Executive Director of the European Medicines Agency
Ms Emer Cooke

via E-mail

Brussels, October 2025

Dear Emer,

We would like to draw your attention to the urgent need for regulatory clarity on male contraceptive innovation. Despite promising candidates in the pipeline, outdated frameworks are creating unnecessary barriers to development and investment.

No regulatory agency has yet published efficacy guidelines specific to male contraceptives. Developers are forced to rely on standards designed for female methods, which do not reflect the unique scientific and clinical features of male products. We believe the EMA should take the lead in developing updated and well-defined guidelines that enable the safe and effective introduction of novel male contraceptives.

An expert committee convened by the Male Contraception Initiative has recently published Male Contraceptive Development and Regulatory Best Practices for public consultation. The group brings together scientists, clinicians, ethicists, former regulators, device experts, and patient representatives. We encourage the EMA to review these recommendations and contribute to the consultation. Your input would send an important signal of leadership and help establish the clear approval pathway developers need.

Three key issues of interest in the recommendations include:

1. Incorporating the concept of shared benefit and risk
Male contraceptives pose a unique regulatory challenge, as any pharmacologic risk is borne by the male user, while the direct clinical benefit, pregnancy prevention, occurs in the female partner. However, these products clearly benefit both partners. Modeling shows that male methods could reduce unintended pregnancies significantly. The recommendations suggest the adoption of a shared risk model in ethical evaluations, recognising that some risks for men may be ethically acceptable

when weighed against the reduced burden on their female partners. This would promote more just and realistic evaluations.

2. Establishing appropriate efficacy thresholds
The continued use of the Pearl Index in male contraceptive trials is both scientifically imprecise and ethically problematic. Instead, the recommendations suggest using biological efficacy measures, such as WHO-established sperm concentration thresholds. This would lessen the dependence on large, costly pregnancy-based trials, which often require the involvement of female partners and pose significant logistical and ethical challenges, as well as financial burdens.

3. Considering alternative or surrogate efficacy endpoints
While pregnancy is currently the standard outcome for contraceptive clinical trials, and will likely remain so for the foreseeable future, efficacy biomarkers such as sperm count may offer viable and important alternatives. Although significant validation will be required, the recommendations suggest the use of a surrogate endpoint, with the potential to significantly reduce costs and facilitate more ethical clinical trials in the future.

The lack of predictable, science-based guidance creates uncertainty for developers and discourages investment. The EMA has an opportunity to establish a forward-looking regulatory framework that allows the application of the relational risk model and equitable efficacy standards based on biological markers, easing logistical, ethical and financial challenges that are currently holding back the development of important public health tools.

We urge the EMA to take leadership in this area and initiate the development of updated, equity-based guidelines to support the marketing authorisation of novel male contraceptives.

Best regards,
Peter Liese and Katarina Barley