BEST-PRACTICE PRINCIPLES

WORKING TOGETHER WITH PATIENT ORGANISATIONS

DONATIONS AND GRANTS, SPONSORSHIPS AND CONTRACTED SERVICES

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Developed by the EFPIA Patient Think Tank

Part 1: Purpose

The aim of this document is to support the pharmaceutical industry and the Patient Organisations[1] to evolve Donations and Grants applications, Sponsorships, Contracted Services, and related reporting processes.

The Best-Practice Principles are intended for EFPIA Members (Member Companies[2] and Member Associations[3]) representing the research-based pharmaceutical industry in Europe, but some of the provisions are applicable for both the pharmaceutical industry and the Patient Organisations.

In addition, the content of this document may be relevant for any organisation working with Patient Organisations.

Part 2: Rationale for Engagement and Overarching Principles for Collaboration

Patients must be at the heart of healthcare, from prevention and awareness, through research and development, regulatory and health technology assessment, to service design and outcomes measurement. They have a unique understanding and first-hand knowledge of their disease, the priorities and challenges when it comes to receiving treatment, managing their condition or their family and social life.

Working with Patient Organisations helps deliver better, more patient centred outcomes for patients, healthcare systems and for society as a whole.

In the past, industry, academia, healthcare professionals, regulators, and Patient Organisations have sometimes worked in silos. In practice, some decisions about patients' care, medical research, health information and service design were taken without direct patient involvement.

This sometimes led to a misalignment between how healthcare was designed and delivered and the outcomes really valued by patients. The paradigm on multisectoral collaboration is evolving. From a pharmaceutical industry perspective, in recent years, many companies have developed new ways to integrate patient insights and to collaborate with the patient community in a transparent, ethical and meaningful way. Patient Organisations have increased their capacity and expertise. In addition to providing a platform for patients to share their experiences and get peer-to-peer support, they provide a strong voice for their communities, gathering and articulating their priorities and preferences in a more systematic, contextualised, evidence-based manner.

The increasing involvement of the views of patients added to the expertise of other stakeholders has led to improvements including in clinical trial designs and outcomes, engagement and communication throughout the entire life cycle of medicines, with the ultimate aim of improving outcomes. This important development is ongoing and the pharmaceutical industry and Patient Organisations are committed to improving collaboration based on the principles outlined in **Working Together with Patient Groups[4] (2017)**:

1 - Patient Organisation are defined as not-for-profit organisations (including the umbrella organisations to which they belong), mainly composed of patients and/or caregivers, that represent and/or support the needs of patients and/or caregivers (EFPIA Code of practice on relationships between the pharmaceutical industry and patient organisations – Scope).

2 - Member Company: as defined in the EFPIA Statutes, means research-based companies, developing and manufacturing Medicinal Products in Europe for human use.

3 - Member Association: as defined in the EFPIA Statutes, means an organisation representing pharmaceutical manufacturers at national level whose members include, among others, research-based companies. Collectively, the national Member Associations or their constituent members, as the context may require, are bound by the EFPIA Code.

4 - https://www.efpia.eu/media/288492/working-together-with-patient-groups-23102017.pdf

1. CLARITY OF PURPOSE

Collaboration between pharmaceutical companies and Patient Organisations fulfil a legitimate need for interactions identified in advance. Pharmaceutical companies and Patient Organisations should be clear about the purpose of the engagement and the desired outcomes.

2. TRANSPARENCY

Transparency of the aims and objectives of any collaboration builds trust and allows for independent external scrutiny. All financial relationships should be transparent and any compensation to Patient Organisations' representative should be proportional and commensurate with experience, expertise and the time invested.

3. INDEPENDENCE

It is the independence of Patient Organisations, in all aspects of their decision-making, development of policies and external communications that helps to ensure credibility and patient confidence. Funding from a wide range of sources is preferable and this can include provision of statutory funding by the EU and member state bodies.

4. RESPECT

In any collaboration, stakeholders bring their own perspectives, skills, and experience. Collaboration should be based on mutual respect, prioritising long-term commitment over short-term needs and valuing each other's contribution."

The *Working Together with Patient Groups* has been adopted by many companies as well as national associations to guide and facilitate their engagement with Patient Organisations. It has been translated in four languages and formed the basis for developing engagement in several countries across Europe.

Establishing an appropriate framework for collaboration, respecting the above principles and complying with the national laws and regulations and codes, is key to forging meaningful, long-term cooperation[5].

Continuing the effort to further establish a more consistent approach and showcase practices that benefit Patient Organisations as well as pharmaceutical industry navigate these relationships, this document supplements previous guidance and outlines additional best-practice principles around working together on Donations and Grants, Sponsorships, and Contracted Services.

5 - In case applicable laws or regulations (incl. national and EU) foresee stricter requirements than the Best-Practice Principles (e.g., legal ban of single-sponsorship instead of just a recommendation) these laws and regulations rules have to be applied.

Part 3: Co-creating processes that work for Patient Organisations and the pharmaceutical industry

These Best-Practice Principles were co-created by representatives of Patient Organisations and the pharmaceutical industry through the EFPIA Patient Think Tank (EFPIA PTT) in collaboration with the pharmaceutical industry's compliance and legal community.

The Best-Practice Principles applicable for Donations and Grants, Sponsorships and Contracted Services with Patient Organisations are underpinned by the general principles for collaboration in Working Together with Patient Groups and are in addition to the **EFPIA Code of Practice**'s requirements for interactions between the pharmaceutical industry and Patient Organisations. It is important that processes are as simple as possible whilst ensuring that all the good governance requirements and standards are met.

Part 4: Scope of the Best-Practice Principles

These Best-Practice Principles relate to EFPIA Members collaborating with Patient Organisations through Donations and Grants, Sponsorships and Contracted Services as per their definition in the EFPIA Code of Practice:

> *"Donations and Grants[6] mean providing funds, assets or services freely given for supporting healthcare, scientific research or education, with no consequent obligation on the recipient to provide goods or services to the benefit of the donor in return."*

> *"Sponsorship[7] is a support provided by or on behalf of a Member Company, when permitted by law, as a contribution to support an activity (including an Event[8]) performed, organised or created by a HCO, PO or a Third Party."*

> *"Contracted Services[9] between Member Companies and HCPs, HCOs, POs or POs' Representatives under which those provide any type of services to Member Companies (not otherwise covered by the Code) are only allowed if such services: (i) are provided for the purpose of supporting healthcare, research or education; and (ii) do not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific Medicinal Products."*

Under a Donation and Grant, Sponsorship or a Contracted Service with a Member Company, Patient Organisations might be required to report about the activities carried out with support offered by a Member Company. The Best-Practice Principles also cover this aspect of the collaboration.

6 - *See EFPIA Code of Practice ARTICLE 12 DONATIONS AND GRANTS TO HCOs AND POs*

7 - *See EFPIA Code of Practice ARTICLE 13 CONTRIBUTION TO COSTS RELATED TO EVENTS AND SPONSORSHIP*

8 - *Events are defined in the EFPIA Code as: All professional, promotional, scientific, educational meetings, congresses, conferences, symposia, and other similar events (including, but not limited to, advisory board meetings, visits to research or manufacturing facilities, and planning, training or investigator meetings for clinical trials and non-interventional studies) organised or sponsored by or on behalf of a Member Company.*

9 - *See EFPIA Code of Practice ARTICLE 15 CONTRACTED SERVICES*

Part 5:
Best Practice Principles for EFPIA Member Companies

GENERAL PRINCIPLES

Section 1 Multi-company sponsorship

To support the independence of the Patient Organisation, no Member Company should require that it be the sole funder or sponsor of a Patient Organisation or any of its programmes or projects[10]. Thus, it is preferable that funding is sought from, and provided by multiple sources.

Patient Organisations are encouraged to fundraise from multiple sources, and to be transparent about the proportion the Member Company's contribution would represent in the overall project.

Section 2 Long-term commitment

While it is understandable that Member Company budgeting cycles may only allow for yearly planning and funding, where appropriate, Member Companies recognise the need of Patient Organisations to plan ahead and facilitate longer-term, strategic projects and activities that may stretch beyond a calendar year.

Section 3 Consistency

EFPIA Members recognise the need for more consistency in the way they work with Patient Organisations in a given country in compliance with national laws, regulations and applicable codes.

Therefore, Member Companies are encouraged to put in place, internally, consistent criteria at a national and regional level for providing Donations and Grants, Sponsorships and Contracted Services, in compliance with all applicable EU and local laws, regulations and applicable codes.

Section 4 Process efficiency

When Member Companies conduct the due diligence on the Patient Organisations, they are encouraged not to request again previously submitted documentation, that is still up to date, however any significant changes should be notified proactively by the Patient Organisation.

INFORMATION PROVISION AND CLARITY

Section 5 A central source of information on applying to Donations and Grants and Sponsorships

A dedicated Member Company webpage identifying the right channels for Patient Organisations' Donations and Grants and Sponsorships applications, would foster transparency and enable identification of opportunities for Patient Organisations.

When possible, Member Companies are encouraged to include comprehensive information on the company's areas of interest, eligibility criteria, conditions, and the process to apply for the funding of Donations and Grants and Sponsorships.

Section 6 Clear, timely communications on content and timelines

Member Companies are encouraged to provide clarity on the application process, requirements, estimated timelines, and eligibility criteria. For example, as feasible for a Member Company, the estimated timelines for Member Company application review as well as the post-application process.

10 - See EFPIA Code of Practice ARTICLE 14 MEMBER COMPANY FUNDING

Providing clear information about the contract, payment terms and conditions, reporting and closeout is critical to support Patient Organisations in navigating the collaboration process. Using an existing contract template may streamline the process.

A Member Company checklist can be helpful to clarify what documents are required from Patient Organisations when applying for a grant or sponsorship. As well, providing a check list of items and a brief description of content, may improve the quality of the application and help streamline the process.

It is recommended that a Patient Organisation and a Member Company align on the common understanding of the terminology used in the application or engagement process, in order to ensure effective communication between the two parties.

The applicable documentation (e.g., the written contract) must clearly articulate the purpose of the funding provided. If relevant, references and explanations of the national laws and regulations may help further describe applicable background.

Both parties are encouraged to take into consideration, wherever possible, the operational requirements of the counterparty throughout the budgeting and invoicing process.

Section 7 A single point of contact and connectivity between relevant functions

Member Companies are encouraged to provide contact details to indicate to whom Patient Organisation can contact for any question related to the application process (submission requirements, conditions, eligibility, etc.).

In order to provide a consistent and supportive environment for collaboration with Patient Organisations across the whole organisation and throughout the collaboration, Member Companies can envisage to build cross-functional teams and/or communications channels that connect patient engagement, compliance, finance and legal functions that play a role in shaping and managing relationships with Patient Organisations.

PROCESS AND REPORTING

Section 8 Reporting Requirements

It is recommended that Member Companies provide clear information on the reporting requirements regarding the use of funds. These should be determined with the core purpose of reporting in mind: being transparent, accountable and able to justify that the funding was spent in accordance with the contract.

A Member Company may be requested, by authorities or auditors, to provide the evidence of the funding spent according to the purpose of the Donations and Grants.

When permitted by national laws and regulations, Member Companies should also aim to avoid duplicating information requirements throughout the process and focus on highlighting any changes or deviations compared to the initial approach described.

This can lead to simplified, more efficient processes.

Section 9 Payment terms should be as short as reasonably possible

For Patient Organisations to be able to carry out their activities as planned, and once the contract is concluded, Member Companies are encouraged to provide timely payment in accordance with the payment schedule agreed in the contract.

As an example, for Donations and Grants, Member Companies are encouraged to provide payment in advance of the planned activity if the contract is in place.

Section 10 Operational costs and/or overheads to be recognized as a separate budget category

Patient organisations should cover their basic regular operational costs independently. However, in certain cases, it may be reasonable for Patient Organisations to request that certain part of the funding for a given project should cover overheads and/or operational costs related to the management of the specific project. The companies should decide on a case-by-case basis if this is permissible.

If such overheads and operational costs are to be included, they should be clearly substantiated, providing detailed cost breakdown in the submitted budget plan, and included in the reporting processes.

Section 11 Disclosure of the transfers of value related to Donations and Grants, Sponsorships and Contracted Services

All the transfers of value provided to a Patient Organisation by a Member Company in the context of Donations and Grants, Sponsorship and Contracted Services must be disclosed every year[11].

11 - See EFPIA Code of Practice ARTICLE 24 DISCLOSURE OF SUPPORT AND SERVICES PROVIDED TO POs

The **EFPIA Patient Think Tank** is a dedicated group of patient organisations and industry representatives that plays a fundamental role in driving patient input in to EFPIA policy development and proposes principles, guidelines on working together.

Scan the QR code to download previous reports and find out more about the Patient Think Tank activities.

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