SMA Europe Code of Practice on Relationships with the Pharmaceutical Industry

Introduction

SMA Europe is an umbrella body of national Spinal Muscular Atrophy patient representative and research organisations in Europe. SMA Europe's objectives are:

- To promote the interests of SMA patients in European health policy
- To drive common action at a European level to advocate SMA in research and pharmaceutical companies
- To raise awareness of SMA with the general public, healthcare practitioners, scientists and industry
- To identify, promote and implement the best practice for SMA care and so improve patient quality of life
- To promote and sustain scientific and medical research in all fields of SMA
- To increase collaboration between member countries
- To collaborate with other worldwide organisations, groups and institutions with similar aims and objectives
- To represent a united, consistent patient voice for SMA in Europe

This Code of Good Practice is designed to guide relations between SMA Europe and the pharmaceutical industry (including their representatives and consultants)

SMA Europe recognises that:

- SMA Europe, as an independent, not-for-profit entity, may depend on voluntary/pro bono work to run its day-to-day operations and activities, and may be financed by public and/or private funds, i.e. membership fees, donations and corporate sponsorships, including the pharmaceutical industry and
- Pharmaceutical companies engage in research, development of products that aim to treat SMA and manage patients' disease, and are viewed as a natural collaborative partner

Through dialogue and cooperation with the pharmaceutical industry, SMA Europe and national patient associations can promote and support their objectives in working towards the best interests of their members.

Purpose of the Code

The purpose of this code is to ensure ethical, accountable and transparent collaboration between SMA Europe, its members and the pharmaceutical industry. SMA Europe also suggests to its members to use this code. The code draws upon the existing *EFPIA (European Federation of Pharmaceutical Industries and Associations) Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations*[i], the World Health Organisation's *Guidelines on Interaction with Commercial Enterprises to Achieve Health Outcomes, eB107/20*[ii] and the *Interaction PVO Standards (pertaining to Pharmaceuticals and Medical Resources*[iii]*.*

SMA Europe, its members and pharmaceutical companies share an inspiration in ensuring that their individual integrity is maintained when collaborating. Hence, all types of collaboration between the parties are not only to apply to any given rules and guidelines, but also to 'good corporate governance, including this document that defines agreed best practice for collaboration between the parties.

In developing relationships with pharmaceutical companies to further the mission of SMA Europe, consideration should be given as to whether the proposed relationship might involve a real or perceived conflict of interest and SMA Europe members' reputation must be ensured.

SMA Europe commits itself to adhering to the provisions of this code in all its dealings with industry. It also encourages its member organisations to commit to adhering to the provisions of this code when dealing with industry. SMA Europe expects pharmaceutical companies to adhere to the provisions of this code in all its dealings with SMA Europe or national patient groups.

Principles of the Code

- SMA Europe shall not promote or show favour to a particular prescription-only or non-prescription medicine
- The pharmaceutical industry shall not request the promotion of a particular prescription-only or non-prescription medication
- All partnerships between SMA Europe and the pharmaceutical industry shall be based on mutual respect, with views and decisions of each partner having equal value
- The objectives and scope of any partnership shall be transparent. Financial and non-financial support provided by the pharmaceutical industry shall always be clearly acknowledged
- SMA Europe welcomes broad funding from multiple sources

Code of Practice

1. Funding Relationships

1.1 SMA Europe welcomes unrestricted grants from industry and will always report these as part of its usual accounting and transparency policy, including in annual reports and on the website. Such donations will not be accepted as an inducement to influence of change its positions on issues, plans or priorities.

1.2 Acknowledgement will be attributed to the funding person or organisation, but not to a specific product or project

1.3 SMA Europe will disclose the percentage of overall income that each funder (individual person, government organisation, industry, etc) represents

1.4 Funds will not be sought or accepted from pharmaceutical companies that have a direct commercial interest in the outcome of the project toward which they would be contributing.

1.5 Wherever possible, SMA Europe will seek to have funding from more than one company

1.6 Private donations to individual officers or members of SMA Europe, whether paid staff or volunteers, are not acceptable.

1.7 When SMA Europe accepts a donation in support of any specific activity it retains control of the content at all times. Any ensuing publication will be the property of SMA Europe and findings may not be used or quoted by the funder without explicit permission. No information in relation to the project should ever be used to promote the use of any specific product or business of the funder.

1.8 SMA Europe welcomes invitations to industry events, providing reasonable travel and subsistence costs can be covered and, where appropriate, an honorarium to SMA Europe to compensate for time invested by staff or elected representatives

1.9 Other situations where industry may propose honoraria to SMA Europe or a member organisation's volunteers or staff include:

1.9.1 Reviewing industry materials, leaflets, protocols, etc

1.9.2 Consultancy on industry policy, advisory committees etc

Payments made to officers or members arising from any such activities should be directed to SMA Europe rather than to the individual participant or officer of SMA Europe personally. This is in line with current practice for health care professionals.

1.10 SMA Europe may accept funds, sponsorship or assistance in kind for its own specific events. Funding should ideally and, where possible, come from more than one source.

2. Nature and Execution of Collaboration between SMA Europe and a pharmaceutical company

Any collaboration between SMA Europe and a pharmaceutical company must be structured and delivered to ensure and consolidate the integrity, reputation and continued success of the involved parties, and on adding value to patients. Collaboration between SMA Europe and a pharmaceutical company must comply with:

a. Relevant national laws and regulations

b. The pharmaceutical company's specific code of practice/internal guidelines

Collaborations should also have specific aims and meet the following basic criteria:

I. The relationship should contribute to improving the health and quality of life of people living with SMA and/or their carers

II. Terms of all relationships should be recorded as an exchange of clearly written letters or agreements indicating the contribution (financial or otherwise) and expectations that each of the parties brings to the relationship

3. Promotional Activities

a. SMA Europe will not take part in any promotional activities related to approved prescription medicines, as required by current EU legislation and respective industry codes of ethics. SMA Europe will always be mindful of potential

conflicts and unintended consequences and ensure it strictly adheres to its own independent, patient-centred agenda.

b. Types of activities that could be considered promotional and therefore might cause a conflict of interest and/or be against the law, include the following:

    i. Disseminating unbalanced, non-validated or partial information about a product/service which is produced, marketed or provided by a company, whether or not it funds SMA Europe

    ii. Being quoted in the company's corporate communications in favour of, or against a product/service

    iii. Participating as a speaker/participant in a company event for the launch of a pharmaceutical product/service

    iv. Participating in an ad hoc meeting sponsored by a single company to inform patients on their products

    v. Agreeing that a company displays/disseminates SMA Europe's own materials on the company's exhibition stand at any commercial or trade exhibition or scientific conference

    vi. Appearing in promotional materials for a certain product/service of the company or to testify as a 'consumer' of that medicine.

c. SMA Europe will refrain from contributing to industry websites.

d. SMA Europe will refuse to be quoted in industry press releases that relate to a marketed product or a product under development

e. If SMA Europe feels the need to communicate to the media about a product/service, it will issue its own press release which is clearly independent of industry

f. Commercial organisations wishing to publicly mention SMA Europe's name should seek prior written authorisation from the latter.

g. If a company quotes SMA Europe's opinion or refers to its own communication materials without its written permission, SMA Europe will object to the company by registered letter with a copy to the company's national industry association.

4. Disease Awareness Campaigns

a. Disease awareness campaigns by Industry

Disease awareness campaigns can be considered as an indirect form of advertising in some EU countries and therefore against the legislation. SMA Europe will always ensure that such campaigns respond to a well characterised public health need, that is agreed and supported by the national and/or European public health authorities.

b. Disease awareness campaigns by SMA Europe

If conducting its own disease awareness campaign, SMA Europe will ensure that any information regarding a commercial product must be based on the Summary or Product Characteristics (SmPC) or another commercially independent and validated source. SMA Europe will also observe the following conditions:

i. Provide a clear statement of how the information was arrived at
ii. Mention the validated source of information
iii. Mention health professional/independent experts who have been consulted
iv. Identify the Editorial Board who has control, responsibility and oversight
v. Ensure there is a Transparency Policy in place, disclosing funders

This Code of Practice has been adopted by SMA Europe and will govern its relationship as a separate body with commercial organisations in the field of Spinal Muscular Atrophy. SMA Europe will encourage its member organisations to adhere to the provisions of the Code of Practice and express itself to be bound by its terms and express the expectation that commercial organisations will adhere to the principles herein contained in all its dealings with national patient and research organisations.

Date: 27th April, 2016

References:

[i] EFPIA code of practice on relationships between the pharmaceutical industry and patient organisations (5/10/2007)

[ii] World Health Organisation (EB107/20, November 2000). Guidelines on interaction with commercial enterprises to achieve health outcomes

[iii] Interaction PVO Standards (November 2009)