Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Response document for MHRA public consultation on the proposal to make Hana available from pharmacies

Ref: ARM 99

MHRA proposes to permit supply of Hana 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: Dr Rick Thomas

Position (if applicable): Researcher

Organisation (if applicable): Christian Medical Fellowship

Email:

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

Yes ☐ No ☒ Not sure ☐

Please provide any comments or evidence to support your response:
We appreciate the work done by MHRA and the evidence they present in favour of reclassifying Hana as a Pharmacy medicine. Our concerns relate primarily to safety, and specifically to an over-reliance on the check list; the responsibility of the customer to trigger a consultation; the capacity of pharmacists to cope with the additional workload; the conflict of interest between the provision of non-directive, unbiased advice and the obligation to the commercial interests of pharmaceutical manufacturers.

We are also concerned about complexity and inaccuracy in the product information leaflet, and insufficient account taken of the impact of non-compliance.

We also have concerns about precedent setting. This would be the first time an oral contraceptive agent was reclassified as a Pharmacy medicine. Other DSG contraceptives would be sure to follow and possibly depot injections. Having opened the door, how wide do you permit it to swing? The pressure to include combined oral contraceptives would be significant, but the associated risks much higher.

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

The leaflet is comprehensive. There is a huge amount of information on it, much of it detailed and technical. Very few women will read to the end. Some will take one look and be defeated by it. PILs suit the learning styles of some people, but not others. At best they are useful reminders of information better given face to face in a confidential setting, where a clinician can ensure clear communication, monitor levels of comprehension, use questions to ascertain the degree of understanding, etc. Leaflets can never replace face to face contact and careful explanation.

The leaflet is not wholly accurate. Under section 1, the final paragraph states that if Hana is taken regularly, it will protect against pregnancy. Desogestrel is indeed a much more efficient ovulation inhibitor than older progesterone-only pills. However, ovulation will still occur about 3% of the time, even with regular and reliable use, and if sperm penetrate the cervical mucus at the same time, then fertilisation is a possibility. Hana, like all hormonal contraception, may have either a direct or an indirect thinning effect on the endometrium so, if fertilisation does occur, the embryo could still be lost. Therefore, for those who wish to be certain that their contraceptive could never act post-fertilisation, Hana would not be an ethical choice. We believe this should be made clear, both in the PIL and in consultations between the customer and pharmacist. This would be especially important for a woman planning to become a first-time user of Hana, and for women who, for religious or other reasons, hold convictions about the sanctity of life from the time of fertilisation.

The packaging, again, has a lot of information crammed into a small space. The wording 'speak to your pharmacists if…' suggests that unless one of the following four bullet-points applies then there is no need to consult the pharmacist. This message is not the one that should be communicated. Surely, every woman should have a personal consultation with the pharmacist before commencing Hana. For example, how else will she know if her BP is normal?

The short checklist that customers will be asked to fill in 'invites' them to tick the 'green' box. A girl of 15, anxious to start the pill, will tick the 16-18 box. No questions asked. No requirement to produce ID. It is easier for her to get the pill in the pharmacy than a pint in a bar. The checklist scenario is a far cry from the picture painted by the consultation document of every woman, particularly every woman starting Hana for the first time, being given a comprehensive consultation with a clinician. There is no question on the check list asking if this would be a first-time supply. In our opinion, this should be corrected, and ID should be mandatory for those claiming to be 16-18 years old.

Our concern is that this will become no more than a quick box-ticking exercise. It places far too much responsibility on the customer to trigger a consultation. To those who might have something to hide, or who are simply in too much of a hurry, the checklist says, in effect, 'tick the green boxes and you won't have to see a pharmacist.'

Overall, and contrary to the view of the Commission on Human Medicines, we believe that it would be unsafe to reclassify Hana as a Pharmacy medicine. We think it is likely to present a direct or indirect danger to human health, even when used correctly, if used without medical supervision. As such, it fails Criterion 1.

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

Criterion 2 refers to the frequency and extent of incorrect use, such as would present a direct or indirect danger to human health. The effectiveness and safety of hormonal contraception depends greatly on compliance. Self-described non-compliance has been reported by 71% of contraceptive pill users.[1] We believe that non-compliance would impact upon the ability of Hana, as a Pharmacy medicine, to satisfy Criterion 2.
Compliance is aided by avoiding a pill-free period between monthly courses, as is the case for Hana, but we are sceptical that the combination of information in the (already dense and technical) PIL and training materials for pharmacists will be sufficient to offset user-error. Whilst medical supervision does not guarantee complete compliance, it will serve to improve it.

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

[1] Lete I et al. Self-described impact of non-compliance among users of a combined hormonal contraceptive method. *Contraception* 2008;77(4):276-282.

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.