

F.6	Human insulin – cartridges and prefilled pens 100U/mL– EML and EMLc
Draft recommendation	<input checked="" type="checkbox"/> Recommended <input type="checkbox"/> Not recommended <p>Justification:</p> <p>The reviewer recommends the inclusion of Reusable insulin pens with cartridges plus the disposable pens in the EML and EMLc to improve compliance and treatment outcomes of Diabetes Mellitus.</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:</p> <p>The reviewer agrees with the report that Diabetes Mellitus is prevalent worldwide, and the medicine indeed addresses the public health need. Data states that diabetes affects 442 million individuals globally and long term complications are more likely when treatment is not optimal and poor outcomes of acute hypoglycaemia occur if insulin dose is too high for the changing conditions. Cartridges and prefilled pens could improve compliance to treatment and hence treatment outcomes.</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:</p> <p>Advantages of insulin cartridges over vials are the lack of need for syringes. Pen devices are safer and more accurate for insulin delivery. Using a syringe required drawing up of the required insulin dose into a syringe, which needs visualisation of the meniscus of the insulin fluid against the marked divisions of volume on a syringe.</p> <p>Pens/cartridges have higher acceptance than needle and syringes, with higher adherence and better control of diabetes with less hypoglycaemia</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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable <p>Comments:</p> <p>No harms have been documented with this alternate delivery method, which has been available in some countries for more than 20 years. Studies found patients preferred pens/cartridges because the cartridge/pen injections were less painful, more convenient, and simpler and resulted in less insulin injections being missed. Patients found they could more easily take insulin for meals outside their home or on vacation. There was less social stigma to cartridges/pen rather than vials and syringes.</p>

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

<p>Are there any adverse effects of concern, or that may require special monitoring?</p>	<p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input checked="" type="checkbox"/> Not applicable</p> <p>Comments:</p>
<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:</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 type="checkbox"/> No</p> <p><input type="checkbox"/> Not applicable</p> <p>Comments:</p> <p>The reviewer agrees that although the cost of the cartridges may be high, the total cost of diabetes care including complications arising out of uncontrolled diabetes as a result of non-adherence to syringes use is definitely higher. There could be cost savings from the use of pens and cartridges. Two claims databases of individuals with type 1 and type 2 diabetes found Vial/syringe use was associated with 35% and 44% greater risk of hypoglycaemia which resulted in vials/syringes use being associated with 89% and 62.7% greater health care costs for hypoglycaemic events than use of pens/cartridges. A proportion of these individuals were using pens with analogue rather than human insulin.</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:</p> <p>The reviewer found that this application does not involve a new medicine and pens are already registered in most regulatory authorities.</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 type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input checked="" type="checkbox"/> Not applicable</p> <p>Comments:</p>