Guidance on the development of artwork in relation to medicines containing codeine and dihydrocodeine

In July 2009 the Committee on Human Medicines undertook a review of abuse and misuse of over-the-counter (OTC) solid dose medicines containing codeine or dihydrocodeine and has recommended a package of measures to minimize the risk of overuse and addiction. These measures involve changes to pack sizes, indications, the patient information leaflet and labeling and advertising and promotional activity.

OTC solid dose medicines containing codeine and dihydrocodeine containing analgesics will only be indicated for the short term treatment of acute moderate pain which is not relieved by paracetamol, ibuprofen or aspirin alone. This statement will be added to the Summary of Product Characteristics (SmPC) followed by the list of permitted conditions for which the product is already authorised. SmPCs will be amended to remove colds, (including sinusitis) flu, cough, sore throat, and fever indications as well as references to the treatment or relief of mild, mild to moderate or strong pain. The information accompanying the product, on pack and the patient information leaflet, or conveyed in advertising or promotional materials must make specific reference to use of the product for no more than 3 days and that it can cause addiction.

This guidance deals with the new requirements for all packaging components. Applications to vary SmPCs to replace existing codeine warnings with the new statements are required to be submitted to the MHRA by 30 October 2009. Applications should be accompanied by artwork reflecting the advice in this document to avoid delays in processing.

Front of pack

Statutory information
Warnings:

In addition to all the normal statutory provisions the following warnings must be prominently displayed on the front of pack.

- Can cause addiction.
- For three days use only.

These statements must appear as two distinct and separate warnings, preferably on two lines. The warnings must appear in mixed case letters and strongly contrasting colours should be used. The position of the warnings on the pack must allow for the statements to be clearly visible on-shelf. The prominence will be determined by taking into account factors such as colour, contrast and font style in addition to the actual size of the text.

All active ingredients must be included on the front of the carton even if the product contains more than three active substances.

Non-statutory information

Non statutory information, such as straplines and graphics, must be subordinate in placement and prominence to the statutory information in particular the warning statements and the active ingredients.

Straplines

Straplines for codeine and dihydrocodeine containing products should not refer to power or strength. For example ‘Powerful pain relief’, ‘Maximum strength pain relief’ or ‘Targets strong pain’ will no longer be acceptable.

Straplines referring to the licensed indications or dual action of the ingredients may be included where space allows provided they are consistent with the SmPC and have a lesser prominence in the information hierarchy.

All straplines will be judged on a case-by-case basis.

Back of pack

The following wording must be included within the critical health information panel.

“For the short term treatment of acute moderate pain when other painkillers have not worked. Do not take less than four hours after taking other painkillers”.

This should be followed by the list of permitted indications for which the product is currently licensed as listed in the amended section 4.1 of the SmPC**.** No additional indications may be added as part of this change.

Superfluous information or claims should not be included within this section.

In addition to the list of indications stated in Section 4.1 of the SPC and the usual statutory provisions the critical health information panel must prominently display the following warnings, which replace the current codeine warnings:

- If you need to take this medicine for more than three days you must see your doctor or pharmacist
- This medicine contains (codeine / dihydrocodeine) which can cause addiction if you take it continuously for more than three days. If you take this medicine for headaches for more than three days it can make them worse.

Prominence will be assessed on a case by case basis having regard to factors such as colour, contrast and font style in addition to the actual size of the text.

Patient information leaflet

All of the information below is required in addition to the statutory information required and should be displayed prominently. Note, that these are intended to replace the current codeine warnings.

Headlines (at the start of the PIL)

- This medicine can only be used for …….(indications)
- You should only take this product for a maximum of three days at a time. If you need to take it for longer than three days you should see your doctor or pharmacist for advice
- This medicine contains codeine [or dihydrocodeine] which can cause addiction if you take it continuously for more than three days. This can give you withdrawal symptoms from the medicine when you stop taking it
- If you take this medicine for headaches for more than three days it can make them worse

Section 2: Before taking –

These warnings should follow the sub-heading do not take

- This medicine contains codeine [or dihydrocodeine] which can cause addiction if you take it continuously for more than three days. This can give you withdrawal symptoms from the medicine when you stop taking it
- If you take a painkiller for headaches for more than three days it can make them worse

Section 3: Dosage

- Do not take for more than 3 days. If you need to use this medicine for more than three days you must speak to your doctor or pharmacist
  These should be in close proximity to the dosage warnings.

- This medicine contains codeine [or dihydrocodeine] and can cause addiction if you take it continuously for more than three days. When you stop taking it you may get withdrawal symptoms. You should talk to your doctor or pharmacist if you think you are suffering from withdrawal symptoms
  This should be given its own sub-heading.

Section 4.

- Some people may have side-effects when taking this medicine. If you have any unwanted side-effects you should seek advice from your doctor,

pharmacist or other healthcare professional. Also you can help to make sure that medicines remain as safe as possible by reporting any unwanted side-effects via the internet at www.yellowcard.gov.uk; alternatively you can call Freephone 0808 100 3352 (available between 10am-2pm Monday – Friday) or fill in a paper form available from your local pharmacy.

New section: How do I know if I am addicted? –
This should be included at the end of section 4 with a separate heading, and not as a new section i.e. section 7.

If you take the medicine according to the instructions on the pack it is unlikely that you will become addicted to the medicine. However, if the following apply to you it is important that you talk to your doctor:

- You need to take the medicine for longer periods of time
- You need to take more than the recommended dose
- When you stop taking the medicine you feel very unwell but you feel better if you start taking the medicine again

For further information contact
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Medicines and Healthcare products Regulatory Agency
October 2009.