F.2	Doxorubicin, pegylated liposomal – injection 2 mg/mL – EML and EMLc	
Draft recommendation		⊠ Recommended
		□ Not recommended
		Justification: Liposomal doxorubicin has a longer half-life, less toxicity in non-target organs, and higher tumour concentrations of drugs.
		Survival is similar to other chemotherapy drugs already approved by EML.
Does the proposed medicine address a relevant public health need?		⊠ Yes
		□No
		□ Not applicable
		Comments
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)		⊠ Yes
		□No
		□ Not applicable
		Comments:
Does adequate evidence exist for the safety/harms associated with the proposed medicine?		⊠ Yes
		□No
(this may be evidence included in the application, and/or additional evidence		□ Not applicable
		Comments: It has fewer side effects than paclitaxel and other drugs which are already on the EML list.
identified duri	ng the review process)	on the Live list.
Are there any adverse effects of concern, or that may require special monitoring?		☐ Yes
		⊠ No
		□ Not applicable
		Comments: Less hematologic toxicities, less alopecia

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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)	☐ Yes ☑ No ☐ Not applicable Comments:
Are there any issues regarding cost, cost-effectiveness, affordability and/or access for the medicine in different settings?	 ☐ Yes ☒ No ☐ Not applicable Comments: generics are available making liposomal doxorubicin more cost effective. MSF is already helping in Africa
Are there any issues regarding the registration of the medicine by national regulatory authorities? (e.g. accelerated approval, lack of regulatory approval, off-label indication)	☐ Yes ☑ No ☐ Not applicable Comments:
Is the proposed medicine recommended for use in a current WHO guideline? (refer to: https://www.who.int/publications/whoguidelines)	 ✓ Yes ☐ No ☐ Not applicable Comments: