Law and Ethics

MEP

Human Medicines Regulations 2012

Consolidated most of the legislation regulating the authorisation, sale and supply of medicinal products for human use, made under the Medicines Act 1968.

This includes regulations on the manufacture, import, distribution, sale and supply of those products; their labeling and advertising; and pharmacovigilance.

For detailed information on the legislation:

http://www.legislation.gov.uk/uksi/2012/1916/contents/made

What is a Pharmacovigilance?

The monitoring of the safety of medicines in clinical use and taking appropriate action to minimise risk.

Just Culture

- Differs from punitive and no-blame culture
- Ensures better safety for patients, and promotes fair and right practice including the ability to raise concerns
- Helps prevent mistakes and accidents from happening
- The NHS Incident Decision Tree embodies just culture principles and is a tool to decide on the appropriate course of action following an incident

Professional empowerment

- It is the process of enabling professionalism at both an individual and wider level.
- Individuals are empowered to develop knowledge, skills, experience and confidence as well as cultivate professional values and behaviours that inspire authority and professionalism.
- Professional empowerment at a wider level is about creating an environment around an individual whereby individual professional empowerment can be achieved.

What are the three classes of medicinal products under the Human Medicines Regulations 2012 and their abbreviations?

Class	Abbreviation
General Sale Medicines	GSL
Pharmacy Medicines	P
Prescription Only Medicines	POM

Day Seven

GSL Medicines

Can be sold or supplied, with reasonable safety, otherwise by or under the supervision of a pharmacist.

All GSL medicines, must be licensed products (except those designated as foods or cosmetics)

Day Seven

Retail Sale of GSL Medicines

GSL medicines can only be sold by retail or supplied:

- In registered pharmacies
- From a premises at which the person carrying on the business is the occupier and which he is able to 'close so as to exclude the public'
- From machines located in a premises in which the occupier is able to close so as to exclude the public
- If the medicinal product has been made up for sale in a container elsewhere and not opened

Day Seven

What is a P Medicine?

A pharmacy medicine is a medicinal product that can be sold from a registered pharmacy premises by a pharmacist or a person acting under the supervision of a pharmacist.

e.g. 30-sachet Fybogel

Day Seven

Retail Sale of Pharmacy Medicines

Can only be sold by retail or supplied by:

- A registered pharmacy
- A person lawfully conducting a retail pharmacy business
- A person who is a pharmacist or selling under the supervision of a pharmacist

Day Seven

POM

Medicinal products which may only be sold or supplied in accordance with a prescription from:

- Doctor
- Dentist
- Supplementary prescriber (pharmacist, midwife, nurse, podiatrist, optometrist etc.)
- Independent prescriber (pharmacist, nurse, podiatrist, optometrist, physiotherapist etc.)
- Community practitioner nurse
- Vet surgeon/practitioner
- EEA or Swiss doctor and dentist, and prescribing pharmacist/nurse (where they exist)

Day Seven

Professional and Legal Issues

P medicines

Day Seven

Pseudoephedrine & Ephedrine

- Unlawful to supply a product or combination of products that contain more than 720mg of pseudoephedrine OR 180mg of ephedrine in a single transaction without a prescription
- Unlawful to sell or supply any pseudoephedrine product at the same time as an ephedrine product without a prescription.

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Oral Emergency Contraceptives as pharmacy medicines

- Levonorgestrel 1500mcg tablet and ulipristal acetate 30mg tablet are licensed as pharmacy medicines for EHC.
- Pharmacists can provide an advance supply of oral emergency contraception to a patient requesting it at a pharmacy.

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Paracetamol & Aspirin

- Not more than 100 non-effervescent tablets or capsules can be sold to a person at any one time.
- No legal limits on quantity of OTC effervescent tablets, powders, granules or liquids that can be sold to a person at any one time.
- Use professional judgment

Day Seven

Codeine & Dihydrocodeine

Tighter Controls & Warnings on packaging of OTC solid dose medicines, which include:

- **Indications:** For the short-term treatment of acute, moderate pain that is not relieved by paracetamol, ibuprofen or aspirin alone.
- **Pack Sizes:** any pack now containing more than 32 dose units now requires a marketing authorisation as a POM. This includes effervescent formulations.

Day Seven

Codeine & Dihydrocodeine

- **PILs & Labels:** the warning "can cause addiction. For three days use only" must now be positioned on the front of the pack. In addition, both pill and packaging need to state the indication and that the medicine can cause addiction or overuse headache if used continuously for more than three days. The PIL must also contain warning signs of addiction.

Day Seven

Criteria for reclassifying POM to P

The medicine is not one or more of the following:

- is likely to present a direct or indirect danger to human health, even when used correctly
- is frequently and to a very wide extent used incorrectly, and as a result is likely to present a direct or indirect danger to human health
- contains substances which the activity requires, or the side effects require, further investigation
- is normally prescribed by a doctor for parenteral administration

Flomax Relief (tamsulosin 400mcg capsules)

Day Seven

POM to P

Used to treat symptoms of benign prostatic hyperplasia (BPH) occurring for a minimum of three months in men aged 45-75 years old, following a consultation with a pharmacist.

Tranexamic Acid 500mg tablets

Day Seven

POM to P

Used to treat heavy menstrual bleeding for women aged 18 to 45 years with a history of regular heavy menstrual bleeding over several consecutive menstrual bleeding.

Nexium Control (esomeprazole 20mg tablets)

Day Seven

P to GSL

Jan 2015: The Medicines and Healthcare products Regulatory Agency (MHRA) has agreed to reclassify Nexium Control from a pharmacy (P) medicine to a general sales list medicine (GSL) in the UK for the short-term treatment of reflux symptoms (e.g. heartburn and acid regurgitation) in adults.

Diclofenac

Day Seven

P to POM

MHRA Drug Alert: Oral diclofenac containing products must not be sold to anyone *without a prescription* from 15th January 2015. This medicine is associated with a small increased risk of serious cardiac effects hence patients need to have a medical assessment before taking diclofenac to determine whether it is suitable for them.

Orlistat 60mg

Day Seven

POM to P

It is used for adults, aged 18 years and over, who are overweight or obese (BMI $\geq$ 28kg/m^2 and can help achieve steady, gradual weight loss when used as directed.

Imigran Recovery (sumatriptan 50mg tablets)

Day Seven

POM to P

Used for the acute relief of migraine attacks with or without aura.

Criteria for supply:

- Migraine must be diagnosed by a doctor or pharmacist
- There is an established pattern of migraine
- Simple analgesics tried and ineffective

Viagra Connect (sildenafil 50mg tablets)

Day Seven

POM to P

MHRA has reclassified sildenafil 50mg tablets for the treatment of adult men (aged 18 years and older) with erectile dysfunction.

Anti-Malarials

Day Seven

POM to P

Maloff Protect 250mg/100mg film-coated tablets (atovaquone with proguanil hydrochloride) were launched as a P medicine in June 2017. Maloff Protect is indicated for the prevention of malaria in adults aged 18 years and over, weighing more than 40kg who are travelling to areas where malaria is widespread.

Maloff Protect is one of four anti-malarial products currently available as P medicines. Others include:

- Avloclor (chloroquine 250mg)
- Paludrine (proguanil hydrochloride 100mg)
- Paludrine/Avloclor Anti-Malarial Travel Pack (proguanil hydrochloride 100mg/chloroquine 250mg)

Oral Lidocaine-containing products for teething in children

Day Seven

GSL to P

- In December 2018, the MHRA issued new advice for the use of oral lidocaine-containing products for teething in children, with new instructions on how to use the products and new advice that they should be used as second-line, after non-pharmacological treatments
- Updates made to the patient information leaflet
- Pack size and packaging of the products will appear different because the pack size of the products is restricted to a smaller quantity of 10g
- Lidocaine-containing products authorised in adults for other indications (e.g. mouth ulcers) will be clearly labelled with a warning: 'Not suitable for treatment of teething in children'.

Other switches include:

Day Seven

- Amorolfine 5% w/v medicated nail lacquer, P medicine
- Chloramphenicol 0.5% w/v eye drops & 1% w/v eye ointment, P medicine
- Oral Emergency contraceptives, P medicine
- Mometasone 0.05% Nasal Spray, P medicine

Day Seven

Professional and Legal Issues

POM

What are the legal requirements for a non-CD prescription?

Day Seven

- Prescription is signed in ink by practitioner giving it
- Appropriate date (of signing or to start treatment)
- Indelible
- Address of and indication of type of practitioner
- Name and address of patient
- Age of patient if under 12

Day Seven

Prescriptions for POMs

- Medicines must be supplied within 6 months from the appropriate date (including any owings). Within 28 days for schedule 2 and 3 controlled drugs.
- A private prescription should be retained for 2 years from the date of supply. Or in the case of a repeatable prescription, 2 years from the date on which the medicine was supplied for the last time. Private CD prescriptions will need to be submitted to the local authority

Day Seven

Repeatable Prescriptions

- Private prescriptions can be repeated as indicated by the prescriber (e.g. repeat x3) if only "repeat" is written then can only be repeated once.
- Exception: Contraceptives, can be repeated 5 times, i.e. dispensed a total of 6 times. First dispensing must be made within 6 months of the appropriate date.
- Pharmacist must use professional judgment.

Day Seven

Prescription Records

The following should be recorded in the case of a sale or supply of a POM in a written or computerised record kept for that purpose either on the day or on the next day following the sale or supply:

a) Date of supply
b) Medicine details
c) Date on prescription
d) Prescriber details
e) Patient details

Day Seven

What are the exemptions to record keeping?

1. A prescription for oral contraceptives
2. Prescriptions for Schedule 2 Controlled drugs where a separate record is made in the CD register
3. The sale is by way of wholesale dealing and the order/invoice is retained for 2 years

Day Seven

Faxed Prescriptions

- A faxed prescription is not legally valid because it is not written in indelible ink and has not been signed in ink by an appropriate practitioner.

Day Seven

Labelling – Legal Requirements

Date of Dispensing

Name of Patient

Directions for Use

100 Paracetamol 500mg tablets
Take ONE to TWO tablets up to FOUR times a day
DO NOT EXCEED THE STATED DOSE
KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

Mr Divesh Patel 05/01/2020

Anytown Pharmacy, 123 Old Oak Lane, W3 0BU

Name of Medicine

Precautions & KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

Name & Address of Pharmacy

Day Seven

Other Labelling

- In addition to standard labeling requirements, the words "Emergency supply" MUST be added to the dispensing label when issuing an emergency supply
- 'Use this medicine only on your skin' where applicable

Good practice:

- Shake the bottle
- For external use only
- Discard …. days after opening
- Prisoner number, where applicable

Day Seven

What are the difference between retail sale and wholesale dealing?

Wholesale dealing constitutes:
Selling to a person in the course of a business carried on by the purchaser who will then:

- Sell it
- Supply it
- Administer it or cause it to be administered to one or more human beings

Day Seven

What is a Patient Group Direction?

A PGD is a written direction relating to supply and/or administration of a specified medicine or medicines by named authorised health professionals to a defined group of patients requiring treatment for an identified clinical condition.

Day Seven

Salbutamol in Schools

Schools are allowed to hold stocks of salbutamol inhalers, which can be supplied in an emergency by persons trained to administer them to pupils who are known to require such medication in schools.

This is subject to the presentation of a written order signed by the principal/head teacher at the school stating:

(1) name of the school

(2) purpose for which the product is required

(3) the total quantity required

Day Seven

Supply of adrenaline auto-injectors (AAI) to schools

Legislation came into force on 1st October 2017 that enables schools to purchase AAIs without a prescription for use in emergencies, from a pharmacy in small quantities provided this takes place on an occasional basis and is not for profit.

This is subject to the presentation of a written order signed by the principal/head teacher at the school stating:

(1) name of the school

(2) purpose for which the product is required

(3) the total quantity required

Day Seven

Optometrist or podiatrist signed patient order

- Can supply certain POMs directly to patients in accordance with a signed patient order from a registered optometrist or podiatrist.
- The medicine requested must be one that can legally sold or supplied by the optometrist or podiatrist rather than one which they can only administer.

Supplying oral retinoids and pregnancy prevention

- Oral retinoids (isotretinoin, alitretinoin and acitretin) are used to treat severe skin conditions. However, there is a risk of causing serious malformations to a foetus, and increases the risk of spontaneous abortions.
- A Pregnancy Prevention Programme (PPP) educates both healthcare staff and patients to ensure females with child-bearing potential do not get pregnant whilst taking oral retinoids (and for at least one month after stopping it).
- Therapy to be initiated by or under the supervision of a specialist and under the conditions of the PPP.
- Rxs valid for 7 days (consider expired after 7 days) with a max supply of 30 days.
- Repeat or faxed prescriptions would be unacceptable

Dispensing valproate for girls and women

- Valproate can cause serious harm to an unborn child when taken during pregnancy and should not be taken by women and girls unless nothing else works and the person taking valproate is part of a pregnancy prevention programme.

Assembled (pre-packed) medicines

This is when bulk containers are broken down into smaller quantities. The re-packed medicine must be labelled with:

- Name of medicine
- Quantity
- Ingredients
- Handling & Storage requirements
- Expiry date
- Batch number

Administration of POMs

- Parenteral POMs can only be administered to another person in accordance with the directions of an appropriate practitioner or by an appropriate practitioner, unless in an emergency that involves saving a life. The list of authorised parenteral medicines for this purpose are under Schedule 19 of The Human Medicines Regulations 2012
- Specific classes of persons, such as midwives, paramedics and others can also administer POMs under certain conditions. Further details are found in Schedule 17 of the Human Medicines Regulations 2012.
- Certain healthcare professionals can also administer medicines in accordance with a PGD.

Professional and Legal Issues

Other

Electronic cigarettes

- Nicotine-containing products (NCPs) that are presented for cutting down, quitting and reducing the harms of smoking are considered to be medicinal products. MHRA is responsible for regulating NCPs such as e-cigarettes
- MHRA is encouraging manufacturers to apply for marketing authorisation to assure quality, safety, efficacy and Good Manufacturing Practice (GMP)
- Research has shown massive variability in quality of electronic cigarettes so pharmacists should consider these risks before selling

Day Seven

Electronic cigarettes

- GPhC:

https://www.pharmacyregulation.org/gphc-outlines-position-sale-e-cigarettes-registered-pharmacies

https://www.pharmacyregulation.org/regulate/article/complying-new-legislation-prohibiting-sales-e-cigarettes-under-18s

- RPS Policy Topic:

https://www.rpharms.com/making-a-difference/policy-a-z/e-cigarettes

- GOV.UK:

https://www.gov.uk/guidance/e-cigarettes-regulations-for-consumer-products

Day Seven

Collection and purchase of medicines by children

If supplying dispensed medicine to a child either for their own use or on behalf of an adult the decision and responsibility lies with the pharmacist (records should be made justifying this action). Factors to consider:

- Knowledge and maturity of the child
- Nature of the medicine(s)
- Prior arrangements and the reason for collection
- Counselling
- Local policies
- Proof of identity

Day Seven

Falsified Medicines Directive (FMD)

- The Delegated Regulation to the FMD came into force in February 2019. It includes new security features on individual packs and a new electronic scanning authentication process to be undertaken at the point of dispensing to make sure medicines supplied in the UK are safe.

https://www.pharmacyregulation.org/regulate/article/preparing-safety-features-delegated-regulation-under-falsified-medicines-directive

Day Seven

Homeopathic & Herbal remedies

- Pharmacists should help patients distinguish the difference between homeopathic ('like treat like') therapy and herbal products (= plant-derived).
- There is no clinical evidence for the effects of homeopathic products, and for this reason pharmacists cannot endorse this as a form of treatment, especially for serious conditions.

Day Seven

Charitable donations

- Guidance has been published for any pharmacist who wishes to donate medicines.
- WHO encourages donating standardised health kit medicines in the acute stage of an emergency, then the donation of money to purchase essential medicines following the acute stage.
- WHO guidelines currently advise against donating patient returns.

Day Seven

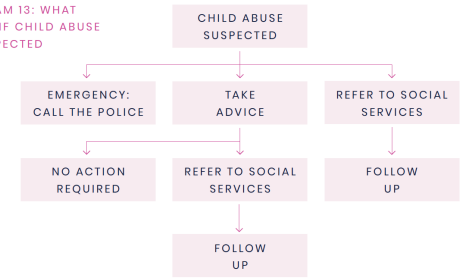
PILs and Child-resistant Caps

- Patient Information Leaflets MUST ALWAYS be supplied for all relevant medicinal products
- Suitable, child-resistant packaging should be used for supplying all solid, all oral and external liquid dose preparations unless:
  - The patient, carer or representative (who is over 16 years of age) specifically requests a packaging that is not child-resistant
  - it is not reasonably practicable e.g. original container is not child-resistant and there are reasons why the medicine should remain in the original container

Safeguarding

Protecting Children & Young People

DIAGRAM 13: WHAT TO DO IF CHILD ABUSE IS SUSPECTED



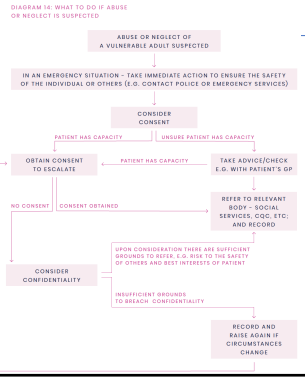
A young woman comes your pharmacy to buy Phenergan Elixir (promethazine 5mg/5ml oral solution) for their 4-year old son, who appears to have Down's syndrome.

Despite questioning the request and stating your concerns, the woman is adamant to purchase the solution as she needs it in order to relax her son and that they both need sleep.

What would you do?

Protecting Vulnerable Adults

DIAGRAM 14: WHAT TO DO IF ABUSE OR NEGLECT IS SUSPECTED



Freedom of Information Act

Caldicott Review on Information Governance

Caldicott Review

The Report recommended that:

- Patients to have full access to all electronic care records about them, across the whole health and social care system, without charge.
- An audit trail that details anyone and everyone who has accessed a patient's record should be made available in a suitable form to patients via their personal health and social care records.
- The Department of Health and NHS Commissioning Board should drive a clear plan for implementation to ensure this happens as soon as possible.

PSNC briefing summarising the Government response to the Caldicott Review:

http://psnc.org.uk/wp-content/uploads/2013/12/PSNC-Briefing-109.13-Information-To-Share-or-not-to-Share.pdf

Day Seven

Drug Driving Offences

Road Traffic Act 1988: Section 4

Driving, or being in charge, when under influence of drink or drugs

- A person who, when driving or attempting to drive on a road or other public place, is unfit to drive through drink or drugs is guilty of an offence.
- A person shall be taken to be unfit to drive if his ability to drive properly is for the time being impaired.

Day Seven

Drug Driving Offences

A new offence of driving with certain specified controlled drugs in excess of specified levels in the body came into force on 2 March 2015

- Screening devices to test saliva can be used to identify if a person has taken a drug. Following a positive result, the person can be requested to provide a blood sample as evidence to enable prosecution for the offence if levels are found to be above the specified limit
- Individuals who have taken their medicine(s) in accordance with the advice of a prescriber can raise the statutory "medical defence" to prevent prosecution
- Advise all patients receiving medicines that may impair driving ability

Day Seven

Drug Driving Offences

Controlled Drugs implicated in drug driving offence:

FIRST GROUP	SECOND GROUP
Cannabis (THC)	Clonazepam
MDMA (ecstasy)	Diazepam
Ketamine	Lorazepam
Methylamfetamine	Oxazepam
Cocaine (and a cocaine metabolite, BZE)	Temazepam
Lysergic acid diethylamide (LSD)	Flunitrazepam
Heroin/diamorphine metabolite (6-MAM)	Methadone
	Morphine
	Amfetamine

Day Seven

Summary of how the new drug driving offence fits in with existing legislation