Pharmacy vs Pharmacist supply – when is self-selection appropriate

Jan MacDonald
• Different legal categories
• Patient perspectives
• Current policy on sale & supply
• Pharmacy vs Pharmacist – examples
• Future
UK Legal Categories

• Three legal categories
  – POM
  – P
  – GSL
• Four POM criteria
• One GSL criterion
POM Criteria

*Regulation 62(3)*

A UK marketing authorisation must … … be available only on prescription if the licensing authority considers that the product—

- is likely to present a direct or indirect danger to human health, even when used correctly, if used without the supervision of a doctor or dentist;
- 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, or preparations of substances, of which the activity requires, or the side effects require, further investigation; or
- is normally prescribed by a doctor or dentist for parenteral administration.
GSL Criterion

*Regulation 62(5)*

A UK marketing authorisation may … … be available on general sale only if the licensing authority considers that the product can with reasonable safety be sold or supplied otherwise than by, or under the supervision of, a pharmacist.
Listening to the Patient

- Patient & Public Engagement
- Confident with self-selection in a small number of areas
- Concerns
  - Is this the right medicine for me
  - What about interactions
  - Will I get side effects
Pharmacist as Gatekeeper

• Pharmacy professionals can
  – Provide screening services
  – Consider wider range of treatment options
  – Be commissioned locally to provide services
  – Will have access to Summary Care Record
  – Undertake training in line with professional requirements
Diagram on decision-making for the supply of oral emergency contraception as a pharmacy medicine

The copper intrauterine device is the most effective form of EC, if this is not a suitable option \(^\text{1}\), EC should be considered.

- **LUPA = Ulpristal acetate**
- **UPA = Ulpristal acetate 3 mg**
- **LNG = Levonorgestrel 1.5 mg**
- **EC = Emergency contraception**
ORLISTAT 60MG P MEDICINE
Quick reference guide
Contraindications (and other referral criteria)

**Interactions:**
- Strong CYP1A2 inhibitors (e.g., ketoconazole, erythromycin)
- Verapamil
- Diltiazem
- Warfarin

**Patient characteristics:**
- Under 45 or over 75 years of age

**Other contraindications:**
- Severe hepatic insufficiency
- Where patient has surgery for glaucoma or cataract scheduled

**Warnings:**
- Enhanced hypotensive effects with other alpha-1 adrenoceptor antagonists i.e.
  - doxazosin
  - indoramin
  - prazosin
  - terazosin

**Symptoms:**
- Symptoms for less than three months
- Dysuria
- Haematuria
- Cloudy urine
- Fever (possible undiagnosed UTI)

**History of:**
- Postural or orthostatic hypotension
- Heart, kidney or liver disease
- Diabetes - if uncontrolled
- Urinary incontinence
- Previous prostate surgery
- Blurred/cloudy vision (undiagnosed)

**Hypersensitivity to:**
- Tamsulosin
- Any other ingredient in the preparation

**Referral criteria:**
- Stop treatment if symptoms have not improved (or are getting worse) after the initial 14 day treatment
- Patients should see their doctor within 8 weeks of starting OTC tamsulosin and confirm continued treatment is appropriate
- Patients must see their doctor at least every 12 months to enable further OTC supply (after the initial six weeks of treatment)
SUPPLY OF ANTI-MALARIALS AS PHARMACY MEDICINES

Quick reference guide

Maloff Protect 250mg/100mg film-coated tablets (atovaquone with proguanil hydrochloride) was launched as a Pharmacy (P) medicine in June 2017. It is indicated for the prevention of Plasmodium falciparum (P. falciparum) malaria in adults aged 18 years and over, weighing more than 40kg who are travelling to areas where malaria is widespread. It is especially recommended for prevention of P. falciparum malaria where the pathogen may be resistant to other anti-malarials.

Maloff Protect is one of four anti-malarial products currently available as P medicines for supply from pharmacies in the UK. Avloclor, Paludrine and Paludrine/Avloclor Anti-Malarial Travel pack are now rarely used due to the development of resistance.

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

Who needs to read this?

Pharmacists and pharmacy staff who may be involved in providing travel advice to patients including the supply of anti-malarials.

What this guidance will tell you?

This guidance provides information on what pharmacists need to consider before supplying anti-malarials as P medicines to patients, information on the condition, the product supplied, other treatment options, malaria prevention measures, signs and symptoms of malaria infection and action required if suspected infection, and signposting to resources for both the pharmacist and their patients.

What this guidance will not tell you?

This guidance does not cover the treatment options for infection with malaria, only prevention. Pharmacists should refer anyone they consider may be infected with malaria to seek immediate medical assistance.

The guidance only covers those anti-malarials that are currently available as P medicines. For information on other anti-malarials that are available see the British National Formulary (BNF) and Summaries of Product Characteristics (SPC) for individual products.
Drug Safety Update

From: Medicines and Healthcare products Regulatory Agency

Miconazole (Daktarin): over-the-counter oral gel contraindicated in patients taking warfarin

Patients taking warfarin should not use over-the-counter miconazole oral gel (Daktarin).

Cardiovascular disease and lipidology and 5 others  Published: 26 September 2017
Drug Safety Update

From: Medicines and Healthcare products Regulatory Agency

Oral diclofenac no longer available without prescription
Oral diclofenac is associated with a small increased risk of cardiovascular side effects and is therefore no longer available over the counter.

Pain management and palliation and 1 others  Published: 22 January 2015
The self-care continuum

Pure self care
- Responsible
- individual

Pure medical care
- Professional
- responsibility

The self-care continuum

- Daily choices
- Self-managed ailments
- Long-term conditions
- Compulsory psychiatric care
- Major trauma

Healthy living

- Minor ailments
- Long-term conditions
- In-hospital care
Patient group directions: who can use them

Updated 10 April 2017

Patient group directions (PGDs) are written instructions to help you supply or administer medicines to patients, usually in planned circumstances. They take a significant amount of time and resource to develop and implement.

You can only supply and administer medicines under PGDs if there is an advantage for the patient without compromising their safety.

PGDs should be put together by a multi-disciplinary group including a doctor, a pharmacist, and a representative of any professional group expected to supply the medicines under the PGD. It's good practice to involve local drug and therapeutics committees, area prescribing committees, and similar advisory bodies.

The expiry date for a PGD needs to be decided on a case-by-case basis in the interest of patient safety. The expiry date should not be more than 3 years from the date the PGD was authorised.

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Consultation Hub  Find Consultations

Items which should not be routinely prescribed in primary care: A Consultation on guidance for CCGs