Medicines & Healthcare products
Regulatory Agency

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12July 2023

FOI 23/375

Dear [redacted]

Thank you for your information request of 24 May 2023. I apologise for the delay in replying. In relation to antidepressant medications, you requested the following information:

1. What test results do the SSRI's such as Sertraline and Paroxetine interfere with?
2. When a drug is known to affect certain markers and test results etc. such as those listed in the Summaries of Product Characteristics (SmPCs), how is this taken into consideration in practice by physicians in the NHS deciphering test results? How are mitigations put in place at the testing end to take into account any interference with test results, how is it determined how to mitigate the effect and what mitigations are applied so that accurate results can be obtained?
3. You had previously wondered whether, since SSRI's are used in the treatment of chronic pain conditions, are considered anti-inflammatory and also serve to regulate the HPA axis function, they might have an effect on certain results and have now seen various studies that have suggested that they affect markers as varied as prolactin, prothrombin, glucose, dopamine, thyroid markers, cortisol, immune markers and inflammatory markers etc. and certain studies have suggested that they can significantly decrease inflammatory markers such as CRP levels etc. In terms of affecting test results other than just blood tests, as an example, you wondered, if inflammation were affected, whether scans such as MRIs would then not detect inflammation etc. Is this the case? Would the SSRIs affect test results of testing such as, for example, nerve studies by changing conduction velocities etc. as a result of decreasing inflammation etc.? What other test results do they affect?
4. You provide two references from the literature and ask who determines, and how they determine, when findings in studies such as these (and those relating to the other markers mentioned) become medical fact and common knowledge to NHS physicians interpreting tests on the front line? You ask how mitigations are put in place at the testing end to take into account any interference with test results,

how it is determined how to mitigate the effect and what mitigations are applied so that accurate results can be obtained?

MHRA reply to point 1

The MHRA approved Summary of Product Characteristics (SmPC) for sertraline and paroxetine which contains information that false positive immunoassay test for benzodiazepine drugs may be recorded in some patients taking sertraline and paroxetine and that this is expected for several days after stopping sertraline.

SSRIs are known to interfere with the results for any other test e.g. producing false positive or negative results. However, SSRIs can affect a variety of biological parameters that may be identified in tests.

The SmPC for both sertraline and paroxetine contain information about the risk of low sodium (hyponatraemia) as a known side effect and that this may be related to in appropriate secretion of antidiuretic hormone (SIADH).

The SmPC for paroxetine and sertraline contain advice that in people with diabetes, all SSRIs use can alter glucose control and be associated with both hypo and hyperglycaemia.

The SmPC for some SSRIs indicate that they can be associated with a high prolactin level in blood tests (hyperprolactinaemia) and high cholesterol.

Some SSRIs can be associated with altered liver function tests and be associated with low platelets. These effects are mentioned in the SmPC for paroxetine and sertraline.

The sertraline SmPC specifically lists hypothyroidism as a known side effect.

MHRA reply to point 2

The remit of the MHRA is to ensure that the medicines' SmPC reflects the most up to date information to guide the benefit and risk discussions between healthcare professionals and patients. The SmPC is one of several authoritative data sources a practicing physician can access , others include national clinical guidelines and guidelines from professional colleges. The individual laboratory analysing the blood samples will also guide the prescriber on results interpretation based on the individual laboratory reference range and this will take into account other medicines the patients might be prescribed. The National Health Service (NHS) provides advice to patients on common blood tests https://www.nhs.uk/conditions/blood-tests/types/.

NHS England issue advice for primary care doctors to optimise blood testing and this includes some guidance on interpretation and cross references relevant clinical guidelines. https://www.nhs.uk/conditions/blood-tests/types/

MHRA reply to point 3

MHRA holds no information about the effect of taking a SSRI medication on magnetic resonance imaging results. Other test results affected by taking a SSRI medicine are reflected in the SmPC as outlined in the reply to point 1.

MHRA reply to point 4

At the time of licensing application, the MHRA assess the totality of data available on the known risks and benefits of a medicine from the clinical development in trials. Once a medicine is approved and the clinical experience with a medicine evolves, new data are required to be submitted to the MHRA at regular intervals in reports from the marketing authorisation holder (MAH). These reports are known as periodic safety update reports (PSURs) and in addition to adverse drug reactions reported to the MAH they include a thorough review of the literature published during the period of each review and regulatory implications of any results.
In addition, MHRA horizon scans and keeps up to date with the latest evidence through routine pharmacovigilance. A multidisciplinary team at MHRA meet on a weekly basis as part of our signal detection process and can seek independent advice from a range of Expert Advisory Groups of the independent Commission on Human Medicines on potential safety signals or new studies and data from all sources including patient reports is considered. If the assessment of the potential signal establishes a safety concern that requires regulatory action such as updates to the product information, the MHRA has several ways of communicating these updates to healthcare professionals including articles in Drug Safety Update and through the liaison with allied healthcare professional organisations updates to clinical guidance.

If you disagree with how we have interpreted the Freedom of Information Act 2000 with regards to your request, you can ask for the decision to be reviewed. The review will be carried out by a senior member of the Agency who was not involved with the original decision.

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.

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

Yours sincerely,

Safety and Surveillance