



Department
of Health

Proposed legal requirements to provide information about health service products

Consultation

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1. Executive summary

The National Health Service Act 2006¹ ('the 2006 Act'), as amended by the Health Service Medical Supplies (Costs) Act 2017² ('the 2017 Act'), provides the Secretary of State with the power to make regulations to require anyone involved in the manufacture, distribution and supply of health service products (a 'UK producer') to record, keep and provide certain information about the products including invoices and information about prices, discounts, rebates, revenues and profits.

The 2017 Act clearly sets out the purposes for which information can be collected and used which are:

- to facilitate the determination of remuneration/payment of community pharmacies and GP practices ('remuneration');
- to help ensure the availability and value-for-money of health service products ('availability/value for money'); and
- to support the cost control provisions in the 2006 Act ('cost control')

We are seeking views on the proposed 'Health Service Products (Provision of Information and Disclosure) Regulations' ('the Regulations') which would be made under these amended powers. The draft Regulations prescribe who would have to provide information about which health service products on a regular basis and what information would need to be recorded and kept and provided on request only. The draft Regulations also include a requirement for the notification of discontinuation or shortages of supply of health service medicines. The intention is for the Regulations to enter into force by the end of the first quarter of 2018.

This consultation document contains 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. (regulation 3)
- 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 manufacturer/importer to pharmacy and others supplying patients). (regulations 4 & 5)
- 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. (regulation 6)
- 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). (regulation 7)

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

² <http://www.legislation.gov.uk/ukpga/2017/23/contents/enacted>

- 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, or within 24 hours on request. (regulations 8 & 9)
- Proposals for disclosure of information (regulation 10), enforcement and appeals (regulations 11 and 12) and review of the regulations. (regulation 13)

A draft impact assessment, a draft equality assessment and draft Regulations have been prepared to support the consultation document.

We are seeking responses by 14 November 2017. How to respond to the consultation is outlined in Chapter 11.

2. Introduction

Health Service Medical Supplies (Costs) Act 2017

- 2.1. The 2006 Act, as amended by the 2017 Act, provides the Secretary of State with the power to make regulations to require anyone involved in the manufacture, distribution and supply of health service products (a 'UK producer') to record, keep and provide information about those products including invoices and information about prices, discounts, rebates, revenues and profits.
- 2.2. This consultation seeks views on the draft Regulations that would implement the Secretary of State's new information powers in the 2006 Act.
- 2.3. The draft Regulations impact on the whole supply chain from manufacturer/importer to pharmacies and others supplying patients with health service products, with the exception of community pharmacies in the devolved administrations and GP practices (and other primary medical services providers) in the devolved administrations.
- 2.4. UK health service products are defined in section 264A of the 2006 Act and are medicines, medical supplies and other related products used for the purposes of the health services in the United Kingdom. The draft Regulations define more narrowly the medical supplies and other related products which would come within the scope of the proposed requirements.
- 2.5. The 2017 Act clearly sets out the purposes for which information can be collected and used which are to:
 - to facilitate the determination of remuneration/payment of community pharmacies and GP practices ('remuneration');
 - to help ensure the availability and value-for-money of health service products ('availability/value for money'); and
 - to support the cost control provisions in the 2006 Act ('cost control')
- 2.6. The requirements are not entirely new. The 2006 Act already provided the Secretary of State with the powers to require the provision of information to operate the cost controls in sections 260 to 265 of that Act. These powers have been used, including for the statutory scheme for branded medicines.

Existing information collections

- 2.7. The practice of information provision is also not new. The Department currently collects considerable amounts of information from manufacturers, wholesalers and pharmacies for specific purposes, most of which is underpinned by voluntary agreements. Table 1 provides an overview of existing information collections.

Table 1: existing information collections

| Scheme | Type of arrangement | Extent | Purpose |
|-------------------------------|---------------------|--------|---------------------------------|
| PPRS ³ | Voluntary | UK | To operate the PPRS |
| Statutory scheme ⁴ | Statutory | UK | To operate the statutory scheme |

³ <https://www.gov.uk/government/publications/pharmaceutical-price-regulation-scheme-2014>

| | | | |
|--|------------------------|---------|---|
| Scheme M ⁵ | Voluntary | England | To inform community pharmacy reimbursement prices |
| Scheme W ⁶ | Voluntary | England | To inform community pharmacy reimbursement prices |
| MoU for manufactured specials ⁷ | Voluntary | England | To inform community pharmacy reimbursement prices |
| Margin survey ⁸ | Statutory ⁹ | England | To determine community pharmacy medicines margin |

The Regulations

2.8. The draft Regulations contain a mix of requirements for regular information provision, on request information provision and information provision under specific circumstances. All information provided can be used for any of the three purposes in the 2006 Act as amended by the 2017 Act (see paragraph 2.5) i.e. remuneration, availability/value-for-money and cost control.

Routine (quarterly) information provision

- 2.9. The draft Regulations would require all manufacturers, wholesalers and importers of unbranded generic medicines and special medicinal products to provide the Secretary of State, every quarter, with information about their sales and purchases. This information is currently obtained on a voluntary basis from some manufacturers and wholesalers and about a number (and not all) products in primary care. Information from all manufacturer, wholesalers and importers for both primary and secondary care is required to (i) improve the robustness of the community pharmacy reimbursement arrangements, (ii) support the cost control provisions in the 2006 Act where appropriate and (iii) be able to ensure the value-of-money of products to the NHS. The regulations would replace the existing voluntary arrangements scheme M, scheme W and the memorandum of understanding for specials.
- 2.10. Because the requirements would significantly increase the number of companies providing information and the number of products that information is provided about, the Department will explore a web-based solution for information provision that would maintain the confidential treatment of the information provided in line with the Department of Health information management policy.

⁴ <http://www.legislation.gov.uk/ukxi/2008/3258/contents/made>

⁵

http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_115260

⁶

http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4114370

⁷ Not published

⁸ <https://psnc.org.uk/funding-and-statistics/pharmacy-funding/margins-survey/>

⁹ <http://www.legislation.gov.uk/ukxi/2013/349/contents/made>

Information provision on request

- 2.11. The draft Regulations would require actors in the supply chain in the UK (from manufacturer/importer to pharmacy and others supplying patients) to record and keep transaction information about all health service product (medicines, medical supplies or other related products) and provide this on request only. Primary care suppliers are exempt in Scotland, Wales and Northern Ireland.
- 2.12. The information provided could be used for any of the purposes in the 2006 as amended by the 2017 Act i.e. remuneration, availability/value-for-money and cost control.
- 2.13. For example, we would use these provision to obtain invoices from pharmacies for the margins survey¹⁰ or to obtain transaction information when there are concerns that a health service product is not providing value-for-money to the NHS and the taxpayer
- 2.14. The draft Regulations would also enable the Secretary of State to request manufacturers, importers and wholesalers to provide information about costs, including about manufacturing costs etc., which could be used for example to determine whether the price of an unbranded generic medicine is warranted when the Secretary of State has concerns about the price. Also, the Secretary of State could request volume and price information about English health service medicines with a price listed in Part VIII of the Drug Tariff from manufacturers, importers and wholesalers when he considers that a product is not available at the price listed and is considering setting a concessionary price;
- 2.15. We do not expect that it would be necessary for anyone in the supply chain to set up new systems to record and keep information, although UK producers may choose to adapt their existing systems, for example in the recording of discounts, rebates or other payments given that cannot be attributed to a particular product. There will be a small burden related to providing the information.

Information about supply disruptions

- 2.16. The 2006 Act, as amended, also enables the Secretary of State, to require the provision of information to ensure that adequate supplies of health service products are available and that these products represent value-for-money. Supply disruptions often lead to increased prices and a financial impact on the NHS for example because patients need to be switched to different medication. As part of this consultation we are also seeking views about including provisions in the Regulations that require the notification of discontinuation and supply disruptions of medicines by Marketing Authorisation holders, in the case of medicines, or otherwise by manufacturers/importers, as well the urgent provision of information from Marketing Authorisation holders/manufacturers/distributors about availability of medicines to help mitigate the impact on patients.

The proposals in this consultation

- 2.17. The remainder of this document is structured as follows. Chapter 3 of this document outlines the problems that we were addressing with the amendments made by 2017 Act and are looking to address with the proposed Regulations. Chapter 4 sets out our overall approach to information provision. Chapter 5 describes, and invites comment on, the Department's preferred option for proposals for:

¹⁰ <https://psnc.org.uk/funding-and-statistics/pharmacy-funding/margins-survey/>

- routine information provision (unbranded generic medicines and special medicinal products)
 - information provision on request (health service products)
 - provision of information about costs (health service products)
 - information provision within 24 hours to inform concessionary prices (English health service medicines in Part VIII of the Drug Tariff)
 - notification of discontinuation and supply disruption (medicines)
 - information provision within 24 hours in relation to supply disruptions (medicines)
 - disclosure of information
 - enforcement and appeals
 - review of the Regulations
- 2.18. Chapter 6 discusses alternative options for routine information provision, and information provision on request, setting out the relative costs and benefits, and invites comments. Chapter 7 provides an assessment of the proposals with respect to the public sector equality duty and family test, and invites comments. Chapter 8 introduces the draft impact assessment, and invites comments and chapter 9 introduces the draft Regulations, and invites comments. A consolidated list of questions can be found in chapter 10 and how to respond to the consultation is outlined in Chapter 11.

Devolved administrations

- 2.19. The 2006 Act, as amended, does not provide the Secretary of State with the power to request information from community pharmacies and GP practices (or other primary medical services providers) in the Welsh, Scottish or Northern Ireland health services, where the information relates to products used for the purposes of the health services in their respective nations. The Secretary of State does however have the power to request information from manufacturers and wholesalers across the UK related to the products used in the NHS in all four nations. This information can be disclosed to the devolved administrations who can use the information for the devolved purposes listed in the section 264A(3) of the amended 2006 Act, i.e. remuneration and availability/value-for-money.
- 2.20. A memorandum of understanding will be developed between the Secretary of State and Ministers in the Wales, Scotland and Northern Ireland Governments underpinning the collaboration of information provision and the disclosure of information.
- 2.21. The exercise of the powers which relate to Northern Ireland as proposed in the draft Regulations will need to be kept under review, pending necessary legislative requirements being progressed in relation to Northern Ireland.

Consultation on statutory scheme regulations

- 2.22. Separately, the Department is consulting on changes to the statutory scheme Regulations to control the cost of branded health service medicines. Some companies may be impacted by both sets of proposed Regulations.

Responding to the consultation

- 2.23. How to respond to this consultation is outlined in chapter 11.

3. What problems are we addressing?

Introduction

- 3.1. The 2006 Act already contained provisions for the Secretary of State to require manufacturers or suppliers of medicines and medical supplies to provide information to support the operation of the cost and price controls in the NHS Act. The 2017 Act amends the 2006 Act to make clear that the Secretary of State can require the provision of information from any UK producer in the supply chain for the purposes set out in section 264(3) of the 2006 Act.
- 3.2. The changes made to the 2006 Act address three weaknesses in the current information gathering/disclosure arrangements:
 - the lack of powers to obtain comprehensive information to support robust community pharmacy and other primary care reimbursement arrangements and the need for flexibility in the use of information,
 - the lack of powers to ensure visibility to the Government of prices and costs across the supply chain to help ensure that product are available and represent value-for-money, and
 - the lack of powers to require specific information and disclose this to facilitate implementation of price controls on individual medicines under section 262 of the 2006 Act.
- 3.3. The draft Regulations that we are consulting on give effect to the new primary powers and put in place a number of requirements on the supply chain for health service products to provide information that would help the Government address these problems.
- 3.4. Whilst the Government currently relies on voluntary agreements for information to support the community pharmacy reimbursement arrangements and for discontinuations and supply disruptions of medicines, we do not think that existing or updated voluntary arrangements are capable of addressing all the weaknesses outlined above. This is because:
 - the Government needs information from all manufacturers, wholesalers and importers on a routine basis and not only from those that sign up to voluntary arrangements to support robust community pharmacy reimbursement arrangements and increase the flexibility of the use of the information;
 - the Government needs to be able to use the information that is collected routinely for other purposes than community pharmacy reimbursement i.e. value-for-money and supporting price controls;
 - the Government needs to be able to disclose the information to others including the Devolved Administrations and other Government departments;
 - the Government needs to be able to require any actor in the supply chain to provide information related to their sales and purchases of any of their health service products; and
 - the Government needs timely information to be able to mitigate any impact on patient care caused by discontinuations and supply disruptions of medicines.

The need for comprehensive information to support robust community pharmacy reimbursement arrangements

- 3.5. Community pharmacies and primary services providers are reimbursed for the costs of every medicine they dispense. Reimbursement prices are published in the monthly Drug Tariff. There are three Drug Tariffs in the UK: one for England and Wales (made in part by the Welsh Government), and Scotland and Northern Ireland have their own Drug Tariffs. All three are constructed in a similar way, drawing where appropriate on similar market intelligence. Where the Drug Tariff is referred to in this consultation document it means the Drug Tariff for England and Wales unless otherwise stated.
- 3.6. Under the current community pharmacy reimbursement arrangements in England, supporting information about sales and purchases of unbranded generic medicines and (manufactured) special medicinal products is provided on a voluntary basis by some manufacturers and wholesalers.
- 3.7. Whilst these voluntary arrangements have worked well, under these arrangements the information is provided only by those manufacturers and wholesalers of unbranded generic medicines and special medicinal products that have signed up to the voluntary arrangements and the use of the information is limited.
- 3.8. The amendments made by the 2017 Act to the 2006 Act enable the Secretary of State to make regulations to require the provision of information from all manufacturers and wholesalers (including importers) of generic medicines and special medicinal products (manufactured and imported) including for the purpose of facilitating the determination of remuneration/payment of community pharmacies and GP practices.
- 3.9. The draft Regulations would therefore require all manufacturers, importers and wholesalers of unbranded generic medicines and special medicinal products to provide the Department with information about their sales and purchases. This would enable the Department to improve the robustness of the reimbursement arrangements. Reimbursement prices would be based on information from the whole market instead of only part of the market. Also, the Department could, subject to consultation with the Pharmaceutical Services Negotiating Committee (PSNC), use the information to consider basing more reimbursement prices on actual sales and purchase information including for example imported special medicinal products. The information provided could also be used to ensure that medicines represent value-for-money and to support the cost control provisions in the 2006 Act.
- 3.10. The draft Regulations would also require the provision of information within 24 hours (on request) about volumes and prices of medicines with a price listed in part VIII of the Drug Tariff for England and Wales which would give a more robust basis for setting concessionary prices for the Drug Tariff. This information would only be required when the Secretary of State considers that a medicine is not available at the price listed and the number of requests will therefore be limited.
- 3.11. Furthermore, the draft Regulations would enable the Department to require pharmacies in England to provide information. The Department already collects information from a sample of pharmacies in England every month for the margins survey under the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. The draft Regulations would provide us with a stronger legal basis for requiring and enforcing the provision of information. The use of any information for the Margin Survey would be subject to the normal negotiating arrangements with the PSNC as would any change to the community pharmacy reimbursement arrangements.
- 3.12. In the devolved administrations arrangements similar to the margin survey in England are in place or are being put in place through quarterly pricing inquiry arrangements.

The need for transparency about prices and costs across the supply chain to ensure that products are available and represent value-for-money

Value-for-money of products

- 3.13. Although the UK Government and the devolved Governments are generally not the purchasers of health service products, they do pay for all these products and therefore have a direct interest in ensuring that the NHS gets value-for-money from their spend on health service products and that the supply chain is efficient. To illustrate the importance of this, the NHS in England spends approximately £16bn a year on medicines, which has grown by 12% over the last two years, compared to an overall growth rate of just over 6% for NHS spending.
- 3.14. The 2006 Act as amended by the 2017 Act enables the Secretary of State to make regulations that would require UK producers to provide information, amongst other things, to help the Government ensure that health service products represent value-for-money.
- 3.15. The draft Regulations would therefore require all actors in the supply chain for health service medicines, medical supplies and other related products (from manufacturer/importer to pharmacy and others supplying patients) to record and keep information about purchases and sales and provide this on request. The information provided could be used for the other purposes in the 2006 Act and equivalent legislation i.e. remuneration and cost control.
- 3.16. The information provided every quarter about purchases and sales of unbranded generic medicines and special medicinal from all manufacturers, importers and wholesalers for remuneration purposes would also be used to ensure that these products represent value-for-money.
- 3.17. We do not expect that it would be necessary for anyone in the supply chain to set up new systems to record and keep information, although UK producers may choose to adapt their existing systems, for example in the recording of discounts, rebates or other payments given that cannot be attributed to a particular product. There will be a small burden related to providing the information.

Availability & supply of products

- 3.18. The Department monitors shortages of medicines and works with the supply chain to manage shortages and put in place contingency arrangements where necessary. To prevent or mitigate any impact on patients it is important that the Department is made aware of any shortages that could impact on patient care.
- 3.19. The Department has agreed best practice guidelines for the notification and management of medicines shortages with the Association of the British Pharmaceutical Industry (ABPI) and the British Generic Manufacturers Association (BGMA). We estimate that under these guidelines manufacturers notify the Department about half of the shortages that impact on patient care. It is notable that in many instances the Department is informed about supply shortages from other parts of the supply chain only when there is already an impact on patients and the costs of medicines.
- 3.20. The 2006 Act as amended by the 2017 Act enables the Secretary of State to make regulations to require manufacturers and others to notify the Department about any supply shortages that could impact on patient care and any permanent discontinuations. The 2006 Act as amended by the 2017 Act also enables the Secretary of State to require manufacturers and wholesalers etc. to provide information about the available volumes of medicines to support the Department's work.

- 3.21. As part of this consultation we are therefore seeking views as to whether it is timely to move to a regulatory basis for notification of medicines shortages, as proposed in the draft Regulations.

The need for information to implement prices controls under section 262

- 3.22. For unbranded generic medicines the Government relies on competition to keep prices down. This generally works well and has in combination with high levels of generic prescribing led to considerable savings. However, there have been instances where companies have been able to increase the prices of unbranded generic medicines to what appear to be unwarranted levels where there are no competitor products to keep prices down. The Department has, where appropriate, been working closely with the Competition and Markets Authority (CMA) to investigate these price increases.
- 3.23. Section 262 of the 2006 Act, as amended by the 2017 Act, provides the Secretary of State with the powers to limit the price of any medicine. The 2017 Act ensured that even when the manufacturer or supplier is in the voluntary scheme (currently the PPRS) but the medicine in question is not covered by the voluntary scheme, the Secretary of State can limit the price. This means that the Secretary of State now has the power to set the prices of unbranded generic medicines of those companies that are in the PPRS for their branded products. Section 262 could also be applied to special medicinal products. The 2006 Act enables the Secretary of State to make Regulations to require the provision of information that would help the implementation of the price controls in section 262.
- 3.24. The information provided every quarter about purchases and sales of unbranded generic medicines and special medicinal from all manufacturers, importers and wholesalers for remuneration purposes would also support the cost control provisions in the 2006 Act including section 262, enabling the Secretary of State for example to monitor prices.
- 3.25. Also, the draft Regulations would require manufacturers to provide the Secretary of State with information about transaction or costs, including manufacturing costs, related to a product. This information would enable the Department to assess whether the price charged for a medicine is justified and could inform decisions by the Secretary of State to limit the price of a medicine under section 262.

4. Our approach to information provision

Options considered

- 4.1. This chapter sets out the Government's overall approach to the statutory requirements for information provision about health service products.
- 4.2. The Department has considered a number of options for the information requirements related to sales and purchases in the supply chain. They range from continuing with the existing voluntary arrangements to requiring all actors in the supply chain for health service products to routinely provide information about every transaction.
- 4.3. The difference between the options considered is the type of information that is required to be provided, on what products, by whom and whether that information is provided routinely or on request. An overview of the options can be found in Chapter 6 and a detailed assessment of the options is set out in the impact assessment that accompanies this document.
- 4.4. The draft Regulations have been drafted based on the Department's preferred option which is to make Regulations that require:
 - Quarterly provision of aggregated sales and purchase information about each unbranded generic medicine and special medicinal product (product-level information), and
 - On request provision of information related to individual transactions in connection with any health service product that is potentially available on prescription or pursuant to directions from a health care professional (transaction-level information).
- 4.5. In all the options considered the Department would propose to make Regulations that require:
 - On request provision of cost information,
 - On request provision of price and volume information within 24 hours (concessionary prices)
- 4.6. The Department is also considering a regulatory approach to provision of information about supply shortages, and has set out draft Regulations to this effect.

Overall approach

- 4.7. The Department's starting point is that only the Regulations would help the Government address the problems outlined in chapter 3. We currently obtain information about unbranded generic medicines and special medicinal products on a voluntary basis from some manufacturers and wholesalers. The provision of this information from all manufacturers, importers and wholesalers would improve the robustness of the community pharmacy reimbursement arrangements. Moreover, we would want to use the information provided routinely for other purposes in the 2006 Act i.e. ensuring value-for-money and supporting the cost control provisions. Where we would have concerns about a product based on the data provided routinely, we would want to be able to require the provision of more detailed information on an ad-hoc basis. We would also want to be able to require anyone in the supply chain for health service products, from manufacturer/importer to those supplying patients with medicines, to provide the Secretary of State with information on a non-routine basis, for example to obtain

information from pharmacies for the margins survey. It would be impossible to achieve all this through the voluntary agreements from all suppliers.

- 4.8. Furthermore, we want to ensure that the requirements to provide information in the Regulations are proportionate and targeted. Therefore, we propose that aggregated transactions information is provided routinely about unbranded generic medicines and special medicinal products (both manufactured and imported). Information about all other health service products would be on request only with the exception of the notification of discontinuations and supply disruptions of medicines.
- 4.9. We do not expect that it would be necessary for anyone in the supply chain to set up new systems to record and keep information, although UK producers may choose to adapt their existing systems, for example in the recording of discounts, rebates or other payments given that cannot be attributed to a particular product. There will be a small burden related to providing the information.
- 4.10. If at any time the information that we are provided with, routinely or non-routinely, demonstrates the need for expanding or reducing the requirements for routine provision of information then we could update the Regulations. The likelihood is that this would be done following a public consultation that would include an impact assessment.
- 4.11. The Department will explore a web-based solution for information provision that would maintain the confidential treatment of the information provided in line with Departmental procedures.
- 4.12. Table 2 provides an overview of the proposed requirements to record, keep and supply information for different product groups and whom in the supply chain they impact. The proposed requirements are described in more detail in the next chapter.

Table 2: proposed requirements in the preferred option

| | Unbranded generic medicines | Special medicinal products | All medicines | Medical supplies and other related products |
|---|--|---|--|--|
| Requirement to provide information every quarter (regulation 3) | Manufacturers Wholesalers Importers | Manufacturers (including NHS manufacturers) Wholesalers Importers | n/a Under separate statutory scheme Regulations: product-level information from companies in the statutory scheme only | n/a |
| Requirement to record and keep information about transactions and provide it on request (regulations 4 & 5) | Manufacturers Wholesalers Health service hospitals Community pharmacies* Primary medical services providers* Others supplying | Manufacturers Importers Wholesalers Health service hospitals Community pharmacies* Primary medical services providers* | Manufacturers Wholesalers Health service hospitals Community pharmacies* Primary medical services providers* Others supplying | Manufacturers Wholesalers Health service hospitals Community pharmacies* Primary medical services providers* Others supplying |

| | | | | |
|---|--|---|--|------------------------------|
| | patients** | Others supplying patients** | patients** | patients** |
| Requirement to record and keep information about costs and provide it on request (regulation 6) | Manufacturers Wholesalers | Manufacturers Wholesalers | Manufacturers Wholesalers | Manufacturers Wholesalers |
| Requirement to provide information within 24 hours on request (concessionary prices) (regulation 7) | Manufacturers Wholesaler Importers | Manufacturers Wholesalers Importers | Manufacturers Wholesalers Importers | n/a |
| Requirement to provide information when a supply disruption arises or when a product is discontinued (regulation 8) | Marketing Authorisation holders Manufacturers Wholesalers Importers | Manufacturers Wholesalers Importers | Marketing Authorisation holders Manufacturers Wholesalers Importers | n/a |
| Requirement to provide information within 24 hours on request (supply shortage) (regulation 9) | Manufacturers Wholesaler Importers | Manufacturers Wholesalers Importers | Manufacturers Wholesalers Importers | n/a |

* England only

** This covers anyone in the UK - other than community pharmacies, providers of primary medical services and NHS hospitals - who supplies health service products to patients including for example home care providers, independent hospitals providing NHS care, prisons and ambulance services.

5. Proposals for information provision

Introduction

- 5.1. This chapter describes the Government's preferred option for provision of information. It should be read in conjunction with the relevant draft regulations, as indicated in the text. The draft Regulations have been published with this document on www.gov.uk. For information regarding other options that have been considered, see chapter 6 and the impact assessment that accompanies this document.
- 5.2. The draft Regulations cover UK health service products only that are potentially available on prescription or pursuant to directions from a health care professional (i.e. all medicines and defined foods, dermatological products and appliances). They do not cover products that are not generally supplied in this way, for example wheelchairs or implants. Manufacturers, distributors or suppliers may be uncertain about whether or not their products are for NHS use, and so the requirements only apply to UK producers if they know or it is obvious to a reasonable person in the circumstances that the individual product is to be for NHS use, or that some or all of the products of that presentation or description are manufactured, distributed or supplied for NHS use. For example, whilst a manufacturer may not know if a particular consignment of medicines is for NHS use, if they know or it's obvious that some or all of the products of that presentation that they manufacture will go for NHS use, then the requirements in the Regulations apply (regulation 2(3)).

Proposals for routine information provision (regulation 3)

These proposals impact on manufacturers, importers and wholesalers of unbranded generic medicines and special medicinal products used for the purposes of the health service.

Introduction

- 5.3. The draft Regulations would require all manufacturers, importers and wholesalers of unbranded generic medicines and special medicinal products (manufactured and imported) to provide information every quarter about the UK sales and purchases of these products (in primary and secondary care) including discount and rebates.
- 5.4. Introducing a statutory requirement to provide information on all manufacturers, importers and wholesalers of unbranded generic medicines and special medicinal products would enable the Department to improve the robustness of the community pharmacy reimbursement arrangements and increase the flexibility of the use of the information. Under the Regulations we would have information from all manufacturers, importers and wholesalers rather than a subset of manufacturers and wholesalers to base reimbursement prices on. Also, we would be able to set the reimbursement prices of more products based on information about sales and purchases.
- 5.5. The Department would also use the information collected for the other purposes in the 2006 Act, i.e. availability/value-for-money and cost control. For example, the Department would use the information to monitor prices to be able to identify high-priced unbranded generic medicines and special medicinal products and to improve the data available on usage of medicines in especially secondary care.

Voluntary versus statutory arrangements

- 5.6. There are currently three voluntary arrangements in place that are used for reimbursement price setting in this context, which are:
- Scheme M between the Department and the British Generic Manufacturers Association (BGMA)
 - Scheme W between the Department and the Healthcare Distribution Association UK (HDA UK)
 - A memorandum of understanding for manufactured specials between the Department and the Association of Pharmaceutical Specials Manufacturers (APSM)

The main reasons to seek statutory information powers by way of the 2017 Act were to address:

- the lack of powers to obtain comprehensive information to support robust community pharmacy and other primary care reimbursement arrangements and the need to increase the flexibility of the use of the information,
 - the lack of powers to require transparency about prices and costs across the supply chain to ensure that product are available and represent value-for-money, and
 - the lack of powers to require specific information and disclose this to facilitate implementation of price controls on individual medicines under section 262 of the 2006 Act.
- 5.7. The current voluntary arrangements do not provide information from sufficient sources to ensure the robustness of this system. The information provided can only be used to inform some community pharmacy reimbursement prices (category M) and cannot be disclosed to anyone. Furthermore, the voluntary arrangements do not include the provision of more detailed information on a non-routine basis.
- 5.8. We have considered whether we could rely on voluntary arrangements to obtain routine information from those companies that are members of the voluntary arrangements and introduce regulations that would require (i) those companies that are not members of the voluntary arrangements to provide routine information and (ii) all companies to provide non-routine information on request. We have concluded that this is not a viable option because the limitations of the voluntary arrangements described above would still apply. Moreover, the Department would be running both a statutory and voluntary system in parallel and there would be no possibility to enforce the provision of information (i.e. by way of sanctions) under the voluntary arrangements.
- 5.9. Whilst we believe that the voluntary arrangements would no longer be needed for the provision of information, we acknowledge that the voluntary arrangements cover more than the provision of information and we will to explore with the relevant representative bodies whether and how these other aspects of the arrangements should be replaced. For example, scheme M and scheme W allow freedom of pricing. The Department remains committed to freedom of pricing where the market is working effectively and competition keeps prices down.
- 5.10. The voluntary arrangements have notice periods ranging from six to 12 months and we therefore may need transitional provisions in the draft Regulations to ensure that during the notice period the Regulations do not apply to those companies that submit information under the voluntary arrangements. This would mean that during this period information would be submitted on either a voluntary basis or a statutory basis. The Department will to explore with the relevant representative bodies whether they would

agree to some flexibility in the notice period to ensure that all companies start providing information under the Regulations at the same time.

Question 1: do you agree with the Department's assessment that the current voluntary arrangements should be replaced by statutory requirements for the provision of information?

Information to be provided under the Regulations

- 5.11. It is proposed that information would need to be provided every quarter by manufacturers, importers and wholesalers about all unbranded generic medicines and special medicinal products sold and purchased.
- 5.12. We would require the information about all medicines in these categories rather than a defined list of products. A list of products would have to be a part of the Regulations which would restrict the flexibility and would require the Department to continually update the Regulations.
- 5.13. The following information would need to be provided for each presentation¹¹:
- 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;
 - 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.
- 5.14. The categories in the first bullet are:
- Category A: sales anywhere in the UK to primary medical services providers and NHS chemists
 - Category B: sales anywhere in the UK to health service hospitals and any others purchasing under NHS framework agreements
 - Category C: sales anywhere in the UK to wholesalers (not being category A and the product is not purchased under an NHS framework agreement)
 - Category D: all other sales anywhere in the UK.
- 5.15. For each category, information for each presentation about quantities sold/bought, sales income, amount paid and discounts, rebate or other payments would need to be provided.
- 5.16. The Department will provide further guidance and templates for the provision of information. We will develop guidance in collaboration with industry including about how to calculate the sales income and how to provide information about discount, rebates or other payments that cannot be attributed to a presentation.
- 5.17. We expect manufacturers to provide us with information about their sales and wholesalers and importers (of both unbranded generic medicines and special medicinal products) with information about both their sales and purchases. The information would need to be provided by the 28st of the month following the end of the quarter.

¹¹ "presentation" means a particular form of health service medicine which may be distinguished from other forms of the medicine by reference to its active ingredients, strength and excipients, pack size, type of packaging, method of administration or formulation.

- 5.18. For unbranded generic medicines information would need to be provided by 28 April, 28 July, 28 October and 28 January for the three preceding months. For special medicinal products information would need to be provided by 28 May, 28 August, 28 November and 28 February.
- 5.19. The differences in the quarters ensure that the Department can spread out the work required for processing and analysing the information.
- 5.20. The information to be provided is similar to the information that is currently provided on a voluntary basis, with some key differences. Instead of a defined list of products we propose to require the provision of information about all unbranded generic medicines and about all special medicinal products. The use of a list would only be possible if the list would be included in the Regulations which would restrict the required flexibility of a list.
- 5.21. We also propose that information is provided about sales to different categories of purchasers (see 5.14). This would improve the information provided and would enable the Department for example to remove secondary care data from the information that is used to inform reimbursement prices in primary care. The information would also enable the Department to use the information for other purposes i.e. value-for-money and controlling costs. For example, we would use the information to monitor prices of products in both settings, which is essential if the Department is to be able to tackle excessive pricing (see also chapter 3). Finally, information about both primary and secondary care sales would provide the Department with much better information about the usage of products across the NHS and especially in secondary care.
- 5.22. We recognise that there may be occasions where a UK producer is not able to distinguish between sales and purchases of UK NHS products i.e. unbranded generics and special medicinal products used in the NHS and sales, and purchases of non-health service products i.e. unbranded generics and special medicinal products not used in the NHS. An example of this is a product that is both sold over the counter and supplied on prescription. Where this is the case, we expect the UK producer to provide the information based on a best estimate of the sales and purchases for health service use including an explanation of the method of calculating this best estimate and why the information could only be provided on the basis of a best estimate. If this explanation is not to the satisfaction of the Department, the default position is that accurate rather than estimated information must be provided.

Question 2: do you have any practical concerns about providing information about all unbranded generic medicines instead of a defined list of products?

Question 3: do you have any practical concerns about providing information about all special medicinal products instead of a defined list of products?

Question 4: do you have views on the information that would be required to be provided?

Question 5: do you have views on the timelines within which the information would need to be provided?

Question 6: do you have views on the proposed categories of purchasers in paragraph 5.14?

Question 7: if you are currently providing information on a voluntary basis, do you have concerns about the additional information that is required to be provided?

Frequency of information provision

- 5.23. While we have proposed a quarterly collection of routine data in order to balance the costs and benefits, the Drug Tariff is published monthly. Therefore, the benefit may be maximised by monthly provision of information in order to change reimbursement prices

on a monthly basis and be more responsive to changes in market prices of medicines. The use of any information would be subject to the normal negotiating arrangements with the PSNC as would any change to the community pharmacy reimbursement arrangements. We recognise that this would affect the burden on businesses, but given the potential benefit, to both business and Government, we would like to seek views on the possibility of monthly information provision. The impact assessment addresses this issue in annex A.

Question 8: what would be the impact of requiring information on a monthly rather than a quarterly basis?

Proposals for information provision on request (regulations 4 and 5)

These proposals impact on all actors in the supply chain of medicines, medical supplies and other related products used for the purposes of the health service: manufacturers, importers, wholesalers, English community pharmacies, English primary medical services providers, hospitals anywhere in the UK and others anywhere in the UK supplying to NHS patients.

Introduction

- 5.24. The draft Regulations would require anyone involved in the manufacture, distribution and supply of health service medicines (regulation 4), medical supplies and other related products (regulation 5) to record and keep specified information related to transactions in connection to these products and provide the information on request. These particular regulations would not apply to NHS chemists and primary medical service providers in Wales, Scotland or Northern Ireland.
- 5.25. These particular regulations would help us ensure that the supply chain for health service products provides value-for-money to the NHS and the tax payer but would for example also be used to obtain information from community pharmacies for the margins survey. Information can be requested for any of the specified purposes in the 2006 Act i.e. remuneration, availability/value-for-money and cost control.
- 5.26. The burden of keeping and recording the information is intended, broadly, to be no more burdensome than the existing requirements for tax purposes to keep records for 6 years. We do not expect that it would be necessary for anyone in the supply chain to set up new systems to record and keep information, although UK producers may choose to adapt their existing systems, for example in the recording of discounts, rebates or other payments given that cannot be attributed to a particular product. There will be a small burden related to providing the information.
- 5.27. The Department would require information to be provided when more transparency is required about transactions in the supply chain. This could be triggered by the assessment of information that has been provided routinely (under regulation 3) or any other concerns about pricing or costs in the supply chain.
- 5.28. We expect that any request would be targeted at specific products and/or parts of the supply chain. The number of requests is expected to be limited initially but could grow in the next few years as the Department increases its commercial and analytical capacity.
- 5.29. If analysis of the information provided demonstrates the need to have information on a routine basis then we could update the Regulations to introduce additional requirements for routine provision of information. The likelihood is that this would be subject to a public consultation and an impact assessment.

Health service products covered by the draft Regulations

Health service medicines

- 5.30. The requirements to keep, record and provide information on request apply to any health service medicine (regulation 4). Given the possibility that a manufacturer, distributor or supplier may not be clear about whether or not medicines are for NHS use, the requirements only apply to a producer if the producer knows or it is obvious to a reasonable person in the circumstances that the particular medicine is to be for health service use, or some or all of their medicines of that particular presentation are to be for health service use.
- 5.31. We recognise that there may be occasions where a UK producer is not able to distinguish between sales and purchases of health service medicine i.e. medicines used in the NHS and sales and purchases of non-health service medicines i.e. medicines not used in the NHS. An example of this is a product that is both sold over the counter and supplied on prescription. Where this is the case, we expect the UK producer to provide the information based on a best estimate of the sales and purchases for health service use including an explanation of the method of calculating of this best estimate and why the information could only be provided on the basis of a best estimate. If this explanation is not to the satisfaction of the Department, the default position is that accurate rather than estimated information must be provided

Medical supplies and other related products

- 5.32. The 2006 Act in section 260 defines medical supplies as including surgical, dental and optical materials and equipment. Equipment is defined as including any machinery, apparatus or appliance, whether fixed or not, and any vehicle. This definition is broad and could for example include ambulances.
- 5.33. Other related products are not defined in the 2006 Act but were included in the 2017 Act to ensure that products that are not medicines or medical supplies but are being prescribed in the NHS are caught. Examples of other related products are vitamins and sun lotion.
- 5.34. In the draft Regulations we have narrowed the meaning of medical supplies and other related products in order not to place a disproportionate burden on producers (see regulation 5(6) of the draft Regulations). The products that would be covered are as follows:
- appliances that are listed in part IX of the Drug Tariff or in equivalent lists in the Drug Tariffs for Scotland or Northern Ireland;
 - foods or dermatological products that—
 - are listed in part XV of the Drug Tariff or in equivalent lists in the Drug Tariffs for Scotland or Northern Ireland, or
 - are not so listed but the UK producer in question knows, or it is obvious to a reasonable person in the circumstances, that the foods or dermatological products are being supplied on NHS prescription to patients for the prevention, diagnosis, treatment or management of clinical conditions;
 - appliances, foods or dermatological products that the UK producer in question knows, or it is obvious to a reasonable person in the circumstances, are being supplied to patients of relevant UK hospitals, in pursuance of prescriptions or directions from registered health care professionals, for the prevention, diagnosis, treatment or management of clinical conditions; and
 - appliances, foods and dermatological products that are available for purchase under an NHS framework agreement and are for supply to patients, in pursuance

of prescriptions or directions from registered health care professionals, for the prevention, diagnosis, treatment or management of clinical conditions.

- 5.35. This definition means that all products listed in part IX and part XV of the Drug Tariff are covered by the draft Regulations. On top of this, all appliances, foods and dermatologic products that are being used in the NHS on prescription or pursuant to directions of a health professional (e.g. in hospitals) would be caught if they are used for standard clinical uses, i.e. for the prevention, diagnosis, treatment or management of clinical conditions.
- 5.36. In the case of products that are not listed in the Drug Tariff, the requirements of the draft Regulations would only apply to a producer if the producer knows or it is obvious to a reasonable person in the circumstances that the particular product comes within the definition and is for health service use or that some or all of the products of that description that are manufactured, distributed or supplied by the producer are to be for health service use.
- 5.37. We recognise that there may be occasions where a UK producer is not able to distinguish between sales and purchases of health service products i.e. products used in the NHS and sales and purchases of non-health service products i.e. products not used in the NHS. An example of this is some covering creams for the concealment of birthmarks that are available both on retail sale and on prescription. Where this is case, we expect the UK producer to provide the information based on a best estimate of the sales and purchases for health service use including an explanation of the method of calculating this best estimate and why the information could only be provided on the basis of a best estimate.

Question 9: do you have views on the proposed definition of medical supplies and other related products that the requirements to record, keep and provide information would apply to?

Question 10: if you have concerns about the proposed approach for medical supplies and other related products, do you have suggestions for an alternative approach?

Information to be recorded, kept and provided on request

- 5.38. It is proposed that the following information would need to be recorded and kept by all actors in the supply chain for all health service medicines, and the medical supplies and other related products described above.
- 5.39. For each presentation of a health service medicine or each medical supply or other related product:
- 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).

5.40. The categories in the first bullet are:

- Category A: sales anywhere in the UK to primary medical services providers and NHS chemists
- Category B: sales anywhere in the UK to health service hospitals and any others purchasing under NHS framework agreements
- Category C: sales anywhere in the UK to wholesalers (not being category A and the product is not purchased under an NHS framework agreement)
- Category D: all other sales anywhere in the UK.

5.41. The information would need to be kept for six years. This date has been chosen to align the requirements with the existing requirements for tax purposes to keep records for six years. We do not expect that it would be necessary for anyone in the supply chain to set up new systems to record and keep information, although UK producers may choose to adapt their existing systems, for example in the recording of discounts, rebates or other payments given that cannot be attributed to a particular product. There will be a small burden related to providing the information.

5.42. The information would only need to be provided on request. Any request would clearly set out what information would be required and by when.

Question 11: do you have views on the information that is proposed to be recorded, kept and provided on request?

Question 12: do you have views on the 6 years' period for which information needs to be kept?

Small producers

5.43. For information provision on request we are proposing to make provisions for small producers. In the draft Regulations a small producer has been defined as 'a UK producer with a total United Kingdom turnover of £5 million or less, as set out in their most recent submitted accounts'.

5.44. Small producers as well as primary medical service providers may provide the requested information in the form of pre-existing documentation, including invoices. Depending on the request however, small producers may find it easier to provide the requested information, especially in case of a simple request. There may be occasions when the Department specifically requires invoices, for example from community pharmacies for the margin survey.

5.45. The Department has experience with information provision by means of invoices. This is how we collect information from a sample of community pharmacies for the margin survey. This has proven to be a small burden on them but a relatively large burden on the department to collect and analyse the invoices.

- 5.46. We recognise that the medical devices and diagnostics industry is comprised of a large number of small and medium enterprises (SMEs) and that if using the EU definition¹² about 98 percent of companies could be considered an SME.
- 5.47. For the purpose of the draft Regulations we have had to balance the burden on SMEs and the burden on the department and are therefore proposing to define a small producer as a UK producer with a total United Kingdom turnover of £5 million or less.

Question 13: do you agree with the proposed definition of small producer?

Question 14: do you agree with the proposed provisions for small producers?

Proposals for the provision of information about costs (regulation 6)

These proposals impact on manufacturers and wholesalers of medicines, medical supplies and other related products used for the purposes of the health service.

Introduction

- 5.48. The 2006 Act as amended by the 2017 Act enables the Secretary of State to make regulations to require the provision of information about costs in connection with the manufacturing, distribution or supply of a UK health service product. These costs would include for example the costs of manufacturing a product, the costs of research and development or the costs of distributing a product.
- 5.49. For costs incurred in connection with the manufacturing, distribution or supply of an individual health service product, the draft Regulations would require the Secretary of State to issue an information notice. A UK producer would be able to appeal against the information notice (see proposals for enforcement), for example if they believe the information requested is beyond the scope of the legislation.
- 5.50. The rationale behind information notices is that information about costs related to an individual product is not as easy to provide as information about transactions because it would require certain costs to be apportioned to an individual product.
- 5.51. If the Secretary of State would require the provision of information on costs that are not related to an individual product but relate to transactions in connection with costs, or the totality of costs (e.g. aggregated company data relating to business costs), then an information notice would not be required and under the proposed draft Regulations; such information would need to be provided following a written request.

Examples of the use of information notices

- 5.52. The Department would have to use information notices for example if it has concerns about the high price of an unbranded generic medicine and it wants the manufacturer to demonstrate that the costs related to manufacture and marketing of the product are proportionate to the price charged.
- 5.53. Information notices would also be required where companies in the statutory scheme for branded medicines ask for a price increase for a particular product and the Department

¹² The EU defines the category micro, small and medium-sized enterprises (SMEs) as made up of enterprises which employ fewer than 250 persons and which have an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million

wants to assess certain costs information. The statutory scheme draft Regulations are subject to a separate consultation.

- 5.54. Another example of the use of information notices is where the Department has no visibility over the costs of a specific product in the supply chain and wants to assure itself that the market is working effectively for that product.

Examples of the use of written requests

- 5.55. The Department could use written requests for aggregated company data where, for example, if it has concerns about the high price of an unbranded generic medicine and the manufacturer explains this to the Department by reference to its broader business costs, for example losses experienced in another part of its business that it is spreading across its business, or increased capital costs.
- 5.56. Where the Department wishes to request aggregated company data, unrelated to particular health service products, it may only do so if it is obvious to a reasonable person in the circumstances that the information could contribute directly or indirectly towards one of the statutory purposes, i.e. community pharmacy remuneration, availability and value-for-money of product and controlling costs under the 2006 Act.

Information to be recorded and kept and provided on request

- 5.57. It is proposed that UK producers that manufacture or distribute health service products are required to record and keep information that they are likely to need to comply with an information notice. This is information that UK producers could 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 their own costs. The information would relate to:
- 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.
- 5.58. We recognise that these costs may not normally be kept and recorded for individual products and therefore we would expect the information to be recorded and kept in such a way that it can be apportioned to individual products when the Secretary of State requests the information. We do not however expect that it is necessary for manufacturers and wholesalers to set up new systems to record and keep the information, and we are proposing to allow for 'best estimates' where there are difficulties apportioning costs between related products, although the producer will also need to provide an explanation of the calculating of this best estimate and why the information could only be provided on the basis of a best estimate. There will however be a burden related to providing the information.
- 5.59. We recognise that there may also be occasions where a UK producer is not able to distinguish between costs that are attributable to health service products i.e. products used in the NHS and costs that are attributable to non-health service products i.e. products not used in the NHS. An example of this is a product that is both sold over the counter and supplied on prescription. Where this is case, we expect the UK producer to provide the cost information based on a best estimate of the health service use,

including an explanation of the calculating of this best estimate and why the information could only be provided on the basis of a best estimate.

- 5.60. There are no record-keeping requirements in relation to requests for aggregated company data, unrelated to particular health service products.

Question 15: do you have views on the information that is required to be recorded, kept provided?

Proposals for information provision within 24 hours (regulation 7)

These proposals impact on all manufacturers, wholesalers and importers anywhere in the UK of English health service medicines with a price listed in part VIII of the Drug Tariff of England and Wales.

Introduction

- 5.61. We propose 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 (see regulation 7). This power only applies in circumstances where the Secretary of State considers that a medicine is not available to NHS chemists and primary medical services providers at the price listed for that medicine in part VIII of the Drug Tariff.
- 5.62. Currently, when the Department is considering setting a concessionary price following a request from the PSNC, it instructs the NHS Business Services Authority (NHS BSA) to seek information from suppliers on a voluntary basis about the available volumes and prices. The Department then uses this information to decide whether a concessionary price needs to be set and what that price should be which is then agreed with the PSNC.
- 5.63. Not all suppliers provide the NHS BSA with information and therefore concessionary prices are based on information from only a part of the market. The requirement to provide information on available volumes and prices of generic medicines and special medicinal products would help make the concessionary price setting process more robust with more information to base decisions on.
- 5.64. The Secretary of State has the power to direct NHS BSA to exercise functions of the Secretary of State and may do so after consultation with NHS BSA.

Information to be provided

- 5.65. It is proposed that for each medicine listed in part VIII of the Drug Tariff, information about the amount of stock that is held by a supplier (who may be the manufacturer or importer) or wholesaler and that is available for distribution to NHS chemists and the price of this stock, is provided within 24 hours on request.
- 5.66. The draft Regulations do not set out how the Department would request the information. Currently, the information may be requested by phone or email and we are likely to want to continue to be flexible in how we communicate these requests.

Question 16: do you have views on the requirement on UK producers to provide information within 24 hours about available volumes prices of generic medicines listed in part VIII of the Drug Tariff?

Question 17: do you have views on how we should approach suppliers (who may be the manufacturer or importer) and wholesalers if information is required to be provided within 24 hours?

Proposals for information provision about supply disruptions of medicines (regulations 8 and 9)

These proposals would impact on Marketing Authorisation holders, manufacturers and importers (regulation 8) of health service medicines and manufacturers, importers and wholesalers (regulation 9) of health service medicines.

Introduction

- 5.67. It is important that the Department is notified timely about any discontinuation of manufacture or supply of a health service medicine and any supply shortage that would impact directly on patients, and is provided with the relevant information to be able to manage the supply problem and mitigate any impact on patients. For example, it enables us to ensure that clinicians have good and timely advice on alternative treatments and engage with suppliers at an early stage. We recognise manufacturers have a strong incentive to avoid shortages, but limited incentive to tell us promptly given the potential commercial disadvantages to losing market share.
- 5.68. The Department has agreed best practice guidelines for the notification and management of medicines shortages with the Association of the British Pharmaceutical Industry (ABPI)¹³ and the British Generic Manufacturers Association (BGMA)¹⁴ and best practice guidelines for product discontinuations with the ABPI¹⁵. We estimate that under these guidelines manufacturers notify the Department about half of the supply shortages that directly impact on patients. In many instances the Department is informed about supply shortages or discontinuations from other parts of the supply chain only when there is already an impact on patients and the costs of medicines.
- 5.69. Whilst some companies work well with the Department in notifying discontinuation and shortages early and providing prompt information on mitigation plans, other companies have a poor record and consistently fail to provide timely notification to the Department. Given these problems with the voluntary arrangements, we are asking for views on whether now is the right time to move notification to a legislative basis. As well as supporting patient outcomes by promoting better management of shortages and discontinuations, this would also help the NHS to save money because the continued availability of medicines and timely management of patients would prevent further costs for example as a consequence of hospitalisation or switching patients to other medicines. Also, price increases may be prevented by managing shortages from an early stage.
- 5.70. A proposed approach is set out in the draft Regulations. Regulation 8 would require all marketing authorisation holders (if they were manufacturers, distributors or suppliers), or

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http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_063330

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http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_063446

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http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4005769

alternatively the manufacturer/importer of a medicine to inform the Secretary of State about any permanent discontinuation of medicines or potential supply shortages of medicines that would result in a direct impact on patients. The notice given would be at least six months or before any impact on patients or, if this is not practically possible, as soon as the marketing authorisation holder/manufacturer/importer becomes aware of the problem. We acknowledge that a judgement by the manufacturer as to whether there will be an impact on patients is required which will be based, to a large extent, on whether they have a significant market share for a product.

- 5.71. In addition to notification of supply shortages and discontinuations, it is essential for the coordination and management of medicines supply shortages and the mitigation of any impact on patient care that the Department has timely access to information about the available amount of stock of a medicine in the supply chain. Currently, this information is obtained on a voluntary basis and not all manufacturers and wholesalers provide the Department with the information when requested or the information is provided late, which is why we are considering a regulatory basis for this type of urgent request for information.
- 5.72. The draft Regulations (regulation 9) would require manufacturers and wholesalers (and any importer who for whatever reason does not fit into either of these categories) to provide the Secretary of State with information about the available amount of stocks of a medicine or any therapeutic alternatives, on request, within 24 hours when the Department is monitoring or managing a supply shortage.

Question 18: do you agree with the Department's rationale for introducing the legal requirements?

Question 19: what would be the consequences of moving to a regulatory approach?

Question 20: do you have views on the trigger for informing the Department about supply shortages i.e. when the shortage would result in a direct impact on patients?

Information to be provided

- 5.73. Moving to a regulatory approach for provision of information relating to supply disruptions will require clarity of the information to be kept, recorded and provided. A proposed approach is set out in draft regulations 8 and 9. It is proposed that for each health service medicine, the Marketing Authorisation holder, if they also manufacture distribute or supply in the UK, or in default of their being such a person, the manufacturer/importer is required to provide the following information when a marketing authorisation holder/manufacturer/importer decides to discontinue the supply of a medicine or when it considers there will be a supply shortage that would impact on patient care:
- 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;
 - 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.

- 5.74. The information would need to be provided at least six months prior to any anticipated impact on patients resulting from the discontinuation or supply shortages, or if that is not possible, as soon as the manufacturer is aware of the supply shortage or discontinuation.
- 5.75. Separately, it is proposed that for each health service medicine, and any therapeutic alternatives, information about the amount of stock that is held by a manufacturer or wholesaler/importer is provided within 24 hours on request when there is a supply shortage of that health service medicine.
- 5.76. The draft Regulations do not set out how the Department would request the information. Currently, the information may be requested by phone or email and we are likely to want to continue to be flexible in how we communicate these requests.

Question 21: do you have views on or concerns about the information that is required to be provided for notification of discontinuations and supply shortages?

Question 22: do you have views on how we should approach companies if information is required to be provided within 24 hours?

Proposals for disclosure of information (regulation 10)

Introduction

- 5.77. New section 264B in the 2006 Act, as inserted by section 8 of the 2017 Act, enables the Secretary of State to disclose information to a range of persons including:
- NHS England
 - Special Health Authorities (such as the NHS BSA)
 - NHS Digital
 - Other Government departments
 - Ministers in the devolved administrations
 - Common Services Agency for the Scottish Health Service
 - Regional Business Services Organisation (Northern Ireland)
 - Any person providing services to any of the persons listed
- 5.78. There are various reasons why the Department would want to disclose information. For example to the devolved administrations to support their community pharmacy reimbursement arrangements or any assessment of value-for-money or availability of health service products. We would also want to be able to disclose information to NHS Digital or the NHS BSA in case they would support us with an analysis or storing of information. Other Government departments and NHS England work closely with the Department and we would need to be able to disclose information to them where appropriate. There may also be occasions where we would want to disclose information to the Competition and Markets Authority.
- 5.79. Where the information that is disclosed is confidential or commercially sensitive these persons may not use the information for any other purposes than those specified in the 2006 Act in relation to that person and they may not disclose the information to anyone else, other than as set out in the 2006 Act, as amended by the 2017 Act.
- 5.80. All information will be handled in accordance with the Department of Health information management policy.

Further persons prescribed in regulations

- 5.81. The 2006 Act enables the Secretary of State to prescribe further persons in regulations to whom information can be disclosed. These are:
- any body appearing to the Secretary of State to represent UK producers
 - NHS foundations trusts
 - any health service body in section 9(4) of the 2006 Act
- 5.82. This Act does not put an obligation on the Secretary of State to disclose information to these persons but merely ensures that the information may be disclosed.
- 5.83. In the draft Regulations (regulation 10) we have suggested prescribing the following industry bodies enabling the Secretary of State to disclose information to them:
- Association of British Healthcare Industries;
 - Association of the British Pharmaceutical Industry;
 - Association of Pharmaceutical Specials Manufacturers;
 - BioIndustry Association;
 - British Association of European Pharmaceutical Distributors;
 - British Generic Manufacturers Association;
 - British Healthcare Trades Association;
 - British In Vitro Diagnostics Association;
 - British Medical Association;
 - Dispensing Doctor's Association;
 - Ethical Medicines Industry Group;
 - Healthcare Distribution Association;
 - Pharmaceutical Services Negotiating Committee; and
 - Proprietary Association of Great Britain.
- 5.84. The draft Regulations also prescribe the purposes for which any confidential or commercially sensitive information that is shared with these bodies may be used. These purposes can only be those that are prescribed in the 2017 Act:
- to facilitate the determination of remuneration/payment of community pharmacies and GP practices ('remuneration');
 - to help ensure the availability and value-for-money of health service products ('availability/value for money'); and
 - to support the cost control provisions in the 2006 Act ('cost control').
- 5.85. There is no legal obligation on the Secretary of State to disclose information to any of these bodies and the Secretary of State would, as a point of principle, not disclose any confidential or commercially sensitive information from a member of one industry body to another industry body. There may be occasions where the Secretary of State would disclose information from a company that is not a member of an industry body but that is active in the industry sector that that body represents.
- 5.86. We have not prescribed any of the pharmacy contractor's representative bodies in the devolved administrations because the Secretary of State does not have the power to require the provision of information from pharmacy contractors in the devolved administrations.
- 5.87. New section 264B of the 2006 Act also provides the Secretary of State with the power to disclose information to NHS foundations trusts or any health service body in section 9(4) of the 2006 Act that is not already listed in the 2006 if these bodies are prescribed in regulations. The Department is not proposing at this stage to prescribe such bodies.

Question 23: do you agree with the list of persons prescribed in the draft regulation or do you think we have missed bodies?

Question 24: do you agree with the purposes prescribed for each industry body?

Question 25: do you have any comments on or concerns about the disclosure of information?

Proposals for enforcement and appeals (regulations 11 and 12)

Introduction

- 5.88. If a UK producer does not provide the information requested or the information is incomplete or inaccurate, or not in the specified form, then the Secretary of State has two options. He can write to the UK producer to request that the information is provided within 28 days or he can issue an enforcement decision and demand that the UK producer pays a daily penalty. If he writes to UK producer to request the information and the information is still not provided properly, then an enforcement decision can also be issued.
- 5.89. Our intention is to enforce the Regulations in a proportionate manner. For example, a mistake in the information provided or missing the deadline by a day or two would not under normal circumstances be a reason to enforce the Regulations. However, consistently missing deadlines by more than a few days or not providing information at all would be a reason to enforce the Regulations.
- 5.90. The provisions that require information to be provided urgently may of necessity need to be enforced in different ways to provisions seeking the non-urgent supply of information.

Penalties

- 5.91. The Schedule to the draft Regulations sets out the penalties. The daily penalty for companies with a total turnover in the United Kingdom of less than £100 million is £2,500 for the first 14 days and £5,000 for subsequent days. For companies with a total turnover in the United Kingdom of more than £100 million the daily penalty is £5,000 for the first 14 days and £10,000 for subsequent days.

Appeals

- 5.92. The 2006 Act as amended allows provision to be made for rights of appeal to any "enforcement decision" made in relation to section 260 (control of maximum prices of medical supplies), section 261 (powers relating to voluntary schemes), section 262 (power to control prices), section 263 (statutory schemes), section 264 (statutory schemes: supplementary) and section 264A (provision of information) of the 2006 Act. Also, the amendments to the 2006 Act requires provision to be made for rights of appeal to any "enforcement decision" made in relation to information notices given under section 264A of the 2006 Act.
- 5.93. "Enforcement decision" is defined in section 265(7) of the 2006 Act and means a decision of the Secretary of State or any other person to--
- (a) require a specific manufacturer or supplier, or other person who is a UK producer, to provide information to him,
 - (b) limit, in respect of any specific manufacturer or supplier, any price or profit,
 - (c) refuse to give his approval to a price increase made by a specific manufacturer or supplier,

- (d) require a specific manufacturer or supplier, or other person who is a UK producer to pay any amount (including an amount by way of penalty) to him.
- 5.94. Currently, enforcement decisions can be appealed within 28 days of the decision under the Health Service Medicines (Price Control Appeals) Regulations 2000,¹⁶ ("the Appeals Regulations"). We propose to update the Appeals Regulations including any updates that have been made to the model provisions under the Deregulations and Contracting Out Act 1994. For example, we propose to update the references to the powers under which these Appeals Regulations have been made and remove references to bodies that no longer exist such as the Council of Tribunals. We propose to update these Appeals Regulations either at the same time or before the draft Regulations come into force.
- 5.95. Appeals will be dealt with by the existing tribunal that has been set up under the Appeals Regulations, the NHS Medicines (Control of Prices and Profits) Appeal Tribunal.
- 5.96. We are considering moving to the Unified Tribunals System under the Tribunals, Courts and Enforcement Act 2007 which is run by HM Courts & Tribunals Service, an executive agency of the Ministry of Justice. Should we decide to proceed with this, our intention is that the proposals would be subject to public consultation at the appropriate time.

Information notices

- 5.97. The 2006 Act as amended introduces the right of appeal for information notices that the Secretary of State is required to issue in respects of the costs incurred by a producer for the manufacturing, distribution or supply of a particular health service product.
- 5.98. These appeals would also be dealt with under the Health Service Medicines (Price Control Appeals) Regulations 2000 and by the NHS Medicines (Control of Prices and Profits) Appeal Tribunal.
- 5.99. Any information notice could be appealed within 28 days from the day the notice is issued.

Question 26: do you have views on the enforcement of the Regulations?

Question 27: do you have any comments or concerns regarding the proposals to update the Appeals Regulations?

Proposals for review of the Regulations (regulation 13)

- 5.100. The draft regulations (in regulation 13) set out that the Secretary of State must undertake a review of the regulations every year and that the conclusions from this review must be published in a report. Additionally, the report should set out the objectives of the Regulations, assess the extent to which these are achieved and remain appropriate, and whether they could be achieved with less of a regulatory burden.

Question 28: do you agree that the Regulations should be subject to an annual review?

¹⁶ <http://www.legislation.gov.uk/uksi/2000/124/contents/made>

6. Options for information provision

Introduction

- 6.1. This chapter outlines the different options that the Department has considered and assessed for setting up systems for the provision of information routinely and on request under the regulations. The draft Regulations and the other chapters of this consultation document have been drafted on the basis of the Department's preferred option. This chapter should be read in conjunction with the impact assessment, which considers the costs and benefits of the different options that underpin the Department's preference.
- 6.2. The 2006 Act, as amended by the 2017 Act, enables the Secretary of State to make regulations to require anyone involved in the manufacture, distribution and supply of health service products (a 'UK producer') to record, keep and provide information about health service products.
- 6.3. Examples of the information that can be requested are listed in section 264A(4) and include prices, discounts, rebates, revenues and profits.
- 6.4. The information can be requested and used for three purposes:
 - to remunerate community pharmacies and GP practices;
 - to ensure value-for-money and availability of adequate supplies of health service products; and
 - to operate the cost controls of health service products in section 260 to 265 of the NHS Act 2006.
- 6.5. Regulations would need to set out what information would need to be provided by whom and for what health service products as well whether the information is required to be provided regularly or on request.

Options considered

- 6.6. We have considered the following options:
 - 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 regulation that require routine provision of information about all health service products at transaction-level (non-routine information provision would not be required under this option)
- 6.7. Under all the options we have assumed we would in addition require:
 - On request provision of cost information,
 - On request provision of price and volume information within 24 hours, and

- Provision of information about supply shortages.

6.8. Table 3 provides an overview of the options considered (not taking into account the requirements listed in 6.7).

Table 3: options considered

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

6.9. Product-level information is information about the total sales income or amount paid for a single presentation. Transaction-level information is much more detailed information about each transaction that has taken place between UK producers. Table four

compares the information that would be required for product-level and transaction-level information.

Table 4: product-level information versus transaction-level information

| Product-level information (Aggregate information about sale and purchases) | Transaction-level information (Information about individual transactions) |
|---|---|
| <ul style="list-style-type: none"> • whether the category of purchaser for each product is category A, B, C or D (see 5.40); • the quantity of each product that is sold or bought; • the sales income received for each product, being the income from the sale of the product after deduction of any discounts or rebates or other payments given that can be attributed to the sale of the product; • the amount that is paid for each product after deduction of any discounts or rebates or other payments received for the amount paid; and • the discounts, rebates or other payments given or received for each presentation which cannot be attributed to that product. | <ul style="list-style-type: none"> • the invoices which relate to the sale or purchase of any products; • the name of the purchaser or seller of any products; • the category of purchaser for any medical products (category A, B, C or D) (see 5.40); • the quantity of any products that are sold or bought; • the sales income received for any products, being the income received from the sale of the supplies or products after deduction of any discounts or rebates or other payments given that can be attributed to that sale; • the amount that is paid for any products after deduction of any discounts or rebates or other payments received for the amount paid; • the discounts, rebates or other payments given or received by the producer which cannot be attributed to a particular product; • the terms which applied to any discounts or rebates or other payments mentioned; • the name of any person who received the discounts or rebates or other payments; and • whether the product is an English health service product, Welsh health service product, Scottish health service product or Northern Ireland health service product. |

Option 0

6.10. Under option 0 we would continue with the existing voluntary arrangements and not introduce Regulations. However, the main reasons to seek statutory information powers by way of the 2017 Act were to enable the Department (i) to obtain information from all companies to support more robust community pharmacy reimbursement arrangements and use this information for other purposes and disclose it where appropriate, (ii) obtain

information to assess whether products are available and represent value-for-money to the NHS and (iii) obtain information to support the cost control provision in the 2006 Act.

- 6.11. The current voluntary arrangements do not always provide information from sufficient sources and about all products which is needed to improve the robustness of this system. The voluntary arrangements also restrict the provision of information to primary care and restrict the use of the information to informing some community pharmacy reimbursement prices and the arrangements do not allow for the information to be used for any other purposes or by the devolved administrations. Furthermore, the voluntary arrangements do not foresee in the provision of more detailed information on a non-routine basis on request. We have therefore concluded that option 0 would not address any of the problems outlined in chapter 3.

Option 1

- 6.12. Under option 1 we would 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.
- 6.13. Manufacturers and wholesalers of unbranded generic medicines and special medicinal products (manufactured and imported) would be required to routinely provide information about the sales and purchases of these products. The required information would be product-level information i.e. total sales income and the total amount paid for each products net of all discounts and rebates (see table 4). This is similar to the information that is currently provided on a voluntary basis.
- 6.14. The whole supply chain would be required to keep and record more detailed information at transaction-level (see table 4) and provide this on request only. For the purposes of all the options, an assumption is made that the other UK health service products about which we would seek information are essentially those appliances, foods and dermatological products that are available on NHS prescription etc. for standard clinical uses.
- 6.15. This option would enable us to improve the robustness of the community pharmacy reimbursement arrangements by requiring all manufacturers and wholesalers to provide us every quarter with information about generic medicines and special medicinal products (manufactured and imported) instead of relying on information only from those that have signed up to the voluntary arrangements. We would also be able to use the information provided more flexibly and for all purposes in the 2006 Act i.e. remuneration, availability/value-for-money and cost control.
- 6.16. This option would also enable us to request more detailed information at transaction-level for example from pharmacies for the margins survey or if the information provided routinely would raise concerns or if we would have any concerns about products not representing value-for-money or further information would be needed to support the community pharmacy reimbursement arrangement or cost control provisions in the 2006 Act.

Option 2

- 6.17. Under option 2 we would 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.

- 6.18. The difference with option 1 is that manufacturers and wholesalers of unbranded generic medicines and special medicinal products (manufactured and imported) would be required to routinely provide information at transaction-level.
- 6.19. The additional benefit of routine transaction-level information would be the increased transparency for the Department about transactions in the supply chain.
- 6.20. Companies providing information routinely may also be faced with requests for non-routine information and may therefore prefer to provide the information at transaction-level in the first place so that there is no need to ask for information on a non-routine basis.
- 6.21. Routine transaction-level information about all unbranded generic medicines and special medicinal products would mean that the Department would need to ensure that it has the capacity to receive and analyse this information.
- 6.22. This option would also enable us to request detailed information at transaction-level about any other prescribable health service products if we would have any concerns about products not representing value-for-money.

Option 3

- 6.23. Under option 3 we would make Regulations that require routine provision of information about any prescribable health service products at transaction-level from all actors in the supply chain from manufacturer/importer to pharmacies/dispensaries and others who supply patients.
- 6.24. This would provide the Department with transparency about transactions across the whole supply chain for all prescribable health service products, maximising opportunity to deliver the Government's objectives.
- 6.25. However, this option could potentially put a large burden on the whole supply chain as well as on the Department who would need to be able to receive and analyse large amounts of information.

Preferred option

- 6.26. The draft impact assessment published with this consultation document sets provides a detailed assessment of the costs and benefits of each option. Option 0 has been disregarded as it would not deliver the policy objective. Option 1 balances improved information to support community pharmacy reimbursement on a routine basis, together with a safeguard for business that more burdensome transaction level data will only be sought on a non-routine basis. Option 2 would require all information at transaction level, with data on unbranded generic medicines and special medicinal products provided routinely, but on a non-routine basis for all other prescribable health service products. It is therefore more burdensome than option 1. Option 3 would require all information on all prescribable products on a routine basis. It would therefore be the most burdensome option, both to businesses and the Department, with a risk that the Department would not have the resources available to analyse all the data supplied. Whilst options 1 and 2 require only modest annual benefits of up to approximately £2.5m - £3.3m per year to be realised in order for the policy as a whole to be considered value for money, the minimum required benefits associated with option 3 are much higher.
- 6.27. Option 1 is the Department's preferred option. This option would enable us to operate a more robust community pharmacy reimbursement system. At the same time, option 1 would provide us with the opportunity to ask any actor in the supply chain for 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.

- 6.28. Our preferred option would increase the number of companies providing information and the number of products on which information is provided. We will therefore explore a web-based solution for information provision.
- 6.29. This consultation document and the draft regulations have been drafted on the basis of this option.

Question 29: do you agree with the Department's view that option 1 is the preferred option?

Question 30: do you have any comments on our assessment of the different options?

7. Secretary of State statutory duties

Introduction

- 7.1. In developing the proposals behind the Health Service Products (Provision of Information and Disclosure) Regulations 2017/8, 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, although this is in essence an outline summary of the Department's considerations.
- 7.2. The need to comply with these duties and the Family Test arises on each occasion that Ministers perform their public functions. The proposals outlined in chapter 5 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 enforcement
 - Proposals for review

Public Sector Equality Duty (Section 149 Equality Act 2010)

- 7.3. 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.
- 7.4. The protected characteristics covered by this duty are age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex and sexual orientation.
- 7.5. 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.
- 7.6. The draft 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 spend 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)

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

- 7.7. 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.
- 7.8. 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)

- 7.9. 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.
- 7.10. 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 spent on health service products.

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

- 7.11. Regard must necessarily be had to the values, principles, pledges and rights in the NHS Constitution.
- 7.12. The NHS Constitution provides the right to drugs and treatments that have been recommended by NICE and for local decisions on funding of other drugs and treatments to be made rationally following a proper consideration of the evidence. Neither measures impact on the rights provided in the NHS Constitution. The measures, as noted above, should have a positive impact by increasing the resources available and ensuring the NHS gets value-for-money for money spent 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)

- 7.13. 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.
- 7.14. 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.
- 7.15. No relevant impacts on particular groups of patients have been identified in relation to this policy. As above, 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 for money spent on health service products.

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

- 7.16. The Secretary 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.
- 7.17. These draft Regulations do not impact on the freedom of NHS bodies or providers to provide NHS services as they see fit.
- 7.18. The draft 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.
- 7.19. Hospitals manufacturing special medicinal products would be covered by the requirement to routinely provide information.
- 7.20. 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 6 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)

- 7.21. 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.
- 7.22. Information provisions from across the supply chain for health service product will ensure the NHS gets value-for-money for money spent 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)

- 7.23. 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.
- 7.24. 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)

- 7.25. 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.
- 7.26. 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

- 7.27. 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?
- 7.28. We have considered the Family test and consider it not applicable to any of the proposed requirements.

Question 31: do you have comments on this summary of the equality assessment?

8. Draft impact assessment

8.1. The draft impact assessment considers the costs and benefits of the options discussed in chapter 6. This document has been published separately.

Question 32: do you agree with our assessment of costs to industry for responding to the routine data requests? If possible, it would be useful if you are able to differentiate between one-off and ongoing costs in your response.

Question 33: would providing transaction-level information be more or less burdensome than providing product level data on a routine basis? Please give estimates of the difference in burden where possible. (As above, it would be useful if you are able to separately consider one-off and on-going costs in your response).

Question 34: do you agree with our assessment of the costs of responding to non-routine data requests?

Question 35: do you agree with our assessment of the costs of responding to requests for cost information?

Question 36: do you have any other comments on the impact assessment?

9. Draft regulations

- 9.1. The different requirements in the draft regulations are based on the proposals in chapter 5. The draft regulations have been published separately.

Question 37: do you have comments on the draft regulations that you have not already submitted as part of the previous questions?

10. Consolidated list of questions

Proposals for routine information provision (regulation 3)

1. Do you agree with the Department's assessment that the current voluntary arrangements should be replaced by statutory requirements for the provision of information?
2. Do you have any practical concerns about providing information about all unbranded generic medicines instead of a defined list of products?
3. Do you have any practical concerns about providing information about all special medicinal products instead of a defined list of products?
4. Do you have views on the information that would be required to be provided?
5. Do you have views on the timelines within which the information would need to be provided?
6. Do you have views on the proposed categories of purchasers in paragraph 5.14?
7. If you are currently providing information on a voluntary basis, do you have concerns about the additional information that is required to be provided?
8. What would be the impact of requiring information on a monthly rather than a quarterly basis?

Proposals for information provision on request (regulations 4 and 5)

9. Do you have views on the proposed definition of medical supplies and other related products that the requirements to record, keep and provide information would apply to?
10. If you have concerns about the proposed approach for medical supplies and other related products, do you have suggestions for an alternative approach?
11. Do you have views on the information that is proposed to be recorded, kept and provided on request?
12. Do you have views on the 6 years' period for which information needs to be kept?
13. Do you have views on the information that is required to be recorded, kept provided?
14. Do you agree with the proposed definition of small producer?
15. Do you agree with the proposed provisions for small producers?

Proposals for information provision within 24 hours (concessionary prices) (regulation 7)

16. Do you have views on the requirement on UK producers to provide information within 24 hours about available volumes prices of generic medicines listed in part VIII of the drug tariff?
17. Do you have views on how we should approach suppliers (who may be the manufacturer or importer) and wholesalers if information is required to be provided within 24 hours?

Proposals for information provision about supply disruptions (regulations 8 and 9)

18. Do you agree with the Department's rationale for introducing the legal requirements?

19. What would be the consequences of moving to a regulatory approach?
20. Do you have views on the trigger for informing the Department about supply shortages i.e. when the shortage would result in a direct impact on patients?
21. Do you have views on or concerns about the information that is required to be provided for notification of discontinuations and supply shortages?
22. Do you have views on how we should approach companies if information is required to be provided within 24 hours?

Proposals for disclosure of information

23. Do you agree with the list of persons prescribed in the draft regulation or do you think we have missed bodies?
24. Do you agree with the purposes prescribed for each industry body?
25. Do you have any comments on or concerns about the disclosure of information?

Proposals for enforcement

26. Do you have views on the enforcement of the Regulations?
27. Do you have any comments or concerns regarding the proposals to update the Appeals Regulations?

Annual review

28. Do you agree that the Regulations should be subject to an annual review?

Options for information provision

29. Do you agree with the Department's view that option 1 is the preferred option?
30. Do you have any comments on our assessment of the different options?

Secretary of State statutory duties

31. Do you have comments on the summary of the equality assessment?

Impact assessment

32. Do you agree with our assessment of costs to industry for responding to the routine data requests? If possible, it would be useful if you are able to differentiate between one-off and ongoing costs in your response.
33. Would providing transaction-level information be more or less burdensome than providing product level data on a routine basis? Please give estimates of the difference in burden where possible. (As above, it would be useful if you are able to separately consider one-off and on-going costs in your response).
34. Do you agree with our assessment of the costs of responding to non-routine data requests?
35. Do you agree with our assessment of the costs of responding to requests for cost information?
36. Do you have any other comments on the impact assessment?

Draft regulations

37. Do you have comments on the draft regulations that you have not already submitted as part of the previous questions?

11. Responding to the consultation

- 11.1. You can respond to this consultation by 14 November 2017.
- 11.2. The preferred method of receiving your response is via the on-line consultation questionnaire, which can be found on:
<https://consultations.dh.gov.uk/pprs/information-regulations>
- 11.3. Alternatively, you may wish to email your responses to the questions to:
informationregulations@dh.gsi.gov.uk.
- 11.4. If you do not have internet or e-mail access, then please write to:
Information Regulations Consultation
c/o Sandor Beukers
Ground Floor North
Wellington House
133-155 Waterloo Road
London SE1 8UG

Comments on the consultation process itself

- 11.5. If you have concerns or comments which you would like to make relating specifically to the consultation process itself please contact the Consultations Coordinator at:
- 11.6. Department of Health
2e26, Quarry House
Leeds
LS2 7UE

e-mail consultations.co-ordinator@dh.gsi.gov.uk

Please do not send consultation responses to this address.

Confidentiality of information

- 11.7. We manage the information you provide in response to this consultation in accordance with the Department of Health's [Information Charter](#).
- 11.8. Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).
- 11.9. If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

11.10. The Department will process your personal data in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties.