Round table no. 4: clinical trials legislation, preparing for the revision of the European Directive scheduled for 2010

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"TAKING OUR IDEAS TO THE HIGHEST LEVEL"

We concentrated our efforts entirely on preparations for the revision of the European Directive on biomedical research. At this stage of drawing up wish-lists and suggestions for changes, French experts from across the board debated in Giens to identify the changes in the directive that professionals are most eager to see. France has traditionally always been in the forefront of regulation on biomedical research, so the partners gathered at this round table were well qualified lay the groundwork for the revision. The current text of the Directive is generally well received by the professionals present.

The general idea is to limit the damaging effects from one European country to the next creating multiple problems. We found that it was possible to modify certain principles without touching the actual wording of the text. By drawing up simple guidelines, it is possible to arrive at internal changes that do not require changes to the directive. Specialists term these "soft laws". It is a highly practical solution, since changing a directive is a cumbersome and time-consuming process.

We therefore directed our attention to three very precise angles of attack:

- How to organise ourselves to call for greater harmonisation in the application of the directive throughout the various European countries.
- How to take the directive forward using regulatory tools to simplify and improve the existing situation without major change.
- We also put forward certain requests for changes: the facilitation of co-sponsoring, for example. In the case of

institutional research, such a plurality of sponsors may clearly make matters easier. We also envisage making a clear proposal on a centralised procedure, along the same model as for marketing authorisation applications where a single country submits one application for the whole of Europe. The promoter would then have a choice between the centralised procedure and the classic country-by-country procedure, on the same terms as marketing authorisation applications. The wider adoption of electronic application submissions would be of great help here.

Lastly, there is considerable support for the need for simplification when it comes to pharmacovigilance. The European Directive inclines sponsors to adopt an umbrella policy under which virtually anything and everything ends up being reported as unexpected and adverse events. As a result, protection committees and the relevant authorities have great difficulty sifting through a mountain of SUSARs to find pertinent information. A simplification of the pharmacovigilance requirements would make it easier to digest information on tolerance during the trial.

We also devoted considerable time to exchanging views on the concept of stratifying protocols according to the level of risk added by the research. This concern was expressed by institutional sponsors, hospitals and research bodies engaged in biomedical drug research and which, as part of the application of the same directive, sponsor trials to compare therapeutic strategies, where the excess risk arising from the research is relatively low compared to the risks of the standard treatment. Such a distinction does not exist in the European Directive. The sponsor should be able to propose a level of "added" risk associated with the research in question, which could be measured on a scale ranging from negligible to a level comparable to that of a pre-marketing authorisation trial. The low level of risk would be equivalent to a standard treatment situation. The consequences for the conduct of the trial, reporting of events, insurance and various protective measures would then be linked to and determined by the level of "added" risk.

The round table also called strongly for the organisation of effective lobbying to improve the directive. Our group in Giens was made up of representatives of various different bodies, and this commonality of views is a basis which the influential people who take part in such gatherings will have every opportunity to use and to work from in taking our ideas to the highest level, ensuring that our recommendations become the proposals France contributes to the negotiations.