

Code of Conduct & Complaint Management

This code of conduct is not intended to replace the legal provisions and regulations applicable to the members of BACHI.

The rules set out in this code are not exhaustive but constitute a common and essential framework aiming at a responsible, ethical and deontological behaviour by the members of BACHI with regard to the mission of the association.

This code is only applicable in Belgium and concerns the business practices carried out on the Belgian territory.

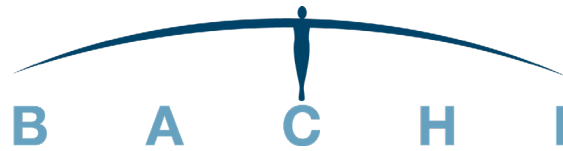
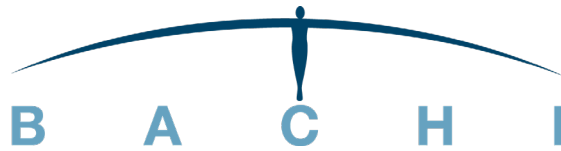


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1. Preamble

BACHI is the Belgian Association of the Consumer Healthcare Industry representing companies commercializing over-the-counter (OTC) healthcare products¹ and defending their common interests.

As a key player active in public health, BACHI promotes a responsible self-medication

- as part of a responsible way of caring for oneself
- in the interest of patients, consumers, pharmacists, healthcare professionals and companies that are members of the association
- for a responsible economic policy regarding medicines and healthcare products

In the light of its mission, BACHI strives to

- stimulate and guarantee a favorable social and political environment for selfcare where the patient-consumer occupies a central position,
- constitute a key interlocutor for healthcare authorities, a force for proposals and a generator of ideas on the status and future of healthcare products, and to
- develop recommendations and position statements leading to a common vision applicable to all its members, taking into account the highest level of ethics and within a respectful, caring and transparent framework.

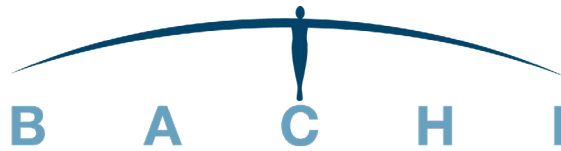
Members of BACHI, concerned about compliance with the law, have decided to set up a code of conduct with the ambition of enabling a self-regulation of the sector through compliance with the principles and procedures set out in the code (as a first step).

This code of conduct is not intended to replace the law, but rather to propose a discussion platform prior to any other action and escalation to the authorities.

The rules set out in this code are not exhaustive but intended to reflect a certain mindset and way of acting in order to meet the requirements of a responsible, ethical and deontological behavior with regard to the mission of BACHI.

With this code of conduct, BACHI aims to formalize a procedure for its members by creating a framework for an impartial handling of possible complaints, including the transparency of opinion adopted.

¹ Term originally used to refer to medicines behind the counter which can be purchased without a medical prescription. Today, in common practice, this term covers all healthcare products sold directly to a consumer, regardless of their status. These products can be medicines (not subject to prescription and not reimbursed), medical devices, food supplements, cosmetics or biocides.



2. Purpose

The purpose of this code of conduct is to:

- set up a self-regulation system for business practices (that includes ethical practices, advertising, communication and promotion in a broader sense) that covers all prescription-free healthcare products regardless of their status;
- formalize the essential commitments of BACHI members in case of potential non-compliance with the law; and to
- define a common framework for complaints management.

The objective of the Code of Conduct is to set-up a non-binding framework to amicably settle possible disputes between companies in an efficient manner and in view of avoiding long procedures. It cannot interpret as preventing members to exercise their legitimate rights, as they follow from the law.

3. Definitions

Self-regulation

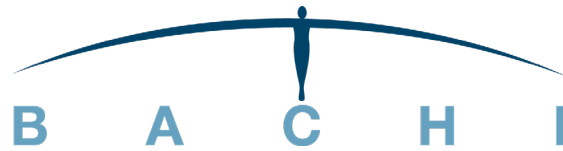
Process whereby members of an industry set and enforce their own rules and standards (through a specific code of conduct). The code of conduct explicitly describes the rules that members commit to follow and respect and on which they will be monitored. A self-regulation system is not a substitute for the law but can be more restrictive than the law.

Selfcare

Practice of individuals looking after their own health using the knowledge and information available to them. It is a decision-making process that empowers individuals to look after their own health efficiently and conveniently, in collaboration with health and social care professionals as needed. Selfcare involves being physically active and eating healthily, avoiding unhealthy lifestyle habits, making responsible use of prescription and non-prescription medicines, assessing and addressing symptoms, in partnership with a healthcare professional where necessary, checking for signs of deterioration or improvement and managing symptoms of disease, either alone, in partnership with healthcare professionals, or alongside other people with the same health condition.

Sunshine Act

The Sunshine Act imposes pharmaceutical and medical devices companies, both Belgian and foreign, to document and annually disclose on the platform Betransparent.be the premiums and benefits that they granted directly or indirectly to healthcare professionals, healthcare organizations or patient associations as from 1 January 2017. The transparency obligation laid down in the Sunshine Act applies to all entities engaged in an economic activity, regardless of their legal status and the way in which they are financed.



4. BACHI members' commitments

4.1. Ethical behavior

BACHI's members are committed to ethical behavior in their operational activities by:

- being aware of their role in public health issues,
- acting as responsible health actors,
- ensuring that their relationships with healthcare professionals and the public are conducted at the highest level of ethics and within a respectful, caring and transparent framework,
- being an example for the other members of BACHI, and
- acting with the required integrity in their interactions with other members and any third parties.

4.2. Compliance with the applicable legislation

4.2.1. BACHI's members shall refrain from any abusive commercial practices towards competitors (such as unfair competition, parasitism, disorganization, imitation, ..., see Code of Economic Law, book VI).

4.2.2. BACHI's members also commit to comply with the rules applicable to their business, including but not limited to:

1) *Rules on advertising (broadly speaking)*

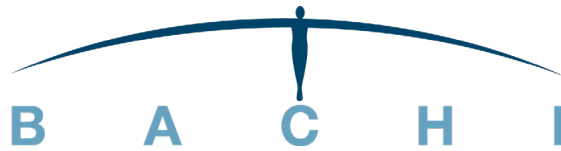
- The Code of Economic Law, when it regulates:
 - the advertising and practices that are contrary to fair business practices between companies or towards one or more companies (in particular Art. VI.103/1 to VI.109/3)
 - unfair commercial practices towards consumers including advertising (in particular Art. VI.92 to VI.103)
 - comparative advertising (Art. IV.17)

2) *Rules on advertising of medicines (if relevant)*

- The law of 25 March 1964 on medicinal products and the Royal Decree of 7 April 1995 about information and advertising concerning medicinal products for human use

3) *Rules on advertising of medical devices (if relevant)*

- Regulation (EU) 2017/745 on medical devices - Article 7 and 21.3, as enforced by art 87.1) of the Law of 22 December 2020 on medical devices.
- Law on medicinal products of 25 March 1964 - Article 9 §4.



4) *Rules on advertising of food supplements (if relevant)*

- Regulation (EU) No 1169/2011 of the Parliament and of the Council of 25 October 2011 on the provision of food information to consumers (in particular its Art. 7 and 36.2.)
- Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods
- The Royal Decree of 17 April 1980 on the advertising for foodstuffs
- Royal Decree of 30 May 2021 on the placing on the market of nutrients and foodstuffs to which nutrients have been added
- Royal Decree of 29 August 2021 on the manufacture of and trade in food supplements containing substances other than nutrients and plants or plant preparations, and related Ministerial Decrees
- Royal Decree of 31 August 2021 on the production of and trade in foodstuffs composed of or containing plants or plant preparations, and related Ministerial Decrees

5) *Rules on hospitality*

- The Act of 25 March 1964 on medicinal products for human use – Art 10

6) *Mdeon/BeTransparent*

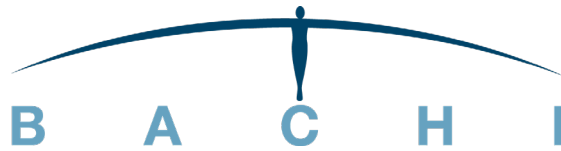
- Royal Decree of 25 February 2007 approving the bodies referred to in Article 10, § 3, of the Law of 25 March 1964 on medicinal products for human use
- Law of 18 December 2016 on various provisions relating to health – Sunshine Act

4.3. **Commitment to go through the BACHI complaints procedure**

- 4.3.1.** If a BACHI member has reasons to believe that another BACHI member does not comply with its commitments, as described under provisions 4.1. and 4.2. of the present code of conduct, and when there is an intention to complain, said BACHI member undertakes to submit a complaint to the BACHI Complaints Committee in accordance with the procedural rules detailed under article 5 below, prior to any other action.

To avoid any misunderstanding, such commitment does not prevent any company to:

- at all times, take any conservatory measures;
- initiate a judicial, administrative or arbitral procedure or action after the introduction of the complaint procedure foreseen by the present code of conduct (whether the company has filed a complaint or is subject to it), if that legal action is **urgently** required and cannot wait for the Code of Conduct Panel's opinion. In this case, the commitment of members is



therefore limited to initiating this self-regulation procedure in first instance (prior to any other action) and properly documenting the complaint file they submit.

- file a complaint with any competent authority.

4.3.2. When such complaint procedure is filed, the BACHI member - subject of a complaint - shall not oppose to the assessment of the issue by the Code of Conduct Panel, in accordance with the procedural rules described below, under Article 5.

4.3.3. Both parties shall:

1. comply with the procedural rules described under Article 5 below;
2. participate in meetings organized by the Code of Conduct Panel;
3. make themselves available to manage the conflict in which they are involved in a responsible way, “as a good father” (participation in meetings, etc.); and
4. respect at all times the confidentiality of information exchanged. In particular, all documents exchanged between the parties and/or with the BACHI Complaints Committee and/or the Code of Conduct Panel are deemed to be confidential, unless they are already in the public domain.

The opinion that will be issued by the Code of Conduct Panel will also be confidential. However, any party to the BACHI complaint procedure has the right to use it in the context of a judicial, administrative or arbitral procedure, against any other party that was also involved in the BACHI complaint procedure.

5. Complaint management

5.1. Key actors

5.1.1. BACHI Complaints Committee

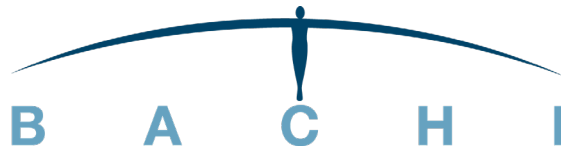
a) Composition – The BACHI Complaints Committee is composed of at least 2 BACHI board members and the Managing Director. This Committee ensures that the complaint is admissible and may be submitted to the Code of Conduct Panel.

The board members composing the BACHI Complaints Committee are elected by the board of directors of BACHI for a period of 3 years.

b) Mission – Its mission is to analyze whether a submitted complaint file is complete and sufficiently documented.

5.1.2. Code of Conduct Panel

a) Composition – The Code of Conduct Panel is composed of at least 6 BACHI members, one or more BACHI staff members and a legal advisor if deemed necessary. It is a pool of at least 6 people with



different knowledges/areas of expertise (at least 2 x 3 type experts in medicines, medical devices, food supplements, etc.). Depending on the type of complaint, 3 people of this pool are assigned to manage the case and participate in the meetings.

b) Mission – Members of the Code of Conduct Panel are elected by the board of directors of BACHI for a period of 3 years. Their mission is to:

- analyze whether the complaint is legitimate,
- ensure compliance with the provisions of the code of conduct and examine any disputes arising from breaches,
- strive to reconcile points of view and ensure that the adversarial principle is respected in the debates,
- make recommendations to the parties involved, and
- issue recommendations in terms of responsible practices

5.1.3. Commitments of the key actors

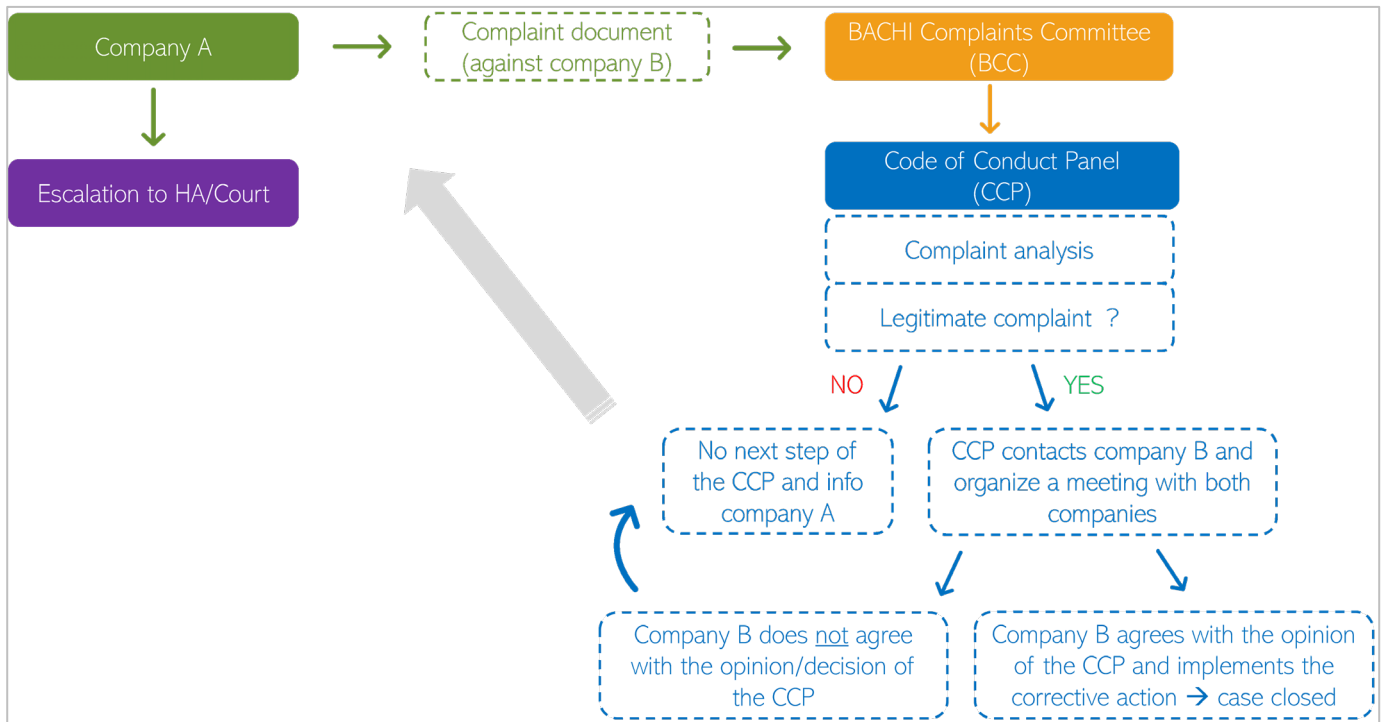
All members of the BACHI Complaints Committee, of the Code of Conduct Panel, as well as all employees of BACHI and of BACHI board of directors, and all external experts involved in a BACHI complaint procedure shall sign on an individual basis a written commitment to:

- 1) act totally independently;
- 2) avoid any conflict of interest when examining the complaint files entrusted to them; they ensure a fair and impartial treatment of the files submitted and undertake to inform the Committee of any links they may have with one of these files. In case of conflict of interest or if they consider that they are not in a position to make an impartial judgement on a submitted file, the concerned member declares himself/herself incompetent or the BACHI Complaint Committee shall remove him/her from his/her duties for the examination of this particular complaint;
- 3) respect the confidentiality of the information received and not to disclose it to any third parties;
- 4) report to the board of directors of BACHI if the situation requires it;
- 5) comply at all times with competition law, in particular when it comes to the exchange of information.

A template of such written commitment is enclosed in Appendix 2 of the present code of conduct. In addition, if need be, a Clean Team Agreement may be concluded between BACHI, the members of the BACHI Complaints Committee, of the Code of Conduct Panel, as well as all employees of BACHI and of BACHI board of directors, and all external experts involved in a BACHI complaint procedure.

5.2. Procedural rules

5.2.1. Schema



5.2.2. Submission of a complaint

Ideally, Company A and Company B discuss first and try to find a consensus. If they cannot reach an agreement, the Complaint procedure starts, by the filing of a complaint document and the payment of the fees (see art. 6 and appendix).

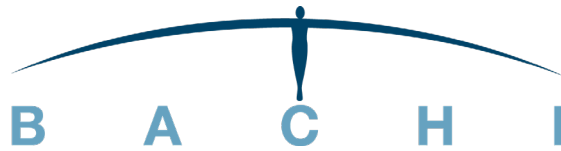
The document has to be sent to BACHI Complaints Committee to the following address: info@bachi.be

5.2.3. Admissibility

The BACHI Complaints Committee verifies, within **1 week** following the submission of the complaint document, if the received complaint file is based on the breach of the BACHI members' commitments under articles 4.1 and 4.2. of the present code of conduct, is complete and sufficiently documented. If so, the complaint is deemed admissible and submitted to the Code of Conduct Panel without undue delay.

5.2.4. First assessment of the case by the Code of Conduct Panel (*legitimate complaint?*)

- a) Upon receipt of the file, the Code of Conduct Panel has a **3-week delay** to:
- analyse the documents submitted with the complaint;
 - contact the plaintiff should the Panel need further information or clarifications;



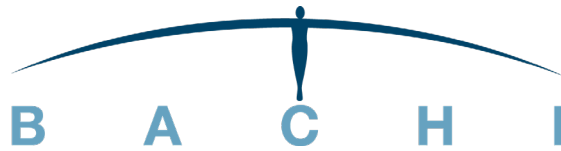
- obtain the opinion of an external expert, if deemed necessary for the assessment of the case;
 - agree on a first assessment of the issue.
- b) If the **Code of Conduct Panel considers that the complaint is not founded**, it informs Company A and communicates its written and reasoned opinion **without undue delay**. Company A may still decide to escalate the issue to the competent authorities/court. This decision is left at its discretion. Company B is nevertheless not informed by BACHI that a complaint procedure had been filed by Company A against one of its commercial practices.
- c) If the **Code of Conduct Panel considers – after a first assessment – that the complaint could be well-founded**, it:
- informs **without undue delay** Company A about the continuation of the procedure and Company B about the existence of the complaint filed by company A and provides company B with all relevant documents related to the case, and
 - organizes a **meeting in the presence of Company A and Company B, that has to take place within 3 weeks**. The objective of the meeting is to allow each party to discuss and present its position with supporting evidence to the Code of Conduct Panel, and to resolve the dispute amicably. Both companies are heard through their legal representative.

5.2.5. Definitive opinion of the Code of Conduct Panel, after a first positive assessment

- a) **Within 3 weeks following the meeting** with the parties, the Code of Conduct Panel shall elaborate a reasoned opinion. This opinion is formalized in a written document, which may include recommendations. The written opinion is communicated to both parties.
- b) If the reasoned written opinion concludes that **the complaint is not founded**, the complaint procedure ends here.
- c) If the reasoned written opinion concludes that **the complaint is founded**:
- If Company B agrees with this opinion, the parties (Companies A and B) commit themselves to enter into an out-of-court settlement agreement in the sense of article 2044 of the [old] Belgian civil code, by which:
 - Company B commits to take the necessary corrective actions;
 - Company A commits not to enter into any judicial, administrative or arbitral procedure in relation to the dispute, or to withdraw from any of these procedures, as the case may be. It also commits not to file a complaint with the administration.
 - Company A will therefore not take any further action in relation to the dispute, unless for the sake of enforcement of the settlement agreement.

The BACHI Complaint procedure closes by the engagement of the parties to enter into such a settlement agreement.

It is highlighted that nothing in this Code of Conduct may be interpreted as preventing any company or member from complying with its own legal obligations, including under competition law or any possible disclosure obligations that would be imposed by Belgian or EU law.



- If Company B does not agree with this opinion or the recommendation of the Code of Conduct Panel, the dispute remains but the BACHI Complaint procedure ends here (no further step or appeal procedure). Company A and/or Company B can then decide to escalate to the competent authorities/court, if not already done. This decision is left at their discretion.

5.2.6. Consequences of the opinion

The written reasoned opinion of the Code of Conduct Panel may be used by the parties in the context of a judicial, administrative or arbitral procedure (or of a complaint with the administration).

5.2.7. Repeated breaches

In case of repeated breaches and if the offending company persists in not following the Panel's recommendation and/or in not executing the agreement, BACHI reserves the right to take action against the offending company. Depending on the context and the severity of the case, the Code of Conduct Panel may bring it to the board of directors of BACHI, which will decide on the sanctions to be imposed on the offending company, in accordance with the provisions of BACHI articles of incorporation.

5.3. Opening of the complaint procedure to non-BACHI members

5.3.1. Any non-BACHI Member has the right to introduce a complaint procedure in accordance with the procedural rules laid down by this code of conduct if it has reasons to believe that a BACHI Member does not comply with its commitments, as described under Article 4.1 and 4.2. of the present code of conduct.

In this case, the BACHI member subject to the complaint procedure shall accept to comply with the rules of the complaint procedure, as laid down in the present code of conduct.

5.3.2. The complaint procedure may also be used when a BACHI member wants to complaint about the business practices of a non-member company. In this case, the latter has to expressly agree to submit the dispute to the BACHI Complaints Committee and to follow the procedural rules laid down in the present document.

6. Funding of the Code of Conduct Panel

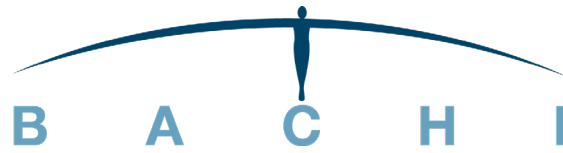
When a company decides to file a complaint against another company, the following fees have to be paid upon submission of the complaint document to the BACHI Complaints Committee:

The costs per complaint submitted are

- 250 EUR for a member of BACHI
- 300 EUR for a non-member²

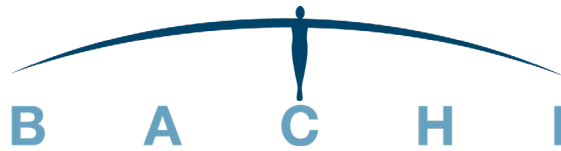
The fees have to be paid on the following bank account: **IBAN BE98 3630 4596 3993**

² These fees will be reviewed annually by the Board of Directors of BACHI and adjusted if necessary.



The complaint procedure starts upon (1) receipt of the complaint document by the BACHI Complaints Committee and (2) receipt of the fees.

Members of the Code of Conduct Panel serve on a voluntary basis and do not receive any remuneration. If deemed necessary, they may seek external advice from a third party (e.g. a legal advisor). BACHI will cover the related costs with the money collected per complaint submission.



Appendix 1 – Complaint Document

- **Complaining company**

Company name: [to complete]

Represented by [name], [function]

Email address, where the company may be contacted: [to complete]

Description of the request / Reason for complaint

[to complete]

- **Denounced company and/or targeted product:** [to complete]

- **Place/Situation/Media used/Date (where & when) + evidence(s) to provide (e.g: invitation symposium, picture of stand, etc.)**

[to complete]

- **Supporting documents (to join in pdf, ppt or jpeg)**

Name & function: [to complete]

Date & signature

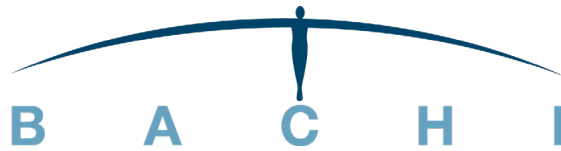
*Please note that the complaint procedure will start upon (1) receipt of the complaint document by the BACHI Complaints Committee **and (2) receipt of the fee.***

(1) The complaint document and its attachment(s) must be sent to info@bachi.be

*(2) For a **member** of BACHI, the fee amounts 250 EUR per complaint submitted – For a **non-member**, the fee amounts 300 EUR per complaint submitted.*

*Please make the payment without delay on the BACHI bank account **IBAN BE98 3630 4596 3993** with the communication “Complaint [name Complaining company] / [name Denounced company] / [name Denounced product]”.*

The related invoice will be sent after receipt of your payment.



Appendix 2 – Template written commitment

(as referred to under article 5.1.3. of the code of conduct)

To whom it may concern

I, undersigned, _____

(please enter full contact details of the individual signing the commitment) hereby commit to, at all times:

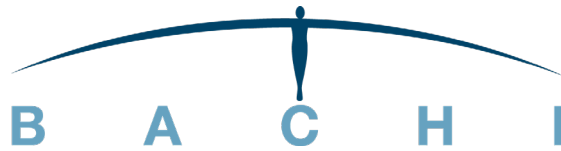
- 1) act totally **independently** in the context of the assessment of a complaint filed before the BACHI Complaints Committee,
- 2) avoid any **conflict of interest** when examining the complaint files entrusted to them. In that respect, I will ensure a fair and impartial treatment of the files submitted and undertake to inform the BACHI Complaint Committee of any links or acquaintance I may have with one of these files. In case of conflict of interest or if I consider not being in a position to make an impartial assessment on a submitted file, I shall declare myself incompetent or agree that the BACHI Complaint Committee remove me from my duties for the examination of this particular complaint;
- 3) respect the **confidentiality** of all and any information that I will receive or will become aware of in the context of a BACHI complaint procedure for at least 5 years upon disclosure of confidential information.

This entails among other things that I shall:

- not disclose the confidential information to any third-party, including any person within the company I work for;
- not copy, modify, or clone said the confidential information;
- not use the confidential information in any circumstances except for those provided in the code of conduct;
- prevent access to the confidential information to any third party, except in circumstances provided in the code of conduct (e.g. communication of information to the Code of Conduct Panel, discussion within the members of the pool of the Code of Conduct Panel, discussion with an expert, also bound by similar confidentiality obligations);
- not disclose the confidential information to any third parties.

By way of exception, information shall not be deemed confidential if:

- a. It is publicly known;
- b. It was in my possession before its disclosure in the context of a complaint procedure;
- c. I became aware of said information through legitimate means other than from the disclosing party;
- d. I receive the express written approval from the disclosing party to disclose such information.



Upon termination of the complaint procedure, I commit to give back to the disclosing party or to destroy all confidential documents or materials containing confidential information.

- 4) **report to the board of directors** of BACHI if the situation requires it;
- 5) comply at all times with the rules of **competition law** in the context of the handling of a BACHI complaint procedure, in particular when it comes to the exchange of information.

Should this commitment contain any provision that would be invalid or unenforceable, the remainder of this unilateral commitment shall into force and the provision at stake will be interpreted so as best to give effect the intent of my commitment.

I acknowledge that if any of the above commitments are not fully complied with, BACHI will have the legitimate right to exclude my participation as a member of the BACHI Complaints Committee, of the Code of Conduct Panel, or of the BACHI board of directors, as the case may be, without any prior notice but by mere written notification.

Date

Place

Signature of the person who take the commitment

Date & Signature of BACHI

As acknowledgement of receipt

Mar Gryseels on behalf of BACHI