Press release: Maloff Protect antimalarial tablets to be available to buy from pharmacies

Every year there are millions of new cases of malaria worldwide and thousands of travellers are diagnosed after returning to the UK, resulting in occasional and tragically avoidable deaths.

The Medicines and Healthcare products Regulatory Agency has today announced the approval of an antimalarial tablet which will be available through pharmacies without prescription.

Sold under the brand name Maloff Protect, the tablets contain two antimalarial agents, atovaquone and proguanil.

Maloff Protect will be sold at pharmacies after a discussion with the pharmacist. They will be made available to adults aged over 18, weighing more than 40kg, travelling to areas affected by malaria and where the malaria parasite is not resistant to the Maloff Protect ingredients.

Pharmacists will be able to advise if Maloff Protect is suitable to protect from malaria depending on which countries are being visited, pre-existing medical conditions, and any other medicines being taken.

Make sure you tell your pharmacist which countries you will be visiting: it is essential that you take an antimalarial that will be effective in those areas. You will need to start the tablets before arriving in a malariaendemic area and to continue taking them for 7 days after leaving.

Pharmacists will also be best placed to advise how to avoid mosquito bites, such as the use of bed nets, repellent sprays and appropriate clothing when outside. They will also be able to reinforce the importance of seeking a full travel consultation, including the need for travel vaccinations.

Maloff Protect was one of a number of medicines currently being considered for reclassification as an over the counter medicine, to help widen access to medicines for the benefit of public health when it is safe to do. This reclassification is a result of a public consultation, held earlier this year.

Dr Sarah Branch, MHRA's Deputy Director of VRMM, said:

Malaria is a very serious disease and taking adequate protection when travelling to malaria infected zones can be life-saving. Today's move to make another antimalarial more widely available will make it easier to access.

Making more preventative medicines more readily available along

with additional healthcare advice for travellers is an important step forward.

A full consultation with a healthcare professional is always recommended before you go to places where malaria is prevalent and pharmacists are well placed to help direct travellers to additional sources of information and information and advice.

Mr Martin Astbury, President of the Royal Pharmaceutical Society, said:

This is great news for both pharmacists and travellers. It means people travelling abroad can access the medicine at their convenience and without a prescription from their GP, which would undoubtedly result in better access to protection from malaria.

Pharmacists already offer a full range of travel advice and in some cases vaccinations. Malaria prevention is a well-established area of expertise for pharmacists and a great opportunity to provide full travel advice to people travelling anywhere in the world.

Pharmacists have access to up to date information and resources and are very well equipped to provide this medicine safely and appropriately. As the professional body for pharmacists, the RPS will be publishing professional guidance on this topic.

Background

- 1. The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe.
- 2. All our work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks. MHRA is a centre of the Medicines and Healthcare products Regulatory Agency which also includes NIBSC and CPRD. The Medicines and Healthcare products Regulatory Agency is an executive agency of the Department of Health.
- 3. Maloff Protect is a medicine to be taken by mouth to prevent malaria infection in adults travelling to areas where malaria is widespread. The active ingredients are atovaquone and proguanil. Both are in a class of drugs called biguanides used to prevent and treat malaria.
- 4. Per the World Health Organization's (WHO) 2016 World Malaria Report, there were 212 million new cases of malaria worldwide in 2015. In 2015, there were an estimated 429 000 malaria deaths worldwide. Malaria is not found in the UK, although about 1,586 travelers were diagnosed with the disease after returning to the UK in 2014, and three people died.

- 5. Following a public consultation, The Commission on Human Medicines (CHM) advised in favour of Pharmacy availability of Maloff Protect. The CHM is an advisory non-departmental public body, sponsored by the Department of Health that advises ministers on the safety, efficacy and quality of medicinal products.
- 6. Maloff Protect has been reclassified from a prescription only medicine to one available in pharmacies. Pharmacists are experts in medicine, and have the necessary skills and training to ensure the safe and efficient supply of pharmacy medicines. The link to the public consultation is here:
- 7. MHRA involved the public and healthcare professionals throughout the decision-making process. We carefully analysed their contribution in the public consultation phases before deciding how to proceed. The responses to the consultation were predominantly positive. Full set of consultation responses can be seen here:
- 8. People travelling should also look at: http://nathnac.net/ and http://www.travax.nhs.uk/ (for Scotland) Other sites include PHE's Advisory Committee on Malaria Prevention updates which are issued annually:, NICE guidance and the [NHS choices site] (http://www.nhs.uk/Conditions/Malaria/Pages/Prevention.aspx).