Reasonable Agreements between Patient Advocates and Pharmaceutical Companies

Project Summary

Introduction and Project Background

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. They typically also contain provisions, mandated by the pharmaceutical industry codes, designed to ensure an appropriate relationship between patient and pharmaceutical company. In the past, the complexity of these agreements has often been challenging for patient advocates to work with due to the contracts being long, difficult to understand and sometimes containing ambiguous clauses.

The patient-led multi-stakeholder project "Reasonable agreements between patient advocates and pharmaceutical companies (RAPP)" is a project of the Workgroup of European Cancer Patient Advocacy Networks (WECAN), coordinated by Myeloma Patients Europe (MPE) in collaboration with Patient Focused Medicines Development (PFMD) and independent participation of 12 pharmaceutical companies respectively. Altogether, the project represents 35 patient organisations, 16 pharmaceutical companies and 7 other project partners.

The project aims to streamline the legal framework between the patient community and the pharmaceutical industry, providing guidance for the content of legal contracts while maintaining reasonable safeguards for both contractual parties. The joint initiative has collectively contributed to and 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) that have been developed in alignment with the Guiding Principles.

Project Methodology

Survey of Patient Advocates

In 2016, MPE collaborated with several WECAN partners and patient advocates to develop a survey to understand perspectives and experiences of patient advocates based on consultancy, collaboration, advisory board and speaker agreements with the pharmaceutical industry. The survey was completed by more than 80 European patient advocates and highlighted pertinent issues in the contracting process. Some insights gathered include:

- More than half of the patient advocates surveyed understood only **some, a few or none** of the clauses in the contracts they received.
- Around 20% of advocates rarely or never read all legal agreements in detail before signing them due to reasons such as lack of legal support, time constraints, or confusing terms.

- The length of the contracts was identified as a hurdle for advocates, and survey respondents reported they can spend almost five hours in negotiating, reading, printing, scanning and sending a contract.
- Several clauses included in contracts were highlighted as unreasonable or unfair from the patient point of view.

The striking results of the survey led to the establishment of the RAPP project and the collaborative multi-stakeholder approach to develop consensus on how to tackle these issues while safeguarding the independence and interests of all parties involved.

Establishing Project Partners and Workgroups

Following the survey of patient advocates, 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. Legal experts from the following companies were involved: AMGEN, Bayer, Bristol-Myers Squibb, Celgene, Janssen, Merck MSD, Novartis, Novo Nordisk, Pfizer, Roche, Servier, Takeda.

Guiding Principles on Reasonable Agreements between Patient Advocates and Pharmaceutical Companies

A series of Guiding Principles were developed via a collaborative approach between the involved parties. The Principles aim to serve as a baseline for the development of contracts and contract templates for patient advocate engagements with industry to ensure reasonable protection for signing parties and to provide guidance to patient advocates whenever they need to review a legal agreement. 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 to simplify the language of the agreements.

The Drafting Workgroup developed the Guiding Principles by 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 rationale, examples and guiding principles for key contractual clauses, including:

- Confidentiality
- Intellectual property
- Recording of meetings
- Data protection and use of personal data
- Indemnification, remedies and conflict resolution
- Financial compensation and reimbursement of expenses

- Adverse event reporting
- Independence and conflict of interest

The consensus draft of the Guiding Principles was reviewed extensively in multiple cycles throughout 2017-2018 with the MSAW. Consensus was reached on most, but not all items, concepts or principles. Areas of non-consensus are marked accordingly in the final publication.

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 a substitute for taking appropriate legal advice on the documents in question.

Next steps for the RAPP project

The Guiding Principles and the corresponding Reference Agreements are now published and are available for use and consultation. Contributors will continue to collaborate to support all parties in the uptake and implementation of the RAPP tools and their 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 strongly 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.