observed. As experience of effects of drugs in this category in humans is limited, results of toxicological studies to date (including reproduction studies in animals) are indicated by allocation to one of three subgroups:

  - *Group B1*. Studies in animals have not shown evidence of an increased occurrence of fetal damage.
  - *Group B2*. Studies in animals are inadequate or may be lacking, but available data show no evidence of an increased occurrence of fetal damage.
  - *Group B3*. Studies in animals show evidence of an increased occurrence of fetal damage, the significance of which is considered uncertain in humans.

    For drugs in the B1, B2 and B3 categories, human data are lacking or inadequate and subcategorisation is therefore based on available animal data. The allocation of a B category does not imply greater safety than the C category.

- *Category C*. Drugs which, owing to their pharmacological effects, have caused or may be suspected of causing harmful effects on the human fetus or neonate without causing malformations. These effects may be reversible. Texts should be consulted for further details.
- *Category D*. Drugs which have caused, are suspected to have caused or may be expected to cause, an increased incidence of human fetal malformations or irreversible damage. These drugs may also have adverse pharmacological effects. Texts should be consulted for further details.

  Drugs in category D are not absolutely contraindicated in pregnancy (e.g. anticonvulsants). Moreover, in some cases the D category has been assigned on the basis of 'suspicion'.
- *Category X*. Drugs that have such a high risk of causing permanent damage to the fetus that they should not be used in pregnancy or when there is a possibility of pregnancy.

The general recommendations provided in this section have been drawn from:

- *Drugs and Pregnancy* (Royal Women's Hospital, 2006)
- *Australian Medicines Handbook* (2008)
- approved Product Information for the drug.

Due to legal considerations, sponsor companies have in some cases applied a more restrictive category than can be justified on the available data. When considering the use of any medicine for a woman who is pregnant, the pharmacist should always consider alternative options, the risks associated with not treating a condition, whether dose adjustments are required, potential adverse effects to the fetus, and any monitoring that may be required.

Breastfeeding

The benefits of breastfeeding, for both mother and infant, are well recognised. Therefore, when the mother requires medication, discontinuing breastfeeding should not be the first choice.

When considering the use of any medication in a woman who is breastfeeding, the pharmacist should first determine:

- whether the drug is necessary—e.g. Are there safer alternatives? Can the treatment be delayed? What are the risks of not treating the condition?
- how the drug is processed by the mother—e.g. To what extent is the drug absorbed systemically by the mother? To what extent is the drug (and any metabolites) excreted in breast milk? What is the half-life of the drug? At what point after a dose will drug milk levels peak?
- how the drug is processed by the infant—e.g. How will the drug (and any metabolites) be absorbed, metabolised and excreted? What are the potential adverse effects? This may differ depending on whether the infant is premature, a neonate or a toddler and whether they have any medical conditions.

The general recommendations provided in this section have been drawn from:

- *Drugs and Breastfeeding* (Royal Women's Hospital, 2006)
- *Australian Medicines Handbook* (2008)
- approved Product Information for the drug.

Breastfeeding safety information is not always included—e.g. where there is no published information available and/or the drug is unlikely to be used by lactating women. In these circumstances, caution would dictate that the drug be avoided in lactation if possible.

Common dosage ranges

Adult and paediatric dosage information is included in this section and is presented as doses or dosage ranges for uses and indications that are typically or most commonly encountered in a community pharmacy setting. This information is intended to be a guide and is not necessarily comprehensive.