FOI 23/238 – adverse events for renal failure and impairment

MHRA RESPONSE
27 April 2023

Thank you for your email dated 29th March 2023, where you asked for the following:

I am interested in retrieving suspected adverse drug events for acute kidney injury. Thus far, I have only been able to identify this information drug-wise, but not ' event'-wise (i.e., acute kidney disease). I was wondering whether you would be able to guide me to find this information.

Further to your request, I can confirm up to and including 25th April 2023 the MHRA have received 13,848 UK spontaneous Yellow Card reports in association with the Higher Level Term (HLT) 'renal failure and impairment'. This HLT includes a range of similar Adverse Drug Reaction (ADR) terms which maybe of interest to you such as 'acute kidney injury, acute kidney failure, acute renal failure, kidney failure etc'.

The attached table provides details of all the drugs which have been reported in association with an acute kidney or renal failure term.

Please note due to a change in policy on how we display data where there are less than 5 reports, the numbers have been replaced with a ^ in order to prevent patient/reporter identification in line with our duty of confidentiality to patients and reporters. Please refer to the attached information sheet for guidelines on how to interpret the report.

When considering the data, it is important to be aware of the following points:

- A reported reaction does not necessarily mean it has been caused by the medicine, only that the reporter had a suspicion it may have. The fact that symptoms occur after use of a medicine, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by it. Underlying or concurrent illnesses may be responsible and such events can also be coincidental.

- It is also important to note that the number of reports received via the Yellow Card scheme does not directly equate to the number of people who suffer adverse reactions and therefore cannot be used to determine the incidence of a reaction or compare the safety profile of different vaccines. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular medicine, and may be stimulated by promotion and publicity about a drug. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time.

I hope the information provided is helpful, but 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 of this response; and can be addressed to this email address.

Yours sincerely,

FOI Team,
Vigilance and Risk Management of Medicines Division