European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 24 July 2008
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for

TADALAFIL LILLY

International Nonproprietary Name (INN): ***tadalafil***

On 24 July 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Tadalafil Lilly, 20 mg, oral use, intended for the treatment of erectile dysfunction. The applicant for this medicinal product is Eli Lilly Nederland B.V.

The active substance of Tadalafil Lilly is tadalafil, a medicinal product used in erectile dysfunction (ATC Code G04BE08). Tadalafil is a selective, reversible inhibitor of cyclic guanosine monophosphate (cGMP)-specific phosphodiesterase type 5 (PDE5). When sexual stimulation causes the local release of nitric oxide, inhibition of PDE5 by tadalafil produces increased levels of cGMP in the corpus cavernosum. This results in smooth muscle relaxation and inflow of blood into the penile tissues, thereby producing an erection. Tadalafil has no effect in the absence of sexual stimulation.

The benefit of Tadalafil Lilly is the improved erectile function for the sexual activity. The most common side effects are headache, dyspepsia, back pain, myalgia, and flushing and nasal congestion. Mechanism of action related vasodilating effect can also be expected.

A pharmacovigilance plan for Tadalafil Lilly, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: “Treatment of erectile dysfunction. In order for tadalafil to be effective, sexual stimulation is required. Tadalafil Lilly is not indicated for use by women”.

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Tadalafil Lilly and therefore recommends the granting of the marketing authorisation.

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* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 8613
E-mail: mail@emea.europa.eu http://www.emea.europa.eu