Witness Name: Prof Alison Strath
Statement No.: 1
Exhibits: AJS
Dated: 19 October 2023

UK COVID-19 INQUIRY

MODULE 2A

WITNESS STATEMENT OF PROFESSOR ALISON STRATH

In relation to the issues raised in the Rule 9 request dated 20 June 2023 in connection with Module 2A, I, Professor Alison Strath, will say as follows:

1. This statement covers the period from 21 January 2020, which is the date on which the World Health Organization (WHO) published its 'Novel Coronavirus (2019-nCoV) Situation Report - 1' and 18 April 2022, which is the date when the remaining COVID-19 restrictions were lifted in Scotland.

2. I have personally prepared this statement, referring to records and materials provided to me by the Scottish Government Covid Inquiry Information Governance Division.

3. Unless stated otherwise, the facts stated in my witness statement are from my own knowledge and recollection, otherwise they are derived from sources to which I refer and are true to the best of my knowledge.

4. References to exhibits in this statement are in the form [AJS/number - INQ000000].

Personal Details

5. I am the Chief Pharmaceutical Officer (CPO) for Scotland, based in the Chief Medical Officer's Directorate (CMOD) of the Scottish Government and have held this post since 1 September 2021.

6. From 1 October 2020 to 31 August 2021, I was acting CPO following the retirement of the previous incumbent and prior to that, from July 2002, I was the Principal Pharmaceutical Officer (PPO).

7. As CPO I am the professional lead for NHS pharmaceutical care and medicines policy in Scotland, providing advice to Scottish Government Ministers and strategic leadership to the pharmacy profession in Scotland.

8. In my previous role as PPO, I provided pharmaceutical expertise to the CPO, covering access to new medicines, the safety, supply and administration of medicines, and the development of community pharmacy services, including the underpinning IT infrastructure and pharmacy workforce developments.

9. I am a registered pharmacist (since 1990), a Fellow of the Royal Pharmaceutical Society of Great Britain (2010) and an emeritus professor at the School of Pharmacy and Life Sciences at Robert Gordon University, Aberdeen (2018).

10. I qualified as a pharmacist from Robert Gordon Institute of Technology in 1989 with a Bachelor of Science (BSc) (Hons) in Pharmacy and having completed a pre-registration training year subsequently worked in the following areas:

    - community pharmacy, including owning two community pharmacies in NHS Tayside (1996-2018) and NHS Fife (1999-2013).
    - academia as Professor of Community Pharmacy Practice at Robert Gordon University's School of Pharmacy and Life Sciences (2008-2018).
    - Scottish Government as Principal Pharmaceutical Officer (2002-2020).

11. I played a substantive role in the Scottish Government's response to the H1N1 pandemic in 2009 as PPO.

12. I am employed as a senior civil servant in Scottish Government. Up until 2021, I worked under various Service Level Agreements for other bodies in response to my role both as Acting CPO and PPO. I provided pharmaceutical and clinical advice in all three roles and therefore this statement covers all of these.

Role during COVID-19

13. From March 2020 until April 2022 when the remaining COVID-19 restrictions were lifted, my role in relation to COVID-19 was focused mainly on providing pharmaceutical and clinical advice in response to the pandemic.

14. I provided advice mainly to other directorates with Scottish Government, including but not limited to, Population Health, Covid Public Health and Enterprise & Life Sciences.

15. My three main areas of responsibility were focused on access to medicines and COVID-19 therapeutics, supply and administration of COVID-19 vaccinations and the delivery of pharmaceutical services. This included but was not limited to:

    - Managing shortages of essential medicines used in intensive care units (ICU) and end of life care
    - Managing shortages of renal replacement therapy
    - Supporting the establishment of a pharmaceutical service to the NHS Louisa Jordan Hospital, including medicines governance issues
    - Securing a stockpile of COVID-19 intensive care, palliative care and antimicrobial medicines
    - Purchasing tools (Rx-Info) to allow the tracking of medicine usage in hospitals
    - Developing deployment models for COVID-19 vaccines
    - Inputting to the development of clinical policies and guidance on COVID-19 therapeutics
    - Developing guidance on palliative care medicines
    - Commissioning guidance on the repurposing of medicines
    - Supporting IT developments in community pharmacy including access to the Emergency Care Summary and the roll out of NHS Near Me
    - Distributing COVID-19 testing kits via community pharmacy
    - Implementing a community pharmacy medicine delivery service
    - Introducing NHS Scotland Pharmacy First Service in community pharmacy

16. My pharmaceutical and clinical advice was provided to inform decisions made by Scottish Ministers and to develop guidance and advice to the health and social care sectors.

17. Some of this guidance was on a Four Nations basis and some Scotland specific. In doing so, I worked with several bodies, including but not limited to, the Department of Health and Social Care (DHSC), NHS England (NHSE), the Medicines and Healthcare products Regulatory Agency (MHRA) and the Home Office (HO).

18. Notably, my advice ensured continuity of access to medicines and vaccines for the treatment of both COVID-19 and non-COVID-19 health conditions, including securing the timely access to and deployment of COVID-19 vaccines within regulatory and extant best practice guidance and the supply of both repurposed and new novel therapeutics for the treatment of COVID-19.

19. There were occasions when I discussed emerging issues that were complex with other professional and clinical colleagues in Scottish Government or the NHS to seek their expert views, for example in relation to the latest epidemiology or procurement or storage processes.

20. In some instances, I would discuss issues with my CPO colleagues from across the UK, or colleagues in the MHRA, for example, delivery of aseptic services or regulatory matters. This allowed me to develop, when necessary, a consensual view to any advice I provided.

21. Alongside reviewing other policy areas' submissions and advice for Ministers, most notably vaccination policy colleagues, the significant areas of written advice which I provided to Ministers were as follows:

    - Suspension and reinstatement of meetings of the Scottish Medicines Consortium in response to COVID-19
    - Shortages, mitigations and allocation processes for COVID-19 critical and supportive care medicines
    - COVID-19 (and EU end of transition period) medicine arrangements proposals and legal implications (relates to building a stockpile of critical and supportive care medicines)
    - COVID-19 stockpile reimbursement
    - Off-label use of vaccines under COVID-19 National Protocols and Patient Group Directions
    - Mutual aid requests for medicines
    - Procurement, storage and distribution and supply of COVID-19 therapeutics

22. I attended meetings with Scottish Ministers, for example regarding the Flu and COVID-19 (FVCV) vaccination programme, the wider NHS response to COVID-19, the remobilisation of the NHS and on access to COVID-19 therapeutics. These meetings were all conducted virtually. I also attended Four Nation Ministerial virtual meetings when they were considering medicine related matters.

23. I provided clinical and pharmaceutical advice for Chief Medical Officer (CMO) letters as well as co-signing professional advisory letters from the CMO, the Chief Nursing Officer (CNO) and myself. These letters tended to be focused on the COVID-19 vaccination programme, however they also covered areas such as clinical trials for vaccinations and access to COVID-19 therapeutics.

24. I was, and in some cases still am, a member of several UK and Scottish COVID-19 advisory groups which are outlined below.

    UK Groups:

    - Four Nations COVID-19 supply cell (initially daily from February 2020 and then twice weekly until the end of March 2020)
    - COVID-19 Medicines Shortage Response Group (weekly during May 2020)
    - Remdesivir COVID-19 Access and Policy Group (weekly during June 2020)
    - Palivizumab National Expert Group (weekly during June 2020 and then ad-hoc)
    - Four Nations Weekly Stockpiling Steering Group (weekly from mid-July 2020 until the end of December 2020)
    - Four Nations Stockpiling Strategic Oversight Group (fortnightly from mid-June 2020 to mid-July 2020)
    - Four Nations Medicine Supply Strategic Advisory Group (fortnightly from mid-July 2020 onwards – this replaced the Four Nations Stockpiling Strategic Oversight Group)
    - Remdesivir Allocation Group (weekly from early October 2020 to early November 2020)
    - COVID-19 Access and Policy National Expert Group (ad-hoc from the end January 2021 onwards)
    - COVID-19 nMAB and Antiviral Access and Policy National Expert Group (ad-hoc from mid-June 2021)

- Antiviral Taskforce Devolved Administration Advisory Group (monthly initially and then weekly from June 2021)

Scottish Groups:

- Professional Advisory Group (PAG) (weekly from March 2020)
- Clinical and Professional Advisory Group (CPAG) – Care Homes (weekly from the end of May 2020 until early March 2021)
- Primary Care Recovery Reference Group (ad-hoc from June 2020)
- NHS Mobilisation Recovery Group (every three weeks from the end of August 2020 until mid-April 2021)
- Flu Vaccination and COVID-19 Vaccination (FVCV) Operational Stand-up Group (daily from November 2020)
- FVCV Delivery Programme Board (ad-hoc from November 2020 and then monthly)
- FVCV Policy Panel (ad-hoc from March 2021)
- COVID-19 Clinical Governance Group (vaccinations) (monthly from March 2021)

25. The above listed groups had different roles and remits. Each had a secretariat which produced advice notes including details on the actual dates of meetings, the attendees and key issues and actions. These were used to inform submissions to Ministers and/or to enable development of detailed sector or health and social care professional guidance.

26. I believe that the approach of establishing advisory and delivery groups with a range of membership both at UK and Scottish levels worked well.

27. It allowed for clinical and scientific advice from relevant experts, alongside input from both the health and academic perspectives, enabling the balance of benefits and risks of different options to be considered in an objective way. This was particularly valuable when considering the outputs from the COVID-19 therapeutics clinical trial platforms, where we benefited from the knowledge and expertise of some of the UK's most respected physicians, epidemiologists and data scientists.

28. The UK groups were also extremely beneficial in ensuring a consistent approach to both the response to medicines shortages and the development of clinical guidance and deployment models for COVID-19 therapeutics.

29. In terms of the Scottish groups, the Professional Advisory Group (PAG) provided expert clinical and professional advice to the CMO in response to the pandemic. It brought together a range of clinical multidisciplinary expertise and I found it helpful as a forum for the review of any draft advice or guidance being developed.

30. I was also a member of the Clinical and Professional Advisory Group (CPAG) which provided clinical and professional advice and guidance for protecting the care home sector during COVID-19.

31. There were also several existing UK groups that undertook COVID-19 related activities:

- UK Medicine Shortage Response Group (MSRG) (every two weeks)
- Four Nations Chief Pharmaceutical Officer Group (weekly from March 2020, moving to monthly from July 2021)
- Four Nations Transitional Period (TP) Planning Forum (EU Exit) (every two weeks)

32. The advice and clinical position changed over time depending on the epidemiology of COVID-19 and the developing evidence base. In addition, the personnel involved in the various programme also changed.

33. I believe the ability to be able to fully utilise both existing and new COVID-19 groups enabled policy officials to build on existing relationships and make progress quickly on the developing situation, whilst helping us pivot to where we needed to be as we gained a better understanding of the impact of COVID-19.

Initial Response to the pandemic January – March 2020

34. I first became aware of the growing concern in relation to COVID-19 in February 2020, after returning to work following a short period of bereavement leave in January 2020.

35. Initially, some of the EU Exit transition planning groups were used to discuss planning around the UK response to COVID-19, providing an opportunity to draw on some of our thinking about how to strengthen the UK medicine supply chain.

36. My first practical involvement was towards the end of March 2020, just prior to the first lockdown period being announced, and this was in response to queries from colleagues in another part of Government about the required alcohol content in hand sanitisers.

37. Thereafter, the advice I provided focussed primarily on medicine policy issues. My team and I worked with NHS colleagues to develop a palliative care toolkit to provide Health Board planners with support for local resilience planning during the COVID-19 pandemic. It was not intended to replace existing palliative care processes and guidance documents, but instead offered a range of practical approaches and tools that could be considered and adapted locally to strengthen any local response to the COVID-19 situation.

38. The CPO at the time handled most actions related to community pharmacy contractual and financial relaxations. This included, but was not limited to, business continuity, flexibilities in opening hours operated by community pharmacy owners, advance funding to alleviate cash flow challenges, prescription medicine delivery service fees and in due course, the provision of personal protective equipment (PPE).

39. I was directly involved in drafting and reviewing several professional letters on these matters given my community pharmacy experience.

40. I also worked with digital and primary care policy colleagues to support access to the Emergency Care Summary (ECS) for community pharmacists. The ECS provides a record of an individual's acute and repeat prescriptions. This access was to support community pharmacists and pharmacy technicians to respond to urgent supply prescription requests. Later, this extended to include access to NHS Near Me, a confidential and secure service which allowed individuals to consult with a healthcare professional using a video call, rather than attending in person.

41. I also worked with policy colleagues in substance misuse on the treatment of patients receiving opiate substitution therapy, including the option to switch to long-acting

subcutaneous injections of buprenorphine in both the Scottish Prison Service (SPS) and, where appropriate, in primary care.

42. To address the potential rise in demand for in-patient capacity and step-down care, the decision was made to stand up the NHS Louisa Jordan at the SECC in Glasgow. I ensured there was appropriate consideration of the pharmaceutical oversight, overseeing the appointment of a chief pharmacist, and the subsequent medicines governance issues, including controlled drugs requirements, which I commissioned via NHS Greater Glasgow and Clyde Health Board.

43. The first few months after March 2020, I was involved in responding to concerns on the impact of COVID-19 on the medicine supply chain, in particular intensive care unit (ICU) and palliative care medicines, as well as more general medicine shortages in response to an unprecedented surge in primary care prescribing. There was also a marked increase in medicine queries, either in response to safety or the possible benefit of certain medicines such as ivermectin.

44. I also worked with cancer policy colleagues to adapt an existing group that considered the off-label use of cancer medicines to focus on our response to the COVID-19 outbreak, renaming it as the National Cancer Medicines Advisory Group (NCMAG).

45. Interim governance arrangements for cancer medicines were issued by the Scottish Government, including oversight of proposed changes to adult Systemic Anti-Cancer Therapy (SACT) practice in the context of COVID-19. The three regional cancer networks worked together to facilitate rapid decision-making and support to ensure consistency in these changes. This was led by NCMAG on a 'Once for Scotland' basis where possible, to implement these interim changes into practice. The agility and collective clinical leadership skills was critical to the success of these arrangements.

46. I put forward a business case to support the procurement of reporting tools from the RX-Info IT system (called Define and Extend) to assist in collecting data on the stock holdings and stock usage in individual hospitals across Scotland. These tools were already in use in NHSE to support the potential impact of medicine shortages in preparation for the EU Exit.

47. I identified the need to establish a Section 93 Agency Agreement for COVID-19 medicines between the Scottish Government and the UK Government. Section 93 of the Scotland Act 1998 provides a mechanism to allow the UK Government to exercise certain functions on behalf of Scottish Ministers. It is necessary for a joint arrangement, known as an "agency arrangement" to be entered into between the Scottish Ministers and the UK Government Department following the making of a section 93 Order setting out how the functions are to be exercised.

48. At the start of the COVID-19 pandemic, the global medicine supply chain was under significant strain, and it became necessary under the circumstances for the UK Government to physically procure medicines to be used for the treatment of COVID-19. It was agreed that each Devolved Government would enter into their own Section 93 Agreement (or an equivalent agreement) with the UK Government.

49. A Section 93 Agency Agreement was required because the supply of medicines to the NHS in Scotland is a devolved responsibility. However, under the devolution arrangements the UK Government has a role in securing the medicines supply chain for the UK.

50. The Agreement is currently still in draft and covers activities undertaken by the UK Government during the COVID-19 pandemic, as well as for any future pandemic/emergency events and for business as usual medicines shortages. For COVID-19, these activities primarily included purchasing and allocating critical medicines for use in response to the pandemic. The draft Agreement is expected to be finalised by Autumn 2023. It has taken longer than initially anticipated due to capacity pressures at both UK and Scottish Government level.

51. My reflections on the initial weeks and months of COVID-19 were that they were intense, and we had to respond quickly to multiple priorities and issues, sometimes with imperfect information.

52. There were several examples of successful four nation working led by one partner to resolve an issue. One example of this was the English CPO seeking advice from the Royal College of Anaesthetists and the Faculty of Intensive Care Medicine, on revised treatment guidelines in the event of shortages of first line ICU treatment options, which benefited the whole of the UK.

53. Another example was the way the four nations, supported by NHSE, planned to procure and allocate ICU medicines in the event of a stock out of certain medicines. These interventions made a real difference to clinicians and healthcare systems working under unprecedented levels of pressure.

54. In addition, across the Scottish Government and with our health and social care partners, we worked in collaboration to co-produce solutions and ensure health and social care was delivered as safely as possible. Closer working relationships were forged during these times and will be a legacy from COVID-19.

55. Throughout the early (and subsequent stages) of the pandemic I was supported across all levels of my organisation to make decisions about the pharmacy and medicines related areas that fell within my policy remit and expertise.

Role in relation to non-pharmaceutical interventions ("NPIs")

56. I was not involved in providing any advice or decisions on COVID-19 regarding the NIKE conference in February 2020 nor the Six Nations ruby match in March 2020.

57. I was not involved in any decision making on the initial national lockdown in March 2020 or the subsequent lockdown period in January 2021.

58. The Scottish Government considered the impact of non-pharmaceutical interventions (NPIs) through a 'Four Harms' lens, with a group that considered direct and indirect harms from COVID-19 alongside wider societal harms such as the economy [AJS/001 - **INQ000131028**]. I was not involved in these meetings. That said, I do think that the 'Four Harms' approach allowed for a wider consideration to be applied to any decision making.

59. I did have to consider the impact of the first lockdown period on other business as usual programmes of work, such as the Scottish Medicines Consortium (SMC).

60. The SMC is a committee of clinicians, pharmacists, Health Board representatives, the pharmaceutical industry and the public, that decides which medicines should be accepted for routine use by NHS Scotland from cost and clinical effectiveness perspective.

61. We opted to suspend all meetings for three months in response to the significant uncertainty surrounding the COVID-19 pandemic and which resulted in a pause in the clinical decision making process.

62. In addition, the CPO at the time would have been involved in NPIs where they directly related to the provision of community pharmacy pharmaceutical services, such as the decisions to remain open during lockdown, social distancing measures and the provision and use of personal protective equipment and face coverings in pharmacies.

Divergence

63. In terms of different approaches across the UK there was some divergence throughout the COVID-19 pandemic. Where this happened, I believe that it was appropriate given the different epidemiology and prevalence levels of COVID-19, different NHS structures and pressures in the healthcare system itself.

64. For example, Scottish Ministers were keen to prioritise residents in care homes for COVID-19 vaccination and so I ensured our deployment model supported that as a priority. Our model ensured that the vaccine was packed down in NHS hospital vaccine holding centres and then it was transported and delivered by NHS nurses in the care home settings, in the absence of a Health Board holding a manufacturing and import authorisations and/or a wholesale distribution authorisation, but within the spirit of extant regulations.

65. Similarly, due to different NHS structures and GP contracting models, the initial availability of the Pfizer BioNTech COVID-19 vaccine and its complex characteristics meant we did not use GP practices in our initial stage of the vaccination programme.

66. This meant that COVID-19 vaccinations were available via GP practices in England ahead of Scotland. In addition, we did not use community pharmacy as part of the core vaccination programme, unlike other parts of the UK, however some Health Boards did use them in their local delivery plan.

67. Another example of divergence is the approach we took in Scotland to the stockpiling of COVID-19 critical and supportive care medicines. Working with the DHSC, NHS

National Procurement (NP) secured a stockpile of a range of around 60 critical care, antimicrobials and end of life medicines for any future COVID-19 waves. These were medicines that were deemed at highest risk of shortage through spikes in demand from further outbreaks.

68. In Scotland, we opted for NP to directly purchase the majority (75% of product lines) of NHS Scotland's share of the identified stock. The remaining 25% was sourced via UK-led sourcing work streams.

69. Whilst NP were guided by the DHSC product list and target volumes, our approach allowed NP to exercise discretion with some antimicrobials and palliative care medicines in terms of which presentations they purchased or whether they would purchase them at all. This helped ensure clinicians were familiar with the products they were administering, reducing the risk of errors.

70. NP also took responsibility for the subsequent management, storage and distribution of all the stockpiled medicines for both primary and secondary care, including, where feasible, the rotation of stock to minimise waste, with ongoing replenishment. This approach delivered financial savings through waste avoidance.

Role in relation to medical and scientific expertise, data and modelling

71. I was not a member of any of Scottish Government medical and scientific advisory committees. I was however, as mentioned previously, a member of the CMO's PAG and the CPAG for Care Homes.

72. Any advice I provided was in relation to COVID-19 vaccinations and therapeutics. I found the PAG, as I mentioned previously, a very helpful forum for review and constructive challenge on any developing guidance and/or advice.

73. From my perspective, my role at the CPAG meetings was more advisory, for example about the importance of care home staff taking up the vaccination offer. I also attended meetings with representatives from health and social care unions which were convened and led by the Scottish Government Workforce Directorate. At these meetings I provided updates on the vaccination programme and answered questions on issues such as the change to dose intervals.

74. I contributed to the UK COVID-19 Access and Policy National Expert Group and UK COVID-19 neutralising monoclonal antibody (nMAB) and Antiviral Access and Policy National Expert Group. These two groups provided 4 Nation interim clinical commissioning advice on each new COVID-19 therapeutic where the evidence from clinical trials demonstrated benefit in both hospitalised and non-hospitalised individuals. This resulted in UK wide clinical access policies for a) repurposed medicines including tocilizumab, sarilumab, dexamethasone, baricitinib and budesonide and b) novel therapies including remdesivir, molnupiravir, nirmatrelvir-ritonavir, Ronapreve® and sotrovimab.

75. I believe that both groups provided an invaluable forum for considering the scientific and clinical data on the emerging evidence base for repurposed and novel therapeutics. It also provided the opportunity to reconsider the evidence over time.

76. I do not recall having routine access to specific data and modelling throughout the COVID-19 pandemic, although I remember seeing modelling data at some of the meetings I attended, including at a UK level.

77. For example, DHSC colleagues routinely shared a COVID-19 data pack which included on their modelling work on priority hospital medicine supply using assumptions on COVID-19 related demand, non-COVID-19 demand, hospital and wholesaler supply, expected future deliveries and COVID-19 stockpiles covering critical care medicines, palliative care medicines, antibiotics and treatment medicines used for COVID-19 patients and primary care medicines. These data packs contained useful information on the supply situation, the analysis of the data, any clinical and policy considerations and any mitigations.

78. I also was presented with analytical data from the FVCV programme as vaccinations commenced and progressed.

79. During the first phase of the pandemic in early April 2020, when we had concerns about the potential for certain critical medicines stock outs, we agreed with NHSE that the Barnett formula would be used to support the regional allocation of stocks of critical and supportive care medicines to Scotland, resulting in 8% of available stock coming to Scotland.

80. Given the wide range of variables that could impact on the demand for a specific critical care lines (patient numbers, differences in therapeutic choices, the volume of stock already held locally and patient differences (e.g. weight based dosing, tolerance)), NP then allocated Scotland's share of UK procured stock to Health Boards based on occupied ICU bed numbers. These bed numbers were reported centrally by Health Boards on a daily basis.

81. The one exception was the scenario where evidence suggested that the NHS would completely stock-out of a medicine. In this case, Health Boards were asked to manually collate hospital stockholding and using that data alongside occupied ICU beds, NP calculated the final regional allocation of stock before a stock-out. The purpose of this was to ensure stock was exhausted around the UK at approximately the same time (for equity reasons and to avoid the need for local sharing). Over time the modelling became more sophisticated with access to better data such as ventilated ICU beds.

82. Once we rolled out the Rx Info reporting tools (Define and Extend) NP was able to track stock that had been ordered in each hospital and what had then been issued to wards. This provided a more detailed central oversight of what stocks hospitals were holding and using. It also identified hospitals that are holding more stock than they currently needed, supporting any mutual aid decisions both across Scotland and with our devolved nation colleagues.

83. Later in the pandemic, I facilitated the collection of data on the number of non-hospitalised patients treated with COVID-19 antivirals and neutralising monoclonal antibodies from weekly reports provided by each Health Board.

Role in COVID-19 public health communications

84. I did not have a direct role in the daily televised media briefings. My personal reflection is that these briefings were valued by both the public and the media. I did participate in one press briefing on 19 November 2020 which was at the start of the COVID-19 vaccination programme, where I discussed some of the challenges associated with the complexity associated with the logistics of the Pfizer BioNTech COVID-19 vaccine.

85. I drafted a Frequently Asked Questions (FAQ) document to support communication with health and social care workers in response to queries about the vaccination programme [AJS/002 - INQ000000000. This was in part to address questions about changes to the dosing schedule of COVID-19 vaccines.

86. As highlighted previously I was also involved in drafting and, in some cases, signing CMO, CMO/CNO/CPO and/or CPO letters on both the vaccination programme and on COVID-19 therapeutics.

87. I was involved in drafting letters to patient groups who were eligible to COVID-19 antiviral treatments. I was also involved in drafting materials for NHS Inform, Scotland's on-line national health information service, on COVID-19 treatments.

Role in public health and coronavirus legislation and regulations

88. I did not have a direct role in advising on legislation or regulations including the Coronavirus (Scotland) Act 2020. Neither was there a need to make changes to secondary legislation in terms of the NHS (Pharmaceutical Services) (Scotland) Regulations 2009.

89. I did have a role in considering amendments to the Human Medicines Regulations 2012.

90. The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 included the addition of regulations to allow for conditions to be attached to the temporary authorisations of an unlicensed medicine, such as a COVID-19 vaccine and for the expansion of the workforce legally able to administer a COVID-19 or influenza vaccine under an approved national protocol and allow vaccinations to happen on sites other than registered pharmacies, subject to the conditions set out in the protocol.

91. The amendments also allowed for healthcare professionals to prepare COVID-19 vaccines prior to administering them without the manufacturing licences or marketing authorisations which would otherwise be required and for COVID-19 and flu vaccines to be moved between premises at the end of the supply chain by NHS and HMS armed forces bodies without the need for a wholesaler dealer's licence.

92. I, alongside the CMO and CNO, clinically authorised the national protocols used in the vaccination programme.

Key challenges and lessons learned

93. I have not provided oral or written evidence to any Scottish or UK Parliament committees on the COVID-19 pandemic. Neither have I directly contributed to any lessons learned exercises.

94. Despite my significant involvement in the H1N1 pandemic of 2009, COVID-19 brought several unexpected pharmaceutical challenges, particularly in the early phase of the pandemic, which I would not have envisaged.

95. The most significant challenge, from my perspective, was medicine shortages in both primary and secondary care.

96. There was no doubt that the six week buffer stock that pharmaceutical companies had been asked to hold on UK soil in response to EU Exit planning helped mitigate the initial risk of medicine shortages.

97. However, the sharp increase in prescribing in March 2020 in primary care led to concerns about the availability of several important medicines such as asthma inhalers and paracetamol. It also led to an increase in workload in community pharmacy and a subsequent financial impact.

98. In addition, there was a complete stock out of some critical care medicines, alongside short supplies of a broader range of secondary care supportive medicines and possible alternatives. The areas of greatest concern included neuromuscular blocking agents, antibiotics and palliation medicines used in end of life care.

99. Whilst a legacy from the H1N1 pandemic was a UK Essential Medicine Buffer Stock (EMBS) it was unable to meet the demand of the emerging COVID-19 related shortages.

100. NHSE stepped up and sourced the required medicines on behalf of the UK. This approach to the procurement of these medicines was critical in ensuring the UK had the buying power to secure significant numbers of these medicines in a competitive

global market. It necessitated the drafting of the Section 93 agreement referenced in paragraphs 46-49.

101. In the early stages it was tricky to get initial insight into the approach that was being taken by the DHSC and NHSE to determining which medicines to procure and the quantities. This was not intentional but reflected the fast-moving nature of the situation. This was rectified relatively quickly and in time for any decision making about stock allocations where there were shortages or complete stock-outs.

102. NHSE led on seeking rapid advice from bodies such as the Royal College of Anaesthetists (RCoA) and the Faculty of Intensive Care Medicine, which allowed the publication of guidance to provide advice to intensive care clinicians in managing the use of alternatives to medicines, such as neuromuscular blocking agents.

103. In terms of lessons learnt I have reflected about whether there was more we could have done in advance of the COVID-19 pandemic. However, I am not sure we would have predicted the global impact of the pandemic on the medicine manufacturing and supply chain.

104. Once the scale of the challenge was understood I think that we worked collectively across the UK to ensure continuity of access to medicines essential for the both the treatment of COVID-19 and any consequences such as palliative care.

105. The pandemic also highlighted our reliance on a just-in-time medicine supply chain across primary and secondary care.

106. Learning from the COVID-19 pandemic in Scotland we have retained a revised stockpile of critical and supportive care medicines to provide a cushion for any future pandemic.

107. We have continued to invest in the RX-Info tools to ensure NP has oversight of the stock situation in hospitals; we have a Section 93 order to support any future UK medicine procurement; and NP are building a buffer stock provision into their contracting model for secondary care medicines.

108. Another challenge was at the initial stage of the vaccination programme. Not only were we handling vaccines with completely different characteristics to existing

vaccines such as storage and handling at ultra-low temperatures, but there was also limited information on the transportation of these novel vaccines.

109. This is not a criticism of the authorisation process, but there was little data available on the stability of these fragile vaccines to support transportation to remote and rural communities, including our three island Health Boards.

110. The MHRA worked incredibly constructively and quickly to seek to address these data and other data issues. It is worth highlighting the excellent briefing sessions run by the MHRA for each new vaccine, as well as the support they provided as we worked through deployment models and emerging issues. Equally, I believe that we worked very collaboratively across policy areas within Government, with stakeholders and across the UK to share information and find solutions.

111. An additional challenge materialised when we used these vaccines in the real world. Vaccinators reported being able to draw up additional doses to what had been specified in published information. This necessitated additional advice on how to do this safely, as well as increasing the volume of combined needles and syringes supplied with the vaccine to accommodate these potential additional doses.

112. In terms of lessons learnt I believe that we have a much better understanding of how to operationalise a mass vaccination programme and what is entailed in both preparing for and handling vaccines with very different characteristics. This was never tested during H1N1.

113. There are a few additional parameters that it would be useful for vaccine manufacturers to consider early in the authorisation process, such as transportation data, although I appreciate there is a balance to be struck between speed of authorisation and having all the ideal data.

114. One of the successful components of the UK Government's approach to COVID-19 was the Antivirals and Therapeutics Taskforce which assisted in identifying and trialling COVID-19 therapeutics, both repurposed and novel new ones, to ensure that the UK population would have access to clinically safe and effective treatments as soon as possible.

115. It was an excellent example of collaborative working across academia, industry and the NHS. The findings also had global reach.

116. I also believe that the approach used to testing novel antivirals through the PANORAMIC clinical trial ensured any decision to widen access to emerging therapeutics was based on robust evidence; again something we did not do when antivirals were used during the H1N1 pandemic.

117. The PANORAMIC clinical trial is a UK-wide study sponsored by the University of Oxford and funded by the National Institute for Health and Care Research to find out in which people new antiviral treatments for COVID-19 in the community reduce the need for hospital admission and improve their recovery. The first arm of the study, which is now closed considered an antiviral called molnupiravir. The second arm, which is still open, is considering an antiviral called Paxlovid®.

Informal communications and Documents

118. I was and still am a member of several WhatsApp groups within my Scottish Government policy area. I have no WhatsApp groups with Scottish Ministers. I am also a member of a Four Nations Chief Pharmaceutical Officers WhatsApp group.

119. These groups were helpful during the COVID-19 pandemic in that they allowed the sharing of relevant information and/or media announcements, facilitated general discussion, provided peer support and/or prompted the need for formal meetings on key issues.

120. This was particularly useful given the fast moving nature of planning during the pandemic. They helped with quick communications, which was particularly valuable when there was such significant volumes of email correspondence.

121. I can confirm that no decisions were taken in WhatsApp groups and all views and decisions with respect to pharmaceutical and clinical advice were fully recorded through Scottish Government email and/or within advice notes or other submission documents, as required by the Scottish Government policy.

122. Messages on these WhatsApp groups have not been retained, as either a default timer for disappearing messages was set, messages were deleted when read and groups are no longer available due to phone updates.

123. It is important to emphasise that in each of the WhatsApp groups, the purpose of them was to provide situational awareness and/or to alert others to emails or meetings that required attention or contained information. None of these groups were used to conduct business or for decision making.

124. I have considered the Module 2A list of issues dated 12 May 2023 and I confirm that I have included all relevant comments in relation to those issues, within the context of the questions asked of me.

Statement of Truth

I believe that the facts stated in this witness statement are true. I understand that proceedings may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief of its truth.

Signed: Personal Data

Dated: 19/10/2023