Quick tips on understanding marketing benefit claims

What is a marketing benefit claim?

A promotional statement designed to inform about the product's availability and benefits so as to form/ alter the audience's opinion of the medication. It can be explicit (i.e. text) or implicit (i.e. images), comparative or non-comparative. It can relate to pharmacological or non-pharmacological properties of the product. Below are some examples of different types of claims, and what type of evidence/sources would be considered acceptable in advertising.

What are some select considerations for particular types of marketing benefit claims?

The following are quick tips. Remember that all provisions of the code and regulations apply when creating your APS. Also remember that while a claim may be acceptable in and of itself, it may be deemed unacceptable due to the context. Additionally, the TMA impacts the acceptable claims and references (e.g. off-label claims are not acceptable regardless of the quality of evidence, therapeutic claims for NOC/c products must emenate from the product mponograph…etc)

Examples of **Marketing Benefit Claims:**

Type:	Claim:	Select considerations:	Source:
Efficacy claim	"Demonstrated reduction in nighttime awakening vs placebo"	Efficacy claims from the TMA are generally acceptable. If a claim isn't in the TMA, it should be consistent with the TMA and must be supported by statistically significant, high quality data of predefined study endpoints from a published and peer-reviewed randomized control trial (s.5.9). Please refer to guidance document on evidence provisions, on the PAAB website.	Terms of Market Authorization (TMA) Non-comparative: Randomized control trial (s.3.1.1) Comparative: Head-to-head randomized control trial (s.5.7)
Non-comparative safety profile claim	"Demonstrated good safety profile"	Non-comparative safety claims should be supported by the TMA. They cannot be overly-selective. Safety profile claims should be accompanied by the *most common adverse events* from the TMA within the APS.	TMA
Comparative safety claim	"Demonstrated lower rate of hypoglycemia versus Brand X"	Similar to efficacy claims, comparative safety claims should come from the TMA or RCT and be limited to a specific outcome.	TMA (s.3.1.1) RCT (s.5.7)

Pharmacokinetic/ dynamic claim	e.g. 1: "Long ½ life (20 hrs)" e.g. 2: Mechanism of Action	These claims should not be linked to clinical claims and should be supported by the TMA.	TMA (s.3.1.4)
Place in therapy	"Recommended as a 1st line treatment option"	Place in therapy claims should be supported by authoritative national consensus guidelines, but must also be consistent with the indicated use in the TMA. Claims must employ the non-proprietary name.	Canadian consenus guidelines (s.3.2) Terms of Market Authorization
Non-clinical product attribute claims (*e.g., taste, smell*):	"8 out of 10 patients liked the smell of Brand X" "Patients preferred the tolerability of drug X" "Patients preferred drug X"	Atrribute claims must be non-clinical in nature. There should be no link to effectiveness and it should not be positioned as a reason to prescribe the product (as this accords clinical significance). This tolerability claim would **not** be acceptable as tolerability is a clinical outcome. This preference claim would **not** be acceptable as it is not explicitly limited to a non-clinical feature.	Survey which is either published & peer reviewed OR Unpublished survey designed, conducted & analyzed without sponsor's influence (s5.10.2)
Price Comparisons:	"Brand X is half the drug acquitistion cost of Brand Y"	Price comparisons should come from the same source and they should not draw any clinical or pharmacoeconomic conclusions or be positioned as a reason to prescribe	Independent data. Must be the same source for all comparators (s5.10.2)
Market Share	"#1 dispensed ACE inhibitor"	Support should come from an independent source. It should reflect known therapeutic categories/classifications etc. and the data should be the most current available (at least within the past 6 months – s.8.4.i)	Authoritative recognized independent source (s.4.2.2 & 5.10.2) Refer to the document "PAAB Guidance Documents for Market Share Claims in Advertising" on the PAAB website.

Please also refer to PAAB code sections 3, 4 and 5 and to the following guidance documents on the PAAB website:

- Guidance on Secondary Endpoints
- Guidance on Subgroup Analysis
- Guidance on Patient Reported Outcomes
- Guidance on Noninferiority Trials
- Guidance on Observational Studies
- Guidance on Bayesian Studies
- Guidance on Pharmacoeconomic Studies