

## Unlicensed specials and imports FAQs

### **The Drug Tariff gives 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."*

### **a) What happens if I receive a prescription for an unlicensed special at the end of October and order it, but then don't actually receive the product until November?**

From 1<sup>st</sup> November 2011 contractors dispensing prescriptions for unlicensed specials and imports will be reimbursed under the new arrangements and products listed in Part VIIIIB will be reimbursed at the fixed Drug Tariff price. Contractors should therefore be careful that any prescriptions received in October are submitted promptly for payment with October's prescriptions, to avoid the risk of items being reimbursed at the November Drug Tariff price, which may be lower than the price they have been charged in October. If necessary contractors should contact their specials manufacturer by telephone to ascertain the invoice price for items ordered in October, if the invoice has not been received by the time the October prescription bundles are being prepared for dispatch to NHS Prescription Services.

### **b) What is happening with imported products?**

Imported products will also be included in these new rules surrounding unlicensed specials.

### **c) How are the basic prices in Part VIIIIB applied for reimbursement?**

For Part VIIIIB products, the minimum reimbursement a pharmacy contractor will receive is the list price for the pack size given. If the quantity on a prescription is more than the Part VIIIIB listed pack size, reimbursement will be paid on the listed pack size plus the 1ml or 1g list price for every additional 1ml or 1g prescribed.

For example, a prescription for 200ml of an unlicensed special with a Part VIIIIB listed pack size of 100ml, the price will be calculated as 1 x 100ml + 100 x 1ml.

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

If you source a product through your wholesaler's 'special obtains' department, it wouldn't automatically be recognised as an unlicensed special. 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. When an order is placed at the wholesaler, the wholesaler will then specifically obtain the product on a bespoke ad-hoc basis. However; many items which are obtained in this way would not be considered a 'special unlicensed medicine', e.g. food products, stoma or incontinence appliances, or vitamin supplement products.

Where the unlicensed special is listed in Part VIIIIB, 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 VIIIIB, 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 a 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).

**e) I have received a prescription for an unlicensed special medicine listed in Part VIIIIB of the Drug Tariff, which specifies the name of a manufacturer where the prescriber wishes the medicine to be obtained from. Will I be reimbursed for obtaining the specific manufacturer's product, or will I only be reimbursed the Drug Tariff Part VIIIIB price?**

Where there is no endorsement or there is an indication that the Part VIIIIB item has been supplied then you will be reimbursed the Part VIIIIB price. If however there is an endorsement of the specific manufacturer requested and an invoice price (IP) then you will be paid as endorsed.

**f) What should I do if I receive a prescription for sodium chloride 5% eye drops preservative free? Isn't that in Part IX of the Drug Tariff?**

It should be noted that whilst sodium chloride 5% eye drops preservative free is a product which appears with other unlicensed specials in Part VIIIIB of the Drug Tariff,

the standard version appears in Part IXA. Therefore, payment will depend on how the product was prescribed.

**g) Can I claim broken bulk on unlicensed specials and imports?**

Broken bulk cannot be claimed on unlicensed specials and imports covered by Part VIIIIB (either listed or unlisted) except where a product not listed in Part VIIIIB has been extemporaneously dispensed by the pharmacy contractor. In these instances, broken bulk can be claimed on the ingredients used to prepare it.

When sourcing unlicensed specials or imports, contractors are encouraged to order the precise quantity – or as close as possible to the precise quantity – required to fulfil the prescription. In accordance with Part II Clause 9 of the Drug Tariff, where a product is not listed in Part VIII, contractors must endorse the pack size used when dispensing a prescription and NHS Prescription Services will use this information to calculate the payment. PSNC is in ongoing discussions with the Department of Health regarding these arrangements.

**h) Can I still claim out of pocket expenses on unlicensed specials and imports?**

Yes, but the way in which they are claimed has changed.

Pharmacy contractors will now be paid a fixed fee (currently set at £20) for each unlicensed special or import that is manufactured or supplied by a company operating under an MHRA specials licence or importer's licence. This fixed fee is to cover all costs incurred when sourcing the product. **'SP' must be endorsed on the prescription to claim this payment.**

If a product is extemporaneously dispensed by the contractor or by a 3<sup>rd</sup> party, costs incurred are covered by another fixed fee (also currently set at £20). **'ED' must be endorsed on the prescription to claim this payment.**

Pharmacy contractors **must not** include these expenses in the total they put on their monthly FP34c submission document.

For more information on endorsing unlicensed specials and imports, check out our unlicensed specials endorsing guide.

**i) Do these new rules for unlicensed specials and imports apply to Welsh prescriptions?**

Yes, these new rules will also apply to Welsh prescriptions.

**j) 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 VIIIIB 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.

**k) Where can I find out the PCT (and its mailing address) of a prescriber?**

If you need to find out who a prescriber's PCT is, use the NHS Choices website ([www.nhs.uk](http://www.nhs.uk)), which holds the most up-to-date information about health organisations.

**l) How do I ensure patient confidentiality when sending the required information to PCTs?**

Due to patient confidentiality reasons, it is important that patient details should not be sent to the PCT. Any patient details on the Certificate of Conformity (COC) or Certificate of Analysis (COA) should be removed before a photocopy is taken to be submitted. The original COC or COA should be kept for your own audit purposes.

**m) I am finding it very difficult to get hold of a Certificate of Analysis (COA)/ Certificate of Conformity (COC) for an imported product, what should I do?**

As of 1<sup>st</sup> January, The Drug Tariff states that for imported unlicensed products not listed in Part VIIIIB, the contractor shall make *every reasonable effort* to obtain a Certificate of Analysis (COA)/ Certificate of Conformity (COC) for each imported product sourced.

However, it also says that where a COA/COC is not available, the contractor must stamp, date, initial and endorse the invoice with the invoice price less discount (where not clearly detailed by the supplier) and the prescriber's details.

At the end of each month, the contractor shall send a copy of the appropriately endorsed COA/COC/invoice to the PCT of the prescriber, allowing the PCT to match expenditure to the special supplied.

**n) How should I endorse a prescription for Midazolam 10mg/1ml oral solution?**

The Department of Health has agreed that, from 1 December 2011, where the contractor has provided the prescribed quantity of Midazolam 10mg/ml oral solution in containers with an integral means of administration, these prescriptions will be reimbursed as multiples of the 5ml basic price listed in Part VIIIIB of the Drug Tariff.

To ensure accurate payment, contractors must clearly endorse where they have supplied containers with an integral means of administration e.g. the quantity dispensed over pack size (20ml/5ml) or as 4x5ml.

Where the prescription is not endorsed to indicate that the contractor has supplied a container with an integral means of administration, payment will be based on the existing arrangements laid out in Part VIIIIB – the minimum volume (5ml) plus the price/ml for any volume dispensed thereafter. Please see illustration below.

Pharmacy Stamp	Age	Title, Forename, Surname & Address
	D.O.B	
<small>Please don't write on your age box</small> Number of days' treatment <small>N.B. Ensure this is stated</small>		NHS Number:
Endorsements	<b>20ml/5ml SP</b> <b>Midazolam 10mg/1ml oral solution</b> <b>20ml</b>	

**o) How will the SP and ED fees be displayed on my monthly Schedule of Payments (FP34)?**

The fees paid for the dispensing of unlicensed medicines will be displayed in the Prescription Fees section on page 1 of the Schedule of Payments. The total value of these fees paid to the contractor for the month in question will be displayed under 'Additional fees – 2A unlicensed medicines'.