

## Retention and market share claims (PAAB s2.1 & 3.1)

### Tip of the month:

Comparative claims/presentations relating to market share and retention in advertising must be based on empirical evidence which is limited to that which is directly observable and measurable.

Let's elaborate on the concept of "directly observable and measurable" through the following examples:

#### **Directly observed/measured**

PAAB could consider a reputable database tracking the number of prescriptions dispensed over time to support a claim that a particular product has the highest total number of prescriptions dispensed of all products in a pharmacologic class. In this scenario, the number of prescriptions dispensed for each product is "directly observable".

#### **Directly observed/measured**

Say there is also interest in determining the comparative number of prescriptions dispensed for a particular disease. This would be "directly observable" **IF** information about the patient's disease was also entered into the same database when each drug was dispensed. This data could be considered by PAAB for a comparative claim/presentation.

#### **Not directly observed/measured (not accepted)**

In the absence of such direct observation, one may decide that an inference of the disease for which each prescription was dispensed will sufficiently suit his/her needs. In that case, the disease for which each prescription was dispensed will be inferred from factors such as:

- Strength of dose
- presence/absence of loading dose and titration
- prescriber specialty
- concomitant medications
- prior medications
- dosage form
- nature of gaps between refills

Once the corresponding disease has been inferred for each prescription dispensed, only those prescriptions which were dispensed for the disease of interest will be included in the dataset. Now we are ready to compare the number of prescriptions dispensed for that particular disease.

Although this approach may be useful as internal market intelligence, it is not sufficiently substantive for comparative claims in drug advertising. The claim and dataset hinge heavily on various assumptions which are built into the inference. The assumptions cannot be sufficiently substantiated and can potentially lead to misleading comparative claims in advertising. PAAB s2.1 & 3.1.

#### **Not directly observed/measured (not accepted)**

Using the dataset inferred above for the specific disease of interest, we'd like to compare the retention rates for each product in the pharmacological class. Again, not accepted for comparative claims/presentations for the same rationale discussed above.

#### **Not directly observed/measured (not accepted)**

Days of supply of each dispensed prescription was estimated from the drug cost and/or dose regimens. Again, not accepted for comparative claims/presentations for the same rationale discussed above.

## In closing

For comparative claims and presentations relating to retention or market share, modifying the directly observable dataset through the use of inferences, assumptions, estimations, or extrapolations is not accepted to in drug advertising. Nor is applying inferences, assumptions, estimations, or extrapolations to interpretation of the dataset in order to generate claims/presentations which exceed that which is directly observable.

## FAQ

**1. What if the claim/presentation is supported by a letter from the company providing the data?**

Nothing changes. The above provisions still apply.

**2. What if the sponsor's product only has one indication?**

The above would still apply. One of the comparators likely has more than one indication. Additionally, off-label use cannot be ruled out.

**3. Where can I get additional PAAB guidance on market share claims?**

Refer to the "PAAB Guidance Document for Market Share Claims in Advertising" on the PAAB website. Visit [www.paab.ca](http://www.paab.ca) for more information.

**4. Is retention data required to be recent (as required for market share data)?**

Yes. Various market factors which can impact retention are dynamic. Although they may be stable for long periods of time, they can also change suddenly and demonstrably. PAAB has encountered instances in which a difference as little as couple of months generated overtly contradictory comparative retention profiles.