Workshop on reasonable legal agreements between patient advocates and pharmaceutical companies

Corporate Compliance & Transparency in the Pharmaceutical Industry
Zurich, 21 Feb 2019
Jan Geissler, WECAN

Objectives of this session

- Provide patient perspective on the challenges of legal agreements between patient advocates and pharmaceutical companies
- Give an update on WECAN‘s „Reasonable Legal Agreements“ collaboration project
- Give an introduction to our Guiding Principles
- Introduce the concept of template contracts
- Making you work!

What patient advocates do

Support patients

- Inform, support, provide navigation to patients
- Run services and meetings, provide tools and apps

Patient-centric policy

- Influence health policy and healthcare provisioning
- Provide input to regulators and institutions

Research reflecting patients's needs

- Provide patients needs to academic and industry research
- Participate in publicly funded projects

Why the reasonable legal agreements project?

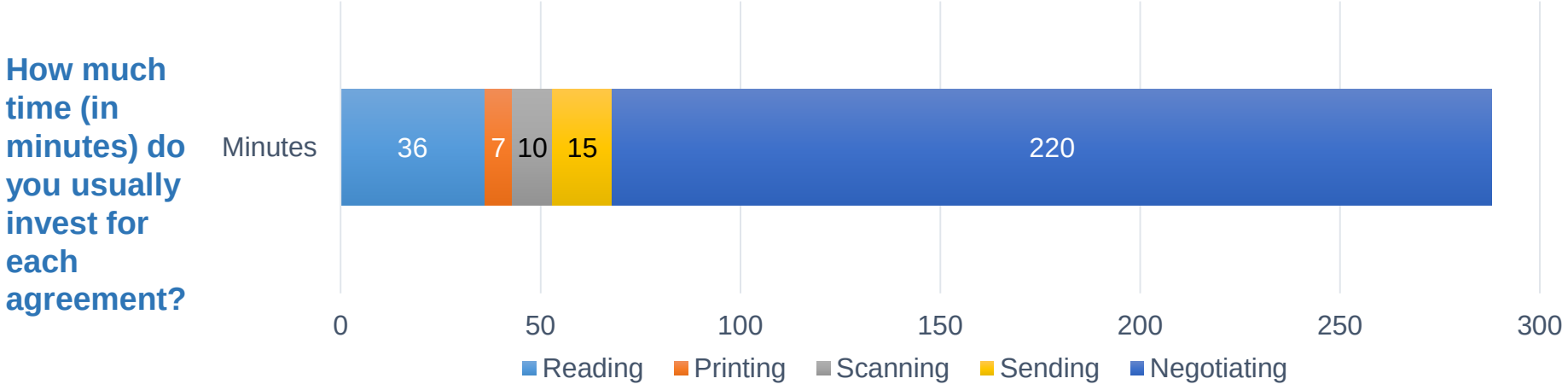
- **Collaboration between pharma and patient advocates requires them to sign contracts**, e.g. speaker agreements, advisory agreements, consultancy or collaboration contracts

- **The contracts are often too long and difficult to understand, unilateral, disproportionate,** 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, the Workgroup of 22 pan-European Cancer Patient Advocacy Networks** wanted to change this and initiated this project in 2016, based on data from a survey

Main issues identified in major survey to over 80 patient advocates in 2016

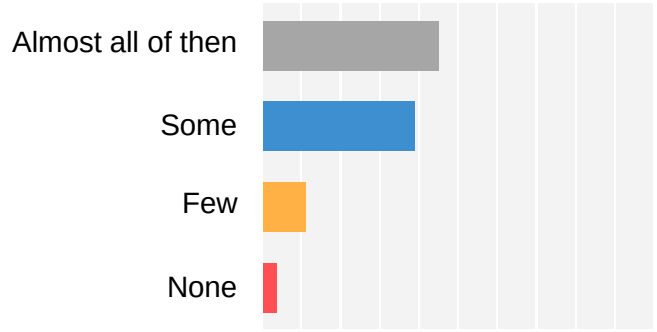
- The contracts provided to patient advocates are often too long and are difficult to understand
- 81% said all contracts are unreasonably extensive in length (6 pages or more, 19% even said they usually get contracts with more than 10 pages)
- Patient advocates invest on average 295 minutes (almost 5 hours) into reading negotiating and processing each contract



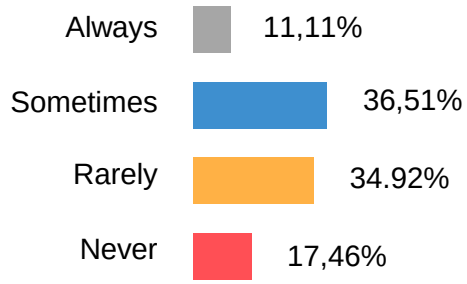
Source: WECAN survey "Reasonable agreements between patient advocacy and the pharmaceutical industry", WECAN (2016)

Main issues identified in major survey to over 80 patient advocates in 2016

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



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



~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

Source: WECAN survey “Reasonable agreements between patient advocacy and the pharmaceutical industry”, WECAN (2016)

Main issues identified in major survey to over 80 patient advocates in 2016

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

- 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 blocks important 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

Source: WECAN survey “Reasonable agreements between patient advocacy and the pharmaceutical industry”, WECAN (2016)

Overall objectives and goals of the project

Objective

- Improve balance between parties by establishing contracts
- Allowing patient organisations to operate in their role and purpose while protecting the pharmaceutical companies from reasonable risk
- Incorporate patient organisation’s capacity, legal expertise and experience on potential consequences in legal contracts
- Better reflect the diversity of relationships in consultancy, advisory, speaker and collaborative roles, which are usually totally different to classical consultancy

Our goal

- Provide guiding principles for reasonable legal agreements
- Provide template contracts with simplified terms and language
- Prevent from unnecessary clauses (that create unnecessary uncertainty)

Who is 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)

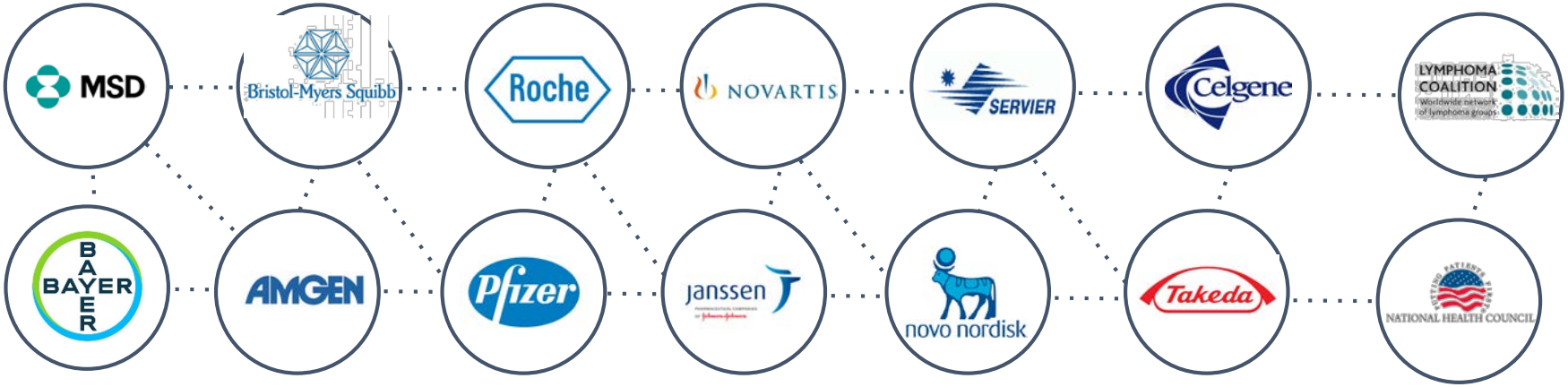
Legal experts

- 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)

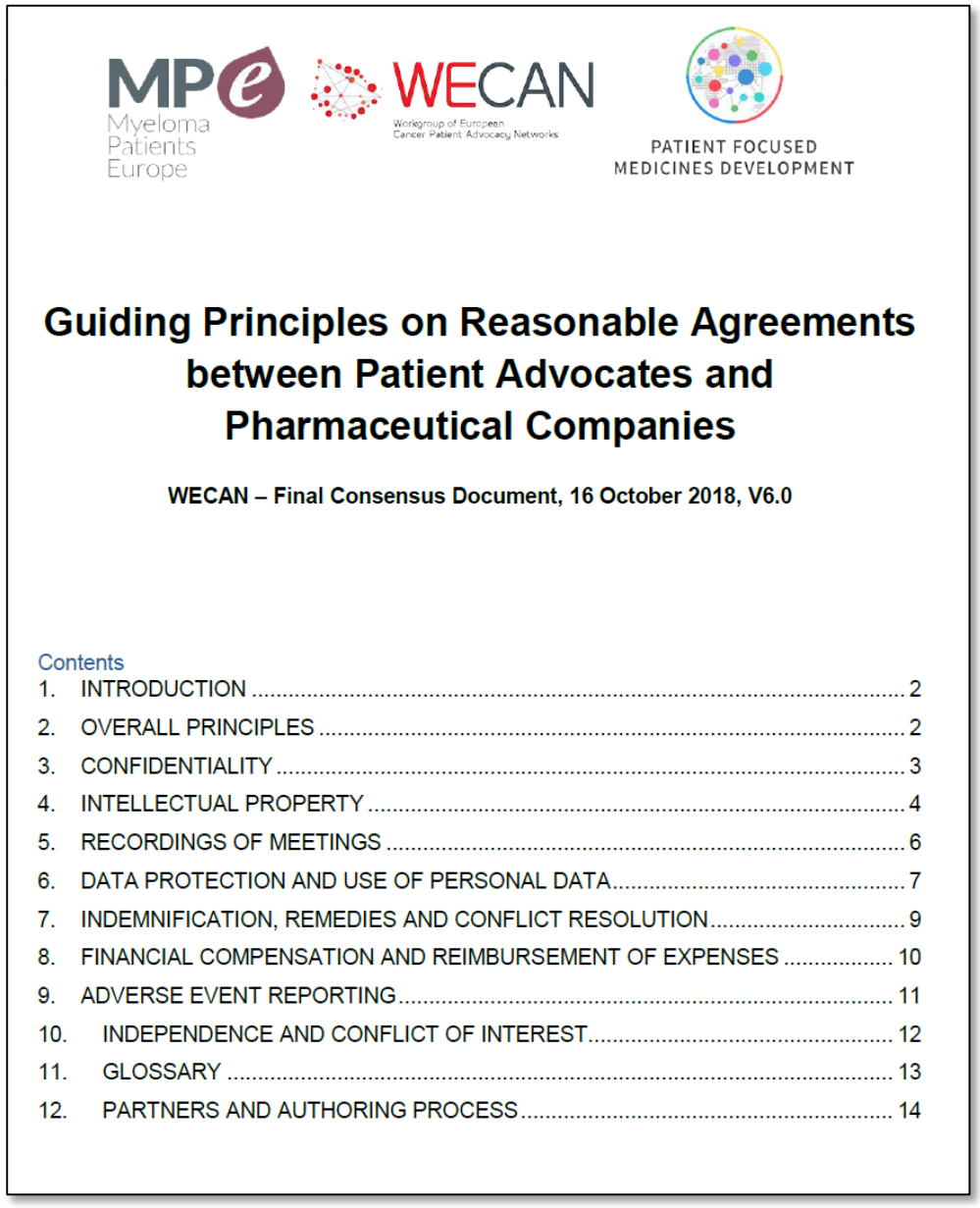


Guiding Principles

- **After several rounds of multi-stakeholder consultation, the "Guiding Principles on reasonable agreements between patient advocates and pharma companies" are finalised**, based on feedback from 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



Guiding Principles on Reasonable Agreements between Patient Advocates and Pharmaceutical Companies

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

Contents

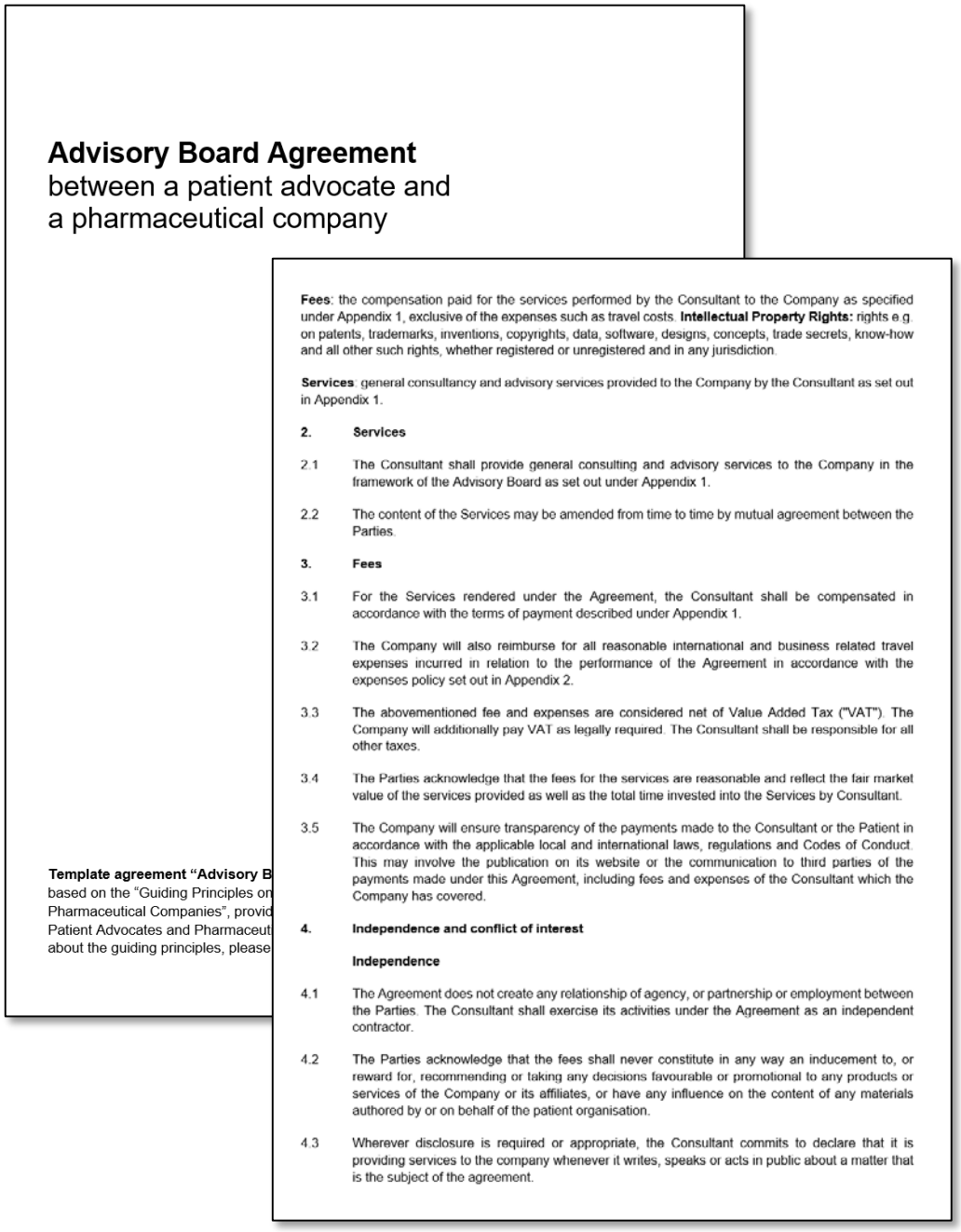
Guiding Principles document finalized on 16 Oct 2018, ratified by WECAN on 21 Oct 2018 and PFMD on 25 Oct 2018

For download at
http://www.wecanadvocate.eu/rapp

All sections have 3 parts:

1. Rationale
2. Examples
3. Guiding principles

For download: www.wecanadvocates.eu/rapp



Templates for

- **Advisory Agreement**
- **Consultancy Agreement**
- **Speaker Agreement**
- **Collaboration Agreement**

currently under development

Soon for download at
http://www.wecanadvocate.eu/rapp

Status and next steps

2017-2018: Drafting work

15 Oct 2018: End of multi-stakeholder consultation

21 Oct 2018: WECAN meeting: approval of guiding principles, advocacy strategy

25 Oct 2018: PFMD Board Meeting

5 Nov 2018: Publication of guiding principles, communication

29 Oct-9 Nov: Collection of “best contracts” from workgroup members

10 Nov 2018: Start of template and toolbox development

January 2019: First contract template finalised

June 2019: toolbox finalised

Advocacy for & adoption of guiding principles

Group exercise

- Make sure you have the following documents:
  - Copy of the **legal agreement for a speaker** at a meeting organized by a pharma company
  - Copy of the **emails** sent between the company and the advocate
  - **Guiding Principles** on Legal Agreements between industry and advocates
- Choose a clause from the speaker agreement on which you will work (clauses 2-9). There needs to be at least one person allocated per clause!

Exercise:

1. **Each table builds a team** and chooses a rapporteur (1 minute)
2. **Choose one clause from the speaker agreement** on which you will work (5 minutes)
3. **Look for "your clause" in the Guiding Principles** document and read the rationale, examples and principles (5 minutes)
4. Make notes of the **changes you would request if you were a patient advocate** and the reason why you would want those changes (10 minutes)
5. Make notes of the **changes you would accept if you were industry** (5 minutes)
6. Make notes of the **changes you would not accept and the reason why** you wouldn't (5 min)
7. Each table to report back & discuss (20 min)

Thank you!

More information:
http://www.wecanadvocate.eu/rapp
Jan Geissler <jan@patvocates.net>

Leave your business card to be updated about the project

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