Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

04 January 2023

Dear [redacted]

FOI 22/1172: Doxycycline and psychotic reactions

Thank you for your e-mail on 05 December. You asked for an update on the assessment of doxycycline and a possible association with psychiatric disorders. The three specific questions you asked, and answers to these, are set out below.

1. Number of further reports of doxycycline and psychotic disorder since 2nd September 2020?

Between 02 September 2020 and 03 January 2022 the MHRA has received 11 UK spontaneous Yellow Cards that report a suspected Adverse Drug Reaction (ADR) from the "Psychosis and psychotic disorders" group of ADR terms (this group is called a Standardised MedDRA Query, SMQ). The Psychosis and psychotic disorders reactions in these reports are summarised in table 1. Please note that total number of reactions in the table is 12; this is because a Yellow Card report may include more than one suspected ADR.

Table 1: ADR terms from 11 the Psychosis and psychotic disorders SMQ reported in Yellow Card reports with a reaction from this SMQ received between 02 September 2020 and 03 January 2023

ADR term	Number reported
Delusion	2
Hallucination	6
Hallucination, auditory	1
Hallucinations, mixed	1
Psychotic behaviour	1
Psychotic disorder	1

2. Number of reports of doxycycline and all other mental health disorders, including the category of mental health disorder.

Between 02 September 2020 and 03 January 2023 the MHRA has received 76 UK spontaneous Yellow Card reports that report a suspected ADR from the “Psychiatric disorders” group of ADR terms (this group is called a System Organ Class, SOC).

Listings of suspected ADRs reported to the MHRA are also available on the MHRA website as interactive Drug Analysis Profiles (iDAPs) here: https://yellowcard.mhra.gov.uk/idaps

When considering the data on the numbers of reports on the MHRA system provided in response to questions 1 and 2 above, it is important to be aware that:

- The likelihood of experiencing an ADR when taking a medicine cannot be estimated from these data. This is because we have limited information about how many people have taken the medicine without experiencing a reaction.
- Reporters are asked to submit Yellow Card reports even if they only have a suspicion that the medicine may have caused the ADR. The existence of an ADR report does not necessarily mean that the medicine has caused the reaction.
- It may be difficult to tell the difference between something that has occurred naturally and an ADR. Sometimes reactions can be part of the condition being treated rather than being caused by a medicine.
- Many factors have to be considered when assessing whether a medicine has caused a reported ADR. When monitoring the safety of medicines, MHRA staff carry out careful analysis of these factors.
- Reporting rates can be influenced by many factors including the seriousness of the ADR, how easy it is to recognise, and the extent of use of a particular medicine.

3. Did the MHRA receive a proposal by the lead marketing authorisation holder (MAH) for the brand-leader doxycycline product to gather further data on the risk of psychotic reactions following doxycycline?

- ***What is the outcome of this data collection?***
- ***Who is the MAH?***

The MHRA is in correspondence with brand leader MAH (Pfizer Limited) discussing how best to gather further data but a proposal has not yet been submitted. The MHRA is continuing to review this issue, including how research could be conducted to generate additional data, and is keeping reports received from the Yellow Card Scheme and all published scientific literature under close review.

Yours sincerely,

FOI Team,
Vigilance and Risk Management of Medicines Division

For information on the reproduction or re-use of MHRA information, please visit https://www.gov.uk/government/publications/reproduce-or-re-use-mhra-information/reproduce-or-re-use-mhra-information

If you have a query about this email, please contact us. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option please write to the Communications Directorate, 4-T, Medicines and Healthcare products Regulatory Agency, (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

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