

Principles on Contracting between Patient Advocates and Pharmaceutical Companies



Sponsors include Allergan, Biogen, Boehringer Ingelheim, Celgene, Grifols, Patient Focused Medicines Development, Sangamo, Servier, UCB, Merck, Novartis, Johnson & Johnson, Pfizer, People-Centered Research Foundation



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1. INTRODUCTION

Collaboration between pharmaceutical companies and patients, caregivers, or patient advocates, often requires both parties to sign contracts that define the terms and conditions of the collaboration, covering such matters as confidentiality, intellectual property, copyright, data protection, compensation, reimbursement, and other responsibilities of one or both parties.

However, these agreements provided to patients e.g., for consultancy, collaboration, advisory boards, or speaking opportunities are often too long, and are difficult to understand. They contain ambiguous clauses, or terms that may conflict with the very nature of patient engagement and advocacy. They may even put the signer at legal risk.

This document was originally developed as part of a project led by Myeloma Patients Europe on behalf of the Workgroup of European Cancer Patient Advocacy Networks (WECAN), and in close partnership with Patient Focused Medicine Development (PFMD). With the permission of these organizations, the National Health Council (NHC) adapted the original document for use in the United States. We acknowledge the foundational work of these three organizations and the National Health Council Fair Market Value Steering and Review committees, which assisted in document adaptation.

The original multi-stakeholder project, “Reasonable agreements between patient advocates and pharmaceutical companies” aimed to make legal agreements between both parties easier to understand and more acceptable while providing adequate protection and rules for both sides. To do so, these guiding principles were developed as a foundation for the development of contracts and contract templates as well as a toolbox for patient advocates and companies.

The work builds on an extensive consensus process by a multi-stakeholder workgroup of patient advocates and legal experts from different pharmaceutical companies, supported by independent legal experts from academia and a legal firm. The NHC also used a multi-stakeholder consensus and relied on independent legal review by a law firm.

How to read this document:

- Each section covers rationale, examples, and guiding principles for legal agreements between pharmaceutical companies and patients.
- The principles listed are a result of consensus work between patient and pharmaceutical company representatives.
- Pharmaceutical companies and patient advocates reached multi-stakeholder consensus on most, but not all items, concepts, or principles.
- **For the purpose of these principles, we use the term “patients” in a broader sense for individual patients, caregivers, and patient organization representatives. You can find the definitions in the [NHC Fair-Market Value Calculator Glossary of Terms](#).**



2. OVERALL PRINCIPLES

- The goal in establishing these guiding principles is to reach a better balance between the parties, to guide patient advocates whenever they need to review a legal agreement, and to develop legal agreements and adaptable templates that reasonably protect both parties.

These following basic considerations should be taken into account when drafting any contract between patient advocates and pharmaceutical companies:

- The limited capacity of most patients 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 is usually covered by these agreements.
- The goal of these guiding principles is not only to boil down the terms of the agreements to the minimum, but also to prevent the add-on of unnecessary clauses generating unnecessary risk for one of the parties, as well as to simplify the language of the agreements.
 - These guiding principles will apply to agreements between pharmaceutical companies and patient advocates.
 - The specific circumstances of the contractual party representing the patient side should be considered when formulating the terms of an agreement.

3. CONFIDENTIALITY

RATIONALE - Why do we need confidentiality clauses?

- Sensitive, non-public information of both parties needs to be protected from disclosure to third parties.
- This is not only about confidentiality of corporate information, but about confidential and competitive information of both partners (e.g., a policy campaign, a service, a tool).
- Any confidentiality clause needs to reasonably take into account:
 - that corporate individuals might forget to earmark confidential information with a “confidential” tag, while commercially sensitive information needs to be protected in the safe environment of a collaboration and
 - that the core task of patient is the spreading of knowledge, the sharing of information with their constituency, and their need for transparency and accountability towards the public. Anything stopping them from providing their support, advocacy, and policy work is not acceptable.

EXAMPLES of confidential information of either contractual party:

- Commercially sensitive information about products or services of the company, e.g., product, financial, or regulatory information
- Strategic plans or processes
- Unpublished scientific data
- Planned public campaigns or policy actions



- Draft project plans or concepts
- Personal data, patient data

GUIDING PRINCIPLES for regulating confidential information:

- **Definition of confidential information:** "Confidential Information" includes all non-public information, written or oral, disclosed or made available to either party, directly or indirectly, by or on behalf of, one party or its affiliates through any means of communication or observation.
- **Disclosure of confidential information requires consent:** Neither party should disclose confidential information, provided by the other party, without getting written consent beforehand. Patients should not disclose any confidential information provided by the company, and the company should not disclose any confidential information provided by the patient, unless they have written consent to do so.
- **Provide justification for requesting confidentiality:** Both parties should identify the type of information that should be confidential, the purpose of the confidentiality, the way they will exchange the confidential information, and its use.
- **Public information is no longer confidential.** General public knowledge, or any confidential information that becomes public knowledge through no breach of the recipient, or if it has been made public by other parties without any obvious evidence of a breach of confidentiality.
- **Ensure deletion of confidential information:** Once the contractual relationship is over or whenever the disclosing party requires it, the party that received confidential information must delete the information, and upon request, confirm the deletion to the other party.
- **Legal requirements and disclosure obligations may override confidentiality:** Confidentiality cannot be required where disclosure is required by law, by governmental authorities, or by applicable codes of practice (e.g., disclosure of transfer of value, or disclosure of the general fact of a contractual relationship).

4. INTELLECTUAL PROPERTY

RATIONALE - Why do we need intellectual property clauses?

- Intellectual property (IP) refers to the protection of creations of the mind, which have both a moral and a commercial value. IP enables people to earn recognition, added value or improved services from their ideas or from what they create.
- IP gives both the pharmaceutical company and the patient the opportunity to further develop the topic independently after a collaboration, based on the ideas and concepts brought in and generated in such meetings (described as "collaborative work"), either jointly or separately, and with competing organizations.
- IP gives the pharmaceutical company the rights to use or leverage all work on its commercial products and services and related activities (described hereto as "consultancy work"), allowing for competitive advantage.
- IP gives the patient the rights to exploit the results of work in initiatives and services that may arise as a result of the collaboration (described here to as "collaborative work") or independently of the collaboration.



- Background IP, like information, projects, and work owned by each party prior to the collaboration, remains the property of that party, so that pre-existing IP is not transferred or lost.
- Generally, the content or results of a meeting are not commercially sensitive and neither do they relate to any commercial product or service. Therefore, patent or trademark clauses only need to be introduced in exceptional cases.
- IP covers not only personal data but also third-party data, defined as data brought into the collaboration by either party or generated within the collaboration or by either party.
- Third-party data communication can be:
 - Internal (within or between either of the parties) or
 - External (to third parties, e.g., general public, media, public bodies, or other third parties).
- Codes and transparency rules may require the disclosure of the collaboration and the involved parties.
- Third-party data and material brought in by any party can be used in the work results of the collaboration, while those referencing third-party material cannot guarantee or sub-license re-use.

EXAMPLES of intellectual property:

- **Consultancy work:** Advice provided on company-sponsored clinical trial protocols, regulatory documents, or product information about the company's products (e.g., drugs), strategic initiatives, and other commercially sensitive projects.
- **Collaborative work:** Concepts and services jointly developed during the term of the agreement, e.g., reports, advice, workshop agendas, patient information materials, or other documents.
- **Presentations, projects, concepts, documents** developed by the patient / patient organization or the company and then presented at the collaborative meeting.
- **Third-party material:** Illustrations or slides of third parties used in a presentation in a workshop or advisory board.
- **Logos of organizations or companies.**

GUIDING PRINCIPLES for regulating intellectual property:

- **Applicable law may prescribe definition of IP terms.** Depending on the applicable law of the agreement, the IP section of an agreement may be required to describe the rights assigned (reproduction, distribution, etc.), the territory, the duration, the target of the assignment, and the amount to be paid (or not).
- **IP on consultancy or collaborative work on specific company products should belong to the company:** For all consultancy work of patient advocates on commercially sensitive products or services of the pharmaceutical company, the pharmaceutical company will receive the exclusive, transferable right of use, so it can drive forward and improve the development of its products and services. The parties may discuss the use of that IP by the patient or patient organization under a license if there is a need to use that IP.
- **IP resulting from collaborative work unrelated to a specific product of the company should be agreed on a case-by-case basis:** This should be based on the principles of (i) purpose of the collaboration and of the co-created material; (ii) which



party has brought which resources to the collaboration; (iii) what are the outcomes; and (iv) how do the parties want to use and leverage them.

- **Authorship rules apply for publications:** Whenever the outcome is a publication, authorship rules apply (i.e., International Committee of Medical Journal Editors (ICMJE)).
- **Background IP remains with the owner:** All information, data, and work owned by each party prior to the collaboration or engagement should remain the property of that party.
- **Rights of third-party material need to be clear and cannot be transferred:** Third-party material can be used in the collaboration if the third party's terms allow this. It is the responsibility of the party bringing the third party's material to the collaboration to ensure that it has the proper rights to do so. No rights on any third-party material can be transferred to the other party within the agreement. Third-party material used in the meeting cannot be freely used.
- **Use of logos requires written consent:** Prior, written consent is needed by both parties to use their respective logos. Each party should indicate how their logo should be used according to the guidelines provided by each organization or company.

5. RECORDINGS OF MEETINGS

RATIONALE - Why do we need clauses about recordings?

- Recordings of a meeting and individual participants might be made for the purpose of compiling minutes or a report of the meeting for internal or external use.

EXAMPLES

- Minutes, documents, quotes, photos, or audio-visual recordings relating to joint meetings, as well as summary of meeting outcomes and concepts. Presentations held by participants of the meeting.

GUIDING PRINCIPLES

- **Agree about use of recordings prior to meeting:** Ideally, at the time of the invitation, it should be disclosed if the meeting will be recorded. The parties should agree about the use of recordings, the minutes, and/or the meeting report during the planning stage of any meeting. There should be clarity on who will have access to the recording and whether deliverables will attribute quotes to specific individuals.
- **Without agreement, internal use of recordings only is a given. Any external use requires prior consent:** Unless agreed otherwise, distribution and use of presentations and recordings is allowed by both parties for internal purposes. External use of these presentations and recordings requires prior consent to protect both intellectual property and public credibility (see Intellectual Property Section).

6. DATA PROTECTION AND USE OF PERSONAL DATA

RATIONALE - Why do we need data protection clauses?

- Personal data of patients or patient advocates needs to be protected in order to avoid any misuse of the information.



- Data protection controls how personal information is used by the company and a patient organization and controls its use to safeguard information about individuals and their privacy.
- Data protection guards patients from having their medical condition disclosed to the public, which may not be in the public domain outside of closed-door meetings.
- Data protection guards the credibility of a patient in a public context.
- Data protection ensures all external data, e.g., data relating to individuals raised via surveys, in meetings, or in clinical trials, are used for limited, specifically stated purposes, and in a way that is adequate, relevant, and not excessive.
- Data protection ensures data are kept for no longer than is absolutely necessary.

EXAMPLES of personal data and use of data

- Personal data means any information relating to an identifiable person, including patients, patient advocates, or any other person involved (e.g., name, age, position, address, affiliation with organizations, medical condition, or other personal details).
- Third party data means any data acquired from a source other than the parties signing the agreement. It can be confidential or public data.
- This data could be used in different contexts:
 - Names or quotes used for internal reporting purposes of the collaborative partners: recordings of the meeting, meeting notes, or minutes;
 - Names or quotes of individuals in their patient or patient advocacy role disclosed in internal or external reports, on websites, campaigns, social media channels, or any other communication means other than reporting from the meeting;
 - Publications on online or offline media in the form of text, audio, or video;
 - Patient data in reported surveys or clinical trials, e.g., about patient preferences, quality of life, or any other clinical topic;
 - Textual information, video, audio, photography, podcast, website, or any other means;
 - Companies' or organizations' names; and
 - Names of involved persons.

GUIDING PRINCIPLES for regulating data protection

- **Personal data is confidential by default:** Personal data of individuals representing either party will be kept confidential. This data may only be used by the other party if required by law or with prior written consent by the individual in question.
- **Agree on good reasons for data disclosure:** In the case that the disclosure of personal data was required to deliver on the defined objectives, there must be a separate clause in the contract, clearly stating which data needs to be released and what the purpose of the disclosure is.
- **Allow sharing of data with affiliates and involved service providers:** The contracts should allow the company to share or transfer personal data to its affiliates. (Contracts should also cover that any such transfer is allowed in and to countries outside the European Economic Area (EEA) under an appropriate protection standard rule like EU-US Privacy Shield Framework¹.)

¹ Welcome to the Privacy Shield. (n.d.). Retrieved from <https://www.privacyshield.gov/welcome>



- **Respect right to withdraw consent:** The owner of the data is entitled to object, access, or request correction or deletion, of his or her personal data anytime. Even if prior consent was given, once the information has been made public, its owner will have the right to have it deleted, and the data source should be removed as per applicable laws and regulations.
- **Data protection rules should comply with applicable privacy laws:** This relates to the collection, use, disclosure, and storage of personal information.
- **Ensure data protection also in countries with lower privacy standards:** If personal data is used in a country with low standards of protection, the company must ensure that an adequate level of protection is applied for the rights of the data subject in relation to the processing of personal data.

7. INDEMNIFICATION, REMEDIES, AND CONFLICT RESOLUTION

RATIONALE - Why do we need indemnification and jurisdiction clauses?

- Indemnification clauses seek to define financial responsibility for specific types of damages, claims, or losses. They aim to ensure that liability of both parties will apply.
- Any remedies or liability clauses should take into account that their execution in a dispute would certainly bring a patient into bankruptcy.
- It is also very unlikely that any pharmaceutical company will ever make use of such an indemnification or liability clause or would achieve a realistic remedy.
- Patients usually do not have sufficient financial and human resources, as well as capabilities, to have international liability insurance for activities covered in such a collaboration agreement. In addition, the volume of a collaboration would be disproportionate to the costs and administrative burden of liability insurance.
- Legal claims between patients and pharmaceutical companies are extremely unlikely to happen. To ensure a fair procedure, the applicable law and jurisdiction should be the one at the defendant's domicile. In any case, the signed legal agreement should require the parties to Alternative Resolution Clauses (e.g., mediation) before initiating legal action.
- In practice, such situations are rare, but in extreme cases, they may arise. However, no case is yet known where liability cases were ever filed by a pharmaceutical company against a patient organization on the basis of a collaboration agreement between such parties.

EXAMPLES of indemnification and remedies

- Misconduct or violation of any clause, which can include disclosure of confidential information, failure to deliver on the contract, a misuse of the information received, or any other kind of conduct that is considered as a major breach of contract.

GUIDING PRINCIPLES

- **Limit liability to a reasonable level.** A liability and indemnification clause for the patient expert or patient organization, if required at all, should only cover extreme cases of gross misconduct and should be proportionate to the nature of the collaboration. In case an indemnification clause was requested by either party, it



should be limited to a maximum of twice the financial volume of the agreement, except for physical injuries.

- **Do not require liability insurance.** Liability insurance by patients should not be required in such a collaboration agreement. If liability insurance is required, it is suggested to check whether liability insurance of the patient could be covered by the company.
- **Define terms for mediation.** A mediation clause should be added in case a dispute arises out of - or relates to - the agreement. This clause should come into force if the dispute is not settled amicably through negotiation or via another neutral third party and shall commit the parties to try in good faith to settle the dispute by mediation.
- **Jurisdiction of defendant should apply.** In case no amicable or mediated solution is possible, in order to discourage legal action and protect the defendant, the jurisdiction, and applicable law chosen should be the one of the defendant's domicile.

8. FINANCIAL COMPENSATION AND REIMBURSEMENT OF EXPENSES

RATIONALE - Why do we need financial compensation and travel reimbursement clauses?

- Patient advocates deserve reasonable financial compensation for their time and contribution when acting in advisory roles, consultancy, speaking roles, or other collaborative work with third-party organizations or institutions.
- In most legal agreements, financial compensation is offered in exchange for contributing with time, ideas, or other means by patient advocates.
- The financial contribution is based on a company and expertise-related "fair market value" and subject to local laws and regulations. This should consider individual expertise, training and education, total amount of time invested, complexity of tasks, country of origin, and other contributing factors.
- Some countries may have established guiding principles and regulations that govern the financial compensation paid to patients.

To learn more about compensation, please see the National Health Council's Compensation Principles, [here](#).

9. ADVERSE EVENT REPORTING

RATIONALE - Do we really need adverse event reporting clauses?

- Regulatory provisions require pharmaceutical companies and their employees and contractors to report any adverse events ("AE") and serious adverse events ("SAE") to regulatory authorities as soon as they become aware. Employees of pharmaceutical companies and contractors usually receive training on how to report AE/SAE.
- Legal agreements from pharmaceutical companies often require consultants to notify the company in writing of any adverse event occurring relating to the company's products as soon as possible within one business day after becoming aware.
- However, in practice, given the nature of an independent advisory-, speaker-, or consultancy role, these obligations are typically impossible for patients and patient



organizations to fulfil, given they are neither set up, nor trained, nor required to fulfil pharmacovigilance requirements.

EXAMPLES of adverse-event reporting

- “The Consultant will inform the company within twenty-four (24) hours of becoming aware of any adverse event.”
- “The Consultant will cooperate with the company to enable the company to comply with applicable laws and regulations.”

GUIDING PRINCIPLES for regulating adverse event reporting

- **The company remains responsible for adverse event reporting.** Should any AE/SAE be uncovered in the collaborative work, it is up to the company to follow applicable laws and regulations to report those AE/SAE to the respective bodies.
- **An agreement between pharmaceutical companies and patients should not require the latter to do adverse event reporting, or it should be limited strictly to the adverse events detected within the collaborative work.** Clauses requiring patients to report AE/SAE should generally be avoided. If applicable at all, reporting should be restricted only to AE/SAE detected within the collaborative work covered by the agreement. Then, the contract should provide a detailed explanation of why and how this reporting should realistically be done. The clause should also specify the period of time in which this obligation is required.

10. INDEPENDENCE AND CONFLICT OF INTEREST

RATIONALE – Why do we need independence and conflict of interest clauses?

- Patients promote the interest of their constituencies, usually patients and caregivers, and the broader patient community.
- Patient advocates and pharmaceutical companies may have similar interests regarding topics that can affect patients’ lives in areas such as research, treatment, care, and access.
- Interactions between patients and pharmaceutical companies will be done in a way that ensures that the decision making of the patient is respected and not influenced by the pharmaceutical company.

EXAMPLES of independence and conflict of interest

- Any incentive or reward of any type that would influence a patient’s decision making, opinions, or statements about any drug or diagnostic tool, among others.

GUIDING PRINCIPLES for regulating independence and conflict of interest

- **Respect the independence and autonomy of the patient.** The pharmaceutical company respects the mission, autonomy, and independence of patients, and does not seek to exert any improper influence on their objectives, activities, or decisions. Specifically, any decision-making by the patient should be respected and not influenced by the pharmaceutical company.
- **Safeguard the independence of patients by avoiding and declaring potential conflicts of interest.** Collaborative work and/or remuneration shall not constitute in



any way an inducement to, or reward for, recommending or taking any decisions favorable to any products or services of the company or its affiliates. An initial declaration of interest may underline that the agreements made between the two parties are conducted independently from any business transactions and decisions in relation to the supply or purchase of goods or services from the company. Both parties are obliged to report to the other party any change in circumstances during the contract that can affect the absence of any conflict of interest.

- **Avoid exclusivity clauses.** To respect the independence of patients, the pharmaceutical company should not request nor expect exclusivity from patient advocates.
- **Refer to applicable Codes and Guidelines.** To keep legal agreements short, they may refer to any Good Practices or Code of conduct such as the [“Code of Practice between Patients’ Organisations and the Healthcare Industry”](#), the [“EFPIA code of practice on relationships between the pharmaceutical industry and patient organisations”](#), or the [“PhRMA Principles on Interactions with Patient Organizations”](#). Some agreements may also refer to local legislation.

11. GLOSSARY

The glossary contains an explanation of some legal terms of typical agreements:

- **Affiliate:** Organization, subsidiary, or other business that is formally attached to, controlled by, or legally connected to a contractual partner.
- **Background Intellectual Property:** Intellectual property that is under control of either party and existed prior to a contractual agreement or is being developed independently of the activities of this agreement.
- **Collaborative work:** It implies two or more people working together on a project, who pursue research or other common objectives. It specifies the intent of the parties to share data, research materials and facilities, and to publish the results of the project.
- **Consultancy work:** Work done by a consultancy or consultant hired by pharmaceutical companies to provide professional advice and support, and may also be contracted to produce documents, or other deliverables. In exchange for the work a fee may be paid.
- **Confidential information:** Sensitive, non-public information of a contractual partner, written or oral, that needs to be protected from being made available to third parties through any means of communication or observation. Confidential information may include, but is not limited to, personal data, other data, know-how, processes, documents, designs, photographs, plans, graphs, drawings, specifications, software and associated information, source or object codes, algorithms, financial models, business plans and marketing plans, reports, customer lists, pricing information, results, inventions, ideas, and other knowledge.



- **Intellectual property rights:** Rights, e.g., on patents, trademarks, inventions, copyrights, data, software, designs, concepts, trade secrets, know-how, and all other such rights, whether registered or unregistered and in any jurisdiction.
- **Patient:** A person living with a condition or with a known risk for getting a condition who can speak to their individual/personal experiences with the disease and related treatments, if applicable. May or may not be affiliated with a patient organization but is not speaking on behalf of a patient organization.
- **Caregiver:** A person that can speak to their individual/personal experience as a nonprofessional, non-paid caregiver of someone with a condition. This person may or may not also be a family member. When it is a family member, this person may be referred to as a “family caregiver.”
- **Family Member:** A person who is a family member, related to the individual with the illness (e.g., sibling, parent), who can speak to their personal experience living with someone with the condition.
- **Patient Group Representative:** An individual employed by a patient organization, typically a non-profit group that focuses on a condition and/or advocates on behalf of patients.
- **The parties:** the pharmaceutical company and patient.
- **Third-party data:** Data acquired from a source other than the parties of the agreement and their affiliates.

12. PARTNERS AND AUTHORING PROCESS

This document was originally developed by Myeloma Patients Europe, WECAN, and Patient Focused Medicines Development. With the permission of these organizations, the National Health Council adapted the document for use in the United States. We acknowledge the NHC Steering and Review committees, which assisted in adapting the document.

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The **Drafting Work Group**, composed of legal experts from Myeloma Patients Europe, WECAN, PFMD, and experts of pharmaceutical companies, developed these Guiding Principles based on community feedback, examples of problematic or reasonable clauses, as well as legal requirements and existing codes of practice. The following persons were members of the Drafting Work Group during this phase of the project:

- Ananda Plate (MPE), Patient advocate, lawyer, WECAN chair and project coordinator;
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- Nicholas Brooke (PFMD), Patient Engagement advocate & PFMD Executive Director;
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The Multi-Stakeholder Alignment Work Group

The Multi-Stakeholder Alignment Work Group, composed of representatives and legal experts of pharmaceutical companies as well as additional patient advocates, provided input into the drafting process, discussed areas of compromise and no consensus, and acted as reviewers in multiple review cycles throughout 2017-2018. The company representatives elected three individuals to join the Drafting Group. The following companies and patient advocates were involved and supported the final Guiding Principles:



AMGEN, Bayer, Bristol-Myers Squibb, Celgene, Janssen, MSD, Novartis, Novo Nordisk, Pfizer, Roche, Servier, Takeda

In addition to the aforementioned patient advocates contributing to the drafting work group, the following additional patient advocates were involved in the multi-stakeholder work group: Guy Bouguet (Lymphoma Coalition Europe) and Marc Boutin (National Health Council).