Annex III

Amendments to relevant sections of the Product Information

Note:

These amendments to the relevant sections of the Summary of Product Characteristics and package leaflet 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.

The following changes to the product information of leuprorelin-containing depot products are recommended (new text **bold** and underlined, deleted text ~~strikethrough~~):

Astellas

Summary of product characteristics

4.2 Posology and method of administration

Method of administration

ELIGARD should be prepared, reconstituted and administered only by healthcare professionals who are familiar with these procedures. ~~For instructions on reconstitution of the medicinal product before administration, see section 6.6.~~ **Instructions for reconstitution and administration must be strictly followed (see section 4.4 and 6.6.).** If the product is not prepared appropriately, it should not be administered.

4.4 Special warnings and precautions for use

Correct reconstitution: ~~Lack of clinical efficacy may occur due to incorrect reconstitution of the product. See section 4.2 and section 6.6 for the instructions for preparation and administration of the product and for evaluation of testosterone levels in cases of suspected or known handling error.~~ **Cases of handling errors which can occur during any step of the preparation process, and which could potentially result in lack of efficacy have been reported. Instructions for reconstitution and administration must be strictly followed (see section 6.6). In cases of suspected or known handling error, patients should be monitored appropriately (see section 4.2).**

GP Pharm

Summary of product characteristics (and corresponding part of Instructions for use)

6.6 Special precautions for disposal and other handling

This section should be amended as follows:

Step 1: Totally remove the flip-off cap from the top of the vial, revealing the rubber stopper. Confirm that no parts of the flip-off cap remain on the vial

Step 2: Place the vial in a standing upright position on a table. Peel the cover away from the blister pack containing the vial adapter (MIXJECT). Do not remove the vial adapter from the blister pack. Place the blister pack containing the vial adapter firmly on the vial top, piercing the vial in a totally vertical position. Push down gently until you feel it snap in place.

[The instructions for use of the product should be revised in order to improve the pictures describing the steps and modifying the wording to make them more understandable to health professionals.]

All leuprorelin-containing depot medicinal products

Summary of product characteristics

4.2 Posology and method of administration

Method of administration

<u><Name of the product> should be prepared, reconstituted and administered only by healthcare professionals who are familiar with these procedures.</u>

Package leaflet

3. How to use <*Name of the product*>

<u><Name of the product> should only be administered by your doctor or a nurse who will also take care of the preparation of the solution.</u>