abimip code of conduct for
over-the-counter drugs

abimip

abimip
associação brasileira
da indústria de medicamentos
isentos de prescrição

1. Introduction

ASSOCIAÇÃO BRASILEIRA DA INDÚSTRIA DE MEDICAMENTOS ISENTOS DE PRESCRIÇÃO - ABIMIP, entity that assembles companies which corporate purpose includes the industrialization and/or import and trade of Over-the-Counter Drugs adopts this Code of Conduct in order to establish the principles that must guide its associated companies ("Partner Companies").

2. General Principles

The scope of this Code of Conduct is the voluntary adoption of the following ethical principles by the Industry of Over-the-Counter Drugs:

a. The Industry must seek at all times the highest ethical standards in their performance;

b. The benefit and safety of the Consumer are the main reasons that justify the existence of this Code of Conduct, and they must guide at all times any initiatives of the Industry related to Over-the-Counter Drugs;

c. The respect to the Consumer, health professionals, professionals related to the health area, health institutions, bodies, associations and companies, in addition to public agents must be the main basis for the proper orientation of the actions conducted by ABIMIP Associated Companies;

d. More than manufacturing and trading products, the Industry must be concerned with the well-being of the Consumer; for such purpose, in addition to market practices, the Industry must be attentive to the guidance offered to the Consumer, health professionals and professionals related to the health area;

e. Over-the-Counter Drugs must be manufactured with the strict observance of the Good Manufacturing and Quality Control Practices according to safety and effectiveness standards strictly following the laws in force;

f. ABIMIP understands that the free access to Over-the-Counter Drugs is a right of the Consumers and their supply shall not require prescription, provided that their rights and safety are protected;

g. The information on products must be balanced, true, complete, updated and, as suitable, supported by scientific and/or market evidences;

h. The Associated Companies bound to this Code of Conduct must not offer, promise or grant undue advantages resulting from the dispensation, prescription, use or promotion of drugs; any action that may be construed as undue interference in the autonomy of the health professionals or professionals related to the health area must be promptly interrupted without prejudice to possible verification of responsibility according to the rules set forth in this Code of Conduct and the laws in force;

i. Promotional actions must respect the therapeutic indications and remaining characteristics approved by the health authority;

j. ABIMIP Associated Companies are responsible for the faithful and full observance of this Code of Conduct; the responsibility of the Associated Companies shall include the acts performed by third parties, particularly distributors and outsourced companies when, and solely when they perform according to their guidance or delegation, in accordance with the provisions of the law; and

k. The full adhesion to this Code of Conduct is a condition indispensable to the joining and permanence in the structure of this Association.

3. Concepts and Definitions

The World Health Organization (WHO) provides definitions of self-care and self medication.

a. Self-Care

The self-care is the behavior of the person who acts with autonomy and considers oneself as self-sufficient to establish and maintain one's own health, prevent and deal with one's own diseases based on life experience, knowledge acquired on health and diseases, in addition to the drugs and other factors that influence health.

It is a wide concept that includes:

- Hygiene (general and personal)
- Eating (type and quality of the food)
- Life styles (sport activities, leisure, and so forth)
- Environmental factors (life conditions, social habits, and so forth)
- Social and Economic Factors (levels of income, culture and so forth)
- Self-medication

b. Self-medication

Self-medication is the choice and the use of drugs made by the individual based on the concept of self-care described above in order to treat disorders and symptoms that are acknowledgeable by the individual. The self-medication is one of the elements of the self-care.

c. Responsible Self-Medication or Use

It is the practice according to which the individuals treat their own disorders and symptoms with drugs approved to be purchased without prescription and are safe and effective when used according to the instructions.

The responsible self-medication requests that:

- the drugs have substantiated safety, quality and effectiveness;
- the drugs used are the ones indicated for conditions easily diagnosable by the individual

and for some chronic diseases (after an initial medical diagnosis); in all cases, said drugs must be formulated specifically for such purpose and they must present adequate dosage and presentation;

- said drugs must be supported by appropriate information.

d. Over-the-Counter Drug (OTC)
Drug may be sold, purchased, requested, supplied, dispensed or donated according to applicable laws, without the need for formalization of document issued by professional legally qualified to prescribe it.

Over-the-Counter Drugs are the drugs indicated for high incidence and low gravity diseases, and that present high safety of use, effectiveness scientifically substantiated or acknowledged traditional and easy use, low risk of abuse and for which the competent health authority considers the orientation of a health professional unnecessary.

e. Health Professionals
Professionals legally qualified to prescribe or dispense drugs.

f. Professionals related to the Health Area
People that may influence in the prescription, dispensation or indication or drugs, both in the private sector initiative and in the capacity of public agents, including, but not limited to nurses, physiotherapists, speech therapists, bio-physician, nutritionists, pharmacovigilance professionals, health students, pharmacy students, nursing students, physiotherapy students, speech therapy students, pharmacy and drugstores attendants, members of product standardization commissions, employees and agents of public or private hospitals, clinics and other entities that maintain relationship with patients or institutions, bodies, associations and companies of the health area.

g. Institutions, Bodies, Associations and Companies of the Health Area
The institutions, bodies, associations and companies of the health areas are the ones that directly or indirectly in the private sector or as part of the public administration, participate in the health area or support it, including the ones that represent the medical, pharmaceutical and patient classes, regulatory agencies, the Ministry of Health, state or municipal Secretariats of Health, or any other private entity or body of the direct or indirect public administration that purchases drugs.

h. Public Agents
Any person who, permanently or temporarily, with or without remuneration, occupies position or is employed by any body or entity of the direct or indirect national or foreign public administration.

i. Promotional Material
Any and all material advertised by the Associated Companies with the intention to promote Over-the-Counter Drugs regardless of support or media used for such purpose.

j. Free Sample
Drug package that contains the total or specific amount in relation to the packaging registered with the Regulatory Agency intended to be gratuitously distributed to professionals qualified to prescribe drugs as an advertisement tool.

4. Advertisement of Over-the-Counter Drugs

4.1. According to the Brazilian laws, Over-the-Counter Drugs may be advertised directly to the Consumer.

4.2. For the purposes of this Code of Conduct, "Advertisement" is the set of techniques and activities of information or persuasion with the intention to spread knowledge, make certain product or brand more known and/or prestigious, regardless of the means used, aiming to influence the public by means of actions that intend to promote and/or induce to prescription, dispensation, acquisition and use of drug.

4.3. In addition to the general principles and provisions set forth hereunder and the legal and regulatory provisions in force, the Advertisement of Over-the-Counter Drugs must meet the following conditions:

4.3.1. All allegations set forth in the promotional material related to the action of the drug, indications, dosage, instructions for use, adverse reactions, effectiveness, safety, quality and remaining characteristics of the drug must be compatible with the information registered with the health authority;

4.3.2. The content of bibliographic references mentioned in the Advertisement of Over-the-Counter Drugs must be available at the Customer Service of the company and the Health Professionals Service;

4.3.3. Ensure the accurate information to the Consumer, health professionals and professionals related to the health area;

4.3.4. Observe the Brazilian laws and particularly the Consumer Code and the Advertisement Self-Regulation Code adopted by Conselho Nacional de Autorregulamentação Publicitária [CONAR];

4.3.5. When the advertisement makes reference to studies, whether scientific or market studies, it must be based at all times on researches properly conducted and construed; the results or conclusions presented to the Consumer must be verifiable;

4.3.6. It must not suggest the cure of any disease that requires treatment under supervision of a health professional;

4.3.7. It must not induce the Consumer to the irrational use of drugs, including, but not limited to the granting of discount to the Consumer in the event of purchase of more than one unit, with exception of the adhesion programs referred to in the Item 6.2;

4.3.8. It must not induce the use of products by children or teenagers without supervision of the parents or legal guardians;

4.3.9. It must not cause fear or apprehension to the Consumer, suggesting that he/she is suffering or may suffer from any disease;

4.3.10. It must not make any offer of refund or other benefit of any sort as a result of the purchase of an Over-the-Counter Drug due to possible dissatisfaction of the Consumer;

4.3.11. It must not contain visual or auditory affirmation or presentation that is obscene, repulsive, rough or discriminatory related to race, gender, religious belief, social or intellectual condition, and it must not inspire violence or spread superstition;

4.3.12. It must not contain any expression that may suggest the clinical superiority of a drug in relation to the other, unless said fact is substantiated by clinical or scientific comparative evidences;

4.3.13. It must not contain any offensive, false, derogatory or deceitful comparison in relation to competitors; and

4.3.14. It must not imitate or become excessively close to the brands and identity / visual layout of products manufactured by competitors, and not reproduce, fully or partially, campaigns, slogans or signature of campaigns of products manufactured by competitors; it must not carry out practices that may characterize unlawful competition, violation of registration of trademark or copyright or that may, in any way, create confusion to the Consumer, according to the provisions of the laws in force.

4.4. The comparative advertisement must respect the following principles and limits:

4.4.1. Not to characterize unlawful competition or denigrate the image of drugs or trademarks of other companies;

4.4.2. Not to cause confusion between competitor drugs;

4.4.3. Aim objectivity and technical substantiation in the comparison;

4.4.4. Be susceptible to substantiation and be accompanied by supporting references, in case of clinical data.

5. Direct Contact with the Consumer

The Associated Companies must respect the following restrictions in any interaction with the Consumer:

5.1. The manifestation about the treatment or conduct possibly adopted by the health professional is prohibited.

5.2. The disclosure of any technical or clinical information of the product, which has not been approved by the health authority is prohibited.

6. Activities carried out in Points of Sale related to Over-the-Counter Drugs

6.1. Make payments, offer gifts, sponsorships or other benefit in favor of the health professional or professional related to the health area in exchange of any implicit or explicit agreement or understanding that the health professional or the professional related to the health area will prescribe, use, acquire, recommend, indicate or dispense certain drug is prohibited.

6.2. Programs of adhesion to treatment and interactions aiming the updating of the health professionals or professional related to the health area are allowed.

7. Advertisement of Drugs and/or Indication not Approved by the Regulatory Agency (off-label)

7.1. The Associated Companies shall only advertise Over-the-Counter Drugs duly registered by the health authority. All items of information and allegations presented in the Advertisement related to the action of the Over-the-Counter Drug, indications, dosage, instructions for use, adverse reactions and remaining characteristics of the product must be compatible with the technical and clinical information set forth in the corresponding registration.

7.2. In exclusively scientific events, in which diseases and existing treatments are addressed, information on Over-the-Counter Drugs not yet registered and/or therapeutic indications not yet approved by the health authority may be disclosed, on condition that the disclosure is intended exclusively to health professionals; the audience is previously informed that it is an off-label information; other options of treatment are addressed and no trademark of the drug or any other promotional element is used.

8. Offer of Gifts

The following conditions must be met in relation to the offer of gifts:

8.1. The offer of gifts must respect the general principles of this Code of Conduct, and the laws or judicial decisions in force.

8.2. The offer of gifts to health professionals or professional related to the health area must not be conditioned to the sale, indication or dispensation of drugs.

8.3. The offer of gifts to the public must be related to the approved use of the drug, and it must not be bound to the sale of more than one unity.

8.4. The gifts offered must be objects of reasonable value, which individual value do not exceed one-third of the minimum wage in force in the Country.

8.5. Under no circumstances may presents, advantages or any other goods that do not observe the laws in force be offered.

8.6. Educational materials, including, but not limited to leaflets, folders, posters and

remaining printed and not customized materials must aim to provide suitable guidance to the patient, and they shall not be considered as gifts.

9. Distribution of Free Samples

9.1. Free samples of drugs must be exclusively distributed to health professionals who have qualification to prescribe drugs, according to the laws in force.

9.2. The offer of free samples to the professionals who prescribe drugs bound to the prescription or indication of products is not allowed.

10. Relationship with Governmental Agents, Representatives and Authorities

10.1. The relationship of the Associated Companies with governmental agents, representatives and entities must be established with ethics and transparence, according to the laws in force.

10.2. The Companies and any of their managers, directors, employees or representatives must not directly or indirectly offer, promote, pay or donate any financial resource or valuables (according to the laws in force) to governmental agents, representatives or entities with the intention to induce or influence the beneficiary to perform or cease to perform any act that may bring undue advantage.

11. Interactions with Health Professionals

11.1. All interactions with health professionals in which Over-the-Counter Drugs are addressed must be based on the highest ethical standards, and they must intend at all times to meet a legitimate need of the business.

11.2. All information disclosed must be correct, complete, accurate and according to the characteristics of the product duly registered by the health authority.

11.3. The payment of meals to health professionals or professionals related to the health area is allowed when it is made with the intention to discuss or exchange scientific or educational information, and it must be limited to modest values and place compatible with the exchange of information. The representative of the Company must be present during the entire time reserved to the meeting.

12. Donations and Contributions to Institutions, Bodies, Associations and Companies of the Health Area

12.1. Donations and Contributions to Institutions, Bodies, Associations and Companies of the Health Area must observe legitimate social interest and be carried out at all times in a transparent manner, without any compensation, particularly the dispensation, prescription, purchase or use of Over-the-Counter Drugs.

12.2. The promotion of the institutions or trademark as compensation for Contributions is exceptionally allowed.

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13. Application and Effectiveness of the Rules of the Code of Conduct

13.1. ABIMIP values and encourages the prior conciliation among its Associated Companies, regardless of mediation, and it places its structure and establishments at the disposal for the debate and settlement of any conflict that may rise. In case there is no conciliation, ABIMIP encourages the Associated Companies to present substantiated denunciation against actions that may characterize violation of the rules set forth in this Code of Conduct.

13.2. The denouncement presented by any Associated Company will be received by ABIMIP to confirm the fulfillment of the formal requirements set forth in this Code of Conduct and the Council of Ethics will be responsible for processing the denouncement and examine the merits of the issue in order to impose suitable penalties.

13.3. Anonymous denouncements or denouncements that do not contain elements sufficient for the due identification of the denouncer will not be accepted for investigation by ABIMIP.

13.4. Only the denouncements that relate to facts occurred within no longer than one (01) year as of the date of receipt of the denouncement by ABIMIP will be accepted. The denouncements made outside said term will be immediately filed without possibility of appeal.

14. Council of Ethics

14.1. The Council of Ethics shall have full independence in the exercise of its prerogative to enforce the faithful observance of the precepts set forth in this Code of Conduct by the Associated Companies.

14.2. For the ad hoc establishment of the Council of Ethics, ABIMIP shall choose the Advisors by raffle in number sufficient to reach the quorum required to form the Ordinary Chamber or the Appeal Chamber, according to the level of jurisdiction and profile of the corresponding members, with the observance of the following parameters:

14.2.1. The Ordinary Chamber shall be comprised of five (05) Advisors, as follows:

- One (01) Advisor chosen by raffled by the national associated companies;
- One (01) Advisor chosen by raffled by the international associated companies;
- One (01) Advisor chosen by raffled by all associated companies (unified raffle); and
- Two (02) Advisors chosen by raffled by the external professionals appointed by ABIMIP.

14.2.2. The Appeal Chamber shall be comprised of up to eight (08) Advisors, as follows:

- Two (02) Advisor chosen by raffled by the national associated companies;
- Two (02) Advisors chosen by raffled by the international associated companies; and
- Two (02) Advisors chosen by raffled by all associated companies (unified raffle); and
- Two (02) Advisors chosen by raffled by the external professionals appointed by ABIMIP.

14.3. Without prejudice to the foregoing provisions, the Council of Ethics may deliberate without the attendance of all members of its decision-making bodies, provided that the following minimum quorum is respected:

- Three (03) Advisors for the Ordinary Chamber, of which no less than one (01) national associated company and one (01) international associated company; and
- Five (05) Advisors for the Appeal Chamber, of which no less than two (02) national associated companies; and two (02) international associated companies.

14.4. The members of the Council of Ethics shall impose sanctions corresponding to the case according to the highest criteria of justice and equity, considering:

a. The severity of the violation;

b. The advantage received or intended by the offender;

c. The commitment or not of the violation;

d. The level of damage, or danger of damage to Companies, Consumers or third parties;

e. The negative effects produced in the pharmaceutical market;

f. Mitigating and aggravating circumstances, according to definition set forth in the Item

15.3. Below; and

g. The financial capacity of the offender based on the gross revenues in its last fiscal year, after taxes.

14.5. The conditions for the establishment and operation of the Council of Ethics shall be defined in suitable regulation, which shall be considered part of this Code of Conduct.

14.6. ABIMIP shall employ its best efforts so that the processing and examination of the denouncements take place within no longer than ninety (90) days, with exception of the cases in which the circumstances and/or complexity of the case under examination justify the processing within longer term.

15. Penalties

15.1. Without prejudice to the immediate cessation of the conduct considered improper, the Company that violates the rules set forth in this Code of Conduct shall be subject to one of the following penalties:

15.1.1. Warning

15.1.2. Reproach

15.1.3. Suspension

15.1.4. Exclusion

15.1.5. Penalty to be established according to the severity of the violation, considering mitigating and aggravating circumstances that may exist:

a. Light violations: from three (03) to one hundred (100) national minimum wages

b. Serious violations: from one hundred (100) to two hundred and seventy (270) national minimum wages

c. Severe violations: from two hundred and seventy (270) to two thousand (2000) national minimum wages

15.2. The violations to this Code of Conduct are classified as:

a. Light: the ones in which the offender is beneficiated by mitigating circumstance;

b. Lerious: the ones in which an aggravating circumstance is verified;

c. Severe: the ones in which the existence of two or more aggravating circumstances are verified.

15.3. The value paid by the Company as penalty shall be directly transferred to assistance entities appointed by ABIMIP. The donation, in cash or converted into equivalent goods shall bear punitive nature and shall not be used by the offender Company for the purposes of inclusion in its balance sheet.

15.4. For the purposes of evaluation of the severity of the violation and the value to the established as penalty, the following circumstances shall be considered:

15.4.1. Mitigating circumstances:

a. Good faith of the offender;

b. The action of the offender is not fundamental for the event;

c. The offender, at his/her free will, immediately tries to repair or reduce the consequences of the damaging act that is attributed to him/her; and

d. The offender is a primary offender.

15.4.2. Aggravating circumstances:

a. The offender is recidivist, that is to say, the ones that have been sentenced by the Council of Ethics over the last three (03) years as of the imposition of the last penalty, regardless of the nature of the violation;

b. The violation cases damaging consequences to the public health;

c. The offender fails to take measures within his/her reach to cease it, being aware of the act that violates this Code of Conduct; and

d. The offender acts with deceitfulness, including occasional deceitfulness, fraud or bad faith.

15.5. In case there are mitigating and aggravating circumstances, the penalty shall be imposed according to the preponderant circumstances.

15.6. The decisions against the offenders shall be published in the form of summary in the restrict area of the website of ABIMIP for educational purposes, without identification of the companies involved.

ATTACHMENT

ETHICS COUNCIL - REGULATION

1. Preliminary provisions

1.1. Any questions on violations of the Code will be subject to inspection by the Ethics Council.

1.2. Resolution of conflicts by the Ethics Council will be limited solely and exclusively to the judgment and imposition of the penalties contained in the Code.

1.3. The Ethics Council meetings will be held at the ABIMIP headquarters or at another location previously indicated by the Entity, in compliance with the schedule of meetings defined by the designated counselors.

1.4. All of the documents, requests and written communications must be presented in a number of copies that corresponds to the number of counselors designated for the resolution of the conflict, in addition to an additional copy to the ABIMIP and another to the denounced Company.

1.5. Communications must be submitted to the address included in ABIMIP records – which must be kept updated on a permanent basis – and it can be made via any means that proves its submission and respective receipt, such as e-mail, registered mail, fax or telegram, among others.

1.6. The terms established in this Regulation will be counted in current days, starting on the first business day subsequent to the receipt of the communication and will include the expiration date. If the expiration falls on a holiday, the term can be extended until the first subsequent business day, whether at the ABIMIP headquarters or any at any of the Companies involved in the accusation.

2. Start of the inspection procedure

2.1. That who wishes to file a complaint will communicate this intention to the ABIMIP – the "Communication" – which in turn will check if the presented elements have sufficient formal and material consistency for the start of the inspection procedure.

2.2. For a complaint to be considered formally consistent, the following requirements must be met:

2.2.1. Identification of the complainant and of the denounced Company;

2.2.2. Brief reports on the supposed violation(s) to the Code with the relevant supporting documentation.

2.3. The material consistency of the complaint will consist of the preliminary inspection, by the Executive Vice-Presidency for ABIMIP, of the truthfulness of the facts and the verification that this is effectively a matter concerning the Code of Conduct.

2.4. Should the complaint be considered formal and materially consistent, ABIMIP will start the inspection procedure upon submission of a Communication to the Company that was notified on the conduct dealt with in the complaint, for expression, within fifteen (15) days.

2.5. If the complaint is considered to be inconsistent, whether formally or materially, ABIMIP will communicate the complainant through an informed decision and determine its filing, automatically closing the proceeding without possibility of appeal. The complaint filed by determination of the ABIMIP Vice-Presidency can be presented again by any interested party, provided that the formal or material vices that gave rise to its filing are remedied.

2.6. Once the complaint has been admitted, ABIMIP will proceed with the inspection procedure for the refusal or by default of any of the interested parties.

3. Ethics Council

3.1. Ethics Council is the committee in charge of the judgment of the complaints presented to the ABIMIP, and is constituted by representatives designated by the external professionals and Companies with proven experience, flawless reputation and notable understanding on the pharmaceutical industry practices.

3.2. Ethics Council will have an ad hoc nature and will always meet with the specific purpose of deliberating upon the case(s) indicated for the agenda of the day. Once the deliberations included in the agenda have been completed, the counselors will be dismissed from their roles in the Ethics Council and can be called again in future meetings to deliberate on new complaints regarding a violation to the Code of Conduct

3.3. In the event that the called counselor is prohibited to participate in the judgment session, they must communicate their prohibition to the ABIMP within no longer than forty-eight (48) hours from the calling, in order for a substitute to be designated. If the minimum deliberative quorum established in the Code of Conduct is ensured, the ABIMIP can, at its discretion, opt for not designating a substitute counselor.

3.4. It should be impossible to convene the minimum deliberative quorum, the session must be postponed and scheduled again within the shortest term possible, by drawing new counselors to substitute the counselors prohibited in their roles within the Ethics Council.

3.5. Those counselors who participate in the deliberation delivered at first instance are prohibited from participating in the convened session to decide the same case by appeal.

3.6. The counselors will sign an Independence, Waiver and Confidential Commitment Agreement, and will deliver the signed document to ABIMIP by the date designated for the judgment session.

3.7. The Executive Vice-Presidency for ABIMIP can determine the permanent substitution of a counselor who fails to comply with the terms and standards of this Regulation.

4. Counselor prohibition claim

4.1. That who wishes to claim the occasional prohibition of a counselor for lack of independence or any other reason must file it with the ABIMIP, within two (2) business days from the moment of the acknowledgement of the facts or circumstances that led them to deduce such an intention.

4.2. The prohibition claim must be directed to the members of the Ethics Council who are designated for the analysis of that specific case through a justified request and the presentation of relevant evidence. The interposition of an appeal against the decision of the Ethics Council that determines the substitution or maintenance of the Counselor whose prohibition has been claimed.

4.3. A counselor who incurs any of the following will be subject to substitution:

4.3.1. becomes unable to exercise their function;

4.3.2. Leaves the Company that designated them for the exercise of this attribution; or

4.3.3. Has a direct or indirect relationship with a competing company of any part involved in the dispute, also understanding the fact that their company has a competing product in the same class as the product dealt with in the complaint

4.3.4. Falls in any of the hypothesis provided for in the Independence, Waiver and Confidential Commitment Agreement.

4.4. Notwithstanding the above provisions, the person designated to participate in the Ethics Council will always be encouraged to spontaneously reveal any fact that denotes or could denote a justified doubt regarding their impartiality and independence.

5. Evidence

5.1 The burden of evidence of the fact or argumentation is up to that who alleges it. The Ethics Council, at its own discretion, can also request that the parties involved in the situation produce the additional evidence deemed necessary or appropriate, when the term for a presentation that is compatible with the complexity that they may require will be set forth.

5.2. Ethics Council should request or allow the addition of new evidence to the

original complaint the other party will be notified to present, within no longer than five (5) days, its expression on the new documents presented.

5.3 If a party that is properly requested to provide evidence or take any other measure fails to do so with the term established by the Ethics Council, without presenting a justified reason for such, this party can deliver the decision based on the new evidence made available in the records.

5.4 The Ethics Council will be allowed to consult with technicians specialized in specific matters related to the claim or request the production of expert evidence whenever it deems convenient obtain a better position with respect to the question. Should a technical opinion report or the production of expert evidence, the parties involved must present items and designate technical assistants within a common period of five (5) days.

5.5 The delivery of confidential materials will be the subject matter of the specific consideration of the Ethics Council with regards to its convenience and opportunity.

6. Judgment session

6.1. The judgment session will preferably take place at the ABIMIP headquarters, except if the Entity, with the agreement of the involved parties, decides otherwise. The change in the location designated for the judgment session must be communicated to the interested parties in sufficient advance.

6.2. The judgment session will take place on the designated date, through the constitution of the Ethics Council, forming the Original Chamber or the Chamber of Appeal, as needed, in compliance with a minimum necessary quorum for deliberation.

6.3. Ethics Council will designate the President of the Session with powers to conduct the proceedings in accordance with the provisions of this Regulation. It will also be the responsibility of the President of the Session to have the casting vote in the event that the present counselors cannot obtain a majority decision on the question proposed for analysis.

6.4. Once the session has started, the representatives of the parties involved will be requested to call up to two (2) the witnesses that they deem convenient. The witnesses will be heard for no longer than fifteen (15) minutes each, answering the questions made to them by the parties and the Ethics Council. The President of the Session must act with the necessary balance to comply with the time designated to the hearing of each witness and the preference in the process of asking questions.

6.5. After the hearing of the witnesses, the representatives of the parties involved will be invited to orally support their argumentation for, at least, ten (10) minutes each, expressing themselves first to the complainant and then to the denounced Company.

6.6. With the exception of the witness evidence, any other evidence can only be presented during the judgment session in exceptional circumstances, at the discretion of the Ethics Council in office, in the event of the verification of circumstances that could justify them. If the presentation of new evidence is admitted during the judgment session, that against whom the evidence was presented can require the suspension of the session for analysis and expression within five (5) days. The session to be suspended must be resumed from the point in which it was interrupted, and the President of the Session is in charge of designating a new date for a term no longer than ten (10) days.

6.7. The personal statement and the hearing of the witnesses can be made via videoconference or another means using data, image and voice communication technology as a means.

6.8. The absence of any interested party will not keep the Ethics Council from drawing a decision upon the question being judged.

6.9. Once the instruction has ended, the Ethics Council will decide upon the question by simple majority, always based on the reports, evidence, and documents included in the records. If a majority agreement is not reached, the vote of the President of the Session should prevail.

6.10. A Counselor who differs from the majority can vote separately if they wish.

6.11. The decision made by the Ethics Council will be submitted to the ABIMIP by the President of the Council in office during that judgment session. The ABIMIP will communicate the decision to the interested parties on the business day subsequent to the day of its receipt, submitting a copy by post or any other means of communication, with acknowledgment of receipt or submitting it directly to the parties upon receipt.

7. Decision of the Ethics Council

7.1. The decision made by the Ethics Council will necessarily include:

7.1.1. The report, which will contain the names of the complainant, the denounced Company and a summary of the conflict;

7.1.2. The grounds of the decision, on which the factual and legal questions will be analyzed;

7.1.3. The votes, the decision and the devices based on which the counselors solved the questions submitted to them;

7.1.4. The term for compliance with the decision, if applicable, the conditions for the denounced Company to prove compliance with the penalty imposed;

7.1.5. The signature of the counselors, representatives of the involved parties and two witnesses

7.1.6. The date and place where the decision was made.

7.2. In the event that some of the counselors or representatives of the parties cannot or do not wish to subscribe the decision made by the Ethics Council, it will be up to the President of the Session to certify such a fact.

7.3. The costs and expenses arising from the process of inspection of conduct are the responsibility of the party that gives rise to them, therefore the complainant, if the complaint is declared invalid or the complainant, in the event that the complaint is declared valid.

7.4. Within five (5) days from the receipt of the notification or the personal acknowledgment of the decision made by the Ethics Council, the interested party, in communication with the other party, request that:

7.4.1. Ethics Council corrects any material error eventually found in the decision; and

7.4.2. Ethics Council clarifies any obscurity or contradiction in the decision, or, expresses itself on the omitted point on which it should have expressed itself.

7.5. If the hypothesis in item 7.4 above is verified, the Ethics Council can hear the other interested party with respect to the argumentation presented, expressing itself within five (5) days. Once the other party has been heard or – if it does not deem this appropriate – received the request, the Ethics Council will decide upon the request made, within ten (10) days, amending the decision, if it judges that the request is valid.

8. Appeal proceeding

8.1. An appeal against the non-unanimous decision made by the Original Chamber for the Ethics Council. The appeal must be directed to the Ethics Council, to the attention of the Vice-Presidency for the ABIMIP, which will be in charge of promoting the necessary measures for the establishment of the Chamber of Appeal with powers to analyze the question.

8.2. The term for the interposition of the appeal will be ten (10) days from the dated of the acknowledgment of the decision made by the Original Chamber, or the decision upon the request for a review due to error, obscurity or contradiction, if requested so.

8.3 The terms and procedures for the establishment of the Chamber of Appeal will be the same as those established for the establishment of the Original Chamber, especially with regards to the conditions for the operation of the Chamber of Appeal, the prohibition of a Counselor and the procedures for the judgment session.

9. Efficacy of the decision made by the Ethics Council

9.1 The decision made by the Ethics Council produces obligations for the parties and their successors, converting itself, when applicable, into written evidence for the substantiation of a future monitory measure or other legally admitted measures.

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10. Costs

10.1 For purposes of the previous processing of the claim to the conduct inspection procedure institution, the interested parties can be requested to pay the amounts established by the ABIMIP.

11. Confidentiality

11.1 Except as otherwise agreed upon, or if required by an applicable law, the counselors will keep the confidentiality of the subjects related to the arbitration. The confidentiality commitment will also be excluded with respect to information that is already in public domain or that has already – somehow – been disclosed prior to being transmitted to the counselors.

11.2 The ABIMIP is held responsible for keeping the materials and documents delivered to them during the course of the proceeding for at least three (3) years, from the filing of the proceeding. After this period, they will be destroyed.

12. FINAL CONSIDERATIONS

12.1 The ABIMIP will not respond for any fact, act or omission, regardless of its nature, that is related to the measures taken by the Ethics Council, except in the event of evidence of negligence or dishonesty with respect to the acts that are relevant to it.


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