Medicines & Healthcare products Regulatory Agency

MHRA Label Warnings Guidance.

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Additional warning statements for inclusion on the label and/or in the leaflet of certain medicines

1. Introduction

The purpose of this guidance is to set out the warning statements which should appear on the label and/or in the patient information leaflet (PIL) of certain medicines. Current UK legislation foresees the need for certain medicines to include warning statements on the label to enable these to be used safely and to best effect.

2. Scope

It is expected that MAHs will apply these warning statements to the labelling and/or the leaflet as appropriate. It will not always be necessary to use the wordings proposed verbatim, but it should be borne in mind that many of these forms of words have already been the subject of user testing and are in use (through the British National Formulary) on dispensing labels applied in pharmacies across the UK. Care should be taken to ensure that any deviation from what is set out below does not cause confusion amongst patients.

The warning statements are divided into general and specific categories and for some medicines warnings from both sections may need to be applied.

Label warning wording should be relevant to the authorised route of administration, i.e. “take” for oral medicines and “use” or “apply” for other routes of administration.

3. General warning statements

3.1 Pharmacy medicines

3.1.1 For pharmacy-only (P) medicines, where the product would have a prescription only (POM) legal status if it contained a higher proportion of the active ingredient, the following warning should be placed adjacent to the directions for use or the recommended dosage instructions:

Do not take more medicine than the label tells you to

3.1.2 If the product is for external use only and is an embrocation, liniment, lotion, cream, liquid antiseptic or other liquid preparation or gel the following statement must appear on the label:

Use this medicine only on your skin

3.1.3 For pharmacy only medicines, the letter **"P" must appear in a box** in which there is no other information. This is a legislative requirement set out in The Human Medicines Regulations 2012 (HMRs) Schedule 25, Part 3 (11).

3.2 Prescription only medicines

For medicines that are only available on prescription the letters **"POM" must appear in a box** in which there is no other information. This is a legislative requirement set out in the HMRs Schedule 25, Part 3 (13).

3.3 Controlled drugs (CDs)

Medicines which are considered as controlled drugs under the Misuse of Drugs Act 1971 should include the following next to the declaration of the legal status on the labelling: **the letters "CD" in an inverted triangle.**

3.4 All medicines

In line with Part 13 of the HMRs:

- a warning that users should "Keep out of the sight and reach of children" should appear on the label of all medicines.

- a statement encouraging patients to report adverse events which they may experience to the competent authority should appear at the end of section 4 of the PIL. In the UK the following form of words should be used:

  "**Reporting of side effects:** Like all medicines, this medicine can cause side effects, although not everybody gets them. If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine."

3.5 Medicines subject to additional monitoring

Medicines which appear on the Additional Monitoring list published on the MHRA website should include the inverted black triangle immediately after the name in the PIL followed by the wording in Schedule 27(13) of HMRs:

"▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects."

The black triangle and the statements should only appear immediately after the declaration of the name of the medicine. The black triangle shall be a black inverted equilateral triangle: the triangle shall be proportional to the font size of

the subsequent standardised text and in any case each side of the triangle shall have a minimum length of 5 mm.

3.6 Drugs and driving

An offence of driving with certain controlled drugs above specified limits in the blood came into force on 2 March 2015. These drugs include some prescribed medicines.

The medicines in the list below are those which are specified within the Road Traffic Act. Where these are licensed medicines, the labelling and leaflet must include warnings relevant to drugs and driving.

Amphetamine	Lysergic Acid Diethylamide (LSD)
Benzoylecgonine (BZE-cocaine metabolite)	MDMA (Ecstasy)
Clonazepam	Methadone
Cocaine	Methylamphetamine
Diamorphine	Morphine
Diazepam	Oxazepam
Flunitrazepam	Temazepam
Ketamine	Tetrahydrocannabinol (THC)
Lorazepam	

The product information for any medicine which contains a substance in the list below are also required to include the warnings. This list is not intended to be complete and the onus is on the marketing authorisation holder (MAH) to ensure that all relevant medicines are covered.

Alfentanil	Lisdexamphetamine
Alprazolam	Loprazolam
Apomorphine	Lormetazepam
Buprenorphine	Meptazinol
Cannabidiol	Methylphenidate
Chlordiazepoxide	Midazolam
Clobazam	Nitrazepam
Codeine	Oxycodone
Dexamphetamine	Papaveretum
Dextromethorphan	Pentazocine
Dihydrocodeine	Pethidine
Dipipanone	Remifentanil
Esketamine	Selegiline
Fentanyl	Tapentadol
Flurazepam	Tramadol
Hydromorphone	

Label:
“This medicine can make you feel sleepy. Do not drive while taking this medicine until you know how it makes you feel. See the leaflet inside for more information.”

Leaflet (include in section “Driving and using machines”):
“The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:

  - The medicine has been prescribed to treat a medical or dental problem and
  - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
  - It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.”

4. Specific statements (listed alphabetically)

Drug substance or class	Conditions	Label and/or leaflet warning
Adenosine	For P medicines, on the label	**Label:** "Do not take more than the label tells you to If you do not get better within 12 weeks talk to your doctor Do not give this medicine to children under 14 years"
Adrenaline	Auto-injectors for emergency use	**Label:** The following vital warnings will be included on the outer packaging of the product such that they will be immediately visible to all concerned in an emergency: "• Administer immediately at the first sign of anaphylaxis. Do not delay, • Call 999 for an ambulance stating anaphylaxis (pronounced "ana-fill-axis"). • Use your second auto-injector if there is no improvement after 5 minutes, • Always carry two adrenaline auto-injectors with you and make sure you know how to use your particular auto-injector." **Leaflet:** The following key messages must be conveyed: **"What to do in an emergency:** • Use your adrenaline auto-injector immediately if you have any signs of anaphylaxis. If in doubt use. Don't delay. • Dial 999 – say anaphylaxis ("ana-fill-axis") – straight after using your auto-injector. • Lie down and raise your legs.

		• Sit up if you are struggling to breathe but don't change position suddenly. • Lie down again as soon as you can. • Stay lying down even if you are feeling better. • You must not stand up even if someone encourages you to. • Use your second auto-injector if you haven't improved after 5 minutes. **Be prepared:** • Carry two adrenaline auto-injectors with you at all times. • You must use your auto-injector as soon as you notice any signs of anaphylaxis. • Make sure you know beforehand what the signs are so you can act swiftly. • Make sure you know how to use your auto-injector before you need to. Get familiar with it. Get a trainer auto-injector from the manufacturer. Practise. If you change brand, get familiar with the new one. Each one is used differently."
Alclometasone	For P medicines, on the label	**Label:** "If you are pregnant talk to your doctor before using. Apply a thin layer over the affected area of your skin. Do this once or twice a day. If you need to use it for longer than 7 days, stop using and talk to your doctor."
Alzheimer's medicines (memantine, galantamine, donepezil and rivastigmine)	Blister pack presentations	Blister packs must be presented in multiples of 7 dosage units. Days of the week and time of day (or appropriate iconography to convey this information) must be presented on the foil.
Aloxiprin	All medicines containing aloxiprin, on the label	**Label:** "Contains an aspirin derivative Do not give to children under 16 years of age unless your doctor tells you to.

		If you do not get better talk to your doctor"
	All medicines containing aloxiprin, on the label where a PIL is **not** separately available.	**Label:** "Aspirin and aspirin derivatives can cause Reye's syndrome when given to children. This is a very rare disease but it can be fatal. Do not give this medicine to children under 16 years of age unless your doctor tells you to."
Aminophylline	For P medicines used for asthma or bronchial spasm, on the label	**Label:** "Warning: Talk to your doctor before using this medicine"
Amphotericin		**Label:** Front of carton in red text main field of view of the immediate label: **Before using this medicine:** **Stop!** Verify product name and dosage [product name] is not equivalent to other amphotericin products
Antidepressants (all classes)	Core wording for section 2 of the PIL	**Leaflet:** **"Thoughts of suicide and worsening of your depression or anxiety disorder** If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer. You may be more likely to think like this: • If you have previously had thoughts about killing or harming yourself. • If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant."

		If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away.** **You may find it helpful to tell a relative or close friend** that you are depressed or have an anxiety disorder and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour."
Antihistamine (non-sedating)	e.g. acrivastine, bilastine, cetirizine hydrochloride, desloratadine, fexofenadine hydrochloride, levocetirizine hydrochloride, loratadine and mizolastine	Medicines which fall into the class of non-sedating antihistamines are known to cause drowsiness in a small number of patients. They **cannot** therefore claim to be non-drowsy on the packaging and should additionally include the following cautionary advice on the label: **Label & Leaflet** "This medicine does not normally make you feel sleepy. However, everyone reacts differently. If you do feel sleepy do not drive or use tools or machines. Do not drink alcohol whilst taking this medicine."
Antihistamine (sedating)	e.g. chlorphenamine, cinnarizine, diphenhydramine, hydroxyzine and promethazine and that are for supply as P medicines	**Label:** Prominently "Warning: This medicine may make you feel sleepy. If this happens do not drive or use tools or machines. Do not drink alcohol"
Arachis (peanut) oil	All medicines containing arachis oil, on the label	**Label:** In the list of ingredients: "Arachis oil (peanut oil)"
	All medicines containing arachis oil, in section 2 of the leaflet	**Leaflet:** "[product] contains arachis oil (also called peanut oil). If you are allergic to peanuts or soya, do not use/take this medicine."

Aspirin	All medicines containing aspirin, unless the product name includes 'aspirin' or the product is for external use, on the label	Unless single dose unit or an effervescent formulation, must be packaged in child-resistant packaging in line with The Human Medicines Regulations 2012, Regulation 273. **Label:** "Contains aspirin"
	All medicines containing aspirin, unless the product is for external use, on the label	Unless single dose unit or an effervescent formulation, must be packaged in child-resistant packaging in line with The Human Medicines Regulations 2012, Regulation 273. **Label:** "If you do not get better talk to your doctor Do not give to children under 16 years of age unless your doctor tells you to."
	All medicines containing aspirin, on the label where a PIL is **not** separately available.	**Label:** "Aspirin can cause Reye's syndrome when it is given to children. This is a very rare disease but it can be fatal. Do not give aspirin to children under 16 years of age unless your doctor tells you to."
Benzodiazepines	All medicines containing benzodiazepines, in the leaflet	Relevant risk of dependence and withdrawal, aligned with the current SmPC should be included in sections 1 (what the medicine is for, 2 (pregnancy) and 3 (stopping treatment and withdrawal). **Label:** "May cause addiction, dependence and withdrawal reactions."
Bifonazole	Topical products available GSL for athlete's foot	**Label:** "Only use this to treat athlete's foot. If you are unsure if you have athlete's foot talk to your doctor or pharmacist first. If your symptoms do not improve after 7 days, stop using this medicine and talk to your doctor or pharmacist."
Bisacodyl and Senna		**Label:**

		“Laxatives do not affect the number of calories absorbed from food. This means they do not help with weight loss.” (this should follow the statement of the product’s indication **Leaflet:** Section 1 `What XXXX are and what they are used for’  “XXXX do not help with weight loss.” (this should follow the statement of the product’s indication)  Section 3, under sub-heading `If you take too much of XXXX’ “It may be harmful to o Take too much of XXXX or o Take XXXX for too long This is because taking too much for too long may lead to: - A `lazy bowel’, where the muscle in the bowel becomes too relaxed. This means that bowel emptying happens less often. This can lead to long-term constipation. - Imbalance of fluid and salts in the body. This can affect the tightness of muscles such as those in the bowel. It can also affect the salts in the blood. - Low levels of potassium in the blood (called ‘hypo-kalaemia’). This can make you tired, dizzy, make your muscles weak and cause an uneven heart-beat. - Dehydration, making you thirsty, feel faint and giving you headaches. It can also mean you cannot pass enough urine.”

Beta blockers	All medicines intended for self-administration, on the label	**Label:** "Do not take this medicine if you have wheezing or asthma."
	All medicines intended for self-administration, in the leaflet	**Leaflet:** "Do not take this medicine if you have wheezing or asthma. Talk to your doctor or pharmacist first."
Budesonide	For products available as P medicines (nasal spray) to treat seasonal allergic rhinitis	**Label & Leaflet:** "If you need to use this medicine for more than 14 days stop using it and talk to your doctor or pharmacist." Recommended duration for continuous use as set out in the SmPC should be stated
	For products available as GSL medicines (nasal spray) to treat seasonal allergic rhinitis	**Label & Leaflet:** "If you need to use this medicine for more than 7 days stop using it and talk to your doctor or pharmacist." Recommended duration for continuous use as set out in the SmPC should be stated
Buprenorphine	3-day transdermal patches	**Label:** **Front of carton**: "Change the patch after 72 hours" (prominently stated) **Back of carton**:  and POM. "Read the package leaflet before use.

<table>
<tr><td></td><td></td><td>Make a note of the day, date and time that you apply the first patch. Change the patch at the same time of day 72 hours (3 days) later.”

An aide memoire should be included to assist the patient with their patch changing schedule, for example:

<table>
<tr><td>Apply</td><td>Mon</td><td>Tue</td><td>Wed</td><td>Thu</td><td>Fri</td><td>Sat</td><td>Sun</td></tr>
<tr><td></td><td>↓</td><td>↓</td><td>↓</td><td>↓</td><td>↓</td><td>↓</td><td>↓</td></tr>
<tr><td>Change</td><td>Thu</td><td>Fri</td><td>Sat</td><td>Sun</td><td>Mon</td><td>Tue</td><td>Wed</td></tr>
<tr><td colspan="8">Time:</td></tr>
</table>
</td></tr>
<tr><td>Buprenorphine</td><td>4-day transdermal patches</td><td>Label:
Front of carton:
“Change the patch twice a week” (prominently stated)

Back of carton:

and POM.

“Read the package leaflet before use.
Choose the pair of days/times that is most convenient for you. Make a note of the day, date and time that you apply the first patch. The patch should then be changed twice a week at the chosen times.”

An aide memoire should be included to assist the patient with their patch changing schedule, for example:</td></tr>
</table>

<table>
<tr><td></td><td></td><td>
<table>
<tr><td rowspan="3">Apply / change</td><td>Morning</td><td>Mon</td><td>Tue</td><td>Wed</td><td>Thu</td><td>Fri</td><td>Sat</td><td>Sun</td></tr>
<tr><td></td><td>↺</td><td>↺</td><td>↺</td><td>↺</td><td>↺</td><td>↺</td><td>↺</td></tr>
<tr><td>Evening</td><td>Thu</td><td>Fri</td><td>Sat</td><td>Sun</td><td>Mon</td><td>Tue</td><td>Wed</td></tr>
<tr><td></td><td colspan="8">Time:</td></tr>
</table>
</td></tr>
<tr><td>Buprenorphine</td><td>7-day transdermal patches</td><td>
Label:
Front of carton:
“Change the patch after 7 days” (prominently stated)

Back of carton:

CD

and POM.

“Read the package leaflet before use.
Make a note of the day, date and time that you apply the first patch. Change the patch on the same day at the same time 7 days later.”

An aide memoire should be included to assist the patient with their patch changing schedule, for example:

<table>
<tr><td rowspan="2">Apply / Change</td><td>Mon</td><td>Tue</td><td>Wed</td><td>Thu</td><td>Fri</td><td>Sat</td><td>Sun</td></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="8">Time:</td></tr>
</table>
</td></tr>
<tr><td>Buprenorphine</td><td>Carton (all patches)</td><td>
Label:
“Disposal after use: Keep the sachet after removing the patch inside. Keep it to put your used patch in. As soon as you take the patch off, fold it firmly in half (sticky sides together) and put it back
</td></tr>
</table>

		in the sachet. Either discard in the bin with the household rubbish or return to the pharmacy.”
Buprenorphine	Leaflet (all patches)	**Leaflet Headlines:** “ • These patches contain a strong pain killer • Ensure that old patches are removed before applying a new one • Patches must not be cut • Do no expose the patches to a heat source (such as a hot water bottle • Do not soak in a hot bath or take a hot shower whilst wearing a patch • If you develop a fever tell your doctor immediately • Follow the dosage instructions carefully and only change your patch on the same day and at the same time 7 days later • If your breathing becomes shallow and weak take the patch off and seek medical help” Section 3 – include table to show when to change the patch
Calcium and colecalciferol (vitamin D3)	For products available as P medicines for prevention and treatment of calcium and vitamin D deficiency and as a supplement to specific osteoporosis treatment	**Label:** P (but NO dispensing label area) The full instructions for use in line with the SmPC i.e. indications, posology etc. The following warnings should be included on the label: “Before taking this medicine consult your doctor or pharmacist if you:

		• are taking any medicines, particularly medicines for the heart • are taking any other medicines or food supplements containing calcium or vitamin D • have sarcoidosis • have kidney problems"
Chloramphenicol	For products available as P medicines	**Label:** **Prominently on outer carton:** "If you do not get better within 48 hours talk to your doctor. If your eye gets worse see your doctor straight away. Do not use these eye drops if you are allergic to chloramphenicol or anything else in the drops. After five days, throw away any eye drops left"
Cimetidine	For products available as P medicines	**Label:** **Prominently on outer carton:** "This medicine may be taken for up to 14 days. If you need to take it for longer than 14 days or your symptoms come back stop taking the medicine and talk to your doctor."
Clobetasone butyrate	For products available as P medicines	**Label:** **Prominently on outer carton:** "If you are pregnant talk to your doctor before using this medicine. Apply a thin layer over the affected area of your skin. Do this once or twice a day. If you need to use it for longer than 7 days, stop using the product and talk to your doctor." See also 'Steroids' for information on potency labelling.
Codeine and dihydrocodeine	For products available OTC and POM	See 'opioids' for information.
Colchicine	Outer and immediate packaging for 1000 microgram strength tablets	**Label:** **"HIGH STRENGTH – CHECK DOSE!"** The warning should appear in the same field of view, in all places where the wording 'colchicine' and '1000 micrograms' are

		presented. The warning should appear in a prominent box, using bold lettering and a contrasting colour to the rest of the pack.
Cytotoxic medicines		**Label:** **Prominently on front face of carton and/or inner label:** "Cytotoxic: handle with caution"
Diclofenac	Topical formulations (P and GSL)	**Label:** "Read the enclosed leaflet before taking this product. Do not use if you: • are allergic to diclofenac or any other ingredient of the product, aspirin, ibuprofen or other related painkillers • are taking other NSAID painkillers, or aspirin • are in the last three months of pregnancy Speak to a pharmacist or your doctor before using this product if: • you have or have ever had a stomach ulcer, perforation or bleeding • you have asthma, diabetes, high cholesterol, angina, high blood pressure, liver, kidney or bowel problems • there is a chance you may be pregnant or you are breastfeeding • you smoke"
Ephedrine	For products available as P medicines indicated for asthma or bronchial spasm	**Label:** "Warning – Talk to your doctor before using this medicine"
Fentanyl	Patches	**Label:**  and POM. **Front of pack**

		Warnings for opioid medicines (see under Opioids) **Back of carton:** “Read the package leaflet before use How to use the patches/medicine [Product name] should be worn continuously for 3 days (72 hours). It is important to change your patch on the correct day at the same time that it was applied. Disposal after use: Keep the pouch after removing the patch inside. Keep it to put your used patch in. As soon as you take the patch off, fold it firmly in half (sticky sides together) and put it back in the pouch. Either discard in the bin with the household rubbish or return to the pharmacy. Keep out of the reach and sight of children.” **Front of pouch:** The front of the pouch should be fully compliant with Schedule 24 (part 3) of the HMR’s **Back of pouch:** “Read the leaflet before use. Dosage: as directed by your doctor. Remove your old patch before applying a new one on a new area of skin. Apply a new patch every 3 days (72 hours)” “Opening instructions [maximum four bullet points, they should be succinct in content] • Gently tear open the pouch at the tear notch and remove the edge of the pouch completely. • Grasp both sides of the opened pouch and pull apart • Take out the patch and use it straight away.

		• Never divide or cut the patch. Do not use the patch if it looks damaged." "Disposal after use: Keep the pouch after removing the patch inside. Keep it to put your used patch in. As soon as you take the patch off, fold it firmly in half (sticky sides together) and put it back in the pouch. Either discard in the bin with the household rubbish or return to the pharmacy." **Leaflet headlines:** • "These patches contain a strong pain killer. • Ensure that old patches are removed before applying a new one. • Patches must not be cut. • Do not expose the patches to a heat source (such as a hot water bottle, heating pads, hot water bottles, electric blankets, heat lamps, saunas and hot whirlpool spa baths). These may affect the way the medicine works. • If you develop a fever tell your doctor immediately. • Follow the dosage instructions carefully and only change your patch every 72 hours. • If your breathing becomes shallow and weak take the patch off and seek medical help."
Flurbiprofen	For products available as P medicines in a lozenge formulation	**Label:** "Read the enclosed leaflet before taking this medicine. Do not take if you • have ever had a stomach ulcer, perforation or bleeding • are allergic to ibuprofen or any other ingredient of the product, aspirin or other related painkillers • are taking other NSAID painkillers, or aspirin with a daily dose above 75mg

		Speak to a pharmacist or your doctor before taking this medicine if you • have asthma, diabetes, high cholesterol, high blood pressure, had a stroke, liver, heart, kidney or bowel problems • are a smoker • are pregnant If you do not get better in X days, talk to your doctor." Duration timeline statement should align with SmPC
Gabapentinoids (Gabapentin and Pregabalin)		**Label:** "May cause addiction, dependence and withdrawal reactions." The symbol below is included on a voluntary basis to appear on outer and immediate packaging subject to full labelling requirements, adjacent to the declaration of legal status (POM). 
Fluticasone	For products available as P and GSL medicines for the prevention and treatment of allergic rhinitis	**Label:** **POM:** "Do not use this medicine for more than 3 months unless your doctor tells you to. If you do not improve in 7 days you should stop using the product and talk to your doctor." **GSL:** "Do not use this medicine for more than 1 month unless your doctor tells you to. If you do not improve in 7 days you should stop using the product and talk to your doctor."
Heparinoid	For products available as GSL medicines for the relief of bruises, sprains and soft tissue injuries	**Label & Leaflet:** Dosage instructions must include maximum duration of use if no improvement is seen, aligned with SmPC

Hydrocortisone and hydrocortisone acetate	For products available as P and GSL medicines	**Label:** "If you are pregnant talk to your doctor before using. Apply a thin layer over the affected area of your skin. Do this once or twice a day. If you need to use it longer than 7 days, stop using and talk to your doctor." See also 'Steroids' for information on potency labelling.
Ibuprofen	For products available as P and GSL medicines (oral formulations)	**Label:** "Read the enclosed leaflet before taking this medicine. Do not take if you • have ever had a stomach ulcer, perforation or bleeding • are allergic to ibuprofen (or anything else in this medicine), aspirin or other related painkillers • are taking other NSAID painkillers, or aspirin with a daily dose above 75mg • are in the last 3 months of pregnancy. Talk to a pharmacist or your doctor before taking if you • have asthma, diabetes, high cholesterol, high blood pressure, had a stroke, liver, heart, kidney or bowel problems • are a smoker • are pregnant If symptoms do not get better or get worse or if you get new symptoms, talk to your doctor." Duration timeline statement should align with SmPC
Iron-containing medicines	More than 24mg elemental iron per dose	Must be packaged in child-resistant packaging in line with The Human Medicines Regulations 2012, Regulation 273.

		Label: "Important warning: Contains iron. Keep out of the reach and sight of children, as overdose may be fatal."
Ketoprofen	Gel formulation	There is a risk of photosensitivity with use of Ketoprofen gel. The following information along with the symbol should appear on the labelling and in section 2 of the PIL: ⚠ "Protect your skin from sunlight even on a bright but cloudy day. Do not use sunbeds. This applies during treatment and for two weeks after stopping"
Lenalidomide and Pomalidomide		**Label:** The following warning should be prominently stated on the front face of the carton: **WARNING:** Risk of severe birth defects. Do not use while pregnant or breast feeding. You must follow the <PRODUCT NAME> Pregnancy Prevention Programme
Loperamide		**Label:** **Back of pack:** "Contains opioid" **Leaflet:** "Consult a doctor before use if you have a history of drug abuse; loperamide is an opioid and addiction is observed with opioids as a class."
Loratadine	For products available as P and GSL medicines (tablet formulations)	Although loratadine may be used in children aged over 2 years of age, all formulations are not suitable for all age ranges. For example, the 10 mg tablets are only suitable for children who weigh more than 30 kg in addition to being over 2 years of age. As a general rule, children who are over 30 kg would usually be

		over 9 years of age. The following information should appear on the labelling and in the PIL of loratadine 10mg tablets: **Label:** "Giving this medicine to children: You must know how much your child weighs. As a guide a child 9 years old will weigh about 30 kg (4 and a half stone). Do not give to children who weigh less than 30 kg. Do not give to children under 2 years of age. A liquid presentation of loratadine may be more suitable for children." **Leaflet:** "Do not give to children under 2 years of age or to children weighing less than 30 kg. As a guide, the average 9-year-old child weighs approximately 30 kg (equivalent to 4 and a half stone). Check your child's weight if you are not sure. For children over 2 years but who weigh less than 30 kg, a syrup form of this medicine may be more suitable."
Mepyramine	Topical products available as P and GSL medicines indicated for bites and stings	**Label:** "Do not use on cut, grazed or sunburnt skin. Apply a thin layer over a small area of the affected skin. If you need to use this medicine for more than 3 days stop using and talk to your doctor."
Methotrexate	Oral formulations	**Label:** Warning regarding dosing frequency should be prominently displayed on front face of the outer carton. "Check dose and frequency - Methotrexate is usually taken once a week" The outer and inner packaging of all methotrexate products for once-weekly dosing will carry a warning about the dosing schedule and the consequences of dosing errors.

		The outer packaging warning will also include a space for the dispenser to write the day of the week for intake.
Montelukast		**Label:** To enable patients/carers to be sure that the right dose is being used for the correct age group tablet presentations must include the following information on the front face of the labelling: **Montelukast 4mg tablets** "For children 2 to 5 years of age" **Montelukast 5mg tablets** "For children 6 to 14 years of age"
Morphine and diamorphine		**Label:** **Front of pack:** Warnings for opioid medicines (see under Opioids)
Morphine and diamorphine	Products for parenteral administration	The product name should include the unit dose per unit volume, e.g. 30mg / ml. If this is not the same as the total dose per total volume, then the latter should be prominently displayed as **'x'mg in 'y' ml**. Total strength in total volume must be presented on both the outer and immediate packaging. For strengths of 30mg and above the wording "Caution – high dose" should be prominently displayed in red text. Product name should be stated on three non-opposing faces and also on the rear face of the carton.
Naproxen	For oral formulation products available for OTC supply as P medicines.	**Label:** "Read the enclosed leaflet before taking this medicine. Do not take if you: • have ever had a stomach ulcer, perforation or bleeding

		• are allergic to ibuprofen (or anything else in this medicine), aspirin or other related painkillers • are taking other NSAID painkillers, or aspirin with a daily dose above 75mg • are in the last 3 months of pregnancy. Talk to a pharmacist or your doctor before taking if you • have asthma, diabetes, high cholesterol, high blood pressure, had a stroke, liver, heart, kidney or bowel problems • are a smoker • are pregnant If symptoms do not get better or get worse or if you get new symptoms, talk to your doctor." Duration timeline statement should align with SmPC
NRT	GSL	**Label:** "If you are pregnant, talk to your doctor, pharmacist or nurse before using this product (*except liquorice flavoured gums – see below) Do not use if you are pregnant or breastfeeding. Liquorice should not be used during pregnancy or during breastfeeding. If you need any advice before starting to use this product, talk to your doctor, pharmacist or nurse." Boxed cartons: "You are more likely to quit smoking when using this product with help from your pharmacist, doctor, a trained counsellor, or a support programme."
Opioids	Alfentanil Buprenorphine Codeine	**Label:**

	Dextromethorphan Diamorphine Dihydrocodeine Dipipanone Fentanyl Hydromorphone Meptazinol Methadone Morphine Opium Oxycodone Papaveretum Pentazocine Pethidine Remifentanil Tapentadol Tramadol	 Where the medicine is a Controlled Drug **Front of pack (OTC medicines)** • "Can cause addiction • Contains opioid • For three days use only" **Front of pack (POMs)** • "Can cause addiction • Contains opioid" This information must be prominently displayed. The leaflets must reflect relevant information regarding dependence and withdrawal as set out in the SmPC.
Paracetamol	Label and leaflet warnings set out in Schedules 25 (Part 4) and 27 (Part 2) must be presented on the packaging and in the leaflet for all medicines containing paracetamol.	Unless single dose unit or an effervescent formulation, must be packaged in child-resistant packaging in line with The Human Medicines Regulations 2012, Regulation 273. Paracetamol warnings are set out in the legislation. They are referenced in regulations 258 and 260 of the Human Medicines Regulations 2012 (as amended) and appear in Part 4 of Schedule 25 and Part 2 of Schedule 27 to those regulations. They must be used verbatim. They are stated here for completeness. **Label:** **Schedule 25 (Part 4) Medicines containing paracetamol** 14. If the product contains paracetamol, except where the name of the product includes the word "paracetamol" and appears on

		the outer and immediate packaging, the words **"Contains paracetamol"**. 15. If the product contains paracetamol the words **"Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor"**, which must appear adjacent to either the directions for use or the recommended dosage. 16. If the product contains paracetamol, unless the product is wholly or mainly intended for children twelve years old or younger, the words **"Do not take anything else containing paracetamol while taking this medicine"** and— (a) if a package leaflet accompanying the product includes the words in quotation marks in paragraph 16 of Schedule 27 (package leaflets), the words **"Talk to a doctor at once if you take too much of this medicine, even if you feel well"**; or (b) if no package leaflet accompanies the product or the package leaflet does not include those words, the words **"Talk to a doctor at once if you take too much of this medicine, even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage"**. 17. If the product contains paracetamol and is wholly or mainly intended for children twelve years old or younger, the words **"Do not give anything else containing paracetamol while giving this medicine"** and— (a) if a package leaflet accompanying the product includes the words in quotation marks in paragraph 17 of Schedule 27 (package leaflets), the words **"Talk to a doctor at once if your child takes too much of this medicine, even if they seem well"**; or (b) if no package leaflet accompanies the product or the package leaflet does not include those words, the words **"Talk to a doctor**

		at once if your child takes too much of this medicine, even if they seem well. This is because too much paracetamol can cause delayed, serious liver damage". 18. If the product is required by this Part of this Schedule to show the words set out in paragraphs 14, 16 or 17, those words must appear in a prominent position. **Leaflet:** **Schedule 27 Part 2 Paracetamol** 16. If a medicinal product contains paracetamol, unless the product is wholly or mainly intended for children twelve years old or younger, the words "**Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage".** 17. If a medicinal product contains paracetamol and is wholly or mainly intended for children twelve years old or younger, the words **"Talk to a doctor at once if your child takes too much of this medicine even if they seem well. This is because too much paracetamol can cause delayed, serious liver damage".** For medicines which are principally for children or are for parenteral use, the wording above should be amended to ensure it makes sense in the context of how the product is used. No other deviations are acceptable
Paraffin containing emollients and other topically applied medicines		**Label:** The following symbol and warning are required on both the outer and immediate packaging for packs of 30 g (or 30 ml) and over.

		 **Additional guidance:** • The symbol and pictogram should be reproduced as shown with the symbol in yellow and the warning presented on an orange background. If it is not possible to use these colours on the pack due to printing constraints, the colours chosen must provide due prominence for this information. An emboldened border in black should be used to increase the prominence of the information presented. The text must be presented in lower case lettering. • For smaller pack sizes (50 g / 50 ml or less) the symbol and warning should be presented on one face of the outer packaging, on which no other information should be applied. • For larger pack sizes, the symbol and warning should be given due prominence on the outer packaging with a minimum font size of 10pt used for the text, as shown in the example above. • On immediate packaging, such as tube, container and bottle labels, the symbol and warning should be prominently positioned in the main field of view, using as large a font size as possible. **Leaflet:** Section 2 of the PIL under the “Warnings and precautions” subheading: “Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact

		with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.”
Penicillin	All penicillin-containing products	**Label:** Front face of carton and most obvious field of view for container labels prominently **“Contains penicillin”**
Potassium chloride (concentrated)		**Label:** **Front face of carton:** “For IV infusion after dilution Dilute at least “w” times with suitable diluent. Mix thoroughly before slow intravenous infusion. “X” g in “Y” ml “Y” ml contains « z » millimoles of potassium” **K** **Top and side:** **K** “Dilute before use” **Ampoule:** “ “X” g in “Y” ml « Y » ml contains « Z » millimoles of potassium Dilute before use”

<table>
<tr><td></td><td></td><td>K

MAHs who have more than one strength of strong potassium chloride solution should ensure clear differentiation between the packs by the judicious use of colour.</td></tr>
<tr><td>Retinoids (Oral)</td><td>Applies to oral retinoids acitretin, alitretinoin and isotretinoin</td><td>Label:
A boxed warning should be added to the outer packaging for the oral retinoids acitretin, alitretinoin and isotretinoin as follows:

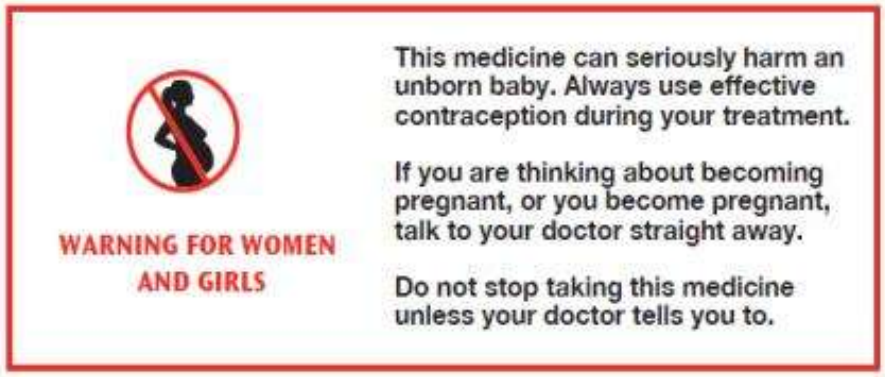
WARNING
CAN SERIOUSLY HARM AN UNBORN BABY
Women must use effective contraception
Do not use if you are pregnant or think you may be pregnant,

invented name:

WARNING
CAN SERIOUSLY HARM AN UNBORN BABY
Women must use effective contraception
Do not use if you are pregnant or think you may be pregnant,

Leaflet:
The following boxed warning should be included in the PL for the oral retinoids acitretin, alitretinoin and isotretinoin, under the

Up to date safety information regarding pregnancy, the pregnancy prevention programme and advice for men must be included in the leaflet</td></tr>
</table>

Sodium valproate	Pack sizes of more than 30 tablets or capsules are not permitted.	**Label:** **Outer carton**  The pictogram and warning should appear exactly as above, including the use of the red text and rectangle. The name and strength of the medicine should be positioned above the warning and pictogram with no other information appearing on the carton face. **Immediate packaging (blister foils, bottle, container, sachet and ampoule labels:**  Only the pictogram is required, without any of the warning text. On blister foils there should be multiple repeats of the pictogram accompanying the product name presented on the foil.

Squill	For products available for OTC supply as P and GSL medicines.	**Label:** **Prominently** "Do not take this medicine if you: • Are an alcoholic • Have breathing difficulties • Have raised pressure in your head • Have heart, liver or kidney problems • Are allergic to anything in this medicine."
SSRIs (selective serotonin reuptake inhibitors)		**Leaflet headlines:** "If you have any concerns about how you feel, or about this medication, it is important that you talk to your doctor - even if you feel anxious or worried about doing so. You may find it helpful to tell a friend or relative that you are depressed or suffering from an anxiety disorder, and that you have been prescribed this medication; it might be useful to show them this leaflet. • **< Product name > may not start to work immediately.** Some people taking antidepressants may feel worse before feeling better. Your doctor may ask to see you again a couple of weeks after you start treatment and then regularly until you start to feel well again. Tell your doctor if you do not start to feel better. • **Some people who are depressed may think of harming or killing themself. If this happens you should see your doctor or go to a hospital straight away** – see in section

		2 'Thoughts of suicide and worsening of your depression or anxiety disorder' • **If you take too many capsules it is important to seek immediate medical attention, even if you feel well, because of the risk of serious side effects** • **Do not stop taking <Product name > or change your dose without the advice of your doctor even if you feel better.** If you stop taking <Product name > abruptly you may get withdrawal reactions – see in section 3 'If you stop taking <Product name >' • **If you have heart problems such as fast or irregular heart rate or high blood pressure you should talk to your doctor before taking <Product name > –** see in section 2 'Before you take <Product name >' • **Taking certain other medicines with <Product name > may cause problems. You should tell your doctor if you are taking any other medicines –** see in section 2 'What you need to know before you take <Product name >' • **See your doctor without delay** if you feel restless and feel like you can't keep still, feel 'high' or very over-excited, have jerky muscle movements which you can't control. See section 4 – 'Possible side effects' for other important information • **If you are pregnant, or intend to become pregnant, or breast-feeding, you should talk to your doctor –** see in section 2 • 'Pregnancy and breast-feeding'

		More information on all of these points is provided in the rest of this leaflet."
Steroids	Products for oral and parenteral administration	**Leaflet headlines:** • **"[Product name] is a steroid medicine**, prescribed for many different conditions, including serious illnesses. • **You need to take it regularly** to get the maximum benefit. • **Don't stop taking this medicine** without talking to your doctor - you may need to reduce the dose gradually. • **[Product name] can cause side effects in some people** (read section x of leaflet). Some problems such as mood changes (feeling depressed, or 'high'), or stomach problems can happen straight away. If you feel unwell in any way, keep taking your tablets, but **see your doctor straight away.** • **Some side effects only happen after weeks or months.** These include weakness of arms and legs or developing a rounder face (read section x of leaflet for more information). • **If you take it for more than 3 weeks, you will get a blue 'steroid card' or a Steroid Emergency Card**: always keep it with you and show it to any doctor or nurse treating you. **Keep away from people who have chickenpox or shingles**, if you have never had them. They could affect you severely. If you do come into contact with chickenpox or shingles, see your doctor straight away."
Steroids	Topical (indicated for eczema and psoriasis)	Topical steroid products must be labelled with information on their potency. Potency will be labelled in line with the ATC code.

		Further information is available here: Topical steroids: introduction of new labelling and a reminder of the possibility of severe side effects, including Topical Steroid Withdrawal Reactions - GOV.UK • Mild steroid • Moderate steroid • Strong steroid • Very strong steroid The potency should be stated on the outer and immediate packaging. On the outer carton the wording should be located on the front panel in a font size and colour that is no different to other statutory wording.
Theophylline	For products available for supply as P medicines for asthma and bronchospasm	**Label**: "Warning: Talk to your doctor before using this medicine"
Vinka alkaloids		**Label:** Prominently on front face of carton: **"For intravenous use only.** **Fatal if given by other routes"**
Z-Drugs		**Label:** "May cause addiction, dependence and withdrawal reactions."

5. Dispensed medicines and medicines supplied by a healthcare professional

Although usually medicines will be supplied in a manufacturer's original pack to a patient, the national regulatory framework requires the healthcare professional who supplies the medicine to include further labelling. These labelling provisions are set out in the Human Medicines Regulations 2012 and cover a number of scenarios which are explained below.

Medicines on prescription
Medicines which are supplied by a pharmacist against a prescription issued by a bone fide prescriber should additionally have a dispensing label applied to the pack. The legal requirements for what should be included in the dispensing label are set out in Part 1 of Schedule 25 to the Human Medicines Regulations 2012.

These are set out below:

1. Where the product is to be administered to a particular individual, the name of that individual.
2. The name and address of the person who sells or supplies the product.
3. The date on which the product is sold or supplied.
4. Unless paragraph 5 applies, such of the following particulars as the appropriate practitioner who prescribed the product may specify –
    (a) the name of the product or its common name
    (b) directions for use of the product
    (c) precautions relating to the use of the product.
5. This paragraph applies if the pharmacist in the exercise of professional skill and judgement is of the opinion that the inclusion of one or more of the particulars mentioned in paragraph 4 is inappropriate.
6. Where paragraph 5 applies, the pharmacist may include such particulars, of the same kind as those mentioned in paragraph 4, as the pharmacist thinks appropriate.

Medicines supplied by doctors, dentists, nurses and midwives.
Medicines which are supplied by doctors, dentists, nurses and midwifes directly to the patient should be labelled according to Part 1 of Schedule 26 to the Human Medicines Regulations 2012. These are set out below:

1. Where the product is to be administered to a particular individual, the name of that individual.
2. The name and address of the person who sells or supplies the product.
3. The date on which the product is supplied.

4. Such of the following particulars as the appropriate practitioner who prescribed the product may specify –
   (a) the name of the product or its common name
   (b) directions for use of the product
   (c) precautions relating to the use of the product.

Pharmacy exceptions

Regulation 4 of the Human Medicines Regulations 2012 and section 10 of the Medicines Act 1968 allow pharmacists to supply medicines in circumstances which do not require the pharmacist to hold either a manufacturer's assembly licence or a marketing authorisation for the medicine in question. Nevertheless, such medicines must be labelled according to the provisions set out in Part of Schedule 26 to the Human Medicines Regulations 2012. These are set out below:

5. Where the product is to be administered to a particular individual, the name of that individual.
6. The name and address of the person who sells or supplies the product.
7. The date on which the product is sold or supplied.
8. Where the product is prescribed by an appropriate practitioner, such of the following particulars as the appropriate practitioner who prescribed the product may specify, unless paragraph 9 applies –
   (a) the name of the product or its common name
   (b) directions for use of the product
   (c) precautions for use of the product.
9. This paragraph applies if the pharmacist in the exercise of professional skill and judgement is of the opinion that the inclusion of one or more of the particulars mentioned in paragraph 8 is inappropriate.
10. Where paragraph 9 applies, the pharmacist may include such particulars, of the same kind as those mentioned in paragraph 8, as the pharmacist thinks appropriate.
11. Where the product is not prescribed by an appropriate practitioner, directions for use of the product, but these may be omitted in circumstances where section 10(3) of the Medicines Act 1968 applies.

Where labels are applied to medicines under the provisions of Schedules 25 or 26 of the Human Medicines Regulations 2012, the following labelling statements should also appear:

- Keep out of the sight and reach of children
- If the product is for external use only and is an embrocation, liniment, lotion, cream, liquid antiseptic or other liquid preparation or gel:

  'Use this medicine only on your skin'

Term/abbreviation	Definition
HMR	Human Medicines Regulations (2012)
POM	Prescription only medicine
P	Pharmacy medicine (legal status)
NRT	Nicotine replacement therapy
GSL	General sales list medicine (legal status)
OTC	Over-the-counter (medicine)
SmPC	Summary of Product Characteristics
MAH	Marketing Authorisation Holder
MA	Marketing Authorisation
PIL	Patient Information Leaflet

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY
June 2026