Translation from Romanian into English

AM MEDICINES AND MEDICAL DEVICES AGENCY

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GOVERNMENT
OF THE REPUBLIC OF MOLDOVA

ORDER
Chisinau municipality

May „14”, 2025

Number ***Rg04-000150***

„On the suspension of the activities of the clinical study mife50 in the Interventional Medicine Center Cardiomed LLC (NovaMed Polyvalent Hospital), Chisinau city, 30 Tudor Strisca Street, Principal Investigator doctor Irina Tripac”

On the basis of Article 12 paragraph (6) letters a) and b) of the Law number 1409/1997 on medicinal products, Government Decision number 71/2013 on the approval of the Regulation, structure and staffing limits of the Medicines and Medical Devices Agency and the Order of the Ministry of Health number 648 of 12.08.2016 on the regulation of the authorization of clinical trials in the Republic of Moldova,

I ORDER:

1. All clinical activity is suspended for the study protocol „ Prospective multi-center single arm open label study of efficacy, safety and acceptability of long-term weekly oral Mifepristone 50 mg as contraceptive” / Principal Investigator doctor Irina Tripac, conducted at the medical unit Cardiomed Interventional Medicine Center LLC (NovaMed Polyvalent Hospital), Chisinau city, 30 Tudor Strisca Street, following the inspection carried out on May 13, 2025 (between 09:30 a.m. - 04:05 p.m.) at the mentioned medical unit. During the closing session, the list of critical nonconformities (Annex), which are identified as serious violations of the Good Clinical Practice in Clinical Trials (GCP) Rules, was verbally addressed, confirming the fraud suspected by the sponsor of the Women on Waves study, the Netherlands, and sent by e-mail on May 6, 2025.
2. The suspension order has immediate effect from the date of approval and is notified to the clinical trial sponsor, the contract research organization Bona Artis CRO and the director of the Cardiomed Interventional Medicine Center LLC (NovaMed Polyvalent Hospital).
3. To produce the inspection report within 7 calendar days.
4. The GCP, GVP, GLP, GRP Service is in charge of the execution of this Order.

Director-General ***/signature/*** **Dragoș GUȚU**

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Annex
to the order number *Rg04-000150* dated *14.05.2025*

Preliminary list of critical non-conformities verbally addressed in the closing session at 03:45 p.m., presented by coordinating inspector Ecaterina Guzinschi

1. The Principal Investigator did not show a willingness and openness for the unannounced inspection and left the inspection site unannounced.
2. The members of the study team, notified to the Medicines and Medical Devices Agency (MMDA), are not employees of Cardiomed Interventional Medicine Center LLC (NovaMed Polyvalent Hospital), but of PRIMAMED EXPERT LLC, managed by the Principal Investigator; moreover, the sub-investigator Cristina Nichitovici does not have a signed contract with PRIMAMED EXPERT LLC.
3. Sub-investigators Cristina Nichitovici and Cristina Noroc, the only sub-investigators available during the inspection, did not sign any documents designating their activities in the mife50 study and were not remunerated for the work carried out in the study.
4. Sub-investigators Cristina Nichitovici and Cristina Noroc are not familiar with the details of the clinical trial protocol and have not received training on its procedures and processes.
5. Sub-investigators Cristina Nichitovici and Cristina Noroc received erroneous information about the study closure from the Principal Investigator: a volunteer's task.
6. From the analysis of the study documents it was identified that the study monitoring procedure was flawed:
- the documents ensuring the identity of the enrolled subjects and their randomization are missing from the medical unit;
- MIC distribution records are missing;
- evidence of training of the study team in study procedures is missing;
- MMDA has not been notified of changes to the blood sample management process;
- Principal Investigator's signature appears differently in different documents (8 signature variants were identified - suspicion of forged signature);
- Subject 22's individual case file is missing Informed Consent Form;
- the old version of the Informed Consent Form was included in all the individual files of the subjects in the sample evaluated;
- in some Informed Consent Forms the signature and handwritten names of volunteers raised suspicion of forged signatures;
- another office was additionally involved in the conduct of the study other than the one approved by the requested GCP inspection of 17.05.2024; the study documentation is kept in this office - on the windowsill; other collaborators than the study team and patients have access to this office;
- progesterone and estradiol tests are non-accredited Moldac tests;
- the USG images cannot be linked to the identity of the subjects, as the identity data are missing on them;
- some USG images show time of investigation 04:00, 05:00, etc;
- there is missing evidence of training of the study team to use the Castor EDC system;
- the access to the Castor EDC system is non-secure, it can be made from any electronic device, including outside the medical facility;

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7. The alleged study medication was identified in a cupboard to which the sub-investigators indicated: 6 boxes of Ginestril medication with a valid expiration date and 1315 tablets with an expired expiration date of August 2024. It was noted:
- Lack of MIC availability information documenting MIC traceability: receipt, distribution to subjects, recall from subjects;
- Additional labeling with text purported to be in Georgian on the secondary packaging of study medication with expired shelf life;
- Inadequate storage of MICs: although a thermometer was identified in the storage cupboard, no documentation of the temperature regime and its verification was identified.

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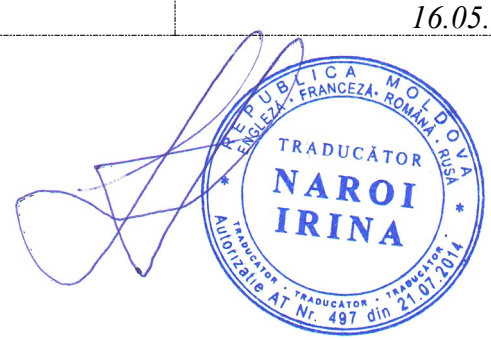
*I, undersigned **Naroi Irina**, an authorized translator of the English language, certify the fidelity of translation of the text in the original, which was signed by me on 16.05.2025.*	*Subsemnata, Naroi Irina, traducător autorizat în limba engleză, certific exactitatea traducerii cu textul înscrisului în original, care a fost vizat de mine la data de 16.05.2025.*

Semnătura traducătorului

Translator's signature



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