

EUROPEAN COURT OF HUMAN RIGHTS
COUR EUROPÉENNE DES DROITS DE L'HOMME

FOURTH SECTION

DECISION

Applications nos. 47039/11 and 358/12,
HRISTOZOV and STAYKOVA-PETERMANN against Bulgaria
and MISHEVA AND OTHERS against Bulgaria

The European Court of Human Rights (Fourth Section), sitting on 21 February 2012 as a Chamber composed of:

Lech Garlicki, *President*,
David Thór Björgvinsson,
Päivi Hirvelä,
George Nicolaou,
Zdravka Kalaydjieva,
Nebojša Vučinić,
Vincent A. De Gaetano, *judges*,
and Lawrence Early, *Section Registrar*,

Having regard to the above applications lodged on 15 July and 5 December 2011 respectively,

Having regard to the President's decision of 9 February 2012 to grant priority to the applications under Rule 41 of the Rules of Court,

Having deliberated, decides as follows:

THE FACTS

1. The applicants in the first application (no. 47039/11), Mr Zapryan Hristozov Hristozov and Ms Anna Staykova-Petermann, are Bulgarian nationals who were born in 1977 and 1954 respectively and live in Plovdiv.

2. The applicants in the second application (no. 358/12), Ms Boyanka Tsvetkova Misheva, Mr Petar Dimitrov Petrov, Ms Krastinka Marinova

Pencheva, Ms Tana Tankova Gavadinova, Ms Blagovesta Veselinova Stoyanova, Mr Shefka Syuleymanov Gyuzelev, Mr Yordan Borisov Tenekev and Mr David Sabbatai Behar, are Bulgarian nationals who were born in 1948, 1947, 1948, 1973, 1948, 1966, 1935 and 1947 respectively and live in Godech, Dobrich, Kazanlak, Plovdiv, Ruse, Samokov and Sofia respectively.

3. All applicants were represented before the Court by Mr M. Ekimdzhiev, Ms K. Boncheva and Ms G. Chernicherska, lawyers practising in Plovdiv.

A. The circumstances of the case

4. The facts of the case, as submitted by the applicants, may be summarised as follows.

5. The first applicant in application no. 47039/11 and all eight applicants in application no. 358/12 have various types of cancer and appear to be in the terminal phase of the illness (the second applicant in application no. 47039/11 is the first applicant's mother). Having either tried a host of conventional treatments (surgery, chemotherapy radiotherapy, hormone therapy, etc.) or obtained a medical opinion that such forms of treatment would not work in their respective cases or were not available in Bulgaria, all of them approached a private clinic in Sofia, the Medical Centre for Integrative Medicine OOD ("*Медицински център Интегративна Медицина ООД*"), where they were informed about an experimental anticancer product (MBVax Coley Fluid) which is being developed by a Canadian company – MBVax Bioscience Inc. According to information from that company, their product has not been licensed for use in any country, but has been approved for compassionate use (for a definition of the term, see paragraph 27 below) in a number of countries (the Bahamas, China, Germany, Ireland, Israel, Mexico, Paraguay, South Africa, Switzerland, the United Kingdom, and the United States of America). In a letter of 9 January 2011 to the Bulgarian Ministry of Health, the company said that within its pre-clinical development phase it would be willing to provide the product free of charge to Medical Centre for Integrative Medicine OOD, for use on cancer patients who could no longer benefit from conventional therapies, in return for data on the treatment's adverse and beneficial effects in each patient. It appears that Medical Centre Integrative Medicine OOD has on a number of occasions in the past few years applied for permission to import and use the product, to no avail.

6. According to the applicants, MBVax Coley Fluid has been used with some success on patients in clinics in Germany, Ireland, the United Kingdom, and the United States of America.

7. It appears that on 23 July 2011 one of the applicants, Mr Petrov, travelled to Germany, where he had the product provided by MBVax

Bioscience Inc. free of charge and administered seven times. However, shortly after that the applicant returned to Bulgaria because he could no longer afford to pay his living expenses in Germany and the fees of the medical institution which administered the treatment.

8. Each of the applicants applied to the Executive Drugs Agency ("*Изпълнителна агенция по лекарствата*") for permission to use MBVax Coley Fluid. In letters of 20 June, 15 July and 1 and 31 August 2011 the Director of the Agency pointed out that MBVax Coley Fluid was an experimental product not yet licensed or undergoing clinical trials in any country, which meant that it could not be authorised for use in Bulgaria under Regulations no. 2 of 2001 (see paragraph 14 and 15 below). He went on to say that Bulgarian law made no provision for the use of unlicensed medicines outside clinical trials, and that, unlike the situation in other European countries, under the current legal framework in Bulgaria the compassionate use of unlicensed medicines was not possible. Under the law of the European Union, there was no obligation to have a harmonised approach to the compassionate use of unlicensed medicines. In some of the letters the Director added, without going into detail, that the information the applicants had about MBVax Coley Fluid was incorrect.

9. Some of the applicants appealed to the Minister of Health, who in a letter of 13 July 2011 fully agreed with the position expressed by the Executive Drugs Agency.

10. Three of the applicants in application no. 358/12 applied to the Ombudsman of the Republic. In letters of 22 July and 4 and 14 September 2011, the Ombudsman also informed them that MBVax Coley Fluid had not been licensed in any country, which meant that the only way in which they could obtain access to it in Bulgaria was within the framework of a clinical trial.

11. The applicants have not sought judicial review.

12. On 27 October 2011 the Sofia Regional Health Directorate decided to strike Medical Centre for Integrative Medicine OOD out of the register of health institutions, citing its carrying out of activities in breach of established medical standards. The clinic sought judicial review of the decision. The proceedings are currently pending before the Sofia Administrative Court. A hearing was held on 8 December 2011 and a second hearing is listed for 24 February 2012.

B. Relevant domestic law

1. The Medical Products in Human Medicine Act 2007 and regulations issued under it

13. Section 9(1) of the Medical Products in Human Medicine Act 2007 (*Закон за лекарствените продукти в хуманната медицина*) provides

that a patient may be treated with a medical product that has not been duly licensed if a hospital makes a request in that respect. The manner and the conditions for doing so are to be laid down in regulations by the Minister of Health.

14. The regulations governing that issue at the time when the applicants made their requests to be allowed to use MBVax Coley Fluid were Regulations no. 2 of 10 January 2001 (*Наредба № 2 от 10 януари 2001 г. за условията и реда за лечение с неразрешени за употреба в Република България лекарствени продукти*).

15. Regulation 2 of those Regulations provided that medical products that had not been licensed in the country could be prescribed if they had been licensed in other countries and were intended for the treatment of rare diseases or diseases having specific symptoms, when treatment with licensed medicines had proved fruitless.

16. The procedure for this was as follows. A panel of three medical doctors appointed by the head of the hospital (one of the doctors being a specialist in the treatment of the disease in issue) had to prescribe the unlicensed product (regulations 3(1) and 3(2)). The prescription could not cover a period of more than three months (regulation 3(4)). After that the prescription had to be approved by the head of the hospital (regulation 3(3)) and sent to the Executive Drug Agency, along with a declaration by the patient (or his or her parent or guardian, as the case might be) that he or she agrees to be treated with the unlicensed product (regulation 4(2)). The Executive Drug Agency had ten working days to decide whether to grant authorisation. If the relevant requirements had not been met, the Agency would issue a negative decision, which could be appealed within seven days before the Minister of Health who had to decide the appeal within seven days (regulation 5(1)).

17. If the need for an unlicensed life-saving product arose in a medical institution other than a hospital, the head of that institution could draw up a document specifying the product and the required quantity and, having obtained the assent of the Executive Drug Agency, apply for permission to the Minister of Health. The Minister could then make a decision setting out the product, the quantity and the recipients (regulation 8(1)).

18. In early December 2011 those regulations were superseded by Regulations no. 10 of 17 November 2011 (*Наредба № 10 от 17 ноември 2011 г. за условията и реда за лечение с неразрешени за употреба в Република България лекарствени продукти, както и за условията и реда за включване, промени, изключване и доставка на лекарствени продукти от списъка по чл. 266а, ал. 2 от Закона за лекарствените продукти в хуманната медицина*).

19. Regulation 1(2) provides that only medical products that can be prescribed by a doctor in another country can be authorised for use under the Regulations. Regulation 2(1) provides that medical products intended

for use by an individual patient may be prescribed if they are allowed for use in other countries and treatment with medicines licensed in Bulgaria is impossible or has failed. Regulation 3(1) provides that hospitals may also obtain unlicensed medical products if those have been made available under "international and national programmes" or by an international organisation which is the only entity in a position to procure those products.

20. The procedure under the new regulations is as follows. A panel of three medical doctors appointed by the head of the hospital (one of the doctors being a specialist in the treatment of the disease at issue) must prescribe the unlicensed product (regulations 4, 5(1) and 6(1)). The prescription has to be accompanied by the written informed consent of the patient (or his or her parent or guardian, as the case may be) (regulations 5(2) and 6(4)), and cannot cover a period of more than three months (regulations 5(3) and 6(2)). The prescription must then be approved by the head of the hospital (regulation 7(1)). After that the Executive Drug Agency must either grant permission or issue a reasoned refusal (regulation 8(1)). It must issue such a refusal if the form of the prescription or the medical products at issue do not meet the requirements of the Regulations (regulation 8(2)). The Agency's refusal is subject to appeal and judicial review (regulation 8(3)).

21. On 21 July 2011 Parliament added a new section 266a to the 2007 Act. It came into force on 5 August 2011 and provides, in subsection 1, that where it is not possible to treat a disease with medicines available in the country, an individual patient may be treated with a product that has been licensed in another Member State of the European Union and under the Act, but is not being marketed in Bulgaria. The Minister of Health must keep a list of such products and update it annually (subsection 2). The explanatory notes to the amendment bill referred to the need to allow Bulgarian patients access to licensed medicines that are not available on the Bulgarian market but are available in other Member States of the European Union.

2. The Code of Administrative Procedure

22. Under the Code of Administrative Procedure, individual administrative decisions may be challenged by those affected by them before a court on grounds of unlawfulness (Articles 145 § 1 and 147 § 1). As a rule, there is no requirement to first exhaust administrative remedies (Article 148).

23. Statutory instruments, such as regulations, may also be challenged before the Supreme Administrative Court (Articles 185 § 1 and 191 § 1). Any individual or organisation whose rights, freedoms or legal interests have been or could be affected by such an instrument may do so (Article 186 § 1). The court's decision has effect *erga omnes* (Article 193 § 2). If the court annuls a statutory instrument, it is deemed repealed from the date on which the court's decision becomes final (Article 195 § 1).

C. Relevant European Union law

24. Article 5 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended, provides, in so far as relevant:

> "1. A Member State may, in accordance with legislation in force and to fulfil special needs, exclude from the provisions of this Directive medicinal products supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of an authorised health-care professional and for use by an individual patient under his direct personal responsibility.
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> ...
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> 3. Without prejudice to paragraph 1, Member States shall lay down provisions in order to ensure that marketing authorisation holders, manufacturers and health professionals are not subject to civil or administrative liability for any consequences resulting from the use of a medicinal product otherwise than for the authorised indications or from the use of an unauthorised medicinal product, when such use is recommended or required by a competent authority in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm. Such provisions shall apply whether or not national or Community authorisation has been granted.
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> 4. Liability for defective products, as provided for by Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States, concerning liability for defective products (1), shall not be affected by paragraph 3."

25. Article 6 § 1 of the same Directive provides as follows:

> "No medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State in accordance with this Directive or an authorisation has been granted in accordance with Regulation (EC) No 726/2004, read in conjunction with Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and Regulation (EC) No 1394/2007."

26. Recital 33 of Regulation no. 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency says the following:

> "In order to meet, in particular, the legitimate expectations of patients and to take account of the increasingly rapid progress of science and therapies ... [i]n the field of medicinal products for human use, a common approach should also be followed, whenever possible, regarding the criteria and conditions for the compassionate use of new medicinal products under Member States' legislation."

27. Article 83 of the Regulation provides as follows:

"1. By way of exemption from Article 6 of Directive 2001/83/EC Member States may make a medicinal product for human use belonging to the categories referred to in Article 3(1) and (2) of this Regulation available for compassionate use.

2. For the purposes of this Article, 'compassionate use' shall mean making a medicinal product belonging to the categories referred to in Article 3(1) and (2) available for compassionate reasons to a group of patients with a chronically or seriously debilitating disease or whose disease is considered to be life-threatening, and who can not be treated satisfactorily by an authorised medicinal product. The medicinal product concerned must either be the subject of an application for a marketing authorisation in accordance with Article 6 of this Regulation or must be undergoing clinical trials.

3. When a Member State makes use of the possibility provided for in paragraph 1 it shall notify the Agency.

4. When compassionate use is envisaged, the Committee for Medicinal Products for Human Use, after consulting the manufacturer or the applicant, may adopt opinions on the conditions for use, the conditions for distribution and the patients targeted. The opinions shall be updated on a regular basis.

5. Member States shall take account of any available opinions.

6. The Agency shall keep an up-to-date list of the opinions adopted in accordance with paragraph 4, which shall be published on its website. Article 24(1) and Article 25 shall apply *mutatis mutandis*.

7. The opinions referred to in paragraph 4 shall not affect the civil or criminal liability of the manufacturer or of the applicant for marketing authorisation.

8. Where a compassionate use programme has been set up, the applicant shall ensure that patients taking part also have access to the new medicinal product during the period between authorisation and placing on the market.

9. This Article shall be without prejudice to Directive 2001/20/EC [the Clinical Trials Directive] and to Article 5 of Directive 2001/83/EC."

28. On 19 July 2007 the European Medicines Agency adopted a Guideline on compassionate use of medicinal products pursuant to Article 83 (EMEA/27170/2006).

D. Relevant comparative material

1. Compassionate use programmes

29. According to a survey published on 12 November 2010 by the European Clinical Research Infrastructures Network ("*Whitfield et al.*: Compassionate use of interventions: results of a European Clinical Research

Infrastructures Network (ECRIN) survey of ten European countries. *Trials* 2010 11:104.", available at http://www.trialsjournal.com/content/11/1/104), Austria, Denmark, France, Germany, Ireland, Italy, Spain, Sweden, Switzerland and the United Kingdom have compassionate use programmes in place.

30. In the United States of America, regulations were issued in May 1987 laying down conditions under which promising new drugs that had not yet been licensed could be made available to persons with serious and life threatening illnesses, for whom no comparable or satisfactory alternative drug or therapy was available. Those regulations were revised and expanded in 2009. They are currently contained in the Code of Federal Regulations, Title 21, Part 312, Subpart I (Expanded Access to Investigational Drugs for Treatment Use), §§ 312.300-320, and make provision for an "expanded access" programme, under which the Food and Drug Administration ("the FDA") may, under certain conditions, authorise the use of an "investigational new drug" in respect of patients suffering from "a serious or immediately life-threatening disease or condition, [when] there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition" (21 CFR 312.305(a)(1)). The general criteria governing FDA's decision is whether "[t]he potential patient benefit justifies the potential risks of the treatment use and those potential risks are not unreasonable in the context of the disease or condition to be treated" and whether "[p]roviding the investigational drug for the requested use will not interfere with the initiation, conduct, or completion of clinical investigations that could support marketing approval of the expanded access use or otherwise compromise the potential development of the expanded access use" (21 CFR 312.305(a)(2) and (3)). The regulations contain separate provisions for individual patients (21 CFR 312.310), intermediate-size patient populations (21 CFR 312.315), and widespread treatment use (21 CFR 312.320).

31. In Canada, sections C.08.010 and C.08.011 of the Food and Drug Regulations make provision for a "special access programme" allowing medical practitioners to request access to drugs that are unavailable for sale in Canada, for the treatment of patients with serious or life-threatening conditions on a compassionate or emergency basis when conventional therapies have failed, are unsuitable, or are unavailable.

32. In Australia, the Therapeutic Goods Administration of the Department of Health and Ageing runs a "special access scheme", which allows, under certain conditions, the importation or supply of an unlicensed medicines for a single patient, on a case by case basis (section 18 of the Therapeutic Goods Act 1989 and regulation 12A of the Therapeutic Goods Regulations 1990).

2. Relevant case-law

33. In *United States v. Rutherford*, 442 U.S. 544 (1979), the United States Supreme Court unanimously dismissed a request by terminally ill cancer patients to enjoin the authorities from interfering with the distribution of an unlicensed drug. The court held that the statutory scheme governing drug licensing did not contain an implicit exemption for drugs intended for use by the terminally ill. In its view, the safety and effectiveness standards laid down in the legislation applied equally to such drugs, because the legislature could be regarded as intending to protect terminal patients from ineffectual or unsafe drugs. For such patients, as for anyone else, a drug was unsafe if its potential for inflicting death or physical injury was not offset by the possibility of therapeutic benefit. In relation to terminally ill people, unlicensed drugs carried a further risk – that the individuals concerned might eschew conventional therapy in favour of a drug with no demonstrable curative properties, with potentially irreversible consequences. In that connection the court noted, on the basis of expert evidence presented to it, that with diseases such as cancer it was often impossible to identify a patient as terminally ill except in retrospect. It went on to say that acceptance of the proposition that the statutory safety and efficacy standards have no relevance for terminal patients would be tantamount to denying the authorities' power to regulate all drugs, however toxic or ineffectual, for such individuals, which would allow abusive marketing of many purportedly simple and painless cures. Lastly, the court observed that its ruling did not foreclose all resort to experimental cancer drugs by patients for whom conventional therapy was unavailing, because the statutory scheme exempted from premarketing approval drugs intended solely for investigative use if they satisfied certain preclinical testing and other criteria.

34. In the more recent case of *Abigail Alliance for Better Access to Developmental Drugs et al. v. von Eschenbach et al.*, in a decision of 2 May 2006 (445 F.3d 470) a three-member panel of the United States Court of Appeals for the District of Columbia Circuit held, by two votes to one, that under the due process clause of the United States Constitution terminally ill patients had the right to decide whether to take un unlicensed drug that was in Phase 2 or Phase 3 clinical trials and that the producer was willing to make available. The court found that that right was deeply rooted in the traditional doctrines of self-defence and interference with rescue, and that federal regulation of the effectiveness of drugs was too recent and haphazard "to establish that the government has acquired title to [that] right by adverse possession". The panel went on to say that that right was "implicit in the concept of ordered liberty".

35. On an application by the FDA, the same court reheard the case *en banc* and in a decision of 7 August 2007 (495 F.3d 695) held, by eight votes to two, that federal regulation of drugs was "consistent with [the] historical

tradition of prohibiting the sale of unsafe drugs". The "arguably limited" history of efficacy regulation prior to 1962, when such regulation in the United States had taken its current shape, did not establish a fundamental right, because the legislature and the executive had "continually responded to new risks presented by an evolving technology" and because the legislature had a "well-established power to regulate in response to scientific, mathematical, and medical advances". The court went on to say that self-defence, the tort of interference with rescue, and the United States Supreme Court's "life or health of the mother" abortion cases provided no support for a right to seek investigational drugs, because those doctrines protected only "necessary" life-saving measures, whereas the claimants sought "access to drugs that [were] experimental and [had] not been shown to be safe, let alone effective at (or 'necessary' for) prolonging life".

36. On 14 January 2008 the United States Supreme Court denied certiorari (552 U.S. 1159).

37. In *Abney et al. v. Amgen, Inc.*, 443 F.3d 540, on 29 March 2006, the United States Court of Appeals for the Sixth Circuit upheld the lower court's decision not to issue an injunction sought by the claimants, individuals involved in a clinical drug trial sponsored by the defendant, a drug manufacturer, to require the defendant to keep on providing them with the drug even though the clinical trial had come to an end.

38. In *Delisle v. Canada (Attorney General)*, 2006 FC 933, the Federal Court of Canada had to deal with applications for judicial review of decisions taken by the Canadian federal health authorities under the above-mentioned special access programme (see paragraph 31 above). The court held that in deciding to restrict access to a drug previously available under the programme, the authorities had failed to strike a proper balance because they had not taken due account of humanitarian or compassionate concerns. It referred the matter back to the authorities with instructions to weigh the "valid objectives of public policy against the humanitarian factor". The judgment was not appealed against, and in 2008 the case was settled, with the authorities agreeing to follow the court's recommendations.

39. In *B (a minor), R. (on the application of) v. Cambridge Health Authority* [1995] EWCA Civ 43 (10 March 1995), the England and Wales Court of Appeal held that the courts could not disturb a properly reasoned decision by the competent health authorities not to fund a round of experimental treatment of a terminally ill child. The Master of the Rolls, Sir Thomas Bingham (as he then was) made two general comments. He firstly pointed out that the case involved the life of a young patient, which was a fact which had to dominate all consideration of all aspects of the case, because British society was one in which a very high value was put on human life and no decision affecting human life could be regarded with other than the greatest seriousness. He secondly observed that the courts were not arbiters as to the merits of cases of that kind, because if they

expressed opinions as to the likelihood of the effectiveness of medical treatment, or as to the merits of medical judgment, they would be straying far from their domain. He went on to say that difficult and agonising judgments had to be made as to how a limited budget was best allocated to the maximum advantage of the maximum number of patients. That was not a judgment which a court could make.

COMPLAINTS

40. The applicants complain under Article 2 § 1 of the Convention that under Bulgarian law there is no possibility whatsoever for individuals who are in the terminal phase of a disease and who have unsuccessfully exhausted all conventional methods of treatment to obtain authorisation to use unlicensed medicines (the so-called "compassionate use"). They further complain of the allegedly incoherent and slow actions of the authorities in relation to their requests to obtain such authorisation, arguing that that was due to the lack of clear rules in that domain.

41. The applicants complain under Article 3 of the Convention that the authorities' refusal to grant authorisation to use the unlicensed medicine in their case amounted to inhuman and degrading treatment.

42. The applicants complain under Article 8 of the Convention that the above-mentioned refusal amounted to an unjustified interference with their right for respect for their private and family life.

43. The applicants complain under Article 14 of the Convention that they are being discriminated against *vis-à-vis* individuals residing in countries in which it is possible to use unlicensed medicines in respect of terminally ill patients on a "compassionate use" basis.

44. The applicants complain under Article 13 of the Convention that they do not have effective remedies in respect of the above-mentioned breaches of the Convention.

THE LAW

45. As the two applications are based on similar facts and as they contain identical complaints, the Court considers it appropriate to join them under Rule 42 § 1 of the Rules of Court.

46. In respect of their complaint that under Bulgarian law there was no possibility for individuals who were in the terminal phase of a disease and who had unsuccessfully exhausted all conventional methods of treatment to obtain authorisation to use unlicensed medicines, the applicants relied on

Article 2 § 1 of the Convention which, in so far as relevant, provides as follows:

> "Everyone's right to life shall be protected by law."

47. In respect of their complaint that the authorities had refused to grant authorisation to use the unlicensed medicine in their cases, the applicants relied on Article 3 of the Convention which provides as follows:

> "No one shall be subjected to torture or to inhuman or degrading treatment or punishment."

48. In respect of their complaint that the refusal to grant authorisation to use the unlicensed medicine in their case had amounted to an unjustified interference with their right for respect for their private and family life, the applicants relied on Article 8 of the Convention which, in so far as relevant, provides as follows:

> "1. Everyone has the right to respect for his private and family life...
>
> 2. There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others."

49. The Court considers that it cannot, on the basis of the case file, determine the admissibility of the above complaints and that it is therefore necessary, in accordance with Rule 54 § 2 (b) of the Rules of Court, to give notice of this part of the application to the respondent Government.

50. In respect of their complaint that they are discriminated against *vis-à-vis* individuals residing in countries in which it was possible to use unlicensed medicines in respect of terminally ill patients on a "compassionate use" basis, the applicants relied on Article 14 of the Convention, which provides as follows:

> "The enjoyment of the rights and freedoms set forth in [the] Convention shall be secured without discrimination on any ground such as sex, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status."

51. The Court observes that Article 14 protects against a discriminatory difference in the treatment of persons in analogous positions in the exercise of the rights and freedoms recognised by the Convention and its Protocols. It notes in this connection that in different countries there is no uniform approach to legislation in particular areas. Whether or not a person can assert a right derived from legislation may accordingly depend on that legislation's territorial reach and the person's location at the material time. For the Court, the difference in treatment between the applicants, as individuals residing in Bulgaria, and individuals residing in other countries is not to be explained in terms of personal characteristics, such as national

origin, but rather in terms of the geographical location where a particular form of medical treatment is authorised and available. Differences between the laws of the Contracting States stem from their sovereign right to regulate differently similar domains and does not amount to discriminatory treatment within the meaning of Article 14 (see, *mutatis mutandis*, *Magee v. the United Kingdom*, no. 28135/95, § 50, ECHR 2000-VI).

52. It follows that this complaint is manifestly ill-founded and must be rejected in accordance with Article 35 §§ 3 (a) and 4 of the Convention.

For these reasons, the Court

Decides unanimously to join the applications;

Decides by a majority to adjourn the examination of the applicants' complaints under Articles 2, 3 and 8 of the Convention concerning the authorities' refusal to grant authorisation to use the unlicensed medicinal product that they wished to use for treatment, and their complaint under Article 13 of the Convention concerning the alleged lack of effective remedies in that respect;

Declares unanimously the remainder of the applications inadmissible.

Lawrence Early
Registrar

Lech Garlicki
President