European Medicines Agency

London, 4 August 2009
Doc. Ref.: EMEA/493724/2009

EMEA 2010 Priorities for Drug Safety Research

Medicine Use in Pregnancy

Clinical trials rarely involve pregnant women unless the drug is intended specifically for use during pregnancy. Reproductive toxicity will normally have been tested in pre-clinical studies but animal studies are not always predictive of the results in man and subtle effects – e.g. on cognition – or latent effects may not be detectable in these studies. Estimations of the percentage of women prescribed drugs during pregnancy vary, but several suggest that the frequency may be as high as 84-99%.

Sometimes it is essential that drugs are taken during pregnancy. This may be because there is a high risk to the mother if medicines are not taken, or where the effects on the foetus if a medicine is not taken is likely to be greater than the risks of the medicine – eg a prolonged epileptic fit may cause more harm than exposure to certain antiepileptic drugs. When there are multiple therapeutic options it is important to know if there are medicines that are relatively safer than others. Therefore it is important to collect all information on drug exposure and timing of exposure during pregnancy and the outcome of pregnancy.

Depression during pregnancy has been estimated at between 10 – 16%. The selective serotonin reuptake inhibitors (SSRIs) were thought to be relatively safe in pregnancy but recent studies suggest that the rate of congenital malformation is increased in mothers taking SSRIs during the first trimester of pregnancy. Therefore the comparative safety of antidepressant use in pregnancy is an important public health issue which needs further research.

Some drugs are known to be teratogenic – eg thalidomide and isotretinoin – and must not be used during pregnancy. For these drugs it is essential that foetal exposure is avoided. Because a woman may not realise that she is pregnant for some weeks, stopping the medicine if a women becomes pregnant is not an effective means of avoiding foetal exposure and prevention of pregnancy may be the only option.

Several medicines in the EU have been authorised on the condition that the marketing authorisation holder establishes pregnancy prevention programmes and provides health care professionals and patients with advice on avoidance. These programmes may be fairly burdensome on both patients and health care practitioners so it is important that they are effective. Research is needed to develop and test methods of preventing or minimising exposure to harmful medicines during pregnancy so that evidence based recommendations can be made.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 68
E-mail: mail@emea.europa.eu http://www.emea.europa.eu.

Research is needed in two main areas:

- Design and testing of effective pregnancy prevention programmes
- Comparative safety of different therapeutic options in pregnancy – e.g. antidepressants.