

Dear

## **ATISN 24479 – Misoprostol**

Thank you for your request to the Welsh Government for information under the Freedom of Information Act (2000) received on 04 March 2025 relating to the approval of misoprostol. You have requested the following:

- *Please provide any information you have about the decision-making process that led to the 2018 approval for misoprostol to be taken at home for the termination of pregnancy*

## **Our Response**

The Welsh Government holds information of this description.

Some information is within the public domain but I have included a link for ease of reference:

1. Email regarding abortion care legislation in Wales – October 2017
2. Email correspondence with legal advice - October 2017
  - a. CMO Scotland letter on Abortion - <https://www.publications.scot.nhs.uk/files/cmo-2017-14.pdf>
3. Email correspondence with documents relating to quality and safety aspects of taking Misoprostol at home
  - a. Astle et al (2011) <https://academic.oup.com/humrep/article/25/5/1087/641970>
  - b. Lohr et al (2010) [Women's opinions on the home management of early medical abortion in the UK](#)
  - c. Hamoda et al (2005) [Home self-administration of misoprostol for medical abortion up to 56 days' gestation - PubMed](#)
  - d. Norwegian experience - [Medical abortion with mifepristone and home administration of misoprostol up to 63 days' gestation](#)
  - e. WHO bulletin - [WHO review.pdf](#)
4. Briefing note: Home administered pill – March 2018
5. Ministerial Advice MA-P/VG/1659/18 Termination of Pregnancy – Administration of second pill at a woman's home - May 2018
6. Ministerial Advice MA-L/VG/0365/18 Termination of pregnancy – administration of second pill at a women's home: update – June 2018
7. [Home-Use-of-Misoprostol-Welsh-Health-Circular-WHC-2018-027-English-compressed.pdf](#)
8. [Written Statement - Approval for Misoprostol to be take at home for Medical Termination of Pregnancy \(29 June 2018\) | GOV.WALES](#)

We have concluded that some of the information requested is exempt from disclosure under the following sections of the Freedom of Information Act:

- Section 40(2) – Personal Information of the Freedom of Information Act.

An explanation of our application of this exemption is set out at Annex 1 to this letter.

## Next Steps

If you are dissatisfied with the Welsh Government's handling of your request, you can ask for an internal review within 40 working days of the date of this response. Requests for an internal review should be addressed to the Welsh Government's Freedom of Information Officer at:

Information Rights Unit  
Welsh Government  
Cathays Park  
Cardiff  
CF10 3NQ  
or Email: [Freedom.ofinformation@gov.wales](mailto:Freedom.ofinformation@gov.wales)

Please remember to quote the ATISN reference number above.

You also have the right to complain to the Information Commissioner. The Information Commissioner can be contacted at:

Information Commissioner's Office  
Wycliffe House  
Water Lane  
Wilmslow  
Cheshire  
SK9 5AF

However, please note that the Commissioner will not normally investigate a complaint until it has been through our own internal review process.

Yours sincerely,

## **Freedom of Information Act 2000: Section 40(2) Personal information about others**

Section 40(2) together with the conditions in section 40(3)(a)(i) or 40(3)(b) provides an absolute exemption if disclosure of the personal data would breach any of the data protection principles.

‘Personal data’ is defined in sections 3(2) and (3) of the Data Protection Act 1998 (‘the DPA 2018’) and means any information relating to an identified or identifiable living individual. An identifiable living individual is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of the individual.

We have concluded that, in this instance, the information caught by your request contains third party personal data.

Under Section 40(2) of the FOIA, personal data is exempt from release if disclosure would breach one of the data protection principles set out in Article 5 of the GDPR. We consider the principle being most relevant in this instance as being the first. This states that personal data must be:

*“processed lawfully, fairly and in a transparent manner in relation to the data subject”*

The lawful basis that is most relevant in relation to a request for information under the FOIA is Article 6(1)(f). This states:

*“processing is necessary for the purposes of the legitimate interests pursued by the controller or by a third party except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child”.*

In considering the application of Article 6(1)(f) in the context of a request for information under FOIA it is necessary to consider the following three-part test:

- **The Legitimate interest test:** Whether a legitimate interest is being pursued in the request for information.
- **The Necessity test:** Whether disclosure of the information/confirmation or denial that it is held is necessary to meet the legitimate interest in question.
- **The Balancing test:** Whether the above interests override the interests, fundamental rights and freedoms of the data subject.

Our consideration of these tests is set out below:

### **1. Legitimate interests**

Your request includes some emails which were caught by your request. I have not identified any legitimate interest that you may have in knowing the identities of those individuals named within the emails.

### **2. Is disclosure necessary?**

We do not believe disclosure of the identities of those involved would allow any greater understanding of the content of the emails.

### **3. The balance between legitimate interests and the data subject’s interests or fundamental rights and freedoms**

As we do not believe disclosure of this personal data is necessary, there is no requirement on us to undertake a test to balance the legitimate interests against the right of individuals, as the fundamental rights and freedoms provided by the DPA are not being challenged.

I have concluded that there is a reasonable expectation that the identity of the living individuals named in the correspondence would not be made public. It is my view, therefore, that disclosure of the redacted information would breach the first data protection principle and thus is exempt from release under section 40 of the FOI Act.