8/12/2016

Dear colleagues,

Good morning and welcome to the first conference in our field.

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

Many of you might ask what motivated us to undertake this initiative. I am sure that some background information would convince you of the necessity of the project.

2015 marked the 50th anniversary of pharmaceutical law. During these 50 years since the historic first Community Directive on medicinal products (65/65/EEC), a huge body of legislation has been produced governing the area of pharmaceuticals, which lies at the intersection of several legal branches, while many consider it as a separate branch of law.

This has happened because the continuous scientific progress, supported by technology, has built a strong **dialectic relationship between the medical and the legal communities**. As an unavoidable consequence, it is necessary to constantly adjust legal rules in line with scientific developments, which means more and more new legislation, rendering 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 end consumers-patients.

With particular regard to our country, the economic situation of recent years has led to haphazard legislative output, which has exacerbated the problems of **legislative inflation**, **fragmentation** or **attachment of provisions to legislative texts that have little or no connection to the main subject matter**. Despite Law 4048/2012 on principles for good law making, the examples are many: the list of prescription medicines can be found in the law on business loan arrears to banks! (Law 3816/2010); provisions on reimbursement (Article 127 of Law 4249) are part of a law on the Hellenic Police Force; the provisions on disclosure are included in the law on the Dementia Observatory; several provisions of relevance to our sector can be found

in the law on women's cooperatives; the settlement of EOPYY arrears and the 8% rebate on pharmaceutical companies are included in the recent Law 4430/2016 on the social and solidarity economy; a new provision repealing part of Article 12 of Legislative Decree 96/1973 can be found in a recent draft law on the simplification of procedures for setting up a business; just a couple of days ago, the legalisation of expenditure was inserted into a law on National Defence (Law 4432/2016), etc.

However, this is not the only problem: the OECD, with which all of us members of the SFEE expert team worked extensively together in a legislation mapping exercise, identified 155 pieces of pharmaceutical legislation, including delegated acts, i.e. presidential decrees, ministerial decisions and circulars. All these contribute to a lack of clarity. It is worth noting that the European Court of Human Rights, which establishes and safeguards European constitutional legality, rests on two key pillars: democracy and the rule of law. However, for the Court the mere existence of a law is not enough; **quality and predictability** also matter crucially.

Therefore, it is quite common for people involved in law practice and/or enforcement to be called upon to determine whether a legislative provision is the only one existing and applicable, whether it has been amended or partially repealed and partially remaining in force, and so on. This **legal uncertainty** is pointed out by the OECD in its recent "Toolkit" as a barrier to the sector's growth.

On the other hand, provisions adopted under Greece's adjustment programmes (MoUs) **often jeopardize the very essence of individual and social rights**, such as the right to health or the freedom of enterprise, posing serious ethical dilemmas to anyone believing in law as a value. Besides, with the long delays in the judicial process - despite the fair trial and conciliation mechanism introduced by Law 4055/2012 (Articles 53 et seq.) to address unreasonable delays in trials, in compliance with relevant rulings of the European Court of Human Rights – legal practitioners often face serious deadlocks and are unable to provide their clients with effective answers and options.

Meanwhile, 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 harmonization**. As we will see next in more specific presentations, a move towards harmonization is visible in several areas such

as pricing, reimbursement, personal data, as well as action to combat the scourge of falsified medicines that costs many human lives and, according to official data (from the 9th sectoral study of the European Union Intellectual Property Office Observatory), costs EUR 10.2 billion annually to the industry, which corresponds to 4,4% of sales at the European level and translates into 37,700 jobs lost.

These trends have also been identified by the United Nations: in its **Third Forum on Business and Human Rights** held in December 2014, the UN 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 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 show the role of SFEE as a **key institutional** counterparty of the State in the legislative process and as a manifestation of the democratic principle, recognizing of course that the relationship of the State with its citizens is not one between legally equal parties and that the executive power is subject to the presumption of competence (or residual power, as called in Cyprus).

A significant innovation introduced by our constitutional revision of 2001 is the notion of post-majority consensus. **The principle of post-majority**. That is, the constant effort to bridge the gap between the opinion of the majority with that of the minority with a view to **reaching a consensus** and providing institutional safeguards for this consensus in the day-to-day governance of public affairs and not only at the time of elections. **This is exactly what SFEE does: it strives for consensus**.

In the era of globalization, **SFEE as an association is a participant in the law making process and plays a productive and educational role**. With its team of experts, it monitors developments, listens to needs, identifies problems, explores solutions, **promotes democratic processes of broader consensus**, recommends to the government the consensus views of the industry, as derived from the necessary consultations among the members, and intervenes as partner and potential social partner.

It fights the legal battles that are worth being fought and has a record of successes, such as the historic decision of the State of Council Plenum no. 3633/2004, which ruled that the provision of Article 45(11) of Law 2992/2002) on the lowest price in the EU was unconstitutional, leading to its substitution by the average of the three lowest prices in the EU, which applies today. In this connection, it is worth noting the extraordinary opinion of the minority, echoing the *Simmenthal* judgment, regarding the direct applicability of the provisions of Directive 89/105 and its **precedence over national law**, a Directive that is a pivotal piece of legislation for our industry and which, as known, was never transposed into national law. Also, we should not omit to mention the more recent success in the matter of the deduction of VAT from the claw-back, having as a legal basis Council of State Decisions nos. 2439-2445/2015 that confirmed the constitutionality of the claw-back, while at the same time referring to the argument in favour of an ex post reduction of the rebatable amount. We also welcome the success of the Panhellenic Medical Association and the Athens Medical Association in having the prescription ceiling abolished by a landmark ruling (CoS Plenum Decision no. 1749/2016) that overturns a provision adopted MoU as unconstitutional. In particular points 16 and 17 of the grounds of this decision place patients at the core of the court's considerations, upholding the right to health both as a social and as an individual right and putting an end to the practice, so common in recent years, of putting numbers before humans. Humans are above everything, says the Council of State which, even with its minority reports, opens paths that advance legal science and are transformed into policy.

Aristotle, in its Nicomachean Ethics, exploring the concept of virtue, which for him was the theoretical foundation for the development of a regulatory model, posits that three elements are required: "Knowledge, Will and Action", and these three elements are indeed what SFEE is committed to.

As part of its action and extroversion, SFEE has taken the initiative, for the first time ever, to bring together the country's legal community in an event providing an opportunity for members of this community, from both the private and the public sector, to get to know each other and exchange knowledge and views with the ultimate goal of **promoting health through an optimal legal and regulatory framework.**

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 in hospitals, etc. Other topics will include the impact of the MoUs on collective labor relations, which SFEE has historically served, and regulatory matters with a European dimension, as seen from the perspective of the European Medicines Agency.

Turning from the regulatory framework to more fundamental legal issues, we will focus on the current legal challenges, such as the limits of free competition in a regulated or even, for some, overregulated market; 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 discuss current developments in the areas of **biosimilars, falsified medicines, medicrime and international negotiation practices**. Of course, we could not possibly address all the issues in a one-day event, but we think that this conference, as a first attempt, covers a broad range of interesting topics.

We hope you enjoy it,

Thank you,

Dimitra Lembessi

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