Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Response document for MHRA public consultation on the proposal to make Lovima available from pharmacies

Ref: ARM 99

MHRA proposes to permit supply of Lovima in pharmacies because we consider that the evidence presented in this application demonstrates that the product does not meet the POM criteria set out in legislation. Your response should address why you agree or disagree with this conclusion and any additional safeguards you consider to be necessary in pharmacies. We will review all responses received to see if the evidence presented changes our conclusion about the product not meeting the POM criteria.

Your details
Name: Yogeeta Shah

Position (if applicable): Professional Support Pharmacist

Organisation (if applicable): Royal Pharmaceutical Society

Email: consultations@rpharms.com

1. Do you consider that Lovima should be available as a Pharmacy (P) medicine?

Yes ✓ No ☐ Not sure ☐

Please provide any comments or evidence to support your response:

Please provide any comments or evidence to support your response:

The Royal Pharmaceutical Society is the professional body for pharmacists and pharmacy in Great Britain.
As professionals in pharmaceutical care, pharmacists are well equipped to offer advice on medicines and sexual health.
The Royal Pharmaceutical Society supports the proposal to make **Lovima** 75 microgram film-coated tablets (Desogestrel) available as a Pharmacy medicine.
Pharmacists are experts in medicines and are well trained to ensure safe supply of medicines to the public. This move will increase access to an effective method of contraception and enable women to make an informed choice about their needs after discussion with a pharmacist. Pharmacists are currently able to sell products for emergency contraception such as ulipristal and levonorgestrel with appropriate advice on regular contraception.

2. Do you have any specific comments on the leaflet, label or pharmacy consultation checklist provided at Annexes 2, 3 & 5?

Leaflet:
None

Label:
Some parts of the label are not clear. Particularly writing in bold. We would suggest making this clear for pharmacists and patients to refer to.

Supply aid checklist:

It is unclear if there are any age restrictions on the supply of Lovima from the checklist.

Can the supply be made to patients under the age of 18 and subsequently under the age of 16? Is there anything a pharmacist should consider if making a supply to patient under the legal age of consent?

3. Do you have any other comments on the reclassification?

We feel with appropriate training healthcare professionals would be confident to make a safe and effective supply to patients, with additional material such as Summary of Product Characteristics to supplement training.

4. The MHRA may publish consultation responses. Do you want your response to remain confidential?

Yes ☐ Partially* ☐ No ✓

*If partially, please indicate which parts you wish to remain confidential. In line with the Freedom of Information Act 2000, if we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. Responses to consultation will not normally be released under FOI until the regulatory process is complete.

Responses can be continued onto a separate page if required. This form should be returned by email (reclassification@mhra.gov.uk) to arrive by **Thursday 4 March 2021.** Contributions received after that date cannot be included in the exercise.