EMA targets women's health: Will it close the evidence gap?

Written by The Life Science Feed Editorial Team · Published 28 July 2026 · Edited by Mara Voss

> Women's health conditions, from endometriosis to menopause, have historically suffered from under-researched and under-resourced therapeutic development. This deficit leaves clinicians with limited evidence-based options and patients with suboptimal care. The European Medicines Agency (EMA) now steps up its focus, aiming to rectify these long-standing disparities in medicine development and access.

KEY TAKEAWAYS

- The Pivot: The EMA established a dedicated expert group to identify and address unmet needs in women's health, focusing on conditions with significant public health impact.
- The Data: While no specific trial data is available for this policy initiative, the underlying problem is clear: women are underrepresented in clinical trials, leading to a paucity of sex-disaggregated data.
- The Action: Clinicians should anticipate future guidance and potentially new therapies, but for now, continue to advocate for better data and consider the limitations of existing evidence in female patient populations.

The EMA's Human Medicines Committee (CHMP) recently established an ad hoc expert group specifically tasked with identifying and addressing unmet medical needs in women's health. This move acknowledges a systemic issue: many conditions disproportionately affecting women, or presenting differently in women, lack robust evidence for optimal treatment. The agency aims to foster a more targeted approach to drug development, ensuring that medicines are not only effective but also appropriately studied in female populations.

This initiative follows a broader recognition that women have been historically underrepresented in clinical trials, leading to a knowledge gap regarding drug efficacy and safety in female physiology. The expert group will focus on conditions such as endometriosis, uterine fibroids, polycystic ovary syndrome (PCOS), and menopause, alongside sex-specific considerations in other disease areas. Their work will involve reviewing existing data, identifying research priorities, and engaging with stakeholders to stimulate innovation.

The Scope of the Problem

The underrepresentation of women in clinical trials is not a new issue. Historically, concerns about hormonal fluctuations and potential reproductive risks led to the exclusion of women, particularly those of childbearing potential, from early-phase studies. This practice, while sometimes well-intentioned, created a significant blind spot in understanding how drugs interact with female biology. Many drugs approved for general use have limited sex-disaggregated data, making it difficult for clinicians to predict differential responses or adverse event profiles in women.

Consider cardiovascular disease, for example. While often perceived as a male-dominated illness, it remains the leading cause of death for women in Europe. But symptoms can differ, and diagnostic criteria, largely based on male presentations, may delay diagnosis in women. Similarly, drug metabolism and pharmacokinetics can vary significantly between sexes, influencing dosing and side effect profiles. The Oxford Handbook of Clinical Medicine (11th ed) highlights these physiological differences, underscoring the need for sex-specific research.

Addressing the Data Deficit

The EMA's expert group will work to identify specific areas where evidence is weakest. This includes not only conditions unique to women but also those where sex-specific differences in presentation, progression, or treatment response are poorly understood. For instance, chronic pain conditions, which disproportionately affect women, often lack therapies developed with female pain pathways in mind. The group will also examine how regulatory pathways can be streamlined or adapted to encourage more targeted research.

One key aspect of this effort will be to advocate for better collection and analysis of sex-disaggregated data in all clinical trials. This means not just including women, but actively analysing outcomes by sex to identify any differential effects. Without this granular data, even trials with adequate female representation may fail to uncover important insights. The goal is to move beyond simply enrolling women to actively understanding the implications of sex and gender on drug action.

Challenges Ahead

The initiative faces considerable challenges. Pharmaceutical companies often prioritise conditions with larger, more easily defined patient populations or established markets. Conditions like endometriosis, while debilitating for millions, have historically struggled to attract significant R&D investment due to diagnostic delays and heterogeneous patient presentations. The EMA's role will be to incentivise this research, perhaps through expedited review processes or scientific advice tailored to women's health indications.

Another hurdle involves the complexity of hormonal influences throughout a woman's life. Menstrual cycles, pregnancy, and menopause all introduce physiological variables that can complicate trial design and interpretation. Developing medicines that account for these dynamic states requires sophisticated research methodologies and a willingness to invest in long-term studies. The expert group will need to provide clear guidance on how to navigate these complexities effectively.

The EMA's renewed focus on women's health is a necessary step towards correcting historical imbalances. It signals a commitment to ensuring that medicines are developed with a comprehensive understanding of female physiology, ultimately leading to better outcomes for patients across Europe. But the real work lies in translating this policy into tangible changes in research and development pipelines.

> **CLINICAL IMPLICATIONS**
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> The EMA's move is long overdue, but welcome. Clinicians routinely manage conditions in women with therapies primarily studied in men, or with limited data specific to female physiology. This often means prescribing off-label or relying on anecdotal evidence, which is hardly optimal practice.
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> This initiative should prompt pharmaceutical companies to re-evaluate their R&D pipelines. The market for

> women's health is substantial, but it requires a commitment to rigorous, sex-specific research, not just repurposing existing drugs. Expect to see more targeted calls for data and potentially new regulatory incentives for studies in areas like PCOS or perimenopausal symptoms.
> For GPs and specialists, this means a future where treatment decisions for female patients might be backed by more robust, relevant evidence. Until then, continue to scrutinise trial data for sex-disaggregated results and remain aware of the limitations when applying general population data to your female patients. The Oxford Handbook of Obstetrics and Gynaecology (4th ed) offers a good starting point for understanding the specific physiological considerations.

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