

# **Best package design for non-prescription medicines**

Helen Darracott

Director Legal & Regulatory Affairs, PAGB

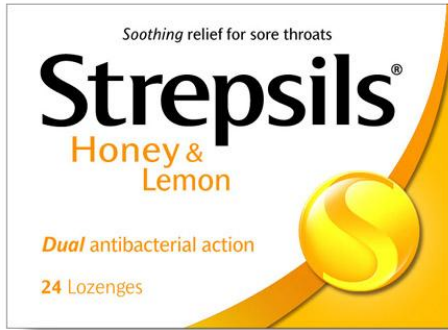
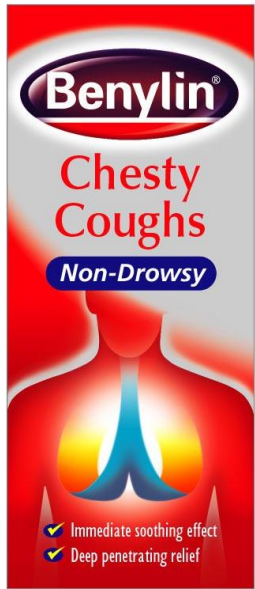


# Code of Practice for Pack Design for OTC medicines

- Clear requirements
- Presentation of information
  - Layout and typography
- When information compatible with SmPC may be considered promotional
- Pack design and graphics
  - Colour
  - Pictograms and symbols
- AESGP Pack Design Guidance under consideration by EMEA



# Why is packaging so important for OTC medicines?



PAGB

AESGP

# Why is packaging so important for OTC medicines?

- Healthcare professional intervention not mandatory in selection of OTC medicines
- Packaging has to provide all information required for consumer to select an appropriate product, use it safely and choose between products

# Trends in the OTC medicines market

## Self Diagnosis/ Self management

Minor self limiting conditions

Headache,  
colds and flu, indigestion  
constipation, diarrhoea,  
athletes foot, cuts, cold sores,  
allergy

Recurrent conditions

Minor arthritic pain,  
cystitis, insomnia, hayfever,  
IBS, thrush, eczema, EHC,  
migraine, headlice, threadworms,UTI?  
menorrhagia

Long term maintenance/  
prevention

Smoking cessation  
Allergy prevention  
Indigestion prevention  
Baldness prevention  
Cholesterol control  
Prevention of heart attack

Short term use

Long term use

Migraine  
Erectile dysfunction?  
Obesity  
Influenza?

Asthma, Diabetes  
Oral contraception and HRT  
Peptic Ulcer, Arthritis  
Skin disorders

Doctor diagnosis and management

# OTC - the consumer environment

- Increase in consumer self medication
- Increasingly diverse therapeutic categories and products
- Packaging design provides visual signposts that aid consumer understanding and navigation

# OTC packaging

- Invented name, critical health information and pack design complement each other
- Each has a role in ensuring
  - Appropriate, safe and effective use of OTC medicines
  - Packaging is “effective” – user friendly, clear and meaningful



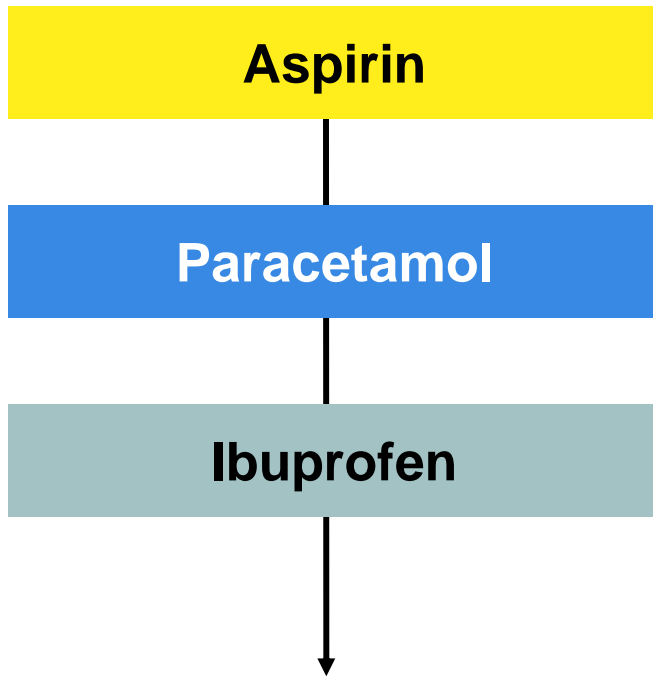
# OTC packaging must address .....

- Complex information and communication needs
  - Consumers and healthcare professionals
  - Consumer need starts with a condition
  - Information needs and priorities vary across different therapeutic categories and from patient to patient



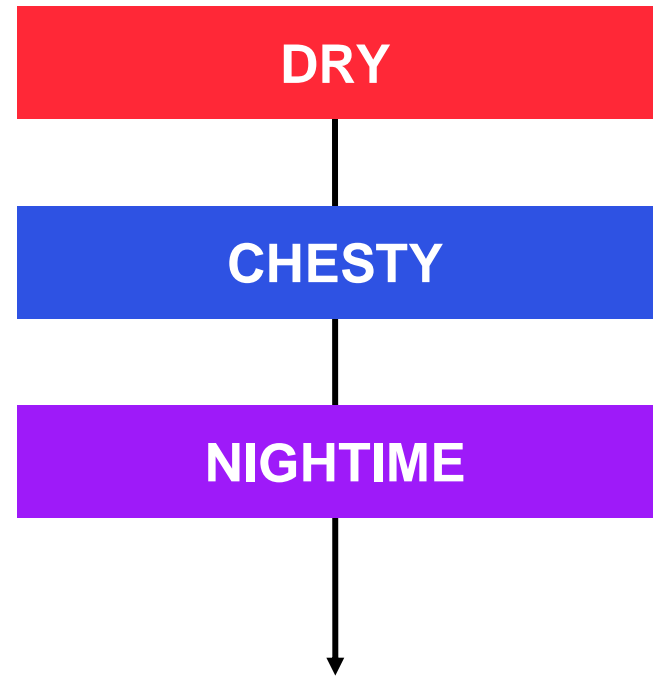
# Information priorities differ between categories

## Analgesics



**Active  
ingredient**

## Cough



**Condition**

# Communication needs vary product by product



**Flavour**



**Category and format**

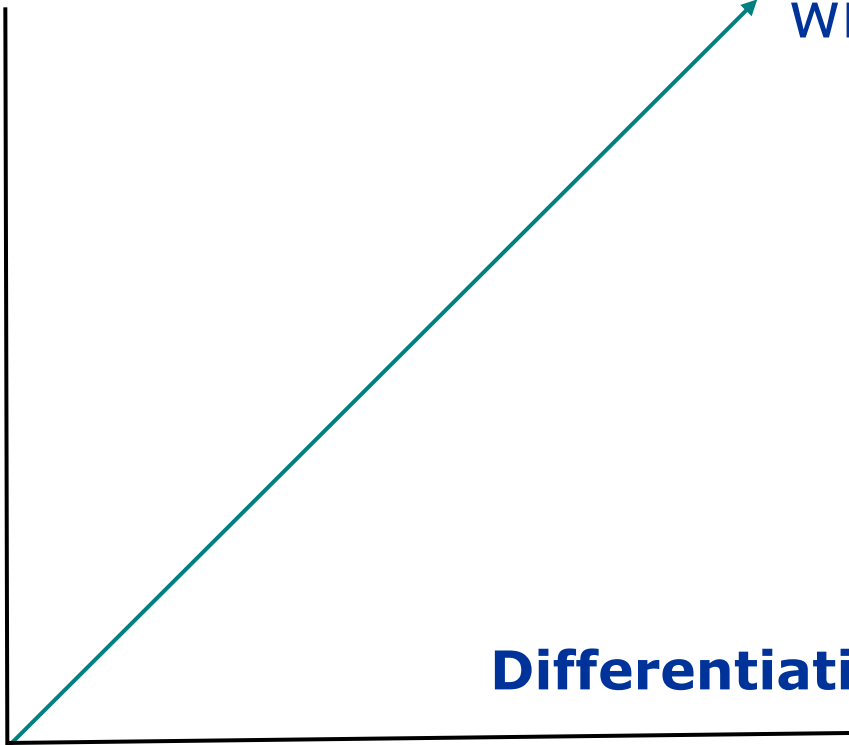


**Condition and benefit**

# Information needs vary by patient

The greater the risk to the patient arising from using the wrong product the greater the need for differentiation within a range

Risk



Differentiation



# Complex information needs met by using a combination of .....

- Statutory information (Article 54)
  - name and critical health information
- Non-statutory information (Article 62)
  - permits the inclusion on the label of information that is compatible with the SmPC and which is useful for consumers provided it is not promotional in nature

# Information must be .....

- Expressed in clear and meaningful ways so that it is easily understood in order to facilitate safe and appropriate choice and use of OTC medicines
- Communicated by use of
  - text, straplines, graphics, symbols, pictograms, colours etc

# Key principles

All information on OTC packs must be:-

- Consistent with Summary of Product Characteristics
- Not promotional in nature
- Meaningful to consumers (and health professionals)



# Statutory Information

## Critical Health Information

(all must appear in same field of vision)

Name of medicine

Expression of strength

Route of administration

Authorised indications

Dosage

Warnings

Batch number

Expiry date

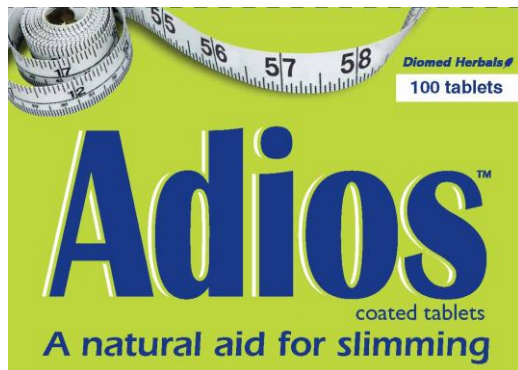
Braille (by 30 October 2010)





# Non-statutory information

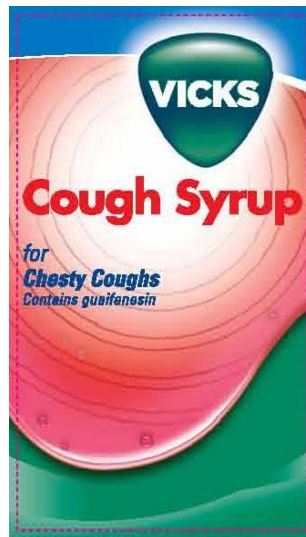
- Statements relating:
  - Condition or indication
  - Onset or duration of action
  - Particular groups of the population

A box of Benadryl Allergy Relief. The box is blue and white. Text on the box includes 'NEW', 'Benadryl', 'ALLERGY RELIEF', 'Acrivastine', and '12 CAPSULES'. A stopwatch is shown on the left. A table on the right lists allergen types with checkmarks.

HISTAMINE BLOCKER	
Hay Fever	✓
Dust Allergy	✓
Pet Allergy	✓
Skin Allergies	✓

# What is promotional – where is the borderline?

- Statements relating to product attributes, formulation, indication
  - SR, long lasting relief, fast
  - non-drowsy,
  - double action,
  - Soluble,
  - Cardio,
  - chesty cough,
  - allergy relief,
  - honey & lemon
- Colour

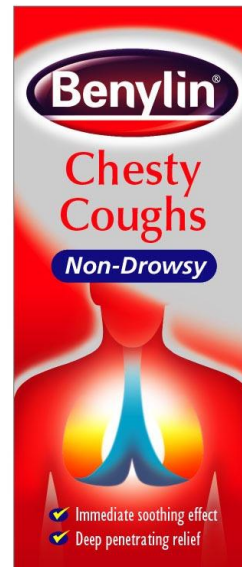
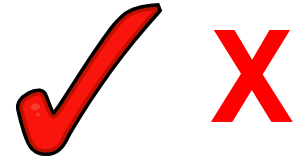
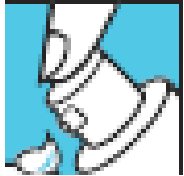


PAGB

AESGP 

# What is promotional – where is the borderline?

- Graphics, symbols, logos



# What is promotional – where is the borderline?

- Signposts to additional sources of information
  - Website addresses
- Statements relating to portability, convenience
  - New handy pack, pocket pack

# What is promotional – where is the borderline?

- General quality or value statements
  - Extra fill, 25% free,
  - Ideal for....., Intensive relief
  
- All elements of pack design considered in context of pack as a whole

# Ensuring packaging is legible and meaningful

- Use lay language – avoid complicated medical terminology
- Layout
  - Critical health information
    - Location of information
    - Arrangement of text
    - Differentiating blocks of text
    - Quantity of information
    - Use of icons
- Font
  - Size and style
  - Colour and contrast
  - Background visual noise

# Ensuring packaging is legible and meaningful

- CAPITAL LETTERS ARE HARD TO READ

Use colour with caution

Use colour with caution

Use colour with caution

Reversed out text appears smaller

Reversed out text appears smaller

# Ensuring packaging is legible and meaningful

- Packaging and printing
  - Package shape and size
    - Type of packaging used (glossy finishes etc.)
    - Printing type
    - Printing quality
- User environmental factors
  - Observation distance
  - Light conditions

# Packaging design brings products to life

**BRAND**

**Cold & Flu**

**Maximum strength**  
Hot lemon sachets  
Non drowsy

**Paracetamol & Phenyleprine**

**Fever, headache, Body aches  
and pains. Sore throat**

**Blocked/runny nose**

**10 sachets**



# Good pack design assists differentiation

**BRAND**  
**Children's**  
**Tickly Cough**

Glycerol

3+months

Sugar & colour free

Apple flavour

Non drowsy

125ml

**BRAND**  
**Children's**  
**Chesty Cough**

Guaifenesin

1-12 years

Sugar & colour free

Strawberry Flavour

Non drowsy

125ml

**BRAND**  
**Children's**  
**Dry Cough**

Pholcodine

1-12 years

Sugar & colour free


Calms & soothes  
tickly coughs

Blackcurrant Flavour


Non drowsy

125ml

**Benylin**  
children's  
**Tickly  
Coughs**  
Glycerol  
**3 MONTHS+**  
✓ Sugar & colour free  
✓ Apple flavour ✓ Non-Drowsy



**Benylin**  
children's  
**Chesty  
Coughs**  
Guaifenesin  
**1-12 YEARS**  
✓ Sugar & colour free  
✓ Strawberry flavour ✓ Non-Drowsy



**Benylin**  
children's  
**Dry  
Coughs**  
Pholcodine  
**1-12 YEARS**  
✓ Calms and soothes tickly coughs  
✓ Blackcurrant ✓ Sugar & colour free  
flavour



- Further information:
- [helen.darracott@pagb.co.uk](mailto:helen.darracott@pagb.co.uk)
- [www.pagb.co.uk](http://www.pagb.co.uk)

