

Presidenza del Consiglio dei Ministri



Abstract

RESPONSE TO MINISTRY OF HEALTH QUESTION ON THE USE OF TRYPTORELIN IN THE CASE OF A DIAGNOSIS OF "GENDER DYSPHORIA"

November 22, 2024

The answer to the question posed by the Ministry of Health concerns strictly and solely the use of the drug in the context indicated by the question.

As a result of expert hearings and the evaluation of available literature, the CNB highlighted, in general, the insufficiency of scientific data on the use of puberty blockers and the need to strengthen them. Consequently, the CNB stresses the need for the Ministry of Health to take charge of funding independent clinical studies aimed at obtaining decisive data on the efficacy and risks of drug administration, of higher quality than those already carried out, which do not appear adequate to the objective.

From an ethical perspective, regarding trial design, the CNB recalls that the gold standard for clinical trials for drug approval is a double-blind, randomized controlled clinical trial. The CNB recommends that clinical evaluations should be multidisciplinary, and the prescription of tryptorelin should only occur following a finding of ineffectiveness of a psychotherapeutic/psychological, and possibly psychiatric, course. The decision-making process should always be thoroughly documented in all its steps.

Given the uncertainty about the risk-benefit ratio of tryptorelin puberty blockade, the CNB would like to see prescriptions only within the scope of trials sponsored by the Ministry of Health.

Even where administrations occur outside of trials, that is, in the case of denial of consent or as a result of specific clinical evaluations by the physician that should always be documented, the CNB recommends that the same criteria indicated for trials be followed, and that in any case all data always be submitted to a dedicated registry. This is also in light of the fact that, at the moment, data on the use of tryptorelin reported by the regions (i.e., on its use during the period 2019-2023) are lacking and fragmentary.

The opinion was approved by a large majority of those present, with 4 of the non-voting members joining, and was accompanied by one dissenting note, one abstention note, and two explanations of vote, one of which was signed by 15 members, and the other by 7.