Department of Health & Social Care

From Maria Caulfield MP
Parliamentary Under Secretary of State
Department of Health & Social Care

39 Victoria Street
London
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12 June 2023

Ms Nadia Persuad

Walthamstow Coroner's Court

Queens Road

Walthamstow

E17 8QP

Dear Ms Persaud,

Thank you for your letter of 13 October 2022, to the then Secretary of State for Health and Social Care, Thérèse Coffey, about the death of Oli Hoque. I am replying as Minister with responsibility for Social Care, and thank you for the additional time allowed.

Firstly, I would like to begin by saying how saddened I was to read of the circumstances of Mr Hoque's death and I offer my sincere condolences to his family and loved ones. It is of course vital that we take learnings where they are identified to improve NHS care, and I am grateful to you for bringing these matters to my attention.

In preparing this response, Departmental officials have made enquiries with the Medicines and Healthcare products Regulatory Agency (MHRA).

You may wish to know that whilst significant progress has been made in the scientific understanding of vaccine-induced thrombosis with thrombocytopenia, at the time of Mr Hoque's death in April 2021, diagnostic criteria had only recently been established and communicated to healthcare professionals. It is therefore not surprising that cases reported were of variable detail and were reclassified over time as more evidence emerged. A Yellow Card report was voluntarily made for Mr Hoque the day after his admission to hospital. Furthermore, the hospital doctor provided the requested clinical information and test results within two days of the initial report being submitted.

MHRA conducted daily, proactive follow up and utilised a Data Sharing Agreement (DSA) with Public Health England (now UK Health Security Agency, UKHSA) for additional case details where needed. MHRA sought the advice of its COVID-19 Expert Working Group and the Commission on Human Medicines on emerging evidence of thrombosis with thrombocytopenia and issued regular press releases as evidence continued to amass.

MHRA do not have jurisdiction over healthcare professionals, and therefore did not comment on your consideration of whether issuance of this Regulation 28 report regarding legislative powers to access NHS case notes would assist the MHRA. There are professional guidelines in place for health care professionals to report safety issues, however, the Department is not aware of any jurisdiction globally that compels relevant clinical follow up information.

MHRA recognises the importance of access to relevant clinical information for pharmacovigilance and ensured that relevant data flows were in place prior to commencement of vaccinations in December 2020 to support its four-stranded proactive vigilance strategy - 1) Enhanced passive surveillance – 'observed vs expected' analysis; 2) Rapid Cycle Analysis and Ecological analysis (analysing anonymised healthcare for pre-defined events as well as monitoring trends); 3) Targeted active monitoring; and 4) Formal epidemiological studies. It is the view of the MHRA that focus should be placed on encouraging reporting and working across the health family to streamline processes and reduce barriers to reporting.

Steps taken to enable this include working with the NHS to enable interoperability and connectivity of reporting system such as the new Learning from Patient Safety Events System (LPSE) to allow automatic electronic upload into MHRA databases in a timely manner. The NHS Digital Clinical Safety Strategy[1] covers integration of LPSE with the Yellow Card system; improvement of adverse events and incident reporting is a commitment made by NHSE and MHRA with a clear strategy and shared responsibilities. A recently published NHS standard contract (NHS England "2023/24 NHS Standard Contract) has a focus on interoperability which will help achieve those aims.[2]

Finally, MHRA continues to educate and promote the Yellow Card scheme with healthcare professionals through its five Yellow Card Centres and campaigns such as the MHRA's annual #MedSafetyWeek.

I hope this response is helpful. Thank you for bringing these concerns to my attention.

Yours sincerely,

[redacted]

MARIA CAULFIELD

[1] https://transform.england.nhs.uk/key-tools-and-info/digital-clinical-safety-strategy/
[2] https://www.england.nhs.uk/nhs-standard-contract/23-24/