



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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17 October 2025  
EMA/335781/2025

**Subject: Response to your Letter on Male Contraceptive Innovation and Regulatory Guidelines**

Dear Dr. Liese and Ms. Barley,

Thank you for your letter of 3 October 2025 and bringing to our attention the important work of the Male Contraception Initiative, including the recent publication of a draft guideline developed by the *Committee for Male Contraceptive Development and Regulatory Best Practices* for public consultation. We appreciate your engagement and your recommendation for EMA to consider developing guidelines to foster the development of novel male contraceptives.

One of the main reasons the EMA has not developed guidelines for male contraceptives is the absence of scientific advice requests or experience with such products via the centralised procedure. Over the past 20 years, all requests for EU scientific advice from the Agency have focused exclusively on development of female contraceptives, particularly oestrogen inhibitors, which are then usually submitted for marketing authorisation assessment at national level.

Since product-specific scientific advice is a key driver for developing and updating regulatory guidelines, the lack of engagement of developers with EMA in this area has meant that no specific demand for guidance has been identified so far.

However, we would like to highlight that our door remains open and the EMA has several frameworks available to support developers of innovative medicines, including male contraceptives. These include:

- Scientific Advice and Protocol Assistance
- Qualification of Novel Methodologies
- Innovation Task Force (ITF) meetings
- PRIME scheme
- SME office briefing meetings

These services are designed to facilitate early dialogue and provide tailored regulatory support to developers. More information about them is available on our website:

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

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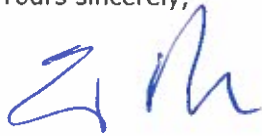
<https://www.ema.europa.eu/en/human-regulatory-overview/research-development#early-development-advice-services-38734>

We recognise that male contraception is an area of growing scientific and societal interest, and we commend the efforts of the Male Contraception Initiative and its expert committee. We encourage the Initiative to continue engaging with relevant learned societies and the broader scientific community to further develop and refine their positions.

In the spirit of collaboration, we will disseminate the draft guidance developed by the Committee for Male Contraceptive Development and Regulatory Best Practices to relevant scientific experts within the EU medicines regulatory network and invite them to provide comments in their personal capacity. Their insights could be valuable in informing any future regulatory considerations in this field.

Thank you once again for your thoughtful letter and for your commitment to advancing innovation in this area.

Yours sincerely,

A handwritten signature in blue ink, appearing to read 'Emer Cooke', written over a light blue horizontal line.

Emer Cooke  
Executive Director