Newsletter

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Clinical Trials - Keeping Research and Innovation in Europe

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Cristian Silviu Busoi, MEP - Member of the Committee on the Internal Market and Consumer Protection

I am pleased to take part in this debate on the revision of the clinical trials legislative framework and I would like to thank the Kangaroo Group for giving attention to this topic, which is, certainly a bit technical, but which is fundamental for the future of medical research and innovation in Europe.

In order to understand what is at stake, I think we have to look at the performance of the current Directive on clinical trials from 2001. Even if it was helpful, even the Commission agrees on the fact that it has not entirely achieved its objectives and that it is partly responsible for the increase in administrative burdens and costs, especially for multinational clinical trials. When we compare the documents required by each Member State for the authorisation procedure, these differ significantly. Between 2007 and 2011, there was a drop of 25% in the number of clinical trials performed in the EU. Obviously, researchers and pharmaceutical companies do research and innovation in the countries which offer the best regulatory environment for this. We are therefore in competition with countries like the US, Canada or Japan, where the authorisation procedures are way shorter than in the EU and where there are no regulatory differences which increase the administrative costs.

Against this background, it is now up to us to take the necessary steps to simplify the procedures and to make the EU a more attractive area for clinical trials. I think this is all the more important as we have the necessary expertise in the EU. That is not the problem. Our problem lies in the administrative obstacles which make the life of researchers harder. I therefore strongly welcome the Commission's proposal for a regulation which takes important steps in the right direction. As the Rapporteur for Opinion in the Internal Market Committee, I have proposed a series of improvements and together with my colleagues I hope to come to a good result tomorrow when our committee will vote on the opinion. Our main objective was to strike the right balance between the need to ensure proper protection of the subjects involved in clinical trials, as well as the robustness of the data and the need to speed up the procedures and to eliminate unnecessary administrative burdens.

Antonio Correia de Campos, MEP - Member of the Committee on the Internal Market and Consumer Protection

First of all, it is very good that we now have a regulation instead of a directive. This will limit the regulatory divergences across the Member States and will provide for more legal certainty for both academics and pharmaceutical companies.

The **creation of the EU Portal** as a single-entry point for authorisation procedures is probably the most important progress because it will significantly simplify the application procedures and will considerably facilitate multinational clinical trials. Even if this is very important for multinational clinical trials, I think it is very important that this also applies

to single-country clinical trials. It is of utmost importance that the requirements for the submission of an application are the same in order to limit the burdens on the sponsors and encourage them to perform clinical trials in the EU. The fact that we now have one part of the assessment to be made in cooperation by Member States under the coordination of a reporting Member State is a very good thing. This will speed up procedures, including those for a subsequent addition of a new Member State to an already authorised clinical trial.

Another crucial point to maintain medical research and innovation in Europe is to **speed up the whole authorisation process**. The timelines proposed by the Commission are quite competitive and may be challenging for the Member States, but if we are serious about Europe's competitiveness in this area, I think we have to give ourselves the means to achieve this objective. Therefore, as Rapporteur for the Internal Market Committee, I have insisted on the need to keep the timelines as proposed by the Commission. An idea that emerged in our committee and which I consider useful is to clarify the timelines for the cooperation between the reporting Member State and the other Member States concerned by laying out a timeframe for the submission of comments to the assessment report. Additionally, to make sure that these timelines are complied with, I think it is fundamental to have the concept of **tacit approval**, without which the effectiveness of this Regulation would be undermined. Moreover, I think we should also be very clear on the fact that once the approval is notified to the sponsor via the EU Portal, the clinical trial can start and is not hindered by any further assessment. However, having smooth procedures doesn't mean we open loopholes. This is why I think we should make it very clear that ethical assessment is an integral part of the assessment procedure. This being said, the name of the body in charge of it, its competences or the number of such committees are a matter of subsidiarity and Member States should be free to organise their own procedures as long as they comply with the strict timelines in the Regulation.

There is also a need for more flexibility on aspects such as the addition of a new Member State to the clinical trial, the conduct of clinical trials on incapacitated subjects or in emergency situations, which is why the IMCO opinion will contain some amendments in this respect. Last but not least, I would like to focus on the issue of **transparency** in clinical trials, which at least in the Parliament, has drawn a lot of attention. I think we should think about this very carefully and avoid any emotional legislation. I think we do need increased transparency in clinical trials - and the EU Portal and the corresponding EU database will significantly contribute to this - but this should not be done at all costs and not by threatening the competitiveness of commercial sponsors because this will discourage innovation in Europe. We don't need transparency for the sake of transparency. The transparency provisions should be fit for purpose. And the purpose is to provide the means to scrutinise the results of clinical trials. I personally don't think we need raw data to be published in order to do this, because one can never be sure of the use that will be made of such data. More importantly I think we have to avoid situations in which competitors use this data for their own commercial interests, which is actually not fair.

My alternative proposal was that before marketing authorisation, only a summary of the results of the clinical trial should be published. I think this summary has to be detailed enough to allow for scrutiny, which is why I have proposed in a new annex the elements which should be covered by the summary and which are based on a Commission technical guidance from January this year. Another important aspect is the timing of the publication. I think we should make sure this summary is not released before its actual publication in a medical journal, which can take some time. If that were to be the case, there would be a risk that the data is actually "stolen" and published by someone else, which would discourage research. This is why my colleague, Dr Philippe Juvin, has proposed to move to 2 years after the end of the clinical trial instead of 1 year proposed by the Commission. For commercial clinical trials, in order to avoid the data being used by competitors, I have also proposed that the summary is released 30 days after marketing authorisation or 1 year after the decision to discontinue the development of the medicinal product.

After marketing authorisation, I think the amount of commercially confidential data is less significant and the EMA is currently working on the proactive publication of results, which I think could be a good idea.

Conclusion

These are the main points that I see as possible solutions to improve the environment for clinical trials in Europe. I think it is very important to take the time to have such exchanges in order to have in the end a legislative framework which really responds to the needs of our research.