



Department  
of Health &  
Social Care

From Rt. Hon Andrew Stephenson CBE MP  
Minister of State for Health and Secondary Care

Steve Brine MP

Chair of the Health and Social Care Select Committee

Monday 11<sup>th</sup> March 2024

Dear Steve,

### **Independent Review into Equity in Medical Devices**

I am writing to you in your position as Chair of the Health and Social Care Select Committee to inform you that the Independent Review into Equity in Medical Devices has been published today, alongside the Government's response.

The NHS is committed to upholding high standards in medical device safety. In response to emerging evidence of potential racial and ethnic bias in the design and use of some medical devices commonly used in the NHS, former Secretary of State, Rt Hon Sajid Javid MP, commissioned an Independent Review.

I want to extend my gratitude to Dame Margaret Whitehead, the review Chair, and the panel members for their thorough work. They embraced a comprehensive approach in involving stakeholders, fostering collaboration with clinical experts, NHS planners, and policy advisors, engaging with health professionals on the front line, educators, and crucially, patients and the public. This deliberate approach underscores the importance and impact of the panel's findings, and their recommendations are integral to our commitment to fostering a fair and healthy future for all.

The panel made 18 recommendations, taking these recommendations in turn:

- Recommendations 1 -3 focus specifically on pulse oximeters and cover immediate mitigation measures to ensure existing devices can perform to a high standard and improvements in international standards for approval of new device models.
- Recommendations 4 – 7 focus on prevention of potential for harm through improved detection of bias in optical devices, including better research and testing, more robust monitoring and auditing and refreshed education for health professionals.
- Recommendations 8 – 14 focus on enabling the development of safe and equitable Artificial Intelligence (AI) medical devices.

- Recommendation 15 underscores the urgency of preparing for the transformative impact of large language and foundation models on healthcare and regulatory systems.
- Recommendations 16 – 18 address equity concerns and societal challenges related to polygenic risk scores (PRS) in genomics. They emphasise the need for regulation in response to the influx of commercial PRS tests in the UK.

The Government's response has been published alongside the final report. The Government welcomes and acknowledges the importance of the outlined recommendations, endorsing its main argument that, unless appropriate actions are taken, biases can occur throughout the entire medical device life cycle.

We are dedicated to ensuring equitable medical device practices, spanning from design through to use. The Government has already initiated substantial efforts addressing many of the essential elements of the report's recommendations, as detailed in the Government response. As we continue to drive progress, we welcome ongoing collaboration with industry partners, which is paramount to embedding best practices and supporting the NHS in delivering optimal and equitable care for all.

We recognise that there is still progress to be made in ensuring equitable use and access of medical devices. I trust that you and your Committee will view today's report and corresponding Government response as a significant step towards achieving this goal.

Yours sincerely,



Rt. Hon Andrew Stephenson CBE MP

**Minister of State for Health and Secondary Care**