

Policy on Review of Materials for Promotion to Healthcare Professionals

Background

The promotion of prescription drug products by Astellas is an important element in educating healthcare professionals (HCPs) about the safe and effective use of our products and helps us to meet the medical needs of patients. The promotional materials used and claims made as part of these educational efforts are subject to internal review processes and will be consistent with the approved local labeling and local regulations.

To ensure that the promotional materials used and claims made as part of these educational efforts do not violate any internal policies and/or regulatory requirements, it is important to have consistency in our approach in their development and review worldwide. To achieve this goal, we have developed this policy which establishes a common set of principles that universally apply to the review of promotional materials and claims intended for HCPs.

Policy

All Astellas affiliates should develop promotional materials and claims about our products that are:

- Accurate
- Not misleading
- Balanced
- Supported by scientific evidence, and
- Consistent with the labeling and prescribing information approved by local regulatory authorities.

In addition, all promotional materials and claims must be reviewed and approved by the appropriate functions consistent with local process prior to their being used. Medical Affairs must be involved in the review and approval process to confirm that the promotional materials and claims are supported by substantial scientific evidence. Legal, Regulatory Affairs or Ethics & Compliance must also be involved in the review to confirm compliance with local regulations, internal policies and this policy. Sales personnel should not be involved in the review and approval process.

Adherence to this policy helps ensure that a consistently high ethical standard is applied to promotional materials used and claims made to HCPs wherever we conduct our business. These high quality materials and the truthful and accurate information they contain will help HCPs better understand the safe and effective use of our products that ultimately benefit the patients for whom they are prescribed.