Witness Name: Professor Isabel Oliver

Statement No. 1

Exhibits: IO/0001- 0141

Dated: 17 May 2023

UK COVID-19 INQUIRY

WITNESS STATEMENT OF PROFESSOR ISABEL OLIVER

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1. I, Professor Isabel Oliver of the UK Health Security Agency, Nobel House, 17 Smith Square, London, SW1P 3JR, will say as follows:

2. I am employed by the UK Health Security Agency ("UKHSA") as the Interim Chief Scientific Officer a post for which I have had since 1 October 2021. Prior to this I was Director, National Infection Service, Public Health England (PHE) from April 2020 to September 2021, Director, Research Translation and Innovation, PHE as an additional role to from June 2019 – to July 2020 and Director, Field Epidemiology Service, Deputy Director, National Infection Service, PHE from April 2013 –to April 2020. Prior to the establishment of PHE, I was Regional Director (November 2009 to April 2013) and regional epidemiologist (August 20014-November 2009) of the Health Protection Agency in the South West.

3. I am a medical doctor with specialist training in public health medicine. I hold a medical degree (LMS) from The Universidad Complutense in Madrid, Spain. I have worked in the UK health system since completing my medical degree and I am a Fellow of the

Faculty of Public Health (FFPH) by examination. I hold other formal qualifications relevant to my current role including the Membership of the Royal College of Physicians (MRCP), a Master's degree in Public Health from the London School of Hygiene and Tropical Medicine and a Postgraduate Certificate in Medical Education. I am a visiting professor at the University of Bristol.

4. I make this statement in response to the request from the UK COVID-19 Inquiry ("the Inquiry"), dated 20 March 2023, under Rule 9 of the Inquiry Rules SI 2006/1838, requiring UKHSA to provide the Inquiry with a further corporate witness statement in respect of specified matters relating to Module 1.

5. UKHSA has already submitted a detailed corporate statement, signed by Professor Dame Jenny Harries. I will not cover in detail the topics already covered within that statement but will aim to provide further clarity on those topics previously discussed and provide additional information on topics that are of relevance to the inquiry's proceedings.

6. This statement is, to the best of my knowledge and belief, accurate and as comprehensive in response to the Rule 9 as is possible within the timescales available, at the time of signing. Notwithstanding this, it is the case that UKHSA continues to prepare for its involvement in the Inquiry and it is possible that additional relevant information may come to light as the Inquiry progresses. In this eventuality the additional information or relevant material will be provided to the Inquiry and a supplementary statement will be made if requested by the Inquiry.

7. The matters in my statement rely on a mixture of my own experience, the records of UKHSA and its predecessor organisations, and the input from a significant number of colleagues within UKHSA, who were employees of PHE or HPA, and some who have since left but hold relevant knowledge. These colleagues have been consulted as far as is practical, in order to provide as robust an account as possible on behalf of UKHSA.

8. Exhibits have been listed in this statement in response to the Inquiry's request and to provide context. I have not been able to review all the documents exhibited and a number of documents and activity discussed are derived outside the boundaries of my

own operational sphere. In this case I have relied upon subject matter experts to assist with the information presented.

Structure of the statement

9. The matters referred to in this statement relate, for the most part, to the date range as specified by the Inquiry, namely between 11 June 2009 and 21 January 2020. I will make it clear where I refer to matters outside this range.

10. In my statement I use the names of organisations as they would have been referred to at the time. For example, I refer to the Heath Protection Agency ("HPA") for specific work conducted between 11 June 2009 and 31 March 2013 and Public Health England ("PHE") for specific work conducted between 1 April 2013 and 21 January 2020. However, for consistency, I refer to the Department of Health and Social Care (DHSC) throughout, rather than the Department of Health (as it was known prior to 2018). The statement refers to a large number of organisations, institutions, frameworks and guidance. As a result, the statement sets out the full name once and then reference to initials which will be used thereafter. A full set of the acronyms used with an explanation is at **[EXHIBIT: IO/M1 0001]**

11. This statement has five sections broadly covering the following topics:
    - Section 1: The HPA (2003 – 2013)
    - Section 2: PHE (2013 – 2021)
    - Section 3: PHE's public health services and response to infectious disease threats
    - Section 4: EPRR arrangements, planning and exercising
    - Section 5: UKHSA (2021 – present)

12. The COVID-19 pandemic has had a profound impact on health and society, particularly among the most vulnerable. I welcome the opportunity to contribute to the work of this Public Inquiry to ensure that we learn the lessons so that in future we are better able to prevent, detect and control threats to health. As we learn lessons it is essential that we secure and maintain investment in public health functions and services to ensure health and prosperity. I would like to recognise the enormous efforts of my public health

colleagues in the fight against the pandemic and their dedication to protecting individuals and communities against infectious diseases and other threats to health.

Section 1: The HPA (2003-2013)

Functions & Accountability

13. As described in the first witness statement of Professor Dame Jenny Harries the Health Protection Agency (HPA) was a predecessor organisation of both the UK Health Security Agency (UKHSA) and Public Health England (PHE).

14. The HPA was established as a special health authority on April 2003, in advance of the Health Protection Agency Act 2004. This act brought together the HPA Special Health Authority and the National Radiological Protection Board (NRPB) to become the HPA in April 2005 as an executive non-departmental public body. In April 2009 the National Institute for Biological Standards and Control (NIBSC) became part of the HPA.

15. On 1 April 2013, as a result of the Health and Social Care Act 2012, the HPA was abolished and its functions were transferred to a new organisation, PHE, with the exception of those carried out by the NIBSC division which were transferred to the Medicines and Health products Regulatory Authority (MHRA).

16. As described in Professor Dame Jenny Harries' statement, the HPA as a non-departmental public body, was accountable to, but operated separately from, its sponsoring department (DHSC), and governance of the organisation was delivered by the following structures:

    - an executive group comprising the divisional directors and the Chief Executive Officer (CEO) /accounting officer that were responsible for day-to-day operations of the agency.
    - oversight was provided by a board comprising a non-executive Chairperson, non-executive members, and executive members. The board determined the Agency's direction, strategy, and business objectives. It ensured that it had adequate resources to meet its objectives and it monitored its performance.

Responsibility for running the business on a day-to-day basis rested with the Chief Executive and the Executive Group.

17. The make-up of the HPA board immediately prior to its abolishment in 2013 is described on page 42 of the 2012/13 Annual Report and Accounts. **[EXHIBIT: IO/M1 0002]**

18. The HPA held responsibility for the protection of the community against infectious diseases and other dangers to health (including chemical or environmental hazards such as extreme weather), the prevention of the spread of infectious disease, and the provision of assistance to any other person who exercised functions in relation to these matters.

19. The agency also held functions in relation to radiation protection including the advancement of the acquisition of knowledge about protection from radiation risks and the provision of information and advice in relation to protection of the public from such risks. In April 2009 the agency also received the functions of the National Institute for Biological Standards and Control (NIBSC). As part of the HPA, NIBSC continued to provide independent testing of biological medicines for the UK market.

20. The activity, strategic aims, governance and financial accounts of the HPA over the period in scope for Module 1 is described within the organisation's annual reports and accounts, which I have exhibited **(EXHIBIT: IO/M1 0003, IO/M1 0004, IO/M1 0005, IO/M1 0006, IO/M1 0007, IO/M1 0008, IO/M1 0009, IO/M1 0010, IO/M1 0011].**

21. As set out in Professor Dame Jenny Harries' first statement, the HPA's five principal roles were:

    I. Advising government on public health protection policies and programmes
    II. Delivering services and supporting the NHS and other agencies to protect people from infectious diseases, poisons, chemical and radiological hazards.
    III. Providing an impartial and authoritative source of information and advice to professionals and the public
    IV. Responding to the new threats to public health

V. Providing a rapid response to health protection emergencies, including the deliberate release of biological, chemical, poison or radioactive substances.

22. Below I provide three specific examples which demonstrate how the Agency carried out its principal roles. These examples focus particularly on the HPA's Emergency Preparedness Resilience and Response ("EPRR") functions:

Avian influenza A(H5N1), 2006

23. The spread of highly pathogenic A(H5N1) avian influenza raised concerns that this virus could lead to the next pandemic. The HPA's response to H5N1 avian influenza was directed by the Influenza and Respiratory Virus Programme Board (IRVPB) with teams across the organisation contributing to preparedness and response efforts. The Local and Regional Services (LARS) Division Pandemic Influenza Implementation Group was responsible for coordinating the implementation of public health actions at local and regional level through local Health Protection Units and regional teams. The Emergency Preparedness and Response (EPR) Division developed training for health professionals and designed and conducted exercises to ensure that local health services were prepared in the event of an influenza pandemic. Recognising the growing importance of pandemic influenza preparedness, the Agency established a Pandemic Influenza Office at its Centre for Infections ("The Office") in October 2005.

24. The Office coordinated the Agency's work on pandemic and avian influenza which was supported by many teams across the organisation. The Office also worked with national and international experts outside HPA. The Agency developed and distributed guidelines and algorithms to colleagues within the organisation, the NHS and other partner organisations. For example, an algorithm for management of returning travellers guided staff through the assessment of a patient with a fever returning from an area of the world where H5N1 was known to be present. Guidance was frequently updated to reflect the changing situation of poultry outbreaks and isolated cases of avian influenza A(H5N1) in wild birds.

25. The guidelines produced ranged from the Agency's Pandemic Contingency Plan to specific pieces of guidance for distinct groups and settings. The Agency's Influenza

Pandemic Contingency Plan and the DHSC's Influenza Contingency Plan were revised in October 2005, to reflect the new WHO phases and revised health impact projections.

26. Specific guidance was developed for funeral directors, prisons, and local authority domiciliary services, among others. All the guidelines were based on up-to-date scientific evidence, consistent and produced in conjunction with the appropriate professional and occupational bodies to ensure the information was relevant and met requirements.

27. All guidance was shared with the Devolved Administrations (DAs) and DHSC to help coordinate preparedness across the UK. Staff across the Agency were kept informed through regular Influenza Pandemic Preparedness Update newsletters. Guidance for the public was available on the HPA website. A system to record information on human cases of pandemic influenza in the UK was developed by the Agency to enable any future public health response. Training sessions were rolled out across England and shared with the DAs to ensure a coherence of UK-wide response.

Influenza A (H1N1)pdm09 virus, (2009 swine flu pandemic)

28. During the 2009 Influenza Pandemic the HPA augmented its influenza surveillance systems with additional elements to provide an early warning of influenza virus activity and respond to the need for timely and detailed information on the new threat. A variety of UK based surveillance outputs were produced including situational reports (SitReps); updates and bulletins published on the HPA website and ad hoc reports for external bodies including the Joint Committee on Vaccination and Immunisation (JCVI), the Scientific Advisory Group for Emergencies (SAGE), the European Centre for Disease Prevention and Control (ECDC) and the World Health Organization (WHO). The HPA gathered international intelligence on influenza through a range of monitoring mechanisms, synthesised it and communicated it to inform public health policy and action.

29. Surveillance data on influenza activity, combined with information from field investigations and research studies, enabled the HPA to provide an epidemiological picture of the occurrence of pandemic influenza in the UK and its impact in the

population. The HPA provided detailed information on circulating viruses including anti-viral drug resistance, the levels of illness occurring in the community and in hospitals and risk factors for severe illness and death. The information was used to inform control and prevention policy, as well as provide health professionals and the public with an understanding of the level of current and future threat and appropriate health protection measures. The HPA also conducted modelling which provided analysis on transmission patterns and quantified the impact of interventions to control the epidemic.

30. Between April and July 2009, the HPA, working closely with the NHS and others, was responsible for implementing measures with the aim of containing the newly emergent pandemic influenza virus in the UK. This included implementing local control measures for containing the virus in households, schools, at ports and in other settings. Local school closure along with mass prophylactic oseltamivir treatment of pupils had been used in England and elsewhere to contain school outbreaks of influenza A(H1N1)pdm09. Contact tracing of cases on board flights was undertaken to contain spread.

31. The HPA played an important role in the pandemic vaccination programme including supporting vaccine development, assessing vaccine effectiveness and safety monitoring safety and uptake.

32. The HPA provided a 24/7 response to media queries relating to the swine flu pandemic, providing information including on: the first cases of swing flu; the treatment of the cases and prophylaxis of close contacts; the management of cases in schools; public health actions in ports; production of the vaccine; mass gatherings; infection control; modelling; surveillance; containment and pregnancy. The HPA also liaised with other bodies to provide information on these areas.

Fukushima Dai-ichi nuclear accident, Japan, 2011

33. Following the Fukushima Dai-ichi nuclear emergency in Japan in 2011, when explosions at a nuclear power plant resulted in the release of radioactivity to the environment, the HPA co-ordinated the UK public health aspects of the response and provided health protection advice to the UK government. This included: (i) urgent

advice about the protection of British nationals in Japan, international travellers, the crews of ships in Japanese waters and products imported from Japan; (ii) environmental surveillance and monitoring; (iii) a modelling capability to assess, within two hours, the impact of a potential future release, and (iv) criteria to trigger monitoring of people coming by plane from Japan. The Agency's radiation protection specialists contributed to SAGE and to international expert panels to assess the levels and effects of radiation exposure caused by the nuclear accident, including the health risks to the Japanese population.

HPA role in health improvement, reducing health inequalities and health care public health

34. The HPA's principal roles related to health protection – as set out above. The HPA contributed health protection elements to national and regional efforts to reduce health inequalities with a focus on hard-to-reach groups and geographical communities that suffer deprivation.

35. The HPA worked closely with NHS Strategic Health Authorities and Primary Care Trusts (PCTs) supporting healthcare public health functions including provision of information to support commissioning of healthcare services. An example is the active role of HPA in supporting the efforts to improve access to genitourinary medicine services, implement chlamydia screening and deliver other improvements in sexual health services. Other examples of the HPA's work relating to health care public health have been provided above, where I have expanded upon the principal roles of the HPA.

36. At the time of HPA's existence, health improvement and healthcare public health functions were delivered by other bodies whose functions later transferred into either PHE or local Government. The categories of organisations that delivered health improvement and health care public health functions whilst the HPA was in existence are described below.

37. **Nationally:** The DHSC was the lead department responsible for the promotion and protection of the public's health and the reduction of health inequalities, setting strategic direction and developing policy. The Chief Medical Officer (CMO) was lead official

responsible for protecting and improving the health of the nation. Screening functions were delivered nationally in England via the NHS screening programmes and the UK National Screening Committee which was responsible for providing advice on screening to the UK countries.

38. **Regionally:** Regional Public Health groups comprised of DHSC and parts of the NHS-based teams. They were located within each of the government office for the regions and each NHS regional strategic health authority. These groups were led by the Regional Director of Public Health (RsDPH) who reported to the CMO and to the Strategic Health Authority (SHA) Chief Executive. The RsDPH were supported by the Public Health Observatories. The Regional Directors of the Health Protection Agency and their teams worked seamlessly with Regional Public Health Groups. The regional and specialist public health observatories produced information, data and intelligence on people's health and healthcare for practitioners, policy makers and the wider community. They worked closely with Regional Epidemiology Teams of the HPA that provided the intelligence function for health protection regionally. The RsDPH provided overall leadership for the public health function at regional level.

39. **Locally**: PCTs commissioned health services and worked with local partners to tackle health inequalities and improve public health. Directors of Public Health (DsPH) led the public health teams based in PCTs, including consultants in dental public health who worked with a range of partners to improve oral health and ensure patient safety and improved quality in dentistry.

40. The National Treatment Agency (NTA) for Substance Misuse was established in 2001 as a special health authority to improve the availability, capacity and effectiveness of drug treatment. The NTA also had a presence in each region.

<u>The extent of HPA's operational independence from the UK government</u>

41. The HPA was initially created as a special health authority in 2003, but subsequently established as an executive non-departmental public body sponsored by the DHSC and accountable to the Secretary of State for Health (SoS DHSC) and the Minister of State for Public Health. The SoS DHSC set out the aims and objectives of the HPA and was accountable to parliament for its performance. I have exhibited a fact sheet which

describes the various models for public bodies in existence at that time. [**Exhibit: IO/M1 0012].**

42. The HPA Board had corporate responsibility for ensuring the aims and objectives of the organisation were achieved and established the overall strategic direction of the agency within the policy and resources framework determined by the SoS DHSC.

43. As described above, the responsibility for running the business on a day-to-day basis lay with the CEO, supported by an Executive Group, and reporting to the Chair of the HPA. At an operational level the HPA: provided impartial, independent, authoritative and evidence-based advice to government, professionals, other agencies and the public; guided and lead its own research and development programme and delivered expert services which generated substantial external income, as well as from research grants.

Section 2: PHE (2013 – 2021)

Establishment of PHE

44. As already set out, on 1 April 2013, as a result of the Health and Social Care Act 2012, the HPA was abolished, and its functions were transferred to the SoS for DHSC. An aim of the reform was to bring together a range of organisations with public health responsibilities into one system directly accountable to the SoS for DHSC. Public Health England (PHE) was tasked with fulfilling the Secretary of State's duty to protect the public's health from infectious diseases and other public health hazards with the exception of those carried out by the NIBSC division which were merged into the Medicines and Healthcare products Regulatory Authority (MHRA).

45. The establishment of PHE brought together the three core strands of public health - public protection, public health improvement and healthcare public health – under the management of a single organisation. The decision to combine these three strands was made by the Government of the time and was considered and approved via highly visible parliamentary processes. Those closer to that decision making process will be best placed to provide specific insight into this decision. However, below I have

provided relevant excerpts describing the aims of this change, as officially set out by the Government within the Healthy Lives, Healthy People white paper in relation to the following areas: **[EXHIBIT: IO/M1 0013 - INQ000090323]**.

46. A new streamlined Public Health England:

> *"For the first time ever, there will be a dedicated and professional public health service, Public Health England, with a mission across the whole of public health – protecting the public from health threats, improving the healthy life expectancy and wellbeing of the population, and improving the health of the poorest, fastest. It will work closely with the NHS to ensure that health services play a strong part in this mission, and it will support them in that task. It will bring together public health functions that are carried out in different parts of the system at present into a new, streamlined whole so as to remove duplication and drive efficiencies and innovation".*

47. Emergency preparedness and response:

> *"…health protection and emergency planning and response functions from the Department of Health, the HPA and SHAs … will provide a high level of scientific expertise, available to all parts of Public Health England, to the NHS, to multi-agency partners, and to central and local government."*

48. Evidence for public health:

> *"Public Health England offers a unique opportunity to draw together the existing complex information, intelligence and surveillance functions performed by multiple organisations into a more coherent form and to make evidence more easily available to those who will use it, in a form that makes it most likely to be used."*

49. Within the series of Health and Social Care Act 2012 factsheets that were published at the time by DHSC, further strategic aims and perceived benefits of these changes were listed, and I have provided below relevant excerpts from these statements.

50. The "Reducing health inequalities" factsheet states: **[EXHIBIT: IO/M1 0014].**

"The White Paper Healthy Lives, Healthy People set out the practical steps we intend to initiate to tackle health inequalities across the life course, and across the social determinants of health that shape people's lives. A key aspect of this strategy is the establishment of Public Health England, a dedicated body to improve the nation's health. Public Health England will streamline the disjointed system of public health that currently exists. It will have an important role in reducing inequalities, enabling and supporting individuals and communities to improve their own health. It will work with the NHS and local government and other agencies to address the wider determinants of health."

51. The "New focus for public health" factsheet states: **[EXHIBIT: IO/M1 0015].**

"At the national level there is a clear rationale for accountability for health protection to rest with central Government, as the nature of various threats to health (ranging from infectious disease to terrorist attacks) are not generally amenable to individual or local action. Instead, they require clear "command and control" arrangements, resting on a clear line of sight from the centre of Government down to local services. To do this the Act abolishes the Health Protection Agency (HPA) and transfers its functions to the Secretary of State. Abolishing the HPA is part of a wider programme of reform that abolishes several other public health organisations in order to streamline a fragmented public health system. The aim of the reform is to exploit synergies across services and reduce inefficiencies due to overlapping responsibilities. Public Health England will bring together a range of organisations into one organisation in a public health system directly accountable to Secretary of State."

Establishment of UKHSA

52. With the subsequent creation of UKHSA, health improvement and healthcare public health functions were separated again from health protection. The SoS DHSC further set the rationale for this decision in a speech, delivered at the Policy Exchange in August 2020, describing the vision of what was then known as the National Institute for Health Protection (later renamed UKHSA) which I have exhibited **[EXHIBIT: IO/M1 0016].**

53. In a policy paper published in March 2021, DHSC set out that:

"To ensure we have a public health system fit for the future, we are ensuring that going forward both health security and health improvement have their own clear, dedicated focus at national level. By giving each the focus it deserves, and carefully managing the important interdependencies between these elements of our overall public health system, we can do both better. [**EXHIBIT: IO/M1 0017].**

54. The Government decision to separate the national health improvement, healthcare public health and health protection functions was made during the COVID-19 pandemic. PHE was not consulted on that decision, however, subsequently, PHE staff contributed to work to inform the design of UKHSA as did NHS Test and Trace staff.

55. From 1 October 2021 the health improvement functions of PHE moved into a new structure - the Office for Health Improvement and Disparities (OHID) within DHSC. Under the leadership of the CMO, OHID's aim is to work across DHSC, the rest of government, the healthcare system, local government and industry to deliver proactive, predictive and personalised prevention and promote good health. The f healthcare public health functions in PHE transferred into OHID, NHS England, NHS Improvement and NHS Digital **[EXHIBIT IO/M1 0018 - INQ000090371].**

56. From 1 October 2021 the health protection capabilities of PHE and of NHS Test and Trace (NHSTT) were combined into the new UKHSA which brought together heath protection scientific capabilities with operational capacity and cutting-edge analytics.

Functions and Accountability

57. The structures through which PHE was accountable to Government were described in the previous statement provided to the Inquiry pursuant to Module 1. This included scrutiny via Health Select Committees. In February 2014 the House of Commons Health Select Committee (HSC) published a report on PHE that was part of PHE's accountability **[EXHIBIT IO/M1 0019 - INQ000090340]**. The report identified some concerns raised by the Committee. Below I have clarified UKHSA's understanding of those concerns and the related actions taken by PHE.

58. The Committee reported on the opinion of the Faculty of Public Health (FPH) (the professional membership body for public health professionals) that the responsibilities for emergency preparedness across the health system were unclear. This action was for the Government, not PHE, to respond to.

59. The full finding of the Committee's report stated: *"The Committee recognises that PHE has worked to clarify responsibilities for emergency preparedness and has addressed a number of concerns raised in advance of the organisation's launch."*

60. The principal EPRR roles of each of the key health organisations post transition to PHE were summarised in The *Health Emergency Preparedness, Resilience and Response from April 2013* **[EXHIBIT: IO/M1 0020].** For PHE these included:

- ensuring there is a comprehensive EPRR system that operates for public health at all levels and assuring itself that the system is fit for purpose
- ensuring that PHE had plans for emergencies in place across the local area and that it was discharging local PHE EPRR functions and duties
- maintaining PHE's capacity and capability to coordinate regional public health responses to emergencies 24/7, and
- supporting the Regional Directors to implement the new EPRR model.

61. The main issue raised by FPH in relation to PHE was the relationship between PHE and local government. PHE's work with partners on EPRR was a major theme of its overall programme of work and had been directly addressed by 2018. By example there was a joint publication between ADPH and PHE on what good looks like for local health protection. **[EXHIBIT: IO/M1 0021].**

62. Since 2014/15 PHE had commissioned Ipsos MORI to carry out its annual stakeholder research, seeking the views and perspectives of leading stakeholders on:

- their working relationships with PHE
- priorities, ambitions and impact
- expectations of PHE now and in the future
- how PHE could improve what it did, and how it worked with stakeholders

63. The Ipsos MORI stakeholder survey was conducted with local authority chief executives and directors of public health, as well as leaders from national agencies, the NHS, academic, voluntary sector, professional bodies, businesses and other Government departments. The results were published on an annual basis, and I have exhibited those reports within scope of Module 1 **[EXHIBIT: IO/M1 0022, IO/M1 0023, IO/M1 0024, IO/M1 0025, IO/M1 0026].**

64. The 2018/19 stakeholder review, conducted by Ipsos MORI stated that 97% of local authorities (LAs) reported that PHE was performing its EPRR functions *well/very well*. For other partners this figure was 96%. Whilst some stakeholders may have considered that there was some lack of clarity about roles and responsibilities across the system, these positive scores would not have been possible unless there was clarity on PHE's role amongst its stakeholders.

65. The committee expressed a concern that in their view the CEO of PHE appeared as though he could not address the Committee on any public health issue without constraint. The Committee's comment was in relation to a question from the Committee on whether government policies had worsened health inequalities. The CEO made clear in his response that he was speaking to the evidence available but also stated that some government actions would be unhelpful. The report quotes him as stating *"As an agency, we are not in a position, from the evidence, to say about specific policies. If you ask a general question about whether Government action is helping or not, there are aspects of what the Government will be doing that are not helpful"*. The CEO's statement was made on 19 November 2013, less than eight months after the agency had been established.

66. PHE did a large amount of work to ensure that stakeholders had confidence in its work. This was very effective, as shown by the 2017/18 stakeholder review where 71% of stakeholders felt that PHE's advice was independent and only 13% felt that it was not.

67. The committee raised some concerns about a perceived insufficient separation between DHSC and PHE. PHE was established as an Executive Agency of the DHSC. As an Executive Agency, PHE was a unit of a central government department, DHSC,

administratively distinct, but legally part of it. PHE was set up to be the country's public health adviser and to:

- provide a single authoritative voice speaking for public health
- challenge central government to adopt evidence-based public health policy
- support local government in identifying their priorities for improving the health and well-being of their local populations.

68. The survey results quoted above showed that the advice provided by PHE was seen as independent by a clear majority of its stakeholders. The Government accepted that PHE would challenge it – in the formal Government response to the HSC report it was stated *"The Government accepts that sometimes what PHE publishes may be challenging, but there is no subject that is out of bounds."*

69. Furthermore, this topic was raised again during a meeting of the Public Accounts Committee in January 2015 discussing local authority grants for public health. The PHE CEO gave evidence at this meeting, providing several specific examples where PHE had published independent evidence which challenged government policy, on the wider determinants of health (through the global disease burden survey) on minimum pricing for alcohol, and on sugar taxation on soft drinks. I exhibit the report and transcript of this meeting **[EXHIBIT: IO/M1 0027, IO/M1 0028].**

70. Linked to the perceived insufficient separation between DHSC and PHE, the committee recommended that *"As part of this process (to clarify the relationship between DoH and PHE) the research priorities of PHE should be based on an analysis of public health priorities in England undertaken by PHE. PHE should not look to the Department or to other parts of Government to prompt its research or, still less, to authorise its findings. PHE can only succeed if it is clear beyond doubt that its public statements and policy positions are not influenced by Government policy or political considerations."*

71. PHE identified and articulated its research priorities to DHSC and research funding bodies such as the National Institute for Health and Care Research (NIHR) and UK Research and Innovation (UKRI). For example, in 2018 PHE conducted an internal process for the identification of future health protection research needs across various

topics in infectious diseases, chemical, radiation and environmental hazards, genomics and behavioural science. Its outputs were used by DHSC to inform the commissioning of NIHR Health Protection Research Units (HPRUs).

72. As already stated, the stakeholder survey results exhibited above showed the majority of stakeholders saw PHE's positions/statements being independent.

73. The committee noted concerns expressed by the Association of Directors of Public Health (ADPH) that suggested a capacity problem was beginning to emerge within local authorities because of unfilled posts, and that some DsPH did not enjoy a direct relationship with the Chief Executive and Cabinet members of their local authority and therefore it was difficult for them to drive public health reform.

74. PHE monitored the vacancy rate for DsPH and, with the DHSC, commissioned the Centre for Workforce Intelligence to conduct a survey of all practising public health specialists to ascertain their career intentions and aspirations over the subsequent five-year period. The survey was conducted in November 2013 and published in May 2014 **[EXHIBIT: IO/M1 0029].**

75. The age profile of the specialist public health workforce and the changes to the public health system indicated a risk that a number of senior public health specialists could be retiring or leaving public health practice. PHE and the DHSC created a suite of leadership initiatives to support the development of the next generation of DsPH and other public health leaders and professionals at all levels post-qualification. These included the Aspirant Director of Public Health Programme; Skills for System Leadership, a DH-funded programme, the Leadership for Change programme, launched in February 2014 and a talent management initiative involving leaders from across the public health system. PHE also worked with Health Education England to significantly increase the number of training places for specialist training, for example, for environmental health officers, health promotion specialists and school nurses.

76. Although there was some variation in line management arrangements for DsPH with not all reporting directly to the CEO, the 2015 ADPH survey stated that

- 98% of substantive appointments reported direct access to Cabinet members – (up from 90%)
- 70% were part of senior management teams in the council, and
- 72% reported appropriate influence across the whole council. **[EXHIBIT: IO/M1 0030].**

77. The Select Committee recognised that PHE's remit required it to engage closely with local authorities who were the employers of DsPH. The Select Committee had been told where there was a concern among public health professional bodies about the arrangements through which DsPH could exert influence with local government, including the annual assurance of the local authority public health grant. PHE responded to these concerns through making changes in the guidance about local management arrangements (though this was ultimately a decision for individual local authorities) and how PHE received assurance that the grant was being used within the terms on which the grant had been established by the Government. The PHE annual accounts, which included the grant, always received an unqualified opinion from the National Audit Office (NAO) and the NAO looked specifically at the issue in 2014 and concluded "The new public health agency Public Health England (PHE) has made a good start in supporting local authorities with their new responsibilities for public health. The National Audit Office considers, however, that it is too soon to tell whether the agency's approach is achieving value for money.".

78. The 2018 ADPH survey of DsPH, conducted five years on from transition from the NHS to LAs, showed that DsPH believed they had a high level of influence over public health **[EXHIBIT: IO/M1 0031].** 88% reported that being in the LA has given them the ability to "more effectively influence" wider determinants of public health and 89% reported being able to have "robust system leadership" over public health.

PHE's income

79. Details on the levels of funding that PHE received from DHSC, and other sources of income that PHE received, were contained in the previous statement to the Inquiry pursuant to Module 1. In addition, I set out below the gross external income figures for

the HPA and PHE in each financial year since 2009 (net income figures are not available). This income was used to maintain capabilities necessary to protect health.

Financial Year	**Gross External Income (£Million)**
HPA	
2009-10	£140.433
2010-11	£146.298
2011-12	£156.649
2012-13	£175,862
PHE	
2013-14	£231.588
2014-15	£235.916
2015-16	£228.116
2016-17	£236.192
2017-18	£246.659
2018-19	£240.884
2019-20	£233.106
2020-21	£193.757
2021-22	£247.145 (£105.353 for 6 months of PHE and £141.792 for 6 months of UKHSA)

80. HPA and PHE received external income from multiple sources including from the provision of services to the NHS, industry and other partners, from research and

development grants and commercial activities outlined below. The PHE income streams detailed above include vaccine sales to the DAs under the Barnett formula - the process used for funding the DAs.

Irrelevant & Sensitive

84. From 2016 – 17, as result of the spin-out of Porton Biopharma, PHE's gross income reduced, and the income was received by PBL. PHE did receive income from PBL in the form of a dividend which covered net profit only and further receipts for site rental. The difference between gross income and PBL income sources varied per year from 2016 but equated to around £25-30m in real terms.

85. PHE, and subsequently UKHSA, owned the patent for Dysport (a pharmaceutical product based on botulinum toxin type A) and had an income stream related to end-sales of this product. Royalties from Dysport were included within gross income. This was an income stream that was essentially all margin as licenced intellectual property (IP) with only very minor costs associated with it. These royalty receipts totalled £15-30m per annum over the period and can all be deemed as wholly contributing directly to public health outputs.

86. Profitability from the rest of the income portfolio varied between years, making the net contribution to public health difficult to quantify with full accuracy. However, it should be noted that all income was retained, therefore some income streams allowed (a) a greater core mass of staff to be employed in addition to the Grant-in-Aid (GIA) funding from DHSC who supported outbreak and incident response and (b) in some cases income directly or indirectly funded direct public health work that was required to be undertaken from the GIA allocation. This was the case within EPRR with external funding of exercises.

Managing funding cuts

87. As described in the previous statement provided to the Inquiry pursuant to Module 1, over its lifetime PHE's funding from central Government was reduced by over 40% in real terms. Below I provide further information on how PHE managed these cost pressures.

88. *Annual cost efficiency/reduction:* in most years PHE asked all budget holders to make savings of approximately 1 or 2% on their budgets – sometimes this included not allocating funding for inflation and pay rises (approximately 1% at this time). This is a common approach across the public sector and the rationale is that local budget managers need to identify actions that they can take to improve efficiency in their teams. Measures include rationalising product ranges to get better prices, taking advantage of new technologies that remove costs and reviewing the need to recruit to vacant posts.

89. *Change programmes:* many public sector organisations run large-scale organisational change programmes to deliver financial targets. PHE ran such a programme called *Securing our future* which started in 2014. The focus of this programme was a fundamental review of PHE's functions in the light of the 2013 Health and Social Care Act. All teams generated options for how they would deliver their functions in the context of an anticipated 20% reduction in budget between 2015/16 and 2019/20.

90. *Income generation:* about a third of PHE's direct running costs were funded through income. This was mainly gross income that enabled scientific capabilities to be sized at a level required to deliver PHE's functions, especially in an emergency response when commercial contracts could be varied. However, there was a small amount of net income, i.e. surplus, which contributed to delivering the reduction in costs required by the financial allocations from the DHSC. PHE did not set significantly higher income targets year-on-year as, in some cases, income targets had been markedly increased by HPA/DHSC to deliver balanced budgets prior to 2013.

91. PHE had a portfolio of income generation that enabled it to maintain core national capabilities at existing levels as well as developing capabilities that, though dependent on external income, could contribute to the national infrastructure and emergency response. For 2020/21, PHE's income budget (i.e. the planned, or anticipated figure for that financial year's income) was £181 million which was 39% of the total operating budget of the agency (£181m income and £287 million grant-in-aid). The net margin of this income above the costs required to deliver the projects equated to approximately £60 million. This funding was used by PHE to mitigate the impact of the real terms' reduction in government GIA funding and limit the effect of funding reductions on the delivery of public health and scientific functions.

92. Although income generation activity covered its costs and generated resources that could be used to help reduce the impact of reductions in government GIA funding on these services, it required significant senior and specialist staff time to make bids and deliver projects to time, quality and budget. There were opportunity costs from the specialist capacity or resource being used to secure income, but this is difficult to quantity due to the number of functions across PHE that contributed to the organisation's preparedness.

EPRR Funding in HPA

93. Exhibits of the previous statement provided to the Inquiry pursuant to Module 1 showed that the core annual funding received by HPA between 2009/10 and 2012/13 reduced from £172.2 million to £142.4 million. Over this period, regional EPRR resourcing, in terms of whole-time equivalents (WTE) capacity and relative seniority, and that of other teams supporting EPRR functions, reduced. Consequently, this impacted on the ability of regional teams to undertake EPRR functions, including engaging in multi-agency pandemic preparedness work. Reductions in funding also impacted on the HPT workforce which would have had a further impact on EPRR capability. Over the same period guidance changes introduced Local Health Resilience Partnerships (joint NHS and Local Government led bodies) to coordinate EPRR across local health economies – these were not always coterminous with LRFs, potentially further increasing demand.

Staffing levels

94. In 2014 PHE undertook a change programme called '*Securing our Future'* at the same time that PHE's operational GIA budget for 2014/15 was significantly reduced. The organisational change programme focused on core themes such as ensuring PHE's science continued to compete with the best in the world and aligning PHE's local presence with how local government organised itself (PHE Annual Report 2014/15, p.34) **[EXHIBIT: IO/M1 0032 - INQ000090405].** To prepare for the budget reduction, voluntary exit and redundancy programmes were agreed with the DHSC and Cabinet Office (CO) to reduce the workforce by around 200 net whole-time equivalents (PHE Annual Report 2014/15, p.88) **[EXHIBIT: IO/M1 0031 - INQ000090405].**

95. Results from the organisational change programme included staff reductions under the '*Securing our Future'* voluntary exit scheme (page 127, PHE Annual Report 2014/15) and a reduction in the number of local PHE centres, from fifteen to nine, t and the establishment of the National Infection Service (PHE Annual Report 2015/16, p.120) **[EXHIBIT: IO/M1 0033 - INQ000090406].** The programme challenged the operational structures in PHE at the time and sought more efficient ways of working to deliver best

value for money, concluding during the 2015/16 year (PHE Annual Report 2015/16, p.84) **[EXHIBIT: IO/M1 0033 - INQ000090406].**

96. In the year 2016/17, approximately 400 staff reductions were planned, for the four years between 2016 - 2020, to ensure the delivery of savings and efficiencies that were required of PHE:

- 2016-2017 – 206 staff scheduled to leave
- 2017-2018 – 146 staff scheduled to leave
- 2018-2019 – 15 staff scheduled to leave
- 2019-2020 – 36 staff scheduled to leave.

97. PHE applied to and received from DHSC transition funding to cover the cost of these anticipated staff exits **[EXHIBIT: IO/M1 0034].**

Local and Regional EPRR Arrangements

98. As detailed within UKHSA's first statement, the reductions in funding to PHE resulted in restructuring of some EPRR functions, particularly within the regional teams. It is not possible to identify the levels of EPRR staffing in the regions and centres in 2010 and 2019 to conclude what change took place in this period.

99. The limited capacity for EPRR in Centres and Regions was a result of the funding and structures transferred from the HPA and the on-going financial constraints on PHE from DHSC allocations. This meant there had to be prioritisation decisions about EPRR work such as attendance at multi-agency groups and general health protection leadership role in this space.

100. The material above in paragraphs 45-50 about the work with local government and the NHS on EPRR shows that despite the restructuring, there was improved understanding about EPRR roles and responsibilities over the period up to 2019.

Staff Morale

101. The frequent reorganisations of the public health system had an impact on staff morale and the delivery of public health programmes but there is limited information available on these impacts. CO produced an annual PHE People's Survey which measured employee satisfaction and engagement across a number of categories or 'themes'. Several 'themes' captured in each survey, between 2014 – 2017, have been identified as proxy measures for the effect of organisational change on staff morale and the capabilities of PHE's workforce as these were not directly measured by the People's Survey.

102. The survey measured employee engagement (designed to measure employees' commitment to their organisation's goals and values, and motivation to contribute to organisational success) through the 'Engagement Index' (EI). Results show the employee EI rose 6% between 2014 and 2017, from 53% to 59%. The EI dropped to 52% in 2015 before rising to 56% in 2016, coinciding with the organisational change that was implemented within PHE at the time.

103. The survey also recorded how staff felt about leadership and managing change in PHE. The percentage of employees satisfied with 'Leadership and Managing Change' rose from 31% in 2014 to 42% in 2017. This figure dropped to 30% in 2015 and rose to 38% in 2016. Employee satisfaction with work rose from 74% in 2014 to 78% in 2017 and rose 2% from 74% in 2015 to 76% in 2016. It should be noted that the survey's questions were asked in relation to the employees' experience at the time as opposed to how staff felt about past organisational changes.

104. The percentage of employees satisfied with 'Pay and Benefits' was the only theme which saw an overall reduction in satisfaction for the period between 2014 and 2017 with 41% of employees satisfied in 2014 compared to 38% in 2017. The figures for 2015 and 2016 were 39% and 40% respectively. Despite this, overall employee well-being rose 3% from 64% in 2014 and 2015 to 67% in 2016, remaining at 67% in 2017 **[EXHIBIT: IO/M1 0035, IO/M1 0036, IO/M1 0037, IO/M1 0038].**

Section 3: PHE's Public Health Services and response to infectious disease threats

Port and Border Health

105. Port health functions in PHE were delivered through a dedicated port health team based at Heathrow airport, PHE local Centres and various specialist teams in the Centre for Radiation Chemicals and the Environment (CRCE) and the National Infection Service (NIS).

106. Local PHE Centres were responsible for the protection of the health of their local population and each region had a response plan at local level should there be a public health incident at the Border. Their staff were also usually appointed as Proper Officers (or Medical Officers) for the Local Authority/Port Health Authority under the Health Protection Regulations 2010, for the purposes of conducting a risk assessment when such an incident is reported. These officers are empowered to undertake specified actions in the Public Health Ships and Aircraft Regulations for the purposes of preventing the spread of hazards and disease. Further actions, should they be required, may also be provided by other public agencies, for example the local ambulance service, local authority or Border Force, informed and supported by public health advice and with our support.

107. The dedicated Port Health team at Heathrow delivered health protection and immigration-related health assessment functions at Heathrow and Gatwick. The Food Water and Environmental (FW&E) Microbiology Laboratories within NIS acted as Official Control Laboratories for the examination of imported foods sampled at Border Inspection Posts and provide sampling, testing and advice regarding food and water hygiene on-board ships.

108. In 2017, the Government made a decision that it would cease the on-entry TB screening programme that HPA had run and had transferred to PHE in 2013. PHE had put in place a system of assurance of overseas in-country TB screening programmes. Alongside this PHE conducted a review of its public health services at Ports, that considered the need to rapidly respond to Public Health Emergencies of International Concern including, for example, the provision of a port of entry screening service as

part of the response to the Ebola outbreak in West Africa, or the response to the Zika outbreak (aircraft disinfection) and Fukushima radiological incident.

109. A key objective of the review was to define the roles and responsibilities of PHE in relation to public health at the border and ensure that these were aligned and agreed with key partners in DHSC and across Government, via a process of stakeholder engagement. Following the review process and engagement, the key public health services and functions to be delivered by PHE at the border are described on pages 18-20 of this review **[EXHIBIT: IO/M1 0039, IO/M1 0040].** This showed that effective UK-wide border health required a wider piece of work and review, not only the work within PHE.

110. As a result, and as described by Professor Dame Jenny Harries in her first statement, in 2019 PHE proposed to DHSC via the EPRR delivery group, that a national port health plan be developed to improve the public health core capacities at ports, as set out in the international health regulations. I have exhibited the initial proposal paper from PHE **[EXHIBIT: IO/M1 0041]** and the action plan **[EXHIBIT: IO/M1 0042]** that was shared with the EPRR Delivery Group in October 2019, outlining the proposal to improve work at Borders. DHSC had agreed that a programme of work should take place, although by January 2020 internal planning had progressed but the external engagement with other partners (such as local government port health authorities, Border Force, port owners etc) had not.

Behavioural Science Capabilities in PHE

111. As described by Professor Dame Harries in her original statement, PHE had a small behavioural science capacity which could be applied as part of the public health response to infectious disease incidents. Below I have described the work of this team by providing two examples of their work on significant outbreaks of infectious diseases over the time period in scope.

112. Swine Flu (2009): The Behavioural Science Team (BST) was based in the Emergency Response Department of the HPA and subsequently in the same department in PHE's Health Protection and Medical Directorate. The team were a largely externally funded (research grants and contracts) applied research and evaluation function, providing

subject matter expertise in the behavioural and psychological aspects of health protection incidents and public health emergencies, with a particular focus on Chemical, Biological, Radiological and Nuclear (CBRN) incidents. In 2009, the team comprised three individuals.

113. The team lead was a participant in SPI-B during the Swine Flu response and provided ad-hoc support as required to the HPA's response. The terms of reference and activities of SPI-B are available from the SAGE Secretariat, however I have exhibited details on the activation of SPI-B exists here: **[EXHBIT: IO/M1 43]** and further information about the role and impact of SPI-B can be found in the independent Hine review **[EXHIBIT: IO/M1 0044].**

114. In parallel, in partnership with academic partners, the BST conducted some applied research during the response, described in the following publications **[EXHIBIT: IO/M1 0045, IO/M1 0046, IO/M1 0047].**

115. Ebola (2014-15): During the Ebola outbreak, the BST contributed a session on the training for PHE staff deploying to West Africa, as part of a multi-day course delivered at PHE Porton Down, preparing predominantly laboratory staff. This 1 hr session was entitled, "*Supporting staff during and after deployment*" and covered topics including recognising sources of anxiety and stress, concerns about exposure, signs of stress, looking after yourself physically, looking out for your colleagues and how to seek support on return. Further, the session sign-posted to a BST authored e-learning module on Psychological First Aid (PFA) for course attendees to complete in their own time and to Mental Health First Aid Training supported by PHE.

116. In parallel, in partnership with academic partners, the BST conducted applied research during the response, described in the following publication **[EXHIBIT: IO/M1 0048].**

Mathematical Modelling Capabilities in PHE

117. As referred to within UKHSA's corporate statement, pursuant to Module 1, PHE had a small mathematical modelling capability that could be applied to assess and predict the potential public health impact of newly emerging and infectious diseases and the

impacts of countermeasures and interventions. I provide more information on this below.

118. There was a considerable amount of work undertaken in the decade between the 2009 H1N1 influenza pandemic and the start of the COVID pandemic in 2019, and I have listed the major pieces of work below.

119. Whilst there was an attempt to undertake real-time modelling during the 2009 H1N1 swine flu pandemic, this was limited by the lack of functioning and tested models in place prior to this pandemic. However, models were developed and whilst not used in real-time, were reported on once the pandemic was over. For example, see **[EXHIBIT: IO/M1 0049].**

120. Over the following decade the models used in the H1N1 pandemic were extensively developed and tested. This was mainly in part due to the awarding of an NIHR Health Technology Assessment grant to further develop the influenza pandemic real-time model which was began during the 2009 H1N1 pandemic. This was published in 2017 and I have exhibited the full report **[EXHIBIT: IO/M1 0050].** Methodological approaches to estimation of severity were also refined and published and I exhibit these **[EXHIBIT: IO/M1 0051].** The severe 2017/18 influenza season was used to test the suit of pandemic influenza models to assess their performance **[EXHIBIT: IO/M1 0052].**

121. All of the above was undertaken to ensure that the UK had a set of functioning and tested models that could provide the basis of nowcasting and forecasting in the event of an influenza pandemic. However, it was always anticipated that they could be repurposed to use alternative informing surveillance data in response to a respiratory pandemic other than influenza, as it happened during COVID-19, as they essentially provide a general means of reconstructing the pandemic via back-calculation.

122. All models are a simplification of real-world phenomena, of which pandemic models are just one example. The real-time pandemic models that have been developed provide a coherent framework within which the dynamics are captured. They also triangulate several important epidemiological parameters such as the reproduction number, infection hospitalisation ratio, infection fatality ratio, by both age group and

geographical region, to provide time varying statistical estimates of these that are most consistent with the surveillance data informing the model **[EXHIBIT: I/M1 0053].**

123. There is no one stream of surveillance data that captures all the dynamics. Some surveillance data capture the shape of the epidemic curve (reported cases, deaths, hospitalisations, etc), others capture the scale of the pandemic (serology), whilst others capture interventions (temporal population mixing matrices, vaccinations delivered, etc), with the pertinent data streams are used to inform the model. The results for the PHE/Cambridge real-time model have been occasionally published. More importantly they were provided to SPI-M-O every week for consideration with other models to be formally combined into consensus statements as to the current situation (nowcasts) and likely futures (forecasts). These provided the regions and age groups estimates of disease incidence, and prevalence and numbers of deaths and hospitalisations in near real time.

124. From 1 April 2014 – 31 March 2020, PHE was part the NIHR Health Protection Research Unit (HPRU) in Modelling Methodology in partnership with Imperial College. Following an open competitive process, since 1 April 2020, PHE has been part of the Modelling and Health Economics NIHR HPRUs with Imperial College London and the London School of Hygiene and Tropical Medicine (LSHTM). NIHR HPRUs are formal partnerships between universities and UKHSA (and its predecessors) established to meet the evidence and research needs of UKHSA.

125. When real-time modelling is used to inform decisions as part of incident response, DHSC wishes to have modelling performed independently by different groups and then compared in SPI-M meetings. This means that during the COVID-19 pandemic PHE/UKHSA modellers worked independently from Modelling HPRU members at Imperial College and at LSHTM for real-time modelling of pandemic influenza, and latterly SARS-COV-2 (with Cambridge being involved in the PHE/UKHSA real-time model).

Infectious Diseases strategy

126. Below I provide information on the strategic approach to infectious diseases and the history of the development of PHE's infectious disease strategy.

127. DHSC holds overall national leadership for infectious diseases control strategy, and in 2002 they authored "*Getting Ahead of the Curve – a strategy for combating infectious diseases*". This strategy led to the establishment of the HPA but was not updated by DHSC during the lifetime of HPA or PHE.

128. In the HPA and PHE, up to the publication of its infectious disease strategy in 2019, strategic direction for infectious diseases was set via the organisations' corporate strategy. Whilst there was not a standalone infectious diseases strategy in place, the organisations set strategic priorities for infectious diseases which ensured continued development of the organisations' capabilities around protection from infectious disease threats.

129. The infectious disease strategic priorities and objectives for PHE, as set out in its annual business plans included:

- Delivering the Collaborative Tuberculosis (TB) Strategy for England, in partnership with NHSE, aimed at reducing and ultimately eliminating TB as a public health problem. The strategy included:
    i. A programme for whole genome sequencing to improve diagnosis, treatment and public health management of TB.
    ii. Working with local partners, including local authorities and NHS, to set up local TB control boards, focusing on areas of high incidence and supporting NHSE to introduce active case finding in underserved populations and the systematic implementation of new errant latent tuberculosis testing and treatment.
- Supporting the Government's ambition to reduce antimicrobial resistance (AMR) by working with the NHS, particularly on reducing inappropriate prescribing including through behaviour change.
- Improving access to HIV testing outside conventional sexual health services through working with local authorities to establish a national home sampling service, delivering up to 50,000 postal kits.

- Delivering routine genome sequencing of specific infectious organisms, enabling developments in whole genome sequencing as part of the 100,000 Genome Project.
- Introducing the hexavalent vaccine for the primary infant vaccinations (diphtheria, tetanus, pertussis, poliomyelitis, Haemophilus influenzae type B and hepatitis B) to the childhood vaccination programme.
- Supporting the international response to Ebola in West Africa and establish a PHE Field Office in Sierra Leone as part of rebuilding its public health capacity.
- Building on PHE's whole genome sequencing capabilities with a view to extending testing to a further three high priority pathogens.
- Working with government and NHS England to develop a joint programme of work and produce plans for the public health system's response to high-consequence infectious disease incidents.
- Developing a new national strategy for infection prevention and control across the health and care system.
- Delivering a new data capture system for reporting healthcare associated infection.

130. From 2008, the HPA Strategic Plan from 2008 – 2013 set out the following strategic priorities for HPA in relation to infections, to support the NHS in:
    - Reducing the incidence and consequences of healthcare associated infections and antimicrobial resistant infections.
    - Reducing the incidence and consequences of infection and hepatitis B and C
    - Reducing the incidence and consequences of HIV and sexually transmitted diseases
    - Reducing the incidence and consequences of infection with vaccine preventable diseases
    - Reducing the incidence and consequences of tuberculosis
    - Combating pandemic Influenza

131. In 2016 PHE established the National Infections Service (NIS) which brought together PHE's epidemiologists, microbiologists, clinical and biomedical scientists and other staff

to further develop collaborative work to protect the public from infectious diseases. The rationale for the development of NIS was to bring together all the expertise at a national level on infectious disease to ensure most effective working and transform services taking advantage of new technologies. This provided an integrated approach across professional groups to focus on priority infections (blood-borne, respiratory, new & emerging etc). It also aimed to enable joined up progress on the genomics and data revolutions – as described in the 2015/16 PHE Annual Report **[EXHIBIT: IO/M1 0033 - INQ000090406].**

132. The then Director of the NIS, Professor Derrick Crook set out a vision for the NIS in the Autumn of 2015 and indicated that pathogen genomics would play a central role in this service **[EXHIBIT: IO/M1 0054].** Having established the NIS, PHE identified a need for a strategy to guide the development of the NIS, and to agree strategic priorities to deliver the benefits that were being sought. Work on this started in early 2018, and PHE published an Infectious Diseases strategy in 2019 **[EXHIBIT: IO/M1 0055 - INQ000090352].**

133. The PHE Infectious Diseases Strategy was developed in consultation with partners across the system, but it primarily provided the framework for PHE activity and prioritisation. The strategy was launched with support from the CMO.

Whole Genome Sequencing (WGS)

134. In addition to information provided in the previous statement to the Inquiry pursuant to Module 1, I provide further information on whole-genome sequencing (WGS) - in terms of its use in surveillance, response to infectious disease outbreaks and the standing capacity for WGS in both PHE and UKHSA.

135. Pathogen genomics is widely acknowledged as a powerful tool in the investigation and management of infectious diseases. WGS has advantages over other diagnostic approaches because of the greater sensitivity and resolution of information generated helping to improve the diagnosis and management of infectious diseases including more effective detection of outbreaks and better characterisation of pathogens and the risks they pose to health. The applications of WGS to health protection include

identification of pathogen characteristics that are associated with more severe illness or greater infectivity, assessment of relatedness of strains, where they have come from and how they have evolved, determining antibiotic resistance rapidly and detection and investigation of outbreaks.

136. Using WGS in outbreak analysis enables helps identify cases and establish whether cases fall within or outside the outbreak, investigate transmission patterns and identify sources of infection, thereby enabling effective public health interventions. The value provided by WGS in an outbreak investigation depends on ascertainment of cases, proportion of cases sequenced, and characteristics of the pathogen, such as rate of evolutionary change.

137. Genomic surveillance was routinely used in PHE to detect clusters of infection. For example, genomic analysis was used routinely to detect outbreaks and guide incident management and contact tracing for Tuberculosis (TB) since 2018 for England. This has included detection and public health management of cases in several multi country, multi-drug resistant outbreaks, as well as institutional outbreaks in prisons and healthcare facilities.

138. Genomic surveillance can be used to monitor pathogens for biological change to determine prevalent variants or trends in drug resistance or vaccine efficacy. Influenza and SARS-COV-2 are examples where genomics is currently used in this way, and this approach is increasingly being developed and used for other vaccine preventable infections such as Streptococcus pneumoniae.

139. The HPA started the development of WGS capabilities for the surveillance and control of infectious diseases including investing in bioinformatics **[EXHIBIT: IO/M1 0056].** PHE supported the delivery of the Government's 100k Genomes project which initially was intended to include infectious diseases **[EXHIBIT: IO/M1 0057].**

140. In 2013 PHE identified the need for a strategic approach to the implementation and application of genomic sequencing technologies in PHE with the aim of realising their public health potential **[EXHIBIT: IO/M1 0058, IO/M1 0059].**

141. The 2019 Infectious diseases strategy furthered the commitment to progressing PHE's WGS capability and included a strategic priority to embed WGS in PHE labs and optimise the use of WGS-based information. The progress of this work was not specifically impacted by EU Exit, or the lack of an infectious diseases strategy prior to this, but the rate of progress was limited by budget constraints.

142. By January 2020 PHE had implemented WGS for the routine diagnosis, surveillance and response to several gastrointestinal infections as well as TB. It was also applied, as required, as a tool in outbreak response. In 2020 WGS was carried out largely within the Central Sequencing Laboratory (CSL) at PHE's NIS laboratory in Colindale, providing high throughput sequencing for a range of pathogens using both Sanger and next generation sequencing technologies. Additionally, sequencing activity was undertaken at Birmingham for TB and at Porton Down for research and to support the imported fever service through the rare and imported pathogens laboratory (RIPL).

143. Prior to the COVID-19 response, PHE's WGS capacity of 45,000 a year was set by the infrastructure built at that time. PHE had capacity for sequencing a range of organisms including Gastro-intestinal organisms, TB, staphylococcus, hepatitis, flu, pneumococcus, group A streptococcus, enteric viruses and legionella. PHE also had sequencing services at PHE Porton Down to support its research functions and the rare and imported pathogens laboratory comprising sequencing of pathogens such as B.anthracis, Brucella spp, Borrelia spp, Chikungunya, Crimean-Congo Haemorrhagic Fever Virus, and Ebola, . In addition, there were limited sequencing capabilities in some PHE regional public health laboratories, as well as outsourced services for meningococcus to Oxford NHS Trust from the PHE Meningococcus Reference laboratory in Manchester. PHE had identified the need to strengthen pathogen genomics but had not had the funding to extend WGS capacity to other priority pathogens.

144. Due to funding constraints, further expansion in High Performance Computing (HPC) to manage the data generated by WGS, and the expansion of services to regional public health laboratories, could not be actioned until the opportunities were presented through COVID-19, which enabled the expansion of laboratory and IT capabilities in

UKHSA in a networked approach to meet the needs of the country. Under current arrangements UKHSA has the capacity to deliver around 300,000 sequences a year with ability to scale further in response to a pandemic.

High Consequence Infectious Diseases Programme

145. In addition to information on High Consequence Infectious Diseases (HCIDs) provided in the previous statement to the Inquiry pursuant to Module 1, I provide more detail on the enhanced risks of HCIDs, additional measures required to investigate and respond to them, and the joint HCID programme led by DHSC and involving PHE and NHS England (NHSE).

146. HCIDs were defined in the UK in 2018 according to the following criteria:
    - acute infectious disease
    - typically has a high case-fatality rate
    - may not have effective prophylaxis or treatment
    - often difficult to recognise and detect rapidly (leading to potential for increased transmission)
    - ability to spread in the community and within healthcare settings
    - requires an enhanced individual, population and system response to ensure it is managed effectively, efficiently and safely.

147. HCIDs are generally rare or imported, into the UK and therefore there is usually limited local experience of their clinical and public health management. There may also be limited evidence from which to draw recommendations for appropriate public health action due to the rare nature of disease globally (such as MERS-CoV or viral haemorrhagic fevers).

148. Due to the potential risks to health outlined above, an enhanced health protection response is required to investigate and respond to HCIDs. These measures include:
    - Triggering the NHS HCID clinical network to enable safe management of case and to prevent exposures in healthcare settings
    - Identification of contacts followed by risk assessment and categorisation according to risk. Contacts are then managed to ensure rapid identification of

secondary cases and prevention of onwards transmission. This may include active monitoring (period of daily health checks with contacts), isolation, IPC measures, chemoprophylaxis and vaccination (where available), and provision of other advice as required.

- Decontamination of settings where there may risk to others via fomites from an infected individual
- Co-ordination of the public health response through an incident management team
- Notification to WHO as required by the International Health Regulations and to other international partners as appropriate
- Reactive/proactive communication with wider public and media (dependent on the nature of the incident and as determined by the incident management)

149. Underpinning all the above is a commitment to the precautionary principle whereby, given the limited evidence available for some of these diseases, a robust health protection response is employed to ensure mitigation against all potential risks to public health that may arise from a HCID in the UK and contained and controlled.

150. The joint HCID programme between PHE, NHSE and DHSC was intended to be 2-year programme and was established as part of the 2014/15 Ebola outbreak legacy. The HCID programme was initiated by NHSE and PHE to improve preparedness for Ebola and other infections that not only endanger the life of the patient, but also pose particular dangers to healthcare workers and the public. Dr Sir Mike Jacobs was the Programme Director for HCIDs in NHSE. In an early meeting it was agreed that PHE should also have a programme of work that covered the public health aspects of the HCID pathway **[EXHIBIT: IO/M1 0060].** Full details of why the HCID programme was closed, are best addressed by DHSC who oversaw the programme.

151. The only direct new investment as a result of the HCID programme that we are aware of was the creation of the NHS hospital designated centres for treating patients with HCIDs that make up the NHS HCID Network. PHE funded its aspects of the programme from within existing resources.

152. Professor Dame Jenny Harries (in her role as PHE's Regional Director for the South and Deputy Medical Director) was asked by the PHE Medical Director, the late Sir Paul Cosford, to act as Senior Responsible Officer (SRO) for the PHE component of the HCID programme. Meetings of the internal PHE HCID programme team were held approximately once a month from May 2016 until May 2018, with further meetings in 2019 to discuss the outstanding actions following closure of the programme **[EXHIBIT: IO/M1 0061].**

153. Delivery of the PHE HCID programme was amongst the corporate objectives set by PHE for 2017/18 **[EXHIBIT: IO/M1 0062 - INQ000090347].** The programme included the following workstreams, and information on the work underlying these workstreams is provided in the programme overview as exhibited **[EXHIBIT: IO/M1 0063 - INQ000090388].**

- Horizon scanning, outbreak response and assessment of threats to the UK
- Professional information flow
- Trigger: Command and control evoked
- Enhanced UK preparedness – ensuring the PHE National Incident Emergency Response Plan (NIERP) was fit for purpose and aligned with NHS England HCID
- Diagnostics and interventions
- Local public health control (for example, epidemiology, contact tracing and management, public health advice and guidance)
- Communications

154. At the end of 2 years, the NHSE funding for the programme ran out. The remaining elements of the PHE programme were moved to the relevant areas within PHE. I exhibit the PHE HCID programme Closedown and Handover report which describes the outstanding actions, and the business-as-usual location that this work was passed to within the organisation**. [EXHIBIT: IO/M1 0064].** Following exercise Broad Street, PHE had a list of outstanding work that was folded into PHE's business as usual activities, and I have exhibited a report describing this exercise **[EXHIBIT: IO/M1 0065 INQ000090442].** The recommendations were still being implemented at the time of the

declaration of the COVID-19 pandemic, and some of the work was progressed as part of COVID response.

155. The purpose of the HCID programme of work was to ensure that the country was prepared to detect, treat and manage HCID cases, protecting health workers and the wider community from infection. As I described above, HCIDs are rare and usually imported infections defined by specific characteristics that require enhanced clinical and public health management. The HCID programme was not designed for preparedness against pandemics nor to manage outbreaks with widespread community transmission or large numbers of cases.

156. Whilst the first few cases of a new and emerging infection including those of pandemic potential are likely to be classified as a HCID and managed via HCID pathways (as was the case with COVID-19 initially), the high volume of cases expected during an epidemic or pandemic wave necessitate other public health and clinical response and control measures that can surge to the capacity required. A recent example of this is with the approach taken in response to specific clades of Mpox that caused outbreaks with significant community transmission in the UK and Europe in 2022 **[EXHIBIT: IO/M1 0066].** Additionally, once an emerging virus is characterised and infection widespread, as it would become during a pandemic, it may be de-classified as an HCID based on emerging evidence, such as information about its clinical severity.

157. The only pathogen for which specific pandemic-scale plans were in place was influenza. PHE contributed to planning for pandemic influenza via the DHSC-led Pandemic Influenza Programme Board (PIPP Board). This planning was co-ordinated Government-wide by the cross-Government Pandemic Flu Readiness Board and Programme which is co-chaired by DHSC and the Cabinet Office Civil Contingencies Secretariat. The terms of reference of both these programmes are described in the National Audit Office (NAO) report into "*The Government's preparedness for the COVID-19 pandemic: lessons for government on risk management"* which I have exhibited **[EXHIBIT: IO/M1 0067].**

158. Pandemic influenza did not meet the HCID definition for the reasons outlined above, although human cases of avian influenza meet the criteria and are managed as such.

As with COVID-19, the initial cases of any new influenza pandemic are likely to be managed as an HCID until sufficient information became available.

159. PHE was not involved in any programmes of work related to specific planning for a pandemic caused by any pathogen other than influenza, or any pathogen-agnostic pandemic planning, i.e., planning that was not specific to a named pathogen, or "Disease X". However, as was the case for COVID-19, aspects of the planning undertaken for influenza would have contributed to overall pandemic preparedness and been adaptable to a specific response many forms of pandemic.

Surveillance of influenza and other respiratory viruses

160. The HPA and PHE undertook surveillance and control of infectious diseases including novel and high consequence pathogens. Below I have described in some detail the organisations' response to Middle East Respiratory Syndrome (MERS) Coronavirus (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS) Coronavirus (SARS-CoV-1). Both HPA and PHE responded to a range of incidents other emerging diseases, and as part of our disclosure to the inquiry we have provided a list of all the health protection events that were declared and managed as a formal incident response within PHE **[EXHIBIT: IO/M1 0068 - INQ000090501]** and provided disclosure related to these incidents. However key examples of emerging infections or HCIDs to note include:

- SARS-CoV-1 in 2003
- MERS-CoV in Saudi Arabia in 2012
- Imported MERS-CoV cases in 2012 and 2018
- Ebola Virus Disease in West Africa (2014)
- MERS-CoV in the Republic of Korea (2015)
- Candida auris (2016)
- Zika virus (2016)
- Multiple incidents of avian influenza in the UK
- Ebola Virus Disease in the Democratic Republic of Congo (DRC) (2017)
- A case of human Rabies in 2018
- Mpox (formally known as Monkeypox) in 2018 and 2020
- Lassa fever in 2019

Surveillance and response to MERS

161. In addition to information provided on MERS-CoV in the previous statement provided to the Inquiry pursuant to Module 1, here I explain the risk to the UK from a MERS-CoV outbreak, recommendations made by both PHE and UKHSA to add MERS-CoV to the list of notifiable diseases and learnings from outbreaks in Saudi Arabia and South Korea. I also provide details of cases of MERS-CoV in the UK, the plans and responses to them as well as lessons learned.

162. From 2014 to 2021 PHE conducted risk assessments of the threat to the UK from MERS-CoV. These risk assessments considered the risk to the UK population posed by importation of a single case or containable outbreak, to advise public health action on that basis.

163. The most recent of these, conducted prior to the COVID-19 pandemic, was published in February 2019, and concluded that the risk to residents in the UK from the virus remained very low **[EXHIBIT: IO/M1 0069].**

164. This risk assessment noted the continued risk of cases being imported from overseas. It observed that the risk of infection to UK residents travelling to the Middle East remained very low but might be higher in those with exposure to specific risk factors within the region such as exposure to camels (or camel products) or the local health care system. In this context, testing for MERS-CoV was recommended for individuals who met the case definition and had a history of travel to or from the Middle East.

165. Guidance was in place for healthcare workers and health protection teams which stressed the importance of early identification and rapid implementation of infection control measures. Testing was recommended for healthcare workers who had contact with a confirmed case and contacts of cases were followed up for 14 days following potential exposure to identify any secondary infections promptly.

166. MERS-CoV was included within the category of all human emerging infectious diseases within the National Risk Register (NRR) in 2017. Therefore, the risk is assessed as an aggregate risk along with other emerging infections such as Zika or Ebola. The NRR

considers that an emerging infectious disease could cause several thousand people to experience symptoms, potentially leading to up to 100 fatalities and the risk is assessed as: likelihood of occurring in the next five years 3 (out of 5), severity of impact 3 (out of 5).

Notifiable disease legislation

167. DHSC is the organisation responsible for proposing and actioning amendments to the legislation relating to notifiable diseases and can provide an explanation on their decisions for which diseases are notifiable. In 2016 PHE recommended to DHSC that MERS-CoV should be added to the list of notifiable diseases.

168. I have exhibited documentation of communications between PHE and DHSC in which it appears that, whilst DHSC agreed in principle to this recommendation, due to the pressures of EU Exit, the amendments had not been completed by the time of the COVID-19 pandemic **[EXHIBIT: IO/M1 0070, IO/M1 0071].**

169. Further recommendations to add MERS-CoV (and other infectious diseases) to the list of notifiable diseases were made by UKHSA to DHSC in 2021 as part of a consultation on planned amendments to the legislation **[EXHIBIT IO/M1 0072].**

170. Subject to the progress of the proposed legislation above, UKHSA would consider that adding MERS-CoV to the list of notifiable diseases should be included in the Module 1 list of recommendations. More widely, there should be consideration as to whether temporary additions to the list of notifiable diseases can be made in a more rapid way for urgent public health situations, through an appropriate change to the regulations.

Outbreaks of MERS-CoV: response and learning

171. Outbreaks of MERS-CoV in Saudi Arabia in June 2012 and in South Korea in May 2015 provided important learning points.

172. The first two cases of what is now recognised as MERS-CoV occurred June 2012, in Saudi Arabia. On 11 September 2012, a Qatari national with travel history to Saudi Arabia and Qatar was transferred to a London hospital. On 14 September the HPA

Imported Fever Service received details of this case of unexplained sever respiratory illness with travel history to Qatar and Saudi Arabia. Due to similarities with the cases reported in June, the HPA undertook testing for the presence of this novel coronavirus, and the virus isolated from the case was genetically virtually identical to that isolated from the Saudi Arabian cases. At the time, this was only the second diagnosis of a case of what became known as MERS-CoV **[EXHIBIT: IO/M1 0073].**

173. An enhanced level 3 incident was instigated by the HPA to put in place immediate steps to prevent onward spread **[EXHIBIT: IO/M1 0074].** No further cases were detected in the UK linked to this imported case **[EXHIBIT: IO/M1 0075].**

174. The HPA carried out a post incident debrief on 16 November 2012 which captured learning from the incident response and identified high level recommendations to be applied to more detailed action planning in subsequent months.

175. The debrief session considered risk assessment, surveillance, contact tracing, guidance and other aspects of outbreak response. The debrief captured elements of the outbreak response that had worked well including: the rapid development of an assay for the detection of the novel coronavirus; prompt publication of guidance for health professionals and travellers; rapid public health response incorporating contact training and guidance for the management of suspected cases and rapid sharing of information with the scientific and public community including scientific publication.

176. The debrief identified the need for more joined up communication, including consideration of physical co-location of response teams to minimise the disruption to the routine work of those not directly involved. Key recommendations included undertaking further detailed assessment of the risk of other cases being imported into the UK; a recommendation to work with the DHSC to improve the public health management of planned medical transfers into the UK and the development of a database to integrate laboratory and public health data for acute respiratory incidents. **[EXHIBIT: IO/M1 0076].**

177. In February 2013, a further case or MERS-CoV was imported to the UK and resulted in two onward transmissions to close family members within the UK **[EXHIBIT: IO/M1**

0077]. Learning from both these importations lead to a new risk assessment process for medical transfers, which was communicated to the NHS in a CMO letter **[EXHIBIT: IO/M1 0078].**

178. In May 2015 a level 3 incident was activated in response to MERS-CoV cases in South Korea. There were no UK cases identified and the response was primarily to monitor the situation closely and provide assurance that robust arrangements were in place to be able to respond to any potential imported cases **[EXHIBIT: IO/M1 0079].**

179. Due to the short duration of the level 3 response and lack of cases in the UK, a formal debrief was not carried out following the de-escalation and closure of the response. Instead, the national incident response team collated key issues and proposed solutions, which included **[EXHIBIT: IO/M1 0080]:**

- The need to improve arrangements for taking and transporting samples from the community for serological testing working with the NHS and other local partners.
- the need to review testing thresholds internationally following a positive test result after an initial negative result
- Need to improve put of hours arrangements for the dissemination of Central Alerting System, CAS (now Patient Safety) alerts.

180. I exhibit a summary that was provided by PHE to the New and Emerging Respiratory Virus Threats Advisory Group (NERVTAG) of a case of MERS-CoV infection in the UK, identified in a person who travelled from Saudi Arabia to Manchester and was confirmed to have the infection on 22 August 2018. The patient first experienced symptoms in Makkah, Saudi Arabia on 14 August and presented to a primary care physician on 16 August where he was prescribed antibiotics **[EXHIBIT: IO/M1 0081].**

181. The case and a relative arrived at Manchester airport on 16 August and travelled by private vehicle to Leeds where he felt unwell and isolated at a private home until attending the Emergency Department at St James' Hospital on 19 August where he was isolated.

182. On 20 August 2018 samples were sent to the PHE regional public health laboratory in Birmingham for viral testing where MERS-CoV presumptive positive result was issued the following day. The result was confirmed at the PHE reference laboratory at Colindale on 22 August 2018. The case was transferred by ambulance to a HCID unit in Liverpool University Hospital on 23 August 2018 as indicated following the diagnosis of a HCID.

183. PHE managed the response to this case as a national enhanced incident and the "First Few Hundred" (FF100) approach to enhanced surveillance for MERS-CoV was instigated. FF100 involves the detailed collection of the clinical and epidemiological characteristics of at least the first confirmed cases of an emerging infectious disease and their close contacts, to provide an evidential base for the detailed characterization of the disease cases and contacts. The approach is detailed in the FF100 protocol published by PHE. **[EXHIBIT: IO/M1 0082].** PHE notified the WHO of the case via the International Health Regulations (IHR) National Focal Point.

184. PHE liaised with Saudi Arabian health authorities, via the IHR National Focal Point, throughout the incident, sharing information to enable relevant investigations within the Kingdom of Saudi Arabia. The UK national enhanced incident response included tracing the contacts of the confirmed case, monitoring those potentially exposed to identify rapidly anyone who developed symptoms and enable prompt testing, clinical and public health management. In addition, persons with the closest exposure to the case were offered asymptomatic testing.

185. There were 80 people identified as having exposure to the case. These comprised three household community contacts,18 aircraft passenger contacts and 59 healthcare worker contacts. Public health follow-up and virological investigation of contacts did not identify any evidence of onward transmission from the case. In addition, laboratory serological investigations did not reveal either any evidence of secondary infections based on samples available for testing.

186. Cases and clusters of MERS-CoV infection are reported by countries to WHO in line with the requirement under the IHR to detect and report events of public health importance. Information on confirmed cases and clusters available to PHE was based

on WHO reporting, either direct via information provided by WHO to national focal points or through information published on the WHO website. However, the detail of every MERS-CoV case may not always have been available via these routes. In addition, individual countries may voluntarily decide to publish additional information on confirmed cases.

187. This information and experience from cases in England including in 2018 was used to inform and refine further planning for the public health management of potential MERS-CoV cases domestically.

188. Internationally, reports of confirmed MERS-CoV cases frequently included the following exposures among cases prior to their onset of symptoms:

- close contact with another MERS-CoV case (particularly in household settings or healthcare environments) or
- exposure to camels or camel products

189. PHE included in plans for a response to MERS-CoV, arrangements for contact tracing of cases. This was intended to ensure that persons exposed to an infectious case were followed-up to identify promptly the development of any symptoms and ensure that any possible secondary cases were managed effectively to contain any further spread. Moreover, learning from the MERS incident fed into the new national guidelines for large scale contact tracing **[EXHIBIT: IS/M 0083]** produced by PHE in 2018.

190. Information from outbreaks in other countries, for example the risk of exposure through camels or camel products, was used to provide information for healthcare professionals to support the identification of possible cases among persons who present with compatible symptoms following recent travel to affected countries and to develop case definitions which health professionals can use, in conjunction with their own clinical assessments, to consider whether MERS-CoV testing is required for patients.

191. These definitions were updated as more epidemiological information became available from international reporting **[EXHIBIT: IO/M1 0084].** For example, the MERS risk

assessment published by PHE in October 2014, summarises the new evidence and applies it to update the case definition **[EXHIBIT: IO/M1 0085].**

192. Plans for responding to a suspected MERS case recommend prompt application of infection prevention and control (IPC) measures to limit transmission to others in healthcare environments, reinforced by reported clusters of cases internationally in healthcare settings and the importance of effective IPC measures in these outbreaks **[EXHIBIT: IO/M1 0086].**

193. In addition to information provided in Professor Dame Jenny Harries' first statement on the role of inequalities on the impact of COVID-19, I provide further information on the role of inequalities on the impact of other coronaviruses (including MERS-CoV) prior to January 2020.

194. The burden and risk of infectious diseases is not equally distributed in the population with some groups being more vulnerable to infection or at greatest risk of poor health outcomes. Certain groups are more affected by coronaviruses than others. For example, it was known that some people are at greater risk of developing severe disease when infected with MERS-CoV including older people, people with weakened immune systems, and those with chronic diseases such as renal disease, cancer, chronic lung disease, hypertension, cardiovascular disease and diabetes. Some sociodemographic factors such as overcrowding also increase the risk of transmission.

195. Prior to January 2020 SARS-CoV-1 and MERS-CoV were the only coronaviruses to have been described as having severe health impacts. There have been only five confirmed cases of MERS-CoV infection in the UK, and no more than three confirmed cases at any one time domestically. Therefore, there has been limited information about the role of inequalities on the impact of MERS-CoV within the UK **[EXHIBIT: IO/M1 0087].** As outlined, the international reports of MERS-CoV highlighted significant morbidity and mortality associated with the infection. As such, the infection was included in the joint HCID programme with NHSE and DHSC in order to ensure a comprehensive health system response to future cases. SARS-CoV-1 affected populations primarily in east Asia as it was determined to be more prevalent among those living in high density housing.

SARS-CoV-1: response and learning

196. In addition to information provided on SARS-CoV-1 in the previous statement provided to the inquiry by Professor Dame Jenny Harries, here I explain the surveillance, public health response and learnings of the SARS-CoV-1 global outbreak in 2003 and up to January 2020, and the threat of a SARS-CoV-1 outbreak prior to January 2020.

197. Severe Acute Respiratory Syndrome (SARS) is a viral respiratory disease caused by the now called SARS -CoV-1 coronavirus. The main symptoms of SARS-CoV-1 are high fever (>38° C), cough, shortness of breath or difficulty in breathing. It was first recognised in March 2003 when WHO issued a global health alert for authorities to be aware of an atypical new pneumonia which had been reported in several countries in Southeast Asia. Between March and July 2003, over 8000 probable cases were reported from around 30 countries.

198. In the United Kingdom (UK) between March and July 2003, 368 reports of suspected SARS cases were made to the HPA. Of these, only nine were initially classified as probable SARS cases, and only one patient, a 23-year-old male, was positive for SARS coronavirus (SARS-Co-V-1) on PCR testing and later showed evidence of seroconversion. There was no onward transmission identified in the UK. **[EXHIBIT: IO/M1 0089].** Nonetheless, the volume of work within the UK in response to SARS was far greater than suggested by the number of potential SARS cases reported to the HPA.

199. Surveillance of SARS cases in the UK began on 17 March 2003. Initial case definitions for “probable” and “confirmed” cases of SARS were in line with the proposed WHO definitions:

> A probable case: An individual with symptoms and signs consistent with clinical SARS (Possible case) and with preliminary laboratory evidence of SARS-CoV infection based on the following: either a single positive antibody test for SARS-CoV or a positive PCR for SARS-CoV on a single clinical specimen and assay.

A confirmed case: The respiratory illness should be severe enough to warrant hospitalisation and include a history of: fever of 38°C (documented or reported); one or more symptoms of lower respiratory tract illness (cough, difficulty breathing, shortness of breath); radiographic evidence of lung infiltrates consistent with pneumonia or Respiratory Distress Syndrome (RDS) OR autopsy findings consistent with the pathology of pneumonia or RDS without an identifiable cause; and no alternative diagnosis to fully explain the illness.

200. On 10 April 2003, suspect cases were sub-classified into 'HIGH' and 'LOW' suspicion categories:

- Suspect LOW case - defined as a person presenting with sudden onset of: high fever (>38°C); cough or difficulty breathing; and having travelled in the 10 days before onset of illness to an area in which there is more than 'limited' local transmission of SARS during the travel period.

- Suspect HIGH case - defined as a person presenting after 1 February 2003 with sudden onset of: high fever (>38°C); cough or difficulty breathing; and had close contact with a probable SARS case from an affected area in the 10 days before onset of symptoms.

201. Categories were also identified for:

- Health care workers (HCWs) - defined as two or more health care workers in the same health care facility fulfilling the clinical definition of SARS and with onset of illness within the same 10-day period.

- Other hospital cluster – defined as hospital acquired illness in three or more persons (HCW and/or other hospital staff and/patients and/or visitors) in, or linked to, the same health care facility fulfilling the clinical case definition of SARS (see below) and with onset of illness within the same 10-day period **[EXHIBIT: IO/M1 0089].**

202. For the purpose of surveillance for SARS in the UK, areas described by WHO as *'potential zones or re-emergence of SARS'* were considered to comprise the whole of mainland China, especially Guangdong Province, and Hong Kong. An individual meeting the clinical case definition of SARS and with recent travel history to China was defined as a possible SARS case.

203. The risk of SARS in the UK was very low. However, surveillance activities aimed to:

- promptly identify and investigate patients with possible SARS
- alert local, regional and national public health authorities
- take appropriate infection control and public health measures to prevent spread
- should a confirmed case of SARS be detected report the case to WHO

204. The crucial trigger for the UK response were the Global alerts issued by WHO to all its Global Outbreak Alert and Response Network (GOARN) partners, as well as more broadly. For the UK, the first substantive incident came at 04:00 on Saturday 15 March 2003 concerning the need to intercept a flight coming to Europe with a SARS patient on board. This led to the formation of the UK SARS Taskforce to co-ordinate a response to SARS, Lessons learned from SARS: The experience of the Health Protection Agency, England **[Exhibit: IO/M1 0088].**

205. The Taskforce was chaired by the HPA, and had representatives from the DHSC, the NHS, national surveillance centres in England and the DAs. The invited participants included virologists, epidemiologists and specialist advisors on clinical infectious disease and infection control, as well as HPA communications staff.

206. The objectives of the Task Force included:

- overseeing and coordinating the surveillance of potential SARS cases
- providing guidance on the management of cases and contacts
- considering and recommending broader public health control measures
- providing timely information to professionals and the public

207. An independent SARS Expert Advisory Group (EAG) was set up on 7 May 2003, to advise the Taskforce, the DHSC and others on research and strategic issues. Its Terms of Reference were to:

- review the clinical, microbiological and epidemiological (including modes of spread) evidence
- advise the UK Departments of Health and the NHS on emerging issues and potential high-risk situations
- anticipate future scenarios, to advise on the work needed to respond to them and to assess the outcome of that work
- advise on future research needed.

208. The EAG met on seven occasions between 07 May 2003 and 22 October 2004. I have exhibited minutes of their first meeting as an example **[EXHIBIT: IO/M1 0090].**

209. The Centre for Infections (CFI) of HPA co-ordinated surveillance of potential cases of SARS including the development and review of case definitions, establishing reporting mechanisms, and dissemination of data and information. The surveillance relied on the reporting of potential cases by hospital and general practice professionals. Patients were classified according to HPA case definitions by CFI epidemiologists and the reporting clinician. Surveillance arrangements were revised during the outbreak to facilitate initial alerting to HPA Regional Offices and ensure that local public health authorities were aware of the potential cases.

210. Sir Liam Donaldson, the then CMO, sent a letter on 29 April 2003 to CEOs of NHS and Primary Care Trusts reminding them of the action to take within their organisations, based on existing protocols for managing infectious patients, as a precaution in case further suspected cases of SARS presented to the NHS, and the action that must be taken when dealing with such a case. I have exhibited this letter **[EXHIBIT: IO/M1 0091].**

211. The HPA published four guidance documents related to SARS, and I have exhibited these [**EXHIBITS: IO/M1 0092, IO/M1 0093, IO/M1 0094, IO/M1 0095]** and an Interim Contingency Plan for SARS - **[Exhibit: IO/M1 0091]** dated December 2003. The plan

was based on a combination of generic planning assumptions, control principles and alert levels that differentiate phases of response. The management of SARS, like any major incident was based on the concept of Integrated Emergency Management, which brings together multi-agency groups at various levels of organisations with the common aim of managing the consequences of the incident. Major incident plans and outbreak control plans already exist at a local level. A command-and-control structure was put in place for SARS which complemented and built on local structures and plans.

212. After the SARS-Cov-1 outbreak in 2003 there was considerable interest in the UK health sector in looking at how it could respond to a similar outbreak with transmission of SARS-CoV-1 in the population.

213. Learning from the SARS-CoV-1 response was used to strengthen preparedness and developed regional response plans, I have exhibited an example of the East of England SARS plan **[EXHIBIT: IO/M1 0096].** Work was also undertaken to strengthen laboratory preparedness, and I exhibit an action plan of this work **[EXHIBIT: IO/M1 0097].**

214. HPA supported an exercise to test the response to a SARS-CoV-1 outbreak in Northern Ireland. Exercise Goliath (2003) tested the Northern Ireland Contingency Response Plan for SARS. I have exhibited the reports which describe the learning from this exercise **[EXHIBIT: IO/M1 0098],** The Department of Health, Social Services and Public Safety of Northern Ireland would have been responsible for taking these actions forward.

215. Exercise Bennachie was a one-day table-top exercise delivered in 2004 which aimed to test overall preparedness for dealing with SARS-CoV-1 in Scotland. I have exhibited the report that describes the learning from this exercise **[EXHIBIT: IO/M1 0098].**

216. There have been no further cases of SARS-CoV-1 identified anywhere in the world since May 2004. The HPA assessed the threat to the UK as *"low"* but stated

"clinicians and other healthcare professionals should remain vigilant to the possibility of SARS". **[EXHIBIT: IO/M1 0099].**

217. Since then, SARS-CoV-1 has fallen under the NRR grouping "all emerging infectious diseases" which are described above in relation to MERS-COV.

Novel viruses of concern

218. As discussed earlier in this statement PHE, often in collaboration with scientific advisory groups such as Human Animal Infections and Risk Surveillance (HAIRS) and NERVTAG conducted risk assessments on known pathogens. This included coronaviruses such as SARS-CoV-1 and MERS-CoV, viral haemorrhagic fevers including Ebola and novel influenza viruses including avian and swine viruses. PHE did not produce risk assessments specifically for unknown diseases. However, the NRR category "emerging infections" covered outbreaks of an unknown pathogen.

Expert Advisory Groups

219. As described in Professor Dame Jenny Harries statement, PHE provided the secretariat for, and/or contributed to, a number of key scientific advisory committees including the NERVTAG and the Joint Committee on Vaccines and Immunisation (JCVI). I exhibit a list of the advisory groups that PHE provided the secretariat, or regularly provided expert input] **[EXHIBIT: IO/M1 0100].**

National Expert Panel on New and Emerging Infections (NEPNEI)

220. In addition to information on expert advisory groups contained in the previous statement provided to the Inquiry pursuant to Module 1, here I provide further information on the National Expert Panel on New and Emerging Infections (NEPNEI). NEPNEI that was established in 2003, with the first meeting taking place in November 2003. Its remit was as an overarching horizon scanning panel responsible for assessing the threat from new and emerging infectious diseases (which are commonly zoonoses), reporting to the CMO and advising DH, with the secretariat provided by the HPA.

221. Between 2003 and 2011 NEPNEI discussed a wide range of topics, some requested by the CMO, and some raised by members of the panel. It was dissolved in October 2012 with functions moving to other expert groups such as the HAIRS Group and the Advisory Committee on Dangerous Pathogens (ACDP).

222. The decision for NEPNEI to be dissolved was a government decision and we do not hold a report that outlines the rationale for the decision. According to GOV.uk, when NEPNEI was stood down there was a strong desire across government to retain the functions undertaken by the HPA including horizon scanning and risk assessment. It was agreed therefore, that the HAIRS group would report into the ACDP with the remit and membership of ACDP to be amended to reflect the changes **[EXHIBIT: IO/M1 0002].**

223. The HAIRS meetings discussed new threats and triaged the risk assessment process. Since its establishment in early 2004 there has been a steady evolution and development of the risk assessment processes used by the HAIRS group. The historic risk assessments carried out and methodology used are available on GOV.UK. In some cases, a risk assessment may have been undertaken by another member of the group, such as the Department for Environment Food and Rural Affairs (Defra), or international bodies and no further action is required.

224. The HAIRS Group had not carried out any risk statements or assessments for potentially zoonotic coronaviruses up to January 2020. Similarly, the HAIRS group had not discussed, or risk assessed, new or emerging respiratory pathogens as these had always been addressed by other groups such as Advisory Committee on Dangerous Pathogens (ACDP) and NERVTAG. Historic risk statements or assessments carried out by the HAIRS group in relation to viruses have previously been shared with the inquiry. Current risk assessments carried out by the HAIRS group in relation to potentially zoonotic incidents involving coronaviruses are listed below. It's important to note that the HAIRS Group does not predict what, where or when new or re-emerging pathogens will occur and does not rank pathogens by level of concern.

- November 2020: Qualitative assessment of the risk that SARS-CoV-2 infection in UK captive Mustelinae populations presents to the UK human population **[EXHIBIT: IO/M1 0101].**

- December 2021: Qualitative assessment of the risk that SARS-CoV-2 infection in UK captive or wild Mustelidae population presents to the UK human population [**EXHIBIT: IO/M1 0102].**
- March 2023: Risk of SARS-CoV-2 to human health through non-food exposures to deer in the UK: qualitative assessment [**EXHIBIT: IO/M1 0103].**
- March 2023: Qualitative assessment of the risk of SARS-CoV-2 being introduced into the cervid population in Great Britain [**EXHIBIT: IO/M1 0104].**

225. Topics and incidents discussed by the HAIRS group and summarised in the HAIRS annual reports, inclusive of pathogens that have zoonotic potential, are set out in the exhibited table **[EXHIBIT: IO/M1 0105].** For the years 2018-2020 pathogens discussed at HAIRS monthly meetings have been included in the minutes that have been shared with the inquiry. The table also includes a list of pathogens assessed by HAIRS, by year, inclusive of the risk rating concluded for each respective pathogen. I have exhibited the annual reports produced by HAIRS from 2001 until 2017 (HAIRS annual reports were not produced beyond 2017): **[EXHIBIT: IO/M1 0106, IO/M1 0107, IO/M1 0108 - INQ000147732, IO/M1 0109 - INQ000147733, IO/M1 0110 - INQ000147734, IO/M1 0111 - INQ000147735, IO/M1 0112 - INQ000147736, IO/M1 0113 - INQ000147737].**

Section 4: EPRR Arrangements, planning and exercising

PHE Pandemic Influenza Co-Ordination Group (PICOG)

226. Further to information on PHE's Pandemic Influenza Co-Ordination Group (PICOG) contained in the previous statement to the Inquiry pursuant to Module, I provide additional information on PICOG here.

227. The Terms of Reference document for PICOG, dated June 2018, confirms the scope of the groups remit to: **[EXHBIT: IO/M1 0114]:**

- support a co-ordinated approach to all work pertaining to pandemic influenza preparedness and response across PHE

- act as a focal point for pandemic influenza preparedness issues within PHE and between other organisations such as DHSC, ECDC and WHO
- review and co-ordinate submissions and PHE activities related to the functioning of the DH led Pandemic Influenza Preparedness Programme Board (PIPP Board)
- bring together those with interest and expertise in pandemic influenza to act as a horizon scanning group monitoring new developments
- identify and recommend appropriate areas of research and audit
- arrange and promote collaboration with others as necessary

228. PICOG's remit was only focused on pandemic influenza preparation and no other causes of pandemics because its role was as a feeder group into the DHSC influenza preparedness group(s) and reflected the work of the NRR.

PHE's role in Risk Assessment: National and Local

PHE's Understanding of the UK Government's Forecast of the National Risk of Pandemic Influenza and Emerging Infections and HCIDs including SARS

229. As described in the first witness statement of Professor Dame Jenny Harries, the UK Government assesses the most serious risks facing the UK or its interests overseas via the National Security Risk Assessment (N(S)RA). For public health-specific risks within the N(S)RA, DHSC is lead department. HPA and PHE provided advice on the risks within the N(S)RA to Government, via DHSC. The N(S)RA is a high-security classified document. A non-classified register of these risk is published as the National Risk Register (NRR).

230. The top-level N(S)RA was generated in consensus meetings held by the Cabinet Office Civil Contingency Secretariat (CCS) including all the leading government departments and relevant agencies. The assessments given at these meetings were usually verbal including those for pandemic influenza / respiratory infections. Only top-level introductions to the relevant NRA sections were provided in the earlier years by PHE. The CCS hold the minutes of these meetings and given the security classification of the minutes PHE would not have had copies of them.

231. Specific submissions of detailed response plans were only required for the N(S)RA elements that had the highest consensus likelihood / impact scores. For Pandemic Influenza, this would have included the DHSC Pandemic Influenza Strategy and the PHE Pandemic Response Plan. Such plans stood alongside the N(S)RA but were not a formal part of the N(S)RA.

232. In 2017 PHE provided a detailed risk assessment on some of these threats **[EXHIBIT: IO/M1 0087].**

233. Of the diseases included within the 2017 NRR (i.e. Pandemic Influenza and the broad category of emerging infections), PHE was aware of a national contingency plan for Pandemic Influenza. Internally, PHE also held plans for importation or an outbreak of SARS-CoV-1 or MERS-CoV. Other emerging infections would have been managed in-line with other generic outbreak control guidance such as the Communicable Disease Outbreak Guidance (2014) and via a national or enhanced incident response (e.g. via the NIERP) or HCID pathways where appropriate. PHE developed and issued specific guidance on management of suspect or confirmed cases of a range of emerging infections including avian influenza, Zika and Ebola.

234. The NRR's assessment of an influenza pandemic being the UK's top non-malicious risk since 2008 was not inconsistent with the HPA's and PHE's risk assessments. Pandemic Influenza has a high likelihood of occurring as it has a periodicity and has been documented to occur throughout human history. Influenza pandemics are also known to have had major impacts on health and although the most recent influenza pandemics had been relatively mild, they still caused severe stress on health and care services. The risk of Pandemic influenza and other respiratory infections was well recognised and included in the NRA over the years.

235. The 2017 NRR's assessment that '*the consequences of emerging infectious diseases may include several thousand people experiencing symptoms and potentially leading to up to 100 fatalities'* is consistent with PHE's risk assessment and a separate risk from that of pandemic Influenza. The emerging infectious disease category is very wide ranging and covers many infectious diseases such as viral haemorrhagic fevers and

respiratory viruses such as MERS-CoV which behave quite differently, and which can arise from varied ecological conditions.

Local risk assessment

236. Local Community Risk Registers (CRR) are developed under the governance of Local Resilience Forums (LRFs) as part of the statutory duties under the Civil Contingencies Act 2004 to help ensure that communities are prepared to cope during an emergency and to recover more quickly. They comprise an assessment of the risk of emergencies in terms of their likelihood and the impacts and are developed in partnership. LRFs bring together local authorities and emergency services and but their governance structures and processes will vary, and the statutory Emergency Preparedness guidance produced by the CO (specifically Chapter 4: Local Responder Risk Assessment Duty) allows for the work to be undertaken through a Risk Assessment Working Group (or equivalent).

237. In practice, local risk assessments drew heavily on the content of the generic national risk assessments. Specialist teams in PHE, and the HPA before it, provided expertise to inform the development of the national risk assessment.

238. Once the national risk assessment had been reviewed, it would be issued to LRFs, with the local PHE/HPA representative contributing to the local contextualisation, assessment and evaluation of risks. This could mean acting as lead assessor for the LRF for certain risks or providing comment as part of the joint assessment of local risks for the area.

239. Local contextualisation would include factors such as population size and demographic profile and identification relevant local plans. For example, the risk of an influenza type pandemic would be contextualised locally by applying the reasonable worst-case scenario over case attack rate and case fatality rate to the local population to inform LRF plans for excess deaths. Local Health Resilience Partnerships, co-chaired by NHSE and local government DsPH, were ideally placed to feed into this local analysis.

240. The extent to which CRR could be amended to the national risk assessment scores for impact and likelihood of a risk varied depending on the local risk assessment guidance in place at the time. To support engagement with partners and maintain consistent input into LRF processes, Local Planning Guidance for PHE Staff (2015) was developed **[EXHIBIT: IO/M1 0015].**

241. National risk assessment guidance defines specific risks, hazards and threats against which LRFs should compile a CRR. This includes risks relating to human infectious disease, and specifically emerging infections. Local risks assessments will have largely been guided by the reasonable worst-case scenarios for each hazard and threat.

242. According to WHO, emerging infectious diseases (EID) are those that either have been detected and affected a population for the first time, or has existed previously but is spreading, either in terms of the number of people getting infected, or to new geographical areas. Many EIDs are zoonotic in origin and often humans may have little or no natural immunity to EIDs, so their impact, on health, society and the economy, are difficult to predict.

243. Given the characteristics above, this is an example where local assessments would draw heavily on the assessment made at national level. Regional and national plans to respond based on these risk assessments will have been developed.

244. During the period 2009-2020 the risk of emerging infections increased in likelihood. The assessment pointed to the emergence of new infectious diseases being unpredictable and becoming more frequent due to factors such as: climate change; the increase in world travel; greater movement and displacement of people resulting from war; the global transport of food and intensive food production methods; humans encroaching on the habitat of wild animals; and better detection systems that spot new diseases. Ebola and Zika featured as case examples.

245. The reasonable worst-case scenario for the risk of emerging infectious diseases was based on the SARS outbreak of 2002-3. Coronaviruses did feature as background and historical evidence. The assessment noted that over a period of 25 years, more than

30 new or newly recognised diseases have been identified. For example, in 2012 a new coronavirus was identified.

246. Individual Risk Assessments (IRA) consider the likelihood and impact of an emergency event relating to the specific hazard or threat taking place, usually within a 5-year time window. They considered the characteristics of the local area that will influence the likelihood and impact of an emergency in the community. This is to establish the vulnerability and resilience of the area to emergencies **[EXHIBIT: IO/M1 0116].** It is not possible to confirm the extent to which local risk registers took into consideration health inequalities more widely. Specific vulnerabilities, resilience factors and response capabilities are considered at each LRF area, or smaller geography/population as appropriate. The vulnerability of individuals, communities and populations is specific to the hazard or threat, and can vary over time in relation to location, health status, mobility, ability/disability, socio-economic status, language and access to services. There is no uniform methodology used in the IRA process, and LRFs may use data on existing health inequalities or social risk factors differently in their assessments. However, as CRRs inform the prioritisation of preparedness activity, the Public Sector Equalities Duty also requires individual responder agencies to consider differential impacts across groups, specifically including those with protected characteristics, in their planning and response.

PHE's Emergency Planning Documents

247. The NIERP and its predecessor response plans were reviewed via a process overseen by in PHE the EPRR Delivery Group. A working group, reporting into the Delivery Group, would form to gather feedback from staff and consider learnings from incidents and exercises in the preceding 12 months. This group would recommend changes to the Delivery Group for approval. I have provided a summary of the main changes between 2013 to 2020:

- 2013: The changes involved a review to previous HPA plan, to reflect the establishment of PHE. This included updates to the terminology, organisational structure, and references to the additional functions brought into the agency **[EXHIBIT: IO/M1 0117].**

- 2016: There was a major revision to incorporate the lessons from the Ebola response. Changes to Standard and Enhanced Incident levels and the introduction of Strategic Response Group enhanced incidents **[EXHIBIT: IO/M1 0118].**
- 2017: Changes incorporated to this version included learning identified from exercises, responses, and consultation with appropriate parties within and outside PHE. The descriptions of incident levels and types were clarified, and strategic roles were defined and clarified **[EXHIBIT: IO/M1 0119].**
- 2018: Changes incorporated into this version included addition of a "Routine" incident level to define incidents that could managed with business-as-usual activities, Standard Level of incidents was added and further guidance on risk assessment **[EXHIBIT: IO/M1 0120].**
- 2019: Interim update based on feedback from across the organisation including the inclusion of specific reference to The Human Rights Act 1998 and the Equalities Act 2010. A section was added to help distinguish between incident response via the NIERP plan, and investigation of incidents (e.g. root cause analysis, and incident reporting via other governance systems) **[EXHIBIT: IO/M1 0121].**
- 2020: There was a major review of the plan, and a final version was produced and planned for testing/exercising in February 2020, with planned publication in April 2020. This was suspended due to the COVID-19 response, and updates to the plan were superseded by that response and changes to organisational structures **[EXHIBIT: IO/M1 0122].**

248. PHE's EPRR Concept of Operations (ConOps) and NIERP provided the principles and operational details of how PHE would respond to and recover from any significant public health or business continuity incident. The NIERP was an all-hazards plan that was intended to be supported by threat and hazard specific plans where necessary – the PHE Pandemic Influenza Plan (2014) was one such example. I have included a list of PHE's other threat and hazard specific plans which existed prior to January 2020. This list includes plans for HCIDs and other emergency infectious diseases. This list has been checked to the best of our ability but due to systems changes may not be fully complete. **[EXHIBIT: IO/M1 0123].** In addition, guidance for the public health response

to specific threats is available to incident teams which covers a range of health conditions and external events such as, deliberate release, adverse weather, and disease outbreaks.

Pandemic Flu Plan

249. At the PICOG meeting of 4 February 2019, the committee discussed the need to refresh the PHE pandemic influenza preparedness framework and response plan in line with the UK national strategy update that was being undertaken by DHSC **[EXHIBIT: IO/M1 0124].** A '*Pandemic flu strategy update*' paper was presented at the meeting **[EXHIBIT: IO/M1 0124].** The main objectives of the update were to:

    1. Ensure that the specific PHE responsibilities, including key response functions, within these pandemic influenza documents remain valid and that any developments since 2014 were included
    2. Ensure that roles and responsibilities were assigned correctly to management units within PHE
    3. Inform the publication of the updated PHE pandemic influenza strategic framework and response plan documents.

250. A proposed workplan was suggested for the update work to be covered in five phases starting in April 2019 and completed in April 2020 with the submission of the final version of the response plan submitted for review to the PHE senior management team.

251. The aim of the update was to reflect the changes in roles and responsibilities for the delivery of the national strategy rather than a change in strategic direction. Within 2019, some changes to the plan had been identified, including mapping the roles and functions within the plan to the latest organisational structures within PHE. However, this had not progressed to a more advanced version before the end of 2019 due to lack of capacity in specialist teams.

Communicable Disease Outbreak Management Operational Guidance (2014)

252. PHE's Communicable Disease Outbreak Management Operational Guidance (2014) provided operational guidance for managing outbreaks of communicable disease in

England at all levels of PHE that held health protection responsibilities **[EXHIBIT: IO/M1 0126 - INQ000090419].** This generic guidance could be applied as a basis to manage any outbreak of infectious disease, with tailoring as appropriate to the specific pathogen. This guidance does not specifically apply to HCIDs (which would usually be managed via the HCID pathway and via a standard or enhanced response structure) but could be applied to other emerging infections. As discussed elsewhere in this statement, PHE had in place a specific plan for MERS-CoV and specific guidance documents for many infections. The 2014 outbreak guidance was tested as part of Exercise Leopold with a recommendation for it to be reviewed and updated. To date, there has been no further review or update conducted and therefore no further exercising of this guidance.

Guidelines for large-scale contact tracing

253. PHE regional Health Protection Teams (HPTs) usually managed day to day small-scale contact tracing activities. Large-scale contact tracing exercises prior to COVID, such as those required as part of the response to Ebola or Novichok, were led, coordinated or supported by the Field Service within PHE. PHE's internal Guidelines for Large-scale Contact Tracing stated: "*Usually, the National Infection Service Field Service (NIS FS) will lead on delivery of large-scale contact tracing during incidents, working with HPTs and other services as necessary*" **[EXHIBIT: IO/M1 0127].** Following the 2014-2016 Ebola outbreak in West Africa and 2018 Novichok incidents in Wiltshire, PHE developed this guidance to incorporate lessons learned from the incidents and the guidance was intended for the scale of such incidents. The arrangements described in this guidance were followed during the early stages of the COVID-19 pandemic, but PHE was not resourced for the whole population scale contact tracing required during the pandemic.

Local Health Resilience Partnerships

254. In addition to information around Local Health Resilience Partnerships (LHRPs) provided in the first statement to the inquiry, I have provided a copy of the Health Select Committee report (Post 2013 Public Health Report 2016) **[EXHBIT: IO/M1 0128].** This report called for an audit of local arrangements for health protection and which PHE

subsequently co-designed with nine other bodies and implemented. In April 2018, PHE published the report on this exercise **[EXHIBIT: IO/M1 0129].** The key lessons were shared with LHRPs for local implementation and PHEHPTs provided tailored feedback to individual partnerships. I have provided examples of this feedback for the North **[EXHIBIT: IO/M1 0130]**, Midlands and East [**EXHIBIT: IO/M1 0131]**, South **[EXHIBIT: IO/M1 0132]** and London **[EXHIBIT: IO/M1 0133].** There were plans to repeat the exercise in 2020-21, however this was not possible due to the COVID-19 pandemic.

Training and Exercising

255. Professor Dame Jenny Harries' statement on behalf of UKHSA describes key examples of how PHE considered inequalities within emergency response planning and exercising. As a further example, during the review of the NIERP in 2019 it was noted in feedback that there had not previously been reference made to the relevant legislation regarding inequalities. As part of the revision in December 2019 both the Human Right Act 1998 and the Equalities Act 2010 were included.

256. As mentioned in the first statement, PHE was normally commissioned by other organisations to conduct exercises, and so the exercise designed to fit the specification of the commissioning organisation. The PHE Exercises Team was not routinely tasked by the commissioning department to include health inequalities as a specific exercise objective, but inequalities were discussed depending on the exercise. UKHSA incident response arrangements and exercises now routinely include this important consideration. However, some exercises did promote discussions and thinking on health inequalities, which would have been appropriately reflected in the exercise report.

257. Exercises were designed to train, validate and test arrangements, to identify areas for improvement and to develop relationships between agencies and responders. Response arrangements and capabilities tested through exercises should have been developed to address identified risks, including specific vulnerabilities at individual, community and population level. Such vulnerabilities may have related variously to health equity issues – such as socioeconomic status, relative deprivation, hard to reach groups, clinical risk factors, exposure and susceptibility to external hazards. The

degree to which differential impacts of an emergency in terms of vulnerability and subsequent outcome would depend on the overall scope of the exercise.

Identifying lessons from Major Public Health Incidents

258. Information on how the HPA and PHE learnt from major worldwide epidemics and pandemics during the period of this module is provided in the previous statement to the Inquiry pursuant to Module 1. Due to its historic nature, HPA and PHE did not specifically generate new learnings from the Spanish flu 1918 (Influenza A (H1N1)), although the body of research and experience from that and other historic epidemics and pandemics has fed into the professional understanding and approach to infectious disease surveillance and health protection. However, a specific example of this is the recognition of the frequency and public health impact of influenza epidemics and pandemics, which has driven the focused work to prepare and respond to seasonal and pandemic influenza. As an example, the 1997 Multiphase contingency plan for Pandemic Influenza refers directly to experience of the 1918 H1N1 pandemic **[EXHIBIT: IO/M1 0134].**

259. The emergence of widespread outbreaks of avian influenza H5N1 in birds between 2003-2005, and numerous clinically severe or fatal human cases associated with contact with infected birds) led to increased concern in the health protection and scientific community about the risk of a pandemic posed by avian influenza.

260. Additional information on PHE's learnings from the SARS-CoV outbreak in 2003, the MERS outbreak in South Korea in 2015, cases of MERS-CoV detected in England in 2013 and 2018 have been provided earlier in this statement.

261. Here, I provide additional information on PHE's learnings from the Mpox outbreak in England in 2018.

262. In September 2018 two cases of imported Mpox were diagnosed in the UK, one in Cornwall, the other in Blackpool. Although there was no evidence for an epidemiological link between these cases, both had travelled in southern Nigeria before coming to the UK **[EXHIBIT: IO/M1 0135].**

263. The focus of the public health response was to contain spread, detecting possible secondary cases early and minimising the potential for onward transmission, as well as ensuring appropriate clinical management of the cases. Response activities also included collaboration with national and international partners, including the Nigeria Centre for Disease Control.

264. A debrief was conducted into the incident to manage the case in Cornwall, and the following learning points were identified:

- there were difficulties obtaining passenger details from the carrier airline to support contact tracing, due to data protection concerns by the airline about sharing this information
- the collection of additional information was required to support contact tracing of foreign nationals and Health Care Workers. It was recommended these additional questions are included within the large scale-contact tracing tool development work that was ongoing at the time
- the response also identified the need for vaccines and medical countermeasures guidance for High Consequence Infectious Diseases to be reviewed or developed **[EXHIBIT: IO/M1 0136].**

265. As described in the academic paper exhibited above **[EXHIBIT: IO/M1 0135]** the detection of these two epidemiologically un-linked cases of Mpox in the UK provided important learning about the importance of infectious disease surveillance, clinical awareness and early recognition and isolation, as well as the need to obtain a full travel history for all patients. This also highlighted the importance of global health security initiatives and the rapid sharing of information, the need for continued collaborations and the strengthening of surveillance systems for emerging and re-emerging infectious diseases globally.

Section 5: UKHSA (2021 – Present)

UKHSA Governance and Organisational Structure

266. UKHSA was established on 1 April 2021 and became fully operational on 1 October 2021 combining the health protection clinical and scientific functions of Public Health England (PHE) with the operational capacity of NHSTT including the analytical

capabilities of the Joint Biosecurity Centre (JBC). Below I provide more information on the governance and organisational structure of UKHSA.

267. UKHSA's Advisory Board was established in April 2022, with the Non-Executive Chair, five Non-Executive Members and three Associate Non-Executive Members appointed by the DHSC SoS **[EXHIBIT: IO/M1 0137].** The first informal meeting of the Board was held in June 2022 and the first formal meetings were held in September and November 2022. The Board has established four committees: an Audit and Risk committee, a People and Culture committee, a Science and Research committee and an Equalities, Ethics and Communities committee. I provide a high-level description of the role of each of these committees below.

268. Audit and Risk Committee (ARC): supports the CEO and Accounting Officer in their personal responsibility for issues of risk, control and governance by reviewing the reliability and integrity of the Accounting Officer's assurances. The ARC provides advice and assurance on the development and maintenance of appropriate corporate governance and internal control arrangements, including assurance of UKHSA's strategic risk management, finances, and major capital projects [**EXHIBIT: IO/M1 0138].**

269. People and Culture committee: assists the UKHSA Advisory Board by providing advice on UKHSA's strategies and plans for talent management; succession planning; capability building performance management; and incentives and rewards. The Committee also advises on whether the organisation's people related processes are effective in helping UKHSA achieve its goals. The Committee will also monitor and review issues relating to the values and organizational culture of UKHSA, drawing as necessary on data and narrative insights to ensure that the culture of the organisation, its skills and capabilities and the well-being of the workforce are consistent with UKHSA's long-term strategy and purpose [**EXHIBIT: IO/M1 0140].**

270. Science and Research committee: advises the UKHSA Board on strategic aspects of UKHSA's scientific work including: the development and implementation of UKHSA science and research strategy, strategy to ensure that UKHSA science and research has greatest impact on health outcomes and update the Advisory Board on important

new developments in science and research and provide advice on change of priorities in the event of public health emergencies or other major developments. **[EXHIBIT: IO/M1 0140].**

271. Equalities, Ethics and Communities committee: assists the Advisory Board by providing advice on UKHSA's ambition to reduce health inequalities and engage with communities. It is also a source of advice for ethical decision making in the field of health security. The Committee provides advice, support and challenge to the organisation, focusing on: development and implementation of the Health Equity Strategy; new developments in addressing health inequalities across the health system; reviewing the organisation's actions related to its statutory duty to protect the nation's health and reduce inequalities linked to its core role of protecting against emergency threats; advising the ethical basis for internal programme activities and decision-making; and advising on how the organisation considers and addresses the needs of different communities to meet its core role of protecting against health threats. **[EXHIBIT: IO/M1 0141].**

272. UKHSA currently comprises 6 groups led by directors general: Clinical and Public Health; Science; Data, Analytics and Surveillance; Health Protection Operations (which incorporates Testing Operations); Strategy, Policy and Programmes; Finance, Commercial and Corporate services; and 3 groups led by Directors: Information Technology; People; and the COVID-19 Vaccine Unit. This spans a very wide range of professions. Each group has a leader who reports to Dame Jenny Harries, Chief Executive. The UKHSA model is designed in such a way that these capabilities work together to provide an integrated all-hazards health protection capability. Below I provide a high-level description of the work carried out by each of these groups.

273. Clinical and Public Health: this group provides advice on the control of infectious diseases and is responsible for developing guidance and advice to protect health from infections and reducing the burden of vaccine preventable diseases in the UK, providing advice to the NHS and developing future immunisation programmes. The Clinical and Public Health group monitors the epidemiology of infectious diseases and provides clinical and public health advice and expertise on the prevention and control of harmful pathogens in the population and healthcare, both in the UK and abroad e.g.,

AMR, Mpox, TB and Polio. This group coordinates the organisation-wide pathogen genomics programme.

274. Science: delivers a range of specialist health protection functions and services including the response to chemical, radiological, nuclear and environmental incidents, ranging from large-scale radiation incidents and hostile biological incidents. The group provides specialised microbiology and laboratory services including national critical infrastructure. This includes the Public Health Microbiology Labs that provide essential services for the NHS and support the control of outbreaks and incidents through investigation of infections. This also includes high containment laboratories that offer diagnostics on pathogens which can cause fatal disease, and research and evaluation labs which support vaccine development and evaluation. The group provides leadership and management of research, evidence analysis, innovation and foresight, behavioural science and evaluation of interventions functions.

275. Data, Analytics and Surveillance: builds on capabilities developed during the pandemic, collecting, monitoring and analysing health threat data to enable effective planning and clinical interventions on a local and national scale. Examples of this include Wastewater surveillance detecting Polio in London, and the monitoring of respiratory viruses to direct NHS Winter planning.

276. Health Protection Operations: the main operational delivery arm of UKHSA's overarching incident management function, providing 24/7 specialist on-the-ground public health expertise to deliver proactive and reactive health protection activities across the country. It comprises regional health protection teams that work closely with directors of public health and other regional and local partners to deliver disease control and prevention and Civil Contingencies statutory duties.

277. Strategy, Policy and Programmes: UKHSA's Strategy, Policy and Programmes function works across UKHSA to deliver on its remit effectively, including by providing critical policy advice to DHSC Ministers on incidents and emerging infectious diseases. This group coordinates vital UKHSA activities including the Centre for Pandemic Preparedness and 100 Days Mission in preparation for future pandemics, working

across Whitehall to ensure join-up on critical activities and political priorities, and ensuring UKHSA remains focused on the most critical health threats.

278. Finance, Commercial and Corporate services: UKHSA's Finance, Commercial and Corporate services enable the Agency to function effectively, manage contracts, meet legal requirements and ensure UKHSA maintains its reputation as an organisation private and academic institutions want to partner with and procure from.

279. People: Delivers critical Human Resources services to UKHSA and its staff, supporting the Agency's value-led culture to attract and retain talent. This includes investment in its leaders and staff, ensuring there's strong learning, development and reward offers in place to promote excellent employee experience. This also includes essential workforce planning support to a young Agency undergoing transformation, ensuring we have a workforce that is flexible and resilient.

280. Information Technology: ensures UKHSA has the vital infrastructure to deliver through essential IT services in the most efficient and effective way supporting laboratory and clinical systems, robust cyber defences, and technological efficiency solutions to reduce administrative resource.

281. COVID-19 Vaccine Unit: The COVID Vaccine Unit took over the enduring responsibility for COVID-19 vaccine supply from the Vaccine Taskforce on 1 October 2022. The innovative approaches, skills, operating models and team that were key to the Vaccine Taskforce's success continue in the COVID Vaccine Unit as an integral part of UKHSA. The unit's priority is to ensure that the UK continues to have the necessary supply of effective COVID-19 vaccines, inline with advice from the JCVI. The COVID Vaccine Unit is also responsible for the 10-year strategic partnership between the government and Moderna. This will reinforce the UK's future pandemic preparedness and see Moderna onshore mRNA production facilities in Harwell, Oxfordshire, as well as provide substantial investment into UK life sciences.

Signed: Personal Data

Dated: 17th May 2023