Witness Name: June Munro Raine
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INFECTED BLOOD INQUIRY

FIRST WRITTEN STATEMENT OF JUNE MUNRO RAINE

Contents

Section 1: Introduction and professional history

Introduction

I, June Munro Raine, will say as follows: -

1.1. My name is June Munro Raine and my date of birth GRO-C 1952, and my home address is GRO-C Hertfordshire GRO-C GRO-C

1.2. I am providing this written statement in response to the Inquiry's Rule 9 request dated 13 June 2022.

Professional history

1.3. I trained in Medicine at the University of Oxford, and in 1978 attained a Bachelor of Medicine and Surgery ('BM BCh') after undertaking an intercalated MSc in Pharmacology by research.

1.4. After undertaking various junior hospital jobs and attaining Membership of the Royal Colleges of Physicians, I trained in general practice, attaining Membership of the Royal College of General Practitioners in 1982.

1.5. In 1985 I joined the Medicines Division of the Department of Health as a Senior Medical Officer working on the Review of Medicines.

1.6. In 1989 I became a Group Manager in the Medicines Control Agency, an Arms-Length Body of the Department of Health, overseeing post-authorisation licensing activities, and from 1992–2005, I was the Principal Assessor to the Medicines Commission.

1.7. In 1998 I was appointed Director of the Post-Licensing Division of the Medicines Control Agency which, in 2006, became the Vigilance and Risk Management of Medicines Division. In this role, I was responsible for the operation of the Yellow Card Scheme which is a mainstay of safety monitoring of medicines in the UK.

1.8. From 2005 I chaired a European Working party on pharmacovigilance and in 2012, I was elected Chairman of the Pharmacovigilance Risk Assessment

Committee of the European Medicines Agency. In this capacity, I was closely involved in the introduction of the new European Union ('EU') pharmacovigilance legislation.

1.9. Since 2003 I have been a member and subsequently co-Chair of the World Health Organisation ('WHO') Advisory Committee on Safety of Medicinal Products.

Chief Executive of the MHRA

1.10. Since 2019 I have been the Chief Executive of the Medicines and Healthcare products Regulatory Agency ('MHRA'). In this role I am accountable to Health Ministers for ensuring that the Agency takes all possible steps to protect the interests of the public, ensuring that medicines, medical devices and other healthcare products meet appropriate standards of safety, quality, efficacy and performance, and providing high standards of services to manufacturers, healthcare professionals, patients and the public.

1.11. Until 2022, the MHRA's activities were undertaken by three distinct centres, the Regulator, the National Institute for Biological Standards and Control ('NIBSC'), and the Clinical Practice Research Datalink. Following the UK's exit from the EU, the publication of the Government's Life Sciences Vision, and taking into account the recommendations of the Independent Medicines and Medical Devices Review ('the Cumberlege Review'), I have led together with the Agency Board, a transformation programme to create one integrated and cohesive Agency which places patients at the centre of all our activities.

Memberships

1.12. Beyond what I have set out above, I can confirm that I have not had any other membership or involvement with any other relevant organisation or group relevant to the Inquiry's Terms of Reference.

Litigation history

1.13. I have not provided evidence or been involved in any other inquiry, investigation or litigation relevant to the Inquiry's Terms of Reference or had any involvement which could be of interest to the Inquiry.

Preparation of this witness statement

1.14. I have prepared the responses in Section 1 of this witness statement in my own words and with my own first-hand knowledge. However, the preparation of the remainder of this witness statement has required the involvement of specialist officials within the MHRA and my legal counsel, using the confidentiality agreements that were approved in advance by the Inquiry.

Section 2: Definitions

2.1. Throughout this statement I refer to the following terms which I have sought to define:

a) **Blood**: means whole human blood collected from a donor and processed either for transfusion or for further manufacturing.

b) **Blood component**: means a therapeutic constituent of human blood (e.g. red cells, white cells, platelets and plasma) that can be prepared by various methods.

c) **Blood product**: means any therapeutic product derived from human blood or plasma.

d) **Blood establishment**: means any person who carries out any of the activities specified in the Blood Safety and Quality (Amendment) (No 2) Regulations 2005 SI 2005/2898 which require an authorisation by virtue of that regulation.

e) **Medicine**: means any substance or combination of substances that may be used by or administered to human beings with a view to restoring, correcting or modifying a physiological function by exerting a pharmacological, immunological or metabolic action, or making a medical diagnosis.

f) **Medical device**: means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used alone or in combination for a medical purpose.

Section 3: MHRA

3.1. The MHRA was established on 1 April 2003 and is responsible for delivering the regulation of medicines, medical devices and blood products for transfusion in the United Kingdom, acting on behalf of the Secretary of State for Health and Social Care.

3.2. The formation of the MHRA in April 2003 was the result of the Government's decision to merge the previous Medicines Control Agency ('MCA') and the previous Medical Devices Agency ('MDA'). The Government then decided to merge the National Institute for Biological Standards and Control with the MHRA in April 2013.

3.3. This means that the MHRA is currently responsible for:

a) ensuring that medicines, medical devices and blood components for transfusion meet applicable standards of safety, quality and efficacy;

b) ensuring that the supply and distribution of medicines, medical devices and blood components are safe;

c) promoting international standardisation and assuring the effectiveness, safety and quality of biological medicines through the development and provision of standards and reference materials, control testing, carrying out applied research and providing scientific advice;

d) informing the public and healthcare professionals about the risks and benefits of medicines, medical devices and blood components, supporting safe use; and

e) contributing to the development of UK and international regulatory frameworks for medical products so they are risk-proportionate, effective and remain relevant in protecting public health as medicine, science and technology continue to advance.

3.4. There is more specific information on the current strategic ambitions of the MHRA in the MHRA Delivery Plan 2021-2023 [WITN7135002].

3.5. As an Executive Agency of the Department of Health and Social Care ('DHSC'), the MHRA is able to protect public health with scientific integrity, independence

in regulatory decision-making, operational delivery and the necessary level of ministerial oversight and accountability to command public confidence.

3.6. The early detection of new and emerging risks, combined with a close working relationship with DHSC and its other Arms-Length Bodies, enables the MHRA to respond quickly to a wide range of public health issues and emergencies to help fulfil the statutory duties of the Secretary of State. This was clearly demonstrated during the COVID-19 pandemic, when the MHRA was able to respond quickly to the urgent demand for scientific advice, accelerated regulatory approvals and strengthened safety monitoring for clinical trials, diagnostic tests, medical devices, therapeutic medicines, vaccines and anti-viral treatments for this new global disease.

3.7. The MHRA is supported in its work by several independent expert advisory committees and working groups, which provide impartial scientific advice to ministers on the safety, efficacy or performance of medicines and medical devices and the investigation of adverse events.

MHRA and Blood

3.8. The MHRA is the UK competent authority for blood and blood components when used for transfusions. The MHRA is also responsible for some of the main 'pathways' for blood which align with other regulations (e.g. medical devices and medicines). The MHRA has powers to inspect blood donation centres and National Health Service ('NHS') blood banks, seeking assurance around quality and safety from donor selection, to blood processing prior to clinical use in the NHS. The MHRA is not responsible for the clinical use of blood in the NHS.

3.9. The MHRA is responsible for haemovigilance, which is a set of surveillance procedures covering the entire chain of activities, from the donation and processing of blood and its components, through to their provision and transfusion to patients, and including their follow-up. The Blood Safety and Quality Regulations 2005 cover areas such as donor selection and testing.

3.10. The MHRA inspects UK blood processing sites, fixed blood collection sites and a representative selection of mobile collection sites before issuing Blood Establishment Authorisations. The MHRA also supervises all Hospital Blood

Banks that receive blood components and inspects a representative number of those sites.

3.11. The MHRA became the Competent Authority for the post-market surveillance of blood components in 2003. The EU blood legislation was transposed into UK law as the Blood Safety and Quality Regulations 2005, with subsequent amendments being made as new EU legislation came into effect. These regulations are primarily for the control of blood components when used for transfusion, but they also regulate components such as plasma when used as a starting material for further manufacture. If these components are then used to manufacture a medicine or medical device, these subsequent activities are regulated by the MHRA according to the relevant medicines or medical devices legislation.

3.12. This legislation has detailed requirements on information to be provided to and obtained from blood donors, in addition to testing requirements, eligibility requirements and temporary or permanent deferral criteria for donors. Further requirements have been set for the storage, transport and distribution conditions for blood components.

Section 4: The MHRA's response to emerging risks

Detection of Emerging Risks

4.1. The MHRA detects emerging risks from the use of medicines, vaccines and medical devices by having several different mechanisms in place to collect data on suspected adverse incidents associated with the use of these products.

4.2. Firstly, manufacturers of medicines and medical devices have strict legal obligations to report adverse incidents to the MHRA when they identify a risk from their own pharmacovigilance systems. The Blood Safety and Quality Regulations 2005 (in addition to the EU Blood Safety Directive), for example, require serious adverse events and serious adverse reactions associated with blood and blood components to be reported to the MHRA.

4.3. Secondly, to support the detection of emerging risks with blood, there is a mandatory reporting mechanism for serious adverse events called the Serious Adverse Blood Reactions and Events scheme ('SABRE'). SABRE is an online system that allows blood establishments and blood banks to electronically submit these reports directly to the MHRA.

4.4. Thirdly, an independent haemovigilance scheme, Serious Hazards of Transfusion ('SHOT'), has been collecting and analysing anonymised information on adverse events and reactions in blood transfusions from all healthcare organisations involved in the transfusion of blood and blood components in the UK since 1996. This data is then made available to the MHRA as another source of information.

4.5. Fourthly, the Yellow Card scheme is the main route by which health professionals and patients can notify the MHRA when they suspect an adverse reaction has occurred. The scheme has evolved since its first introduction in 1964 following the thalidomide disaster. The Yellow Card scheme has been opened to all healthcare disciplines, patients and carers and reporting has been facilitated through developments in technology, such as the new Yellow Card website, a mobile App and through its integration into other healthcare systems and General Practitioner ('GP') prescribing systems.

4.6. The new MHRA SafetyConnect digital technology development programme now enables the MHRA to use specialist software to configure smart forms using conditional logic and schedule requests for additional information automatically based on the content of an initial Yellow Card report.

4.7. Further work is ongoing to make even more effective use of technology and data to detect emerging risks. Examples of this include extending the integration of Yellow Card with other NHS systems such as the NHS App and the new Learning From Patient Safety Events ('LFPSE') system, as well as making more use of artificial intelligence software to assess increasingly large volumes of data in the future.

4.8. The MHRA also actively reviews the published medical literature to identify any data that may be relevant to the safety of medicines, vaccines or medical devices. We recognise that there is usually a lag time between healthcare

professionals reporting adverse reactions to the MHRA and articles appearing in the medical literature.

4.9. Finally, the MHRA can request additional studies to be undertaken and/or registries to be created as part of a risk management plan to investigate or monitor potential harms where there could be a risk from a particular product. The data is collected and reviewed by the MHRA on a continuing basis to identify emerging risks at the earliest possible opportunity.

4.10. These examples demonstrate how the MHRA is seeking information and data from several different sources to detect emerging risks on the products it regulates. The investment in new technology, access to more data sources and the expansion of the Yellow Card Scheme mean that the MHRA is no longer reliant on a limited number of spontaneous paper-based reports from a small number of health professionals, as it may have been in the past.

Assessment and Response

4.11. Specialist MHRA Assessors review emerging risks and produce a Benefit-Risk assessment for specific products drawing on data from the wide range of sources listed above. This assessment will also be informed as appropriate by stakeholder engagement and input from patients, the public, the health system and the medical technology or pharmaceutical companies marketing the product. In more complex cases, where the benefits and risks of a medicine are more finely balanced or require specific measures to be in place in order for the benefit risk to remain positive, additional advice may be sought from the Commission on Human Medicines and its expert working groups. An example of a more complex case is that of the antiepileptic sodium valproate, an effective medicine which is associated with harmful effects when given in pregnancy and therefore requires a Pregnancy Prevention Plan to be in place in women of childbearing potential. The assessment will then consider all the available evidence and its robustness so that conclusions can be drawn on the potential or likely impact on patients from the use of that product comparing any risks to its benefits, both in individual patients and the population as a whole.

4.12. Benefit-Risk assessments lead to balanced scientific judgements and need to be updated and reconsidered when new or additional data becomes available.

Patient Involvement and Engagement

4.13. Increasing patient involvement at every stage of the regulatory process, from clinical trials and licensing through to post-marketing surveillance, is a priority for the MHRA. For example, the benefit-risk assessment review template includes a section for views from individual patients or patient representative organisations, and patients have given evidence directly to Expert Advisory Groups. In addition, a recent meeting of the Commission on Human Medicines was live-streamed and all of the MHRA Board Meetings held in public have been live streamed since 2020, with recordings published on our website, increasing transparency on the work of the MHRA to the public. It is anticipated that more MHRA regulatory meetings will be live-streamed in the future to maximise transparency and increase public trust in the regulatory system.

4.14. As an example of how patient involvement can affect regulatory decisions, recent MHRA engagement with patients living with diabetes and using insulin pumps helped to inform a National Patient Safety Alert on these products.

4.15. The MHRA has published a Patient Involvement Strategy 2021-2025 to provide more detail on how the public and patients will be involved throughout our regulatory work [WITN7135003].

Communication and Dissemination of Safety Information

4.16. The MHRA communicates information, advice and directions to healthcare professionals by publishing an electronic bulletin 'Drug Safety Update' every month and by issuing National Patient Safety Alerts to the healthcare system via the Central Alerting System ('CAS') when required. In addition, educational workshops and sessions are held with healthcare professionals.

4.17. An example of targeted safety communication was during the COVID-19 pandemic, when the MHRA produced a weekly email update on COVID-19 related issues, as well as emailing advice and information on specific safety issues to relevant stakeholders. Supplementary engagement was conducted through social media, the MHRA website and traditional media channels.

4.18. Another example of disseminating safety information to healthcare professionals has resulted from the integration of the MHRA Yellow Card

system into GP prescribing software so that the system flags safety warnings to the GP about the medicines being considered for prescription.

4.19. The MHRA also provides information on potential safety issues with medical devices to specific NHS Trusts or healthcare organisations where devices are being used. Devices' safety information is also published on the MHRA website.

4.20. In addition to disseminating information across the medical profession, the MHRA communicates information and advice regularly to the public and patients. This is done in person through MHRA events, workshops and research, as well as virtually through online consultations and via our Customer Service Centre, which receives over 1,000 enquiries per month. The MHRA also has a Patient Group Consultative Forum which provides a diverse pool of patients and patient organisations for the MHRA to consult and engage in the work of the agency. Other examples of public involvement include the four full-day MHRA Citizens Juries held in early 2022 to inform the development of the Yellow Card Biobank and the first pilot of a MHRA Patient Listening Event on surgical mesh in April 2022.

4.21. Finally, the MHRA engages the public through social media, the 'gov.uk' website, and the media as well as via specific advertising campaigns such as the 'Fake Meds' campaign highlighting the dangers of counterfeit medicines (see https://fakemeds.campaign.gov.uk/).

Working with the UK health system

4.22. In responding to evidence of an emerging risk of harm from a treatment, medicine or device, the MHRA liaises closely with the following bodies:

a) the NHS England Improvement Patient Safety Team to exchange information on adverse incidents;

b) the Adverse Incident Centres of the Devolved Governments of Scotland, Wales and Northern Ireland to exchange information on reports and availability of medical devices;

c) the UK Health Security Agency ('UKHSA') to exchange information, particularly in the area of infectious diseases; and

then participates in Incident Response Teams if applicable.

4.23. Depending upon the safety issue, the MHRA may also liaise with other key partners in the broader health system as required, such as the Medicines and Medical Technology Directorates of DHSC, as well as NHS Blood and Transplant, the National Institute of Health and Care Excellence, Health Research Authority, Human Tissue Authority and/or Care Quality Commission.

Preparedness for emergencies

4.24. The MHRA is integral to the emergency response capability of the UK, operating as it does across the research and development pathway for healthcare products. The MHRA facilitates safe and rapid approval of clinical trials, medical devices and medicines in response to the priority needs of the UK, NHS and public health systems in any given emergency. The MHRA is recognised as part the UK Government capability and capacity to respond and our role is referenced in the National Risk Register.

4.25. In addition to our role nationally, throughout the recent COVID-19 pandemic the MHRA operated as part of an international collaborative, the International Coalition of Medicines Regulatory Authorities (ICMRA). The role of ICMRA is now evolving and as part of this, recent work by MHRA in partnership with the Brazilian Health Regulatory Agency, Agência Nacional de Vigilância Sanitária ('ANVISA'), has developed the ICMRA Crisis Management Protocol that details how regulatory bodies will respond to emergencies such as pandemics and how they will leverage their respective national infrastructure to safeguard not only their own populations, but also support global health objectives.

4.26. The MHRA aims to learn from each major health incident to prepare for the next. The most significant and recent national response by the MHRA was provided during the COVID-19 pandemic, which led to considerable learning and developments in relation to innovative trial designs, early access to clinical data, rolling reviews of company data, parallel work processes and the ability to share insights with other global regulators. Another key learning was the need to communicate with all partners regularly so that flexible and pragmatic regulatory guidance could be provided at the earliest opportunity.

4.27. The MHRA's Safety and Surveillance teams continually assess evidence of risks associated with medicines and medical devices and reprioritise their work

based on these risks. The MHRA's staff can be redeployed across the organisation to respond quickly and effectively to new health challenges.

4.28. The MHRA works closely with the World Health Organisation on Influenza standards every year and is frequently asked to advise on new and emerging health risks in the UK and internationally. Critical responses are currently being provided to WHO on monkeypox and have previously been provided on significant international diseases such as Polio, Ebola and Zika.

Changes following the IMMDSR

4.29. Since the Independent Medicines and Medical Devices Safety Review (IMMDSR) was published in July 2020, the MHRA has reflected on its recommendations and has taken decisive action. This report reminded everyone that patient safety outcomes are a central thread in all the MHRA does and this underpins all regulatory decisions and strategies.

4.30. A new Chief Safety Officer role was created on the MHRA Executive Committee and Board to bring together the safety functions of both medicines and medical devices under one single leadership to coordinate activities, drive best practice and provide more flexible resourcing for emerging safety issues. This role brought together vigilance functions that historically had operated separately.

4.31. The MHRA Board also established a new Patient Safety and Engagement Assurance Committee to scrutinise the agency's performance in this area and provide regular assurance to the MHRA Board Meetings held in Public.

4.32. The MHRA has developed and started to implement a Patient and Public Involvement Strategy 2021-2025 (referenced in 4.15 above), with the result that patient and public involvement has become a central component of the MHRA Delivery Plan 2021-2023 (referenced in paragraph 3.4 above) and the personal objectives of every member of staff.

4.33. This strategic priority has also been supported by a significant investment in new technologies. The first example of this is the evolution of the Yellow Card reporting system (described above) on a new and more user-friendly web platform that is more intuitive and informative for patients, which reflects the feedback from patients that the MHRA sought.

4.34. The next major system transformation is a new and comprehensive SafetyConnect vigilance system, which will be deployed later in 2022 with the aim of strengthening safety signal detection from more data sources and managing signals of adverse events even more effectively.

Section 5: Compliance and Regulatory Action

Medicines and blood products compliance

5.1. As the Competent Authority, where there is an existing Blood Establishment Authorisation in place, the MHRA has the power to take action against an organisation by revoking (usually initiated by issuing a 'Cease and Desist' notice) or restricting its Authorisation (for example by imposing conditions as deemed appropriate). In situations where patients are considered to be at imminent risk, the Authorisation can be revoked immediately via the MHRA's Inspection Action Group. These powers are provided by regulation 5 of the Blood Safety and Quality Regulations 2005 (RLIT0001543).

5.2. For Blood Banks, where the site does not hold a manufacturing licence, the MHRA can issue a 'Cease and Desist' notice (under the guidelines for the Blood Safety and Quality Regulations 2005 (NHBT0203832).

5.3. The MHRA may also take action relating to an organisation's activity in other areas using guidance such as Good Practice Guidelines for Blood Establishments, Good Laboratory Practice, Good Clinical Practice and Good Pharmacovigilance Practice where actions taken can range from compliance management, removal from compliance monitoring programmes (specifically Good Laboratory Practice), warning and infringement notices through to stopping activities and criminal prosecution.

Medical device compliance

5.4. In response to the Inquiry's questions on other areas of compliance, the MHRA does have a range of powers available when breaches of the Medical Devices Regulations 2002 have been identified. Whilst the MHRA aims to work with organisations in order to bring them into compliance, the MHRA has a number

of legal notices which can be served on a company or individual found to be in breach of the regulations, including:

a) A compliance notice which outlines the specific breaches identified and instructs the subject to address the issues within 28 days of receiving the notice.

b) An information notice which requires that a company produces the information specified in the notice within a set time period.

c) A suspension notice which can be served immediately onto a subject that prevents the product from being supplied, offering to supply it, agreeing to supply it, exposing it for supply or possessing it for supply.

d) A safety notice which forces the company to remove a product from the market indefinitely.

5.5. It is a criminal offence to breach any of these notices and there is a maximum punishment of 51 weeks of imprisonment and/or an unlimited fine for doing so.

5.6. The MHRA also has the power to issue civil sanctions on an individual or business found to be in breach of the Medical Device Regulations 2002, as well as to enforce a recall of devices on the market if necessary to restrict the availability of a medical device in order to protect health

Section 6: Conclusions

6.1. As described throughout this statement, patient and public safety is the highest priority for the MHRA. It is also important to recognise the scale of the MHRA responsibilities in detecting and mitigating safety risks in a proportionate and responsive way on around 20,000 medicines, vaccines and blood products, as well as over 2 million medical devices used in the UK.

6.2. The MHRA organisation and its processes have evolved and have been strengthened since its establishment in 2003, particularly in the use of technology, integration with the NHS and with the involvement of patients.

6.3. The MHRA welcomes the opportunity that the Inquiry provides to reflect again on how our regulatory work and processes on blood products can be further strengthened to help keep patients safe in the future. We are committed to

doing our part in ensuring these lifesaving medicines meet the highest possible standards of safety.

Statement of Truth

I believe that the facts stated in this witness statement are true.

Signed……GRO-C……

09/08/2022

Dated……