WE WORK TOGETHER WITH PATIENTS

GUIDELINES FOR COOPERATION BETWEEN PATIENTS, PATIENT ORGANISATION REPRESENTATIVES AND CARERS WITH THE PHARMACEUTICAL INDUSTRY

Updated 2025 version

Prepared by IFPA and VGA in accordance with EFPIA Patient Guidelines

CHAPTER I. Patients hold the key to more successful research, better healthcare and improved outcomes

Collaboration with patients, including their carers, and patient organisations must be ethical, transparent and based on genuine need, with the ultimate goal of improving healthcare management, patient outcomes and patient well-being. The primary means of engaging with patients is through patient organisations. However, pharmaceutical companies and associations may engage patient experts on an individual basis, depending on the circumstances, the nature of the service required, and the experience and expertise involved, in accordance with national laws and regulations.

Patients[1] are entitled to receive remuneration for services provided, commensurate with their experience, knowledge and time spent, in accordance with the principles set out in this document.

Cooperation is also possible when pharmaceutical companies provide solutions for patients. Such solutions or services include Patient Support Programmes, screening and diagnostic support for target groups, if such services are not covered by the national health system; information materials or services, such as reminders on how to use medicines correctly; assistance related to aspects of the disease, including side effects, mental health, nutrition and physical activity.

Decisions may be linked to a specific medicinal product, but must always be linked to the company's therapeutic area.

1 See Appendix 1 for definitions of terms.

CHAPTER II.
Purpose of the document

The pharmaceutical industry recognises that collaboration with patients and their organisations is essential to better understand their experiences and knowledge. These insights help to develop and improve medicines and achieve the best possible outcomes for patients. Patients and their organisations play an important role in providing valuable insights into patient needs.

The guidelines also present principles and objective criteria on the basis of which patients, representatives of patient organisations and caregivers may be remunerated for services provided to pharmaceutical companies and associations[2]. The guidelines are based on the principles of cooperation with patients set out in the EFPIA Code of Ethics and supplement the provisions of the IFPA and VGA Code of Ethics for Pharmaceutical Marketing, which regulate communication between the pharmaceutical industry and patient organisations.

CHAPTER III.
Scope

The principles set out in this document relate to cooperation and remuneration for the services of patients, representatives of patient organisations and caregivers to IFPA and VGA members. These services may include consulting, video recordings, media or social media posts, presentations at internal company meetings and events, and external events and conferences, where advertising is strictly prohibited during the presentation by the patient or patient organisation. The principles do not apply to remuneration related to participation in scientific medical research.

The principles apply to persons providing services, which is not the same as supporting a patient organisation for a specific project (i.e. helping with communication, contributing support in organising a congress, etc.). Such activities are outside the scope of this document and are discussed in the Code of Ethics for Pharmaceutical Marketing.

In addition, the principles in this document also cover patient-oriented decisions. These are any type of service, programme or solution designed to benefit existing or potential individual patients, including Patient Support Programmes. These solutions may or may not be linked to a specific medicinal product, but must be related to the company's therapeutic area.

Patient-focused solutions may include support for screening and diagnosis of target groups, assisting healthcare professionals (HCPs) in determining the most appropriate treatment option, and/or helping individual patients manage their disease.

These guidelines do not cover: compassionate use programmes; disease awareness communications unless they form part of a broader patient-oriented solution; discounts, patient co-payments, drug reimbursement or patient access programmes; any information related to reimbursement; activities organised and implemented by independent third parties where the company participates only as a funder (grant, donation, sponsorship); non-personalised, non-interactive information (e.g. leaflets left in a doctor's office); clinical and health economic studies, including non-interventional studies; pre-approval, expanded use, post-clinical trial and continued access programmes; public-private partnership initiatives that provide support to patients but are not directly initiated or controlled by pharmaceutical companies.

2 This document is not legally binding. It has been prepared as a supplementary resource to the Code of Ethics for Pharmaceutical Marketing, which sets out the obligations of IFPA and VGA members and a set of ethical rules adopted for the advertising of medicines to healthcare professionals and for communication with healthcare professionals, healthcare organisations and patient organisations, to ensure that these activities are conducted in accordance with the highest ethical standards of professionalism and responsibility. This code applies to all types of communication and interaction (traditional and digital).

CHAPTER IV.
Principles

Principles applicable to interactions with patients:

- Patient decisions and cooperation with patients should not encourage the prescription or sale of medicines.
- All decisions made for patients must be based on the patient's medical needs.
- Decisions must not interfere with the normal doctor-patient relationship.
- If any component of the decision involves a medical device, the company must comply with applicable medical device regulatory requirements and legislation.
- The value of a patient-facing solution must be transparent, and information about the support provided by the pharmaceutical company, such as funding, should be disclosed.
- Data protection requirements (GDPR and relevant national legislation) apply both to the provision of services to pharmaceutical companies and to the life cycle of the solution provided to patients – from design to implementation, execution and completion.
- In accordance with Directive 2001/83/EC, patient-oriented solutions must not promote the prescription, supply, sale or use of medicinal products to the general public, including patients, and must not in any manner include incentives for healthcare professionals (HCPs) to prescribe a specific medicinal product.
- No remuneration may be offered to a patient for agreeing to participate in a patient decision. Similarly, no payment or other incentive may be offered to a healthcare professional (HCP) for involving a patient in a decision.
- Patient decisions may not involve the use of medicinal products for off-label indications.
- If the decision concerns the use of a prescription medicine already prescribed to the patient or instructions for its use, the patient must be involved in the decision through a healthcare professional (HCP), and information about the existence of such a decision regarding prescription medicines must first be provided to the HCP. Once the HCP has informed the patient, additional information may be provided to the patient (through traditional or digital channels).
- The company must have clear, objective and documented criteria for patient involvement in a specific decision. These criteria must be communicated to the HCP and other relevant stakeholders throughout the entire period of validity of the decision.
- The design or implementation of a patient-oriented decision may be carried out with the assistance of third parties (HCPs, HCOs, patient organisations or others). In such cases, third parties may be compensated for their support in accordance with a written agreement. The same principles apply to the design or implementation of a solution through a third party.
- The overall costs of the solution must be reasonable and proportionate to the value provided.
- Patient-oriented solutions must comply with pharmacovigilance requirements.
- Each patient-specific solution must clearly indicate the company's support and role in the implementation of the solution for the patient.
- Disclosure of directly and indirectly transferred values (HCPs, HCOs, patient organisations) must be complied with.
- Patient-focused solutions must be properly monitored, and any extension, renewal or termination of the solution must be reviewed to ensure that the patient's medical needs remain the primary focus.
- The duration of the decision must be predetermined, limited to its objectives and justified by the identified patient need. The duration and justification must be communicated to all stakeholders at the start of the decision. If the decision is terminated early, the parties must be informed in advance and a smooth end to the decision must be ensured.
- If the patient is an HCP, stricter principles must be followed and disclosure of transferred values must be ensured.

Non-exhaustive list of examples of patient-oriented decisions as defined in these guidelines:

- Providing patients with education on the use of medicines, based on approved and updated SmPC and package leaflet information, e.g. nurses teaching patients how to self-administer medicines.
- Providing information and solutions related to treatment adherence, e.g. medication reminder programmes.
- Where possible, facilitate the delivery of the medicinal product or the transport of the patient to the healthcare facility.
- If the national healthcare system does not fully cover the costs, provide test kits and/or diagnostic solutions to help determine the most appropriate treatment.
- Assistance in managing related aspects of the disease, including related adverse events such as mental health, nutrition and diet, and physical exercise.

When providing services to patients or patient organisations, cooperation with pharmaceutical companies must be based on the general principles applicable to any purchased services: identifying the existing need, defining the required service, signing a written agreement, reporting on the work performed, etc. A list of these principles is provided below.

1. RIGHT TO REMUNERATION

When providing services to pharmaceutical companies, it is fair to compensate patients for their time, experience and knowledge. This compensation should be based on the principles listed below.

2. FAIR AMOUNT OF REMUNERATION

The remuneration paid to patients should be fair, reasonable, appropriate and should not exceed the actual market value of the services provided.

Although the amount of remuneration and the principles for determining it are set by the companies themselves, pharmaceutical companies may take into account a number of criteria in order to determine an appropriate amount of remuneration, including:

- the patient's personal experience: knowledge, prior training or experience related to the service provided;
- attendance at previous scientific meetings, applicable skills related to the task;
- the complexity of the tasks, e.g. national or international meetings;
- the time allocated to the task, including preparation time and duration of the commitment;
- taking into account the cost of living index in the country (e.g. GDP level);
- travel time, which may be compensated.

However, in cases where pharmaceutical companies provide solutions for patients, payment is not permitted either to patients for their participation or to healthcare professionals (HCPs) who have offered the solution to patients.

3. NON-DISCRIMINATION

All patients must be treated equally and fairly.

4. RESPECT

Any communication between patients and the pharmaceutical industry should be based on mutual respect, with each partner's opinions and decisions treated as equal. The independence of patients must be respected.

5. NON-PROMOTIONAL ACTIVITIES

Communication with patients should be professional and ethical. Pharmaceutical companies may not ask patients to directly or indirectly promote a specific medicinal product. Cooperation with patients should not be an incentive to recommend a specific medicinal product, medical device or service. When cooperating with patients, companies should also take into account other laws in force in the country.

6. TRANSPARENCY

The objectives and scope of cooperation with patients should be transparent and clear to both parties. Financial and non-financial support provided by the pharmaceutical industry should always be specified and clearly understood by both parties. Under the Code of Ethics for Pharmaceutical Marketing, payments to patient organisations are already disclosed annually, as are payments to healthcare professionals and healthcare organisations. Pharmaceutical companies may consider whether payments made to individual patients should also be disclosed as a transfer of value, if the patient agrees. Any potential conflict of interest should be disclosed.

7. APPROPRIATE PAYMENTS

The scope of services provided should not exceed what is necessary to meet the identified need, and the remuneration should be proportionate to the size of the task. If the patient officially holds the position of representative of a patient organisation, the remuneration should be paid to the patient organisation rather than to the patient, in accordance with national legislation. Travel, accommodation and other hospitality expenses may be covered by pharmaceutical companies. All travel-related expenses must be justified and directly related to the meetings, in accordance with the principles of moderation.

8. CONSISTENCY

Pharmaceutical companies and associations should follow a consistent policy on remuneration of patients, ensuring that collaborating patients are remunerated in accordance with uniform principles and in line with applicable national legislation and guidelines.

9. RIGHT TO DECLINE REMUNERATION

Patients have the right to refuse remuneration for services rendered.

CHAPTER V.
Payment terms

When services are provided to pharmaceutical companies, payment terms should be flexible and tailored to the needs of patients. Pharmaceutical companies should take into account that if patients have to pay for their travel and accommodation expenses in advance, they should be reimbursed as soon as possible[3].

For this reason, whenever possible, pharmaceutical companies should arrange travel and accommodation for patients themselves. Ideally, travel and accommodation costs should not be reimbursed, but paid directly by the organising partner.

APPENDIX 1.
Glossary

In this document, the term *patients* includes:

- *individual patients* who have personal experience of what it means to live with a particular disease; they may or may not have technical knowledge of research and development or regulatory processes, but their main role is to contribute by sharing their subjective experience of the disease and its treatment;
- *patient representatives* who have the knowledge and experience to help a wider group of patients with a specific disease; they may or may not belong to an organisation;
- *Patient experts* who, in addition to their knowledge of a specific disease, have acquired technical knowledge of research and development and/or regulatory matters through experience or specific training.

The principles may also apply to:

- *representatives of patient organisations* who are tasked with representing the patient organisation and expressing its general position on a specific issue or on a particular area of disease;
- *caregivers* who provide individual care to patients, such as family members or paid or volunteer assistants.

APPENDIX 2.
Links to the content of other organisations' documents

The following publications and initiatives were considered, reviewed and discussed in the development of the EFPIA principles:

- EUPATI Guidelines for Patient Involvement in Drug Research and Development; Guidelines for Pharmaceutical Industry-Initiated Drug Research and Development
- The Change Foundation's tool "Should money be paid?"
- PFMD* resources
- Fair market value remuneration for patient experts, WECAN Fair Market Value Working Group: Jan Geissler, Ananda Plate, Gilliosa Spurrier, Judith Taylor, Kathy Oliver, Gordon Oliver. Jan Geissler, 28 October 2018. Principles for Fair Agreements between Patient Representatives and Pharmaceutical Companies, WECAN Final Contract Document, 16 October 2018, p. 11, http://www.wecanadvocate.eu/wp-content/uploads/2018/10/Guiding-Principles_final- document_clean_proofread.pdf.
- EFPIA Code of Practice Annex 4, EFPIA Guidance on Patient-Oriented Decisions, 26 February 2025.

3 Principles for Fair Agreements between Patient Advocates and Pharmaceutical Companies, WECAN Final Contract Document, 16 October 2018, V6.1, Section 8: "Pay within 30 days: parties should endeavour to agree to pay invoices within 30 days of issue. The same applies to the reimbursement of expenses."

** (Patient Focus Medicines Development) Patient Focus Medicines Development Project Resources*

Approved by IFPA and VGA

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