

MHRA

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Steve Hinks

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R.E. FOI 15/095

17th March 2015

Dear Mr Hinks,

Thank you for your FOI request on the 25th February where you requested the total number of Yellow Card reports raised each of the years between 2002 and 2015 in association with vaccine damage.

Further to your request, I can confirm that the Yellow Card Scheme has no relationship to the Vaccine Damage Payment Scheme. If you wish to provide us with the specific medical diagnosis relevant to the vaccine damage payments, then we would be happy to confirm if we have received any suspected Adverse Drug Reaction (ADR) reports in relation to the corresponding medical conditions reported via the Yellow Card Scheme. However, please bear in mind that these may not be the same cases as the vaccine damage payments, and that a Yellow Card report is not necessarily proof of a vaccine side effect in any individual case.

As you may be aware the Yellow Card Scheme primarily acts as an early warning system for the identification of previously unrecognised adverse reactions and also provides valuable information on recognised ADRs, allowing the CHM and MHRA to identify and refine the understanding of risk factors that may affect the clinical management of patients. The Yellow Card Scheme allows health professionals and patients to report suspected ADRs on a voluntary basis. In addition, there is a legal requirement for companies to report suspected ADRs to their drugs. A Yellow Card report is not proof of a side effect occurring, but merely a suspicion by the reporter that the vaccine/medicine may have caused the side effect. Yellow Card reports may therefore relate to true side effects or they may be coincidental. The value of the scheme has been demonstrated many times and it has helped to identify numerous important safety issues.

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 receipt of the response to your original letter.

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

If you are not content with the outcome of the internal review, you have the right to apply directly to the Information Commissioner for a decision. The Information Commissioner can be contacted at: Information Commissioner's Office, Wycliff House, Water Lane, Wilmslow, Cheshire, SK9 5AF.

Yours sincerely,

FOI Team,
Vigilance and Risk Management of Medicines Division.

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