FOI 23/358 – authorisation of Covid-19 vaccines

MHRA RESPONSE
20 June 2023

Dear

Thank you for your email.

Please find below answers you have raised to the questions you have raised below.

1- Can you tell me if any of the COVID-19 vaccines currently in use in the UK are experimental ?

A. The COVID-19 vaccines authorised for use in the UK are not experimental.

A marketing authorisation was granted for the Pfizer/BioNTech vaccine (Comirnaty) 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://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ema.europa.eu%2Fen%2Fmedicines%2Fhuman%2FEPAR%2Fcomirnaty&data=05%7C01%7CFOILicensing%40mhra.gov.uk%7C59b99f1964df45f1cf0808db344fe921%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638161290034312111%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=A3vp0R6ZNnD5Su3WJ%2Bmkc%2B8y%2FERz493IVYHe32cAAhE%3D&reserved=0

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://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.gov.uk%2Fgovernment%2Fpublications%2Fregulatory-approval-of-covid-19-vaccine-moderna&data=05%7C01%7CFOILicensing%40mhra.gov.uk%7C59b99f1964df45f1cf0808db344fe921%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638161290034312111%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=nLaKF%2BFk1oWbtFNRpQ2YQUFFEk5plzl45Lw1s5bUQ3s%3D&reserved=0
https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ema.europa.eu%2Fen%2Fmedicines%2Fhuman%2FEPAR%2Fcovid-19-vaccine-moderna&data=05%7C01%7CFOILicensing%40mhra.gov.uk%7C59b99f1964df45f1cf0808db344fe921%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638161290034312111%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=drp%2BrJWrfkXQ1R%2F63S9GWHKdLC6i3w5mK5bf0OcoF3c%3D&reserved=0

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://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.gov.uk%2Fgovernment%2Fpublications%2Fregulatory-approval-of-covid-19-vaccine-janssen&data=05%7C01%7CFOILicensing%40mhra.gov.uk%7C59b99f1964df45f1cf0808db344fe921%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638161290034312111%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=D0Bqgn2ZT1Zdhu1ips4CAktCKe%2Bg0VpkEA%2Bmkzgvhd8%3D&reserved=0

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://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.gov.uk%2Fgovernment%2Fpublications%2Fregulatory-approval-of-covid-19-vaccine-astrazeneca&data=05%7C01%7CFOILicensing%40mhra.gov.uk%7C59b99f1964df45f1cf0808db344fe921%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638161290034312111%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=DPk93kKvL6mS%2Bl%2BVTdD0lMVihgrKEbHXRzEgMp%2FjBA0%3D&reserved=0

https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ema.europa.eu%2Fen%2Fmedicines%2Fhuman%2FEPAR%2Fvaxzevria-previously-covid-19-vaccine-astrazeneca&data=05%7C01%7CFOILicensing%40mhra.gov.uk%7C59b99f1964df45f1cf0808db344fe921%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638161290034312111%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=u%2FPKRdqAVWhXQ7LtX1D6iJaXkqfg%2BA%2BEuBLrq0Zwt5U%3D&reserved=0

A marketing authorisation was granted for Valneva suspension for injection (PL 43185/0002) on 13 April 2022. A link to the Public Assessment Report is provided below:
https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fmhraproducts4853.blob.core.windows.net%2Fdocs%2F27680d2f701880f90f62740cab6adb4d939b54b4&data=05%7C01%7CFOILicensing%40mhra.gov.uk%7C59b99f1964df45f1cf0808db344fe921%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638161290034312111%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=bXFwn3kilWl5nvmW0zilaJmGzWShKjNuVsP5hoQ8YAI%3D&reserved=0

Further information on other vaccines for Covid-19, including the bivalent vaccines are available on the MHRA website, please see the link below:
https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fmhraproducts4853.blob.core.windows.net%2Fdocs%2F27680d2f701880f90f62740cab6adb4d939b54b4&data=05%7C01%7CFOILicensing%40mhra.gov.uk%7C59b99f1964df45f1cf0808db344fe921%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638161290034312111%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=bXFwn3kilWl5nvmW0zilaJmGzWShKjNuVsP5hoQ8YAI%3D&reserved=0

MHRA has authorised the Spikevax and Comirnaty bivalent vaccines for use in protecting against Covid-19 infection. Links to further information, including the Public Assessment Reports (PARs) published by the European Medicines Agency and MHRA are provided below:
https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fproducts.mhra.gov.uk%2Fsearch%2F%3Fsearch%3DSpikevax%26page%3D1&data=05%7C01%7CFOILicensing%40mhra.gov.uk%7C59b99f1964df45f1cf0808db344fe921%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638161290034312111%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=Om7do1B3IuZG73UlyPaQ8KjQRb53828ESJ81KsPwPk0%3D&reserved=0
https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fproducts.mhra.gov.uk%2Fsearch%2F%3Fsearch%3DComirnaty%26page%3D1&data=05%7C01%7CFOILicensing%40mhra.gov.uk%7C59b99f1964df45f1cf0808db344fe921%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638161290034312111%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=47JT9RYp9oG%2FEUkEcq4K%2BLeLXGoS%2BXs8OqbzCup%2Fb5s%3D&reserved=0
https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ema.europa.eu%2Fen%2Fmedicines%2Fhuman%2FEPAR%2Fcomirnaty&data=05%7C01%7CFOILicensing%40mhra.gov.uk%7C59b99f1964df45f1cf0808db344fe921%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638161290034312111%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=A3vp0R6ZNnD5Su3WJ%2Bmkc%2B8y%2FERz493IVYHe32cAAhE%3D&reserved=0
https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ema.europa.eu%2Fen%2Fmedicines%2Fhuman%2FEPAR%2Fspikevax&data=05%7C01%7CFOILicensing%40mhra.gov.uk%7C59b99f1964df45f1cf0808db344fe921%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638161290034312111%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=%2B3kcPs%2FBJcaYZhv8fHXq5hJm9jZlGnzG8jyQcZ9Uawc%3D&reserved=0

2- Can you tell me if any of the COVID-19 vaccines used in the UK were ever defined as experimental and from which dates were they no longer considered experimental ?

A. From the date of initial authorisation of each vaccine, they were no longer considered to be “under development” or “an investigational medicinal product” for the indications that had been authorised.

3- From what dates were the COVID-19 vaccines used under EUA licensing ?

A. Regulatory approval of specific batches of the Pfizer vaccine under Regulation 174 was on 01 December 2020. Further information on this is provided below:
https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19

Regulatory approval of specific batches of the AstraZeneca vaccine under Regulation 174 was on 30 December 2020. Further information on this is provided below:
https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca

Regulatory approval of specific batches of the Moderna vaccine under Regulation 174 was on 08 January 2021. Further information on this is provided below:
https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-moderna

All vaccines authorised under Regulation 174 have subsequently been granted marketing authorisations (see response to Q1 above).

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

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

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner’s Office
Wycliffe House
Water Lane
Wilmslow
Cheshire

SK9 5AF

Yours sincerely

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