IN THE MATTER OF THE UK COVID-19 PUBLIC INQUIRY
BEFORE BARONESS HALLETT

MODULE 4: SECOND PRELIMINARY HEARING ON 22 MAY 2024 WRITTEN SUBMISSIONS FROM THE FEDERATION OF ETHNIC MINORITY HEALTHCARE ORGANISATIONS ("FEMHO")

A. INTRODUCTION

1. These written submissions are provided on behalf of FEMHO in advance of the second Module 4 preliminary hearing on 22 May 2024. They address the following items identified by Counsel to the Inquiry ('CTI') in the Note for the Preliminary Hearing dated 2 May 2024: (1) Update on scope of Module 4, (2) Rule 9 requests (3) Parliamentary Privilege (4) Disclosure; (5) Expert witnesses; and (6) Timetable and Future Hearings.

2. Module 4 seeks to examine important matters in the sphere of Vaccines and Therapeutics. FEMHO, as a consortium of Black, Asian and Minority Ethnic health and social care workers ('HCWs'), provides the Inquiry with a uniquely informative voice, given the unequal impact of the pandemic on Black, Asian and Ethnic Minority HCWs and communities. Our members shed light on this disproportionate impact and can speak directly to each of the areas to be considered in the provisional list of issues in this module. They will do so by bringing the benefit of their professional expertise and personal lived experience of the impact of the pandemic at all levels within the health care systems across the UK and also from the perspective of the communities where the disparity in the devastating and direct health outcomes are a well-trodden and firmly established path.[1] FEMHO look forward to actively participating in this important module.

[1] This Inquiry has helpfully illuminated and contextualised the clear link between health inequality within the healthcare system. Professor Clare Bambra, in addressing the question posed in the course of her evidence in Module 1 of what the impact of racism and inequality is, stated: "*People from minority ethnic groups are much more likely to be living in deprivation, so everything that Professor Marmot outlined in terms of the health impacts of poverty, housing and so on applies kind of even more so, it's amplified for people from minority ethnic groups. So, for example, 50% of Bangladeshi and Pakistani households are in the 20% most deprived neighbourhoods, compared to 17% of the white population."* [16 June 2023, p.18 lines 14-22]

3. In addition, FEMHO recognises the urgent need to address systemic inequalities and institutional barriers that have contributed to the disparate impact of the pandemic on Black, Asian and Minority Ethnic communities. They are committed to advocating for policy reforms which were shown to be lacking in Module 1, exposed in Module 2 and accordingly, relevant to the issues highlighted in Module 4, as well as initiatives aimed at promoting equality, diversity, and inclusion within healthcare. By actively participating in this module, FEMHO seeks not only to provide insights into past shortcomings but will assist the Inquiry by contributing constructively to the development of solutions that will safeguard the health and well-being of all individuals, regardless of ethnicity or background going forward.

B. UPDATE ON SCOPE

4. FEMHO notes that the provisional scope of Module 4 has been amended to reflect the Chair's ruling following Core Participant ('CP') submissions made at the last preliminary hearing, though we appreciate it remains necessarily provisional. FEMHO acknowledges that the overriding focus will be on: "*the systems, processes and outcomes relating to the development, procurement, manufacture, approval, eligibility for and access to vaccines and therapeutics during the Covid-19 pandemic, and how they can be improved; on preparedness and the core decision-making (including of course the decisions of the Vaccine Taskforce and the Antivirals and Therapeutics Taskforce); on the general impact of those decisions, especially on marginalized groups and communities*." FEMHO particularly welcomes the assurance that the Inquiry will expressly address the impact of all decisions on marginalised groups and communities.

5. We further welcome that the amendments include confirmation that the scope will cover whether Vaccine as a Condition of Deployment ('VCOD') was or would have been effective in limiting transmission and its impact on "vaccine hesitancy/lack of confidence." We are pleased that the Inquiry has addressed our concerns made at the last preliminary hearing regarding the use of terminology that better reflects the sensitivities and complexity of the issues at play.

6. Additionally, we are encouraged that misinformation and post-marketing surveillance including the Yellow Card scheme and UK Vaccine Damage Payment Scheme are included which were further matters FEMHO made submissions on at the last hearing.

Linked to these issues we would be grateful for clarity on whether the investigation will cover the interrelationship between the vaccine and Long Covid.

7. The CTI note states that the Inquiry "*will address the safety-related debate over vaccines*" but that it will not reach a conclusion on the safety of specific vaccines or seek to quantify risks of vaccination. Nor will it interrogate scientific analysis underpinning the decision-making "*though it will investigate the steps that were taken to mitigate known risks of the vaccines*." These are important issues for FEMHO and it is currently unclear how far the Inquiry will consider these issues; we would welcome further clarity from CTI on this at the preliminary hearing. Certain aspects of the commercial negotiations and contractual arrangements for vaccines and therapeutics have been excluded from the investigation, including unit prices, discounts and pricing structures; details of supply chains and manufacturing processes; IP rights and licensing issues; and details of assessment procedures (CMC processes).

8. We reiterate the key importance of the Inquiry's stated resolute commitment to placing "*possible inequalities*" at the "*forefront*" of its investigation, which must involve an unflinching and thorough exploration of whether institutional and structural racism and inequality[2] played a part in the development, procurement and use of Covid-19 therapeutics and vaccines (including the implementation of the vaccine rollout programme) and, if it did, the resulting impact on those vulnerable groups in the healthcare system across the UK.

9. This exploration is crucial because the effects of such racism and inequality, if found to have occurred, would have had a profound impact on vulnerable groups across the UK. We therefore repeat our request that the issues in Module 4 are all investigated through an inequality lens. By way of a few illustrative examples:
   a) we consider it vital that the examination of the development, trialling and procurement of Covid-19 vaccines and the implementation of the vaccine rollout programme investigates if and how pre-existing knowledge in the identification of, and any pre-emptive and/or mitigating action was taken in respect of ethnic groups which were the subject of unequal uptake and whether there was sufficient effort to ensure equitable representation and diversity in trials;

[2] See BMA analysis of the CRED (Commission on Race and Ethnic Disparities) published its Race report on 31 March 2021.

b) closely related to the above, how consideration and evaluation of 'at risk' groups was approached by vaccine manufacturers and decision-makers, specifically including in relation to ethnic minority groups (given existing knowledge) and in relation to other linked vulnerabilities for example higher rates of conditions such as sickle cell disease and clotting diseases;

c) in relation to decision-making on vaccines and treatment, we consider it vital that the Inquiry explores whether there was appropriate consideration of vulnerability, needs and mitigating measures to protect minority ethnic HCWs and/or communities in light of pre-existing known risk factors and, related to this, whether data disaggregated by ethnicity was available, collated and analysed to identify disparities and risks or not;

d) in considering the issue of vaccine confidence a careful examination of the multi-factorial underlying issues surrounding confidence in Black, Asian and minority ethnic HCW's and communities must be carried out, to include the extent to which pre-existing knowledge was taken into account and the role which thematic lack of data played;

e) Whether the vaccine damage payment scheme has been equitable in its application, by reference to data disaggregated by ethnicity if available;

f) accessibility and cultural competence in surveillance, including the Yellow Card Scheme, and community outreach and engagement should be examined such that recommendations can be made to improve preparedness for the next pandemic; and

g) in considering the role of communication and messaging, and the decisions taken by the vaccine taskforce regarding the roll out, linguistic accessibility, cultural competence and the approach to dealing with poor uptake, ensuring accessibility to vaccine centres, spread of misinformation and the use of "hard to reach" mantra must be carefully examined as well as what efforts have continued since the pandemic and can be added to now on how trust can be rebuilt for future.

10. We invite the Inquiry team to revisit our previous detailed submissions in relation to scope and the other specific issues that we urge the investigation to cover; these can be found at paragraphs 10-30 of our submissions dated 5 September 2023.

11. Given the gravity of the situation and the potential implications for public health and societal trust, it is essential that the Inquiry does not shy away from investigating these

complex and sensitive issues. The disproportionate impact of the pandemic on minority ethnic communities has already underscored the urgent need to address systemic inequalities within the healthcare system. Failure to thoroughly examine the role of institutional and structural racism and inequality in the context of vaccine and therapeutic development and distribution would not only undermine the credibility of the Inquiry but also perpetuate existing disparities and injustices.

12. Therefore, by prioritising the exploration of these issues, the Inquiry demonstrates its commitment to justice, equity, and transparency. It is only through a comprehensive examination of all potential factors contributing to healthcare disparities that meaningful lessons can be learned and mistakes not repeated, ensuring the fair and equitable distribution of healthcare resources and services for all individuals, regardless of ethnicity or background.

C. RULE 9 REQUESTS

13. FEMHO acknowledges the progress made thus far, with over 120 Rule 9 requests issued to a diverse range of entities and approximately 80 draft statements received, with another 15 or so in contemplation. However, concerning the Inquiry's decision not to disclose Rule 9 requests to CPs, FEMHO respectfully reiterates its previous requests for the Inquiry to reconsider this position .

14. FEMHO suggests that this stance appears somewhat incongruous with the Inquiry's significant invitation to CPs to propose additional Rule 9 requests. Without access to the requests themselves and with disclosure expected on a rolling basis, it will be exceedingly difficult for CPs to identify any gaps in evidence before the evidential hearings. This approach significantly heightens the risk that there will be insufficient time to address these gaps effectively or that there may be delays in obtaining the necessary material to fill them. Such delays could directly impact the preparation and examination of issues in Module 4 and pose a risk of derailing the overall timetable of the Inquiry. Therefore, FEMHO urges the Inquiry to reconsider its decision on the disclosure of Rule 9 requests to facilitate more effective participation by CPs.

15. FEMHO further makes the observation of inequalities not being mentioned, and perhaps being given insufficient consideration in the Rule 9 requests. Not having had sight of the Rule 9 requests themselves our analysis on this matter is based purely on the information shared with CPs in Annex A (update on Rule 9 requests) to the Inquiry legal team's update note dated 29 April 2024, which purports to summarise the areas that recipients have been asked to address in their statement.

16. Additionally, the subject of inequalities appears notably absent, however, from several significant Rule 9 requests. By way of example, entry 2 HM Treasury (inequalities not directly mentioned); entry 4. The Scottish Government (inequalities not directly mentioned); and entry 6.Department for Health & Social Care (inequalities not directly mentioned. Further, where inequalities is mentioned there is no detail as to what exactly the recipient is being asked to comment on; rather it often appears (as seems to have been the case in previous modules) as a final "catch-all" topic. See, for example, the Cabinet Office summary where "inequalities and vaccine safety" appears at the very end. The same is true of lessons learned, also often seen as the final topic. Such placement raises a concern that insufficient contextual exploration is being afforded to vital inequality issues.

17. Given that we only have the broad topics for the Rule 9s listed, there is a general issue regarding whether and/or what specific questions are being asked that address FEMHO's concerns. It appears that the inquiry may have missed good opportunities to ask questions in relation to points raised by FEMHO. For example:
    a) The Inquiry appears to have asked Professor Wei Shen Lim (Joint Committee on Vaccination and Immunisation ('JCVI')) about the following topics: (i) JCVI's structure, role, people and processes; (ii) JCVI key decisions and actions and documents; (iii) JCVI's involvement in vaccine delivery and uptake; (iv) public messaging; (v) unequal uptake; (vi) vaccine safety; and (vii) lesson learning. We are in the dark, however, as to whether the professor has been asked to cover surveillance including the yellow card system. FEMHO has previously raised the importance of obtaining JCVI evidence on this issue in submissions, namely:

> *We are keen to explore what if any consideration and/or steps were taken by government (in particular the Joint Committee on Vaccination and Immunisation ("JCVI") to address the above points [in relation to making the Yellow Card scheme more accessible and effective for ethnic minorities]*[3]

[3] See para 19 of FEMHO's Written Submissions for the 1st Module 4 Preliminary Hearing dated 5 September 2023.

b) In the "vaccine safety and lesson learning" section, for example, we are keen to know whether the question(s) posed to the Professor encapsulates some of FEMHO's simple proposals for improvements to the yellow card system[4], an example being:

> *To make the Yellow Card scheme more accessible and effective for ethnic minorities, easy to implement steps could and should have been taken rapidly to produce yellow cards in multiple languages and make them (and information / guidance on them) readily available tailored to demographic populations e.g. at pharmacies and community hubs.*

c) The Cabinet Office lists "eligibility and prioritisation" as a topic. Were vital questions asked about what consideration was given to prioritising the rollout of vaccine (and PPE) to ethnic minority communities and HCWs? In relation to "roll out," a standalone topic, have questions been asked in relation to Equality Impact Assessments? Were questions asked in relation to what consideration was given to offering the vaccine in trusted community spaces and adjustments afforded to enable the process to be culturally accessible to all[5]?

18. There is an overall concern that the scope of requests may constitute and result in an insufficient contextual exploration of inequality issues. Whilst it is acknowledged that the Inquiry may have included equality related questions in other topics such as vaccine delivery and roll-out procedures, eligibility and prioritisation decisions, barriers to vaccine uptake, and vaccine safety issues, there remains ambiguity regarding the clarity and comprehensiveness of the inclusion of inequality issues in these requests. is not clear and important evidence may be missed. The concern is that the detailed and nuanced critical points of relevance raised by FEMHO, and the lessons which we say should be learned, simply may not be covered by the Rule 9 questions and thus not be addressed sufficiently, if at all, by the recipients. CPs are then further hindered by not being permitted to direct questions at those witnesses on these issues when it comes to the public hearings. This is why we respectfully disagree that the provision of these summaries is a viable workaround to simply disclosing the Rule 9 requests themselves to CPs and why we continue to request that this decision is revisited and reversed.

[4] See para 17 of FEMHO's Written Submissions for the 1st Module 4 Preliminary Hearing dated 5 September 2023.
[5] For example, privacy screens in vaccination centres as the act of receiving a vaccine otherwise requires skin to be shown in public which is incompatible with some religions and cultures.

19. Additionally, and consistent with the Inquiry's encouraging position to expressly address the impact of all decisions on marginalised groups and communities, FEMHO urges the Inquiry to prioritise calling a proportionate number of witnesses who are from diverse backgrounds, disciplines, and locations across the UK, and who can speak to a range of systemic issues relevant to Module 4. FEMHO has many such witnesses who can provide this evidence and we very much hope that a number will be called to give impact evidence. While the Every Story Matters project is commendable in its own right, it is insufficient for this purpose. It is evident the diverse voices of HCWs lived experiences are essential to be heard within this module and sufficient time should be afforded to their evidence.

D. PARLIAMENTARY PRIVILEGE

20. FEMHO notes the position of the Inquiry on Parliamentary privilege and the practical steps taken to avoid it becoming a difficulty so far. Namely, the Inquiry can seek the same information to which parliamentary privilege would otherwise apply by formulating its Rule 9 requests to reflect what the Inquiry already knows the witnesses to have already said or provided to Parliament. In addition FEMHO notes the submissions made by the Migrant Primary Care Access Group (MPCAG) and the dispute. Accordingly FEMHO reserves its right to make further submissions on this matter, should this become a disputed live issue.

E. DISCLOSURE

21. FEMHO welcomes the confirmation in CTI's Note that disclosure will continue to be released on an ongoing basis to CPs and that so far two witness statements have been disclosed with many more to follow after review and amendment. While we recognise the immense pressure the Inquiry Team is undoubtedly facing, we, along with other CPs, strongly urge the Inquiry to prioritise early disclosure of material wherever possible for Module 4. Such early disclosure is imperative to facilitate and enable proper preparation and exploration of the varied technical and scientific issues anticipated to arise. Additionally, such disclosure will further in the effective preparation and formulation of questions to witnesses. We are cognisant of the serious problems encountered with disclosure relating to both Module 1 and Module 2, emphasising the crucial importance of improving the disclosure process moving forward.

22. We respectfully suggest that disclosure be made incrementally as information becomes available, rather than waiting to release it all at once in a single bulk. This approach would help prevent delays and enable concerned parties to "frontload" their preparation. Failure to adopt this method risks placing concerned core participants in a position where they are unable to adequately digest and analyse the evidence in time to contribute meaningfully to the hearings. This problem is enhanced particularly in circumstances where many CPs will be actively participating in, and working on, concurrent back-to-back modules.

F. EXPERT WITNESSES

23. FEMHO welcomes the update on the instruction of experts and the topics to be addressed in their evidence, as well as confirmation that CPs will have the opportunity to provide observations on the draft reports in due course. However, we would like to reiterate our previous request that Professor James Nazroo and Dr Laia Becares be instructed to produce a joint addendum report addressing the race inequality issues pertinent to Module 4. We consider there would be high value in their providing an addendum report to the Inquiry, and to be made available for questions during the evidential hearings for Module 4.

24. Should this request not be met, FEMHO requests that as a minimum all experts (including those already identified and any further experts instructed) are explicitly instructed to consider and address inequalities as it pertains to their remit. On this, we welcome the express indication in CTI's note that at least one of the Experts has already been instructed to opine on inequality issues we have raised previously. For example, the welcome assurance that Prof Kasstan-Dabush's report on the vaccine roll-out and hesitancy will cover known disparities in coverage, the underlying causes and barriers, foreseeability as well as response and the interplay between the roll out and pre-existing inequalities and structural discrimination. However, we seek confirmation that the other experts will similarly be asked to address the issues detailed in our previous submissions, for example in the equity and representation (as well as any bias) in vaccine and therapeutic development, trials and clinical use; assessment of data on antiviral and other treatments given to ethnic minority populations; and accessibility and cultural competence of messaging in the roll-out and communications and surveillance systems. We invite the Inquiry team to revisit these submissions when considering and finalising the instructions to the prospective experts.

25. It remains imperative that Module 4 extensively examines and embeds whether, and if so how, structural inequalities and cultural competencies influenced issues such as vaccine rollout, VCOD and the yellow card system alongside other central matters to Module 4. This must be considered together with the extent to which due regard was given to the Public Sector Equality Duty to eliminate discrimination and concomitant equality impact assessments undertaken. The Inquiry, with the assistance of evidence from FEMHO members, will need to grapple with how structural and systemic, economic, political and social factors coalesced to produce these adverse, racialised outcomes during the pandemic.

G. TIMETABLE AND LISTING OF FUTURE HEARINGS

26. We note that a further preliminary hearing for Module 4 will take place in October 2024 with the public hearing occurring between 14 and 30 January 2025. FEMHO maintains a genuine concern as to the limited time afforded to the evidential hearings for Module 4, given the breadth of the scope and issues to be investigated. We are mindful that with the Inquiry's practice of sitting 4 days a week and incorporating opening and closing submissions from CPs this would likely leave a mere 10 days for questioning of witnesses. Whilst we are of course keen that the Inquiry progress as expeditiously as possible, for it to be a meaningful and effective, we respectfully seek that the Inquiry allocates additional days for Module 4 hearings within the Inquiry timetabling.

H. CONCLUSION

27. FEMHO appreciates the full consideration of the Chair given to all the matters raised above. We are grateful for the attention paid to these important matters and remain hopeful that they will be carefully addressed within the inquiry process.

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