

ARE YOUR HCP PROMOTIONAL MATERIALS TRUSTWORTHY?



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Helping international B2B companies develop strategic & creative communication solutions.

Updating promotional materials in accordance with SMPC changes and ensuring these updates are reflected in the API text in the materials is essential for maintaining regulatory compliance and patient safety, as well as professional trust with HCPs.

At the W Communication Agency, an important task that we are often asked to perform is to update promotional materials for a pharmaceutical product, targeted at Healthcare Professionals (HCPs).

Being specialists in pharmaceutical and life science communications. W is well versed in the various country rules on the promotion of a pharmaceutical product (POM – prescription only medicine) aimed at both HCPs and patients. Knowledge of the rules on the promotion of a pharmaceutical product is vital

when developing and/or updating promotional materials.

When developing and/or updating promotional materials for HCPs, it is a mandatory requirement that all promotional materials include the Abbreviated Prescribing Information (API) about the product. In some markets, like Norway, additional safety information text is required to ensure that this important information is easily accessible on promotional materials, such as product advertisement.

The API is a summary or condensed version of the full prescribing information or summary of product characteristics (SMPC). The API text provides critical details about a pharmaceutical product, focusing on key aspects that HCPs need to know for safe and effective use of the product in patients.

As the clinical and real-world data about a pharmaceutical product increase, the regulatory authorities will occasionally update the SMPC, and these changes will be reflected in the API text.

Such updates might include changes to a product's indication and/or additional information about the safety profile. These updates are then subsequently captured in the API.

Updating promotional materials for HCPs when the SMPC/API is updated for a pharmaceutical product is critical for several reasons:

PATIENT SAFETY

ACCURATE INFORMATION: HCPs depend on promotional materials from pharmaceutical manufacturers to make informed decisions about prescribing medicines. If these materials are outdated, they may not reflect the most current safety information, dosage recommendations, interactions or contraindications, potentially leading to patient harm.

PROFESSIONAL TRUST

MAINTAINING TRUST: HCPs trust pharmaceutical manufacturers to provide accurate, up-to-date information. Failure to do so can damage a company's reputation and its relationships with HCPs. Hence, manufacturers have an ethical responsibility to provide HCPs with the most current and accurate information to ensure the best possible care for patients.

REGULATORY COMPLIANCE

ADVERTISING STANDARDS: Pharmaceutical companies are legally required at a country level to ensure that all promotional materials are consistent with the SmPC. Failure to update promotional materials in line with SmPC changes can lead to financial penalties or legal action.

In summary, updating promotional materials in accordance with SMPC changes and ensuring these updates are reflected in the API text is essential for maintaining regulatory compliance and patient safety, as well as professional trust with HCPs.