Bundesamt für Sicherheit
im Gesundheitswesen

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PHV-issue: Levonorgestrel – hältige Intrauterinpessare– Änderungen der Fach- und Gebrauchsinformationen

Sehr geehrte Damen und Herren,

basierend auf einer Routinesignaldetektion kam das Pharmacovigilance Risk Assessment Committee in der Sitzung vom April 2014 zu der Empfehlung, europaweit Ergänzungen in die **Fach- und Gebrauchsinformation** aller Levonorgestrel **–** hältigen Intrauterinpessare aufzunehmen und gemäß EMA/PRAC/229812/2014 (http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/04/WC500165809.pdf) eine Worksharing Variation beim RMS (SE) einzureichen.

The product information should be updated with regard to the following points:

- Information on the perforation rate should be updated based on the incidence observed in the study.
- Information on breastfeeding and post-partum status as risk factors should be updated.
- Information on possible delayed diagnosis of perforations should be included.
- The need for thorough follow-up of the correct IUD position as clinically indicated (e.g. in women with risk factors) according to diagnostic standard should be emphasized. Further on, information to consider limitations of physical examination for detection of partial perforation should be included.
- Information on the possible need of an operative procedure to remove the IUD in case of perforation should be included in the PI.
- A recommendation should be included to educate patients on possible signs of uterine perforation (severe low abdominal pain, loss of threads, etc.).