



Feidhmeannacht na Seirbhíse Sláinte  
Health Service Executive

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Circular No. 009/10

29<sup>th</sup> April 2010

**Re: Exempt Medicinal Products (Unlicensed Medicines)**

Dear Pharmacist,

You will be aware of the legislative provisions in supplying an Exempt Medicinal Product (Unlicensed Medicine) i.e. that it must be supplied in response to an unsolicited bona fide request from a Medical Practitioner.<sup>1</sup> You will also be aware that such products should only be prescribed or supplied where a licensed product is not available to address patient need. The Department of Health & Children developed a protocol for the supply of such products in 1999 which was circulated to all pharmacies at the time and again earlier this year with Circular 002/10. This protocol was intended to address ongoing patient requirements rather than short term supply issues arising. The HSE is anxious to ensure that the usage of Exempt Medicinal Products is minimized to those situations where no suitable licensed alternative is available for the patient.

Notwithstanding the above, it is the intention of the HSE to streamline its internal procedures in processing bona fide requests for Exempt Medicinal Products by circulating on a regular basis a list of those products which satisfy the protocol including the HSE Reimbursement Price (Copy of List enclosed). This will mean that where such products are prescribed, you can dispense and claim for the products electronically. The Exempt Medicinal Products on the attached document will no longer require individual authorization by the Local Health Office under the discretionary Hardship Arrangements.

You should use the codes specified in the attached list for these products when prescribed for Medical Card Patients on properly completed GMS prescription forms and submit them in the normal manner with your monthly claims. This will reduce the administrative burden for Pharmacists in a practical way. It is important to note that the attached document will be subject to ongoing clinical review with additions and deletions provided to Community Pharmacists on a regular basis.

This initiative does not mean that Exempt Medicinal Products (unlicensed medicines), not included on this list, will not be reimbursed; these, where prescribed by a Hospital Consultant, still require approval by the Local Health Office and subsequent submission to that office for payment.

The prescribing of Exempt Medicinal Products usually arises in the following circumstances (i) where a new substance has been developed and is not licensed in Ireland to date (ii) where the usage of a product has decreased and a commercial decision has been made by the manufacturer not to renew the license in Ireland. Where an individual patient's specific need can be safely met by a licensed therapeutic alternative the licensed alternative should be prescribed. The HSE will communicate with Prescribers over the coming months in those circumstances where it appears that a licensed or more cost effective unlicensed alternative is available. As is the case for GPs, Pharmacists are asked to ensure that patients understand when they are prescribed an unlicensed medicine and the value of using a licensed product where possible.

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<sup>1</sup> Medicinal Products (Control of Placing on the Market) Regulations 2007 (SI 540 of 2007).

Exempt Medicinal Products must be Consultant initiated. However, while the dispensing Pharmacist should be satisfied that the original prescriber was a specialist in the relevant field, the HSE will accept a GP prescription further to the initial hospital prescription.

The HSE is satisfied that Pharmacists can access the listed Exempt Medicinal Products at the prices outlined. A supplier to the community pharmacy market, Medisource, has confirmed that the prices on the attached list will remain in place for a period of six months. Due to the exceptional circumstances in which prescriptions for these products have arisen, the HSE will accept invoices for products already acquired at a different price than listed, for May and June 2010 claims. In such cases, submission to the Local Health Office must be made for subsequent payment.

Pharmacists will note that in some situations, there is a significant price differential in substitutable available Exempt Medicinal Products e.g. Lidocaine patches. In these circumstances, patients should be advised to contact their Prescriber for a generic prescription as it is the intention shortly to cease reimbursement for the more expensive preparations.

The HSE will be confirming with the Hospital Network that Novel Exempt Medicinal Products (i.e. those which have not been prescribed before in Ireland) will not automatically be reimbursed under the Department of Health & Children protocol from the 1<sup>st</sup> June 2010. These Novel Exempt Medicinal Products will require submission to the HSE, including pricing information, by the relevant prescribing Consultant with the rationale for reimbursement. Until such time that a decision to reimburse is made by the HSE, the hospital generating the prescription will retain responsibility for ensuring that the patient continues to access supplies of the Novel Exempt Medicinal Product. The HSE believes that proceeding in this manner will ensure that initiation of novel unlicensed substances will arise only where existence of an unmet clinical need can be demonstrated.

The attached list of products with their claiming codes should also be used for claims under the DPS and where relevant for LTI and HAA. As outlined above, the HSE will accept invoices for products already acquired at a different price than listed, for May and June 2010 claims, which should be submitted through the established arrangements using the '777xx' codes.

*A copy of the relevant invoice should accompany the claim for all Schemes whether to the Primary Care Reimbursement Service or the Local Health Office.*

This is the first of a number of initiatives to streamline internal HSE procedures which will benefit all stakeholders. The HSE will review the usage of these products after four months.

There is a FAQ document enclosed for your information. If you have any further queries in relation to this matter, please contact your local HSE Pharmacist.

Yours faithfully



Patrick Burke  
Primary Care Reimbursement Service



**Frequently Asked Questions for Pharmacists**

**Q 1. The prescription specifies an Exempt Medicinal Product (unlicensed medicine) which is on the HSE list - does the patient need to apply to the Local Health Office to have it covered under Hardship Arrangements?**

A. If the Exempt Medicinal Product (ULM) (i) is consultant initiated, (ii) is on the HSE list and (iii) the cost claimed is not more than the maximum permitted, the patient does not have to apply for the product to be covered under the discretionary Hardship Arrangements.

**Q 2. Can I make an electronic claim for the Exempt Medicinal Product dispensed?**

A. Providing the item (i) is consultant initiated, (ii) is on the HSE list and (iii) the cost claimed is not more than the maximum permitted, an electronic claim can be made by using the relevant codes from the HSE list. Those pharmacies who still code manually must also use these codes when submitting their claims to the PCRS.

**Q 3. What do I need to submit as supporting paperwork? I have been supplying the locally approved product on foot of a valid prescription, do I need to get a new prescription for each claim and submit it to PCRS?**

A. In many cases, the prescription will already be written on the patients' GMS prescription form. Where this is not the case, arrangements should be made to get it written on a GMS prescription form for submission in the usual way at the end of the month.

You will also need to submit the invoice when providing the supporting paperwork to the PCRS.

**Q 4. Will the HSE reimburse me with the invoice price of the Exempt Medicinal Product?**

A. The amount the HSE will reimburse is the reimbursement price specified on the HSE list.

**Q 5. My supplier has charged carriage - will the HSE reimburse me for this?**

A. The maximum amount the HSE will reimburse is the reimbursement price specified on the HSE list. A supplier, Medisource, has confirmed to the HSE that carriage will not apply for any products on the list which are sourced from them.

**Q 6. Can I claim the balance of stock in hand in the same way as I can for GMS items?**

A. No.

**Q 7. The patient has been getting the Exempt Medicinal Product under the discretionary Hardship Arrangements for some time, but the product is not on the HSE list, does the patient need to apply to the Local Health Office to have it covered under these arrangements?**

A. If the patient has been previously approved for an Exempt Medicinal Product (ULM) at local level and the approval and prescription are still valid, the Pharmacist can continue to claim reimbursement from their Local Health Office until further notice.

*List of Frequently Asked Questions for Pharmacists which Accompanies Circular 009/10 April 2010*

**Q 8. The prescription specifies an Exempt Medicinal Product which is on the HSE list, but is written by a GP - does the patient need to apply to the Local Health Office to have it covered under these arrangements?**

A. The HSE will accept a GP prescription where the Pharmacist is satisfied that the product has been consultant initiated. This is to ensure that existing patients do not experience any difficulties in the transition. For new patients, who have not previously received an Exempt Medicinal Product on the list, the Pharmacist should make a note on the pharmacy computer which Consultant at which hospital initiated the therapy.

**Q 9. The prescription specifies an Exempt Medicinal Product which is on the HSE list, but my supplier is charging me more than the list price – what do I do?**

A. A supplier, Medisource, has committed to the HSE that it can supply Pharmacists with these products in a timely fashion at a price the HSE is prepared to pay. If you choose to use an alternative supplier and are charged a higher price, then you will only be reimbursed the HSE reimbursement price.

**Q 10. What other products will still require prior approval from the Local Health Office?**

A. All products other than Exempt Medicinal Products outlined in the list attached will still continue to require approval from the Local Health Office.

**Q 11. What do I do if I get a new prescription from a Consultant for an Exempt Medicinal Product for a GMS patient that is not on the attached document?**

- A. Where the product had been previously approved for this patient, but local authorisation has expired, application should be made by the patient / pharmacy to the Local Health Office for approval for a further period.
- B. Where the product has not been previously approved for this patient, the patient / pharmacy should make application to the Local Health Office for approval.
- C. Where the product has been previously approved by the Local Health Office for other patients, the patient / pharmacy will be informed that the product is approved.
- D. Where the product has never been previously approved by the particular Local Health Office, the Local Health Office has been instructed to seek clarification whether the product conforms with the Department of Health & Children protocol for the supply of Exempt Medicinal Products in the community. You cannot assume that approval from the Local Health Office will be forthcoming.

*Summary:*

This initiative will provide greater equity for patients and clarity for Pharmacists. If a Medical Card Patient is prescribed a product on the list, Pharmacists will be able to submit claims for the Exempt Medicinal Product written on a properly completed GMS Prescription Form at the end of the month in the usual manner.

The list of products with their claiming codes should also be used for claims under the DPS and where relevant for LTI and HAA.