Patient Engagement open forum

Beyond Aspiration

Legal Agreements between Patients, Patient Advocates and Pharma

Patient Engagement Open Forum

19.9.2019

PATIENT FOCUSED MEDICINES DEVELOPMENT

WECAN
Workgroup of European Cancer Patient Advocacy Networks

MPE Myeloma Patients Europe

What is WECAN

WECAN
= **W**orkgroup of **E**uropean **C**ancer Patient **A**dvocacy **N**etworks

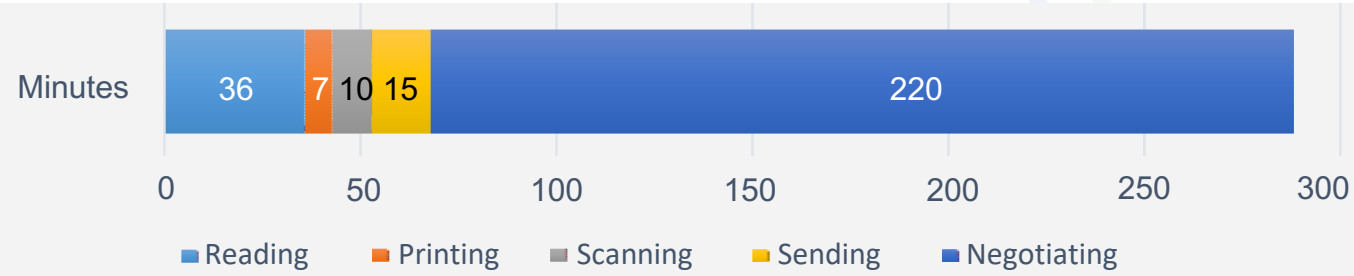
Informal workgroup of leaders of the 23 pan-European cancer patient umbrella organisations

Increasing the level of **collaboration, alignment** and **mutual support** between the organisations

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

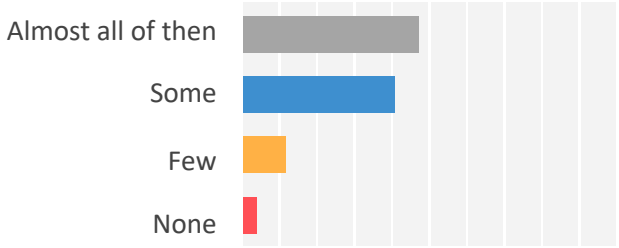
How much time (in minutes) do you usually invest for each agreement?



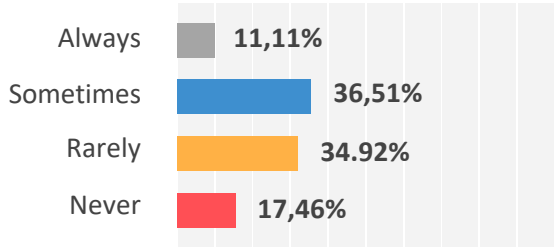
Source: WECAN survey "Reasonable agreements between patient advocacy and the pharmaceutical industry", WECAN (2016)

WECAN Survey of patient advocates on legal agreements

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:

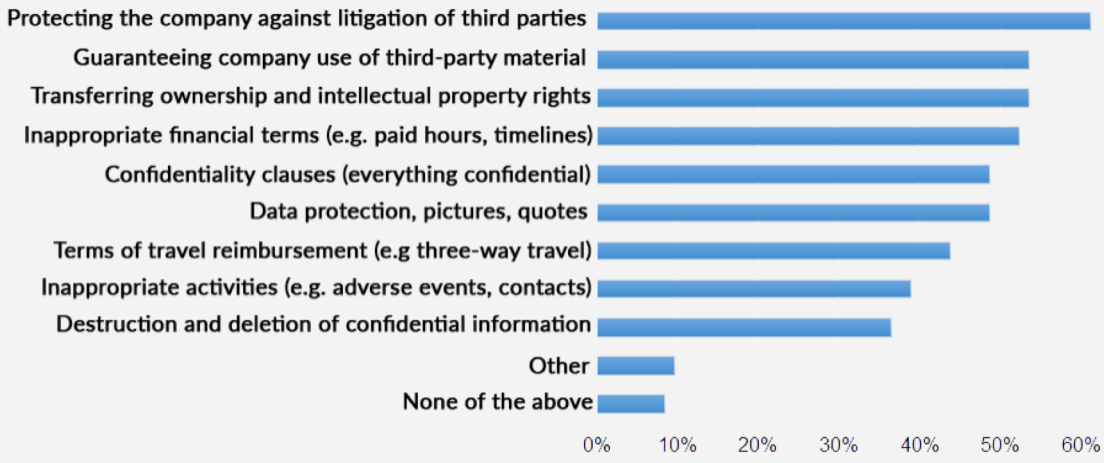
- no legal support,
- no time to check contracts,
- trusting pharmaceutical companies,
- other reasons such as the length of the contract, or the confusing terms used

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

Main issues in 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 clause in legal agreements do you usually find unreasonable?



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

- 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)

Who is involved?

Drafting Group

WECAN MPE Myeloma Patients Europe

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

Overall objectives

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)

Deliverables

Most contracts patient advocates 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.

OBJECTIVES

Deliver 4 preferred reference contract co-created with pharma and patients

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

Delivered → Guiding principles on reasonable agreements between pharma and patients & Patient Advisory Board reference contract

Guiding Principles on Reasonable Legal Agreements

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

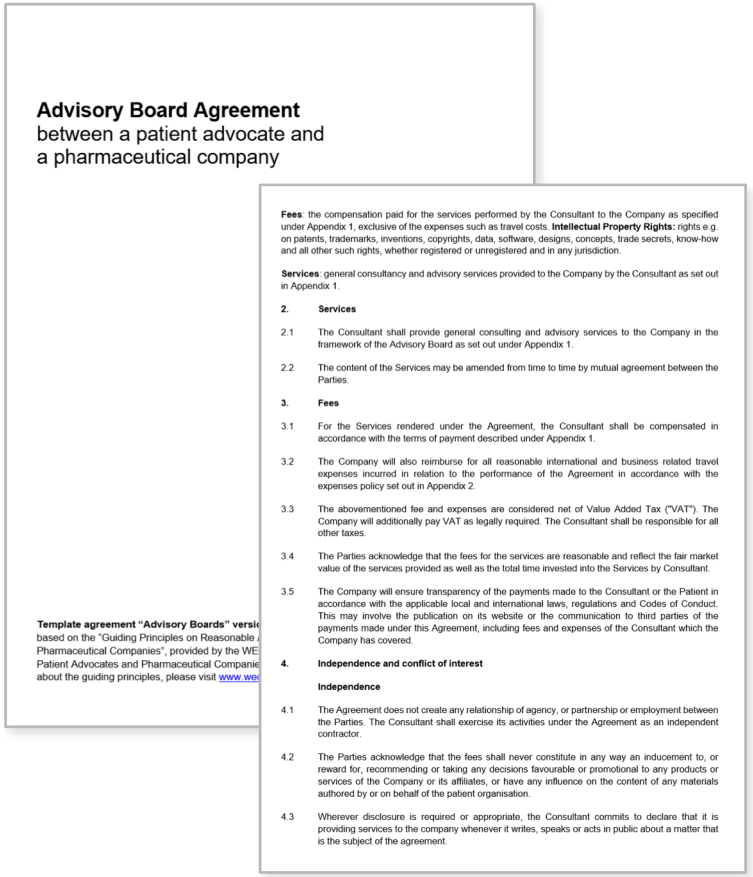
Covered topics

- 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 document finalized on ratified by WECAN and PFMD

All sections have 3 parts:

1. Rationale
2. Examples
3. Guiding principles



Advisory Board Agreement
between a patient advocate and
a pharmaceutical company

Fees: the compensation paid for the services performed by the Consultant to the Company as specified under Appendix 1, exclusive of the expenses such as travel costs. **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.

Services: general consultancy and advisory services provided to the Company by the Consultant as set out in Appendix 1.

2. Services

2.1 The Consultant shall provide general consulting and advisory services to the Company in the framework of the Advisory Board as set out under Appendix 1.

2.2 The content of the Services may be amended from time to time by mutual agreement between the Parties.

3. Fees

3.1 For the Services rendered under the Agreement, the Consultant shall be compensated in accordance with the terms of payment described under Appendix 1.

3.2 The Company will also reimburse for all reasonable international and business related travel expenses incurred in relation to the performance of the Agreement in accordance with the expenses policy set out in Appendix 2.

3.3 The abovementioned fee and expenses are considered net of Value Added Tax ("VAT"). The Company will additionally pay VAT as legally required. The Consultant shall be responsible for all other taxes.

3.4 The Parties acknowledge that the fees for the services are reasonable and reflect the fair market value of the services provided as well as the total time invested into the Services by Consultant.

3.5 The Company will ensure transparency of the payments made to the Consultant or the Patient in accordance with the applicable local and international laws, regulations and Codes of Conduct. This may involve the publication on its website or the communication to third parties of the payments made under this Agreement, including fees and expenses of the Consultant which the Company has covered.

4. Independence and conflict of interest

Independence

4.1 The Agreement does not create any relationship of agency, or partnership or employment between the Parties. The Consultant shall exercise its activities under the Agreement as an independent contractor.

4.2 The Parties acknowledge that the fees shall never constitute in any way an inducement to, or reward for, recommending or taking any decisions favourable or promotional to any products or services of the Company or its affiliates, or have any influence on the content of any materials authored by or on behalf of the patient organisation.

4.3 Wherever disclosure is required or appropriate, the Consultant commits to declare that it is providing services to the company whenever it writes, speaks or acts in public about a matter that is the subject of the agreement.

Template agreement "Advisory Boards" versi
based on the "Guiding Principles on Reasonable
Pharmaceutical Companies", provided by the WE
Patient Advocates and Pharmaceutical Companie
about the guiding principles, please visit www.we

Templates for

- **Advisory Agreement**
  - ready and downloadable on the wecanadvocate.eu website
- **Consultancy Agreement**
  - draft in consultation
- **Speaker Agreement**
  - draft in consultation
- **Collaboration Agreement**
  - draft in consultation

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Next steps

Status and next steps

October 2018

Publication of Guiding principles on WECAN website & starting PFMD communication activities

November 2018

Start of template & toolbox development, advocacy for adherence to the Guiding principles

Q1 2019

Reviewing first contract template
Development of Guiding principles booklet

Q2 2019

Guiding principles booklet produced as conference and workshop material.

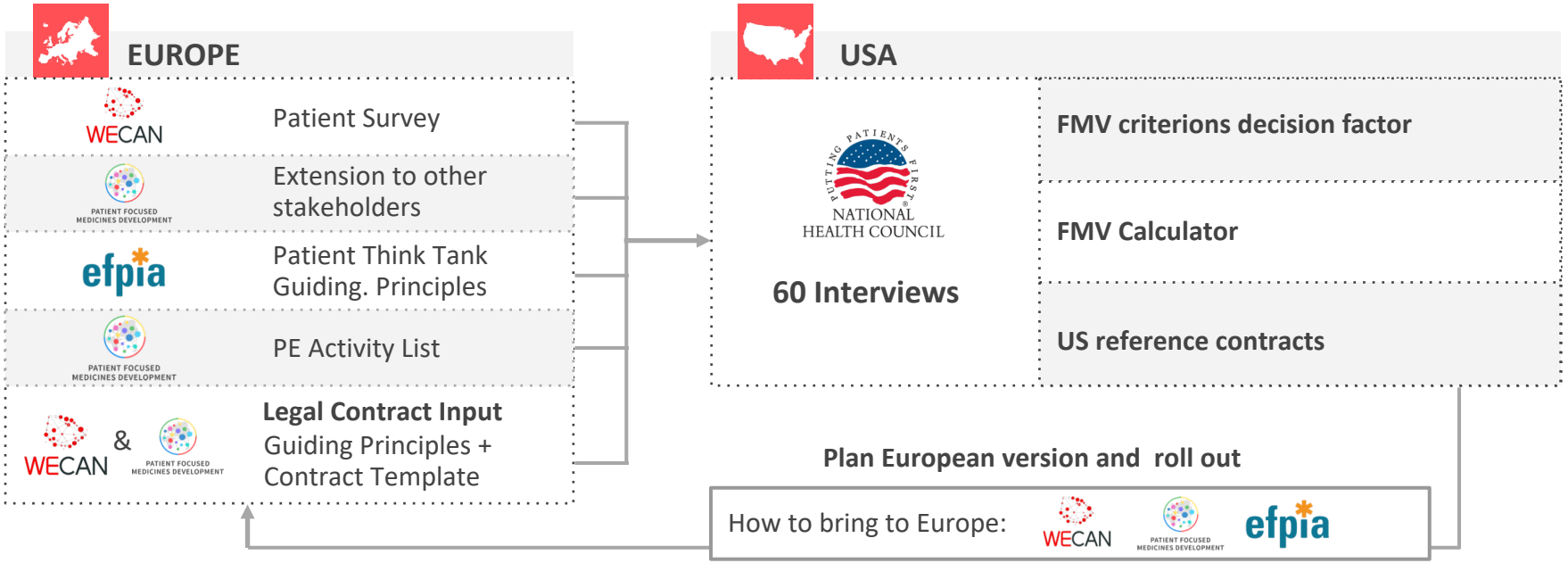
Advisory Board template released

Q4 2019

Drafting remaining 3 contract templates
&
creating toolkit

Getting Fair Market Value (FMV) Right

FMV Input



Exercise on Patient Advisory Board Contract

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

Exercise:

1. **Each table builds a team** and chooses a rapporteur. You will be assigned to one of 3 groups (1 minute)
   - 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.)
2. **Look for "your clause" in the Guiding Principles** document and read the rationale, examples and principles behind. Read the emails and thee section of the agreement **(10 minutes)**
3. 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)**
4. Make notes of the **changes you would accept if you were industry (5 minutes)**
5. Make notes of the **changes you would not accept and the reason why** you wouldn't (5 min)
6. Each table to report back & discuss **(20 min)**

Guiding principles Summary - Discussion

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 media 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**