

Repatriation of specials

Medicine optimisation projects in this area are aimed at optimising prescribing by reviewing the continued need for a special (an unlicensed medicine), offering an alternative licensed product or by suggesting how to contain prescribing of the special. If after reviewing the continued need for the special, the special remains the most appropriate option, then repatriation back to the specialist could be considered. This bulletin looks at the potential to commission a service to repatriate specials prescribing to the specialist. Tools and guidance are provided for commissioners considering such a scheme. Other potential schemes are also discussed.

Recommendations

- Before prescribing a special, consider if a medicine is needed at all.
- If a medicine is required, a stepped approach is suggested to choose an appropriate preparation, especially where an adult has difficulties swallowing:
 1. Licensed medicines administered as intended.
 2. Licensed medicines administered in an unlicensed manner.
 3. Imported products licensed in a different country.
 4. Special-order products.
- A special should only be prescribed when there is no available licensed medicine which fully meets the patient's clinical needs.
- Decisions about the prescribing of specials should be based on professional judgment and an understanding of individual patient need as accountability for prescribing a special rests with the prescriber.
- Review patient's prescribed specials to ensure that a special is (and remains) the most appropriate option and the medicine is still required.
- Consider a local service which may include developing a system whereby all specials are dispensed from secondary care.
- Consider if there is a possibility to repatriate all specials back into secondary care, being mindful that the prescriber will be taking on the legal responsibility and also around the practicalities involved in transfer of care of medicines.
- Each Integrated Care Board (ICB) in England, Health Board (HB) in Scotland and Wales should work on a shared policy and an agreed formulary for specials, used across their health system.
- Ensure that there are good working relationships between all parties involved, as good communication is essential to make this work.
- Adapt the resources provided and localise them to support your own scheme.

Background

A special is an unlicensed medicine that does not have a UK Marketing Authorisation (MA). It is manufactured, imported or supplied to meet the special clinical needs of an individual patient. A special may only be supplied when there is no available licensed medicine which fully meets the patient's clinical needs. The clinical need for a special does not include reasons of cost, convenience or operational need. Specials can be prescribed when it is judged by the prescriber and agreed with the patient or carer that, based on available information, a special is the most appropriate option for the patient.¹ The General Medical Council (GMC) advises that prescribers should usually prescribe licensed medicines in accordance with the terms of their licence. However, prescribers may prescribe unlicensed medicines where, based on an assessment of the individual patient, they conclude, for medical reasons, that it is necessary to do so to meet the specific needs of the patient.²

There are certain clinical situations where a special may be judged to be the most appropriate or only available option, for example:^{1,2}

- For children, in some circumstances specials are routinely prescribed to achieve the lower doses required.
- In dermatology and ophthalmology, a large number of specials are in use and formularies are available.
- For patients who require alternatives to solid dosage forms that are not available as a licensed oral liquid, for example those patients with PEG and naso-gastric tubes, a special is one of a range of options available.
- A suitably licensed medicine that would meet the patient's need is not available. This may arise where, for example, there is a temporary shortage in supply.
- The prescribing of the special forms part of a properly approved research project.
- There is a serious risk to public health and the Medicines and Healthcare products Regulatory Agency (MHRA) has temporarily authorised the sale or supply of an unlicensed medicine, such as a vaccine or treatment, in response.
- A prescription only medicine that is unlicensed in Northern Ireland has been supplied under the Northern Ireland MHRA Authorised Route (NIMAR).
- For patient's intolerant or allergic to a particular ingredient.³
- For patients with an inability to ingest solid oral dosage forms.³

The GMC states that when prescribing an unlicensed medicine, you must:²

- Be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy.
- Take responsibility for prescribing the medicine and for overseeing the patient's care, monitoring and any follow up treatment, or make sure that arrangements are in place for another suitable doctor to do so.
- Make a clear, accurate and legible record of all medicines prescribed and, where you are not following common practice, your reasons for prescribing an unlicensed medicine.

The GMC also discusses information for patients about the licence for their medicines:²

- You must give patients (or their parents or carers) sufficient information about the medicines you propose to prescribe to allow them to make an informed decision.
- Some medicines are routinely used outside the terms of their licence, for example in treating children. In emergencies or where there is no realistic alternative treatment and such information is likely to cause distress, it may not be practical or necessary to draw attention to the licence. In

other cases, where prescribing unlicensed medicines is supported by authoritative clinical guidance, it may be sufficient to describe in general terms why the medicine is not licensed for the proposed use or patient population. In the case of a medicine supplied under NIMAR, it's not usually necessary to draw attention to it being unlicensed in Northern Ireland. This is because the medicine will be licensed in Great Britain and have met the MHRA's requirements for safety, quality and efficacy. You must always answer questions from patients, or their parents or carers, about medicines fully and honestly.

- If you intend to prescribe unlicensed medicines where that is not routine or if there are suitably licensed alternatives available, you should explain this to the patient, and your reasons for doing so.
- You should be careful about using medical devices for purposes for which they were not intended.

Considerations when prescribing specials

Decisions about the prescribing of specials rely heavily on professional judgment based on understanding the individual patient need. As with licensed medicines accountability for prescribing a special rests with the prescriber, and a pharmacist shares with the prescriber accountability for supplying a special to a patient.¹ Prescribing medicines outside the recommendations of their marketing authorisation alters (and probably increases) the prescriber's professional responsibility and potential liability. The prescriber should be able to justify and feel competent in using such medicines, and also inform the patient or the patient's carer that the prescribed medicine is unlicensed.^{2,4} The aim is to ensure patient safety, through timely supply of a suitable medicine and where possible provide best value to the NHS.

- When prescribing, supplying or reviewing a special already prescribed, consider if the medicine is still needed or needed at all.^{1,5}
- If it is needed ensure that there is no licensed medicine available which will fully meet the patient's clinical needs.¹ A new licensed product may now be available as an alternative to the unlicensed special.
- If a licensed medicine administered as intended is not available as an alternative, a stepped approach is suggested to choose an appropriate preparation:^{3,5}
 1. Licensed medicines administered in an unlicensed manner (also referred to as 'off label').
 2. Imported products licensed in a different country.
 3. Special-order products.

There are several factors that will impact the individuals concerned (patients, prescribers, suppliers) and need to be considered when specials are recommended to be prescribed to patients in primary care including licensing, legal, quality, safety, efficacy and patient information. These are discussed further in the [PrescQIPP bulletin 301: Specials prescribing](#) and are of particular importance when patients are having their care transferred from one care setting to another, where responsibility for prescribing and/or supplying the special may change.^{1,6}

Obtaining the medicine

A review of the supply of unlicensed medicines for children after discharge from a children's hospital found that problems were frequently encountered by parents when attempting to obtain further supplies of their child's unlicensed medicine. Problems included GPs refusing to prescribe the medicine, GPs prescribing a dose or formulation that differed to what had been prescribed previously, pharmacists who were unable to source a suitable medicine, medicines that were not labelled with administration instructions and delays in obtaining the medicine. Action or intervention by the parent was often required to overcome the problems faced. The necessity of these actions or interventions, and the implication of not succeeding, frequently caused parents anxiety, frustration and dissatisfaction. The

review authors concluded that strategies for improving the process of medicine supply during the transition between secondary and primary care are necessary and must involve greater communication among healthcare professionals and carers. GPs and community pharmacists should have access to greater support and guidance to facilitate the safe prescribing and supply of unlicensed medicines.⁷ Specials can also be expensive and there is a risk that if a special cannot be sourced at a reasonable price, it can impact negatively on the relationship between the GP and the Community Pharmacy, as well as impact the relationship between Community Pharmacy and the patient.

The MHRA maintains a register of [‘special-order’ manufacturers and specialist-importing](#) companies that supply unlicensed medicines. Licensed hospital manufacturing units also manufacture ‘special-order’ products as unlicensed medicines, the principal NHS units are listed in the [BNF](#). As well as being available direct from the hospital manufacturer(s) many NHS-manufactured specials may be bought from the [Oxford Pharmacy Store](#), owned and operated by Oxford Health NHS Foundation Trust.⁴

[The Association of Pharmaceutical specials Manufacturers](#) may also be able to provide further information about commercial companies.

Costs

Parts VIIIB and VIID of the Drug Tariff include high volume and high-cost unlicensed specials and imports, with set reimbursement prices based on volume or pack size. The prices are set by the analysis of a selection of wholesaler and unlicensed specials manufacturer’s prices, with a margin included for pharmacy purchase profit.⁸ When a special or an imported medicine which is listed in the Drug Tariff is prescribed, the pharmacy contractor will be reimbursed the set Drug Tariff price for dispensing the product, no matter how the product is sourced.⁹ Prescriptions for specials not listed in the Drug Tariff Part VIIIB and Part VIID will be paid depending on how the special was sourced and the price endorsed on the prescription form.⁹ There is no set pricing for these pharmaceutical specials, and no national pricing structure governing the products or local regulation of the cost of products to the NHS. The unknown and variable cost of specials has financial implications for the NHS and can be a significant cost pressure.

The Scottish Drug Tariff, Part 7, includes a list of unbranded medicinal products and ingredients for which a price has been agreed for the current month.¹⁰ Reimbursement arrangements for special preparations and imported unlicensed medicines depends on whether a reimbursement price is listed in Part 7S of the Scottish Drug Tariff or not. If the preparation concerned is included in the list, the reimbursed price will be the price listed. Part 7S lists unlicensed specials obtainable from specials manufacturers, Part 7U lists commercially available products that do not have a product licence. A pharmacy contractor needs to seek reimbursement authorisation from the Health Board (HB) for all specials manufactured medicines, unlicensed or imported medications that are not listed in Part 7S or Part 7U of the Scottish Drug Tariff.¹¹

Please note there is currently no Part VIIIB to the Drug Tariff in Northern Ireland. Therefore, there are no set reimbursement prices for any specials.¹²

In England, approximately £49 million is spent annually on prescribing specials (unlicensed medicines). (NHSBSA June – August 2022)

All patients prescribed a special should be regularly reviewed to ensure that a special is (and remains) the most appropriate option.¹

What are the options around supply of specials to individual patients?

Local system governance arrangements should be in place to support the safe and effective procurement and supply of specials in order to provide consistently safe and effective specials to treat their patients.¹

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Each Integrated Care Board (ICB) in England, HB in Scotland and Wales should work on a shared policy and an agreed formulary for specials, used across their health system. The policy should cover the following information regarding specials:

- The most appropriate clinical setting for initiation of the special.
- Which specials are included in the policy, i.e. Part VIII B and Part VIII D Drug Tariff specials and /or non-Drug Tariff specials.
- Continued prescribing of the special, for example by whom and in which clinical setting.
- Transfer of care of patients prescribed specials, how this is done and what information needs to be provided to prescribers and patients. There must be a clear transfer of information that ensures a safe, consistent and timely supply of the special for the patient. [PrescQIPP bulletin 278: Transfer of care around medicines](#) covers good practice for safe and effective transfer of care between different care settings.
- How full prescribing history will be shared between prescribers to ensure patient safety.
- The procurement and supply of the special to the dispensing pharmacy and to the patient. The policy should describe how the procurement of specials will contribute to the [NHS Net Zero and Social Value goals](#).
- The monitoring required and who is responsible for this.
- The process to follow when a special is discontinued to ensure that information is shared with GP practice and the patient record updated.

The policy and formulary should be written by individual specialities and requires input and consultation across the ICB and HB from secondary care, primary care and community pharmacy.

To minimise the frequent problems associated with obtaining specials, different options around the choice and supply of specials should be considered.

Table 1 looks at some different options and considers some of the advantages and disadvantages of these options.

Table 1: Options for alternative supply of specials

Option	Advantage	Disadvantage
<p>1. Do nothing – Primary Care procurement and supply.</p>	<ul style="list-style-type: none"> • No change in workload for primary care, secondary care and community pharmacy. • No time needed to implement change. • No cost to implement change needed. • No need to go through a tendering process. 	<ul style="list-style-type: none"> • Risk to patient with quality and consistency of special. • Legal implications for primary care prescribers. • Supply issues associated with supply from community pharmacies. • Unknown cost implications for the NHS, no set pricing. • Potential to source more costly specials.
<p>2. Repatriation of specials requested from secondary care back to the prescribing hospital.</p>	<ul style="list-style-type: none"> • Ensures good quality and consistency of special (if provided by the hospital pharmacy) - NB if provided by outpatient hospital pharmacy that is outsourced to a community pharmacy, the same risks could exist, as if provided in primary care, unless there are restrictions on the supplier or ability to use in-house products. • No legal implications to primary care prescriber. • Potential to source less costly specials. • Known costs for specials. • Less risk to patient as from a consistent reliable known source. • Less risk of supply issues. • Can set up a service with one hospital/department at a time and address problems as they arise and then expand as needed. • Reduced workload for primary care and community pharmacy. 	<ul style="list-style-type: none"> • Time required to implement any change. • Cost required to implement any change. • Impact on community pharmacy - reduced business. • Increased workload for secondary care. • Relationship breakdown: community pharmacy and GP, community pharmacy and patient. • The need to go through a tendering process. • Primary care prescribers may continue to prescribe despite a service being set up. • Issues around direction of prescription. • Potential inconvenience for the patient. • Need to ensure full patient medicine records are available to all parties involved for patient safety, e.g. interactions

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<p>3. Repatriation of all specials through a single local new NHS service.</p>	<ul style="list-style-type: none"> • Ensures good quality and consistency of special. • No legal implications to primary care prescriber. • Potential to source less costly specials. • Known costs for specials. • Less risk to patient as from a consistent reliable known source. • Less risk of supply issues. • Reduced workload for primary care and community pharmacy. 	<ul style="list-style-type: none"> • Time to implement any change. • Cost to implement any change. • Impact on community pharmacy - reduced business. • The need to go through a tendering process. • Consider if full patient medicine records are available to all parties involved for patient safety, e.g. interactions and risk of duplication of prescribing. • Primary care prescribers may continue to prescribe despite a service being set up. • Relationship breakdown: community pharmacy and GP, community pharmacy and patient. • If done all at once may cause problems/delay resolution of problems. Increased workload for the new service initially. • Issues around direction of prescription. • Potential inconvenience for the patient.
<p>4. Community Pharmacy Enhanced Service scheme with a robust service specification.</p>	<ul style="list-style-type: none"> • Use approved list of suppliers, to ensure good quality and consistency of special. • Upfront cost known. • Less risk to patient as approved list of suppliers. • All prescribing from one system so reduced risk of separating items and risks attached to this. 	<ul style="list-style-type: none"> • Legal implications to primary care prescriber if still prescribed from primary care. • Time to implement any change. • Cost to implement any change. • Still may get issues associated with supply from community pharmacies. • Potential to source more costly specials.

Option 1: Do nothing**Table 2: SWOT analysis - Do nothing**

Strengths	Weaknesses
<ul style="list-style-type: none"> No disruption to any service. No change in workload to any service. No financial or time investment required to start up a new project. 	<ul style="list-style-type: none"> Unknown costs to NHS, as specials have no fixed price other than those listed in the Drug Tariff. Risk to patient in terms of quality, safety and efficacy of medicine as not necessarily sourced from same supplier and product has not gone through any quality assurance process.
Opportunities	Threats
<ul style="list-style-type: none"> Increased trust in community pharmacies to source products at a reasonable cost to the NHS. 	<ul style="list-style-type: none"> Conflict between prescribers and community pharmacies especially if not sourced at a reasonable price Legal implications to prescriber. Supply issues associated with supply from community pharmacies.

Table 3: STEP analysis - Do nothing

Sociological	Technological
<ul style="list-style-type: none"> Patient risk increased as prescribed unlicensed preparations. 	<ul style="list-style-type: none"> New licensed products on market which were previously considered specials.
Economic	Political
<ul style="list-style-type: none"> NHS resources. 	<ul style="list-style-type: none"> Medicines optimisation agenda.

Option 2: Repatriation of specials to secondary care

Table 4: SWOT analysis - Repatriation of specials requested from secondary care back to prescribing hospital

Strengths	Weaknesses
<ul style="list-style-type: none"> • Quality, consistency and cost of medication. • Reduced risk to patient. • Reduced litigation for primary care prescribers. • Reduced supply issues associated with community pharmacy. • Improved relationship between primary and secondary care. • Reduced workload for primary care and community pharmacy. • Easy to move to a licensed product if one replaces the special as centrally supplied 	<ul style="list-style-type: none"> • Time and cost to set up process/tender. • Continual changes as newly licensed formulations. • Relationships between primary care prescribers and community pharmacies may become negative. • Increased workload for secondary care. • Inconvenience to the patient. • Issues around direction of prescription. • All parties need access to patient medicine record.
Opportunities	Threats
<ul style="list-style-type: none"> • Becoming a champion to change. • Good relationship building between primary and secondary care. • Management of NHS resources. 	<ul style="list-style-type: none"> • Primary care prescribers time to undertake this workload. • Risk if: <ul style="list-style-type: none"> » Drug not added to patient record as third-party supplier - will not flag up potential drug interactions. » If not stopped from current repeat template, could be duplicated or will not flag up drug interactions. • Disinvestment in community pharmacy. • Conflict between GPs and community pharmacies. • Primary care prescribers may continue to prescribe despite a service being set up. Risks duplicate prescribing of the same item.

Table 5: STEP analysis - Repatriation of specials requested from secondary care back to prescribing hospital

Sociological	Technological
<ul style="list-style-type: none"> • Patient risk increased as prescribed unlicensed preparations. • Financial impact on community pharmacies. 	<ul style="list-style-type: none"> • New licensed products on market which were previously considered specials.
Economic	Political
<ul style="list-style-type: none"> • NHS resources. 	<ul style="list-style-type: none"> • NHS guidance. • Medicines optimisation agenda. • Community Pharmacy contract. • Direction of prescriptions.

Option 3: Repatriation of specials through a local NHS service**Table 6: SWOT analysis - Repatriation of all specials through a single local NHS service**

Strengths	Weaknesses
<ul style="list-style-type: none"> • Quality, consistency and cost of medication. • Reduced risk to patient. • Reduced litigation for primary care prescribers. • Reduced supply issues associated with community pharmacy. • Improved relationship between primary and secondary care. • Reduced workload for primary care and community pharmacy. 	<ul style="list-style-type: none"> • Time and cost to set up process/tender. • Continual changes as newly licensed formulations. • Relationships between primary care prescribers and community pharmacies may become negative. • Inconvenience to the patient. • Issues around direction of prescription.
Opportunities	Threats
<ul style="list-style-type: none"> • Becoming a champion to change. • Good relationship building between primary and secondary care. • Management of NHS resources. 	<ul style="list-style-type: none"> • Primary Care prescribers time to undertake this workload • Risk if: <ul style="list-style-type: none"> » Drug not added to patient record as third-party supplier - will not flag up potential drug interactions. » If not stopped from current repeat template, could be duplicated or will not flag up drug interactions. • Conflict between GPs and community pharmacies. • Primary care prescribers may continue to prescribe despite a service being set up. Risk of duplicate prescribing of the same item.

Table 7: STEP analysis - Repatriation of all specials through a single local NHS service

Sociological	Technological
<ul style="list-style-type: none"> • Patient risk increased as prescribed unlicensed preparations. • Financial impact on community pharmacies. 	<ul style="list-style-type: none"> • New licensed products on market which were previously considered specials. • Fewer specials prescribed as more clinical systems flag up unlicensed medicines more readily.
Economic	Political
<ul style="list-style-type: none"> • NHS resources. 	<ul style="list-style-type: none"> • Medicines optimisation agenda. • Community pharmacy contract. • Direction of prescriptions.

Option 4: Community pharmacy enhanced service scheme**Table 8: SWOT analysis - Community pharmacy enhanced service scheme**

Strengths	Weaknesses
<ul style="list-style-type: none"> • Quality, consistency and cost of medication as approved list of suppliers used. • Reduced risk to patient as known source of supply. • Reduced litigation for primary care prescribers as known source of supply. • Improved relationship between primary care and community pharmacy. • Upfront costs known. 	<ul style="list-style-type: none"> • Time and cost to set up process/tender. • Continual changes as newly licensed formulations, so regular review of contract needed. • Buy in from community pharmacies to undertake enhanced service. • Risk that patient can't access a suitable pharmacy for supply. • Range and location of community pharmacies that undertake enhanced service. • Legal implications to primary care prescriber if still prescribed from primary care. • Still may get issues associated with supply from community pharmacies. • Potential to source more costly specials.
Opportunities	Threats
<ul style="list-style-type: none"> • Becoming a champion to change. • Good relationship building between primary and secondary care. • Management of NHS resources. 	<ul style="list-style-type: none"> • Cost to set up service. • Disengagement from community pharmacies that are not part of enhanced service.

Table 9: STEP analysis - Community pharmacy enhanced service scheme

Sociological	Technological
<ul style="list-style-type: none"> • Patient risk increased as prescribed unlicensed preparations. • Financial impact on primary care. 	<ul style="list-style-type: none"> • New licensed products on market which were previously considered specials. • Less specials prescribed as more clinical systems flag up unlicensed medicines more readily.
Economic	Political
<ul style="list-style-type: none"> • NHS resources. • Cost to set up as enhanced service. 	<ul style="list-style-type: none"> • Medicines optimisation agenda. • Community pharmacy enhanced services contract. • Direction of prescriptions.

Options appraisal

An options appraisal is very important to ensure that a pathway is chosen that suits all the organisations involved.

When considering working with secondary care, ensure to build up strong relationships with good communications and be adaptable and flexible. If considering repatriation of specials to secondary care, it may be easier to start with one hospital/department as a small pilot project and then develop the project as services become embedded. Think about how patients will access their supply and if access to prescribing records is available to mitigate risk.

Working with community pharmacies will also require strong relationships with good communication and to be adaptable and flexible. Community pharmacy will be affected by any changes in the procurement of specials, and in any of the agreed changes proposed it would be more beneficial to ensure good working relationships. Consider engaging with the Local Pharmaceutical Committee (LPC) early in the process to get them on board, help communicate the messages and have an agreed way forward that works for all parties involved, especially the patient. It is important that the specification written for the enhanced service is robust and an equality and diversity analysis is undertaken so as not to disadvantage anyone. It would be important to seek advice from the procurement team within the organisation.

Funding options

Top slice the prescribing budget - current spend on specials is reimbursed against the primary care prescribing budget and if spend on specials in primary care decreases, these savings can be released to pay for the commissioned service where specials are sourced at less cost to the whole system.

Business case – this may be needed should there be any upfront costs (also known as “pump priming” the service); ongoing future costs would be met through prescribing budget top slice arrangements. Upfront funding may be required for staff to support the project- one option would be to share the funding of post(s) across health care sectors. The PrescQIPP website has [business case training](#) webinars which provide support in writing business cases.

Supporting documents

In addition to this bulletin, several resources have been included to support systems and organisations when considering repatriation of specials to secondary care. Most of these additional resources were produced by Birmingham CrossCity CCG working with their local Clinical Commissioning Groups (Birmingham South Central CCG and Solihull CCG) and Birmingham Women's and Children's NHS Foundation Trust, as a part of a systemwide project to deal with the repatriation of specials. In these examples, all specials initiated by the hospital and prescribed in primary care were repatriated back into the secondary care Trust. These documents can be adapted to meet local needs and, if used, please acknowledge their source as we do in this bulletin.

- Attachment 1 - Repatriation Standard Operating Procedure: this gives guidance on the hospital referral process and supporting documents.
- Attachment 2 - GP Referral Form: to be completed fully by the GP and emailed or posted to the hospital pharmacy once the clinical decision has been made to refer back to the hospital prescribing the special.
- Attachment 3 - Medicines for Children – Information for parents and carers. Unlicensed Medicines: Patient Information Leaflet aimed at unlicensed medicines use in children, this leaflet supports patients/parent/carers with regards to what an unlicensed medicine is.
- Attachment 4 - specials Prescribing Policy Template: for practices to adapt to help define in-house procedures for this process.

- Attachment 5 - Significant Change GP Communication Form: information to be emailed or posted to the hospital pharmacy team should there be any significant change in the patient's medication/health/change in other prescribed medicines etc.
- Attachment 6 - Repatriation Shared Care: outlines the responsibilities of all parties involved and it is recommended that it should be filed/scanned into patient's notes as per the Standard Operating Procedure.
- Attachment 7 - Consent Letter and Form: if the GP wishes to seek consent from an existing patient/parent/ carer to refer specials prescribing back to the hospital.
- Attachment 8 - Questions and Answers for Practices: Explains to prescribers why this process is being considered and what is required of them.
- Attachment 9 - GP letter: to advise Primary Care Prescribers where a special has been retained in Secondary Care and confirm that patient consent has been obtained.
- Attachment 10 - Repatriation Flow Chart of Methods: Diagram shows the different supply routes and options for specials initiated in Secondary Care.
- Attachment 11 - Repatriation Process Map: Illustrates the process flow and links with different health care sectors.

The [PrescQIPP specials webkit](#) brings together all the PrescQIPP specials resources and suggests good practice and how to optimise the use of licensed medicines, alternatives and reviews to be done to support the reduced use of specials.

Summary

A special is an unlicensed medicine that does not have either a centrally authorised Marketing Authorisation in the European Union, or a UK Marketing Authorisation. It is manufactured, imported or supplied to meet the special clinical needs of an individual patient.¹ Prescribing should be optimised by reviewing the continued need for a special and offering an alternative licensed product and reviewing the continued need for the medicine at all.

ICBs in England and HBs in Scotland and Wales should work on a shared policy and an agreed formulary for specials. The policy and formulary should be written by individual specialities and requires input and consultation across the ICB and HB from secondary care, primary care and community pharmacy.

When appraising different options around the choice and supply of specials, it is beneficial to have an open communication network with support mechanisms in place to ensure that good quality and cost-effective specials are acquired which meet the patient's needs. Often prescribers (particularly in secondary care) are unaware of the huge cost impact of specials in primary care. An equality and diversity impact analysis for any service model under consideration should be undertaken to ensure no patient group(s) is disadvantaged by the proposed methodology. Where there is a decision to go out to procurement, a conversation with your local procurement team within the ICB or HB could also be beneficial to ensure current procurement rules are considered.

The options included in the bulletin are some examples that may be considered, but other models may also be contemplated. It is important to consider the practicalities for the individual organisations involved to help support any proposal moving forward, as engagement will be required from everyone.

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Additional PrescQIPP resources

Briefing	https://www.prescqipp.info/our-resources/bulletins/bulletin-317-repatriation-of-specials/
Implementation tools	

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