

Drug Company External Submission Format

In order to complete the evaluation request. Dossier submission should include the below requirements and follow the below sequence.

Section 1: Executive Summary

Requirement	Submission	CCHI Comments
Therapeutic and Pharmacoeconomic Value of the Intervention		
1. Therapeutic benefits	<input type="checkbox"/> Yes <input type="checkbox"/> No	
2. Pharmacoeconomic Benefits	<input type="checkbox"/> Yes <input type="checkbox"/> No	
3. Summary	<input type="checkbox"/> Yes <input type="checkbox"/> No	

Section 2: Therapeutic benefits

Requirement	Submission	CCHI Comments
Description of Intervention and Target Disease		
1. Description of Intervention	<input type="checkbox"/> Yes <input type="checkbox"/> No	
2. Placement of Intervention in Therapy of Target Disease	2.1 Target Disease Description	<input type="checkbox"/> Yes <input type="checkbox"/> No
	2.2 Treatment Approach	<input type="checkbox"/> Yes <input type="checkbox"/> No
	2.3 Society Clinical guideline supporting their role in the indication (National and International)	<input type="checkbox"/> Yes <input type="checkbox"/> No
Supporting Clinical Evidence: Summary of Key Clinical Studies		
1. All Relevant Support Data for Labelled Indications with a copy of published evidence	<input type="checkbox"/> Yes <input type="checkbox"/> No	
2. All Relevant Support Data for Off-Label Indications with a copy of published evidence	<input type="checkbox"/> Yes <input type="checkbox"/> No	
3. Clinical Evidence Spreadsheet	<input type="checkbox"/> Yes <input type="checkbox"/> No	
4. Noncompany sponsored supporting evidence	<input type="checkbox"/> Yes <input type="checkbox"/> No	
5. Secondary Source Evidence Summary	<input type="checkbox"/> Yes <input type="checkbox"/> No	

Section 3: Pharmacoeconomic Benefits

Requirement	Submission	CCHI Comments
1. Model Overview	1.1 Modeling for Decision Making	<input type="checkbox"/> Yes <input type="checkbox"/> No
	1.2 Model Types	<input type="checkbox"/> Yes <input type="checkbox"/> No
	1.3 Additional Details	<input type="checkbox"/> Yes <input type="checkbox"/> No
2. Modeling Methodology	2.1 Rationale and Framework • Guidelines	<input type="checkbox"/> Yes <input type="checkbox"/> No

and Rationale	<ul style="list-style-type: none"> • Analysis Framework • Modeling Methodology • Payer Perspective and Timeframe 		
	2.2 Data Sources <ul style="list-style-type: none"> • Effectiveness & Efficacy • Expert Opinion • Safety Data • Economic Data • Utilities • Surrogate Markers • Expected Demographics and Projected Practice Pattern 	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	2.3 Analysis	<input type="checkbox"/> Yes <input type="checkbox"/> No	
3. Interactive Modelling and Modeling Report	3.1 Transparency Statement	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	3.2 Reporting Format	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	3.3 Interactive Model	<input type="checkbox"/> Yes <input type="checkbox"/> No	

Section 4: Other Supporting Evidence

Requirement	Submission	CCHI Comments
1. SFDA registration certificate	<input type="checkbox"/> Yes <input type="checkbox"/> No	
2. Reimbursement status (Saudi and non-Saudi)	<input type="checkbox"/> Yes <input type="checkbox"/> No	
3. Pricing	<input type="checkbox"/> Yes <input type="checkbox"/> No	
4. Supporting Data (References, Appendices)	<input type="checkbox"/> Yes <input type="checkbox"/> No	

Kindly note that the evaluation requires 3-6 month from receiving a complete dossier submission based on the priority of the request. Incomplete submission will not be accepted.

For further clarifications feel free to contact us through IDF@chi.gov.sa