Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

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6th September 2021

Dear Mr Anderson,

Our Ref: FOI 21/907

Thank you for your email dated 6th August 2021, where you requested information on the following under the Freedom of Information (FOI) act:

- *How many Deaths has there been from all Covid-19 vaccines? Has there been deaths within 3 days or 28 day after taking the vaccine?*
- *Are there any other reporting AI system monitoring system like Yellow Card reports system others that government is tracking for ADS/adverse reactions?*
- *Are Covid-19 Vaccines still under trial stages? And getting monitored still not been approved only Emergency Authorisation is this right? Are they still not officially approved?*
- *How many deaths has there been in last 20 years by previous Vaccines without covid-19 Vaccines compared with covid-19 Vaccines related death?*
- *What happens if a there is a new vaccine or new drug? What process and monitoring do they go through?*
- *Is there ongoing on safety and effectiveness? If the Vaccine or Drug is proven unsafe what cut off point will MHRA say this is unsafe for humans because of the data and say all Covid-19 vaccines are proven unsafe? Like swine flu vaccine 53 deaths proven unsafe for humans is there cut off point with Covid-19 All Vaccines*

To address your first question, whereby you asked how many deaths from all COVID-19 vaccines have there been within 3 days or 28 days after taking the vaccine, unfortunately the MHRA does not hold complete information on timing of death or death statistics and so would suggest you contact the Office of National Statistics (ONS) (Contact us - Office for National Statistics (ons.gov.uk)) for this particular aspect of your enquiry.

The MHRA collects reports of suspected side effects to the COVID-19 vaccines, including those with a fatal outcome, via the Yellow Card scheme. I would like to assure you that the MHRA takes all reports of fatal events in patients who have received a COVID-19 vaccine with the utmost seriousness. The MHRA publishes a weekly summary of Yellow Card reporting which summarises information received via the Yellow Card scheme and includes details of other safety investigations carried out by the MHRA under the COVID-19 Vaccine Surveillance Strategy. Section 3, titled Analysis of Data, contains information on events with a fatal outcome.

You additionally asked in your follow up correspondence with us what the cut-off point is for when the vaccines may be considered unsafe. The MHRA's role is to continually monitor safety during widespread use of a vaccine. We have in place a proactive strategy to do this which can be assessed using the link above. We also work closely with our public health partners in reviewing the effectiveness and impact of the vaccines to ensure the benefits continue to outweigh any possible side effects. It is important to note that vaccination is the single most effective way to reduce deaths and severe illness from COVID-19. All vaccines and medicines have some side effects. These side effects need to be continuously balanced against the expected benefits in preventing illness. Following widespread use of these vaccines across the UK, the vast majority of suspected Adverse Drug

Reaction (ADR) reports so far confirm the safety profile seen in clinical trials. Please be assured that should any safety concerns be identified during routine pharmacovigilance activities, these will be communicated to the patients and healthcare professionals alike with the upmost importance.

Further to your request where you have asked if there are any other adverse incidence reporting systems that the government is using to track adverse reactions, the MHRA uses other epidemiological studies, anonymised GP-based electronic healthcare records and international experience to proactively monitor safety alongside the spontaneous reports received via the Yellow Card scheme. The MHRA also runs the Yellow Card Vaccine Monitor programme to aid our safety monitoring. We continue to work closely with our public health partners to ensure optimal monitoring is carried out.

You also queried if the COVID-19 vaccines are still under trial stages and are only approved for Emergency authorisation. The temporary authorisations of the Pfizer/BioNTech, Oxford/AstraZeneca and Moderna vaccines was done through an expedited rolling review. A 'rolling review' can be used to complete the assessment of a promising medicine or vaccine during a public health emergency in the shortest time possible. This is done as the packages of data become available from ongoing studies on a staggered basis. The temporary authorisation under Regulation 174 permits the supply of identified vaccine batches, based on the safety, quality and efficacy data submitted to MHRA. These authorisations do not constitute a marketing authorisation.

The temporary authorisations for use of the COVID-19 vaccines in the UK followed a rigorous scientific assessment of all the available evidence of quality, safety and effectiveness by the MHRA. The MHRA expert scientists and clinicians reviewed data from the laboratory pre-clinical studies, clinical trials, manufacturing and quality controls, product sampling and testing of the final vaccine, and also considered the conditions for its safe supply and distribution. The decision was made with advice from the Commission on Human Medicines (CHM), the government's independent expert scientific advisory body. Regarding the MHRA approval of the Pfizer/BioNTech and the Oxford/AstraZeneca COVID-19 vaccines, further information (including information for physicians and recipients of the vaccine, and Public Assessment Reports [PARs] for each vaccine) are available on the MHRA website. Links to these are provided below:
https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19
https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca
https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-moderna

Please note that a marketing authorisation was granted for the Pfizer/BioNTech vaccine following a European Commission (EC) decision on 21 December 2020 (PLGB 53632/0002). Further information is available on the European Medicines Agency (EMA) website, a link to this is provided below:
https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty

Please also note that a marketing authorisation was granted for the Moderna vaccine on 31 March 2021 following an EC Reliance Procedure (PLGB 53720/0002). Further information is available on the MHRA website and the EMA website, links to these are provided below:
https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-moderna
https://www.ema.europa.eu/en/medicines/human/EPAR/covid-19-vaccine-moderna

A marketing authorisation has been granted for the Janssen Covid-19 vaccine on 28 May 2021. Further information is available via the below link:
https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-janssen

In addition, a marketing authorisation was granted for the Oxford/AstraZeneca vaccine on 24 June 2021 following an EC Reliance Procedure (PLGB 17901/0355). Further information is available on the MHRA website and the EMA website, links to these are provided below:
https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca
https://www.ema.europa.eu/en/medicines/human/EPAR/vaxzevria-previously-covid-19-vaccine-astrazeneca

As with any vaccine or medicine, COVID-19 vaccines require continuous safety monitoring and that the benefits in protecting people against COVID-19 outweigh any side effects or potential risks. This is a process known as

safety monitoring (pharmacovigilance). This ensures that any potential medium and long term safety issues are promptly and adequately evaluated. As part of our signal detection processes, all adverse reaction reports received are individually assessed and cumulative information reviewed at regular intervals. Be reassured that the MHRA is working in collaboration with partners in the health system to rapidly assess all available safety data in real time and communicate any emerging issues, as necessary.

A PAR is available for the assessment by MHRA of the Pfizer/BioNTech vaccine in adolescents, please refer to Annex 1 in the above-linked PAR for the Pfizer/BioNTech vaccine.

It was noted from your request that you asked us to provide data on how many deaths there had been in the last 20 years by previous vaccines without COVID-19 vaccines compared with COVID-19 vaccine related deaths. Please note that the MHRA does not hold complete information on death statistics only data concerning Yellow Card reports in which the reporter has suspected a side effect to a vaccine, some of which will include a fatal outcome.

It should be noted that a comparison is not feasible for a number of reasons. There are a range of factors that can lead to variable reporting of one vaccine over another, for instance, socio-demographic factors of vaccine recipients or whether or not they have been encouraged by information, or a healthcare professional, to make a report. Large volumes of COVID-19 vaccines have also been administered when compared to other routine vaccinations within the same time period. No robust inferences can be drawn from such comparisons.

As you will be aware, the COVID-19 vaccines have been given to millions of people in the UK and we have worked to ensure that people know to report suspected side effects to the Yellow Card scheme. In addition to social media campaigns, we have issued a Drug Safety Update, a press release, and run social media campaigns informing healthcare professionals and members of the public that reporting to the Coronavirus Yellow Card reporting site help will enable the MHRA to rapidly identify new and emerging side effects. The public have been encouraged to report during the televised press briefings. Vaccination materials have also signposted individual to the Coronavirus Yellow Card reporting site, which may contribute to the increased rate of reporting for these vaccines.

Overall, the number and nature of suspected adverse reactions reported so far is not unusual for an immunisation programme, and the data published and analysed by the MHRA tell us that the safety of the COVID-19 vaccines is as expected based on the robust clinical trial data that supported the authorisations. The general safety profiles of the COVID-19 vaccines authorised in the UK are broadly similar to other types of routinely used vaccines. Our robust regulatory work continues to reinforce that the safety profile of the vaccines remains positive, and the benefits continue to far outweigh any known side effects.

The MHRA has received a total of 404 UK spontaneous suspected ADR reports for any vaccine between 01/01/2001 – 25/08/2021 associated with a fatal outcome. Please note this number excludes reports received for the COVID-19 vaccines as further information is provided on these vaccines in the weekly summary of Yellow Card reporting which can be found via the link referenced above.

When considering 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 or vaccine and may be stimulated by promotion and publicity. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time.

You should refer to the product information (Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL)) for details on the possible side effects of each COVID-19 vaccine, which can be found here.

To answer your final question regarding what happens with a new vaccine or new drug, and what process and monitoring do they go through, I can confirm that all vaccines and medicines alike are tested through three phases of clinical trials to ensure they meet the gold standard. Phase 1 trials are with a small group of people to make sure there are no safety concerns and determines the appropriate dosage for the best immune response. Phase 2 trials are conducted on a larger group of people to check the vaccine works consistently and that the immune response is sufficient. Phase 3 trials test the vaccines on thousands of people for scientists to assess if the vaccine is producing immunity that will prevent disease. Usually, these phases are run in sequence, but in an effort to find a safe and effective COVID-19 vaccine as quickly as possible, once safety has been ascertained through Phase 1, Phases 2 and 3 are being run in parallel. Extensive checks and balances are required at every stage of the development of a vaccine, and this is no different for a COVID-19 vaccine. No stages in the vaccine development processes were bypassed with further detail of the COVID-19 vaccine authorisations available above. The MHRA also continue to monitor the safety of these vaccines throughout their use via our pharmacovigilance processes as detailed in our strategy referenced above.

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: info@mhra.gov.uk. Please remember to quote the reference number above in any future communications.

Due to the ongoing Covid-19 situation, we are not able to accept delivery of any documents or correspondence by post or courier to any of our offices.

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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