



Policy Statement on Communications with Healthcare Professionals

Purpose

Santen is always expected to act with integrity and make ethical decisions in all aspects of our business based on Santen's Values and Santen Code of Practice. Santen understands that it is the duty of the Healthcare Professionals (HCPs) to ensure the appropriate treatment for their patients and to take reasonable care to avoid causing harm. As part of that duty, HCPs must make highly critical decisions on the appropriate use of medical products (drugs or devices) that considers the safety and efficacy of such products, as well as the balance of risk versus benefit to the patient. As part of the relationship Santen share with HCPs and the medical community, we too must ensure we support this effort by providing information on Santen products that is truthful, non-misleading, accurate and scientifically/clinically relevant. This policy defines our global commitment to advance the well-being of patients through ethical and appropriate information provision to and communication with HCPs, and describes the primary responsibility of Santen to ensure that its communication conforms to those applicable laws and regulations, as well as regulatory and professional requirements.

Policy

1. Promotional Communication

Promotional communications include activities that raise awareness of a product/brand, or activities where the purpose is to gain customer adoption of a product or to influence the purchase of a product. Wherever Santen operates, it promotes our products only for the uses for which they have been approved by local regulatory authorities and never engage in any unlawful promotion (e.g., pre-approval and off-label promotion). All such communications with HCPs, regardless of the function from which the communication arises, must be: truthful, accurate and not misleading, fair and balanced between the risks and the benefits involved, and fact based - avoiding one's own opinions and conclusions. Communications with HCPs may include verbal and written communications with HCPs as well as internal documents and training materials related to communications with HCPs.

Santen shall never solicit inquiries about unapproved use of products. Only certain Santen functions may respond to questions about unapproved use of products. The following topics are not permitted to be discussed during promotional communications with HCPs:

- Unapproved use of the product, including unapproved doses of the product; and
- Unsubstantiated or misleading comparative benefit of the product to alternative therapies.

Final versions of promotional materials must be reviewed and approved under Santen's internal review process prior to being provided to HCPs in order to comply with this Policy, local laws/regulations and industry standards.

2. Non-Promotional Communications

Non-promotional communications include educational communication (i.e., activities with the primary purpose to educate the public and/or HCPs about clinical data or scientific information) and scientific exchange (i.e., activities where the bona fide exchange of medical and scientific information is conducted in a non-promotional context). All such communication, verbal or written, must be truthful, accurate and not misleading, fair and balanced between the risks and the benefits involved, and fact based - avoiding one's own opinions and conclusions. Santen does not take advantage of such non-promotional circumstances to promote the use of specific Santen products.



Santen allows only scientifically covered persons (SCPs) may hold such scientific exchange with HCPs. Scientific exchange must be conducted in a manner that does not result in promotional communications. When a HCP has questions or requests information about unapproved use of Santen products, Santen generally directs the HCP to the relevant SCPs so that they may respond to such unsolicited questions or requests, provided that their responses are narrowly tailored only to address them and also the responses are appropriately recorded in accordance with designated local procedures. Requests or questions from HCPs must not be used as a basis for providing additional information about unapproved use of Santen products.

This policy statement summarizes our internal policies, guidelines, and SOPs for the captioned matter for ease of understanding material points.