

[REDACTED]

From: Raine, Dr June
Sent: 28 April 2022 10:00
To: [REDACTED]
Cc: Branch, Sarah; Cave, Alison; [REDACTED]; Tregunno, Phil; Bosworth, Rachel; [REDACTED]; [REDACTED] Tr [REDACTED] rine;
Subject: RE: Coronavirus Vaccine - summary of Yellow Card reporting DLP 20/04/2022 for publication 28/04/2022

Dear [REDACTED]

Thank you for the ADR summary publication (DLP 20/04/2022) for publication 28/04/2022. I have read through the track-change version.

I agree that this can now be published. Separately, I'd be interested to know if any further cases of TTS have occurred after the risk minimisation measures were introduced.

Many thanks to everyone who contributed to this important communication.

Kind regards
June

Dr June Raine
CEO, MHRA
10 South Colonnade
Canary Wharf
London E14 4PU

Tel: 020 3080 6100
Email June.raine@mhra.gov.uk

From: [REDACTED]
Sent: 28 April 2022 08:55
To: Raine, Dr June <June.Raine@mhra.gov.uk>
Cc: Branch, Sarah <Sarah.Branch@mhra.gov.uk>; Cave, Alison <Alison.Cave@mhra.gov.uk>; [REDACTED]; [REDACTED] Tregunno, Phil <Phil.Tregunno@mhra.gov.uk>; Bosworth, Rachel <Rachel.Bosworth@mhra.gov.uk>; [REDACTED]; [REDACTED] Tregunno, Catherine <Catherine.Tregunno@mhra.gov.uk>; [REDACTED]; [REDACTED]
Subject: Coronavirus Vaccine - summary of Yellow Card reporting DLP 20/04/2022 for publication 28/04/2022

Dear June,

Please see the attached and below link for the ADR summary publication (DLP 20/04/2022) for publication 28/04/2022. The report has been signed off by Alison Cave and is ready for CEO clearance.

S&S Final Clean: [Coronavirus vaccine - summary of Yellow Card reporting 20.04.2022 CLEAN.docx](#)

In the two weeks reporting period since 6th April there has been an increase in 300,000 doses of the Pfizer vaccine administered to under 18s and 300 for Moderna vaccine. The increase on Yellow Cards reports has been 134 for Pfizer, 2 for Moderna and 2 where no brand has been specified. The current reporting rate is 0.37 per 1000 doses compared to 1.9 per 100 for the 18+ age group.

There have been no major changes to the sections of the report which are listed below:

- Pregnancy
- Breastfeeding
- Under 18's
- Booster vaccinations
- Anaphylaxis
- Bell's Palsy
- Thrombo-embolic events with concurrent low platelets
- Thrombo-embolic (blood clotting) events without concurrent low platelets
- Immune thrombocytopenia
- Capillary Leak Syndrome
- Menstrual disorders
- Myocarditis and pericarditis
- Delayed hypersensitivity reactions
- Guillain-Barre Syndrome
- Swelling of vaccinated limb
- Facial swelling with dermal fillers
- Events with a fatal outcome

Where report numbers have been updated for the currently described topics, these have not changed the Agency's current opinion and conclusion on safety already presented within the summary.

Many thanks,

Pharmacovigilance Information Coordinator
Vigilance and Risk Management of Medicines

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade, Canary Wharf, London E14 4PU
Email:

gov.uk/mhra

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