



## PRIX GALIEN *Italia*

### ANNEX-(B)

## Award “Medical Devices/Technologies in Physical and Rehabilitation Medicine” (award category no.7)

The present annex applies exclusively to award category no. 7 **Medical Devices/Technologies** established in collaboration with the *Società Italiana di Medicina Fisica e Riabilitativa* (SIMFER) and it supplements the information provided in the main document (Prix Galien Italy Call for Applications 2021, published on [www.prixgalien.it](http://www.prixgalien.it)), which should be consulted for more general indications.

### Definition of Medical Devices/Technologies in Physical and Rehabilitation Medicine

This award recognizes mobility aids, prostheses and orthoses (as described by the Italian Ministry of Health) as well as other equipment/devices that can be used in any phase of a patients' rehabilitation, as detailed below:

1	<b>MOBILITY AIDS</b>	Instruments, tools or equipment allowing a disabled person to perform actions that he or she would be unable to perform under normal conditions (e.g., wheelchair)
2	<b>PROSTHESIS</b>	A device replacing a missing body part.
3	<b>ORTHOSIS</b>	Equipment improving the function of an impaired body part (e.g., orthopedic shoes).
4	<b>Devices and/or equipment for patient assessment</b>	Example: wearable devices for gait analysis. (Provided they contribute to defining the patient's Individual Rehabilitation Plan, IRP)
5	<b>Devices and/or equipment supporting the rehabilitation treatment</b>	Example: equipment for respiratory rehabilitation, electromyographic feedback, equipment for robotic rehabilitation, virtual reality systems used for rehabilitation purposes



## PRIX GALIEN

Italia

5	<b>Equipment for administering physical therapies</b>	Example: machines for shockwave therapy, tecar therapy, laser therapy, ultrasound therapy.
6	<b>Equipment for controlling symptoms</b>	Where a symptom (e.g., pain, fatigue) negatively impacts the patient's adherence to the rehabilitation treatment.
7	<b>Applications and software specifically designed for rehabilitation purposes</b>	Example: applications for cognitive rehabilitation, applications for goniometric measurement of range of motion.

### Entry requirements – eligible products

- Medical devices not yet marketed in Italy may apply provided that they have received European Conformity CE marking. For a medical device to be sold in the European Union, it must have received or must bear a CE mark. CE marking indicates the product's conformity with EU regulatory requirements and allows marketing of the product in 32 European countries.
- Medical devices that are ineligible for this award category and that incorporate a medical substance having a primary, not merely ancillary, action relative to the device itself, can be entered as a medicinal product under the relevant drug award category.

### Selection of the winner of the “medical devices” award

- Assessment of products nominated for the award Medical Devices/Technologies in Physical and Rehabilitation Medicine (award category no. 7) will be carried out by an *ad hoc* Committee consisting of members identified in collaboration with the *Società Italiana di Medicina Fisica e Riabilitativa* (SIMFER) (see [www.prixgalien.it](http://www.prixgalien.it)). The assessment criteria are listed below. The winners will be selected by the Committee.
- Winning entries will be announced and the awards presented during the SIMFER National Conference. The precise venue and date of the awards ceremony will be posted on the website [www.prixgalien.it](http://www.prixgalien.it) and directly communicated to all participants



## PRIX GALIEN *Italia*

### 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 instructions provided in the present annex
- The documentation must be sent **by 23:59 hours (CEST, Central European Summer Time) of 30 June 2021** via e-mail (as \*.doc \*.docx \*.pdf file attachments) to the following address: [shcmilan@springer.com](mailto:shcmilan@springer.com) with a courtesy copy to [leonora.zanaboni@springer.com](mailto:leonora.zanaboni@springer.com) and indicating in the subject line: “Prix Galien Italy 2021 Application”.

### Outline for preparing the entry documentation

<b>1. COVER LETTER</b>
<ul style="list-style-type: none"><li>• Name of the device being entered for the competition and indications for use</li><li>• Short description of the innovative features justifying the entry.</li><li>• Composition of the device research and development group and, in the case of international projects, the possible contribution of the Italian team.</li><li>• Details of the innovative features of the device as compared with pre-existing devices (e.g., impact on rehabilitation, technology and/or care management).</li><li>• Date of introduction in the market and class of the medical device.</li><li>• Date of first use (in Italy and/or Europe).</li><li>• Name, surname and contact details of the person in charge of the application (e-mail address and at least one phone number).</li><li>• Consent to publish the 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).</li><li>• Place, date and signature.</li></ul>
<b>2. APPLICATION DOSSIER</b>
<b>2.1. Name of the device and indications for use</b>
<b>2.2. <i>Technical overview</i></b> <ul style="list-style-type: none"><li>• Device development plan.</li><li>• Area of application.</li><li>• Method for development.</li></ul>



## PRIX GALIEN

*Italia*

- Examples of detailed technical performance (evidence from CE dossier).
- Level of risk.
- Studies published in indexed academic journals and sector journals.

### **Health benefits**

- Further specifications regarding the innovativeness of the device based on its nature, intended purpose, etc.
- Clinical efficacy for those benefiting from the device (assessment, prevention, treatment, etc.).
- Impact on care organization also in relation to the rehabilitation setting in which the device will be used.
- Possible integration with an e-health program.
- Possible specification of sustainability of costs for society and possible eligibility for reimbursement.

### **3. MATERIALS FOR COMMUNICATION WITH THE PRESS**

- Name, surname and contact details of the person in charge of communications with the press (e-mail address, at least one phone number).
- Text presenting the drug/device being entered for the competition (length: 800 characters including spaces) to be used in communications with the press and published on the website [www.mediciloggi.it](http://www.mediciloggi.it). The text should contain the following information:
  1. Name of the device,
  2. Therapeutic indications
  3. Notes on the mechanism of action
  4. Approval/marketing status in Italy
  5. Copyright-free illustration to accompany the presentation text, to be freely shared with the press.

### **Assessment criteria adopted by the jury (award category no.7)**

#### **Devices/Technologies in Physical and Rehabilitation Medicine**

- Compliance and completeness of the dossier.
- Innovativeness of the device based on its nature, intended purpose, etc.
- Clinical efficacy for those benefiting from the device (assessment, prevention, treatment, etc.).
- Impact on care organization also in relation to the rehabilitation setting in which the device will be used.



## PRIX GALIEN

*Italia*

- Possible integration with an e-health program.
- Possible specification of sustainability of costs for society and possible eligibility for reimbursement.
- Organizational, ethical, social and legal aspects related to the use of medical devices (HTA) may also be considered. The jury will also take into account the impact of the devices of the different classes of users, and transparency in collecting the information on which to base their judgements.