



Medicines & Healthcare products  
Regulatory Agency



**Caron Ryalls**

Sent via email: [request-293069-9b2287f6@whatdotheyknow.com](mailto:request-293069-9b2287f6@whatdotheyknow.com)

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**14<sup>th</sup> October 2015**

Dear Ms Ryalls,

**FOI 15/472**

Thank you for your email dated 18 September 2015, where you requested:

*A. For each vaccine available in the UK, please provide me with the following information for the period of time 2000-2007 (inclusive)*

- 1. Total number of ADR reports*
- 2. Total number of ADR reports categorised as serious*
- 3. Total number of ADR reports categorised as non-serious*
- 4. Total number of doses administered*
- 5. Total number of doses distributed*
- 6. Total number of ADRs by type of reporter (e.g. GP, pharmacist, patient etc.)*
- 7. Total number of ADRs by nature of ADR (broadest heading - e.g. neurological conditions etc.)*
- 8. Total number of deaths reported*

*I would like the information provided per vaccine (and per brand, if more than one brand has been used, or state unknown if brand is not known when reported)*

*B. Please provide the same information for the period of time 2008 - current date (inclusive)*

*I would image this information can be pulled from a database so time will not be an issue, however if time is thought to be an issue, the period of time 2008- current date (inclusive) is the priority.*

Section 12 of the Freedom of Information Act (FOIA) makes provision for public authorities to refuse requests for information where the cost of dealing with them would exceed the appropriate limit, which for central government is set at £600. This represents the estimated cost of one person spending 24 working hours in determining whether the department holds the information, locating, retrieving and extracting the information.

It may be helpful if I explain the work necessary to fulfil your request. In order to provide the data by vaccine and by brand, this would be in excess of 50 different brands for the vaccines currently on the immunisation schedule. There are also multiple groupings within your request which would stratify the data further, for example for request number 7 you have asked for a breakdown by



broadest heading (System Organ Class (SOC)), for which there are 26; this would in turn create very large tables for all 50 brand names which may not be in a form which is useful to you.

We estimate that it will take us in excess of 24 working hours to extract the information for all years (2000- current date) with the subsets you reference in your request. In order to be able to provide ADR data within the time limit under FOI procedures, we would suggest that the time frame is limited to the period of 2008 to current date inclusively and the data broken down by vaccine substance rather than individual brands.

Please also note that we do not hold data pertaining to the number of doses administered or distributed, so are unable to fulfil request 4 and 5. For this information please contact Public Health England (PHE) who may be able to provide you with this.

I hope the information provided and explanation regarding the exemption 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.

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, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF

Yours sincerely,

FOI Team,  
Vigilance and Risk Management of Medicines Division

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