All Party Parliamentary Group on Skin

*This paper was prepared by the Group's secretariat Decideum Ltd**

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Parliamentary questions on Specials [2018]

Background:

Specials are unlicensed, bespoke, and specially prepared to order medicines for patients who cannot take mainstream drugs or with conditions for which no authorised drugs exist.

The APPGS is concerned about the lack of availability of Specials for patients, who report refusal of GPs to prescribe, or of Clinical Commissioning Groups (CCGs) to fund, on the grounds of cost.

The current system for the reimbursement of Specials in England and Wales is no longer fit for purpose for the NHS and overcharging by some suppliers is preventing many patients from receiving the correct treatment. The England & Wales Specials Tariff needs to be investigated.

Parliamentary outreach and tabled questions:

05th September
Dr Philippa Whitford MP: To ask the Secretary of State for Health and Social Care, what estimate he has made of the cost to the NHS in England of special medicinal products over the last 12 months.
Steve Brine MP: In the most recent 12 month period for which data is available (June 2017 to May 2018) the cost of National Health Service special medicinal products dispensed in the community in England was £70.5 million down from £135.5 million in 2010.

04th September
Dr Philippa Whitford MP: To ask the Secretary of State for Health and Social Care, whether he has undertaken an impact assessment on the potential beneficial effects of regulating the dispensing of special medicinal products in England.
Steve Brine MP: We have made no such assessment. The supply of special medicinal products is regulated in the United Kingdom by the Human Medicines Regulations 2012. In addition, in England, NHS dispensing by pharmacies is regulated by the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

12th July
Mary Glindon MP: To ask the Secretary of State for Health and Social Care, whether he plans to reduce the cost to the NHS of reimbursement prices for special medicinal products; and if he will make a statement.
Steve Brine MP: Since 2011 for the most commonly prescribed special medicinal products, known as "specials", a reimbursement price is listed in the Drug Tariff. We have continued to expand the number of products for which there is a reimbursement price listed in the Drug Tariff, thus reducing the cost and the variation in what the National Health Service pays. Since these reimbursement arrangements were introduced in 2011 we have observed that in England the average cost for specials listed in the Drug Tariff decreased by 58% between 2011 and first quarter of 2018.
We have taken powers in the Health Service Medical Supplies (Costs) Act 2017, which enable the Government to reimburse for specials dispensed in primary care in different ways such as considering quotes of suppliers and not reimbursing pharmacies at all if, for example, they have been provided the medicine by a central service. We are developing proposals, which will be subject to consultation with relevant stakeholders.

12th July

Mary Glindon MP: To ask the Secretary of State for Health and Social Care, what information on the costs of goods he will require of manufacturers of special medicinal products under the Health Service Medical Supplies (Costs) Act 2017 and subsequent regulations; and if he will bring forward further regulatory proposals to control the costs of those products.

Steve Brine MP: Under the Health Service Products (Provision and Disclosure of Information) Regulations 2018, manufacturers, importers and wholesalers of special medicinal products are required to provide the Department, every quarter, with purchase and/or sales information about products already listed with a price in the Drug Tariff and products that are being considered for listing with a price in the Drug Tariff. This information will be used to inform the reimbursement prices for special medicinal products. In addition, under the same Regulations, the Department can request ad-hoc information about sales and purchases as well as costs about any special medicinal products. The Health Service Medical Supplies (Costs) Act 2017 enables the Government to reimburse for specials dispensed in primary care in different ways such as considering quotes of suppliers and not reimbursing pharmacies at all if, for example, they have been provided the medicine by a central service. We are developing proposals, which will be subject to consultation with relevant stakeholders.

06th July

Wera Hobhouse MP: To ask the Secretary of State for Health and Social Care, if he will close the legal loopholes to make the market for unlicensed medicinal products less restricted.

Jackie Doyle-Price MP: The Medicines and Health products Regulatory Agency (MHRA), the Government body responsible for the safety and licensing of medicines in the United Kingdom, is not aware of any legal loopholes for the supply of human unlicensed medicinal products. Before a human medicine can be marketed or sold in the UK, a number of licences are required. The product itself must have a licence called a 'marketing authorisation' unless an exemption applies. UK medicines legislation contains a provision for the supply of an unlicensed medicine (commonly known as 'specials') which is provided for by way of an exemption from the requirement for a marketing authorisation. In the interests of public health this exemption is narrowly drawn because these products, unlike products holding a marketing authorisation, will not have been assessed and approved against the criteria of safety, quality and efficacy in the UK. Unlicensed medicines can be manufactured in the UK under European Union good manufacturing practice or imported into the UK by the holder of an appropriate licence issued by the MHRA. Notifications prior to importation of unlicensed medicines are required and are assessed by the MHRA and objections may be raised where there are prohibitive safety or quality concerns. Any person that sells or supplies an unlicensed medicine is required to keep records and report suspected adverse drug reactions.

28th June

Nigel Dodds MP: To ask the Secretary of State for Health and Social Care, with reference to his Department's consultation, Proposed changes to the statutory scheme to control the cost of branded health service medicines, whether his Department plans to introduce fixed tariff prices for prescribed special medicinal products.

Steve Brine MP: The statutory scheme regulates the cost of branded medicines. It is not the vehicle for setting reimbursement prices for special medicinal products (also known as 'specials'). In England since November 2011 reimbursement prices for the most commonly prescribed specials are listed in the Drug Tariff (i.e. 'fixed tariff prices'). However, we recognise that there are issues with the reimbursement arrangements for specials which do not have a reimbursement price listed in the Drug Tariff. The powers in the Health Service Medical Supplies (Costs) Act 2017 enable the Government to reimburse for specials dispensed in primary care in different ways such as considering quotes of suppliers and not reimbursing pharmacies at all if, for example, they have been provided the medicine by a central service. We are developing proposals, which will be subject to consultation with relevant stakeholders.

21st June

Nigel Dodds MP: To ask the Secretary of State for Health and Social Care, who is responsible for developing the Government's forthcoming proposals on the reimbursement of special medicinal products.

Steve Brine MP: Amendments were made by the Health Service Medical Supplies (Costs) Act 2017 to allow for a new approach to be taken to the remuneration of community pharmacies in England and

Wales for the special medicinal products that they dispense. No changes were made to the equivalent powers to determine the remuneration for community pharmacies in Scotland and Northern Ireland. The proposals being developed for England are being considered by the Department. Any proposals will be subject to consultation with relevant stakeholders.

16th May
Baroness Masham of Ilton: To ask Her Majesty's Government what plans they have to publish proposals for further consultation relating to the implementation of their powers in the Health Services Medical Supplies (Costs) Act 2017.
Lord O'Shaughnessy: The powers in the Health Service Medical Supplies (Costs) Act 2017 enable the Government to reimburse for special medicinal products (also known as 'specials') dispensed in primary care in different ways such as considering quotes of suppliers and not reimbursing pharmacies at all if for example they have been provided the medicine by a central service. The Government is considering how to implement its powers in the 2017 Act and any proposals to implement changes will be subject to consultation with relevant stakeholders. Further to the Health Service Medical Supplies (Costs) Act 2017, the Government ran a consultation on new Regulations for the provision of information about health service products. We are finalising the Regulations which are expected to be laid and come into force later this summer. The Information Regulations include requirements in relation to special medicinal products which will ensure that the Government obtains information from all manufacturers and importers. This information will make the reimbursement arrangements for the most commonly used special medicinal products more robust. However, where there are concerns about an individual price, it will also enable us to request from suppliers' information on the costs of supplying a product. In 2017 the Government also consulted on the Statutory Scheme to control the cost of branded medicines. Those Regulations were made under powers in the NHS Act 2006 that were amended by the Health Service Medical Supplies (Costs) Act 2017 and are now in force.

16th May
Baroness Masham of Ilton: To ask Her Majesty's Government what plans they have to introduce secondary legislation to implement the provisions of the Health Services Medical Supplies (Costs) Act 2017 relating to remuneration in respect of special medicinal products.
Lord O'Shaughnessy: The powers in the Health Service Medical Supplies (Costs) Act 2017 enable the Government to reimburse for special medicinal products (also known as 'specials') dispensed in primary care in different ways such as considering quotes of suppliers and not reimbursing pharmacies at all if for example they have been provided the medicine by a central service. The Government is considering how to implement its powers in the 2017 Act and any proposals to implement changes will be subject to consultation with relevant stakeholders. Further to the Health Service Medical Supplies (Costs) Act 2017, the Government ran a consultation on new Regulations for the provision of information about health service products. We are finalising the Regulations which are expected to be laid and come into force later this summer. The Information Regulations include requirements in relation to special medicinal products which will ensure that the Government obtains information from all manufacturers and importers. This information will make the reimbursement arrangements for the most commonly used special medicinal products more robust. However, where there are concerns about an individual price, it will also enable us to request from suppliers' information on the costs of supplying a product. In 2017 the Government also consulted on the Statutory Scheme to control the cost of branded medicines. Those Regulations were made under powers in the NHS Act 2006 that were amended by the Health Service Medical Supplies (Costs) Act 2017 and are now in force.

23rd April {Grouped Questions}
Anne Marie Morris MP: To ask the Secretary of State for Health and Social Care, whether his Department plans to adopt the Scottish model of tariff-setting for specials.
Anne Marie Morris MP: To ask the Secretary of State for Health and Social Care, what the process is for setting the Specials Drug Tariff; and who is responsible for implementing that tariff.
Anne Marie Morris MP: To ask the Secretary of State for Health and Social Care, with reference to the Health Service Medical Supplies (Costs) Act 2017, when he plans to bring forward legislative proposals to regulate the costs of specials dispensed in community pharmacies.
Lord O'Shaughnessy: Since 2011 for the most commonly prescribed specials, a reimbursement price, which is determined by the Secretary of State, is listed in the Drug Tariff. We have continued to expand the number of products for which there is a reimbursement price listed in the Drug Tariff by prioritising

products of the highest cost to the National Health Service or highest prescribing volume, thus reducing the cost and the variation in what the NHS pays. These reimbursement prices are set by using data from specials suppliers. The powers in the Health Service Medical Supplies (Costs) Act 2017 enable the Government to reimburse for specials dispensed in primary care in different ways such as considering quotes of suppliers and not reimbursing pharmacies at all if, for example, they have been provided the medicine by a central service. Any proposals to implement changes will be subject to consultation with relevant stakeholders. Further to the Health Service Medical Supplies (Costs) Act 2017, the Government ran a consultation on new Regulations for the provision of information about health service products. We are finalising the Regulations which are expected to be laid and enter into force later in 2018. The Information Regulations include requirements in relation to special medicinal products which will ensure that the Government obtains information from all manufacturers and importers. This information will make the reimbursement arrangements for the most commonly used special medicinal products more robust. However, where there are concerns about an individual price, it will also enable us to request from suppliers information on the costs of supplying a product.

16th April
Anne Marie Morris: To ask the Secretary of State for Health and Social Care, whether he plans to prioritise for addition to the Specials Tariff the shortlist of Specials prepared and agreed by the Royal Colleges of Paediatrics and Child Health and of Ophthalmologists, the Association for Palliative Medicine, the British Association of Dermatologists, Metabolic Medicine, Oral and Mucosal Medicine and the Society for Endocrinology.
Steve Brine: Since 2011, for the most commonly prescribed specials a reimbursement price is listed in the Drug Tariff. We have continued to expand the number of products for which there is a reimbursement price listed in the Drug Tariff by prioritising products of the highest cost to the National Health Service or highest prescribing volume, thus reducing the cost and the variation in what the NHS pays.

16th April
Baroness Finlay of Llandaff: To ask Her Majesty's Government what is their estimate of the amount of money, if any, that NHS England would have saved in 2017–18 if all pharmaceutical specials dispensed in community pharmacies had been procured according to the Scottish Government's framework for the procurement of specials.
Lord O'Shaughnessy: No such assessment has been made.

16th April {Grouped Questions}
Baroness Finlay of Llandaff: To ask Her Majesty's Government whether they have any plans to adopt the Scottish Government's framework for the procurement of specials for community pharmacies in England.
Baroness Finlay of Llandaff: To ask Her Majesty's Government whether they intend to bring forward secondary legislation to regulate the costs of specials dispensed in community pharmacies in England.
Lord O'Shaughnessy: The powers in the Health Service Medical Supplies (Costs) Act 2017 enable the Government to reimburse for specials dispensed in primary care in different ways such as considering quotes of suppliers (similar to the Scottish arrangements) and not reimbursing pharmacies at all if for example they have been provided the medicine by a central service. The Government is considering how to implement its powers in the 2017 Act and any proposals to implement changes will be subject to consultation with relevant stakeholders. Further to the Health Service Medical Supplies (Costs) Act 2017, the Government ran a consultation on new Regulations for the provision of information about health service products. We are finalising the Regulations which are expected to be laid and enter into force later in 2018. The Information Regulations include requirements in relation to special medicinal products which will ensure that the Government obtains information from all manufacturers and importers. This information will make the reimbursement arrangements for the most commonly used special medicinal products more robust. However, where there are concerns about an individual price, it will also enable us to request from suppliers' information on the costs of supplying a product.

22nd March
Baroness Finlay of Llandaff: To ask Her Majesty's Government, further to the Written Answers by Lord O'Shaughnessy on 8 March (HL5784 to HL5786), whether they propose to have fixed tariff prices

for prescribed special medicinal products; and when they will table their proposals for consultation with stakeholders.
Lord O'Shaughnessy: Since 2011 for the most commonly prescribed special medicinal products (also known as “specials”) a reimbursement price is listed in the Drug Tariff (i.e. a “fixed Tariff price”). We have continued to expand the number of products for which there is a reimbursement price listed in the Drug Tariff, thus reducing the cost and the variation in what the National Health Service pays. As stated in my earlier response, the Government is considering how to implement its powers in the 2017 Act on the way it reimburses all special medicinal products. Any proposals will be subject to consultation with relevant stakeholders in due course.

8th March {Grouped Questions}
Baroness Finlay of Llandaff: To ask Her Majesty's Government what progress they have made towards implementing the provisions of the Health Service Medical Supplies (Costs) Act 2017, specifically in relation to remuneration in respect of special medicinal products.
Baroness Finlay of Llandaff: To ask Her Majesty's Government what consultations they have held with interested parties regarding implementation of the provisions of the Health Service Medical Supplies (Costs) Act 2017 relating to special medicinal products.
Baroness Finlay of Llandaff: To ask Her Majesty's Government when proposals on the legal requirements for the provision of information relating to the sale and purchase of health service products used in the NHS under the Health Service Medical Supplies (Costs) Act 2017 will be brought forward.
Lord O'Shaughnessy: The Government ran two public consultations implementing the powers in the Health Service Medical Supplies (Costs) Act 2017. We consulted on changes to the statutory scheme regulations for branded medicines and on new regulations for the provision of information about health service products. We are finalising both sets of regulations which will be laid and enter into force in spring 2018. The information Regulations include requirements in relation to special medicinal products which will ensure that the Government obtains information from all manufacturers and importers. This information will make the reimbursement arrangements for the most commonly used special medicinal products more robust. Separately, the Government is considering how to implement its powers in the 2017 Act on the way it reimburses special medicinal products. Any proposals will be subject to consultation with relevant stakeholders.