Classification of Medicines as ‘Pharmacy only’ and ‘General Sales’

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Overview

- Introduction
- OTC Medicines classification in Europe
- Classification of OTC medicines in UK
- General sales list products
- Impact on work of Committee of Experts on Legal Classification
Healthcare delivery in Europe

• Variability:
  – Medical practice
  – Pharmacy practice
  – OTC availability
  – OTC medicines
  – Reimbursement policy
  – Consumer attitude and expectations
OTC medicines classification in Europe

Legal Classification governs Modes of Supply

• from pharmacies only, under the supervision of a pharmacist, e.g. Austria, France

• in a pharmacy, on self-selection where the pharmacist does not have to be involved in the purchase, e.g. Germany, Norway, Sweden, Lithuania

• outside pharmacies, but requiring a qualified medicines advisor to be present e.g. a druggist in the Netherlands

• outside pharmacies and with no professional supervision i.e. general sales supply as in the UK
OTC Legal Classification in UK  

- **P** Pharmacy availability  
  - under the supervision of a pharmacist

- **GSL** General Sale List  
  - general retail outlets, e.g. petrol stations

\[ P + GSL = \text{Over-the-counter (OTC), non-prescription} \]
Medicines which can with reasonable safety be sold or supplied otherwise than by or under the supervision of a pharmacist.

- “With reasonable safety” may apply in circumstances where:
  - the hazard to health,
  - the risk of misuse, or
  - the need to take special precautions in handling are small, and

- where wider sale would be a convenience to the purchaser.
UK perspectives on OTC

- Empowering patients to make informed choices in prevention, self diagnosis and treatment of disease and disability
- Broadening patient choice through widening access to medicines, including through reclassification where it is safe to do so
- Making best use of pharmacists' expertise
- Making better use of GP, and urgent and emergency care services
UK GSL Products
- Self limiting conditions

- Acne
- Bites and stings
- Cold
- Cold sores
- Constipation
- Diarrhoea
- Fever
- Flu symptoms
- Haemorrhoids
- Hayfever treatment and prevention
- Headache

- Indigestion/heartburn
- Male pattern baldness
- Mild to moderate pain
- Minor cuts and bruises
- Mouth ulcer
- Smoking cessation
- Sore throat
Products only for Pharmacy supply in UK

- Codeine containing analgesics
- Pseudoephedrine decongestant
- Azithromycin for Chlamydia
- Chloramphenicol eye drops/ ointment
- Sedating antihistamines
Nicotine Replacement Therapy

• Smoking is the biggest public health target in the UK

• There are no circumstances in which it is safer to smoke than to use NRT

• Widest possible availability, in a variety of forms, for a range of patient populations, is key to achieving the greatest positive impact on public health
GSL Pros and Cons

Convenience for patient
• Numbers of outlets
• Longer opening hours
• Location, especially in rural areas
• Self service (empowering)

• Lack of professional advice
• Less choice
Pack label for safe use (+ website)

alli®
60 mg capsules
orlistat

To see if alli® is right for you, find your height on the chart. If you weigh less than the weight shown for your height, do not use alli®.

<table>
<thead>
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Being overweight increases your risk of developing several serious health problems such as diabetes and heart disease. You should see your doctor for a check-up.

Read the package leaflet before use.

Keep out of the reach and sight of children.

Ingredients: Each hard capsule contains 60 mg orlistat.

alli® is used for weight loss alongside reduced calorie, lower-fat meals in overweight adults, aged 18 or over.

alli® is clinically proven to help you lose more weight than dieting alone. The capsules work only in your digestive system to stop about a quarter of the fat in your meals from being absorbed. This fat passes out of your body and may cause changes to your bowel movements. Eat lower-fat meals to help manage these effects.

Do not use
■ if you are under 18.
■ if you are pregnant or breast-feeding.
■ if you are taking ciclosporin.
■ if you are allergic to orlistat or any of the ingredients.
■ if you have cholestasis (condition where the flow of bile from the liver is blocked).
■ if you have problems absorbing food (chronic malabsorption syndrome).
■ if you are taking warfarin or any other medicines used to thin the blood.

Talk to your doctor or pharmacist before taking alli®
■ if you are taking amiodarone for heart rhythm problems.
■ if you are taking a medicine for diabetes.

Talk to your doctor or pharmacist when taking alli®
■ if you are taking a medicine for high blood pressure.
■ if you are taking a medicine for high cholesterol.

How to use
■ oral use.
■ take one capsule whole with water, three times a day with each main meal containing fat.
■ do not take more than three capsules a day.
■ you should take a multivitamin (containing vitamins A, D, E and K) once a day, at bedtime.
■ you should not take alli® for more than six months.
Label Warning

Being overweight increases your risk of developing several serious health problems such as diabetes and heart disease. You should see your doctor for a check-up.
Committee of Experts on the Classification of Medicines

Current work includes
• Consideration on the classification of medicines
• Prescription and non prescription

Proposal to expand non-prescription
• Pharmacy only
• General sales

Participants views welcome