

- **Amendments to the Product Information**

During the assessment of the information in the PSUR the following issue was considered:

The product information for Desogestrel Teva should be updated in accordance with the previous PSUR work sharing procedure (SE/H/PSUR/0001/002; see Annex I) and in accordance with the guideline on summary of product characteristics revision 2.

It has been agreed that the following amendments to the Product Information are required for Desogestrel Teva:

SmPC wording

Section 4.3:

Delete: known or suspected pregnancy

Section 4.6:

A warning should be added as follows:

<Product name> is not indicated during pregnancy. If pregnancy occurs during treatment with <Product name>, further intake should be stopped.

Section 4.8

The following adverse reaction(s) should be added under the SOC Psychiatric disorders with a frequency common: depressed mood

Below the table add: In addition, (aggravation of) angioedema and/or aggravation of hereditary angioedema may occur (see Section 4.4).

Package leaflet

The package leaflet should be updated accordingly.