(1) Does the application adequately address the issue of the public health need for the medicine?
   Yes ☑ No ☐

   Please provide brief details:

(2) Have all important studies that you are aware of been included in the application?
   Yes ☐ No ☑

   Please provide brief comments on any relevant studies that have not been included:

   Eur J of Repro Health Care review 2010 is provided for efficacy; reviews and updated search for safety are included.

(3) Does the application provide adequate evidence of efficacy/effectiveness of the medicine for the proposed use?
   Yes ☑ No ☐

   Briefly summarise the reported outcomes (e.g. clinical, surrogate, other) and comment, where possible, on the magnitude of clinical benefit associated with use of the medicine:
   Above 2012 review lists contraceptives by hierarchy of effectiveness; long acting hormonal at top after sterilization, using “Pearl index” Data from individual studies (table 2) on reduction of excessive menstrual bleeding

(4) Is there evidence of efficacy in diverse settings and/or populations?
   Yes ☐ No ☑

   Please provide brief details: yes, see table 2

(5) Has the application adequately considered the safety and adverse effects of the medicine? Are there any adverse effects of concern, or that may require special monitoring?
   Yes ☑ No ☐ ☐

   X
Please provide brief details: Application cites Exp Rev of Obstet Gynecol 2013 review; and search of studies from last 5 years. Data collected primarily from women using the L-IUD for menorrhagia. Non-RCT studies indicated bloating, weight gain, breast tenderness. Comparisons to copper IUD show similar findings (table 1). Numeric data not provided.

ADDITIONAL CONSIDERATIONS:

(6) Are there special requirements or training needed for the safe, effective and/or appropriate use of the medicine?

<table>
<thead>
<tr>
<th>Yes</th>
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Please provide brief details: health professional required for insertion

(7) Are there any issues regarding the registration of the medicine by regulatory authorities? (e.g., recent registration, new indications, off-label use)

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<th>Yes</th>
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Please provide brief details: registered widely, available in public sector. Two different types are available – Mirena is the Bayer brand name product

(8) Is the medicine recommended for use in a current WHO GRC-approved Guideline (i.e., post 2008)?

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(9) Please comment briefly on issues regarding cost and affordability of this medicine.

Available in public sector in some countries

(10) Any additional comments?

(11) Please summarise the action you propose the Expert Committee takes.

Add – will provide an option for heavy menstrual bleeding, as well as contraception