Annex III

Summary of product characteristics and package leaflet

Note: These amendments to the summary of product characteristics and package leaflet are valid at the time of the Commission Decision.
After the Commission Decision the National Competent Authorities will update the product information as required.

Amendments to be included in the relevant sections of the summary of product characteristic

The valid summary of product characteristics is the final version achieved during the Coordination group procedure with the following amendments (highlighted below in bold underlined) in the section 4.2:

4.2 Posology and method of administration

Medical termination of developing intra-uterine pregnancy up to 63 days of amenorrhea.

The method of administration is 200 mg of mifepristone in a single oral dose, followed 36 to 48 hours later by the administration of the prostaglandin analogue gemeprost 1 mg per vaginam.

The dose of 200 mg should not be exceeded.

Paediatric population

No data are available for women under 18 years.

Amendments to be included in the relevant sections of the package leaflet

The valid package leaflet is the final version achieved during the Coordination group procedure with the following amendments (highlighted below in bold underlined) in section 3:

3. HOW TO USE MIFEPRISTONE LINEPHARMA

Always take Mifepristone Linepharma exactly as your doctor has told you.

Mifepristone Linepharma is for oral use.

The method of administration is 200 mg of mifepristone (1 tablet) should be taken, followed 36 to 48 hours later by the administration of a prostaglandin analogue (1 pessary containing 1 mg of gemeprost placed in the vagina).

The dose of 200 mg should not be exceeded.

The Mifepristone Linepharma tablet should be swallowed with some water in the presence of a doctor or a member of his/her medical staff.