European Medicines Agency
Press office

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PRESS RELEASE

European Medicines Agency gives first positive opinions on medicinal products for use outside the European Union

The European Medicines Agency today gave, for the first time, a scientific opinion in the context of cooperation with the World Health Organization (WHO) for medicinal products intended exclusively for markets outside of the European Union.

The revised EU pharmaceutical legislation has introduced a new provision, which allows the Agency's Committee for Medicinal Products for Human Use (CHMP) to give opinions, in cooperation with the WHO, on products that are intended for use outside of the EU. Previously, the CHMP could only review products intended for the EU market.

Medicines eligible for this new procedure are used to prevent or treat diseases of major public interest. This includes vaccines used in the WHO Expanded Programme on Immunization or for protection against a public health priority disease, as well as medicines for WHO target diseases such as HIV/AIDS, malaria, or tuberculosis.

Thomas Lönngren, EMEA Executive Director, said: "It is very positive that the European Medicines Agency has been able to work with the WHO on putting in place this new way of assisting countries outside the EU to allow faster access to important medicines in response to public health challenges."

The first products undergoing the new procedure are Lamivudine GSK 150 mg film-coated tablets and Lamivudine/Zidovudine GSK film-coated tablets, from Glaxo Group Limited, both intended as part of an antiretroviral combination therapy for the treatment of human immunodeficiency virus (HIV) infected children and adults.

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NOTES:

1. Summaries of opinion for Lamivudine GSK (lamivudine) and Lamivudine/Zidovudine GSK are published on the EMEA website and can be found here.
2. The legal basis for a CHMP scientific opinion in the context of cooperation with the World Health Organization is Article 58 of Regulation (EC) No 726/2004, which enters fully into force on 20 November 2005. The text of the Regulation can be found here.
3. An EMEA guideline on CHMP scientific opinion in the context of cooperation with the World Health Organization (WHO) has been published and can be found here.
4. WHO target diseases include HIV/AIDS, malaria, tuberculosis, lymphatic filariasis (elephantiasis), trachoma, leishmaiasis, schistosomiasis, African trypanosomiasis (sleeping sickness), onchocerciasis (river blindness), dengue fever, Chagas disease, leprosy.
5. This press release together with other information about the work of the European Medicines Agency can be found at the EMEA website: www.emea.eu.int.
6. Information about the WHO can be found at www.who.int.

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