



RULES OF THE PRIX GALIEN 2023 (42nd edition)

ARTICLE 1

The Prix Galien is organised annually by Roularta HealthCare (RHC). RHC is the licensee for Belgium. The owner of the Prix Galien organisation and 'brand' is: Galien Foundation - 99 John Street - Suite 2502 - New York, NY 10038 – USA represented by Mr Bruno Cohen, chairman.

RHC is bound by an agreement to follow the brand and organizational guidelines and to adapt to the regulations of the Galien Foundation if necessary.

The panel awards four prizes each year.

The first prize is a gold medal which is awarded for the **medicine** for human use from among those submitted that is judged to be the most significant. It must have marketing approval or be accepted as a new and significant clinical indication in Belgium, Luxembourg or EMEA between 01.01.2023 and 31.12.2023.

The second prize is a gold medal and the sum of €5,000, to be awarded to a researcher or team of researchers (a maximum of three) for a piece of clinical and/or fundamental work in **pharmacology** within the European Union. The work must be carried out mainly in a Belgian or Luxembourg institution. Candidates must be under the age of 40 on 1 January of the year in which the prize will be awarded. Their work may not have been carried out within the pharmaceutical industry.

The third prize is a gold medal which is awarded for the **medical device** judged to be the most innovative and most likely to lead to better treatment. This medical device and its distributor must meet the legislative requirements of Belgian royal decrees and European regulations concerning medical devices, including CE marking. The entry must be put forward by a distributor approved by the FAMHP. In addition, the medical device must be innovative and have been recently introduced on the market in Belgium.

A fourth prize, a gold medal, rewards the most promising and innovative **medical device that is in its final design phase**. This prize focuses on the technology that (hypothetically) stands out the most in terms of Value-Based Healthcare (clinical value, socio-economic value, process efficiency) and/or ecological sustainability. The submitting company is ISO 13485:2016 certified and has demonstrable commercialization plans for the medical device. The product is in a "Design Freeze," and the path to CE marking is clearly planned.



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ARTICLE 2

1. Medecine Prize:

Each participating company shall inform the Prix Galien secretary of its intention to submit a dossier by no later than 31.01.2024.

This can only be done by email to secretary@prixgalien-galenusprijs.be, indicating:

- the name of the medicine
- the name of the molecule
- the company
- the contact person
- the contact person's telephone number
- the contact person's email address

or by filling out the online form via <https://prixgalien.be/application-pharmaceuticals>

All participants agree that information about their molecule will appear in articles about the Galenusprijs in all publications of Roularta HealthCare.

Dossier fees* will be charged for each submitted dossier:

1st dossier:	€4,000
2nd dossier:	€3,500
3rd dossier:	€3,000
Each following dossier:	€2,000

*amount excluding VAT, includes 2 seats for the award ceremony

1. Submission of the dossier:

The information about the medicine nominated for the prize should be provided no later than 15.03.2024, with the mention "Candidate for the Prix Galien."

2. Form and Content:

The dossier (font: Calibri 11 pt, line spacing: 1.5) must be prepared in English and submitted digitally.

The dossier is introduced by a clear summary of a maximum of 3 pages in Dutch and a maximum of 3 pages in French.



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Each dossier (up to 60 pages) contains the following elements:

- The chemical-pharmaceutical description of the molecule
- Toxicology
- Pharmacokinetics
- Animal and human pharmacology
- Clinical trials, along with an argument demonstrating the therapeutic significance of the substance in question
- A link to the EMA website that references the EPAR (European Public Assessment Report)
- List of abbreviations
- Other (references, conclusions, etc.)

Finally, there should be an argumentation demonstrating why the proposed molecule qualifies for the Medecine Prize and highlighting the significance of the submitted medicine.

A explanatory list of the used abbreviations should also be included.

The dossier must be submitted in digital form, as a single file.



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2. Pharmacology Prize:

Each participant shall inform the Prix Galien secretary of their intention to submit a dossier no later than 31.01.2024.

This is done via email at secretary@prixgalien-galenusprijs.be, specifying:

- The title of the work
- The name of the university
- The candidate's full name
- The candidate's date of birth
- The candidate's nationality
- The candidate's mobile phone number
- The candidate's email address
- The candidate's mailing address

or by completing the online form via <https://prixgalien.be/application-pharmaceuticals>

1. Submission of the dossier:

Candidates must digitally submit the text of their work, accompanied by a curriculum vitae and a high-resolution portrait photo, no later than 15.03.2024.

2. Form and content:

This manuscript (font: Calibri 11 pt, line spacing: 1.5), written in English, must not exceed 10 pages (equivalent to 30,000 characters, including spaces), including figures and tables. It should be accompanied by relevant publications supporting the candidacy (up to a maximum of 5).

Lastly, the dossier must include an explanatory list of the abbreviations used and must be submitted in digital format.

In the case of a group project, each candidate's contribution must be clearly indicated.

Candidates must specify any other scientific awards they have received in the last 5 years when submitting a dossier.



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ARTICLE 3

The jury decides completely autonomously. There can be no appeal against the decisions.

From the candidates, the jury selects one winner for the Medical Prize and one winner for the Pharmacology Prize during the deliberation. The top 3 will be presented later during the award ceremony as "the nominees".

The deliberation takes place approximately 5 to 6 weeks before the award ceremony.

Composition of the jury for the Medecin & Pharmacology Prize 2023:

President of the jury

Mr J. de HOON

Professor aan de KU Leuven

Mr K. AUGUSTYNS

Professor aan de Universiteit Antwerpen

Mr Y. BEGUIN

Professeur à l'Université de Liège

Mr G. BERCHEM

Professeur au Centre Hospitalier de Luxembourg

Mrs M. CASTEELS

Professor aan de KU Leuven

Mr J.L. BALLIGAND

Professeur à l'Université Catholique de Louvain

Mrs T. DE BACKER

Professor aan de Universiteit Gent

Mr G. DE MEYER

Professor aan de Universiteit Antwerpen

Mr B. NEYNS

Professor aan de Vrije Universiteit Brussel

Mr J.-M. KRZESINSKI

Professeur à l'Université de Liège

Mrs S. LUCAS

Professeur à l'Université Catholique de Louvain

Mr C. BLANPAIN

Professeur à l'Université Libre de Bruxelles

Mrs S. ROTTEY

Professor aan de Universiteit Gent



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Mrs I. SMOLDERS

Professor aan de Vrije Universiteit Brussel

Mr P. van de BORNE

Professeur à l'Université Libre de Bruxelles

ARTICLE 4

After the deliberation, the three nominees will be informed.

They will be presented in a video segment of up to 3 minutes during the academic session; these segments will either be provided by the companies or produced in collaboration with and at a cost by Roularta HealthCare.

Leading up to the award ceremony, Roularta HealthCare plans to introduce the candidates in its publications.

Therefore, participating companies must submit the following by February 16, 2024:

- A brief introduction of the product in Dutch and French (1000 characters including spaces)
- The company's logo
- The product's logo.



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ARTICLE 5

The prizes will be awarded on Tuesday **21 May 2024** during an academic session.

The award ceremony proceeds as follows:

- All candidates are introduced in a short video presentation, which is produced by Roularta HealthCare.
- The 3 nominees are then presented in a video presentation of up to 3 minutes. These videos are either provided by the companies or produced in collaboration with and at a cost by Roularta HealthCare.
- The jury chairman announces the winner and provides an explanation of the jury's motivation.
- At the end of the academic session, the medals are presented.
- After the academic part, there will be a reception and dinner.

Dinner guests will either receive an invitation from the sponsors (paying tables) or be invited by Roularta HealthCare.

HCPs are welcome at a price of €450 per person. The sale of places and sponsorship will be arranged by RHC.

The detailed sponsorship dossier is available.

ARTICLE 6

Important date Prix Galien 2023, 42nd edition: award ceremony: 21.05.2024

ARTICLE 7

Entries should be sent to the following address:

Artsenkrant/Le journal du Médecin

For the attention of Virginie Meysmans

Prix Galien Secretary

Rue de la Fusée 50

B-1130 Brussels

Email: secretary@prixgalien-galenusprijs.be

More information at: www.prixgalien.be