



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

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Target audience:

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

Contact details:

Department of Health and Social Care
Medicines and Pharmacy Directorate
Medicines Pricing team
39 Victoria Street
London
SW1H 0EU

Statutory_scheme_consultation@dh.gsi.gov.uk

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Contents

Contents	3
Executive summary	4
1. Introduction	5
Statutory price control of branded medicines	5
Pharmaceutical Price Regulation Scheme	5
2. Why changes are required	7
3. Summary of the proposals	8
4. Payment percentage	9
Allowed growth rate and forecast	9
Impact of the proposed allowed growth rate	9
Proposed payment percentages	10
5. Biological health service medicines	12
6. Framework agreements and public contracts	13
7. Statutory requirements	15
Consultation requirements regarding exercise of powers in section 263 of the NHS Act 2006	15
Statutory duties under the NHS Act 2006 and the Public Sector Equality Duty	16
8. Forecasting model	21
9. Responding to the consultation	26
Comments on the consultation process itself	26
Confidentiality of information	26
10. Summary list of questions	28

Executive summary

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

In April 2018, the Government introduced changes to the statutory scheme, as set out in the Branded Health Service Medicines (Costs) Regulations 2018. The principal element of this was a shift from a system of price cuts to one of payments made of a percentage of the value of branded health service medicines sales by the relevant manufacturer or supplier (referred to as companies for the purposes of this document) in addition to price controls. This was felt to be a more effective and reliable mechanism for controlling the cost of branded health service medicines and also re-established an appropriate level of broad commercial equivalence with the PPRS that had been lost when the 2014 PPRS agreement adopted a payment percentage mechanism.

The 2018 Regulations introduced a payment system in the statutory scheme. The payment percentage applied in the statutory scheme was set at 7.8%. This was aligned with the payment percentage operational in the final year of the 2014 PPRS – the calendar year 2018.

The current voluntary scheme expires on 31 December 2018. Negotiations are underway on a successor. Concurrently, the Government is proposing changes to the statutory scheme from the beginning of the calendar year 2019, in order to ensure that the statutory scheme continues to achieve its primary purpose of safeguarding the financial position of the NHS.

The proposals, which are summarised in chapter three and set out in detail in the subsequent chapters, cover three areas:

1. Changing the payment percentage;
2. Including all biological medicinal products (including biosimilars) within the scope of health service medicines captured by the payment mechanism, price controls and information requirements; and
3. Changing the application of the payment system for sales of medicines supplied under a contract with a contracting authority based on a framework agreement or under a public contract.

The changes proposed in this consultation do not prejudge the outcome of ongoing negotiations around a successor to the 2014 PPRS. In making changes to the statutory scheme following this consultation, we propose to, where possible, continue taking into consideration the principle of broad commercial equivalence of the statutory scheme to a future voluntary scheme, if agreed.

In proposing changes to the statutory scheme, the Government is required to consider, and specifically consult on, a number of specific areas, such as the Public Sector Equality Duty and the Secretary of State's duties as set out in the NHS Act 2006. Our assessment of the proposals in relation to these statutory duties is set out at Chapter 7, with additional information provided in the accompanying Impact Assessment. This assessment did not find any significant negative impacts to the public, NHS or industry, but did show that the proposals are likely to deliver benefits through increasing the resources available to the NHS so that the public's access to treatment and services can be improved.

1. Introduction

Statutory price control of branded medicines

- 1.1. In 2008, the Government consulted on regulations to set up a statutory scheme to control the cost of branded health service medicines, the purpose of which was to safeguard the financial position of the NHS by ensuring that there would be similar limits to those in the voluntary PPRS in force at the time on the cost of branded health service medicines supplied by companies that decided not to join the PPRS.
- 1.2. The regulations governing the statutory scheme were set out in the [Health Service Branded Medicines \(Control of Prices and Supply of Information\) \(No.2\) Regulations 2008](#) ("the 2008 Regulations"), and the [Health Service Medicines \(Information Relating to Sales of Branded Medicines etc.\) Regulations 2007](#) ("the 2007 Regulations"), as amended by [SI 2013/2881](#) and [SI 2015/233](#). The control mechanism was a system of cuts to the list price of branded medicines.
- 1.3. The 2014 PPRS established a different approach to cost control, via a system of payments based on a percentage of branded medicine sales. In 2015, the Government undertook a consultation on proposals to amend the 2007 and 2008 Regulations, in particular to provide for broad commercial equivalence of the statutory scheme to the 2014 PPRS.
- 1.4. The principal proposed change was the introduction of a payment system, similar to that introduced through the 2014 PPRS. Following the 2015 consultation, [the Health Service Medical Supplies \(Costs\) Act 2017](#) ("the 2017 Act") was introduced, putting beyond doubt that the Secretary of State can introduce a payment system in the statutory scheme, such as that which exists in the 2014 PPRS.
- 1.5. The [Branded Health Service Medicines \(Costs\) Regulations 2018](#) ("the 2018 Regulations") came into force on April 1st 2018, introducing a payment system in the statutory scheme, and replacing the 2007 and 2008 Regulations. The payment percentage applied to sales of relevant medicines was set at 7.8%, the same level as the payment percentage for the 2018 calendar year operational in the 2014 PPRS. The 2014 PPRS ends on 31 December 2018.
- 1.6. The 2018 Regulations include a number of exemptions to the application of the payment system, including for small companies, low cost presentations, parallel distributed presentations and parallel imports (the latter not explicitly referenced, but effected through the definition of "relevant medicine"), and sales of medicines supplied under a contract with a contracting authority based on a framework agreement or supplied under a public contract where the relevant framework agreement or public contract was entered into before the coming into force of the 2018 Regulations.

Pharmaceutical Price Regulation Scheme

- 1.7. The [Pharmaceutical Price Regulation Scheme 2014](#) ("the 2014 PPRS" or "2014 voluntary scheme") is a voluntary scheme agreed between the Department of Health and Social Care, on behalf of the UK Governments, and the Association of the British Pharmaceutical Industry (ABPI). (The pricing of medicines is reserved to the UK Government, with the exception of Northern Ireland. Many other aspects of health policies, including those affecting the use and availability of medicines, are devolved

matters). It supports the NHS by ensuring that the branded health service medicines bill stays within affordable limits. It aims to strike a balance to promote the common interests of patients, the NHS, the industry and the taxpayer. The 2014 PPRS ends on 31 December 2018.

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

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

1.9. The Government and the ABPI are currently in negotiations on a successor voluntary scheme to the 2014 PPRS, which would operate from 1 January 2019, if agreed. The changes proposed in this consultation do not prejudge the outcome of these ongoing negotiations.

2. Why changes are required

- 2.1. The 2018 Regulations introduced a payment system in the statutory scheme with a view to establishing broad commercial equivalence of the statutory to the voluntary scheme following the approach taken in the 2014 PPRS.
- 2.2. The 2014 PPRS ends on 31 December 2018. The Government and the ABPI are currently negotiating a successor agreement, which would become operational, if agreed, from 1 January 2019. In the context of the ongoing negotiations on the voluntary scheme, it is important to offer as much clarity as possible to those companies subject to the statutory scheme, as well as to other pharmaceutical companies operating in the UK, on the Government's intended approach to the statutory scheme.
- 2.3. This consultation sets out proposals for the statutory scheme from the beginning 2019. These proposals do not prejudge the outcome of the voluntary scheme negotiations. With negotiations ongoing, there cannot currently be a default assumption of continuing alignment with any potential voluntary scheme provisions. The Government is negotiating in good faith to seek agreement on a new voluntary scheme which supports patients, the NHS and an innovative life sciences industry. However, in the event that agreement is not reached on a new voluntary scheme, all companies will become subject to the statutory scheme. The proposed timing of the implementation of the proposals therefore reflects the Government's primary purpose of safeguarding the financial position of the NHS.
- 2.4. The current payment percentage in the 2018 Regulations was set to align with that operating in the current voluntary scheme. To ensure that the Government's objective of safeguarding the financial position of the NHS can be met, we propose that any revised statutory scheme should come into force on 1 January 2019 immediately after the voluntary scheme expires on 31 December 2018. As Government requires sufficient time to consider both responses to this consultation and any final voluntary scheme agreement if concluded, as well as to reflect any changes stemming from these in Regulations, we have to begin consulting now, in parallel with the voluntary scheme negotiations. This consultation will run for a 6 week period, closing at 23:59 on 18 September. This gives consultees sufficient time to review and respond, given that the Government consulted on the main changes to the statutory scheme in the recent 2017 consultation and that the proposed changes for 2019 are limited in scope.
- 2.5. The 2017 consultation on changes to the statutory scheme and the government response identified a number of policy areas which would be reviewed in future, subject to experience of operating the scheme, relevant future developments in the structure of the medicines market and changes to broader Government or NHS policy. This included the treatment of medicines supplied under contracts with a contracting authority based on framework agreements or medicines supplied under public contracts. The changes proposed in this consultation set out our thinking on our approach to these agreements going forward.

3. Summary of the proposals

3.1. In order to address the issues identified in the last chapter, we propose introducing a number of changes.

3.2. The principal elements of these changes are:

- Setting out the expected annual payment percentages between 2019 and 2021 in Regulations, with an annual review provision, such that the statutory scheme delivers a level of savings that balances the Government's objectives of delivering best value for the taxpayer and NHS patients while ensuring both continued support for pharmaceutical research & development (R&D) and the availability of medicines to the health service on reasonable terms.
- Amending the application of the payment percentage with respect to sales of medicines supplied under a contract with a contracting authority based on a framework agreement or supplied under public contracts (henceforth, "Agreements"):
 - Retaining the exemption for sales where the relevant Agreement was entered into following an invitation to tender that closed on or before 1 April 2018;
 - Continuing the application of a 7.8% payment percentage to sales where the relevant Agreement was entered into following an invitation to tender that closed between 1 April 2018 and 31 December 2018; and
 - Treating sales where the relevant Agreement was entered into following an invitation to tender that closed after 31 December 2018 as subject to the payment percentage in force in the same way as all other sales captured by the payment mechanism, and to any revisions of the payment percentage should the Regulations be amended in the future.
- Including all biological medicinal products (including biosimilars) within the scope of health service medicines captured by the payment mechanism, price controls and information requirements:
 - All biological medicinal products (including biosimilars) which are licensed under a combination of International Non-Proprietary Name (INN) and company name, to come within scope of the payment mechanism, price controls and accompanying information requirements.

4. Payment percentage

4.1. The overarching aim for the Government in setting the proposed payment percentages in the statutory scheme from the beginning of 2019 is to achieve an overall level of spend on branded health service medicines that delivers optimum value to the taxpayer and NHS patients while safeguarding the continuing supply of medicines to the health service on reasonable terms, and taking due account of the cost of research and development (R&D). The proposals set out here do not prejudice any outcome of the ongoing negotiations around a successor voluntary scheme to the 2014 PPRS.

Allowed growth rate and forecast

4.2. The level of branded health service medicine sales that delivers these objectives can be expressed as an annual allowed growth rate of sales, in a similar way as was done for the purposes of the 2014 PPRS. This allowed growth rate can then be compared to a forecast growth rate for branded health service medicines sales to calculate a set of payment percentages which recovers the difference between the allowed and forecast level of relevant sales.

4.3. The Department has constructed a forecast against which the payment percentage for 2019 can be set. The details of the forecast methodology are set out in Chapter 8 of this consultation. The payment percentage is then set to recover the difference between forecast sales value and allowed sales value in each year.

4.4. Relevant sales are defined as sales of branded health service medicines of members of the voluntary scheme as well companies subject to the statutory scheme, including sales of parallel imports but with the following exclusions:

- sales of small companies (those with annual sales below £5m) for both statutory and voluntary schemes; and
- sales of presentations supplied under extant contracts with a contracting authority based on a framework agreement or under public contracts (entered into on the basis of an invitation to tender that closed on or before 1 April 2018) for the statutory scheme.

4.5. We propose to set an allowable growth rate on relevant branded health service medicine sales for the period 2019-2021 that is consistent with the average annual growth rate agreed for the duration of the [2014 voluntary scheme](#).

4.6. An alternative “do-nothing” option of retaining the current payment percentage of 7.8% has also been considered. The annual growth rate of branded health service medicines sales resulting from retaining this payment percentage, calculated on the basis of the Government’s forecast, would rise from 6.7% in 2019 to 8.8% in 2021.

Impact of the proposed allowed growth rate

4.7. The Impact Assessment published alongside this consultation demonstrates the significant benefits to overall population health and the UK economy which are achievable through limiting expenditure on branded health service medicines sales and reinvesting the resulting savings in the health service. The analysis therefore points to lower allowed growth rates delivering better overall value for the taxpayer.

- 4.8. In choosing an allowed growth rate, the Department is mindful of the need for medicinal products to be available for the health service on reasonable terms, and of the costs of research and development.
- 4.9. On the basis of the available evidence, we believe that any impacts on R&D investment in the UK life sciences sector would be limited. As the pharmaceutical industry operates in a global market, investment decisions are taken with a view to overall expected global returns on an investment, on which the relatively small UK market has only limited impact. It is possible that lower than expected revenues from branded health service medicine sales as a result of these proposals may have an impact on boardroom sentiment towards the UK. However, the available independent research points to supply side factors such as the availability of a skilled labour force, strong research environment and infrastructure, and a favourable tax regime as the key determinants in determining a country's share of global R&D investment.
- 4.10. Potential negative effects on the supply of branded health service medicines can be mitigated by the existing provisions allowing for price increases for specific products, where the application of the payment percentage makes continuing supply no longer commercially viable.
- 4.11. These assessments are further supported by experience from the 2014 PPRS, where the available evidence suggests there were no material negative supply effects; and, according to the information supplied to the Department by members of the 2014 PPRS, companies have remained profitable throughout the scheme.

Proposed payment percentages

- 4.12. The table below sets out the proposed payment percentages for our preferred option. These are calculated from currently available data and based on an allowed annual rate of growth, from the expected 2018 baseline, on relevant branded health service medicines sales that is consistent with the average annual allowed growth rate agreed in the [2014 voluntary scheme](#). We will continue to receive updates to verify this data. The payment percentage figures may then change slightly, to be either slightly higher or slightly lower, at the point any decision is made as to whether to amend the current payment percentage and the extent of that change.

Table 1: Proposed payment percentages

Year	2019	2020	2021
Proposed payment percentage	9.9%	15.8%	21.7%

- 4.13. In contrast, a 'do nothing' scenario in which the payment percentage in the statutory scheme remained unchanged at 7.8% would result in a compound annual growth rate of branded health service medicines sales after application of the payment percentage of 7.9% over the period 2018-2021, which would result in significantly lower levels of savings for the NHS, and thereby lower health gains for patients and lower overall value to the taxpayer.
- 4.14. The Government proposes to continue the exemptions currently operating in the scheme, with the exception of a change to the exemption for sales of branded health service medicines supplied under contracts with a contracting authority based on a framework agreement or supplied under public contracts, as outlined in chapter 6.

- 4.15. When reaching a final determination, we will take into account any responses received to this consultation on the proposed payment percentages and the methodology underlying their calculation. Given the aim to achieve, where possible, broad commercial equivalence of the statutory scheme to any future voluntary scheme, subject to any responses on that approach, we will also take into account any final agreement reached in the ongoing negotiations around a successor voluntary scheme. This does not prejudge the outcome of the ongoing voluntary scheme negotiations.
- 4.16. We will use the annual review of the statutory scheme to consider whether the payment percentages set out for the period 2019-2021 remain appropriate as the scheme continues.

Consultation questions

- 1) Do you have any comments on the proposed payment percentages or the methodology used in determining the payment percentages? Please give reasons to explain any comments and provide any additional evidence or analysis you may have.**
- 2) Do you agree with the overarching aim of maintaining broad commercial equivalence of the statutory to the voluntary scheme? If not, please give your reasons.**

5. Biological health service medicines

- 5.1. Branded biological (as defined at regulations 8(1) of the Human Medicines Regulations 2012) health service medicines (including biosimilars) are currently within the scope of the payment mechanism of both the 2018 Regulations and the 2014 PPRS. As biosimilars, while interchangeable by the prescribing clinician, are not substitutable at the point of dispensing medicines, competitive forces generally act more slowly. Further, decreases in actual selling prices are likely to be lower than if competition were arising from identical generics. Analysis undertaken by the Department has shown that the average price decline upon loss of exclusivity is significantly lower for biological medicines than for non-biological medicines, with a c.70% average drop in expenditure for non-biological medicines compared to a c.45% drop for biological medicines. We remain of the view, therefore, pending any additional evidence and analysis received as part of this consultation, that it is appropriate for these health service medicines to be captured by the payment system, price control mechanisms and information requirements in the statutory scheme as market forces do not operate in the same way as they do for identical unbranded generics.
- 5.2. The Medicines and Healthcare products Regulatory Agency (MHRA) requires biosimilars to be marketed as branded medicines, which brings them within the scope of the payment system of the statutory scheme. Recently, however, the European Medicines Agency (EMA) has granted a marketing authorisation to a biosimilar medicine under a combination of International Non-Proprietary Name (INN) and company name.
- 5.3. To ensure all biosimilars continue to fall within the scope of the payment system irrespective of the naming convention, we therefore propose to amend the 2018 Regulations to bring all biological health service medicines, including biosimilar medicines and those marketed under a combination of INN and company name, within the scope of the payment mechanism, price control mechanisms and information requirements in the statutory scheme.

Consultation questions

- 3) **Do you agree with the proposal to bring biological medicinal products (including biosimilars) marketed under a combination of INN and company name within the scope of the payment mechanism, price controls and corresponding information requirements? Please give your reasons**
- 4) **Do you have any evidence of other products marketed under a combination of INN and company name for which competition is limited and which could therefore be considered for inclusion in the statutory scheme?**

6. Framework agreements and public contracts

- 6.1. The 2018 Regulations exempt from the payment percentage any income from sales under public contracts or contracts with a contracting authority based on framework agreements (together referred to as “Agreements” in the remainder of this chapter) that were entered into on or before, or entered into following an invitation to tender which closed on or before (for short, “entered into” in the remainder of this chapter) the date of coming into force of the 2018 Regulations.
- 6.2. This exemption from the payment percentage does not apply to medicines supplied under Agreements entered into after 1 April 2018. Consequently, sales under Agreements entered into after 1 April 2018 are currently subject to a 7.8% payment percentage.
- 6.3. From 1 January 2019 onward (the date on which new Regulations are expected to come into force), there will therefore be three cohorts of Agreements, segmented by the time they were entered into:
- Cohort A: Presentations supplied under Agreements entered into before 1 April 2018, currently exempt from the payment percentage for the duration of those Agreements;
 - Cohort B: Presentations supplied under Agreements entered into on or after 1 April 2018, but before 1 January 2019, currently subject to a payment percentage of 7.8%
 - Cohort C: Presentations supplied under Agreements entered into on or after 1 January 2019
- 6.4. We propose to apply the payment percentages differently according to the cohort to which the Agreement belongs. The proposal is set out below:
- 6.4.1. In keeping with the rationale for the exemption of medicines supplied under extant Agreements set out in our response to the 2017 consultation, we propose to retain the existing exemptions included in the 2018 Regulations for Cohort A for the duration of the relevant Agreement.
- 6.4.2. Presentations supplied under Agreements in Cohort B are currently subject to a payment percentage of 7.8%. We have considered changing the applicable payment percentage for this cohort to the levels set out in Chapter 4, or keeping the payment percentage at the current level for the lifetime of the Agreements. On the basis that companies that have entered into such Agreements will not have had any notice as to the Government’s approach with respect to the treatment of sales under these Agreements before entering into them, we propose not to apply any future changes to the payment percentage to the sales of presentations supplied under Agreements in Cohort B. We propose to amend the 2018 Regulations to maintain the payment percentage for Cohort B products at 7.8% for the lifetime of their current Agreement.
- 6.4.3. In the 2017 consultation response, the Government was not able to confirm a proposed approach for setting future payment percentages at the time. For presentations supplied under Agreements in Cohort C, we have considered two options:

(1) retaining the payment percentage for each agreement at the level applicable at the time the agreements are entered into;

(2) subjecting these agreements to the payment percentages set out in Chapter 4, including any potential future revisions.

Option (1) would treat sales under Agreements in Cohort C in the same way as sales under Agreements in Cohort B, while Option (2) would treat them in the same way as all other sales within the scope of the payment mechanism (i.e. those not made under Agreements).

As set out in the 2017 consultation, the reason for not exempting Agreements entered into on or after the date of coming into force of the 2018 Regulations was that companies were able to take into account the application of the payment percentage as part of their tenders. Going forward, we therefore propose to apply the payment percentages as set out in Table 1, along with any changes to payment percentages that may result from future annual reviews of the agreed values, to Cohort C, given that companies will be aware before entering into an Agreement that they will be subject to a payment percentage on their sales (the level of which may vary depending on the outcome of the annual reviews) from January 2019. For clarity, this would mean that sales of presentations under an Agreement entered into on or after 1 January 2019 would be subject to a payment percentage of 9.9% in 2019, 15.8% in 2020, and 21.7% in 2021, unless the annual review resulted in a change to the payment percentage, in which case the sales under the Agreement would be subject to the payment percentage proposed as part of the annual review.

6.5. We believe that taken together the proposed changes would contribute to delivering savings without significantly increasing the complexity of operating the statutory scheme or unduly disadvantaging companies that have taken commercial decisions based on the information available at the time.

Consultation questions

5) Do you agree with the proposed treatment of the Agreements within each of the cohorts? Please give your reasons

7. Statutory requirements

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

- 7.1. The Health Service Medical Supplies (Costs) Act 2017 amended the NHS Act 2006 to include requirements that consultation about the exercise of powers in section 263(1) (statutory schemes) must include consultation about:
- The economic consequences for the life sciences industry in the UK;
 - The consequences for the economy of the UK; and
 - The consequences for patients to whom any health service medicines are to be supplied and for other health service patients.
- 7.2. These requirements are in addition to the historical requirements in the NHS Act 2006 for the Secretary of State to bear in mind the particular need for medicinal health service medicines to be available for the health service under reasonable terms, and the cost of research and development (NHS Act 2006, section 266(4) and (4A)).
- 7.3. An assessment of the likely impact of the proposals, including on the above areas, is set out in full in the Impact Assessment which accompanies this consultation. However, a summary of the assessment relating to those areas outlined in the NHS Act 2006 is detailed below.
- 7.4. The baseline assumption in the impact assessment is that the volume of sales subject to the statutory scheme grows in line with the Department's forecast for overall branded health service medicines sales.
- 7.5. This assessment shows that the gross revenues of pharmaceutical companies is expected to reduce in the period 2019-2021 as a result of the proposals outlined in this document, compared to a "do-nothing" option of retaining a 7.8% payment percentage for the same time frame. As it is estimated that 30% of pharmaceutical revenue is ordinarily taken as profit, the reduction in revenue would lead to an estimated reduction in profits of £49 million in 2021. As only 10% of drug spend is estimated to be spent on domestic production, and assuming that revenue is allocated in the same proportion, this implies a loss of profit to UK shareholders of £4.9 million. Taking account of the weighting of lost profits according relative wealth, in line with HMT's Green Book, the resulting in a loss of profit to UK shareholders is estimated to be £3.4 million in 2021.
- 7.6. The reduction in revenue may have a negative impact on the level of R&D investment made by statutory scheme companies, of which a portion may be in the UK. Based on the estimated proportion of revenues pharmaceutical companies devoted to R&D (estimated at 36%), and the expected level that would be invested in the UK (around 10%), and the estimate of the value of R&D investment to the UK (30%), it is estimated that the loss to the UK economy arising from the proposals would have a value of £1.8 million in 2021.
- 7.7. It has been suggested that decreasing NHS spending on pharmaceuticals could make the UK a less attractive location for foreign investment in R&D. However, the available evidence suggests factors such as availability of expert scientific labour and favourable tax conditions impact are of greatest significance in decisions to locate

R&D activity, and there is no obvious reason why company revenues from the NHS should affect the attractiveness of the UK as a location for R&D.

- 7.8. The proposals are expected to have benefits to the UK economy as a whole, and to health service patients, as well as to the availability to the NHS of medicinal health service medicines under reasonable terms. The proposals should reduce the cost of branded medicines to the NHS, thus providing additional resources to provide NHS treatments and services that will improve the health of NHS patients. The value of the health benefits provided by these additional treatments and services is estimated at £651 million in 2021. Improving patient health is expected to have beneficial consequences for the UK economy through increased workforce productivity and reduced use of resources, such as formal and informal care, which are estimated to have a value of £151 million in 2021.
- 7.9. In addition to the results of the baseline scenario described above, an alternative scenario has been considered in which the statutory scheme applies to the entirety of branded health service medicines sales in the UK, including those of current voluntary scheme members. This scenario illustrates either a situation in which no voluntary scheme is agreed, or the limit of a situation in which companies switch from the voluntary into the statutory scheme.
- 7.10. The analysis shows that both costs and benefits would increase by the same magnitude, such that the net effect of the proposals would remain significantly positive. The value of health benefits is estimated at £5,026m in 2021, while additional benefits to the UK economy from increased workforce productivity and reduced use of resources are estimated at £1,167m. Lost UK shareholder profits are estimated at £38m in this scenario, while lost benefits from R&D spill-overs are estimated at £14m in 2021.

Consultation questions

6) Do you agree with the analysis in the accompanying Impact Assessment on:

a) The impact of our proposals?

b) The effect on those areas where the NHS Act 2006 requires we consider and consult?

7) Do you have any evidence that would help inform, and improve the quality of, our analysis?

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

- 7.11. In considering the proposed changes, Ministers must comply with the Public Sector Equality Duty (PSED) and consider the Family Test. Ministers must also comply with their general duties under the National Health Service Act 2006 (NHS Act 2006), where applicable. Some further information about these duties is given below.
- 7.12. The need to comply with the PSED and the Family Test arises on each occasion that Ministers perform their public functions. The general duties in the NHS Act 2006 require the Secretary of State to have regard to certain things (such as the need to reduce health inequalities) or to act with a view to certain things (such as improving

the quality of health services) whenever he is exercising functions “in relation to the health service” in England.

7.13. We consider that, in this case, the Family Test does not apply to these provisions. Our analysis is set out below.

Public Sector Equality Duty (Section 149 Equality Act 2010)

7.14. This duty comprises of three equality objectives, each of which needs to be considered separately. Ministers must have regard to the need to:

- Eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010;
- Advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it;
- Foster good relations between persons who share a relevant protected characteristic and persons who do not share it.

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

7.16. We considered the implications for each of the three equality objectives in relation to the proposals outlined above. The Government’s assessment is that there is no 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. The Government also recognises the necessity for provisions to allow for either temporary or permanent increases in maximum price in order to address short term or long term supply problems and ensure continued adequate supply of essential medicines.

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

7.17. The Secretary of State is required to continue the promotion in England of a comprehensive health service designed to secure improvement:

- in the physical and mental health of the people of England; and
- the prevention, diagnosis and treatment of physical and mental illness.

7.18. In the 2017 consultation response document, we set out the Government’s view at the time that the facility to increase prices was the right way to address short or long-term supply problems, where these circumstances are dependent on UK pricing.

7.19. We have given this further consideration in the intervening period, and have not seen any further analysis or evidence to suggest that price increases are an insufficient mechanism to address these potential concerns, particularly in light of other activity described below. We envisage, therefore, that if it became economically unviable to supply a medicine at the current price, companies could increase prices to the limit of the maximum price, or, if necessary, seek temporary or permanent increases in the maximum price for supply reasons. It was recognised that, if this action was required, the savings produced by the payment system for that health service medicine would be offset partially, or in full, by the increase in price. However, this would allow for the market to determine the most efficient level of price increase (and reduction in savings to the NHS) necessary to secure adequate supply.

7.20. In addition, by generating greater savings for the NHS, the proposals should have a positive impact by increasing the resources available to provide effective treatments and services to patients across the NHS.

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

7.21. The Secretary of State is required to exercise his NHS functions with a view to securing continuous improvement in the quality of services provided to individuals in connection with the prevention, diagnosis or treatment of illness, or public health.

7.22. The expected benefit of the statutory scheme measures is increased savings which will have a positive indirect impact to secure continuous improvement in the quality of services by increasing the resources available to the NHS to provide treatment and other services to patients.

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

7.23. Regard must necessarily be had to the values, principles, pledges and rights in the NHS Constitution.

7.24. The changes to the statutory scheme do not have a negative impact on the rights provided by the NHS Constitution. The changes should have a positive impact by decreasing the cost of the NHS drugs bill and thereby increasing the resources available to the NHS, which can be used to provide additional treatment and other services to patients to improve lives.

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

7.25. When exercising his functions in relation to the NHS, the Secretary of State must have regard to reduce inequalities between the people of England with respect to the benefits that they can obtain from the NHS.

7.26. It is important to emphasise that this duty is separate from the PSED. Socio-economic impacts need therefore to be considered in terms of other socio-economic factors such as income, social deprivation and rural isolation.

7.27. The 2017 consultation noted that concerns were raised around the ability of some segments of the medicines market to absorb a payment percentage, specifically the market for blood products. Such effects on specific sub-segments of the market have the potential to disadvantage certain patient groups, e.g. those suffering from haemophilia. We have not seen any evidence that the introduction of a payment percentage in the statutory scheme has had detrimental effects on the supply of medicines to the health service.

7.28. We do not consider, therefore, that the changes to the statutory scheme will adversely affect health inequalities. Additionally, by generating greater savings for the NHS, the proposals should have a positive impact by increasing the resources available to provide effective treatments and services to patients across the NHS.

To promote autonomy (section 1D NHS Act 2006)

7.29. The Secretary of State must have regard to securing, so far as is consistent with the interests of the NHS:

- That any other person exercising NHS functions or providing services for its purposes is free to exercise those functions or provide those services in the manner that it considers most appropriate; and
- That unnecessary burdens are not imposed on any such person.

7.30. The changes to the statutory scheme do not impact on the freedom of NHS bodies or providers to provide NHS services as they see fit.

To promote research (section 1E NHS Act 2006)

7.31. In exercising his functions in relation to the NHS, the Secretary of State must promote:

- Research on matters relevant to the NHS; and
- The use in the NHS of evidence obtained from research

7.32. In addition, the Secretary of State is also required, under National Health Service Act 2006, s266 (4) (b), to bear in mind the costs of research and development.

7.33. The proposed measures are expected to reduce the revenues of pharmaceutical companies, compared to the “do nothing” option, which may result in decreased investment in R&D – of which a portion may be in the UK, providing “spill-over” losses to the UK economy.

7.34. The proportion of pharmaceutical company revenues devoted to R&D has been estimated at 36%. Of this, not more than 10% would be expected to be invested in the UK, according to the UK’s proportion of the global pharmaceutical industry.

7.35. Investment in R&D is not, of itself, a net benefit (as it represents deployment of resources that would otherwise have found some other use). However, the Department considers that R&D investment leads to “spill-over” effects – for example through the generation of knowledge and human capital - which generate net societal benefits, compared to other uses. The Department for Business, Enterprise, Investment and Skills estimates the value of these additional benefits to be 30% of the value of the investment.

7.36. Applying the estimates above to the projected decrease in pharmaceutical revenues gives a loss of £1.8m to the UK economy from reduced R&D investment in 2021.

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

7.37. The Secretary of State must exercise his NHS (and other) functions as to secure that there is an effective system for the planning and delivery of education and training for the persons employed, or considering becoming employed, in the NHS or connected activities.

7.38. We have considered this duty in relation to the measures and none of the measures impact on the Secretary of State’s functions to secure education and training.

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

7.39. The Secretary of State is required to keep under review any matter, including taxation, which might affect the ability of health care providers to provide NHS services or the reward available to them for doing so.

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

The Family Test

7.41. The Secretary of State must consider, and where sensible and proportionate, apply the Family Test when making policy. The five family test questions are:

- What kinds of impact might the policy have on family formation?
- What kind of impact will the policy have on families going through key transitions such as becoming parent, getting married, fostering or adopting, bereavement, redundancy, new caring responsibilities or the onset of a long-term health condition?
- What impacts will the policy have on all family members' ability to play a full role in family life, including with respect to parenting and other caring responsibilities?
- How does the policy impact families before, during and after couple separation?
- How does the policy impact on those families most at risk of deterioration of relationship quality and breakdown?

7.42. We have considered the Family Test and consider it not applicable to the changes to the statutory scheme.

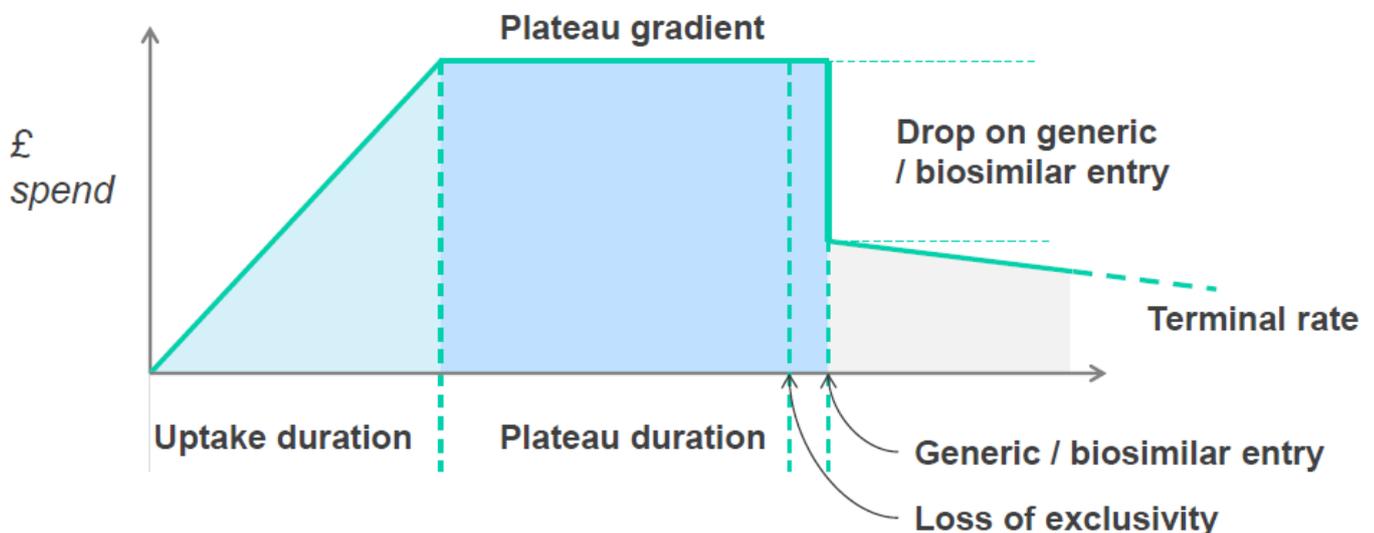
Consultation questions

8) We welcome any comments, including any evidence, on our assessment of proposals in relation to the public sector equality duty and Secretary of State duties under the NHS Act 2006.

8. Forecasting model

- 8.1. In order to determine the payment percentages required from the beginning of 2019 to deliver the Government's overall allowable growth rate as set out in Chapter 4, the value of total sales of branded medicines has to be forecast. The payment percentage can then be set based on the difference between forecast sales and allowable sales under the Government's affordability target.
- 8.2. The forecasting methodology is based around a lifecycle approach to expenditure.
- 8.3. Figure 1 outlines the different phases in a product lifecycle, together with the key parameters for which values have been estimated as part of the modelling. We have taken an evidence-driven, statistical approach to deriving these parameters using observations of historical data.

Figure 1: Product lifecycle and key parameters



8.4. Key parameters of the product lifecycle in the model are:

- *Uptake duration*
Measures the time between product launch (derived from the first significant expenditure on the molecule in our data source) and the point at which the trend in expenditure changes (often due to the target patient population having been reached). The method by which the value for the parameter has been calculated (together with the cohort growth assumption, see below) is through a best fit of historic data for spend on products launched from 2008. Uptake gradient is not estimated as a fixed parameter; rather it is generated based upon the individual product data (i.e. continuing the existing trend).
- *Plateau duration*
Taken as the time between the end of the uptake phase and patent expiry. The date of patent expiry has been taken from known sources for each molecule. This is predominantly a UK database which includes Supplementary Patent Certificates and similar extensions. The European date is used in any cases where these were not available.

- *Plateau gradient*
Rate of change in spend between end of uptake period and patent expiry, estimated from observed change of spend in data.
 - *Gap between loss of exclusivity and generic entry*
When a branded medicine loses exclusivity (due to the expiry of their intellectual property) it is likely that a generic or biosimilar competitor will enter the market, causing expenditure to drop. We have approximated this reduction in expenditure through a step-change. In many cases, the drop in expenditure will be more gradual due to the time required to either for the competitors to enter the market and for these generic or biosimilar medicines to get used. In order to avoid over-estimating the speed with which this reduction can be achieved we have incorporated a delay between loss of exclusivity and observable drop in spend.
 - *Drop on generic/biosimilar entry*
This reflects the blended impact of price decay once a branded medicine goes off patent (as generic, branded generics and biosimilars typically seek to obtain market share through lowering prices) and a volume shift as prescribers move from branded to generic medicines. The parameter is estimated by looking at the percentage point difference in the level of expenditure before and after patent expiry for non-biological medicines. For biological medicines, initial estimates were clinically validated and revised upwards to account for expected larger price declines in future due to policy intervention, namely the stated objective of NHS England to increase the uptake of biosimilar medicines.
 - *Terminal rate*
Estimated from actual spend data; as estimates were not materially different from zero, the terminal growth rate is assumed to be 0% in the model.
- 8.5. Following patent expiry, we have applied an assumption regarding the proportion of expenditure on a molecule that can be attributed to expenditure on the branded originator and expenditure on the generics.
- 8.6. The estimation of parameters was carried out using two data sources. For primary care medicines, [NHS BSA prescribing data](#) for the period February 2008 to March 2017 was used. For secondary care medicine, Pharmex, which is a recording system used for invoices by hospital pharmacies, data for the period January 2007 to March 2017 was used. These are England only sources, and therefore a standard scaling factor of 1.25 has been applied to approximate to UK spend.
- 8.7. The product lifecycle parameters have been estimated at a category level for four different categories of medicines that from our data evidently behaved differently over their lifecycle. The model distinguishes between biological and non-biological medicines, and separate sets of parameters have been estimated for both categories for primary and secondary care sales.

Consultation question

9) Do you have any comments on our use of a data-driven approach to forecasting based on product lifecycles? Please give your reasons

8.8. Table 2 below shows the parameter values used for producing the central forecast.

Table 2: Parameter values overview

Parameter	Primary care: Non-biological	Primary care: Biological	Secondary care: Non-biological	Secondary care: Biological
Uptake duration	80 months	80 months	70 months	70 months
Plateau duration	78 months	78 months	88 months	88 months
Plateau gradient	-1%p.a.	1%p.a.	5%p.a.	8%p.a.
Loss of exclusivity/generic entry gap	6 months	6 months	6 months	6 months
Drop on generic entry	70%	45%	70%	45%
Terminal growth rate	0%	0%	0%	0%
Cohort growth rate	10%	10%	0%	20%

8.9. We used our parameters to generate the forecast differently depending on whether a product is already launched, and therefore has a reliable time series of historic expenditure to create an individual forecast, or whether it is a recent or future launch, where we do not have this capability.

8.10. For products already on the market that were launched prior to 2015 (“established products”), we applied the set of parameters estimated for that particular category of medicine to the individual historic spend data to generate an individual product lifecycle. The product lifecycle is aligned to the loss of exclusivity date (see Plateau duration above). The plateau duration and uptake duration periods are defined in relation to this. For example, a primary non-biological product with a loss of exclusivity date in January 2025 would have a plateau period defined as July 2018 to January 2025 and an uptake period defined as November 2011 to July 2018.

8.11. The plateau gradient parameter captures a particularly complex market dynamic. This is because it is representing the stage of a lifecycle where there are most likely to be two counteracting effects on the trend for molecules in our historic dataset, which our methodology captures and incorporates into the forward projection. The first is competition within a therapeutic class, when the cannibalisation of a given product’s sales from new, branded competitors succeeds in capturing some of the market share of the medicine, despite it still being protected from generic competitors by the patent. In addition to the potential impact on share, the manufacturer may reduce the price of the product to ensure it remains competitive. This would result in a negative impact on plateau growth. However, increasingly pharmaceutical companies pursue an R&D strategy based around the licensing of additional indications for new therapeutic purposes, which may launch some years after the original indication came to market. Market prognosis reports show this is a particularly prominent trend in oncology. This will increase sales and create a positive growth, even after the main period of uptake has ended, by expanding the patient population that could be eligible for treatment.

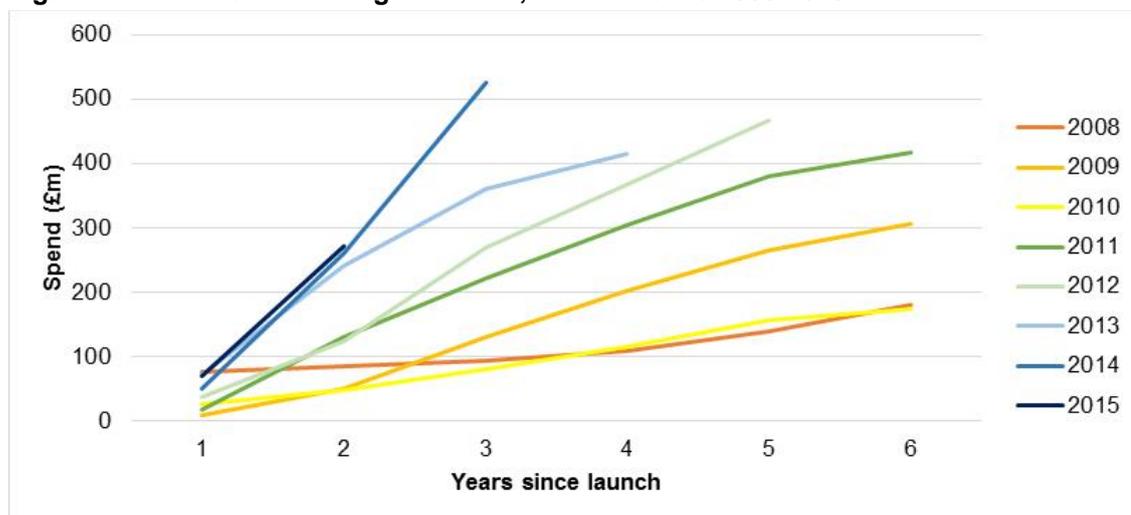
8.12. Our analysis established that in primary care, the two effects broadly cancel out, resulting in trends of -1 and 1 per cent respectively for non-biological and biological medicines. However, our analysis shows that the former effect is outweighed by the

latter for biological medicines in secondary care, reflected in a high plateau gradient. The result is that we do expect secondary care medicines launches over the last decade to still contribute to the overall trend of branded medicines growth.

10) Do you agree with our approach to modelling plateau gradient in the lifecycle? Please give your reasons and provide any evidence or analysis that would support the refinement of our assumptions.

- 8.13. For products launched after 2015 (“recent launches”), where there is either only a short series of historical data or no expenditure at all, we have applied the parameters to the aggregated total expenditure for all products launched or to be launched during the course of that year, which we term an annual cohort. The lifecycle is generated as these cohorts. This approach is also applied to assumed products launched in future (i.e. from 2019 onwards – termed “future launches”).
- 8.14. We can also look at data on historic medicines spend split by annual launch cohort in the same way, displayed in Figure 2 below. When we do this normalised disaggregation it shows that for more recently launched products, spend at each given point in their lifecycle is higher than was observed for the cohorts launched in earlier years at the exact equivalent point in their lifecycle. In effect, expenditure for the totality of all products launched in 2015, one year after their launch, grows more steeply and reaches a higher point than expenditure on the totality of products in 2014 had reached one year after their launch.

Figure 2: Normalised cohort growth rate, new launches 2008-2015



- 8.15. This effect is assumed to continue throughout the forecast period and is captured in the model through the estimation of an annual cohort growth rate parameter. This parameter was calculated (together with the uptake duration) to best match the observed spending profile for products launched since 2008. It explains why the impact of new medicines in our forecast is assumed to increase over time. The size of future cohorts is scaled however only to the lifecycle shape of the most recent cohorts (2015, 2016 and 2017).

Consultation question

11) Do you agree with our approach to modelling cohort growth rates? Please give your reasons and provide any evidence or analysis that would support the refinement of our assumptions.

- 8.16. We have looked at aggregated trends across settings, therapy area and type of molecule and triangulated this with expert opinion and analyst views. We believe the trends suggest our model is face valid.
- 8.17. The model was used to generate a series of forecast growth rates for total branded medicines spend for the period 2018 to 2021. These growth rates were then applied to the level of sales in 2018 to 2021, which is required for the calculation of the payment percentage as described in Chapter 4.

9. Responding to the consultation

- 9.1. The consultation questions set out in this document are set out in chapter 10 below. The consultation will run from 7 August 2018 to 18 September 2018. We welcome responses from any interested person, business, or organisation.
- 9.2. You can respond to this consultation by **18 September 2018** via an online template, which can be accessed using the following link:
<https://consultations.dh.gov.uk/medicines-pricing-and-supply/changes-to-statutory-scheme-for-branded-medicines>
- 9.3. If you have additional evidence you wish to submit, this can be sent by email to Statutory_scheme_consultation@dh.gsi.gov.uk, or you can send your response by hard copy to:

Statutory Pharmaceutical Pricing Scheme Consultation
C/o Samuel Jackson
Medicines Pricing team
39 Victoria Street
London
SW1H 0EU

Please note that although hard copy responses will be accepted, electronic responses via the online form are preferred. We ask that hard copies are therefore only submitted by those unable to use the online form.

Comments on the consultation process itself

- 9.4. If you have concerns or comments which you would like to make relating specifically to the consultation process itself please contact the Consultations Coordinator at:
- Department of Health and Social Care
2e26, Quarry House
Leeds
LS2 7UE
E-mail consultations.co-ordinator@dh.gsi.gov.uk

Please do not send consultation responses to this address.

Confidentiality of information

- 9.5. We manage the information you provide in response to this consultation in accordance with the Department of Health and Social Care's [Information Charter](#).
- 9.6. Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 2018 (DPA) and the Environmental Information Regulations 2004).
- 9.7. If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of

confidence. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

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

10. Summary list of questions

- 1) Do you have any comments on the proposed payment percentages or the methodology used in determining the payment percentages? Please give reasons to explain any comments and provide any additional evidence or analysis you may have.
- 2) Do you agree with the overarching aim of maintaining broad commercial equivalence of the statutory scheme to the voluntary scheme? If not, please give your reasons.
- 3) Do you agree with the proposal to bring biological medicinal products (including biosimilars) marketed under a combination of INN and company name within the scope of the payment mechanism, price controls and corresponding information requirements? Please give your reasons
- 4) Do you have any evidence of other products marketed under a combination of INN and company name for which competition is limited and which could therefore be considered for inclusion in the statutory scheme?
- 5) Do you agree with the proposed treatment of the Agreements within each of the cohorts? Please give your reasons
- 6) Do you agree with the analysis in the accompanying Impact Assessment on:
 - a. The impact of our proposals?
 - b. The effect on those areas where the NHS Act 2006 requires we consider and consult?
- 7) Do you have any evidence that would help inform, and improve the quality of, our analysis?
- 8) We welcome any comments, including any evidence, on our assessment of proposals in relation to the public sector equality duty and Secretary of State duties under the NHS Act 2006.
- 9) Do you have any comments on our use of a data-driven approach to forecasting based on product lifecycles? Please give your reasons
- 10) Do you agree with our approach to modelling plateau gradient in the lifecycle? Please give your reasons and provide any evidence or analysis that would support the refinement of our assumptions.
- 11) Do you agree with our approach to modelling cohort growth rates? Please give your reasons and provide any evidence or analysis that would support the refinement of our assumptions.