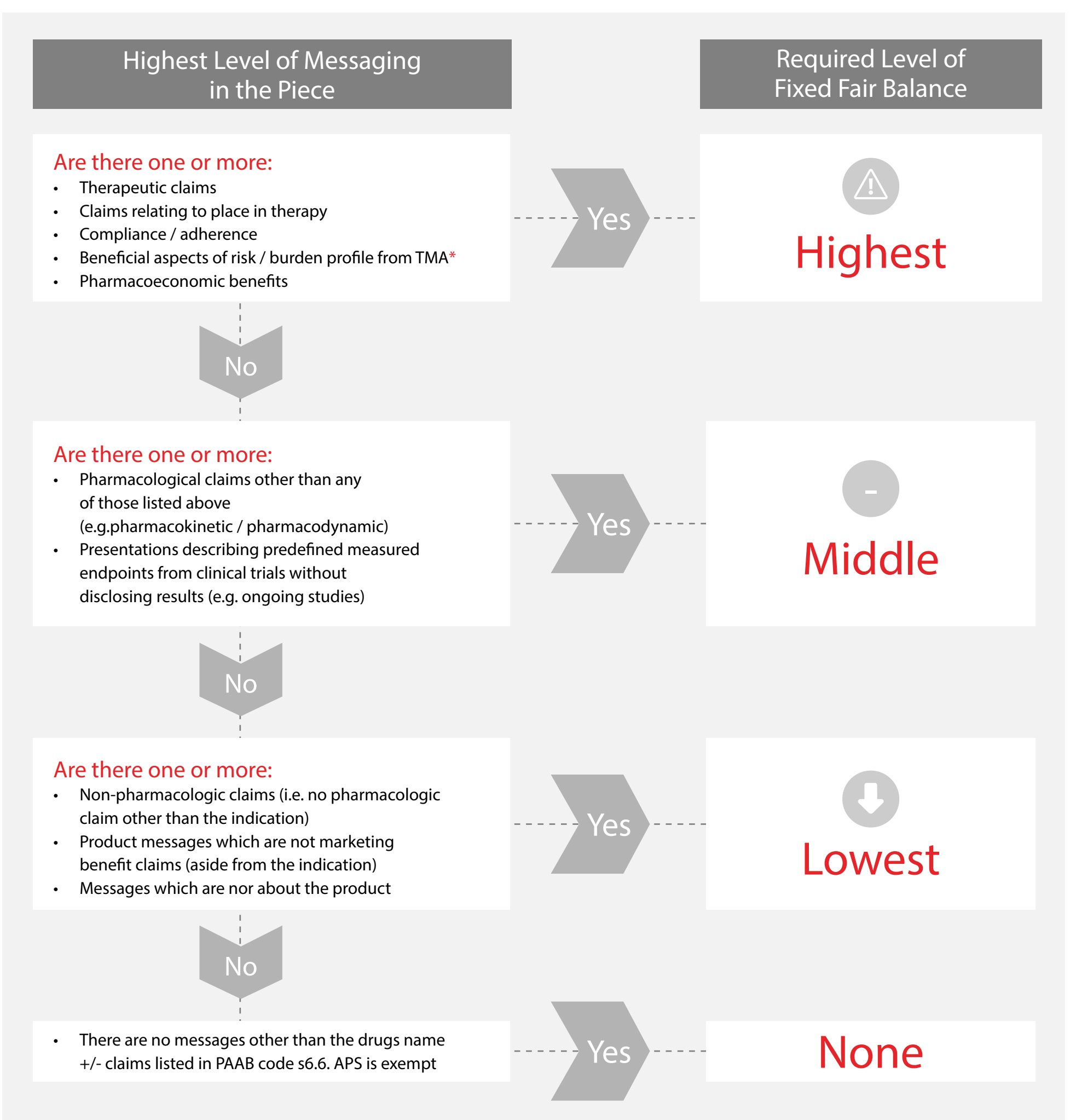


Creating Fair Balance Checklist

Fair balance disclosure requirements for all medications other than over the counter, natural health, and homeopathic products. Refer to PAAB code section 2.4.3 for these other products.



1. Choose: The right level of fair balance



*TMA = Terms of Market Authorization. See guidance document for details relating to beneficial aspects of risk/burden profile from TMA.

2. Format: Visual presentation of all three levels

Do you have all the headlines that apply to your product?
E.g. If you do not have "Most serious warning and Precautions" you do not need to include this headline (see 'Populate' section for a more detailed description)

Does the copy appear to be part of the main body copy presentation?
E.g. not faded out, not condensed font, not grey on slightly lighter grey etc.

Are the headlines bolded, underlined with a line of white space separating each section? (Highest)

Highest	Middle	Lowest
<p>Indications and clinical use:</p> <ul style="list-style-type: none"> xxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxx <p>Contraindications:</p> <ul style="list-style-type: none"> xxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxx <p>Most Serious warnings and precautions: Bolded topic: description of risk Bolded topic: description of risk</p> <p>Other relevant warnings and precautions:</p> <ul style="list-style-type: none"> xxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxx <p>For more information: xxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxx</p>	<p>Indications and clinical use (or replace clinical use with instructions to refer to the product monograph)</p> <p>Consult Product Monograph at www.ProductX.ca/PM for important information on:</p> <ul style="list-style-type: none"> Contraindications in... Most serious warnings and precautions... Other relevant warnings and precautions... Conditions of clinical use, adverse reactions, drug interactions and dosing instructions <p>The product monograph is also available by calling us at 1-800-xxx-xxx</p>	<p>Indication Statement</p> <p>Consult the Product Monograph at www.ProductX.ca/PM for important information on contraindications, warnings, precautions, adverse reactions, interactions, dosing.</p> <p>The product Monograph is also available by calling us at 1-800-xxx-xxx</p>

3. Populate: What to include in fair balance

Note: The following is guidance on what to include in the fair balance as a minimum standard. The manufacture always has the option to include more information than what is listed.

<p>Indication and clinical use</p> <ul style="list-style-type: none"> The complete verbatim indication statement must appear at least once in the piece If multiple indications are promoted, then it must be clear what other content (e.g. clinical use, warnings etc.) relates to which indication (see PAAB Code section 2.1) <p>Remaining content may be summarized provided it captures the complete essence of the TMA copy</p>	<p>Contraindications</p> <p>Highest Each contraindication appears as a separate bullet</p> <p>Middle Listed in series separated by a comma</p> <p>Lowest Statement that alerts the reader that there are contraindication</p>
<p>Most Serious Warnings and Precautions</p> <p>The warnings and precautions which are emphasized in the TMA (bolded, <u>underlined</u>, CAPLOCKED etc.)</p> <p>Highest Each description begins with a bolded topic and is separated by a line of white space</p> <p>Middle Listed in series separated by a comma</p> <p>Lowest Statement that alerts the reader that there are serious warnings and precautions</p>	<p>Other relevant warnings and precautions</p> <p>The rest of the warnings and precautions related to promoted indication(s)</p> <p>Highest A bulleted list of risks identified, without the description required (manufacturer may choose to include)</p> <p>Middle List in series separated by a comma</p> <p>Lowest Statement that alerts the reader that there are relevant warnings and precautions</p>
<p>For more information:</p> <ul style="list-style-type: none"> A direct link to the TMA and direct the reader to seek more information about adverse events, drug interactions and dosing When a product has important interactions or dosing/administration issues (e.g. bolded, boxed, all-caps, underlined, framed as "serious" or affects more than 1 in 5 prospective patients) which are mentioned in the Warnings and Precautions section of the TMA, they should be identified in the fair balance (i.e. Please consult the product monograph at www.product.ca/TMA 2015 for important information relating to adverse reactions, drug interactions (particularly interactions with CYP3A4), and dosing information.) On print pieces, this copy should also include a phone number in case the HCP has limited internet access 	<p>Other headlines</p> <p>Other headlines can be added at the manufactures discretion (i.e. Adverse events; Dosing and Administration). However, they should appear after the required standard headlines.</p>

Want more guidance?

Remember you always have access to the guidance documents on the PAAB website: <http://www.paab.ca/advisories-guidance.htm>. Check out "Guidance on Generating the Three Base Fair Balance Levels" and "Guidance of Base Fair Balance Level Selection and Placement" for more details.