

ARBITRARE ARBITRATION RULES
(Reference and Generic Medicines)

CHAPTER I

GENERAL PROVISIONS

Article 1

Scope of Application

The present Rules shall apply to arbitration proceedings concerning disputes arising out of industrial property rights, regarding reference and generic medicines, subject to compulsory arbitration under Law no. 62/2011, 12th December, that are referred for dispute resolution to ARBITRARE - Arbitration Centre for Industrial Property, Domain Names, Trade Names and Corporate Names, hereinafter referred to as ARBITRARE.

Article 2

Competence of ARBITRARE

Disputes arising out of invocation of industrial property rights, including interim measures, related to reference and generic medicines, irrespective of whether they involve process patents, product patents, use patents or supplementary certificates of protection, may be submitted to ARBITRARE to be resolved by an Arbitral Tribunal.

Article 3

Powers of ARBITRARE Chairman of the Board

1 - In the absence of a specific provision in these Rules, the Chairman of the Board of ARBITRARE is responsible for deciding all incidents that may arise until the constitution of the Arbitral Tribunal, preserving the jurisdictional powers of the arbitrators.

2 - All powers conferred by these Rules to the Chairman of the Board may be delegated to one of the members of the Board.

Article 4

Bilingual Nature of the Centre

- 1 - ARBITRARE can operate in the Portuguese or English language.
- 2 - The parties decide, upon agreement, which of the languages mentioned in the previous paragraph is chosen for the procedural acts.
- 3 - Failing indication by the parties or agreement between them concerning the language to adopt, the parties shall accept, if necessary, the use of both languages in the same arbitral proceedings and the parties mutually forego the necessity to translate the procedural documentation.
- 4 - When, under the terms of the previous paragraph, the Portuguese and English language are being used in the same proceedings, the arbitral award is made in Portuguese and, if requested by the party disputing in English, it can be translated into English by the ARBITRARE Services.
- 5 - If any evidence or other document, relevant to the proceedings, is presented in a different foreign language, the Arbitral Tribunal can order the parties to provide the respective translation into Portuguese or English.
- 6 - Notwithstanding the provisions outlined in paragraphs 1 and 2, any party may be accompanied by a translator during the required procedural acts and, when so justified, the Tribunal may determine that any of the parties ensures a translator or interpreter at its own expense.

Article 5

Value of the Proceedings

The value of the proceedings corresponds to the value resulting from the application of the Portuguese Civil Procedure Law.

Article 6

Interim Measures

The acceptance of the present Rules shall involve granting the Arbitral Tribunal the powers to order appropriate interim measures, in accordance with the Portuguese Law on Voluntary Arbitration.

CHAPTER II

ARBITRATORS AND ARBITRAL TRIBUNAL

Article 7

Number of Arbitrators

- 1 - The Arbitral Tribunal may comprise a sole arbitrator or three arbitrators.
- 2 - When the parties fail to agree on the number of arbitrators, the Arbitral Tribunal shall comprise three arbitrators, with the exception provided in the following paragraph.
- 3 - If a party appoints a sole arbitrator and the other party fails to give his opinion on this choice, the Arbitral Tribunal shall consist of the appointed arbitrator.

Article 8

Requirements of Arbitrators

- 1 - Arbitrators shall be individuals with full legal capacity, independent and impartial.
- 2 - The Arbitral Tribunal shall be composed of arbitrators selected from a list approved by ARBITRARE, containing, in alphabetical order, the names of renowned and reputed persons whose experience and professional qualifications offer guaranties of integrity and reputability to perform the role of arbitrators, notwithstanding the provisions of the following article.

Article 9

Appointment of Arbitrators

- 1 - If the Arbitral Tribunal comprises a sole arbitrator, he shall be appointed by agreement of the parties or, if the parties fail to appoint, by the Chairman of the Board of ARBITRARE, and chosen from the list of arbitrators referred to in article 8 paragraph 2 within 5 days of being notified to make such appointment.
- 2 - If the Arbitral Tribunal comprises three arbitrators, each party shall appoint one arbitrator and the arbitrators thus appointed shall appoint the third arbitrator, who shall act as chairman of the Arbitral Tribunal, within 5 days of being notified to make such appointment.
- 3 - In the event that any of the parties fails to appoint the arbitrator to be appointed by it, or agree on the presiding arbitrator, the Chairman of the Board of ARBITRARE shall appoint such arbitrator

choosing from the list referred to in article 8 paragraph 2, within 5 days of being notified to make such appointment.

4 - In the event that any of the parties fails to appoint or agree on the presiding arbitrator, the Chairman of the Board of ARBITRARE shall appoint the presiding arbitrator, in accordance with the previous paragraph.

5 - When the Chairman of the Board of ARBITRARE is required to choose any arbitrator, only exceptionally and by reasoned order may he appoint a person not included in the list of arbitrators referred to in article 8 paragraph 2.

6 - The arbitrator or arbitrators chosen by the parties to constitute the Arbitral Tribunal may not be part of the list mentioned in article 8 paragraph 2.

Article 10

Multiple Claimants and Defendants

1 - In case of multiple Claimants or Defendants, when the Arbitral Tribunal comprises three arbitrators, the Claimants jointly appoint one arbitrator and the Defendants appoint another. The third arbitrator, who chairs the tribunal, is appointed in accordance with the provisions of article 9 paragraph 4.

2 --When the Arbitral Tribunal is composed of three arbitrators, if a group of parties fails to agree on the choice of the arbitrator they are entitled to appoint, such appointment shall be made by the Chairman of the Board of ARBITRARE, in accordance with the provisions of article 9 paragraph 3.

3 - In the case provided for in the preceding paragraph, the Chairman of the Board of ARBITRARE may furthermore, if so deemed justified, chose to appoint all arbitrators and designate amongst them the chairman, in which case any previous appointment of an arbitrator made by the parties shall be void.

Article 11

Acceptance of Appointment

1 - No one may be obliged to act as arbitrator, however, once the appointment is accepted, an arbitrator may only legitimately excuse himself on the grounds of supervening circumstances that prevent him from fulfilling his duties, once this is acknowledged by the Chairman of the Board of ARBITRARE, under penalty of being held liable for the damages caused.

2 - Each appointed arbitrator shall confirm his acceptance in writing, within the 5 days following the communication of his appointment. If the acceptance is not communicated within such time-limit or

the intention to act as arbitrator is not revealed in any other way, it is understood that the designation was not accepted.

3 - On accepting the appointment, the arbitrator shall sign a statement of independence and impartiality, in which he shall mention any circumstances which may reasonably give rise to doubts concerning his independence or impartiality.

4 - The Arbitral Tribunal shall be deemed to be constituted on acceptance of the mandate by all comprising arbitrators.

Article 12

Challenge of Arbitrators

1 - An arbitrator may only be challenged whenever there are circumstances that may raise justified doubts as to his independence or impartiality, or if he lacks the qualifications agreed upon by the parties.

2 - During the course of the arbitration proceedings, the arbitrator shall, without delay, make known any new circumstances which may give rise to justified doubts as to his independence or impartiality.

3 - A party may only challenge an arbitrator it has solely or jointly appointed, based on events that came to its knowledge after the appointment of the arbitrator.

4 - The refusal is inferred by application to the Chairman of the Board of ARBITRARE within 5 days counting from the day on which the grounds for challenge became known to the party making the challenge. The application is notified to the opposite party, to the arbitrator whose refusal is at issue, and to the other arbitrators, and any of them may issue an opinion within the time-limit of 5 days. The Chairman of the Board of ARBITRARE is responsible for the assessment of the refusal of the arbitrator.

Article 13

Replacement of an Arbitrator

1 - In the event of death, permanent incapability of an arbitrator to exercise its function, or if the arbitrator submits an excuse, or if by any other reason the appointment becomes ineffective, such arbitrator shall be replaced in accordance with the rules applicable to his appointment with the necessary adaptations, unless the parties waive such replacement.

2 - The arbitrators may propose the appointment of another arbitrator, but only if the parties who nominated them gave them such a power.

3 - Should a replacement of an arbitrator take place, the Arbitral Tribunal, after hearing the parties, shall decide if the procedural acts that already took place should be considered and to what extent.

Article 14

Location and Operation of the Arbitral Tribunal

1 - ARBITRARE has national scope and is seated in Lisbon.

2 - The arbitration shall take place in the headquarters of ARBITRARE or in any other suitable location chosen upon agreement of the parties.

CHAPTER III

CONDUCT OF PROCEEDINGS

Article 15

Fundamental Principles

The procedural formalities of arbitration should meet the following fundamental principles:

- a) The parties shall be treated with absolute equality;
- b) The Defendant shall be ordered to present defence;
- c) In all stages of the proceedings, a strict observance of the contradictory principle shall be guaranteed;
- d) The parties must be heard, orally or in writing, before the final award is made.

Article 16

Initial Petition

1 - The party who wishes to invoke its industrial property right, shall apply to ARBITRARE by filing an Initial Petition to this effect.

2 - The Initial Petition must contain, in particular:

- a) The identification of the parties, their respective addresses as well as their email addresses;
- b) The account of the facts and contentions of law which form the basis for the Initial Petition, as well as a succinct but precise presentation of the claims;
- c) The composition of the Arbitral Tribunal;
- d) Means of proof related to the alleged facts;
- e) Indication of the value of the dispute;
- f) Reference to the language chosen to be adopted in the arbitral proceedings, under the terms foreseen in article 4.

3 - The Initial Petition must be accompanied by the documents the Claimant intends to use to prove the facts alleged to fundament the Initial Petition and also by proof of payment of the procedural costs under the terms of the ARBITRARE Regulation for Procedural Costs.

4 - Once the Initial Petition is received, ARBITRARE shall notify the Defendant, informing it about the filing of the proceedings, its object, the composition of the Arbitral Tribunal and also inviting the Defendant to accept, within the time-limit of 5 days, the appointed sole arbitrator or to appoint its party arbitrator.

Article 17

Answer to the Initial Petition

1 - The Defendant is ordered to present his written Answer, within the time-limit of 30 days, which must contain the following:

- a) Complete identification, address and email address where the defendant shall be notified;
- b) Account of the facts and contentions of law for opposing the claim of the Claimant;
- c) Probative elements of the alleged facts;
- d) Reference to the language adopted in the arbitral proceedings, under the terms foreseen in article 4.

2 - The Answer of the Defendant must be accompanied by documentary evidence of the facts alleged, as well as by proof of payment of the procedural costs, under the terms of the Regulation for Procedural Costs.

Article 18.º

Absence of Answer

- 1 - If the Defendant fails to file an Answer within the time-limit set, the commercial or industrial exploitation of the generic medicine will not be permitted whilst the industrial property rights invoked by the Claimant are in force.
- 2 - The absence of any Answer shall be notified by electronic means to the parties, to INFARMED – The Portuguese National Authority of Medicines and Health Products, and to the Portuguese National Institute of Industrial Property.

Article 19

Subsequent Formalities

- 1 - Once the Answer has been received, and whenever new facts or contentions of law have been presented by the Defendant, the Arbitral Tribunal shall notify the Claimant to reply within 15 days, at its discretion.
- 2 - After expiry of the time-limit referred to in paragraph 1 of the present article, or if no new facts or contentions of law have been presented by the Defendant, the date and time of the hearing for taking oral evidence must be set, except if the hearing has been waived in accordance with the following article.
- 3 - The hearing referred to in the previous paragraph shall take place within 60 days following the filing of the written Answer.

Article 20

Waiver of the Hearing

- 1 - Unless otherwise agreed by the parties, the oral hearing for taking evidence may be waived by the Arbitral Tribunal, when the simplicity of the case, the sufficiency of the procedural documentation or the evidence presented by the parties, makes it dispensable.
- 2 - However, the Tribunal must hold one or more hearings for taking evidence, whenever required by one of the parties, unless the parties have previously agreed to renounce such hearings.
- 3 - When the hearing is waived, the parties are convened to a session, taking place within 30 days following the presentation of the last submission, to produce oral or written Pleadings, at their discretion.

Article 21

Means of Proof

- 1 - The Arbitral Tribunal accepts any evidence accepted by law, including testimonial and expert evidence, and such evidence shall be produced or presented by the parties.
- 2 - Each party may present a maximum of five witnesses, except in particularly complex cases, where the maximum limit may be increased to eight witnesses, although no more than two witnesses per fact shall be accepted.
- 3 - On its own initiative or on request of one or both parties, the Arbitral Tribunal may:
 - a) Hear personal depositions from the parties;
 - b) Hear third parties;
 - c) Arrange for the delivery of documents in possession of the parties or third parties;
 - d) Appoint one or more experts, define their terms of reference and receive their depositions or reports;
 - e) Conduct first hand examinations or inspections.

Article 22

Hearing

- 1 - The parties shall be notified at least 5 days before the beginning of all hearings of the Arbitral Tribunal and of all actions carried out with the purpose of examining documents and locations.
- 2 - The Arbitral Tribunal can ask any other entities to co-operate or designate its representative for the actions to be carried out when evidence is to be produced in a place other than the seat of the arbitration.
- 3 - By agreement of all parties and whenever adequate conditions exist, the hearing can be carried out by videoconference.
- 4 - When the taking of evidence is terminated, the Arbitral Tribunal shall convene the parties for a session to produce oral or written Pleadings, within the following 30 days, at the discretion of the parties.

Article 23

Suspension of the Hearing

- 1 - The Arbitral Tribunal may only suspend the hearing on one of the following grounds:
 - a) Temporary absence of a witness whose testimony is indispensable for the resolution of the dispute;
 - b) Presentation of documents or production of another means of proof;
 - c) Indication that the parties may come to an agreement.
- 2 - The hearing cannot be suspended more than once or for a period of over 10 days.

Article 24

Settlement

Until the end of the hearing, the parties may conciliate and terminate the proceedings by settlement, which shall be duly noted in the record of the proceedings, ratified by the arbitrator and shall have the same value as an arbitral award.

Article 25

Award and Notification

- 1 - On completion of the Pleadings, the Arbitral Tribunal shall rule within the time-limit of 30 days.
- 2 - The Arbitral Tribunal shall decide in accordance with the law.
- 3 - Once the award has been made, the parties, INFARMED – The Portuguese National Authority of Medicines and Health Products and the Portuguese National Institute for Industrial Property, I.P., shall be notified by electronic means within the time-limit of 5 days, and the original document shall be deposited at ARBITRARE.

Article 26

Duration of the Proceedings

- 1 - The arbitral award is made within a time-limit of 6 months counting from the constitution of the Arbitral Tribunal, except if the parties have provided for a longer period in the arbitration agreement or in a document signed before designating the arbitrators.

2 - The time-limits set in accordance with paragraph 1 may be freely extended upon agreement by the parties or, alternatively, by decision of the Arbitral Tribunal, up to the twice its initial duration and such derogation shall be duly justified. The parties may, however, by mutual agreement, oppose to the referred derogation.

3 - Arbitrators who unjustifiably hinder the award being made within the stipulated time-limit are liable for damages caused, under the terms of the law.

Article 27

***Res Judicata* and Enforceability**

1 - Once the parties have been notified of the arbitral award, it is considered *res judicata* as long as it is not open to ordinary appeal.

2 - By law, the arbitral award has the same enforceability the sentence of a Court of First Instance.

CHAPTER IV

MISCELLANEOUS

Article 28

Presenting Written Submissions and Documents

The written submissions, in particular the Initial Petition and the Answer shall be submitted, as a rule, electronically through the application available on the ARBITRARE internet page.

Article 29

Orders and Notifications

1 - In the arbitral proceedings, Orders shall be done by registered mail with acknowledgement of receipt or by any other legally admissible means.

2 - The notifications provided for in these Rules shall be made, whenever possible, by email. The expedition date is deemed the date of performance of the action.

3 - When it is not possible to notify in accordance with the previous paragraph, the notification shall be made by registered mail or by any other written document with acknowledgment of receipt by the addressee.

4 - For the purpose of receiving ARBITRARE notifications, the parties are obliged to communicate any changes to their electronic mail and address.

Article 30

Time-Limits

1 - Unless otherwise provided, the count of all time-limits specified in these Rules is continuous.

2 - The count of time-limits shall commence on the first working day following the day on which the Orders, notifications or communications are deemed to be received by the means described in the preceding article.

3 - When the time-limit for an act ends on a day on which ARBITRARE is closed, its term will be extended to the next working day.

4 - For purposes of the preceding paragraph, ARBITRARE is considered closed on non-working days.

5 - The time-limit for carrying out any acts not foreseen in these Rules or that do not result from the will of the parties, shall be 7 days.

Article 31

Procedural Costs

Under the ARBITRARE Regulation for Procedural Costs, all parties are subject to the payment of a sum destined to cover procedural costs.

CHAPTER V

FINAL PROVISIONS

Article 32

Applicable Rules

1 - In addition to the applicable legal rules, the submission of the dispute to ARBITRARE requires acceptance by the parties of the present Rules and subsequent amendments made to it, as well as the acceptance of the Regulations that complement it and their respective amendments.

2 - The applicable Rules in the arbitration procedure are the ones in force on the date the proceedings have been filed.

Article 33

Supplementary Rules

In all matters not foreseen in the present Rules and in Law no. 62/2011, 12th December, the Portuguese Law on Voluntary Arbitration shall be applied subsidiarily.