

Ministerial Advice

To: Cabinet Secretary for Health and Social Services

From: REDACTED

Date: 25 May 2018

Subject: Termination of Pregnancy – Administration of second pill at a woman's home

MATS Reference number: MA - P/VG/1659/18

When is a decision required from the Minister? Urgent

1. What is the issue you are asking the Minister to consider?

Following your announcement in Plenary that you intend to enable women in Wales to self-administer the second medication in a medical abortion at home, this briefing is to offer options on the next steps.

2. What action(s) are you recommending to the Minister?

You are advised to consider the following options–

1. proceed to issue a formal approval allowing the second dose to be self-administered while accepting that this carries a risk of challenge; or
2. agree that officials await the outcome of the case in Scotland before deciding whether to issue an approval for women in Wales to self-administer the second dose in a medical abortion

3. Deputy Director, Statement of Assurance

☐ I, **REDACTED**, confirm that I have quality assured this advice.

I am satisfied that the recommended decision or action, if agreed, would be lawful and affordable. Welsh Government policy priorities and cross portfolio implications have been fully considered in line with delivery of the [government objectives](#) in [Prosperity for All: the national strategy](#).

Advice

a) Context - What is the situation that has led to this advice?

Medical abortion

In 2016, there were 8,246 abortions in Wales. Medical abortions accounted for 75% of the total number of abortions carried out.

An early medical abortion (the "abortion pill") involves taking two different medicines,

36 - 48 hours apart. On the first visit to the hospital in Wales, the patient is given an abortion pill called *mifepristone*. On the second visit, the patient is given the second medicine, a prostaglandin called *misoprostol*. The effect of the medication is similar to an early natural miscarriage. Termination of pregnancy (TOP), including pain, fever, vomiting and bleeding, can start anytime after the woman receives the second dose.

Under the Abortion Act 1967 ("the Act") any treatment for the termination of pregnancy must be carried out in a hospital or other "approved place". Medical abortion was not possible at that time.

The current arrangements mean a woman is required to attend a clinical setting twice in order to have a medical TOP. There is a risk of women not wanting to go with these arrangements for personal reasons, however. Some women, for example, may seek to purchase treatments online from abroad and carry out the TOP in an uncontrolled fashion, with consequent risks to their physical and mental health. Allowing the second pill to be taken at home might limit this scenario as well as improve the patient's experience. The Scottish Ministers have sought to allow this by designating a woman's home as an "approved place" under section 1 of the Act. As detailed below, the Scottish Ministers' decision to allow the second dose to be taken at home is subject to a legal challenge.

Changes to TOP arrangements

A number of clinicians and women's support organisations have called on the Welsh Government to allow women in Wales to take the second pill of a medical TOP outside a clinical setting.

Advocates of the proposed change in practice suggest it would lead to improvements in the quality of medical TOP for those accessing the provision as it would mean women attending a clinic only once. This would reduce the burden currently placed on clinical resources, enable more appointments to be available for women wanting to access TOP services and increase the number of women accessing such provision at an earlier point in their pregnancy.

A report by the World Health Organisation has suggested that home-based medical abortion may improve the acceptability of medical abortion by allowing greater privacy than in-clinic abortion, giving women greater control over the timing of abortion and making it possible for family members or friends to be present to provide emotional support. In studies from France, Sweden, Tunisia and the USA, the majority of women opted for home-based medical abortion when offered the choice between home and clinic. Self-administration of misoprostol is already common in France and the United States. The WHO report also concluded that there is no evidence that home-based medical abortion is less effective, safe or acceptable than clinic-based medical abortion.

Officials are considering the impact such a change might have, not only in terms of quality and efficiency, but also organisational challenge and safety. For example, we would need to ensure that the second pill was actually taken by the person for whom it was prescribed. The clinical provisions to support women are already in place as the current arrangements mean a woman may, if she chooses, leave the clinic after taking the second medication, misoprostol. This includes advice and relevant contact numbers should support be required

b) What is your advice to the Minister?

In October 2017, the Scottish Ministers issued an approval under section 1 of the Act to allow a pregnant woman to take misoprostol at their home. The Welsh Ministers have the same power under section 1 of the Act to approve a place in which treatment for the termination of pregnancy can be carried out. If the Welsh Ministers approved a person's home then this would enable the second dose to be taken at home and avoid a second attendance at hospital.

The decision of the Scottish Ministers, however, is being challenged by the Society for the Protection of Unborn Children who argue that the Scottish Ministers' approval is unlawful as it is not within the scope of the powers under the Act. Officials understand that the case will be heard in the Court of Session on 14-15 May 2018.

Option 1

You have indicated you wish to issue an approval as soon as possible. The Court in Scotland may decide that such an approval is unlawful. It is possible that a separate challenge against the Welsh Ministers' approval would be launched as soon as the approval is given. Given the views of clinicians and women's groups about improving patient experience, this is the option recommended by officials.

Officials have considered guidance developed by Scottish Government and by clinicians across health boards in Wales and are using these to produce a consistent protocol for the whole of Wales. The protocol will set out guidelines for the provision of the medication for consumption at home. Subject to your agreement to issue an approval, officials will draft the written instrument.

Option 2

The alternative approach is to await the outcome of the case in Scotland before proceeding to issue an approval in Wales. Awaiting the outcome of the case would enable the Court's judgment to be taken into account before a decision is made about how to proceed.

○ **What legal or policy obligations are relevant to this advice?**

Under section 1 of the Act any treatment for the termination of pregnancy must be carried out in a hospital or other "approved place". The Welsh Ministers have power, under section 1(3) and (3A) of the Act, to approve a place in which treatment for the termination of pregnancy can be carried out.

The proposal is to approve a person's place of ordinary residence in Wales as a class of place where the dose of medication in an early termination may be taken. Without this approval, self-administration of an abortion medication at home would be unlawful.

Proceeding on this basis is not without risk. There is a case that the approval would be unlawful because

1. Under section 1(1) of the Act a pregnancy can only be lawfully terminated by a registered medical practitioner. There is a question as to whether allowing a woman to self-administer the second dose breaches this provision because there would not be a registered medical practitioner in charge when the second dose is consumed at home.
2. In addition, while the Welsh Ministers have power to approve a “class of place” for termination of pregnancy, it is arguable that a person’s home is too broad a category to be a meaningful restriction on the place where a termination can take place and is not therefore a lawful use of the power.

These arguments are not without merit. Legal Services consider that there is a medium to high risk that a court would regard the approval to be an unlawful use of the power under section 1(3) and (3A) of the Act.

Another concerning factor is that at the time that section 1(3A) was inserted into the Act by the Human Fertilisation and Embryology Act 1990 the Secretary of State for Health stated in the House of Commons that the suggestion that medication to terminate pregnancy could be taken at home was mistaken and that it would “be administered only in closely regulated circumstances under the supervision of a registered medical practitioner”.

The Society for the Protection of Unborn Children has lodged a judicial review against the Scottish Ministers’ decision to allow the second dose to be taken at home. Officials understand that the case will be heard in the Court of Session on 14-15 May. Awaiting the outcome of the case would enable the Court’s judgment to be taken into account before a decision is made about how to proceed.

Policy officials are also aware that the Society for the Protection of Unborn Children has directed their members in Wales to write to their Assembly Member to oppose the proposed approval and approximately 20 letters have so far been received. This significantly increases the risk of a challenge being brought if an approval is issued in Wales.

In summary, there is a medium to high risk that designating a person’s home as an approved place under the Act is an unlawful use of the power under section 1 and, given the involvement of the Society for the Protection of Unborn Children, there is a high risk of such a challenge being made.

Should the Cabinet Secretary wish to precede, an approval under section 1 of the Act may be made by issuing a formal document recording the approval and the circumstances in which it applies.

a) What are the financial implications of Ministers agreeing to this advice and which budget will this be paid through?

There are no financial implications arising from this decision. Termination of

Pregnancy provision will be delivered within existing resources and budgets.
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<p>b) What communication or media activity is planned following this decision?</p>

<p>There has been some media interest since your announcement in Plenary on 17 April. Policy officials are working with Communications colleagues to ensure there are relevant lines in place.</p>
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<p>Officials are aware The Society for the Protection of Unborn Children (SPUC) have directed their welsh members to write to their Assembly Member and approximately 20 letters have so far been received. Officials have prepared lines for correspondence from AMs and members of the public and are working with Communications and HSS Government Business Unit to ensure a suitable response.</p>

<p>Annex A: Copy Recipients</p>
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All mandatory copy recipients (as indicated in the guidance).

Additional copy recipients specifically interested in this advice:

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Mandatory cc (MA Policy Advice)
REDACTED