

Equality and Health Impact Assessment

Progesterone (Prometrium®) to prevent miscarriage in women who present with bleeding in their first trimester of pregnancy and who have a history of recurrent miscarriages

AWTTC fill in an Equality and Health Impact Assessment in parallel with each development stage of our projects. This will help us to follow the five ways of working for public bodies, and work to achieving the wellbeing goals, outlined in the Well-Being of Future Generations (Wales) Act 2015.

Date: 04/03/2026

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| 1. | AWTTC contact details | Tel: 02921 826900 Email: awttc@wales.nhs.uk |
| 2. | State the objectives of the project. | <p>AWTTC will prepare an evidence summary report (ESR) for a limited AWSMG assessment for the use of progesterone vaginal capsules (Prometrium®) for the prevention of miscarriage in women who present with bleeding in the first trimester of pregnancy and who have a history of recurrent miscarriages.</p> <p>Off-label vaginal progesterone products are currently offered in NHS Wales for the prevention of miscarriage in women presenting with bleeding in the first trimester of pregnancy and who have a history of recurrent miscarriages. NICE and the Royal College of Obstetrics and Gynaecology guidelines recommend the use of vaginal progesterone products. Prometrium® is the first product licensed for use in women who present with bleeding in the first trimester and who have a history of miscarriages. There is published evidence that micronised vaginal progesterone is likely to be clinically effective and a cost-effective intervention for this patient population. Progesterone treatment is included in clinical guidelines.</p> |

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| | | <p>The AWMSG Scrutiny Panel consider that clinical effectiveness of progesterone has been established. AWTTTC's ESR which will be informed by a submission from the pharmaceutical company (marketing authorisation holder for Prometrium®), will focus on current use, equity of access and budget impact only. AWTTTC will also request views from patient organisations.</p> <p>The ESR will be sent to the company and to clinicians in Wales for comment. Clinicians, company representatives and representatives from patient organisations will be invited to attend the Licensed One Wales Medicines Assessment Group (LOWMAG) meeting. The LOWMAG constitution is available online.</p> |
| <p>3.</p> | <p>Evidence and background information considered. For example:</p> <ul style="list-style-type: none"> • population data • staff and service users' data, as applicable • needs assessment • engagement and involvement findings • research • good practice guidelines • participant knowledge • list of stakeholders and how stakeholders have engaged in the development stages • comments from those involved in the designing and development stages <p>Population pyramids are available from Public Health Wales Observatory.</p> | <p>Recurrent miscarriage is generally defined as the loss of three or more pregnancies, and can stem from a variety of factors (Royal College of Obstetricians and Gynecologists [RCOG] guideline). These include genetic, anatomical, hormonal, autoimmune and lifestyle-related causes, although the cause is not known in about 50% of cases (European Society of Human Reproduction and Embryology [ESHRE] guideline). Recurrent miscarriage affects around one in 100 women (RCOG).</p> <p>Two large multicentre, double-blind, placebo-controlled, randomised trials, PROMISE and PRISM, were conducted predominantly in the UK, and results showed that treatment with progesterone vaginal capsules increased the rates of live births and newborn survival among women with unexplained recurrent miscarriages. The results of these trials have informed guidelines for the clinical management of bleeding in the first trimester in women who have a history of recurrent miscarriage.</p> <p>The NICE guideline NG126: Ectopic pregnancy and miscarriage: diagnosis and initial management was updated in 2021 to include a recommendation that vaginal progesterone 400 mg twice daily should be offered to women with an</p> |

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| | | <p>intrauterine pregnancy confirmed by a scan, if they have vaginal bleeding and have previously had a miscarriage, and should be continued until 16 completed weeks of pregnancy if a fetal heartbeat is confirmed. The guideline states that this recommendation was made because there is good evidence that this medication increases the number of live births in women with early pregnancy bleeding and a previous miscarriage.</p> <p>The RCOG guideline on recurrent miscarriage (June 2023) states that progesterone supplementation should be considered in women with recurrent miscarriages who present with bleeding in early pregnancy (for example, 400 mg vaginal progesterone twice daily at the time of bleeding until 16 weeks of gestation). The ESHRE guideline on the management of recurrent pregnancy loss was updated in 2022 to conditionally recommend that vaginal progesterone may improve the live birth rate in women with three or more pregnancy losses and vaginal blood loss in a subsequent pregnancy.</p> <p>The company holding the marketing authorisation for Prometrium® in the UK estimates that about 1% of women in Wales trying for a baby will be eligible for Prometrium® treatment, based on published prevalence data for first trimester bleeding and for recurrent miscarriages. A clinical expert from NHS Wales confirmed that 1% of all pregnancies may require progesterone therapy for bleeding after previous recurrent miscarriages.</p> <p>Office of National Statistics data for Wales show there were 38,811 conceptions in 2022, of which 30.1% led to a legal abortion. Of the 27,129 remaining pregnancies, we estimate that 271 women per year in Wales may be eligible for treatment with Prometrium®.</p> |
| 4. | Who will this project affect? | Women who present with bleeding in the first trimester of pregnancy and who have a history of recurrent miscarriages, and their partners and their families, and healthcare workers caring for them. |

5. EQIA - How will the project impact on people?

Questions in this section relate to the impact on people based on the 'protected characteristics' of the Equality Act 2010, and other factors.

| How will the project impact on, or affect: | Potential positive and/or negative impacts | Recommendations for improvement/ mitigation | Actions taken (and who by). |
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| <p>5.1 Age For most purposes, the main categories are people aged:</p> <ul style="list-style-type: none"> • under 18 years; • between 18 and 65 years; • over 65 years. | <p>We do not expect a potential negative, or unequal, impact on people based on their age. We may expect a positive impact on women of childbearing age.</p> <p>[Note: For prescription medicines we expect the prescriber to have prescribed or advised their use within the terms of their UK marketing authorisations. Healthcare professionals should take note of the contraindications, warnings, safety recommendations and any monitoring needs for the medicine. These are explained</p> | <p>Any patient-facing resources produced will be provided on the AWTTC website in accessible formats that can be printed.</p> | <p>N/A</p> |

| How will the project impact on, or affect: | Potential positive and/or negative impacts | Recommendations for improvement/ mitigation | Actions taken (and who by). |
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| | in the Summary of Product Characteristics (SmPC) for the medicine or the British National Formulary .] | | |
| <p>5.2 Persons with a disability as defined in the Equality Act 2010 Those with physical impairments, learning disability, sensory loss or impairment, mental health conditions, long-term medical conditions such as diabetes.</p> | We do not expect a potential negative, or unequal, impact on people with a disability. | All related documents published on the AWTTC website will meet accessibility requirements. Any patient-facing materials will also be produced in easy read formats in Welsh and English. | N/A |
| <p>5.3 People of different genders: Consider men, women, people undergoing gender reassignment.</p> <p>N.B. Gender-reassignment is anyone who proposes to, starts, is going through or who has completed a process to change his or her gender with or without going through any medical procedures. Sometimes referred to as Trans or Transgender.</p> | We do not expect a potential negative, or unequal, impact on people based on their gender, or on people undergoing gender reassignment. We may expect a positive impact on people biologically able to become pregnant. | N/A | N/A |

| How will the project impact on, or affect: | Potential positive and/or negative impacts | Recommendations for improvement/ mitigation | Actions taken (and who by). |
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| <p>5.4 People who are married or who have a civil partner.</p> | <p>We do not expect a potential negative, or unequal, impact on people based on their marital status or being in a civil partnership.</p> | <p>N/A</p> | <p>N/A</p> |
| <p>5.5 Women who are expecting a baby, who are on a break from work after having a baby, or who are breastfeeding. They are protected for 26 weeks after having a baby whether or not they are on maternity leave.</p> | <p>We might expect a positive impact on women who are pregnant and who present with bleeding in the first trimester of pregnancy and have a history of recurrent miscarriages. We do not expect a potential negative, or unequal, impact on women who are breastfeeding, or are on a break from work after having a baby.</p> <p>The manufacturer of Prometrium® states that no association has been found between the maternal use of natural progesterone in early</p> | <p>Prescribers should take account of the Summary of Product Characteristics (SmPC) when prescribing any medicines for women who are pregnant, or who are breastfeeding.</p> | <p>The SmPC criteria specify which people are excluded from treatment due to the associated risks of treatment. This will be identified for consideration of any change to the advice at the next review if there is a change to the current advice for pregnant and breastfeeding women.</p> |

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| | <p>pregnancy and fetal malformation, and that there is no known harmful effect on fertility.</p> <p>Taking Prometrium® is not advised when breastfeeding. Detectable amounts of progesterone enter the breast milk. Please refer to the SmPC.</p> | | |
| <p>5.6 People of a different race, nationality, colour, culture or ethnic origin including non-English speakers, gypsies and travellers, migrant workers.</p> <p>The Runnymede Trust</p> | <p>We do not expect a potential negative, or unequal, impact on people of a different race, nationality, colour, culture or ethnic origin.</p> <p>People of different race and ethnicities can have varying responses to medicines.</p> | <p>Any patient information leaflets produced will be available in Welsh and English.</p> | <p>N/A</p> |
| <p>5.7 People with a religion or belief or with no religion or belief. The term 'religion' includes a religious or philosophical belief.</p> | <p>We do not expect a potential negative, or unequal, impact on people who have a religion or belief, or people with no religion of belief.</p> | <p>N/A</p> | <p>N/A</p> |

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| <p>Implications of religious beliefs on selection of medicines (BMJ)</p> <p>In practice: guidance on religion, personal values and beliefs (General Pharmaceutical Council)</p> | <p>Some medicines are made from certain animal products and people might not want to take them because of religion or belief.</p> | | |
| <p>5.8 People who are attracted to other people of:</p> <ul style="list-style-type: none"> • the opposite sex (heterosexual); • the same sex (lesbian or gay); • both sexes (bisexual). <p>Stonewall</p> | <p>We do not expect a potential negative, or unequal, impact on people based on who they are attracted to.</p> | N/A | N/A |
| <p>5.9 People who communicate using the Welsh language in terms of correspondence, information leaflets, or service plans and design.</p> | <p>We do not expect a potential negative, or unequal, impact on people who communicate using the Welsh language.</p> <p>Any patient-facing materials will be produced in Welsh and English, in line with the Welsh language standards, including easy read booklets.</p> | <p>Any patient-facing materials will be produced in Welsh and English, in line with the Welsh language standards, including easy read booklets. These will be provided on the AWTTC website in accessible formats that can be printed.</p> | N/A |
| <p>5.10 People according to their income related group.</p> | <p>We do not expect a potential negative, or unequal, impact on</p> | N/A | N/A |

| How will the project impact on, or affect: | Potential positive and/or negative impacts | Recommendations for improvement/ mitigation | Actions taken (and who by). |
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| | <p>people based on their income-related group.</p> <p>In Wales, all prescription medicines are free-of-charge for patients; positive recommendations through this project will not affect people depending on their income-related group.</p> | | |
| <p>5.11 People according to where they live.</p> | <p>We do not expect a potential negative, or unequal, impact on people based on where they live.</p> | <p>N/A</p> | <p>N/A</p> |
| <p>5.12 Consider others who face health inequalities, such as:</p> <ul style="list-style-type: none"> • Looked after and accommodated children and young people • Carers: paid/unpaid, family members • People who are homeless or those who experience homelessness: people on the street; those staying temporarily with | <p>We do not expect a potential negative, or unequal, impact on people who face health inequalities.</p> | <p>N/A</p> | <p>N/A</p> |

| How will the project impact on, or affect: | Potential positive and/or negative impacts | Recommendations for improvement/ mitigation | Actions taken (and who by). |
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| <p>friends/family; those in hostels/B&Bs</p> <ul style="list-style-type: none"> • People involved in the criminal justice system: offenders in prison or on probation, ex-offenders • People with addictions and substance misuse problems • People who have poor literacy • People living in remote, rural and island locations | | | |
| <p>5.13 Consider any other groups and risk factors relevant to this project.</p> | N/A | N/A | N/A |

6. HIA - How will the project impact on the health and wellbeing of people in Wales and help address inequalities in health?

Questions in this section relate to the impact on the overall health of individual people, and the impact on the population in Wales.

| How will the project impact on, or affect: | Potential positive and/or negative impacts and any particular groups affected | Recommendations for improvement/ mitigation | Actions taken (and who by) <i>Refer to where the mitigation is included in the document, as appropriate.</i> |
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| 6.1 People being able to access the service offered. | We do not expect a potential negative, or unequal, impact on people's ability to access the service offered. | N/A | N/A |
| 6.2 People being able to improve or maintain healthy lifestyles. | We do not expect a potential negative, or unequal, impact on people's ability to improve or maintain healthy lifestyles. | N/A | N/A |
| 6.3 People in terms of their income and employment status. | We do not expect a potential negative, or unequal, impact on people in terms of their income and employment status. | N/A | N/A |
| 6.4 People in terms of their use of the physical environment. | We do not expect a potential negative, or unequal, impact on people's use of the physical environment. | N/A | N/A |
| 6.5 People in terms of social and community influences on their health. | We do not expect a potential negative, or unequal, impact on people in terms of social and community influences on their health. | N/A | N/A |

| How will the project impact on, or affect: | Potential positive and/or negative impacts and any particular groups affected | Recommendations for improvement/ mitigation | Actions taken (and who by) <i>Refer to where the mitigation is included in the document, as appropriate.</i> |
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| 6.6 People in terms of macro-economic, environmental and sustainability factors. | We do not expect a potential negative, or unequal, impact on people in terms of macroeconomic, environmental and sustainability factors. | N/A | N/A |

7. Please fill in section 7.1 after completing the EqHIA, and fill in the action plan.

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| <p>7.1 Please summarize the potential positive and/or negative impacts of the project.</p> | <p>No potential negative impacts identified. We might expect a positive impact for women who experience bleeding during their first trimester and who have a history of recurrent miscarriages.</p> |
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Action plan for mitigation or improvement and implementation

| | Action | Lead(s) | Timescale | Actions taken (<i>state who by</i>) |
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| <p>7.2 What are the key actions identified as a result of completing the EqHIA?</p> | <ul style="list-style-type: none"> • AWTTC to consult with clinical experts in Wales, patient organisations, patients and carers in Wales (or the UK) and invite comments through the AWTTC website or questionnaire by email • AWTTC to prepare an Evidence Summary Report (ESR) • Licensed One Wales Medicines Assessment Group (LOWMAG) meet to consider and make a recommendation to AWMSG. • AWMSG meet to consider and endorse the LOWMAG | <p>AWTTC</p> | <p>May 2025 - April 2026</p> | <p>Clinical experts consulted by AWTTC – May–July 2025</p> <p>Patient organisations contacted by AWTTC – December 2025</p> <p>ESR prepared by AWTTC – March 2026</p> |

| | Action | Lead(s) | Timescale | Actions taken (<i>state who by</i>) |
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| | recommendation to Welsh Government about the use of Prometrium in Wales. | | | |
| 7.3 Is a more comprehensive Equalities Impact Assessment or Health Impact Assessment needed? | No | | | |
| 7.4 What are the next steps? | AWTTC to conduct a limited assessment and submit an evidence summary report to the Licensed One Wales Medicines Assessment Group (LOWMAG). | AWTTC | Mar – Apr 2026 | |
| 7.5 Review of project and EqHIA | | AWTTC | [TBC] | |

AWTTC's EqHIA template is adapted from the Cardiff & Vale University Health Board EHIA template.