Bundesamt für Sicherheit
im Gesundheitswesen

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Datum: 03.10.2014
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Unser Zeichen: 16c-140930-00051-A-PHV
Ihr Zeichen:

PHV-issue: Leuprorelin– Änderungen der Fach- und Gebrauchsinformationen

Sehr geehrte Damen und Herren,

basierend auf einer Routinesignaldetektion kam das Pharmacovigilance Risk Assessment Committee in der Sitzung vom September 2014 zu folgenden Empfehlung für alle Leuprorelin-hältigen Arzneispezialitäten.

Summary of Product Characteristics:

Section 4.4 - Special warnings and precautions for use
Lack of clinical efficacy may occur due to incorrect reconstitution of the product (see section 4.2).

The MAH should also submit to the NCA, within 1 month, a room temperature storage variation to allow storage of the product at room temperature for up to 1 month. Additionally, they should submit within 6 months, a variation to modify the device so that it will be impossible to remove the blue plunger rod without removing the grey stopper.

Finally, the PRAC recommended the following actions to be submitted within 1 month:

1) The MAH should submit the proposed poster in English language with the following revisions: The poster should be simplified, showing only the critical steps during reconstitution, leaving out the other parts of the product information.

2) The MAH should clarify why in the proposed DHPC it is stated “PRODUCT AT ROOM TEMPERATURE: Timely removal from the fridge (approximately 30 minutes prior to reconstitution)”, considering that the French SmPC as well as the authorized Italian SmPC don’t indicate the time of removal from the fridge. A proper justification of this statement should be submitted with the DHPC proposal.

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3) The MAH should submit a proposal for the dissemination of the DHPC and the poster, based on the health care professionals involved in the administration of Eligard (with accurate ratios of different HCPs per country) and submit a respective communication plan. After adoption by the PRAC the correct set of the HCPs to be reached by these additional RMMs should be agreed at national level.

4) The MAH should submit the final results of the pilot survey to evaluate the effectiveness of the DHPC.

5) The contents of the effectiveness study protocol are partially endorsed. Timelines for the conduct of the study should be submitted. In addition, the MAH should assess the effectiveness of the risk minimisation by means of a comparison of the reporting rate of medication error cases and lack of efficacy cases before and after the DHPC. An accordingly updated study protocol should be submitted.

6) The MAH's response does not address the PRAC request to make a proposal for a new presentation of Eligard with fewer and easier handling steps nor does the MAH provide a justification against it. The MAH should submit a timetable for the reformulation of the product. In the absence of a proposal from the MAH for a new presentation, the marketing authorisation of the current presentations may be reconsidered.