



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: Yogeeta Shah

Position (if applicable): Professional Support Pharmacist

Organisation (if applicable): Royal Pharmaceutical Society

Email: consultations@rpharms.com

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:

The Royal Pharmaceutical Society is the professional body for pharmacists and pharmacy in Great Britain. As professionals in pharmaceutical care, pharmacists are well equipped to offer advice on medicines and sexual health.

The Royal Pharmaceutical Society supports the proposal to make Hana 75 microgram film-coated tablets (Desogestrel) available as a Pharmacy medicine.

Pharmacists are experts in medicines and are well trained to ensure safe supply of medicines to the public. This move will increase access to an effective method of contraception and enable women to make an informed choice about their needs after discussion with a pharmacist.

Pharmacists are currently able to sell products for emergency contraception such as ulipristal and levonorgestrel with appropriate advice on regular contraception.

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

Leaflet:

Leaflet states *'In some circumstances it may not be more appropriate to take Hana or it may be necessary to consult a doctor before taking Hana'* We would suggest the addition of pharmacist, as pharmacists will be carrying out a consultation with patient to determine appropriateness of supply.

'Talk to your doctor if you find Hana doesn't suit you or if you are finding it difficult to take as instructed' We would suggest the addition of pharmacist as pharmacists can suggest alternatives and are in a position to refer appropriately. There is information on taking emergency contraception ulipristal and advice associated with this. Is there any advice associated with other emergency contraception such as levonorgestrel.

Label:

None

Supply aid checklist:

Under section how old are you, we would suggest having a bullet point ensuring the patient is not a vulnerable adult or child.

Further information on pregnancy exclusion tool may be required.

The supply checklist could perhaps be user friendly and clearer in some parts. It is not initially clear that the second table is based on starting Hana. Perhaps this could be highlighted to provide better flow and understanding of the process.

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

We feel with appropriate training healthcare professionals would be confident to make a safe and effective supply to patients, with additional material such as Summary of Product Characteristics to supplement training.

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

Yes

Partially*

No

*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 **Thursday 4 March 2021**. Contributions received after that date cannot be included in the exercise.