

SUMMARY AND NEXT STEPS

Global Meeting on Regulation and Policy for Women's Health

U.K. Houses of Parliament | 30 April 2026

WHAT THE MEETING ESTABLISHED

The meeting brought regulators, policymakers, multilateral institutions, clinicians and industry together around one finding: women wait too long for the innovations that would improve their health and a major cause is policy, financing and the way regulation is set up.

Two themes ran through the afternoon. The first was the need for open dialogue between regulators and the companies developing products, early enough that the right evidence is collected the first time. The second was that women have to be included in the clinical trials for the innovations meant to treat them. When they are, the results work for the people who will actually use them.

In the year leading up to the meeting we engaged regulators across continents and 23 individual countries. That groundwork is what the next phase builds on.

INSIDE THE ROOM

The afternoon opened with the framing case: women spend around a quarter of their lives in worse health than men, the burden runs across every system in the body, and the science is well ahead of the systems meant to deliver it. Government and diplomatic voices set the stakes, the economic case for investing in women's health was made alongside a life-course view of it, and a clinical lead set out what the gap looks like in everyday practice.

The discussion kept returning to where the system breaks down. Funding does not follow the burden, much of it sits with a small number of conditions, while areas that weigh heavily on women, from heart disease to migraine and mental health, get comparatively little. The evidence base is thin, because too little research looks at how disease and treatment differ in women in the first place. And even where the science exists, it often does not turn into products that reach women. Participants made the point that these problems feed each other and will not fix themselves, which is why action is needed across funding, trial design, regulation and the incentives to bring products to market at once.

Regulators then took the floor. The UK MHRA spoke to the evidence gap in women's health and NICE to how innovations are assessed for real-world use, before a statement from EMA as well as voices from GPhC and GMC addressing where the delays actually sit, and what each system would need from the others to move faster.

The technical anchor of the day was a facilitated session led by the MHRA and NICE on what a faster regulatory approval pathway for the health of women could look like in practice. The question on the

table was direct. What would industry need from regulators to bring new diagnostics, therapeutics and treatments forward, and what would regulators need from each other to make that pathway usable across borders.

Participants then worked in roundtables and workshops, putting forward recommendations on regulation, research and development, public awareness, and clinical practice and treatment. Each table shared back, and multilateral and editorial voices closed the discussion before participants were asked to make a written commitment. Those recommendations and commitments are what the working groups now carry forward.

One thread cut across the upstream debate about innovation. Better products do not help women who cannot reach them. In low-income and crisis settings, whether a woman seeks care is shaped by gender norms, by how freely she can move, and by violence and control at home. The evidence is now hard to dismiss, violence against women rises during disease outbreaks, driven in part by the lockdowns and service disruptions used to control them, and abuse in pregnancy carries a much higher risk of preterm birth, low birth weight and stillbirth. Violence is not a separate issue from the health of women. It is one of the things that decides it. Safe, confidential routes to information and services, including the digital safe spaces built for women and girls in these settings, were raised as part of what 'closing the gap' has to include.

The regulatory roundtable returned a set of practical points. The current landscape is complex and dispersed, with no single point of visibility, which duplicates work for anyone operating across jurisdictions. Earlier clarity on what regulators expect would let companies design for compliance from the start, since late failures are expensive, and there may be value in regulators endorsing advisors who can give consistent guidance early. Mutual recognition, so that approval in one jurisdiction helps open others, would cut cost and speed global scaling. Mandatory standards for equal representation of women in clinical trials would make sure the evidence is generated, and building equality requirements into procurement would reinforce the same priorities further down the chain.

THE BLUEPRINT AND THE REGULATORY FAST TRACK

The organising goal of the meeting is the Global Blueprint for women's health which will include a Fast Track for Innovations for the women's health. The starting point is the COVID-19 response. During the pandemic, regulators, governments and industry coordinated at a speed nobody had attempted before, and they did it without inventing new legal powers. They applied the powers they already had, together. The blueprint asks what the same coordination looks like when it is built to last rather than to meet an emergency, and pointed at the health of women.

The fast track is the regulatory heart of that work. It is a priority lane for innovations for the health of women, built on tools that already exist, reliance and work-sharing between regulators so an assessment in one system can speed approval in another, adaptive and accelerated review for priority areas, and earlier alignment between regulators, health technology assessment bodies and the health

systems that decide whether a product is actually funded. Approval on its own does not reach a woman. Reimbursement and adoption have to move with it.

Two design choices matter. First, eligibility is deliberately wide. It covers new products, but also the re-testing and re-formulation of existing drugs and devices that were approved largely on male trial populations, where the dose, the effect or the usability for women was never properly established. A product can qualify even where the condition affects both sexes, or men more, if the work makes it better suited to women. Second, the design treats sex and race together: stratifying trials by sex alone is not enough, and the blueprint draws on UK data showing how differently maternal outcomes fall across ethnic groups.

THE THREE WORKING GROUPS

The commitments and recommendations from the meeting now feed three global working groups. Each one carries a different part of the journey from evidence to the woman who needs it. Partners can take a seat on one, two or all three.

01 Regulation

A fast-track, adaptive regulatory route for innovations for the health of women, built with regulators across jurisdictions.

02 Policy development and implementation

A national policy and financing framework governments can adapt, turning commitment into delivery and bringing innovation to scale.

03 Clinical access

Earlier diagnosis, better treatment and fairer access across the conditions that affect women, working with clinicians and civil society.

WHAT PARTICIPANTS COMMITTED TO

Organisations across the room left a written commitment. Grouped by the three areas the working groups will carry, they already point to where the work begins.

Regulation and evidence. Regulators committed to examine how innovations for the health of women can move through accelerated and adaptive pathways, and to engage developers earlier so the right evidence is gathered the first time, several drawing on direct trial and self-sampling experience. Industry partners committed to align their own regulatory processes around the health of women and to work with commissioners on what good evidence looks like. Professional and pharmacy bodies committed to use their regulatory weight to put the health of women at the front and to tackle the inequalities and

discrimination women face. One partner committed to halve stillbirth and build a regulator-first platform to do it.

Policy, financing and innovation. Partners committed to build an investment framework that treats the health of women as an investable asset, aligning the language of investors, companies and governments. Investors committed to keep backing innovation in the areas of greatest need, including venture-building to close the gap in Europe. An industry partner committed to position the health of women as an economic as well as a health priority, with menopause treatment reaching women of every background. Multilaterals committed to build sustainable innovation pathways and to improve equitable access to medicines for women in low- and middle-income countries, and advocates committed to press government for greater investment in maternity care.

Clinical access, awareness and the workforce. On evidence and innovation, partners committed to feasibility work on biomarker screening for endometriosis, evidence for heavy menstrual bleeding, non-antibiotic technology for recurrent infections with an NHS pilot, and the inclusion of pregnant and breastfeeding women in clinical trials. On access, partners committed to scale consumer-health reach to underserved women with privacy built in, to signpost women to services they do not know exist, and to advocate for women in digital health, while clinicians committed to protect the research time of the workforce generating the evidence. On awareness, media and editorial partners committed to keep the health of women on the agenda and to end the effective censorship of women's health content, while educators, youth programmes and women's councils committed to build awareness from school age upward, including work that centres Black and Indigenous women on the principle of nothing for us without us.

A UK WORKING GROUP, WITH AN EYE ON THE G20

Alongside the three global groups, we are convening a UK working group. The United Kingdom holds the G20 presidency in 2027, and this group will work to encourage the government to make the health of women part of its G20 agenda. It gives the wider work a clear route from this room into a global policy moment.

A note on language

Why we say 'the health of women', not 'women's health'.

The two are not the same. Women's health, as the term has been used for decades, is reproductive and maternal health. The conditions specific to female biology. Pregnancy, menstruation, the gynaecological cancers.

The health of women is wider. It is every condition that affects a woman across her life.

Cardiovascular disease, the leading cause of death in women globally, sits within it. So does

autoimmune disease, osteoporosis, dementia, migraine, the cancers that disproportionately affect women, the chronic pain women carry for years, the mental health consequences of violence, and the reproductive and maternal health that women's health was already meant to cover.

The language matters because the funding, the regulation and the clinical attention have all followed the older, narrower definition. Moving to the health of women is the first step in moving the rest.