Recente wijzigingen inzake klinische proeven

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The European Commission on the one hand and Belgium on the other hand have amended their clinical trial-regulation on posting and publication of results-related information on clinical trials and on the fees for an annual review of adverse effects in clinical trials.

Clinical trials are vital to ensure high-quality health care in Belgium and, more widely, in Europe.

This high quality of products and enhanced knowledge are probably a key to success in an ever changing world, where innovation and tailoring are competitive assets, one should use in order to remain and become more competitive in life sciences.

Since regulation should aim to rein in human and industrial activity, changes in clinical trial regulation are occurring steadily. Some of those changes, which are minor in their direct impact, do however reveal political means.

In our opinion, the two minor changes that have been implemented by the European Commission and the Belgian authorities are part of this evolution.

The European Commission adopted a guideline on posting and publication of results-related information on clinical trials in relation to the implementation of Article 57(2) of Regulation (EC) No 726/2004 and Article 41(2) of Regulation (EC) No 1901/2006. Those guidelines aim “to make the results of clinical trials publicly available”, which is felt necessary to enhance the quality of the research and prevent non-compliance and factual inaccuracy. It aims to be compliant with this policy of publicity which is retained in the new proposition for a regulation of the European Parliament and of the Council on clinical trials on medicinal products for human use.

This proposition, adopted on 17 July 2012 will repeal Directive 2001/20/EC and replace it by a regulation. This regulation would only apply to clinical trials on medicinal products, but with a very broad scope, only excluding studies that do not involve an ‘intervention’.
Peculiar to Belgium is the Royal Decree of 16 July 2012. This new regulation is only meant to fix a specific fee for the yearly review of adverse effects in clinical trials. This fee is fixed to a rather limited amount of € 650. More important to us is the fact that, by adopting such a regulation, the Belgian authorities are drawing attention to the fact that this yearly report of adverse effects should be compulsory. This regulation, therefore, is yet further evidence of the importance of safety in the conduct of clinical trials.

Through minor changes, the Belgian and European authorities emphasize their specific interest in high-quality and safe clinical trials. The upcoming new regulation of the European Parliament and the Council on clinical trials on medicinal products for human use should be understood from that perspective.