Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Feidhmeannacht na Seirbhíse Sláinte
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25th July 2016

Circular 037/16.

High Tech Medicines Arrangement – Electronic High Tech Stock Return System

Dear Pharmacist,

Further to circular 033/16, dated 23rd June 2016, in relation to Electronic High Tech Stock Return System, please find attached the High Tech Stock Return (HTSR) Pharmacy User Guide.

This system is now available for use and the user guide gives instruction as to how the system can be accessed and returns processed.

I am also using this opportunity to enclose two other documents which may be of interest:

1. A copy of circular recently issued to General Practitioners to remind them that *GP Visit cardholders are not entitled to receive drugs, medicines or appliances under the GMS Scheme and should therefore not be issued with GMS prescription forms.*

2. A copy of a Clinical Advisory Note from the Early Warning Emerging Trends Subcommittee of the National Advisory Committee on Drugs and Alcohol.

Given the significant cost of medicines, in particular High Tech, we very much appreciate your continued co-operation.

Yours sincerely,

Anne Marie Hoey

Anne Marie Hoey
Assistant National Director
Primary Care Reimbursement & Eligibility

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Circular 035/16

GP Visit Card Holders

14 July 2016

Dear Doctor,

The GP Visit card was introduced for people in Ireland who are not eligible for a GMS medical card, to obtain GP services free of charge.

GP Visit cards are provided to eligible individuals and families who meet the qualifying criteria. All applications for GP Visit Cards and associated GP claims are processed and reimbursed by the Primary Care Reimbursement Service.

GP Visit cardholders are not entitled to receive drugs, medicines and appliances under the GMS Scheme and should not therefore be issued with a GMS prescription form. GPs are reminded to issue private prescriptions for this cohort.

Should you have any queries in relation to this circular please contact Doctors Unit on 01 8647100.

Thank you for your assistance.

Yours sincerely,

Anne Marie Hoey

Anne Marie Hoey
Primary Care Reimbursement & Eligibility

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

High Tech Stock Return System

Pharmacy User Guide

1. Introduction

PCRS provide an online facility for Pharmacies to manage High Tech stock returns with manufacturers.

This guide provides details of

- Process Stages
- User Access
- Initiate New Stock Return
- View Status of Returns

2. Process Stages

There are up to five stages in the online stock return process.

* HTSR = High Tech Stock Return online system

Stage	User	Action
1	Pharmacy	Pharmacy submits details of new stock return using HTSR.
2	Supplier	The Supplier will also have a login to HTSR. This will show the stock return requests assigned to them. They can acknowledge or reject the request.
3	Pharmacy	Pharmacy can check the status of return requests they have submitted. If Supplier acknowledges return the pharmacy will see change of status on request. At this point the stock can be returned to the supplier.
4	Supplier	The Supplier will collect the stock return and examine. They will use HTSR to indicate if they accept return.
5	Pharmacy	When Pharmacy reviews requests using HTSR they will see updated status after Supplier has accepted return.

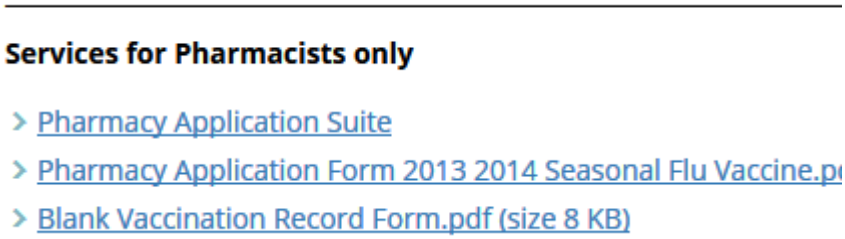
3. User Access

It is recommended that you use Firefox or Google Chrome web browser. If you are using Internet Explorer please note you must use version 8 or higher.

A PCRS username is required to gain access. If you require a username or have any issues logging in, please send an email to cert.info@hse.ie

Existing users can access the system through a web browser.

URL http://www.hse.ie/eng/staff/PCRS/Online_Services/
Once you have entered the above web page you should scroll down until you see the following entry.



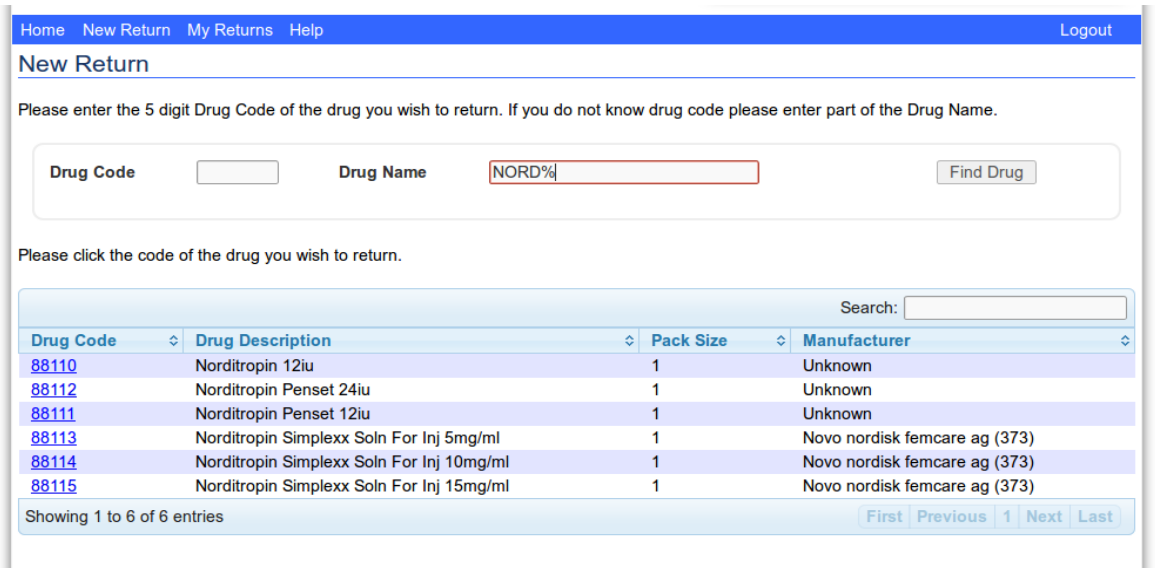
Access to the High Tech Stock Return system is via the Pharmacy Application Suite option above.

4. New Stock Return

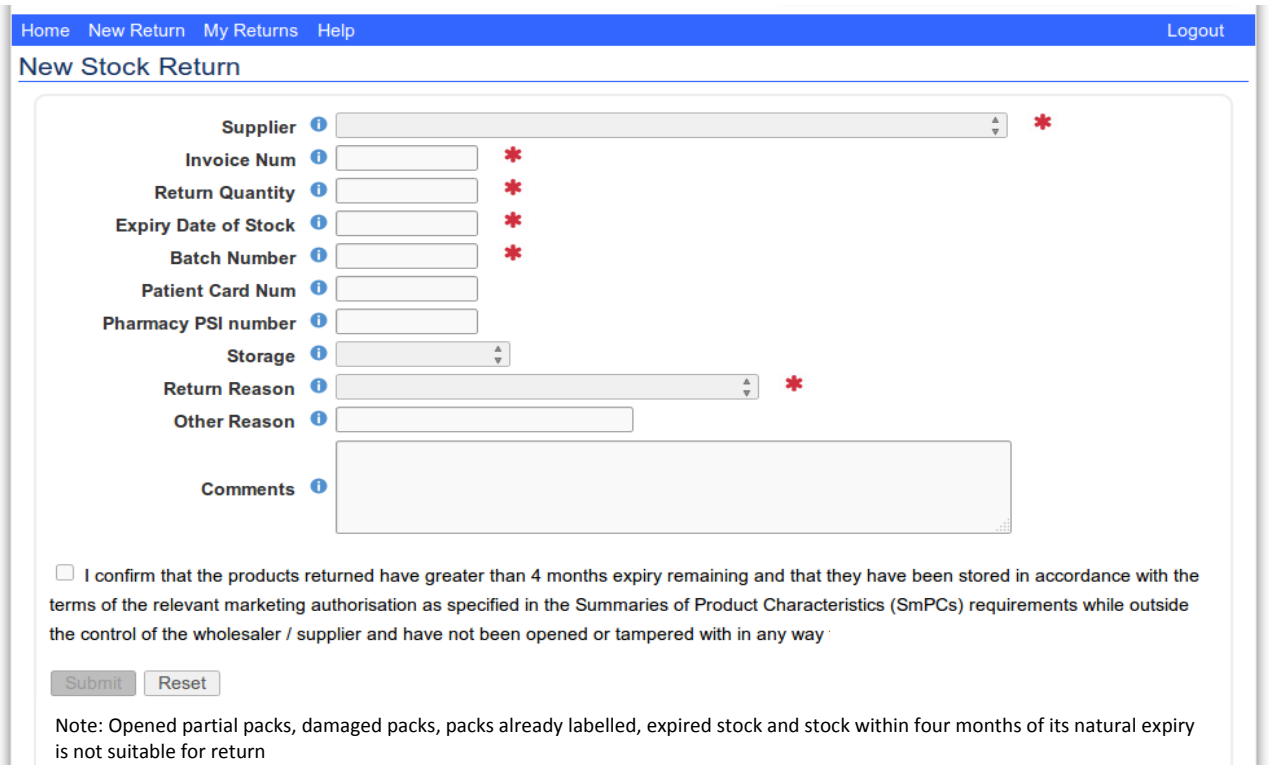
The pharmacy must select the drug they wish to return. The Online system provides a facility to search for a drug by either Drug Code or Drug Name.

If you choose to search by name you can submit a search by only entering the first few letters of the drug name followed by a '%' sign. In the example below the search has returned all drugs beginning with the letters 'NORD'. Please note the search facility is not 'case-sensitive'.

Example: Partial drug name search

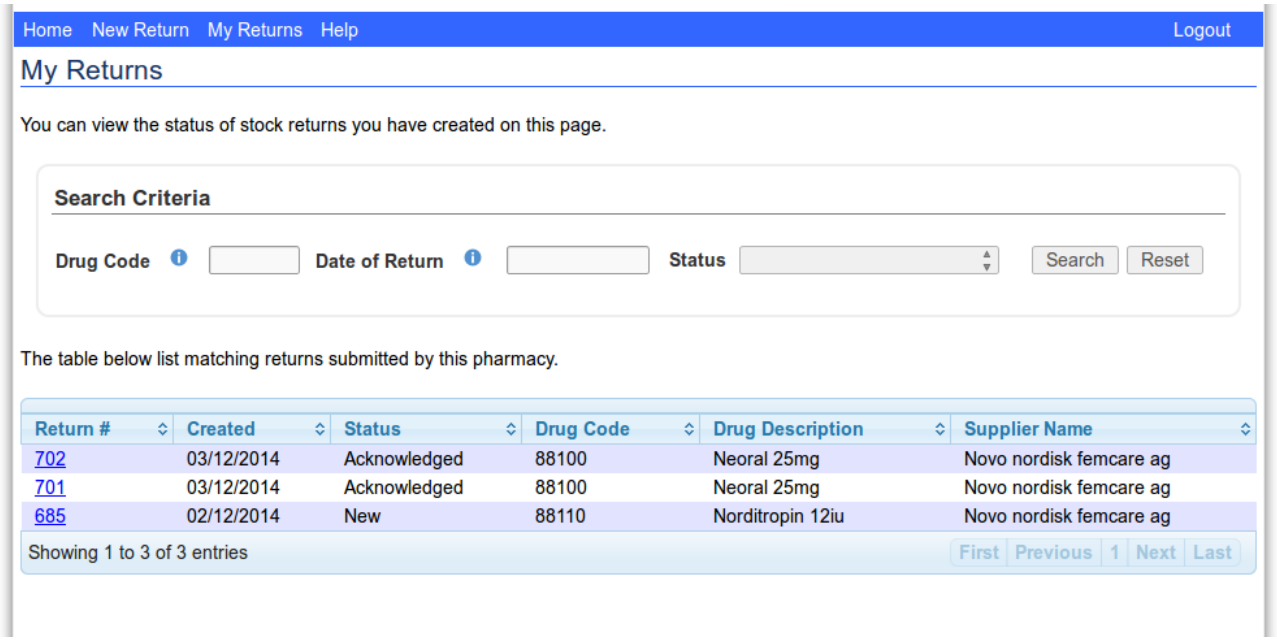


When a drug is selected the user will complete a form with the following fields. Required fields are marked with red asterisk.



5. Viewing Returns

Pharmacies can view status of returns they have submitted when they click the “My Returns” menu.



6. Stock Return Status

The pharmacy will be able to see the current status of a return request in the Status column in the figure above. The following are the different status settings that the pharmacy may see.

Description
New – Response Pending
Acknowledged
Return Rejected
Credit to HSE Agreed
Credit to HSE Refused

Clinical Advisory

To: **Prescribing Doctors, Pharmacists, Emergency Department Doctors and Emergency Department Nurses**

From: The Early Warning Emerging Trends Subcommittee of the National Advisory Committee on Drugs and Alcohol

Date: June 2016

Subject: Medicines containing **PREGABALIN** and GABAPENTIN: being used abused and misused recreationally

Dear Healthcare Professional,

Call for vigilance and reporting

The Early Warning and Emerging Trends (EWET) subcommittee[1], in agreement with the Department of Health wishes to highlight the need for vigilance when prescribing and dispensing pregabalin and gabapentin as both of these drugs present a risk of addiction and a potential for illegal diversion and medicinal misuse. Prescribers should always undertake a risk benefit assessment prior to prescribing either of these medicines for patients under their care.

Summary

The EWET subcommittee wishes to inform you of the serious concern regarding the misuse of prescription-only medicines containing PREGABALIN (Pregabalin, Lyrica, Brieka) and to a lesser extent, GABAPENTIN (Gabapentin, Gabin, Neurontin, Neurostil) and the exponential rise in prescribing rates of these medicines.

Over the past 2 years the EWET has received a number of anecdotal reports on the misuse of pregabalin and to a lesser extent the misuse of gabapentin. Recently this information has been bolstered with evidenced based reports about the misuse of these medicines for recreational use and through their appearance in post mortem toxicology screening tests. Furthermore, dispensing data from the PCRS over the past 5 years shows a dramatic and continued increase in the volume of dispensed pregabalin, suggesting that those who are misusing these drugs may be sourcing them through legal as well as illegal channels.

While this dispensing increase may be partly attributable to the greater number of authorised indications for pregabalin, it appears from the emerging evidence that the misuse of this drug may also be a significant factor in the escalating numbers of pregabalin items being dispensed in Ireland.

Background

Pregabalin and gabapentin were originally developed and authorised as treatments for epilepsy. However, further research has shown that it can also be beneficial in treating other conditions, e.g. generalised anxiety disorder and neuropathic pain.

Initially it was considered that pregabalin and gabapentin had a low potential for misuse, however the EWET Subcommittee is aware of concerns and reports that suggest that abuse of these medicines is on the increase. In 2013 there were 33 drug-related deaths in England and Wales where pregabalin was mentioned on the death certificate. Of 10 patients attending a Belfast hospital following recreational pregabalin abuse, six presented with seizures.

Information as to the numbers of deaths related to pregabalin in Ireland is not available at this time.

Evidence on the misuse of Pregabalin and harm potential

A study into the potential for *misuse of pregabalin* was conducted by researchers at the HSE National Drug Treatment Centre Laboratory in Dublin between June and August 2014. The study found that of 440 people tested, 39 tested positive for pregabalin, representing 9.2% of the total sample, indicating that the misuse of pregabalin is a "serious emerging issue". Only 10 patients from this group had been prescribed the drug. These findings have been published in the Irish Medical Journal - "Pregabalin Abuse amongst Opioid Substitution Treatment Patients"[2].

A report published in the UK Emergency Medical Journal in 2013 entitled "Lyrica Nights–Recreational Pregabalin Abuse in an Urban Emergency Department" J Millar, S Sadasivan, N Weatherup, S Lutton, which was based on the outcomes from a one year review of all patients presenting to the Emergency Department of the Royal Victoria Hospital, Belfast after recreational drug abuse. Those who admitted to pregabalin usage were identified and case notes were reviewed. The study found that in Belfast, emergency departments (ED) have witnessed a recent increase in the number of patients presenting after recreational abuse of pregabalin. "Patients, state that the medication induces a state similar to drunkenness, hence the street name 'Budweiser's'… Patients are either taking tablets whole or cutting [, crushing] and snorting them. 60% of patients in this case series presented to the ED with seizures and 20% required ICU admission."

Harm potential related to the recreational use of pregabalin and gabapentin include: physical dependencies; central nervous system depression, resulting in drowsiness, sedation, and respiratory depression; pregabalin and gabapentin related mortalities.

The Therapeutics Today newsletter dated May 2013, No. 5, produced by the National Medicines Information Centre at St. James's Hospital (SJH) Dublin 8 and Dept of Therapeutics Trinity College, included a "Focus on Pregabalin" to highlight that patients may experience withdrawal symptoms after both short and long-term pregabalin therapy[3].

Known issues in other jurisdictions

United Kingdom: In 2013, there were 19 deaths implicated with pregabalin and 17 deaths implicated with gabapentin in the UK. In September 2015, the UK Office for National Statistics (ONS) released registrations information on deaths related to drug related poisoning, which highlighted a significant

increase in deaths from 2012 onwards. In 2014, there were 38 deaths where pregabalin was mentioned on the deceased's death certificate; and, 26 deaths where gabapentin was mentioned on the deceased's death certificate[4].

Germany: Since 2008 pregabalin abuse and dependence has been reported with increasing frequency to a German medical regulatory body (BfArM)[5].

Finland: The University of Helsinki has undertaken an assessment of pregabalin and gabapentin in opioid overdose deaths, noting that pregabalin abuse with high doses is increasingly common and can be fatal when combined with opioids.

USA: In 2005 the Drug Enforcement Administration placed pregabalin under Schedule V of the Controlled Substances Act; citing that the abuse of pregabalin may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule IV[6].

Please remember that any suspected adverse events should be reported to the Health Products Regulatory Authority (formerly the Irish Medicines Board), via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

References

1. Early Warning Emerging Trends Subcommittee (EWET) are a subcommittee of the National Advisory Committee on Drugs and Alcohol and comprises representation from the following organisations:
- An Garda Sìochàna,
- HSE Addiction Services,
- Health Research Board,
- Forensic Science Ireland,
- Department of Justice and Equality,
- Department of Health,
- Medical Bureau of Road Safety,
- State Laboratory,
- HSE,
- National Poisons Information Centre,
- Revenue Customs Service,
- Health Products Regulatory Authority,
- Frontline Services Provider,
- Academic Expert.

2. "Pregabalin Abuse amongst Opioid Substitution Treatment Patients" S McNamara, S Stokes, R Kilduff, A Shine, HSE National Drug Treatment Centre, McCarthy Centre, 30-31 Pearse Street, Dublin 2; The Irish Medical Journal, November December 2015 Vol. 108 No. 10. http://www.imj.ie//ViewArticleDetails.aspx?ArticleID=15406

3.http://www.stjames.ie/GPsHealthcareProfessionals/Newsletters/TherapeuticsToday/TherapeuticsToday2013/Therapeutics%20Today%20May%20%202013.pdf

4. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/491854/ACMD_Advice_-Pregabalin_and_gabapentin.pdf

5. http://www.ncbi.nlm.nih.gov/pubmed/23292158

6. http://www.deadiversion.usdoj.gov/fed_regs/rules/2005/fr0728.htm