# Response

**Medicines and Healthcare products Regulatory Agency**

## Hana 75 microgram film-coated tablets and Lovima 75 microgram film-coated tablets (Desogestrel): Public Consultation

March 2021

**reclassification@mhra.gov.uk**
**(deadline 5 March 2021)**

For enquiries regarding this response please contact office@thecca.org.uk

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**About the Company Chemists' Association (CCA)**

Established in 1898, the CCA is the trade association for large pharmacy operators in England, Scotland and Wales. The CCA membership includes ASDA, Boots, LloydsPharmacy, Morrisons, Rowlands Pharmacy, Superdrug, Tesco, and Well, who between them own and operate around 6,000 pharmacies, which represents nearly half the market. CCA members deliver a broad range of healthcare and wellbeing services, from a variety of locations and settings, as well as dispensing almost 500 million NHS prescription items every year. The CCA represents the interests of its members and brings together their unique skills, knowledge and scale for the benefit of community pharmacy, the NHS, patients and the public.

**Executive summary**

The CCA welcome the landmark consultations which proposes reclassifying the contraceptive pill 'Hana' and 'Lovima' (75mg Desogestrel) from a Prescription Only Medication ('POM') to a Pharmacy medicine ('P medicine'). We have responded to these proposals together. In summary:

- The CCA is supportive of plans to provide the public with more access to sexual health services through community pharmacy.
- Pharmacy teams are proficient in consulting with women to provide Emergency Hormonal Contraceptives (EHC). Training for pharmacy teams will need to be provided prior to the launch of P med desogestrel contraceptives so that they can provide women with the information they need to make an informed choice.
- There may be a role for the GPhC to reissue their guidance on personal values and beliefs to support this. We would not like to see women face any unintended barriers to access whether that be through cost or local availability.
- We highlight our call for a nationally commissioned framework for sexual health services. We note that today The Faculty of Sexual and Reproductive Healthcare (FSRH), the Royal College of Obstetricians and Gynaecologists (RCOG) have called for desogestrel contraceptives to be available and free for all women wishing to access them community pharmacy.

The consultation documents state that the Commission on Human Medicines has approved Desogestrel as suitable for a POM to P switch. The contraceptive pill has been available to women for 60 years and this is a positive step to enable greater access. Furthermore, pharmacists are clinically competent healthcare professionals with a wide range of experience interacting with the public about medicines and health and well-being. Additionally, pharmacy teams are all trained in safeguarding and experienced in having patient centered consultations and applying the Gillick competency and Fraser guidelines, which ensure that vulnerable patients are detected and supported. This is demonstrated through the locally commissioned emergency hormonal contraceptive (EHC) service in England, and nationally commissioned services in Scotland and Wales, where assessment and consultation skills would be similar to those required for Desogestrel. [1]

However, one key drawback of the pharmacy EHC service in England is that that patients face a 'postcode lottery' and inconsistent provision of care across geographies. The CCA has called for a nationally commissioned framework for EHC.[2] We suggest that the introduction of POM to P

[1] See https://psnc.org.uk/?our-services=emergency-contraception

[2] https://thecca.org.uk/blog-why-contraception-in-england-needs-national-commissioning-approach/

contraceptive medicines would be an opportunity to embed consistency and greater access for all women through nationally commissioned EHC and contraceptive services across the nations.

We believe that central to this switch is an approach around person centered care. There has been a steep decline in funding for sexual health services over the last few years.[3] Services have greatly impacted by the Covid-19 pandemic, and during the first wave community pharmacies had to manage queries from concerned individuals who could not access support and advice. Therefore, we would urge that greater availability of Desogestrel is utilised to empower women to make choices that suit them and is not seen, in any way, to replace much needed services for the prevention, and treatment of, sexual health issues. We also suggest that MHRA reach out to patients and representative groups from across all demographics (including ethnicity and the gender spectrum) to understand the cultural and social differences in requesting contraceptives so that they do not face any barriers.

Some patients who have a consultation for Hana or Lovima may find that it is not suitable or that they do not have the financial means for a P medicine. In such circumstances, it is important that these patients can be referred swiftly to their GP or a sexual health clinic, and not face real or perceived barriers to accessing contraceptives.

The proposals in the consultation mark an overdue shift in the provisions for women's health. Additionally, POM to P switches provide more community pharmacists opportunities to use their professional skills in clinical services and patient centered consultation. This provides women with more choice around accessing healthcare and removes the need to see their General Practitioner which, in turn, allows GPs to focus on complex cases.

**Response**

**1. Do you consider that Hana and Lovima should be available as a Pharmacy (P) medicine?**
**Yes x** **No ☐** **Not sure ☐**

**Please provide any comments or evidence to support your response:**

We agree that Hana and Lovima should be available as a P medicine.
There are many benefits to offering more availability and choice around contraceptives to women of a child-bearing age. We have outlined in our executive summary some of these benefits and reiterated our call for a nationally commissioned service around sexual health services.
If Hana and Lovima are available to buy, they may only be accessible to women of working age who are too busy to attend the GP. However, women in areas of higher deprivation face greater barriers to healthcare generally so this needs to be considered. Additionally, the term 'P' medicine does not factor in the consultation element of a transaction between the pharmacist and the patient. Pharmacists can have these consultations, as demonstrated with EHC now available through pharmacies without a prescription. However, as the contraceptive pill is a longer supply, monitoring needs to be factored in to screen for adverse side effects. If the monitoring is to be undertaken by the pharmacist, then this also needs to be factored into the model under which contraceptive P medicines are delivered.

[3] https://www.kingsfund.org.uk/blog/2018/12/sexual-health-services-and-importance-prevention

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

Steps should be taken to align the suggested documents to support patient consultations to avoid confusion. It is unclear whether Hana and Lovima will be available together for patients to choose or whether pharmacies will stock one or the other. Consideration may need to be given to the fact that both Hana and Lovima appear to be unsuitable to those who are intolerant to lactose and Lovima is not suitable to those allergic to peanuts or soya. It is important to have a similarly set out process for consultation if both brands are to be available in pharmacies. However, CCA members have suggested that they may prefer to stock one brand if that means rolling out one set of training to their teams.

*Hana*

The packaging details at Annex 3 are clear and the patient leaflet at Annex 2 is comprehensive. The leaflet should not be a replacement for a patient centred consultation, and patients should be aware of dosing information, side effects and contraindications before they are initiated. One concern is the brand name sounds similar to the codeword for the Home Office domestic abuse scheme ('ANI').

On the summary of product characteristics for Hana (Annex 4) it is noted that the efficacy and suitability for under 18s has not been tested. However, the 'pharmacy supply aid checklist' (Annex 5) includes steps for the pharmacist to check for appropriateness to under 18s. Therefore, it should be clear to pharmacists whether the product should be made available to all age groups. Annex 5 directs pharmacists to seek permission before undertaking the consultation and advises pharmacists to make patients aware of other options for contraceptives, including visiting their GP which is a positive step as women should be made aware that contraceptives are available without charge.

As community pharmacy provide emergency hormonal contraceptives (EHC) such as EllaOne the contraindications may need to be more clearly defined in the pharmacy supply aid checklist. As the leaflet explains, both Hana and some EHC both contain ulipristal acetate which bind to the progesterone receptor. Therefore, a 5-day (120 hour) delay must be in place before Hana is initiated after taking an EHC with ulipristal acetate to avoid the effect of either of these drugs being impacted. However, it is likely that a consultation for the contraceptive pill could be initiated from request and supply of EHC and therefore it would help to have this contraindication outlined in a more pronounced way.

*Lovima*

The packaging at Annex 3 is clear and the patient information leaflet at Annex 2 is comprehensive. Annex 5 the 'Pharmacy Consultation Checklist' is unclear about the appropriate steps or advice to give with regards to thrombosis. It states that it is not contraindicated but suggests that patients may wish to discuss alternatives with their doctor. It is suggested that more clarity is give to this direction and that patients are directed to their GP. The checklist is clear that Lovima may be taken immediately with the EHC containing levonorgestrel and no sooner than 5 days after EHC containing ulipristal.

The 'follow up' questions provided in the checklist cover issues with abnormal bleeding and whether the patient has introduced any health-related changes (e.g. herbal medicines). However, it does not include the important questions around any issues with adherence, mood changes or symptoms of depression and steps to track blood pressure.

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

The switch from POM to P for Desogestrel will provide women of a childbearing age with options around their healthcare. It will be role of the pharmacist to facilitate patient choice by providing the requisite information and redirecting patients where necessary. Pharmacists should be a barrier to women of childbearing age accessing contraceptives and therefore suitable training will need to be provided to ensure that women receive the right advice and support, based on their needs. Therefore, personal beliefs and opinions of pharmacy colleagues should not influence the supply of contraceptives. It may be appropriate for the General Pharmaceutical Council to republish their standards and ethics guidance on this topic.[4]

**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.

[4] https://www.pharmacyregulation.org/regulate/article/religion-personal-values-and-beliefs-providing-emergency-hormonal-contraception-0