European Medicines Agency
Press office

London, 23 March 2007
Doc. Ref. EMEA/132706/2007

PRESS RELEASE
Meeting highlights from the Committee for Medicinal Products for Human Use, 19-22 March 2007

http://www.emea.eu.int/pdfs/human/press/pr/13270607en.pdf

Referral procedure concluded
The CHMP finalised a review procedure for mifepristone-containing medicines that started in December 2005. The review was triggered by France, following safety and efficacy concerns regarding the use of the approved dose of 600 mg **mifepristone,** as compared to the use of a 200 mg dose, in the medical termination of developing intra-uterine pregnancy in sequential use with prostaglandin analogue.
The CHMP concluded that the available data support the effectiveness of a 600 mg dose of mifepristone, followed by the use of prostaglandin analogues, for the termination of pregnancy up to 63 days of amenorrhoea (absence of menstrual periods). In pregnancies up to 63 days, comparative studies between 200 mg and 600 mg mifepristone in combination with 1 mg gemeprost delivered vaginally suggest that 200 mg mifepristone may be as effective as 600 mg mifepristone. However, in pregnancies up to 49 days, comparative studies between 200 mg and 600 mg mifepristone in combination with 400 µg misoprostol delivered orally cannot exclude a slightly higher risk of continuing pregnancies with the 200 mg dose. Based on the available published data, the benefit/risk profile of mifepristone in combination with oral misoprostol for pregnancy from 50 to up to 63 days is unfavourable due to poor efficacy.

The CHMP also recommended the addition of new safety information regarding:
- the risk of fatal infections when 200 mg mifepristone is followed by non-authorised vaginal administration of misoprostol tablets for oral use,
- the interactions of mifepristone with other medicines,
- the use of mifepristone and prostaglandin analogues in patients with haemostatic disorders or severe anaemia.

The procedure was carried out in accordance with Article 31 of the Community Code on medicinal products for human use (Directive 2001/83/EC). This type of procedure is initiated to review medicinal products authorised at Member State level, because of public health concerns.