

**ANSM**  
**January 14, 2020**

**Permanent Scientific Committee**  
**Monitoring and Pharmacovigilance**  
**SIGNAL Restricted Training**

*Editor's note: This English translation was done by a third party. The original digital report can be accessed [here](#).*

**Section 3: Surveillance and Pharmacovigilance SIGNAL Restricted Training**

Update on finasteride 1mg (PROPECIA): This medication is indicated in men between the ages of 18 and 41 for poorly developed stages of alopecia.

The benefit/risk ratio is reviewed every year by the PRAC. Periodic reports have an annual frequency. A communication was made in December 2019 to patients using an information sheet delivered by pharmacists. Several actions are underway following the various significant cases previously transmitted:

- **A notable case of meningioma:** awaiting the results of the arbitration procedure on the risk of meningioma under cyproterone, in particular on the opinion as to the progestogenic nature of this type of tumor. Extrapolation to other substances such as finasteride can then be discussed.
- **A significant case of testicular cancer:** expert analysis will be sought for this file.
- A European signal is being evaluated on the risk of type II diabetes with a first evaluation report expected on February 18, 2020.

The members of the PSC questioned the need to set up a pharmacovigilance survey in the current context media coverage and discussions with patient associations. Increased surveillance is ensured on new significant cases, the review of National Pharmacovigilance Base data and on any new signal identified through statistical signal detection performed every three months. In general, ANSM and the members of the Public Health Code agree to share information on a regular basis about the existing exchanges between the different stakeholders (ANSM, regional pharmacovigilance centers, regional health agencies, patient associations) that is suitable as public information.

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