Annex III

Amendments to relevant sections of the product information

Note:

These amendments to the relevant sections of the product information are the outcome of the referral procedure.

The product information may be subsequently updated by the Member State competent authorities, in liaison with the reference Member State, as appropriate, in accordance with the procedures laid down in Chapter 4 of Title III of Directive 2001/83/EC.

Amendments to relevant sections of the product information

Ulipristal acetate 5mg medicinal products

The existing product information shall be amended (insertion, replacement or deletion of the text as appropriate) to reflect the agreed wording as provided below (deletion ~~strikethrough~~, additions **bold underlined**).

A. Summary of Product Characteristics

Section 4.1 Therapeutic indications

[The following indication should be deleted]

~~Ulipristal acetate is indicated for one treatment course of pre-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age.~~

[The following indication should be amended as follows:]

Ulipristal acetate is indicated for intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women **who have not reached menopause** ~~of reproductive age who are not eligible for surgery~~ **when uterine fibroid embolisation and/or surgical treatment options are not suitable or have failed.**

Section 4.4 Special warnings and precautions for use:

[In the sub-section 'Hepatic injury' the following sentence should be amended as follows:]

Hepatic injury

During the post-marketing experience, cases of liver injury and hepatic failure, **some requiring liver transplantation** ~~were~~ **have been** reported (see section 4.3).
[…]

Section 4.8 Undesirable effects

[The following wording should be reflected in this section]

System Organ Class	**Frequency not known**
Hepatobiliary disorder	Hepatic failure *****

* see section "Description of selected adverse reactions"

Description of selected adverse reactions

Hepatic failure
During the post-marketing experience, cases of hepatic failure have been reported. In a small number of these cases, liver transplantation was required. The frequency of occurrence of hepatic failure and patient risk factors are unknown.

C. Package Leaflet

Section 1 What [product name] is and what it is used for

[This section should be amended as follows:]

[…]

This medicine acts by modifying the activity of progesterone, a naturally occuring hormone in the body. It is used ~~either before an operation of your fibroids or~~ for long term treatment of your fibroids to reduce their size, to stop or reduce bleeding and to increase your red blood cell count.

Section 4 Possible side effects

[This section should be amended as follows:]

Stop using Esmya and immediately contact a doctor if you experience any of the following symptoms:

- […]
- nausea or vomiting, severe tiredness, jaundice (yellowing of the eyes or skin), dark urine, itching or upper stomach ache. These symptoms may be signs of liver injury (frequency not known)**, which in a small number of cases led to liver transplantation**. See also section 2 Warnings and precautions.
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PATIENT ALERT CARD

WHAT YOU NEED TO KNOW BEFORE USE?

[Product name] can cause side effects although not everybody gets them. One possible side effect is serious damage to your liver. **Cases of liver failure have been reported in women taking [Product Name]; in a small number of these cases liver transplantation was required.**

This card provides information on blood tests you will need throughout treatment and on what you should do if liver side effects occur.

Do not take [Product Name] if you have liver problems.Tell your doctor if you know that you have problems with your liver or if you have any doubts about the condition of your liver.

WHAT TO DO BEFORE, DURING AND AFTER YOUR TREATMENT?
[…]