



THE PRIX GALIEN AFRICA CHARTER

PREAMBLE

The Galien Foundation, in partnership with the Galien Africa Association;

- Aware that the sustained promotion of scientific progress is the foundation for sustainable development;
- Convinced that the application of technology for health, helps promote the breakthrough of discoveries and innovations in Africa;
- Considering that the development and resilience of health systems requires a comprehensive and concerted approach;
- Guided by its vision;
- Deeply committed to the principles of responsibility and solidarity;
- Taking into account the many health and welfare challenges facing humanity, and in particular the African continent;

Decides as follows:

CHAPTER I : DEFINITION

Article 1.- For purposes of this Charter, the following definitions apply:

- **Academic institution:** An institution of higher education, studies and research consisting of the combination of various establishments, named according to the traditions "colleges", "faculties", "institutes", "departments", "centers", "sections", "units" or specific schools but also library or workshop, media library or museum... forming a coherent administrative whole with a defined, public private or possibly mixed legal status.
- **Alicament:** Food the explicitly formulated composition of which implies an active effect on the health of the consumer.
- **Biopharmaceutical science:** A discipline of pharmaceutical sciences at the interface between galenics and pharmacokinetics. It studies the impact of galenic forms of a drug on its absorption by the body.
- **Biotechnological product:** products resulting from techniques using living beings (micro-organisms, animals, plants), generally after modification of their genetic characteristics, for the industrial manufacture of biological or chemical compounds (medicines, industrial raw materials) or for the improvement of agricultural production (transgenic plants and animals) or GMOs.
- **Board of Directors:** A meeting of people who deliberate and give their opinion.



- **Conflict of interest:** A situation where a person or several people, an institution or several institutions are at the centre of a decision-making process, where their objectivity, their neutrality can be called into question.
- **Consortium:** An agreement between several people, associations or companies with a view to cooperation for the execution of one or more economic, financial, scientific or cultural operations.
- **Controlled clinical trials:** Trials that compare the efficacy of the substance tested to that of a placebo or a known active substance: some of the participants take a placebo or another active substance and constitute a "control" group.
- **Declaration of interest:** A declaration of conflict of interest.
- **Diagnostic products:** Clinical or complementary products that enable a practitioner or individual to make a specific medical diagnosis.
- **Digital solution:** This term refers to the integration of new technologies in all the activities of a company in order to simplify the work of employees and improve its performance. This process changes the way companies work and the way they respond to consumer needs.
- **Ethical pharmaceutical companies:** Pharmaceutical companies that incorporate ethical criteria into their operations.
- **Governmental Agency:** An agency created by law or decree, whose majority of officers and directors are appointed by the government or by one of its ministers, and which enjoys some autonomy, even if half of its overall funding comes from the state.
- **Initiatives:** Actions of a person who proposes, undertakes, organizes something as the pioneer.
- **Innovative science:** A science that innovates, introducing something new to replace something old in a field.
- **Innovative therapies:** Treatment by the introduction of gene therapy, somatic cell therapy and tissue engineering
- **Institution:** A structure of customary or legal origin, made up of a set of rules oriented towards an end, which participates in the organization of society or the State.
- **Marketing Authorization (MA):** The agreement given to a holder of exploitation rights of an industrially manufactured medicinal product to market it. This procedure exists in both human medicine and veterinary medicine.



- **Medical devices:** instruments, apparatus, equipment or software developed by its manufacturer and intended for human use, for purposes, in particular, of diagnosis, prevention, control, treatment, mitigation of a disease or injury.
- **Medical technology:** This term refers to the study of techniques and processes for implementing advanced technologies in areas such as surgical technology, laboratory equipment, physiotherapy products, communication systems, diagnostic products and other medical products.
- **Molecular biology:** A science devoted to the study of molecules studying the hereditary message and in particular nucleic acids. Nucleic acids are DNA (deoxyribonucleic acid).
- **Non-governmental organization:** A civil society organization of a public interest or of humanitarian nature that is not dependent on a State or an international institution.
- **Pharmaceuticals:** Pharmaceuticals are chemical, natural or synthetic substances used for medical purposes for human or veterinary use. They are generally composed of one or more excipient(s) and one or more active substance(s); this active substance is developed to have a beneficial effect on biological targets.
- **Pharmaceutical industry:** An economic sector that brings together the research, manufacturing and marketing activities of medicines for human or veterinary medicine. This activity is carried out by pharmaceutical laboratories and biotechnology companies.
- **Pharmaceutical science:** A science that focuses on the design, mode of action, preparation and dispensing of medicines.
- **Prix Galien Africa:** A distinction awarded annually and exclusively in Africa from 2021 onwards, for highly convincing or promising products, services and initiatives in the field of innovative discoveries and therapies in the service of humanity and recently introduced into the African market.
- **Phytotherapy product:** Finished medicinal products that contain as active ingredients exclusively plants (aerial or underground parts), other plant materials or combinations of plants, in the raw state or in the form of preparations.
- **Researcher:** A person who devotes himself to scientific research.
- **Services:** The provision of technical or intellectual capacity or the provision of work directly useful to the user, without transformation.



- **Social innovation:** The development of new responses to new or poorly met social needs under current market conditions and social policies, involving the participation and cooperation of relevant actors, including users and service users. These innovations concern both the product and service and the mode of organization and distribution, in areas such as ageing, early childhood, housing, health, the fight against poverty, exclusion and discrimination, etc. These 4 www.prixgalienafrique.com innovations go through a multi-stage process: emergence, experimentation, dissemination, evaluation.
- **Synthetic chemistry:** A chemical transformation carried out by human beings.
- **Tobacco industry:** Any entity directly involved in the production, manufacture, distribution or sale of tobacco or tobacco products or representing the interests of such an entity.
- **Traditional therapy products:** Products of unconventional medical practice based on approaches presented as traditional in some African communities.

CHAPTER II: MISSION AND PURPOSE

Article 2.- A distinction called “Prix Galien Africa” is created

Article 3.- “The Prix Galien Africa” recognizes excellence and innovation. This price is awarded for highly convincing or promising products, services and initiatives in the field of innovative discoveries and therapies in the service of humanity.

It aims to reward researchers, pharmaceutical institutions and industries in the public or private sector that have developed initiatives, services, pharmaceutical, biotechnological, herbal medicine, diagnostic products and medical devices recently introduced to the African market.

CHAPTER III: SELECTION AND AWARD CRITERIA

Article 4.- The Prize is open to researchers, institutions and pharmaceutical industries from the public or private sector, having developed pharmaceutical, biotechnological, herbal medicine, diagnostic products and medical devices, marketed in the countries of the African zone and having obtained marketing authorization (MA), issued by at least one African pharmaceutical regulatory authority.

Pharmaceutical, biotechnological, herbal medicine, diagnostic and medical devices must be based on innovative science, developed by synthetic chemistry or molecular biology or manufactured naturally with plants according to precise criteria, specifications, tested in controlled clinical trials and marketed by ethical pharmaceutical companies.

The initial marketing authorization must be valid for a maximum of five years as of December 31 of the competition year. Exemptions could be granted for digital technology or solutions and for Traditional therapy products.



As the MA is not applicable to digital technology or solutions and Traditional therapy, the selection criteria are defined by an assessment grid drawn up by the Jury.

Article 5.- The Jury can accept the nomination of candidates.

Article 6.- No more than one special distinction can be awarded per edition, proposed by the Jury to the Honorary Committee and whose criteria are defined by the Jury.

Article 7.- The Jury will develop an assessment grid for each award category.

Article 8.- “The Prix Galien Africa” rewards pharmaceutical sciences that improve human condition, mainly on the basis of the following criteria:

- Innovation and/or discovery
- Impact on the African continent.
- Collaboration with an African institution for products presented by non-African institutions

Article 9.- Will not be taken into consideration:

- The size of the market,
- The size of the company,
- Development costs or distribution contingencies

Article 10. - Depending on the results of the jury's evaluation of the dossiers, the jury may decide not to award a distinction in a given category in a given year.

CHAPTER IV: CATEGORIES TO BE AWARDED

Article 11.- Four prizes are awarded. The jury awards following categories:

- The best pharmaceutical product,
- The best product for traditional therapy,
- The best biotechnological product,
- The best medical technology or digital solution (medical device, diagnostic, e-health, telemedicine, patient records, etc.).

The Prix awards innovations that have already been implemented in Africa and does not support ideas, prototypes, concepts or products that are still under development.

Article 12.- In addition, at the discretion of the Honorary Committee and the Jury and within the framework of their attributions, the “Prix Galien Africa” will award a special humanitarian distinction to a person, a company, an academic institution or a non-governmental organization that has contributed to improving human condition through the application of biopharmaceutical science to the problems of developing or underserved populations in the world.



In line with the mission of Prix Galien Africa, the special prize may take into account other criteria (Start-up, Young Investigator, Woman in STEM, Social Innovation, Community Agent, etc.).

At the discretion of the Jury, these prizes will be judged by the members of the Honorary Committee.

CHAPTER V: GOVERNING BODIES AND MANDATE

Article 13.- The governing bodies are:

- The Jury,
- The Honorary Committee,
- The Board of Directors (BoD).

Article 14.- The governance bodies are supported by a 3-member secretariat, which prepares and draws up the minutes of the meetings it attends. Members of the secretariat are bound by a strict confidentiality clause and have no voting rights.

Section 1: The Jury

Paragraph 1: Composition and role

Article 15.- The Jury consists of eleven (11) members and an honorary member chosen by the Board of Directors of the Galien Foundation.

Article 16.- The president and the vice-president are chosen by the Honorary Committee.

Article 17.- The honorary member cannot chair the jury and does not have the right to vote.

Article 18.- Ideally, the Jury must consist of at least two experts for each award category.

Article 19. - However, experts may be called in, subject to scrupulous compliance with the confidentiality clause. These experts do not have the right to vote.

Article 20.- The main role of the Jury is to choose the winners of the Prix Galien Africa and to propose a Special Prize to the Honorary Committee.

Paragraph 2: Appointment and mandate

Article 21.- Jury members must be former members of the Honorary committee or come from the academic and research communities and scientific divisions, companies involved in the development of human therapies.

Article 22.- The members of the jury are chosen among distinguished personalities from the world of science and research, mainly in Africa, with at least one international member international.



Article 23.- In addition to academic degrees conferred by the highest degree in a discipline, jury members must have proven expertise and understanding of human therapeutics and be familiar with health issues.

Article 24.- The term of office of the members of the jury shall be three years, renewable only once.

Section 2: The Honorary Committee

Paragraph 1: Composition and roles

Article 25.- The Honorary committee is composed of a maximum of nine (09) members.

Article 26.- The Honorary Committee shall appoint the president and the vice-president of the jury.

Article 27.- The Honorary Committee receives the Jury's proposals for the attribution of the special prize.

Article 28.- The Honorary Committee, on a proposal from the Board of Directors, appoints the Chairman of the Board of Directors.

Paragraph 2: Appointment and mandate

Article 29.- The members of the Honorary Committee must be internationally recognized moral authorities (international institutions, foundations, public or private institutions, Nobel Prize winners, etc.).

Article 30.- The members of the Honorary Committee appoint a Chairman within them.

Article 31.- The mandate of the members of the Honorary Committee shall be three years, renewable only once.

Section 3: The Board of Directors

Paragraph 1: Composition and roles

Article 32.- The Board of Directors of the Prix Galien Africa consists of a maximum of five (5) persons..

Article 33.- It is responsible for checking the completeness and compliance of applications. It decides on their admissibility and submits them to the Jury for assessment.

Article 34.- The Board of Directors, in relation with the Honorary Committee, chooses a chairperson



Article 35.- The Board of Directors is assisted by a secretariat composed of three (3) members, which collects applications, prepares the meetings it attends and draws up the minutes of those meetings.

Paragraph 2: Appointment and mandate

Article 36.- Its members must have the professional qualities to ensure the good coordination of all the actors concerned on the local logistic level.

Article 37.- The mandate of the members of the Board of Directors shall be three years, renewable once.

CHAPTER VI: CALL FOR APPLICATIONS AND APPLICATION FORM

Article 38.- A call for applications will be published by March 31 of the competition year.

Article 39.- The application document, written in English and French, is available from the Board of Directors.

Article 40.- Applications must be sent in English or French with a maximum two-page summary of the pharmaceutical, biotechnological, herbal medicine, diagnostic products, medical device and digital solution presented.

Article 41.- For further information, if necessary, the jury may interview a candidate if it deems it necessary.

Article 42.- The deliberations of the Jury shall take place in person or by videoconference.

Article 43.- The announcement of the results will take place no later than two weeks before the awards ceremony.

Article 44.- The awards ceremony will take place in Dakar (Senegal), during the Galien Forum Africa.

CHAPTER VII : DELIBERATIONS AND LAUREATES

Article 45.- The jury is sovereign. The Jury's deliberations shall take place behind closed doors.

Apart from the members of the Jury, no other member, whether from a governing body of the Prix Galien Africa or sponsor, shall participate in the deliberations.

Article 46.- Decisions concerning the choice of laureates are final.

Article 47.- The nature of the Prix Galien Africa and that of the special prizes will be determined by the governing bodies of the Prix Galien Africa.



CHAPTER VIII: CONFLICT OF INTEREST AND ETHICAL CONSIDERATIONS

Article 48.- Jury members must avoid any conflict of interest and abstain from voting if such is the case.

The conflict of interest rules are designed to identify and avoid any potentially compromising situation and to preserve the credibility of the jury and its work.

A conflict of interest may reasonably be perceived as being likely to:

1. influence the objectivity and independence of the advice given (remuneration, financial assistance, donations, etc.: financial conflict)
2. confer an unfair competitive advantage to one or more members or to people or institutions with which he or she has financial or business interests (e.g. children or adult siblings, close work colleagues, administrative unit or department: conflict of mission and family interests).

Article 49.- In the same way, the members of the jury shall not be allowed to participate in the elaboration of the scientific program of the Galien Forum Africa. This mission is entrusted to the scientific committee of the forum, which is a totally independent body of the jury.

Article 50.- The conflict of interest is likely to be of varying degrees. If a declared interest is potentially significant, one or a combination of the three options, as described in the following article, may be considered to determine, possibly, under what conditions the jury member may participate in the deliberation.

Article 51.- The Chairman of the Board of Directors should always consult with the Chairman of the jury before disclosing the interest of one of its members to the other participants in the meeting or considering any of the following measures:

- i) Conditional participation: Under this formula, the Board shall decide to maintain the participation of the jury member in the meeting or in the proceedings and to disclose the interest of the said member to all participants at the beginning of the meeting and in the jury's report. This approach is particularly appropriate where the interest of the expert is relatively minor.
- ii) Partial Exclusion: The BoD limits the member's participation:
 - a) By excluding him/her from that part of the meeting or work for which a conflict of interest has been identified and/or;
 - b) By excluding him/her from the decision-making process. In both of these cases, and after consultation with the Chairman of the jury, the reported interest should also be disclosed to the other members of the jury and recorded in the jury report. Partial exclusion should be carefully controlled. It may only be used to allow other jury members to view the research results or opinions of the most qualified members with the potential bias of those members in mind.



- iii) Full exclusion: A jury member shall be excluded entirely from the meeting or from the work when the nature of the conflict of interest would unduly impair the purpose of the meeting or the work, or when it is impossible to limit the member's participation to only part of the work. Any decision to exclude a member of the jury should always be made in consultation with the Chairman of the Jury of Directors and the Chairman of the Honorary Committee.

The conflict-of-interest rules apply to members of other governance bodies in any situation that may give rise to a conflict of interest.

Article 52.- In order to protect the integrity and credibility of Prix Galien Africa, members of the governance bodies are required to declare any circumstances that may give rise to a real or apparent conflict of interest.

Article 53.- In its mission to serve health and humanity, all members of the governing bodies are also required to declare any employment or other work for the tobacco industry. Disclosure to this effect shall not necessarily be considered grounds for disqualification of a Jury member.

Article 54.- Members of the Prix Galien Africa Jury and other governance bodies should:

- Demonstrate the highest level of scientific integrity as public health practitioners and/or researchers;
- Ensure the security of any confidential information provided or generated by Galien Africa;
- Report suspected irregularities or violations of the principles, rules, regulations or policies of the Galien Africa in matters of ethics using existing mechanisms (Integrity Problem Reporting System);
- Comply with ethical principles and act in good faith, with intellectual honesty and fairness;
- Apply the same discretion and caution in their communications, e-mail messages and social media activities in both professional and private spheres.

Article 55.- Jury members shall be responsible for their actions, decisions as well as the consequences thereof. They are supposed to:

- Define clear and realistic objectives and results for their work in consultation with the other bodies;
- Commit themselves to carry out the functions attached to their office to the best of their ability;
- Demonstrate a high level of professionalism and loyalty;
- Follow professional development in their field of activity in order to maintain technical excellence.



Article 56.- The members of the Jury, the Board of Directors and the Honorary Committee must be independent and impartial. They should conduct themselves with the interests of Galien Africa exclusively in mind and under the sole authority of the President, and ensure that personal opinions and beliefs do not undermine the ethical principles, missions or interests of the said Foundation. They must resign before engaging in any political campaign or appointment process.

Article 57.- Members of governance bodies are expected to respect the dignity, merit, equality, diversity and privacy of all. They must ensure compliance with national and local laws at all times.

CHAPTER IX: BRAND PROTECTION

Article 58.- The medals, acronyms, logos and any element of information or promotion concerning the Prix Galien Africa, constitute a registered and protected brand. Their use can only be carried out in accordance with the regulations established by the head office of Galien Africa.

CHAPTER X: TRANSITIONAL AND FINAL PROVISIONS

Article 59.- This Charter is effective from the date of signature.

Article 60.- The meeting of the different governing bodies of the Prix Galien Africa, for the purpose of revising this Charter, may be held at places and dates to be determined by the President of the Galien Africa.

Article 61.- Any modification to this Charter recommended by at least one of the governing bodies will take effect once it is signed by the President.

By the two signing Presidents below

Bruno COHEN
President of the Galien Foundation

And

Prof. Awa Marie COLL SECK
Chair of the Association Galien Africa

Done in Dakar, March 30, 2024