



Department
of Health &
Social Care

*From Baroness Merron
Parliamentary Under-Secretary of State*

39 Victoria Street
London
SW1H 0EU

To: Baroness Manningham-Buller, LG, DCB

29 July 2024

Dear Eliza,

Thank you for sharing with me a copy of the University of Birmingham/Birmingham Health Partners Report: 'Healthy Mum, Healthy Baby Healthy Future'. I am indebted to you and Professor Brocklehurst as co-chairs, the commissioners and to all of those involved, including baby charities and experts across a broad range of sectors for helping to bring together such an important and informative report.

I shared the report with officials in the Department to consider the key findings and recommendations. One of the key points that resonated throughout the report, was around the evaluation and development of medicines for use in pregnancy.

The Department as you may know, commissions research through the National Institute for Health and Care Research (NIHR), its Research and Development arm. The NIHR funds a range of research in maternal and neonatal health and care, focussing on the safety of maternity and neonatal services. Since the Healthy Mum, Healthy Baby, Healthy Future Report was published, the NIHR has funded a £2.7 million research study to optimise outcomes in pregnant women with epilepsy and their babies. In addition, the NIHR have contracted a £2.6 million research award to establish and evaluate a novel data system to determine the uptake and safety of medications during pregnancy, which is expected to start in February 2025. Furthermore, noting ongoing concerns around reproductive risks associated with several antiepileptic drugs, the NIHR actively welcomes proposals from researchers seeking to understand the comparative risks of harm associated with different medicines in order to inform more individualised risk/benefit discussions between patients and healthcare professionals and protect women from potential harm.

I was very interested to note the point raised in the report that pregnant women do not always have the opportunity to take part in all clinical trials of medicines that could be used in pregnancy. The government has set out a vision for the Future of UK Clinical Research Delivery which aims to create a patient-centred, pro-innovation and digitally enabled clinical research environment. The Department considers it a priority to ensure that opportunities to participate in clinical research are available to

as many people as possible in order to strengthen the findings of clinical studies and to widen access to novel treatments through research. All clinical trial protocols should set out whether those who are pregnant are eligible to participate in the trial and describe in detail the process for monitoring and managing pregnancy occurrences in a trial. Sometimes it may not be appropriate for those who are pregnant to participate in clinical trials, due to safety concerns (as acknowledged in the report). However, we are committed to ensuring that where it is safe to do so, pregnant individuals are provided opportunities to participate in clinical research in order to build the evidence about the impact, safety and efficacy of such interventions in pregnancy.

The Health Research Authority (HRA) is developing guidance to improve practices in this area. This guidance will help researchers to consider if certain groups of people may be unnecessarily excluded and consider putting measures in place to address this. In addition, the [NIHR Research Inclusion Strategy 2022-2027](#) sets out how NIHR will become a more inclusive funder of research and widen access to participation in clinical trials. Through the ongoing and proposed systematic collection of data on sex, ethnicity and age of participants taking part in NIHR research, we can monitor progress and continue to champion the inclusion of under-represented groups such as pregnant women.

Another important issue raised in the report was the recommendation to establish a UK-wide national network of research centres encouraging major public and private investment and collaboration in pregnancy research expertise and infrastructure. As part of its research funding offer, the Department invests significantly in centres of excellence and collaborations, services and facilities to enable and deliver research in England. This NIHR infrastructure drives forward innovation and encourages funders to invest in research, including maternal health research. For example, researchers in the NIHR Oxford BRC have developed a new, standardised tool to help identify and respond to signs of deterioration in the health of pregnant women. The new “Maternity Early Warning Score” is based on patient data and is being rolled out across the country by NHS England. By funding this underpinning infrastructure, government ensures that there is a mechanism in place to support the health and care research funded by government, research councils, charities and the life science industry (biopharmaceuticals, MedTech, genomics, diagnostics and digital health), pulling discovery science into practice. NIHR works closely in partnership with the Medical Research Council (funded by Department of Science, Innovation and Technology), who also fund similar, complementary infrastructure.

Enabling access to safe and effective treatments is the top priority of the MHRA, who recognise the important issues regarding the use of medicines in pregnancy. The MHRA is reflecting carefully on the report and will consider how best to take account of its findings in their work. The MHRA offers product-specific scientific and regulatory advice on development for new and existing medicines for use in pregnancy. Examples of this include updated guidance on antiepileptic drugs in

2020, a major safety review of topiramate which resulted in the introduction of materials to minimise associated risks in pregnancy in 2024, and regular updates, including improvements based on stakeholder feedback, to valproate regulations, such as Pregnancy Prevention Plans (PPP), to ensure that women taking the drug are aware of the risks and the need to avoid use in pregnancy. In line with the recommendations on the Commission on Human Medicines Expert Working Group on Optimising Data on Medicines used During Pregnancy, pregnancy registers and linkage between mother and child records are available to identify women exposed to medicines and provide data on the evolving patterns of prescribing for antiepileptics in girls and women of childbearing age.

The MHRA also actively engages with other stakeholders, through workshops and roundtables aimed at promoting research and information for medicines to treat conditions during pregnancy; and with other regulators and the pharmaceutical industry, under the umbrella of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), to develop international guidance on inclusion of pregnant and breast-feeding women in clinical trials. I understand that the draft guidance will be open for public consultation in due course. The MHRA also offers product-specific scientific and/or regulatory advice on development for new and existing medicines for use in pregnancy. In addition to this, the Gates Foundation has funded the MHRA to evaluate existing mathematical physiologically-based pharmacokinetic (PBPK) models to examine more effective use of medicines during pregnancy and breastfeeding.

Finally, I do want to assure you and all who participated in the report that it will be the mission of this government to build an NHS fit for the future. We will take action to make maternity and neonatal care safer for all women and babies, including training more midwives and tackling the appalling maternity inequalities.

Thank you again for sharing this report with me.

With my very best wishes,

Personal Data

Baroness Merron

I hope you have an enjoyable summer recess.