EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Multistakeholder workshop on women's health

Medicines regulators and stakeholders shaping the future together

28 September 2026, 09:30 – 17:15 (CEST)
29 September 2026, 09:00 – 17:30 (CEST)

Hybrid meeting/ EMA, Amsterdam

Background and objectives

Advances in healthcare have improved outcomes for women across the European Union and globally. However, important opportunities remain to further strengthen women's health: women live longer than men on average, but they spend a larger proportion of their lives in poorer health, reflecting areas where prevention, diagnosis, and treatment can be further enhanced.

There is a clear momentum building therefore, across the EU and globally, in support of strengthening women's health. At European level, the importance of women's health is being highlighted through the

European Parliament's Committee on Women's Rights and Gender Equality (FEMM) and implemented through other initiatives; for example, the EU Safe Hearts Plan places a strong focus on sex-specified risks, early detection in women, and reducing inequalities in cardiovascular care.

The current situation is influenced by a combination of factors, including gaps in understanding sex-based differences, the historical underrepresentation of women in clinical research, and the need to consider these differences more systematically in the development and use of medicines. As a result, some treatments may not fully reflect women's specific needs, and certain conditions affecting women remain insufficiently recognised or addressed. In addition, progress in innovation for women's health therapeutics presents opportunities to further expand the range of targeted medicinal products.

Addressing these areas is important for supporting health equity, improving quality of life, and have considerable socio-economic impact. These considerations highlight the value of coordinated action across stakeholders to strengthen the evidence base, foster innovation, and ensure equitable access to safe and effective medicines for women across all life stages.

In this context, the European Medicines Agency (EMA), together with its partners in the European Medicines Regulatory Network (EMRN), plays a key role in advancing women's health. This includes driving regulatory science, supporting innovation and developing guidelines. It also includes providing guidance on the generation and use of real-world data (RWD) and real-world evidence (RWE) to support regulatory decision-making, alongside its core responsibilities for the assessment of medicines and certain high-risk medical devices.

The workshop is structured to support a stepwise discussion, and aims to:

- highlight the contribution of the EMRN partners to women's health, including the impact of regulatory frameworks, scientific committee activities, and epidemiological evidence;
- take stock of current gaps and challenges, drawing on epidemiological data, clinical research, and patients' and healthcare professionals' experience;
- explore opportunities to strengthen the evidence base and support more inclusive and representative clinical research;
- bring together perspectives from patients, healthcare professionals, academia, industry, and global partners to identify priority areas for action; and
- contribute to the identification of actionable steps and potential indicators to measure meaningful progress.

The discussions will support a shared understanding of priorities and contribute to shaping concrete actions within the EMRN and beyond. The outcomes of the workshop will be captured in a public report summarising key findings, lessons learned and proposed next steps to advance women's health in the European Union. This is done while recognising that medicine development is a global endeavour, and that advances benefiting women in Europe are likely to benefit women globally.

EMA Multistakeholder Workshop on women's health

Medicines regulators and stakeholders shaping the future together

Day 1 – 28 September 2026, 09:30 – 17:15 (CEST)

Chaired by Emer Cooke (EMA) and Maria Lamas (HMA, AEMPS)

09:00	**Joining and technical checks**	
09:30	**Welcome and opening remarks**	
	Opening remarks from co-chairs	**20'**
09:50	**Session 1: Setting the scene**	
	Session introduction	**5'**
	Patient perspective	**15'**
	Healthcare professional perspective	**15'**
	The EU perspective	**30'**
	Women's health in medicines regulation and guidelines in the EU	**15'**
11:10	**Coffee break**	
11:30	**Session 2: Uncovering gaps in data**	
	Session introduction	**5'**
	Learning from epidemiological studies	**30'**
	Representation of women in clinical trials	**15'**
	Developing an infrastructure for data generation on medicine safety in pregnancy and breastfeeding	**15'**
	Panel discussion and audience interaction	**60'**
13:35	**Lunch break**	
14:35	**Session 3: Progress and challenges in medicines development**	
	Session introduction	**5'**
	European Commission perspective	**15'**

	Healthcare professional perspective	**15’**
	Industry perspective	**15’**
	Patient perspective	**15’**
	Academic perspective	**15’**
	Panel discussion and audience interaction	**60’**

16:55 Closing remarks for Day 1

	Wrap up of Day 1	**20’**

Day 2 – 29 September 2026, 09:00 – 17:30 (CEST)

Chaired by Emer Cooke (EMA) and Maria Lamas (HMA, AEMPS)

08:45	**Joining and technical checks**	
09:00	**Welcome and opening remarks**	
	Recap of Day 1, welcome to Day 2	**15'**
09:15	**Session 4: Making it happen, defining actions**	
	Session introduction	**5'**
	Patient perspective	**15'**
	Healthcare professional perspective	**15'**
	Industry perspective	**15'**
	Global perspective	**15'**
	Panel discussion and audience interaction	**60'**
11:20	**Coffee break**	
11:40	**Session 5: Reproductive health – Medicines in pregnancy & breastfeeding**	
	Session introduction	**5'**
	Patient and HCP perspectives on including pregnant and breastfeeding women in clinical trials	**30'**
	Good pharmacovigilance practices (GPV) guidelines	**15'**
	EMA-initiated post-authorisation studies of medicines in pregnancy	**15'**
12:45	**Lunch break**	
13:45	**Session 6: Reproductive health - Inclusion of pregnant & breastfeeding individuals in development programs**	
	Session introduction	**5'**
	Clinical trials in pregnancy & breastfeeding	**15'**
	Clinical trial principal investigator perspective	**15'**
	Industry perspective	**15'**

	Assessor perspective	**15’**
	Panel discussion and audience interaction	**60’**

15:50 Coffee break

16:10 Session 7: Shaping the way forward

	Session introduction	**5’**
	Panel discussion and audience interaction	**60’**

17:15 Closing remarks

	Closing remarks	**15’**