



PRIX GALIEN

Italia

PRIX GALIEN ITALY

AWARDS FOR INNOVATION

CALL FOR APPLICATIONS 2021

Springer Healthcare Italy is pleased to announce the call for applications for Prix Galien Italy 2021 (formerly “*Premio Galeno*”) for innovation in drugs, medical devices, and digital medicine & therapeutics.

Award addressees and participation categories

- Applications for Prix Galien Awards Italy can be submitted by national or multinational companies (headquartered also in Italy) producing/distributing drugs¹, medical devices, and digital medicine and therapeutics, in accordance with the rules and calendar set out in this call for applications.
- There are eight award categories:

1. Chemical Synthesis Drug Award

This award addresses non-biological drugs, whose active ingredients are obtained by chemical synthesis.

For a full description of the products eligible for this award category, the assessment criteria, the documents required for submission and the related deadlines, please refer to **ANNEX-(A)** at www.prixgalien.it

2. Biological Drug Award

In bearing with the definition of “biological drug” from AIFA (the Italian Medicines Agency)², this award recognizes drugs whose active ingredient consists of a molecule produced by, or extracted from, a biological system. The category covers biotechnological medicines (produced by recombinant DNA techniques), hormones, enzymes, blood products, immunoglobulins and monoclonal antibodies. Immunological drugs, such as toxins, sera and allergens, are excluded and may apply under category no. 3 (Immunologic drug award).

¹ In this document the term “drugs” refers to active ingredients, treatments and medical devices incorporating as an integral part a medicinal substance not having a merely ancillary action relative to the device itself

² AIFA’s Second Concept Paper on biosimilars, 15/06/2015



PRIX GALIEN

Italia

For a full description of the products eligible for this award category, the assessment criteria, the documents required for submission and the relevant deadlines, please refer to **ANNEX-(A)** at www.prixgalien.it

3. *Immunologic Drug Award*

In bearing with the definition of “immunologic drug” provided by AIFA³, this award recognizes drugs consisting of vaccines, toxins, sera or allergens, and specifically comprises agents employed to induce active or passive immunity and agents used to diagnose a state of immunity.

IMPORTANT: should only one nomination be received for this award category, the category itself will be cancelled and the application will be moved into one of the main reference categories (chemical synthesis or biologicals)
For a full description of products eligible for this award category, the assessment criteria, the documentation required for submission and the relevant deadlines, please refer to **ANNEX-(A)** at www.prixgalien.it

4. *Orphan Drug Award*

This award is for drugs contained in AIFA’s list of medicines included in the European Union register of orphan medicinal products⁴ and any medicinal product that has received marketing approval in Italy with an indication for the treatment of rare diseases or conditions listed in the Orphanet inventory (<http://www.orphanet.net/>), even if not included in the European Union register of orphan medicinal products.

IMPORTANT: should only one nomination be received for this award category, the category itself will be cancelled and the application will be moved into one of the main reference categories (chemical synthesis or biologicals)
For a full description of the products eligible for this award category, the assessment criteria, the documents required for submission and the relevant deadlines, please refer to **ANNEX-(A)** at www.prixgalien.it

³ AIFA, Biologic Drugs (FAQs). <http://www.agenziafarmaco.gov.it/content/medicinali-biologici-faq>

⁴ EC Regulation No. 141/2000 of the European Parliament and Council of 16 December 1999



PRIX GALIEN *Italia*

5. **Advanced Therapy Medicinal Products (ATMP)**

In bearing with the definition provided by EMA⁵, advanced therapy medicinal products (ATMP) include: (a) medicines for gene therapy, (b) medicines for somatic cell therapy; (c) tissue engineering products, (d) one of the above ATMP in combination with a medical device (combination products). Applications for this award are only open to products classified as ATMP by the EMA Committee for Advanced Therapies (CAT) and for which EMA has already published its "Summaries of scientific recommendations on classification of advanced therapy medicinal products"⁶

IMPORTANT: should only one nomination be received for this award category, the category itself will be cancelled and the application will be moved into one of the main reference categories (chemical synthesis or biologicals)

For a full description of the products eligible for this award category, the assessment criteria, the documents required for submission and the relevant deadlines, please refer to **ANNEX-(A)** at www.prixgalien.it

6. **Real World Evidence Award**

This award is for drugs studied by post-approval studies (in Italy or worldwide) conducted with the aim of confirming or redefining the efficacy and safety of the drug in real world clinical practice or which, through an investigation of the drug, contribute to the understanding of a medical condition.

IMPORTANT: this award category is only open to drugs approved by EMA or AIFA before and including 01.01.2013, regardless of previous submissions to Italian or international Prix Galien editions. See the section "Requirements for application"

For a full description of the products eligible for this award category, the assessment criteria, the documents required for submission and the relevant deadlines, please refer to **ANNEX-(A)** at www.prixgalien.it

⁵EMA Regulation (EC) No. 1394/2007

⁶http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000301.jsp&mid=WC0b01ac05800862c0



PRIX GALIEN *Italia*

7. Award for Medical Devices/Technologies (in Physical and Rehabilitation Medicine)

This award recognizes aids, prostheses and orthoses as well as equipment and applications used in any phase of the patient's rehabilitation process. Any medical device incorporating a medicinal substance having a primary, not merely ancillary, action relative to the device itself can apply as a medicinal product under the relevant drug award category (categories no.1-6).

For a full description of the products eligible for this award category, the assessment criteria, the documents required for submission and the relevant deadlines, please refer to ANNEX-(B) at www.prixgalien.it

8. Award for Digital Medicine & Therapeutics

This award is for digital health products, defined as software as well as possible hardware solutions, based on proven clinical efficacy and devised for measurements or interventions aiming to improve the patients' health outcomes. A subclass of this award category includes Digital Therapeutics, defined as treatment interventions addressing a specific disease and developed through randomized controlled studies, in which the element responsible for the clinical effect is represented by an algorithm rather than by an active ingredient of chemical or biological origin.

For a full description of the products eligible for this award category, the assessment criteria, the documents required for submission and the relevant deadlines, please refer to ANNEX-(C) at www.prixgalien.it

- On applying, companies may indicate a preference category for their product, but the final allocation of products to each category will be decided on by the Scientific Committee of Prix Galien Italy (see below).
- The organizers of Prix Galien Italy reserve the right to activate additional award categories: for a full description of other eligible products, the relevant assessment criteria, the documents required for submission and the deadlines, please refer to the Annexes to this call for applications posted on www.prixgalien.it .



PRIX GALIEN

Italia

Conditions for participating

- Pharmaceutical companies may submit a maximum of two entries for each award category, for a total 6 entries. A single product cannot be entered for more than one category.
- Entries for products not yet marketed in Italy are accepted, provided they meet the specific requirements detailed in the relevant **ANNEX-(A),(B),(C)**.
- Entries for products that have won and/or competed in previous editions of Prix Galien in countries other than Italy are accepted, whereas entries for products that have won and/or competed in previous editions held in Italy are not accepted (with the only exception of entries for award category no. 6, which are accepted in either case).
- If a product has won a previous international Prix Galien award, this does not automatically entail that it will also be assigned an award in the current Italian edition nor will a previous award be considered a merit when the application is assessed

Application fee and Communication package

- Each entry for a Prix Galien award will be charged an application fee payable by the applicant pharmaceutical company, as detailed below:

Application type	Fee (excluding VAT)
Standard Application	4000 euro
Application submitted by small companies (as defined by Ministerial Decree of 18 April 2005) that are not drug producers/distributors	1000 euro
Application submitted by innovative startups (as defined by Decree of Law no. 179 of 2012) or micro-companies (as defined by Ministerial Decree of 18 April 2005)	free

- The application fee covers dissemination of a press release and publication on the Prix Galien Italy website www.prixgalien.it and on the portal of the Italian medical communication journal www.mediciloggi.it of an abstract presenting the drug, based on the text provided by the applicant company.



PRIX GALIEN

Italia

- Participating companies can activate a Communication Package that comprises the issue of press releases and social media posts and the development of video interviews with company executives, research scientists and clinicians involved in the product development. Please note that these activities are supplementary to those covered by the application fee and that specific information material detailing the costs and the activities included is available on request.

Required documentation for applications and application deadline

- Companies intending to apply should prepare the required documentation following the outline provided for each category and send it to Springer Healthcare Srl's address, as indicated in the specific annex for each award category:

Award category	Indications on documentation required for applications and application deadline
Categories 1-6 (Drugs)	See ANNEX-(A)
Category 7 (Devices in Physical and Rehabilitation Medicine)	See ANNEX-(B)
Category 8 (<i>Digital Medicine & Therapeutics</i>)	See ANNEX-(C)

- Each entry should be submitted together with a slide set (in PowerPoint format), the content of which may be presented during the awards ceremony. Further details on the length of the slide set will be provided by Springer once the overall application process has been completed.

Application assessment process, winner awards

- An independent Scientific Committee of experts, nominated by Springer Healthcare (presented in detail on www.prixgalien.it), will assess the applications for the different award categories, according to the criteria detailed in the relevant **ANNEX-(A),(B),(C)**. Winners will be selected by the Scientific Committee in the presence of representatives from Springer Italia who will sit in on the meetings without voting rights.



PRIX GALIEN

Italia

- No joint awards are permitted. For each category, a single winner will be identified and, where appropriate, a special mention.

Announcement of winners and awards ceremony

- The winners will be announced and the awards presented before the end of 2021. Information about the venue, date and manner in which the awards ceremony will take place will be posted on the website www.prixgalien.it and directly communicated to all participants.

Disclaimer

- The Organizer of Prix Galien Awards Italy reserves the right to modify the present rules at any time. Any changes to the rules will not affect a call for applications that has already been published or the awarding of prizes in its context.

Information and contacts

- Organizer of the Award: Springer Healthcare Italia, via Pier Candido Decembrio 28a, 20137 Milan.
- The documentation must be sent by via e-mail (as file attachments in *.doc *.docx *.pdf format) to: shcmilan@springer.com with courtesy copy to eleonora.zanaboni@springer.com and indicating in the subject line: "Priz Galien Italy 2021 application".