

Monika Urbaniak

Selected legal aspects of conducting clinical medical examinations in Poland

Summary

Clinical tests of pharmaceuticals on people have for long stirred much controversy, also of legal and financial nature, and, in particular, regarding the obligation put on the sponsor of the tests to co-finance the treatment with the use of tested drugs together with the National Health Fund. The existing regulations of the above procedure are not very extensive and the main legal act governing clinical tests today is the Act of 6 September 2001 called: Pharmaceutical Law. Pursuant to its Art. 37k para. 1 in force as of 1 May 2011, the sponsor finances the work needed to be performed by health service units to conduct clinical tests that are covered by a clinical test protocol, and which are not part of the guaranteed health care services referred to in the Act on health care services financed from public funds. In particular, as the Act provides, the sponsor is responsible for supply, free of charge, of the tested pharmaceuticals to all participants of clinical tests, as well as for the provision of other appliances needed to administer the tested drugs. Another important issue related to clinical tests is the obligatory insurance when it comes to clinical tests. This issue is been only recently regulated in Poland. The first relevant ordinance came in force on 11 May 1999 and it regulates the specific principles of creating and financing bioethics committees and the manner in which they should function. The ordinance introduced an obligation of insuring the patients participating in clinical tests. Another Act issued pursuant to Art. 37b para. 3 of the Act: Pharmaceutical Law was the ordinance of the Minister of Finance of 30 April 2004 on the obligatory civil insurance of the researcher and the sponsor, which determined a detailed scope of their civil liability for damages caused or arising from clinical tests, leaving apart, however, the issues related to the liability insurance of the research centre. Hence, in spite of the existence of some regulation of the issues connected with conducting clinical tests in Poland, there is still a need for a more complex regulation to be contained in one Act on clinical tests.

Keywords: clinical tests, financing of clinical tests, financing of guaranteed health services, the National Health Fund