



## RULES OF THE PRIX GALIEN 2023 (9<sup>th</sup> 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. Prix Galien - Recently Commercialized Medical Device:

Each participating company informs the Galien secretariat of its intention to submit a dossier no later than **30.11.2023**.

This can only be done by completing the online form : [http://www.prixgalien-galenusprijs.be/DEV\\_INT\\_EN.html](http://www.prixgalien-galenusprijs.be/DEV_INT_EN.html) or sending an email to [secretary@prixgalien-galenusprijs.be](mailto:secretary@prixgalien-galenusprijs.be), indicating:

- the name of the medical device
- the use of the medical device
- the company
- the contact person
- the telephone number of the contact person
- the email address of the contact person.

Each participating company gives consent to Roularta HealthCare for the publication of articles about the medical device submitted for the Prix Galien in all Roularta HealthCare titles.

Dossier fees\* will be charged for each submitted dossier:

1st entry:	€ 2,000
2nd entry:	€ 1,500
3rd entry:	€ 1,000
Each additional entry:	€ 500

*\*amount excluding VAT, incl. 2 places at the awards evening*

#### 1. Submission of the entry:

The information relating to the medical device presented for the prize must be provided in digital form in a file with the words 'Candidature Prix Galien ' by 15.12.2023.



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### 2. Format and contents:

Each entry (Calibri font, 11 pt, 1.5 line spacing) will be written in English and submitted in digital form.

The entry will also be preceded by a summary with a maximum length of 3 pages in Dutch and a summary with a maximum length of 3 pages in French.

The dossier must summarize the key characteristics of the medical device.

#### **a. History of the medical device:**

##### a) origin of the product

- CE marking date
- risk class according to MDR 2017/745
- notification number at the Federal Agency for Medicines and Health Products (FAGG) of the distributor for Belgium
- date of commercialization (worldwide/Belgium)

##### b) description of the discovery and its development

##### c) composition of the research team

##### d) overview of the reasons for participating in the Prix Galien and innovative features of the medical device.

#### **b. Treatment:**

Information on the innovative nature of the medical device:

- quality, safety, effectiveness
- quality of life and comfort for the patient
- benefits and added value of the medical device.

#### **c. Financial aspect:**

- Possible reimbursement modalities for the medical device, as well as the price-quality ratio or information regarding an ongoing reimbursement application.

A complete bibliography with a separate list of the most important publications should be included in the dossier.

It will conclude with a statement (in English) setting out the reasons why the proposed medical device is worthy of the Medicine Prize and highlighting the significance of the submitted medical device.

The entry must also include an explanatory list of abbreviations used.



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The dossier must be submitted in digital format, as a single file. Non-compliant applications will not be considered.

### Summary criteria:

- Treatment: innovative nature
- Quality, safety, effectiveness
- Benefits and added value of the medical device
- Financially: potential reimbursement + price-quality ratio
- Bibliography/publications
- Motivation (why/significance)

### **2. Prix Galien – Most innovative and promising Design of a Medical Device:**

Each participant must inform the secretariat of the Prix Galien of its intention to submit an entry by **30.11.2023** at the latest.

To do this, simply complete [the online form: http://www.prixgalien-galenusprijs.be/DEV\\_INT\\_EN.html](http://www.prixgalien-galenusprijs.be/DEV_INT_EN.html) or send an email to [secretary@prixgalien-galenusprijs.be](mailto:secretary@prixgalien-galenusprijs.be) containing the following information:

- the name of the design of the medical device
- the use of the medical device
- the company
- the contact person
- the telephone number of the contact person
- the email address of the contact person.

Each participating company gives consent to Roularta HealthCare for the publication of articles about the design of the medical device submitted for the Prix Galien in all Roularta HealthCare titles.

Dossier fees\* will be charged for each submitted dossier:

1st entry: € 700

Each additional entry: € 500

*\*amount excluding VAT, incl. 2 places at the awards evening*



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### 1. Submission of the entry:

The information relating to the medical device design presented for the prize must be provided in digital form in a file with the words 'Candidature Prix Galien ' by 15.12.2023.

### 2. Format and contents:

Each entry (Calibri font, 11 pt, 1.5 line spacing) will be written in English and submitted in digital form.

The entry will also be preceded by a summary with a maximum length of 3 pages in Dutch and a summary with a maximum length of 3 pages in French.

The contact person with all necessary details is mentioned at the beginning of the dossier.

The dossier must summarize the key characteristics of the design of the medical device.

#### **a. History of the design of the medical device:**

##### a) origin of the product

- planned/expected risk class according to MDR 2017/745
- ISO certification 13485:2016 of the company
- demonstrable Technology Readiness Level (TRL) greater than or equal to 4
- development plan outlining the route and timing to CE marking.

##### b) description of the discovery and its development

##### c) composition of the research team

##### d) overview of the reasons for participating in the Prix Galien and innovative features of the medical device

#### **b. Treatment:**

Information on the innovative nature of the medical device:

- quality, safety, effectiveness
- quality of life and comfort for the patient
- benefits and added value of the medical device.
- hypothetical model that describes and calculates clinical and/or socio-economic and/or ecological value-added.

#### **c. Financial aspect:**

- once on the market, who will ultimately finance this medical device?

A complete bibliography with a separate list of the most important publications should be included in the dossier.



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It will conclude with a statement (in English) setting out the reasons why the proposed medical device is worthy of the Prix Galien for the Most promising Design of a Medical Device and highlighting the impact of the submitted design of a medical device.

The entry must also include an explanatory list of abbreviations used.

The dossier must be submitted in digital format, as a single file. Non-compliant applications will not be considered.

### **Summary criteria:**

- Planned/expected risk class
- ISO certification 13485:2016
- Technology Readiness Level (TRL)  $\geq 4$
- Development plan CE marking
- Description: discovery and development
- Composition of the research team
- Treatment: innovative nature
- Quality, safety, effectiveness
- Benefits and added value of the medical device
- Bibliography/publications
- Motivation (why/impact)
- Hypothetical model clinical and/or socio-economic and/or ecological added value
- Financial aspect: who will finance?

### **ARTICLE 3**

The deliberation takes place just before the award ceremony.

The jury decides autonomously.

The top 3 will be presented during the ceremony as "the nominees."

The panel's decisions are final.



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### Composition of the Medical Device jury 2023:

<b>Mrs M. LOUAGIE</b>	<b>President of the jury</b> Advisor-General, Medical Directorate, RIZIV/INAMI
Mr P. LANCELLOTTI	Professor at the University of Liège
Mr L. ANNEMANS	Professor at the University of Ghent
Mr K. KAS	Professor at the University of Ghent
Mrs M. MERTENS	Doctor of Plastic, Reconstructive, and Aesthetic Surgery (Antwerp)
Mr C. POLITIS	Professor at the Catholic University of Leuven
Mr P. VERDONCK	Professor at the University of Ghent

### ARTICLE 4

In the weeks leading up to the awarding of the prize, Roularta HealthCare plans to feature the candidates for the Prix Galien in its publications. Participating companies must therefore have provided the following **by 15 January 2024**:

- a brief presentation of the product in 1,000 characters (including spaces) in French and Dutch.
- a product logo.
- a company logo.



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### ARTICLE 5

The prizes will be awarded on Thursday **14 March 2024** at a ceremony.

The award ceremony will take place as follows:

- All candidates present themselves at 14:00 p.m. during a 3-minute pitch.
- Afterwards, the jury deliberates and selects 3 nominees. These nominees are then announced.
- During the academic session at 16:00 p.m., the president of the jury announces the winner and provides an explanation of the jury's motivation. The president of the jury will announce the winner and give a brief explanation of the decision made by the jury.
- At the end of the ceremony, the medals will be handed out.
- The ceremony will be followed by 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 €300 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, 9th edition: award ceremony: 14.03.2024

### ARTICLE 7

Entries should be sent to the following address:

**Le journal du Médecin**

For the attention of Virginie Meysmans

Prix Galien Secretary

Rue de la Fusée 50

B-1130 Brussels

Tel: 02 702.70.30 Email: [secretary@prixgalien-galenusprijs.be](mailto:secretary@prixgalien-galenusprijs.be)

More information at: [www.prixgalien-galenusprijs.be](http://www.prixgalien-galenusprijs.be)