Global Principles for remunerating the patient community for interactions with the pharmaceutical industry
**Introduction to this document and supporting work**

The Global Principles for remunerating the patient community for interactions with the pharmaceutical industry are part of a broader global project examining the overall process and methodology for remunerating the patient community and determining Fair Market Value (FMV), led by PFMD.

**Background**

In recent years there has been substantial collaborative work to enable ethical and compliant interactions between the patient community and the pharmaceutical industry. Key initiatives and deliverables have laid the foundation, such as the Workgroup of European Cancer Patient Advocacy Networks (WECAN) Reasonable Agreements between Patient Advocates and Pharmaceutical Companies project (RAPP)\(^1\), The European Federation of Pharmaceutical Industries and Associations (EFPIA) Working Together With Patients\(^2\), the National Health Council (NHC) Patient Compensation Tools\(^3\), International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) Note for Guidance on Patient and Patient Organization Interactions\(^4\), European Patients’ Forum and EFPIA public-private partnership via the EU funded IMI PARADIGM\(^5\) project and others. However, remuneration of the patient community continues to be a tension point, reducing the ability of both parties to have meaningful and efficient interactions, leading to a call to action for global consistency and transparency.

**About the Project**

Building on the significant work to date, this project aims to deliver Global Principles and Methodology for remunerating the patient community for interactions with pharmaceutical companies, which will also inform the development of a digital tool helping to apply standards to the calculation of remuneration per the Methodology. The methodology will be structured around activities, expertise required and the participant type, respectively, and will utilize a market-based approach. Elaborating these elements will build on previous work from the NHC, EUPATI, IMI PARADIGM and others.

The project is led by a Steering Committee with representatives from the patient community and the pharmaceutical industry. Broad public consultation on all deliverables is critical to ensure representativeness of all communities, drive adoption, and the systemic change required whilst ensuring compliance with relevant Codes of Conduct and local regulations.

**About the Principles**

The Principles included here harmonize and build on previous collaborative work to encompass globally recognized and co-created Principles for remunerating the patient community for interactions with the pharmaceutical industry.

Please note: The sections titled Types of activities and Expertise referenced in the Principles are currently being co-created and will be included at a later stage of the project.

For more information on this project please contact Nicole Wicki nicole@thesynergist.org

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\(^1\) WECAN, PFMD, MPE (2018), [https://wecanadvocate.eu/rapp/](https://wecanadvocate.eu/rapp/)


\(^3\) NHC (2020), [https://nationalhealthcouncil.org/additional-resources/patient-compensation-tools/](https://nationalhealthcouncil.org/additional-resources/patient-compensation-tools/)

\(^4\) including the US FMV Calculator [https://nationalhealthcouncil.org/fair-market-value-calculator/](https://nationalhealthcouncil.org/fair-market-value-calculator/)


\(^5\) PARADIGM (2017), [https://imi-paradigm.eu/](https://imi-paradigm.eu/)
Structure

I. Purpose of this document
II. Scope of the Principles
III. Core Principles
   1. Right to remuneration
   2. Fair remuneration
   3. Non-discrimination
   4. Respect
   5. Non-promotional scope
   6. Consistency
   7. Time invested
   8. Payment terms
   9. Reimbursement of related expenses
   10. Transparency
   11. Disclosure of Conflicts of Interest
   12. Contractual party
   13. Written agreement
   14. Raise concerns
IV. Types of Participants
V. Expertise
VI. Types of Activities
I. Purpose of this document

The purpose of this document is to set out the Principles and objective criteria on which remuneration is paid to the Patient Community, including those living with a condition (Individual Patients), Carers/Caregivers\(^6\), Patient Advocates, Patient Experts, Patient Organization Representatives (jointly referred to as “Participants”) for the work undertaken with pharmaceutical companies and pharmaceutical associations (jointly referred to as “Companies”).

The Principles were co-created by PFMD, in collaboration with individual patients, representatives from patient organizations, pharmaceutical companies, and pharmaceutical associations.

The Principles were developed in the context of existing provisions for contracting with and remunerating Participants and aim to cover the specific activities and key elements related to remuneration of such interactions.

Like other types of experts or consultants, Participants should be reasonably compensated for their time, expertise, and contributions based on these global Principles.

This document also includes Principles related to reimbursement for related expenses such as travel (see Section 9 “Reimbursement of related expenses”).

The Principles listed here are general and not intended to be prescriptive. They should be adapted as required by individual circumstances.

These Principles are intended to be embedded in Codes of Conduct.

II. Scope of the Principles

The Principles relate to remuneration for services provided by Participants (see “Types of Participants” section) to Companies. These may include various activities, e.g. developing and reviewing materials, contributing as an invited expert to a set topic or questions, participation in Company internal events or non-promotional external events and conferences (see “Types of activities” section). Participants require specific expertise to be engaged in an activity (see “Expertise” section).\(^7\)

If local laws or regulations do not allow transfers of value to the Participants, an interaction with such Participants falls out of scope for this document.

The Principles relate to the Participant providing services and therefore differ from the support given to a patient organization for a specific project (i.e. providing in–kind support for organizing a congress, etc., covered by grants, sponsorships, and/or donations). These activities are out of scope for this document.

These Principles should apply to interactions between Participants and Companies. However, these Principles do not apply to remuneration for clinical trial participation. For further guidance on remunerating patients for participation in clinical trials please refer to Guideline 13 of Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Health-related Research Involving Humans.\(^8\)

For Principles governing confidentiality, intellectual property, recordings of meetings, data protection, indemnification and remedies, adverse event reporting please refer to “Guiding principles on legal agreements between patient advocates and pharmaceutical companies”.\(^9\)

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\(^6\) Carer and caregiver terms can be used interchangeably and in some countries a specific term might be more prevalent than the others.

\(^7\) These documents will be finalized at a later stage.

\(^8\) Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO) (2016) International Ethical Guidelines for Health-related Research Involving Humans

III. Core Principles

1. Right to remuneration

1. It is appropriate that Participants are remunerated for their experience, contribution time, and expertise. This remuneration should be based on the Principles detailed in this document, local regulations and Industry Codes that govern the pharmaceutical industry (“Codes of Conduct”).

2. Participants also have the right to refuse remuneration and should know that working as a non-remunerated volunteer does not impact their ability to participate.

3. In the event that the Participant declines monetary compensation, if allowed by local regulations, non-monetary forms of remuneration may be offered (e.g., provision of IT and technical equipment), however, the non-monetary forms of remuneration should be fair and consistent and not exceed the value of the monetary compensation that is offered. If non-monetary payment is made to a patient organization it should be disclosed by both parties.

4. Participants should be aware that their social benefits, payable taxes or tax status may be affected when receiving remuneration for an activity. While it is not the responsibility of the Company to provide tax or legal advice, the Company may suggest that the Participant seek tax or legal advice before entering into agreements to avoid unintended/unanticipated tax liability or tax status issues.

5. Participants should be educated via a clear disclosure or other communication that accepting payment from a Company could affect disability payments or other forms of government benefits. Participants should be made aware that accepting non-monetary remuneration can still have tax or social security implications.

2. Fair remuneration

1. When determining fair market value, these principles refer to the remuneration for work performed by the Participants that should inform decision making within a Company.

2. It is expected that Participants receive fair remuneration for interactions with Companies, similar in philosophy and process to the widely established practice for health care professionals\(^{10}\).

3. A fair market value can only be determined by examining the market (i.e. country) where the Participant resides. Typically, this is carried out by the third parties conducting market research with the aim to ensure that compensation paid for work performed is comparable to similar activities in that market.

4. Remuneration for services should be reasonable, appropriate, and represent the fair market value of the legitimate and necessary services provided, considering complexity of tasks, expertise required and training, total amount of time invested, urgency, country of origin, local regulations, and other contributing factors.

5. Companies should take into account a number of factors to determine the appropriate remuneration, including:
   - Wages lost. Since the Participant is being compensated for their time commitment for the activity, it is not recommended to compensate them for wages lost. This should be considered if it impacts recruitment of a representative target population and assessed on a case-by-case basis.
   - Care Support. To ensure representativeness of a target population, it may be necessary to provide care reimbursement for a dependent. This should be considered on a case-by-case basis.

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3. Non-discrimination

1. All Participants should be treated equally and fairly.
2. This includes Participants with mental health conditions, older adults, young patients, and patients who are being represented by a Carer/Caregiver due to their legal or physical incapacity.
3. There should be no discrimination on any other factor related to gender, marital status, family status, age, disability, race, sexual orientation, religious belief, or ethnic background.¹¹
4. There should be no discrepancies, especially for any one activity when remunerating Participants from the same country, doing the same work requiring the same expertise for the same Company.

4. Respect

1. Companies respect the mission, autonomy, and independence of the Participants, and do not seek to exercise any improper influence on their objectives, activities, or decisions. Specifically, any views or decisions of the Participants should be respected and not influenced by the Companies.
2. In order to respect the independence of Participants, Companies should not request nor expect exclusivity from Participants, meaning that the Participants are free to engage with any other Company of their choosing.

5. Non-promotional scope

1. Interactions with Participants should be conducted professionally and ethically.
2. Companies shall not request, nor shall Participants undertake, the direct or indirect promotion of a particular medicinal product, device or service, unless it is allowed by local laws and regulations.
3. The engagement of Participants should not be an inducement to recommend a particular medicinal product, device or service.
4. Participants should not be offered reduced-price goods or services that may influence switching from competitor medicinal products, devices or services.

6. Consistency

1. Companies should be consistent in the way they remunerate Participants.
2. Companies should ensure that any legal entities and affiliates of a Company remunerate the Participants they engage by using these Principles and applying the same methodology while taking into account that such legal entities and affiliates are required to adhere to applicable local laws and regulations.

7. Time invested

1. Remuneration for an activity is paid on an hourly basis and the calculation should consider the total time invested by the Participant.

2. Time commitment should include the onboarding for the specific activity, preparation, meetings (including planning and review meetings), the activity itself, follow-up for project deliverables, and other post-activity engagement.

3. Expected total number of hours for all events and all activities, including the process of amending the hours, if they exceed the pre-agreed number of hours, should be mutually agreed in writing prior to an engagement, unless it is not possible given the specifics of an activity.

4. Subject to local regulations, the Participant may be compensated for travel time, including local or long-distance travel. Participant travel time may be compensated at the full hourly rate, some portion thereof, or based on distance traveled. Expenses incurred as a result of travel are discussed under Section 9 “Reimbursement of related expenses”.

8. Payment terms

1. Payment terms should be sensitive to the needs of Participants. The parties should strive to agree on settlement of a payment within 30 days. The same should apply to reimbursement of expenses incurred.

2. Participants and the Company should agree in advance of the activity how and when the remuneration and/or reimbursements will be paid, in what currency, whether the Company will cover banking and transfer fees, and if any conditions are attached or documentation required.
9. Reimbursement of related expenses

1. Reimbursement for travel, associated costs or other expenses required to participate in an activity should be viewed as separate and distinct from remuneration, as the associated costs and reimbursement represent expenses incurred by the Participant that he/she would not otherwise incur.

2. The Company should make every effort to arrange and pay for major expense items such as patient travel in advance (e.g. air, train, taxi fares, accommodation) and only incidental expenses, such as meals, own car mileage, parking (small ticket items) should fall under the definition of reasonable reimbursable expenses. For further considerations please refer to “Enhancement EUPATI industry guidance: Events and hospitality”\(^\text{12}\). If this is not possible, the payment terms stated under Section 8 “Payment terms” should be followed.

3. The Company should clearly lay out in advance for the Participants what is reimbursable. Descriptions for expenses should be included, e.g.:
   - transportation (mileage, car-sharing service, taxi, or shuttle)
   - accommodations
   - meals
   - conference registration
   - banking and transfer fees
   - incidental expenses such as hotel internet or parking, or if the Company has limits to expenses (e.g., daily rates)

4. All travel-related expenses shall be reasonable and directly related to the meetings. Limits may be placed on the amounts covered for travel and meal expenses in accordance with local laws and regulations.

5. Sometimes Participants’ work requires having two subsequent meetings at different locations. A Participant should not be required to travel from/to their home city to each meeting separately. Such travels should be permitted and also reimbursed by Companies, subject to a valid reason based on proof of reason for travel. The additional costs related to such travel should be reasonable in relation to the cost of travel to the Company meeting from the home city. Generally, these trips should be paid by the Company or third party to which the Participant is traveling. Alternatively, the costs can be shared whenever this is possible with the Company or third party where the second meeting is held.

6. If the Participant or, when applicable, the accompanying person, provides a justified professional or medical reason for staying at the same location for more than 24 hours after the meeting ends, the Company should cover the return flight and associated costs even though it is more than 24 hours before and/or after the meeting.

7. Where air travel is required and there are underlying health reasons, considerations should be given for traveling in business class.

8. Companies should take into account a Participant’s specific needs, physical or mental, e.g. mobility limitations, when arranging transportation (e.g. deciding on whether or not to hire a car service).

9. Before signing the agreement the Participant should notify the Company about additional expenses that may be medically necessary (e.g., adequate number of hotel nights before and after a meeting, rental mobility scooter, rental oxygen, or certain seat assignments for air travel).

10. In case a Participant has a justified medical need to be accompanied by other persons, travel costs of the accompanying person should be paid by the Company at the same level as the Participant.

\(^{12}\) PARADIGM (2020), Enhancement EUPATI industry guidance: Events and hospitality.
10. Transparency

1. The objectives and scope of any direct and indirect interaction between Participants and Companies should be open and transparent to both parties.

2. Financial and non-financial support provided by the Company should always be clearly and publicly acknowledged by both parties as required under local regulations and the Codes of Conduct.

11. Disclosure of Conflict of Interest

1. Any potential financial and non-financial conflicts of interests should be disclosed to a third party as required under local regulations, including respective Codes of Conduct, including, but not limited to relevant public authorities when it relates to the activities between the Participant and the Company.

2. Participants should be aware that accepting a payment from a Company can result in a conflict of interest when the Participant takes part in other patient engagement activities with government and other public organizations, such as serving as a patient representative on a formulary, technical, Health Technology Assessment (HTA), or guideline writing committee. In such cases Company and Participant should assess whether a conflict exists and if conflict mitigation is possible.

12. Contractual party

1. If allowed by local regulation, the Participants should have the choice of whether the contracting party receiving the remuneration is the legal entity or the individual.

2. Patient Organizations should consider implementing conflict-of-interest policies that specify if and when their employees can receive payment individually for work done for the Companies.

13. Written agreement

1. A written agreement between the Participant and Company should be developed outlining terms, responsibilities of the Company, the Participant and any other third party, which will support the activity, time frame, expectations, type of the activity, scope, amount of the payment or the type of support prior to the start of the activity and considering all provisions of this document.

2. An agreement should be written in a clear and easy-to-understand language. Companies are encouraged to use co-created templates of such agreements13.

3. The Company should identify a contact person from a non-commercial function whom Participants should contact if any questions or concerns arise regarding remuneration or reimbursement.

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14. Raise concerns

1. Participants should be aware they have the right to express concern if they believe the remuneration offered for their participation is insufficient or excessive, or if the Participants feel the activity they are asked to be engaged in is in conflict with these principles.

2. Discussion of remuneration and options should be in private with individual Participants before they agree to participate in the activity. This encourages the Participants to make specific needs or accommodation requests without fear of judgement.

IV. Types of Participants

1. In this document, the term “Participants” includes:
   - “Individual Patients” who are persons with personal experience of living with a disease. 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 organization.
   - “Patient Experts”, who, in addition to disease-specific expertise, have the technical knowledge (e.g. in research and development and/or regulatory affairs) through training or experience.
   - “Patient Organization Representatives” who are persons who are mandated to represent and express the collective views of a patient organization on a specific issue or disease area.
   - “Carers/Caregivers”, who are persons supporting Individual Patients such as family members as well as paid or volunteer helpers.

2. Companies sometimes contract with celebrities (i.e. a person of public interest) who have been diagnosed with a certain condition. These individuals often have an established contractual rate for speaking and other efforts. Interactions with these patients are outside the scope of these Principles. Companies should have separate policies in place for remunerating celebrity patients.

3. Individuals, who regularly generate digital content online, including via blogs, vlogs, or various social media platforms may also be identifiable as “Social media influencers”. Such individuals can be Individual Patients, Patient Advocates, Patient Experts, Patient Organization Representatives, or Carers/Caregivers. However, for a meaningful patient engagement activity, it is not their social media status that is compensated for, but their personal experience, attributable to one of the Participants types and should be remunerated similarly to other Participants within the same category. If individuals do not fall under any of the Participant types, then such interactions are outside the scope of these Principles. Companies should have separate policies in place for remunerating such individuals.

V. Expertise

NB: This section will be elaborated in a later version

VI. Types of activities

NB: This section will be elaborated in a later version