



## Case of Hristozov v. Bulgaria

Applications nos. 47039/11 and 358/12

**Country:** Bulgaria

**Region:** Europe

**Year:** 2012

**Court:** The European Court of Human Rights

**Health Topics:** Health care and health services, Hospitals, Medicines

**Human Rights:** Right to family life, Right to health, Right to life, Right to privacy

### Facts

The applicants were all terminally ill cancer patients (four of them died since the filing of the application). They were unsuccessful in trying to find a cure and tried many conventional treatments such as chemotherapy, radiotherapy and hormone therapy. Thereafter they approached a private clinic in Sofia and found out that an anti-cancer experimental product had been developed by a Canadian company and it was allowed in some countries for compassionate grounds (life-threatening diseases which could not be treated successfully).

The company had applied to the Bulgarian Ministry of Health about the product and that they would provide it for free in return, they would seek the data on the effects of the treatment. The applicants sought permission to use the product but were denied on the ground that the product was not authorised for use in Bulgaria. The applicants complained that this was a violation of Article 2, Article 3 and Article 8 of the Convention.

### Decision and Reasoning

The Court held that there had been no violation of Article 2, Article 3 and Article 8 of the Convention. With respect to Article 2 of the Convention, it stated that while Article 2 imposes a duty on the state to put in place legal framework to protect people's lives, it could not include a duty to allow access to an unauthorised and experimental medicine. In respect of Article 3, the Court stated that although the non-access to the drug had caused the applicants mental suffering, Article 3 could not be said to impose a duty upon the State to equalise the differences between health-care available in different countries. In respect of Article 8, the Court stated that a fair balance has to be made between compelling interests of the individual and the community. There was not enough data on the efficacy on the drug or its side-effects. The Bulgarian authorities under certain conditions did allow the use of unauthorised drugs where authorised drugs had failed to treat an illness but only if the said drug had been authorised in another country. The drug had not received authorisation in another country. The Court stated that the States had wide margins in this matter and held that the State's action did not violate Article 8 of the Convention.

The dissenting judges stated that to treat oneself and to make to make an informed and free choice in terms of the treatment one seeks is within the notion of private life under Article 8 of the Convention and hence the refusal to give access to the experimental drug violated Article 8 of the Convention.

### Decision Excerpts

It is true that the positive obligations under Article 2 may include the duty to put in place an appropriate legal framework, for instance regulations compelling hospitals to adopt appropriate measures for the protection of their patients' lives (see *Calvelli and Ciglio*, cited above, ¶49), or regulations governing dangerous industrial activities (see *Öneroğlu v. Turkey* [GC], no. 48939/99, ¶90, ECHR 2004-XII). Nevertheless, it cannot be said that Bulgaria does not have in place regulations governing access to unauthorised medicinal products in cases where conventional forms of medical treatment appear insufficient. Such regulations exist and have recently been updated (see paragraphs 23-32 above). The applicants rather take issue with the terms of those regulations, arguing that they are overly restrictive. However, in the Court's view Article 2 of the Convention cannot be interpreted as requiring access to unauthorised medicinal products for the terminally ill to be regulated in a particular way. It should be noted in this connection that in the European Union this matter remains within the competence of the member States (see paragraphs 45-51 above), and that the Contracting States deal differently with the conditions and manner in which access to unauthorised medicinal products is provided. (Para. 108)

the Court considers that this claim puts an extended construction on the concept of inhuman or degrading treatment that it cannot accept. It cannot be said that by refusing the applicants access to a product “ even if potentially life-saving “ whose safety and efficacy are still in doubt, the authorities directly added to the applicants’ physical suffering. It is true that the refusals, inasmuch as they prevented the applicants from resorting to a product which they believed might improve their chances of healing and survival, caused them mental suffering, especially in view of the fact that the product appears to be available on an exceptional basis in other countries. However, the Court does not consider that the authorities’ refusal reached a sufficient level of severity to be characterised as inhuman treatment. (Para. 113)

The countervailing public interest in regulating the access of terminally ill patients such as the applicants to experimental products appears to be based on three premises. Firstly, to protect them, in view of their vulnerable state and the lack of clear data on the potential risks and benefits of experimental treatments, against a course of action which may prove harmful to their own health and life, their terminal condition notwithstanding (see, *mutatis mutandis*, Haas, cited above, § 54). (Para 122)

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