

FSRH representation to MHRA on their consultation to make Hana available from pharmacies

5 March 2021

The Faculty of Sexual and Reproductive Healthcare (FSRH) welcomes the opportunity to submit a representation to the MHRA on their consultations on the proposal to make Hana a progestogen-only pills available from pharmacies. FSRH is the largest UK multidisciplinary professional membership organisation representing more than 15,000 members working at the frontline of Sexual and Reproductive Healthcare (SRH) in a range of settings in the community and primary care. Our members are specialists, GPs, nurses, pharmacists and other healthcare professionals delivering services commissioned by local authorities (via Public Health grant), Clinical Commissioning Groups and NHS England (NHSE). Our goal is to ensure that high standards in Sexual and Reproductive Healthcare are achieved and maintained through appropriate funding and commissioning to ensure the population can access services which realise [our Vision](#) for high-quality and holistic SRH across the life course.

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

Yes No Not sure

Improving Access

1. FSRH fully supports the reclassification of Hana as a Pharmacy (P) medicine. We have worked for many years with partners to encourage the reclassification of progestogen-only contraceptive pills as they are safe, reliable, easy to use and they are a very popular contraceptive method. Their availability in pharmacies will make it easier for some women to access essential contraception to avoid unplanned pregnancies. We believe that the reclassification of Hana to a Pharmacy (P) medicine is the first step to removing barriers faced by women in accessing contraceptive methods. The Sexual & Reproductive Healthcare system in the UK is complex and tough for women to navigate.
2. The 2012 Health and Social Care Act (HSCA) had two key objectives, to improve care for patients and 'facilitate' choice. It has been unsuccessful in both these respects, as it has resulted in a fragmented commissioning landscape leading to reduced access to contraception. The provision of the progestogen-only pill to buy in pharmacies will improve access to a popular form of contraception. This would make a substantial difference to the lives and health of women throughout the UK.
3. In England, local authority public health grant funding experienced a real-terms cut of £700 million between 2014/2015 and 2019/2020 – equating to a per person cut of some 25%. Despite rising demand, (a 13% increase at Sexual Health services between 2013 and 2017) these budget cuts have resulted in clinic opening hours being reduced.
4. Many GP surgeries no longer offer a full range of contraceptive provision and lack the trained staff to provide it. We believe the reclassification of Hana will be beneficial for healthcare professionals too, as it could relieve the unnecessary pressures on GPs, reducing the number of patients seen for repeat prescriptions.
5. However, buying contraception should not be the default solution. We are calling for progestogen-only pills to be available to everyone free of charge in community pharmacies, as well as the reclassification of other oral contraceptives moving forwards.

Safety

6. Progestogen-only contraceptive pills have, until now, been Prescription-Only Medicines (POM). 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 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 75mcg desogestrel POPs would be safe.
7. Available evidence and extensive experience of use indicate that the 75mcg desogestrel POP can be taken from menarche to menopause with very low risk of serious adverse events. There are few medical contraindications.
8. Pharmacy provision of Hana would include safeguarding and consideration of wider sexual and reproductive health along with a discussion of more effective long-acting reversible methods of contraception (LARCs). The pharmacy setting may be more accessible and acceptable to those prepared to pay for this method. However, we must reiterate that we do believe this to be only the first step and that buying contraception should not be the default solution. We are calling for progestogen-only pills to be available to everyone for free over the counter in community pharmacies.
9. Pharmacists already have training and experience in giving contraceptive advice and providing oral emergency contraception. By allowing the sale of Hana in pharmacies, you will utilise and build upon their skills. The well-designed recent study "Use of effective contraception following provision of the progestogen-only pill for women presenting to community pharmacies for emergency contraception (Bridge-It): a pragmatic cluster-randomised crossover trial" by Cameron, et al 2020¹ reported that individuals receiving levonorgestrel emergency contraception from a pharmacy are more likely to be using effective contraception four months later if they also receive a three-month supply of progestogen-only pills.
10. Over 600 individuals took part in the study and were randomised into either the control or intervention groups. At four months, subjects in the intervention group were 20% more likely to be using effective contraception than those in the control group, and significantly less likely to have required further emergency contraception (EC).
11. This study indicates that provision of a 3-month bridging supply of a desogestrel POP by a pharmacist when an individual presents to the pharmacy requesting oral EC could increase their future use of effective contraception. In the UK, most oral EC is provided in pharmacies.
12. While some initial training may be required, improving access will save the NHS money. Investment in contraceptive services represents good value to the NHS; it is estimated that every £1 spent on contraceptive services saves the health service £9.

¹ [Pragmatic cluster randomised cohort cross-over trial to determine the effectiveness of bridging from emergency to regular contraception: the Bridge-It study protocol | BMJ Open](#)

13. The case for reclassification is clear; the reclassification of Hana to a Pharmacy (P) drug will be of benefit to women and clinicians alike, removing barriers and obstacles to women while saving time and costs for clinicians.

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

14. All three documents ([the leaflet, label and pharmacy consultation checklist](#)) are informative and easy to digest. They each provide clear and concise guidance although it is not totally aligned with the guidance produced by the FSRH Clinical Effectiveness Unit which can be read in full [here](#). For instance, there is no medical reason why diabetics cannot take this POP. The 'missed POP advice' also differs from national guidance. The language used throughout is accessible, clear and easy to understand with little risk of it being misunderstood. It clearly lists all circumstances in which the progestogen-only pill may not be suitable and when a doctor should be consulted.
15. The Pharmacy Training Guides and Pharmacy Checklists for Hana 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.
16. The leaflet (Annex 2) provides a succinct breakdown in uncomplicated language of all the pertinent information women need to take Hana safely. It provides a useful resource for women to refer back to in their own time.
17. The label (Annex 3) summarises the information contained in the leaflet in concise, easily digestible bullet points which can be quickly referred to by the user.
18. The pharmacy consultation checklist (Annex 5) provides a concise and thorough checklist for the Pharmacist to go through with the patient before prescribing the medicine.

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