

## Arrangements for payment for Specials and Imported Unlicensed Medicines

The arrangements laid out in this Part cover specials and imported unlicensed medicines (except for those specials and imported medicines listed in Part VIIIA)

### Basic price of certain Specials and Imported unlicensed medicines

The price listed in respect of a drug specified in the following list is the basic price on which payment will be calculated pursuant to Part I Clause 5B 1 for the dispensing of that drug.

Drugs listed in this Part have a minimum quantity and price for that quantity and a price per subsequent ml/g/tab/cap unless in a special container.

The Secretary of State determines the price based on information submitted by manufacturers that hold Specials Manufacturers Licences issued by the Medicine and Healthcare products Regulatory Agency (MHRA).

**Formulations** - The Tariff covers the formulations specified. The following symbols are used in Part VIIIB.

STD	Standard formulation including standard flavours
SF	Sugar free
AF	Alcohol free
CF	Colour free
FF	Flavour free
LF	Lactose free
PF	Preservative free
NSF	Non standard flavours
■	Special Container
§	Selected List Scheme (SLS)

**Price** - All unlicensed medicines are listed with a minimum quantity and corresponding price, which is payable for any amount prescribed up to the minimum quantity. Unless in a special container, subsequent quantities will be payable at the additional price per ml/g/tab/cap up to the total quantity prescribed. The price of each product listed in this Part covers the formulations specified and this price will be paid regardless of how the product was sourced.

### Arrangements for payment for all other Specials and Imported unlicensed medicines

Prescriptions for specials not listed in this Part will be paid depending on how the special was sourced. Where the special has been sourced

- From a manufacturer holding a MHRA specials licence, the contractor will be paid the price endorsed on the prescription form. This price should be invoice price **less** any discount or rebate which may be linked to the procurement of this product.
- Under the manufacturing part of the Section 10 exemption from the Medicines Act 1968, the contractor will be paid the cost of the ingredients used to manufacture the special.

Prescriptions for imported unlicensed medicines not listed in this Part will be paid the price endorsed on the prescription form. This price should be invoice price **less** any discount or rebate which may be linked to the procurement of this product.

### Endorsement requirements above Part II Clause 9

It is not necessary to endorse prescription forms for unlicensed medicines listed in this Part other than with the endorsement requirements outlined in Part II Clause 9. For products not listed in this Part, contractors shall endorse the form according to how the unlicensed medicine was sourced.

1. Where the unlicensed medicine is manufactured under a specials licence or sourced under an importers licence issued by the MHRA, the contractor shall endorse the
  - pack size from which the order was supplied
  - invoice price per pack size from which the product was supplied **less** discount/rebates
  - manufacturer's/importer's licence number
  - batch number of the unlicensed medicine.
2. Where the special has been prepared under the manufacturing part of the Section 10 exemption from the Medicines Act 1968, by the contractor or by a third party, the contractor shall endorse the names, quantities and cost of the ingredients used in preparing the special.

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### Further requirements when supplying unlicensed medicines

Contractors shall

- a Keep the following records 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
- b Make available these records for inspection by the Licensing Authority.

For specials not listed in this Part, the contractor or his representative must stamp, date, initial and endorse the Certificate of Analysis (COA)/Certificate of Conformity (COC) with the invoice price less discount and prescriber's details and retain the COA/COC for 5 years.

For imported unlicensed products not listed in this Part, the contractor or his representative shall make every reasonable effort to obtain a Certificate of Analysis (COA)/Certificate of Conformity (COC) for each imported product sourced and retain the COA/COC for 5 years.

- Where a COA/COC is available, the contractor must stamp, date, initial and endorse the COA/COC with the invoice price less discount and prescribers details.
- Where a COC/COA 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.