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OPINION

ETHICS ON RESEARCH AND CARE

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OPINION ON PARTICIPATION IN CLINICAL TRIAL PROTOCOLS ON NEW TREATMENTS FOR HIV-INFECTED PATIENTS NEVER HAVING TAKEN ANTIRETROVIRAL MEDICATION

In a letter dated 12 November 2004, the inter-association group known as HIV-Infection Treatment and Therapeutic Research (TRT-5), alerted Conseil national du SIDA to the problems raised by a number of international clinical trial protocols dealing with a new class of anti-HIV drugs and involving infected patients never having received antiretroviral treatment. The problems appeared significant enough for CNS to decide, under Article L1121-21 on the Public Healthcare Code, to issue an opinion on the ethical issues regarding "participation in clinical trial protocols on new treatments for HIV-infected patients never having taken antiretroviral medication".

Patients never having taken antiretroviral medication, with severe immune depression (CD4<200/mm3) or AIDS, show a higher risk of morbidity and mortality in the three years following the start of care. This is why it is vital that they receive, as early as possible in the care cycle, treatment that offers optimal and confirmed efficacy.

For this reason, Conseil national du sida deems that promotors should first, in the early stages during which optimal doses are determined, ascertain that the new treatment, when combined with other antiretroviral medication, is both effective and well-tolerated in patients whose illness is little-advanced, e.g. with CD4 levels exceeding 200/mm3 and viral load below 100 000 copies/ml.

Regarding the need to also obtain data regarding treatment-naïve patients2 at a later stage of illness, CNS feels that they can be included in the assessment of the new treatment, but only later in the process, once safety and efficacy have been confirmed for lower-risk patients.

CNS reminds promotors that all patients included in a trial are entitled to the same level of monitoring as patients who are not taking part in biomedical research. Consequently, monitoring criteria for the trials must comply with the recommendations in effect in France.

[1] "The interests of those who agree to take part in biomedical research always prevail over those of science and society alone".

[2] Patients having never received previous antiretroviral treatment.