NHS
PCA (P) (2015) 17

Healthcare Quality and Strategy Directorate
Pharmacy and Medicines Division

Dear Colleague

PHARMACEUTICAL SERVICES
AMENDMENTS TO DRUG TARIFF IN RESPECT OF SPECIAL PREPARATIONS AND IMPORTED UNLICENSED MEDICINES

Summary

1. This Circular advises of changes in the Drug Tariff effective for dispensings 1 September 2015 in respect of reimbursement of costs borne by community pharmacy contractors when dispensing NHS prescriptions for specialist preparations and imported unlicensed medicines not listed in Part 7S.

Background

2. Professionally NHS Boards and clinicians have responsibilities regarding the use of unlicensed medicines under Article 5.1 of Directive 2001/83/EC.

3. Unless there is a specific clinical reason, clinicians are advised by the Chief Pharmaceutical Officer that they should not continue to use an unlicensed preparation where there is a licensed product which has been accepted for use within NHS Scotland by the Scottish Medicines Consortium (SMC) and is available. This reflects the Medicines and Healthcare Products Regulatory Agency (MHRA) advice on this issue.

21 August 2015

Addresses

For action

Chief Executives, NHS Boards

For information

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4. Reimbursement arrangements for unlicensed medicines are currently detailed at paragraph 14 of Part 1 to the Drug Tariff. Separate arrangements apply depending on whether a reimbursement price is listed in Part 7S or not, when the contractor must seek pre-authorisation from the Health Board of costs before dispensing.

Detail

With effect from 1 September 2015 dispensings

5. This Circular advises of revised arrangements for approval of reimbursement costs in respect of special preparations for which a reimbursement price is not listed in Part 7S of the Tariff. These changes are intended to streamline the approval process whilst continuing to ensure that value for money is achieved for NHS Scotland. In parallel the list of items included in Part 7S has been reviewed and additional items added for which reimbursement prices are available from supplier price lists. This list will continue to be subject to regular review and items may be removed from the list if pricing information is no longer available, and/or new prices may be added and will be removed once a licensed product becomes available. Contractors are therefore advised to check the Tariff each time before dispensing a special preparation.

6. The existing Drug Tariff section in respect of specials and unlicensed medicines is discontinued and replaced by the following revised provisions, in respect of dispensings from 1 September 2015 onwards:

SPECIAL PREPARATIONS AND IMPORTED UNLICENSED MEDICINES

<u>Reimbursement for Preparations listed in Part 7S</u>

Where the preparation concerned is included in the list from time to time in force in Part 7S to this Tariff the reimbursed price will be the price listed there. These Tariff prices are set to include a handling allowance. Other than in exceptional cases as detailed below no further remuneration or reimbursement will be made in respect of such a dispensing and no out of pocket expenses may be claimed in respect of any such dispensing.

In exceptional cases only where next day dispensing is considered to be necessary the contractor must seek prior Health Board authorisation (from the officer nominated by the Health Board concerned for this purpose and notified to all community pharmacy contractors in its area) for any net additional costs arising above the base Tariff price. The Health Board should then timeously respond to the contractor concerned either prospectively approving reimbursement of the prospective additional costs arising or advising what alternative course of action it would consider to be more appropriate clinically and/or represent better value in meeting the needs of the patient as identified by the prescriber. In the latter case the Health Board should share the advice with the prescriber concerned. Where such prior approval is obtained the prescription should be endorsed with the net additional costs concerned when submitted for reimbursement supported by the supplier's invoice.

Where a pharmacist contractor for some reason cannot dispense the prescription extemporaneously or elects to dispense it as either a special preparation or to dispense an imported unlicensed medicine, the pharmacist contractor must **unless it is a special preparation listed in Part 7S** seek reimbursement authorisation from the contractor's Health Board as may be required in accordance with the ***Generic Framework for Specials Authorisation Process across Scotland*** from time to time in force before dispensing including any additional expenses incurred. NHS Circular PCA (P) (2015) 17 includes at Annex A the detail of the ***Generic Framework for Specials Authorisation Process across Scotland***, to apply for dispensings from 1 September 2015 until repealed or amended.

Reimbursement for Preparations not listed in Part 7S but available as a commercially made up item

In order to:

- ensure consistency of procedure and decision making by Health Boards and PSD,
- minimise the need for repeated approvals in cases of repeat dispensings of the same preparation, and
- improve guidance for contractors,

the ***Generic Framework for Specials Authorisation Process across Scotland*** from time to time in force should be followed for approval decisions in respect of preparations not listed in Part 7S.

A Q & A guide for community pharmacy contractors is included at Annex B to NHS Circular PCA (P) (2015) 17.

If a contractor has any doubt about whether approval is needed he/she should seek further advice from the Health Board concerned.

The Health Board should then respond timeously to the contractor concerned either prospectively approving reimbursement of the dispensing proposed or advising what alternative course of action it would consider to be more appropriate clinically and/or represent better value in meeting the needs of the patient as identified by the prescriber.

The contractor will be paid the price endorsed on the prescription form, in accordance with the requirements of the ***Generic Framework for Specials Authorisation Process across Scotland***.

Reimbursement of items prepared by the contractor under the manufacturing part of S.10 of the Medicines Act 1968

Where the special has been prepared 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.

Endorsement requirements for reimbursement of Special Preparations and Imported unlicensed medicines

It is not necessary to endorse prescription forms for unlicensed medicines listed in Part 7S other than where prior approval for additional costs for next day dispensing has been sought and received from the Health Board or with the endorsement requirements otherwise outlined elsewhere in the Drug Tariff.

In respect of non Part 7S listed items, the prescription shall be endorsed as laid down in the ***Generic Framework for Specials Authorisation Process across Scotland***.

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.

Only in exceptional circumstances, where it is not possible to follow the procedure laid down in the framework document, will the claim for reimbursement be processed without pre-authorisation by the HealthBoard.

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 Part 7, the contractor or the contractor’s 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.

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

The contractor shall retain either the original endorsed COA/COC or an electronic copy thereof for a period of 5 years or for such other period as may from time to time be required by MHRA and/or requirements for GPhC inspections.

Consultation

7. Community Pharmacy Scotland has been consulted on the Drug Tariff amendments advised of above, and on the contents of this Circular.

Action

8. **Health Boards are advised to send a copy of this Circular to all community pharmacy contractors, GP practices and Community Health Partnerships in their areas.**

Community pharmacy contractors should observe the revised procedures herein when dispensing special or unlicensed medications.

Whilst these arrangements relate explicitly to dispensing by community pharmacy contractors, dispensing practices are also advised to note and follow these arrangements when they dispense special or unlicensed medicines.

Yours sincerely

Rose Marie Parr
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Deputy Director, Pharmacy & Medicines Division