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Your details

Name: Tanya Rogers

Position (if applicable): Professional Support Pharmacist

Organisation (if applicable): Royal Pharmaceutical Society

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1. Do you consider that Maloff Protect should be available as a Pharmacy medicine?

**Yes**

Please provide any comments or evidence to support your response:

The Royal Pharmaceutical Society supports the reclassification of Maloff Protect from POM to P. Pharmacists are experts in medicine, and have the necessary skills and training to ensure the safe and efficient supply of pharmacy medicines. Other anti-malarials are already being sold in pharmacies for the prevention of malaria. Pharmacy services currently exist where pharmacists supply Proguanil hydrochloride 100mg, Atovaquone 250mg via Patient Group Directions (PGD).

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2. Do you have any specific comments on the leaflet or the label provided in the public Reclassification report for Maloff Protect?

**Public consultation document**

3. Proposal to make Maloff Protect available as a Pharmacy medicine

**-Maximum pack size:** 36 tablets (total number of tablets dispensed dependent on duration of travel with maximum of 93 tablets for 12 weeks travel).

We suggest that the maximum quantity of tablets that may be supplied for 12 weeks travel (93) is communicated clearly in the SPC. Does this mean that if patients will be in an area where malaria is widespread for more than 12 weeks that a pharmacist will be unable to make the supply and the patient will have to have the medication prescribed, which will require signposting to a prescriber? Will this information be clearly available for pharmacists in the Training resources such as Pharmacy guide, screening questionnaire, pack calculator and pharmacist checklist?

**Medication label**

**How to take:**

**Adults:**

'Take one tablet once a day with food or a milky drink where possible'.

Some patients may not read the PIL and will only refer to dosage on the outer label. We suggest that it is changed to '*take one tablet once a day at the same time each day*' to reflect the PIL.

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3. Do you have any other comments on the reclassification? N/A

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

**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.gsi.gov.uk) to arrive by 6 April 2017. Contributions received after that date cannot be included in the exercise.