

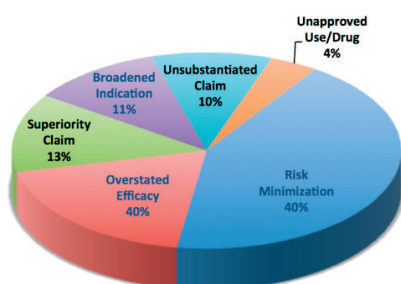
Assets for Health Professionals Summary



Remember: The term 'health professional' is usually considered to be wider than just prescribers and those directly involved in patient care. It also encompasses those who may purchase or recommend medicines (e.g. those who hold drugs budgets and those who contribute to local or national guidelines on use of medicines) and may also include certain administrative roles in health services.

1 Materials should encourage rational prescribing or use of a medicine

Top reasons for FDA warning letters in 2013



Safety Information

- Is there a critical piece of safety information that should be highlighted?
- Is there other important information missing that is needed to support appropriate prescribing?
- Could omission of that information potentially cause a patient safety issue?
- Does omission of any information make the statements misleading?

Overstated efficacy?



Consider the artwork as well as the text.
Is this a typical response to treatment?

Unsubstantiated claims



Ideally claims should be supported by approved product information. When considering supportive data from the literature or from internal 'data on file' remember that claims must reflect the full and current body of evidence.

Be careful when dealing with emerging scientific opinion – balance is most important in these situations.

Broadened Indication

It is always best to quote a licensed indication faithfully.

If you do see an indication paraphrased (perhaps because of space constraints) you need to think about whether this results in a broadening of the indication.



2 Standards of Evidence



The standard of evidence required to support a particular claim will depend on the nature of the claim and the therapy area. In an area that has been well studied, systematic reviews may be easy to find. However in some therapy areas such as very rare conditions the totality of evidence may be from layers lower down in the evidence hierarchy.

Published clinical trials and systematic reviews are generally preferred for substantiating claims, and have been subject to peer review, but studies still have important limitations. Consider:

- Do the study design, comparator, study population, and endpoints used support the claim being made?
- Do the statistical considerations support the claim, e.g. statistical power, was the primary endpoint met, were the analyses pre-defined, are the p values adjusted, has multiplicity been considered?
- Have the tools used in the study been validated?

Only robust, well conducted real world studies should be used for promotion. No definitive statement or claim of effect should be made on the basis of real world data.

3 Comparison with competitors

Comparisons must be fair and capable of substantiation. A useful tip when considering fairness of comparisons is to imagine you work on the competitor product