

Dispensing Factsheet: Unlicensed Specials and Imports

The requirements for endorsing unlicensed specials and imports vary depending on whether the product is listed in Part VIII B or not and how the product was sourced. Contained within this guide are examples of different products and how they should be endorsed.

What is an “unlicensed special”?

The Drug Tariff provides this definition of a special:













“Specials are unlicensed medicinal products manufactured in the UK for human use which have been specially prepared to meet a prescription ordered for individual patients without the need for the manufacturer to hold a marketing authorisation for the medicinal product concerned.”

What is an “unlicensed import”?

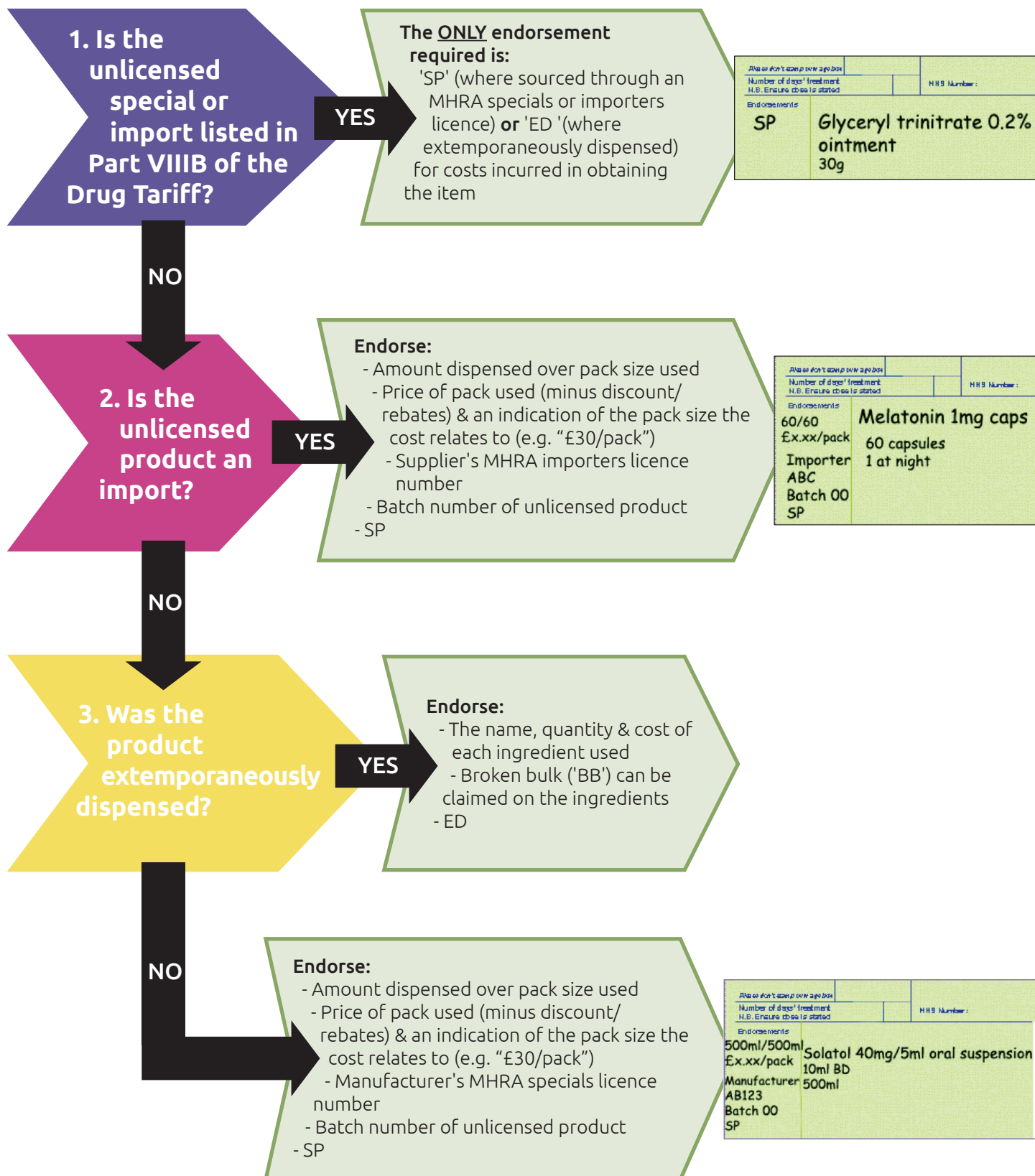
This is a product which is manufactured and may hold a license in another country but it is not a licensed product in the UK.

Please note: If a medicine does not meet either of the above descriptions, then the details contained in this factsheet do not apply.

Additional fees that can and cannot be claimed for unlicensed specials and imports

Type of claim	Part VIII B products	Non-Part VIII B products	Extemporaneously dispensed Part VIII B products
Broken bulk			 (can be claimed on the ingredients used)
Out of pocket expenses	 (endorse ‘SP’ to claim the appropriate fixed fee instead)	 (endorse ‘SP’ to claim the appropriate fixed fee instead)	 (endorse ‘ED’ to claim the appropriate fixed fee instead)
Discount not given (also known as zero discount)	 (Part VIII B prices include margin)	 (no endorsement required as they are automatically recognised as discount not given lines)	 (no endorsement required as this is now an automated process for any eligible ingredients)
Costs incurred in obtaining the item	 (use ‘SP’ to claim a fixed fee of £20)	 (use ‘SP’ to claim a fixed fee of £20)	 (use ‘ED’ to claim a fixed fee of £20)

How and when to endorse unlicensed specials and imports



Endorsement and payment for Part VIIIB items

Products listed in Part VIIIB, endorse 'SP' for products sourced under an MHRA specials license or importers license OR 'ED' for products prepared under the Section 10 exemption from the Medicines Act 1968 (see picture below).

Where a quantity is below or equal to the Part VIIIB listed minimum volume, reimbursement will be the price for the minimum volume. If the quantity prescribed is more than this minimum volume, reimbursement will be paid on that price plus the 1ml or 1g list price for every additional 1ml or 1g prescribed.

Worked example:

- Total quantity prescribed – 200ml
- Part VIIIB minimum volume listed – 100ml
- Listed price for minimum volume – £100*
- Listed price for each extra ml – £0.50*
- Reimbursement calculation:
1x100ml + 100x1ml, which equals £100 + (100 x £0.50) or £100 + £50 = **£150***

Please don't stamp over this box		NHS Number:
Number of days' treatment N.B. Ensure dose is stated		
Endorsements SP	Zopiclone 7.5mg/5ml oral suspension 200ml	

**All prices used are example prices only; please check Part VIIIB of the current Drug Tariff for the latest reimbursement information.*

Please note: Products which are classified as unlicensed specials are not recognised by the MHRA as having brand names. For example, products such as Anoheal (Diltiazem hydrochloride 2% cream) and Epistatus (Midazolam 10mg/ml oral solution) are always paid on the price of the generic version as listed in Part VIIIB of the Drug Tariff.

Endorsement and payment of non-Part VIIIB items

Please look at this worked example to see how to endorse items that are not listed in Part VIIIB and how this endorsement is used to calculate the reimbursement price.

Worked example: (see picture opposite)

- Quantity dispensed – 15 capsules
- Pack size – 30 capsules
- Product should be endorsed with quantity dispensed over pack size used.
- Price should be the **price per pack less any discount/rebates** and not the total invoice price.
- Reimbursement calculation:
One pack of 30 costs £30, so pro-rata the Pricing Authority will pay **£15** for dispensing 15 (example price only)

Please don't stamp over this box		NHS Number:
Number of days' treatment N.B. Ensure dose is stated		
Endorsements 15/30 £30/pack	Melatonin 1mg caps 15 capsules 1 at night	
Importer ABC Batch 00 SP		

Additional endorsing requirements:

- Special Manufacturer's or Importer's MHRA licence number
- Batch Number of the product
- Specials Procurement Fee (SP)

Record sending requirements for non-Part VIIIB items

- At the end of each month, a copy of the endorsed Certificate of Analysis (COA)/ Conformity (COC) or invoice must be sent to the prescriber's Area Team.
- Don't forget to remove/black out any patient details before sending these to the Area Team.
- For **specials not listed in Part VIIIB**, stamp, date, initial and endorse the COA/COC with the invoice price paid per pack less any discount/rebates and the prescriber's details.
- For **imports not listed in Part VIIIB**, make every reasonable effort to obtain a COA/COC. Where one is available, endorse as above. Where one is not available, stamp, date, initial and endorse the invoice with the invoice price less discount and the prescriber's details.
- If you are unsure who to send the COC/COA form to at the Area Team, contact your LPC for further guidance.

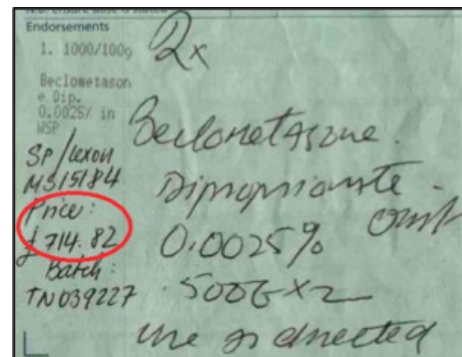
How NOT to endorse your unlicensed medicines

You should ALWAYS endorse the price per pack size dispensed and make sure this is clear.

Opposite is an example of where the product price is unclear and may affect payment. It is not clear whether the price endorsed relates to the quantity that has been dispensed or the pack size that was used.

Pharmacy staff should always endorse the price per pack size as shown above, i.e. **price/pack size (£30/30 or £30/pack)***

***NB. The invoice price endorsed on a prescription for a non-Part VIII B special/ import MUST be the actual price paid per pack less any discounts/rebates.**



For the most up to date information on unlicensed specials and imports, please visit the **PSNC website: psnc.org.uk/specials**

Unlicensed medicines: Frequently Asked Questions

Q. I normally source my specials through a wholesaler – how will I be paid for (and how should I endorse) my specials?

Wholesalers typically categorise products as being either a “standard line” or “special obtain” item. Items classified as “special obtains” are those which the wholesaler may not have readily available in stock and has to “obtain specially” on a bespoke ad-hoc basis. Items which are obtained in this way are not automatically considered as a ‘special unlicensed medicine’, e.g. food products, stoma or incontinence appliances, or vitamin supplement products.

To identify an unlicensed special, pharmacy staff should look for the wholesaler’s MHRA specials licence number on the product packaging and invoice. For unlicensed imports, the invoice will state the wholesaler’s MHRA importers licence number.

Where the unlicensed special is listed in Part VIII B, the contractor will be paid this price regardless of how the product was sourced. However, for those unlicensed specials and imports not listed in Part VIII B, the contractor will be paid according to how the product was manufactured. Where the product is manufactured under an MHRA specials licence, pharmacy contractors need to endorse:

- the wholesaler’s invoice price less discount;
- the pack size used to dispense from;
- the manufacturer’s licence number;
- the batch number of the product.

Where the product is manufactured under the section 10 exemption of the Medicines Act 1968 (when a product can be made on a pharmacy premises without the need for a licence), pharmacy contractors need to endorse the names, quantities and cost of the ingredients used in preparing the product.

Along with payment for the product, the contractor will also be paid the appropriate additional payment depending on whether the product was manufactured by an MHRA licensed specials manufacturer under their licence (they must endorse SP) or manufactured under the section 10 exemption by the contractor or by a 3rd party (they must endorse ED).

Q. What should I do with COCs/ COAs for prescriptions from other parts of the UK?

For prescriptions for unlicensed specials and imports not in Part VIII B originating from Wales, Scotland or Northern Ireland, the COCs and COAs should be retained for audit purposes, but there is no requirement for them to be sent to their health bodies.



Looking for more help sorting your monthly prescription bundles?

PSNC has produced a series of factsheets explaining exactly how to sort your bundles, with top tips to increase the chances of accurate pricing.

Download them at **psnc.org.uk/payment**