



WECAN

Workgroup of European
Cancer Patient Advocacy Networks



**PATIENT FOCUSED
MEDICINES DEVELOPMENT**

Compliance and (reasonable) legal agreements

**MPE Annual General Meeting
Munich, 16 March 2019
Jan Geissler, WECAN**

Objectives of this session

- Provide patient perspective on the challenges of legal agreements between patient advocates and pharmaceutical companies
- Tell you about the WECAN's „Reasonable Legal Agreements“ project
- Provide you with a practical example

Basic rules for interactions of industry with patient advocates



WE CAN
Workgroup of European
Cancer Patient Advocacy Networks



PATIENT FOCUSED
MEDICINES DEVELOPMENT

MPe
Myeloma
Patients
Europe

The interaction...

- serves a **healthcare interest** or is considered to be normal in legal transactions.
- **does not lead to being directly or indirectly influenced** to promote the prescription, supply or use of medicines
- does not extend beyond what is **necessary** to achieve the intended goals
- takes place in an honest and transparent manner whereby the **nature, object and scope** are laid down beforehand in a written agreement
- does not affect the **independence, reliability and credibility**
- limit the **amount of reimbursement and compensation** to what is strictly necessary; does not go beyond comparable compensation of healthcare professionals.

Source: CGR (NL)

Interacting while ensuring compliance to rules



- Pharmaceutical companies can **support** the work of patient organisations with financial support
- Pharmaceutical companies can also **interact** with patient advocates (users) or healthcare professionals to incorporate their perspective in their work, e.g.
 - to act as expert advisors (advisory boards, consultancy)
 - to speak at meetings
 - to contribute to projects
- **Policies, standard operating procedures (SOP) and working practices** regulate that interaction, supervised by their "compliance" departments.

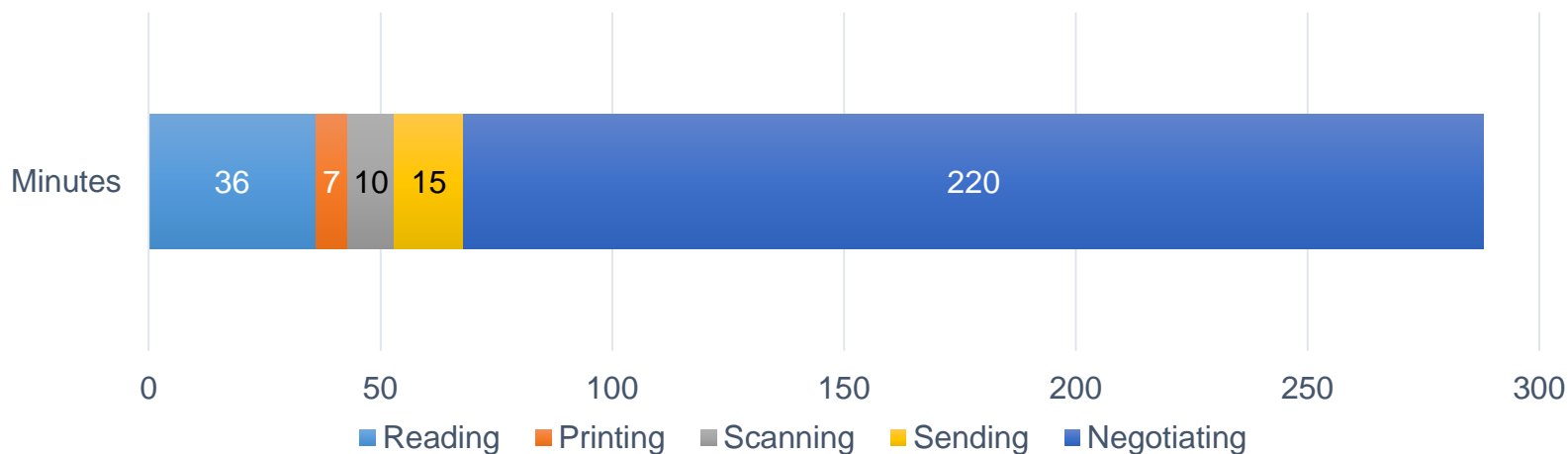
What's the issue about the contracts?

- **Contracts aim to protect the independence and ensure transparency by defining the rights and obligations, e.g. ownership of results, confidentiality, compensation, public disclosure etc.**
- **Contracts are often too long and difficult to understand, and contain ambiguous clauses or terms that are in conflict with the nature of patient advocacy. They may even put the patient advocate at legal risk**

WECAN Survey of patient advocates on legal agreements

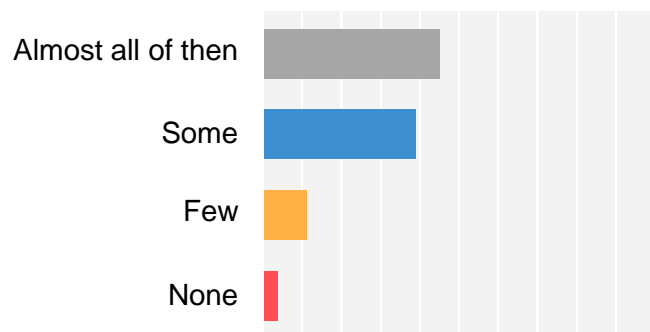
- 81% said all contracts are unreasonably extensive in length (6 pages or more)
- Patient advocates invest on average almost 5 hours into reading negotiating and processing each contract

How much time (in minutes) do you usually invest for each agreement?



WECAN Survey of patient advocates on legal agreements

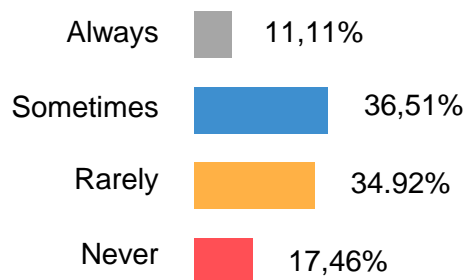
54% of patient advocates only understand some, few or none of the contracts they receive



~20% rarely or never read all legal agreements in detail before signing because:

- no legal support,
- no time to check contracts,
- trusting pharmaceutical companies,
- other reasons such as the length of the contract, or the confusing terms used

If you tried to change unreasonable clauses, did the companies agree to change these clauses to your satisfaction?



Main issues identified in WECAN survey on legal agreements



The contracts provided to patient advocates contain ambiguous clauses or terms that are in conflict with the very nature of patient advocacy.

Which clauses are usually found in contracts?

Protecting the company against litigation or

Guaranteeing company use of third-party

Transferring ownership and intellectual property

Inappropriate financial terms (e.g. paid hours)

Confidentiality clauses (everything)

Data protection, privacy

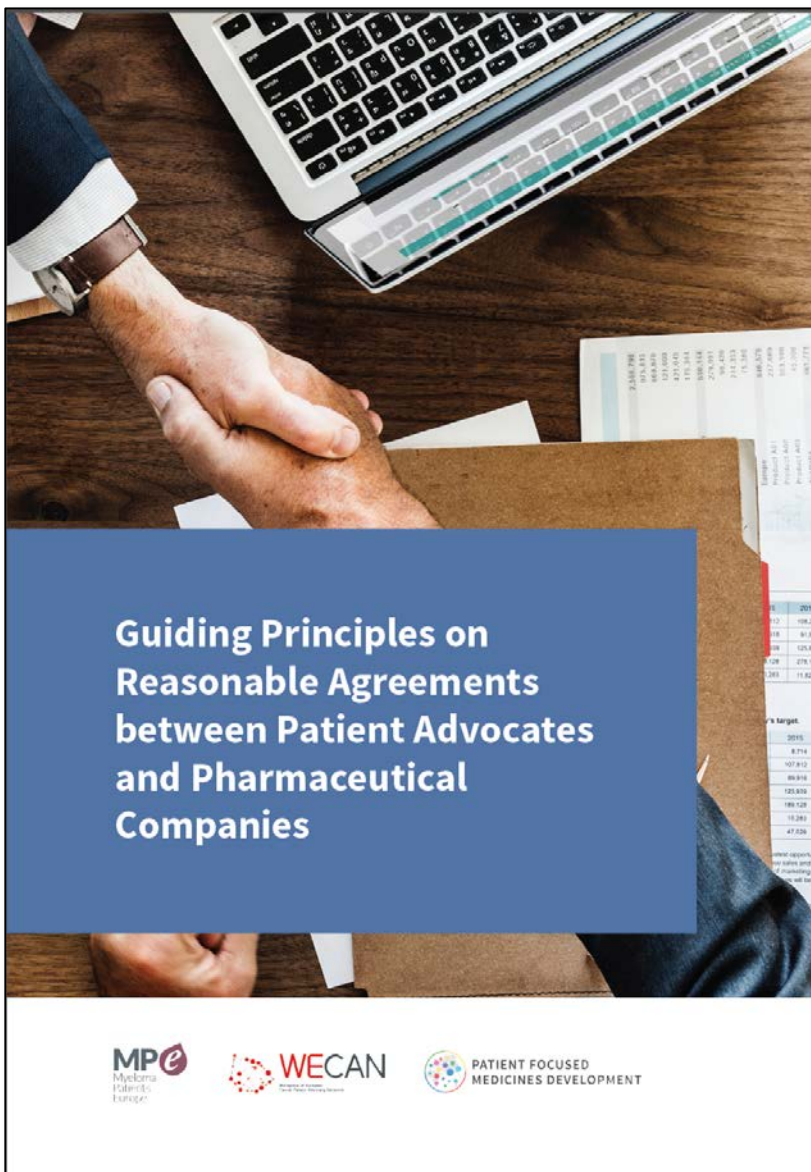
Terms of travel reimbursement (e.g. through

Inappropriate activities (e.g. adverse events)

Destruction and deletion of confidential

Non-

- Litigation will ruin the organization or individual if ever executed
- Losing the rights on your own ideas and contributions
- Time invested in work not fairly reflected
- Confidentiality of non-sensitive work may block patient advocacy work
- Unfair travel conditions for busy patient advocates and for frail individuals
- Unlimited use of photos, quotes and recordings put credibility at risk



Guiding Principles document finalized on 16 Oct 2018, ratified by WECAN on 21 Oct 2018 and PFMD on 25 Oct 2018

- Re-establish contractual balance between patient advocates and industry
- Allowing patient organisations to operate in their role and purpose while protecting the pharmaceutical companies from reasonable risk
- Provide guiding principles for reasonable legal agreements as a "contract checklist" for both sides

Table of contents

1. How to read this document	4
2. Overall principles	5
3. Confidentiality	6
4. Intellectual property	10
5. Recordings of meetings	15
6. Data protection and use of personal data	17
7. Indemnification, remedies and conflict resolution	21
8. Financial compensation and reimbursement of expenses	24
9. Adverse event reporting	28
10. Independence and conflict of interest	31
11. Glossary	34
12. Partners and authoring process	36



All sections have 3 parts:

1. Rationale
2. Examples
3. Guiding principles

Who was involved?

Drafting group



- Ananda Plate (MPE, project lead)
- Ana Vallejo (MPE)
- Šarunas Narbutas (POLA)
- Gordon Oliver (IBTA)
- Jan Geissler (CMLAN)
- Kathy Oliver (IBTA)

- Nicholas Brooke (PFMD)

Legal experts

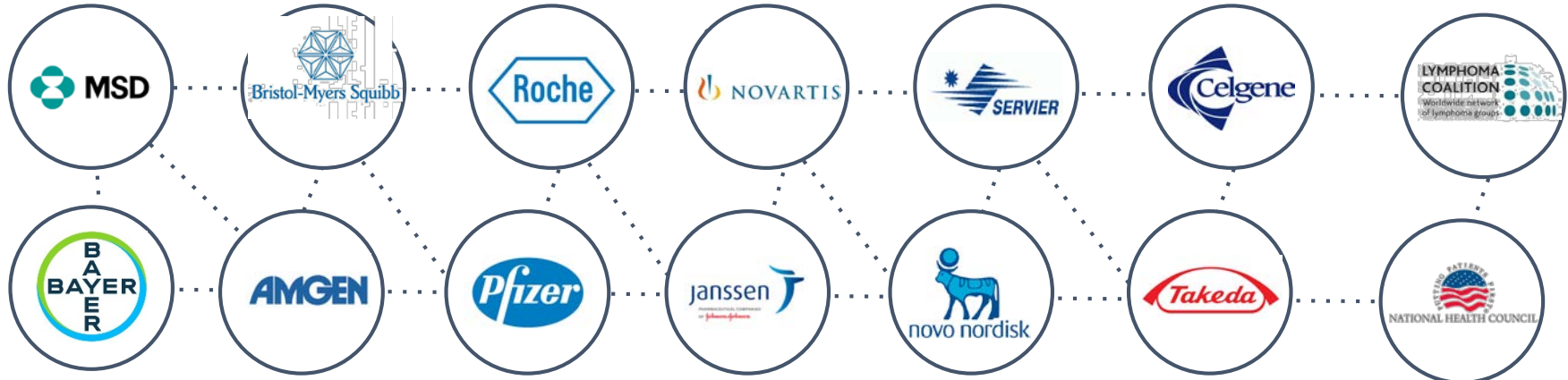
- Jean-Francois Germain (Fieldfisher)
- Imma Barral (University of Barcelona)

3 pharmaceutical companies' representatives

- Andrea Herrmann (Takeda)
- Jordane Fura Cosse (Novartis) – now replaced by Gregor von Arx
- Virginie Vassart (Merck MSD)



Multi-stakeholder Alignment Workgroup (MSAW)



Case study



- You are invited by a pharma company as a speaker at a company meeting on 4 September 2019 to present your ideas about **"The patient perspective on mobile apps to improve adherence to therapy"** and to participate in a panel discussion.
 - Your presentation will contain a lot of ideas on functionality, screenshots of what a good app would look like.
 - The panel discussion with other patient advocates aims to brainstorm and discuss future concepts.

- Meeting schedule:

3 September 2019	4 September 2019
16:30 Speaker slide review 19:00 Welcome presentation, followed by dinner	9:00 Welcome coffee 9:30 Meeting starts 11:30-11:45 Your presentation 15:30-16:15 Your panel discussion 16:30 Meeting ends

- On 5 September 2019, your patient organization will have a meeting in Brussels which you are expected to attend

Case study: Your task



- Make sure you have the following documents:
 - **Emails** sent between the company and the patient advocate
 - **Speaker agreement**
 - **Booklet** "Guiding Principles on Legal Agreements"
- **Each group takes care of 2 clauses from the speaker agreement, and chooses one rapporteur**
 - Group 1: Intellectual Property (2.) and Recordings (3.)
 - Group 2: Confidentiality (4.) and Indemnification & Liability (5.)
 - Group 3: Travel & Accommodation (6.) and Financial arrangements (7.)
- **Read the emails, the agreement, and corresponding guiding principles**
Make notes of the changes you would request as a patient advocate, and the reason why you would want those changes (10 minutes)
- **Reporting** of the 3 different sections (5 minutes per group)

Questions?

More information:

<http://www.wecanadvocate.eu/rapp>

Jan Geissler <jan@patvocates.net>

Backup slides

Guiding principles: Summary of key points

Confidentiality

Rationale	Examples	Guiding Principles
<ul style="list-style-type: none">• Protect sensitive information of both contractual parties <p>Take into account that</p> <ul style="list-style-type: none">• company representatives may forget to label confidential• patient advocates' core task is spreading information and knowledge	<ul style="list-style-type: none">• Commercially sensitive information about products or services• Strategic plans, project plans, concepts or processes• Unpublished scientific data of either contractual party• Planned campaigns or policy actions• Personal data, patient data	<ul style="list-style-type: none">• Provide definition of confidential information• Have consent on disclosure of confidential information• Provide justification for requesting confidentiality• Ensure labelling of confidentiality level of information, define status of unlabeled information• Agree that public information is no longer confidential• Ensure deletion of confidential information• Acknowledge that legal requirements and disclosure obligations may override confidentiality

Intellectual property (IP)

Rationale	Examples	Guiding Principles
<ul style="list-style-type: none"> • IP protects creations of the mind, which have both a moral and a commercial value • IP gives both parties the opportunity to further develop ideas and concepts brought in and generated in such meetings, either jointly or separately, and also with competing organisations • IP allows to exploit the results of work in products, initiatives and services • IP rules ensure information, projects and work owned by a party prior to the collaboration remains their property • Most content or results of a meeting are not commercially sensitive 	<ul style="list-style-type: none"> • Consultancy work: Advice provided on company documents, strategic initiatives and other commercially sensitive projects. • Collaborative work: Jointly developed concepts and services, e.g. reports, advice, workshop agendas, patient information materials • Presentations, projects, concepts, documents presented at a meeting • Third-party material: Illustrations or slides of third parties in the meeting • Logos of organisations or companies. 	<ul style="list-style-type: none"> • Applicable law may prescribe definition of IP terms • IP on consultancy or collaborative work on specific company products should belong to the company • IP resulting from collaborative work unrelated to a specific product of the company should be agreed on a case-by-case basis • Authorship rules apply for publications • Background IP remains with the owner • Rights of third-party material need to be clear and cannot be transferred • Use of logos requires written consent

Recordings of meetings

Rationale	Examples	Guiding Principles
<ul style="list-style-type: none">Recordings of the meeting and of individual participants are made for the purposes of compiling minutes or a report of the meetingThese may be produced for<ul style="list-style-type: none">internal useexternal use	<ul style="list-style-type: none">Minutes, documents, quotes, photos or audio-visual recordings in joint meetingsSummary of meeting outcomes and conceptsPresentations held by participants of the meeting	<ul style="list-style-type: none">Agree about use of recordings prior to meeting.Without agreement, internal use of recordings only is a given.Any external use requires prior consent.

Data protection and use of personal data



WECAN
Workgroup of European
Cancer Patient Advocacy Networks



Rationale	Examples	Guiding Principles
<ul style="list-style-type: none"> • Personal data of patients or patient advocates needs to be protected in order to avoid any misuse of the information • Protecting patients' medical condition from becoming known in the public domain • Protecting the credibility of a patient advocate in the public • Ensuring all external data are used for limited, specifically stated purposes, and in a way that is adequate, relevant and not excessive • Ensures data are kept for no longer than is absolutely necessary 	<ul style="list-style-type: none"> • Personal data: information related with an identifiable person (e.g. name, age, position, address, affiliation with organisations, medical condition, or other personal details) • Third parties data: data acquired from another source, confidential or public • Use in quotes, internal or external reports, websites, campaigns, social media channels, offline media 	<ul style="list-style-type: none"> • Personal data is confidential by default • Agree on good reasons for data disclosure • Allow sharing of data with affiliates and involved service providers • Respect right to withdraw consent • Data protection rules should comply with applicable privacy laws • Ensure data protection also in countries with lower privacy standards

Indemnification, remedies, conflict resolution

Rationale	Examples	Guiding Principles
<ul style="list-style-type: none">• Indemnification clauses seek the financial responsibility for specific types of damages, claims or losses• Remedies or liability clauses should take into account that their execution in a dispute would certainly ruin a patient advocate or organisation• It is very unlikely that any pharma company will ever make use of such an indemnification or liability clause• Patient advocates usually don't have sufficient resources and capabilities to have an international liability insurance	<ul style="list-style-type: none">• Misconduct or violation of any clause, which can include disclosure of confidential information• Failure to deliver on the contract• Misuse of the information received, or any other kind of conduct that is considered as a major breach of contract• No case is yet known where liability cases were ever filed by a pharmaceutical company against a patient organisation on the basis of a collaboration agreement between such parties.	<ul style="list-style-type: none">• Limit liability to a reasonable level• Do not require liability insurance• Define terms for mediation• Applicable law of defendant should apply

Financial compensation and reimbursement of expenses

Rationale	Examples	Guiding Principles
<ul style="list-style-type: none"> • Patient advocates deserve a reasonable financial compensation for their time and contribution when acting in advisory roles, consultancy, speaking roles or other collaborative work • Financial compensation is offered in exchange for contributing with time, ideas or other means by patient advocates • Financial contribution is based on a company and expertise-related “fair market value” and subject to local laws and regulations 	<ul style="list-style-type: none"> • Contribution to a meeting, conference, advisory board or committee organised by the company itself or by a third party. • Reviewing materials, leaflets, protocols, guides, recordings, concepts, etc. and providing feedback on those. • Consultancy work on products or services of the company. • Develop materials together with pharmaceutical companies e.g. patient information. 	<ul style="list-style-type: none"> • Compensate according to fair market value, taking into account e.g. individual expertise and training, total amount of time invested, complexity of tasks, country of origin, similar to other highly trained professionals • Reflect total time invested, incl. physical presence and preparatory time. Consider also part of travel time. • Respect the right to refuse compensation • Cover reasonable travel expenses • Long-distance flights justify higher flight class • Reasonable 3-way travel costs on advocacy duty should be covered • Multi-day stopover on advocacy duty should be permitted • Pay within 30 days

Adverse event reporting

Rationale	Examples	Guiding Principles
<ul style="list-style-type: none">• Regulatory provisions require pharmaceutical companies and its employees and contractors to report adverse events through its pharmacovigilance department to regulators• Legal agreements from pharmaceutical companies often require consultants to notify the company in writing of any adverse event occurring relating to company's products• Due to the nature of an independent advisory/speaker/consultancy role and the organisational structure of POs, these obligations are impossible for patient advocates to fulfil	<ul style="list-style-type: none">• "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."	<ul style="list-style-type: none">• Company remains responsible for adverse event reporting• An agreement between pharmaceutical companies and patient advocates should not require the patient advocates to do adverse event reporting, or it should be limited strictly to the adverse events detected within the collaborative work

Independence and Conflict of Interest

Rationale	Examples	Guiding Principles
<ul style="list-style-type: none">• Patient advocates promote the interest of their constituencies, usually patients and carers, 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 patient advocates and pharmaceutical companies shall be done in a way that ensures that the decision-making of the patient advocate side is respected and not influenced by the pharmaceutical company.	<ul style="list-style-type: none">• Any incentive or reward of any type that would influence the decision making, the opinion or statements a patient advocate could do about any drug or diagnostic tool, among others.	<ul style="list-style-type: none">• Respect the independence and autonomy of patient advocate• Safeguard the independence of patient advocates by avoiding conflicts of interests and declaring potential conflicts of interest• Avoid exclusivity clauses• Refer to applicable Codes and Guidelines