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| I.7 | Mifepristone-misoprostol – intrauterine fetal demise – EML |
| Draft recommendation | <input checked="" type="checkbox"/> Recommended <input type="checkbox"/> Not recommended <p>Justification: This application requests the extension of the indication for combination regimen of mifepristone-misoprostol for medical management of Intrauterine Fetal Demise (IUFD). IUFD may be managed expectantly or treated surgically with dilation and evacuation (D&E) or medically. Evidence shows medical management of IUFD with a combination mifepristone-misoprostol is effective. Studies show that combination mifepristone-misoprostol results in enhanced and expeditious expulsion of the products of conception and is more effective than either drug alone.</p> |
| Does the proposed medicine address a relevant public health need? | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable <p>Comments: About 1% of all pregnancies are complicated by IUFD. IUFD refers to the clinical condition where the fetus is no longer alive, but the uterus has not yet started to expel its contents and the cervix remains closed. Several studies demonstrated that IUFD can be associated with hemorrhage and sepsis leading to increased morbidity and mortality. Following IUFD, the need for transfusion of blood and blood products ranges from 18-28%.</p> |
| Does adequate evidence exist for the efficacy/effectiveness of the medicine for the proposed indication? (this may be evidence included in the application, and/or additional evidence identified during the review process) | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable <p>Comments: Studies show that combination mifepristone-misoprostol results in enhanced and expeditious expulsion of the products of conception and is more effective than either drug alone</p> |
| Does adequate evidence exist for the safety/harms associated with the proposed medicine? (this may be evidence included in the application, and/or additional evidence identified during the review process) | <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Not applicable <p>Comments: This combination is already listed in the EML for another indication.</p> |
| Are there any adverse effects of concern, or that may require special monitoring? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Not applicable <p>Comments: This combination is already listed in the EML for another indication.</p> |

24th WHO Expert Committee on Selection and Use of Essential Medicines
Expert review

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| <p>Are there any special requirements for the safe, effective and appropriate use of the medicines?</p> <p>(e.g. laboratory diagnostic and/or monitoring tests, specialized training for health providers, etc)</p> | <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input checked="" type="checkbox"/> Not applicable</p> <p>Comments: This combination is already listed in the EML for another indication.</p> |
| <p>Are there any issues regarding cost, cost-effectiveness, affordability and/or access for the medicine in different settings?</p> | <p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No</p> <p><input type="checkbox"/> Not applicable</p> <p>Comments: The product is available on the global market.</p> |
| <p>Are there any issues regarding the registration of the medicine by national regulatory authorities?</p> <p>(e.g. accelerated approval, lack of regulatory approval, off-label indication)</p> | <p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No</p> <p><input type="checkbox"/> Not applicable</p> <p>Comments: The product is registered across different regulatory authorities globally</p> |
| <p>Is the proposed medicine recommended for use in a current WHO guideline?</p> <p>(refer to: https://www.who.int/publications/who-guidelines)</p> | <p><input checked="" type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Not applicable</p> <p>Comments: Medical management of IUFD using this combination regimen has been included in WHO guidelines on medical management of abortion since 2018.</p> |