Presidenza del Consiglio dei Ministri

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COMITATO NAZIONALE
PER LA BIOETICA

Abstract

ON THE QUESTION OF AIFA'S REQUEST REGARDING THE ETHICALITY OF THE USE OF THE DRUG TRIPTORELIN IN THE TREATMENT OF ADOLESCENTS WITH GENDER DYSPHORIA

13 July 2018

In response to a query from the Italian Medicines Agency (AIFA), the Italian Committee for Bioethics has issued an opinion on the ethicality of the use of the drug triptorelin in the treatment of adolescents with gender dysphoria (GD).

Gender dysphoria is frequently accompanied by psychiatric illnesses, emotional and behavioural disorders, with self-harm, and a high incidence of suicidal behaviours. The prescription of this drug for GD is currently possible according to the method of *off label* use for "indications other than those authorised".

On the basis of this classification, unless individual local authorities dispose otherwise, the therapeutic decision, the preparation and the obtaining of informed consent are entrusted exclusively to the responsibility of the individual doctor, without an evaluation by an ethical committee.

The document, after outlining the benefits and risks of its use, without going into the merits of a historical-sociological reconstruction and the philosophical discussion about gender, puts forward several recommendations, inspired by caution and evaluation on a case-by-case basis, as well as recalling that diagnosis and proposed treatment should come from a multidisciplinary and specialized team, that the treatment should be limited to cases where other psychiatric and psychotherapeutic interventions prove ineffective, and that treatment should provide for consent to be freely and voluntarily expressed, with the subject understanding the information received in the specific physical and psychological conditions of the adolescent.

The Committee also highlights the importance of providing adequate training for the paediatrician, the basic social-health network and the educational institutions involved in these issues and recommends the preparation of studies on safety, efficacy and physical-psychological follow-up on the cases treated as well as the provision of a policy of equitable and homogeneous access to triptorelin.

Lastly, the Committee recommends that AIFA should regulate the particular conditions of administration of the drug in the diagnosis of GD in adolescence.

The document was supplemented by the personal remarks of Prof. Assuntina Morresi, published along with the Opinion.