A draft act on clinical research was sent to the Minister of Health

The works on the draft act on clinical research on medicinal products have been finalised. They were carried as a part of implementation of the Clinical Research Development Programme prepared by the Medical Research Agency. The team for preparation of the draft act, nominated by the Minister of Health, on Wednesday (29 January) delivered a ready concept to the Minister.

The new regulation is supposed to adapt the Polish law to EU regulations and, first of all, to improve the organisation of the market of clinical research in our country, increase its attractiveness for non-commercial and commercial subjects, and, at the same time, make it safer and more available for patients.

The draft provides for solutions that would increase competitiveness of Poland as a place where clinical research is carried out through implementation of transparent regulations enabling application of European standards and introduction of further facilitations and mechanism that encourage clinical research.

The draft handed over to the Minister of Health defines additional mechanisms of support for clinical research, offers a new definition of non-commercial clinical research or a new system of ethical evaluation of an application for authorisation of a clinical trial. The daft act also provides for creation of the Fund for Protection of Trial Subjects and specifies regulations concerning investigator and sponsor's responsibility and financing the pensions by sponsors and NFZ.

The document also stipulates nomination of the Supreme Bioethics Committee working for the Medical Research Agency. At the same time, for organisational reasons, it is not possible for this body to issue opinions on all the applications, therefore they shall also be reviewed by bioethics commissions that go through the accreditation process. Also the Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products was indicated to be a competent body, engaged in assessment of the application for authorisation of a clinical trial.

Clinical research insurance system, based on a Guarantee Fund and the researcher and sponsor's third party insurance, is also a new solution. Although according to the draft, additional burden connected to participation in the fund will be placed on sponsors, the costs of conducting studies are supposed to be lower, inter alia, through decreasing the minimal sum guaranteed resulting from the third party liability insurance. Currently, irrespective of the type of the trial, the costs of insurance policies are as high as several hundred thousand zloty.

Moreover, the daft assumes that for the need of processing of specific patients' claims, each time the President of the Fund shall nominate a commission composed of medical experts and lawyers who will

decide on legitimacy of payment of possible benefit for the patient if there is a high risk of damages connected to the trial, irrespective of fault. The Fund is supposed to be financed from the contributions paid by the sponsors of the clinical trial.

The draft act assumes that the cases will be reviewed within the maximum of 4 months, which will significantly increase the speed of recovering money from the claims and influenced the sense of security of the patients. Another change which is important for patients is ensuring access to the Central Register of Clinical Research kept by the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. This will enable opening the publicly available database of clinical trials, which will be the source of information about the trials carried out.

The undertaken legislative actions should re-define the Polish market of clinical research, creating a friendly and competitive environment for their implementation. We have a very specific and clear declaration of the Minister of Health that, after the draft is submitted, the act will be transferred to the Parliament. We hope that in no time it will be binding and it will adapt our legal system to European legislation as well as it will solve organisational problems - sums up Radosław Sierpiński, MD, PhD, acting President of the Medical Research Agency.

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