

F.6	Human insulin – cartridges and prefilled pens 100U/mL– EML and EMLc
Draft recommendation	<input type="checkbox"/> Recommended <input checked="" type="checkbox"/> Not recommended Justification: What is considered as essential is the availability of the human insulin itself and the proposed device will not likely to improve insulin availability and access in many countries. Although the device is believed to improve the experience of the insulin user yet the improvement is not of high clinical importance and not based on high level of evidences.
Does the proposed medicine address a relevant public health need?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable Comments: Diabetes is a major public health problem. Insulin is lifesaving in type 1 diabetes and may be required in type 2 diabetes. However what is being proposed in the application is the packaging of the insulin.
Does adequate evidence exist for the efficacy/effectiveness of the medicine for the proposed indication? <small>(this may be evidence included in the application, and/or additional evidence identified during the review process)</small>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Not applicable Comments: Certainty of the evidences are low and the importance of the effect is small
Does adequate evidence exist for the safety/harms associated with the proposed medicine? <small>(this may be evidence included in the application, and/or additional evidence identified during the review process)</small>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable Comments: No harm is reported.
Are there any adverse effects of concern, or that may require special monitoring?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Not applicable Comments:

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Expert review

<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 checked="" type="checkbox"/> No</p> <p><input type="checkbox"/> Not applicable</p> <p>Comments: Considered as easier and more convenient than the existing device.</p>
<p>Are there any issues regarding cost, cost-effectiveness, affordability and/or access for the medicine in different settings?</p>	<p><input checked="" type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Not applicable</p> <p>Comments: The cost is higher than the existing device</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>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 checked="" type="checkbox"/> No</p> <p><input type="checkbox"/> Not applicable</p> <p>Comments: Current guideline did not specifically state about any preferred device.</p>