'Healthy mum, healthy baby, healthy future'—one year on, what progress have we made?

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Most pregnant women will have a healthy pregnancy and give birth to healthy babies. An increasing number of women, however, will either

have one or more health conditions before they become pregnant which require on-going treatment, or they may develop complications of pregnancy which require treatment.

The care of these women is severely hampered by a lack of suitable medicines, that we definitively know to be safe and effective for use in pregnancy or during breastfeeding. As a consequence, women and babies worldwide continue to become sick and die during or immediately after pregnancy. Despite this, over the last 40 years, only two new medicines have been approved for use in pregnancy.

The 2021 report by the University of Birmingham and Birmingham Health Partners, "Safe and Effective Medicines for Use in Pregnancy: A Call to Action," highlighted the absence of research and information on the safety of medicines in pregnancy. It also drew attention to the urgent health needs of this neglected group both nationally and internationally, and the potential for saving and improving millions of lives globally.

Healthy mum, healthy baby, healthy future

As a direct response to this report the University of Birmingham and Birmingham Health Partners convened a Policy Commission focusing on the UK, canvassing knowledge and opinions from key parties including patient groups, the pharmaceutical industry, scientists, clinicians, NHS leaders, regulators and insurers. It aimed to explore the scale of the problems that are preventing the evaluation and development of safe medicines for use in pregnancy and collected recommendations for how these could be overcome.

The Commission report was published in May 2022 and entitled, "Healthy Mum, Healthy Baby, Healthy Future." It made a series of eight recommendations related to advocacy, widening participation of pregnant women in clinical trials, updating information on existing

medicines, de-risking the insurance process for clinical trials, incentivizing industry to develop pregnancy specific medicines, establishing a UK-wide network of research centers, improving the use of routine data, and appointing a UK steering committee to deliver these recommendations.

Over the last year, members of the Commission have been working to develop the steering group and engage with industry and insurance companies to drive forward these recommendations. There are challenges in driving this agenda forwards which can be broadly described as a de-prioritization of women's health, and particularly pregnancy, by industry and in the delivery of clinical trials related to workforce and capacity.

Without combined efforts from all stakeholders; public, scientific, clinical, industry, regulatory and governmental sectors, we will not see any progress. The first step will be through coordinated efforts via the recently formed steering committee and renewed approaches for engagement with industry and insurance providers.

The UK is well placed to become a global pioneer of maternal health research innovation. It has the health infrastructure of our NHS, with its birth-to-death records. The medicines regulator is able to fast-track drug development and make changes to streamline the process, as well as working globally with Europe, the US and other regions.

There is an urgent need for action to address the underserved area of medicines use in pregnancy. Without it, women and babies will continue to die when they could be saved. They will continue to experience long-term health effects, disability and distress, which might be avoided. It is no longer ethical to deny pregnant women and their unborn babies access to safe, modern medicines that the rest of the population enjoys.