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WORKING TOGETHER WITH PATIENTS

PRINCIPLES FOR REMUNERATING PATIENTS, PATIENT ORGANISATION REPRESENTATIVES & CARERS FOR WORK UNDERTAKEN WITH THE PHARMACEUTICAL INDUSTRY

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Developed by the EFPIA Patient Think Tank

SECTION ONE: Patients hold the key to better research, better healthcare and better outcomes

Patients[1] must be at the heart of healthcare, from prevention and awareness, through research and development, regulatory and health technology assessment processes, to service design and outcomes measurement. Working with Patients throughout the process delivers better outcomes for Patients, for healthcare systems and for society as a whole.

In the past, industry, academia, healthcare professionals, regulators, and patient organisations have largely worked in silos. In practice, many decisions about Patients' care, medical research, health information and service design were taken without meaningful Patient involvement. This led to inefficiencies and low value in process and outcomes.

But this is starting to change. In recent years, many companies have developed new ways to incorporate Patient insights and to collaborate with Patients and patient organisations in a transparent and ethical way.

This has led to better trials, better engagement, better communication throughout the entire life cycle of medicines – and ultimately better Patient outcomes. This development is not yet universal but the direction of travel is there. The industry and patient organisations are committed to improving collaboration and building trust across the entire spectrum of stakeholders.

"Patients with knowledge or experience of a condition will be able to provide true picture of what it is like to live with a specific condition, how care is delivered, how that impacts on them, their Carers and families and how medicines and other treatments can change their quality of life and meet their needs.[2]"

This requires us to recognize the vital role that patient organisations, communities and individual patients play in sharing knowledge as equal and valued partners. Alongside leadership from patient organisations, individual Patients are coming together online to share information and experiences concerning their diseases and conditions. Capturing these insights and using this data to inform medical research could help to deliver more patient centered treatments and services.

The evolution in patient engagement is matched by the rapid progression of the science that underpins research and development of medicines. This progress allows for more personalised medicines that target individual Patient needs. In order to support this transition, all stakeholders must explore new models of engagement between Patients, healthcare providers and industry.

These collaborations must be ethical, transparent, and based on a legitimate need, ultimately driving better health care management and Patient outcomes. The primary route for engagement with Patients is through patient organisations. However, when permitted by national laws and regulations, pharmaceutical companies and associations may engage with individual patient experts depending on the circumstances, type of service, experience and expertise required.

Patients have the right to be remunerated for the service they have provided based on their experience, expertise and time. To support a consistent and ethical approach this document sets out a series of principles on which remuneration decisions can be based.

1 - See Appendix 1 for definition

2 - Working Together with Patient Organisations White Paper developed by the EFPIA Patient Think Tank in September 2017.

SECTION TWO:
The aim of this document

The aim of this document is to set out the principles and objective criteria on which remuneration is paid to Patients, Patient Organisation Representatives and Carers for work undertaken with pharmaceutical companies and associations. The principles were co-created by Representatives of Patient Organisations and the research-based pharmaceutical industry through the EFPIA Patient Think Tank (EFPIA PTT)[3] with input from external organisations such as WECAN and PFMD.

The principles for remuneration of Patients, Patient Organisation Representatives and Carers are in addition to these EFPIA Code of Practice's provisions on interactions between the pharmaceutical industry and Patient Organisations. The principles were developed in the context of existing provisions for contracting with and remunerating healthcare professionals, healthcare organisations and Patient Organisations. These new principles aim to cover the specific roles and needs of Patients, Patient Organisation Representatives and Carers.

The principles are intended to be a useful reference point for EFPIA member companies and associations developing their own guidelines on remunerating Patients, Patient Organisation Representatives and Carers. They are not intended to be a code of conduct.[4]

SECTION THREE:
Scope

The principles relate to remuneration for services provided by Patients, Patient Organisation Representatives and Carers to EFPIA members. These may include acting in advisory roles, consultancy or speaking at internal meetings (attended by staff of pharmaceutical companies) or non-promotional external events and conferences. They do not apply to remuneration in relation to the participation in clinical trials.

The principles relate to individuals providing services and thus differs from the support given to a Patient Organisation for a specific project (i.e. supporting communication, providing in kind support for organising a congress, etc). These activities are out of scope for this document and are covered by the EFPIA Code of Practice.

SECTION FOUR:
Principles

Appropriate and effective collaboration between Patients and the pharmaceutical industry has the potential to co-create and co-develop better health outcomes.

This collaboration must be based on general principles applicable to any contracted services: identification of a legitimate need, definition of the service required, signature of a written agreement, reception of the deliverable, etc. The principles are:

1. THE RIGHT TO REMUNERATION

It is right that Patients are remunerated for their work time, experience and expertise. This remuneration should be based on the following principles:

3 - The EFPIA Patient Think Tank provides a forum for an open exchange of ideas, information and perspectives between Patient Organisations and industry on topical issues impacting on Patients. More information at https://efpia.eu/relationships-codes/patient- organisations/the-patient-think-tank/

4 - This document is not legally binding, it is intended to be used as useful reference in addition to the EFPIA Code that constitutes the collection of ethical rules agreed by EFPIA members for the Promotion of Medicinal Products to HCPs and the interactions with HCPs, HCOs and POs, with the intent of guaranteeing that these activities are conducted while respecting the most stringent ethical principles of professionalism and responsibility. This Code applies to all types of communication and interaction (traditional and digital).

2. THE LEVEL OF REMUNERATION SHOULD BE FAIR

Remuneration to Patients should be fair, reasonable, appropriate and should not exceed the fair market value of the services provided.

While the level of remuneration, including its methodology, is an internal company decision, pharmaceutical companies should take into account a number of factors to determine the appropriate remuneration, including:

- Individual expertise of the Patient: level of experience, prior training, or experience relevant to the service provided, attendance at previous scientific meetings, transferable skills relevant to the engagement
- Complexity of the tasks assigned, for example international vs national meetings
- Total of time invested: including preparatory time, length of the engagement
- Country of residence – taking national cost of living index (e.g. GDP level) into consideration
- Travel time can be compensated

3. NON-DISCRIMINATION

All Patients should be treated equally and fairly.

4. RESPECT

All interactions between Patients and the pharmaceutical industry should be based on mutual respect, with the views and decisions of each partner having equal value. The independence of Patients should be respected.

5. NON-PROMOTIONAL SCOPE

Interactions with Patients should be conducted professionally and ethically. Pharmaceutical companies shall not request, nor shall Patients undertake, the direct or indirect promotion of a particular medicinal product. The engagement of Patients should not be an inducement to recommend a particular medicinal product, device or service.

6. TRANSPARENCY

The objectives and scope of any collaboration with Patients should be open and transparent to both parties. Financial and non-financial support provided by the pharmaceutical industry should always be clearly and publicly acknowledged by both parties. Payments to Patient Organisations are already being disclosed yearly as outlined in the EFPIA Code of Practice as are payments to health professionals and healthcare organisations. Pharmaceutical companies may also consider whether the payments provided to individual Patients should be disclosed as transfers of value. Any potential conflict of interests should be disclosed.

7. APPROPRIATE PAYMENTS

The extent of the service provided should not be greater than is reasonably necessary to achieve the identified need and remuneration commensurate with the scale of the task. If the Patient is representing a patient organisation in an official capacity, remuneration should be paid to the patient organisations and not to the Patient, respecting local regulation. Travel, accommodation and hospitality may be reimbursed by the pharmaceutical companies. All travel related expenses shall be reasonable and directly related to the meetings.

8. CONSISTENCY

Pharmaceutical companies and associations should be consistent in the way they remunerate Patients. Consequently, pharmaceutical companies are encouraged to put in place their own criteria ensuring that any entities of a pharmaceutical company will remunerate the Patients they engage in the same way, taking into account that such entities would need to adhere to applicable national regulations and guidelines.

9. RIGHT TO REFUSE REMUNERATION

Patients have the right to refuse remuneration.

SECTION FIVE: Payment terms

Payment terms should be sensitive to the needs of Patients. Pharmaceutical companies should take into consideration that Patients need to be reimbursed as soon as possible when they pay their travel costs and accommodation in advance.

For this reason, where possible, pharmaceutical companies should arrange the travel and accommodation for the Patients. Ideally travel and accommodation costs would be paid directly by the organising partner rather than being reimbursed. If this is not possible, pharmaceutical companies are encouraged to reimburse the costs of travel and accommodation in a short timeline.[5]

APPENDIX 1: Glossary

In this document the term ''Patients'' includes:

- "Individual Patients" who are persons with personal experience of living with a disease. They may or may not have technical knowledge in R&D or regulatory processes, but their main role is to contribute with their subjective disease and treatment experience.
- "Patient Advocates" who are persons who have the insight and experience in supporting a larger population of Patients living with a specific disease. They may or may not be affiliated with an organisation.
- "Patient Experts", who, in addition to disease-specific expertise, have the technical knowledge in R&D and/or regulatory affairs through training or experience.

In addition, the principles can also be applied to:

- "Patient Organisation Representatives" who are persons who are mandated to represent and express the collective views of a patient organisation on a specific issue or disease area.
- "Carers", who are persons supporting individual Patients such as family members as well as paid or volunteer helpers.

APPENDIX 2: Recognition of other organisation content

In developing the principles, the following publications and initiatives were considered, reviewed and discussed:

- EUPATI guidance for patient involvement in medicines research and development (R&D); Guidance for pharmaceutical industry-led medicines R&D
- The Change Foundation: Should Money come into it?
- PFMD Resources
- Compensation for patient experts at fair market value, WECAN Workgroup on FMV: Jan Geissler, Ananda Plate, Gilliosa Spurrier, Judith Taylor, Kathy Oliver, Gordon Oliver. Jan Geissler, 28 Oct 2018. Guiding Principles on Reasonable Agreements between Patient Advocates and Pharmaceutical Companies – WECAN Final Consensus Document 16 October 2018 – Page 11 http://www.wecanadvocate.eu/wp-content/uploads/2018/10/Guiding-Principles_final- document_clean_proofread.pdf

5 - "Guiding Principles on Reasonable Agreements between Patient Advocates and Pharmaceutical Companies WECAN – Final Consensus Document, 16 October 2018, V6.1 – Chapter 8.: "Pay within 30 days: The parties should strive to agree on settlement of a payment within 30 days after the date of the invoice. The same should apply to reimbursements of costs."

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