Good Dispensing Practice – High Tech Scheme

Pharmaceutical Society of Ireland

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Contents

1. Introduction

The purpose of this guidance is to assist pharmacists in meeting their legal and professional requirements when dispensing medicines under the High Tech Scheme.

The management of the supply of medicinal products under the High Tech Scheme by a pharmacist from a retail pharmacy business requires specific and particular care. The pharmacist plays a critical role in partnership with the patient in the management of health status and the use of medicinal products.

When dispensing any medicine, patient care is the primary responsibility of the pharmacist. The dispensed medicine should be assembled, checked and recorded in a diligent and careful manner and supplied to the patient or their carer while ensuring they have sufficient and correct information regarding the proper use and storage of the medicine. Patients receiving care and treatment under the High Tech Scheme have complex medical and health needs, and management frequently involves vital treatment regimens with novel and/or toxic medicines.

2. Legal Considerations

2.1 Prescription Requirements

A prescription issued for a High Tech medicinal product is subject to the same legal controls as any other prescription. The **maximum** validity period for any prescription issued is six months from the date of issue, when so indicated. Some prescriptions may only authorise a single supply, and care must be taken to ensure the prescriber's instructions are correctly interpreted. Irrespective of whether the product is indicated for lifelong use the pharmacist must ensure that the prescription authorising supply is valid for each and every dispensing. The supervising pharmacist must ensure that he/she continues to meet his/her personal and professional obligations in respect of the patient, and particularly on the occasion of each visit by or on behalf of the patient.

Where necessary a General Practitioner may also issue a repeat prescription in respect of a High Tech medicine provided that the product is for use within the date of review of therapy specified by the consultant on the High Tech prescription form.

A registered Nurse Prescriber may also issue a repeat prescription for a specific High Tech medicinal product. As with all prescriptions, the pharmacist must be satisfied that this is within the provisions of the legislation and that the nurse is operating and prescribing within his/her scope of practice having due regard to his/her place of practice. A Nurse Prescriber is not authorised to initiate High Tech drug therapies under the scheme.

3. Guidance

3.1 Operation of the High Tech Scheme

The operation of the scheme is under the auspices of the HSE and any pharmacist participating and delivering care to any patient under this service must ensure that they adhere fully to the operational requirements published by the HSE.

This scheme operates as a **patient-specific pharmaceutical care and treatment programme** with a nominated pharmacy responsible for a specific patient and their complete and complex medication and health needs. Patient-specific dispensing occurs with a particular product obtained for a particular individual patient. Patient-specific monitoring is required on an ongoing basis and the pharmacist monitors overall medicines therapy notwithstanding that a High Tech medicinal product may not be required at a particular patient visit. The supervising pharmacist has a primary responsibility in respect of the pharmaceutical care and treatment programme.

3.2 Supply of High Tech Medicines

Medicinal products, where possible, should be dispensed in the manufacturer's original pack. As such products are not routinely dispensed, or stocked, in a retail pharmacy business; care must be taken to ensure patients understand the necessity to allow adequate notice for ordering their own patient specific product.

Comprehensive patient counselling on the correct use, adverse effects, warnings on precautions and storage of the medicines is required to ensure a patient is aware of the appropriate use of the medication.

There must be constant vigilance around adverse drug reactions, drug interactions and other adverse events. Procedures and policies must be in place for the documentation of any adverse events or errors and their management, including notification and /or referral of any important information to other healthcare professionals involved in the care of the patient.

The requirement that these products be obtained, stored and dispensed, in a manner which ensures a complete audit trail and accountability in their management is essential. This is the responsibility of the supervising pharmacist.

The supervising pharmacist in a pharmacy practice delivering such a programme of care must ensure that all practitioners involved in the service are thoroughly familiar with the specific medicinal products and the conditions which they are used to treat, and that all pharmacists keep their professional knowledge of these products up to date. This knowledge must be sufficient for the provision of appropriate care to these patients who have complex medical and health needs.

3.3 Policies and Procedures

In the clinical management of the dispensary, the supervising and superintendent pharmacists must ensure that clear, structured management procedures and policies are in place, with adequate and proper records maintained in respect of adherence to these requirements. These policies and procedures should include quality assured, safety-checking systems for **before, during** and **after** the dispensing of prescribed medication. Ongoing evaluation of policies and procedures, with review and amendment if necessary, must be undertaken and basic requirements such as the expiration of the validity period of a prescription must be clearly addressed therein.

Patient safety considerations warrant that the supervising pharmacist personally audits all dispensing under their jurisdiction. Superintendent pharmacists must satisfy themselves that protocols and procedures are in place and that they are followed in each pharmacy for which they are responsible. It is essential that the requirements of Regulation 9 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (SI 488 of 2008), relating to the *"Review of medicine therapy and counselling of patients in the supply of medicinal products on foot of a prescription"*, are fully complied with. Appropriate policies must be in place to ensure that the necessary review and counselling requirements are met. Due diligence must be exercised to ensure any patient availing of the High Tech Scheme presents, or obtains his or her supplies on foot of, a valid prescription and that such prescriptions are also reviewed within the appropriate time frame as may be provided for under the scheme.

Relevant legislation can be accessed through the PSI website www.thePSI.ie, and is also available from www.irishstatutebook.ie.

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1	June 2009
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4. Self-assessment Checklist

This self-assessment checklist is a practical tool intended to aid compliance with this guidance and to assist superintendent and supervising pharmacists in drawing up the relevant policies and SOPs. The checklist captures many important elements of the guidance; it is not exhaustive and should only be used to assess pharmacy practice in combination with this guidance and all other relevant guidance and requirements.

Ask Yourself	Yes	No	N/A	Required Action
Is the pharmacist aware that a prescription issued for a High Tech medicine is subject to the same legal controls as any other prescription?				
Is the original High Tech prescription checked at each dispensing to ensure that the supply is within the review period, and the dose is suitable for the patient?				
Is there a legally valid prescription for the supply of the medicine, either the original High Tech prescription or an alternative legally valid prescription?				
Are all pharmacists involved in dispensing these medicines familiar with the specific products and the conditions they are used to treat?				
Are High Tech medicines, where possible, dispensed in the manufacturer's original pack?				
Is comprehensive patient counselling on the correct use, potential adverse effects, and warnings on precautions and appropriate storage of the medicines, given at each dispensing?				
Are High Tech medicines obtained, stored and dispensed in a manner which ensures a complete audit trail and accountability in their management?				
Are there written policies and procedures in place for all aspects of the dispensing of High Tech medicines?				
Is the superintendent pharmacist and supervising pharmacist satisfied that all pharmacists practising in the pharmacy, and relevant staff members, are trained on, and following, the policies and procedures?				
Is there an error and incident management system in use within the pharmacy?				