

A.29 Triple fixed-dose combinations of antihypertensives – EML

Reviewer summary	<input checked="" type="checkbox"/> Supportive of the proposal <input type="checkbox"/> Not supportive of the proposal Justification (based on considerations of the dimensions described below): Triple combination is already recommended as part of hypertension management and single pill combination is preferred than multiple pills.
Does the EML and/or EMLc currently recommend alternative medicines for the proposed indication that can be considered therapeutic alternatives? (https://list.essentialmeds.org/) Single and dual fixed dose combination.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable
Does adequate evidence exist for the efficacy/effectiveness of the medicine for the proposed indication? (e.g., evidence originating from multiple high-quality studies with sufficient follow up. 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
Evidence from systematic review of 19 RCTs	
Does adequate evidence exist for the safety/harms associated with the proposed medicine? (e.g., evidence originating from multiple high-quality studies with sufficient follow up. 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
Safety is similar with current available treatment.	
Overall, does the proposed medicine have a favourable and meaningful balance of benefits to harms?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable
Are there any special requirements for the safe, effective and appropriate use of the medicines? (e.g. laboratory diagnostic and/or monitoring tests, specialized training for health providers, etc) Improved blood pressure control and adherence to medication with similar adverse events to current available treatment.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable Renal function test is needed as it is not recommended for patient with severe renal impairment. However, the test is also required to identify comorbidities in hypertension patients.
Are there any issues regarding price, cost-effectiveness and budget implications in different settings? Until now the cost is at best similar with the sum of the cost of the individual pills, but there is potential to be lower if production is increased.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable
Is the medicine available and accessible across countries? (e.g. shortages, generics and biosimilars, pooled procurement programmes, access programmes)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Not applicable
Available in US and Europe, but limited in Asia, Africa and South America.	

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Does the medicine have wide regulatory approval?	<input checked="" type="checkbox"/> Yes, for the proposed indication <input type="checkbox"/> Yes, but only for other indications (off-label for proposed indication) <input type="checkbox"/> No <input type="checkbox"/> Not applicable
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