WHO prequalifies first medicine for treatment of a neglected tropical disease

For the first time, the WHO Prequalification of Medicines Programme has prequalified a medicine for treatment of a neglected tropical disease. NTD002, is a 100 mg tablet of diethylcarbamazine (DEC), manufactured by Eisai Co., Ltd., a Japanese pharmaceutical company, that has committed to donate — over an initial six-year period — 2.2 billion DEC tablets to WHO, for use in preventive chemotherapy aimed at elimination of lymphatic filariasis. Acceptance of the donation by WHO was dependent on prequalification of the product by WHO, to verify that it meets international pharmaceutical quality standards.

The timeline from submission of the application of the product to WHO for evaluation, to prequalification, was less than 10 months, reflecting a smooth and efficient evaluation process. “Our counterparts at Eisai set an example for all manufacturers seeking prequalification. Their readiness to respond to WHO requests for further information and data concerning their product, and their willingness to open the manufacturing site of the finished product for inspection, were exemplary”, commented Dr Lembit Rāgo, WHO coordinator for medicines quality and safety.

Lymphatic filariasis: a disfiguring and incapacitating disease

Neglected tropical diseases (NTDs) form a group because all are strongly associated with poverty, flourish in impoverished environments and thrive especially in tropical areas. Lymphatic filariasis, commonly known as elephantiasis, is one of these. Over 120 million people are currently infected with lymphatic filariasis, about 40 million of whom are disfigured and incapacitated by the disease. A further 1.4 billion people, most of whom are among the world’s poorest are at risk. Approximately 65% of those infected live in the WHO South-East Asia Region, 30% in the African Region, and the remainder in other tropical areas.

Infection with lymphatic filariasis occurs when filarial parasites are transmitted to humans through mosquitoes. When a mosquito with infective stage larvae bites a person, the parasites are deposited on the person’s skin from where they enter the body. The larvae then migrate to the lymphatic vessels where they develop into adult worms in the human lymphatic system. Infection is usually acquired in childhood, but the painful and profoundly disfiguring visible manifestations of the disease occur later in life. Whereas acute episodes of the disease cause temporary disability, lymphatic filariasis leads to permanent disability.

Progressing towards elimination

In Asia, the Middle East and some countries in East Africa, control and elimination of the disease could be achieved through expansion of large-scale preventive chemotherapy interventions. The recommended regimen for treatment through mass drug administration is a single dose of two medicines given together — albendazole (400 mg) plus DEC in areas where onchocerciasis is not endemic, or ivermectin, in areas where onchocerciasis (river blindness) is also endemic. These
medicines clear microfilariae from the bloodstream; at least five rounds of treatment are required to eliminate lymphatic filariasis in a given population.

Following prequalification of NTD002, Eisai and WHO will work together to ensure that DEC is made available to all eligible countries. “We can now accelerate progress towards the elimination of lymphatic filariasis worldwide”, says Dr Lorenzo Savioli, Director of WHO’s Department of Neglected Tropical Diseases

**WHO medicines prequalification**

WHO medicines prequalification consists of a comprehensive evaluation of the submitted product, based on dossier information submitted by the manufacturer, and on an inspection of the corresponding manufacturing facilities and clinical sites. This is done through a standardized procedure that is based on WHO-recommended quality standards. Prequalified medicines help optimize use of health resources and improve health outcomes.

**For further information contact:**

Dr Matthias Stahl, Head of Assessments, WHO Prequalification of Medicines Programme

*By email: stahlm@who.int*
*By phone: +41 22 791 3717*

Dr Denis Daumerie, Programme Manager, Neglected Tropical Diseases Department

*By email: daumeried@who.int*
*By phone: +41 22 791 3919*