February 2022

PSNC Briefing 005/22: Part VIIID – Specials with reimbursement prices relative to commonly identified pack sizes

Background

From March 2022, the Drug Tariff **will include a new section, Part VIIID, which sets out payment arrangements for specials and imported unlicensed medicines (specials) to be paid relative to an identified pack size. This is the first of many changes expected to drug reimbursement following the publication of** Department of Health and Social Care's (DHSC's) response to the 2019 consultation on community pharmacy drug reimbursement reforms.

Introduction

Q. Why is there a new section for specials in the Drug Tariff?

A. Specials currently listed in Part VIIIB of the Tariff are restricted to manufactured non-solid dosage forms (for example liquids, creams, ointments and lotions etc) which, except for products classed as special containers, are reimbursed based on a price per unit above a minimum quantity. In comparison, **majority of the specials listed in Part VIIID will be unlicensed medicines (mainly unlicensed tablets and capsules), with reimbursement prices calculated relative to commonly identified pack sizes.** The pack size listings are to support Broken Bulk claims which will be permitted for specials (except those classed as special containers) listed in Part VIIID from March 2022. Please note: Broken Bulk **CANNOT** be claimed for any specials listed in Part VIIIB of the Tariff or for any non-Tariff special.

Q. Why has this been implemented?

A. According to DHSC's consultation response, there is no incentive for pharmacy contractors to source non-Tariff specials at the cheapest price possible because they are reimbursed the invoice price (less any discount or rebate). Consequently, the prices paid for those specials vary enormously and, in some instances, pharmacy contractors appear to have been charged excessive prices that do not reflect the cost of manufacturing the special. By introducing specials (mainly unlicensed tablets and capsules) into Part VIIID, contractors will be reimbursed a fixed price relative to a commonly identified pack size. This will help the NHS reduce its overall spend on specials.

Q. How many products will be added to Part VIIID?

A. Initially, **47** specials with different formulations have been added to Part VIIID in the March 2022 Drug Tariff (published in the preface section of the February 2022 Drug Tariff). Examples of Part VIIID specials include:

Product	Pack size(s)	Formulation(s)
Albendazole 400mg tablets	1	STD
Benzbromarone 100mg tablets	30	STF, FF, LF, SF
Levothyroxine 50microgram capsules	28	STD, LF, SF
Metolazone 2.5mg tablets	4 100	STD, LF, SF

Price-setting of specials listed in Part VIIID

Q. How are reimbursement prices for Part VIIID specials determined?

A. Specials listed in Part VIIID have a pack size listing and a price which has been determined by the Secretary of State, based on information submitted by manufacturers and wholesalers that hold a Specials Manufacturers Licences or a Wholesale Dealer's Licence as issued by the Medicines and Healthcare products Regulatory Agency (MHRA). Similar to Part VIIIB, reimbursement prices for specials listed in Part VIIID will be updated quarterly based on information obtained under the Health Service Products (Provision and Disclosure of Information) Regulations 2018. In calculating Part VIIID reimbursement prices, for tablets and capsules, pack sizes up to and including 250-unit doses will be considered.

Q. Will the quarterly price-setting for Part VIIID specials follow the same timetable as Part VIIIB?

A. Sales and volume data for Drug Tariff specials (Part VIIIB and Part VIIID) are obtained from suppliers under the Health Service Products (Provision and Disclosure of Information) Regulations 2018. This information is used to determine their reimbursement prices each quarter. Prices for Part VIIID specials will be updated quarterly in the same months as current Part VIIIB specials (February, May, August and November). With implementation of Part VIIID starting in March 2022, Part VIIID prices will be updated next in May 2022 to bring it in line with the quarterly price-setting timetable for Part VIIIB specials.

Q. Why are some specials not listed in the Drug Tariff?

A. Only specials that meet the minimum spend and volume requirements are included in the Drug Tariff. Initially, Part VIIID specials will mainly include tablets and capsules. However, in time, further formulations will be considered (e.g. imported patches, sprays etc).

Q. How are the pack size listings for Part VIIID specials determined?

A. As it would not be practical to list every available pack size of a special listed in Part VIIID, only the most common identified pack size(s) based on the latest two quarters' (Jul-Sep 21 and Oct-Dec 21) specials data submitted by suppliers to DHSC are listed. For some Part VIIID specials, more than one pack size may be listed if this is supported by the available data. The pack size listing is intended to support Broken Bulk claims which are permitted for specials listed in Part VIIID.

Dispensing and endorsing requirements

Q. How should a prescription for a Part VIIID special be endorsed?

A. The following endorsements apply for specials listed in Part VIIID:

- '**SP**' – to claim the £20 fixed fee to cover the costs incurred when sourcing the special.

	Prescribed Medication
SP	**Co-proxamol 32.5mg/325mg tablets** **100 tablets** **As directed**

- **Where appropriate, Broken Bulk may be claimed for Part VIIID specials (unless the item is classed a special container)**. The prescription must be endorsed with **'BB'**.

	Prescribed Medication
SP	**Co-proxamol 32.5mg/325mg tablets**
BB	**56 tablets**
	As directed

Note: **For Broken Bulk claims for Part VIIID specials, where the contractor endorses the prescription form 'BB' and regardless of any pack size endorsement, payment will be made for the nearest pack size or multiple of Drug Tariff listed pack size(s) sufficient to supply the quantity prescribed.** If, however, a listed pack size of a Part VIIID special is unobtainable in any given month, PSNC can request a change to the pack size listing for that month. Once a pack size listing change is agreed, DHSC will publish details of any pack sizes which will be accepted for Broken Bulk claims and preparations to which this applies and the month(s) in which it applies.

Q. When can a new Broken Bulk claim be made for a Part VIIID special?

A. Contractors should only submit a Broken Bulk claim if it is **unlikely that they will be able to dispense any remaining balance of a product within the following six months**. When Broken Bulk is claimed for a Part VIIID special, contractors are reimbursed for **the nearest pack size or multiple of Drug Tariff listed pack size(s) sufficient to supply the quantity prescribed**. Subsequent prescriptions for the same Part VIIID special, received during the next six months, will be deemed to have been supplied from the remainder and no further payment will be made to drug costs other than fees and consumables and container allowances until that remainder has been or is deemed to have been used up. A new Broken Bulk claim for the Part VIIID special can only be submitted once the remaining balance is used up or after six months of the original claim, whichever is earlier.

Q. Can Broken Bulk be claimed for specials listed in Part VIIIB and on non-Tariff specials?

A. No, Broken Bulk claims are ONLY permitted for specials listed in Part VIIID. Note: Broken Bulk **CANNOT** be claimed for any Part VIIIB special. Also, Broken Bulk **CANNOT** be claimed for any non-Tariff special unless the claim is for the individual ingredients used to prepare an extemporaneously dispensed specials under the manufacturing part of the Section 10 exemption from the Medicines Act 1968).

Q. If a prescriber orders a Part VIIID special by brand name (or supplier), will a contractor be reimbursed based on their endorsement or the Part VIIID price?

A. If a prescriber orders a Part VIIID special by brand or includes details of a specific supplier to obtain the special from, contractors will be reimbursed based on their endorsement (i.e., as a non-Tariff special). For specials ordered via EPS, the prescriber will need to select the correct product description (AMP) if available on prescribing systems or, consider providing a replacement paper FP10 prescription from with the brand or supplier specified as part of the drug name to ensure that it can be accurately priced by the NHSBSA.

Q. A prescriber has specified a particular brand (or supplier) of a Part VIIID special in the dosage area of an electronic prescription. Will the specials be reimbursed based on the contractors' endorsement or as per the price listed in Part VIIID?

A. Any additional/supplementary product information added by a prescriber to a different part of an electronic prescription (for example the dosage area or notes section), is not captured by the NHSBSA during pricing. Therefore, regardless of the brand or supplier specified in the dosage area of an EPS prescription, contractors will only be reimbursed the Part VIIID price and not their endorsed price.

If an electronic prescription annotated with additional/supplementary product information is received by a pharmacy, it is strongly recommended to have such prescriptions appropriately rewritten/re-issued by the prescriber before dispensing. For specials, the prescriber will need to select the correct product description (AMP) if available on prescribing systems or, consider providing a replacement paper FP10 prescription form with the brand or supplier specified as part of the drug name to ensure that it can be accurately priced by the NHSBSA. Further information can be found in the PSNC factsheet on dealing with EPS product information within the dose area.

Q. Can price concessions be granted for any specials listed in the Drug Tariff? What do I do if I cannot source a product at the price indicated in Part VIIID of the Drug Tariff?

A. Yes, price concessions can be granted for any specials listed in the Drug Tariff. Any pricing issues affecting Part VIII drugs (including specials) can be reported to PSNC for further investigation. Contractors should report pricing issues to PSNC here.

Submission

Q. Do prescription red separator sorting requirements apply to FP10 paper prescriptions for Part VIIID specials?

A. Yes, all FP10 paper prescription forms for Drug Tariff-listed and non-Tariff specials are required to be placed in the relevant red separator for end of month submission.

Q. Do COA/COCs for non-Tariff specials need to be submitted by contractors to the local NHSE&I team of the prescriber?

A. The Drug Tariff no longer has a requirement for contractors to submit copies of the Certificate of Analysis (COA) or Certificate of Conformity (COC) to the local NHS England and NHS Improvement (NHSE&I) team of the prescriber after dispensing unlicensed specials or imports not listed in the Drug Tariff.

As contractors are still required to keep the necessary records of unlicensed specials or imports they dispense for a period of five years, any COAs and COCs obtained should be retained by the pharmacy for this purpose.

Q. How will contractors know how much they were paid for a Part VIIID product they dispensed?

A. If the value of the Part VIIID special dispensed exceeds £100 this will be detailed on the Schedule of Payments under section titled Summary of expensive items. Payment information can also be accessed on the Prescription Item (Px) Report which is a monthly data report containing item-level payment information showing the reimbursement and remuneration calculated by the NHSBSA for each item submitted for payment. For more information see our Factsheet: How to access your Prescription Item Reports.

Further support and guidance

If you have queries on this PSNC Briefing or require more information, please email PSNC's Dispensing and Supply Team on info@psnc.org.uk or call 0203 1220 818.

Appendix 1: Prescription endorsing requirements for specials and imported unlicensed medicines

The prescription endorsement requirements for specials and imported unlicensed medicines vary depending on whether a product is listed in the Drug Tariff (Part VIIIB or Part VIIID) but also how the special was sourced. Below are examples of the different prescription endorsement requirements for both Drug Tariff-listed and non-Tariff specials.

Endorsement details required

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1. Specials listed in Part VIIIB

	Prescribed Medication
SP	**Bisacodyl 2.5mg/5ml oral suspension** **100ml** **As directed**

- **'SP'** – to claim the £20 fixed fee for preparations manufactured under a Manufacturer 'Specials' Licence or sourced under a Wholesale Dealer Licence issued by the MHRA. This fixed fee is to cover all costs incurred when sourcing the product.

  Note: Alternatively to the 'SP' endorsement, the '**ED**' endorsement can be used to claim the £20 fixed fee for specials extemporaneously prepared by the contractor or a third party under the Section 10 exemption from the Medicines Act.

- No other endorsements are required.

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2. Specials listed in Part VIIID

a. without a Broken Bulk (BB) claim

	Prescribed Medication
SP	**Co-proxamol 32.5mg/325mg tablets** **100 tablets** **As directed**

- **'SP'** – to claim the £20 fixed fee for preparations manufactured under a Manufacturer 'Specials' Licence or sourced under a Wholesale Dealer Licence issued by the MHRA. This fixed fee is to cover all costs incurred when sourcing the product.

  Note: Alternatively to the 'SP' endorsement, the '**ED**' endorsement can be used to claim the £20 fixed fee for specials extemporaneously prepared by the contractor or a third party under the Section 10 exemption from the Medicines Act. However, it is unlikely that the 'ED' endorsement will apply to any specials listed in Part VIIID.

- No other endorsements are required.

b. with a Broken Bulk claim

	Prescribed Medication
SP BB	**Co-proxamol 32.5mg/325mg tablets** **56 tablets** **As directed**

- '**SP**' – to claim the £20 fixed fee of £20 for preparations manufactured under a Manufacturer 'Specials' Licence or sourced under a Wholesale Dealer Licence issued by the MHRA. This fixed fee is to cover all costs incurred when sourcing the product.

  Note**:** Although unlikely to apply for Part VIIID specials, the '**ED**' endorsement, alternatively to the '**SP**' endorsement can be used to claim the £20 fixed fee for any specials extemporaneously prepared by the contractor or a third party under the Section 10 exemption from the Medicines Act.

- **Broken Bulk** may be claimed if necessary. To claim for Broken Bulk, the prescription must be endorsed with **'BB'**.

  Note: Regardless of any pack size endorsement, payment will be made for the nearest pack size or multiple of Drug Tariff listed pack size(s) sufficient to supply the quantity prescribed.

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3. Specials not listed in the Drug Tariff

*a. non-Tariff **manufactured** special*

	Prescribed Medication
SP £x.xx/pack 100/100 Batch No Manufacturer ABC1234	Clopidogrel 25mg/5ml oral suspension (Special Order) 100 ml As directed

- '**SP**' – to claim the £20 fixed fee for preparations manufactured under a Manufacturer 'Specials' Licence or sourced under a Wholesale Dealer Licence issued by the MHRA. This fixed fee is to cover all costs incurred when sourcing the product.

  Note**:** Alternatively to the 'SP' endorsement, The '**ED**' endorsement can be used to claim the £20 fixed fee for specials extemporaneously prepared by the contractor or a third party under the Section 10 exemption from the Medicines Act.

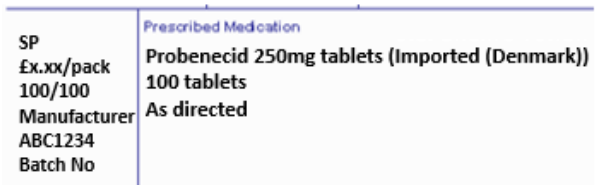
- **Invoice price per pack size** from which the product was supplied less any discount/ rebates.

- **Pack size** from which the order was supplied.

- MHRA **Manufacturers' Specials licence number**.

- **Batch number** of special.

*b. non-Tariff **imported** unlicensed medicine*



SP £x.xx/pack 100/100 Manufacturer ABC1234 Batch No	Prescribed Medication Probenecid 250mg tablets (Imported (Denmark)) 100 tablets As directed

- '**SP**' – to claim the £20 fixed fee for preparations manufactured under a Manufacturer 'Specials' Licence or sourced under a Wholesale Dealer Licence issued by the MHRA. This fixed fee is to cover all costs incurred when sourcing the product.
- **Invoice price per pack size** from which the product was supplied less any discount/ rebates.
- **Pack size** from which the order was supplied.
- MHRA **Wholesale Dealer licence number**.
- **Batch number** of imported unlicensed medicine (if available).

Please note:

- **Use of 'OOP'/ 'XP' endorsement for any out-of-pocket expense claims is not permitted for any specials or imported unlicensed medicines (both Drug Tariff and non-Tariff).**
- **Broken Bulk claims are ONLY permitted for specials listed in Part VIIID. Broken bulk CANNOT be claimed for any Part VIIIB or non-Tariff specials.**
- **FP10 paper prescriptions for specials or imported unlicensed medicine should continue to be placed in the relevant red separator as part of the end of month submission process.**

Appendix 2: Comparison of key features of Drug Tariff-listed and non-Tariff specials

	Drug Tariff listed specials		Non-Drug Tariff specials
	Part VIIIB	**Part VIIID**	
Pricing arrangements	Specials and imported unlicensed medicines listed in Part VIIIB are currently restricted to manufactured non-solid dosage forms (for example liquids, creams, ointments and lotions etc.) which, except for products classed as special containers, are **reimbursed based on a price per unit above a minimum quantity.**	Products listed in Part VIIID will be specials and imported unlicensed medicines (mainly unlicensed tablets and capsules) with **reimbursement prices calculated relative to commonly identified pack sizes**.	All non-Drug Tariff specials are **reimbursed based on endorsement of the invoice price (less any discount and rebate) of the pack size used**.
Broken Bulk	Broken Bulk **CANNOT** be claimed on specials and imported unlicensed medicines listed in Part VIIIB.	**Broken Bulk CAN be claimed on specials and imported unlicensed medicines listed in Part VIIID** (unless the product is classed as a special container). To claim for Broken Bulk, the prescription must be endorsed with '**BB**'. Note: For Broken Bulk claims for Part VIIID specials, where the contractor endorses the prescription form 'BB' and regardless of any pack size endorsement, payment will be made for the nearest pack size or multiple of the pack size(s) listed in the Drug Tariff to the quantity prescribed.	Broken Bulk **CANNOT** be claimed on any non-Drug Tariff unlicensed specials and import unless the claim is for the individual ingredients used to prepare an extemporaneously dispensed specials under the manufacturing part of the Section 10 exemption from the Medicines Act 1968).
Discount deduction	**All Part VIIIB specials and imported unlicensed medicines are subject to the discount deduction scale** unless the product meets any of the Group Items Discount Not Deducted (DND) criteria for example a Schedule 2 or 3 Controlled Drug or require cold storage.	**All Part VIIID specials and imported unlicensed medicines are subject to the discount deduction scale** unless the product meets any of the Group Items Discount Not Deducted (DND) criteria for example, a Schedule 2 or 3 Controlled Drug or requires cold storage.	As Group Items, all specials and imported unlicensed medicines not listed in the Drug Tariff **are automatically exempt from any discount deduction** i.e. all non-Drug Tariff specials are automatically granted DND status
Price concessions	**Price concessions can be granted for any product listed in Part VIIIB. Please report any**	**Price concessions can be granted for any product listed in Part VIIID. Please report any**	N/A

	Drug Tariff listed specials		Non-Drug Tariff specials
	Part VIIIB	Part VIIID	
	Part VIIIB pricing issues to PSNC here.	**Part VIIID pricing issues to PSNC here.** Note: If a Part VIIID listed pack size is not available, a pack size concession can be granted by the Department. The updated pack size will be used for any Broken Bulk claims. Please report any pack size availability concerns to PSNC.	
Certificate of Analysis (COA) / Certificate of Conformity (COC)	No COA / COC needed	No COA / COC needed	For non-Drug Tariff specials, contractors must stamp, date, initial and endorse the COA / COC with the invoice price less discount and prescriber's details and retain the COA / COC for 5 years. For non-Tariff imported unlicensed medicines, contractor shall make every reasonable effort to obtain a COA / COC for each imported product sourced and retain the COA/COC for 5 years. Where a COA / COC is available, contractors must stamp, date, initial and endorse the COA / COC with the invoice price less discount and prescriber's details. If COC / COA is not available, the contractor must endorse required information on the invoice.
Record keeping requirements	When supplying an unlicensed special or imported unlicensed medicine to a patient, in all instances the pharmacy is required by the MHRA to keep a record of the following information for 5 years: • The source of the special or imported unlicensed product • The person to whom and the date on which the special or imported unlicensed product was sold or supplied • The prescriber's details • The quantity of each sale or supply • The batch number of the special		