Reasonable agreements between patient advocacy and the pharmaceutical industry

Ananda Plate, Myeloma Patients Europe

WECAN meeting
21 Oct 2018

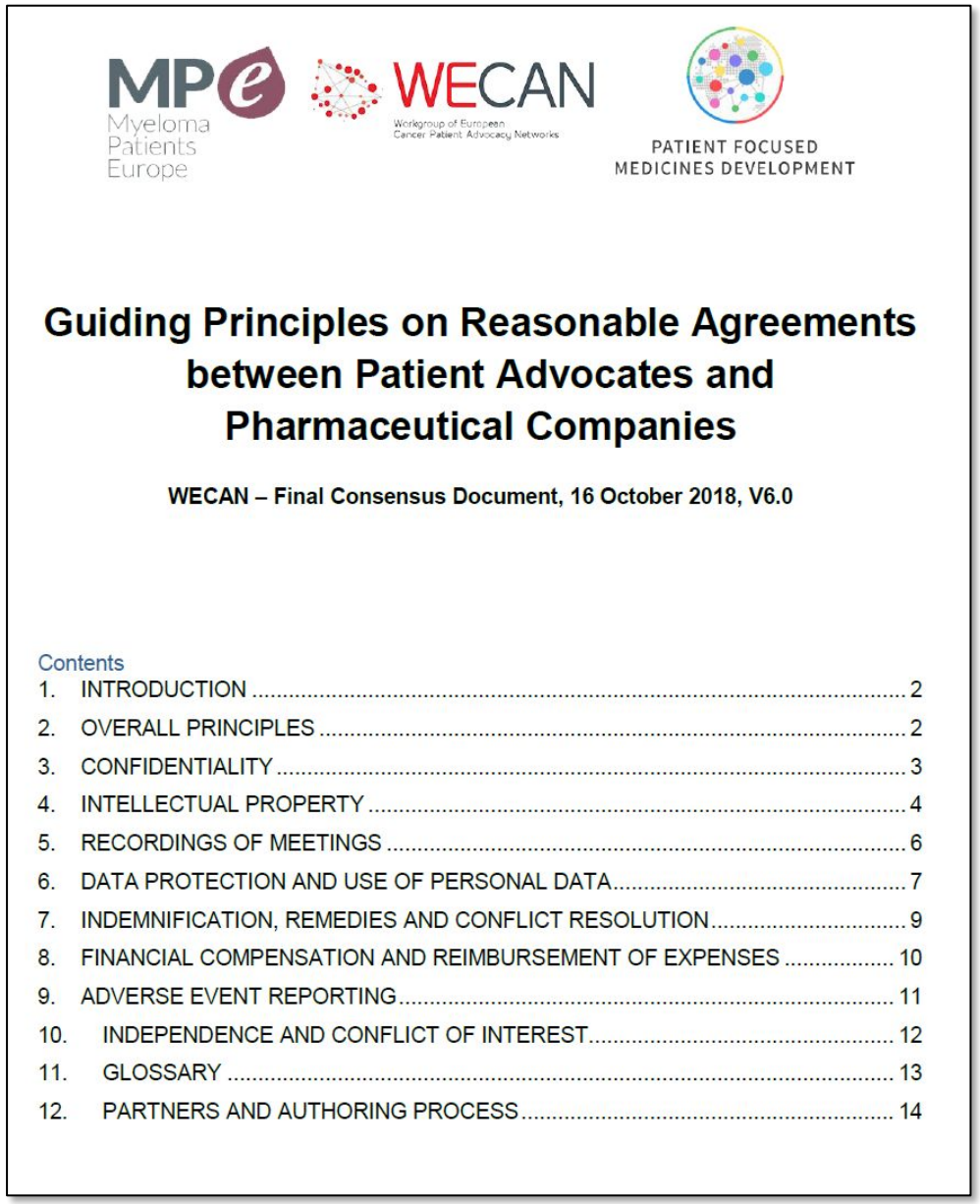
What's the issue

- ➔ Consultancy agreement
- ➔ Collaboration agreement
- ➔ Advisory board agreement
- ➔ Community speaker agreement

- Most contracts we receive are excessive in length, with inappropriate clauses on e.g. intellectual property, confidentiality, liability, adverse event reporting, travel restrictions, use of our name and of recordings, payment terms for expenses
- Industry incl. EFPIA is increasingly sensitive about the topic, and companies claiming they now have "good templates" – but practice is different
- WE CAN change this by applying the guiding principles to every contract we receive, given the principles are based on multi-stakeholder consensus with industry representatives of 11 companies an PFMD support

Project status

- **After several rounds of multi-stakeholder consultation, the guiding principles document is finalised**, based on comments by advocates and company representatives.
- **Contract types:**
  - Consultancy agreement
  - Collaboration agreement
  - Advisory Board agreement
  - Speaker agreement
- **Covered topics:**
  - Confidentiality
  - Intellectual property
  - Recordings of meetings
  - Data protection and use of personal data
  - Indemnification, remedies and conflict resolution
  - Financial Compensation and reimbursements of expenses
  - Adverse event reporting
  - Independence and conflict of interest
  - Glossary



Myeloma Patients Europe
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Workgroup of European Cancer Patient Advocacy Networks
PATIENT FOCUSED MEDICINES DEVELOPMENT

Guiding Principles on Reasonable Agreements between Patient Advocates and Pharmaceutical Companies

WECAN – Final Consensus Document, 16 October 2018, V6.0

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Guiding Principles document finalized on 16 Oct 2018

All sections have 3 parts:

1. Rationale
2. Examples
3. Guiding principles

Who was involved?

Drafting group

WECAN MPE

- Ananda Plate (MPE, project lead)
- Ana Vallejo (MPE)
- Charlotte Roffiaen
- Šarunas Narbutas (POLA)
- Gordon Oliver (IBTA)
- Jan Geissler (CML Advocates Network)
- Kathy Oliver (IBTA)

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- 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 replace by Gregor von Arx
- Virginie Vassart (Merck MSD)

Multi-stakeholder Alignment Workgroup (MSAW)

MSD, Bristol-Myers Squibb, Roche, Novartis, Servier, Celgene, Lymphoma Coalition, Bayer, Amgen, Pfizer, Janssen, novo nordisk, Takeda, National Health Council

Status and next steps

- **Timeline**
  - 15 Oct: Multi-stakeholder consultation has ended
  - 21 Oct: WECAN discussion and advocacy strategy
  - 25 Oct: PFMD board meeting
  - November: Start of template & toolbox development, advocacy strategy implementation

- **To be discussed today:**
  - WECAN strategy to push for implementation, e.g. rejection of contracts with major violation of guiding principles with reference to guiding principles

  - Publication of guiding principles on WECAN website (full document, summary, flyer?) – does publication e.g. in RI&E make sense?

Guiding principles: Summary of key points

Confidentiality

Rationale	Examples	Guiding Principles
• **Protect sensitive information of both contractual parties** Take into account that • company representatives may **forget to label confidential** • patient advocates' core task is **spreading information and knowledge**	• **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**	• **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
• 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	• **Consultancy work:** Advice provided on company documents, strategic initiatives and other commercially sensitive projects. • **Collaborative work:** Jointly developed concepts and servies, 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.	• 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

• Recordings of the meeting and of individual participants are made for the purposes of compiling minutes or a report of the meeting
 	
• These may be produced for
  • internal use
  • external use
	• **Minutes, documents, quotes, photos or audio-visual recordings** in joint meetings
	• **Summary of meeting outcomes** and concepts
	• **Presentations** held by participants of the meeting
		• **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

Rationale	Examples	Guiding Principles
• 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**	• **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 medica channels, offline media	• **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
• 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**	• **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.	• **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
• 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	• **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.	• 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
• **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**	• "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."	• **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
• **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.**	• 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.	• **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**

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Questions?

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