Medicines & Healthcare products
Regulatory Agency

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[redacted]

07 August 2023

FOI 23/564

Dear [redacted]

Thank you for your information request, dated 10th July 2023, where you asked:

Government documents state 5 to 6 percent of patients prescribed corticosteroids suffer severe side effects including suicide and really aggressive behaviour resulting in death. Could you provide me with examples of these types of cases government is aware of please. I'd be interested in knowing how many known suicidal cases have resulted as a result of the prescription to a patient of this drug. Also the number of cases and examples known to government of people loosing their lives or being seriously injured as a result of aggressive behaviour caused by the prescription of this drug to a patient. Any changes in the law made by government on discovering these type of cases, indeed any useful information you can provide in this area.

As you may know, a wide range of psychiatric reactions have been reported in association with systemic corticosteroids (those which work throughout the whole body), including affective disorders, psychotic, behavioural disturbances, irritability, anxiety, sleep disturbances and cognitive dysfunction. A review of systemic steroids and these potential side effects was conducted in 2007. As part of this an article in the MHRA's monthly Drug Safety Update bulletin on Corticosteroids: early psychiatric side-effects was published in order to highlight to healthcare professionals the need to consider these common psychiatric reactions and warn patients and their carers about the risks. Within the DSU article, a study was quoted which found the frequency of severe psychiatric reactions might be as high as 5–6%.

Consequently, patients/and or carers should be warned that potentially severe psychiatric adverse reactions may occur with systemic steroids. Symptoms typically emerge within a few days or weeks of starting the treatment and patients/carers are encouraged to seek medical advice if worrying psychological symptoms develop,

especially if depressed mood or suicidal ideation is suspected. Patients/carers should be alert to possible psychiatric disturbances that may occur either during or immediately after dose tapering/withdrawal of systemic steroids, although such reactions have been reported infrequently. Particular care is required when considering the use of systemic corticosteroids in patients with existing or previous history of severe affective disorders in themselves or in their first-degree relatives. These would include depressive or manic-depressive illness and previous steroid psychosis.

There is currently no evidence to suggest that more severe psychiatric adverse reactions are associated with topical, inhaled or intranasal steroids. For inhaled and intranasal corticosteroids, psychiatric events are listed as possible side-effects as a precautionary measure given the low risk of systemic exposure during use of high doses for a long time by the inhaled route.

To minimise the risk of side effects, the lowest possible dosage adequate to control the disease process should be prescribed by physicians. Risks may be higher with high doses/systemic exposure, although dose levels do not allow prediction of the onset, type, severity, or duration of reactions. Most reactions recover after either dose reduction or withdrawal, although specific treatment may be necessary.

Further to your request for adverse drug reactions reported to the MHRA, this is published as interactive Drug Analysis Profiles (iDAPs) which can be accessed here on the Yellow Card website. iDAPs provide a complete listing of all suspected adverse reactions that have been reported to the MHRA via the Yellow Card scheme for all medicines, including suicide and/or aggressive behaviour. This includes all reports received from healthcare professionals, members of the public, and pharmaceutical companies.

iDAPs provided on this website are regularly updated, however there is a time lag of around one month from receipt of a report to it appearing in the iDAP.

When reviewing the data within an iDAP it is important to do so in the context of the essential guidance at the bottom of the report to ensure that you do not misinterpret the data. This information does not present a complete overview of the potential side effects associated with specific medicines. A list of the recognised adverse effects to corticosteroids is found in the product information which can be found via our website. Conclusions on the safety and risks of medicines cannot be made on the data shown in the iDAPs.

You have requested information on the number of people who have lost their lives or been seriously injured as a result of aggressive behaviour caused by the prescription of this drug to a patient. We do not hold this information. Yellow Card reports relate to the patient taking the medication and not those affected by the individual patients' behaviours.

Medicines & Healthcare products
Regulatory Agency

In your request you also asked if any changes had been made to law as a result of these type of cases. I thought it would be useful the explain who the MHRA are and what actions we can take. The Medicines and Healthcare products Regulatory Agency (MHRA) is an executive agency of the Department of Health with a responsibility to protect and promote public health and patient safety by ensuring that medicines, healthcare products and medical equipment are used safely and meet appropriate standards of safety, quality, performance and effectiveness. We ensure that guidance on the use of a medicine, including warnings and precautions for prescribers and patients, is appropriately described in the authorised product information, the Summary of Product Characteristics (SmPC) and in the PIL. MHRA considers data from Yellow Card reports, along with relevant information from other sources in their overall assessment of whether there may be a causal link between a medicinal product and an adverse event. Should a new link between a medicine and a safety concern be confirmed, the MHRA will take regulatory action, such as updating product information or publishing information in Drug Safety Update as we did in 2007.

Finally, I would also like to assure you that the MHRA assesses the balance of risks and benefits of all medicines at the time of initial licensing and throughout their use in clinical practice.

Yours sincerely,

FOI Team,
Safety and Surveillance

If you have a query about the information provided, please reply to this email

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk

Please remember to quote the reference number above in any future communications.

Medicines & Healthcare products
Regulatory Agency

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF