided within 28 days of receipt of a request

## Non-UK confidentiality agreements

- 2.16. Some respondents raised concerns that UK producers may be in breach of an obligation of confidentiality which may exist in their contracts with foreign suppliers if they provide the information on transactions or costs which the Department may require and therefore there should be an exemption.
- 2.17. It is standard practice for contracts to permit the disclosure of confidential or commercially sensitive information required for regulatory purposes and it would be advisable for producers to ensure that their contracts with overseas suppliers do permit the provision of information about health service products required by these Regulations.
- 2.18. The information obtained can only be used for the statutory purpose specified in section 264A(3) of the NHS Act 2006. Given the statutory limits on the uses which the Department may make of the information, the restrictions on disclosure in section 264B and the fact that the Act expressly states that the provision of information by virtue of section 264(A) does not breach
- any obligation of confidence owed by the person providing it, or
  - any other restriction on the provision of information (however imposed)
- 2.19. The Department does not consider that the provision of information under the Regulations would be likely to amount to an actionable breach of confidence and therefore there is no need for an exemption to accommodate any confidentiality provisions in contracts with overseas suppliers.

## Period for which information is required to be kept

- 2.20. We proposed that the information would be required to be kept for a period of six years. This period was chosen to align with the existing requirement to keep information for tax purposes.
- 2.21. 64 percent of respondents said they had views on the six years' period whilst 36 percent had no views. Respondents generally said that whilst the information is included in the information that is required to be kept for tax purposes, it may not be easy to extract the information from their systems as often the information is on invoices. Respondents suggested that the Department should shorten the retention period to between two and four years.
- 2.22. We acknowledge the concerns raised about the difficulty of extracting information and have therefore reduced the period for which information has to be kept from six to four years. In most circumstances we would ask for recent information (i.e. from the past

year) but there may be circumstances, for example where we would want to understand how the price of a product has increased incrementally over several years, when we would ask for information going back up to four years.

## Provisions for small producers

- 2.23. We proposed that small producers would be able to provide the information requested by means of pre-existing material such as invoices.
- 2.24. 56 percent of respondents agreed with the provisions whilst 44 percent did not. Those that did not agree did so for a variety of reasons. Some respondents thought that small producers should not be treated any differently at all. Others suggested additional provisions for small producers such as longer timelines to reply to requests.
- 2.25. We have not made any changes to the provisions for small producers. We have included a general timeline for responding to request of 28 days which we believe is sufficiently long for all UK producers including small producers.

## Definition of small producer

- 2.26. We proposed to define a small producer as a UK producer with an annual UK turnover of £5m or less. Primary medical service providers would be allowed to submit information in the form of pre-existing material including invoices.
- 2.27. 45 percent agree with the proposed definition whilst 55 percent did not. Of those who did not agree most argued that the definition should not be based on annual UK turnover but on income from NHS sales as the Regulations only apply to health service products. The community pharmacy sector thought that for community pharmacies the annual reimbursement income should be used for the threshold. Some in the community pharmacy sector argued that a community pharmacy should always be considered a small producer. The medical devices sector suggested aligning with the EU definitions of small and medium sized companies.
- 2.28. We have changed the definition of small producer so that it covers:
- primary medical service providers (unless they are a wholesaler with a net NHS wholesale income of over £5m);
  - English NHS chemists with an annual remuneration of £5m or less (unless they are also a wholesaler with an income of over £5m);
  - NHS hospital purchasers (i.e. the hospital purchaser of UK health service products) with a net annual NHS expenditure of £5m or less (unless they are a wholesaler with an income of over £5m);
  - any other UK producer with net annual NHS sales of £5m or less in the United Kingdom.
- 2.29. Whilst we have some sympathy for the proposal that NHS chemists should automatically be considered a small producer, this would mean that large pharmacy chains would be considered a small company which would not be appropriate. Independent community pharmacies are likely to fall within the new definition of small producer.
- 2.30. We have not adopted the EU definitions of small and medium sized companies as that would increase the number of small producers considerably.

## 3. Information about costs

### Information that is to be recorded, kept and provided

- 3.1. We proposed that manufacturers and wholesalers of health service products would be required to record, keep and provide on request the following information (following an information notice if it is about a particular health service product):
- the manufacturing costs,
  - the supply costs,
  - the distribution costs,
  - the research and development costs,
  - the capital costs
  - the business costs, and
  - any other costs related to the manufacture, distribution or supply of that product.
- 3.2. This is information that producers can reasonably be expected to record and keep for the ordinary and proper conduct of their business, having regard to the desirability for any business to understand its own cost.
- 3.3. 78 percent of respondents had views about the information and 22 percent had no views. The industry for branded medicines thought that the sector should be exempted from this regulation as prices are controlled by the Pharmaceutical Price Regulation Scheme (PPRS) and the statutory scheme Regulations for branded medicines. They argued that, for branded medicines, the Department pays the price that is considered cost effective and therefore, the Department would have no use for cost information about branded medicines. Other concerns included the lack of a possibility to appeal requests, the need for the Department to include the reason for an information notice because otherwise the notice could not be appealed and the lack of clarity in the difference between information notices and requests. Furthermore, respondents thought it was important that the Department issued guidance for apportioning costs to individual products.

### Cost information

- 3.4. We agree with the industry for branded medicines that the Department would not normally need to request further information about the costs of branded medicines as prices of those medicines are controlled unlike the prices of unbranded generic medicines, special medicinal products and appliances. However, there may be circumstances in which we would want to ask for information about the distribution/supply costs incurred by the producer in connection with a particular branded medicine, for example where the product is not sold to a wholesaler but is supplied by the wholesaler on behalf of the manufacturer or is supplied directly to pharmacists. Therefore, we have clarified in the Regulations that for branded medicines we can only require cost information related to the distribution or supply of a particular presentation of health service medicine and not in relation to its manufacture.
- 3.5. For unbranded generic medicines, special medicinal products and appliances we encourage competition to keep prices down. The Secretary of State does however have the power to introduce cost controls for these products under sections 260 to 265 of the NHS Act. The Department may need to request information about costs including the costs of manufacture to support the use of these cost control provisions.



## Information about costs

- 3.6. Relevant costs are defined in the Regulations (see Part 5) as any costs (including, for example, manufacturing, supply, distribution, research and development, capital and business costs) other than costs which relate to any transaction between the producer and a UK producer for the relevant health service product. These are the same as the costs referred to in the consultation draft regulations.

## Appeal of a request

- 3.7. Some respondents felt that a producer should be able to appeal a request for information, including when they think the request is too onerous. See paragraph 2.14 on appeals.

## Guidance

- 3.8. When the Department issues an information notice or request there will be accompanying guidance for the apportioning of costs to ensure consistency of the information provided.

## 4. Information provision for concessionary prices

### Information to be provided

- 4.1. We proposed to introduce a requirement on manufacturers, wholesalers and importers to provide information within 24 hours about available volumes and prices of generic medicines and special medicinal products with a price listed in part VIII of the Drug Tariff. The Department would use this information to inform any concessionary prices.
- 4.2. 75 percent of respondents had views on this whilst 25 percent had no views. The biggest concern was that 24 hours is a very short period and this would not work on weekends or bank holidays. Some also expressed concern about the lack of clarity about what prices the Department would require. Finally, the penalties for not providing information or providing it late were considered disproportionate.
- 4.3. We have changed the deadline for providing information from 24 hours to within two working days beginning with the day on which the request is received. We have also clarified that we require information on prices net of any discounts, rebates and other payments. Concerns about the level of the penalties have been addressed in the revised penalties regime (see enforcement).

### Approaching suppliers

- 4.4. We sought views on how suppliers wanted to be contacted by the Department for the information.
- 4.5. 62 percent of respondents had views on how we should approach suppliers whilst 38 percent had no views. Most favoured an email followed up with a phone call but this would require the Department to keep an up-to-date contact list. Some respondents warned of unintended effects of asking for information to inform concessionary prices which could increase shortages.
- 4.6. We will use a combination of email and phone to seek information from suppliers.

## 5. Information provision about discontinuation and supply shortages

### Rationale for introducing the legal requirements

- 5.1. We consulted on proposals for the notification of discontinuations and supply shortages of medicines. We estimate that less than half of companies inform us about discontinuations and supply shortages under the existing voluntary guidelines. The Department is informed about many discontinuations and shortages by the NHS when it is too late to take action to mitigate the impact on patients. The Department therefore believes that moving to a regulatory approach is appropriate.
- 5.2. 47 percent of respondents agreed with the Department's rationale whilst 53 percent disagreed. Both ABPI and BGMA and their members expressed a strong preference for continuing with the voluntary guidelines. They also questioned whether the Secretary of State has the power under the 2017 Act to require notification of discontinuations and supply shortages. Concerns were also raised about duplication of the notification requirement by Medicines and Healthcare Products Regulatory Agency (MHRA) for discontinuations and the notification requirement applying to special medicinal products and parallel imported medicines.
- 5.3. Any discontinuation and supply shortage can have a direct impact on patients when their medicine is no longer available. Mitigating the impact on patients can also lead to additional cost pressures on the NHS. Where the Department is not notified and is therefore unable to mitigate the impact on patients in a timely manner, the impact on patients and the associated costs can be even greater for example as a consequence of increased GP visits or hospitalisations. Therefore, despite the concerns raised, we have decided to move to a regulatory approach because we believe that is the only way to ensure timely notification of discontinuations and supply shortages.
- 5.4. The relevant powers are provided in section 264A(3)(c),(f),(i) and (k). These enable the Secretary of State to require information that enables or facilitates the consideration by him or by Welsh Ministers, Scottish Ministers or a Northern Ireland Department of whether (i) adequate supplies of health service products are available and (ii) the terms on which those products are available represent value-for-money. The information suppliers will be required to provide about discontinuations or supply shortages will assist such consideration.
- 5.5. There is already an obligation on Marketing Authorisation holders in regulation 73 of the Human Medicine Regulations to inform the Medicines and Healthcare products Regulatory Agency (MHRA) about discontinuations within two months before the discontinuation. This is for the purpose of determining the status of the licence. The requirement to inform the Department is for an entirely different purpose as noted above.
- 5.6. For the purpose of managing the impact of a discontinuation on patients two months may not be sufficient and, therefore, the Department requires six months' notice of a discontinuation or supply shortage (or if there is less than six months to go as soon as reasonably practicable after the producer becomes aware there may be a supply shortage or takes the decision to discontinue a medicine).
- 5.7. We have restricted the notification requirement to authorised medicines only so special medicines are excluded as they are made bespoke and cannot be in shortage. We have

also exempted parallel imported products because the importer of these products is unable to know whether a medicine is being discontinued or is in shortage.

### Trigger for notifying the Department

- 5.8. We asked what would be the consequences of moving to a regulatory approach. We received 36 responses to this question. We also asked for views on the trigger for notifying the department which we proposed would be when the shortage would result in a direct impact on patients. 73 percent of respondents said they had views on the proposed trigger whilst 27 percent said they had no views. In response to both questions the same concerns were raised. Most concerns focused on the lack of a definition of a supply shortage and lack of clarity of the trigger point. The industry for unbranded generic medicines also said that it would be difficult for a manufacturer to assess whether a shortage would result in a direct impact on patients when there are multiple manufacturers on the market.
- 5.9. As noted in paragraph 5.6, we require six months' notice of a discontinuation or supply shortage that will have a direct impact on patients. However, if a producer becomes aware of the likely shortage less than six months before the anticipated impact, we require the producer to notify us as soon as reasonably practicable after the producer becomes aware of the likely shortage. This meets the Department's need for sufficient notice to help manage the adverse impacts of a supply disruption. It also acknowledges that a producer will have to decide on a case-by-case basis, as it does presently, whether the supply shortage would be likely to have an impact on patients and therefore the Department must be notified. Any definition of a supply shortage would inevitably lead to shortages falling outside of the scope of the definition and therefore not being notified. The same approach was taken in the voluntary guidelines agreed with the ABPI and BGMA. We have therefore not made any changes to the trigger.
- 5.10. We recognise that manufacturers of unbranded generic medicines often operate in a competitive market where it may be harder for them to assess whether a medicine is in shortage. Nevertheless they are subject to the same information requirements and would be required to notify the Department in the same way to help manage the potential impact on patients. Whilst this will inevitably lead to more notifications of potential shortages, the information will help the Department in mitigating any impact on patients.

### Information that is required

- 5.11. We consulted on the information that would be required to be provided as part of a notification of a discontinuation or supply shortage. We proposed the following information:
- the name of the presentation;
  - the licensed uses of the presentation and the unlicensed uses of the presentation that are known to the designated UK producer;
  - the reasons for the discontinuation or supply shortage;
  - the anticipated duration of the supply shortage;
  - the amount of stock held by the producer for that presentation;
  - the anticipated date, if any, of the next delivery of the presentation;
  - the designated UK producer's market share for the presentation;
  - the steps taken, if any, to address any anticipated supply shortage;

## Information provision about discontinuation and supply shortages

- the name and contact details of a representative for the UK producer who can provide updated information to the Secretary of State and answer any queries he may have about the supply shortage or discontinuation.
- 5.12. 72 percent of respondents had views on the information whilst 28 percent had no views. Respondents had concerns that not all of the information may be known at the point of notifications.
- 5.13. We have clarified that the producer is required to only provide the uses of the medicines that the producer is aware of and that the producer can estimate its market share. Following responses to the consultation we are also requiring that producer let us know whether the medicine is available under an NHS framework contract when notifying the Department.
- 5.14. The notification requirements will enter into force on 1 January 2019 to enable the Department to publish complementary guidance and to provide industry with additional time to prepare for the requirements.

## Urgent information

- 5.15. We also proposed that if there is a supply shortage of a health service medicine, the Secretary of State can require the provision of information about available stock from manufacturers and wholesalers for that medicine or any therapeutic alternatives. We asked how we should approach companies if information is required to be provided within 24 hours.
- 5.16. 72 percent of respondents had views on the information that is to be provided urgently whilst 28 percent had no views. The concerns expressed were similar to the concerns about urgent provision of information to inform concessionary prices. The biggest concern of respondents was that 24 hours is a very short period and this would not work on weekends or bank holidays. The penalties for not providing information or providing it late were considered disproportionate.
- 5.17. We have changed the deadline for providing information from 24 hours to within two working days beginning with the day on which the request is received. Concerns about the level of the penalties have been addressed in the revised penalties regime (see Chapter 7 enforcement).
- 5.18. 69 percent of respondents had views on how we should approach companies for information. Most favoured an email followed up with a phone call but this would require the Department to keep an up-to-date contact list. Some respondents warned for unintended effects of asking for information about available volumes which could increase shortages.
- 5.19. We will use a combination of email and telephone to seek information from suppliers.

## 6. Disclosure of information

### Trade bodies prescribed in the Regulations

- 6.1. Section 264B of the NHS Act 2006 enables the Secretary of State to disclose information provided under these Regulations to the persons listed in s264B(1) with various confidentiality requirements. In addition, there is the power to prescribe in the Regulations further bodies representing UK producers to whom information can be disclosed. We proposed to prescribe the following industry bodies:
- the Association of British Healthcare Industries;
  - the Association of the British Pharmaceutical Industry;
  - the Association of Pharmaceutical Specials Manufacturers;
  - the British Generic Manufacturers Association;
  - the British Medical Association;
  - the Healthcare Distribution Association;
  - the Pharmaceutical Services Negotiating Committee;
  - the Dispensing Doctor's Association;
  - the British Healthcare Trades Association;
  - the British In Vitro Diagnostics Association;
  - the Proprietary Association of Great Britain;
  - the British Association of European Pharmaceutical Distributors;
  - the BioIndustry Association; and
  - the Ethical Medicines Industry Group.
- 6.2. 38 percent of respondents agreed with the trade bodies prescribed and 62 percent did not. 55 percent agreed with the prescribed purposes whilst 45 percent did not. A number of responding trade bodies thought that they should be included as they represent UK producers. Concerns were also raised in response to this question about when and what information the Secretary of State would disclose. This is addressed below under 'disclosure of information'
- 6.3. In addition to the trade bodies we proposed to prescribe, we have included the following bodies that represent UK producers.
- Company Chemists' Association
  - National Pharmacy Association
  - Association of Independent Multiple Pharmacies
  - NHS Pharmacy Production Committee
  - NHS Pharmaceutical Quality Assurance Committee
  - Surgical Dressings Manufacturers Association
  - Urology Trade Association
- 6.4. Section 264B also includes a power to prescribe NHS foundations trusts and any health service body within the meaning of section 9(4) of the NHS Act 2006. We were not intending to prescribe NHS foundation trusts or other health bodies. However consultation responses highlighted that information about supply shortages would need to be shared within the NHS and to enable us to continue to do this, we have therefore prescribed:
- Any NHS foundation trust (England)

## Disclosure of information

- Any NHS trust established under the 2006 Act (England)
- Any clinical commissioning group (England)
- Any NHS trust established under the 2006 Wales Act; (Wales)
- Any Local Health Board (Wales)
- Any Health Board constituted under section 2 of the 1978 Act (Scotland)
- The Regional Health and Social Care Board established under s 7 of the Health and Social Care (Reform) Act Northern Ireland 2009

## Disclosure of information

6.5. The consultation document set out a number of principles. Nevertheless, 50 percent of respondents said they had concerns about the disclosure of information. These concerns included:

- The wide range of bodies to whom the Secretary of State may disclose information provided under the Regulations
- The circumstances in which information may be disclosed
- Disclosing commercially confidential information of a member from one trade body to another trade body
- Information sharing across the countries in the UK
- The lack of consultation of companies about disclosing their information
- Release of information under the Freedom of Information

## Disclosure policy

6.6. Section 264B of the NHS Act 2006 enables the Secretary of State to disclose information provided under the Regulations to a range of persons but does not require that.

6.7. There may however be circumstances where we would want to disclose commercially confidential information including to:

- NHS Digital or the NHS Business Services Authorities to receive, store or analyse the information on behalf of the Secretary of State;
- the Devolved Administrations to support their community pharmacy reimbursement arrangements or any assessment of value-for-money or availability of health service products;
- trade bodies but this would only ever be commercially confidential information concerning the members of that trade body, for example, the Secretary of State is required to consult the relevant industry body before exercising his powers in s262 to limit any price which may be charged by any manufacturer or supplier for the supply of any health service medicine;
- NHS England or other Government departments to exercise functions connected with any of the matters specified in s264A(3)(a) to (c), (l) or (m).

6.8. Any confidential or commercially sensitive that is disclosed by the Secretary of State to such persons may not be disclosed to another person. And in all cases the information can only be used for limited, specified purposes which are connected with the statutory purposes in section 264A(3):

- to facilitate the determination of remuneration/payment of community pharmacies and GP practices;
- to help ensure the availability of adequate supplies of health service products and value for money; and



## Legal requirements to provide information about health service products

- to support the cost control provisions in s260-265 of the NHS Act 2006.
- 6.9. For each prescribed body in Schedule 4 to the Regulations the relevant purpose for which confidential or commercially sensitive information may be used is also prescribed (see column 2 of Table 1 and Table 2).

## Freedom of Information Act

- 6.10. Much of the information provided under the Regulations will be commercially confidential information. Section 43 of the Freedom of information Act provides an exemption where disclosure would be likely to prejudice commercial interests:
- Section 43(1) provides an exemption under FOIA for information which is a trade secret.
  - Section 43(2) exempts information of which disclosure would, or would be likely to, prejudice the commercial interests of any person (an individual, a company, the public authority itself or any other legal entity).
- 6.11. Section 43 is a qualified exemption, subject to the public interest test. A blanket use of exemption for all information provided under the Regulations as suggested by some respondents would not be appropriate. For each request under the FOIA the Department will need to decide whether the balance of the public interest in maintaining the exemption outweighs that of disclosing the information. In carrying out this test, the Department is required to consider the circumstances at the time at which it deals with the request and decide on the likelihood of prejudice to commercial interests arising on the facts of the case. As part of this, the Department will consult the companies that have provided the information.



## 7. Enforcement and appeals

### Enforcement of the Regulations

- 7.1. We proposed that if a producer does not provide the information or the information is incomplete or inaccurate then the Secretary of State can either request the information again or issue a penalty. The daily penalty would be calculated based on the UK producer's total annual turnover in the United Kingdom.
- 7.2. 67 percent of respondents had views on the enforcement of the Regulations. Most concerns focused on the level of the daily penalties which were considered disproportionate especially for smaller companies. Concerns were also expressed about the possibility that a penalty can be issued immediately if the information provided is incomplete or inaccurate. The need for proportionality in the enforcement of the Regulations was also stressed.
- 7.3. As noted in the consultation document, we will enforce the Regulations in a proportionate manner. A mistake in the information provided or providing information one or two days late would be unlikely to result in a penalty. However consistently missing deadlines or failing to provide information would be likely to result in a penalty.
- 7.4. We have amended the Regulations to ensure that the Secretary of State has to issue a compliance notice (asking for information again and providing an extended deadline) before being able to issue a penalty. We have introduced a single penalty of £1000 for breaching the requirements to provide information urgently to inform concessionary prices or in relation to supply shortages. We have also introduced more bands based on financial thresholds to calculate the daily penalty including one for small producers.

## 8. Options considered

- 8.1. In the consultation document we considered a number of options for information provision:
- Option 0: do nothing - continue to rely on the existing voluntary arrangements
  - Option 1: make regulations that require (i) routine provision of information about unbranded 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 unbranded 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 regulations 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)
- 8.2. Under all the options we assumed we would in addition require:
- on request provision of cost information,
  - on request provision of price and volume information within 24 hours, and
  - provision of information about supply shortages.
- 8.3. Option 1 was the Department's preferred option. This option enables us to operate a more robust community pharmacy reimbursement system and use the information provided for the other purposes in the 2017 Act i.e. remuneration, availability and value-for-money and cost control. At the same time, option 1 would provide us with the opportunity to ask any actor in the supply chain for more detailed transaction-level information allowing for targeted information provision. It therefore balances the benefits of the powers with the burden on companies that provision of detailed transaction level information would bring.
- 8.4. 75 percent of respondents agreed with our assessment that option 1 is the preferred option whilst 25 percent did not agree. The 25 percent that did not agree either thought that option 0 should be the preferred option or thought that option 2 would be favourable although the latter was preferred by respondents who would themselves not be subject to the information provision requirements.
- 8.5. The Regulations have been based on option 1.

## 9. Review of the Regulations

- 9.1. We proposed that the Regulations should be subject to an annual review and that the conclusions of that review should be published in a report. That report would set out the objectives of the Regulations and whether they have been achieved and are still appropriate or whether they could be achieved with less of a regulatory burden.
- 9.2. 77 percent of respondents agreed with the proposals for reviews. Some respondents stressed that the burden on companies should be included in the review which we believe is already included. Some also thought that the annual review would automatically lead to changes to the Regulations but this is not the case.
- 9.3. We have not made any changes to the annual review provisions.

## 10. Secretary of State duties assessment

- 10.1. 18 percent of respondents had comments on the duties assessment. Those comments have been incorporated in the updated duties assessment that is attached at Annex A.

# 11. Impact assessment

- 11.1. The impact assessment has been updated by:
  - Changing the costs of the routine collection to reflect changes in the Regulations
  - Changing the IT costs for the Department
  - Changing the costs of supplying non routine data to reflect consultation response
  - Removing the options that we are no longer taking forward
- 11.2. The impact on business, charities or voluntary bodies is the cost of complying with the new information requirements. In particular, UK suppliers of health service medicines, medical supplies or other related products will incur costs associated with collating and providing data to the Secretary of State. It is estimated that over a period of 10 years, the cost would be in the region of £19.6m.
- 11.3. The impact on the public sector is that there will be costs of developing additional systems to collect, process and analyse the data. There may also be some enforcement costs. It is anticipated that over a period of 10 years the cost would be in the region of £3m.
- 11.4. The information powers will also deliver benefits by providing greater visibility to the Department on the functioning of the supply chain for health service products, and ensuring greater value-for-money to the NHS and the tax payer. However these benefits remain unquantified.
- 11.5. The updated impact assessment can be found on [legislation.gov.uk](https://legislation.gov.uk)

# Annex A: Secretary of State Duties Assessment

## Introduction

- 11.6. In developing the proposals behind the Health Service Products (Provision of Information and Disclosure) Regulations 2018 and the Health Service Medicines (Price Control Penalties) and Health Service Medicines (Price Control Appeals) (Amendment) Regulations 2018, Ministers must comply with the Public Sector Equality Duty (PSED) and the Secretary of State's duties in the NHS Act 2006 and consider the Family Test. Some further information about these duties is given below.
- 11.7. The need to comply with these duties and the Family Test arises on each occasion that Ministers perform their public functions. The following proposals are considered in this assessment:
- Proposals for routine information provision
  - Proposals for information provision on request
  - Proposals for the provision of information about costs
  - Proposals for information provision within 24 hours
  - Proposals for information provision about supply disruptions
  - Proposals for disclosure of information
  - Proposals for appeal and enforcement
  - Proposals for review

## Public Sector Equality Duty (Section 149 Equality Act 2010)

- 11.8. This duty comprises of three equality objectives, each of which needs to be considered separately. Ministers must have regard to the need to:
- Eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010;
  - Advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it;
  - Foster good relations between persons who share a relevant protected characteristic and persons who do not share it.
- 11.9. The protected characteristics covered by this duty are age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex and sexual orientation.
- 11.10. We have considered the implications in relation to the proposals outlined above and we do not expect a differential impact on any of the groups with protected characteristics.
- 11.11. The Regulations will provide the Department with information that will help set reimbursement prices for community pharmacies and assure the Department that the supply chain for health service products provides value-for-money to the NHS and tax payer to the benefit of patients. Ensuring that the NHS gets value-for-money from its expenditure on healthcare products will help increase the resources available to provide treatment and other services to patients including those with protected characteristics.

## Duties under the National Health Service Act 2006 (NHS Act 2006)

- 11.12. Whilst this an assessment of the duties in relation to England the assessment will equally apply to the Devolved Administrations.

**Duty in relation to promoting a comprehensive health service (section 1 NHS Act 2006)**

- 11.13. The Secretary of State is required to continue the promotion in England of a comprehensive health service designed to secure improvement:
- in the physical and mental health of the people of England; and
  - the prevention, diagnosis and treatment of physical and mental illness.
- 11.14. The expected benefit of the measures should be a positive indirect impact on the promotion of a comprehensive health service, by increasing the resources available to provide treatment and other services to patients and ensuring the NHS gets value-for-money for money spent on health service products.

**Duty as to improvement in quality of services (section 1A NHS Act 2006)**

- 11.15. The Secretary of State is required to exercise his NHS functions with a view to securing continuous improvement in the quality of services provided to individuals in connection with the prevention, diagnosis or treatment of illness, or public health.
- 11.16. The expected benefit of the measures should be a positive indirect impact on securing continuous improvement in the quality of services by increasing the resources available to provide treatment and other services to patients and ensuring the NHS gets value-for-money for money from expenditure on health service products.

**Duty to have regard to the NHS Constitution (section 1B NHS Act 2006)**

- 11.17. Regard must necessarily be had to the values, principles, pledges and rights in the NHS Constitution.
- 11.18. The NHS Constitution provides the right to drugs and treatments that have been recommended by the National Institute for Health and Care Excellence (NICE) and for local decisions on funding of other drugs and treatments to be made rationally following a proper consideration of the evidence. None of the proposals impact on the rights provided in the NHS Constitution. The proposals, as noted above, should have a positive impact by increasing the resources available and ensuring the NHS gets value-for-money from expenditure on health service products therefore providing more effective, fair and sustainable use of those resources to provide treatment and other services to patients to improve lives.

**Duty as to reducing inequalities (section 1C NHS Act 2006)**

- 11.19. When exercising his functions in relation to the NHS, the Secretary of State must have regard to the need to reduce inequalities between the people of England with respect to the benefits that they can obtain from the NHS.
- 11.20. It is important to emphasise that this duty is separate from the PSED. Socio-economic impacts need therefore to be considered in terms of other socio-economic factors such as income, social deprivation and rural isolation.
- 11.21. Many special medicinal products are used by children, the elderly and patients requiring palliative care. More information about special medicinal products will inform Drug Tariff prices and has the potential to make these products cheaper to purchase and therefore easier to access for these groups.
- 11.22. The expected benefit of the measures should be a positive indirect impact on all NHS patients in the quality of services by increasing the resources available to provide treatment and other services to patients and ensuring the NHS gets value-for-money from expenditure on health service products.

## Legal requirements to provide information about health service products

### Duty as to promoting autonomy (section 1D NHS Act 2006)

- 11.23. The Secretary of State must have regard to securing, so far as is consistent with the interests of the NHS:
- that any other person exercising NHS functions or providing services for its purposes is free to exercise those functions or provide those services in the manner that it considers most appropriate; and
  - that unnecessary burdens are not imposed on any such person.
- 11.24. These Regulations do not impact on the freedom of NHS bodies or providers to provide NHS services as they see fit.
- 11.25. The Regulations impact on all actors in the supply chain for medicines, medical supplies and other related products including those that are NHS providers such as hospitals, pharmacies and GP practices.
- 11.26. Hospitals manufacturing special medicinal products would be covered by the requirement to routinely provide information.
- 11.27. Hospitals, community pharmacies and GP practices, and anyone supplying medicines to patients would be covered by the requirement to keep and record information and provide it on request. The burden on the supply chain should be small because information about transactions is already required to be kept for tax purposes for six and the Regulations require the retention of information for four years. Once the new system is up and running, the costs over and above what businesses need to be doing anyway should be minimal. Moreover, there are provisions for small producers and GP practices that will make it easier for them to provide the information if they are asked to provide information.

### Duty as to research (section 1E NHS Act 2006)

- 11.28. In exercising his functions in relation to the NHS, the Secretary of State must promote:
- Research on matters relevant to the NHS; and
  - The use in the NHS of evidence obtained from research.
- 11.29. Information provisions from across the supply chain for health service products will ensure the NHS gets value-for-money from expenditure on health service products. The information will provide evidence of where the supply chain is not working properly and where there is potential for the Secretary of State to take action.

### Duty as to education and training (section 1F NHS Act 2006)

- 11.30. The Secretary of State must exercise his NHS (and other) functions so as to secure that there is an effective system for the planning and delivery of education and training for persons employed, or considering becoming employed, in the NHS or connected activities.
- 11.31. We have considered this duty in relation to the measures and they do not impact on the Secretary of State's functions to secure education and training.

### Duty with regard to reviewing treatment of providers (section 1G of the NHS Act 2006)

- 11.32. The Secretary of State is required to keep under review any matter, including taxation, which might affect the ability of health care providers to provide NHS services or the reward available to them for doing so.
- 11.33. We have considered this duty in relation to the measures and consider that they positively affect the ability of health care providers to provide NHS services by



supporting more accurate reimbursement of community pharmacy and GP practices; and better value for money from, and availability of adequate supplies of, health service products.

### The Family Test

- 11.34. The Secretary of State for Health of the United Kingdom must consider, and where sensible and proportionate, apply the family test when making policy. The five family test questions are:
- What kinds of impact might the policy have on family formation?
  - What kind of impact will the policy have on families going through key transitions such as becoming parents, getting married, fostering or adopting, bereavement, redundancy, new caring responsibilities or the onset of a long-term health condition?
  - What impacts will the policy have on all family members' ability to play a full role in family life, including with respect to parenting and other caring responsibilities?
  - How does the policy impact families before, during and after couple separation?
  - How does the policy impact those families most at risk of deterioration of relationship quality and breakdown?
- 11.35. We have considered the family test and consider it not applicable to any of the requirements in the Regulations.

## Annex B: statement on prices of unbranded generic medicines

Unlike prices of branded medicines, prices of unbranded generic medicines are not controlled by the Department. Where unbranded generic medicines can enter the market, the Department's view is that effective competition between manufacturers/suppliers acts as an effective means of cost control, ensuring NHS patients have access to crucial medicines at a price which balances the need to secure best value for the NHS with the need to ensure the reliable availability of high quality products.

The Department recognises that allowing freedom of pricing encourages competition, leads to quicker entry to market and has led to the UK paying some of the lowest prices in Europe for unbranded generic medicines. This success has been recognised by the OECD<sup>4</sup> and a recent study by the Millbank Quarterly<sup>5</sup>. The Department is committed to allowing freedom of pricing for unbranded generic medicines where there is effective competition. This means that the Department will allow any changes in market prices to be influenced by existing market mechanisms and that where there is effective competition the Department will not interfere in the operation of the market. What effective competition means will need to be judged on a case-by-case basis.

The Competition and Markets Authority (CMA) has several live investigations into excessive pricing of unbranded generic medicines. It has become clear that where competition is not working effectively, some manufacturers or suppliers have increased their prices to what appear to be unwarranted levels. The Department recognises that there may be legitimate reasons for price increases. However, in cases where unwarranted prices are being charged, the Department has concluded that control of those prices is necessary.

Should the Department identify potentially unwarranted prices that indicate that the normal market mechanisms have failed to protect the NHS from significant increases in expenditure then the Department may intervene to ensure that the NHS pays a reasonable price for the unbranded generic medicines concerned. The Department is proposing to have regard to a range of factors when deciding whether to control the price which may be charged by any manufacturer or supplier for the supply of an unbranded generic medicine including:

- the direct and indirect costs associated with the medicine
- the pricing history of the medicine
- the price of the medicine elsewhere
- the volume of use
- any regulatory requirements
- any investments in and innovation of the medicine
- an appropriate margin for manufacturers and suppliers including wholesalers

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<sup>4</sup> Health at a Glance 2017, OECD

<sup>5</sup> Comparing Generic Drug Markets in Europe and the United States: Prices, Volumes, and Spending, The Millbank Quarterly, volume 95, issue 3, September 2017

## Impact assessment

Any intervention in the price of an unbranded generic medicine by the Department would start with engagement with the company. The Department would use its powers to require the provision of information about the costs of the unbranded generic medicine under the Regulations and use this information in discussion with the company about the price level of the product. If necessary, the Department may use its powers under section 262 of the NHS Act 2006 to limit the price of an unbranded generic medicine. As required by the Act, we would consult the relevant industry body prior to any price determination under section 262. The Department may refer cases to the Competition and Markets Authority for further investigation and action.

If the Department has not engaged with a company about the price of its unbranded generic medicine this must under no circumstance be understood as approval of that price.

The Department will consult the relevant industry bodies, the British Generic Manufacturers Association (BGMA) and the Healthcare Distribution Association (HDA), about its proposed policy and procedures for limiting the price of an unbranded generic medicine under section 262.