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Legal requirements for prescriptions

- A) 1) Be in ink, signed and dated
 2) Prescribers address (unless GMS Rx)
 3) Prescriber’s name and qualification clearly – usually on headed paper, signature not enough. Doctor must have IMC number, nurse must have PIN.
 4) Patient name, address and age if under 12.
Can still dispense if only one of above 4 missing
Extra requirements for nurse.
- B) Rx is less than 6months old/is it post-dated.
 Isotretinoin internal products (Roaccutane) for women of childbearing age must be dispensed within 7days and treatment on Rx no longer than 30days.
- C) Is the product licensed in Ireland?
- D) Prescription and Control of Supply Regulations:
S1A: can only be repeated if in prescriber’s writing/typing (not if pre-printed)
- No mention of repeat – dispense once only
 - “Repeat” but no number of occasions – dispense twice only (one repeat)
 - States number of occasions to repeat – can dispense that many occasions but only within the 6months of the Rx.
 - “Repeat monthly/weekly” but doesn’t give number of occasions – dispense max 3 times (two repeats)
 - **CD 2/3 = S1A**
- E) **Dentists cannot write repeat prescription (DTSS or private) except for sodium fluoride tablets**

Clinical issues

- 1) Dose – for patient, mg/mcg
- 2) Dosage schedule – number per day, timing, treatment duration
- 3) Instructions – specified strength, quantity, duration
- 4) Contra-indications
- 5) Interactions – check PMR
- 6) Therapeutic duplication
- 7) Is drug appropriate for patient
- 8) Is form appropriate for patient

Administrative issues

- 1) Is product on scheme?
- 2) Payment – levy, emergency supply
- 3) Methadone – card, proper Rx form, week supply (unless exceptional)
- 4) Hosp. Emergency
- 5) Tourists – restrictions
- 6) Psych scheme – address must be in greater Dublin area
- 7) Nicknames or two people in family with same name

Ethical Issues

- 1) Is prescribed therapy inappropriate
- 2) Potential for misuse – deliberate or accidental
- 3) Confidentiality issues
- 4) Potential for wastage – co-prescribing of 30s with 28s
- 5) Potential to develop dependence

Name, quantity, strength, no. of occasions, frequency

- Specify each piece of info for every product
- Name specific products i.e brand name, not just name of drug
- No. of occasions = how many times you will supply the product e.g 6 dispensings.
Consider a) Legal Status, b) Prescriber's intent
- Frequency of dispensing- intervals in dispensing. If single dispensing, then frequency = N/A monthly, weekly

- No. of occasions can't be N/A- 5 dispensing, 4 repeats

Counselling Points

- Name and description of meds
- Method and route of admin
- Duration of therapy
- Special directions – preparation
- Importance of compliance and self-monitoring
- Side-effects, ADRs, interactions, contra-indications – avoidance and what to do if occurs
- Storage
- Repeat info
- **Show PIL**
- Administrative matters
- Matters specific to patient

Pricing Structures and Tax

1. Fee per item on GMS, DPS, LTI, HAA:
 - €5.00 per item for first 1667 items per month
 - €4.50 per item for next 833 items per month
 - €3.50 per item for all other items in month
2. Wholesale mark-up on all above schemes = 10%
3. Retail mark-up for DPS, LTI, HAA and EEA = 20%. GMS no mark-up
4. GMS pay €2.50 levy per item to a max of €25 per family per month.
5. No levy for DPS, LTI, HAA, **HT**, Methadone (ie: methadone only)
6. GMS Rx on phased basis – levy is charged for the first instalment only
7. Children in HSE care with own medical card – no levy.
8. Tax refunds: patient's can reclaim income tax on paid medical expenses including prescriptions and doctor's fees. Expenses from 2007 onwards have no threshold and no need for relationship between taxpayer and patient. Before 2007 threshold of €125 for individual and €250 for multiple people. Only possible to claim for last 4 years. Tax refund is at **20%**.

VAT

- Oral medicines (and prescription fees on oral medicines), for human or animal consumption, and inhalers are zero-rated for VAT. This excludes mouthwashes, but it includes lozenges (e.g. for a sore throat) as long as they are packaged and designated specifically for a medical condition, otherwise 21% VAT applies.
- Throat and mouth sprays are also zero-rated, as are items such as urinary drainage bags and stoma bags.
- Non-oral medicines (and prescription fees on non-oral medicines) including injections and topical preparations are subject to VAT at 21%- also applicable to items such as pregnancy tests

Pharmacy Records

Dispensed prescriptions must be kept for 2 years.

Date of supply; name and quantity of product; prescriber's name and address if unknown; patient's name and address; date on Rx; ref number for each entry. Repeat dispensing = same as before but include ref number to first dispensing or where in a different pharmacy their name and address and Rx ref number.

ULM – same as above but also: source; date of sale/supply; batch number; details of any ADRs associated with product. Records kept for 5 years.

Claims (other than methadone) must be sent in electronically by day 3 of next month and by post by day 5.

Stock Order Forms (SOFs)

Doctors may obtain bulk stocks from pharmacies using stock order forms. Two types exist:

1)

- That most commonly presented in pharmacies is the form for non-insulin 2-10 ml disposable syringes, needles and dressing materials intended for use on medical card patients in the doctor's surgery.
- Permissible SOF items are listed in a section of the PCRS code book. The doctor has a triplicate SOF, one copy for himself and two copies for presentation to the pharmacist. The pharmacist fills in the appropriate codes and quantities for the items provided, and **supplies them free of charge to the doctor**, who signs the SOF (again) to confirm receipt.
- One copy of this coded, signed form is then submitted to the PCRS for payment (= flat rate given in PCRS price list regardless of brand used + 25%).

2)

- If there is no pharmacy within 3 miles of a doctor's centre of practice he may dispense drugs for his own patients. He obtains drug supplies from a pharmacy within his practice area.
- A special 4-copy SOF exists for this purpose. The doctor must submit three signed copies of the SOF to the Health Service Executive, which then forwards two copies to the pharmacy nominated by the doctor
- Only then may the pharmacist supply the doctor with medication. As for dressing SOFs, the form is coded, signed again by the doctor to confirm receipt and one copy is submitted by the pharmacist to the PCRS for payment

Hospital Emergency

1. Must be on day of issue of Rx or following day.
2. Patient has been discharged or from ER.
3. Drug must be generic name – usually still give
4. Name of prescriber in block capitals
5. Medical card number must be on script
[if some of these are missing can still dispense if: patient agrees to pay; or pays for items then gets GMS Rx within following days and then you repay; or you can contact GP and they agree to write a GMS Rx to cover the items and will send to pharmacy]
6. **7 DAYS SUPPLY**
7. €2.50 levy on each item dispensed as hospital emergency.
8. Code for prescriber 61559

Patient returns with Rx from GP after getting HE with no complications: can give a full month supply (ie: do not have to deduct the 7 days gotten in emergency)

To claim: submit patient medical card number, regular GP's GMS number, details of items, signature of person collecting Rx and photocopy of the hospital Rx.

Emergency Supply at Request of Patient

1. Interview patient and must be satisfied that:
 - Necessary immediately (ie:valid emergency) and impractical to get Rx
 - Been prescribed before by prescriber registered in Ireland (no need to view previous Rx)
 - Pharmacist can safely specify the appropriate dose
2. When entering in PMR – **Alt+E** (to record emergency supply)
3. No more than 5 days given – unless pre-packed
4. Product is not CD 1, 2, 3 or 4 nor does it contain any drug in Sch. 4 (see reverse). This includes isotretinoin and Mifepristone.
Exception = phenobarbitone and derivatives for epilepsy
5. **“Emergency Supply”** – type **ES** after directions
6. Nature of emergency in PMR.

Payment: GMS patient – ask for informal deposit which you will refund when the patient brings in a GMS Rx. Remember €2.50 levy

Records: all usual + Where previous supply was at another pharmacy, that pharmacy's name and address, and their Rx register ref. no. + **nature of emergency**

Emergency Supply at Request of Doctor/Nurse

1. Must be valid reason why practitioner cannot supply Rx.
2. Practitioner must promise to supply Rx within 72hours.
3. Product is not CD 1, 2, 3 or 4. Exception = phenobarbitone and others for epilepsy
4. When entering in PMR – **Alt + R** (Rx required)
5. Product supplied in accordance with practitioner instructions – give whatever amount practitioner requests.
6. “Emergency Supply” does not appear on label.
7. Remember €2.50 levy for GMS.

Records: all usual + date on which actual Rx received.

Long Term Illness

1. LTI book with patient's registration number.
2. Only meds relating to the LTI covered
3. If patient has medical card, medicines with GMS code **must** be dispensed under the GMS scheme – €2.50 levy, even if for LTI condition. If item with GMS code is not on GMS Rx necessary to get it transcribed as this is administrative problem – will not be able to claim without proper Rx form.
4. Items with only LTI code – dispense under LTI scheme and no €2.50 levy.
5. If DPS patient comes in with LTI book + normal Rx for item covered by LTI illness – dispense this item for free under LTI scheme, advise patient to get it transcribed into book and staple into book in the meantime.
6. Any items prescribed for the first time that do not form part of the treatment of the primary condition – make sure to explain to patients that these are not covered by LTI and the need to pay (DPS or €2.50).
7. Community Drug Schemes folder, PCRS circular – shows automatically approved items for diabetes mellitus and epilepsy.
8. If patient has LTI Rx for unapproved item patient can either pay (if no GMS card/code) or get verbal approval from HSE to dispense the item free of charge (make sure to document call) and then get patient to contact local health office to seek approval for item. PCRS will process unapproved item for 4 months to allow patient to get approval from health office but this is tightly monitored therefore get verbal approval.
9. If item in LTI book is **S1B** – can be dispensed for up to 6months

*Insulin pens usually not on LTI as come directly from manufacturer for free – just hand to patient for free or dispense under “drug refund”

High Tech

1. Special Rx form, valid for 6 months.
2. Patient nominates pharmacy
3. Rx can be repeated between the specified starting and finishing dates – enter into system as repeat.
4. Look up list in Community Drug Schemes to see what is covered under HT and get GMS code.
5. Dispense original packs, even if more than one month, unless patient on only one month of treatment.
6. Nurse prescriber cannot initiate High Tech treatment but can issue a repeat Rx.
7. Important that pharmacist monitors patient both high-tech and regular meds and comprehensive counselling.

Payment: pharmacy gets drugs free from wholesaler (HSE pays wholesaler), patient pays €144 max if DPS, GMS (no levy), HAA and LTI no charge. PCRS then pays pharmacy a patient care fee per month per HT patient (€62.03)

Psychiatric Scheme

1. Being discontinued – confined to south Dublin region
2. Patient must live in south Dublin
3. Rx must be from HSE psychiatric clinic
4. Rx must be for **psychiatric meds only**
5. Rx can be dispensed in **any pharmacy nationwide**. Often difficult for pharmacies not in actual area to get paid, advised to claim from local HSE office.
6. Meds **free of charge** – but GMS patient must go to GP and get transcribed onto GMS Rx, **€2.50 levy**
7. Pharmacist claims **payment from administrative centre** associated with the clinic.
8. Rx must be from Dr, **cannot be nurse prescriber**

HAA Scheme – Health Amendment Act

1. Patients who have contracted Hep.C
2. Receive a **card – valid for life**
3. **Free prescribed medication and medical appliances**
4. Can obtain from **any pharmacy**
5. No levy
6. Can be nurse prescriber
7. Pharmacy claims from PCRS
8. No special Rx form or format

Foreign Patients

From EU/EEA: look up SS practical where did this scheme

- Must be short-term visit (not living here full-time)
- Rx is **free of charge** BUT must be **on GMS paper**
- Where GMS number should be – have **EHIC number**
- UK residents – social security number, NHS number or other details to show residency.
- **€2.50 levy** as treated as GMS.

From outside EU:

- Must pay for all prescriptions
- EXCEPT Australia – treated on the same basis as an Irish citizen (DPS only pay €120, over 65 get GMS, qualify for LTI). Must prove they are from Australia.

Nurse Prescribing

1. Rx must clearly indicate:
 - Prescriber's name
 - State that the person is a registered nurse
 - Include registration number (PIN) – validity checked on Bord Altranais website
2. Nurse prescriber cannot initiate High Tech treatment but can issue a repeat Rx and can change dose.
3. Nurse can write repeat prescription, hospital prescription (GMS/private), LTI, HAA and Emergency Request.
4. Nurse cannot prescribe ULM or psychiatric scheme

Schedule 8 of Misuse of Drugs 2007 Amendment: Nurse Prescriber and CDs

1. No extra restrictions for CD4/5.
2. CD2/3 limited to certain drugs in certain forms and certain circumstances:
 - Part 1:
Pain relief patient in hospital with probable MI.
Relief of acute/severe pain patient in hospital after trauma
For post-op pain relief of patient in hospital in either above situations
Drugs which can be used = morphine sulfate (oral, IV, IM) and codeine phosphate (oral)
 - Part 2:
Drugs for palliative care – morphine, hydromorphone, fentanyl, buprenorphine, oxycodone, methylphenidate and codeine (oral, SC or transdermal)
 - Part 3:
Drugs for midwifery – Pethidine (IM) and pentazocine (CD3)
 - Part 4:
Drugs for neonatal care in hospital – morphine sulphate (oral, IV) and fentanyl (IV)

Midwives

A midwife may only possess product containing Pethidine or Pentazocine (CD2) if it has been obtained on foot of a **written order** which includes:

- Name and address of midwife
 - Purpose of drug
 - Quantity to be obtained (words and figures)
 - Midwife's signature
 - Signature of doctor/nurse prescriber in midwives's area
- NB: if midwife is also a nurse prescriber then no need for counter signature*

Supplying a CD1, 2,3 to nursing sister within hospital/home

Nursing sister = nurse in charge of ward, department, theatre

Must supply a written **requisition** with:

- Sister/acting sister's signature
- Total quantity to be supplied
- Pharmacist must mark the requisition to show it has been complied with
- Pharmacist retains a copy in the hospital dispensary and sister keeps other copy

I think charging for a requisition put in as "local scheme"

Animal Remedy Prescriptions

VPO-1 and VPO – can't dispense (check route of sale at IMB)

Prescription specifications:

1. Vet can only prescribe for animal under his care – new regulation regarding how often a vet must have visited a farm before prescribing.
2. Rx must be used for animal specified and use is justified.
3. Must not be C/I, incompatible with a previous treatment, cause adverse rxn.
4. Rx must be written in **ink/printed**, legible and indelible.
5. Rx must be issued in **triplicate** – vet x 1, owner x 2 (1 to pharmacy).
6. Vet can only prescribe **quantity needed for relevant condition** (none for future use)
7. **Food-producing animal – max 6 months supply** from date of issue. (new reg = 12)
8. Rx **expires 6 months** after date of issue even if all 6 months supply has not been given. (new reg = 12)
9. CD2 CD3 drugs - **controlled drug guidelines**
10. Vets **can write requisitions** to get CDs for their own stock

Details that must appear on Rx (sch.3 2009 regs):

- a) Serial number
- b) Declaration by vet that the animal is under his care
- c) Details of remedy. Must specify:
 - **at least 2 alternatives if exist** (new reg 1 alternative)
 - The **authorised name**
 - The **VPA number** – 2009: no need for this if the remedy has already been supplied at time of prescribing
- d) Quantity – new in 2009
- e) Date of issue
- f) Manner and site of administration
- g) Dose rate and **withdrawal period even if nil**

- h) Description of animal to which Rx relates
- i) Name and address of owner
- j) Period for which Rx is valid
- k) Special instructions, precautions, risks
- l) Name and address of vet in **block capitals**
- m) Signature of vet in ink

Note: it is at the pharmacist's own discretion that if some of this information is missing whether to continue to dispense or declare Rx invalid.

Emergency Supply on request of vet

POM without Rx can be given in the following circumstances:

- Request is by vet. **Animal owner CANNOT request em supply**
- Genuine emergency – Rx cannot be provided
- Vet undertakes to provide Rx within **72hours** – if vet fails to do this the pharmacist cannot make an emergency supply at his request again.
- Not CD1 or CD2. **Can request emergency supply of CD3.**
- Remedy is sold/supplied **according to vet's directions**
- **Label and records as per normal Rx**

Note: not stated that it is necessary to record the date that you get the actual Rx

Requisitions for CDs (1, 2, 3):

- Signed by recipient (ie: vet/prescribing nurse)
- Name, address and occupation of recipient
- Purpose of drug
- Total quantity (NO need to be in words and figures)
- Pharmacist satisfied that signature and recipient are genuine

Exception: practitioner (vet/nurse) may be provided with CD1/2/3 in advance of pharmacist receiving requisition form, but practitioner must undertake to provide the form within 24hours.

Marking and retaining Rx/requisition:

Completely dispensed - both original and carbon copy marked with:

- Word “dispensed”
- Date dispensing completed
- New reg – dispenser’s signature

Pharmacist retains original for **5 years**

Carbon returned to customer

Partial dispensing: - each occasion both original and carbon copy marked with:

- Quantity dispensed
- Date dispensed
- New reg – dispenser’s signature

New reg – pharmacy must retain a photocopy of Rx and return original and carbon copy to owner.

Requisitions and CD Rx:

- record in register (same way) and retain Rx for 5 years
- say in register authority to possess the CD (Rx, practitioner stocks)
- if in installments, retain original after 1st installment.

Pharmacy records:

Vets, pharmacists and LMs must keep records of all outgoing/incoming transactions for **5 years**. Necessary for all meds even worm tablets. For vets include quantities administered

Must record:

- Date transaction
- Precise identity product – name, form, pack size
- Batch number and expiry date (new reg = date no longer necessary)
- Quantity received or supplied – includes returned/expired meds for disposal
- Name and address of supplier/recipient

New reg - record Rx serial number for VPO-1, VPO and POM.

Additional labelling by pharmacist for Rx products (without obscuring manufacturer's):

1. Supplier's (pharmacy/LM/vet) name and address
- 2. Rx serial number**
3. Prescriber's name
4. Date of supply
5. New reg – dosage and duration unless already indicated on label

Note that it is illegal to sell/supply or even possess an animal remedy if the manufacturer's label or package leaflet has been removed or altered, unless authorised by the IMB.

Supplying broken bulk, labelling requirements:

- a. Proprietary name
- b. "For animal treatment only"
- c. Species
- d. Mode of administration
- e. Dose rate
- f. Name of person to whom sold - owner
- g. Name and address of supplier (pharmacy, LM)
- h. Withdrawal period
- i. Precautions regarding administration

Sterile products (eg: intramammary preps) may NOT be provided in broken bulk

CD Prescriptions – CD 2 and 3 (S1A) (4 and 5 = regular Rx)

QicScript – F3 – product name – schedule box – CD2/3 (all CD2 + 3 are S1A)

CD1 = highly abusable, no therapeutic value (coca leaf, raw opium)

CD2 = natural and synthetic opiates (morphine, dihydrocodeine)

One barbituate quinalbarbitone

CD3 = all other barbituates (exception phenobarbitone <100mg)

Potent analgesics (pentazocine)

Minor stimulants (phentermine)

Flunitrazepam and temazepam – benzodiazepines

CD4 = other benzos

Selegiline

Phenobarbitone <100mg

Zolpidem

CD 1, 2, 3 in cabinet

Prescription specifications:

- Be in ink, signed and dated – sig is genuine (contact if nec)
- Prescribers address (unless GMS Rx) – must be in the 26 counties
- Prescriber's name and **qualification** clearly (PIN number)
- Prescriber's **telephone** number
- If to be in instalments – amount of instalments and intervals (CD2 and 3 **cannot be repeated**)
- **May not be dispensed 14days from date on Rx** – if instalments then first instalment within 14days and no other instalment later then 2months from Rx date. If giving a CD drug in installments – mark date of each installment on Rx and keep in pharmacy after first installment.
- May not be dispensed before the date on it.

In handwriting:

- Name (incl **first name**) and address of patient
- **Dose + Form** and where appropriate strength
- Total **quantity** to be supplied – **words and figures** (just quantity).

Requisitions – CD(1), 2, 3

Pharmacist must obtain a written requisition form before supply of any CD1, 2, 3 to any of the following:

- Practitioner – Dr. Dentist, vet
- Person in charge of a lab
- Master of a foreign ship in an Irish port
- Ship owner/master of ship with no doctor on crew
- Matron of hospital/nursing home
- Manager of offshore installation

Requisitions have special **format** which must include:

- **Signature** of recipient and name, address and occupation of recipient
- Specify the **purpose** for the drug
- Specify the total quantity to supply (NO need words and figures)
- Be **counter-signed** on certain situations eg:
 - Matron by Dr/dentist in same hospital/home
 - Master of foreign ship, statement that quantity is necessary and signed by medical officer at health board where ship's port located
 - Installation manager, statement that quantity is necessary and signed by Industrial Medical Advisor (Offshore Installations).
- Pharmacist must be satisfied that signature is genuine and recipient is engaged in occupation.

Emergency supply, without requisition form, may be given to practitioner only (Dr, dentist, vet) but practitioner must undertake to provide requisition form of this within **24hours** of supply.

CDs to prescribing nurses, midwives and ward sisters done already

CD Register – CD (1) and 2 only

1. Must be a bound book. DO NOT KEEP BOOK IN SAFE
2. Entries must be in ink or some other indelible form

3. No cancellation, obliteration or alteration (no Tippex) – where correction is made the original entry must still be obvious with correction being made as a marginal note specifying date on which correction made.
4. Entries should be made on day of transaction or at latest next day.
5. At head of page specify the class of drug to which entries on that page relate.
6. Kept for **two years** from date of last entry.

Details recorded in CD register

- Date of transaction
- Name and address of supplier or recipient
- Where pharmacist is **supplying to customer**: details of the authority by which the recipient is entitled to possess the controlled drug (eg Rx and Dr name)
- **Amount** obtained or supplied
- **Form** in which obtained or supplied
- Running stock balance

Methadone

Methadone treatment card with name, address and telephone of prescribing Dr and name of nominated pharmacy, valid for ONE YEAR.

Only one week supply given except in exceptional circumstances

CD2 requirements:

- Be in ink, signed and dated – sig is genuine (contact if nec)
- Prescribers address – must be nominated Dr.
- Prescriber's name and **qualification** clearly
- Prescriber's **telephone** number
- Will be in instalments – amount of instalments and intervals
- Specify whether supervision necessary and when (everyday, every second day). If no supervision should specify this also.
- If being supervised for one day and taking home the remainder of the week, must show this in PMR – do 2 dispensings or do a phased dispensing (one day + other 6)

In handwriting:

- Name (**first name**) and address of patient – imprint from embossed card is enough
- **Dose + Form** and where appropriate strength
- Total **quantity** to be supplied – **words and figures** (just quantity).

Records:

Info of each installment on Rx and PMR – just **one entry in CD register** when Rx is complete.

Forward original Rx to central register and retain duplicate for **2 years**.

Must also forward details of any methadone given to Dr on requisition, **forward requisition form** which does not need to be on special paper.

Must be forwarded by the **14th of the month** following the month in which supplied.

Exemptions:

1. Rx issued in a hospital/home/clinic run by public authority:
 - For administration to the patient to whom the prescription relates

- For supply (in exceptional circumstances) to the patient himself who has attended for the treatment of opiate dependence or attended as an in-patient who is opiate dependent.
2. Central treatment list and need for drug treatment card don't apply if methadone prescribed for a purpose other than opiate dependence, where the prescription is:
 - **issued by a consultant**, or
 - issued by another doctor **but initiated by a consultant** whose name and address are **included on the prescription**.

(But still **special forms, forwarded to central records and CD reg etc.**)
 3. For palliative care, same as in 2. **Methadone covered on GMS and DPS**. Can supply **more than 7 days** – not considered exceptional circumstance.

Counselling:

1. Ask patient how he/she coping
2. Would the like to have the methadone ready for them at same time everyday
3. Any side-effects – respiratory depression, changes in HR (mainly slowing), if new to treatment – nausea, constipation
4. If missed a days dose – ring Dr. Cannot give them the dose and Rx will still only be valid for 7 days.
5. Palliative care – because of side-effects important not to exceed prescribed dose. If not giving adequate pain relief, important to contact prescriber to increase dose.

ULMs

1. If says "ULM POA", no code in PA column, no PCRS code, not on imb.ie
2. Must be consultant initiated but GP can prescribe subsequent
3. No licensed product available
4. Must be the only item on the script.
5. If not on list of exempt medicinal products must apply for reimbursement through Hardship Scheme and must get approval from local health office.
6. If on the list then applies to GMS, DPS, LTI and HAA.
7. **Can be repeated** – rem GMS special repeat script and if specified by Dr.
8. To enter Rx: go to drug file and change code to that on the Exempt Medicinal Products list.
9. **€2.50 levy** if GMS.

Lidocaine patches – very expensive – contact GP to prescribe generic

If foreign patient, by the time the product has been ordered in they may have left the area – suggest alternative

Reimbursement: get the amount specified on list. Medisource had included carriage in this price. Any other company may charge more. Send copy of invoice with the top copy of GMS script or the DPS receipt and in certain circumstances an explanation for prescribing and dispensing.

Counselling:

- Explain to patient that it is an unlicensed med and that the quality, safety and efficacy of the medicinal product has not been established in this country.
- Explain ULM process and the wait for meds to be delivered.

Hardship

JF 1.4 for example

- For **patients with medical cards only** to get non-GMS items
- Generally items over €20.
- Outside remit of GMS – instead HSE
- Item is not under the HSE-PCRS exempt med products list
- Prescriber must formally request their patient get Hardship med. Usually pharmacies have the application form (HD1 application form) which they complete as much as possible and then send on to GP for signing.
- **€2.50 levy**

Process:

1. Pharmacist estimates price. Fills in on HD1 application form, signed by patient, pharmacist and Dr and sent to Local Area Health Board. Keep copy in pharmacy.
2. If approved they send out a purchase order to the pharmacy requisitioning the item
3. When purchase order received, patient can receive item free of charge.
4. Usually dispense the item (if in stock) once get verbal approval from local office that they are going to send out a purchase order.
5. For payment, the pharmacist submits (to the office from which the order originated but payment is from PCRS) an itemised invoice (HD2 claim form) outlining: Pharmacy number, patient name and GMS number, product, quantity, date dispensed, ingredient cost, VAT, dispensing fee and copy of invoice.
6. HD2 contains all the hardship items for that month.
7. Claims must be submitted by the 3rd of the following month.

Payment:

- Cost price + dispensing fee. DF for first 1667 items is €5.
- Cost price is the price pharmacist pays to the wholesaler. HSE has decreased wholesaler mark-up to 10% but wholesalers have not changed their original mark-up of 17.66%. Therefore, HSE pays the pharmacist 110% + €5 but the pharmacist has to pay the wholesaler 117.66%. Often works out at a loss to the pharmacist.

Extemporaneous

1. Manufacturer's license for extemp compounding is not required in a pharmacy with supervision by pharmacist as long as:
 - Genuine, unsolicited order by prescriber for a specific patient and takes responsibility
 - Manufactured according to specifications of prescriber for specific patient, or keeping stock for med product prescribed exclusively by that prescriber or in accordance with pharmacopoeial formulation for supply to customers of pharmacy.
 - Extemp product is not advertised
 - No licensed product on market
2. Can be VAT (oral products) or non-VAT (topical preps).
3. GMS extemp code = 33333
4. DPS extemp code = 99999
5. Where normally put product brand name enter "extemp" and then choose either dispensing VAT or NO VAT.
6. Make note of ingredient costs as they are entered
7. When this done then need to change name to actual name of product name include the quantity (xg/xL)
8. In the quantity box enter the price in cents
9. Price :
 - Non-VAT = cost-price + mark-up + dispensing fee
 - VAT = cost price + mark-up + dispensing fee + VAT (21%)Mark up for GMS is zero. For DPS is 50%
Dispensing fee on list.