

THE PRIX GALIEN AFRICA CHARTER

PREAMBLE

The Galien Foundation, in collaboration with African partners;

- Aware that the sustained promotion of scientific progress is the foundation for sustainable development;
- Convinced that the application of technology to 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 shall 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.
- **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.
- **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 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.

In keeping with the spirit of the mission of the Prix Galien Africa, special distinctions may be awarded, proposed by the Honorary Committee and submitted to the jury for consideration.

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 MA must be no more than five years old as of December 31 of the year of grant.

Article 5 - The Prix Galien Africa rewards pharmaceutical sciences that improve human condition, mainly on the basis of two criteria:

- Innovation and/or discovery
- Impact on the African continent.

Article 6.- Will not be taken into consideration:

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

Article 7.- 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 8.- 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 (medical devices, diagnostic devices, etc.).

Article 9.- 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.

Other prizes, in line with the Prix Galien Africa mission, are planned (Digital health, Start up, Young Investigator, Social Innovation 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 10.- The governing bodies are:

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

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

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

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

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.

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.

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.

The term of office of the members of the Jury shall be three years, renewable only once.

The Jury meeting as well as the award ceremony will take place in Dakar (Senegal).

The main role of the Jury is to choose the winner of the Prix Galien Africa and to propose special prizes.

Article 12.- The Honorary committee is composed of a maximum of nine (09) members. They must have a moral authority of international renown (Director General of the WHO, President of a foundation, public or private institution ...).

The members of the Committee shall appoint a chairman from among themselves.

The mandate of the members of the Committee shall be three years, renewable only once.

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

The Honorary Committee submits to the appreciation of the jury, the attribution of special distinctions.

The Honorary Committee and the Board of Directors shall appoint the Chairman of the Board of Directors.

Article 13.- The Board of Directors of the Prix Galien Africa is composed of a maximum of five (5) persons.

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

The Board of Directors, in relation with the Honorary Committee, chooses a chairperson whose mandate is for three years renewable only once.

The term of office of the other members is also three years, renewable once.

It is in charge of collecting applications and submitting them to the Jury.

The Board of Directors is assisted by a secretariat composed of three (3) members.

Article 14.- A call for applications will be published by March 31 of the competition year.

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

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

A first selection will determine the list of nominees for the Prix Galien Africa and other distinctions.

For further information, if necessary, the Jury may interview a candidate if it deems it necessary.

The deliberations of the Jury (face-to-face or in hybrid format including videoconference) will take place between July and mid-October of the year of the competition.

The announcement of the results will take place no later than the first two weeks of November of the competition year.

The award ceremony will take place in Dakar, during the Galien Forum Africa scheduled for December of each year.

CHAPTER VI: DELIBERATIONS AND LAUREATES

Article 15.- The jury is sovereign.

Decisions on the selection of the winners shall be final.

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 16.- 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 VII: CONFLICT OF INTEREST AND ETHICAL CONSIDERATIONS

Article 17. - 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 18.- 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 19. - 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 20.- 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 and the Chairman of the Honorary Committee.

Article 21.- In order to protect the integrity and credibility of the Prix Galien Africa, the members of the jury are required to declare any circumstance that could give rise to a real or apparent conflict of interest.

Article 22.- In its mission to serve health and humanity, all jury members are also required to declare any employment or other work in the service of the tobacco industry. The provision of information to this effect shall not necessarily be considered grounds for disqualification of a Jury member.

Article 23. - The members of the Jury of the Prix Galien Africa must:

- Demonstrate scientific integrity of the highest level 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 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 24.- 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 25.- Jury members should 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 should ensure that their personal opinions and convictions do not infringe upon the ethical principles, missions or interests of Galien Africa.

They should resign before undertaking a political campaign or appointment process.

Article 26.- The members of the Jury are required to respect the dignity, merit, equality, diversity and privacy of all. They should ensure compliance with national and local laws at all times.

CHAPTER VIII: BRAND PROTECTION

Article 27.- 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 IX: TRANSITIONAL AND FINAL PROVISIONS

Article 28.- This Charter is effective from the date of signature.

Article 29.- The meeting of the different organs 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 30.- 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

The President of the Galien Foundation

And

The President of the Scientific Committee of the Galien Forum Africa

Done in Dakar, March 29, 2021

PRIX
GALIEN *Africa*



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