Medicines & Healthcare products Regulatory Agency

Miss Kirsty Gomersal
Area Coroner for the County of Cumbria
By email: [redacted]

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

[redacted]

Reference: CSC 97973

20th June 2022

Dear Miss Gomersal,

Report to Prevent Future deaths - Edward Jorge Capovila

I am writing in response to the Regulation 28 Report concerning the tragic death of Mr Edward Capovila from [redacted] overdose, likely from the inhalation of [redacted] from prescribed patches.

It may be helpful to first outline the role of the MHRA, which is to monitor the safety of all medicines to ensure that up-to-date information on the benefits and risks of a medicine is available for healthcare professionals and patients. The authorised Summary of Product Characteristics (SmPC) for a medicine provides information for healthcare professionals about the medicine, including warnings and precautions of use in higher risk situations. The same information is provided to patients in a patient information leaflet, which is written in language that can be understood by the lay person and accompanies each medicine.

The MHRA became aware that if a patch is exposed to heat, it will increase the speed at which the fentanyl is absorbed into the body and therefore the patient is likely to be exposed to a higher initial dose than prescribed. In December 2014, the MHRA issued a drug safety bulletin[1] warning healthcare professionals and patients of the risk of overdose and death with exposure of the [redacted] patch to increased heat including the instruction that the patch should not be cut.

In 2019 the MHRA undertook a review of the benefits and risks for all [redacted] medicines in the treatment of non-cancer pain and risks associated with dependence and addiction and sought the advice of an [redacted] Expert Working Group of the Commission on Human Medicines, the MHRA's advisory body. The Expert Working Group considered the benefit-risk profile of [redacted]-containing medicines and made recommendations for regulatory action to better support appropriate use of prescription [redacted] including [redacted], with educational initiatives to increase the awareness of both patients and healthcare professionals of the risks of dependence, addiction, tolerance, withdrawal reactions, and risks of neonatal abstinence syndrome during pregnancy.

Following this review, in April 2019, warnings were added to the packaging of all [redacted] to highlight that the medicine contains an opioid and the risk of addiction. This information was relayed to the public through several media outlets including the Guardian[2] and BBC news[3]. In 2020, additional

[1] [redacted]

warnings about the risk of addiction were included in the Summary of Product Characteristics for healthcare professionals and in the patient information leaflets. Further to this action, an article was published in the MHRA's drug safety bulletin, Drug Safety Update (DSU) on 23 September 2020[4] highlighting the risk of addiction with [redacted] containing medicines and the potential for overdose which could be fatal. An additional patient leaflet that is linked to the DSU article was recently updated in August 2021 following user-testing to ensure that patients understood the messages.

We are aware that fentanyl is available illicitly in several different forms. The MHRA works closely with other regulators and has highlighted this case to the Advisory Council on the Misuse of Drugs (ACMD). The ACMD undertook a review in 2020 on the misuse of [redacted] patches and [redacted] analogues. The ACMD found that poison centre telephone enquiries of the misuse of [redacted] patches is uncommon and prescribing had decreased between 2016 and 2018[5].

We note that Mr Capovila was also prescribed [redacted]). A warning is included within the product information for [redacted] of a high risk of respiratory depression and an increased risk of opioid-related death when taken concomitantly with an [redacted]. A similar warning is included within the product information for opioids when used concomitantly with any central nervous system (CNS) depressant or sedative, like [redacted].

The product information for all [redacted] licences is currently being updated to ensure that the warning of concomitant administration of [redacted] as further examples of CNS depressants is clearly stated with the risk of coma or death. This action is being taken to ensure that all relevant product information is consistent.

We continue to monitor the benefits and risks of opioid containing medicines and will take further prompt regulatory action when required.

Yours sincerely,

[redacted]

[redacted]
Chief Executive
Medicines and Healthcare products Regulatory Agency

E [redacted]

[redacted]