Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

MHRA
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United Kingdom

www.gov.uk/mhra

11th June 2021

Dear

MHRA Ref: FOI 21/590

Thank you for your latest email dated 29th May 2021, where you requested information; for a list of all new vaccines in use in the UK, the number of vaccine deaths, per vaccine, per month for each year from 2010 to 2020 for all the new vaccines in use.

The MHRA continuously monitors the safety of vaccines through a variety of pharmacovigilance processes including the Yellow Card scheme. As part of our signal detection processes all adverse reaction reports received by the Yellow Card scheme are individually assessed and cumulative information reviewed at regular intervals. Vaccines encompass a wide variety of products with different indications, different ingredients and different mechanisms of action and as such safety for each vaccine is considered individually rather than as a group.

As per your request, please find attached the list of marketing authorisations granted by MHRA for new vaccines from 2010 to 2020. Table 1 shows a total of 20 new vaccines that were granted authorisation, along with the authorisation holder company name, the date of granting and authorisation number, of each vaccine. Further to your request, regarding the number of vaccine deaths, per vaccine, per month for each year from 2010 to 2020, I would like to kindly direct you to the enclosed Drug Analysis Prints (DAPs) for the vaccines listed in Table 1. Please note that we do not have any reports of Adacel.

As you may be aware, the Pfizer/BioNTech COVID-19 vaccine was authorised for supply by the MHRA on 2nd December 2020 following a thorough review of safety, quality and efficacy information from clinical trials. In clinical trials, the vaccines showed very high levels of protection against symptomatic infections with COVID-19. Currently a summary of reporting for all COVID-19 vaccines is published here alongside analysis prints which provides a list of reactions reported any whether they were fatal.

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

- A reported reaction does not necessarily mean it has been caused by the vaccine, only that the reporter had a suspicion it may have. Each year, millions of doses of routine vaccinations

are given in the UK alone, and when any vaccine is administered to large numbers of people, some recipients will inevitably experience illness following vaccination. The fact that symptoms occur after use of a vaccine or 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.

As these data do not necessarily refer to proven side effects, you should refer to the product information which can be found here: https://www.medicines.org.uk/emc/ for details on the possible side effects of each vaccine. In addition, you can also find the product information for the Pfizer/BioNTech COVID-19 vaccine, which includes information relating to the composition of the individual vaccines and associated listed side-effects available on the Yellow Card Coronavirus website.

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

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
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