

Inquiry into Specials:

A report of the All-Party Parliamentary Group on Access to Medicines and Medical Devices

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Foreword

I am pleased to present the second report of the APPG on Access to Medicines and Medical Devices. The Group was set up in Autumn 2018 to examine the pricing, funding and wider access issues relating to the availability of medicines and medical technologies on the NHS in England. The topic of ‘specials’ presented the APPG with an inquiry topic that perfectly fulfilled the remit of the Group – namely to ensure specials are available to patients and NHS England’s spend is appropriate.

I first became aware of an issue involving specials after being contacted by a concerned party who alerted me of an issue over their safety. Since then, I have spoken to a number of healthcare professionals, manufacturers, industry representatives, procurers, commissioners and suppliers who have added further layers of concern to a multifarious area of medicine.

The tax-funded NHS is currently undergoing financial strain to remain free at the point of use and a world-leading system. Therefore, drives for efficiency should include all types of medicines, including the unlicensed. Yet, excessive pricing of specials was rooted in a majority of evidence submissions to the inquiry.

Between December 2017 and November 2018, NHS England spent £65.6m on specials in primary care. Research has indicated that tens of millions of pounds could be saved each year via different procurement practices relying on sourcing cheaper quotes.ⁱ

Of equal, if not greater, importance to the APPG is the access to specials for patients, and access in the appropriate medical setting. Some evidence has uncovered GPs that are unwilling to continue ongoing special prescriptions,

either due to concerns about the high costs of these medications, or often because their local CCG pharmacists have specifically stopped them from prescribing due to high costs.

We also heard of the distress and inconvenience caused to patients when treatment with specials in primary care is stopped, resulting in prescribing reverting back to secondary care.

Therefore, NHS England should have a nationwide Red Amber Green (RAG) classification of each special that is agreed by the respective disease bodies.

Finally, I would like to say that the recommendations contained in this report represent what we believe are the most crucial and implementable solutions that could be considered by the government and implemented by NHS England. However, we appreciate that further focus could be given to other important aspects of the manufacture and procurement of specials that has only been lightly touched upon in our inquiry – such as the pressures faced by aseptic services.



Anne Marie Morris

Anne Marie Morris MP,
Chair of the APPG on Access to
Medicines and Medical Devices

Executive Summary

The APPG examined specially manufactured unlicensed medicines known as ‘specials’. The inquiry was set up after concerns were raised to the Group over the costs of specials prescribed in the community being excessively high and some patients struggling to access them.

We were keen to uncover whether stakeholders involved in the manufacturer, distribution, commissioning, prescription and sale of specials in England had insight into issues surrounding their pricing, procurement and availability.

The Group wrote a consultation document outlining some of the core issues involving specials that had been raised to the APPG via preliminary research and discussions with experts. This document and its included consultation questions were sent out for public consultation. We received responses from a range of individuals and groups involved in the entire lifecycle of specials. This included manufacturers, procurers, commissioners, prescribers, suppliers and pharmacists.

The Group then held an oral evidence session with three expert witnesses to discuss the findings of the written consultation and to develop key recommendations.

The report analyses a range of alternative procurement practices that could replace the current system in England. All are

shown to have their strengths and weaknesses. Therefore on balance, the APPG recommends not overhauling the current system.

The inquiry’s findings recognise that the introduction in 2011 of the England and Wales Special Tariff Part VIIB has had a successful impact upon reducing the cost of specials for those included on the Tariff. We also believe a decrease in the price of specials is beginning to be seen following the recent requirement for quarterly reporting of pricing and other information from manufacturers, distributors and suppliers.

However, the APPG calls on more specials to be added to the Tariff so that it more accurately reflects the prescribing practices of expert clinicians. To this end, we propose that the Department of Health and Social Care (DHSC) and NHS England (NHSE) works closely with expert medical speciality group that routinely prescribe specials.

We would also like DHSC and NHSE, working with expert medical specialty groups, to create a national formulary of Red Amber Green (RAG) coded specials so that there is not regional disparity in their use between Clinical Commissioning Groups (CCGs). This should largely prevent patients being unnecessarily stuck in secondary care – with all the associated financial and logistical problems.

Introduction

The overwhelming majority of medical treatments in England are delivered by prescription of licensed medicines, which have been approved by a Marketing Authorisation via the Medicines and Healthcare products Regulatory Agency (MHRA) or the European Medicines Agency (EMA). This ensures that medicines are safe and efficacious.

However, for some conditions, the range of appropriate licensed medicines may be limited, and prescribing can rely on unlicensed medicines ('specials') containing active constituents in a range of concentrations and bases. Those particularly affected include children, the elderly, those with life-shortening illnesses, needing palliative care, those with mental health issues, and those with oral and throat disease, eye disease, endocrine problems and skin disease.

Specials are specially manufactured or imported to the order of a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber for the treatment of individual patients. They have not been assessed by a licensing authority against the criteria of safety, quality and efficacy.

They are usually liquids, ointments, injections or eye drops. They are manufactured singly or in batches in the UK. In the last 10-15 years, individual pharmacies have largely stopped preparing these medicines. Instead they are produced by private manufacturers or by NHS Specials Manufacturing Units. In primary care, specials are delivered to the

pharmacy via a third-party wholesaler or distributor.

Specials are an esoteric medical area that is under researched and under considered by some policymakers, healthcare decision-makers, healthcare professionals and other stakeholders. For example, in the King's Fund 2018 report on "*The rising cost of medicines to the NHS*"ⁱⁱ, specials are not referenced or considered. This is surprising given that specials cost NHS England (NHSE) £65.6m in primary care alone in the latest available 12 months of data (Dec 2017 to Nov 2018).

Therefore, the APPG felt that an inquiry into specials was long overdue.

Although specials are often only made bespoke for a single person, access to a special is of paramount importance to each individual patient. Therefore, a key inquiry theme of the analysis centres around patient access to specials.

We also examine the pricing of specials and whether there are any problems with the pricing and reimbursement system that could be improved.

The overall aim of the inquiry was to discuss whether a new system of procurement for specials could improve patient care and reduce the total spend of NHSE, or whether the direction taken by the government via recent legislation and policies is working.

Methodology

The Group set about launching its inquiry in April 2019. It began collecting information from preliminary research and discussions with experts.

This led to the writing of a consultation document. It was produced because the APPG sought to investigate specials through the entire lifecycle of their use, from manufacturer through to eventual consumption, and most experts work in only a part of the process. The consultation document enabled the APPG to summarise for its respondents the background to the issues, some problems with the current system of procurement of specials, patient access issues, safety elements, current legislation, and other types of procurement systems.

The document asked respondents if they agreed with its content and the evidence used.

The APPG sent the consultation document with the included survey questions out for public response. Written evidence was received from a range of stakeholders involved in the manufacture, procurement, commissioning, prescribing and dispersal of specials.

Further expert input on the commissioning side of specials was supplied to the APPG via communication with members of the British Association of Dermatologists' Medicines Working Group, an interest group also representing other medical specialties.

Anne Marie Morris MP also chaired an oral evidence session in May 2019 and heard from three expert witnesses that specialise in the manufacture and prescribing of specials. They discussed the written evidence findings and, in collaboration with the Group, came up with recommendations.

The survey was split into five areas and asked the following questions:

1.

Q. In what capacity are you responding to this consultation?

Q. Please briefly outline your experiences with the consumption, procurement, delivery or system design of specials.

Q. Has all the relevant evidence for this consultation document been taken into account? If 'No', please give details.

2.

Q. Please comment on the medical specialisms and disease areas that you are aware are affected most by the procurement of specials.

Q. Do you agree with the consultation document's findings regarding price-inflation, multiple fees and additional hidden costs for specials in England?

Q. Do you believe a saving could be made to NHS England if a new procurement system were put in place?

Q. Do you agree with the statement that the current procurement of specials in England impacts patient access to medicines in primary care?

3.

Q. Do you believe that there is an issue with regards to the safety of specials in England within (i) primary care and (ii) secondary care?

Q. What mechanisms do you think should be in place to ensure the safety, efficacy, quality and consistency of specials?

Q. Is batch testing a viable solution to improve patient safety for specials?

4.

Q. Can you explain whether existing legislation ensures that the level of remuneration for specials is reasonable?

Q. Does the Health Services Medical Supplies (Costs) Act provide the necessary powers to alter the procurement practices for specials in a satisfactory manner?

Q. Do you believe that The Health Services Products (Disclosure and Information)

Regulations 2018 have adequately improved the provision of information on the pricing of specials.

5.

Q. Please provide any comments that you may have about the potential merits and limitations of the solutions outlined in this document:

- a. Increasing number of specials in the Drugs Tariff
- b. Central procurement
- c. Batch production
- d. Strict price control
- e. Warning system

Q. Are there any changes, additions or new procurement systems that you would like to propose?

Q. If you support a new procurement system, which do you favour and why?

Q. Please provide any additional comments on the consultation document.

Findings

The written and oral evidence spoke to a range of topics: safety, aseptic services, prescribing, on-Tariff prescribing, off-Tariff prescribing, patient access in primary and secondary care, information, and alternative procurement practices.

Safety

The MHRA regulates the manufacturers of specials. Private companies have to be granted a manufacturing specials (MS) licence from the regulator. NHS hospital pharmacy manufacturing units also require a license if they manufacture a special for another trust.

Evidence revealed that adverse events are rare, as stringent procedures are put in place. Furthermore, we heard that most specials are low risk since specials are often lower strengths of licensed medicines or in another form.

There were no examples provided of unsafe practices linked to the manufacturing of specials. However, a consultee reported an incident whereby a patient was prescribed and supplied a different strength of a liquid special to their usual preparation, without the family realising that the strength and therefore volume for administration had changed. This resulted in a serious adverse event.

Some responders highlighted prescribing errors that have happened due to pharmacists picking the product incorrectly on the clinical system or due to poor communication between secondary and primary care.

A consultee group called for information to be provided on excipients in specials,

such as a standardised crib sheet, to highlight ingredients that can cause adverse reactions to particular patients. They also suggested the creation of a standardised patient information leaflet that is written in layman's terms. It would cover key information about the medicine (e.g. how to give it, when to give, what side effects to look out for and how the medicine should be stored).

Oral evidence agreed that more information could be provided to patients on the ingredients and instructions, but queried whether there is enough time to make a technical data sheet in the quick turnaround required for each special. However, a generalised patient information leaflet could be beneficial. A further oral consultee suggested that it was the responsibility of the clinician prescribing the special to fully inform patients rather than the manufacturer.

The evidence overall suggested that specials in England and Wales are normally safe, but that the government could consider steps to improve the information provided to patients on their ingredients and use.

Aseptic services

Few consultees were able to comment on aseptic services. The applicable responses we did receive noted that aseptic compounding pharmacies are facing significant and increasing capacity pressures, relating to both estate and workforce. These pressures are also in the context of rising demand for aseptically prepared products.

A response argued that it is imperative that aseptic compounding pharmacies are

operated in a way that ensures limited capacity is being channelled where it is most needed – i.e. only for specials where no licensed medicine is available to meet the clinical needs of the patient.

There is a professional, ethical and logistical imperative to ensure that specials are not being manufactured when licensed products are available for the patient's needs. Any incidences should be reported to DHSC and any relevant medical speciality group.

Prescribing:

There was near universal agreement from responders that there is an issue surrounding price inflation and overly high prices paid for specials. Notably this included some medicines management pharmacists in CCGs who are directly involved in the commissioning decisions of medicines.

Some said the current system does not provide the necessary checks and balances to ensure the price being charged for a special is fair and reasonable. One consultee said that they *“regularly see the same products in different practices with vastly different reimbursement costs, hundreds of pounds in some cases”*.

The additional hidden costs of failure to prescribe specials was also noted in some pieces of evidence. This included prescribers, in the absence of access to the appropriate special, relying on alternative treatments that tend to be far more expensive, such as biologic drugs.

A pharmacy organisation disagreed that there was an issue with the pricing of specials, and highlighted how the Drug Tariff fixes prices and thus curbs excessive pricing. They also said that an annual margins survey is conducted to measure any margin earned by independent community pharmacies and this ensures that pharmacists only earn

the agreed amount of margin, whilst professionals' fees are set by the pharmacy contract global sum. They also highlighted how the current reimbursement system means pharmacy contractors cannot claim for any broken bulk and, therefore, they are *“effectively subsidising the NHS out of their own pockets”*.

Specials may be legally supplied only in circumstances where there is no licensed alternative available to meet the clinical needs of the individual patient.ⁱⁱⁱ However, several consultees said that they were aware of Community Pharmacists ordering specials when a licensed product of the specified strength is available. This could be because they are not aware that a licensed product is equivalent, there is a shortage of a licensed product, the licensed product is not available from the linked wholesaler, or a Pharmacist has a business link to an individual manufacturer.

On-Tariff Prescribing:

The England and Wales Specials Drug Tariff Part VIIB contains some commonly prescribed specials. DHSC analyses a selection of manufacturer prices for a particular special in order to set a reimbursement price on the Drug Tariff.

This system was praised in a number of written and oral evidence for controlling the costs of specials. It eliminates a 'postcode lottery' scenario where different CCGs will reimburse different costs for the same special depending upon their prescribing formularies and historical purchasing patterns. Pharmacies tend to shop around and source the cheapest supplier to improve their margins. Therefore, this system functions well for items listed on the Drugs Tariff.

However, concerns were raised that the current list, which is regularly revised, does not accurately reflect expert clinical use of some specials. For example, some

of the strength preparations, formulations and dose sizes on the Tariff are not accurate reflections of common use, whilst other common specials are not included.

Focusing on standardising the strength of preparations will reduce the number of products and ensure other more relevant specials can be added to the Tariff.

An oral witness argued that approximately 250 products capture more than half of the specials market; therefore, getting the majority of specials on the Tariff is feasible.

There was disagreement amongst consultees on whether adding to the Drugs Tariff was the best solution to the issues raised in the consultation document.

A piece of evidence outlined how a special had been put on the Tariff which led to a price rise since *“pharmacies were buying them from the hospital at a fraction of the tariff cost”*. Therefore, DHSC needs to be vigilant to any loopholes that arise, for example inappropriate Tariff prices due to poor data on available prices from other manufacturers.

However, feedback broadly outlined how the inclusion of specials onto the Tariff ensures that the NHS pays a fairer reimbursement price.

Off-Tariff Prescribing:

An off-Tariff special can be sold at an unrestricted price. Many consultees remarked that excessive pricing of specials, including those that undergo sudden price inflation, are exclusively related to off-Tariff medicines.

A consultee argued that the main problem stems from pharmacists not having an incentive to source the cheapest quote for an off-Tariff special if good margins are already assured. Therefore, NHS England

ends up reimbursing at a premium. Pharmacists may be linked to particular wholesalers with higher prices and have no incentive to seek the item from a cheaper wholesaler.

We heard that off-Tariff pricing in secondary care does not result in the same high prices as primary care. This is because hospitals have an incentive to source cheap specials because the medicine spend comes out of their own budgets.

Patient Access in Primary Care:

There was some disagreement over whether patient access has been hindered by the current system of procurement for specials. Some said prescription would not be restricted purely on cost reasons. Clinicians treating patients disagreed with this.

One consultee said that they find *“GPs are very unwilling to continue ongoing [special] prescriptions due to the high costs of these medications – even when the GP is aware that treatment has been helpful to the patient”*.

Difficulties in access seems to be a combination of a lack of familiarity with a product in primary care, as well as GP reluctance to prescribe on cost grounds.

Some consultees said that they regularly see patients being unable to continue treatment with specials in primary care, resulting in prescribing reverting back to secondary or tertiary care. This increases the costs to the NHS.

Patient Access in Secondary Care:

The NHS uses a Red Amber Green (RAG) classification for the prescribing of each medicine. A red designation means secondary care use only, amber means that primary care can prescribe it as a continuation after initiation in secondary

or tertiary care, and green means that primary care can freely prescribe the medicine.

Oral evidence revealed that most CCGs have not been using the classification system for its original purpose – as a safety mechanism – but have been classifying specials as red purely on the grounds of cost. A red medicine will be removed from the local formulary list so GPs cannot routinely prescribe them and the local budget is not depleted. Consultees suggested that some red coded drugs could, and should, be used in primary care.

If a medicine is designated red, but clinical experts believe a medicine is, in fact, safe for primary care prescribing, then patients can be unnecessarily trapped in secondary care.

Many consultees highlighted concerns over patients being unduly sent to secondary care to source special prescriptions.

A variety of patient experience issues can result from unnecessary secondary care appointments. This includes the distress and inconvenience to patients and their families of travel. We were told that it is not unheard of for patients and their families to travel many hours to access specials in hospitals, whilst some cannot even access specials because of the distance. Due to the fact that shelf lives are often short, these visits can be very frequent, weekly in some cases. Respondents also informed the Group that the personal financial costs of extra visits to hospital (e.g. travel and parking charges) can be high.

One respondent stated that travelling to hospital to get prescriptions “blocks follow-up slots in clinics and subsequently delays new patient referral as clinics are blocked with well controlled patients simply requiring repeat prescriptions”.

We were told that some patients with complex needs may be on many different medicines, some licensed and some not, and have to collect different medicines from different pharmacies. This can create a poor patient experience.

Evidence revealed that some patients run short of medicine before their appointment is due and have to stop using it or ration its use – leading to inadequate treatment of their condition. We were also told that rationing can occur when insufficient quantities of medicine are prescribed due to concerns over the cost of a special or the need for frequent follow up appointments. This can result in clinicians prescribing instead more expensive licensed biologics .

Even in secondary care there have been some reported problems with patients accessing specials, leading to clinician de-skilling and a shift towards the use of costly and potentially more toxic immunosuppressants.^{iv}

Witnesses spoke on the need to rigorously analyse the RAG classification of each special by the representatives of the professional bodies that prescribe them to ensure that the correct and safe use of specials is provided in the optimal setting.

Information:

An improved mutual awareness between stakeholders of the prices being paid for an individual special could improve the choices made – particularly for the sourcing of cheap quotes.

Some consultees called for further education and information to be provided. For example, a consultee said “community pharmacists rarely contact the prescriber to let them know that they have prescribed an unlicensed special and how much it might be”. However, others disagree, and argue that GPs and CCGs are informed by pharmacies of the

costs, but that this tends to put them off prescribing specials.

A CCG Medicines Optimisation Team said it is engaging in considerable work to educate and raise awareness of the costs of specials with prescribers across primary care, community pharmacies and with secondary care. Their main aim is to encourage the use of licensed products instead of specials, but they also work with community pharmacies to encourage cost effective procurement of specials.

Consultees suggested that the quarterly reporting introduced following the Health Service Medical Supplies (Costs) Act 2017 has led to steadily declining prices for specials. This is because the government can identify companies that are outliers and significantly overcharging on price.

Licensed medicines & supplements

Evidence indicated that there are a small number of medicines which are licensed, and therefore not specials, but have similar patient access issues. We heard that these licensed products can be in short supply and unavailable in some localities, often due to excessive pricing.

Specialists in metabolic conditions also highlighted difficulties in obtaining and prescribing certain supplements, e.g. amino acids. These supplements can be important to support the internal functions of the body. Although not a special, patient access to supplements is a significant concern.

Alternative procurement practices:

The inquiry received views on a number of alternative procurement practices.

Central procurement would involve pharmacies contacting a centralised service that would procure specials on their behalf. The benefit of this system is that a centralised buyer has the

advantage of a greater purchasing power so can negotiate and obtain cheaper prices.

Some pieces of evidence favoured this approach as they believed it would reduce NHSE spend on specials.

However, concerns were raised over supply issues if there was only one (or very few) suppliers, as any disturbance could severely impact supply. Consultees also queried whether there could be extra costs, for example, with onward distribution or due to a monopolistic situation.

A group said that central procurement might have worked in Scotland because of its smaller size, but that it may prove difficult in England as it would require a significant increase in the number of NHS production units to cater for demand in each geographical location or require each unit to increase its production capacity. This would take time and could lead to supply problems if a manufacturing issue arose and there were only a couple of sources of product.

Oral witnesses argued that it would be overly onerous and time consuming to follow the previous Scottish system in asking pharmacists to seek three quotes before procuring a special. However, the consolidation of procurement to a few centres throughout England would reduce distribution costs and could curb overall costs to the NHS.

Batch production involves the manufacture of specials in bulk. It relies on unifying prescribing, and channelling demand to a more limited number of specials. This could reduce costs, while improving quality and availability. It is mostly applicable to specials used in secondary care, which tend to be manufactured in NHS units.

There were consensus that batch testing would only work for some more commonly used specials. Generally,

consultees believe it would have a cost advantage for these products, but has limited scope to deal with the wider issues surrounding specials. If there was a move towards enforcing pharmacists to source a special from a particular manufacturer then batch production would result. This would channel demand, lead to economies of scale and fair profits. Oral witnesses argued that if this was adopted then there should be a minimum of two manufacturers so that any disruption to an individual manufacturer does not temporarily limit patient access.

Strict price control: The Government could mimic Scotland's former method of requiring a certain amount of quotes, including an NHS one, when purchasing non-Tariff specials and for the cheapest to be used. Nowadays, Scotland's procurement system allows dispensing without pre-authorisation if an NHS manufacturer is used.

Several responders stated their preference for the strict price control system as a model. They highlighted its

success with a supply of standard strength products and reduced cost.

Warning system, in the form of a reporting helpline, could be created for patients and doctors. This will enable medicine shortages and price hikes to be identified at an early stage. Some consultees were in favour of this system.

DHSC already have a system in place for reporting medicine shortages and could choose to extend this for medicines that have incurred a significant price hike.

No change: Oral witnesses agreed that due the limitations or challenges to implementation that are inherent in all the alternative procurement systems, wholesale changes should not be sought. Instead, DHSC/NHSE should focus on putting more of the correct specials on the Tariff. This will lead to a gradual reduction in price of any newly added Tariff special.

Recommendations:

Special Tariff

The APPG recommends that the content and capacity of the Special Tariff Part VIB is evaluated and updated.

The evidence we collected suggests that some of the strengths and doses of preparations used in the Tariff are not indicative of clinical practice. Further, some more specials that are relatively common should be added to the Tariff.

The government and NHSE should work with the medical specialty groups that routinely prescribe specials. The APPG hopes a dialogue can be initiated to facilitate the corresponding updating of the Drugs Tariff.

RAG coding

The government and NHSE should create a national formulary of Red Amber Green (RAG) coded specials so that all CCGs have a consistent designation of specials. This should largely prevent patients being unnecessarily stuck in secondary care and postcode lottery access to specials in primary care.

As part of this inquiry, experts in Endocrinology, Dermatology, Metabolic Disease, Ophthalmology, Oral medicine, Paediatrics and Palliative care have individually produced a RAG coded list of their routinely prescribed specials that they believe accurately reflects the clinical preference and use of specials in England and Wales [see Annex B]. The government and NHSE should be open to working with these and other expert groups, and should co-opt or produce their own national formulary of RAG coded specials.

The list should have ongoing evaluation to make sure that it up-to-date and reflective of clinical practice. This could be facilitated by an annual meeting with medical specialty groups.

Off-Tariff prescribing

The government should initiate a formal review into off-Tariff prescribing.

Some alternative mechanisms of procurement and pricing have been discussed in this inquiry. We have not proposed a preference since rigorous and extended engagement on the logistical ramifications of each needs to be conducted. However, a system that improves the pricing competition of specials would be favoured.

This should encompass an analysis of whether specials are being ordered in primary care when a licensed product of the specified strength is already available and, if so, strategies to prevent this should be developed.

It could consider whether a change of legislation is needed to compel pharmacists to seek a cheap quote that may involve getting at least one quote from an NHS manufacturer.

Although licensed medicines and supplements were not included within the original remit of the inquiry, the government and NHSE should also consider approaches to improving their access. It should review why some supplements and licensed medicines are currently experiencing shortages and patient access issues [see Annex C & D].

Warning system

The government should create a warning system that patients and doctors can use to inform the authorities of price hikes and access issues.

Publish data

The government should make readily available an analysis and summary of its findings from the quarterly medicine reporting it receives from manufacturers, distributors and suppliers. This will lead to a better understanding of its effects and whether further systemic changes are required.

Conclusions

It is clear from the inquiry that many problems are associated with specials, including cost issues, patient care and patient access. However, there are implementable steps that can be taken to improve patient experience and the financial burden on NHS England.

The recommendations of this report range from updating the special Drug Tariff, to creating a national formulary of RAG

coded specials, in cooperation with expert clinicians, to launching a formal governmental inquiry into the procurement and pricing of off-Tariff specials.

The APPG will be taking these to the government and NHS England to see if there is scope for dialogue and change.

Acknowledgments

The Group would like to extend thanks to all involved in giving evidence, especially those who took the time to attend the oral evidence sessions. We would also like to

thank DHSC for giving feedback to the inquiry and for being open to meeting the APPG and listening to our concerns.

Annex

Annex A:

Red Amber Green (RAG) medicines classification	
Red For secondary or tertiary care initiation and long-term maintenance of prescribing	
Amber Drugs which are appropriate to be initiated and stabilised by a specialist in secondary or tertiary care, once stabilised the drug may be appropriate for responsibility to be transferred from secondary to primary care	
Green Drugs which may be initiated, stabilised and maintained in a primary, secondary or tertiary care setting	

Annex B:

Formulary of Red Amber Green (RAG) coded specials

The following lists have been produced by expert medical speciality groups and detail the routinely prescribed specials in England and Wales [accurate as of February 2020]. Medicines have been RAG coded.

Dermatology

1.	Propylene glycol 20% w/w in aqueous cream 100 g	Special
2.	Propylene glycol 40% w/w in aqueous cream 100 g	Special
3.	Propylene glycol 50% w/w in water 100 ml	Special
4.	Beclomethasone dipropionate 0.0025% w/w in WSP BP ointment (formerly known as Propaderm® 1 in 10) 100 g	Special
5.	Salicylic acid 2% w/w and sulfur 2% w/w in aqueous cream	Special
6.	Salicylic acid 5% w/w in emulsifying ointment	Special
7.	Salicylic acid 10% w/w in emulsifying ointment	Special
8.	Salicylic acid 20% w/w in emulsifying ointment	Special
9.	Triamcinolone acetonide 0.1% w/w in Orabase	Special
10.	Salicylic acid 5% w/w / propylene glycol 47.5% w/w in	Special

	clobetasol propionate 0.05% (Dermovate®) cream	
11.	Propylene glycol 40% w/w in clobetasol propionate 0.05% (Dermovate®) Cream 100 g	<i>Special</i>
12.	Coal tar solution BP 5% w/w in betamethasone valerate 0.025% w/w ointment 100 g	<i>Special</i>
13.	Coal tar solution BP 3.3% w/w and propylene glycol 20% w/w in fluocinolone acetonide 0.025% (Synalar®) gel 100 g	<i>Special</i>
14.	Coal tar scalp application ('coal tar pomade'; coal tar solution BP 6% w/w / salicylic acid 2% w/w in emulsifying ointment)	<i>Special</i>
15.	Coal Tar BP 2% w/w in YSP	<i>Special</i>
16.	Coal Tar BP 5%w/w in YSP	<i>Special</i>
17.	Coal Tar BP 10% w/w in YSP	<i>Special</i>
18.	Coal tar solution BP 6% w/w and salicylic acid 6% w/w in Ung. Merck	<i>Special</i>
19.	Ichthammol 1% w/w and zinc oxide 15% w/w in YSP 200 g	<i>Special</i>
20.	Dithranol in Lassar's paste 0.1% w/w	<i>Special</i>
21.	Dithranol in Lassar's paste 0.5% w/w	<i>Special</i>
22.	Dithranol in Lassar's paste 1% w/w	<i>Special</i>
23.	Dithranol in Lassar's paste 2% w/w	<i>Special</i>
24.	Dithranol in Lassar's paste 4% w/w	<i>Special</i>
25.	Dithranol in Lassar's paste 10% w/w	<i>Special</i>
21.	Dithranol in Lassar's paste 15% w/w	<i>Special</i>
22.	Dithranol scalp application 0.4% w/w ('dithranol pomade'; dithranol 0.4% w/w, salicylic acid 2% w/w, emulsifying wax BP 25% w/w, liquid paraffin to 100%)	<i>Special</i>
27.	Tacrolimus 0.1% w/w in Orabase	<i>Special</i>
28.	Tacrolimus 0.3% w/w in Orabase	<i>Special</i>
31.	Glycopyrrolate 2% w/w in cetomacrogol cream 100 g	<i>Special</i>
32.	Hydroquinone 5% w/w, hydrocortisone 1% w/w and tretinoin 0.1% w/w in a non-aqueous gel 100g	<i>Special</i>
33.	Reflectant (Dundee) sunscreens – coffee, coral pink, beige 50 g	<i>Special</i>
34.	Eosin solution 2% w/v 100 ml	<i>Special</i>
35.	Sucalfate 4% in emulsifying ointment 50 g	<i>Special</i>
36.	Sirolimus 0.1% in WSP 30 g	<i>Special</i>
37.	Sirolimus 0.5% in WSP 30 g	<i>Special</i>
38.	Phenol 2% w/w in compound zinc paste BP	<i>Special</i>
39.	Diphenylcyclopropenone in acetone 0.00001-6.0% w/v 10 ml	<i>Special</i>
40.	Trichloroacetic acid 90% w/w	<i>Special</i>

Metabolic

1.	Sodium benzoate 500 mg tablets	<i>Special</i>
2.	Sodium benzoate 500 mg / 5 ml liquid	<i>Special</i>
3.	Sodium benzoate 500mg capsules	<i>Special</i>
4.	L-Arginine injection 5g / 10 ml	<i>Special</i>
5.	Co-careldopa 5 mg / mL & 1 mg / mL oral liquid	<i>Special</i>

6.	Sodium phenylbutyrate liquid 250 mg / ml (100 ml)	Special
7.	Sodium phenylbutyrate injection 2 g in 10 ml	Special
8.	Sodium benzoate injection 1 g / 5 ml	Special
9.	Ketamine 50 mg / 5 mL oral solution	Special
10.	Sodium dichloroacetate 50 mg / mL oral solution	Special
11.	Sodium D,L-3- hydroxybutyrate powder	Special

Ophthalmology

1.	G.Cefuroxime 5% (50 mg / mL) PF 10 mL	Special
2.	G. Chlorhexidine 0.02% (0.2 mg / mL) PF 10 mL	Special
3.	G Natamycin 5% (50 mg / mL) preserved 15 mL	Special
4.	G.Polihexanide (polyhexamethylene biguanide or PHMB) 0.02% (0.2 mg / mL) PF 10 mL	Special
5.	G.Polihexanide (polyhexamethylene biguanide or PHMB) 0.06% (0.6 mg / mL) PF 10 mL	Special
6.	G. Hexamidine isethionate (Desomedine) 0.1% (1 mg / mL) PF 10 mL	Special
7.	G.Trifluorothymidine (Trifluridine or F3T) 1% (10 mg / mL) preserved 10 mL	Special
8.	Oc. Erythromycin 0.5% (5 mg / 1 g) 3.5 g tube	Special
9.	G.Acetylcysteine 10% (100 mg / mL) PF 10 mL	Special
10.	Acetazolamide 250 mg / 5mL oral liquid	Special
11.	G.Prednisolone 0.1% (1 mg / mL) preserved and PF 10 mL	Special
12.	Oc.Ciclosporin 0.2% w/w (2 mg / g) 3.5 g tube	Special
13.	G.Cysteamine/ Mercaptamine eye drops 0.55% (5.5 mg / mL) PF 10 mL	Special
14.	G. Disodium edetate 0.37% (3.7 mg / mL) PF 10 mL	Special
15.	G. Heparin 5000 IU / mL preserved and PF 5 mL	Special
16.	G. Potassium ascorbate 10% (100 mg / mL) preserved and PF 10 mL	Special
17.	G. Atropine 0.01% (0.1 mg / mL) preserved 10 mL	Special
18.	G. Sodium citrate 10.11% (101.1 mg / mL) PF 10 mL	Special

19.	G. Amikacin 2.5% (25 mg / mL) PF 5 mL	Special
20.	G.Amphotericin 0.15% (1.5 mg / mL) PF 5 mL	Special
21.	G. Ceftazidime 5% (50 mg / mL) PF 5 mL	Special
22.	G. Chlorhexidine 0.05% (0.5 mg / mL) PF 10 mL	Special
23.	G.Chlorhexidine 0.2% (2 mg / mL) PF 10 mL	Special
24.	G.Gentamicin 1.5% (15 mg / mL) preserved and PF 10 mL	Special
25.	G. Penicillin 0.3% (3 mg / mL) PF 5 mL	Special
26.	G. Vancomycin 1.4% (14 mg / mL) preserved and PF 5 mL	Special
27.	G. Vancomycin 5% (50 mg / mL) PF 5 mL	Special
28.	G. Voriconazole 1% (1 mg / mL) preserved and PF 5 mL	Special
29.	G. Teicoplanin 1% (10 mg / mL) PF 4 mL	Special
30.	G.Glycerol 15% (150 mg / mL) preserved 10 mL	Special
31.	G. Pilocarpine 0.1% (1 mg / mL) preserved 10 mL	Special
32.	G. Pilocarpine 4% (40 mg / mL) PF 10 mL	Special
33.	G. Adrenaline 0.1% (1 mg / mL) PF 10 mL	Special

34.	G. Adrenaline 0.01% (0.1 mg / mL) PF 10 mL	Special
35.	G. Ethanol 18% (180 mg / mL) preserved 10 mL	Special
36.	G. 5-Fluorouracil 1% (10 mg / mL) preserved 10 mL	Special
37.	G. Interferon alfa 2b 1 million units / mL 5 mL	Special
38.	G. Mitomycin 0.02% (0.2 mg / mL) PF 5 mL	Special
39.	G. Mitomycin 0.04% (0.4 mg / mL) PF 5 mL	Special
40.	G. Riboflavin 0.1% (1 mg / mL) single-dose as 1.5 mL / unit	Special

Oral Medicine

1.	OM1 mouthwash	Special
2.	0.25% Tacrolimus mouthwash 250 mg / 5ml	Special

Paediatrics

1.	Chloral Hydrate 1 g / 5 ml oral solution	Special
2.	Phenobarbital 50 mg / 5 ml oral solution	Special
3.	Clopidogrel 25 mg / 5 ml oral suspension	Special
4.	Azathioprine 50 mg / 5 ml oral suspension	Special
5.	Spironolactone 50 mg / 5 ml oral suspension	Special
6.	Sertraline 50 mg / 5 ml oral suspension	Special
7.	Hydrocortisone 5 mg / 5 ml suspension	Special
8.	Clonidine 25 microgram / 5 ml suspension	Special
9.	Tacrolimus 5 mg / 5 ml suspension	Special
10.	Pyrazinamide 500 mg / 5 ml suspension	Special
11.	Ethambutol 400 mg / 5 ml suspension	Special
12.	Isoniazid 50 mg / 5 ml suspension	Special

Palliative

1.	Levomepromazine 6 mg tablet	Special
2.	Levomepromazine 6 mg / 5 ml suspension	Special
3.	Tranexamic acid oral solution 500 mg / 5ml	Special
4.	Ketamine oral solution 50 mg / 5ml	Special
5.	Clonazepam injection 1 mg / ml	Special
6.	Antacid and oxetacaine 5 ml (contains 10 mg Oxetacaine, Aluminium hydroxide equivalent to 200 mg aluminium oxide + 100 mg magnesium hydroxide)	Special

Annex C:

List of licensed products

Evidence collected indicated that there are a number of medicines which are not specials, but have similar access and pricing issues.

The following lists have been produced by expert medical speciality groups and detail the licensed products that healthcare professionals have difficulty in obtaining and prescribing [accurate as of February 2020]. Medicines have been RAG coded.

Endocrinology

1.	Carbimazole 5 mg and 20 mg tablets	<i>Licensed product</i>
2.	Propylthiouracil 50 mg tablets	<i>Licensed product</i>
3.	Dexamethasone 0.5 mg and 2 mg tablets	<i>Licensed product</i>
4.	Metyrapone 250 mg (dose range up to 1000 mg tds) capsules	<i>Licensed product</i>
5.	Ketoconazole 200 mg (dose range up to 800 mg bd) tablets	<i>Licensed product</i>
6.	Fludrocortisone 100 mcg tablets	<i>Licensed product</i>
7.	Synacthen injection (both 250 mcg and 1 mg doses) (change in the licence holder, and a new indication for depot synacthen)	<i>Licensed product</i>
8.	Tri-iodothyronine (T3) (5 mcg tablets and 20 mcg tablets)	<i>Licensed product</i>

Metabolic

1.	Vitamin E (alphatocopheryl) 400 unit capsules	<i>Licensed product</i>
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Ophthalmology

1.	G.Acetylcysteine 5% (50 mg / mL) 10 mL	<i>Licensed product</i>
2.	Omeprazole 10 mg / 5 ml & 20 mg / 5 ml oral suspension	<i>Licensed product</i>

Paediatrics

1.	Melatonin 1 mg / ml oral solution/liquid	<i>Licensed product</i>
2.	Sodium Chloride 1 mmol / ml oral solution	<i>Licensed product</i>

Palliative

1.	Tranexamic acid 500 mg tablets, 500 mg / 5ml injection	<i>Licensed product</i>
2.	Ketamine injection 200 mg / 10 ml and 500 mg / 10 ml vial for injection	<i>Licensed product</i>
3.	Clonazepam 500 microgram and 2 mg tablets	<i>Licensed product</i>

Annex D:

List of supplements

Evidence collected indicated that there are a number of supplements which have similar access issues to specials.

The following list has been produced by an expert medical speciality group and details the supplements that healthcare professionals have difficulty in obtaining and prescribing [accurate as of February 2020]. Medicines have been RAG coded.

Metabolic

1.	Biotin 5 mg tablets	<i>Supplement</i>
2.	L-Arginine 1g tablets	<i>Supplement</i>
3.	Riboflavin capsules 50 mg	<i>Supplement</i>
4.	Creatine Powder 5 g in 6 g pack	<i>Supplement</i>
5.	5-Hydroxy-L-Tryptophan 100mg tablets	<i>Supplement</i>
6.	Cholesterol 150 mg / mL oral suspension	<i>Supplement</i>
7.	L-arginine 500 mg capsules	<i>Supplement</i>
8.	Creatine monohydrate powder 100 g	<i>Supplement</i>
9.	5-hydroxytryptophan 50 mg capsules	<i>Supplement</i>
10.	Mannose 50 g powder	<i>Supplement</i>

11.	Betaine tablets 500 mg	<i>Supplement</i>
12.	Betaine liquid 500 mg / ml (100ml)	<i>Supplement</i>
13.	L-Carnitine capsules 500 mg	<i>Supplement</i>
14.	Chenodeoxycholic acid Capsules 250 mg	<i>Supplement</i>
15.	Copper histidine 500 microgram / ml	<i>Supplement</i>
16.	Glycine 1 g powder sachets	<i>Supplement</i>

Bibliography

ⁱ Data from Richard Croker/ Ben Goldacre 2018 (OpenPrescribing, Oxford). Potential saving of £23.3m, based upon their 2017 figures and assuming the 10th centile best value of price quotes had been used to source items

ⁱⁱ <https://www.kingsfund.org.uk/sites/default/files/2018-04/Rising-cost-of-medicines.pdf>

ⁱⁱⁱ <http://www.legislation.gov.uk/uksi/2012/1916/contents/made>

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