Medicines & Healthcare products
Regulatory Agency

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Ms Joanne Kearsley
HM Senior Coroner
[redacted]

2 February 2024

Dear Ms Kearsley,

Regulation 28 Report – Charlene Roberts

I would like to thank you for your email dated 11 December 2024 regarding the Regulation 28 Report for the death of Charlene Roberts. I would like to express our condolences to the Roberts family and hope that the information provided below may help at this difficult time.

Following receipt of the Regulation 28 Report we have considered the point addressed to the MHRA regarding the information sought by pharmacists when patients request over the counter cyclizine.

Firstly, it may be helpful if to provide background information relating to the MHRA and the work we carry out. The MHRA is the executive Agency of the Department of Health and Social Care that acts on behalf of the Ministers to protect and promote public health and patient safety by ensuring that medicines and healthcare products are used safely and meet appropriate standards of safety, quality, performance, and effectiveness. The MHRA assesses the balance of risks and benefits of medicines throughout their use in clinical practice in a process known as pharmacovigilance. This involves the collection of information and assessment of any potential risks, followed, when necessary, with communications and regulatory action to minimise those risks.

Cyclizine is available both as a prescription only product for intravenous formulations and as a pharmacy only product for oral formulations. Pharmacy only products can only be purchased from a pharmacy in the presence of a pharmacist. These medicines are not usually displayed on open shelves and pharmacy staff may discuss with the purchaser how the medicine is to be used, ask questions to make sure that the chosen medicine is appropriate, and check if the person needs to see another health professional such as a doctor, this helps prevent inappropriate use.

Within the Risk Management Plan (RMP) for cyclizine, “drug abuse and misuse” is an important identified risk and is therefore detailed within section 4.4 of the Summary of Product Characteristics (SPC), which states that “there have been reports of abuse with cyclizine, either oral or intravenous, for its euphoric or hallucinatory effects”. As an important identified risk for this product, this risk is routinely reviewed by the Market Authorisation Holder (MAH) in Periodic Safety Update Reports to identify any new evidence of this risk and evaluate the whether the risk minimisation measures remain effective.

To date the MHRA have received a total 27 UK, spontaneous suspected adverse drug reaction (ADR) reports of cyclizine within the following Higher Level Terms (HLTs); Intentional product misuses; Intentional product use issues and; Substance related and addictive disorders. This reporting is in the context of over one million prescriptions of cyclizine in 2022 alone.

It is also important to note that the fact that an ADR has been reported does not necessarily mean that the drug has been proven to cause it and reporters are only required to have a suspicion of an association to report an ADR. Many factors have to be taken into account in assessing causal relationships including the time between taking the suspect drug and experiencing the adverse effect, contribution of other medication, and any underlying disease. Additionally, reporting rates are influenced by a number of factors and for this reason the number of reports should not be used as a basis for determining incidence.

The MHRA keeps the safe and effective use of medicines, including cyclizine, under continual review. We will consider the case raised in this report as well as wider evidence regarding the misuse of cyclizine and determine whether the current risk minimisation measures are sufficient. If further action is required, we will communicate this to healthcare professionals and patients.

While we work closely with healthcare system partners, clinical practice is not within the remit of the MHRA. We would consider that concerns regarding the information provided by the pharmacy when patients request to purchase cyclizine without a prescription, and any consultation patients should receive, would be relevant to raise with the General Pharmaceutical Council, or GPhC, who are responsible for the regulation of the pharmacy profession, or the Care Quality Commission, or CQC, who regulate health and social care in the UK.

I hope the information provided is useful, please do not hesitate to contact me if I can be of further assistance.

Yours sincerely,

[redacted]

[redacted]
Chief Safety Officer
Medicines and Healthcare products Regulatory Agency