

# Department of Health and Social Care: Consultation on proposed changes to the availability of puberty blockers

**25 September 2024**

## **Introduction**

As the regulator for pharmacists, pharmacy technicians and registered pharmacy premises in Great Britain, our role is to protect, promote and maintain the health, safety and wellbeing of patients and the public who use pharmaceutical services. We have a statutory role in relation to ‘system’ regulation (as we regulate registered pharmacies) as well as ‘professional’ regulation of individual pharmacists and pharmacy technicians. Our main work includes:

- setting standards for the education and training of pharmacists, pharmacy technicians and pharmacy support staff, and approving and accrediting their qualifications and training
- maintaining a register of pharmacists, pharmacy technicians and pharmacies
- setting the standards that pharmacy professionals must meet throughout their careers
- investigating concerns that pharmacy professionals are not meeting our standards, and taking action to restrict their ability to practise when this is necessary to protect patients and the public or to uphold public confidence in pharmacy
- setting standards for registered pharmacies which require them to provide a safe and effective service to patients
- inspecting registered pharmacies to check if they are meeting our standards

As the pharmacy regulator, we welcome the opportunity to respond to the consultation on the proposed changes to the availability of puberty blockers. We have limited our response to areas where we feel our work is directly relevant to the proposed changes.

## **The emergency order**

**To what extent do you agree or disagree with making the arrangements in the emergency order permanent?**

- Strongly agree

- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

#### **Positive impacts**

**In your experience, what have been the positive impacts of the emergency order?**

**Please provide evidence to support your answer.**

N/A

#### **Negative impacts**

**In your experience, what have been the negative impacts of the emergency order?**

**Please provide evidence to support your answer.**

N/A

#### **Benefits**

**In your experience, are there benefits in making the arrangements permanent?**

- Yes
- No
- Don't know

**Please provide evidence to support your answer and explain how you think those benefits could be maximised?**

#### **Risks**

**In your experience, are there risks in making the arrangements permanent?**

- Yes
- No
- Don't know

**Please provide evidence to support your answer and explain how you think those risks could be mitigated?**

#### **Impacts on protected groups**

**Do you think the accompanying equality impact assessment (EQIA) appropriately reflects the potential impact on protected groups which might arise from the proposal to make the order permanent?**

- Yes

- No
- Don't know

**Do you have any further comments or evidence about the potential impact on protected groups? If yes, please specify.**

The proposal to make the Order for puberty blockers permanent has significant repercussions for some protected groups, as identified in the EQIA. On this basis, we would strongly encourage you to consult fully and comprehensively with these groups, to ensure their direct, lived experience and views are taken into account. This includes patients who may seek services from different service providers. In addition, if a permanent ban is to be introduced, appropriate support needs to be provided to people under the age of 18, who will not be able to access puberty blocker, and to their parents and carers.

It is also important to seek the views of patient groups and expert organisations, and to ensure that the language of the EQIA and associated documentation is appropriate and does not reinforce negative stereotypes or stigma, particularly around neurodiversity and Autism Spectrum Disorder (ASD). One example includes, “Around 70% of people with autism also meet diagnostic criteria for at least one (often unrecognised) psychiatric disorder that *further impairs psychosocial functioning*, for example, attention deficit hyperactivity disorder or anxiety disorder. Intellectual disability (*an IQ less than 70*) coexists in approximately 50% of children and young people with autism”.

We encourage you to consider the impact on the healthcare professionals and teams, particularly pharmacy professionals. Regard should be had to managing the potential impact on NHS mental health services at a time when those services are already having capacity issues, on the availability of specialised trained professionals and resources, which are essential for helping people with gender dysphoria and/or gender incongruence.

We also note that this consultation coincides with the publication of Lord Darzi’s report into the NHS and makes reference to the increase in multiple long-term conditions. This includes mental health in young people. This is a factor that should be considered in the context of this EQIA as it may bear relevance to the provision of and availability of access to mental health service provision for young people who may need specialist mental health support.

#### **Additional evidence**

**If you have any additional evidence (including clinical or patient feedback) you wish to provide, please outline it here.**

If a permanent order is to be introduced, the drafting should support patients and healthcare professionals to easily understand the prohibition and the various requirements to be satisfied for a supply to be lawfully made. At present, the drafting is overly complex making it difficult to interpret.

If a permanent order is intended to replicate the two existing criminal offences under the temporary prohibition order which include: 1) contravening the prohibition order (i.e. making a supply), and 2) being in possession of GnRH analogues knowing or having reasonable cause to suspect that it was sold, supplied, or imported in contravention of a prohibition order, DHSC should clarify whether the offences are strict liability or whether a statutory or other defence is potentially available. Presently it is unclear. A notable contrast is that there are statutory defences within the Medicines Act 1968 for pharmacy professionals involved in an assembly/dispensing error (provided the statutory pre-conditions can be satisfied), but not within the temporary dispensing order – is it intended there should be no available

defence in cases where a supply has been made in good faith believing the legal requirements to have been satisfied?

We invite DHSC to provide clarity indicating the circumstances for when it would or would not be in the public interest to prosecute a pharmacy professional involved (perhaps unwittingly) in making a prohibited supply.

Furthermore, to help stakeholders to better understand the order, we welcome the inclusion of further detail within the explanatory memorandum of the permanent order as to how the order is intended to operate. There is very little detail within the explanatory memorandum in the temporary prohibition order.

We hope this is helpful and please do get in touch if you would like to discuss this further.

Yours sincerely,

**Louise Edwards**

**Chief Strategy Officer & Deputy Registrar**