DAY THREE: REGULATORY FRAMEWORKS

CHAIR OPENING REMARKS

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Ladies and gentlemen, dear friends,

Good morning and a warm welcome to all of you to this second day of the Informa EU Pharmaceutical Law Forum on Regulatory Frameworks.

My name is Jordi Faus. I am a lawyer by education, based in Barcelona, with a degree on European Union law by the College of Europe in 1987, and I am one of the founding partners of Faus & Moliner, a boutique law firm in Barcelona, fully devoted to pharmaceutical law and life sciences matters since we created it in 1997.

I would like to start by thanking all of you for your attendance, our speakers for their availability, and the great team at Informa for their continued effort to make this great event possible despite all the difficulties associated with Covid-19.

As you know, today we will have the privilege of listening to very qualified speakers about extremely interesting topics. We shall have presentations about the Commission Pharmaceutical Strategy for Europe, about the most recent case law on transparency of data, the review of regulations as important as those governing paediatric and orphan medicines; and about the challenge of securing availability of medicines and avoid shortages. All of these followed by a panel discussion, a roundtable and four Dual Dialogues each one of them of great interest.

Today being a Wednesday in the middle of November, I am sure you all have lots of things to do, but today's agenda is so attractive that I do recommend you to close your outlook, put your phone far away from your table; and enjoy this session, which is a great opportunity to take a break in daily matters and learn a lot from the very best.

I must say (Informa asks me to remind you of this) that presentations and slides will be available on demand for the next 30 days on the platform in all cases where Informa has received permission to share. Still, nothing equals a live event, which is what we would all have preferred to have were we not going through this pandemic, so don't let the virus win and please stay in the virtual conference with us.

In this regard, I also have a special request to make = Don't be shy and do ask questions through the Q&A facility. I did so yesterday and realised the system and I am aware the system is hard on you because it limits how many characters you may use, it's like Twitter. Still, do take the challenge, please. I will receive your questions and do my best to pass them to the speakers.

On my side, would only like to make some quick introductory comments about pharma regulatory frameworks.

I am sure you all remember the words of President Von Der Leyen when talking about the way out of the pandemic she said that none of us will be safe until we all are. Great words which I hope will inspire developments in building a stronger European Health Union.

Allow me to use these words to say that none of us will have good regulatory frameworks until we all have them, all being first and foremost the patients, followed by healthcare professionals and our extremely valuable public healthcare systems, without leaving aside private research institutions and pharmaceutical companies. The interests and needs of public administrations may also need to be considered, of course. We cannot expect that all of these stakeholders to have the same view as to what is a good regulatory framework, and this is why events such as this one today are so important. Close dialogue and making efforts to understand the concerns and points of view of other relevant actors are great tools to work on the search of the common good through rules that meet the requirements of the principle of legal certainty being clear and precise, rules whose effects and consequences can be foreseeable.

I would like to finish by making two comments specifically addressed to my fellow colleagues at legal departments of companies and at law firms.

My first comment: The best clients we have are those who devote an important part of their revenue to R+D. Some refer to 10% or event 20% of their revenue. I always say that the best lawyers, in this field, are the ones who devote 10% or even better 20% of their time to study, read and learn about the law and also about how health care systems may be better ones in the future. Today is one of those days where you can meet this objective.

My second and last comment: Our best clients are also those who fight hard with the objective of treating patients and curing diseases, which is much more than simply bringing a product to the market. I have had the privilege of working with many of these companies and a lot of them come to my mind now, but rather than naming

them I will only quote a phrase which is in the slides of one of our speakers today: "We wont rest until we make rare diseases even rarer". We are talking about companies that work hard to find solutions. If possible, to find a cure. I am truly convinced that we lawyers should also make efforts to find solutions and to work towards a future where the quality of our regulatory frameworks is so good that it may then work smoothly with less lawyers and less litigation.

I will stop here and hand over to our first speaker today, Florian Schmidt, Deputy Head of Unit of the Commission's pharmaceutical unit B.5 in DG SANTE, who has kindly accepted the invitation to talk to us about the new EU Pharmaceutical Strategy for Europe. Florian joined the Commission in 2004 and is undoubtedly one of the most valued speakers on pharma regulation.

After Florian, we will have the opportunity to listen to Stefano Marino, Head of the Legal Department of the European Medicines Agency, an institution he joined in 2013 after a very successful career as in-house counsel. Stefano will talk to us about the most recent case law on transparency of data.

After these two keynote presentations, we shall enjoy two more presentations which I shall introduce then.

Florian, the floor is yours.