Reclassification of progestogen only contraceptives to P medicines

BPAS submission to MHRA public consultation on the proposal to make Hana/Lovima available from pharmacies – March 2021

Consultation Questions

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

Progestogen-only contraceptive pills (POPs), like Hana/Lovima, are safe, reliable, easy to use and are an incredibly popular contraceptive method. This is an uncontroversial move which will make it easier for women to access essential contraception during and beyond COVID-19.

POPs containing desogestrel have been used in the UK for more than 20 years and around 1.5 million people a year in the UK use them every year. As recognised by the MHRA, Hana/Lovima is a well-established product, and its safety profile is well known. Like other POPs, this form of Progestogen-only contraceptive can be used by most women irrespective of age, smoking status and many medical conditions, including stable/treated high blood pressure and cardiovascular diseases.

According to the MHRA's Yellow Card scheme, desogestrel in the proposed formulation (single active ingredient) is very safe. Throughout its lifetime as a licensed POM medication with a single active ingredient, there have been only 3 linked fatalities. This compares to other well-established drugs classified as P, including the recently-reclassified sildenafil (Viagra) which has reported 52 fatalities in the last 10 years alone, and paracetamol which has recorded 12 – 59 annual deaths in the last decade. There is no justification, on the basis of safety, to retain desogestrel's current classification.

Requiring people to attend a GP or sexual health clinic to access POPs like Hana/Lovima is unnecessary, for many visiting a GP or sexual health imposes an extra barrier to access. It can be difficult to get an appointment with a GP, a 2019 survey by Pulse found that the average waiting time for an appointment was almost 15 days, with more than one in five of GPs who responded saying the wait for a routine appointment exceeded three weeks. The difficulty in accessing GP appointments has been exacerbated by the Covid-19 pandemic and many sexual health and family planning clinics have shut or reduced their hours. Allowing access to Hana/Lovima through pharmacies will remove the wait for contraception and may even help to prevent pregnancies that might have occurred in the wait for an appointment with a GP or sexual health clinic.

There are also cultural, domestic and economic reasons that mean a person may not want to, or be able to safely, visit a GP to access contraception. For those in abusive relationships, where their partner does not want them to use contraception and their movement and communication is being monitored, attending a GP appointment without good reason could put them in danger. Similarly, for those from certain cultural or religious backgrounds where a woman may need to conceal

sexual activity, a GP appointment may feel out of reach, however an over-the-counter service would provide vital choice and freedom for these women.

The reclassification of Hana/Lovima is an uncontroversial decision. It is already possible to buy Emergency Hormonal Contraception (EHC) from pharmacies and hundreds of thousands of women choose this method every year over visiting a doctor or clinic. A 2018 Public Health England study that aimed to gain a better understanding of people's experiences of and preferences for reproductive health and healthcare found that a total of 80% of people using contraceptive pills received them from the GP, but that more than half would prefer to receive them elsewhere such as in pharmacy or online. The preferences of those accessing contraceptive healthcare should not be ignored, instead decision making should be led by these preferences.

Contraception should be affordable and accessible to all and re-classifying Hana/Lovima as a P medicine would enable women greater control over their own fertility.

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

BPAS does not believe that an indication that formal consultation is necessary prior to providing desogestrel with a P classification is necessary. We welcome the framing of the consultation and checklist as 'optional', but are concerned that pharmaceutical bodies and regulators may consider this a requirement to provision. As detailed above, desogestrel is a safe drug which the MHRA has recognised meets none of the grounds to retain POM status – and perceived 'conditions' to provision such as a consultation or use of a checklist can only be justified by an incorrect perception that the availability of contraception is somehow controversial or needs to be controlled. This suggestion should be strongly resisted by regulators.

Our work on the accessibility of Emergency Hormonal Contraception is relevant here – as similar provisions exist for the sale of levonorgestrel and ulipristal acetate over the counter. Putting consultation decision-making in the hands of pharmacists has led to varying consultation experiences for those seeking to access contraception as a P medication.

In 2018, research conducted by BPAS found that women described mixed experiences of their consultation for EHC - ranging from: "Awful. Made to feel like a whore" and "Quizzed and made to feel slightly slutty," to "informative, respectful and swift" and "easy and pain free". When accessing EHC women also describe instances of being denied the medication they requested, including one case ending in unplanned pregnancy and abortion. Whilst many pharmacists provided a swift, non-judgemental service, there were notable exceptions in the research we undertook, with our mystery shopper being asked to show ID and in one case even take a pregnancy test before the pharmacist would sell her EHC.

Pharmacists are trained healthcare professionals who are used to providing routine guidance and advice during the purchase of over the counter medication and the dispensing of prescription medication – often those with a more complex risk profile than desogestrel or EHC. They are used to asking customers whether they are taking any other prescription medications, whether they have underlying health conditions, and providing guidance on how to administer medications and when to seek help.

We believe that the risk of providing a formal checklist for pharmacists only services to 'other' contraception – making it appear more dangerous or complicated than its risk profile and level of usage reflect. We also believe that providing a checklist is likely to result in pharmacists being strongly encouraged to make use of it rather than relying on their professional judgement – something which this consultation makes clear is not necessary.

As a result, we believe the checklist should be removed, and that pharmacists are instead provided with key information to include in the sales discussion and advised to consult the BNF for further information.

Do you have any other comments on the reclassification?

We see this as positive step forward and hope that the MHRA will look as a priority as reclassifying levonorgestrel to GSL – further increasing accessibility and reducing the risks of unplanned pregnancy.

Contact
Molly Boydon
Public Affairs Officer
British Pregnancy Advisory Service
molly.boydon@bpas.org
07436 181056