Witness Name: Malcolm Qualie
Statement No.: WITN5761001
Exhibits: WITN5761002 – WITN5761003
Dated: 07/062021

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF MALCOLM QUALIE

I MALCOLM QUALIE, Head of Medicines within the Specialised Commissioning Directorate of NHS England and NHS Improvement (NHSEI) provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 2 June 2021 and will say as follows:-

Section 1: Introduction

1. I have been a qualified pharmacist for nearly 37 years and am a Fellow of the Royal Pharmaceutical Society. I am a registered pharmacist and therefore adhere to professional standards set by the General Pharmaceutical Council. I have worked as a clinical pharmacist within the NHS since qualifying having worked for nearly 20 years in the acute hospital sector (8 years within infectious diseases) and then from 2007 onwards in specialised commissioning initially working in the East Midlands Region as Policy Lead then at a national level within NHS England from its inception in 2013 as Pharmacy Lead and latterly Head of Medicines.

2. In relation to hepatitis C specifically, I was and still am a member of NHS England's national Hepatitis C Oversight Group providing pharmaceutical expertise and support in relation to hepatitis C treatments. I have also attended several NICE committee meetings as an expert commissioner witness in relation to hepatitis C treatments being considered by NICE as part of their Technology Assessment programme.

3. Except where otherwise indicated, the facts and matters referred to in this Statement are made within my own knowledge and I believe them to be true. Where they are not within my personal knowledge, I confirm they are true to the best of my knowledge, information and belief and the source of that information is set out in this Statement.

4. I have also considered the first written statement of Claire Foreman which was provided to the IBI on behalf of NHS England on the 14 February 2020 (WITN3953001). In my view, Ms Foreman's

statement also addresses the early access treatment programme that NHS England implemented in 2014 with regards to the emergence of new oral Directly Acting Antiviral drugs (DAAs) onto the market.

Section 2: Response to W3988

5. I make this statement to respond to an issue raised by an Inquiry Witness relating to a comment made to them by a clinician (Professor Thursz) in relation to a hepatitis C diagnosis and treatment, specifically regarding early access to a new Interferon-free DAA in 2014.

6. Specifically, the witness statement says *"Professor Thursz told us about his concerns regarding Malcolm Qualie, Lead Pharmacist NHS England, who was saying that they had to follow a process to fund the treatment. Professor Thursz said that in reality they were 'inventing the process and creating hurdles along the way'. Exhibited before me at Exhibit WITN3988056 is an email from Professor Thursz to the patient dated 7 April 2014. "*

7. The email from Professor Thursz referred to in the statement is dated 7th April 2014 ("the Email") and includes within the chain an email from me to the then Chief Executive of the Hepatitis C Trust relating to approval of the early access scheme for people at risk of dying from hepatitis C within the next year. My email confirmed the current position of NHS England and stated:-

   "As you know we have a process that we need to follow. This is particularly important given we are a national body and we need to demonstrate fairness in decision making across the population we serve. We have always stated both to the CRGs and Gilead that May is our intended target for a decision and this will still be 6 months prior to any NICE decision. I fully appreciate that patients may be waiting for this particular treatment and we will hopefully have a recommendation in the not too distant future".

8. In summary, my email confirmed that NHS England was following its processes in relation to the early access scheme and that a decision was expected on its approval in May 2014. In fact, the policy was published earlier on 19 April 2014.

9. It should be noted that at this time only one DAA had received a Marketing Authorisation from the European Medicines Agency (sofosbuvir) and no DAA had received approval for use in the NHS from NICE because these drugs were new and emerging. However, by the time of the Email and contrary to the view expressed by Professor Thursz to the witness, NHS England was taking proactive steps to make DAAs available for the benefit of the most severely ill patients.

10. At the time of the Email I was the Pharmacy Lead for Specialised Commissioning within the national team and provided professional pharmaceutical advice and leadership to Specialised Commissioning colleagues both nationally and regionally.

11. There appear to be two criticisms made in the witness statement. First, that NHS England was inventing the process of making DAAs available to patients and second, that NHS England was creating hurdles to their access. Both are unfounded.

12. With respect to the suggestion that NHS England was inventing the process of making DAAs available to patients, this is not correct. NHSE as a public body, must have processes in place in terms of its decision-making to ensure that it complies with its legal obligations and the NHS Constitution. I attach a copy of the process in place at the time entitled "Developing Clinical Commissioning Policies and Policy Statements for Specialised Services: A guide for Clinical Reference Groups" [WITN5761002]. This document set out guidance for a consistent approach to the development of NHS England specialised services clinical commissioning policies and policy statements. I also refer to NHS England's Commissioning Policy: Ethical framework for priority setting and resource allocation [WITN5761003]. This document set out that the purpose of setting out the principles and considerations to guide priority setting is (i) to provide a coherent framework for decision-making (ii) to promote fairness and consistency in decision-making and (iii) to ensure the reasons behind decisions are clear and comprehensive.

13. These new DAAs had not yet received NICE recommendations and had only received EMA approval in January, May and August 2014. The usual process for new drugs emerging onto the market is that they are made available to patients once they receive NICE recommendations. However, NHS England took the decision to make these emerging DAAs available in advance of NICE recommendations and in the case of daclatasvir/ledipasvir before an MA was granted because it recognised that there were some patients who could not wait. Ms Foreman's statement at paragraphs 11, 30, 121–124 further explains (i) NHSE's processes where funding of treatments has not been reviewed by NICE and (ii) the early access programme for the DAAs in 2014. Ms Foreman's statement confirms that Professor Graham Foster proposed the development of a policy to provide access to these new HCV treatments for patients with decompensated cirrhosis and that it was progressed in accordance with NHS England's policy (see preceding paragraph) and which involved clinical experts in the assessment of evidence and the setting of criteria for access. Between November 2013 to the publication of the interim policy on DAAs, we were also actively engaging with the relevant pharma companies to ensure supplies were available once the policy was approved.

14. With regards to the suggestion that "hurdles" were being put in the way of making DAAs available, this is again, incorrect. Whilst Professor Thursz may have thought the process was taking longer than it should have done, NHS England has a statutory obligation to ensure that its processes and

procedures are followed. Following EMA approval for one of the products (sofosbuvir), the policy was published three months later. However, in order for sofosbuvir (a DAA) to clear the HCV virus in a patient, it must be given with other DAAs according to its marketing authorisation. No other DAAs were licensed at the time so NHS England approved the use of two other DAAs prior to receiving their EMA approvals, so that sofosbuvir could be used earlier.

15. With respect to NHS England's obligation to follow due process in ensuring all patients have equal access to treatments based on clinical need I refer also to paragraphs 25, 27, 30 and 31 of Ms Foreman's statement. Ms Foreman's statement also confirms at paragraphs 123-124 that the early access programme cost £18 million and was able to treat 1,000 patients months in advance of NICE recommendations. As such, NHS England facilitated early access to DAAs for the sickest patients. This programme was put into effect in April 2014, the same month that the Email was sent and the interim policy is exhibited to Ms Foreman's statement at [WITN3953031].

16. With respect to NHS England's desire and objective to provide hepatitis C treatments at pace but in a structure that supported all patients with a clinical need and specifically those at high risk of organ damage I also refer to paragraphs 152-154 of Ms Foreman's statement.

17. NHS England's obligations to remain within budget and ensure all patients have equal access to treatments based on clinical need can be found at paragraphs 15-21 and 202-203 of Ms Foreman's statement.

18. It should also be noted that throughout the development of the early access scheme, NHS England was advised by NHS clinicians working within infectious disease and hepatology services.

19. In conclusion, NHS England took proactive steps to make the new DAAs available to the sickest patients and months in advance of NICE's recommendations and prior to some of the recommended medicines receiving EMA approval.

Statement of Truth

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

Signed GRO-C

Dated 07/06/2021