

## References Checklist

### References (Quick Reference Checklist; See below for elaboration):

Item No	Checklist Item (Clients can use this tool to help ensure the completeness of references within their submissions)	√
1	Provided	
2	Complete	
3	Legible	
4	Searchable	
5	Up to Date	
5.1	- Terms of Market Authorization (TMA)	
	a) New Submission	
	b) Renewal	
	c) Ongoing Submission	
6	Sourced	
7	Named Logically	
8	Orientation	

## References Checklist (p.2 of 3)

	Item No	Clarification
<b>Provided</b>	1	<p><b>All</b> references relating to the piece are provided as separate PDF documents in the initial submission (generally not required for renewals except for updated references and reconfirmation of time-sensitive claims).</p> <p>Submission control # on TMA must match that on the HC approval letter. (If it does not due to level III or IV changes, please upload a letter from the manufacturer stating this)</p>
<b>Complete</b>	2	e.g. entire study, entire guideline, for books = front cover + copyright page + entire chapter
<b>Legible</b>	3	Even if scanned.
<b>Searchable</b>	4	Even if scanned, document must be text searchable (i.e. not provided in image or screen capture format).
<b>Up to Date</b>	5	<p>The provided references are the most recent available. Common issues to double check include (not an exhaustive list):</p> <ul style="list-style-type: none"> <li>• There have been no <b>product monograph updates</b> (or product license updates in the case of NHPs) since the provided monograph/license (see 5.1 Terms of Market Authorization)</li> <li>• There have been no updates to the provided consensus <b>guidelines</b>.</li> <li>• References supporting <b>time sensitive claims</b> are up to date (e.g. less than 6 months old for market share or retention claims).</li> </ul>
	5.1	<b>Terms of Market Authorization (TMA) Update</b>
	a)	<p>New Submission</p> <p>Annotated TMA included with each new submission for the first 3 months after notifying PAAB of TMA change (or product license updates in the case of NHPs).</p>
	b)	<p>Renewal</p> <p>Annotated TMA included if the TMA has been updated since the APS was last accepted.  <i>Note: If the TMA has undergone multiple updates since the APS was last accepted, the submission must include an outline of all TMA changes throughout that period.</i></p>
	c)	<p>Ongoing Submission</p> <p>Annotated TMA provided immediately. <i>Note: Product monograph updates provided during the course of a review which mandates any re-review of piece (even partial) will incur a new file number and new fee.</i></p>
<b>Sourced</b>	6	The specific sections of the reference which support APS messages must be highlighted and labelled (sourced). The labelling must coincide with the convention used for reference support copy in the APS (see APS Checklist).

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<b>Named Logically</b>	7	When uploading references to the eFile system the document naming convention must coincide with the convention used for reference support copy in the APS (see APS Checklist).
<b>Orientation</b>	8	The document should open right side up.

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