ANNEX TO THE AGREEMENT

Title of the training
Regulatory Affairs and Intellectual Property Protection in the Pharmaceutical Industry

Public
This training program is addressed to regulatory officers, patent attorneys and in-house lawyers, as well as public servants working in public health organizations, who must navigate through the several legal domains of relevance in pharmaceutical research, development and innovation.

Prerequisites
English language is mandatory.

Entrance requirements
This is a non-degree training course.
Admission upon validation of the application file.

Objectives
Analysing and debating around topics like the interface between patent law, supplementary protection certificates and test data protection.

Program

Content:
The interface between regulatory and IP exclusivities
This module focuses on the protection given to test data submitted for the grating of pharmaceutical marketing authorization. The pharmaceutical dossier, the types of information protected, key concepts, the duration of the protection and the acts against which the information is protected will be discussed. Likewise, EMA policies relating disclosure of test data, the specificities for biological products, and litigation strategies impacting test data protection will also be the object of analysis,

Supplementary Protection Certificates
This module explores the legislative background and litigation strategies concerning Supplementary Protection Certificates in the European Union. EC Regulation 469/2009 will allow to discuss time lines, where to apply, substantive requirements, and scope of protection during term of protection awarded by the SPC. Controversial areas such as which is the product protected by the basic patent, paediatric extensions and the relationship with patent claims drafting will be explored in this session.

Orphan drugs exclusivity
The final day is devoted to orphan drugs exclusivity, its nature, effects and interaction with other exclusivities. Lecturers will address aspects such as how to obtain this exclusivity, situations of mixed orphan/non-orphan indications for the same active pharmaceutical ingredient, scope and breaking protection of orphan drugs exclusivity, how to enforce orphan drugs exclusivity.

Duration (for information purposes):
The next edition of this seminar will take place on the 12th, 13th and 14th of January 2023 for a duration of 19 hours (without counting breaks).

Tutors:
Teachings will be provided by lecturers, researchers and university professors specialised in the relevant fields.

Teaching methods
Distance learning/lecturing:
- Visual presentations;
- Class discussion;
- Individual follow-up/advice for participants
- Q&A between the pedagogical coordinators and participants.

Technical and pedagogical frame

- Access to the online session will take place via the connection to an online platform. The connection information will be made available to the participant in advance.
- The participant must have appropriate technical equipment to participate in the online session, in particular a laptop or similar device and high speed WIFI.

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Training material

Materials will be made available to the participant by the CEIPI.

Validation

An attestation of completion shall be delivered upon full attendance of the participant.

Location

On site in Strasbourg as well as online.

Fee

1.600€* for any Early Bird registration (before the 15th of November 2022)
1.800€* fee after the Early Bird period
500€* students fee
* subject to validation by the university authorities

Contact for information, enrolment and technical support*

Phone: +33 (0)3 68 85 80 27 email:
pharma-seminar@ceipi.edu

Technical support regarding the online system can be provided by the CEIPI team.
Educational support is provided by the speakers and teaching lecturers.
Do not hesitate to contact us for technical support or in case of questions related to the connection to the online training. However, the CEIPI does not assume any legal responsibility in the event of a malfunction of the platform used during the online sessions or a lack of speed/network quality among participants and tutors.