PRIX GALIEN
Italia

ANNEX-(A)

Awards for categories:

1. **“chemical synthesis drugs”**
2. **“biological drugs”**
3. **“immunologic drugs”**
4. **“orphan drugs”**
5. **“ATMP”**
6. **“real-world evidence”**

The present annex applies only to the award categories addressing medicinal products, and it supplements the information provided in the main document (Prix Galien Italy Call for Applications 2021, published on www.prixgalien.it), which should be consulted for more general indications.

Entry requirements – eligible products

- Award categories no. 1, 2, 3, 4, 5 address exclusively drugs, or their routes of administration or delivery, that (A) have been approved by EMA or AIFA **after 31.12.2016** and (B) have never won or been entered for a previous edition of the Prix Galien Italy Awards.
- Award category no. 6 (“Real World Evidence”) addresses drugs, or their routes of administration or delivery, approved by EMA or AIFA **before 01.01.2013**; it is also (but not exclusively) open to drugs that have won or have been entered for a previous edition of the Prix Galien Italy Awards.
- Award categories no. 1, 2, 3, 4, 5 are also open to drugs not yet marketed in Italy (provided they have been approved by EMA or AIFA by the dates indicated above)
- Award categories no. 1, 2, 3, 4, 5, 6 are also open to drugs that have won o have participated in previous editions of Prix Galien held in countries other than Italy,

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Required documentation and deadlines for application

- Companies wishing to enter the competition should send Springer the following documents: (1) Cover letter, (2) Application dossier, (3) Materials for communication with the press. These documents should be prepared following the outlines provided in the present annex
- The documentation must be sent **by 23:59 hours (CEST, Central European Summer Time) of 15 April 2021** via e-mail (as *doc *docx *pdf file attachments) to the following address: shcmilan@springer.com with a courtesy copy to eleonora.zanaboni@springer.com and indicating in the subject line: "Prix Galien Italy 2021 Application".

Outlines for preparing the entry documentation

1. COVER LETTER (up to 3500 characters including spaces)
• Name of the molecule being entered for the competition and its therapeutic indications • Description of the rationale supporting the innovativeness of the drug and an overview of the drug's main properties • Date of the marketing authorization issued by EMA or AIFA • Description of the drug formulation • Statement of the award category for which the company is applying. (The category will subsequently be officially validated by the Scientific Committee). • Name, surname and contact details of the person in charge of the application (e-mail address and at least one phone number) • Consent to publish the pharmaceutical company's logo on the Prix Galien Italy website (if consent is provided, please attach to the application dossier the logo image to be used) • Place, date and signature

2. APPLICATION DOSSIER

2.1. Therapeutic indications.

- Provide the therapeutic indications reported in the summary of product characteristics, along with the recommended dose(s) and any recommendations for use

2.2. *Source, Discovery, Characteristics of the Product, Development Plan and Research Team*

- "Source" of the active ingredient (chemical synthesis, natural origin, biological/ biotechnological product) and/or of the innovative route of administration and delivery of the drug formulation being entered.
- Discovery of the active ingredient and/or of the innovative route of administration and delivery of the drug formulation being entered (research laboratory, etc.).
- Any innovative physical-chemical characteristics of the active ingredient or formulation.
- Development plan. Brief outline of the development plan leading from pre-clinical to clinical research and to the application for EMA or AIFA marketing authorization.
- Research Team. Overview of the research team(s) responsible for the discovery of the active ingredient or formulation. Mention should be made of the possible involvement in the project of Italian teams or Italian researchers

2.3. *Pharmacological Characteristics*

- Pharmacokinetics and pharmacodynamics. This section highlights the innovative features of the drug as a progenitor of a new class of drugs or as a drug having characteristics that are significantly different or innovative, as compared with either other active ingredients belonging to the same pharmacological and/or therapeutic classes or with other formulations.

2.4. *Clinical Development Plan: Methods and Research Groups Involved*

- Detailed description of the clinical development plan (with special emphasis on phase II and phase III studies).
- Detailed analysis of possible innovative research methodologies implemented in the clinical studies or in data collection and forming part of the clinical development plan. List of publications (especially original research papers, but also reviews or meta-analyses) published in indexed peer-reviewed journals and addressing the results obtained by studies conducted within the clinical development plan or by independent studies.
- List of possible Italian research groups involved in the studies conducted within the pre-clinical or clinical development plan or in independent studies, and description of their involvement.

2.5. Therapeutic Efficacy

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

2.6. Safety and Well-Being

- Report drug tolerability and possible warnings related to the active ingredient or formulation in terms of acute toxicity, chronic toxicity, genotoxicity, teratogenicity, or carcinogenicity. List and specify all the contraindications.
- Adverse events. Describe the safety profile emerging from the clinical studies (including post-marketing surveillance studies) and, where applicable, indicate the adverse events presumably related to the pharmacodynamics of the active ingredient as well as those unrelated to it.
- Quality of life. Briefly describe the impact of the active ingredient or formulation and of their administration routes on the treated patients' psychological-physical well-being, perceived well-being, quality of life and, where appropriate, its impact in terms of improving the quality of life of the caregivers

3. DOCUMENTATION REQUIRED FOR COMMUNICATION WITH THE PRESS

- Name, surname and contact details of the person in charge of communication with the press (e-mail address, at least one phone number)
- Text presenting the drug/device being entered for the award (length: 800 characters including spaces) to be used in communications with the press and published on the website www.medicioggi.it. The text should contain the following information:
    1. Name of the drug, nature of the active ingredient /its pharmacological class
    2. Therapeutic indications
    3. Notes on its mechanisms of action
    4. State of approval in Italy
- Copyright-free illustration to accompany the presentation text, to be freely shared with the press (an artistic and/or schematic rendering of the mechanism of action or molecule is suggested)

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Assessment criteria adopted by the jury

“Chemical synthesis drug”, “Biological drug”, “Immunological drug”, “Orphan drug”, “ATMP”
• Compliance and completeness of the dossier • Novelty/innovation • Medical and scientific impact • Social impact • Safety • Literature references
Real World Evidence (RWE)
• Compliance and completeness of the dossier • Novelty and relevance of the scientific data emerging from the post-approval studies of the drug (RWE) • Impact of post-approval studies in terms of improving clinical practice and possibly advancing the understanding of the disease • Social impact (long-term perspective) • Safety (long-term perspective) • Literature references