Adverse effects of clinical trial data transparency – should we worry?

July 13 2015

New legislation forces drug developers to disclose most of their clinical trials data when applying for approval of a new drug. Many will probably think that this is a good idea. However, too much transparency in drug development might be problematic, according to Timo Minssen, researcher at the University of Copenhagen. He warns that the new regulations might make it difficult for companies to patent new medical uses for known drugs. Without sufficient alternatives, this may inhibit the full development of new medical uses towards market approval.

Transparency and big data is the new mantra in the drug industry

The drug industry is not as closed now as it was 5-10 years ago. Regulation in both the United States and Europe is forcing drug companies to disclose most of their clinical data. It is no longer enough just to publish the summarizing reports. This looks at first sight like a positive development. Associate Professor Timo Minssen from the Faculty of Law acknowledges the benefits related to disclosing clinical data:

"Many good things can be said about openness in connection with trial data: It increases consumer confidence and, at the same time, makes it easier for scientists to share their knowledge and work together in research. However, there are also negative effects that need to be mitigated. Among other things, the new legislation can make it more

difficult, in some cases, to patent new uses for known drugs. This might discourage the drug industry from fully developing such new uses with the consequence that these benefits might not reach patients in need."

Too much transparency might inhibit development

Timo Minssen has in collaboration with the American researcher W. Nicholson Price II, compared the recent changes in European and US regulations resulting in increased clinical trials data transparency with the relevant patent legislation. This has resulted in an article published in the scientific journal *Nature Biotechnology* explaining how these two fields might hamper each other. Timo Minssen elaborates:

"In order to patent something it has to be new and innovative. Today, pharmaceutical research often focuses on developing new and innovative uses for an already known drug based on a better systematic understanding of chemical and microbiological processes. This has to be clearly differentiated from the so-called "life cycle management" debates mostly relating to trivial changes of drug formulations to extend their life-cycle. For example, drugs exists that originally were developed to treat allergies, but today it has been discovered that they might also be used to treat cancer. By requiring firms under the new legislation to publish their full clinical trials data as part of the approval procedure, novel indications are often revealed. It can be difficult to patent a further, significant use of the drug at a later date, as the positive new effect has already been made public and is therefore not new or has become obvious. In the worst case such new applications would then not be further developed due to the lack of patent incentives. The recently adopted regulations take some account of this problem, but do not sufficiently address it with regard to new, innovative and significantly beneficial uses for known drugs."

An efficient innovation system requires a common

effort

Although Timo Minssen acknowledges that more public involvement could be considered in some specific areas of drug development, he believes that an effective biomedical and pharmaceutical innovative system still requires the incentives provided by patent protection or other forms of exclusivities. The limited monopoly guaranteed by a well-designed and administered patent system ensures that companies which have carried out the very expensive process of developing and testing a new drug or new uses of known drugs - can recoup their investment for a number of years after the drug has been released. Moreover, a part of the profit would be invested in the development of new drugs. With full transparency and fewer patents, some of this work could perhaps be conducted by public bodies or by public private partnerships. Yet, it can be expected that many highly beneficial new uses of drugs will only reach patients in need with the specific skills, technical experience and financial input from drug companies.

How is it possible to increase transparency in the drug industry without ruining the companies' incentive to further develop innovative uses of already approved drugs?

In the article published in *Nature Biotechnology* Timo Minssen and W. Nicholson Price II argue that the clashes between the patent system and regulatory law could be solved by more flexibility in designing regulatory exclusivity periods, other complementary forms of incentives, and by strengthening communication and collaboration between the relevant stakeholders:

"The problem is the lack of communication between specialists with expertise in both fields. Patent experts, companies, patients groups, and public authorities regulating the drug industry's clinical trials data must become better at collaborating and sharing skills to identify and mitigate

foreseeable problems," Timo Minssen says.

He suggests that the laws covering patents, regulatory exclusivities and transparency in the drug industry should be coordinated and developed across all areas of expertise and across the divide between private and public sectors:

"The public authorities do a good job in controlling the drug industry, but the private sector possesses considerable knowhow that is needed to ensure the proper functioning of the innovation system and the interaction between the patent system and trial data transparency. Only by analyzing and tackling the problem from different perspectives, can you mitigate unwanted adverse effects of new regulations and coordinate various areas law. Ultimately, this will help to optimize the pharmaceutical innovation system to achieve the greatest public benefit."

More information: "Will clinical trial data disclosure reduce incentives to develop new uses of drugs?" *Nature Biotechnology*, No 33, pp 685–686 (2015), www.nature.com/nbt/journal/v33 … 7/full/nbt.3243.html

Provided by University of Copenhagen