Medicines & Healthcare products Regulatory Agency

Global email

11 March 2026

CEO update on the Pathways clinical trial

Dear colleagues,

I am writing to you all to address the issue of the Pathways clinical trial into puberty blockers for young people experiencing gender dysphoria. This is both a complex medical-scientific issue and a societal debate that generates strong, and often polarised, public and media opinion.

The scientific dialogue that is going on between the trial sponsors at King's College London (KCL) and the MHRA, with the National Institute for Health Research (NIHR), the Health Research Authority (HRA) and the Commission on Human Medicines (CHM) as other interested and respected parties, is not so unusual. It is not uncommon for complex clinical trials to go through stages of iteration. What is highly unusual in this case is the level of public, media and legal attention.

I will always stand up for our central role in the protection of patient safety. Wherever and whenever there are reasonable scientific concerns about the design of a clinical trial or the licensing of a medicine, it is always the right thing to pause and review the evidence to be sure before proceeding. That is what the MHRA has done in this case. I believe it will ensure that this proposed trial has the best chance of achieving the most appropriate benefit-risk design for the young people who might be its participants.

As an agency, we are in a mature and collegiate scientific dialogue with the trial sponsors at KCL and I am grateful to them for the way in which they have entered into these discussions. These are highly regarded, experienced and principled clinician-scientists who are doing their best to support the current and future needs of young people with gender dysphoria. Their scientific credibility and principled motivations are not in doubt.

One of the central points of the Cass Review was that this area of gender medicine lacks a strong evidence base. That is why clinical trials are needed to build the evidence for safe and effective treatment, and to ensure that if young people access this treatment pathway they do so in a safe and regulated way. It is entirely reasonable therefore that expert and experienced scientists will have different perspectives on the current, limited evidence base. That constructive debate and dialogue is the energy that fuels scientific enquiry and discovery. It is a strength, not a weakness.

I also want to place on record my support for our Chief Medical and Scientific Officer, Professor Jacob George. Jacob is an ethical man and a highly experienced clinician-scientist with an admirable career record. That is why he was appointed to his leadership role in our unique organisation. It is a matter of deep regret that any dedicated scientist should have their

actions politicised in the way that has happened recently in the media. Colleagues may also know that Jacob has been dealing recently with a family bereavement, which is why he is temporarily on compassionate leave.

There is no doubt that in his consideration of issues concerning the Pathways trial, Jacob had nothing but the best intentions of interrogating the evidence and trying to come to the most appropriate benefit-risk balance with the trial sponsors. Indeed, I believe the MHRA intervention will help to test and potentially enhance the trial design, thanks to the scientific expertise that has been brought to bear from KCL and the MHRA working together in a mature scientific dialogue.

For the avoidance of doubt, any civil servant is entitled to hold their own beliefs and values within the law and the expectations of the Civil Service code. That is a fundamental right of our society and our profession, which we would lose at our peril. We do not expect everyone to agree all of the time, but we do expect everyone to be respectful of each other and to uphold the Civil Service values of integrity, honesty, objectivity and impartiality.

Where our personal beliefs may risk the perception of affecting our judgement on complex ethical matters in the public sphere, it is an entirely legitimate response to recuse oneself from a particular topic area. This can both avoid personal ethical dilemmas and avoid the perception or accusation of partiality. After discussion with me, Jacob chose to recuse himself from further involvement with the Pathways trial and I respect and support this judgement. Whilst this has been an unusually high-profile issue, it will not be the first or the last time that colleagues in this organisation will avail themselves of the option for recusal, and I will support them where that is their choice.

I am very grateful to Dr Alison Cave, our Chief Safety Officer, who has taken on the executive scientific leadership role of the continuing assessment of the Pathways clinical trial. Alison is another wise, experienced and excellent scientist. She is being supported by a first-rate group of medical assessors from within the agency who collectively have extensive expertise across all of the relevant medical specialties.

Since I had the honour to become your CEO, I have said consistently that I will try to encourage a culture of trust, openness and empowerment. I wanted to write to you in that same spirit on this important issue for society and our agency.

I hope this letter assures you of our organisation’s commitments to patient safety and benefit, to the practice of responsible, ethical science and medicine, to supporting and respecting each other and our interlocutors, and to freedom of expression within the law and the Civil Service code.

Lawrence