PROMOTIONAL PRACTICES

GRI Standards :

417-1 Requirements for product and service information and labeling

417-2 Incidents of non-compliance concerning product and service information and labeling

417-3 Incidents of non-compliance concerning marketing communications

EXECUTIVE SUMMARY

As a global pharmaceutical company, Sanofi ensures compliant and ethical marketing as well as ethical interaction with healthcare professionals and patients by adhering to the codes on promotional activities governing our industry worldwide. Those are international rules as well as effective ethical pharmaceutical promotion legislation enforced nationally.

To ensure that our ethical principles are applied in marketing practices and that our documents are providing quality information about the products, Sanofi's Regulatory Affairs and Ethics & Business Integrity Departments have developed internal policies, processes, and trainings.

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1. BACKGROUND

Good promotional practices require international rules adhered to by as many countries as possible, as well as effective ethical pharmaceutical promotion legislation enforced nationally. As a global pharmaceutical company, Sanofi adheres to the codes on promotional activities governing our industry worldwide (IFPMA), in Europe (EFPIA) and the United States (PhRMA) and Sanofi's internal codes are based on these codes and refer to them explicitly.

1.1. Codes and Principles

Below is a list of codes and principles adhered by Sanofi:

- IFPMA Code – International Federation of Pharmaceutical Manufacturers Associations – Code of Pharmaceutical Marketing Practices
- WHO – World Health Organization – Ethical Criterial for Medicinal Drug Promotion
- WSMI – World Self-Medication Industry Advertising of non-prescription medicines to the public
- EFPIA Code of Practices – European Federation of Pharmaceutical Industries and Associations – https://www.efpia.eu/relationships-code/the-efpia-code/
- PhRMA Code – Pharmaceutical Research and Manufacturers of America – Principles on Responsible sharing of truthful and non-misleading information about medicines with healthcare professionals and payers
- EU Directive – European Commission – Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use
- Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency : https://eur-lex.europa.eu/eli/reg/2004/726/2019-03-30
- LEEM - http://www.leem.org/article/charte-de-visite-medicale
- CODEEM - Professional ethics provisions. Rules applicable to persons in charge of scientific information in the regions (2018). https://www.leem.org/codeem

1.2. Definitions

Significant efforts have been made by the international pharmaceutical industry in order to ensure compliant and ethical communication and interaction with healthcare professionals and patients. The quality of healthcare for patients depends on scientific information of medical products and therapeutic environment made available to them. The information should thus be scientifically accurate, transparent and fair in a view to support good patient care. These information are classified as "*promotional*", "*scientific engagement*" or "*scientific information*".

Promotional material: all communications, materials, messages or events created, controlled, disseminated by or on behalf of the Sanofi group that mention, characterize or discuss a product approved for marketing, to promote the prescription, recommendation, sale, supply, administration or consumption of its products. It includes all media types i.e. paper, video, radio and digital.

Scientific engagement: non-promotional interaction and exchange of information between Sanofi and external communities in order to advance scientific and medical understanding. This includes the appropriate development and use of our medicines, understanding the management of disease and improving patient care.

Scientific information: any information on a particular disease or product.

The definition of promotion material is not fully consistent across countries. However, the *objectives*, *context of use*, *format*, *type*, and *final target audience* will determine if it is promotional or non-promotional. These are the criteria identified for each material considering applicable industry commitments on promotional practices, local regulations and laws within Sanofi.

Moreover, as a pharmaceutical company, Sanofi is under the obligation to provide information on its product portfolio upon the requests of patients, healthcare professionals or general public.

2. POLICIES AND PROCESSES

2.1. Code of Ethics

Sanofi's Code of Ethics reaffirms the Group's commitment to comply with high ethical standards when promoting our products. Under the code, the Group must comply with Group rules, local regulations on the supply of promotional aids to healthcare professionals, the Sanofi pharmaceutical product promotion principles and rules, as well as international codes (in particular IFPMA and EFPIA, PhRma, etc.).

For more information, see:

- Code of Ethics – *Interacting with the Scientific community*, *Being transparent about our products* (Please refer to Sanofi Code of Ethics in the Document Center).

2.2. Policies

The core mission of our promotional activities is to provide quality information about the product presented in compliance with the marketing authorization for that product, and to promote correct use of the product among healthcare professionals.

Our Regulatory Affairs and Ethics & Business Integrity Departments have established procedures and directives that comply with international standards:

- on scientific information provided via promotional or non-promotional materials: best practice guidelines on the use of promotional documents or materials to communicate information about medicines and healthcare products, and on the provision of items of medical utility, etc.;
- on using websites, social media and mobile applications to provide scientific and promotional information: Digital Governance has established an approval procedure and life cycle process covering all website, social media and mobile applications of Sanofi and its subsidiaries worldwide; and
- on interactions with healthcare professionals: hospitality rules associated with scientific events, and rules governing the remuneration and selection of experts with whom we contract to provide services.

To ensure that our ethical principles are applied in practice, we are also committed to:

- providing continuing professional education for sales representatives, and assessing our sales visit activities;
- applying the strictest ethical standards on scientific materials;
- providing precise, up-to-date and objective scientific information so that our employees are knowledgeable in their interactions with healthcare professionals and comply with the relevant regulatory requirements;
- supplying documentation that enables healthcare professionals to make objective assessments about the quality of our products and the uses for which they were developed;
- ensuring that information about our products is based on scientifically proven results;
- conducting internal audits to ensure that our subsidiaries comply with the approval procedures for scientific materials, and with internal and external codes of conduct and currently applicable laws and regulations governing promotion;

Early 2020, at the start of the COVID19 pandemic we also issued specific guidance on remote interactions (mainly digital) with healthcare professionals in full compliance with the principles laid out above.

2.3. French Charters for Medical and sales representatives

On October 15, 2014, LEEM (the French Pharmaceutical Companies Association) and CEPS (Economic Committee for Healthcare Products, a French government agency) signed a charter governing the promotional information delivered to healthcare professionals by the sales representatives. It is designed to safeguard the quality of the information provided to healthcare professionals and to promote the proper use of medicines.

Based on this charter, the HAS (the French National Authority for Health) published a new certification framework which was published in the Official Journal on April 13, 2016 (last update published March, 2017). Based on this referential, a yearly external certification audit of French affiliate ensures that:

- the company is capable of reliably delivering on its declared policy and objectives,
- the company's management system complies with the specified requirements and is effectively implemented, especially in the following areas: quality policy for promotional information (built into our global quality approach), ethical standards, the training and assessment of individuals in charge of the promotional information.
- the company complies with promotional and non-promotional activities and responsibilities requirements.

Those provided an opportunity to enhance the expertise of our sales representative teams and our overall operational excellence while maintaining an ethical and responsible approach, thereby ensuring that activities within the scope of the charter are fully compliant.

Promotional activities of Sanofi France are certified since February 2007.

Since 2019, a pharmaceutical code in France reinforces the role of medical representatives who exchange with healthcare professionals only scientific and non-promotional information, respectful of the principles of scientific integrity.

We also provide a dedicated hotline for healthcare professionals to give feedback on the quality of medical sales visits.

2.4. Medico-Marketing Materials Management System

Sanofi's foremost concerns are patient safety and the proper use of our products. The promotional materials related to Sanofi products are based on scientifically proven results and undergo an internal review process to ascertain that they are objective and fair before they can be used. Our Medical and/or Regulatory Affairs teams at the global levels and in each country are responsible for reviewing materials and approving them prior to use.

In 2020 a new global centralized technology platform has been deployed to review and approve promotional and non-promotional materials. This system called 4M (medico-marketing materials management system) will facilitate sanofi's end-to-end global review process and increase collaboration worldwide. Within the system approximately 200K pieces are reviewed annually.

2.5. Complaints mechanism

Sanofi has set up a complaints management procedure for the promotional and non-promotional materials and activities. This process is focused on local complaint handling and tracking according to local rules and regulations. For global brands, the procedure requires proper communication between local and global teams to ensure corporate insights and ability to take appropriate global action.