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Medicines & Healthcare products Regulatory Agency

Questionnaire to help design a form that explains the risks of puberty blockers

Introduction

The Medicines and Healthcare products Regulatory Agency (MHRA) has been asked by Ministers to participate in the wider work being undertaken to make sure puberty blockers are prescribed safely. The medicines used to block puberty are called gonadotropin-releasing hormone analogues (GnRHa) but are more commonly known as "puberty blockers".

To do this, the MHRA is creating a form that explains the risks of using these medicines. Prescribers are to be advised to fill in this risk acknowledgement form with the patient and/or their parent or guardian when they first prescribe puberty blockers to children or young people under 18, who have gender incongruence and/or gender dysphoria. The form may be filled in during the first face-to-face appointment. It may also be used for people who were already taking these medicines before this form was introduced.

This questionnaire will help the MHRA decide what to include in the risk acknowledgement form. The form is important because it helps patients, and their families, understand the possible risks of taking these medicines.

We would like your thoughts on:

1. How the form should explain known and possible risks

2. What else should be included in the form, aside from describing risks

3. Who should sign the form and when

We appreciate you taking the time to share your views. The questionnaire should take no more than 20 minutes to complete. The deadline for responses is 12 October 2025.

Data protection and privacy information

Although there is no intention to collect or process any information that may identify an individual, we would like to make you aware how the data you provide will be used. This survey is conducted by MHRA to gain insights from key stakeholders on the contents of the risk acknowledgment form for puberty blockers when used for gender dysphoria. Data is processed as necessary for the performance of this task which is carried out in the public interest and under the official functions of the MHRA.

Responses will be shared with the MHRA, who will consider all of the responses and share the analysis confidentially with the Commission on Human Medicines (CHM) and its expert advisory groups and retained for 24 months following closure of the questionnaire. For full

details on how we handle your data, please see MHRA Privacy Notice at Medicines and Healthcare products Regulatory Agency Privacy Notice - GOV.UK.

Background

The development of the risk acknowledgement form is part of the government's work to look at how puberty blockers are given to children and young people.

The Department of Health and Social Care asked a group of independent experts called the Commission on Human Medicines (CHM) to share their advice on the information gathered as part of the government's work in this area. The CHM helps the government decide if medicines are safe and work well. One of their ideas was to use a form that explains the risks of puberty blockers. This form would be used when prescribers give these medicines to people under 18 who have gender incongruence and/or gender dysphoria.

The Department of Health and Social Care asked the MHRA to create this form. The Department will also help make sure the form is used effectively across the health system once developed.

The government's response to the work in this area and the CHM's report are both online. You can read them before filling in this questionnaire.

There is also an independent review called the Cass Review. It looks at gender identity services for children and young people in England. The final report was published in April 2024 and is also available online.

Section 1 - About you

This part of the questionnaire asks questions about you. If someone is helping you fill it in, please give your own answers, not theirs. Patients and their parents or guardians can each fill in their own copy so that everyone's views are included.

Which organisation are you from?

Royal Pharmaceutical Society

In this question we hope to learn a little more about your experience with puberty blockers. Please select the statement below which is most relevant to you:

- ○ I have taken these medicines in the past for gender incongruence and/or gender dysphoria
- ○ I am currently taking these medicines for gender incongruence and/or gender dysphoria
- ○ I have considered/am considering taking these medicines for gender incongruence and/or gender dysphoria
- ○ I am the parent/guardian of an individual who has taken/is taking these medicines for gender incongruence and/or gender dysphoria
- ○ I am the parent/guardian of an individual who has considered/is considering taking these medicines for gender incongruence and/or gender dysphoria
- ○ I am a healthcare professional involved in the care of patients who have taken or may consider taking these medicines for gender incongruence and/or gender dysphoria
- ○ I work in another professional capacity with individuals who have taken or may consider taking these medicines for gender incongruence and/or gender dysphoria
- ○ Other

Professional Leadership Body

Section 2 – References to risks in the risk acknowledgment form

When a medicine is approved for use by the MHRA, it means they have been checked to make sure they are safe, work well, and are made to high standards. When used the right way, the benefits of these medicines are greater than the risks.

Approved medicines come with clear labels and information. They include:

• A leaflet for patients and carers

• A summary for healthcare professionals

These explain any side effects, warnings, and how to use the medicine safely. This information is only for the approved uses. Current authorised intended uses for GnRH analogues in children include treatment for puberty that occurs at a very young age, otherwise known as early puberty.

The use of puberty blockers for gender affirming care in children and young people is an off-label indication. This means that the use of these medicines within children and young people for gender incongruence and/or gender dysphoria is outside of the licensed uses, and as such the benefits and risks of the medicine for use in this specific population have not been assessed. There is limited or no long-term data on the safety of these medicines for gender affirming care and how well they work in children and young people.

Healthcare professionals and patients can find a list of possible side effects for GnRH analogues when used within their intended uses in two places:

• The Patient Information Leaflet (PIL), which is written for patients and carers.
• The Summary of Product Characteristics, which is written for healthcare professionals.

Both of these are available on the MHRA website: https://products.mhra.gov.uk.

Puberty blockers (GnRH analogues) include medicines which contain or consist of; buserelin gonadorelin, goserelin, leuprorelin acetate, nafarelin or triptorelin.

Do you think the risk acknowledgement form should direct the patient and their parent/guardian to the Patient Information Leaflet to allow them to better understand the known risks of the medicine, when used in the intended population (such as for early puberty)?

Yes

No

Don't Know

Do you think the risk acknowledgement form should have a section whereby the patient and their parent/guardian confirm they have read and understood the known risks of the medicine, when used in the intended population, listed within the Patient Information Leaflet?

Yes

No

Don't Know

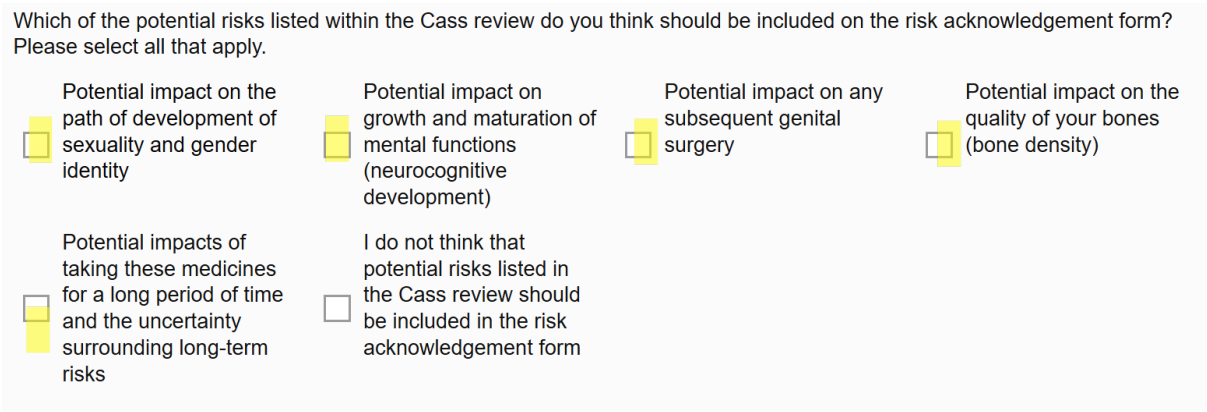
Do you think any of the known risks listed within the Patient Information Leaflet should be specifically highlighted on the risk acknowledgement form?

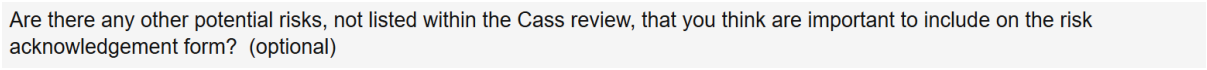
Yes

No

Don't Know

The Independent Review of Gender Identity Services for Children and Young People (commonly, the Cass Review) considered the evidence-base around puberty blockers, including the risks of using puberty blockers in ways that are not officially approved (See page 177). These are risks that are suspected to be associated with long term use for gender dysphoria but there is limited evidence to confirm this.





Additional risks which need to be described include the time for treatment effects to be seen and a description of what happens when treatment is stopped. E.g. which effects are reversible and which are not. Also, consideration of risks relevant to the stage of puberty at time of initiation.

Section 3 – Other content within the risk acknowledgment form

This part of the questionnaire is about what else should go in the risk acknowledgement form, apart from information about the known or potential risks. Prescribers are advised to fill in the form face to face with the patient and their parent or guardian. A copy of the form will be given to them so they can read it and think about the information.

Do you think it would be useful to have a dedicated section of the risk acknowledgment form for the patients and their parents/guardians to take notes during consultations or jot down questions to ask prescribers?

Yes

No

Don't Know

Do you think it would be useful to have a dedicated section of the risk acknowledgment form containing the contact details of the prescribing team if needed?

Yes

No

Don't Know

What other information do you think it would be useful to include within the risk acknowledgement form? (optional)

In Section 2 we've selected "Don't Know" to the questions and discuss the reasons for this below. As the majority of the medicines are used off-label, the information in the Patient Information Leaflet may not be appropriate – there may be a mixture of relevant and non-relevant information which patients and their families will need support to interpret and understand. The form may need to incorporate specific patient information for the off-label indication. This may need to be given to patients and their families with the opportunity to discuss and ask questions in advance of the risk acknowledgement form being completed.

A large number of patients in this cohort are neurodiverse so consideration will need to be given on how to present the information in the form to ensure that patients understand the information.

As patients may have a long treatment journey, it may be useful to build on the form, akin to the "Red Book" that is issued in childhood, which can grow into a patient-held reference for the patient and the multidisciplinary team.

A strategy that ensures the contextual information around the off-label use, specific risks and benefits of treatment is presented to patients and their carers is important. Similarities can be drawn to the information resources designed to inform patients and their carers about off-label medicines use in pregnancy, breast feeding and in children. It will be important to determine who holds the responsibility for preparing this information in formats that meet the needs of this patient cohort. This will also include information in different languages and ensuring those with sight or hearing loss have appropriate arrangements in place. E.g. Braille, sign language interpreter.

For Section 3, this aspect of consent mirrors those used in adult gender care. For signatures, it will be important to define who is the lead prescriber and who can countersign – and whether a counter signature can be made by a non-medical prescriber. Learning could be taken from the development of resources around the prescribing of teratogenic medicines such as valproate.

In other clinical areas where children will be provided medicines which have an extensive or significant side-effect profile, a period of reflection is used to allow everyone the opportunity to digest information. It is also to allow children the opportunity to ask questions or raise concerns at home with their care givers which they may not do in front of a healthcare professional. A gap between the decision to start treatment and treatment initiation would support this objective.

Section 4 – The risk acknowledgment form and consent

Risk acknowledgement forms usually have a space for the lead prescriber to sign. This shows they have explained the risks of the medicine to the patient and/or their parent/guardian. Sometimes, another prescriber also signs the form to confirm the patient understands the risks. There is also a space for the patient, and/or their parent or guardian, to sign to say they understand the risks too. Please tell us how much you agree or disagree with the following statements.

It would be helpful for a patient (or their parent/guardian/carer), and prescriber to both sign the form as part of joint treatment decision making.

Strongly Agree

Agree

Neither agree or disagree

Disagree

Strongly Disagree

The risk acknowledgement form should require a signature from both the lead prescriber as well as another countersigning prescriber.

Strongly Agree

Agree

Neither agree or disagree

Disagree

Strongly Disagree

It can sometimes take a while for a patient to think about whether they would like to take a medicine given the risks associated with its use, particularly where there is uncertainty or limited evidence. After receiving the information in the risk acknowledgement form, do you think it would be helpful to require the patient and/or parent/guardian a period of reflection before consenting and starting treatment?

Yes

No

Don't Know

You have indicated that you feel it would be beneficial to require a period of reflection. Please can you describe how you would like this period of reflection to happen, and what length of period would be helpful.

Building on our answer in Section 3, a period of reflection would take place between two appointments with at least 1 week between.

Thank you for filling in this questionnaire. Your answers are important and will help us create the risk acknowledgment form for these medicines.

If you want to know how the form is coming along, or if you have any questions, you can email: info@mhra.gov.uk.

If you are worried about gender care or medicines, please speak to your doctor or healthcare professional.

If you think you've had side effects from a puberty blocker (GnRH analogue), you can tell the MHRA using the Yellow Card website: https://yellowcard.mhra.gov.uk/ You can also use the free Yellow Card apps on your phone or call 0800 731 6789 (Monday to Friday, 9am to 5pm). You can leave a message outside these hours. Please give as much detail as you can when reporting side effects. This helps us learn more about the safety of the medicine.