Finasteride
SE/H/PSUR/0002/007

Recommendations:

- **Amendments to the Product Information**

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

It has been agreed that the following amendments to the Product Information are required, already approved for nationally approved product Propecia (except a few editorial changes in the package leaflet):

SmPC wording

Section 4.8

- SOC Immune system disorders, frequency category Not known:
  angioedema (including swelling of the lips, tongue, throat, and face).

- After the side effect table:

In addition, the following have been reported in post-marketing use: Persistent sexual dysfunction(decreased libido, erectile dysfunction and ejaculation disorder) after discontinued treatment with fiansteride; Male breast cancer (see section 4.4 Special warnings and precautions for use)

Package leaflet wording

Section 4

Add under frequency category not known (cannot be estimated from available data) the following side effect:

Stop using [product name] and immediately contact a doctor if you experience any of the following symptoms (angiooedema): swelling of face, tongue or throat; difficulty swallowing; hives and breathing difficulties.

You should promptly report to your doctor any changes in the breast tissue such as lumps, pain, enlargement of the breast tissue or nipple discharge as these may be signs of a serious condition, such as breast cancer.

persistent difficulty having an erection after discontinuation of treatment
persistent decrease in sex drive after discontinuation of treatment.
persistent problems with ejaculation after discontinuation of treatment.

The existing SmPC and package leaflet should be amended (insertion, replacement or deletion of the text as appropriate) to reflect the wording as provided above.