

# **Regulations Prix Galien Awards 2023 / 2024**



With effect from 2022 and following the international example, the Prix Galien

Award will be divided into 2 categories 'Pharmaceutical' and 'Biological'. The division of the original Pharmaceutical Award also does justice to the diversity of the therapeutic interventions. The Prix Galien consists of a gold medal.

# Article 1

The **Prix Galien** '**Pharmaceutical**' **Award** rewards the most meaningful and/or innovative product for human use:

#### Prix Galien 'Pharmaceutical' Award 2023

- was placed (introduced) on the Dutch market between <u>January 1<sup>st</sup> 2022</u> and <u>December</u> <u>31<sup>st</sup> 2022</u>;
- received a Dutch or European marketing authorisation (EMA) not older than five (5) years before the introduction or was registered with the CBG;
- already has a reimbursement status or has been admitted to the Compassionate Use Program (CUP).

### Prix Galien 'Pharmaceutical' Award 2024

- was placed (introduced) on the Dutch market between <u>January 1<sup>st</sup> 2023 and December</u> <u>31<sup>st</sup> 2023;</u>
- received a Dutch or European marketing authorisation (EMA) not older than five (5) years before the introduction or was registered with the CBG;
- already has a reimbursement status or has been admitted to the Compassionate Use Program (CUP).

# The **Prix Galien** 'Biological' Award rewards the most meaningful and/or innovative biological for human use:

### Prix Galien 'Biological' Award 2023

- was placed (introduced) on the Dutch market between <u>January 1<sup>st</sup> 2022 and December 31<sup>st</sup> 2022;</u>
- received a Dutch or European marketing authorisation (EMA) not older than five (5) years before the introduction or was registered with the CBG;
- already has a reimbursement status or has been admitted to the Compassionate Use Program (CUP).

# Prix Galien 'Biological' Award 2024

- was placed (introduced) on the Dutch market between <u>January 1<sup>st</sup> 2023 and December 31<sup>st</sup> 2023;</u>
- received a Dutch or European marketing authorisation (EMA) not older than five (5) years before the introduction or was registered with the CBG;
- already has a reimbursement status or has been admitted to the Compassionate Use Program (CUP).

# Article 2

The registration can be made online until the <u>**15<sup>th</sup> of December 2023**</u> through <u>www.prixgalien.nl</u> (**Application Prix Galien Awards**);

1. the dossier on the product proposed for the Award consists of a maximum of fifteen (15) A4 pages;

- 2. this dossier must contain at least the following elements:
  - a **motivation** in which the applicant states why the product is eligible for the Prix Galien Award (innovative/meaningful);
  - the' EPAR summary for the public' containing a link to the underlying EPAR file;
  - additional information relating to preclinical and clinical evaluation to the extent not presented in the EPAR;
  - relevant publications to the extent not included in the other paragraphs.
- 3. the file must be sent by e-mail to <a href="mailto:philip.delorme@prixgalien.nl">philip.delorme@prixgalien.nl</a> as one PDF by 17<sup>th</sup> of March 2024, with the entry 'Candidate Prix Galien Pharmaceutical Award 2023 respectively 2024' or 'Candidate Prix Galien Biological Award 2023 respectively 2024'
- 4. only digital files will be accepted.



#### Article 3

Applying for the Prix Galien Awards 2023 also means participating in the composition of the Prix Galien Magazine 2023. It consists of an editorial page including image and logo of the product submitted. The costs of candidacy for the Prix Galien are  $\in$  5,950 excl. VAT. The applicants are also expected to deliver a short product video of up to 1.5 minutes which will be shown at the award ceremony.

#### Article 4

The winners of the **Prix Galien Pharmaceutical 2023 / 2024** and **Prix Galien Biological Award 2023** / **2024** are also eligible for the competition of the International Prix Galien which will be awarded biannually.

#### Article 5

The judging takes place by the jury of the Prix Galien Awards. Also see the evaluation form

#### Article 6

The jury's decisions are irrevocable.

#### Article 7

The result regarding the nomination of the candidates and winner of the **Prix Galien Awards 2023** / **2024** will be announced during the award ceremony itself. It is not possible to correspond about the results.