**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: Anna Zecharia**

**Position (if applicable): Director, Policy & Public Affairs**

**Organisation (if applicable): British Pharmacological Society**

**Email:**

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| * 1. **Do you consider that Hana should be available as a Pharmacy (P) medicine?**   Yes 🞏 No 🞏 Not sure X  Please provide any comments or evidence to support your response:  In terms of the pharmacology, and what counselling the pharmacist provides purely about the drug itself, when to take it, how to take it, and potential interactions, the Society has no concerns. Desorgestrel has relatively few contra-indications, and the most common adverse events tend to be troublesome rather than serious. It is our opinion that this medication meets the usual MHRA specifications for Pharmacy medicines.  However, we have also considered our recommendation in a wider social and healthcare context. Considering the question in this light, we see reasons to support reclassification but have also identified areas of concern. We have identified the information and reassurance we require before we feel able to make a recommendation. We would appreciate the opportunity to comment further if these could be addressed as part of further consultation, perhaps in the form of a Q&A document.  **Reasons to support reclassification**  Making this contraceptive more readily available may reduce unwanted pregnancy, and be welcomed by women who are healthy and empowered to make informed, free choices:   1. Many women have difficulty accessing GP or sexual health clinic services for contraceptive advice, and this has been exacerbated during the pandemic. 2. In most cases, the risks of not being able to access contraception are higher than the potential risks of this particular agent. 3. Pharmacy-led consultations may have more time for a detailed conversation about the drug. 4. Some patient groups who might be classified as vulnerable might be more able to access contraception via the pharmacies than through the GPs.   **Areas of concern**  However, there are risks associated with the proposed approach such as reduced contact with the GP and the opportunity to discuss wider sexual and other health issues, including the full range of available contraceptive options. We would also raise concerns about a reduced ability to detect signs of exploitation or abuse – areas which those currently prescribing contraception (i.e., doctors and nurses working in primary care or sexual health) will have had training and good experience of.  **Therefore, we would like to understand how the risk of a woman receiving a lower quality of care will be addressed.** Specifically:   1. Usually, a GP can cross-check against existing medical history in support of safe use, although that would not be the case for stand-alone sexual health clinics. 2. For a woman who chooses a progesterone only method, often a Long-acting Reversible Contraceptive (LARC) might be more appropriate e.g., due to improved adherence, lower failure rate. We note that the reclassification may result in more pressure to take a less effective option, either through ease of access or lack of awareness of other options. 3. Ideally the full range of contraceptive options should be discussed and considered and tailored to the individual needs of the woman. 4. We recommend clear guidance and requirements for the pharmacy-led consultations to be documented and audited. Whilst Annexe 5 looks comprehensive, it is not considered mandatory. 5. We would like assurances regarding the consistency of advice women would receive and would recommend that Annexe 5 be made mandatory. We would also recommend that training is available to support this. We would also note that even in well-equipped pharmacies, it can sometimes be difficult to have a confidential conversation. 6. We have some concerns about vulnerability, potential abuses and safeguarding issues – within a medical consultation, some of these might be addressed, but we are not clear whether the pharmacist would be able to pick up and act upon concerns. It might be argued that those who are in abusive or exploitative situations would find it even harder to access the GP than the pharmacist, so perhaps the risks and benefits are both present in this age group, particularly those in the socially challenging situations. 7. We recommend further clarification about the statement: ‘under 18s to be given a 3-month supply only’. Currently it is unclear whether teenagers of any age would be able to access this service without any involvement of the GP, and we would like to understand the details of this (for example, will there be a lower age limit or proof of age requirements) further. 8. Contraceptives are available free from GPs and sexual health clinics. It is not clear whether there would be cost implications for the reclassification, and we would value clarity on this point regarding whether any change would pose a barrier to access. |

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| **2. Do you have any specific comments on the leaflet, label or pharmacy supply aid checklist provided at Annexes 2, 3 & 5?**  The annexes are sufficiently clear and detailed. Annexe 5 provides a very strong framework for the pharmacy-led consultation, but begins with the statement that following the Annexe is optional. We recommend it should be mandatory.  As we stated in our response to question 1, we recommend clear guidance and requirements for the pharmacy-led consultations to be documented and audited. Further, in the event of any complication or harm, the reporting and documentation process should be made clear. |

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| 1. **Do you have any other comments on the reclassification?**   Within any population, there are different subgroups with specific needs. We can see how this could work well for a group of healthy, empowered women who have busy lives and want to be able to quickly access their contraceptive of choice.  At the same time, we have concerns about other groups of women who might be complex or vulnerable for the reasons detailed in Q1. |

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| * 1. **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. |

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.