THE UK COVID-19 INQUIRY

MODULE 4

CLOSING STATEMENT ON BEHALF OF THE MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

Introduction

1. This brief closing statement is made on behalf of the Medicines and Healthcare products Regulatory Agency ("MHRA").[1]

2. The MHRA is grateful to the Chair and the Inquiry Legal Team for the opportunity to contribute to this key module. In line with its first priority of patient safety, the MHRA seeks to assist the Chair in making findings and recommendations for future pandemics, to best protect our nation's public health. The MHRA also extends its gratitude to the appointed experts who have brought the benefit of their specialised knowledge and opinion to this module, especially as the vaccination sphere is the subject of widespread misunderstanding, misinformation and disinformation.

3. The MHRA joined the collective endeavours of many individuals and organisations which led to the UK approving effective vaccines which prevented at least 100,000 deaths here and many more worldwide. The UK saw the highest number of lives saved during the pandemic due to Covid-19 vaccinations in the entire World Health Organisation Europe region.[2] In the context of that success, however, the compelling evidence of those who have been injured or bereaved following receipt of a Covid-19 vaccine or treatment will not be forgotten. The MHRA has listened carefully to the evidence and reiterates its deepest regret and condolences to all those affected. Through and beyond this Inquiry, the MHRA will continue the work of strengthening its systems to promptly identify and minimise risks associated with medical products.

4. By this closing statement, the MHRA does not seek to rehearse the evidence which has been heard, rather it focuses on specific matters which have a particular bearing upon the MHRA and its work. At paragraphs 11-17 of Dame June Raine's first statement for Module 4 she summarised the role, functions and aims of the MHRA

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[1] References to evidence heard are to the day, page and line of the transcript, i.e. [**d/p/l**].
[2] Report of Professor Daniel Prieto-Alhambra, paragraph 6.3 [**INQ000474703_0070**].

[**INQ000474337_0007-0008**]. Dame June gave evidence in person before the Inquiry on 22 January 2025 [**7/114/9 – 7/189/1**].

Findings

5. The Chair is invited to find that the MHRA responded quickly and adeptly to the pandemic. It adapted various working practices and utilised its regulatory flexibilities, including through the use of rolling reviews of data (see, in particular, Dame June's first statement, paragraphs 138-141, 150-170 and 818-820),[3] which has been commented upon favourably by a number of witnesses including:
   a. Clara Swinson [**4/86/13 – 4/88/16**];
   b. Dame Kate Bingham [**6/29/20 – 6/32/15**];
   c. Professor Stephen Evans [**7/38/17 – 7/40/17**];
   d. Dr Justin Green [**8/156/10 – 8/157/10, 8/186/2-8**]; and
   e. Ben Osborn [**8/124/5 – 8/127/24**].

6. The result was that the MHRA was the first regulator in the world to authorise for use a vaccine against Covid-19 on 1 December 2020. This in turn led to the world's first administration of such a vaccine taking place in the UK on 8 December 2020.[4] No other regulator reached a materially different decision.[5] Since that pivotal moment, over 14 million lives globally have been saved by Covid-19 vaccines.[6]

7. Notwithstanding the significant challenges and pressures which the pandemic presented, the Chair is invited to find that the MHRA robustly maintained its independence throughout (see the evidence of Dame June Raine [**INQ000474337_0022-0023** at paragraphs 60-64] as well as Clara Swinson [**4/71/25 – 4/74/19**], Professor Sir Jonathan Van-Tam [**5/130/13 – 5/135/6**] and Professor Stephen Evans [**7/31/3 – 7/32/2**]), and did not compromise on the rigour with which it approached and assessed patient safety and benefit-risk.[7]

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[3] Statement of Dame June Raine [**INQ000474337_0043-0044, 0046-0052, 0229-0230**].
[4] Statement of Dame June Raine, paragraphs 197-210 [**INQ000474337_0060-0063**].
[5] Report of Professor Stephen Evans, paragraphs 2.33-3.19 [**INQ000474707_0018-0032**].
[6] Professor Daniel Prieto-Alhambra [**7/75/23 – 7/76/25**].
[7] Statement of Dame June Raine, paragraphs 60-83 [**INQ000474337_0022-0029**] and Dame June Raine [**7/117/16 – 7/119/17**].

8. In his oral evidence, Professor Sir Nicholas White referred to "regulatory authorities…for example, across the Atlantic" and "[t]he US FDA [Food and Drug Administration]" which "bent under political pressure" [**12/31/2-13**]. The MHRA does not understand this criticism to have been directed towards the UK regulator, however for the avoidance of doubt, any implication that the MHRA was "pressurised by government" and changed its approach in light of any such pressure, is entirely rejected.

9. In its efforts, the MHRA's expertise and experience was supported and enhanced by the independent scientific advice of the Commission on Human Medicines and its Expert Working Groups, alongside further independent expert input.[8] The MHRA is grateful to all those who generously provided their time and expertise, without whom the complex tasks of authorising and monitoring the safety of the Covid-19 vaccines and medicines would have been severely impeded.

10. The MHRA invites the Chair to accept the evidence of Professor Stephen Evans that the authorisation processes which the MHRA adopted for vaccines and therapeutics were appropriate; they were in line with other international regulators; and they did not impact on the scientific assessment of the safety of the vaccines which was in line with international standards. Indeed, as Professor Evans explained, the processes adopted meant that the scrutiny afforded is likely to have been greater than would normally have been the case (see paragraphs 3.4-3.5, 3.19, 6.1, 6.15-6.17, 7.1 of Professor Evans' report [**INQ000474707_0027-0028, 0032, 0050-0052, 0058-0059, 0075**] and Professor Evans' oral evidence [**7/35/12 – 7/40/17**]). Reassurance should be drawn from the expert opinion that there was no deviation from the typical efficacy and safety standards in authorising the Covid-19 vaccines (Professor Evans' report, paragraphs 6.15-6.17 [**INQ000474707_0058-0059**]). High quality evidence from large clinical trials suggested that the three major vaccines deployed for use in the UK were effective "*well above the threshold set out by most of the regulators internationally*" at the time of their authorisation (Professor Prieto-Alhambra [**7/84/23 – 7/85/10**]).

[8] As explained and expanded upon in Dame June Raine's statement at paragraphs 41-45, 472, 490, 540-541, 632, 666, 688-691, 711, 744, 830-833 [**INQ000474337_0017-0018, 0135-0136, 0140-0141, 0154, 0176-0177, 0186, 0193, 0199, 0208-0209, 0232-0233**]. See also Dame June Raine's oral evidence [**7/117/16 – 7/119/17, 7/123/6-13, 7/124/21 – 7/125/10**] and Professor Daniel Prieto-Alhambra [**7/33/3-22**].

11. As to clinical trials, the Chair is invited to accept that the oversight mechanisms were robust and consistent with pre-pandemic standards (see Professor Stephen Evans' report, paragraphs 3.5, 6.1-6.5, 7.2 [**INQ000474707_0028, 0050-0053, 0075**] and his oral evidence [**7/16/23 – 7/18/6**]). These well-designed and appropriately-sized trials generated a considerable amount of data from studies in different countries reflecting different demographics and ethnicities.[9]

12. Nevertheless, as Professor Evans told the Inquiry, "*in nearly all trials the degree of diversity is not ideal for a whole host of reasons*" [**7/46/18-19**]. Noting practical problems inherent in investigating specific side effects in different ethnic minority communities, Professor Evans stated that considerable effort had been made to include people from different racial backgrounds in trials for the AstraZeneca (Vaxzevria) vaccine [**7/46/19 – 7/48/11**]. Professor Prieto-Alhambra emphasised the twofold importance of greater diversity in pre-approval clinical trials: to improve the understanding of risk-benefit profiles and to reduce vaccine hesitancy among under-represented groups [**INQ000474703_0019**]. Action to improve representativeness in clinical trials is highlighted as one of the MHRA's principal recommendations below.

13. Professor Sir Nicholas White posed important questions about how some clinical trials were run and regulated: in particular whether steps should be taken to improve the effectiveness of Phase II trials and ensure that they are not underpowered.[10] The opportunity to have these questions further discussed will arise with the forthcoming implementation of the new UK clinical trials legislation: regulations amending the Medicines for Human Use (Clinical Trials) Regulations 2004 have been laid before Parliament in December 2024.

14. In respect of post-authorisation surveillance, the Chair is further invited to accept the evidence of Professors Evans and Prieto-Alhambra:

    a. First, the MHRA's strategic approach to post-authorisation monitoring of Covid-19 vaccines was reasonable and was built upon tried and trusted methods of analysis, bolstered by innovations such as drawing data from electronic health

[9] Report of Professor Stephen Evans, paragraphs 3.15, 6.6-6.14 [**INQ000474707_0031, 0054-0058**]; report of Professor Daniel Prieto-Alhambra, paragraphs 4.19-4.26 [**INQ000474703_0019-0020**]; Professor Stephen Evans [**7/18/7 – 7/19/10, 7/49/11 – 7/50/5**]; and Professor Daniel Prieto-Alhambra [**7/50/6-25**].

[10] Report of Professor Sir Nicholas White, paragraphs 5.2-5.25, 5.76 [**INQ000474743_0029-0043, 0065**] and Professor Sir Nicholas White [**12/9/6 – 12/11/6, 12/11/7 – 12/15/8, 12/17/6 – 12/18/17**].

records within the Clinical Practice Research Database and the targeted Yellow Card Vaccine Monitor.[11] The Yellow Card Scheme worked well as the main source of signals, although it was not the only means through which the MHRA identified such potential signals.[12] Despite at times facing almost a twenty-fold increase in the volume of adverse event reports received, the quality of the work performed by the MHRA was assessed as high.[13] The MHRA's four pillar strategy for surveillance was described by Professor Evans as a "*strong attempt to monitor safety of vaccines and therapeutics in an active way and not simply to rely on passive surveillance*" (paragraph 5.13 [**INQ000474707_0046**]).

b. Second, the MHRA's evaluation of those signals was done well, with output which was very similar in substance and value to other regulators in Europe and the United States of America.[14] As part of its robust and sophisticated safety analysis, the MHRA consulted with and drew upon the independent expertise of the Commission on Human Medicines and its Expert Working Groups. Professor Prieto-Alhambra stated that the formation of the Covid-19 Vaccines Benefit Risk Expert Working Group and other advisory groups responding to emerging signals was fundamental in positively informing decision-making.[15]

c. Third, the system responded effectively to safety concerns which emerged following the authorisation of the Covid-19 vaccines. The response to the emerging signals of myocarditis, pericarditis and thrombosis with thrombocytopenia syndrome was appropriate and consistent with other comparable international regulators.[16] Professor Prieto-Alhambra explained that the UK's identification of the thrombosis with thrombocytopenia syndrome

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[11] Report of Professor Stephen Evans, paragraphs 5.5-5.22 [**INQ000474707_0043-0049**] and statement of Dame June Raine, paragraphs 328-329 [**INQ000474337_0092-0097**].
[12] Report of Professor Stephen Evans, paragraph 7.4 [**INQ000474707_0075**]; Professor Stephen Evans [**7/61/19 – 7/62/9**]; and Professor Daniel Prieto-Alhambra [**7/64/17 – 7/65/4**].
[13] Report of Professor Stephen Evans, paragraph 5.12 [**INQ000474707_0046**].
[14] Report of Professor Stephen Evans, paragraph 6.37 [**INQ000474707_0066**]; Stephen Evans [**7/67/16 – 7/68/10**]; report of Professor Daniel Prieto-Alhambra, paragraph 3.17 [**INQ000474703_0014**]; and Professor Daniel Prieto-Alhambra [**7/67/16 – 7/68/16**].
[15] Report of Professor Daniel Prieto-Alhambra, paragraph 3.18 [**INQ000474703_0014**].
[16] Report of Professor Daniel Prieto-Alhambra, paragraphs 5.7-5.49 [**INQ000474703_0032-0041**]; report of Professor Stephen Evans, paragraphs 6.38-6.42, 7.5 [**INQ000474707_0066-0067, 0075-0076**]; Professor Stephen Evans [**7/72/25 – 7/73/12**]; and Professor Daniel Prieto-Alhambra [**7/73/13 – 7/74/2, 7/93/23 – 7/95/22**].

signal at a slightly later time may have been caused by the greater use of the AstraZeneca (Vaxzevria) vaccine in younger populations in continental Europe compared to the UK [**7/73/13 – 7/74/2**]. He also pointed out that suspending or halting the use of a Covid-19 vaccine in the face of emerging safety signals could potentially cause harm, including deaths, for people not protected through vaccination. This counter-factual must be assessed carefully within the risk/benefit analysis conducted [**7/93/23 – 7/95/22**]. Professor Evans considered that safety signals were examined by the MHRA in a timely and thorough manner and stressed the finely balanced nature of risk/benefit assessments in a pandemic.[17]

Recommendations

15. In Dame June Raine's principal statement for this module of the Inquiry, she set out various reflections from lessons learnt and suggested 12 improvements which could be made for future pandemics (see paragraphs 796-859 [**INQ000474337_0222-0240**]). Those are not repeated herein, rather three matters are highlighted as offering an opportunity to ensure that the United Kingdom is as well-prepared as it can be for the next pandemic.

Access to data

16. Access to data has often been raised throughout this module as a key enabler.[18] Data generation is essential to robust benefit-risk profiles. There is clear potential to use real-world data more effectively in support of robust and timely regulatory decisions. In the context of his evidence on the response to the thrombosis with thrombocytopenia signal in 2021, Sir Munir Pirmohamed told the Inquiry that "*deep linkages are going to be critical in the future for us to be able to get the best information as quickly as possible for these kind of serious, complex events*" [**11/151/16 – 11/153/4**]. Better data linkages between healthcare datasets in particular offer the opportunity to move closer to real-time signal detection. It will be important to further consider how signal detection can be done in large clinical datasets, using all the tools now available such as Artificial Intelligence.

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[17] Report of Professor Stephen Evans, paragraph 7.5 [**INQ000474707_0075**].
[18] See, for example, Professor Sir Chris Whitty [**5/48/9 – 5/54/14**]; the report of Professor Daniel Prieto-Alhambra [**INQ000474703_0070-0071**]; the report of Professor Sir Nicholas Evans [**INQ000474707_0077-0078**]; Professors Daniel Prieto-Alhambra and Evans [**7/79/20 – 7/80/23**]; and Dr Justin Green [**8/186/9 – 8/187/17**].

Representativeness in clinical trials

17. The Inquiry has heard about the challenges of ensuring genuinely representational clinical trials (for example, Lord Sharma [**4/48/7 – 4/51/23**] and Professor Stephen Evans [**7/46/15 – 7/48/11**]). More, however, can and should be done to promote greater diversity within those trials.[19] The MHRA has heard the core participants' evidence and agrees that central and interrelated issues underpinning vaccine and medicine confidence are trust and participation.[20] The new clinical trials legislation now being introduced offers a generational opportunity to herald a new era of truly representative studies. This is important not just to get more robust data but to assist in reassuring all users of medicines and vaccines that an authorised product has been tested in someone like them.

Ensuring the scientific expertise, capacity and capability of the regulator

18. During the pandemic the MHRA relied on the extraordinary efforts of highly skilled staff, who were able to be redeployed to review complex information at pace, to produce high quality approval and safety processes for vaccines and therapeutics for the UK. As Professor Evans commented, "*That the MHRA staff worked extraordinarily hard at peak periods is undoubtedly true*".[21] It is vitally important that there is continued investment in the MHRA's capability for pandemic preparedness.[22] It is equally important that the Agency is able to stay competitive with industry as an employer in retaining and recruiting people with the types of skills and expertise needed, in the best interest of patients and the public.

Conclusion

19. The MHRA keenly anticipates the Chair's findings and recommendations for this module, which will be critical in ensuring that the United Kingdom stands in good stead for the next public health crisis. To that end, the Agency remains committed to supporting the Inquiry, listening to core participants, implementing recommendations and continually improving the ways in which it works.

12 February 2025

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[19] Report of Professor Daniel Prieto-Alhambra, paragraph 6.5 [**INQ000474703_0072**]; and Dame June Raine [**7/143/24 – 7/144/14, 7/182/8-25**].
[20] Kamran Mallick [**2/169/22 – 2/171/23**]; Dr Salman Waqar [**3/3/3 – 3/8/20**]; and Professor Heidi Larson [**3/171/16 – 3/173/15**].
[21] Report of Professor Stephen Evans, paragraph 5.20 [**INQ000474707_0048**].
[22] Report of Professor Daniel Prieto-Alhambra, paragraph 6.5 [**INQ000474703_0070**].