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Eisai gets WHO prequalification, will donate 2.2 bn doses

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Singapore: The WHO has prequalified Eisai's drug NTD002, a 100 mg tablet of diethylcarbamazine (DEC) for treatment of elephantiasis, and the Japanese firm has committed to donate 2.2 billion DEC tablets to the WHO over an initial period of six years.

The 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.

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 RÃ?Æ?Ã?Â¤go, WHO coordinator for medicines quality and safety.

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.

Following prequalification of NTD002, Eisai and WHO will work together to ensure that DEC is made available to all eligible countries in Asia, Middle East and parts of Africa. "We can now accelerate progress towards the elimination of lymphatic filariasis worldwide", said Dr Lorenzo Savioli, director, department of neglected and tropical diseases, WHO.