



Royal Pharmaceutical Society of Great Britain

Helping pharmacists achieve excellence

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Dear Ms Popo

Re: ARM 39 – Request to reclassify Cyclo-F 500 mg tablets from POM to P

I write on behalf of the Royal Pharmaceutical Society of Great Britain to respond to the above consultation.

The Royal Pharmaceutical Society of Great Britain is the professional and regulatory body for pharmacists in England, Scotland and Wales. It also regulates pharmacy technicians on a voluntary basis, which is expected to become statutory under anticipated legislation.

The primary objectives of the Society are to lead, regulate, develop and represent the profession of pharmacy.

The Society leads and supports the development of the profession within the context of the public benefit. This includes the advancement of science, practice, education and knowledge in pharmacy. In addition, it promotes the profession's policies and views to a range of external stakeholders in a number of different forms.

The Society has responsibility for a wide range of functions that combine to assure competence and fitness to practise. These include controlled entry into the profession, education, registration, setting and enforcing professional standards, promoting good practice, providing support for improvement, dealing with poor performance, dealing with misconduct and removal from the register.

The Society requests that the following points be taken into consideration:

See Application Details (page 1): 'The recommended dose for women over 18 years is 2 tablets 3 times daily for as long as needed, but for a maximum of 4 days. If there is very heavy

bleeding, the dosage may be increased. A total dose of 4g daily (8 tablets) should not be exceeded. The pack size is 18 tablets.' Based on the above dose and pack size numbers do not correlate ie $6 \times 4 = 24$, $8 \times 4 = 32$. Pharmacy pack size will not cover 4 days. The maximum daily dose (8 tablets) is two tablets above the recommended dose (six tablets) and may potentially cause confusion.

See Section 2 (page 1); 'It is believed that a much higher proportion of women consider themselves to have heavy menstrual bleeding'. Concern regarding whether these women will still fall within the criteria used for supplying the product over-the-counter.

See Section 2 (page 2): 'As long as heavy menstrual bleeding occurs in menstrual cycles that are regular, it is *very unlikely* to be caused by any underlying pathology'. The Society requests the evidence base for this statement.

Irregular periods: Concern that women may not necessarily record the regularity of their periods.

Questionnaire: Although some pharmacists may find a questionnaire useful to elicit information during the consultation, use of a questionnaire should not be mandatory. In addition, some customers may object to completing a questionnaire.

Dosage: 'once bleeding becomes less of a concern, the number of tablets taken per day should be reduced'. Details on what the dose should be reduced to would be helpful.

See Section 2.1 (page 2, paragraph 3): There are a number of conditions (eg endometrial cancer and cervical cancer) where self-diagnosis and self-medication could hypothetically incur a risk of masking an underlying condition and delay a correct diagnosis and appropriate treatment'. Concern regarding how this will be prevented.

See Section 2.1 (page 3, paragraph 6): Need to highlight that if the treatment does not help reduce bleeding after three months or seems to stop working, women should see their doctor.

See Section 2.1. (page 3, paragraph 7): Concern regarding describing menorrhagia as a 'defined disease'. Careful consideration needs to be given to the type of information to be included in the pharmacists training pack – how to diagnose the condition and exclude other causes etc. Consideration needs to be given to whether a prior doctor diagnosis is required.

See Section 2.2 (page 3, paragraph 1): Clarification sought on whether the statement also refers to over-the-counter use.

See Section 2.2 (page 3, paragraph 2): 'Considering the nature of the molecule and its effects, any addition or habituation would appear highly unlikely'. The Society requests the evidence base for this statement.

See Section 4: The pack size should be sufficient to cover one course of treatment.

See Section 6: Reference should be made to haemophilia, patients with long term iron deficiency, use of aspirin, dipyridamole etc.

Patient Information Leaflet: Concern that the leaflet is too long. Existing medical conditions need to be known before purchase. Patients who have already purchased the product may not be aware that it may not be suitable for them. The Society also has concerns regarding patients understanding of terminology eg antifibrinolytic.

Section 2 – ‘Take special care with Cyclo-F’: Leaflet makes reference to individuals who may be ‘overweight’ but does not give a definition based on body mass index.

Section 3: ‘How to take Cyclo-F’: A pack size of 18 tablets will not be sufficient for three months.

Section 4 – ‘Possible side effects’: Concern regarding patient safety issues.

We hope these comments are helpful.

Thank you for consulting the Society.

Yours sincerely

Sadia Khan
Lead Pharmacist for Self-care