

# Medicines which are promoted for use during pregnancy: Guidance for the pharmaceutical industry

## 1. Purpose of this guideline

This guidance has been developed by Medicines and Healthcare products Regulatory Agency (MHRA), in consultation with industry representatives and advertising regulatory bodies.

This guidance is supplementary to the regulatory framework as set out in the Part 14 of the Human Medicines Regulations 2012 (SI 2012/1916 as amended – the Regulations).

This guidance is intended for advertisers to ensure safe and responsible advertising of medicines which may be promoted for use during pregnancy. It reflects the general principles that caution should always be taken when medicines are used during pregnancy and that advertising should not convey messages that it is usual for pregnant women to take medicines. It is anticipated that this guidance will raise awareness of the risks of taking medicines during pregnancy and encourage women who are or may be pregnant to take medicines only when absolutely necessary and to seek professional advice.

The decision on whether a particular advertisement complies with the Regulations will be taken by the MHRA on a case by case basis, having regard to the facts of the particular case.

## 2. Scope of guidance

- This guidance covers the advertisement of any licensed medicine which is being promoted for use during pregnancy.
- The guidance covers both advertising to the public and promotion to 'persons qualified to prescribe or supply' for all licensed medicines.
- This guidance may not apply in its entirety to advertisements for folic acid or other health promotional campaigns where the use of the product provides a general benefit to pregnant women.

## 3. General statement

An important general principle is that caution should always be taken when medicines are prescribed/taken during pregnancy and the risks to both the mother and fetus should always be considered.

The British National Formulary (BNF) states that drugs can have harmful effects on the fetus at any time during pregnancy and that it is important to bear this in mind when prescribing for a woman of childbearing age. The *Prescribing in pregnancy* section of the BNF includes the following boxed warning:

Drugs should be prescribed in pregnancy only if the expected benefit to the mother is thought to be greater than the risk to the fetus, and all drugs should be avoided if possible during the first trimester. Drugs which have been extensively used in pregnancy and appear to be usually safe should be prescribed in preference to new or untried drugs; and the smallest effective dose should be used.

Few drugs have been shown conclusively to be teratogenic in humans but no drug is safe beyond all doubt in early pregnancy. Screening procedures are available where there is a known risk of certain defects.

**Absence of information does not imply safety.**

#### 4. Principles

The following principles apply for the advertising of any licensed medicine which is promoted for use during pregnancy:

##### 4.1 Advertising to the general public

Regulations 282 to 293 of the Human Medicines Regulations 2012 lay down the requirements and restrictions for advertising medicines to the general public. In addition, the following guidance is provided for the advertising of any licensed medicine which is promoted for use during pregnancy:

- (a) Advertisements to the general public mentioning the use of the product during pregnancy are only acceptable for medicines where a positive statement in section 4.1 or 4.6 the Summary of Product Characteristics (SPC) supports the use of the product in pregnancy – providing the other principles/guidance are followed (see below). This does not preclude the general advertising of other products for common conditions, even where the advertising may be seen by pregnant women, provided that the advertisement does not promote, in words or images or context, the use of the product in pregnancy.
- (b) Advertisements should not convey the message that it is usual for pregnant women to take medicines. Advertisers are encouraged to include advice on non-pharmacological measures where appropriate.

- (c) Advertisements should not state or imply that the advertised product, or any other medicine, cannot harm the developing fetus and ultrasound scans or images of a fetus should not be used in promotion of a medicine.
- (d) Advertising should reflect any warning statements on the licence concerning use at particular times during pregnancy (for example, a product which should not be used close to the expected date of delivery).
- (e) Advertisements should actively encourage seeking advice from a doctor, pharmacist or other healthcare professional concerning use of the product at any time during pregnancy.
- (f) All advertisements for medicines promoting use in pregnancy directly to pregnant women should include a general warning message appropriate to the medium being used (e.g. print, television, radio). An example of appropriate wording is given below. We would also encourage the inclusion of such a warning in any general advertising for a systemic medicine where the target audience is mainly pregnant women (e.g. in a pregnancy magazine).

*“Medicines can affect the unborn baby. Always talk to your doctor or pharmacist before taking any medicine in pregnancy”.*

#### **4.2 Advertising to ‘persons qualified to prescribe or supply’**

Advertising to healthcare professionals includes promotion of prescription only medicines and over-the-counter products. Regulations 294 to 300 of the Human Medicines Regulations 2012 lay down the requirements and restrictions for advertising medicines to persons qualified to prescribe or supply. In addition the following guidance is provided for the advertising of any licensed medicine which is promoted for use during pregnancy:

- (a) Where there is a specific indication for use in pregnancy in section 4.1 of the SPC, medicines may be promoted for use in pregnancy.
- (b) Where there is not a specific indication for use in pregnancy in section 4.1, textual information may be included in the advertising material (additional to the prescribing information) regarding the use of the product during pregnancy, reflecting section 4.6 of the SPC. The use of images of pregnant women is not appropriate in this situation.
- (c) All the information contained in the pregnancy and lactation section of the SPC (section 4.6) should be conveyed in the prescribing information in the advertisement.

- (d) Advertisements should never state or imply that the advertised product, or any other medicine, cannot harm the developing fetus. The use of ultrasound scans or images of a fetus may be considered inappropriate in the advertising of medicines for use in pregnant women.
- (e) Advertising should reflect any warning statements on the licence concerning use at particular times during pregnancy (for example, a product which should not be used close to the expected date of delivery).
- (f) All advertisements for medicines promoted for or providing information on use in pregnancy should include a general warning message appropriate to the medium being used. An example of appropriate wording is as follows:

*“Care should be taken when prescribing in pregnancy as medicines can cross the placenta and may affect the fetus.”*

## 5. The marketing authorisation

The general requirements on advertising are set out in Part 14 of the Regulations and state that advertising should always comply with the Summary of Product Characteristics (SPC).

The SPC for all licensed medicines contains a section dealing with pregnancy and lactation (section 4.6). The guidelines on the SPC states that in the overall assessment, all available knowledge should be taken into account, including clinical studies and post-marketing surveillance, pharmacological activity, results from non-clinical studies, and knowledge about compounds within the same class.

In the section on pregnancy, it states that the following should be mentioned:

- Recommendations on the use of the medicinal product during the different periods of gestation, including the reason(s) for these recommendations.
- Recommendations for the management of exposure during pregnancy when appropriate.

**MHRA**  
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