



PHORUM USER GUIDE

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Table of contents

Competition compliance guidance	3
Supplier interactions	6
Information sharing	8
Use of online collaboration platform	11
Intellectual Property	12
Guidance on communicating BioPhorum in the public environment.....	Error!
<i>Bookmark not defined.</i>	



Competition compliance guidance

Introduction

BioPhorum takes compliance with anti-trust / competition law seriously and this guidance applies to all members and attendees of the Phorums. Members represent competing firms and certain activities / discussions might lead to a breach of competition law, which can have serious consequences both for the members and BioPhorum itself. These include substantial financial penalties of up to 10% of the annual worldwide group turnover, private actions for damages, reputational damage, and criminal liability in some countries for price fixing /market sharing. It is therefore paramount to make sure that activities of members of the Phorums are fully compliant with the requirements of competition law.

Possible breaches

1) Cartels / Price fixing / market sharing

A fundamental requirement of competition law is that companies act autonomously in the market and take commercial decisions independently of their competitors. Any actions which might lead to fixing prices or sharing markets and which therefore reduce strategic uncertainty as to the future market behavior of competitors will be in breach of competition law.

2) Exchange of competitively sensitive information

While discussions between members on best practice and how to improve safety and efficiency as well as discussions on how to respond to legislative proposals are all welcomed, the exchange of *competitively sensitive information* might be a breach of competition law. Importantly, even a single and one-way exchange of competitively sensitive information suffices for there to be a breach, and even if the parties have not implemented what was discussed.

The exchange of information that is in the public domain, which is old and aggregated (see section on benchmarking) is unlikely to raise competition concerns. On the other hand, information not in the public domain, which is current (or relates to future) as well as individualized could be a breach of the law.

In particular, this is likely to cover any information regarding:

- prices and pricing, including price components, discounts, price changes, price calculations, price strategies, costs
- market shares, profit margins, product portfolio development and optimization
- details of contracts with third parties, terms of delivery or payment, delivery quantities, capacities



- current and future market strategy (e.g., size, numbers, areas of activity, planned investments).

3) Benchmarking

Benchmarking exercises (and market surveys) are generally intended to improve the efficiency and competitiveness of the participants and can therefore have pro-competitive effects. However, they may also raise competition law concerns when the companies involved are actual or potential competitors, particularly where the benchmarking exercise entails the exchange of confidential information.

In order to avoid competition issues, benchmarking exercises should be carried out by an independent third party (which could be BioPhorum) and should be limited to topics necessary to understand the area being benchmarked. Data should be anonymised and aggregated and should include a sufficient large number of participants so that it is not possible to reverse engineer the data.

Benchmarking should never be carried out on competitive sensitive information such as future plans (especially on pricing, new product development, marketing strategies), profitability models, etc. If in doubt, please seek competition law advice.

Best practice for the meetings of the Phorums

Members participating in the Phorums are strictly prohibited from exchanging *competitively sensitive information* with competitors not only during meetings of the Phorums but also outside of meetings of the Phorums. This includes off-the-record occasions such as coffee breaks and social events as well as online collaboration platforms.

Representatives of members of the Phorums should be required to complete a competition law training annually provided by their employer (the Member company) and at the beginning of each meeting of the Phorums, the chairperson of the meeting should remind the participating members of their obligations under competition law and arrange for this reminder to be mentioned in the minutes.

A draft agenda should be agreed by the participants and circulated prior to each meeting. The agenda should have a clear wording and be as detailed as possible. Generic points such "Any other business" should be avoided. The participants should always follow the agenda.

If members participating in the Phorums believe that a point on the agenda is likely to give rise to competition law issues, they should contact the chairperson of the meeting in order to object to the point being included in the agenda and ask for a legal review.

The chairperson should stop the discussion if it digresses into subject matter which involves *competitively sensitive information*.



After each meeting of the Phorums, the minutes should be prepared and promptly made available to all participants. The participants should have an opportunity to comment on the contents of the minutes and object to any misleading wording.

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Supplier interactions

1. BioPhorum facilitates a cross industry collaboration process for developers and manufacturers across different business sectors with the aim of accelerating the rate at which the operational practices are advanced.
2. Collaboration modes include best practice sharing, benchmarking, joint-solution development to common challenges, definition of standards requirements and formation of collective perspectives to mutual opportunities and regulatory guidelines.
3. Developers and manufacturers recognize the legally enforceable duties they have including the responsibility to control the quality of materials from their suppliers. From time-to-time BioPhorum facilitated collaboration requires, and benefits from, supplier interaction.
4. Suppliers are providers of supply chain materials such as chemicals, glass, components, excipients, and media. They are also providers of process equipment such as single use systems, engineering parts and consumables. BioPhorum-facilitated supplier interactions may involve, amongst other things:
 - harmonizing manufacturer requirements/standards and communicating these to suppliers
 - seeking feedback on proposed standards
 - gaining opinions and ideas related to business process improvement
 - use of problem-solving tools; and
 - gaining support for new ways of working
5. The goal of the Phorum collaboration is to strengthen competition, agreeing on industry standards, assure product quality, reduce waste, improve efficiency, and protect patient supply.
6. The purpose of this document is to set out the principles and policies that BioPhorum follows is to ensure that BioPhorum facilitated supplier interactions are conducted in the correct and appropriate way to meet all legal and business compliance requirements.

Underlying principles and policies

7. **Competition Laws**
All members interactions with suppliers must comply with anti-trust and competition laws relevant to the members and have regard to BioPhorum's competition compliance guidance.



8. Member responsibilities

Individual members are responsible for defining their requirements of suppliers.

9. Innovation and commercial interests

All supplier interactions will recognise and respect the need for suppliers to innovate and pursue their own commercial interests.

10. Intellectual Property

All supplier interactions will respect suppliers' intellectual property rights.

11. Confidentiality / Non-Disclosure

All supplier interactions will consider, respect, and encourage compliance with confidentiality and non-disclosure agreements.

12. Equal treatment

All suppliers will be treated equally

13. Communication

These principles, policies and procedures will be communicated to Phorum members and suppliers whenever supplier interactions are planned or are taking place.

14. BioPhorum responsibilities

It is the responsibility of Phorum facilitators to ensure that these principles and policies are upheld, and procedures are in place to support them.

BioPhorum will educate and train its staff, so they understand and follow these principles and policies and are able to communicate them when needed.

BioPhorum documentation will reference or directly include relevant parts of the Supplier Interaction Policy.

BioPhorum will establish and maintain records to demonstrate compliance with these principles and policies.



Information sharing v5.1

Introduction

BioPhorum Operations Group (BioPhorum) is a cross industry collaboration with the aim of sharing best practice in the area of Operational Excellence. Participation in BioPhorum is restricted to authorized member company representatives as described in the Principles of Membership Agreement.

While sharing information is central to the process of this collaboration, it is important to understand what information is appropriate to share. Our companies have a great deal of confidential information and intellectual property that should not be shared within BioPhorum. This document seeks to guide the reader so that the individuals and companies involved follow the correct code of conduct and problems are avoided. It is the clear and stated intention of BioPhorum that the Group and its activities are conducted at all times in full compliance with relevant competition/anti-trust rules.

Responsibilities

It is the responsibility of every person who participates in a BioPhorum event or sharing activity to make sure they are aware of what information is appropriate to share. When sharing third party documents on The BioPhorum Hub (or other IT systems), participants should use links to documents to avoid breaching copyright requirements.

BioPhorum are responsible for reminding all participants of their obligations with respect to information sharing and will ensure that the relevant watermark will be included on documents.

Participants should not share outside workstream/Phorum teams unpublished material including but not limited to:

- Ask BioPhorum or survey responses including summary data
- Meeting preparation material or minutes of BioPhorum meetings
- Draft papers (including but not exclusively documents currently marked Membership draft)
- Individual opinions of representatives or their companies spoken at BioPhorum meetings
- Industry feedback captured using tools such as virtual whiteboards, polls or surveys.

Members can share BioPhorum confidential information (including documents marked Membership published) within their own organization, but the key contact (L2) for each member should ensure confidentiality and that IP issues are highlighted to their colleagues and all applicable company policies regarding external collaboration and public disclosure are adhered to. All participants are responsible for vetting information to be shared via their



company's public disclosure review processes and that all information shared is free of any 'Confidential' label.

Participants' contact details

Every person who participates in the BioPhorum collaboration will have access to the business contact details of other participants. These details should only be used for making contact with other participants in matters that relate directly to their work in BioPhorum.

- Use of these contact details by participants in the following circumstances is prohibited:
- Compilation of mailing lists and advertising or marketing of any kind
- Creating a database of contact details in any circumstances
- Recruitment and job advertising
- Participants who are unsure as to whether their use of contact information is acceptable or not should refer to their BioPhorum representative.

Sharing information

The following list is representative of the types of disclosures commonly allowed by corporate policies. Phorum participants should review their company policies to ensure they are complying prior to any disclosures. Information in the following areas is typically allowed:

- Operational excellence best practice models
- Management approaches and philosophies
- Organizing and planning ways of working
- Non-product or process specific generic operating procedures
- Information in the public domain
- Information provided by suppliers which would ordinarily be shared with customers
- Non-product or process specific generic engineering or technical information relating to process equipment
- General learning and 'context' conclusions from QA and Regulatory activity

Sharing information from the following areas is typically prohibited by corporate policies:

- Product related information
- Product related process data which constitutes intellectual property
- Specific audit or regulatory inspection findings or observations
- Product specific analytical methods
- Specific cost numbers where a market advantage may result, or a supplier might be disadvantaged
- Information that is marked as confidential by the member company or a supplier
- Price information of any type
- Proprietary information including intellectual property and patented processes and equipment



BioPhorum event participants should direct all questions regarding information disclosure to their L2 BioPhorum representatives or corporate legal departments.

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Use of online collaboration platform

1. BioPhorum uses an online collaboration platform (IMeetCentral) to carry out discussions, workflows, sharing of data between members of a Phorum.
2. All Members shall comply with the terms of use of IMeetCentral (see: <https://app.imeetcentral.com/terms>).
3. Representatives of Members shall use their work email address and contact details at all times and shall not display their personal email address.
4. Further, Members shall comply with all its obligations under their applicable laws including, but not limited to, anti-competition or anti-trust laws, when using the online collaboration platform.
5. A representative of a Member who is found to be in breach of the terms of use and/or this policy shall be reported to the representative's management.
6. BioPhorum shall be entitled to take any action it deems necessary, including the suspension or termination of membership in relation to any breach of the terms of use and/or this policy.



Intellectual Property

1. All publications made by BioPhorum as a result of collaboration between members of the Phorums are the intellectual property of BioPhorum.
2. All Phorum members who had contributed to the collaboration are entitled to use the publication on a royalty free basis for discussions or further research within the member's organisation.
3. If Phorum members intend to quote or otherwise refer to the publication, the Phorum members must provide suitable attribution and ensure that any quote from the document shall not exceed 10% of the total text in the publication
4. Any party who ceases to be a member of the Phorum shall no longer have the right to quote or otherwise refer to the publication without the express permission of BioPhorum.



Guidance on communicating BioPhorum in the public environment

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Contents

1. Purpose
2. Types of communications
3. Copyright and licensing
4. Reviews and approval
5. Summary

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1.0 Purpose

- 1.1 BioPhorum Operations Group (BioPhorum) facilitates a series of Phorums that are missioned to advance and improve the capabilities and performance of the global biopharmaceutical manufacturing industry. As such, the teams in the collaboration routinely communicate with the rest of the industry by speaking at conferences and publishing articles and technical papers that position surveys, user requirements, risk assessment approaches and guidance documents.
- 1.2 The purpose of this guidance is to ensure these communications are approved, published, and presented in a controlled way that is in-line with the needs of the BioPhorum community and the member companies.
- 1.3 It is the joint responsibility of the BioPhorum facilitators and the L2 Leaders in each of the Member Companies to ensure these guidelines are followed.
- 1.4 **Good practices** are identified in this guideline, and it is highly recommended that they be followed. Mandatory practices are identified as '**must** be followed'.
- 1.5 This guidance is written in line with BioPhorum's Principles of Membership, Anti-Trust statement and other policies.
- 1.6 When a team is about to embark on the writing of an article or paper it is considered **good practice** to read this first and then the BioPhorum Paper writing and publishing best practice.

2.0 Types of communications

2.1 Articles

2.1.1 These are written by workstream and sub-teams to communicate a point of view or comment about a best practice, benchmark analysis or proposed approach in connection with their workstream's mission. The team, having shared their information would have made a decision as part of their charter and workstream planning to make some of that public.

2.1.2 It is considered **good practice** to clearly identify the purpose of the external communication. The reasons could be, but are not limited to:

- broadcasting the intention of a team to explore and address an industry challenge, and ensure all third parties are aware and can comment
 - predisposing the industry to a proposed way of working or point of view that ultimately eases implementation
 - seeking feedback to concepts and ideas that would lead to the strengthening of those concepts and ideas
 - attracting other ideas and contributions not thought of by the team
 - laying a platform for further innovation and advancement in the area
- Industry magazines, such as BioProcess International and the ISPE's Pharmaceutical Engineering would be typical publishers of articles.

2.1.3 When publishing benchmarking data and analysis individual companies **must not** be identified against data points unless this is specifically intended.

2.1.4 It is considered **good practice** that draft magazine articles are subject to peer review either by others in the BioPhorum community or by external subject matter experts.

2.1.5 For magazine articles the workstream team members (company representatives) would jointly author and be shown as co-authors. Their names, job titles and companies would normally be listed in the publication. The team is most likely to contain a subset of the Phorum membership. Those representatives who did not write or make a major contribution to the article, can be named in the acknowledgements where they want to be seen as supporting the points being made.

2.1.6 Generally, the views expressed are those of the team members rather than the companies they represent but clearly the credibility / reputation of the companies involved need to be considered when reviewing the material.

2.1.7 Company logos would not normally be shown in these documents.

2.1.8 L2 Leaders **must be** notified of the existence of draft magazine articles during their creation to provide an opportunity for comment and to ensure visibility, where in the



reasonable opinion of BioPhorum that L2 will be impacted/affected by the article. BioPhorum account managers will include external communications as an agenda item during the monthly account meetings with L2s.

2.1.9 As part of the planning process for magazine articles sufficient time **must be** given for review and approval to take place by all workstream participants. Deadlines must be clear and agreed by the team members.

2.1.10 Where magazine articles are authored only by a BioPhorum facilitator then L2 coordinators **must be** notified in advance of publication and a draft made available where requested.

2.2 Technical papers

2.2.1 These are written by BioPhorum teams and contain a justified technical or scientific proposition or hypothesis in connection with the workstream mission. There would be deeper technical or scientific content compared to magazine articles. There might be reference to experimental / test data either from publicly available sources or from studies done by individual companies and conclusions drawn. Technical papers may include:

- statements of user requirements
- guidance documents on harmonized assays, methods and approaches
- risk and criticality assessments
- industry definitions and maturity profiles
- roadmaps

2.2.2 It is considered **good practice** to clearly identify the purpose of the external communication. The reasons could be to:

- introduce the industry to a proposed scientific advance connected with a new way of working
- seek feedback on new concepts and ideas that would lead to the strengthening of those concepts and ideas
- attract other ideas and contributions not thought of by the team
- lay a platform for further innovation and advances in the area

2.2.3 Specialized (peer reviewed) technical journals would be typical publishers of these technical papers (e.g., PDA Journal).

2.2.4 When publishing benchmarking data and analysis individual companies must not be identified against data points unless this is specifically intended.

- 2.2.5 Draft technical papers must be subject to independent peer review by others in the BioPhorum community and where requested by publishers, external subject matter experts.
- 2.2.6 The BioPhorum workstream team would author the articles. Their names and companies would be listed in the publication. The team is most likely to contain a subset of the whole Phorum membership. Those representatives who did not write or make a major contribution to the article, can be named in the acknowledgements where they want to be seen as supporting the points being made.
- 2.2.7 The views expressed are those of the team members, but the credibility / reputation of the companies involved need to be carefully considered when reviewing the material.
- 2.2.8 Company logos would not normally be shown in these documents.
- 2.2.9 As part of the planning process for technical papers sufficient time must be given for review and approval to take place by all workstream participants. Deadlines must be clear and agreed by the team members.
- 2.2.10 Where a scientific or technical approach is proposed by the workstream team and there are valid alternatives put forward within the team then they must be fully explored by the team. If consensus on the way forward is not reached it is considered **Good Practice** to include those alternative viewpoints within the body of the paper or as a footnote.
- 2.1.11 L2 Leaders must be notified of the existence of draft technical papers during their creation to provide an opportunity to comment and to ensure visibility, where in the reasonable opinion of BioPhorum the L2 will be impacted/affected by the article. BioPhorum account managers will include external communications as an agenda item during the monthly account meetings with L2s.

2.3. Conference presentations

- 2.3.1. Summaries or sub-sets of any of the above documents (articles and papers) could be presented verbally with supporting slides on a public platform. Alternatively, presentations could be stand-alone case studies or points of view.
- 2.3.2 It is considered **good practice** to clearly identify the purpose of the external communication. The reasons could be to:
- broadcast the intention of a team to explore and address an industry challenge and ensure all third parties are aware and can comment
 - predispose the industry to a proposed way of working or point of view that ultimately eases implementation
 - seek feedback to concepts and ideas that would lead to the strengthening of those concepts and ideas



- attract other ideas and contributions not thought of by the team
- lay a platform for further innovation and advances in the area
- in a conference situation, panel sessions (often with other SMEs and industry stakeholders present) provide an opportunity to have Questions and Answers aired to support the above objectives.

2.3.3 The types of conferences that would normally be considered would be industry recognized events including those run by:

- ISPE
- PDA
- BioProcess / Informa
- CASSS

The preferences and relative merits of the conferences would be discussed in the workstream team, and a consensus reached as to which one(s) to attend.

2.3.4 When presenting BioPhorum workstream material it is considered **good practice** to use standard BioPhorum slide templates, or the template specified by the conference provider. Appropriate reference can be made to the presenter's affiliation.

2.3.5 Member company logos **must** never be used in presentations.

2.3.6 It is considered **good practice** to identify all conference presentations by workstream representatives in the BioPhorum conference tracker, About BPOG calendar on iMeet Central and to make abstracts available for review. It is **good practice** for BioPhorum account managers to include external communications as an agenda item during the monthly account meetings with L2s.

2.3.7 L2 Leaders must be notified of the existence of draft conference presentations during their creation to provide an opportunity to comment and to ensure visibility, where in the reasonable opinion of BioPhorum the L2 will be impacted/affected by the presentation. BioPhorum account managers will include external communications as an agenda item during the monthly account meetings with L2s.



3.0 Copyright and licensing

- 3.1 BioPhorum Operations Group Ltd owns the copyright of all outputs from the collaboration to protect the interests of the community and members.
- 3.2 Where work is completed in a consortium with a trade, professional or standards body copyright can be shared. Where this is the case, this **must be** agreed in suitable a Memorandum of Understanding or contract agreed and approved by the Directors of the BioPhorum Operations Group Ltd. This will define how the documents are controlled and can be made available by both parties.
- 3.3 Licensing agreements for all magazine articles, technical papers and presentations **must** be appropriately and properly set up following the normal rules of the member companies.
- 3.4 Generally, these would be to retain copyright (i.e., not to assign it to the publisher) but to allow the rendered (image) of the publication to be owned by the publisher.
- 3.5 All co-authors should be clear on what agreements have been signed and by whom. All agreements will be held on SharePoint in a central accessible folder.

4.0 Reviews and Approval

4.1. Internal company review

- 4.1.1 Two elements of internal review **must** be recognized: Technical / Regulatory Reviews and Legal Approval.
- 4.1.2 Every member company has a clearly defined legal approval process for external communications this will include all BioPhorum interactions. The level of content (technical / regulatory) review may vary from company to company. All co-authors / presenters of each type of communications listed above **must** follow their own internal company review procedures without exception.
- 4.1.3 It is considered **good practice** to complete the Technical Review, with all participating companies first, and then having consolidated all changes into an agreed technically correct document, submitted for legal approval. all changes will be consolidated prior to the legal approvals being sought.
- 4.1.4 It is considered **good practice** that workstream team members provide an early advanced warning to their internal colleagues to prevent problems and delays later.
- 4.1.5 It is considered **good practice** that the BioPhorum facilitator in conjunction with the workstream team ensure that timeline plans allow sufficient time for internal company review and that a draft is made available in a timely way.
- 4.1.6 Where appropriate, it is considered **good practice** to consult Regulatory Interactions team early in the development of the paper where there could be a regulatory component or impact arising from the concepts contained in the communication.
- 4.1.7 Approvals of a paper **must be** signalled by email by the representative of a company or the Lead L2. As these approvals are received the workstream facilitator **must** retain copies and collate and track approval status in one place. It is considered **good practice** to update L2 Leaders of progress of approval through the Account Management process.

4.2. Independent peer review

- 4.2.1 Some publications will require a paper to go through an independent peer review as they will not consider the normal debate in the BioPhorum team an independent reviewer. The purpose of this review is to ensure there are no significant errors, misleading arguments, or gaps in the content of the paper.
- 4.2.1 The publication may use their own peer review panel, or they may ask the team to identify/nominate four-five respected reviewers for this process. These names will

need to be given during the submission process. In these cases, it is considered **good practice** for the team to identify them well before submission.

4.3. L2 review

4.3.1 For all papers and presentations listed above, the L2 Leaders **must** ensure their workstream representatives have followed the correct review process. There is no suggestion that they review the content of the communication unless they would like to.

5.0 Summary

Reviews and subsequent approvals **must** be obtained and documented prior to committing to a publication or presentation.

	Internal (Legal) company review by each co-author	Internal (Technical / Regulatory) company review by each co-author	Independent peer review	Coordinators (L2) process review	Example content	Comments
Magazine articles	Yes	Yes, unless there is no internal requirement	Yes, but could be others in BioPhorum	Yes	Benchmarks Case Studies Point of view	Discussion prompting
Technical papers	Yes	Yes	Yes	Yes	Scientifically justified proposal	New approaches backed up with technical arguments
Conference presentations	Yes	Yes, unless there is no internal requirement	No	Yes	Summary of any of the above	