

# Principles of Nominated Signatory Review Summary

## 1 History and Purpose of Review

Various historical tragedies (many due to unforeseen side effects) such as the thalidomide disaster, the addictive properties of heroin and the diethylstilbestrol story serve to remind us that nominated signatory review helps to protect patients. It should ensure that promotion is consistent with approved product information and is not deceptive or inaccurate - these form the basis of legal requirements for promotion of medicines in all countries.



## 2 What needs Nominated Signatory Review?



Always refer to your global and local SOPs to determine the level of review required. Adhere to the stricter requirement between global policies and local regulations. Ensure assets comply with all applicable company global policies and standards, including the Ethical Interactions policy as well as your local regulations and codes of practice.

## 3 Establish what you are reviewing



In order to categorise an asset and apply the correct rules to it, you need to know some key information such as: its purpose, its target audience and how it is to be distributed.



**Remember:** Assets can change 'category' depending on how they are used or by whom, and may be approvable in one context but not in another.



### Purpose

This is critical to know-examples are promotional, educational, internal training, to increase awareness of a disease, to provide budgetary information for payers, or to provide support for patients.



### Target Audience

Material should only be distributed to people whose need for, or interest in it, can reasonably be assumed. Material can breach regulations if used with a different audience to that approved.



### Mode of Distribution

Precise information is important - clarify general terms such as 'digital'.

## 4 Promotional or Non-promotional?

Sometimes an asset can be one or the other, depending on how it is to be used and who is going to use it. In addition, the impression created by the asset or associated activities can influence whether it is deemed promotional or not. Think about 'disguised promotion'.



As a general rule, any activity conducted or attended by, or an asset utilized by sales personnel should be viewed as promotional.

## 5 Obligatory Information

Establish which regulations and codes apply to each asset. Consider the need for:



Prescribing Information



Unique identifying number



Prep & expiry dates



AE reporting information

Clear and prominent declaration of AZ involvement