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Principles on Contracting between Patient Advocates and Pharmaceutical Companies

WECAN – Final Consensus Document, 23 October 2018, V6.2

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26 **1. INTRODUCTION**

27
28 Collaboration between pharmaceutical companies and patient advocates often requires both
29 parties to sign contracts that define the terms and conditions of the collaboration, covering
30 such matters as confidentiality, intellectual property, copyright, data protection,
31 compensation and other responsibilities of one or both parties.

32
33 However, these agreements provided to patient advocates e.g. for consultancy,
34 collaboration, advisory boards or speaking opportunities are often too long, and are difficult
35 to understand. They contain ambiguous clauses, or terms that are in conflict with the very
36 nature of patient advocacy. They may even put the signing patient advocate at legal risk.

37
38 The multi-stakeholder project “Reasonable agreements between patient advocates and
39 pharmaceutical companies” aims to make legal agreements between both parties easier and
40 more acceptable while providing adequate protection and rules for both sides. To do so, it
41 has developed these guiding principles, which should provide the guiding baseline for the
42 development of contracts and contract templates as well as a toolbox for patient advocates
43 and companies.

44
45 The project is led by Myeloma Patients Europe on behalf of the Workgroup of European
46 Cancer Patient Advocacy Networks (WECAN), in close partnership with Patient Focused
47 Medicine Development (PFMD). It builds on an extensive consensus process of a multi-
48 stakeholder workgroup of patient advocates and legal experts from different pharmaceutical
49 companies, supported by independent legal experts from academia and a legal firm.

50

How to read this document:

- Each section covers rationale, examples and guiding principles for legal agreements between pharmaceutical companies and patient advocates
- The principles listed are a result of consensus work between patient advocates and pharmaceutical companies’ representatives
- Pharmaceutical companies and patient advocates reached multi-stakeholder consensus on most, but not all items, concepts or principles. Whenever consensus could not be reached, these sections are marked accordingly.
- **For the purpose of these principles, we use the term “patient advocates” in a broader sense for patient organisation, individual patient, carer, patient advocate, patient organisation representative, patient expert** (see EUPATI guidance for full description of each concept)

51 **2. OVERALL PRINCIPLES**

- 52
- The goal in establishing these guiding principles is to reach a better balance between
53 the parties, to guide patient advocates whenever they need to review a legal
54 agreement and to develop legal agreements and adaptable templates that reasonably
55 protect both parties.

56
57 These following basic considerations should be taken into account when drafting any
58 contract between patient advocates and pharmaceutical companies:

- 59 ○ The overall role and purpose of patient advocates and the environment
60 required for it to operate effectively and efficiently, while at the same time
61 acknowledging the need to protect the interest of pharmaceutical companies
62 and patient advocates.
- 63 ○ The limited capacity of most patient advocates to deal with the workload, lack
64 of legal expertise and the potential legal consequences arising from
65 agreements signed with pharmaceutical companies.
- 66 ○ The diversity of relationships between the parties, not limited to classical
67 consultancy that is usually covered by these agreements.
- 68 ● The goal of these guiding principles is not only to boil down the terms of the
69 agreements to the minimum, but also to prevent the add-on of unnecessary clauses
70 generating unnecessary risk for one of the parties, as well as to simplify the language
71 of the agreements.
- 72 ● These guiding principles will apply to agreements between pharmaceutical companies
73 and patient advocates.
- 74 ● The specific circumstances of the contractual party representing the patient advocate
75 side should be taken into account when formulating the terms of an agreement.

76 3. CONFIDENTIALITY

77

78 RATIONALE - Why do we need confidentiality clauses?

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

92

93 EXAMPLES of confidential information:

- 94 ● Commercially sensitive information about products or services of the company, e.g.
95 product, financial or regulatory information
- 96 ● Strategic plans or processes of either contractual party
- 97 ● Unpublished scientific data of either contractual party
- 98 ● Planned public campaigns or policy actions
- 99 ● Draft project plans or concepts of either contractual party
- 100 ● Personal data, patient data

101

102 GUIDING PRINCIPLES for regulating confidential information:

- 103 ● **Definition of confidential information:** "Confidential Information" includes all non-
104 public information, written or oral, disclosed or made available to either party, directly
105 or indirectly, by or on behalf of, one party or its affiliates through any means of
106 communication or observation.
- 107 ● **Disclosure of confidential information requires consent:** Any disclosure of
108 confidential information to third parties requires prior written consent of the owner,
109 which for specific third parties already can be agreed upon in the legal agreement.
- 110 ● **Provide justification for requesting confidentiality:** Both parties should identify the
111 type of information that should be confidential, the purpose of the confidentiality, the
112 way they will exchange the confidential information, and its use.
- 113 ● **Ensure labelling of confidentiality level of information:** Both parties shall make
114 reasonable efforts to label confidential documents with the mark "confidential".
- 115 ● **Define confidentiality status of unlabelled information.** In case of lack of labelling,
116 both parties should make reasonable efforts to ensure that the disclosing party
117 clarifies whether the information is confidential or not.
118 There is still a difference in positions on whether non-labelled documents should be
119 presumed to be confidential or not: (i) Pharmaceutical companies' position is that, if
120 no clarification is made by the disclosing party, the information should be presumed to
121 be confidential; (ii) Patient advocates' position is that, if no clarification is made by the
122 disclosing party, the information should be presumed to be public.
- 123 ● **Public information is no longer confidential.** General public knowledge, or any
124 confidential information that becomes general public knowledge through no breach of
125 the recipient, or if it has been made public by other parties without any obvious
126 evidence of a breach of confidentiality.
- 127 ● **Ensure deletion of confidential information:** Once the contractual relationship is
128 over or whenever the disclosing party requires it, the party that received confidential
129 information must delete the information, and upon request, confirm the deletion to the
130 other party.
- 131 ● **Legal requirements and disclosure obligations may override confidentiality:**
132 Confidentiality cannot be required where disclosure is required by law, by
133 governmental authorities, or by applicable codes of practice (e.g. disclosure of
134 transfer of value, or disclosure of the general fact of a contractual relationship).

135 4. INTELLECTUAL PROPERTY

136

137 RATIONALE - Why do we need intellectual property clauses?

- 138 ● Intellectual property (IP) refers to the protection of creations of the mind, which have
139 both a moral and a commercial value. IP enables people to earn recognition, added
140 value or improved services from their ideas or from what they create.
- 141 ● IP gives both the pharmaceutical company and the patient advocate the opportunity to
142 further develop the topic independently after a collaboration, based on the ideas and
143 concepts brought in and generated in such meetings (described as "collaborative
144 work"), either jointly or separately, and also with competing organisations.
- 145 ● IP gives the pharmaceutical company the rights to exploit all work on its commercial
146 products and services and related activities (described hereto as "consultancy work"),
147 allowing for competitive advantage.

- 148 ● IP gives the patient advocate the rights to exploit the results of work in initiatives and
149 services that may arise as a result of the collaboration (described hereto as
150 “collaborative work”) or independently of the collaboration.
- 151 ● Background IP, like information, projects and work owned by each party prior to the
152 collaboration, remains the property of that party, so that pre-existing IP is not
153 transferred or lost.
- 154 ● Consultancy work should be an exception in the relationships between
155 pharmaceutical companies and patient advocates and does not interfere with other
156 collaborative work.
- 157 ● Generally, the content or results of a meeting are not commercially sensitive and
158 neither do they relate to any commercial product or service. Therefore, patent or
159 trademark clauses only need to be introduced in exceptional cases.
- 160 ● IP covers not only personal data but also third-party data, defined as data brought into
161 the collaboration by either party or generated within the collaboration or by either
162 party.
- 163 ● Third-party data communication can be:
 - 164 ○ Internal (within or between either of the parties) or
 - 165 ○ External (to third parties, e.g. general public, media, public bodies, or
166 other third parties).
- 167 ● Codes and transparency rules may require the disclosure of the collaboration and the
168 involved parties.
- 169 ● Third-party data and material brought in by any party can be used in the work results
170 of the collaboration, while those referencing third party material cannot guarantee or
171 sub-license re-use.

172 **EXAMPLES of intellectual property:**

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

185 **GUIDING PRINCIPLES for regulating intellectual property:**

- 187 ● **Applicable law may prescribe definition of IP terms.** Depending on the applicable
188 law of the agreement, the IP section of an agreement may be required to describe the
189 rights assigned (reproduction, distribution, etc.), the territory, the duration, the target
190 of the assignment and the amount to be paid (or not).
- 191 ● **IP on consultancy or collaborative work on specific company products should
192 belong to the company:** For all consultancy work of patient advocates on
193 commercially sensitive products or services of the pharmaceutical company, the

194 pharmaceutical company will receive the exclusive, transferable right of use, so it can
195 drive forward and improve the development of its products and services. The parties
196 may discuss the use of that IP by the patient organisation under a licence, if there is a
197 need for the patient organisation to use that IP.

- 198 • **IP resulting from collaborative work unrelated to a specific product of the**
199 **company should be agreed on a case-by-case basis:** This should be based on the
200 principles of (i) purpose of the collaboration and of the co-created material; (ii) which
201 party has brought which resources to the collaboration; (iii) what are the outcomes
202 and how do the parties want to use and exploit them.
- 203 • **Authorship rules apply for publications:** Whenever the outcome is a publication,
204 authorship rules apply (usually referred to as ICMJE rules, ICMJE being the
205 International Committee of Medical Journal Editors)
- 206 • **Background IP remains with the owner:** All information, data and work owned by
207 each party prior to the collaboration or engagement should remain the property of that
208 party.
- 209 • **Rights of third-party material need to be clear and cannot be transferred:** Third-
210 party material can be used in the collaboration if the third party's terms allow this. It is
211 the responsibility of the party bringing the third party's material to the collaboration to
212 ensure that it has the proper rights to do so. No rights on any third-party material can
213 be transferred to the other party within the agreement. Third-party material used in the
214 meeting cannot be freely used.
- 215 • **Use of logos requires written consent:** Prior written consent it is needed by both
216 parties to use the respective logos. Each party should indicate how their logo should
217 be used according the guidelines provided by each organisation or company.

218 5. RECORDINGS OF MEETINGS

219

220 RATIONALE - Why do we need clauses about recordings?

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

223

224 EXAMPLES

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

228

229 GUIDING PRINCIPLES

- 230 • **Agree about use of recordings prior to meeting:** Before the start of the meeting, the
231 parties should agree about the use of recordings, the minutes and/or the meeting
232 report.
- 233 • **Without agreement, internal use of recordings only is a given. Any external use**
234 **requires prior consent:** Unless agreed otherwise, distribution and use of
235 presentations and recordings is allowed by both parties for internal purposes. External
236 use of these presentations and recordings requires prior consent to protect both
237 intellectual property and public credibility (see intellectual property section).

238 6. DATA PROTECTION AND USE OF PERSONAL DATA

239

240 RATIONALE - Why do we need data protection clauses?

- 241 • Personal data of patients or patient advocates needs to be protected in order to avoid
242 any misuse of the information.
- 243 • Data protection controls how personal information is used by the company and the
244 patient organisation and controls its use to safeguard information about individuals and
245 their privacy.
- 246 • Data protection protects patients from having their medical condition disclosed to the
247 public, which may not be in the public domain outside of closed-door meetings.
- 248 • Data protection protects the credibility of a patient advocate in a public context, given
249 his/her, interaction with pharmaceutical companies is under close public scrutiny¹.
- 250 • Data protection ensures all external data, e.g. data relating to individuals raised in
251 surveys, in meetings or in clinical trials, are used for limited, specifically stated
252 purposes, and in a way that is adequate, relevant and not excessive.
- 253 • Data protection ensures data are kept for no longer than is absolutely necessary.

254

255 EXAMPLES of personal data and use of data

- 256 • Personal data means any information relating to an identifiable person, including
257 patients, patient advocates or any other person involved (name, age, position, address,
258 affiliation with organisations, medical condition, or other personal details)
- 259 • Third parties' data means any data acquired from a source other than the parties
260 signing the agreement. It can be confidential or public data.
- 261 • This data could be used in different contexts:
 - 262 ○ Names or quotes used for internal reporting purposes of the collaborative
263 partners: recordings of the meeting, meeting notes, minutes
 - 264 ○ Names or quotes of individuals in their patient or patient advocacy role disclosed
265 in internal or external reports, on websites, campaigns, social media channels, or
266 any other communication means other than reporting from the meeting
 - 267 ○ Publications on online or offline media in the form of text, audio or video
 - 268 ○ Data of patients in surveys or clinical trials e.g. about patient preferences, quality
269 of life or any other clinical topic
 - 270 ○ Textual information, video, audio, photography, podcast, website or any other
271 means
 - 272 ○ Companies' or organisations' names
 - 273 ○ Names of involved persons

274

275 GUIDING PRINCIPLES for regulating data protection

¹ Non-governmental organisations have the responsibility to demonstrate to the public that their operations are consistent with their values. Interaction between patient groups and the pharmaceutical industry is always under public scrutiny and patient groups should ensure that a patient representative's personal data or other information (logo, quotes, videos, recording...) will be protected independently of the relation they may have with the pharmaceutical industry.

- 276 • **Personal data is confidential by default:** Personal data of individuals representing
277 either party will be kept confidential. This data may only be used by the other party if
278 required by law or with prior written consent by the individual in question.
- 279 • **Agree on good reasons for data disclosure:** In case that the disclosure of personal
280 data was required to deliver on the defined objectives, there must be a separate clause
281 in the contract, clearly stating which data needs to be released and what the purpose
282 of the disclosure is.
- 283 • **Allow sharing of data with affiliates and involved service providers:** The contracts
284 should allow the company to share or transfer personal data to its affiliates. Contracts
285 should also cover that any such transfer is allowed in and to countries outside the EEA
286 (European Economic Area) under an appropriate protection standard rules like EU US
287 Privacy Shield Framework.
- 288 • **Respect right to withdraw consent:** The owner of the data is entitled to object,
289 access or request correction or deletion, of his or her personal data anytime. Even if
290 prior consent was given, once the information has been made public, its owner will
291 have the right to have it deleted and the data source should be removed as per
292 applicable laws and regulations.
- 293 • **Data protection rules should comply with applicable privacy laws:** This relates to
294 the collection, use, disclosure and storage of personal information.
- 295 • **Ensure data protection also in countries with lower privacy standards:** If personal
296 data is used in a country with low standards of protection, the company must ensure
297 that an adequate level of protection is applied for the rights of the data subject in
298 relation to the processing of personal data.

299 7. INDEMNIFICATION, REMEDIES AND CONFLICT RESOLUTION

300

301 RATIONALE - Why do we need indemnification and jurisdiction clauses?

- 302 • Indemnification clauses seek to define financial responsibility for specific types of
303 damages, claims or losses. They aim to ensure that liability of both parties will apply
- 304 • Any remedies or liability clauses should take into account that their execution in a
305 dispute would certainly bring a patient advocate into bankruptcy
- 306 • It is also very unlikely that any pharmaceutical company will ever make use of such an
307 indemnification or liability clause or would achieve a realistic remedy
- 308 • Patient advocates usually don't have sufficient financial and human resources as well
309 as capabilities to have an international liability insurance for activities covered in such a
310 collaboration agreement. In addition, the volume of a collaboration would be
311 disproportionate to the costs and administrative burden of a liability insurance
- 312 • Legal claims between patient advocates and pharmaceutical companies are extremely
313 unlikely to happen. To ensure a fair procedure, the applicable law and jurisdiction
314 should be the one at the defendant's domicile. In any case, the signed legal agreement
315 should require the parties to Alternative Resolution Clauses (e.g. mediation) before
316 initiating legal action.

317

318 EXAMPLES of indemnification and remedies

- 319 • Misconduct or violation of any clause, which can include disclosure of confidential
320 information, failure to deliver on the contract, a misuse of the information received, or
321 any other kind of conduct that is considered as a major breach of contract
- 322 • In practice such situations are rare, but in extreme cases they may arise. However, no
323 case is yet known where liability cases were ever filed by a pharmaceutical company
324 against a patient organisation on the basis of a collaboration agreement between such
325 parties.

326 327 **GUIDING PRINCIPLES**

- 328 • **Limit liability to a reasonable level.** A liability and indemnification clause for the
329 patient expert or patient organisation, if required at all, should only cover extreme
330 cases of gross misconduct and should be proportionate to the nature of the
331 collaboration. In case an indemnification clause was requested by either party, it
332 should be limited to a maximum of twice the financial volume of the agreement, with
333 the exception of physical injuries.
- 334 • **Do not require liability insurance:** Liability insurance by patient advocates should not
335 be required in such a collaboration agreement. If liability insurance is required, it is
336 suggested to check whether liability insurance of the patient advocate could be
337 covered by the company.
- 338 • **Define terms for mediation:** A mediation clause should be added in case a dispute
339 arises out of - or relates to - the agreement. This clause should come into force if the
340 dispute is not settled amicably through negotiation or via another neutral third party
341 and shall commit the parties to try in good faith to settle the dispute by mediation.
- 342 • **Jurisdiction of defendant should apply:** In case no amicable or mediated solution is
343 possible, in order to discourage legal action and protect the defendant, the jurisdiction
344 and applicable law chosen should be the one of the defendant's domicile.

345 **8. FINANCIAL COMPENSATION AND REIMBURSEMENT OF EXPENSES**

346

347 **RATIONALE - Why do we need financial compensation and travel reimbursement** 348 **clauses?**

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

360

361 **EXAMPLES of compensation and travel reimbursements**

- 362 • Contribution to a meeting, conference, advisory board or committee organised by the
363 company itself or by a third party.
- 364 • Reviewing materials, leaflets, protocols, guides, recordings, concepts, etc. and
365 providing feedback on those.
- 366 • Consultancy work on products or services of the company.
- 367 • Develop materials together with pharmaceutical companies e.g. patient information.
368

369 **GUIDING PRINCIPLES for regulating compensation and travel reimbursements**

- 370 • **Compensate according to fair market value:** Honorarium or financial compensation
371 for services should be reasonable and it should represent the fair market value, taking
372 into account individual expertise and training, total amount of time invested, complexity
373 of tasks, country of origin, and other contributing factors, similar to compensation of
374 other highly trained professionals or consultants. A proposal on a methodology should
375 be discussed between patient advocates and pharmaceutical companies.
- 376 • **Reflect total time invested:** Any honorarium should cover time of physical presence
377 and real preparatory work done to carry out the service (e.g. pre-read material, pre-
378 meeting surveys). It may also cover part of travel time.
- 379 • **Respect the right to refuse compensation:** Patient advocates shall have the choice
380 to refuse compensation overall.
- 381 • **Provide choice of contractual partner wherever possible:** If allowed by local
382 regulation, the patient advocate should have the choice whether the contracting party
383 receiving the honorarium is the patient organisation or the individual. Other options
384 such as donations to an independent third party or grants may be discussed on a case
385 by case basis.
- 386 • **Reasonable travel expenses should be covered:** Travel reimbursement should
387 cover inbound and outbound flight and/or train cost, accommodation, transfer to and
388 from the meeting venue. The agreement must fix the terms of the payment. Travel
389 planning, conditions and reimbursement should take into account the specific needs,
390 physical or mental, of the patient's condition, including adequate number of hotel nights
391 before and after the meeting. In case an individual patient has a justified medical need
392 to be accompanied by other persons, travel costs of accompanying person should be
393 paid by the pharmaceutical company.
- 394 • **Long-distance flights justify higher flight class:** For health reasons, flights lasting
395 more than six hours should not be required to be in economy class. WHO or the EU
396 institutions' travel policies should be taken as a reference.
- 397 • **Reasonable three-way travel costs on duty should be covered:** Sometimes patient
398 advocates' work requires having two subsequent meetings with different
399 pharmaceutical companies or organisations at different locations, all within the patient
400 advocacy duties. A patient advocate should not be required to travel from or to their
401 home city in these cases. Three-way trips on duty should be permitted and also
402 reimbursed by pharmaceutical companies, based on proof of reason for "travel on
403 advocacy duty to all locations". The additional costs of the three-way travel should be
404 reasonable in relation to the cost of travel to the company meeting from the home city.
405 Generally, these trips should be paid by the pharmaceutical company to which the
406 patient is travelling. Alternatively, the costs can be shared whenever this is possible
407 with the organisation where the other meeting was held.

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- **Multi-day stopover on advocacy duty should be permitted:** If the patient advocate justifies the need to stay on advocacy duty for more than 24 hours after the meeting ends (e.g. the meeting will be held the first day of an important four-day congress), the company should cover the return flight even though it is more than 24 hours after the end of the meeting.
 - **Pay within 30 days:** The parties should strive to agree on settlement of a payment within 30 days after the date of the invoice. The same should apply to reimbursements of costs.

416 9. ADVERSE EVENT REPORTING

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418 RATIONALE - Do we really need adverse event reporting clauses?

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- Regulatory provisions require pharmaceutical companies and their employees and contractors to report any adverse events (“AE”) and serious adverse events (“SAE”) through their pharmacovigilance department 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 and due to the organisational structure of patient organisations, these obligations are impossible for patient advocates to fulfil, given they are supporting patients on a day to day basis outside of this collaboration, but they are neither set up, nor trained, nor required to fulfil pharmacovigilance requirements.

433 EXAMPLES of adverse event reporting

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- “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.”

439 GUIDING PRINCIPLES for regulating adverse event reporting

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- **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 patient advocates 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 patient advocates 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.

451 **10. INDEPENDENCE AND CONFLICT OF INTEREST**

452

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

- 454 • Patient advocates promote the interest of their constituencies, usually patients and
455 carers, and the broader patient community.
- 456 • Patient advocates and pharmaceutical companies may have similar interests regarding
457 topics that can affect patients' lives in areas such as research, treatment, care and
458 access.
- 459 • Interactions between patient advocates and pharmaceutical companies will be done in
460 a way that ensures that the decision making of the patient advocate side is respected
461 and not influenced by the pharmaceutical company.

462

463 **EXAMPLES of independence and conflict of interest**

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

466

467 **GUIDING PRINCIPLES for regulating independence and conflict of interest**

- 468 • **Respect the independence and autonomy of the patient advocate:** The
469 pharmaceutical company respects the mission, autonomy and independence of patient
470 advocates, and does not seek to exert any improper influence on their objectives,
471 activities or decisions. Specifically, any decision-making by the patient advocate should
472 be respected and not influenced by the pharmaceutical company.
- 473 • **Safeguard the independence of patient advocates by avoiding and declaring**
474 **potential conflicts of interest:** Collaborative work and/or remuneration shall not
475 constitute in any way an inducement to, or reward for, recommending or taking any
476 decisions favourable to any products or services of the company or its affiliates. An
477 initial declaration of interest may underline that the agreements made between the two
478 parties are concluded independently from any business transactions and decisions in
479 relation to the supply or purchase of goods or services from the company. Both parties
480 are obliged to report to the other party any change in circumstances during the contract
481 that can affect the absence of any conflict of interest.
- 482 • **Avoid exclusivity clauses:** In order to respect the independence of patient
483 advocates, the pharmaceutical company should not request nor expect exclusivity from
484 patient advocates.
- 485 • **Refer to applicable Codes and Guidelines.** To keep legal agreements short, they
486 may refer to any Good Practices or Code of conduct such as the "Code of Practice
487 between Patients' Organisations and the Healthcare Industry" or the "EFPIA code of
488 practice on relationships between the pharmaceutical industry and patient
489 organisations". Some agreements may also refer to local legislation.

490 **11. GLOSSARY**

491

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

493

- 494 • **Affiliate:** Organisation, subsidiary or other business that is formally attached to,
495 controlled by, or legally connected to a contractual partner.
496
- 497 • **Background Intellectual Property:** Intellectual property that is under control of either
498 party and existed prior to a contractual agreement, or is being developed
499 independently of the activities of this agreement.
500
- 501 • **Collaborative work:** It implies two or more people working together on a project, who
502 pursue research or other common objectives. It specifies the intent of the parties to
503 share data, research materials and facilities, and to publish the results of the project.
504
- 505 • **Consultancy work:** Work done by a consultancy or consultant appointed by
506 pharmaceutical companies to provide professional advice and support, and may also
507 be contracted to produce documents, or other deliverables. In exchange for the work a
508 fee may be paid.
509
- 510 • **Confidential information:** Sensitive, non-public information of a contractual partner,
511 written or oral, that needs to be protected from being made available to third parties
512 through any means of communication or observation. Confidential information may
513 include, but is not limited to, personal data, other data, know-how, processes,
514 documents, designs, photographs, plans, graphs, drawings, specifications, software
515 and associated information, source or object codes, algorithms, financial models,
516 business plans and marketing plans, reports, customer lists, pricing information,
517 results, inventions, ideas and other knowledge
518
- 519 • **Intellectual property rights:** rights e.g. on patents, trademarks, inventions,
520 copyrights, data, software, designs, concepts, trade secrets, know-how and all other
521 such rights, whether registered or unregistered and in any jurisdiction.
522
- 523 • **Patient advocate:** patient organisation, individual patient, carer, patient advocate,
524 patient organisation representative, patient expert (see EUPATI guidance for full
525 description of each concept)
526
- 527 • **The parties:** the pharmaceutical company and patient advocate
528
- 529 • **Third party data:** Data acquired from a source other than the parties of the agreement
530 and their affiliates.

531 12. PARTNERS AND AUTHORING PROCESS

532 In order to develop these guiding principles, two workgroups were established:
533

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

- 539 • Ananda Plate (MPE), Patient advocate, lawyer, WECAN chair and project
540 coordinator
- 541 • Ana Vallejo (MPE), Patient advocate and project manager
- 542 • Jan Geissler (Leukemia Patient Advocates Foundation), Patient advocate and
543 WECAN member
- 544 • Nicholas Brooke (PFMD), Patient Engagement advocate & PFMD Executive Director
- 545 • Imma Barral (University of Barcelona), Lawyer
- 546 • Gregor von Arx (Novartis), Pharmaceutical company representative
- 547 • Andrea Herrmann (Takeda), Pharmaceutical company representative
- 548 • Virginie Vassart (MSD), Pharmaceutical company representative
- 549 • Jordane Fura Cosse (Novartis)

550

551 **The Multi-Stakeholder Alignment Workgroup**

552

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

559

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

562

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

566

567 *Reviewed by the Myeloma Patients Europe, WECAN, Patient Focused Medicines
568 Development and AMGEN Europe.