Dear colleagues,

It is a great honour and pleasure for us to be hosting the first pharmaceutical law conference, which we aspire to establish as a regular event.

Over the 50 years that have passed since the historic first Community Directive on medicinal products (65/65/EEC), developments have been thick and fast; as a result, the area of pharmaceuticals now finds itself at the intersection of several legal fields, while many consider it as a separate field of law.

The continuous scientific progress, supported by technology, has built a strong **dialectic relationship between the medical and the legal communities**. It is therefore necessary to constantly adjust legal rules in line with scientific developments, which renders any attempt at consolidation and codification practically impossible. **Scattered provisions** here and there regulate evolving matters and relationships and are expected to address a wide variety of issues, ranging from clinical research to manufacturing and delivery of medicinal products to patients.

Furthermore, the economic situation of our country in recent years has led to a haphazard legislative output, which has exacerbated the problems of **legislative inflation**, **fragmentation** or **attachment of provisions to legislative texts with little or no connection to the main subject matter**.

It is quite common for people involved in law practicing and/or enforcement to be called to determine whether a legislative provision has been abolished or not. This **legal uncertainty** is in fact stressed in the OECD's recent "Toolkit".

Provisions adopted under Greece's Economic Adjustment Programmes (MoUs) often j**eopardise the very essence of individual and social rights**, such as the right to health or the freedom to conduct a business. Besides, with the long delays in the judicial process, legal practitioners face serious deadlocks. Against this background, interpretation issues continually arise, along with the need to reassess the value underpinnings of fundamental legal principles.

On the other hand, pharmaceutical law increasingly acquires a **European dimension**: we can see a sharp shift from the national to the European level and a steady transition from the coordination of laws to harmonisation.

In December 2014, the United Nations held the **Third Forum on Business and Human Rights**, which expressed the strong belief that businesses can only flourish in societies that respect, protect and fulfil human rights and highlighted as overarching rights those relating to health, safety, work, freedom of assembly and association, labour relations and property.

All the above show that **the legal community**, all the more now, **needs to keep abreast of developments** and cannot stay indifferent to the unfolding legal phenomena.

In addition, they also clearly indicate the role of SFEE as a **key institutional** counterparty of the State in the legislative process, representing the democratic principle that provides the Government with legitimacy. In the era of globalisation, SFEE as an association plays an important and productive role in the legislative process. With its team of experts, it monitors developments, listens to the needs, identifies problems, explores solutions, promotes democratic processes and consensus, recommends to the Government and intervenes as partner and potential social partner.

In its framework of action and extroversion, SFEE has taken the initiative, for the first time, to hold an event bringing together the Country's legal scientific community for an exchange of knowledge and views with the overriding objective the of promoting health.

Distinguished speakers from Greece and abroad, University Professors of Law and Medicine, researchers and lawyers with years of study and work in this field will share with us their knowledge and experience, as well as the latest developments in their areas of expertise.

Our conference will cover legal issues arising from the regulatory framework for medicinal products, such as the major challenges of pricing, promotion of prescription medicines, public procurement with a focus on hospitals. Other topics include the impact of the MoUs on collective labour relations, which SFEE has historically served, and regulatory aspects with a European dimension, as seen from the perspective of the European Medicines Agency. We will shed light on the limits of free competition in a regulated market and on issues relating to unfair competition.

We will focus on the current legal challenges, such as the limits of transparency and ethics in view of data protection, transatlantic data flows, and the civil liability of companies from clinical studies to pharmacovigilance. Finally, we will cover current developments in the areas of biosimilars, falsified medicines, medicrime and international negotiation practices.

We will be very happy to welcome you to this event and look forward to a fruitful discussion and exchange of views.

Yours sincerely,