C.5	Deferasirox & deferoxamine – change representative medicine within square box listing – EML and EMLc	
Draft recommendation		⊠ Recommended
		☐ Not recommended
		Justification: Deferasirox is an effective iron chelator for reduction of iron overload in patients. Following patent expiration, deferasirox has become more widely available globally from several manufacturers and its generic version is now a cost effective medicine.
		List the orally used iron chelator deferasirox as the main representative agent, while maintaining parenterally used deferoxamine as a therapeutic alternative to the 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
/*h:		□ Not applicable
(this may be evidence included in the application, and/or additional evidence		Comments:
identified dur	ing the review process)	
·	adverse effects of	⊠ Yes
	nat may require special	□No
		□ Not applicable
		Comments:

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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: require monitoring tests for serum ferritin.
Are there any issues regarding cost, cost-effectiveness, affordability and/or access for the medicine in different settings?	 ☐ Yes ☒ No ☐ Not applicable Comments: deferasirox show comparative cost effectiveness with deferoxamine in most setting.
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: