Reasonable agreements between patient advocates and pharmaceutical companies

MPe Myeloma Patients Europe

WECAN Workgroup of European Cancer Patient Advocacy Networks

PATIENT FOCUSED MEDICINES DEVELOPMENT

Introduction and Objective

Collaboration between pharmaceutical companies and patient advocates often requires both parties to sign contracts covering various types of activities such as consultancy, collaborations, speaking engagements and advisory boards. These contracts define the terms and conditions of the engagements, covering such matters as confidentiality, intellectual property, copyright, data protection, compensation and other responsibilities of both parties.

The multi-stakeholder project “Reasonable agreements between patient advocates and pharmaceutical companies (RAPP)” is a Workgroup of European Cancer Patient Advocacy Networks (WECAN) project coordinated by Myeloma Patients Europe (MPE) in collaboration with Patient Focused Medicines Development (PFMD) and independent participation of 12 pharmaceutical companies respectively.

The project aims to streamline the legal framework between the patient community and the pharmaceutical industry, providing guidance in the content of legal contracts while ensuring maintaining reasonable safeguards for both contractual parties. The joint initiative has previously released the Guiding Principles on Reasonable Agreements between Patient Advocates and Pharmaceutical Companies and is now launching four Reference Agreements for different types of engagements (Advisory Boards, Collaborations, Speaking Engagements and Consultancy) with the Guiding Principles.

Project Partners and Workgroups

The legal agreements project took another step forward with the formal launch of the RAPP initiative. Interested parties provided legal experts to contribute to the project, representing individual pharmaceutical companies, WECAN members, MPE, PFMD members, the National Health Council and external experts.

To launch the project, two workgroups were established – the Drafting Workgroup and the Multi-Stakeholder Alignment Workgroup (MSAW). The Drafting Workgroup was comprised of seven patient advocates, two legal experts, a PFMD representative and three representatives from pharmaceutical companies. The MSAW represents all RAPP project partners with legal expertise from patient advocacy and pharmaceutical companies. `

Both workgroups provided multiple cycles of review and feedback throughout the project and ideas and advice on all documents drafted

Guiding Principles on Reasonable Agreements between Patient Advocates and Pharmaceutical Companies

The goal of the Guiding Principles is not only to simplify the terms of typical agreements, but also to prevent the addition of unnecessary clauses for either party and simplify the language of the agreements.

The Drafting Workgroup developed the Guiding Principles based on reviewing pre-existing contracts from pharmaceutical partners, highlighting problematic and reasonable clauses, as well as legal requirements and existing codes of practice. The document outlines rational, examples and Guiding Principles for key contractual clauses:

1. Confidentiality
2. Intellectual property
3. Recording of meetings
4. Data protection and use of personal data
5. Indemnification, remedies and conflict resolution
6. Financial compensation and reimbursement of expenses
7. Adverse event reporting
8. Independence and conflict of interest

Reference Agreements

Using the Guiding Principles as a basis, the RAPP project members worked with external legal experts to draft 4 Reference Agreements for use in varied patient community representative engagements, such as Advisory Boards, Collaborations, Speaking Engagements and Consultancy. The MSAW worked together to review and provide comments on the content and structure of the agreements, identifying areas of consensus, compromise and non-consensus.

These Reference Agreements are intended to constitute a resource for legal parties responsible for drafting agreements with patient advocates. The Reference Agreements require tailoring by a competent legal advisor according to the needs of the users and the context of use although flexibility has been safeguarded to ensure the templates can be used in the widest possible set of circumstances.

Adaptation on a case by case basis to comply with national legislation and language requirements is also needed. The Reference Agreements represent a sensible approach but are not substitute for taking appropriate legal advice on the documents in question.

Next Steps for the Project

The Guiding Principles and the corresponding Reference Agreements are now published and are available for use and consultation. All contributors will continue to collaborate to support all parties in the uptake and implementation of the RAPP tools and its dissemination across geographies, conditions and various communities and networks. This will include periodic teleconferences to discuss challenges in implementation and opportunities to leverage the multi-stakeholder group and maintain the project's ambitions to safeguard a constructive legal framework and contracting relationship between parties.

The patient community encourages pharmaceutical partners in the RAPP project and beyond to highlight this initiative and resources to local and European trade federations.

The RAPP project members are also partnering with IMI PARADIGM to develop a toolkit for patient advocates to aid in navigating legal parameters in engagements with the pharmaceutical industry, leveraging the **Guiding Principles** and the **Reference Agreements**.

Key Messages

Engagements with the industry and the patient community often lead to requiring a legal agreement.

The RAPP project was established to collaborate in the design of a balanced legal framework between patient advocates and pharmaceutical companies. The project is a collaboration between MPE, WECAN, PFMD, the National Health Council and 12 individual pharmaceutical companies respectively.

The fundamental objective of this collaborative project is to set a reasonable basis for contracts between pharmaceutical companies and patient advocates and their organisations.

The Guiding Principles and Reference Agreements are designed for constructive and productive collaboration between parties.

The nature of patient advocacy has unique legal considerations and legal agreements need to consider:

- The overall role and purpose of patient advocates and the environment required for it to operate effectively and efficiently, while at the same time acknowledging the need to protect the interest of pharmaceutical companies and patient advocates.
- The limited capacity of most patient advocates to deal with the workload, lack of legal expertise and the potential legal consequences arising from agreements signed with pharmaceutical companies.
- The diversity of relationships between the parties, not limited to classical consultancy that are covered by these agreements and should be reflected as such.

The process of developing the Guiding Principles and Reference Agreements has been a multi-stakeholder approach and a positive collaboration. Although consensus could not be reached across all stakeholders on certain legal parameters , a new level of understanding among parties has been established.

Pharmaceutical industry partners have begun incorporating the Guiding Principles in their internal legal framework and have committed to adapting company contract templates to be closely aligned with the Reference Agreements.

The MSAW is committed to maintaining project momentum, including sharing this work with local and European trade federations.

The MSAW will continue to meet regularly to support implementation of the Guiding Principles and Reference Agreements, working together to address challenges and leverage opportunities.

Social Media Messages

Channels	Messages
Twitter	Making #PatientEngagement feasible: @MyelomaEurope @WECANadvocate @PFMDwithPatient & 12 pharma companies have co-created 4 Reference Agreements for effective collaboration between #patient advocates & #Pharma companies. Find more: http://www.wecanadvocate.eu/rapp #patientengagement
Twitter	Four types of Reference Agreements for #PatientEngagement between #patient advocates and #pharma companies have been co-developed: Consultancy Agreement, Collaboration Agreement, Advisory Board Agreement, Speaker Agreement. Check them out now: http://www.wecanadvocate.eu/rapp
Twitter	8 Guiding Principles on Reasonable Legal Agreements in #PatientEngagement were co-created by legal experts & #patients advocates from @MyelomaEurope @WECANadvocate @PFMDwithPatient & industry representatives, providing the basis for 4 Reference Agreements. Check them out now: http://www.wecanadvocate.eu/rapp
LinkedIn	The "Reasonable agreements between patient advocates and pharmaceutical companies (RAPP)" project, a collaboration between Myeloma Patients Europe, WECAN, Patient Focused Medicines Development (PFMD) and 12 pharmaceutical companies, has released 4 Reference Agreements for effective #PatientEngagement of #patient advocates and #pharma companies: Consultancy agreement, Collaboration agreement, Advisory Board agreement, Speaker agreement. Discover more http://www.wecanadvocate.eu/rapp
Facebook	Engagements between the pharma industry and the patient community often require having a legal agreement in place. That's why the patient-led multi-stakeholder project "Reasonable agreements between patient advocates and pharmaceutical companies," co-developed 8 Guiding Principles and 4 Reference Agreements for productive #PatientEngagement. Check them out! http://www.wecanadvocate.eu/rapp