Polish clinical trials market poised to grow by 5% in 2010

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In 2010, the clinical trials market in Poland is expected to grow by 5% year on year, and to reach PLN 718m (€170m), according to the latest report by PMR. If barriers to market growth, including unclear legislation and difficult trial registration procedures at the Central Register of Clinical Trials (the CEBK), were removed, the clinical trials market could develop even more rapidly.

Market worth PLN 718m in 2010

The clinical trials market in Poland[1] slowed in 2009, in comparison with previous years. Between 2006 and 2008, it grew at a rate of 8-10% per annum, whereas 2009 saw a year-on-year increase of only 1%, based on PMR estimates. *"This poor market growth rate was, evidently, caused by the economic crisis, as a result of which companies cut down on expenditure on R&D projects, including clinical trials. On the other hand, the market is already quite saturated, which is why, according to us, it is not expected to grow at an exponential rate in the future"* says Agnieszka Stawarska, a PMR Pharmaceutical Market Analyst and the report co-author. PMR forecasts that in 2010 the market will expand by around 5% year on year and will be worth PLN 718m (€170m).

Work on Clinical Trials Act still in progress

The Clinical Trials Act has been in preparation for years; the objective of the act is the regulation of clinical trials through the clarification of existing regulations and the addition of new areas which have not previously been subject to legal regulation. The assumptions underlying the bill were published in December 2009, whereas the bill is expected to be ready in the first half of 2010.
Among other things, the Clinical Trials Act will clarify and amend regulations applicable to the proceedings of ethics committees. The bill is based on the assumption that a clinical research coordinator (chosen from among the principal investigators) will be required to file applications with the bioethics committee with jurisdiction over the coordinator's registered office and with all of the relevant bioethics committees with jurisdiction over the location at which the clinical trial is carried out. In addition, the bill proposes the introduction of an obligation to publish information on clinical trials run in Poland on publicly available websites.
If the assumptions underlying the bill are reflected in the final version of the Clinical Trials Act, patients will be able to claim for bodily injury resulting from participation in clinical trials (non-fault insurance – despite giving their informed consent for a clinical trial, patients may be awarded damages for bodily injury; at present, the liability of sponsors and investigators is fault-based).
The assumptions upon which the bill is based also include a proposal to pay not only healthy subjects but also patients suffering from illness who participate in phase I trials.

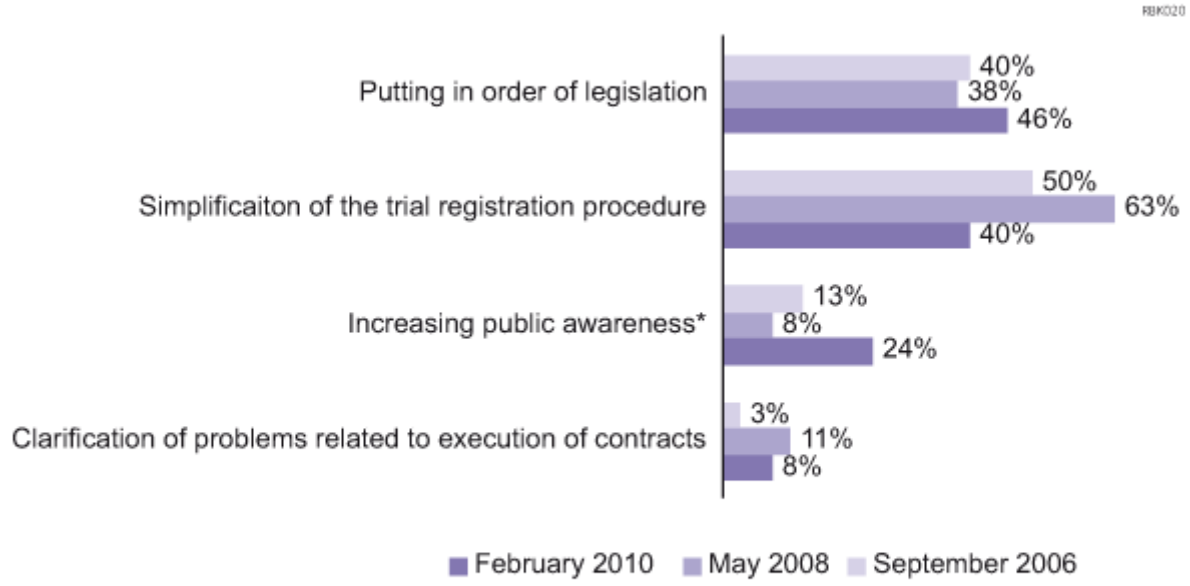
"Tidying up" of legislation to stimulate market growth

In the opinion of the respondents to the PMR survey, the "tidying up" of the relevant legislation is a factor which could have the most extensive effect on the development of the market in the next few years. *"Respondents cited measures such as a clear-cut definition of a sponsor's duties, the liberalisation of the law (which is too detailed), and the introduction of transparent and consistent guidelines applicable to all of the parties involved"* says Monika Stefanczyk, a PMR Head Pharmaceutical Market Analyst and the report co-author.
There is no single statutory instrument in force in Poland which could regulate the clinical research market comprehensively. The relevant provisions pertaining to the clinical trials market are contained in a number of legal instruments of various categories, including those relating solely to the pharmaceutical market (e.g. the Pharmaceutical Act), but also

[1] Phase I-IV clinical trials and bioequivalence trials.

to the Civil Code and the Penal Code. It is frequently the case that the provisions of legal instruments are inconsistent with each other.
In the opinion of almost 40% of respondents, the key market growth factor is the simplification of the trial registration procedure at the CEBK. However, this view was taken by significantly fewer respondents than in previous surveys carried out by PMR, in 2006 and 2008. In comparison with 2006 and 2008, significantly more respondents identified improvements in public awareness of clinical trials as a key factor which could drive market development. This could be because of the negative media coverage of clinical trials and unfavourable reports on the clinical trials market published in the Polish press in recent years.

Key factors which could stimulate development of clinical trials market in Poland, 2006, 2008 and 2010



** including doctors*
Note: Based on answers provided by 82 respondents in 2006, 64 respondents in 2008 and 63 respondents in 2010; excluding no data and "I don't know" responses. Respondents could give up to three answers.
Source: report „Clinical trials in Poland 2010. Development forecasts for 2010-2012", PMR, 2010

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