**Title of the training**

Regulatory affairs and intellectual property protection in the pharmaceutical industry

**Public concerned**

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**

This is a non-degree course. Although there are no pre-requisites to register for this course, a good command of English is recommended.

**Access conditions / Admission procedure**

Candidates must complete an online pre-registration form.

**Teaching objectives**

The development, authorisation and commercialisation of medicinal products in the pharmaceutical sector are amongst the most regulated and complex areas of European Union (EU) law. The legal framework governing the regulation of medicinal products can affect a broad range of private rights, intellectual property law, competition law and consumer law. In particular, patents, supplementary protection certificates (SPCs) and regulatory rewards, notably regulatory data protection, constitute a sophisticated legal framework of overlapping exclusivities that influences both innovation and competition. This complexity creates challenges for experts tasked with understanding a rapidly evolving legal and regulatory landscape.

The CEIPI Advanced Training Program on Regulatory Affairs and Intellectual Property Protection in the Pharmaceutical Industry, now in its fifth edition, is a unique educational proposal targeting regulatory and intellectual property professionals in the pharmaceutical sector. The three days of intensive training revolve around the intersections of patent and regulatory law. In this respect, leading legal professionals and experts in the field will teach issues such as SPCs and regulatory data protection, amongst other relevant topics.

This interactive course aims to provide an up-to-date overview of the European pharmaceutical regulatory environment, procedures and obligations as well as on the patent and SPC related landscape. It will create a space for discussion on how to interpret and apply legislation in this sector in light of new developments. These developments include an overview of the current state of the European Commission's proposals for the revision of the EU pharmaceutical legislation and of the SPC legislation.

**Content**

DAY 1 : The interface between regulatory and IP exclusivities: Regulatory Data Protection and the role of Marketing Authorisations

This module focuses on the protection that may be accorded to data and information submitted for the granting of certain types of marketing authorisations for medicinal products for human use. The pharmaceutical dossier, the types of information protected, key concepts, the duration of the protection and acts against which information is protected will be discussed. The approach of the European Medicines Agency (EMA) towards reactive and proactive transparency, including, the manner in which it handles data and information pertaining to medicinal products will be discussed and analysed.

Topics include:

• The EU centralised procedure for obtaining marketing authorisations (MAs) for medicinal products for human use
• The framework of regulatory data protection
• The legislation, internal policies and case law that inform EMA's approach towards transparency.
• How to enforce and challenge regulatory data protection
• Interface between regulatory data protection and competition law

DAY 2 : Supplementary Protection Certificates (SPCs) and Practical Cases

This module explores the legislative background and litigation strategies concerning Supplementary Protection Certificates (SPCs) in the European Union. Participants will become familiarized with timelines, where to apply for SPCs, substantive requirements, and the scope of protection during the term of protection awarded by an SPC. Controversial areas, such as which is the product protected by the basic patent and the relationship between SPCs and patent claims drafting, will also be explored in this session.

Topics include:
• The SPC legal framework
• The interface between competition law and SPCs
• Patent claims and SPCs
• Strategies to obtain and challenge SPC protection
• Manufacture for export waiver

DAY 3 : Orphan Market Exclusivity and Paediatric Extensions

The final day is devoted to orphan market exclusivity and paediatric exclusivity extensions. Orphan market exclusivity in terms of its nature, effects, and interaction with other exclusivities will be discussed, along with conditions for applying for paediatric extensions. Lecturers will address aspects such as how to obtain orphan market exclusivity, situations of mixed orphan/non-orphan indications for the same active pharmaceutical ingredient, the scope of orphan drugs exclusivity, and enforcement (strategies for breaking protection).

Topics include:
• Award of orphan market exclusivity
• Situations of mixed orphan/non-orphan indications for the same active substance
• How to enforce and challenge orphan market exclusivity
• Applying for and obtaining paediatric extension to an SPC

**Duration and Timetable (indicative)**

The advanced training program has a total duration of 18 hours, distributed in three days:

- Thursday October 9, 9:00-12:45 and 14:00-18:00
- Friday October 10, 9:00-12:45 and 14:00-18:00
- Saturday October 11, 9:00-13:00

(Subject to modification)

**List of Lecturers**

Peter Thomsen, President of the EPI
Alexander Meier, VP, Head, Legal Regulatory Strategy and Global Regulatory Policy at Moderna
Pierick Rousseau, Former Intellectual Property Director at Pierre Fabre
Thomas Lemieux, Associate Professor of Law, CEIPI, University of Strasbourg

Centre d'études internationales de la **propriété intellectuelle** | CEIPI
*Center for International* ***Intellectual Property*** *Studies*
*Institut für internationale Studien des* ***geistigen Eigentums***
Université de Strasbourg

**Academic direction**

Peter Thomsen, President of the EPI
Alexander Meier, VP, Head, Legal Regulatory Strategy and Global Regulatory Policy at Moderna
Pierick Rousseau, Former Intellectual Property Director at Pierre Fabre
Thomas Lemieux, Associate Professor of Law, CEIPI, University of Strasbourg

**Teaching methods and language of the training**

Presentations, discussions and exchange of experiences, case studies.
The training is in English.

**Nature and certification of training**

This training constitutes an adaptation and skills development action. A certificate of completion is issued at the end of the training.
A satisfaction survey will be sent to participants at the end of the training.

**Course materials**

The speakers' presentations and other documents will be available via a download link.

**Location and Delivery Mode**

The on-site courses will take place in Strasbourg (Batiment Le Cardo, 7 rue de l'Écarlate 67000, Strasbourg).
Distance learning will be held via the Zoom videoconferencing platform.

**Pedagogical and Technical Support**

- Educational support for participants is provided by each instructor or instructor for the portion that applies to them.
- The educational tools and resources related to the training are made available to each participant via a download link. Access to the tools and resources is available throughout the training.
- Online sessions are organized via a remote conferencing platform, accessed via a login link sent by email to each participant.
- Participants must have suitable technical equipment, including a computer, a high-speed internet connection, and a valid email address.
- The CEIPI provides technical assistance to users to identify any malfunctions and provide an acceptable solution as quickly as possible. However, the CEIPI assumes no legal liability in the event of malfunctions of the services used or poor bandwidth/network quality for participants or instructors.
- CEIPI Technical Support Contact:
pharma-seminar@ceipi.edu

**Fees**

Professionals:
1 685 € TTC (early bird) before July 20 2025
1 885 € TTC (full price) for all registrations after July 20 2025
Students:
525 € TTC * (initial training)

*subject to validation by the university authorities

**Information and registration**

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