



Department
of Health

Proposed changes to the statutory scheme to control the cost of branded health service medicines

August 2017

Title: Proposed changes to the statutory scheme to control the cost of branded health service medicines

Author: Medicines and Pharmacy Directorate

Document Purpose: Consultation

Publication date: 23 August 2017

Target audience:

- **Pharmaceutical manufacturers**
- **Pharmaceutical suppliers**
- **NHS**
- **Members of the public**

Contact details:

Department of Health

Medicines and Pharmacy Directorate

Medicines Pricing team

Wellington House

133-155 Waterloo Road

London

SE1 8UG

Statutory_scheme_consultation@dh.gsi.gov.uk

You may re-use the text of this document (not including logos) free of charge in any format or medium, under the terms of the Open Government Licence. To view this licence, visit www.nationalarchives.gov.uk/doc/open-government-licence/

© Crown copyright 2017

Published to gov.uk, in PDF format only.

www.gov.uk/dh

Contents

Contents	3
Executive summary	5
1. Introduction	8
Powers to limit prices and profits	8
Pharmaceutical Price Regulation Scheme	8
Statutory price control	8
Statutory scheme - 2015 consultation and Government response	9
Health Service Medical Supplies (Costs) Act 2017	9
Application of the amended NHS Act 2006 to Northern Ireland	10
Consultation on information requirements	10
2. Why changes are required	11
Relationship to the PPRS	11
Price limits	12
Enforcement	13
3. Summary of the proposals	14
4. Payment system	16
Companies in scope	16
Payment percentage	17
Health service medicines covered	17
Exemptions	19
Operational elements	22
5. Control of maximum prices	24
Maximum price	24
Maximum price lists	24
Directions	25
New presentations	25
Temporary exemptions	28
Price increases	29
Price decreases	31
Operational elements	31
6. Information requirements	33
Retention and provision of sales income information	33
Provision of information	33
Operational elements	35

Administrative requirements	37
7. General	39
Appeals	39
Revocation of existing regulations	39
Annual review	40
8. Statutory requirements	41
Consultation requirements regarding exercise of powers in section 263 of the NHS Act 2006	41
Statutory duties under the NHS Act 2006 and the Public Sector Equality Duty	42
9. Consolidated list of questions	48
10. Responding to the consultation	51
Comments on the consultation process itself	51
Confidentiality of information	51

Executive summary

The 2014 Pharmaceutical Price Regulation Scheme (PPRS), and the statutory scheme for pharmaceutical pricing, safeguard the financial position of the NHS by limiting the cost to the NHS of branded health service medicines. The PPRS is a voluntary agreement with industry, and the statutory scheme is in place to cover those companies that choose not to join the PPRS.

In 2015, the Government consulted on changes to the statutory scheme. The principal element of this was a shift from a system of price cuts to one of payments, to re-establish a level of alignment with the PPRS that had been lost with the 2014 PPRS agreement. In light of doubts raised about the legal powers to introduce a payment system in the statutory scheme, the Government noted in the 2016 response to the consultation that changes should be made to primary legislation, and that it would consult again once this had been taken forward. Subsequently, the Health Service Medical Supplies (Costs) Act 2017, which amends the National Health Service Act 2006 ("the NHS Act 2006"), was introduced. This puts beyond doubt that the Government has the power to introduce such a payment system in the statutory scheme. It also establishes new information powers, the proposed application of which, including the requirements that it will impose on manufacturers and suppliers (referred to as "companies" for shorthand purposes in this document), will be consulted on at the same time as this consultation.

A number of key challenges in relation the operation of the statutory scheme informed both the statutory scheme consultation in 2015 and the proposals in this consultation document. As set out in chapter 2, these challenges are:

- The statutory scheme produces lower savings relative to the health service sales covered by the scheme than the 2014 PPRS.
- The need to re-align the statutory scheme savings with the PPRS to promote a more level playing field between the two schemes.
- The difficulty in re-aligning the schemes because of the differential effect that the statutory scheme price cut has on companies depending on the level of discount they offer the NHS, and because each scheme uses a different cost control mechanism.
- The current regulations leave the Department with challenges relating to price controls, such as lack of transparency over maximum price levels, and enforcement.

A summary of the proposed changes in this consultation is set out in chapter 3. These cover three main areas, namely: i) the introduction of a payment system; ii) making changes to provisions on maximum prices; and iii) making changes to the information requirements. These proposals, many of which are small in scale and are consequential to the more substantive changes, are structured to reflect the ordering of the draft regulations which accompany this document.

Our proposals relating to the introduction of a payment system in relation to the sales of presentations are set out in chapter 4. The term "presentation" is used in the draft regulations to describe a particular form of a medicinal product which has a brand name and is used for the purposes of the health service. The main elements of these proposals are:

- Making it clear which companies are in scope of the payment system, and will be responsible for payment on sales of presentations. We propose that that this

should be the first manufacturer or supplier in the UK, including those with a manufacturer's licence or wholesale dealer's licence, to supply an item of presentation into the NHS supply chain.

- That the payment percentage to be applied in the payment system would be set at the same level as the payment percentage for the 2018 calendar year in the 2014 PPRS.
- That all medicinal products used for the purposes of the health service and which have a brand name, including those required to have a brand name by the Medicines and Healthcare Products Regulatory Agency, should be captured within the scheme, with payments due on sales by the relevant company.
- That over the counter presentations continue to be excluded from the statutory scheme, and that presentations sold under framework agreements extant at the time the regulations come into force, and sales of low cost presentations, should be exempt from the payment. We also propose that the small company exemption be extended to the payment system.
- That no facility be introduced to allow for temporary exemptions to the payment system.
- Extending the existing recoverable sum and penalty provisions so that they also apply to the payment system. This is to ensure that there are appropriate measures to ensure compliance with the payment requirements.

Chapter 5 contains our proposed changes in relation to the control of maximum prices. The main elements of our proposals are:

- Revising provisions on the maximum price, so that the current 15% price cut on the maximum price based on prices as at 1st December 2013 is reversed. We also propose that where a presentation was not on sale at 1st December 2013, that the maximum price be the price at which it was first placed on the market, or the price subsequently specified by the Secretary of State. Additionally, we propose that price lists be compiled which will hold information on the agreed maximum prices of all presentations.
- Revising the process for agreeing prices for new presentations and price increases, and setting out the factors that we propose should be taken into account by the Secretary of State in making a decision.
- Revising the process for agreeing price decreases.
- Changing the temporary exemption provision which applies to the maximum price, so that where it is applied a new temporary maximum price must be agreed with the company.
- Extending the penalty arrangements to the maximum price arrangements, but where this would apply to a company which does not provide the required notification before a new presentation launch (described in the regulations as "placed on the market"), that the penalty be a single penalty of up to £100,000, rather than a daily penalty.

Our proposed changes to the information requirements are set out in chapter 6, and the main elements are:

- Revising the information requirements on companies, in particular to introduce the additional requirements which are needed to enable the operation of the payment system, and setting out specific requirements for small companies and new companies.

- Setting out definitions of key terms, and clarifying certain operational elements, such as the need for written declarations of approval to assure the quality of information provided, and the application of penalties.
- Setting out how we propose to limit the administrative burden on companies arising from the introduction of the payment system.

In line with these changes, and as described in chapter 7, we also intend to extend the existing appeals arrangements, so that they apply to the additional elements of the statutory scheme, such as the payment system.

In proposing changes to the statutory scheme, the Government is required to consider, and specifically consult on, a number of specific areas, such as the Public Sector Equality Duty and the Secretary of State's duties as set out in the NHS Act 2006. Our assessment of the proposals in relation to these statutory duties is summarised at chapter 8, with additional information provided in the accompanying draft impact assessment. This assessment did not find any significant negative impacts to the public, NHS or industry, but did show that the proposals are likely to deliver benefits through increasing the resources available to the NHS so that the public's access to treatment and services can be improved.

1. Introduction

Powers to limit prices and profits

1.1. The Secretary of State's powers to limit the prices of, or the profits accruing from, health service medicines, are set out in sections 261-266 of the National Health Service Act 2006 ("the NHS Act 2006").¹ Section 261 of the NHS Act 2006 makes reference to the existence of a voluntary scheme made by the Secretary of State with the industry body, the Association of the British Pharmaceutical Industry (ABPI). The current voluntary scheme is the 2014 Pharmaceutical Price Regulation Scheme ("the 2014 PPRS")². The powers also allow the Secretary of State, after consultation with the industry body, to make a statutory scheme for the purpose of limiting the prices of, or profits accruing from, the sales of branded health service medicines by companies that choose not to be members of the voluntary PPRS agreement.

Pharmaceutical Price Regulation Scheme

1.2. The 2014 PPRS is a voluntary agreement made between the Department of Health, on behalf of the UK Government and Northern Ireland,³ and the ABPI. It commenced on 1st January 2014 and ends on 31st December 2018. It supports the NHS by ensuring that the branded health service medicines' bill stays within affordable limits, and aims to strike a balance to promote the common interests of patients, the NHS, the industry and the taxpayer.

1.3. The 2014 PPRS covers all licensed, branded health service medicines supplied by members of the scheme. It does not cover:

- Sales of health service medicines on private prescription or other use outside the health service in the UK.
- Health service medicines without a brand name (generics).
- Branded health service medicines available without prescription (over the counter (OTC)) medicines, also known as Pharmacy and General Sale List (P & GSL) medicines), except when these are prescribed.

1.4. The 2014 PPRS introduced, for the first time, a payment system whereby companies that are members of the scheme make payments to the Department of Health on their sales of branded health service medicines which are covered by the scheme.

Statutory price control

1.5. In 2008, the Government consulted on regulations to set up a statutory scheme, the purpose of which was to safeguard the financial position of the NHS by ensuring that there would be similar limits to the PPRS on the cost of branded health service

¹ www.legislation.gov.uk/ukpga/2006/41/contents

² www.gov.uk/government/publications/pharmaceutical-price-regulation-scheme-2014

³ The pricing of medicines supplied for the purposes of the National Health Services run by the devolved administrations is reserved to the UK Government, with the exception of Northern Ireland. Many other aspects of health policies, including those affecting the use and availability of medicines, are not reserved matters.

medicines supplied by manufacturers and suppliers (referred to as "companies" for shorthand purposes in this document) that decided not to join the PPRS.

1.6. The regulations governing the statutory scheme are set out in the Health Service Branded Medicines (Control of Prices and Supply of Information) (No.2) Regulations 2008 ("the 2008 Regulations")⁴, and the Health Service Medicines (Information Relating to Sales of Branded Medicines etc.) Regulations 2007 ("the 2007 Regulations")⁵, as amended⁶.

1.7. The principal elements of the statutory scheme include:

- Establishing the maximum price which can be charged for the supply of a presentation, and making provision for adjustments to this price.
- Setting out the information which companies are required to provide to enable price limiting mechanisms to operate.
- Providing for certain exemptions to elements of the scheme including in relation to low cost presentations.
- Setting out provisions to cover the enforcement of the scheme.

Statutory scheme - 2015 consultation and Government response

1.8. In 2015, the Government undertook a consultation on proposals to amend the 2007 and 2008 Regulations.

1.9. These proposals were intended to address several challenges, in particular to re-align the statutory scheme with the 2014 PPRS, and thereby promote stability and support control of the cost of the overall medicines bill to the NHS.

1.10. The principal proposed change was the introduction of a payment system, similar to that introduced through the 2014 PPRS. However, doubts were raised during the consultation as to whether the Government had the powers to introduce such a system.

1.11. Responding to the consultation in 2016, the Government said that it would make amendments to primary legislation to put the issue of legal powers beyond doubt, and once done would consult again on its proposals.

Health Service Medical Supplies (Costs) Act 2017

1.12. The Health Service Medical Supplies (Costs) Act 2017⁷ ("the 2017 Act") received Royal Assent on 27 April 2017, and makes several important amendments to the NHS Act 2006. With respect to the statutory scheme, the NHS Act 2006 as amended puts beyond doubt that the Secretary of State can introduce a payment system in the

⁴ www.legislation.gov.uk/uksi/2008/3258/contents/made

⁵ www.legislation.gov.uk/uksi/2007/1320/contents/made

⁶ These Regulations have been amended by the Health Service Medicines (Control of Prices and Supply of Information) (Amendment) Regulations 2013 www.legislation.gov.uk/uksi/2013/2881/contents/made and the Health Service Medicines (Control of Prices and Supply of Information) (Amendment) Regulations 2015 www.legislation.gov.uk/uksi/2015/233/contents/made

⁷ www.legislation.gov.uk/ukpga/2017/23/contents/enacted

statutory scheme, such as that which exists in the 2014 PPRS, and can, where necessary, take enforcement action by recovering payments through the courts. These amendments confirm that the Secretary of State has the legal powers to make the proposed changes to the statutory scheme.

- 1.13. The NHS Act 2006, as amended, also provides the Secretary of State with the power to control the prices of medicines when the company responsible for the supply is in the voluntary scheme, but the health service medicine is not covered by the voluntary scheme. It also sets out in detail the Secretary of State's power to make regulations to obtain sales and purchase information of health service medicines, and other medical supplies, required for the health service from across the supply chain for purposes specified in the NHS Act 2006.

Application of the amended NHS Act 2006 to Northern Ireland

- 1.14. The exercise of powers in relation to the statutory scheme is reserved with respect to Wales and Scotland, but devolved with respect to Northern Ireland. The UK Government hopes to be in a position to exercise its powers in relation to the statutory scheme across the whole of the UK as proposed in the draft statutory scheme regulations. However, the exercise of the power in relation to Northern Ireland will need to be kept under review, pending necessary legislative requirements being progressed in relation to Northern Ireland.
- 1.15. On the basis that it might become necessary to have a statutory scheme which applies to England, Wales and Scotland only, comments are sought on the burden that it would place on companies to separate out data relating to England, Scotland and Wales from data relating to Northern Ireland. We know from the PPRS that in the past it has been a challenge for some companies to split their data by country. See paragraph 6.36.

Consultation on information requirements

- 1.16. In addition to the proposed information requirements in this consultation, the Government is also consulting on new regulations to implement the new information requirements in the NHS Act 2006, as amended by the Health Service Medical Supplies (Costs) Act 2017. The additional requirements proposed in that consultation may have an impact on companies covered by the statutory scheme regulations, so it is advised that respondents to this consultation also review the consultation on information requirements⁸.

⁸ www.gov.uk/government/publications?publication_filter_option=consultations

2. Why changes are required

2.1. As identified in the 2015 consultation, there are several key challenges with respect to the operation of the statutory scheme which need to be addressed. These are:

- The statutory scheme produces lower savings relative to the health service sales covered by the scheme than the 2014 PPRS.
- We need to re-align the statutory scheme savings with the PPRS in order to promote a more level playing field between companies in the two schemes, and in order to contribute to an overall stable and predictable spend on medicines, which is a core objective of the PPRS.
- It is currently difficult to re-align the savings from the schemes because of the differential effect that the statutory scheme price cut has on companies depending on the levels of discount they offer the NHS, and because each scheme uses a different cost control mechanism.
- The current regulations leave the Department with challenges relating to price controls, such as lack of transparency over maximum price levels, and enforcement, such as determining the size of a company for the purposes of applying a penalty, which we need to address.

Relationship to the PPRS

2.2. The key objectives of the 2014 PPRS include support for the availability and use of effective and innovative medicines for patients, and to provide stability and predictability to the Government and the pharmaceutical industry. The PPRS gives pharmaceutical companies the certainty and backing they need to flourish both here and in the global market and keeps the branded health service medicines' bill within affordable limits.

2.3. The purpose of the statutory scheme is to safeguard the financial position of the NHS by ensuring similar limits on the costs to the NHS of branded health service medicines apply to companies that choose not to be members of the voluntary PPRS. Companies may move between the two schemes. The two schemes have different rules and different mechanisms for achieving savings on branded health service medicines.

2.4. The current statutory scheme operates through setting maximum prices, which comprise a cut of 15% applied to the price charged (the list price) to the NHS on 1st December 2013 for a presentation (i.e. the particular form of a branded health service medicinal product - see page 18-19) on the market on that date. The maximum price, therefore, essentially becomes the new NHS list price. In many cases, the NHS list price is higher than the actual price charged to NHS organisations due to discounts.

2.5. By contrast, the 2014 PPRS does not include cuts to the list price of medicines. Instead, companies make payments to the Department – calculated as a percentage of their total branded medicines sales to the NHS (subject to certain exclusions and after deduction of discounts and Value Added Tax (VAT)).

2.6. As the price cut in the statutory scheme applies to the published list price, and not the actual price paid by NHS organisations, the scheme produces lower savings in relative terms than the 2014 PPRS, where the payment percentage is applied to actual selling prices rather than the list price.

- 2.7. In addition, there are no savings made in the statutory scheme on new health service medicines launched (described in the draft regulations as "placed on the market") post December 2013. By contrast, spend on new health service medicines is included within the calculation of PPRS growth rates and reflected in the payments made by all PPRS companies against older health service medicines.
- 2.8. The 2014 PPRS states⁹ that the Department would consult on amendments to the statutory scheme to ensure that, for companies that leave the PPRS, the price cuts applied to those companies in the statutory scheme reflect, at a minimum, the level of payment they would otherwise have paid in the PPRS.
- 2.9. As reported in the previous consultations, we have concluded that developing provisions aimed specifically at companies that leave the voluntary scheme would be complex and might lead to undesirable behaviour. We do, nevertheless, consider it important to encourage companies to remain in the voluntary scheme in order to maintain the agreed objectives of the PPRS. This means that we need to consider how to re-align the statutory scheme broadly with the PPRS so that the savings made through the statutory scheme reflect at a minimum the savings contributed by companies in the PPRS. Such re-alignment is also necessary to promote a more level playing field for companies in either scheme.

Price limits

- 2.10. The Secretary of State may make regulations to limit the maximum price that a company charges for a branded health service medicine. While the maximum price is generally understood to be the NHS list price, and is generally equivalent to the manufacturer's published price, there is no definition of NHS list price in the statutory scheme regulations.
- 2.11. The NHS list price is used to inform the primary care reimbursement price paid to dispensing contractors and it is therefore important that the published price is not higher than the maximum price that has been agreed by the Department. In secondary care, medicines are procured by hospitals, often below the maximum price. While in most cases the company publishes an NHS list price which is the same as the maximum agreed under the PPRS or the regulations, in some cases the manufacturer either does not publish a price or chooses to publish a price which is different from the maximum price. There is, therefore, no definitive and publically available list of maximum prices covering all presentations – either for the statutory scheme or the PPRS.
- 2.12. We consider that it is important to have more transparency regarding a presentation's maximum price. This will provide clarity with regard to the maximum price that a company may charge and in turn inform the primary care reimbursement price. It will also establish greater transparency with regard to maximum prices in secondary care. We also think it is important to have a transparent record of prices of new presentations and all other price changes to existing presentations that have come into effect since 1st December 2013, in order to contain the risk of price inflation.

⁹ Chapter 3, paragraph 3.12 of the 2014 PPRS

Enforcement

2.13. While it is our experience that companies cooperate with the Department and comply with the regulations, there may be rare occasions where there is non-compliance. The Department will always try and work with these companies to secure compliance but it also needs to be fair, consistent and transparent in its implementation of the legislation. Therefore, the Department needs to be able to challenge non-compliance and where necessary demand payment of appropriate penalties, and we need to ensure that the enforcement provisions in the statutory scheme are fit for purpose. The Secretary of State has the power to recover as a debt any amount required to be paid to the Secretary of State through the courts.

3. Summary of the proposals

3.1. In order to address the issues identified in the last chapter, and building on the 2015 consultation proposals and our 2016 response, we propose introducing a number of changes. The main proposal is the introduction of a payment system to replace the current system of price cuts, with other amendments being largely consequential to this, and generally small in scale.

3.2. The principal elements of these changes are:

- Introducing a payment system similar, but not identical, to that introduced in the 2014 PPRS (see chapter 4), elements of which include:
 - Defining the companies which will be in scope of the payment system.
 - Setting the payment percentage which will apply to the scheme.
 - Identifying the presentations covered by the scheme.
 - Identifying the exemptions from the proposed payment system, such as presentations sold through extant framework agreements, OTC presentations, and low cost presentations.
 - Various operational elements, such as enforcement procedures around recoverable sums, and penalties.
- Making changes to provisions on maximum prices (see chapter 5), including:
 - Removing the existing 15% price cut.
 - Establishing maximum price lists to provide transparent and publicly available information.
 - Making provision for the Secretary of State to issue directions to set the maximum price of a presentation in certain circumstances.
 - Providing greater clarity on the process for agreeing prices for new presentations, including setting out revised factors that would be taken into account by the Secretary of State.
 - Making provision for the setting of a new maximum price where a temporary exemption to the existing maximum price is granted.
 - Setting out the factors that would be taken into account when considering requests for price increases.
 - Putting in place a process for handling price decreases.
 - Changes to certain operational elements, such as enforcement procedures around recoverable sums, and penalties.
- Making changes to the information requirements (see chapter 6), including:
 - Removing the requirement under regulation 3A of the 2007 Regulations to retain sales income information and provide this where requested, but only if a similar requirement is incorporated in the proposed information regulations.
 - Setting out revised requirements for the provision of information, including around information needed to support the payment system, and the different arrangements for small companies and new companies.
 - Setting out definitions of key terms, and clarifying certain operational elements, such as providing audited information and written declarations of approval to assure the quality of information provided, and the application of penalties.
 - Identifying how we propose to limit the administrative burden on companies from the introduction of the payment system.

- Making general changes (see chapter 7), including:
 - Amending the requirement to review the regulations underpinning the statutory scheme, so that these are reviewed by the Government annually, rather than every 7 years.
 - Updating the Health Service Medicines (Price Control Appeals) Regulations 2000, so that these are extended to cover the new payment provisions.
- 3.3. The full proposals are set out in detail below. These proposals have also been incorporated into a set of draft regulations, which consolidate the 2007 and 2008 Regulations, and which accompany this consultation document. The proposals have been ordered to align generally to the structure of these draft regulations. Additionally, for ease of reference, the relevant section of the draft regulations is noted in each section below.
- 3.4. As these regulations are intended to be subject to annual review, other changes may be considered in the future. In particular, we may look to make changes in light of discussions on any successor to the 2014 PPRS, which ends on 31st December 2018.
- 3.5. Subject to this consultation and subsequent consideration of responses, it is envisaged that any new regulations will come into force on 1 April 2018.

4. Payment system

- 4.1. Our proposed introduction of a payment system into the statutory scheme, as initially outlined in the 2015 consultation and set out in the Government's 2016 response, is the principal element of our proposals. Many of the other proposed changes are minor in scope and are required to underpin this payment system, and to support alignment with some of the existing provisions.
- 4.2. The main elements of the payment system are detailed below, alongside references to the relevant parts of the draft regulations.
- 4.3. The proposed payment system would require companies in the statutory scheme to make a payment to the Department of a percentage of their sales of branded health service medicines (having excluded VAT, deducted discounts and taking account of the exclusions set out below). Like the PPRS, this percentage would be set nationally, and paid quarterly in arrears. The Department would take account of expected payments when setting NHS England's budget. As with the PPRS payments, the Department would ensure that all the income it receives from the payments in England is reinvested in the NHS for patients' benefit. Scotland, Wales and Northern Ireland would receive a proportional share of payments received.

Companies in scope

- 4.4. We propose that the companies which will be liable to make a payment under these new arrangements would be the first manufacturer or supplier in the UK (including those that hold a manufacturers' licence or a wholesale dealers' licence), to supply an item of presentation into the NHS supply chain in the UK. However, for the most part we do not expect many wholesalers to be affected, as they are unlikely to make the first sale in the UK supply chain.
- 4.5. This approach is intended to broadly align to the approach in the 2014 PPRS, where companies that hold the marketing authorisation for a branded health service medicine are generally held to be responsible for making a payment. However, the differences between these statutory scheme proposals and the 2014 PPRS arrangements reflect the variety of operating arrangements companies adopt, and the need to make clear within the regulations which companies would be responsible for making payments. This is not necessary in the more flexible voluntary arrangement of the 2014 PPRS, which only applies to those companies that choose to join that scheme.
- 4.6. Where the Secretary of State reasonably considers that operating arrangements made by a company assist that company, or another, to undermine the purposes of the statutory scheme as set out above, we propose that the Secretary of State be able to specify the company that should be responsible for making a payment through issuing a direction. In doing so, we further propose that the direction should indicate the date from which the direction applies to a company.
- 4.7. We also propose (see paragraphs 4.23 - 4.24 and 4.27 - 4.31) that sales of low cost presentations and sales under extant framework agreements be excluded from the payment system, and that the current small company exemption be applied to the payment system.
- 4.8. See regulations 3 and 4 of the draft regulations.

4.9. We recognise that there may be circumstances when a company may not know whether the sales of certain branded medicines were for health service use. We propose, therefore, that where this applies a company provides estimated information. The proposed arrangements are set out more fully at paragraphs 6.18 - 6.21.

Consultation questions

- 1) Do you have any concerns with the proposed approach to determine the companies in scope or the relevant draft regulations? Please say why**
- 2) Do you agree with the proposed process for determining the proportion of sales liable for payment where it is uncertain if the supply was ultimately for health service use? Please say why**

Payment percentage

4.10. The payment percentage, which would be applied to a company's relevant sales to determine the required payment, would be set in the regulations following this consultation - see regulations 3 and 4 of the draft regulations. The aim is to keep complexity to a minimum by setting a payment percentage which is equivalent to that in the 2014 PPRS, but that this percentage will be applied as part of a simpler payment system than the PPRS, which will not include features such as modulation or brand equalisation. We propose that the payment percentage for the statutory scheme will be the same as the 2018 payment percentage for the 2014 PPRS.

4.11. The 2014 PPRS payment percentage for 2018 will not be known until December 2017. Following an agreement with the ABPI to revise the PPRS¹⁰, this will not be below 2.38% and will not exceed 7.80%. The payment percentage for the statutory scheme would be reviewed on an annual (or possibly more frequent) basis and, if necessary, adjusted in future following consultation.

Consultation questions

- 3) Do you agree that we should introduce a payment system to align the statutory scheme more closely with the PPRS? Please give your reasons**
- 4) Do you have any concerns with aligning the initial payment percentage level with the payment level in the PPRS for 2018? Please give your reasons**

Health service medicines covered

Key definitions

4.12. The draft regulations include a number of definitions to describe the medicinal products which would come within scope of the statutory scheme, and build on the definitions used in the NHS Act 2006. In particular, the term "health service medicine" is defined in the NHS Act 2006 as a medicinal product used to any extent for the purposes of the health service. It is proposed that the proposed payment mechanism and price control mechanism should only apply to those health service medicines:

- That have a brand name that enables the health service medicine to be identified without reference to a generic drug name.

¹⁰ www.gov.uk/government/publications/pprs-payment-percentage-2017

- For which a marketing authorisation has been granted.
 - For which a parallel distribution notice has not been given.
 - That are prescription only medicines.
 - Which are not blacklisted (i.e. medicinal products that cannot be prescribed by GPs on the NHS).
- 4.13. The draft regulations define these medicines as "relevant medicines". Where it is necessary to make a distinction within the draft regulations between, for example, the different pack sizes or strengths of a particular relevant medicine, the draft regulations refer to a "presentation" of a relevant medicine. We propose that a small amendment be made to the current definition of presentation within the 2007 and 2008 Regulations, whereby reference to "clinical indications" is removed.
- 4.14. Additionally, to underpin the introduction of a payment system, it is necessary to define gross and net sales income, so that it is clear what income the payment percentage will be applied to.
- 4.15. See regulation 1 of the draft regulations.

New presentations

- 4.16. As set out in the 2015 consultation, we propose that the payment percentage should apply to new presentations and that the payment percentage is applied equally to all presentations. This is different to the approach in the 2014 PPRS, where sales of new presentations which contain a new active substance (NAS) do not attract a payment percentage, but the percentage on other presentations is grossed up to take account of NAS presentation sales. We have considered other options, in particular to: a) exclude new presentations and still apply the proposed payment percentage level (i.e. equivalent to the PPRS payment percentage for 2018), and b) adopt a similar approach to the PPRS to exclude new presentations and gross up the payment percentage on old presentations.
- 4.17. However, our view is that approach a) fails to deliver equivalent savings in the statutory scheme as compared to the PPRS, given the role new presentations play in PPRS growth and payment calculations. Additionally, for b) we still consider that it is not reasonable to expect the smaller number of companies in the statutory scheme affected by the regulations¹¹ to pay a higher percentage on their older presentations to make up for the cost of new presentations. The negative impact of b) is likely to be limited in the short term, due to the treatment of presentations procured under framework agreements (see below), but as these agreements expire, the impact would increase.
- 4.18. Companies are, of course, able to join the PPRS if they consider that it would be in their best interests to do so given their product portfolio.

Types of health service medicine

- 4.19. We propose that the payment mechanism and price control mechanism should apply to branded health service medicines. This would mean that any medicine with a brand name, including where the medicine is required to have a brand name by the Medicines and Healthcare products Regulatory Agency (MHRA), or where a company has chosen to give that medicine a brand name in circumstances where the

¹¹ At the time of writing 17 companies in the statutory scheme are above the smaller companies threshold, compared to 76 in the PPRS

medicine is not required to have a brand name, would come within the scope of the statutory scheme (see definition of "relevant medicine" in the draft regulations).

- 4.20. Medicines which are required to have a brand name by the MHRA are generally not as interchangeable as unbranded generics. Therefore, competitive forces will act more slowly and less effectively, which means that decreases in actual selling prices are likely to be lower and price regulation is required. It may be that the price reductions for these types of medicines are at the optimal level, due to additional pharmacovigilance and other manufacturing and licencing requirements, but we have not identified evidence to support this. Excluding medicines required by the MHRA to have a brand name would also create a disparity with the 2014 PPRS, given that such products come within the scope of the 2014 PPRS payment mechanism. Excluding such medicines from the statutory scheme could therefore encourage companies to leave the PPRS to the detriment of scheme stability and overall savings to the NHS.
- 4.21. As noted above, a company may choose to apply a brand name to a product where there is no requirement to do so, and where that product has identical generic competitors. In these circumstances the company has made a commercial decision to market the product as a brand, and expects to generate greater revenue as a consequence. We do not, therefore, propose to exclude such products from the statutory scheme. We also do not believe it is tenable to exclude such products by including a provision in the statutory scheme equivalent to the "brand equalisation deal" provision in the 2014 PPRS, which formed part of the overall 2014 PPRS negotiated package. Even though we seek to broadly align the savings from the statutory scheme with those of the 2014 PPRS, we do not seek to mirror all of the 2014 PPRS arrangements, which is reflective of the fact that the statutory scheme acts as a back-up to the voluntary PPRS. Mirroring the PPRS 2014 exactly would considerably increase the administrative burden on statutory scheme companies and increase the complexity of the operation of the scheme, which runs counter to our stated objectives.

Consultation questions

- 5) Do you have any comments on the definition of "relevant medicine"?**
- 6) Do you agree with the proposed inclusion of new presentations in the payment system? Please give your reasons**
- 7) Do you agree with our proposed inclusion of all branded health service medicines, except parallel imports and parallel distributed medicines, in the payment system? Please give your reasons and provide any additional evidence and analysis you may have**

Exemptions

OTC medicines

- 4.22. In the 2015 consultation, we proposed aligning the treatment of branded OTC medicines to the treatment in the 2014 PPRS, which would mean some sales of prescribed branded OTC medicines would be brought within the scope of the price controls (in the 2014 PPRS, sales of prescribed OTC branded medicines are captured, but there is discretion to waive sales for individual medicines where these OTC sales are below £50,000). However, as set out in the 2016 Government response to the consultation, we now propose that all sales of OTC medicines would

be excluded for the purposes of the regulations, including from the payment system. This is in line with the 2008 Regulations. This reflects concerns raised during the consultation that with current information systems it is not possible to obtain an accurate estimate of sales of OTC medicines under NHS prescriptions, and our aim to minimise the administrative burden associated with our proposals.

Framework agreements

4.23. As originally set out in the 2015 consultation, it is proposed that the payment would not apply to sales of presentations where the item of presentation is procured under one or more extant framework agreements under the Public Contracts Regulations 2006¹², the Public Contracts (Scotland) Regulations 2012¹³, the Public Contracts Regulations 2015¹⁴ or the Public Contracts (Scotland) Regulations 2015¹⁵ (i.e. that were entered into on or before, and/or were entered into following a tender which closed on or before, the date of coming into force of the new regulations). However, as confirmed in the Government's 2016 response, we do not propose to extend the exemption to future framework agreements that were not extant when the regulations would be brought into force. This is because companies would be able to take into account as part of their tenders any payment required by the payment system.

Low cost presentations

4.24. The current 2008 Regulations contain an exemption from the price cut for presentations which were on sale for less than £2.00 on 1st December 2013. We propose that this exemption be retained at the same level and be amended so that it applies to the payment system. This is reflective of comments made during the passage through Parliament of the Health Service Medical Supplies (Costs) Act 2017, where the importance of the exemption was emphasised, and a recognition of the low prices already being charged for these presentations.

Parallel imports

4.25. For parallel imports, we propose to exclude these from the payment system (and the statutory scheme provisions more broadly), in line with the 2014 PPRS. This is because we would not expect parallel importers to have the type of commercial relationship that a wholesaler of the kind captured by these regulations (for example, making the first point of supply to the UK market acting as principal distributor for a manufacturer) would have. They would not, therefore, be in a position to negotiate a decreased price from the manufacturer to offset the payment percentage, in the way that a wholesaler of the type identified above would be able to do. We also think it is likely that parallel imports would have already have been subject to regulatory measures to control prices in the country of origin. Parallel importers can also offer significant savings to the NHS, with one estimate from the British Association of European Pharmaceutical Distributors putting this at up to £100 million (although the level of savings would be subject to continual fluctuation on the basis of exchange rates and relative price differences between the UK and EU markets).

¹² www.legislation.gov.uk/uksi/2006/5/contents/made

¹³ www.legislation.gov.uk/ssi/2012/88/made

¹⁴ www.legislation.gov.uk/uksi/2015/102/contents/made

¹⁵ www.legislation.gov.uk/ssi/2015/446/contents/made

4.26. We also propose that parallel distributed branded health service medicines should be excluded, as the operational arrangements for parallel distributors would be similar to parallel importers.

Small companies

4.27. The Government continues to recognise the need to balance the interests of the NHS and patients in having access to medicines on reasonable terms, with the need to minimise the burdens on smaller companies and to take account of the cost of research and development.

4.28. Currently, the statutory scheme contains an exemption from the price cut for companies which, during the most recent complete calendar year, supplied branded medicines for health service use in the UK, from which it derived sales income of less than £5 million. As proposed in the 2015 consultation, we are committed to retaining this protection for small companies, with the £5 million exemption applied to the proposed payment system, which would be in line with the equivalent exemption in the 2014 PPRS. Although the £5 million level is not aligned to a EU Commission definition¹⁶, we believe this is reasonably equivalent to, or in some cases more generous than, the EU Commission definition, which is set at annual turnover or annual balance sheet total of €10 million or less, and headcount of less than 50. This is because the statutory scheme definition only takes account of UK branded health service sales, not total sales.

4.29. Additionally, having taken account of feedback from the last consultation, and as set out in the 2016 Government response and in line with the above, we propose that all health service sales of OTC medicines should be excluded from the £5 million threshold calculation. This will help minimise the administrative burden on some companies (see also paras 6.32 - 6.35), which we recognise is an area of concern for some companies in the statutory scheme, and will further benefit small to medium-sized companies as more sales will be excluded.

4.30. The application of the small companies' exemption is set out in schedule 2 of the draft regulations. This also includes proposed approaches to the application of the £5 million threshold to differing accounting periods and setting out time periods by which information on sales should be provided.

4.31. We also propose introducing specific provision for circumstances where the application of this exemption is being considered in relation to a new company. This is set out in schedule 3 of the draft regulations. In particular, it sets out that where a company is in its first accounting period, the application of the small company exemption is based on the company's estimate of their sales, if the Secretary of State accepts that this is reasonable. It also makes provision for instances where a company extends their accounting reference period.

Temporary exemptions

4.32. As set out in the 2016 consultation response, the Government has considered the representations made to extend the current temporary exemption provision for the maximum price in the 2008 Regulations to the proposed payment system. However, we remain of the view that the facility to allow for a temporary or permanent price

¹⁶ Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (2003/361/EC) www.eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32003H0361

increase (see regulations 10 and 11 of the draft regulations) is the right way to address short or long-term supply problems where these are dependent on UK pricing. See paragraphs 5.24-5.29 for more detail.

Consultation questions

8) Do you agree that OTC health service medicines should be excluded from the price control provisions? Please give your reasons

9) Do you agree that only extant framework agreements should be excluded from the payment system? Please give your reasons

10) Do you agree that parallel imports, and parallel distributed medicines, should be excluded from the statutory scheme provisions? Please say why, and provide any evidence or analysis to support this

11) Do you agree that the small companies' exemption should be retained, at the current level, and extended to the payment system? And that the application of this exemption to new companies is reasonable? Please give your reasons

Operational elements

Definitions

4.33. To enable operation of the payment system, time periods need to be defined to inform the assessment of the required payment under the proposed payment system, and to be clear on the timeframe for companies to make these payments.

4.34. We have set out our proposed timeframes for making payments in schedules 1 and 3 of the draft regulations, which are consistent with the requirements in the 2014 PPRS. These also draw on definitions in regulation 1 of the draft regulations, specifically for: 'financial year', 'accounting reference period', 'quarter', and 'remaining period'.

Enforcement of recoverable sum

4.35. The 2008 Regulations contain a provision which imposes a liability on companies who have supplied presentations to the NHS above the maximum price, to pay, upon a demand from the Secretary of State, a recoverable sum calculated in accordance with the schedule to those regulations.

4.36. To ensure that the proposed payment system is properly enforced, with repercussions for companies that do not comply with the requirements of the scheme, we propose that the current recoverable sum provision is amended so that it also applies to the payment system. See regulation 5 of the draft regulations. Where a company does become liable for a recoverable sum, we propose that this would be calculated in accordance with schedule 4 of the draft regulations. This would be set at the amount of the payment which is outstanding multiplied by a given percentage, depending on the number of times that the company had failed to provide the required payment. We further propose that where a demand for payment is made under this regulation, that this demand is required to state the company's appeal rights.

4.37. In addition, where a recoverable sum is not paid in full in the timeframe required, we propose that the company will be liable to pay interest on the outstanding sum, in most instances at a rate of 2.5 per cent above the Bank of England base rate. See regulation 6 of the draft regulations.

Penalties

- 4.38. The 2007 Regulations provide for a daily penalty to be applied to companies where they do not provide required information in the set timescales. We propose that these penalty arrangements be extended to cover instances where a company does not pay the recoverable sum resulting from the failure to make a required payment, or the interest on the late payment of the recoverable sum. We do not propose to change the current daily penalty rates, as established by the 2007 Regulations, in terms of their application to the failure to pay the recoverable sum, or interest on that sum (although one change is proposed relating to a company's failure to notify the Secretary of State of its intention to launch a new presentation - see para 5.42). However, we do propose that the provision determining which of the daily penalty rates is applied be amended, so that where information on total net sales income of relevant medicines is not available, a determination would be made on total UK sales. Moreover, where information is not available because the company in question is a new company, then we propose that it is assumed that total UK sales are less than £100 million.
- 4.39. We also propose a further amendment to the provision, to the effect that any letter to a company demanding payment of the penalty is required to set out the company's appeal rights.
- 4.40. See regulation 7 and schedule 5 of the draft regulations.

Consultation questions

12) Do you think the time periods set out in schedules 1 and 3 are reasonable?

Please give your reasons

13) Do you agree with the definitions? If not, why?

14) Do you have any concerns with the proposal to extend the recoverable sum and penalty provisions to the proposed payment system, or the application of the penalty rates as proposed? Please give your reasons

5. Control of maximum prices

- 5.1. As noted above, the 2008 Regulations make provision for establishing a maximum price that can be charged for a presentation, by reference to the price at which the presentation was on sale on 1st December 2013. A key element of these provisions is the imposition of a price cut, currently 15%, on those 1st December 2013 prices.
- 5.2. To complement and support the proposed introduction of a payment system, a number of changes are being proposed to the current regulatory provisions for maximum prices.

Maximum price

- 5.3. There is a need for a limit on the maximum price of a presentation (as with the 2014 PPRS) in order to avoid price inflation and protect the savings to the NHS provided by the scheme. It is proposed that generally the limit should apply to the maximum price for which the presentation was on sale on 1st December 2013 (i.e. the reference point against which the 15% price cut was applied), which would be generally in line with the PPRS. This would mean that companies would no longer be required to apply the 15% price cut, though conversely, companies would not be required to increase the actual prices charged to the NHS and the price agreed under extant frameworks would not be changed. In the event that a company did choose to increase prices, they would be free to do so, except where planned increases exceeded the maximum price, for which an application would need to be approved by the Secretary of State.
- 5.4. In the event that the Secretary of State had already agreed an increase on the 1st December 2013 price, then it is the increased price that would be the maximum price.
- 5.5. For presentations without a price on 1st December 2013, the limit would apply to the maximum price as specified by the Secretary of State at the time the presentation was launched, or subsequently in response to an application for a price increase or decrease. However, where a price has not previously been specified, we propose that the Secretary of State be able to do so by direction to a specific company.
- 5.6. See regulation 8 in the draft regulations.

Consultation questions

15) Do you think it is right that the existing price cut should be reversed, and that maximum prices be determined by the price as at 1st December 2013, or a price subsequently agreed by the Secretary of State? If not, why?

Maximum price lists

- 5.7. Broadly in line with our proposals in the 2015 consultation, we believe there is a need for transparent and publicly available information on maximum prices, for both the statutory scheme and the 2014 PPRS.
- 5.8. We propose establishing two lists. The first will be an archive list, which will be referenced in the regulations and published, and will set out the maximum prices for all presentations as at the commencement of the regulations, which for statutory scheme health service medicines, in line with paras 5.3 - 5.5 above, will be either the

price the presentation was on sale as at 1st December 2013 or the price as specified by the Secretary of State. For health service medicines in the 2014 PPRS, new presentation launches where these contained a NAS would be at the price determined by the company and confirmed by the Secretary of State, and for other presentations would be prices as agreed by the Secretary of State.

- 5.9. A second, live, list will be a continually updated version of the archive list, and will provide a reference for any changes to the maximum prices of presentations (such as through modulation in the PPRS, or by direction by the Secretary of State following a request for a price increases), and the introduction of new presentations.
- 5.10. See regulation 8 in the draft regulations.
- 5.11. Where an error is identified in the lists, including where a price has been omitted, then the Secretary of State would make a correction.

Consultation questions

16) Do you agree with the proposal to establish maximum price lists? Please give your reasons

Directions

- 5.12. We believe that there is a need for a formal mechanism to establish or confirm a maximum price. As referenced in the previous two sections, we propose to make provision for the Secretary of State to be able to issue directions to set the maximum price where:
- A presentation was launched after 1st December 2013, but a price was not specified by the Secretary of State.
 - A new presentation is launched.
 - A company fails to comply with the proposed notification period for the launch of a new presentation.
 - A decision has been made to provide a temporary exemption from the maximum price.
 - A decision has been made to make a permanent increase in the maximum price.
 - A decision has been made to make a permanent decrease in the maximum price.
 - The regulations apply to a company which has left the PPRS, and the price of the presentation is different to the price set out in the archived list because of changes to the price whilst the company was a member of the PPRS.
- 5.13. Where a price is listed on the price list, and there has been a subsequent direction issued by the Secretary of State, or where the Secretary of State has issued several directions, then the maximum price will be the price in the most recent direction.
- 5.14. See regulations 8 to 13 of the draft regulations.

Consultation questions

17) Do you agree that the proposed directions are an appropriate mechanism to determine the maximum prices in the circumstances identified? If not, why?

New presentations

- 5.15. There is currently a lack of detail in the regulations around the process for agreeing prices for new presentations. In particular, as described in the 2015 consultation, companies often adopt a process similar to that used in the 2014

PPRS, where they are required to give the Department a minimum of 28 days' notice before the launch of a new presentation, and cannot launch the presentation until it receives confirmation of the pricing position. However, there is no requirement to this effect in the regulations.

- 5.16. There are also no provisions in the 2008 Regulations which stipulate that any specific information should be provided to inform the Secretary of State's decision, although regulation 5 of the 2008 Regulations does list factors that the Secretary of State would take into account. We propose, therefore, to clarify the new presentation provisions - see below, and regulation 9 of the draft regulations.
- 5.17. In doing so, account needs to be taken of the NHS Act 2006, as amended by the Health Service Medical Supplies (Costs) Act 2017, which includes certain restrictions on the collection of information. In particular, the Secretary of State will be required to give a company an information notice if information is required in respect of the costs incurred by the company in connection with the manufacturing, distribution or supply of a particular product (other than costs which relate to any transaction between companies for that product).

Definition

- 5.18. We propose linking the definition of new presentation to the maximum price lists referenced above. Specifically, we propose that a new presentation would be one which, at the time of submission to the Secretary of State for a launch, was not listed in the archive price list referenced above, nor had a price specified in a direction by the Secretary of State.

Process

- 5.19. We propose that where a company plans to launch a new presentation:
- The company would need to follow 3 stages:
 - Stage 1 - the company must make a notification in writing, providing the Secretary of State with at least 60-days' notice before the proposed launch date, which:
 - a) specifies the presentation in respect of which the notification is made;
 - b) specifies the summary of the product characteristics;
 - c) specifies the proposed launch date;
 - d) specifies the proposed maximum price; and
 - e) includes any relevant information relating to those factors, specifically those where to request the information there is no need for an information notice, to be taken into account for the purposes of determining the price.
 - Stage 2 - with respect to information for which an information notice is required await an information notice from the Secretary of State and provide the information relating to the factors set out in the draft regulations.
 - Stage 3 - Provide any further information requested (including, where appropriate, by an information notice) by the Secretary of State.
 - We propose that within 28 days of receiving a notification under stage 1, the Secretary of State must give the company an information notice under stage 2. Also, where the Secretary of State has not received all the information required under stage 1 and stage 2, the Secretary of State must within a period of 28 days of receipt of the information under stage 2, notify the company that further information is required.

- The Secretary of State must specify the maximum price through a direction no later than 28 days after receipt of all of the information requested via the three stages.
- Where a company fails to notify the Secretary of State of its intention to launch a new presentation in the specified time period, or fails to provide the information requested, then the Secretary of State may specify the maximum price of that presentation.

Factors to take into account

5.20. In the 2015 consultation, we consulted on a suggested range of factors that should be taken into account when considering price increases. In considering this further, and reflecting on the consultation responses, we believe that this should inform changes to the factors identified in the 2008 Regulations in relation to setting prices of new presentations. We propose, therefore, that the factors that should be considered should include, but not be limited to, the following.

5.21. Where information should be submitted with stage 1 of the notification:

- The clinical need for the presentation.
- The cost of therapeutically equivalent or comparable medicines.
- The cost of the new presentation in the European Economic Area, and any other markets.
- Whether the presentation contains a NAS (as defined in regulation 9(10) of the draft regulations).
- The date on which the patent protections for each indication of the new presentation expires.
- The total profit of the relevant company, before interest charges and taxes, as set out in the company's statutory accounts.
- The estimated total supply and sales income of the new presentation for the first 5 financial years, or where the patent protection expires before the end of this period, up to the point the patent protection expires.

5.22. Where information would be requested through an information notice (stage 2 of the application):

- The reasonableness of the estimated costs from sales of the presentation over the first 5 financial years of sale, or up to the period of patent protection expiry, including:
 - manufacturing and supply costs;
 - research and development costs;
 - operational costs; and
 - any other costs.
- The price at which a company's reasonable costs for that presentation, as determined by the Secretary of State, would be met.

5.23. See regulation 9 of the draft regulations.

Consultation questions

18) Do you agree that the proposed process, including the time periods for providing information and making decisions, is reasonable? If not, why not?

19) Do you have any comments with respect to the type of information that the Secretary of State is considering requesting as part of the information notice?

Temporary exemptions

Maximum price

- 5.24. As referenced in chapter 4, Regulation 5 of the 2008 Regulations allows for an urgent, temporary exemption from price controls to address imminent threats to continuity of supply. The provision can be applied to exempt presentations from the other provisions in the regulations relating to the control of maximum prices, including new presentations, and the price limit on low cost presentations. As set out in the 2015 consultation, we believe that a provision of this nature is important in providing a flexible and rapid response to ensure continued adequate supply of essential medicines, and that it should be retained.
- 5.25. However, regulation 5 does not limit the level of the price increase and therefore a company could increase the maximum price beyond a price that is reasonable to mitigate the risk to supply. To address this, we propose that, in line with our proposal in the 2015 consultation, a provision should be included in the regulations that would require the company to agree a temporary maximum price with the Secretary of State. See regulation 10 of the draft regulations.

Exemption from payments

- 5.26. The 2015 consultation also proposed that the temporary exemption should not be extended to cover the proposed payment system, which would be in line with the approach taken in the 2014 PPRS. Some respondents to that consultation raised concerns about the negative impact this might have on maintaining adequate supplies of essential medicines, with a particular emphasis on blood plasma health service medicines.
- 5.27. In the 2016 consultation response document, we set out the Government's view at the time that the facility to increase prices was the right way to address short or long-term supply problems, where these circumstances are dependent on UK pricing.
- 5.28. We have given this further consideration, and have not seen any further analysis or evidence to suggest that price increases are an insufficient mechanism to address these potential concerns, particularly in light of other activity described below. We envisage that if it became economically unviable to supply a medicine at the current price, companies could increase prices to the limit of the maximum price, or, if necessary, seek temporary or permanent increases in the maximum price for supply reasons. It was recognised that, if this action was required, the savings produced by the payment system for that medicine would be offset partially, or in full, by the increase in price. However, this would allow for the market to determine the most efficient level of price increase (and reduction in savings to the NHS) necessary to secure adequate supply.
- 5.29. Additionally, we believe that the maintenance of adequate supplies of essential medicines will be supported by the use of different procurement approaches for framework agreements adopted by the Commercial Medicines Unit at NHS England, such as incorporating incentivised aggregate discount schemes within frameworks (such as for recombinant clotting factors and a recent albumin framework), procuring on a UK wide basis, and indicating the specific health service medicines which are likely to be used by the NHS (such as for immunoglobulin). These approaches offer a stronger basis for guaranteeing supply with a plurality of providers.

Consultation questions

20) Do you agree that the temporary exemption provision should be amended so that a company is required to agree a revised, temporary maximum price? Please give your reasons

21) Do you agree that companies should not be able to seek an exemption from the payment mechanism, and that the option for a company to apply for a price increases will address any supply issues? If not, do you have any analysis and evidence to show why not?

Price increases

5.30. Regulation 6 of the 2008 Regulations enables a permanent increase in the maximum price of a presentation. Although this regulation sets out the process which a company should follow in making an application, including the reasons for the price increase, the provision does not currently set out the factors which the Secretary of State will use to decide whether or not to allow an increase in the maximum price.

5.31. Building on our stated intention in the 2015 consultation, we propose retaining the facility for a price increase but also including factors in the regulations, which reflect, where appropriate, the factors identified for new presentations. We also propose amending the process so that this reflects the introduction of the requirement to issue information notices to require certain types of information.

Process

5.32. We propose that where a company applies for an increase in the maximum price:

- The company would need to follow three stages:
 - Stage 1 - make a written request for a price increase which:
 - a) specifies the presentation for which the request is made;
 - b) states the reasons for the increase;
 - c) specifies the proposed increased maximum price; and
 - d) includes any relevant information relating to those factors, specifically those where to request the information there is no need for an information notice, to be taken into account in any decision.
 - Stage 2 - with respect to information for which an information notice is required await an information notice from the Secretary of State and provide the information relating to the factors set out in the draft regulations.
 - Stage 3 - Provide any further information requested (including, where appropriate, by an information notice) by the Secretary of State.
- We propose that the Secretary of State must give a company an information notice under stage 2 within 28 days of receipt of the information provided under stage 1. Also, where the Secretary of State has not received all of the information required under stage 1 and stage 2, the Secretary of State must within a period of 28 days of receipt of the information under stage 2, notify the company that further information is required.
- After receipt of the information required under the three stages, the Secretary of State must specify the maximum price through a direction no later than 90 days after receipt of that information, unless the number of applications makes it impractical for the Secretary of State to reply to all of the applications.
- Where the number of applications makes it impractical for the Secretary of State to reply to applications within the 90 days the Secretary of State may extend the 90 day period for a further 60 days. Where this is necessary the Secretary of State must inform the company within the initial 90 day period.

Factors to take into account

5.33. We propose that the factors that should be taken into account for a price increase should include, but not be limited to, the following.

5.34. Where information should be submitted with stage 1 of the application:

- The clinical need for the presentation.
- The likelihood of a shortage of supply of that presentation.
- The cost of therapeutically equivalent or comparable medicines.
- The cost of the presentation in the European Economic Area, and any other markets.
- The date on which patent protections for each indication of the presentation expires.
- The total profit of the relevant company, before interest charges and taxes, as set out in the company's statutory accounts.
- For the last complete financial year (or up to the latest complete month in the current financial year for new companies), the total quantity supplied of a presentation and the total net sales income, and for the next five financial years, estimates of the total quantity of that presentation to be supplied, and the total net sales income.
- For the latest complete financial year (or up to the latest complete month in the current financial year for new companies), the total quantity sold of all the company's statutory scheme health service medicines and the total net sales income, and for the next five financial years, estimates of the total quantity of all the company's statutory scheme health service medicines to be supplied and the total net sales income.
- For all a company's statutory scheme health service medicines, the reasonableness of the estimated costs for the last complete financial year (or up to the last complete month in the current year for new companies), and the estimated costs for the next five financial years (or up to the period of patent protection expiry), including:
 - manufacturing and supply costs;
 - research and development costs;
 - operational costs; and
 - any other costs.
- The price at which the company's reasonable costs for the presentation, as determined by the Secretary of State, would be met.
- The estimated total net sales income from the presentation, after deduction of reasonable costs as determined by the Secretary of State, for the most recent complete financial year (or up to the last complete month in the current year for a new company), and the next five financial years if:
 - the presentation was supplied at its current maximum price; and
 - the presentation was supplied at the proposed increase in the maximum price.
- All the company's reasonable costs as determined by the Secretary of State over the most recent complete financial year (or up to the last complete month in the current year for a new company), and the next five financial years.

5.35. Where information will be required through an information notice (stage 2 of the application):

- The reasonableness of the estimated costs of the presentation for the last complete financial year (or up to the last complete month of the financial year for

new companies), and the reasonableness of the estimated costs for the presentation for the next five financial years (or up to the period of patent protection expiry), including:

- manufacturing and supply costs;
- research and development costs;
- operational costs; and
- any other costs.

5.36. See regulation 11 of the draft regulations.

Consultation questions

22) Do you agree with the proposed process, factors to be considered and information likely to be requested for price increases? Please give reasons

Price decreases

5.37. Currently, there are no specific provisions in the 2008 Regulations setting out a process for managing price decreases. We propose, therefore, that the Secretary of State may, on an application by a company, decrease the price via a direction. Where a company applies for a price decrease:

- The company would need to follow 2 stages:
 - Stage 1 - make a written request:
 - a) specifying the presentation for which an application is made;
 - b) stating the reasons for the application; and
 - c) specifying the proposed reduced maximum price.
 - Stage 2 - providing further information where this is requested by the Secretary of State. In line with our proposals for price increases we propose that, where the Secretary of State has requested further information under stage 2, the Secretary of State informs the company that further information is required, including where appropriate by information notice, within 28 days after receipt of the information under stage 1.
- The Secretary of State must specify the maximum price through a direction no later than 90 days after receipt of all of the information required under stages 1 and 2, unless the number of applications makes it impractical for the Secretary of State to reply to all of the applications.
- Where the number of applications makes it impractical for the Secretary of State to reply to applications within the 90 days the Secretary of State may extend the 90 day period for a further 60 days. Where this extended period is necessary the Secretary of State must inform the company within the initial 90 day period.

5.38. See regulation 12 of the draft regulations.

Consultation questions

23) Do you agree with our proposed process for handling price decreases? If so, do you think what we have proposed is reasonable? Please give reasons

Operational elements

Recoverable sum

5.39. As set out above, the 2008 Regulations make provision to impose a liability on companies who have supplied presentations above the maximum price to pay, upon a demand from the Secretary of State, a recoverable sum calculated in accordance

with the schedule in those regulations. It also includes provision to impose a liability to pay interest on late payment of a recoverable sum. We do not propose removing the requirement as currently set out in those provisions. However, we do propose adding an amendment to the first provision, requiring that any letter to a company demanding payment of the recoverable sum set out the company's appeal rights.

5.40. See regulations 14 and 15, and schedule 4 of the draft regulations.

Penalties

5.41. We proposed above that the penalty arrangements in the 2007 Regulations should be extended to cover instances where a company does not pay a recoverable sum resulting from the failure to make a required payment, or did not pay the interest on the late payment of the recoverable sum. We also propose extending these penalty arrangements so that they apply to a company that charges a price above the maximum price, and where a company does not provide the proposed 60-days' notice for the launch of a new presentation.

5.42. However, where these apply to a breach of the proposed 60-day notice period, we propose a single penalty of up to £100,000 should apply, rather than a daily penalty. We believe this is necessary as larger companies in particular may not find daily penalties a disincentive from breaching the notice period. We propose that a determination of the level of the penalty would be informed by:

- Whether the company had previously breached the 60-day notice period.
- The size of the company.
- The anticipated sales volume of the presentation.
- The difference between the gross sales income accruing from the unauthorised price at which a presentation was launched and the gross sales income that would have accrued at the price finally agreed by the Secretary of State.

5.43. As above, we propose that where information on total net sales income of relevant medicines is not available, that a determination of the daily penalty rate which applies is made on total UK sales. Also in line with the above, we propose that any letter to a company demanding payment of the penalty is required to set out the company's appeal rights.

5.44. See regulation 16 and schedule 5 of the draft regulations.

Consultation questions

24) Do you agree with our proposals to extend the penalty arrangements, and also to apply a single penalty where there is a breach of the notice period for the launch of new health service medicines? Please give your reasons

6. Information requirements

- 6.1. The 2007 Regulations set out a range of information requirements to underpin the functioning of the statutory scheme. In particular, it includes requirements for companies to provide a range of information on sales income within certain prescribed timescales.
- 6.2. To support the introduction of the proposed payment system, a number of changes are needed to these information requirements.

Retention and provision of sales income information

- 6.3. The 2007 Regulations (as amended¹⁷) set out a requirement to record and keep for a period of six years information on sales income for each presentation, and quantity sold, and to provide this upon request from the Secretary of State. Having given this some consideration, we believe that a variant of this provision, whilst still necessary, would sit better within the regulations on information powers that are being consulted on in tandem with this consultation.

Provision of information

Scheme information

- 6.4. We propose making some amendments to the regular sales income information which we already require through the 2007 Regulations. We propose that the existing requirement to provide information separately for sales of presentations to GMS contractors, PMS contractors and dispensing doctors will be removed, and instead, information will be required on aggregated sales to primary medical service providers (as defined in regulation 1 of the draft regulations). Additionally, we propose that information on the quantity supplied of each presentation, and the associated gross and net sales income, to each sector should exclude sales of low cost presentations and sales under extant framework agreements, which should be provided separately. See regulation 21 of the draft regulations.
- 6.5. The companies from which we require this information will be in line with those companies that fall within our proposals around companies in scope for the payment system (see paragraphs 4.4-4.8). We are not looking to make changes to the 2-month time period within which companies have to provide the information, although we are proposing that the period for which the information should be provided will be the relevant financial year.
- 6.6. We also propose introducing a requirement for companies to provide a copy of their statutory audited accounts for the company's financial year within nine months of the last day of that financial year. We also propose making arrangements to take account of changes to a company's financial year and accounting reference period, including making provision in specific circumstances for the Secretary of State to determine the periods within which information should be provided.
- 6.7. To enable the effective operation of the payment scheme, and generally in line with the requirements in the 2014 PPRS, we propose that companies provide sales

¹⁷ www.legislation.gov.uk/uksi/2015/233/contents/made

reports each quarter within 30 days of the last day of that quarter, and for any remaining period within 30 days of that remaining period. A definition of "remaining period" is set out in regulation 1 of the draft regulations.

6.8. We also propose arrangements to take account of changes to a company's financial year and accounting reference period, and to accommodate the application of the information requirements to instances where a company is liable for the payment percentage for only part of a reporting period.

6.9. See schedules 1 and 3 of the draft regulations.

New companies

6.10. With regard to the information arrangements for new companies, we propose that where companies do not meet the small company exemption criteria (see paragraphs 4.27 - 4.31) they should provide sales reports in line with those for existing companies (as set out in the section on scheme information). Alternatively, where a company estimates that it will have relevant sales of less than £5 million in its first financial year, the sales report information should be provided within 30 days of the last day of the financial year. Where the accounting reference period is more than 12 months, the information should cover the final 12 months of the financial year, and it should be provided within 30 days of the last day of the final 12 months of the financial year.

6.11. We propose that the Secretary of State may request an audited annual sales report, which companies are required to provide no earlier than 3 months from the request, and no earlier than 9 months from the last day of the company's financial year, if there is reason to believe that this is required to verify the previously submitted information. We also propose that if this audited information shows that the company should have qualified for the small company exemption, then the Secretary of State, either independently or through an application by the company, should make a payment to the company equal to the amount paid for the financial year in question.

6.12. As above, we also propose arrangements to take account of changes to a company's financial year and accounting reference period, including making provision in specific circumstances for the Secretary of State to determine the periods within which information should be provided.

6.13. See regulation 18 and schedule 3 of the draft regulations.

Small companies

6.14. In line with the current small company exemption, and the proposed extension of this to the payment scheme, we also propose that small companies will be exempt from providing the payment scheme information referenced above. However, we propose that small companies should be required to provide details of their total net sales income for relevant health service medicines for the most recent financial year, and that this should be provided within 30 days of either the regulations coming into force, or from the time the regulations start to apply to that company. As above, we also propose arrangements to take account of changes to a company's financial year and accounting reference period, including making provision in specific circumstances for the Secretary of State to determine the periods within which information should be provided.

6.15. Unlike the requirement for the payment scheme information, we are not requiring that these annual returns should be routinely audited, as we acknowledge that this

would present a burden to small companies. However, we think that at times it may be uncertain as to whether a company does meet the £5 million exemption criteria. Consequently, in line with the proposal for new companies, we propose that provision should be made to require a company to provide, within 3 months of the request, but not before 9 months from the last day of the company's financial year, audited annual sales information if this is deemed necessary.

6.16. See regulation 19 and schedule 2 of the draft regulations.

Consultation questions

25) Do you agree with our proposals around scheme information, in particular to require a copy of a company's statutory audited accounts and the requirements for information to underpin the payment system? Please give your reasons

26) Do you agree with our proposals on the information requirements for new companies? Please give your reasons

27) Do you think the proposals on the information requirements for small companies is necessary and reasonable? Please give your reasons

Operational elements

Sales report

6.17. We propose that, as detailed in regulation 20 of the draft regulations, sales reports submitted by companies should set out:

- The total net sales income of the company.
- The total net sales excluding sales under framework agreements extant at the time the regulations came into force, and sales of low cost presentations.
- The total payments required from the company.
- Details of the framework agreements where sales are excluded, as above, and total net sales associated with this.
- The low cost presentations supplied and the total net sales income received.
- Products other than medicinal products supplied, and the total net sales income received in respect of those products.
- The medicinal products supplied outside the UK and the total net sales income received in respect of those products.
- The medicinal products supplied for non-health service use and the total net sales incomes in respect of those products.
- The unbranded generic health service medicines supplied and the total net sales income received in respect of those medicines.

6.18. As referenced at paragraph 4.9 above, we recognise that in some cases it may be unclear whether a medicinal product was supplied for health service use. To address this, we propose including a provision to require companies to include in their sales report information on those sales where there was uncertainty about whether this was the case. We also propose that companies should provide an estimate and the methodology behind the estimate, on sales which were likely to have been for health service use, and set out why the information could only be provided on the basis of an estimate.

6.19. See regulation 20 of the draft regulations.

6.20. Once estimated information has been provided, we propose that the Secretary of State should have the opportunity to validate the best estimate, including by, but not limited to:

- Reviewing presentation level data supplied under the regulations.
- Reviewing Prescription Costs Analysis data.
- Requiring information from suppliers further down the supply chain to determine the final destination of the supply.

6.21. We suggest that any validation should be completed within 12 months of the receipt by the Secretary of State of the end of year presentation level report covering the sales report in question.

Audited information

6.22. Where we have proposed that audited sales reports should be provided, we further propose that these must be prepared and approved by the company and audited by a qualified, independent auditor, and that they should be accompanied by the following information:

- A statement from the qualified, independent auditor that the audited sales report or audited information has been audited in accordance with applicable auditing standards.
- The specific applicable auditing standards relied on by the independent auditor.
- A report prepared and signed by the independent auditor that provides reasonable assurance that the information in the audited report or information has not been materially misstated.
- The final audit plan prepared in accordance with the applicable auditing standards.

6.23. See regulation 22 of the draft regulations.

Written declaration of approval

6.24. To ensure that there is appropriate governance in relation to the provision of information on sales income by companies for the purposes of these regulations, in line with the 2014 PPRS we propose that any such returns are accompanied by a written declaration of approval to the effect that the information gives a true and fair account of the information required. We further propose that this approval should only be provided by the director of the company, or, in the case of a small company, by a designated senior official, where the director or the board of the company gives that individual the authority to do so. See regulation 23 of the draft regulations.

Review

6.25. As it is possible that a review of estimated or audited sales report information could lead to an assessment that a company had over or underpaid via its quarterly payments, we think it is important that provision is made to allow for making repayments to a company, or to require additional payments. We therefore propose that the Secretary of State should be able to determine, either on his own motion, or further to an application from a company, that such a repayment or payment should be made. We further propose that in doing so, the Secretary of State should be able to take account of any information it has on medicinal products, not just that submitted under the regulations.

6.26. In terms of process, we propose that any demand for further payment should be made in writing, setting out:

- The amount to be paid.
- The time period which the identified underpayment related to.
- The period within which the payment must be made, which must be no less than 28 days.
- The company's appeal rights.

6.27. See regulation 24 of the draft regulations.

Penalties

6.28. As referenced above, the 2007 Regulations contain provision to apply penalties if a company did not supply the required information in the established time periods. We intend to maintain the penalty arrangements, including the penalty rates. However, as stated above, we propose that the provision determining which of the daily penalty rates is applied be amended, so that where information on total sales income of relevant medicines is not available, that a determination is made on total UK sales.

6.29. We also propose that, where a company has failed to make a payment as per draft regulations 3 and 4, and failed to provide the required information for the same periods, a demand for a penalty could only be made for one of these breaches at any one time, not both.

6.30. Additionally, we propose that any demand for the payment of a penalty be made in writing, and that in line with the proposals on penalties at 4.38 - 4.40 and 5.41 - 5.44, the existing provision in the 2007 Regulations be amended to require that the letter states the company's appeal rights.

6.31. See regulation 25 and schedule 5 of the draft regulations.

Consultation questions

28) Do you agree that the proposed definition for sales income, and the proposed requirements around the content of sales reports, audited information and the written declaration of approval are reasonable? If not, why?

29) Do you have any comments about the proposed handling of estimated sales, and the suggested timeframe for reviewing that information?

30) Do you agree with the proposal to allow repayments to companies, or requests for additional payments, if further information shows that there may have been under or over-payments? Please give your reasons

31) Do you agree with the proposed amendments to the penalty arrangements around determining which daily penalties should apply and the requirement that any demand for payment should set out a company's appeal rights? Please give your reasons

Administrative requirements

6.32. In the 2015 consultation, we stated our aim of keeping the complexity and administrative burdens arising from our wider proposals to a minimum. Therefore, as per the last consultation, and as identified above, we are proposing that the payment system will incorporate a simple percentage payment rather than seeking to reproduce the equivalent to the 2014 PPRS payments mechanism in the statutory scheme.

6.33. Additionally, we are not proposing to carry across all the audit arrangements from the PPRS. In particular, we are not proposing to carry across the following aspects of the audit arrangements from the PPRS:

- Tripartite audit engagements.
- The requirements to submit the audit plan prior to the completion of the audit.

6.34. We also have no intention of introducing the requirements in the PPRS for a more detailed annual sales breakdown for companies with sales of branded health service medicines between £1m and £5m a year.

6.35. Again, to maintain administrative simplicity, we do not propose to introduce any new regulations providing for price modulation, flexible pricing or Patient Access Schemes under the statutory scheme. These pricing flexibilities continue to be available to companies that are, or choose to become, members of the 2014 PPRS.

Application to Northern Ireland

6.36. As referenced in chapter 1, 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. It may, therefore, be the case that the statutory scheme will only apply to England, Scotland and Wales for an undefined period, which could mean that for the operation of the scheme companies might be required to separate out data relating to Northern Ireland.

Consultation questions

32) Do you have any comments on, or suggestions further to, our proposals to keep administrative complexity to a minimum?

33) Would splitting out data for Northern Ireland present a significant burden to companies? Please give reasons

7. General

Appeals

- 7.1. The NHS Act 2006 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 Act. Also, the amendments to the NHS Act 2006 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 Act.
- 7.2. "Enforcement decision" is defined in section 265(7) of the NHS Act 2006 and means a decision of the Secretary of State or any other person to:
- Require a specific manufacturer or supplier, or other person who is a UK producer, to provide information to him.
 - Limit, in respect of any specific manufacturer or supplier, any price or profit.
 - Refuse to give his approval to a price increase made by a specific manufacturer or supplier.
 - 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.
- 7.3. Currently, enforcement decisions can be appealed within 28 days of the decision under the Health Service Medicines (Price Control Appeals) Regulations 2000¹⁸ ("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 1994¹⁹. 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.
- 7.4. 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.
- 7.5. 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.

Revocation of existing regulations

- 7.6. The draft regulations would consolidate, and amend, the existing 2007 and 2008 Regulations. If, following consultation, regulations are brought into force which make

¹⁸ www.legislation.gov.uk/uksi/2000/124/contents/made

¹⁹ www.legislation.gov.uk/ukpga/1994/40/contents

the provisions in the 2007 and 2008 Regulations unnecessary, the 2007 and 2008 Regulations will be revoked.

Annual review

7.7. The 2007 and 2008 Regulations set out that the Secretary of State must undertake a review of the regulations every 7 years, and that the conclusions from this review must be published in a report. Additionally, the report should set out the objectives of the statutory scheme established by 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.

7.8. We propose that these review requirements are retained, except that the review would be required annually.

7.9. See regulation 28 of the draft regulations.

Consultation questions

34) Do you agree with our proposals to update the Appeal Regulations? If not, why?

35) Do you agree that the regulations should be subject to an annual review?

8. Statutory requirements

Consultation requirements regarding exercise of powers in section 263 of the NHS Act 2006

- 8.1. The Health Service Medical Supplies (Costs) Act 2017 amended the NHS Act 2006 to include requirements that consultation about the exercise of powers in section 263(1) (statutory schemes) must include consultation about:
 - The economic consequences for the life sciences industry in the UK.
 - The consequences for the economy of the UK.
 - The consequences for patients to whom any health service medicines are to be supplied and for other health service patients.
- 8.2. These requirements are in addition to the existing requirements in the NHS Act 2006 for the Secretary of State to bear in mind the particular need for medicinal health service medicines to be available for the health service under reasonable terms, and the cost of research and development (NHS Act 2006, section 266(4) and (4A)).
- 8.3. An assessment of the likely impact of the proposals, including on the above areas, is set out in full in the impact assessment which accompanies this consultation. However, a summary of the assessment relating to those areas outlined in the NHS Act 2006 is detailed below.
- 8.4. This assessment shows that gross revenues of pharmaceutical companies are expected to reduce by an estimated £30 million, assuming a payment percentage of 5.09% (with a possible range of £9 to £51 million for payment percentages of 2.38% and 7.8%, respectively) between 1st April 2018 and 31st March 2019 as a result of the proposals outlined in this document. As it is estimated that 30% of pharmaceutical revenue is ordinarily taken as profit, this would lead to estimated lost profits of £9 million. As only 10% of drug spend is estimated to be spent on domestic production, and assuming that revenue is allocated in the same proportion, it implies a loss of profit to UK shareholders of £0.9 million. Taking account of the weighting of lost profits according to relative wealth, in line with HMT's Green Book, this results in a value of lost profit to UK shareholders of £0.6 million (with a range of £0.2 to £1 million).
- 8.5. The reduction in revenue may have a negative impact on the level of R&D investment made by statutory scheme companies, of which a portion may be in the UK. Based on the estimated proportion of revenues pharmaceutical companies devoted to R&D (estimated at 36%), and the expected level that would be invested in the UK (around 10%), and the estimate of the value of R&D investment to the UK (30%), it is estimated that the loss to the UK economy arising from the proposals would be around £0.3 million (with a range between £0.1 and £0.6 million).
- 8.6. It has been suggested that decreasing NHS spending on pharmaceuticals could make the UK a less attractive location for foreign investment in R&D. However, the available evidence suggests factors such as availability of expert scientific labour and favourable tax conditions are of greatest significance in decisions to locate R&D activity, and there is no obvious reason why company revenues from the NHS should affect the attractiveness of the UK as a location for R&D.

8.7. The proposals are expected to have benefits to the UK economy as a whole, and to health service patients, as well as to the availability to the NHS of health service medicines under reasonable terms. The proposals should reduce the cost of branded medicines to the NHS, thus providing additional resources to provide additional NHS treatments and services that will improve the health of NHS patients. The estimated value of the health benefits provided by these additional treatments and services is £120 million. Improving patient health is expected to have beneficial consequences for the UK economy through increased workforce productivity and reduced use of resources, such as formal and informal care, which are estimated to have a value of £28 million (with a range of £8 - 48 million).

Statutory duties under the NHS Act 2006 and the Public Sector Equality Duty

8.8. In considering the proposed changes, Ministers must comply with the Public Sector Equality Duty (PSED) and consider the Family Test. Ministers must also comply with their general duties under the NHS Act 2006, where applicable. Some further information about these duties is given below.

8.9. The need to comply with the PSED and the Family Test arises on each occasion that Ministers perform their public functions. The general duties in the NHS Act 2006 require the Secretary of State to have regard to certain things (such as the need to reduce health inequalities) or to act with a view to certain things (such as improving the quality of health services) whenever he is exercising functions “in relation to the health service” in England.

8.10. Our analysis of these duties with respect to the proposals set out in this consultation document is summarised below. Related information is also set out within the draft impact assessment, in particular around the impact on industry and research and development, and the general benefits arising from additional revenue available to the NHS as a result of these proposals.

Public Sector Equality Duty (Section 149 Equality Act 2010)

8.11. This duty comprises 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.

8.12. The protected characteristics covered by this duty are age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex and sexual orientation.

8.13. We considered the implications for each of the three equality objectives in relation to the proposals for the payment scheme, price controls and information provisions of the statutory scheme outlined above, including in relation to the companies who would have obligations under the statutory scheme, as well as patients who might be indirectly affected by the consequences of the operation of the scheme.

- Eliminate discrimination - we do not consider that the proposals negatively impact on this aspect, or that, given the nature of this area of work, there is any scope to generate a positive impact.
 - Advance equality of opportunity - the proposals should generate savings to the NHS which, when reinvested in the NHS, will contribute to better health support for the general public, including those with a protected characteristic, and in so doing should help achieve greater equality of opportunity.
 - Foster good relations - we do not consider that the proposals have any negative impact on good relations between those with a protected characteristic and those without, nor do we consider that there any direct opportunities to promote good relations given the nature of this work. However, we consider that there may be an indirect positive impact as a consequence of the generation of savings to the NHS from the proposed changes, which will increase the overall funding available to the NHS to spend on patient care, including for those with the protected characteristics.
- 8.14. As part of this assessment, we have considered the views and evidence put forward in responses to the 2015 consultation and during the passage of the Health Service Medical Supplies (Costs) Act 2017 through Parliament, of how the proposals might affect particular groups. For example, we have considered the concerns raised about the risk posed by the payment mechanism on the supply of certain blood plasma health service medicines, and the consequential risk this might pose for patients with conditions such as haemophilia.
- 8.15. We recognise the serious impact that the shortage of supply could have on such groups, and therefore we propose that the existing provision for the Secretary of State (either on his own motion or on application from a company) to agree a price increase of the maximum price be retained. We also propose to retain the provision for the Secretary of State to agree a temporary exemption from the maximum price where the circumstances require, including where in an emergency situation there is not enough time for the application process for price increases to be completed. We believe that these steps together with the maintenance of adequate supplies of essential medicines supported by the use of different procurement approaches for framework agreements (see further comments below) would mean that these groups of patients would not be disadvantaged by the proposed payment mechanism.
- 8.16. Overall, the Government's assessment is that the proposals would not have a detrimental impact on particular protected groups. By generating greater savings for the NHS, the proposals should have a positive impact by increasing the resources available to provide treatments and services to patients across the NHS, including those with protected characteristics.

To promote a comprehensive health service (section 1 NHS Act 2006)

- 8.17. 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.
 - The prevention, diagnosis and treatment of physical and mental illness.
- 8.18. Some industry members have raised concerns about the impact of a payment scheme on the continuing supply of certain types of health service medicines, in particular blood plasma health service medicines. Should supply be disrupted, this could mean that patients with specific conditions such as haemophilia could be denied access to treatment.

- 8.19. In the 2016 consultation response document, we set out the Government's view at the time that the facility to increase prices was the right way to address short or long-term supply problems, where these circumstances are dependent on UK pricing
- 8.20. We have given this further consideration, and have not seen any further analysis or evidence to suggest that price increases are an insufficient mechanism to address these potential concerns, particularly in light of other activity described below. We envisage, therefore, that if it became economically unviable to supply a medicine at the current price, companies could increase prices to the limit of the maximum price, or, if necessary, seek temporary or permanent increases in the maximum price for supply reasons. It was recognised that, if this action was required, the savings produced by the payment system for that health service medicine would be offset partially, or in full, by the increase in price. However, this would allow for the market to determine the most efficient level of price increase (and reduction in savings to the NHS) necessary to secure adequate supply.
- 8.21. Additionally, we believe that the maintenance of adequate supplies of essential medicines will be supported by the use of different procurement approaches for framework agreements adopted by the Commercial Medicines Unit at NHS England, such as incorporating incentivised aggregate discount schemes within frameworks (such as for recombinant clotting factors and a recent albumin framework), procuring on a UK wide basis, and indicating the specific health service medicines which are likely to be used by the NHS (such as for immunoglobulin) . These approaches offer a stronger basis for guaranteeing supply with a plurality of providers
- 8.22. In addition, by generating greater savings for the NHS, the proposals should have a positive impact by increasing the resources available to provide effective treatments and services to patients across the NHS.

To act with a view to securing continuous improvement in the quality of services (section 1A NHS Act 2006)

- 8.23. 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.
- 8.24. The expected benefit of the statutory scheme measures is increased savings which will have a positive indirect impact to secure continuous improvement in the quality of services by increasing the resources available to the NHS to provide treatment and other services to patients.
- 8.25. Additionally, by aligning the statutory scheme savings to those of the 2014 PPRS, and thereby supporting the stability of the schemes, the proposals should underpin the 2014 PPRS objectives around improving access to innovative medicines within the NHS.

To have regard to the NHS Constitution (Section 1B NHS Act 2006)

- 8.26. Regard must necessarily be had to the values, principles, pledges and rights in the NHS Constitution.
- 8.27. 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.
- 8.28. The changes to the statutory scheme do not have a negative impact on the rights provided by the NHS Constitution. The changes should have a positive impact by

decreasing the cost of the NHS drugs bill and thereby increasing the resources available to the NHS, which can be used to provide additional treatment and other services to patients to improve lives.

To have regard to the need to reduce health inequalities (section 1C NHS Act 2006)

- 8.29. When exercising his functions in relation to the NHS, the Secretary of State must have regard to reduce inequalities between the people of England with respect to the benefits that they can obtain from the NHS.
- 8.30. 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.
- 8.31. Concerns have been raised by some industry members about the potential impact of a payment scheme on the continuing supply of certain types of products, in particular blood plasma products. If supply were impacted, this could have an adverse impact on vulnerable groups, specifically patients with specific conditions such as haemophilia, who could be denied access to treatment. However, as noted at paragraphs 8.19 - 8.21, we believe that the facility for price increases, in conjunction with procurement approaches adopted by the Commercial Medicines Unit, are an effective mechanism for addressing supply issues which are dependent on UK pricing.
- 8.32. We do not consider, therefore, that the changes to the statutory scheme will adversely affect health inequalities. Additionally, by generating greater savings for the NHS, the proposals should have a positive impact by increasing the resources available to provide effective treatments and services to patients across the NHS.

To promote autonomy (section 1D NHS Act 2006)

- 8.33. The Secretary of State must have regard to securing, so far as is consistent with the interests of the NHS:
- That any other person exercising NHS functions or providing services for its purposes is free to exercise those functions or provide those services in the manner that it considers most appropriate.
 - That unnecessary burdens are not imposed on any such person.
- 8.34. The changes to the statutory scheme do not impact on the freedom of NHS bodies or providers to provide NHS services as they see fit.

To promote research (section 1E NHS Act 2006)

- 8.35. In exercising his functions in relation to the NHS, the Secretary of State must promote:
- Research on matters relevant to the NHS.
 - The use in the NHS of evidence obtained from research.
- 8.36. In addition, the Secretary of State is also required, under National Health Service Act 2006, s266 (4) (b), to bear in mind the costs of research and development.
- 8.37. As set out more fully in the draft impact assessment, the proposed measures are expected to reduce the revenues of pharmaceutical companies, compared to the “do nothing” option, which may result in decreased investment in R&D – of which a portion may be in the UK, providing “spill-over” losses to the UK economy.

- 8.38. The proportion of pharmaceutical company revenues devoted to R&D has been estimated at 36%. Of this, not more than 10% would be expected to be invested in the UK, according to the UK's proportion of the global pharmaceutical industry.
- 8.39. Investment in R&D is not, of itself, a net benefit (as it represents deployment of resources that would otherwise have found some other use). However, the Department considers that R&D investment leads to "spill-over" effects – for example through the generation of knowledge and human capital - which generate net societal benefits, compared to other uses. The Department for Business, Enterprise, Investment and Skills estimates the value of these additional benefits to be 30% of the value of the investment.
- 8.40. Applying the estimates above to the projected decrease in pharmaceutical revenues gives a loss of £0.3m to the UK economy from reduced R&D investment over the period under consideration. The corresponding values for low- and high-percentage scenarios are £0.1m and £0.6m respectively.

To secure education and training (section 1F NHS Act 2006)

- 8.41. The Secretary of State must exercise his NHS (and other) functions so as to ensure that there is an effective system for the planning and delivery of education and training for the persons employed, or considering becoming employed, in the NHS or connected activities.
- 8.42. We have considered this duty in relation to the measures and none of the measures impact on the Secretary of State's functions to secure education and training.

To review treatment of providers (section 1G of the NHS Act 2006)

- 8.43. 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.
- 8.44. We have considered this duty in relation to the changes being proposed, and these do not impact on the ability of providers to perform their functions.

The Family Test

- 8.45. The Secretary of State 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 parent, 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 on those families most at risk of deterioration of relationship quality and breakdown?
- 8.46. We have considered the Family Test and consider it not applicable to the proposed changes to the statutory scheme.

Consultation questions

- 36) Do you have any comments with respect to the effect of the proposals on the economic consequences for the life sciences industry in the United Kingdom, as set out above and in the draft impact assessment?**
- 37) Do you have any comments with respect to the effect of the proposals for the economy of the United Kingdom, as set above and in the draft impact assessment?**
- 38) Do you have any comments with respect to the consequences for patients to whom any health service medicines are to be supplied and for other health service patients, as set out above and in the draft impact assessment?**
- 39) Do you have any comments on the impact that the proposals may have on the three public sector equality duty objectives described above?**
- 40) Do you have any comments on the impact that the proposals may have on the other Secretary of State's duties under the NHS Act 2006 set out above?**
- 41) Do you agree with the analysis in the accompanying Impact Assessment on the impact of our proposals? If not, why?**
- 42) Do you have any evidence that would help inform, and improve the quality of, our analysis?**

9. Consolidated list of questions

- 1) Do you have any concerns with the proposed approach to determine the companies in scope or the relevant draft regulations? Please say why
- 2) Do you agree with the proposed process for determining the proportion of sales liable for payment where it is uncertain if the supply was ultimately for health service use? Please say why
- 3) Do you agree that we should introduce a payment system to align the statutory scheme more closely with the PPRS? Please give your reasons
- 4) Do you have any concerns with aligning the initial payment percentage level with the payment level in the PPRS for 2018? Please give your reasons
- 5) Do you have any comments on the definition of "relevant medicine"?
- 6) Do you agree with the proposed inclusion of new presentations in the payment system? Please give your reasons
- 7) Do you agree with our proposed inclusion of all branded health service medicines, except parallel imports and parallel distributed medicines, in the payment system? Please give your reasons and provide any additional evidence and analysis you may have
- 8) Do you agree that OTC health service medicines should be excluded from the price control provisions? Please give your reasons
- 9) Do you agree that only extant framework agreements should be excluded from the payment system? Please give your reasons
- 10) Do you agree that parallel imports, and parallel distributed medicines, should be excluded from the statutory scheme provisions? Please say why, and provide any evidence or analysis to support this
- 11) Do you agree that the small companies' exemption should be retained, at the current level, and extended to the payment system? And that the application of this exemption to new companies is reasonable? Please give your reasons
- 12) Do you think the time periods set out in schedules 1 and 3 are reasonable? Please give your reasons
- 13) Do you agree with the definitions? If not, why?
- 14) Do you have any concerns with the proposal to extend the recoverable sum and penalty provisions to the proposed payment system, or the application of the penalty rates as proposed? Please give your reasons
- 15) Do you think it is right that the existing price cut should be reversed, and that maximum prices be determined by the price as at 1st December 2013, or a price subsequently agreed by the Secretary of State? If not, why?
- 16) Do you agree with the proposal to establish maximum price lists? Please give your reasons
- 17) Do you agree that the proposed directions are an appropriate mechanism to determine the maximum prices in the circumstances identified? If not, why?
- 18) Do you agree that the proposed process, including the time periods for providing information and making decisions, is reasonable? If not, why not?

- 19) Do you have any comments with respect to the type of information that the Secretary of State is considering requesting as part of the information notice?
- 20) Do you agree that the temporary exemption provision should be amended so that a company is required to agree a revised, temporary maximum price? Please give your reasons
- 21) Do you agree that companies should not be able to seek an exemption from the payment mechanism, and that the option for a company to apply for a price increases will address any supply issues? If not, do you have any analysis and evidence to show why not?
- 22) Do you agree with the proposed process, factors to be considered and information likely to be requested for price increases? Please give reasons
- 23) Do you agree with our proposed process for handling price decreases? If so, do you think what we have proposed is reasonable? Please give reasons
- 24) Do you agree with our proposals to extend the penalty arrangements, and also to apply a single penalty where there is a breach of the notice period for the launch of new health service medicines? Please give your reasons
- 25) Do you agree with our proposals around scheme information, in particular to require a copy of a company's statutory audited accounts and the requirements for information to underpin the payment system? Please give your reasons
- 26) Do you agree with our proposals on the information requirements for new companies? Please give your reasons
- 27) Do you think the proposals on the information requirements for small companies is necessary and reasonable? Please give your reasons
- 28) Do you agree that the proposed definition for sales income, and the proposed requirements around the content of sales reports, audited information and the written declaration of approval are reasonable? If not, why?
- 29) Do you have any comments about the proposed handling of estimated sales, and the suggested timeframe for reviewing that information?
- 30) Do you agree with the proposal to allow repayments to companies, or requests for additional payments, if further information shows that there may have been under or over-payments? Please give your reasons
- 31) Do you agree with the proposed amendments to the penalty arrangements around determining which daily penalties should apply and the requirement that any demand for payment should set out a company's appeal rights? Please give your reasons
- 32) Do you have any comments on, or suggestions further to, our proposals to keep administrative complexity to a minimum?
- 33) Would splitting out data for Northern Ireland present a significant burden to companies? Please give reasons
- 34) Do you agree with our proposals to update the Appeal Regulations? If not, why?
- 35) Do you agree that the regulations should be subject to an annual review?
- 36) Do you have any comments with respect to the effect of the proposals on the economic consequences for the life sciences industry in the United Kingdom, as set out above and in the draft impact assessment?
- 37) Do you have any comments with respect to the effect of the proposals for the economy of the United Kingdom, as set above and in the draft impact assessment?

- 38) Do you have any comments with respect to the consequences for patients to whom any health service medicines are to be supplied and for other health service patients, as set out above and in the draft impact assessment?
- 39) Do you have any comments on the impact that the proposals may have on the three public sector equality duty objectives described above?
- 40) Do you have any comments on the impact that the proposals may have on the other Secretary of State's duties under the NHS Act 2006 set out above?
- 41) Do you agree with the analysis in the accompanying Impact Assessment on the impact of our proposals? If not, why?
- 42) Do you have any evidence that would help inform, and improve the quality of, our analysis?

10. Responding to the consultation

- 10.1. The preferred method for responding to this consultation is via the on-line consultation questionnaire, which can be accessed at:
<https://consultations.dh.gov.uk/pprs/statutory-pharmaceutical-pricing-scheme>
- 10.2. Alternatively, you may wish to email your responses to the questions to:
Statutory_scheme_consultation@dh.gsi.gov.uk
- 10.3. If you do not have internet or email, then please write to:
Statutory Pharmaceutical Pricing Scheme Consultation
c/o Stephen Lock
Ground Floor North
Wellington House
133-155 Waterloo Road
London SE1 8UG
- 10.4. The consultation closes on 17 October 2017.

Comments on the consultation process itself

- 10.5. 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:
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

- 10.6. We manage the information you provide in response to this consultation in accordance with the Department of Health's [Information Charter](#).
- 10.7. 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).
- 10.8. 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.

- 10.9. 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.