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Patient Engagement
Remuneration & Fair
Market Value

PFMD Remuneration and Fair Market Value Project for interactions between the patient community and pharmaceutical companies

Public consultation on activity & expertise frameworks to support the determination of FMV

This document will provide you with all the necessary information to enable your contribution to the public consultation on the Activity and Expertise Frameworks. This is the second public consultation in our overall project.

The goal of the Public Consultation is to maintain ongoing dialogue with key stakeholders including, organizations, and networks to shape, refine and validate the draft Activity and Expertise Frameworks.

Consultation Timeline

June 13th, 2021 - September 1st, 2022

How to participate

1.

Review this document and watch this video to understand the project and the instructions for this public consultation

2.

Review the Frameworks

- **Activity Framework**
- **Expertise Framework**

3.

Share your inputs through this survey

Who should participate

Anyone with an interest in the topic of remuneration of the patient community for interactions with pharmaceutical companies. Especially:

Patient community, including patient organizations and networks, individual patients and carers/caregivers, patient advocates, and patient experts.

Pharmaceutical companies and associations, including all functions that play a part in patient engagement and remuneration, such as patient engagement and advocacy, legal, ethics and compliance, research and development, medical affairs, and many others.

As part of our co-creation approach, **we need your involvement in reviewing and providing input on the current Activity and Expertise Frameworks.** It is only through this broad consultation that we continue the co-creation process and ensure quality deliverables, ultimately leading to impactful outputs benefiting all stakeholders. By creating well-defined Frameworks we will:

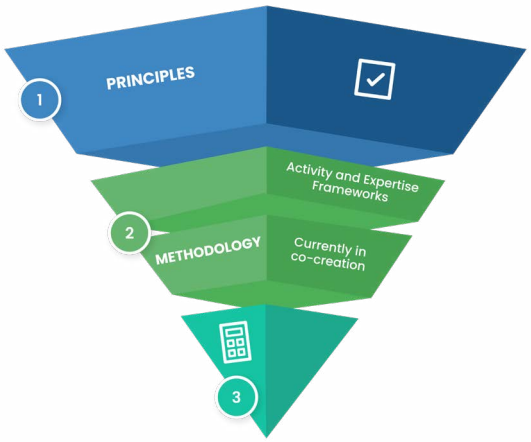
- establish the foundation of a global methodology for determining fair remuneration
- Increase the level of transparency and reduce real and perceived risks associated with fair remuneration to the patient community.
- Inform the development of a digital tool to support patient engagement remuneration.

About the project

The overall aim of this project is to collaborate with key stakeholders to co-create transparent Global Principles and a standard methodology to support the determination of fair remuneration for the patient community for interactions with the pharmaceutical industry. More details are in Annex 1.

The deliverables of the project, defined below, allow the pharmaceutical industry and patient community to review their existing practices and adapt accordingly. Creating more transparency in their processes whilst ensuring compliance with relevant Codes of Conduct and local regulations. Deliverables include:

1. **Global Principles** for remunerating the patient community for interactions with the pharmaceutical industry. Available here.
2. A **Global Methodology** to operationalize the **Global Principles** for fair remuneration at market value in a standard process.
   - Leveraging the **Global Frameworks** for remuneration, defining **Activities, and Expertise** (for review in this consultation).
3. **A Digital tool** applying the Frameworks and Methodology for determining fair remuneration



How is the remuneration methodology being developed?

The methodology aims to operationalize the Global Principles.

According to **Principle III. 1. 1.**: It is appropriate that Participants are remunerated for their experience, contribution time, and expertise and **Principle III. 2. 4.**: Remuneration for services should be reasonable, appropriate, and represent the fair market value of the legitimate and necessary services provided, considering the ***complexity of tasks, the expertise required and training,*** the total amount of time invested, urgency, country of origin, local regulations, and other contributing factors.

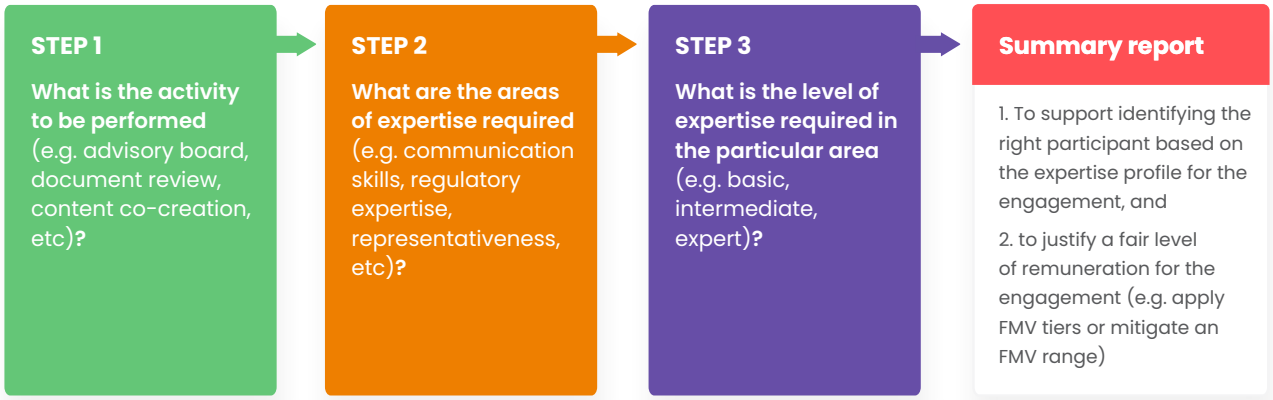
The methodology is therefore composed of the Activity and Expertise Frameworks which build on previous collaborative work from the National Health Council[1] and IMI-PARADIGM[2]. The Frameworks we are asking you to review were co-developed by the PFMD project Steering Committee and integrate inputs from a Patient Engagement Open Forum Session in April 2022. These frameworks and subsequent methodology will be integrated into a digital tool.

[1] Please see National Health Council (2021) Patient Activities Framework: https://nationalhealthcouncil.org/wp-content/uploads/2020/06/NHC_FMV_Activities_List.pdf

[2] Please see IMI PARADIGM (2020) Planning Patient Engagement activity - Recommendations on how to find the right match for the right patient engagement activity: https://imi-paradigm.eu/PEtoolbox/identification-of-patient-representatives.pdf

How can the remuneration methodology be used?

To operationalize the Principles, the first part of the methodology will be to determine the activity to be performed with the engaging partner, in this case, the pharma company, and evaluate the expertise required to perform the activity. Key questions to be answered about the engagement include:



In responding to these questions and applying the Frameworks, users of the methodology will be able to consistently differentiate and outline a profile of the expertise including experience, skills, and knowledge required to perform the engagement. This then will be used to determine the appropriate application of an FMV rate for the engagement.

Stakeholders can use the Frameworks and methodology in part or as a whole to support the implementation of the Global Principles.

It is important to note that the **expertise required** is defined in relation to the **activity** that is selected, it is not an assessment of an individual. Participant Type as defined in the Global Principles or assessment of an individual does not determine fair market value in this process. Rather, the identification of the required expertise helps to identify the right participant for the activity.

Public Consultation Instructions: Activity and Expertise Frameworks

Once you have read this document (and/or watched this video) and reviewed the content below, please respond to the survey here. Some of the survey questions are already included below to guide your review.

Activity Framework in review

The Activity Framework provides a list and definitions of the most common types of patient engagement activities with pharmaceutical companies. When reviewing the Framework below, please reflect on the following:

- How is this a useful Framework for selecting a patient engagement activity?
- Are there any other routine pharma-patient activities missing?

Remuneration and Fair Market Value Project Activity Framework	
Type of Activity	**Definitions/Descriptors**
Content co-creation	Multi-stakeholder collaboration with shared objectives to develop deliverables and documents (e.g., interview guides, inclusion/exclusion criteria, surveys, reports, manuscripts, patient support materials, consent forms, disease education and awareness materials).

Remuneration and Fair Market Value Project Activity Framework	
Type of Activity	**Definitions/Descriptors**
Content co-creation	Multi-stakeholder collaboration with shared objectives to develop deliverables and documents (e.g., interview guides, inclusion/exclusion criteria, surveys, reports, manuscripts, patient support materials, consent forms, disease education and awareness materials).
Pre-activity engagement	Pre-engagement planning to agree on a patient engagement activity or collaboration. May include planning meetings, pre-screening participants for an engagement, or research before conducting an activity.
Presentation/speaker	
Personal testimonial	Speak to personal experience; typically, a short presentation or recording.
Panel or roundtable speaker	Speak as part of a small group of presenters; typically, each speaker addresses the same topic from various perspectives.
Event, Conference, Symposium speaker	Speaking as an expert to experts at medium- to large-size gatherings, typically with a scientific or policy theme.
Keynote	Provide an extended speech, as the sole speaker, on a thematic topic.
Facilitator / moderator / chair	Lead and facilitate discussions and provide thought leadership at an event or meeting.
Group engagement	Group activity advising on a specific topic, sharing experience or overseeing the conduct of a project (e.g. advisory boards, councils, focus groups, roundtables, etc.)
Governance Boards	
Governance Board participant	Invited to participate as an invited expert to oversee the conduct of a project, organization, etc.
Chair or Co-Chair of a Governance Board	Lead and facilitate discussions and provide thought leadership on the conduct of a project, organization etc.
Interviews	
Interview participant	A one-on-one interview. Typically includes a trained interviewer who follows a discussion guide.
Interview facilitator	Facilitating an interview utilizing a prepared discussion guide.
Survey responder	Answer a set of standard questions in a questionnaire.
Reviewer	Reviewing documents/materials to provide input, critique, suggestions, edits, etc.

Remuneration and Fair Market Value Project Activity Framework	
Type of Activity	**Definitions/Descriptors**
Facilitating Community Review	Dissemination of a document or materials to patients or patient community in order to receive feedback or approval.
Dissemination	Supporting communication, dissemination, and awareness-raising activities.
Pilot testing	Testing a data collection tool (e.g. interview guide, survey).
Research and data activities	
Data collection	Collecting or compiling of data from patients and/or patient community (e.g. surveys, registries).
Data Analysis	Analyzing or synthesizing data, including patient registries.
Interpretation	Interpreting or placing findings in context.
Publication co-authorship	Contribute to a journal article or manuscript.
Recruitment for a study or clinical trial	Recruiting participants for a study or clinical trial.
Mock Trial Participant	Walk through the experience of being part of a clinical trial according to the protocol.
Other	Any other engagement activity not listed above

Please note that this Activity Framework was adapted from the National Health Council's Patient Engagement Activities Framework: https://nationalhealthcouncil.org/wp-content/uploads/2020/06/NHC_FMV_Activities_List.pdf

Expertise Framework in review

The Expertise Framework provides a list of the potential expertise types required to perform a given patient engagement activity with a pharmaceutical company. It also captures and defines the different levels of expertise (i.e. basic, intermediate, expert).

When reviewing the framework below, please reflect on the following:

- How is this a useful Framework for selecting the **expertise** required for a specific activity?
- Note the **expertise** types included, their definitions, and how the levels of expertise are differentiated;
- Are there **expertise** types required for pharma-patient engagements missing?

Remuneration and FMV Project Expertise Framework to support FMV determination[3]					
Expertise		**Definition**	**Basic**	**Intermediate**	**Expert**
Personal framework	Personal experience and representativeness	Personal disease-specific experience and ability to share the views of people living with a disease	Direct experience of living with a disease, with a known risk for a diagnosis of the disease or providing care to someone living with the disease.	Direct and indirect personal experience with a disease. Demonstrated ability and experience representing and working with the disease-specific population.	Directly affected by and formally connected with others living with a disease. Recognized and acknowledged as a formal representative by patient organizations, institutional, and/or industry bodies
	Interaction and involvement with the patient community	Active and structured involvement in the patient / carer community in a specific area	Direct interaction and shared experience with other people living with the disease through informal networks.	Broad insights into the different needs of a specific patient community and frequent interaction with different community members regionally and/or internationally.	Experience in structured approaches and decision making when representing or interacting with people across an entire disease community (including subpopulations, and/or sub-groups). Demonstrated representation on a global or international level with healthcare decision-making bodies.
System expertise	Regulatory understanding, knowledge and expertise	Knowledge and understanding of regulatory processes related to evaluation, market authorization & safety	Basic knowledge of applicable regulatory assessments and approval processes.	Understanding and demonstrated experience with regulatory processes in medicines development and/or completion of a recognized relevant training program.	Advanced regulatory knowledge and recognized expertise on specific regulatory topics. Experience representing patients/carers as an official member of regulatory committees at national or international level. Experience as an advisor to industry or regulatory bodies.

[3] Adapted from: IMI PARADIGM. (2021). PARADIGM Patient Engagement Toolbox - Planning Patient Engagement: https://imi-paradigm.eu/petoolbox/

Remuneration and FMV Project Expertise Framework to support FMV determination[3]					
Expertise		**Definition**	**Basic**	**Intermediate**	**Expert**
System expertise	Market access, reimbursement and Health Technology Assessment (HTA) expertise	Knowledge of market access, reimbursement and Health Technology Assessment (HTA), e.g. evaluation process, access barriers and conditions	Basic knowledge of reimbursement and HTA processes, most likely at local and/or national level.	Understanding and experience with reimbursement and HTA methodology, data collection and submission and/or decision making. e.g. participation in market access / reimbursement committees or processes at national or international level.	Advanced understanding of and involvement in reimbursement systems and HTA, and expertise to help shape global access and HTA decision-making (e.g. contribution to publications).
	Health systems expertise	Knowledge and participation in healthcare decision making systems and processes	Basic understanding of the organization of healthcare delivery at a national level from public and private healthcare providers in the relevant field of activity.	Understanding of services in the healthcare system across countries in the relevant field of activity, understanding of metrics measuring healthcare systems performance (e.g. related to patient impact/patient care).	Advanced understanding of funding, organization, performance, and metrics of healthcare systems in different countries. Experience with initiatives involving various healthcare system stakeholders at the national or international level. Expertise in shaping healthcare decisions on a global scale (e.g. contribution to publications).

[3] Adapted from: IMI PARADIGM. (2021). PARADIGM Patient Engagement Toolbox - Planning Patient Engagement: https://imi-paradigm.eu/petoolbox/

Remuneration and FMV Project Expertise Framework to support FMV determination[3]					
Expertise		**Definition**	**Basic**	**Intermediate**	**Expert**
Method-ological expertise	Communication expertise	Navigation and delivery of purpose-driven communications and engagement practices.	Ability to communicate key perspectives, messages and topics to a defined audience or in a collaborative/ group setting. Knowledge of basic communication tools and their use (e.g. digital and social media, presentations)	Ability to adapt communication to different stakeholders and audiences and to appreciate different viewpoints. Confidence in public speaking and contributing to collaborative activities. Ability to convey ideas and information through different dissemination channels (e.g. articles, presentations, social media, interviews, etc.)	Advanced skills in public speaking and presenting to large and varied audiences. Experience contributing to international and multi-stakeholder collaborative activities, including facilitation and/or moderation. Experience defining multi-channel communication strategies and navigating social, political and cultural factors in a given field. Experience authoring peer-reviewed publications.
Scientific and medi-cal exper-tise	Disease-specific scientific and medical expertise	Knowledge about the disease, treatments, care and quality of life of those affected by the disease	Basic understanding of the disease, patient reported outcomes and available treatments.	Advanced understanding of the disease (e.g. treatment options, side-effects, complications, co-morbidities, clinical developments).	Expert level understanding of the disease. Including standards of care for different patient sub-populations, treatment pathways in different countries, clinical guidelines, medical and scientific advancements and/or co-authorship of peer-reviewed publications.

[3] Adapted from: IMI PARADIGM. (2021). PARADIGM Patient Engagement Toolbox - Planning Patient Engagement: https://imi-paradigm.eu/petoolbox/

Remuneration and FMV Project Expertise Framework to support FMV determination[3]					
Expertise		**Definition**	**Basic**	**Intermediate**	**Expert**
Scientific and medical expertise	Research and development expertise	Knowledge about the research process for the discovery of medicines and their development	Understanding of clinical / health research and ability to reflect the experiences of the study population. Understanding of unmet needs and disease burden.	Experience with and understanding of clinical trials and methodology, research protocols and consent forms, data collection, identification of patient-important themes in data, ethics considerations, and/ or completion of a recognized and relevant training program.	Advanced understanding of the medicines discovery and development process. Expert level understanding of clinical and health outcomes research and experience in evidence generation, co-authoring peer-reviewed publications, or co-designing clinical or health outcomes research.

Please note that this Expertise Framework was adapted from the IMI PARADIGM Patient engagement in medicines development: Recommendations on how to find the right match for the right patient engagement activity: https://imi-paradigm.eu/PEtoolbox/identification-of-patient-representatives.pdf

After you review both the Activity and Expertise Framework, share your inputs through this survey.

[3] Adapted from: IMI PARADIGM. (2021). PARADIGM Patient Engagement Toolbox - Planning Patient Engagement: https://imi-paradigm.eu/petoolbox/

Annex 1
About the project

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.

The Remuneration & Fair Market Value project is led by PFMD and is guided by a Steering Committee with representatives from EPF, EUPATI, Gilead, Global Heart Hub, Global Skin, GSK, MPE, Novartis, Patient Access Partnership, Servier, and WECAN. It builds on existing bodies of work in this area from the National Health Council (NHC)[3], The European Federation of Pharmaceutical Industries and Associations (EFPIA)[4], the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)[5], the Association of the British Pharmaceutical Industry (ABPI)[6], IMI-PARADIGM[7] and others.

PFMD membership and contributors are participating in a comprehensive co-creation effort involving key stakeholders to harmonize previous collaborative work and establish a trusted process to remunerate the patient community for interacting with the pharmaceutical industry through patient engagement activities.

More details and materials on the project are available in the Patient Engagement Management Suite.

[3] Patient Compensation Tools. Available at: https://nationalhealthcouncil.org/additional-resources/patient-compensation-tools/

[4] Working together with patients. Available at: https://www.efpia.eu/media/413114/workingtogetherwithpatients_patient-remuneration-principles.pdf

[5] Note for Guidance on Patient and Patient Organization Interactions. Available at: https://www.ifpma.org/wp-content/uploads/2020/07/NfG-Interactions-with-Patients_final_202001313-1.pdf

[6] Working with patients and patient organisations. Available at: https://www.abpi.org.uk/media/soxhy21z/abpi_workingwithpatients_webbrochure_v8.pdf

[7] PARAGIDM Patient Engagement Toolbox. Available at: https://imi-paradigm.eu/petoolbox/