

FSRH CEU response to public consultations on reclassification of Desogestrel 75mcg progestogen-only pills Hana[®] and Lovima[®] as Pharmacy medicines

18th February 2021

Progestogen-only contraceptive pills have, until now, been **Prescription-Only Medicines (POM)**. The Medicines and Healthcare products Regulatory Agency (MHRA) is currently consulting the public regarding licensing of two brands of desogestrel 75mcg progestogen-only pill (POP) as **Pharmacy Medicines (P)**. The products are Hana[®] (Laboratoire HRA Pharma) and Lovima[®] (Maxwellia Ltd).

Pharmacy medicines can be bought by the user from a pharmacy under the supervision of a pharmacist, without a prescription. Up to 3 months' supply of Hana or Lovima could be sold to new users (up to 12 months for current or recent users aged 18 and over). These products would not be on the General Sales List and would not, therefore, be available off the shelf in pharmacies or other retail outlets.

Pharmacy provision of these desogestrel 75mcg POPs would be safe

Available evidence and extensive experience of use of the desogestrel 75mcg POP indicate that it can be taken from menarche to age 55 with very low risk of serious adverse events. There are therefore few medical contraindications.

Hana and Lovima are equivalent to the existing brands of desogestrel 75mcg POP, and current FSRH guidance applies to them. It is noted that criteria for provision of Pharmacy medicines commonly differ from those for their POM equivalents. There may be some medical conditions (eg diabetes) that are considered to be contraindications to Pharmacy provision of Hana and Lovima that do not contraindicate provision of a desogestrel 75mcg POP on prescription. There may also be some subtle differences in user information.

In addition to the information given in the Summary of Product Characteristics, additional materials would be available to pharmacists to support provision of Hana and Lovima, including a Pharmacy Training Guide and a Pharmacy Checklist that identify potential contraindications. Both products are supplied with comprehensive patient information.

Pharmacy provision of Hana and Lovima would include safeguarding and consideration of wider sexual and reproductive health

It is recognised that a contraception consultation is an opportunity for safeguarding, for offering more effective long-acting reversible methods of contraception and for provision of wider sexual and reproductive health care, advice and information. However, accessing existing contraceptive services in general practice and sexual health clinics can, for some individuals, be a barrier to achieving effective contraception. The pharmacy setting may be more accessible and acceptable to those prepared to pay for this method.

Pharmacists already have training and experience in giving contraceptive advice and providing oral emergency contraception. The Pharmacy Training Guides and Pharmacy Checklists for Hana and Lovima would support safeguarding, provision of information about alternative contraceptive methods, safer sex, cervical screening, and breast awareness and screening. The checklists would help pharmacists identify vaginal bleeding that requires further investigation.

When a desogestrel 75mcg POP is sold as a Pharmacy medicine, FSRH CEU suggests that the provider would:-

1. Assess competence of the individual to consent to and comply with use.
2. Assess competence of the individual to consent to sexual activity.
3. Assess current risk of pregnancy, any current requirement for emergency contraception and any recent use of emergency contraception.
4. Identify current abnormal vaginal bleeding that may require investigation.
5. Assess medical eligibility.
6. Take a drug history to exclude interaction that could affect effectiveness or safety of either the POP or the other drugs taken.
7. Discuss:-
 - ▶ effectiveness with perfect and typical use of the desogestrel 75mcg POP
 - ▶ bleeding patterns and side effects
 - ▶ when to start taking the desogestrel 75mcg POP, how to take it, missed pill rules, and how to access emergency contraception if missed pill rules are not followed.
 - ▶ alternative contraceptive options, including long-acting reversible contraception, and where to access them locally.
8. Explain that the desogestrel 75mcg POP is available free of charge from primary care and community clinics.
9. Signpost the user to the information required for safe, effective use of the product. Information should be available in a format that is accessible to the user.
10. Provide information about safer sex and accessing STI testing.
11. Encourage engagement in cervical and breast screening programmes.

The materials provided to support Pharmacy provision of Hana and Lovima are considered to align with this approach.

FSRH CEU conclusion

FSRH CEU welcomes this new development, which gives individuals the option to buy this safe, effective contraceptive method from a local pharmacy.

FSRH encourages you to respond to the public consultations for Hana and Lovima at <https://www.gov.uk/government/news/views-sought-on-making-the-oral-contraceptive-pill-desogestrel-available-from-pharmacies>

The deadline for submissions is **5 March 2021**

There are no changes to FSRH guidance for provision of the desogestrel 75mcg POP on prescription.

The Clinical Effectiveness Unit (CEU) was formed to support the Clinical Effectiveness Committee of the Faculty of Sexual & Reproductive Healthcare (FSRH), the largest UK professional membership organisation working at the heart of sexual and reproductive healthcare. The FSRH CEU promotes evidence based clinical practice and it is fully funded by the FSRH through membership fees. It is based in Edinburgh and it provides a members' enquiry service, evidence-based guidance, new SRH product reviews and clinical audit/research. [Find out more here.](#)