(1) Does the application adequately address the issue of the public health need for the medicine?

Yes ☑ No ☐

Please provide brief details: proposal is for specific indication, use in breast feeding women.

(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: systematic review not yet completed, but data from individual studies 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:

Comparative, open label cohort studies have been conducted. Systematic review in progress. Highly effective for pregnancy prevention. Similar duration of breastfeeding and infant weight gain in comparison groups (Table 1). Ongoing trial in India comparing efficacy and safety to CU IUD.

(4) Is there evidence of efficacy in diverse settings and/or populations?

Yes ☑ No ☐

Please provide brief details: studies from Latin America and Asia.

(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 □ X  No □

Please provide brief details: low adverse events, although vaginal anomalies, bleeding greater than 15% of women

ADDITIONAL CONSIDERATIONS:

(6) Are there special requirements or training needed for the safe, effective and/or appropriate use of the medicine?
   Yes □  No □ X

Please provide brief details: user control of insertion can be an advantage

(7) Are there any issues regarding the registration of the medicine by regulatory authorities? (e.g., recent registration, new indications, off-label use)
   Yes □  No □ X

Please provide brief details: registered in Latin American countries

(8) Is the medicine recommended for use in a current WHO GRC-approved Guideline (i.e., post 2008)?
   Yes □  No □ X

Please provide brief details: WHO RPH guidelines currently being updated; systematic review will be included

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

Affordable compared to other contraceptives (Table 5)

(10) Any additional comments?
Application notes that data are from females over 18 years of age, but may be indicated for younger

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

Add for specific use in breastfeeding women