

UK regulator strengthens opioid warnings

People who take prescribed or over-the-counter medicines containing opioids for non-cancer pain will now be given stronger warnings about the risk of dependence and addiction, the Medicines and Healthcare products Regulatory Agency (MHRA) announced today.

Healthcare professionals have been asked by the MHRA to discuss these warnings with any patient taking or planning to take an opioid-containing medicine. These discussions should also involve agreement of a treatment plan, including how long treatment should last, to minimize the risk of dependence.

Additional warnings are now to be added to the patient information leaflet to reinforce those warnings, making it clear that the medicine is an opioid, which can cause addiction, and that there can be withdrawal symptoms if people stop taking it suddenly. More information and warnings are provided throughout the leaflet.

Minister for Innovation Lord Bethell said:

Opioid addiction is a serious and life-threatening issue and people need to be aware of these risks before they take medicines with such a high rate of dependency.

It is vital that patients are given the right support and guidance on the dangers of long term use and the strengthening of these labels is a crucial step forwards in protecting patients and saving lives.

The MHRA Director of Vigilance and Risk Management of Medicines, Sarah Branch said:

Patient safety is our highest priority and that is why we continually monitor the benefits and risks of opioid medicines.

Last year, we announced that opioid-containing medicine packaging must carry warnings. Now, we are strengthening those warnings to ensure that opioid medicines are supplied with consistent information on how to manage the risk of addiction.

This is a further step forward in helping to promote the safe use of these pain-relieving medicines.

Opioids have a serious risk of dependence and addiction, especially with

long-term use. Following concerns raised about the prescribing rates of opioids in the UK, the Opioid Expert Working Group (EWG) of the Commission on Human Medicines (CHM) developed a set of recommendations to improve information for prescribers and patients and to protect public health. These recommendations were fully supported by CHM and formed the basis of the MHRA's new warnings.

While the CHM continues to consider opioids as important and effective medicines in the treatment of short-term pain relief, they have advised against their long-term use in the treatment of non-cancer pain, due to the risk of dependence and addiction.

For more information on the risks of opioid addiction, please read our [patient guidance](#).

Patients experiencing any suspected side effects from these medicines can report these via our [Yellow Card scheme](#).