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New Rules Put Clinical Testing in Doubt

By Yulia Shmidt

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Clinical testing of medication may become illegal in Russia after the government issued insurance requirements for participating patients that are practically impossible to satisfy.

The new rules for mandatory insurance of clinical test patients were set by government order on Sept. 13.

Without going through clinical testing in Russia, no new medication can come to the market, as dictated by the law on distributing medicines, which came into effect in September. To get permission for clinical tests, a company must provide officials with copies of the life and health insurance policies of patients who have agreed to be treated with experimental drugs.

But this will not be easy for pharmaceutical companies to do, because the rules say the insurer must be given the names and passport data of participants who will be covered by the policy.

"As a result, the list of patients needs to be finalized even before the testing is approved by the Health and Social Development Ministry. But getting the agreement of a potential participant

before receiving the permission is impossible — it violates all international standards," said Svetlana Zavidova, head of the Association of Clinical Testing.

"Even after the start of the test, the list of patients can be in flux for months and even years," she said.

There are many cases when the list of patients expands for several years after the testing begins, said Ramil Abdrashitov, director of clinical testing for Russia and Ukraine at pharmaceutical company AstraZeneca.

Under the rules now, the tests cannot start without a signed insurance policy that includes a list of patients, and getting the insurance policy is impossible because the exact list of patients may not be clear, Zavidova said. Any attempt to start tests would violate the law or the government's order.

Previously, the rules for civil liability were used when insuring people for clinical testing, and there was no need to submit a list of patients, said Dmitry Shishkin, head of civil liability at Ingosstrakh. "Unfortunately, when preparing the new rules, nobody checked with the insurance industry, and the result turned out to be basically unworkable."

The Health and Social Development's press service responded that the new "mandatory insurance policy conforms to the requirements of civil law."

The ministry has already suggested a workaround to companies. To receive permission to start clinical testing, the company may submit a preliminary insurance agreement indicating the number of patients to be covered, Abdrashitov said.

But that would also be a violation of the law, which requires that the signed insurance agreement be presented — not a preliminary version, Zavidova said.

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