Dear Healthcare Professionals,

**Transdermal fentanyl patches for non-cancer pain: do not use in opioid-naive patients**

Your attention is drawn to the Medicines and Healthcare products Regulatory Agency’s (MHRA) announcement that the Commission on Human Medicines (CHM) has recommended that fentanyl transdermal patches are contraindicated in opioid-naive patients in the United Kingdom, following a review of the risks associated with use of opioid medicines for non-cancer pain.

Considerable concern has been raised regarding the prescribing of opioids in the United Kingdom. In 2019, CHM convened an Expert Working Group to examine the benefits and risks of opioids in the relief of non-cancer pain. During this review it was noted that there have been reports of serious harm, including fatalities, associated with fentanyl patches in both opioid-naive patients and opioid-experienced patients. Up to May 2020, MHRA has received 13 Yellow Card reports in which opioid-naive patients have experienced respiratory depression following use of fentanyl and additional Yellow Card reports in which respiratory depression was reported in patients switched from another opioid to an inappropriately high dose of fentanyl. There was no evidence of intentional overdose in these cases. There is considerable risk of respiratory depression with the use of fentanyl especially in opioid-naive patients. There is also significant risk with too rapid an escalation of dose, even in long-term opioid users.

Fentanyl is a potent opioid analgesic, a 12 microgram (μg) per hour fentanyl patch equates to daily doses of oral morphine of up to 45mg a day. Because of the risk of significant respiratory depression, in non-cancer patients fentanyl patches should only be used in those who have previously tolerated opioids. CHM has recommended a strengthening of the current warnings and a contraindication for use in opioid-naive patients in the United Kingdom for non-cancer pain.

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The initial dose of fentanyl should be based on a patient’s opioid history. Please consult the Summaries of Product Characteristics (SmPC) for each medicine for information on starting doses and dose conversion. Prescribers should take into account the morphine equivalence of fentanyl.

Advice for healthcare professionals:

- Fentanyl is a potent opioid, a 12 microgram (μg) per hour fentanyl patch equates to daily doses of oral morphine of up to 45mg a day.
- Do not use fentanyl patches in opioid-naive patients.
- Use other analgesics and other opioid medicines (opioids) for non-cancer pain before prescribing fentanyl patches.
- If prescribing fentanyl patches, remind patients of the importance of: not exceeding the prescribed dose; following the correct frequency of patch application, avoiding touching the adhesive side of patches, and washing hands after application; not cutting patches and avoiding exposure of patches to heat including via hot water (bath, shower); ensuring that old patches are removed before applying a new one; and following instructions for safe storage and properly disposing of used patches or patches that are not needed, it is particularly important to keep patches out of sight and reach of children at all times.
- Make patients and caregivers aware of the signs and symptoms of fentanyl overdose and advise them to seek medical attention immediately if overdose is suspected.
- Remind patients that long-term use of opioids in non-cancer pain (longer than 3 months) carries an increased risk of dependence and addiction, even at therapeutic doses; before starting treatment with opioids, agree with the patient a treatment strategy and plan for end of treatment.

Please refer to the following website in MHRA for details:


In Hong Kong, there are 4 registered pharmaceutical products which are transdermal patch containing fentanyl, namely Durogesic Transdermal Patch 12mcg/h (HK-53883), Durogesic Transdermal Patch 25mcg/h (HK-53755), Durogesic Transdermal Patch 50mcg/h (HK-53753) and Durogesic Transdermal Patch 100mcg/h (HK-53754). All products are registered by Johnson & Johnson (Hong Kong) Ltd, and are prescription-only medicines. So far, the Department of Health (DH) has received one case of adverse drug reaction related to fentanyl, but this case is not related to respiratory depression. In light of the above MHRA’s announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

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Please report any adverse events caused by drugs to the Undesirable Medical Advertisements and Adverse Drug Reaction Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under “ADR Reporting”: http://www.drugoffice.gov.hk/adr.html. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,

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for Assistant Director (Drug)

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