



Department
of Health &
Social Care

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

Consultation response

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Defined terms

For the purposes of this consultation response the following terms will be used as follows:

- **2007 Regulations** - Health Service Medicines (Information Relating to Sales of Branded Medicines etc) Regulations 2007
- **2008 Regulations** - Health Service Branded medicines (Control of Prices and Supply of Information)(No.2) Regulations 2008
- **2014 PPRS** - Pharmaceutical Price Regulation Scheme 2014
- **2018 Regulations** - Branded Health Service Medicines (Costs) Regulations 2018
- **Appeal Regulations** - Health Service Medicines (Price Control Appeal) Regulations 2000
- **Branded health service medicine** - branded medicine used to any extent for the purposes of the NHS.
- **Company** - a manufacturer or supplier of branded health service medicines
- **DHSC** - Department of Health and Social Care
- **Information Regulations** - Health Service Products (Provision of Information and Disclosure) Regulations 2018
- **Item of presentation** - an individual pack of a presentation
- **MA holder** - a marketing authorisation holder
- **Penalties and Appeals Regulations** - Health Service Medicines (Price Control Penalties) and Health Service Medicines (Price Control Appeals) (Amendment) Regulations 2018
- **Presentation** - a particular form of a branded health service medicine
- **Secretary of State** - Secretary of State for Health and Social Care
- **Small company** - company with sales or estimated sales of branded health service medicines of less than £5m
- **Voluntary scheme** - any Pharmaceutical Price Regulation Scheme

Executive summary

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

Last year the Government consulted on changes to the current statutory scheme which operates under the 2007 and the 2008 Regulations. This document analyses the 31 responses received to that consultation and sets out the Government's intentions.

In summary, the Government intends to revoke the 2007 and the 2008 Regulations and make new Regulations. The 2018 Regulations will establish a statutory scheme which will require certain specified companies to pay to the DHSC 7.8% of their net sales income received from the supply of specified presentations. The statutory scheme will also limit the maximum price that a company in the scheme may charge for the supply of presentations. A record of those maximum prices will be included in a list published by the DHSC. The operation of the statutory scheme will be supported by the requirement for companies to record and keep information and to provide that information in accordance with the 2018 Regulations.

Chapter 2 sets out the Government's consideration of the responses received on its proposals for a payment mechanism. Following consideration of the responses made to the consultation, the Government intends to change its approach with respect to its proposals for a payment mechanism in the following key areas:

- classification of companies in scope of the payment mechanism
- supply of presentations exempted from the calculation of the payment
- scope of the Secretary of State's power to make a direction to require a payment
- enforcement procedures, including appeal rights.

Chapter 3 sets out the Government's consideration of the responses received on limiting prices which may be charged by a company. Following consideration of the responses made to the consultation, the Government intends to change its approach with respect to its proposal for limiting prices in the following key areas:

- determination of maximum prices of presentations that were on sale for health service use on 1st December 2013
- use of maximum price lists
- treatment of application for a price increase in line extensions
- timetable for a decision on price decreases
- enforcement procedures, including appeal rights.

Chapter 4 sets out the Government's consideration of the responses received on the provision of information and other outstanding issues. Following consideration of the responses made to the consultation, the Government intends to change its approach with respect to its proposal in the following key areas:

- period for which information must be kept
- determination of a small company, and the type of information and period within which information must be provided by a small company
- information to be provided under a sales report
- circumstances when a company may be required to correct information provided to the Secretary of State

- enforcement procedures, including appeal rights

The Government recognises that companies may need to adjust their processes to comply with these new information requirements. During the initial implementation phase of the 2018 Regulations, the DHSC will be open to engagement with companies to discuss flexibilities with regards to the deadlines for these requirements, where the company considers it will not be able to meet the deadlines.

Chapter 5 sets out the Government's consideration of the responses received on the appeals system and review requirements. Following consideration of the responses made to the consultation, the Government intends to proceed with its proposals as set out in the consultation. The Government notes that some companies are concerned that annual reviews will lead to continuous changes to the 2018 Regulations. However the fact that changes to the regulations do not automatically follow from an annual review of the regulations is emphasised. The Government notes the probable need for changes to the 2018 Regulations should an agreement be reached on a successor to the 2014 PPRS, in order to provide some level of alignment between the voluntary and statutory schemes.

In chapter 6, views expressed on our assessment of the impact of our proposals and implications for statutory duties of the Secretary of State for Health are considered. The Government has made some changes to the impact assessment as a result of the responses received and these are detailed in this chapter. Consideration of the relevant statutory duties in relation to the final decisions made about the statutory scheme is presented at Annex A, and the final impact assessment has been published separately.

Some further minor and technical amendments have been made to the 2018 Regulations to ensure clarity and that they deliver the stated policy intention. The new arrangements will come into force on [1 April]. Operational guidance will be published to support companies in planning for the new scheme coming into force.

1. Introduction

- 1.1. 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 2014 PPRS has sought to give pharmaceutical companies the certainty and backing they need to flourish both here and in the global market and to keep the branded medicines bill within affordable limits.
- 1.2. 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.
- 1.3. On 23 August 2017, the Government published a consultation on proposed changes to the statutory scheme to control the cost of branded health service medicines. (see www.gov.uk/government/consultations/statutory-scheme-to-control-cost-of-branded-medicines-consultation). The purpose of the proposals was to address certain challenges in the operation of the existing statutory scheme. In particular:
 - The statutory scheme produces lower savings relative to health service sales covered by the scheme than the 2014 PPRS
 - The need to re-align the statutory scheme savings with those from the 2014 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 that they offer, and because each scheme uses a different cost control mechanism.
 - The 2007 and 2008 Regulations leave the DHSC with challenges relating to price controls, such as enforcement and transparency over maximum price levels.
- 1.4. The principal element of the proposals was the introduction of a payment system to replace the system of price cuts, but to retain maximum price controls. The other proposed amendments were, in large part, consequential to this, and generally small in scale.
- 1.5. The main elements of the proposed changes were:
 - Introducing a payment system similar, but not identical, to that introduced in the 2014 PPRS, elements of which include:
 - Defining the companies which will be in scope of the payment system
 - Setting the payment percentage which will apply to companies
 - 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, including:
 - Removing the existing 15% price cut.
 - Establishing maximum price lists to provide transparent and publicly available information.

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- 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, 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 the DHSC proposes to limit the administrative burden on companies from the introduction of the payment system.
 - Making general changes, 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.
 - The Government's intention to update the Appeals Regulations 2000
- 1.6. The consultation on these proposals closed on 17 October 2017. Overall, the DHSC received 31 responses to the consultation, of which 5 were from health service bodies, and 26 from industry, including industry representative bodies. The rest of this document summarises the key issues raised in the responses to this consultation, and sets out the Government's response to those issues. It also includes an analysis of the impact of the final statutory scheme changes on the various statutory duties, such as the public sector equality duty, and the Family Test further to responses received to the consultation.
- 1.7. A related consultation was also published on 23 August 2017 in relation to Regulations to implement the new information requirements in the NHS Act 2006, as amended by the Health Service Medical Supplies (Costs) Act 2017. A response to that consultation will be published shortly.

2. Responses on the payment system

- 2.1. After review of the consultation responses the Government has decided to proceed with establishing a payment system whereby certain specified companies to whom the statutory scheme applies pay a percentage, initially set at 7.8%, of eligible NHS sales to the DHSC. These payments will be apportioned between all four UK countries. For England, the DHSC will pass payments received to the NHS.
- 2.2. The 2018 Regulations set out the criteria for determining companies and sales in scope. Small companies will be exempt from the payment mechanism. They also make exemptions from calculation of net sales income for the following:
 - Any item of presentation supplied under a contract based on a framework agreement where that framework agreement was entered into before the coming into force date of the 2018 Regulations, for the duration of that contract
 - Any item of presentation supplied under a public contract entered into before the coming into force date of the 2018 Regulations, for the duration of that contract
 - Any item of presentation with a maximum price of £2 or less
 - Any item of parallel distributed or voluntary scheme presentations
- 2.3. The Regulations include provisions for a company that fails to make the required payment to be liable to interest on that payment and a daily penalty which the Secretary of State can demand by issuing a written notice to the company in question.
- 2.4. A summary of the issues raised on the payment system (and linked questions on other aspects of the proposals), and the Government response to those issues is set out below.

Q1. Do you have any concerns with the proposed approach to determine the companies in scope or the relevant draft regulations? Please say why

- 2.5. We proposed that the companies which will be liable to make a payment under these new arrangements would be the first company in the UK (including those that hold a manufacturer's licence or a wholesale dealer's licence), to supply an item of presentation in to the NHS supply chain in the UK. This approach was intended to broadly align to the approach in the 2014 PPRS, where companies that hold the marketing authorisation for a presentation are generally held to be responsible for making a payment.
- 2.6. We also proposed that, where the Secretary of State reasonably considered that operating arrangements made by a company assist that company, or another, to undermine the purposes of the statutory scheme, the Secretary of State be able to specify the company that should be responsible for making a payment through issuing a direction.
- 2.7. Out of the 31 responses, 16 said they had concerns about the approach. It was noted that in particular:
 - There was a risk of double charging on sales of the same presentation. It was maintained that a PPRS company based outside of the UK might be making payments in relation to the supply of its medicines as a result of being a member of the PPRS, but that if the first sale within the UK was by a non-PPRS company then a payment would also be required under the statutory scheme.
 - There was a risk that targeting the first manufacturer or supplier in the UK would not always capture sales made by a MA holder in the UK, which could result in a substantial underpayment of the payment percentage with respect to that

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presentation (for example, where the first supply of a presentation in the supply chain was between a manufacturer to the MA holder).

- 2.8. In addition, it was noted that there was a need to have a robust mechanism in place to direct specific companies to make a payment if it was apparent that, despite any changes made to Regulations concerning companies in scope, company arrangements were such that no payment, or a limited payment, was made on a sale of a presentation. Concerns were also raised that the direction making power was too broad.

Government response

- 2.9. Our intention is that the MA holder of an item of presentation should generally be responsible for paying the percentage payment on the net sales of eligible presentations, as is the case with the 2014 PPRS.
- 2.10. However, the difficulty of providing for such an approach in the statutory scheme is that the MA holder may be based outside of the UK, or if they are based within the UK, may not be the company that supplies the item of presentation.
- 2.11. The 2018 Regulations will therefore require the payment percentage to be paid on the first occasion that the item of presentation is supplied by a company in the UK to another person in the UK. There will be a requirement to pay 7.8% of the net sales income received in respect of the relevant presentations to the DHSC.
- 2.12. However we acknowledge the challenges raised in the consultation and accept that changes should be made to address these points.
- 2.13. In particular, to address the concerns raised that the first supply may occasionally be made by a company, such as a manufacturer, to the MA holder. As a result the 2018 Regulations provide that where on the first occasion an item of presentation is supplied to the MA holder of that branded health service medicine or a company in the same group as the MA holder, the requirement to make the payment falls on the company responsible for the next occasion in the supply chain that the item of presentation is supplied. The Regulations also make clear that for these purposes the supply of an item of presentation between two companies in the same group does not count as a form of supply. This is so that a company that is responsible for the first or next occasion on which the item of presentation is sold cannot avoid making the required level of payment by selling that pack to a company in their group at a low price.
- 2.14. In response to consultation feedback saying that the direction making power was too broad, the circumstances when the Secretary of State can give a company a direction to make a payment will be specified in the Regulations. Specifically, the direction making power will apply where the Secretary of State considers that a company has entered into arrangements whose main purpose or one of whose main purposes is to reduce or avoid a payment in respect of sales of items of presentations that either that or another company would be liable to under regulation 3.
- 2.15. The 2018 Regulations will also require the Secretary of State to specify in any such direction the reason why the Secretary of State considers the company should pay the amount, the payment that the company must make, the period within which the payment must be paid and the company's appeal rights (Regulation 4).

Q.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?

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

- 2.16. In the original proposals we recognised that there may be circumstances when a company may not know whether the sales of certain branded medicines were for health service use. We proposed, therefore, that where this applies a company provides estimated information in their sales report. In the majority of cases companies should be able to provide a split of this information from their own records (e.g. using secondary care contract information or direct to pharmacy systems. Where end-sale information is not available, companies should provide a justification for the estimate, and the method used to arrive at it.
- 2.17. Once estimated information has been provided, we proposed that the DHSC should have the opportunity to validate the 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 study
- 2.18. We suggested that any validation should be completed within 12 months of the receipt by the DHSC of the end of year presentation level report covering the sales report in question.
- 2.19. For Q.2, 17 responses agreed with the approach, with 3 disagreeing. Whilst for Q.29, 9 had comments with the approach, whilst 22 did not, or did not answer the question. Whilst responses were generally content with the proposed approach, some concerns were raised. This included a concern about the lack of accuracy, including the fact that this would need to be taken into account in considering any application of penalties. The proposal that any review of estimates by DHSC should take 12 months was also challenged, as this was considered too long and could have potential implications for companies' processes if a review raised queries.

Government response

- 2.20. Responses generally endorsed the approach proposed. Addressing the areas of concern, we are clear that for a minority of companies there will be a need to utilise estimates as companies may not always be able to track presentations from manufacture to point of sale. On the 12-month time period for review of estimates, we think it is right that a sufficient time period is allowed given the potential for complex cases. However, in the main, we would not expect reviews to take this long. Moreover, we wish to make it clear that penalties would only be considered where these review mechanisms, involving engagement with the company concerned, do not provide a successful resolution.

Q.3 Do you agree that we should introduce a payment system to align the statutory scheme more closely with the PPRS? Please give your reason

Q.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

- 2.21. The consultation stated that 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 proposed that the payment percentage for the statutory scheme should be the same as the 2018 payment percentage for the 2014 PPRS.

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- 2.22. Although some responses agreed with the proposals, the majority did not. Out of the 31 responses, 17 disagreed with the introduction of a payment system, whilst 18 had concerns about aligning the payment percentage to the 2014 PPRS. However, the reasons were varied, and not all were aligned. Some responses argued that the statutory scheme and 2014 PPRS should be distinct, with no need for alignment, as they provide for different types of company and have historically been different, and that aligning as proposed would penalise small companies. There was also disagreement about introducing such changes now, and that this should not be done ahead of any negotiation around a successor to the 2014 PPRS.
- 2.23. Alternatively, it was suggested that the statutory scheme should be made less favourable than the 2014 PPRS, with a higher percentage, and that using the PPRS payment percentage would allow statutory scheme companies to benefit from the artificially limited 2018 PPRS payment percentage, which PPRS companies had paid for via an artificially inflated figure in 2017. There was also a suggestion that a higher percentage should be applied, as statutory scheme companies had benefited from making a relatively lower contribution to savings over the last several years, compared to the 2014 PPRS companies. There were also concerns about how the payment system and percentage would operate in future years, and the negative impact this would have on predictability.

Government response

- 2.24. The 2016 Government response to the 2015 statutory scheme consultation (www.gov.uk/government/consultations/pricing-of-branded-health-service-medicines), noted the lack of suggested alternatives to the introduction of a payment system, and it remains the only viable option given the need to achieve savings and support stability of both schemes. We do recognise the concerns made by respondents with respect to the timing of these changes, and the uncertainty in the short term with regard to future changes to the wider medicines pricing system. However, it has always been our intention to align the two schemes (as noted in paragraph 3.12 of the 2014 PPRS), but we listened to concerns raised in response to our original proposals, and introduced primary legislation in order to clarify the Secretary of State's powers.
- 2.25. With respect to historical differences between the statutory scheme and the PPRS, it is only partially true. There have been greater periods of alignment, when both schemes operated on a list price cut basis, and most recently during the 2009 PPRS when both schemes had the same payment percentage with parallel annual adjustments, and the statutory scheme has not been designed for specific types of company.
- 2.26. We do not agree with the suggestions that the statutory scheme payment percentage should be higher than that in the 2014 PPRS, either to incentivise membership of the 2014 PPRS or so that statutory scheme companies make up for having made relatively lower contributions to savings than 2014 PPRS companies. It may be that as a result of the changes we are taking forward some companies decide to switch to the 2014 PPRS, but that is not our objective. Nor we do think that retrospective payments would be fair, or that they are likely to work, given that companies could just switch schemes to avoid a higher percentage.
- 2.27. Taking the above into account, and the consistency of approach with our 2015 consultation proposals, we do not consider that any changes should be made to our proposals.

Q.5 Do you have any comments on the definition of 'relevant medicine'?

Q.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

- 2.28. The draft regulations defined 'relevant medicines' which would come within the scope of the statutory scheme. This built on the term 'health service medicine' which is defined in the NHS Act 2006 as a medicinal product used to any extent for the purposes of the health service. It was proposed that the payment and price control mechanisms 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
 - For which a marketing authorisation has been granted
 - That do not have a parallel distribution notice
 - That are prescription only medicines
 - Which are not blacklisted (i.e. medicinal products that cannot be prescribed by GPs on the NHS)
- 2.29. In relation to the definition of relevant medicine, 20 responses had comments, whilst 6 responses were content. Several issues were raised with the definition, namely:
- That there was a need for clarity on the treatment of unlicensed medicines and 'specials' (i.e. an unlicensed, named-patient medicine) and companies providing aseptic preparation services to the NHS (i.e. sterile, compounding services), as if not excluded it could lead to double-charging.
 - That the inclusion of 'identification without reference to a common name' could create gaps in coverage, as it was possible that a presentation could be identified via a numerical code.
 - That the reference to 'parallel distribution notices' could mean that significant numbers of presentations are exempted, not just those which are parallel distributed into the UK.
 - That branded generics, including those where the MHRA require a brand name, and those branded medicines which are subject to competition, should not be captured by the scheme.
- 2.30. On the specific question on the inclusion of all branded health service medicines, bar parallel imports and parallel distributed medicines, 16 responses disagreed, whilst 6 agreed. However, the treatment of different types of branded presentations, specifically those subject to competition and those where the MHRA require a brand name, and the treatment of parallel imports, were raised in response to a number of questions.
- 2.31. Only 9 responses took issue specifically with the application of the payment system to branded generics, whilst one other made some allusion to this. However, 15 responses highlighted the need to exempt sales where there was some form of competition, in particular through framework agreements. The principal concerns and comments made included:
- Where there is evidence that a competitive market operates for branded generics, there should be an exemption
 - Where the MHRA require medicines to have a brand name, these medicines are interchangeable and often are interchanged, with competition resulting in reduced prices. Therefore, unless the framework exemption is applied to all contracts, the payment will be challenging to sustainability of supply (see also the section on framework agreements at paragraphs 2.50-2.53)

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- Contrary to the position in the consultation document, branded generics are giving comparable savings to small molecule, unbranded generics, taking into account higher costs e.g. around pharmacovigilance and research and development.
 - Prices will have to be reduced significantly, perhaps by up to 80-90%, to compete with generics in tenders, and then be forced to make a payment which generic suppliers would not need to do.
 - There are already signs of instability in the biosimilar market due to pressures on prices.
- 2.32. Issues raised in relation to parallel imports and parallel distribution are set out in paragraphs 2.54-2.62.

Government response

- 2.33. In relation to unlicensed medicines, specials and aseptic preparation services, we agree that these should not be captured through the statutory scheme. However, these were already excluded through the draft consultation Regulations as relevant medicines must also have a MA, and such presentations do not. Similarly, whilst a presentation may also be identifiable by a numerical code, this does not invalidate the approach in the draft consultation Regulations, as it is the ability to identify the presentation through a brand name (not a numerical code) without reference to a common name that is key.
- 2.34. We agree with the concerns raised about parallel distribution notices. The 2018 Regulations will reflect these concerns to ensure that they exclude parallel distribution notices only where these notices are for distribution into the UK.
- 2.35. Regarding branded generics, there was no new evidence to alter the position as stated in the consultation. We continue to be of the view that 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 licensing requirements, but we have not identified evidence to support this, either previously or through the consultation responses. Excluding such medicines from the statutory scheme could therefore encourage companies to leave the 2014 PPRS to the detriment of scheme stability and overall savings to the NHS.
- 2.36. For out of patent branded medicines, we assume the market will continue to determine the most efficient price level to secure adequate supply. A company may choose to apply a brand name to a presentation where there is no requirement to do so, and where that presentation has identical generic competitors. In these circumstances the company has made a commercial decision to market the presentation as a brand, and expects to generate greater revenue as a consequence. We do not, therefore, propose to exclude such presentations by including a provision in the statutory scheme equivalent to the 'brand equalisation' provision in the 2014 PPRS. 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 reflects the fact that the statutory scheme acts as a back-up to the voluntary 2014 PPRS. Mirroring the 2014 PPRS 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.
- 2.37. Whilst further information was provided by some respondents on the additional investment required for the development and production of biosimilars, as compared to

small molecule, chemical generics, and the price pressures that already exist for this class of presentations, we do not consider that this justifies an exemption. Whilst we accept that research and development costs will be higher than for unbranded generics, they will still be less than the originator, whilst post-marketing costs should be similar between the originator and the biosimilar. Moreover, market conditions for biosimilars are not homogenous. Competition for a given biosimilar is likely to increase alongside the length of time it is on the market, but will also be affected by the variation in similarity of composition between biosimilars and originators. In addition, unless a biosimilar is a new active substance (NAS), which would be exempt from the payment under the 2014 PPRS, then biosimilars would not be at a commercial disadvantage under the statutory scheme, except to the extent that price modulation may be used by a 2014 PPRS company to lower their presentation prices. However, if this were to prove a significant issue for a company, then they could consider whether switching to the 2014 PPRS may be more commercially advantageous for them.

Q.6 Do you agree with the proposed inclusion of new presentations in the payment system? Please give your reasons

- 2.38. We proposed 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.
- 2.39. Out of the 31 responses, 16 agreed with the proposal, whilst 10 disagreed. Where respondents disagreed with the approach they raised various concerns, the principal ones being:
- That it creates a disparity with the 2014 PPRS, where the stated intention is to align the two schemes
 - It is a tax on innovation, providing a clear dis-benefit for being in the statutory scheme. It also provides a disincentive to launch new presentations in the UK, penalising transformational companies, and is not supportive of the life sciences industry
 - It reduces the incentive for these presentations to be part of the NHS tendering process
 - It is not right to classify as new presentations those that have just been repackaged.

Government response

- 2.40. We recognise that the proposed approach does represent a disparity with the 2014 PPRS. However, it has never been our stated intention that schemes be completely aligned, and we think it would be unreasonable, as recognised in a number of responses, to expect the relatively small number of companies in the statutory scheme to cover the payments for these new presentations.
- 2.41. We have re-considered the options, in particular whether to (a) exclude new presentations and still apply the proposed payment percentage level (i.e. equivalent to the 2014 PPRS payment percentage for 2018), or (b) adopt a similar approach to the 2014 PPRS to exclude new presentations and gross up the payment percentage on old presentations.
- 2.42. However, our view is that approach (a) fails to deliver equivalent savings in the statutory scheme as compared to the 2014 PPRS, given the role new presentations play in 2014

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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 2018 regulations to pay a higher percentage on their older presentations to compensate for the exclusion of new presentations. (At the time of writing, 17 companies in the statutory scheme are above the smaller companies threshold, compared to 76 in the PPRS). 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.

- 2.43. Companies are, of course, able to join the 2014 PPRS if they consider that it would be in their best interests to do so given their product portfolio.
- 2.44. Regarding the potential adverse impact on the life sciences industry, we have addressed this in detail in the impact assessment. We do not consider that the application of a payment will have a significant impact on investment decisions for the life sciences industry, as the evidence suggests that supply-side factors are the most important. Moreover, no evidence was provided to support the claim that new presentations would not be launched in the UK. We consider that companies would still bring new presentations to the UK market, as it would be in their commercial interests to do so, as to do otherwise would be to miss out on potential profits.
- 2.45. In relation to the NHS tendering process, where new presentations are NASs and potentially transformative, we consider it unlikely that a company would offer any significant price concessions as part of any tendering arrangements.
- 2.46. We do not consider, therefore, that the proposed approach for handling new presentations should be changed.
- 2.47. However, with respect to classifying medicines that have simply been repackaged as new presentations, we accept that it is not necessary to categorise them as new presentations, and could present problems in terms of payments being required twice for what is, essentially, the same presentation. We have, therefore revised the definition of presentation to remove the reference to type of packaging.

Q.8 Do you agree that OTC presentations should be excluded from the payment mechanism? Please give your reasons

- 2.48. There was significant support for the proposed exclusion of over the counter (OTC) presentations, with 20 responses agreeing with the approach and only 2 disagreeing. Where the OTC exclusion was challenged, this was on the basis that this could be abused, and that there should be alignment with the 2014 PPRS approach, whereby pharmacy only and general sale list (P&GS) sales are included where sales reach a certain value.

Government response

- 2.49. We do not intend to make any changes to our proposed approach. We recognise the general support from the responses, and remain of the view that a partial inclusion of these presentations, in line with the 2014 PPRS, would be inconsistent with our aim to keep administrative complexity of the scheme to a minimum.

Q.9 Do you agree that only extant frameworks should be excluded from the payment system? Please give your reasons

- 2.50. As originally set out in the 2015 consultation, we proposed that the payment would not apply to sales of presentations which are procured under one or more extant framework agreements under the Public Contracts Regulations 2006

(www.legislation.gov.uk/uksi/2006/5/contents/made), the Public Contracts (Scotland) Regulations 2012 (<http://www.legislation.gov.uk/ssi/2012/88/contents/made>), the Public Contracts Regulations 2015 (www.legislation.gov.uk/uksi/2015/102/contents/made) or the Public Contracts (Scotland) Regulations 2015 (www.legislation.gov.uk/ssi/2015/446/contents/made). 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 2018 Regulations. However, as confirmed in our 2016 consultation response, we did not propose to extend the exemption to future framework agreements that were not extant when the 2018 Regulations would be brought into force. This is because companies would be able to take into account any payment required under the scheme as part of their tenders.

- 2.51. Of the 31 responses, 10 agreed with the proposal, whilst 15 disagreed. However, in disagreeing, only 1 response argued that there should be no exemption for framework agreements at all, on the basis that this would exempt a substantial proportion of sales from the payment system, leading to lower savings for the NHS. Conversely, of those who commented on the proposal, 16 argued that the proposal did not go far enough. The principal issues raised were:
- That all frameworks, or all sales made through a competitively tendered process should be exempt from the payment system, as they are already delivering competitive, discounted prices
 - There will need to be protection for framework agreements for future changes to the payment percentage i.e. when a framework agreement is not exempt, and therefore a company is required to make a payment, any future increase in the percentage should not apply
 - The lack of predictability over future changes to the payment percentage, so that companies cannot take this into account when preparing replies to multi-year tenders.

Government response

- 2.52. We acknowledge the points made about the level of competition that many framework agreements and public contracts provide, and the impact this has in driving down the prices paid by the NHS. However, it is also the case that for some presentations framework agreements and public contracts are agreed which do not provide any significant reductions in price, such as where there are no competing suppliers for that presentation. We maintain that our approach would not disadvantage any company in a tender process, as companies would be able to take into account as part of their tenders any payment required by the payment systems. The market would then determine the most efficient price level to secure supply through a tender process. However, we will keep this under review: in particular as part of future work to assess any further changes to the statutory scheme to reflect the outcome of the discussions over any successor arrangements to the 2014 PPRS. In the meantime, the exemption for presentations supplied under extant framework agreements made under the Public Contract Regulations mentioned in paragraph 2.44 will also apply to extant public contracts made under those same Public Contract Regulations in the 2018 Regulations. Definitions of framework agreements, public contracts and contracting authority have been added to Regulation 1 of the 2018 Regulations.
- 2.53. In relation to future changes to the payment percentage, we recognise the concerns raised, and that it is important for companies that there is a reasonable level of predictability to the operating environment, However, given the discussions around potential successor arrangements to the 2014 PPRS, and the fact that the setting of the

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payment percentage is so potentially dependent on future PPRS arrangements, we do not think it is right to confirm an approach at this time. However, we will, of course, fully consider the responses to this consultation when developing proposals for how the payment system will function in the longer term. Any proposed changes to the 2018 Regulations will be subject to the usual consultation processes at the appropriate time.

Q.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

- 2.54. We proposed excluding parallel imports 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 relationships that a wholesaler of the kind captured by companies in scope of the payment mechanism in the 2018 Regulations would have, meaning they would not be in a position to negotiate a decreased price from the MA holder to offset the payment percentage. We also think it is likely that parallel imports would have already been subject to regulatory measures to control prices in the country of origin.
- 2.55. We also proposed that parallel distributed branded health service medicines should be excluded, as the operational arrangements for parallel distributors would be similar to parallel importers.
- 2.56. Of the 31 responses, 6 indicated they agreed with the proposals, although 1 of these contained a number of caveats, whilst 18 did not. Health service respondents, and the parallel importers representative body, were generally supportive. One response, as well as endorsing the arguments made in the consultation document, also provided some evidence of the typical level of profit margins in the parallel import sector, and the likelihood that a payment percentage as proposed in the consultation would make it uneconomic for importers to continue to supply medicines for use in the NHS. It also flagged the important role of parallel imports as the only source of price competition for many in-patent branded medicines.
- 2.57. However, most of the industry responses were against the proposal. The principal concerns and issues raised were:
- The exclusion would give importers an unfair advantage and distort the market
 - Importers exploit differences in exchange rates and whether they can negotiate prices with suppliers is irrelevant
 - Profits are determined by the list price in the drug tariff and not low prices overseas
 - It is inconsistent to present as an argument for exclusion the likelihood of parallel imports being subject to two sets of price regulations, when the fact that branded generics and biosimilars are already subject to competition is not deemed a justifiable reason for exclusion
 - The exclusion is inconsistent with the Government's stated desire to encourage UK investment by industry.

Government response

- 2.58. We recognise that there are some valid arguments both for, and against maintaining an exclusion for parallel imports. However, on balance we consider that, at present, and for the reasons set out below, the exclusion should be implemented, as proposed.
- 2.59. Parallel imports are an important source of supply chain diversity for the NHS, and any changes which might lead to the withdrawal of this form of supply is likely to reduce the

supply chain resilience of the NHS, and might lead to patients being unable to access medicines. In particular:

- With respect to exchange rates, whilst we would expect companies to absorb any changes to rates, we would contend that parallel importers have fewer mechanisms for mitigating the risk of changes to such economic factors compared to an MA holder. In particular, they cannot agree a temporary price increase, nor are they likely to be able to negotiate a better price with the supplier. This could, therefore, limit the ability to supply.
- As regards the drug tariff and reimbursement prices dictating the viability of parallel import sales, we do accept that there is some value in this argument. However, we would maintain that regulatory measures in the country of origin could potentially have some impact on the purchase price, thereby constraining margins for parallel imported presentations. Therefore, a payment percentage might then make supply unviable.

2.60. Moreover, we recognise that it is possible that in some cases the application of a payment percentage might set a limit to the level of reduction in net UK prices which a company can deliver; however, this might be at a level which, except for the exemption, would not be at a level amenable to parallel imports. This could be disadvantageous to industry. However, parallel imports are the only source of competition for many branded presentations which are still under patent, and therefore are important as a means of maintaining some limits on prices, and therefore costs to the NHS.

2.61. With respect to the alleged inconsistency with the treatment of branded generics, we do recognise the parallels between some of the arguments outlined for the exclusion of parallel imports and the arguments made by industry for the exclusion of branded generics. However, we consider that these are not identical, as there is no flexibility in negotiation and pricing for parallel imports, unlike for other companies, as we set out in the consultation document.

2.62. In relation to the argument that the exclusion is inconsistent with encouraging investment by the industry, we would contend that this is not the case. As set out in the consultation document and the accompanying impact assessment, the available independent evidence is that companies will target research and development and manufacturing investment where it is most efficient for them to be, based on supply factors. We have noted industry responses to the consultation which challenged this general assessment, stressing the impact of wider considerations on investment decisions, such as the uncertainty caused by Brexit. However, we do not consider that the treatment of parallel imports would have material significance in these investment decisions.

Q.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

2.63. We proposed retaining an exemption for small companies in line with that in the current statutory scheme - an exemption for companies which, during the most recent complete financial year supplied branded medicines for health service use in the UK, from which it derived sales income of less than £5 million. This would be in line with the equivalent exemption in the 2014 PPRS. Although the £5 million level is not aligned to an EU Commission definition, we believe this is reasonably equivalent to, or in some cases more generous than, the EU Commission approach. This is because the statutory scheme definition only takes account of UK branded health service sales, not total sales.

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

- 2.64. Of the 31 responses, 14 agreed with the proposal, with some recognising that it was right that it should be aligned to the exemption in the 2014 PPRS. A further 10 responses agreed with the exemption in principle, but argued that it should be more generous. Just 1 response said that no exemption should be provided.
- 2.65. Where it was argued that changes should be more generous, the principal reasons given were that:
- Generally, the level of the exemption was too low. It was noted that the 2009 PPRS had been more generous, i.e. where a companies' sales were up to £25m, the first £5m was exempt, and that not including this provision in the 2014 PPRS took away a valuable mechanism to support small companies in their formative years
 - It was erroneous to assume that small companies which breached the £5m threshold would be able to absorb the full impact of the payment percentage in a one-year period.
- 2.66. The reason given for not providing any exemption was that it would provide small companies with a competitive advantage where they were competing on frameworks.

Government response

- 2.67. Given the level of support for the proposal, we will proceed with the inclusion of the small company exemption. However, we do not intend to change the level at which the exemption is set. To increase the exemption level would create a level of disparity with the 2014 PPRS, providing an incentive for some companies to switch to the statutory scheme, conflicting with our aim of maintaining scheme stability, whilst also leading to a consequent reduction in savings to the NHS.
- 2.68. In finalising the regulatory provisions relating to small companies, a number of technical amendments have been made to schedule 2 (small manufacturers and suppliers), in particular:
- Clarifying the definition of a company and the information requirements that apply to it:
 - During the first financial year that the payment mechanism under the 2018 Regulations apply to a company, the Secretary of State will determine whether that company is a small company (and therefore exempt from the payment mechanism) based on whether that company is likely to receive net sales income for branded health service medicines of less than £5million during the first financial year that the 2018 Regulations apply to that company. To support the Secretary of State's determination, a company that thinks it should be exempt from the payment mechanism because it is likely to have sales of less than £5million of net sales income in the first financial year that the 2018 Regulations apply to it, that company must provide estimated net sales income information for that financial year to the Secretary of State within 30 days of the 2018 Regulations applying. It must also provide net sales income information to the Secretary of State at the end of that financial year so that the Secretary of State can verify the estimated information.
 - After the first complete financial year that the 2018 Regulations apply to that company, the Secretary of State will determine whether that company is a

small company based on whether it has received net sales income for branded health service medicines of less than £5million in its previous financial year. To support the Secretary of State's determination of whether a company is a small company in such circumstances, the company must provide net sales income information for its previous financial year.

- Clarifying requirements when the 2018 Regulations begin to apply to a company part way through their financial year
- Removal of Secretary of State discretion in Schedule 1-3 of the 2018 Regulations where the Accounting Reference Period has changed, and instead reliance on the requirement for companies to provide information in relation to any remaining period as per the relevant Schedule.

Q.12 Do you think the time periods set out in schedules 1 and 3 are reasonable? Please give your reasons

Q.14 Do you agree with the definitions? If not, why?

- 2.69. 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.
- 2.70. We proposed timeframes for making payments in schedule 1 and 3 of the draft regulations, which are consistent with the requirements in the 2014 PPRS. These also drew on definitions in regulation 1 of the draft regulations, specifically for: 'financial year', 'accounting reference period', 'quarter', and 'remaining period'.
- 2.71. The majority of the respondents agreed with our approach. In relation to the time periods, 17 responses considered these reasonable, whilst 7 had concerns or disagreed, whilst 18 agreed with the definitions, with only 3 disagreeing.
- 2.72. The reasons for disagreement included:
- That 30 days is not sufficient time to make a payment, as companies will not be able to determine that a sale via a third party is a health service sale, as wholesaler and framework data won't come through until after 30 days. Providing more time is particularly important given the potential use of penalties for incorrect payments
 - It is not realistic to expect the delivery of a presentation report 2 months after the end of the financial year; this should be aligned to audited sales reports
 - The presentation report requirement creates a two-step process that is more burdensome than the current scheme or the PPRS.

Government response

- 2.73. We remain of the view that the proposed timeframes for payments in the Schedules are consistent with the 2014 PPRS requirements, which operate effectively. Moreover, whilst we recognise that industry may have greater concerns about potentially delivering inaccurate reports and payments given the penalty arrangements within the scheme, we are clear that quarterly payments are likely to be estimates and will be revised as part of the audit process. We want to reassure companies, therefore, that this will be fully taken into account before any possible consideration around utilising the penalty arrangements.
- 2.74. Similarly, the timeframe for the presentation reports is the same as the requirements under the existing 2007 Regulations. This has operated effectively, with no significant concerns raised by companies. However, we understand that the potential application of penalties may be a cause for concern. Again, we want to reassure companies that we

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will be flexible where there may be difficulties in meeting the deadlines, and we will work with companies to address this, with the application of penalties being a last resort.

Q.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

Q.24 Do you agree with our proposals to extend the penalty arrangements [to where a company charges a price above the maximum price], 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

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

- 2.75. The consultation set out proposals for recovery of sums (multiplied by a given percentage as set out in schedule 4) where a company has failed to make payments owed, including proposals for interest to be charged. (Regulations 5 and 6). Penalty provisions were proposed where a company has failed to provide information, and where a company has failed to make payments owing. Demands for payments would include information about rights to appeal. (Regulation 6 and schedule 4).
- 2.76. For Q.14, of the 31 responses, 14 did not have any concerns, whilst 8 did. For Q.24, 15 agreed with the proposal, whilst 9 did not. Finally, for Q.31, 18 agreed with the proposal, whilst 3 did not.
- 2.77. Where there was disagreement, the principal concerns raised were:
- An appropriate level of tolerance should be applied to allow for administrative error and any lack of familiarity with the rules, e.g. because of the complex information requirements
 - The levels of the penalties and interest rates are too high, and extending penalties to the payment system creates an extra administrative burden. There should also be more clarity on the how the level of the single penalty will be determined
 - There should be a 'stop clock' guarantee, whereby the accumulation of penalties is frozen after an appeal is lodged.

Government response

- 2.78. We recognise that there are concerns from some companies around the proposals. In particular, these seem to arise from a perceived tension between the need to make estimates, and the possibility that unavoidable issues arise such that information returns and payments end up being late, and the statutory nature of the requirements. There appears to be a concern that the statutory nature of the requirements means that, unlike in the 2014 PPRS, there is no inherent flexibility in the system before the penalty arrangements start to apply. We wish to provide assurances that in applying the 2018 Regulations we will allow for, and take account of, genuine mistakes or problems which might impede delivery against the established deadlines. That said, a clear framework for payments is required, and we have clarified in regulation 5 that a company will be liable to pay interest during the period the payment is overdue.
- 2.79. On the level of penalties, the maximum figures are set out in primary legislation, and these have been in place for a number of years. Given that these are of long-standing, and that no changes have been made to take account of inflation, we do not believe that these should be amended. This also applies to the single variable penalty, and, given

the general support for this measure, we remain of the view that the proposal should stand, and that the considerations for determining the level of the penalty as outlined in the consultation document are sufficient. However, we anticipate that companies will need some time to get up to speed with the requirements, and we will therefore be flexible around the application of the requirements when they are first introduced. We will also consider each case on its merits, with companies able to make representations to the DHSC if they consider that there are reasons why the penalty should not apply.

- 2.80. The 2018 Regulations will not include a provision that increases the amount payable with respect to each contravention. Also, with respect to the 'stop clock' suggestion, we recognise the concerns raised about penalties continuing to accrue after an appeal is made, and we also acknowledge that there is a need to better clarify how the system would work. Therefore, under the 2018 Regulations where a penalty is applied, this will accrue only until such time as the payment is paid, or an appeal is made. Where the final determination following an appeal supports the Secretary of State's position, the penalty will continue to accrue until the payment is made but the penalty that accrued during the period that the appeal was brought will be deducted from the calculation of the level of penalty.

3. Responses on the control of maximum prices

- 3.1. After review of the consultation responses the Government has decided to proceed with limiting the prices that may be charged by a manufacturer or supplier. The limit on maximum prices will apply to any manufacturer or supplier that is not a member of the voluntary scheme.
- 3.2. The 2018 regulations clarify that generally, the maximum price will be the price which the presentation was on sale for health service purposes on 1st December 2013 without regard to any discount or rebate, as determined by the Secretary of State.
- 3.3. For a presentation that was launched after 1st December 2013, the price at which the presentation was on sale for health service purposes without regard to any discount or rebate as agreed by the DHSC in accordance with the 2008 Regulations at the time that the presentation was launched;
- 3.4. For a presentation where a price increase has subsequently been agreed by the DHSC under the 2008 Regulations then the increased price (if this is higher than the price as at 1st December 2013) without regard to any discount or rebate will be the maximum price.
- 3.5. If there are any branded health service medicine launched after 1 December 2013 for which the Secretary of State has not previously determined the maximum price, the 2018 Regulations make provision for the Secretary of State to give a direction to the relevant company setting out the maximum price.
- 3.6. Any 15% price reduction made by companies as part of the existing statutory scheme regulations will no longer be applied to the 1st December 2013 price.
- 3.7. The DHSC will also publish a record of the maximum prices of branded health service medicines as determined under the 2018 Regulations and the 2014 PPRS. For companies currently in the 2014 PPRS, the maximum price list will not include any modulated price changes or temporary price reductions agreed by the DHSC under the 2014 PPRS.
- 3.8. The current proposal is that the maximum price list will be updated periodically to reflect changes in the maximum price of a presentation (e.g. where the Secretary of State makes a direction for price increase under the 2018 Regulations or agrees to a price increase under the 2014 PPRS) or when a new presentation is launched.
- 3.9. For the purposes of compiling the prices for the maximum price list the DHSC will use the information held on the NHS Business Services Authority's Dictionary of Medicines and Devices (Dm+d), internal departmental pricing records and notifications from companies.
- 3.10. Part 2 of the 2018 Regulations make provision for enforcement of the maximum price. This includes requiring the difference between the amount charged and the amount that should have been charged had the maximum price provisions been complied with to be paid to the Secretary of State as a recoverable sum. The Regulations provide for this amount to be increased by a specified percentage over every month that the contravention continues. Provision is also made for interest to be applied to that recoverable sum. A company is also liable to pay a penalty for contravening the maximum price provisions, and the 2018 Regulations provide the Secretary of State with

the power to issue a notice demanding payment of the recoverable sum, interest and penalty.

- 3.11. A summary of the issues raised on maximum prices (and linked questions on other aspects of the proposals), and the Government response to those issues is set out below.

Q.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?

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

- 3.12. With respect to reversing the price cut, of the 31 responses, 21 agreed with the proposal, although some suggested that it did not go far enough. Just 4 disagreed. On establishing maximum price lists, 19 responses agreed with the proposal, whilst 7 disagreed.
- 3.13. Of the reasons provided for disagreeing with the proposals, or the concerns raised about the approach, the principal ones were:
- That keeping the price cut would help address lost savings from the statutory scheme. Additionally, there could be supply chain problems if high-priced drugs increased by 15%
 - Presentations launched after 1 December 2013 should also be allowed a 15% price increase, as the prices of these presentations would have been benchmarked against presentations where a 15% price cut had been applied. They will, therefore, be disadvantaged, as the pre-1 December 2013 comparators will have their maximum price increased by 15%
 - If the price agreed as part of framework agreements is not changed, it may encourage companies to withdraw from these agreements so that they can increase their prices
 - It was not clear that there was any benefit from an archive price list, and it needed to be made very clear that this list does not provide net prices
 - Price list should not be overly burdensome for companies. It was suggested that the second, live list could be delivered through simply amending the Dictionary of Medicines and Devices (dm+d), held by the NHS Business Services Authority
 - Maximum price lists should not apply to voluntary scheme members.

Government response

- 3.14. As set out in our response to Q.3 and Q.4, we do not agree that we should be making changes to make up for historically lower savings delivered by the statutory scheme. Nor do we consider that there are significant risks of supply chain problems as a result of a sudden 15% increase in prices. As discussed in the impact assessment, net prices of most drugs are significantly below the list price as a consequence of competitive pressures, and the reversal of the price cut will not change this.
- 3.15. The principal concern for those who did not think the proposals went far enough, was the perceived unfairness in relation to presentations launched after 1 December 2013. We consider that there is some merit to the arguments made, specifically in relation to medicines that are essentially the same as the originator medicine but with certain changes such as strength, pack size or formulation. In determining prices for these type of medicines, the DHSC would in most cases have pro-rated to the originator medicine, e.g. a new pack of 10 tablets would be priced on the same price per tablet basis as an

original pack of 5 tablets, or a change in strength would be priced according to price per milligram of the original presentation.

- 3.16. However, for other types of medicines, whilst pricing would have been influenced by the prices of available comparators, they are not identical to the comparator medicines. This means that with respect to such medicines, prices of comparators will not have been the only criterion used for the purpose of determining the maximum price, and it is possible that, for various reasons, prices may have been agreed which are higher than that of comparators.
- 3.17. Therefore, the DHSC will generally agree to an application for price increases for presentations where
- That presentation is essentially the same as the originator presentation, and the only difference between it and the originator presentation is strength, pack size or formulation
 - The originator presentation was on the market as at 1 December 2014, and
 - That originator presentation benefits from the price cut reversal
- 3.18. However, the DHSC will need to consider such applications on a case by case basis.
- 3.19. On the framework agreement concern, although we acknowledge that companies could pull out of frameworks to increase the price of older presentations, we do not accept that this is likely to be the case, or, at least, that prices will increase by such an amount, given the amount of competition. We also expect that the exemption for extant framework agreements will provide an incentive for companies to stay in established framework agreements.
- 3.20. In relation to price lists, we continue to believe that these can provide helpful clarity on maximum prices. We have considered the suggestion that dm+d is adapted to deliver the live price list. However, we do not think this would be viable, in part because companies might have a NHS list price that is lower than the maximum price, and it is the NHS list price that is reflected in dm+d, so there would be potential for confusion. However, on review, we consider that the approach can be simplified, with a requirement for only one list. This is achieved by having the price list function only as a record of the various decisions on price made by the Secretary of State, rather than the maximum price being determined by a published list. This is reflected in the 2018 Regulations accordingly.
- 3.21. The DHSC continues to consider that the list should include the maximum prices of medicines covered by the 2014 PPRS, in case the manufacturer or supplier that is a member of the 2014 PPRS should decide to join the statutory scheme.

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

- 3.22. We proposed that Secretary of State should be able to issue directions to set the maximum price where
- A presentation was launched after 1 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 2018 Regulations apply to a company which has left the voluntary scheme, and where the price of the presentation is different to the price set out in the list because of changes to the price whilst the company was a member of the voluntary scheme
- 3.23. 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 (regulations 8 to 13).
- 3.24. Of the 31 responses, 17 agreed with the approach, whilst 7 disagreed. Where specific concerns were raised, these generally related to pricing decisions. In particular, one response noted that, whilst recognising that the DHSC should have the power to intervene where there is a serious abuse of a dominant market position, clarity is needed on how it would determine the need for an intervention. Also, elsewhere it was noted that proposals for setting prices for new medicines should be aligned with the arrangements in the 2014 PPRS.

Government response

- 3.25. We consider that, where concerns have been raised, respondents have conflated the use of directions with wider issues around determining appropriate pricing levels. A direction is the legal process we proposed by which the Secretary of State would set a price. However, this direction making power is to be used within the context of the wider proposals, that is, whenever a maximum price is set by the Secretary of State, following consideration of any pertinent and required information, such as for a price increase, price decrease, or for a new presentation.

Q.18 Do you agree that the proposed process [on new presentations], including the time periods for providing information and making decision, is reasonable? If not, why not?

Q.19 Do you have comments with respect to the type of information [on new presentations] that the Secretary of State is considering requesting as part of the information notice?

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

- 3.26. The proposed process for new presentations as set out in the consultation document involves 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
 - Specifies the presentation in respect of which the notification is made
 - Includes the summary of the product characteristics
 - Specifies the proposed launch date and maximum price
 - 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 2018 Regulations

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- *Stage 3* - provide any further information requested (including, where appropriate, by an information notice), by the Secretary of State
- 3.27. The proposals included time limits for each stage of the process, and further provided that the Secretary of State must specify the maximum price through a direction no later than 28 days after receipt of all the information requested via the three stages
- 3.28. 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.
- 3.29. We proposed that the factors to be considered should include, but not be limited to, the following:
- 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
 - 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 where the patent protection expires
- 3.30. Where information is requested through an information notice (stage 2 of the application) factors considered could also include:
- 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.
- 3.31. On Q.18, of the 31 responses, 9 responses agreed with the proposals, whilst 15 disagreed. For Q.19, 22 responses had comments on the types of information to be requested, whilst 4 indicated they did not. For Q.22, 9 responses agreed with the proposals, whilst 14 did not.
- 3.32. The principal concerns raised included:
- The proposals breach the principle of freedom of pricing at launch for NAS, and there should be a distinction in the handling of NAS and other new presentations
 - The process is too slow. The 60-day period for new presentations does not fit with the Committee for Medicinal Products for Human Use (CHMP) opinion, and there needs to be recognition that a draft Summary of Product Characteristics (SPC) would be acceptable. Also, speed of decision for new prices is one of the few remaining attractive elements for the UK as a place to invest, and this change negates that. Additionally, the 90 days for price increases is too long
 - There is a need for clarity over how the Secretary of State determines the reasonableness of any given price for a presentation

- The information requirements are disproportionate, and exceed in scale information previously requested, including through the 2014 PPRS. Also, in most cases, it is not possible to identify research and development, manufacturing, supply and operational costs by presentation
- Prices should be based on value, not cost
- The information gathering powers are excessive, and in the future these could be used to gather commercially sensitive data for innovative and patented medicines. They go beyond the area focused on during the passage of the Health Service Medicines Supplies (Costs) Act 2017 through Parliament, which was on unbranded medicines, and there is a need for appropriate safeguards in the regulations
- There should be clarity on the remit of information notices, e.g. whether this is for the UK only, or also for a group or parent company.

Government response

- 3.33. Freedom of pricing for NAS is an important element of the 2014 PPRS, which was one of the concessions to industry agreed through negotiation. Freedom of pricing was not subsequently extended to the statutory scheme, though NAS status does carry heavy weighting when pricing decisions for new presentations in the statutory scheme are being made. Given this, and the number of responses where no concerns were raised about this point, we believe that our approach remains reasonable.
- 3.34. We recognise that the processes for both new presentations and price increases has been complicated by the requirement (introduced in the Health Service Medical Supplies (Costs) Act 2017) that certain information can only be requested via an information notice. This has had an inevitable impact on the timescales, with the need for sufficient leeway to be incorporated into the 2018 Regulations to ensure that these are deliverable. However, we want to make it clear that the time taken to reach decisions will, in the vast majority of circumstances, be much quicker. To expedite speed of turnaround, the DHSC is exploring systems to speed up the information notice process, with more details available in the draft operational guidance. Moreover, we are fully supportive of the suggestion that draft CHMP/SPC opinions be used to inform our initial assessments, with the final opinions provided when available. Consequently, we are of the view that the attraction of the UK market as a source of quick pricing decisions should be retained.
- 3.35. In relation to the volume and types of information, we have sought to be clear about the range of information that we consider we might need to have access to in order to make a properly informed decision. However, the information requested for these price setting processes will vary depending on the presentation, and in many cases it will be a much less extensive range of information than listed in the regulations which will be needed. The 2018 Regulations cover the key factors which the Secretary of State may want to take into account, which is different from routine requirements. However, we have made a change in respect to the proposed sales forecasts information that would be required. We still consider that 5 year forecasts are required for new presentations, as it will take time to build up to the steady state level of sales, but for price increases, where a presentation is already established in the market, we have amended the 2018 Regulations so that only 3 year forecasts are required. The operational guidance for companies will set out standard operational processes and reporting requirements.
- 3.36. Respondents stated that it is not possible to attribute research and development, manufacturing and supply costs to individual presentations. However, industry already supply cost information to the DHSC as part of the PPRS, when seeking approval for

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price changes, or to set prices of line extensions or new presentations in the statutory scheme. We do not therefore accept that it would not be possible for this information to be supplied.

- 3.37. The presence of a NAS in a presentation carries considerable weight when the Secretary of State considers launch price proposals. However NAS without clinical comparators are generally referred to NICE which enables a full cost-effectiveness assessment to be made at the proposed launch price. We also note that in other circumstances, costs are a significant issue that companies would have us take into account, such as when companies assert that supply is at risk due to increased manufacturing costs and therefore a price increase is needed.
- 3.38. With respect to costs information, the information notice will relate to applications made for new presentations and price increases, and the costs incurred in relation to that presentation. If a company provides information about costs within their company group, the Secretary of State would take this information into account as part of the factors set out in the relevant new presentation and price increase regulations.

Q.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

- 3.39. This question concerned the provision in the existing statutory scheme for a temporary exemption of a presentation from price controls in order to address supply problems, and whether this should be replaced by a temporary maximum price provision.
- 3.40. Of the 31 responses, 20 agreed with the proposal, whilst 2 disagreed. Where comments were made, these included the suggestion that there should be a limit on both the duration of an increase, and the ability to make repeat applications for a given presentation. Also, it was noted that there should be more clarity on timescales, and that decisions will need to be rapid if the provision is to be of use in addressing supply issues.

Government response

- 3.41. We agree that there should be a limit on the length of time that the exemption applies, and this was already captured within the draft consultation Regulations. However, we don't consider that there is a need to more clearly articulate the timescales. The reason for the exemption is to allow the Secretary of State to provide a response to supply problems, which may require rapid action, and the 2018 Regulations allow this.

Q.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 increase will address any supply issues? If not, do you have any analysis and evidence to show why not?

- 3.42. We set out our proposed policy that a provision to allow companies to seek a temporary price increase was sufficient to address potential supply problems, and that extension of the temporary exemption provision to include the payment mechanism was not necessary.
- 3.43. Out of the 31 responses, 11 indicated that an exemption provision was not needed. However, in a couple of instances, this was conditional on the successful operation of the scheme, in particular that price increases were confirmed rapidly, and one response did note that the exemption should be by exception only (so there would, in fact, need to be an exemption provision).

- 3.44. Alternatively, 9 responses argued that the exemption provision should be provided. This was on the basis that price increases are not a sufficient safety valve where a presentation operates in a competitive environment, and that the timelines for price increases, and the unclear decision process, do not provide an adequate mechanism.
- 3.45. In 4 responses, specific concerns were raised in relation to blood plasma presentations, which, given their unique nature and the consequent limitations in global supply, are the class of presentations that potentially would most benefit from an exemption provision as a means of mitigating supply issues. However, not all of these stated that an exemption provision would be needed to address such supply issues. The principal issues raised were:
- Price increases are not sufficient to address shortage issues when a market like that for blood plasma is supplied by different size companies, as larger companies may be better able to absorb a payment. A payment may, therefore, disrupt the market and create a level of uncertainty which may not exist in overseas markets, which are bidding for scarce supplies alongside the UK
 - Due to particular market and presentation characteristics of certain blood plasma presentations, such as the long lead in time for manufacturing, price increases would not be sufficient to address supply shortages
 - Predictability is key to the blood plasma industry, with the framework agreement exemption going some way to address this. However, there is a need for planning certainty in the longer term, e.g. through fixed payment percentages
 - A reliance on price increases presents challenges for the front line NHS, as they will face pressures on their budgets, with the scheme payment offsetting these increases not being ring-fenced, and a likelihood that the payments will not make their way to relevant local commissioners.

Government response

- 3.46. We have given the question of a temporary exemption from the payment mechanism further consideration in light of the consultation responses. However, we remain of the view that allowing companies to seek a temporary price increase provides sufficient flexibility to address supply concerns. 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. We recognise that, if this action were 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.
- 3.47. As set out in the consultation document, we also 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.
- 3.48. Regarding the challenge that the maximum price exemption process is slow and unresponsive, there are no set processes and time periods associated with the

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proposed provision allowing for a temporary exemption from the maximum price. This means that there is inherent flexibility to allow for a rapid decision to be made, as long as a company can evidence why an exemption is needed, which they should be able to do if the situation is so critical that the normal price increase provision is not an acceptable route.

- 3.49. With respect to blood plasma presentations, we noted that of the limited number of responses referencing this class of presentations, only some of them claimed that an exemption provision was needed. In addition, at a meeting with representatives from the blood plasma sector during the consultation period, companies recognised that the measures outlined in the consultation document, in particular the procurement approaches adopted by the Commercial Medicines Unit, would help them to plan effectively and mitigate potential supply issues to a significant extent.
- 3.50. However, we do recognise that any future changes to the level of, and the method for calculating, the payment percentage will impact on the predictability of the market for blood plasma and other sectors. Any changes will need to be considered in light of the discussions around the potential successor to the 2014 PPRS. However, in taking forward those discussions, we clearly recognise the need to take account of the concerns raised in this consultation around the importance of predictability.
- 3.51. On the challenge that reliance on price increases will present a challenge to the front-line NHS, we do not consider that this is a significant issue. The statutory scheme payments will be passed in full to the NHS in the four countries. In England, whilst the payments will not be ring-fenced for spend on medicines, the relevant NHS organisations will have the facility to take account of any local cost pressures that may arise should there be increases to the prices of certain medicines.

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

- 3.52. The proposals for handling price decreases were set out in the consultation and draft consultation regulations. A two-stage process was proposed: that the company makes a written application for a price decrease supplying relevant information, followed by the Secretary of State requesting any further information (by means of an information notice if appropriate). The Secretary of State will then set a new maximum price for the presentation by means of a direction. Time periods were set out for all stages of the process, including 90 days for the Secretary of State to issue the direction after receipt of all relevant information.
- 3.53. Of the 31 responses, just 6 agreed with the proposed process, whilst 16 did not. The reasons given for disagreement were that the time periods were too long, which wasn't helpful where a decrease may support reduced costs to the NHS. There was a suggestion that the maximum time period for a decision should be 30 days, or that there should be a simple requirement that the company notify the Secretary of State as to whether a price decrease is temporary or permanent.

Government response

- 3.54. We recognise that the timescales proposed are too long. We have therefore amended the regulations so that the timetable for a decision is shortened, with a maximum of 28 days being allowed for each step. However, even so, we want to make it clear that in most instances, the DHSC will seek to make decisions much sooner. The 2018 Regulations now also set out that information must be recorded and kept for a period of

6 years, and a request for further information included in the original proposals has been removed, as on further consideration this was not necessary.

4. Responses on the information requirements

- 4.1. After review of the consultation responses the Government has decided to proceed with requiring information to be provided by companies to support operation of the scheme. Companies will be required to record, keep and provide the information set out in the regulations and accompanying schedules, including presentation and sales reports, of the 2018 Regulations. Auditing requirements are also set out. The DHSC will verify returns using additional information, including audited information.
- 4.2. The 2018 Regulations also provide for the Secretary of State to determine payment levels where on review of the information provided, the DHSC has concerns about estimated or audited information – including in respect of information about small and new companies. Companies may appeal such determinations.
- 4.3. Enforcement provisions make a company that contravenes any of the information requirements liable to a penalty. The Secretary of State can issue a written notice to demand payment of that penalty.
- 4.4. A summary of the issues raised on the scheme's information requirements (and linked questions on other aspects of the proposals), and the Government response to those issues is set out below.

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

- 4.5. It was proposed in the draft consultation regulations that companies subject to the payment mechanism would be required to provide the following information:
 - Sales reports for each quarter within 30 days of the last day of that quarter, and for any remaining period within 30 days of that remaining period
 - Audited sales reports for each financial year within 9 months of the last day of each financial year
 - Presentation report for each financial year within 2 months of the last day of each financial year
 - A copy of their statutory audited accounts for the company's financial year within nine months of the last day of that financial year
 - Arrangements to take account of changes to a company's financial year and accounting reference period were proposed, including making provision in specific circumstances for the Secretary of State to determine the periods within which information should be provided.
- 4.6. Of the 31 responses, 21 agreed with the proposal, whilst only 1 disagreed. Where comments were made, the principal issues raised were:
 - The information requirements will present a significant burden on small companies. It was suggested that a pragmatic, less burdensome approach be taken to reflect that they have less administrative and financial capacity
 - Where a company's accounts differ significantly from a previous year, the company should be asked to provide the DHSC with a reason for the difference
 - The DHSC will have to accept that it is not always possible for a company to distinguish between primary care and secondary care sales, so figures provided

may well be best estimates. This is compounded by the fact that some information will need to come from wholesalers, so will not be available within the 30-day period.

Government response

- 4.7. With respect to the burden that these proposals will place on small companies, we consider that we have already taken account of the need to minimise the administrative and financial burden by proposing less extensive information requirements than for larger companies e.g. we did not propose to routinely require annual audited information returns. As a result of feedback received, we also have made some further technical changes which are set out at paragraph 2.68. However, we remain of the view that to ensure effective operation of the scheme, it may be necessary to ask for annual audited returns on an occasional basis. However, we do not think it is necessary to require a justification from a company where accounts differ significantly between years, as we would expect the accounts themselves to contain an explanation in the event of such a change.
- 4.8. On the issue of estimates, we accept that information will at times need to be best estimates, as it will not always be possible to identify the final destination of sales in the 30-day time period.

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

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

New companies

- 4.9. For new companies, we proposed they should provide sales reports in line with those for existing companies. 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.
- 4.10. 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.
- 4.11. We also proposed 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.

Small companies

- 4.12. We proposed that small companies will be exempt from providing the payment scheme information referenced above. However small companies should be required to provide details of their total net sales income for relevant health service medicines for the most

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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.

- 4.13. Unlike the requirement for the payment scheme information, we did not propose 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 proposed 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.
- 4.14. For both Q.26 and Q.27, of the 31 responses, 18 agreed with the proposals, whilst no one disagreed or answered the question. The principal comment was that small companies should be exempt from the requirement to provide annual statutory audited accounts.

Government response

- 4.15. We welcome the support for our approach. With regard to the statutory audited accounts requirement, it was always our intention that this would not apply to small companies. However, we have amended the 2018 Regulations to put it beyond doubt that this requirement does not routinely fall on small companies.
- 4.16. Additionally, upon further consideration, we have made some technical changes to the 2018 Regulations. These are set out at paragraph 2.68.
- 4.17. With respect to new companies that meet the small company threshold, the small company information requirements will apply. Other new companies will be required to provide estimated sales within 30 days of the 2018 Regulations applying to them, in addition to the general information requirements to provide quarterly sales reports, annual audited sales reports, presentation reports and statutory audited accounts. This is a simpler process that originally proposed as part of the consultation.

Q.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?

- 4.18. We set out proposals for the range of information to be included in the sales report. This included details of sales exempt from the payment (including those under framework agreements that qualify as exempt, low cost presentations, sales outside of the UK and sales of unbranded generic health service medicines).
- 4.19. We recognised that in some cases it may be unclear whether a medicinal product was supplied for health service use. We therefore proposed including provision for estimates of sales to the health service in sales reports, with companies required to provide a justification for use of an estimate and the method employed.
- 4.20. Once estimated information has been provided, we proposed that the Secretary of State should have the opportunity to validate the best estimate, and this process should be completed within 12 months of receipt of the relevant end of year presentation report.

Audited information

- 4.21. 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 specified information.

Written declaration of approval

- 4.22. We proposed that sales reports should be accompanied by a written declaration of approval to the effect that the information gives a true and fair account of the information required. 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. This aligns with the arrangements in the 2014 PPRS.
- 4.23. Of the 31 responses, 19 agreed with the proposals, whilst just 4 did not. Where there was disagreement with the proposals, it was noted that there did not seem to be a clear justification for why sales reports should include sales of presentations outside of the UK, non-medicinal or generic presentations. Moreover, it was noted that the requirement for information on unbranded generic sales conflates with requirements under the new information regulations, and will trigger more work, or require that work to be brought forward.

Government response

- 4.24. We welcome the broad support for the proposals, and will implement these with the following amendments:
- Requirement for information on over-the-counter (OTC) medicines (so they can be exempted from calculation of payments due)
 - Requirement for information about public contracts, reflecting the extension of the exemption for extant framework agreements to include extant public contracts
- 4.25. Although we recognise the concerns raised over the collection of non-medicinal, generic and non-UK sales information, it is necessary for us to collect this to allow for a comprehensive assessment of a company's sales to the health service, and to allow a reconciliation back to a company's statutory accounts. This information is necessary for the purposes of operating the statutory scheme, to verify the sales of branded health service medicines. This is the same as the requirements under the 2014 PPRS.
- 4.26. With regard to the challenge over duplication with the information regulations, we acknowledge that there may be some cross-over between the sales report information requirements in relation to unbranded generics, and the information that might be collected through the information regulations. The DHSC has sought to limit any duplication as much as possible, though the responses to the consultation on the information regulations are still being considered.

Q.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

- 4.27. Of the 31 responses, 21 agreed with the proposals, whilst only 1 did not. Where comments were made, the principal ones related to the need for flexibility in the timelines, particularly where a sizeable payment had to be made, and the need for a clear process. Moreover, there was some disagreement that the Secretary of State should, of his own volition, be able to make a decision based on the information available to him, as given the broad powers in relation to information notices, it was not

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proportionate for the Secretary of State to make decisions from information sources to which the company may not have access.

Government response

- 4.28. We welcome the broad support for this proposal. With only 1 respondent disagreeing, and given the very limited number of respondents raising any concerns, there is little support for making any changes to the proposals.
- 4.29. Responding to the comments about flexibility and process, as drafted the 2018 Regulations provide inherent flexibility, with no maximum date established by which a payment must be made. This ensures that the Secretary of State can work with the company to agree a reasonable date if there are issues that might justifiably mean that a company could not pay before a certain date. On process, we have amended the 2018 Regulations to make the process clearer.
- 4.30. We do not agree with the one respondent that indicated the Secretary of State should not, on his own volition, be able to make a decision on a payment. It is right that the Secretary of State should be able to make a determination based on the evidence submitted by a company for the purposes of the scheme, and other pertinent information that is available. However, we want to make it clear that the DHSC would seek to engage collaboratively with companies prior to any determination being made. In addition, the company would always have a right of appeal if they did not agree with the determination.
- 4.31. We expect that this provision will be used primarily where Secretary of State is concerned about the use of estimates, where there is reason to believe that they are sufficiently inaccurate to lead to either over- or underpayments. This regulation applies to all companies, including new and small companies as defined in this scheme, and review may result in companies being required to provide corrected information where necessary.

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

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

- 4.32. For Q.32, of the 31 responses, 11 had comments on the proposals, whilst 20 did not, or did not answer the question. For Q.33, 14 responses said that splitting out data for Northern Ireland would be a burden, whilst 5 did not. The principal comments made, and reasons for disagreement, were:
- That the DHSC should engage with companies in circumstances where, to deliver a quarterly return, a company needs to undertake significant manual analysis due to the complexity of the product portfolio
 - That information requirements should be staggered based on the size of the company to reflect the increased administrative burden that would be faced by smaller companies
 - The processes for information notices and price changes are burdensome and should be slimmed down e.g. for new presentations, this should only include forecast sales data, reference to existing presentations and related information
 - The changes should be delayed until after the conclusion of discussions around any potential successor to the 2014 PPRS

- There would be a significant burden to companies in splitting out Northern Ireland sales, given that wholesalers are responsible for much of the distribution, and to a questionable degree of certainty
- Due to cost constraints, small companies do not buy data at levels of granularity that would be sufficient to identify Northern Ireland sales
- To address the Northern Ireland question, the DHSC should estimate Northern Ireland sales, and apportion accordingly.

Government response

- 4.33. We recognise that some companies may find the quarterly returns burdensome. We want to make it clear therefore, that the DHSC will be open to engagement with companies to discuss flexibilities with regard to time frames, especially for the time period when the 2018 Regulations first come into force.
- 4.34. With respect to staggering the burden by size of company, this is something that we have already done. We have limited the burdens which would be placed on small companies by the payment system, which would be the companies most likely to struggle to cope with additional admin burdens.
- 4.35. In relation to the burden imposed by the information notice and price setting processes, we have sought to be clear about the full range of information that we might reference. However, information requested for this process will depend on the type of presentation, and as set out above, we are clear that in many cases all the information listed in the 2018 Regulations will not be needed, thereby limiting the burden.
- 4.36. As set out above, we do not accept that the changes should be delayed until after the negotiations over a potential successor to the 2014 PPRS. The financial pressures facing the NHS, and the potential challenges to undertaking any non-Brexit related legislation post April 2018, are such that action should be taken now to introduce these changes.
- 4.37. With respect to Northern Ireland, we accept that for some companies it may be very burdensome to properly split out Northern Ireland sales. Taking this, and other factors into account, we have decided to proceed with implementation of the scheme for the whole of the UK.

5. Responses on appeals and review of the regulations

- 5.1. The 2018 Regulations provide for a right of appeal where the Secretary of State makes an enforcement decision with respect to the statutory scheme. They also provide that where a company appeals an enforcement decision, the period during which that appeal is running will not be included in the calculation of the period of time used to calculate the recoverable sum, interest or penalty.
- 5.2. The Appeal Regulations set out the requirements for tribunal panel members, the process for making an appeal and for it to be considered. It is our intention to amend the Appeal Regulations to make technical and procedural changes to bring them into line with current Ministry of Justice practice on the operation and composition of appeal tribunals. The 2018 regulations provide manufacturers and suppliers a right of appeal in relation to enforcement decisions as defined under section 265 of the National Health Service Act 2006.

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

- 5.3. Our proposals confirmed that appeals will be dealt with by the existing tribunal that has been set up under the Appeal Regulations, with the provisions being updated to reflect any changes to the model provisions under the Deregulations and Contracting out Act 1994 (www.legislation.gov.uk/ukpga/1994/40/contents). It was also noted that 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.
- 5.4. Out of the 31 responses, 19 agreed with the proposals, whilst just 1 did not. What limited comments were made noted that a consultation would be welcome on any move to the Unified Tribunals System, and one response noted a preference for the appeals process to stay with the DHSC.

Government response

- 5.5. We welcome the broad support for the proposed approach, and it is our intention to amend the Appeal Regulations accordingly. Moreover, it is our intention to take the opportunity to include in the Penalties and Appeal Regulations penalty provisions so that any manufacturer or supplier who contravenes a direction made under section 262(1)(a) of the NHS Act 2006 is liable to pay, on demand, a daily penalty for that contravention in accordance with the amount that will be specified in the Schedule to the Penalties and Appeals Regulations. This was included to ensure that where the DHSC, after consultation with the industry body, limits the price that may be charged for the supply of, for example, an unbranded generic medicine, it can enforce the price limit by applying a daily penalty for any contravention as required by the NHS Act 2006. As part of the related consultation on new information regulations, we consulted the relevant industry bodies on this addition to the Penalties and Appeals Regulations between 13 and 28 November. None of them submitted any views or concerns.
- 5.6. With respect to any move to the Unified Tribunals Service, it is possible that we would determine that there is no need for consultation, depending on the scale of the final

change. However, we would expect that regulatory change is likely to be needed and, therefore, that we would consult.

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

5.7. Of the 31 responses, 12 agreed that the 2018 Regulations should be reviewed annually, whilst 13 did not. The principal comments made, and reasons for disagreement given, were:

- That, ideally, a way would be identified to avoid the requirement for annual regulatory changes e.g. such as around the level of the payment percentage
- That the 2018 Regulations should only be subject to annual review if changes to the payment percentage are made with sufficient time remaining for companies to decide which scheme would suit them best before the changes come into force
- Frequent changes will lead to uncertainty, and would have significant operational implications, as well as creating an administrative burden through the need to respond to multiple consultations
- Annual reviews could be seen by the DHSC as an option to address short-term financial issues, and support NHS budgets.

Government response

- 5.8. Notwithstanding that the Secretary of State can consult on changes to the statutory scheme at any time, an annual review does not necessarily mean that the 2018 Regulations will be amended annually. Rather, we will consider as part of the annual review whether any changes are necessary.
- 5.9. We do consider that a review, and likely changes, will be required during 2018, should an agreement be reached on a successor to the 2014 PPRS, in order to provide some level of alignment between the schemes. However, it is in both the DHSC's and companies' interests to avoid annual changes, given the administrative burdens involved. In the event that a review determines that changes are needed, this would entail consultation, and we would do everything possible to ensure that plenty of time was allowed for any consultation that may be required and for companies to make any necessary administrative changes.
- 5.10. With respect to the use of the statutory scheme to address short-term financial issues, NHS budget pressures will always be a consideration when contemplating changes to medicines pricing arrangements, as identified in the consultation document. However, fairness to, and impact on, industry is also always a consideration, and it is our expectation that future changes would be informed principally through the need to provide a level of alignment with any potential new voluntary scheme.

6. Responses on the statutory requirements

Q. 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 UK, as set out above and in the draft impact assessment?

Q.37 Do you have any comments with respect to the effect of the proposals for the economy of the UK, as set out above and in the draft impact assessment?

- 6.1. For Q.36, of the 31 responses, 22 had comments on the effect of the proposals on the life sciences industry, whilst just 2 did not. For Q.37, 12 responses had comments on the effect of the proposals on the UK economy, whilst 8 did not.
- 6.2. The principal comments made were:
 - That the estimated 1-day per quarter administrative burden for providing the required scheme information is too low. A range between 4 to 7 days would be more appropriate
 - Some of the basic assumptions are not valid, such as the estimate that 30 per cent of pharmaceutical company revenue is profit being too high, and the assessment that the loss to the UK economy from the proposals is £0.1m to £0.6m is not credible
 - A challenging NHS commercial environment, such as through no exemption for new presentations, exclusion for parallel imports and no improvement to the uptake environment, will make the UK less attractive for investment in research and development, which will be exacerbated by departure of the UK from the EU. Also, the contention in the impact assessment that supply-side considerations are key with respect to investment decisions will not apply to all companies

Government response

- 6.3. Any impact from the UK's departure on individual companies should be considered to be part of the prevailing business environment - the purpose of an impact assessment is to isolate the impacts of the proposed policy independently from these wider factors.
- 6.4. Although respondents argued that decisions to invest in the UK would be impacted by the proposals, no new evidence was provided to substantiate this view. Based on an assessment of the literature, and consideration of the economic rationale for investment decisions, the DHSC's view remains that other supply side factors such as the availability of skilled staff and favourable tax conditions are of significantly greater importance in the decision of where to locate research and development activity.
- 6.5. On the admin burden involved in the quarterly returns, no 2014 PPRS company has raised challenges over providing the information. Additionally, we would expect that most companies would want this level of detail in order to inform their activities, e.g. development of their marketing strategies, in which case it would be available. Moreover, we would expect that companies would set up systems to obtain this information regularly to reduce the quarterly burden. Bearing this in mind, we think it appropriate to reflect a slightly increased burden of 2 days per quarter.

Q.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 in the draft impact assessment?

Q.39 Do you have any comments on the impact that the proposals may have on the three public sector equality duty objectives?

Q.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?

6.6. For Q.38, out of the 31 responses, 11 had comments on the consequences for patients, whilst 20 did not, or did not answer the question. For Q.39, just 2 responses had comments on the public sector equality duty, whilst 29 did not, or did not answer the question. For Q.40, 9 responses had comments on the Secretary of State duties, whilst 22 did not, or did not answer the question.

6.7. The principal comments made were:

- The main risk to patients would be from the interruption to supply where the price in the UK is significantly lower than in other countries. This would be a particular concern where global supply was not sufficient to meet demand, such as is the case for blood plasma presentations
- The payment may mean that branded generics and biosimilars are withdrawn from the market, and there would be a consequent loss of their potential benefits, such as ease of prescribing and patient adherence
- Whilst the proposals are not generally seen to impact on equality issues, if there were supply issues this might have a disproportionate impact on disadvantaged groups. Also, it was suggested that there is a risk to patients, i.e. through lack of access to new treatments, if NAS launches in the UK are discouraged

Government response

6.8. We have considered the potential impact on supply above, and in particular at paragraphs 3.42-3.51 and concluded that the facility for price increases, and the measures undertaken by CMU in terms of procurement, are sufficient to address supply issues where price is a factor.

6.9. We have also considered branded generics and biosimilars above (see in particular paragraphs 2.28-2.37), and concluded that the proposals should not have a significant impact on the supply of such medicines in the UK.

6.10. With respect to the risk of a decrease in the launch of new presentations in the UK as a result of reduced prices, whilst we have not proposed that NAS should have freedom of pricing, NAS status will be a major consideration (as now) in agreeing prices, and is one of the listed factors in the 2018 Regulations. Additionally, it remains a fact that, whilst it is not something that we are looking to promote or even encourage, given that the 2014 PPRS has an exemption from the payment for NAS, a company could decide that it was in its commercial interest to switch schemes.

Q. 41 Do you agree with the analysis in the accompanying impact assessment on the impact of our proposals? If not, why?

Q.42 Do you have any evidence that would help inform, and improve the quality of, our analysis?

6.11. For Q.41, of the 31 responses, 3 agreed with the analysis in the impact assessment, whilst 13 did not. For Q.42, 5 responses indicated that they had additional evidence, whilst 15 did not.

6.12. The principal reasons given for disagreement with the analysis were:

- Supply issues are not as simplistic as suggested by the impact assessment

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- The proposals will negatively impact how parent companies will view the UK as a place to invest. Additionally, the Life Sciences Industrial Strategy, which recognised the life sciences sector as an important asset to the UK, gives the lie to the assertion that falling revenues will not affect the attractiveness of the UK as a place to do business
- It is mistaken to assume that reduced drugs spend will result in similar direct gains, as it will lead to fewer incentives to collaborate, reduce prices and invest
- The impact assessment assumes that presentations will be viable following the application of a payment percentage. Where margins are low this will not necessarily be the case.

Government response

6.13. Although respondents argued that decisions to invest in the UK would be impacted by the payment percentage and other proposals, no significant new evidence was provided to substantiate this view. Based on a thorough assessment of the literature, the DHSC's view remains that other supply side factors such as the availability of skilled staff and favourable tax conditions are of significantly greater importance in the decision of where to locate research and development activity.

Annex A: Statutory requirements

1. The NHS Act 2006 includes both general duties for the Secretary of State, and also specific duties relating to statutory schemes which control the costs of medicines. These include the new duties to consult on the economic consequences for the life sciences industry in the UK, the consequences for the UK economy and the consequences for patients, as well as a specific duty for the Secretary of State to bear in mind the need for medicinal products to be available for the health service on reasonable terms and the costs of research and development.

Duties under the NHS Act 2006

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

2. 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.
3. 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 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)).
4. 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 response. However, a summary of the assessment relating to those areas outlined in the NHS Act 2006 is detailed below.
5. 22 respondents had comments on the consequences for the life sciences industry of the proposals, whilst 2 did not. 7 did not answer the question. 11 respondents had comments on the consequences for the UK economy and for patients of the proposals, whilst 9 did not. 11 did not answer the questions.
6. Themes amongst responses were:
 - Estimate that 30% of pharma revenue is profit is too high
 - Impact on small companies – further squeezing of tight margins unhelpful
 - Underestimate in consultation of administrative burden on companies of the proposals
 - Challenging NHS commercial environment plus the UK's departure from the EU impacting on the attractiveness of the UK in relation to R&D investment and for launching new medicines
7. The impact on companies of the UK's departure from the EU should be considered to be part of the prevailing business environment – the purpose of an impact assessment is to isolate the impacts of the proposed policy independently from these wider factors. We will

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take account of any key issues arising during the year when conducting annual reviews of the 2018 Regulations.

8. Although respondents argued that decisions to invest in the UK would be impacted by the payment percentage, no new evidence was provided to substantiate this view. Based on a thorough assessment of the literature, our view remains that other supply side factors such as the availability of skilled staff and favourable tax conditions are of far greater importance in the decision of where to locate R&D activity.
9. On the administrative burden involved in the quarterly returns, no PPRS company has raised challenges over providing the information. Additionally, we would expect that most companies would want this level of detail in order to inform their marketing strategies etc, in which case it would be available. Moreover, we would expect that companies would set up systems to obtain this information regularly to reduce the quarterly burden. Bearing this in mind, we have changed the impact assessment to reflect the greater administrative burden of the proposals on companies as highlighted by respondents compared to our original estimate. We do not believe that this has any consequential impact on the statutory duties and family test assessment.
10. Comments made centred around the impact for patients if presentations were removed from the market as a result of these changes. We conclude that the exemption for presentations supplied under framework agreements and public contracts, the small companies exemption and flexibility for price increases all mitigate the risk of the new scheme impacting on supply of medicines to patients. In terms of the risk of reduced launch of new presentations in the UK as a result of reduced prices, whilst we have not proposed that new active substances should have freedom of pricing, NAS status will be a major consideration (as now) in agreeing prices and is one of the listed factors in the 2018 Regulations.

Duty to bear in mind the need for medicinal products to be available for the health service on reasonable terms and the costs of research and development

11. As well as this specific duty, the Secretary of State also has general duties to
 - promote 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.
 - have regard to the NHS Constitution by ensuring that health service products provide value-for-money, and therefore increase the resourcing available to provide treatments and services to patients
 - have regard to the need to reduce health inequalities between the people of England with respect to the benefits that they can obtain from the NHS. It is important to emphasise that this duty is separate from the public sector equality duty. Socio-economic impacts need therefore to be considered in terms of other socio-economic factors such as income, social deprivation and rural isolation.
 - to act with a view to securing continuous improvement in the quality of health services provided to individuals in connection with the prevention, diagnosis or treatment of illness, or public health.
12. 9 respondents had comments on the Secretary of State duties, whilst 10 did not. 12 did not answer the question. Comments centred around risks to supply, and our assessment of this is set out above in the section around consequences for patients. The proposals for the

statutory scheme overall 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. Our overall assessment against these duties as set out in the impact assessment is unchanged as a result of responses received to the consultation.

13. We have considered the Secretary of State's other duties in relation to education and training, autonomy and treatment of providers; as well as the Family Test and do not consider them to be applicable. Further details about these duties are set out in the consultation document.

Public Sector Equality Duty (section 149, Equality Act 2010)

14. 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.

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

16. 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 are 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.

17.2 respondents had comments on the impact on the PSED, whilst 18 did not. 11 did not answer the question. As with the other duties, responses centred on the risk of supply of medicines being affected and the impact that this might have on specific patient groups.

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18. Overall, our assessment at the time of consultation was 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.
19. We do not consider that any of the assertions made in the consultation responses, or changes to the 2018 Regulations made as a result of the consultation would change our assessment of the statutory scheme against PSED.