

ANNEX

**CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE
OF THE MEDICINAL PRODUCT TO BE IMPLEMENTED BY THE MEMBER STATES**

Medicinal product no longer authorised

CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF MEDICINAL PRODUCT TO BE IMPLEMENTED BY THE MEMBER STATES

The Member States should ensure that all conditions or restrictions with regard to the safe and effective use of the medicinal product described below are implemented:

The Marketing Authorisation Holder (MAH) shall ensure that, prior to launch, all healthcare professionals who are expected to prescribe FABLYN or order gynaecological ultrasound of patients treated with FABLYN, are provided with access to risk minimisation educational programme.

The programme shall have both electronic and printed form, which are identical in terms of content.

The programme materials shall be provided via the following means:

- Web-based
- On CD
- Printed on paper

The programme shall convey the following key messages:

- FABLYN increases risk of venous thromboembolism (VTE).
- The approaches recommended for mitigation of risk of venous thromboembolism based on the SmPC, including contraindication of FABLYN in patients with active or past history of VTE.
- FABLYN causes morphologic changes, particularly the cystic atrophy of endometrium. It results in increased mean endometrial thickness.
- Based on the clinical trials, the morphologic changes caused by FABLYN are benign and do not require further investigation unless vaginal bleeding occurs.
- References to authoritative international guidelines relevant for uterine surveillance.
- The need to stop treatment with FABLYN and investigate when unexplained uterine bleeding occurs.

The programme shall include the full text of the SmPC.

The MAH shall also provide access to educational programme for pathologists. This programme should focus on interpretation of endometrial biopsy of women treated with FABLYN. It must be in line with authoritative international guidelines and supported by evidence published in peer reviewed medical journals.