PRIX GALIEN
Italia

CALL 2018

Galien Award Italy For Drug Innovation And Medical Devices Call 2018

Introduction to the Award

Springer Healthcare Italia is pleased to announce the call of the Galien Award Italy for Drug Innovation and Medical Devices 2018[1]. The 2018 edition of Galien Award Italy for Drug Innovation includes the following categories for which applications may be submitted:

1. **Chemical synthesis drug award**
   This award addresses non-biological products whose active ingredients are obtained by chemical synthesis.

2. **Biological drug award**
   According to the definition of a biological drug from AIFA (the Italian Drug Agency)[2], the award is addressed to drugs whose active ingredient consists in a molecule produced by, or extracted from, a biological system. Biotechnological medicines (produced by recombinant DNA techniques), hormones, enzymes, blood products, immunoglobulins and monoclonal antibodies are included in the category of biological drugs.
   Immunological drugs, such as toxins, serums and allergens are excluded and can apply under category n. 3 (Immunologic drug award).

3. **Immunologic drug Award**
   According to the definition of "immunological drug" indicated by AIFA[3], this award is referred to drugs consisting of vaccines, toxins or serums and allergens. Vaccines, toxins and serums shall cover, in particular, the agents used to induce an active or passive immunity and agents used to diagnose the state of immunity.
   IMPORTANT: in case the minimum number of two candidate drugs will not be reached for this category, the application will be merged into the main reference category (chemical or synthesis).

4. **Orphan drug award**
   This award addresses drugs listed in the AIFA document included in the European Union register of orphan medicines[4] and any medication with a marketing authorization in Italy, only for therapeutic indications aimed at treating rare diseases or conditions included in the Orphanet inventory of rare diseases (http://www.orpha.net/), even if not included in the European Union register of orphan medicines.
   IMPORTANT: in case the minimum number of two candidate drugs will not be reached for this category, the application will be merged into the main reference category (chemical or synthesis).

1 In this document the term ***drugs*** refers to molecules, active principles, treatments or medical devices

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

3 AIFA FAQs http://www.agenziafarmaco.gov.it/it/content/medicinali-biologici-faq

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

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5. **Real-World Evidence (RWE) award**
   This award addresses drugs whose efficacy and safety, in the context of real world clinical practice, have been confirmed after post-approval studies (in Italy or worldwide).
   Drugs that have won or have participated in previous Prix Galien Awards (Italians or international) can apply for the RWE category, provided that they have been approved by EMA before and including 31.12.2009.

6. **Advanced Therapy Medicinal Products (ATMP) award**
   According to the definition provided by the EMA[5], Advanced therapy medicinal products (ATMP) include: (a) medicines for gene therapy, (b) medicines for somatic cell therapy, (c) tissue engineering products, (d) a combination of one of the ATMP mentioned above combined with a medical device (combined products).
   Applications for this award are open only for drugs classified as ATMP by the EMA Committee for Advanced Therapies (CAT) and for which EMA has already published the related "Summaries of scientific recommendations on classification of advanced therapy medicinal products"[6].
   IMPORTANT: in case the minimum number of two candidate drugs will not be reached, the application will be merged into the main reference category (chemical or synthesis).

7. **Medical Device/Technologies (in Physical and Rehabilitative Medicine)**
   This award addresses aids, prostheses and orthoses as well as equipment and applications used in any phase of the patient's rehabilitation process.
   More details regarding this category, as well as the documentation required and the evaluation criteria, can be received upon request.
   IMPORTANT: medical devices that do not fall into this category and that contain a medicinal substance with a role more than ancillary may be merged into the other categories (1-6).

Conditions for participating

- The call is open to national and multinational pharmaceutical companies and to companies producing/distributing *medical devices* headquartered in Italy or abroad, according to the rules and schedules described in this call.
- Pharmaceutical companies can submit a maximum of two applications for each category, for a maximum total of SIX applications.
- The company may indicate a preference category while applying
- The applications will be assessed by an independent Scientific Committee, performing its duties without any compensation. The Scientific Committee will have the final saying for the formal allocation of each application to a specific category.
- The same drug cannot apply for more than one category.
- Only Drugs approved by the European Medicines Agency (EMA) from 1 January 2014 can apply.
  Please note that the Real World Evidence category is addressed to drugs approved by EMA before and including 31.12.2009.

5 EMA Regulation (EC) No 1394/2007

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

- Even drugs that are not on the Italian market are eligible, as long as they have been approved by EMA.
- Drugs that took part or won previous international Prix Galien Awards can apply for the Italian award.
- Drugs having previously won other Prix Galien international editions can also apply. The international awards do not entail the automatic awarding by Galien Award Italy.
- Every application should be submitted together with a slide set (Powerpoint format), the content of which may be presented during the award assignment ceremony. Further details on the length of the slide set will be provided by Springer once the overall application process is completed.
- Drugs that have already taken part in previous Italian editions (except the RWE category applications) can't submit their application again.

Application fee and Communication Package

- For each application, Springer Healthcare will charge 4000 € (exclusive of VAT).
- The application fee includes: transmission of two press releases and the publication of the drug application abstract on the Prix Galien Italian website www.prixgalien.it and on the Italian language medical communication journal www.medicioggi.it.
- The Communication Package is for winners and special mentions only
- It includes press releases, social media activities and video interviews. Please note that this option is not included in the application fee. More details can be provided upon request.

Deadlines and call regulations

- **June 15th, 2018** - h 23:59 (CEST Central European Summer Time) is the new deadline for submitting to Springer the application, which must be completed with the following documents (the documentation will not be returned): (a) Cover letter, (b) Application dossier, (c) Essential documentation required to prepare the communication activities with the press, before and after the awarding event.

Please see ANNEX 1 (SECTION 1) for full indications on the documentation required for the drugs' application.Award assignment process and evaluation criteria

- Springer Healthcare Italia appointed an independent Committee of experts (see list at www.prixgalien.it).
- The winners will be selected by the Committee. Springer Italia representatives will attend the Committee meetings as non-voting members.
- Please see ANNEX A (SECTION 2) for the drugs' evaluation criteria
- There will be a winner and a special mention for each category.
- Winners will be announced and prize will be awarded not before June 2018; venue and date of the ceremony will be posted on the website www.prixgalien.it and notified to all participants.

Disclaimer

The Organizer of Galien Award Italy reserves the right to modify the present rules at any moment. Any changes will not affect a call already published or an already awarded prize.

Information and contacts

Organizer of the Award: Springer Healthcare Italia, via Decembrio 28a, 20137 Milano.
The documentation must be sent by e-mail, as attached files in *.doc, *.docx or *.pdf formats, to shcmilan@springer.com, and to eleonora.zanaboni@springer.com in cc. The subject of the e-mail must be: “Galien Award 2018 application”.

ANNEX A

SECTION 1 – Required documentation for the drugs' application (award category 1-6)

1. **Cover Letter**

The length of the text must be no more than 3500 characters, spaces included, and shall contain the following information:

- Description of the rationale supporting the innovative characteristics of the drug and an overview on the main features of the product
- Date of marketing authorization released by EMA or by AIFA
- Description of drug formulation
- It is compulsory to specify the drug award category for which the company will be applying. The Galien Award Indepedent Committee will eventually be validating the official category
- Name, surname, and contacts of the application representative (beside email address, please indicate at least one phone number)
- Consent to publish the pharmaceutical company logo on the Galien Award Italy website (if the consent is given, please attach the logo image to be used to the application dossier)
- Name of the molecule subject of the application
- Place, date and Signature

2. **Application dossier**

2.1 Source, Discovery And Characteristics of the Product, Development Plan and Research Team

- Source of the active agent (chemical synthesis, natural origin, biological/biotechnological product) and/ or of the innovative administration and delivery routes of the candidate formulation.
- Discovery of the active ingredient and/or the innovative administration and delivery routes of the candidate formulation (research lab, etc.)
- Physico-chemical characteristics of the active ingredient or of the formulation, which can be possibly deemed as innovative.
- Development plan. Brief outline of the development plan leading the process from pre-clinical research to clinical research and to the marketing authorization application to EMA or to AIFA.
- Research Team. Overview of the research group(s) responsible for the discovery of the active ingredient or of the formulation. The possible involvement and activity of Italian research teams in the project and the possible contribution of Italian scientists should be mentioned.

2.2 Pharmacological Characteristics

- Pharmacokinetics and Pharmacodynamics. The innovative features of the candidate drug are highlighted as the progenitor of a new class of drugs or as a drug with characteristics that are significantly different or innovative, as compared with other active ingredients of the same pharmacologic and/or therapeutic classes or with other formulations.

2.3 Clinical Development Plan: Methods and Research Groups Involved

- Detailed description of the clinical development plan (with particular emphasis on phase II and phase III studies)
- Detailed analysis of possible innovative research methodologies, both clinical and related to data collection, exploited by the studies that are part of the clinical development plan.
- List of the publications (especially original articles, but also reviews and meta-analyses) accepted by indexed journals and related to the results obtained by studies that are part of the clinical development plan or by independent studies.
- List of the Italian research groups and information about their involvement in the studies that are part of the pre-clinical or clinical development plan and in the independent studies.

2.4 Therapeutic Efficacy

- Therapeutic indications. Provide the therapeutic indications reported in the summary of product characteristics, with recommended dose(s) and possible recommendations for use.
- Clinical evidence of efficacy. Report the results of the key clinical studies showing the efficacy of the active ingredient or of the formulation.

2.5 Safety and Well-Being

- Drug safety. Report safety or possible warnings related to the active ingredient or to the formulation, in term of acute or chronic toxicity, genotoxicity, teratogenicity, or carcinogenicity. List and specify all possible contraindications.
- Adverse events. Describe the safety profile of the clinical studies (post-marketing studies included) and, when applicable, indicate the adverse events presumably related to the pharmacodynamics of the active ingredients and the unrelated events as well.
- Quality of life. Provide a brief description of the impact of the active ingredient or of the formulation, as well as of their administration routes, on the state of physical and perceived psycho-physical well-being of the treated patients. Specify also the impact on the quality of life of the treated patients and of the care-giver, when applicable.

3. **Documentation required for communication activities with the press**

- Name, surname and contacts of the application representative for the communication activities with the press (beside email, please indicate at least one phone number)
- Presentation (*doc or *docx formats, 500 characters spaces included) of the drug subject of the application, to be communicated to the media and to the website www.medicioggi.it. The text should specify whether the drug is marketed in Italy or not.
- Illustrative image/picture, copyright-free, to be communicated to the media (e.g. cartoon/ picture on mechanism of action, molecule, disease, etc.)

SECTION 2. Drugs' evaluation criteria (award category 1-6)

Award for Chemical Synthesis Drug, Biological Drug, Immunologic Drug, Orphan Drug and "ATMP"

- Compliance and completeness of the dossier
- Novelty / innovation
- Medical and scientific impact
- Social impact
- Safety
- Literature cited

Evaluation criteria: Award for REAL WORLD EVIDENCE (RWE)

- Compliance and completeness of the dossier.
- Novelty and relevance of scientific data of post-approval studies of the drug (RWE).
- Impact of post-approval studies on the improvement of clinical practice and possibly to the disease understanding.
- Social impact (long-term perspective).
- Safety (long-term perspective).
- Literature cited