



EXCiPACT asbl

Governance and Compliance Policy

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The EXCiPACT association, being non-profit making, has the aim of providing for independent 3rd party certification of manufacturers, suppliers and distributors of pharmaceutical excipients worldwide. This will help ensure patient safety, through improved supplier quality, whilst minimising the overall risks and costs for assuring the excipient supply chain. To that end, the activities of the Association shall include international co-operation.

EXCiPACT has two types of membership:

- I. Trade Associations that represent groups of organisations who have an interest in manufacturing, distributing or using excipients
- II. Associate membership may be granted to companies or associations that are not eligible for full membership but are engaged in producing excipients or engaged in operating distribution facilities. Associate Members may also be individuals with no specific affiliation to a company or association but who have experience and knowledge of excipient manufacture and distribution.

Introduction

Recognising the legitimate public interest in corporate social responsibility, governance and institutional transparency, this document formally records the Governance and Compliance Policy and Values which apply to all activities conducted by EXCiPACT.

Internally, and with regard to its Members and Stakeholders, it is essential that EXCiPACT applies transparency in the way it is organised and operates. Transparency of operation can be found in EXCiPACT's Articles of Association, and By-laws (Quality Manual), which describe the fundamental rules of operation of its statutory bodies and related structures. These documents are not just a "private association contract", but have formal approval from the Belgian authorities, giving EXCiPACT the status of a Belgian "Association sans but lucratif".

In order to support the values and related perceptions of our industry, it is essential that EXCiPACT not only complies with statutory provisions and legal requirements regarding the essential features of the association (e.g. conduct of non-profit activities, fulfilment of the financial / taxes obligations), but also operates to the highest level of ethical standards.

This Policy applies to all EXCiPACT staff and Member representatives as well as all participants who are managing its activities.

This policy does not apply to individual companies for their own operations outside EXCiPACT activities or control.

Governance in EXCiPACT

For a non-profit organisation such as EXCiPACT, governance is a vital component of its internal support and cohesion and of its external recognition by public and private Stakeholders. It is a set and a combination of fundamental values, regulations, processes, internal disciplines and codes of conduct which shall enable EXCiPACT to achieve its published objectives and fulfil its mission, whilst:

- Meeting both legal obligations and social expectations within each region of global operation
- Defining its key references and values
- Providing a robust umbrella and framework to EXCiPACT activities with clear recognized identity, thus bringing added value to its work

Whom does it concern?

Governance values and disciplines should be shared and applied by all those involved in delivering EXCiPACT products and services. Within EXCiPACT, this particularly implies:

- Clear ownership of EXCiPACT governance by its leading bodies: the General Assembly, the Board of Directors, and the Director General (if appointed)
- Understanding and compliance with regard to all related activities, and by all representatives of the membership
- Full awareness and compliance of the executive management and staff of EXCiPACT, under the supervision, guidance and co-ordination of the EXCiPACT General Legal Counsel

Fundamental Driving Values

ROBUST, EFFECTIVE AND TRANSPARENT RULES FOR EXCiPACT'S STATUTORY BODIES AND RELATED STRUCTURES

- This will apply to any activity of EXCiPACT so that effective and transparent rules of operation are established, understood and followed when managing those activities.
- There should be a risk committee (or at least this item on board agenda's) so that risks to EXCiPACT are proactively assessed and appropriate plans made to mitigate those risks ((these could be financial, personnel, commercial or Health, Safety or Environment related).

RESPECT THE LAW

- All relevant Local, National, and International laws will be respected. Special focus shall be given to practical guidance regarding compliance with competition law described in Appendix 1 of this Document.

MAINTENANCE OF HIGH CREDIBILITY VIS-À-VIS INSTITUTIONS

(The details of this are described in Appendix 2 of this Document)

- The EXCiPACT organisation should always be represented in a non-equivocal manner, on the basis of clear definition of aims and issues to be discussed
- Members will work together to encourage consistency and cohesion of advocacy. Ensuring a clear distinction between EXCiPACT stated positions and any diverging opinions which they may hold on behalf of the company / association they represent
- EXCiPACT representatives must behave with integrity and the highest ethical standards
- Information required by the organization must be obtained by lawful means
- Any form of active or passive corruption (such as blackmail, offers of influence, promises and gifts) of inappropriate value to the activity concerned are strictly forbidden

- A register of all gifts received will be kept by the Secretariat and all EXCiPACT officers will declare receipt of any gifts to the Secretariat.
- Institutions' codes of conduct, or recommendations on dealing with Institutions, civil servants, MEPs and others, when existing, will be complied with. Members must declare their EXCiPACT representation in all such dealings
- Requirements governing the protection of private life will be strictly complied with
- Statistics regarding the industry will be gathered, referenced and used in an open and transparent way
- Behavioural ethical principles will be strictly followed when making advertising
- There should be a mechanism for whistleblowing

PROTECTION OF CONFIDENTIAL INFORMATION

- Confidential information and Intellectual Property rights of third parties, including Members, and auditees will be fully respected by EXCiPACT staff, Members and others acting on EXCiPACT's behalf.

The EXCiPACT Board is empowered to promulgate and amend from time to time as and when required, the processes, the internal disciplines and codes of conduct covering the implementation of these Fundamental Driving Values.

The EXCiPACT Association shall have a formal quality management system and a Board member designated as Quality Manager.

Processes and Implementation

COMPLIANCE PROCESSES ARE CORE VALUES OF EXCiPACT/ OVERALL CONSISTENCY

The implementation of Compliance Programmes is part of the general policy of EXCiPACT and will be applied and respected with regard to all EXCiPACT activities. They are organized and run by the EXCiPACT Board, which will also ensure consistency by having, inter alia, (i) a set of written rules and standards and (ii) a mechanism for enforcement.

This is done in support of other EXCiPACT services and constituencies, and in turn, staffs at all levels are responsible for the effective appropriation and application of the Compliance Programmes by the Members of their teams.

EDUCATION, REPORTING, OPEN DISCUSSIONS AND CONSULTATION

EXCiPACT has put in place the necessary structures and responsibilities (including documentary and operational), to achieve this widespread compliance and practice.

EXCiPACT Association shall only engage in advocacy where there is a direct impact on the Certification Scheme or the activities of the Association. In general, EXCiPACT Association should leave matters of advocacy to the Full Members of the Association.

EXCiPACT Association shall not engage in any political involvement.

EXCiPACT Association is a not for profit association and is reliant on income from its services and registration fees to meet its expenditures. EXCiPACT Association will accept philanthropic donations where these are made with conditions or without any indication of a conflict of interest to either party.

With regard to employees there should be

- Freedom of association
- Anti-discrimination
- Programmes to reduce health and safety incidents, including reporting of metrics

Appendix 1: Respect of Competition Law

PRACTICALITIES

Guidance for staff and members involved in EXCiPACT activities

Respect of competition law is a core value applying to all EXCiPACT activities. It is developed through the effective management of the following principles:

Staff and Members' responsibility

Any infringement will be considered as professional misconduct, and ignorance will not be accepted as an excuse for infringement.

A brochure is distributed to EXCiPACT staff and EXCiPACT Members.

All staff and members attending EXCiPACT Meetings are expected to read and be familiar with the content of this brochure.

Awareness and Education

All staff will be required to attend a periodic compliance training session, as well as other targeted information platforms as required.

Record Keeping

Organising the necessary maintenance and archiving of meeting documents, including minutes, agendas, and other important documents necessary to reflect the discussions.

Advice

The EXCiPACT Board, conducts the drafting and circulation of, for example compliance documents, consultations.

Co-operation in inquiries and Inspection

In addition to maintaining compliance, EXCiPACT pursues a policy of transparency to competition authorities involved.

Do and Don't Checklist

The following list is designated for application by EXCiPACT staff and Member Representatives who are responsible for the management of meetings. It is also intended to be read and followed by attendees of these meetings. These rules do not relieve individuals of their responsibility to use their own judgement in inappropriate situations.

COMPETITION LAW CHECKLIST FOR MEETINGS

This checklist is for the conduct of EXCiPACT-sponsored meetings. Prohibited discussion topics apply equally to social gatherings incidental to those meetings. The checklist is not exhaustive.

DO ENSURE STRICT PERFORMANCE IN AREAS OF:

Oversight / supervision

- Each meeting of the EXCiPACT must have a representative of the secretariat in attendance
- Consult with appropriate counsel on all questions which might be related to competition law.
- Limit meeting discussions to agenda topics. Provide each attendee with a copy of this checklist, and have a copy available for reference at all meetings

Recordkeeping

- Have an agenda and minutes that accurately reflect the matters which occur
- Ensure the review of agendas, minutes and other important documents by appropriate staff or counsel, in advance of distribution
- Fully describe the purposes, structures and authorities of the groups

Vigilance

- Protest any discussion or meeting activities which appear to violate this checklist; ask for those activities to be stopped so that appropriate legal check can be made by counsel. Disassociate yourself from any such discussion or activities and from the attendees, leave any meeting in which they continue (and have it minuted)

DON'T

DO NOT, IN FACT OR APPEARANCE, DISCUSS OR EXCHANGE INFORMATION NOT IN CONFORMITY WITH COMPETITION LAW, INCLUDING FOR EXAMPLE:

Prices

- Individual company / industry prices, price changes, price differentials, discounts, allowances, credit terms, etc.
- Individual company data on costs, production, capacity, inventories, sales, etc.

Production

- Plans of individual companies concerning the design, production, distribution or marketing of particular products, including proposed territories or customers
- Changes in the industry production capacity or inventories, etc.

Transportation rates

- Rates or rate policies for individual shipments, including basing point systems, zone prices, freight, etc.

Market procedures

- Company bids on contracts for particular products; company procedures for responding to bid invitations

- Matters relating to actual or potential individual suppliers or customers that might have the effect of excluding them from any market or influencing the business conduct of firms toward them, etc.
- Blacklist or boycott customers or suppliers

Appendix 2: Maintenance of High Credibility vis-à-vis Institutions and Stakeholders

PRACTICALITIES

Guidance for staff and members involved in EXCiPACT activities

The organisation should always be represented in a non-equivocal manner, on basis of clear definition of aims and issues to be discussed. The objective is to ensure that different audiences receive the same messages from all EXCiPACT representatives. EXCiPACT is represented by its own staff or authorized delegates (e.g. members of related associations, or consultants).

All refer to agreed common objectives and guidelines to speak in the name of EXCiPACT:

- When working in an advocacy team, individuals should refrain from acting in isolation, retaining information which may be useful to everyone.
- There is a need for a networking system to act in a collegial and coherent manner (EXCiPACT/related associations).

Members will work together to encourage consistency and cohesion of advocacy. They are expected to support EXCiPACT positions as adopted in accordance with its By-Laws and Quality Manual. In case of disagreement Members are expected not to use the EXCiPACT name when holding diverging opinions.

Conflicts of interest between the personal interests of staff and Member Representatives and the interests of EXCiPACT must be avoided. Staff and Member Representatives must act purely in the interests of EXCiPACT, and not be influenced by their personal interests. Requirements governing the protection of private life must be strictly complied with. This is especially important in relation to, for example, data banks, electronic networks.

Any form of active or passive corruption (such as blackmail, offers of influence, promises and gifts) are strictly forbidden. Gifts and invitations which may be interpreted as an attempt to corrupt must not be offered. Similarly, any behaviour which may be interpreted as soliciting third parties with the intention to receive gifts or invitations must be avoided.