Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

Our Ref: FOI 22/1217

23 January 2023

Dear [redacted]

Thank you for your email dated 21 December 2022 in which you have asked some further questions concerning the COVID-19 vaccines following our response to FOI 22/798. Please see below for a response to each of your additional questions.

1) **The number of people who received the AstraZeneca COVID-19 vaccination for the years 2020(*), 2021 and 2022, broken down by month within each year if possible. If this is not technically possible, please provide a breakdown for each calendar year**

This information is not held by the MHRA. To obtain this information you will need to contact the UK Health Security Agency (UKHSA). Information on how to contact the UKHSA, including general enquiries and making Freedom of Information act requests, can be found on the UKHSA website.

However, in order to contextualise the data provided below we can provide the estimated number of first second and third or booster doses that have been administered in the UK. As of 11 September 2022, an estimated 24.9 million first doses and 24.2 million second doses of the COVID-19 Vaccine AstraZeneca had been administered. As of 26 December 2022, an estimated 60,800 third or booster doses of COVID-19 Vaccine AstraZeneca had been administered.

2) **The number of people who experienced the medical issues listed below as referenced in your original response, attached below. For the years 2020, 2021 and 2022, again, broken down by month within each year if possible. If this is not technically possible, please provide a breakdown for each calendar year. Please include any occurrences in 2020 prior to the launch of the vaccine to help provide context.**

   I26.- Pulmonary embolism
   I82.8 Embolism and thrombosis of other specified veins
   I82.9 Embolism and thrombosis of unspecified vein

Firstly, I would like to clarify what the data the MHRA can provide will show. The Yellow Card scheme, which is run by the MHRA, is the UK program for collecting experiences of side effects from healthcare professionals and patients and is used to monitor the safety profile of all medicines and vaccines. It is a voluntary scheme for healthcare professionals and members of the public; however, there is a legal requirement for pharmaceutical companies to report any side effects that they have been informed of to the scheme.

A reported reaction to the Yellow Card scheme 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. Adverse Drug Reaction (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.

The categories you provide in your enquiry (I26.- Pulmonary embolism; I82.8 Embolism and thrombosis of other specified veins; and I82.9 Embolism and thrombosis of unspecified vein) are codes from the International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10). ICD is used to report and code worldwide health data in order to record health information and derive statistics. However, the MHRA does not use ICD codes to code data reported by the Yellow Card scheme. The MHRA uses the Medical Dictionary for Regulatory Activities (MedDRA), which is the internationally agreed list of terms used for Medicines Regulation. MedDRA terms are used to capture reactions within our ADR reports. MedDRA groups related ADR terms in a hierarchical structure whereby the 'Lowest Level Term' (LLTs) is the most specific term. LLTs are then grouped under the heading 'Preferred Term' (PT), which are in turn then grouped into 'Higher Level Terms' (HLT) which are grouped under 'Higher Level Group Terms' (HLGT).

As such, we are not able to provide data grouped using ICD-10 codes, however we are able to provide data grouped using MedDRA terminology. As such, we have provided below a breakdown of spontaneous UK suspected ADR reports received by the MHRA concerning the AstraZeneca COVID-19 vaccine and terms within the MedDRA HLGT 'Embolism and thrombosis' which we feel is most relevant to the data you have requested. The data provided below is the number of spontaneous Yellow Card reports we have received of events in the MedDRA Embolism and Thrombosis HLGT where the reporter suspects there is a possibility that COVID-19 AstraZeneca vaccine may have caused or contributed to the occurrence of this event. **The reported reactions have not been proven to be related to the vaccines and should not be interpreted as such.**

No spontaneous UK reports were received in 2020 reporting terms in the Embolism and Thrombosis HLGT in association with the AstraZeneca COVID-19 vaccine. Reports below are grouped by the initial date they were received by the MHRA, although some reports may have been updated with further information after this date. In addition, please note that the date that the MHRA received the Yellow Card report does not necessarily reflect the date that the suspected adverse event occurred, reports can be submitted at any time after the event has occurred.

In 2021, the MHRA received a total of 3645 reports in which one or more terms within the Embolism and Thrombosis HLGT was reported in association with the AstraZeneca COVID-19 vaccine. The table below shows the number of reports received per month in 2021 (Table 1). Where there are fewer than 5 reports for a given category, report numbers have been replaced with a ^ in order to prevent patient/reporter identification in line with our duty of confidentiality to patients and reporters.

Table 1 Breakdown of the number or reports received in 2021 in which one or more term within the Embolism and Thrombosis HLGT was reported in association with the COVID-19 AstraZeneca vaccine by month

Month	Number of ADR reports containing terms within the Embolism and Thrombosis HLGT
January	^
February	22
March	652

April	1093
May	635
June	489
July	275
August	140
September	109
October	67
November	67
December	93
Total	**3645**

In 2022, the MHRA received a total of 198 reports in which one or more term within the Embolism and Thrombosis HLGT was reported in association with the AstraZeneca COVID-19 vaccine. The table below shows the number of reports received per month in 2022 (table 2).

Table 2 Breakdown of the number or reports received in 2022 in which one or more term within the Embolism and Thrombosis HLGT was reported in association with the COVID-19 AstraZeneca vaccine by month

Month	Number of ADR reports containing terms within the Embolism and Thrombosis HLGT
January	49
February	25
March	19
April	17
May	17
June	19
July	11
August	9
September	7
October	6
November	7
December	12
Total	**198**

With regard to your request for us to “include any occurrences in 2020 prior to the launch of the vaccine to help provide context.” We would like to clarify, that we could provide the total number of Yellow Card reports we have received that report an event within the Embolism and Thrombosis HLGT with all medicines and/or vaccines. However, we cannot provide the background rate of occurrence of these medical events in the general population and similarly Yellow Card data should not be used to determine the incidence of a reaction as outlined in the points above. Please submit a further FOI request if you would like us to provide you with the total number of Yellow Card reports we have received reporting events within the Embolism and Thrombosis HLGT for all medicines and/or vaccines. If you are interested in the background rate for these events we would suggest you contact the Office for National Statistics (ONS). Information on how to contact the ONS is provided on their website: Contact us - Office for National Statistics (ons.gov.uk)

3) **Confirm when the Astra Zeneca vaccine was first made available in the UK**

The COVID-19 vaccine developed by Oxford University/AstraZeneca was given temporary authorisation under Regulation 174 by the Medicines and Healthcare products Regulatory Agency (MHRA) on 30/12/2020 following a rigorous, detailed scientific review by the MHRA’s expert scientists and clinicians and on the basis of the advice of its scientific, independent advisory body, the Commission on Human Medicines. The vaccine was approved after meeting the required safety, quality and effectiveness standards. You can find out more about the approval of the vaccine from our press release: Oxford University/AstraZeneca COVID-19 vaccine approved - GOV.UK (www.gov.uk). The first dose of the Oxford-AstraZeneca vaccine given in the UK was given on 04/01/2021.

4) **Confirm when the Astra Zeneca vaccine was withdrawn from use in the UK.**

The recommendations made by the Joint Committee on Vaccination and Immunisation (JCVI) regarding which individuals should and should not be vaccinated with the AstraZeneca COVID-19 vaccine have changed over time, for example, please see these statements from 07/04/2021 and 07/05/2021. The UK Health Security Agency (UKHSA) publication of the national protocol for administration of the AstraZeneca COVID-19 vaccine was withdrawn online on 02/02/2022 with the quoted reason that all stock of this vaccine has expired. As such, this product is not currently in use in the UK. However, please be aware that the AstraZeneca COVID-19 vaccination is still authorised for use in Great Britain under a conditional authorisation and as such if further stock of the vaccine became available it could be used in Great Britain in accordance with official recommendations.

As these data do not necessarily refer to proven side effects, you should refer to the product information which can be found here: MHRA Products | Home for details on the possible side effects of each vaccine.

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
Patient Safety Monitoring

The Information Commissioner’s Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF