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: Roisin Hughes

Position (if applicable): Policy & Communications Officer

Organisation (if applicable): Pharmacy Forum NI

Email: roisin.hughes@psni.org.uk

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

Yes X No ☐ Not sure ☐

Please provide any comments or evidence to support your response:

The medicine contained within both products is a well-established contraceptive medicine, for which we have a comprehensive understanding of potential risks/SEs. We feel that this medicine poses no risk to public health in general and is not one which may be subject to misuse or inappropriate use. As such we are confident that this medicine can safely be provided as a P medicine.

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

We note that there appears to be a licencing disparity between the products; this being the case, it is important that attentions are drawn to any key differences in any training materials and that this is clear and obvious to any product users.

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

- We acknowledge that the reclassification from POM to P offers users more choice in terms of supply accessibility and removes barriers which may have previously stopped patients accessing this medicine in a timely fashion.

- Pharmacists are equipped and capable to supply/sell this product, but would ask that training materials and governance mechanisms are robust to give confidence to all stakeholders during the early roll-out of this new P medicine.
- NICE recommends 12 monthly blood pressure and weight checks with this medication.
- We would encourage further innovations to improve accessibility to this medicine at no cost to the patient – perhaps a local or national pharmacy-led programme allowing pharmacists to prescribe this on a prescription or pharmacy voucher. This approach could allow for routine monitoring of the patient at the pharmacy. In order to facilitate effective monitoring, pharmacists need access to previous patient readings, history and records. This gap needs to be addressed.
- We seek further detail related to responsibilities for pharmacists to have an "optional" checklist to complete or patient records to maintain in order to supply the medication. The service worked through and pharmacists' time involved in this process to ensure this medication is supplied safely needs to be priced for/reimbursed. We encourage greater accessibility in terms of pricing to ensure it is either free or a viable option for the patient.
- We seek guidance/support for pharmacists who are requested the medication by an under 18 y/o and are uncomfortable in doing so.
- We observe that offering greater choice has the potential to reduce the need for emergency supplies of COC or POP medicines during 'out of hours' services. There may be requests for this product form patients who normally use a different drug as their contraceptive and so we ask that training materials provide clear guidance to help handle these requests.

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

Yes ☐ Partially* ☐ No X

*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 **Friday 5 March 2021.** Contributions received after that date cannot be included in the exercise.