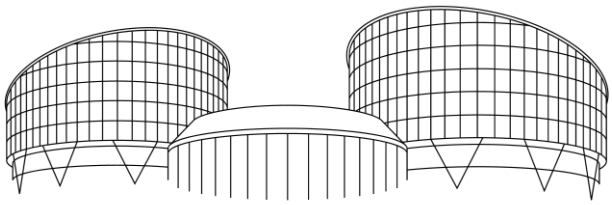

EUROPEAN COURT OF HUMAN RIGHTS
COUR EUROPÉENNE DES DROITS DE L'HOMME

FOURTH SECTION

**CASE OF HRISTOZOV AND OTHERS v. BULGARIA**

*(Applications nos. 47039/11 and 358/12)*

JUDGMENT

STRASBOURG

13 November 2012

*This judgment will become final in the circumstances set out in Article 44 § 2 of the Convention. It may be subject to editorial revision.*

**In the case of Hristozov and Others v. Bulgaria,**

The European Court of Human Rights (Fourth Section), sitting 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 deliberated in private on 9 October 2012,

Delivers the following judgment, which was adopted on that date:

# PROCEDURE

1. The case originated in two applications (nos. 47039/11 and 359/12) against the Republic of Bulgaria lodged with the Court under Article 34 of the Convention for the Protection of Human Rights and Fundamental Freedoms ("the Convention") by ten Bulgarian nationals, Mr Zapryan Hristozov Hristozov, Ms Anna Staykova-Petermann, 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 ("the applicants"), on 15 July 2011 and 5 December 2011 respectively.

2. The applicants were represented by Mr M. Ekimdzhiev, Ms K. Boncheva and Ms G. Chernicherska, lawyers practising in Plovdiv. The Bulgarian Government ("the Government") were represented by their Agent, Ms N. Nikolova, of the Ministry of Justice.

3. The applicants alleged, in particular, that the authorities' refusal to give them authorisation to use an experimental medicinal product that they wished to have administered by way of "compassionate use" had been in breach of their right to life, had amounted to inhuman and degrading treatment, and had breached their right to respect for their private and family life. They also alleged that they did not have an effective remedy in that respect.

4. On 31 August 2011 Mr Hristozov died. His mother and father, who are also his legal heirs, Ms Staykova-Petermann (the second applicant in application no. 358/12) and Mr Hristoz Zapryanov Hristozov, expressed the wish to pursue the proceedings in his stead. On 20 December 2011 Mr Petrov also died. His widow and daughter, who are also his legal heirs,

Ms Zhivka Stankova Ivanova-Petrova and Ms Veneta Petrova Dimitrova-Paunova, expressed the wish to pursue the proceedings in his stead. On 16 December 2011 Mr Behar also died. His widow and two sons, who are also his legal heirs, Ms Vera Petrova Behar, Mr Leonid David Behar and Mr Samson David Behar, expressed the wish to pursue the proceedings in his stead. On 6 March 2012 Ms Pencheva died as well. Her widower and daughter, who are also her legal heirs, Mr Yordan Penev Penchev and Ms Vera Yordanova Peykova, expressed the wish to pursue the proceedings in her stead.

5. On 9 February 2012 the President of the Fourth Section, to which the cases had been allocated, decided to give priority to the applications under Rule 41 of the Rules of Court.

6. On 21 February 2012 the Court (Fourth Section) decided to join the applications. It declared them partly inadmissible and gave the Government notice of the complaints concerning the authorities' refusal to allow the applicants to use the above-mentioned experimental medicinal product and of the complaint concerning the alleged lack of effective remedies in that respect. It was also decided to examine the merits of the applications at the same time as their admissibility (Article 29 § 1 of the Convention).

# THE FACTS

## I. THE CIRCUMSTANCES OF THE CASE

7. The applicants were born in 1977, 1954, 1948, 1947, 1948, 1973, 1948, 1966, 1935 and 1947 respectively and live(d) in Plovdiv, Godech, Dobrich, Kazanlak, Plovdiv, Ruse, Samokov and Sofia respectively.

8. The first applicant in application no. 47039/11 and all eight applicants in application no. 358/12 have/had various types of cancer and appear to be in its terminal phase. (The second applicant in application no. 47039/11 is the first applicant's mother.) Four of them succumbed to the illness shortly after lodging their applications (see paragraph 4 above).

9. 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 told 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 authorised in any country, but has been allowed for "compassionate

use" (for a definition of that term and comparable terms, see paragraphs 50, 56 and 57 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, but to no avail.

10. The parties were in dispute as to whether MBVax Coley Fluid had recently started undergoing clinical trials. The applicants said that according to data extracted on 18 April 2012 from the website of the United States National Cancer Institute and a website maintained by the United States National Library of Medicine, Mixed Bacteria Vaccine (MBV) was undergoing a phase one clinical trial in Germany. On that basis, they argued that it complied with the requirements of Article 83 § 2 of Regulation (EC) no. 726/2004 (see paragraph 50 below). The Government disputed that averment and submitted that it was not permissible to establish the existence of clinical trials in Germany through information from websites in the United States of America.

11. The Government further submitted that MBVax Coley Fluid could not be described as a medicinal product within the meaning of the applicable European Union and domestic provisions. The applicants replied that the fact that it had not been authorised did not mean that it was not a medicinal product within the meaning of those provisions.

12. 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. In support of their averment, the applicants presented a number of letters and electronic mail messages from medical practitioners.

13. It appears that on 23 July 2011 one of the applicants, Mr Petrov, travelled to Germany, where he obtained the product from MBVax Bioscience Inc. free of charge and had it administered seven times. However, shortly afterwards he returned to Bulgaria because he could no longer afford to pay his living expenses in Germany or the fees of the health-care institution which administered the treatment.

14. Each of the applicants – including Ms Staykova-Petermann who acted on behalf of her sick son – applied to the authorities for permission to use MBVax Coley Fluid. In letters of 20 June, 15 July and 1 and 31 August 2011 the Director of the Executive Medicines Agency (*Изпълнителна агенция по лекарствата*), the authority in charge of supervising the

quality, safety and efficacy of medicinal products, pointed out that MBVax Coley Fluid was an experimental product not yet authorised 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 25 and 26 below). He went on to say that Bulgarian law made no provision for the use of unauthorised medicines outside clinical trials, and that, unlike the situation obtaining in other European countries, in Bulgaria the compassionate use of unauthorised products was not possible. Under the law of the European Union, there was no obligation to have a harmonised approach in this area. In some of the letters the Director added, without going into detail, that the information the applicants had about MBVax Coley Fluid was incorrect.

15. 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 Medicines Agency.

16. 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 authorised 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.

17. The applicants have not sought judicial review.

18. 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 by the Sofia Administrative Court. A hearing was held on 8 December 2011. A second hearing was listed for 24 February, but was adjourned for 14 June 2012, then for 5 October 2012, and then for 12 October 2012. The case is still pending before the Sofia Administrative Court.

## II. RELEVANT DOMESTIC LAW

### A. The Constitution

19. Article 52 of the Constitution of 1991 provides, in so far as relevant:

> "1. Citizens shall be entitled to medical insurance guaranteeing them affordable healthcare, and to free health care under the conditions and in the manner provided for by law.
>
> ...
>
> 3. The State shall protect the health of all citizens ... .

4. No one may be subjected to forcible medical treatment or sanitary measures except in cases provided for by law.

5. The State shall exercise control over all health-care establishments and over the production of and trade in medicines, biologically active substances and medical equipment."

20. In a decision of 22 February 2007 (реш. № 2 от 22 февруари 2007 г. по к. д. № 12 от 2006 г., обн., ДВ, бр. 20 от 6 март 2007 г.) the Constitutional Court said that unlike classical fundamental rights, such as the rights to life, freedom and security, private life, freedom of thought or of religion, the rights under Article 52 § 1 of the Constitution were social rights. They could not be directly enforced by the courts, and required State action for their realisation. For that reason, the Constitution specified that health care was to be carried out in a manner provided for by law.

## B. The Medicinal Products in Human Medicine Act 2007 and related regulations

21. Medicinal products in human (as opposed to veterinary) medicine are regulated by the Medicinal Products in Human Medicine Act 2007 (*Закон за лекарствените продукти в хуманната медицина*). Section 3(1) of that Act, which echoes Article 1 § 2 of Directive 2001/83/EC (see paragraph 44 below), defines a "medicinal product in human medicine" as (a) any substance or combination of substances presented as having properties for treating or preventing disease in human beings, or (b) any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis. Section 3(2), which echoes Article 1 § 3 of the Directive, in turn defines "substance" as any matter whose origin may be human (human blood, human blood products, etc.), animal (microorganisms, animal organs, extracts, secretions, toxins, blood products, etc.), vegetable (microorganisms, plants, parts of plants, vegetable extracts, secretions, etc.), chemical (elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis, etc.).

22. Section 7(1) of the Act lays down the general rule that only medicinal products which have been authorised – in Bulgaria or under the centralised authorisation procedure under Regulation (EC) no. 726/2004 (see paragraph 48 below) – may be produced, imported, traded in, advertised, or used for medical treatment, prophylaxis or diagnostics.

23. The following sections set out certain exceptions to that rule. Section 8 provides that no authorisation is required in respect of, in particular, (a) medicinal products prepared in a pharmacy in accordance with a medical prescription for an individual patient (the magistral formula);

(b) medicinal products prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia (the officinal formula); and (c) medicinal products for "high-technology therapy" prepared for an individual patient in accordance with the individualised specifications of a medical doctor and for use in a health-care institution under the doctor's direct personal responsibility. Section 10(1) empowers the Minister of Health to allow, under certain conditions, treatment with an unauthorised medicinal product in the case of an epidemic or of a chemical or nuclear contamination, if there is no suitable authorised medicinal product. Section 11(1) empowers the Minister to allow, under certain conditions, the use of a product which has not been authorised in Bulgaria but has been authorised in another Member State of the European Union.

24. Section 9(1) provides that a patient may be treated with a medicinal product which has not been authorised 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.

25. 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*). They superseded Regulations no. 18 of 28 June 1995 (*Наредба № 18 от 28 юни 1995 г. за условията и реда за лечение с нерегистрирани лекарствени средства*). Both of those regulations had been issued under section 35(3) of the Medicines and Pharmacies in Human Medicine Act 1995 (*Закон за лекарствата и аптеките в хуманната медицина*), superseded by the 2007 Act, which provided that medicinal products needed for the treatment of diseases having specific symptoms, when treatment with authorised medicinal products had proved fruitless, were to be exempted from authorisation under conditions and in a manner laid down by the Minister of Health.

26. Regulation 2 of Regulations no. 2 provided that medicinal products which had not been authorised in the country could be prescribed if they had been authorised in other countries and were intended for the treatment of rare diseases or diseases having specific symptoms, when treatment with authorised medicinal products had proved fruitless.

27. Similar requirements had been laid down in regulation 1 of Regulations no. 18. Under that provision, medicinal products not registered in Bulgaria could be used only if registered in other countries and if the disease that they were purported to treat could either not be treated with products registered in Bulgaria or such treatment had proved fruitless.

28. The procedure under Regulations no. 2 was as follows. A panel of three medical doctors appointed by the head of a hospital (one of the doctors being a specialist in the treatment of the disease in issue) had to prescribe the unauthorised 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 Medicines Agency, along with a declaration by the patient (or his or her parent or guardian, as the case might be) that he or she agreed to be treated with the unauthorised product (regulation 4(2)). The Executive Medicines Agency had ten working days to decide whether to grant permission. 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)).

29. If the need for an unauthorised life-saving product arose in a health-care 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 Medicines 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)).

30. On 6 December 2011 Regulations no. 2 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*).

31. Regulation 1(2) provides that only medicinal products which can be prescribed by a doctor in another country can be allowed for use under the Regulations. Regulation 2(1) provides that medicinal products intended for use by an individual patient may be prescribed if they are authorised in other countries and treatment with medicinal products authorised in Bulgaria is impossible or has failed. Regulation 3(1) provides that hospitals may also obtain unauthorised medicinal 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.

32. The procedure under Regulations no. 10 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 unauthorised 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 Medicines Agency must either grant permission or issue a reasoned refusal

(regulation 8(1)). It must issue a refusal if the form of the prescription or the medicinal 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)).

33. 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 medicinal products available in the country, an individual patient may be treated with a product which has been authorised 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 authorised medicines that are not available on the Bulgarian market but are available in other Member States of the European Union.

34. There is no reported case-law under any of the three successive regulations (Regulations no. 18, Regulations no. 2 and Regulations no. 10).

### C. The Code of Administrative Procedure 2006

35. Under the Code of Administrative Procedure 2006, 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).

36. 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).

### D. Case-law provided by the Government

37. In a decision of 11 December 2008 (реш. № 13627 от 11 декември 2008 г. по адм. д. № 11799/2008 г., ВАС, петчл. с.) the Supreme Administrative Court struck down regulations which required telephony and internet service providers to give the Ministry of Internal Affairs "passive" technical access to the communications data they were storing. The court held that, in not laying down any conditions or procedures for the grant of such access, the regulations made possible disproportionate interferences with the rights protected under Article 32 (private life) and Article 34 (correspondence and communications) of the 1991 Constitution and under

Article 8 of the Convention, whereas such interferences had to be made subject to appropriate safeguards against abuse. The court went on to say that the regulations ran counter to various provisions of Directive 2006/24/EC on the retention of data generated or processed in connection with the provision of publicly available electronic communications services or of public communications networks and amending Directive 2002/58/EC.

38. In decisions of 25 March and 21 April 2011 (реш. № 384 от 25 март 2011 г. по адм. д. № 1739/2009 г., БАС; реш. № 701 от 21 април 2011 г. по адм. д. № 660/2011 г., ПАС) the Burgas and the Plovdiv administrative courts set aside international travel bans imposed on account of unpaid judicially established debts. In doing so the courts held that the provisions of Bulgarian law under which those bans had been ordered ran counter to Article 27 of Directive 2004/38/EC on the right of citizens of the European Union and their family members to move and reside freely within the territory of the Member States. Just before that, on 22 March 2011, the Supreme Administrative Court held, in a binding interpretative decision (тълк. р. № 2 от 22 март 2011 г. по т. д. № 6/2010 г., ВАС, ОСК), that such bans should be set aside if in breach of the Directive.

39. In a decision of 17 May 2010 (реш. от 17 май 2010 г. по адм. д. № 206/2010 г., МАС, I с.) the Montana Administrative Court set aside an order for the removal of an alien who had come to Bulgaria at a very young age and had lived in the country with his family for a number of years. The court held that the order, which had not taken into account the alien's family situation and level of integration in the country, and corresponding lack of ties with the country to which he was to be removed, had been disproportionate. To come to that conclusion, the court relied not only on the relevant provisions of Bulgarian law, but also on Article 8 of the Convention and on Article 78 § 1 of the Treaty on the Functioning of the European Union and Articles 16, 20 and 21 of Directive 2003/109/EC concerning the status of third-country nationals who are long-term residents.

40. In decisions of 28 June 2010 and 9 March 2012 (опр. № 14 от 29 юни 2010 г. по ч. к. а н. д. № 162/2010 г., ХАС, II к. с.; опр. № 10 от 9 март 2012 г. по к. н. а. х. д. № 117/2012 г., КАС) the Haskovo and Kyustendil administrative courts quashed lower courts' decisions to discontinue proceedings for judicial review of fines imposed by the authorities in respect of administrative offences (which had been excluded from judicial review by statute). The courts relied on Article 6 § 1 of the Convention and the Court's judgments in the cases of *Öztürk v. Germany* (21 February 1984, Series A no. 73) and *Lauko v. Slovakia* (2 September 1998, *Reports of Judgments and Decisions* 1998-VI).

## E. The rights of patients

41. A patient – defined as any person who has asked for or who is being given medical treatment (section 84(1) of the Health Act 2004) – has the right to, *inter alia*, (a) respect for his or her civil, political, economic, social, cultural and religious rights; (b) clear and accessible information on his or her state of health and the methods of treatment, if any; (c) security and safety of the diagnostic and treatment procedures used for his or her treatment; and (d) access to modern methods of treatment (section 86(1)(1), (1)(8), (1)(10) and (1)(11) of the same Act). Section 87(1) of the Act lays down the general rule that medical procedures may be carried out only with the patient's informed consent. In order to obtain such consent, the treating medical doctor has to inform the patient of (a) the diagnosis and the character of the disease; (b) the aims and the nature of the proposed treatment, the reasonable alternatives, the expected results and the prognosis; (c) the potential risks entailed by the proposed diagnostic and treatment methods, including side effects and adverse reactions, pain or other inconveniences; and (d) the chances of positive effects, as well as the risks to health entailed by other methods of treatment or by a refusal to submit to treatment (section 88(1)). All this information has to be given in an appropriate volume and form, so as to ensure the freedom of choice of treatment (section 88(2)). In cases of surgical intervention, general anaesthesia or other diagnostic or treatment methods which entail a heightened level of risk to life or health, this information – as well as the patient's informed consent – have to be in writing (section 89(1)).

## F. Regulation of the medical profession

42. The Medical Institutions Act 1999 governs, *inter alia*, the registration and licensing of medical institutions. By section 39(1), institutions for non-hospital care and hospices are subject to registration, which has to be carried out by the territorially competent health inspection (section 40(1)). By section 46(1), hospitals, complex oncological centres, and some other institutions which are not relevant to the present case are subject to licensing. The licence is issued by the Minister of Health (section 46(2)). Medical institutions can carry out their activities only if they have been registered or licensed, as the case may be (section 3(3)). Their medical activities are subject to control by the authorities (section 4(3)).

43. Practising medical professionals need to have an appropriate degree (section 183(1) and (2) of the Health Act 2004), and need to be registered members of a professional association (section 183(3)).

## III. RELEVANT EUROPEAN UNION LAW

44. In the European Union, a medicinal product may as a rule be placed on the market only when authorised, either via the so-called centralised authorisation procedure or under national procedures (there are detailed rules as to which products must or may go through the centralised procedure). The relevant provision, Article 6 § 1 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 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."

45. There are, however, exceptions to this rule, such as the possibility of obtaining an unauthorised medicinal product via "individual patient use", "compassionate use" or "off-label use". Article 5 § 1 of the above-mentioned Directive, which took up wording first introduced in 1989 by the now repealed Directive 89/341/EEC, governs "individual patient use". It reads as follows:

> "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."

46. On 29 March 2012 the Court of Justice of the European Union, in the case of *European Commission v. the Republic of Poland* (C-185/10) ruled that Poland, which had argued that its domestic law complied with the derogation envisaged by that provision, had failed to fulfil its obligations under the above-mentioned Article 6 of the Directive by allowing the importation and placing on the market of unauthorised medicinal products which were cheaper than and similar to products already authorised in Poland. The court said the following in relation to the construction to be put on the derogation provided for under Article 5 § 1 of the Directive:

> "30 As is apparent from the wording of that provision, implementation of the derogation for which it provides is conditional on fulfilment of a set of cumulative conditions.
>
> 31 In order to interpret that provision, it must be taken into account that, generally, provisions which are in the nature of exceptions to a principle must, according to settled case-law, be interpreted strictly (see in particular, to this effect, Case C-3/09 *Erotic Center* [2010] ECR I−2361, paragraph 15 and the case-law cited).

32 More specifically, as regards the derogation referred to in Article 5(1) of Directive 2001/83, the Court has already pointed out that the possibility of importing non-approved medicinal products, provided for under national legislation implementing the power laid down in that provision, must remain exceptional in order to preserve the practical effect of the marketing authorisation procedure (see, to this effect, Case C−143/06 *Ludwigs-Apotheke* [2007] ECR I−9623, paragraphs 33 and 35).

33 As the Advocate General stated in point 34 of his Opinion, the power, which arises from Article 5(1) of Directive 2001/83, to exclude the application of the directive's provisions can be exercised only if that is necessary, taking account of the specific needs of patients. A contrary interpretation would conflict with the aim of protecting public health, which is achieved through the harmonisation of provisions relating to medicinal products, particularly those relating to the marketing authorisation.

34 The concept of 'special needs', referred to in Article 5(1) of that directive, applies only to individual situations justified by medical considerations and presupposes that the medicinal product is necessary to meet the needs of the patient.

35 Also, the requirement that medicinal products are supplied in response to a 'bona fide unsolicited order' means that the medicinal product must have been prescribed by the doctor as a result of an actual examination of his patients and on the basis of purely therapeutic considerations.

36 It is apparent from the conditions as a whole set out in Article 5(1) of Directive 2001/83, read in the light of the fundamental objectives of that directive, and in particular the objective seeking to safeguard public health, that the derogation provided for in that provision can only concern situations in which the doctor considers that the state of health of his individual patients requires that a medicinal product be administered for which there is no authorised equivalent on the national market or which is unavailable on that market."

47. Separately, Article 126a of the Directive permits a Member State to allow a medicinal product authorised in another Member State to be placed on its market, under certain conditions. Paragraph 1 of that Article reads:

"In the absence of a marketing authorisation or of a pending application for a medicinal product authorised in another Member State in accordance with this Directive, a Member State may for justified public health reasons authorise the placing on the market of the said medicinal product."

Further conditions are laid down in paragraphs 2 and 3.

48. A further exception to the general prohibition laid down in Article 6 § 1 of Directive 2001/83/EC is contained in Article 83 of Regulation (EC) 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.

49. Recital 33 of the Regulation says, in so far as relevant:

"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."

50. Article 83 of the Regulation provides:

"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 [medicinal products to be authorised either mandatorily or optionally via the centralised authorisation procedure, listed in an annex to the 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."

51. In July 2007 the European Medicines Agency adopted a Guideline on compassionate use of medicinal products pursuant to the said Article 83 (EMEA/27170/2006). It says that the implementation of compassionate use programmes remains the competence of a Member State, that Article 83 is complementary to national legislations, and that the existence of a Community authorisation for a medicinal product is without prejudice to any national legislation relating to compassionate use. The guideline goes on to specify that the objectives of Article 83 are threefold: (a) facilitate and

improve the access of patients in the European Union to compassionate use programmes; (b) favour a common approach regarding the conditions of use, the conditions for distribution and the patients targeted for the compassionate use of unauthorised new medicinal products; and (c) increase transparency between Member States in terms of treatment availability. It also makes it clear that Article 83 is not applicable to products which are not eligible for the centralised authorisation procedure, and to compassionate use on a named-patient basis, envisaged in Article 5 of Directive 2001/83/EC (see paragraph 45 above).

52. The European Medicines Agency has until now given two opinions under Article 83 § 4 of the Regulation. The first, given on 20 January 2010 in respect of Finland, concerned the product "IV Tamiflu". The second, given on 18 February 2010 in respect of Sweden, concerned the product "IV Zanamivir".

53. A guideline drawn up by the European Commission pursuant to Article 106 of Directive 2001/83/EC and Article 24 of Regulation (EEC) no. 2309/93, and entitled "*Volume 9A – Guidelines on Pharmacovigilance for Medicinal Products for Human Use*", says the following:

> "**5.7. Reporting from Compassionate/Named-patient use**
>
> Compassionate or named-patient use of a medicine should be strictly controlled by the company responsible for providing the medicine and should ideally be the subject of a protocol.
>
> Such a protocol should ensure that the Patient is registered and adequately informed about the nature of the medicine and that both the prescriber and the Patient are provided with the available information on the properties of the medicine with the aim of maximising the likelihood of safe use. The protocol should encourage the prescriber to report any adverse reactions to the company, and to the Competent Authority, where required nationally.
>
> Companies should continuously monitor the risk-benefit balance of medicines used on compassionate or named-patient basis (subject to protocol or not) and follow the requirements for reporting to the appropriate Competent Authorities. As a minimum, the requirements laid down in Chapter I.4, Section 1 [Requirements for Expedited Reporting of Individual Case Safety Reports] apply.
>
> For inclusion of experience from compassionate or named-patient use in Periodic Safety Update Reports, see Chapter I.6 [Requirements for Periodic Safety Update Reports]."

## III. RELEVANT COMPARATIVE MATERIAL

### A. Rules governing access to unauthorised medicinal products

#### *1. In some Contracting States*

54. In November 2010 the European Clinical Research Infrastructures Network published a survey of "compassionate use" programmes in ten

European countries: Austria, Denmark, France, Germany, Ireland, Italy, Spain, Sweden, Switzerland and the United Kingdom ("*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."). It found that with one exception (Hungary) the laws of all countries surveyed made provision for compassionate use/expanded access programmes. However, it also showed that there were more differences than similarities in those programmes. Some countries were without formal regulatory systems, and for those who had adopted rules, they were varied in content and comprehensiveness. For instance, some countries allowed "compassionate use" solely on a "named/individual patient" basis. The contents and requirements of the application for permission also varied. The survey called for European Union legislation to be more explicit with regard to regulatory requirements, restrictions and responsibilities in that area.

55. On the basis of more recent material available to the Court in respect of twenty-nine Contracting States, it appears that twenty-two States (Austria, the Czech Republic, Croatia, Estonia, France, Finland, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, the Netherlands, Poland, Romania, Serbia, Slovenia, Spain, Turkey and the United Kingdom) have in place rules – often adopted quite recently – allowing access to unauthorised medicinal products outside clinical trials for certain patients, notably, those who are terminally ill. The matter appears to be regulated in both primary and delegated legislation. In addition, in two States (Sweden and Russia) access to such products appears to be possible despite the absence of specific rules. Five States (Albania, Cyprus, Moldova, Montenegro and Ukraine) appear not to have in place rules allowing access to unauthorised medicinal products outside clinical trials. However, in two of those (Albania and Ukraine) domestic law appears to contain somewhat unclear provisions which could be interpreted as allowing access. At the same time, there is a variety of practices among States as regards the type of access provided and the procedure to be followed. For instance, it appears that in four States (Croatia, Lithuania, Poland and Romania), access to unauthorised medicinal products is possible only if those products have been authorised in another jurisdiction. Seven States appear to allow access only for individual patients, and fifteen States allow access for both individual patients and groups (or cohorts). The procedures for individuals and groups as a rule vary, with the conditions attaching to group access being more stringent.

*2. In other States*

56. 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 the FDA's decision are 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, including for emergency use (21 CFR 312.310), intermediate-size patient populations (21 CFR 312.315), and widespread treatment use (21 CFR 312.320).

57. 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.

58. 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).

### B. Relevant case-law

#### *1. In the United States of America*

59. In the case of *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.

60. In the more recent case of *Raich v. Gonzales*, in a decision of 14 March 2007 (500 F.3d 850) the United States Court of Appeals for the Ninth Circuit held, *inter alia*, that, as things stood, there was no right under the due process clause of the United States Constitution to use medical marijuana on a physician's advice to preserve bodily integrity, avoid intolerable pain, and preserve life, even when all other prescribed medications and remedies had failed.

61. In the 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".

62. 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".

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

64. In the case of *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 a 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.

*2. In Canada*

65. In the case of *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 57 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.

*3. In the United Kingdom*

66. In the case of *B (a minor), R. (on the application of) v. Cambridge Health Authority* [1995] EWCA Civ 43 (10 March 1995), the 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.

67. In the case of *Simms v Simms and an NHS Trust* [2002] EWHC 2734 (Fam) (11 December 2002), the parents of two teenagers suffering from variant Creutzfeldt-Jakob disease sought judicial declarations that their children could receive an experimental treatment which research on mice had shown could possibly inhibit the advance of their terminal condition. The High Court of Justice (Family Division) allowed the applications, holding, among other things, that the lack of an alternative treatment for the incurable disease meant that it was reasonable to use an experimental treatment that presented no significant risk to the patient. The President of the Family Division, Dame Elizabeth Butler-Sloss, observed that the treatment was an untried one, and that until then there had been no validation of experimental work done abroad. However, she went on to say that if one waited for full certainty in experimental treatments, no innovative work such as the use of penicillin or performing heart transplant surgery would ever be attempted. Referring to, *inter alia*, Articles 2 and 8 of the Convention and "a very strong presumption in favour of a course of action which will prolong life", and having regard to the patients' prospects with and without treatment and the fact that no alternative treatment was available, she concluded that it was in their best interest that the treatment should be carried out. In reaching that conclusion, she also considered the wishes and feelings of the families, finding that their advocacy of treatment "should carry considerable weight".

# THE LAW

## I. PRELIMINARY ISSUE

68. The Government requested that the applications be partly struck out of the list of cases in accordance with Article 37 § 1 (c) of the Convention,

challenging the right of the heirs of four applicants who died in the course of the proceedings (Mr Hristozov, Mr Petrov, Ms Pencheva and Mr Behar – see paragraph 4 above) to pursue the applications in their stead. In their view, those heirs could not claim to be indirect victims and did not have a valid interest in obtaining a ruling by the Court because the alleged breaches of Articles 2, 3 and 8 of the Convention did not affect them, for two reasons. First, the authorities' refusal to allow the applicants access to the unauthorised medicinal product that they wished to have administered did not affect other individuals, such as their heirs. Secondly, the rights invoked by the applicants had been deeply personal in nature. Moreover, it was not the Court's task to determine in the abstract whether the relevant domestic law provisions were in line with the Convention.

69. The applicants did not comment on this point.

70. Article 37 § 1 of the Convention provides, in so far as relevant:

> "The Court may at any stage of the proceedings decide to strike an application out of its list of cases where the circumstances lead to the conclusion that
>
> ...
>
> (c) for any other reason established by the Court, it is no longer justified to continue the examination of the application.
>
> However, the Court shall continue the examination of the application if respect for human rights as defined in the Convention and the Protocols thereto so requires."

71. In a number of cases in which applicants have died in the course of the proceedings the Court has taken into account the statements of their heirs or close family members expressing the wish to pursue the proceedings, or the existence of a legitimate interest claimed by another person wishing to pursue the application (see, for example, *X v. France*, 31 March 1992, § 26, Series A no. 234-C; *Lukanov v. Bulgaria*, 20 March 1997, § 35, *Reports* 1997-II; and *Malhous v. the Czech Republic* (dec.) [GC], no. 33071/96, ECHR 2000-XII, with further references). Conversely, the Court and the former Commission have struck applications out of their lists in situations where the applicants had died in the course of the proceedings and either no one had come forward with the wish to pursue the application (see, for example, *Öhlinger v. Austria*, no. 21444/93, Commission's report of 14 January 1997, unreported, § 15; *Ibish v. Bulgaria* (dec.), no. 29893/06, 31 January 2011; and *Korzhenevich v. Russia* (dec.), no. 36799/05, 28 June 2011), or the persons who had expressed such a wish were not heirs or sufficiently close relatives of the applicants, and could not otherwise show a legitimate interest to pursue the application (see *Scherer v. Switzerland*, 25 March 1994, §§ 31-32, Series A no. 287; *S.G. v. France* (striking out), no. 40669/98, §§ 6 and 16, 18 September 2001; *Thévenon v. France* (dec.), no. 2476/02, ECHR 2006-III; *Léger v. France* (striking out) [GC], no. 19324/02, §§ 47-51, 30 March 2009; *Mitev v. Bulgaria* (dec.), no. 42758/07, 29 June

2010; and *Yanchev v. Bulgaria* (dec.) [Committee], no. 16403/07, 20 March 2012).

72. In the present case, the requests to pursue the proceedings were submitted by persons who have provided evidence of their status as both direct heirs and very close relatives of the deceased applicants (see paragraph 4 above).

73. It is true that under Article 34 the existence of a victim of a violation is indispensable for putting the Convention's protection mechanism into motion. However, this criterion cannot be applied in a rigid, mechanical and inflexible way throughout the proceedings (see, as a recent authority, *OAO Neftyanaya kompaniya YUKOS v. Russia* (dec.), no. 14902/04, § 441, 29 January 2009). The Court's approach to cases introduced by applicants themselves and only continued by their relatives after their death differs from its approach to cases in which the application has been lodged after the death of the direct victim (see *Fairfield and Others v. the United Kingdom* (dec.), 24790/04, 8 March 2005; *Biç and Others v. Turkey*, no. 55955/00, § 20, 2 February 2006; *Direkçi v. Turkey* (dec.), no. 47826/99, 3 October 2006; and *Grădinar v. Moldova*, no. 7170/02, § 91, 8 April 2008; *Dvořáček and Dvořáčková v. Slovakia*, no. 30754/04, § 39, 28 July 2009; and *Kaburov v. Bulgaria* (dec.), no. 9035/06, § 52, 19 June 2012). Moreover, the transferability – or otherwise – of the applicant's claim is not always decisive, for it is not only material interests which the successors of deceased applicants may pursue by their wish to maintain the application (see *Capital Bank AD v. Bulgaria*, no. 49429/99, § 78, ECHR 2005-XII (extracts)). Cases before the Court generally also have a moral or principled dimension and persons close to an applicant may thus have a legitimate interest in obtaining a ruling even after that applicant's death (see *Malhous*, cited above). This is particularly true in the present case, for two reasons. First, it concerns the application of the most fundamental provisions in the Convention system. Secondly, its subject matter is closely connected with the four applicants' deaths. In these circumstances, it would be contrary to the Court's mission to refrain from ruling on the complaints raised by the deceased applicants just because they did not, due to their serious diseases, have the strength and the time to await the outcome of the proceedings before it.

74. It cannot therefore be said that it is no longer justified to continue the examination of the applications in so far as they concern the four deceased applicants.

75. In view of this conclusion, the Court does not consider it necessary to address the question whether respect for human rights requires the continued examination of the applications, in so far as they concern the four deceased applicants (see *Karner v. Austria*, no. 40016/98, § 25, ECHR 2003-IX, and *Hirsi Jamaa and Others v. Italy* [GC], no. 27765/09, § 58, 23 February 2012).

## II. ADMISSBILITY OF THE COMPLAINTS UNDER ARTICLES 2, 3 AND 8 OF THE CONVENTION

### A. Victim status

76. The Government submitted that the applicants could not claim to be victims of a violation, for three reasons. First, they had received adequate medical treatment, had not been denied such treatment, and there was no indication that their state of health had worsened. Secondly, Bulgarian law allowed the "compassionate use" of unauthorised medicinal products. Thirdly, the applicants had not enrolled in a clinical trial that would have allowed them access to such products. Under European Union law there was no obligation, but simply a recommendation, to have a harmonised approach to the "compassionate use" of unauthorised medicinal products. MBVax Coley Fluid had not been authorised in any country and did not meet the criteria for "compassionate use" under European Union law.

77. The Government further argued that Ms Staykova-Petermann could not claim to be a victim of a violation in her own right.

78. The applicants did not comment on these points.

79. The Court observes that the issues raised by the first limb of the Government's objection are closely bound up with the merits of the complaints (see, *mutatis mutandis*, *Doğan and Others v. Turkey*, nos. 8803-8811/02, 8813/02 and 8815-8819/02, § 93, ECHR 2004-VI (extracts); *Al-Skeini and Others v. the United Kingdom* [GC], no. 55721/07, §§ 106-07, ECHR 2011-...; and *Hirsi Jamaa and Others*, cited above, § 111). The Court will therefore deal with those points when examining the substance of the complaints.

80. As for the second limb of the objection, the Court finds that, sadly, at this juncture the question whether Ms Staykova-Petermann may personally claim to be a victim is of no practical importance, because her late son was also an applicant and because, following his death, she expressed the wish to pursue the proceedings in his stead and the Court accepted that she was entitled to do so (see paragraphs 4, 73 and 74 above, and *Georgel and Georgeta Stoicescu v. Romania*, no. 9718/03, §§ 41-43, 26 July 2011).

81. The Government's objection must therefore be rejected.

### B. Exhaustion of domestic remedies

#### *1. The parties' submissions*

82. The Government submitted that the applicants had failed to exhaust domestic remedies in respect of their complaints under Articles 2, 3 and 8 of the Convention, because they had not sought judicial review of the decisions denying them the possibility to use MBVax Coley Fluid. They

said that they were not aware of cases in which the Bulgarian courts had dealt with the "compassionate use" of unauthorised medicinal products, and pointed out that those courts were not competent to declare what type of medical treatment should be applied in a particular case. It was nevertheless possible to refer the question raised by the case to a domestic court, and rely on arguments based on the Convention or on European Union law, in as much as the Convention was incorporated in Bulgarian law and the relevant rules of European Union law were directly applicable. The Government went on to draw attention to the conditions under which patients could seek access to unauthorised medicinal products, and expressed the view that in the applicants' cases those conditions had not been met.

83. In their additional observations on this point, the Government again argued that the applicants could have sought judicial review of the decisions denying them the possibility to use MBVax Coley Fluid or of the regulations on which those decisions had been based. In such proceedings the applicants could have relied on the Convention: the Bulgarian courts had on a number of occasions set aside administrative decisions or struck down regulations on account of their being inconsistent with the Convention or European Union law. The Government conceded that they could not speculate as to the outcome of such proceedings, but emphasised that in their view neither the decisions nor the regulations in issue were in breach of the Medicinal Products in Human Medicine Act 2007 or European Union law. The Act itself was fully consistent with the relevant European Union law, and therefore not in breach of the Convention. Regulations no. 2 and Regulations no. 10 both required that the medicinal product in issue be authorised in another country, which was not the applicants' case. However, this was fully in line with Article 83 of Regulation (EC) no. 726/2004, which required that the product concerned either be the subject of an application for a marketing authorisation or be undergoing clinical trials, which was again not the applicants' case.

84. The applicants replied that an application for judicial review of the decisions of the Director of the Executive Medicines Agency was not an effective remedy, for three reasons. First, in view of the wording of the applicable regulations, it would not have had any reasonable prospects of success. Secondly, its examination would have taken too long. Thirdly, the national courts would not have been in a position to obtain impartial expert opinions. An application for judicial review of the regulations themselves was not an effective remedy either because such proceedings could have led only to the annulment of the regulations, not their modification.

85. In their additional observations on this point, the applicants again argued that applications for judicial review of the decisions of the Executive Medicines Agency would not have stood a reasonable prospect of success, for several reasons. First, the requirements laid down in the applicable regulations were vague. Secondly, in the absence in Regulations no. 2 of

provisions dealing with the possibility of judicial review, and of any case-law under that regulation or under the regulations that preceded it, it was unclear which would be the competent court and even whether the courts would consider the Agency's pronouncements as administrative decisions subject to judicial review. Thirdly, there was no guarantee that the applicants would be able to obtain unbiased expert opinions. The impossibility to secure objective opinions by medical experts was a systemic problem in Bulgaria, as illustrated by a number of cases concerning medical negligence and reports in the press. Fourthly, all those procedural uncertainties made it very likely that any legal challenges brought by the applicants would not have been determined before their death. In support of that assertion the applicants pointed to several cases in which proceedings brought by ill persons in relation to the State's failure to provide them with medicines had been marred by delays and had dragged on for years; in some of those cases the claimants had died long before the courts had dealt with their claims. As for proceedings concerning challenges to statutory instruments, their average duration was two years. Fifthly, the regulations in issue were not contrary to Bulgarian law, and could thus be challenged only on Convention grounds. However, as evident from their case-law, the Bulgarian courts were likely to take into account Convention-related arguments only if they were based on clear and consistent case-law of this Court in relation to Bulgaria, which was not the case. There was an abundance of Bulgarian judicial decisions which had given short shrift to Convention-based arguments. In sum, the prospect of a national court providing redress to the applicants before their death was illusory. Nor could they realistically hope to obtain from the authorities a different decision under newly issued Regulation no. 10: it likewise required that the medicinal product in issue be authorised in another country.

*2. The Court's assessment*

86. Concerning the possibility to seek judicial review of the decisions of the Director of the Executive Medicines Agency, the Court observes that at the relevant time the impossibility for the applicants to obtain access to the unauthorised medicinal product that they wished to have administered flowed directly from the wording of regulation 2 of Regulations no. 2 of 10 January 2001, preceded and superseded by similar texts (see paragraphs 25 and 30 above). Under the express terms of that regulation, and of the regulations that preceded and superseded it, medicinal products which had not been authorised in another country – which was the case here – could not exceptionally be allowed for use in Bulgaria (see paragraphs 26, 27 and 31 above). It has not been disputed that in his decisions in relation to each of the applicants the Agency's Director applied that provision correctly; this is confirmed by the opinion expressed by the Ombudsman of the Republic (see paragraph 16 above) and by the

Government's submissions (see, *mutatis mutandis*, *Immobiliare Saffi v. Italy* [GC], no. 22774/93, § 42 *in limine*, ECHR 1999-V; *Urbárska Obec Trenčianske Biskupice v. Slovakia*, no. 74258/01, § 86, 27 November 2007; *Ognyan Asenov v. Bulgaria*, no. 38157/04, § 32, 17 February 2011; and *Valkov and Others v. Bulgaria*, nos. 2033/04, 19125/04, 19475/04, 19490/04, 19495/04, 19497/04, 24729/04, 171/05 and 2041/05, § 72, 25 October 2011). As for the possibility to rely on the direct application of European Union law, the Court takes note of the examples cited by the Government in which the Bulgarian courts relied on that law to set aside administrative decisions (see paragraphs 38 and 39 above). However, the Court observes that, as evident from the terms of its relevant provisions, European Union law enables but does not require the Union's Member States to allow the "compassionate use" of unauthorised medicinal products (see paragraphs 45-51 above). There was therefore no basis to argue that the Director's decisions were in breach of that law. Lastly, the Court is not persuaded that the applicants could have successfully challenged the decisions on the strength of Convention-based arguments. It takes note of the examples cited by the Government in which the Bulgarian courts relied on the Convention and the Court's case-law to set aside administrative decisions or to hold that they have jurisdiction to review such decisions (see paragraphs 39 and 40 above). However, it cannot be overlooked that in all those examples the Bulgarian courts based their decisions on established case-law of this Court, whereas there is to date no firm basis in the Court's case-law on which to hold that the impossibility to have access to unauthorised medicinal products on a "compassionate use" basis is in breach of the Convention. The issue is novel and not free from doubt. The Court is mindful that its role is intended to be subsidiary to that of national systems safeguarding human rights, and that the national courts should normally have the initial opportunity to determine whether domestic law is compatible with the Convention (see *Burden v. the United Kingdom* [GC], no. 13378/05, § 42, ECHR 2008-...). However, it considers that the examples cited by the Government cannot lead to the conclusion that in the specific circumstances of this case a domestic legal challenge based on Convention-related arguments would have stood a reasonable prospect of success (see, *mutatis mutandis*, *Slavgorodski v. Estonia* (dec.), no. 37043/97, 9 March 1999, and *Odièvre v. France* [GC], no. 42326/98, §§ 21 and 23, ECHR 2003-III). The Court also notes that, by the Government's own admission, the Bulgarian courts have never dealt with the use of unauthorised medicinal products; it appears that since 1995, when the Minister of Health for the first time laid down regulations on this matter, no cases have been reported under those regulations (see paragraph 34 above).

87. The burden of proof is on the Government claiming non-exhaustion to satisfy the Court that the remedy to which they point offered a reasonable

prospect of success (see, as a recent authority, *Nada v. Switzerland* [GC], no. 10593/08, § 141, 12 September 2012). In view of the above reasons, the Court is not satisfied that applications for judicial review of the decisions of the Director of the Executive Medicines Agency could be regarded as offering such a prospect.

88. Nor is the Court persuaded that the applicants would have been able successfully to seek judicial review of the regulations on which those decisions were based. Those regulations do not appear to run counter to a higher-ranking statutory or constitutional rule, or to a rule of European Union law. There was thus no domestic law or European Union law basis to challenge them. The Court is not persuaded that the applicants could have successfully challenged the regulations on the strength of Convention-based arguments either. It is true that the Supreme Administrative Court has previously struck down statutory instruments on the ground that they were contrary to the Convention, when the discrepancy between the two was clear (see the decisions cited in paragraph 37 above and in *Bochev v. Bulgaria*, no. 73481/01, § 45, 13 November 2008). However, in cases where the incompatibility was not immediately apparent, it has refused to do so (see the decisions cited in *Ponomaryovi v. Bulgaria*, no. 5335/05, §§ 23-24, ECHR 2011-...). As already noted, in the present case it is far from clear that the impossibility to have access to unauthorised medicinal products on a "compassionate use" basis is in breach of the Convention.

89. In view of these conclusions, the Court does not find it necessary to inquire whether the effectiveness of the remedy proposed by the Government would have been hindered by uncertainties as to whether a legal challenge against the Director's decisions or the underlying regulations would have been heard on the merits, by the alleged impossibility to obtain impartial expert opinions, or by the allegedly limited powers of the Supreme Administrative Court in proceedings for review of statutory instruments. Nor is it necessary to speculate whether such judicial review proceedings would have lasted so long as to render a ruling in the applicants' favour devoid of practical purpose.

90. The Government's objection must therefore be rejected.

### C. Compatibility *ratione materiae*

91. The Government submitted that the complaint under Article 2 was incompatible *ratione materiae* with the provisions of the Convention because that Article could not be construed as requiring the State to allow access to unauthorised medicinal products. The same was true for the complaint under Article 3 of the Convention. The refusal to allow the applicants access to the experimental product MBVax Coley Fluid, whose safety and efficacy had not been established, could not be regarded as inhuman treatment.

92. The applicants did not comment on this submission.

93. The Court notes that the Government's arguments concern the interpretation and application of Articles 2 and 3 of the Convention and in particular the extent of the State's positive obligations under those Articles in relation to the provision of unauthorised medicinal products to terminally ill patients. Considered in those terms, the objection that the complaints are incompatible *ratione materiae* with the provisions of the Convention is closely linked to the substance of the complaints and is more appropriately addressed at the merits stage (see, *mutatis mutandis*, *Bozano v. France*, 18 December 1986, § 42, Series A no. 111; *Vo v. France* [GC], no. 53924/00, § 44, ECHR 2004-VIII; *Rantsev v. Cyprus and Russia*, no. 25965/04, § 211, 7 January 2010; and *Austin and Others v. the United Kingdom* [GC], nos. 39692/09, 40713/09 and 41008/09, § 50, 15 March 2012).

### D. The Court's conclusion as to the admissibility of the complaints

94. The Court further considers that these complaints are not manifestly ill-founded within the meaning of Article 35 § 3 (a) of the Convention. No other ground for declaring them inadmissible has been established. They must therefore be declared admissible.

## III. MERITS OF THE COMPLAINTS UNDER ARTICLES 2, 3 AND 8 OF THE CONVENTION

95. The applicants complained under Article 2 § 1 of the Convention that under Bulgarian law individuals who were in the terminal phase of a disease and who had unsuccessfully exhausted all conventional methods of treatment could not exceptionally be allowed to use unauthorised medicinal products. They further complained of the allegedly incoherent and slow actions of the authorities in relation to their requests to obtain such permission, arguing that that had been due to the lack of clear rules in that domain.

96. The applicants also complained under Article 3 of the Convention that by barring them access to the experimental medicinal product that they wished to use the authorities had subjected them to inhuman and degrading treatment.

97. Lastly, they complained under Article 8 of the Convention that the authorities' refusal to allow them to use the product had been an unjustified interference with their right for respect for their private and family life.

98. Articles 2, 3 and 8 of the Convention provide, in so far as relevant:

**Article 2 (right to life)**

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

**Article 3 (prohibition of torture)**

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

**Article 8 (right to respect for private and family life)**

"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."

## A. The parties' submissions

### *1. Concerning Article 2 of the Convention*

99. The Government pointed out that Bulgarian law made provision for the "compassionate use" of unauthorised medicinal products. However, they emphasised that such products carried serious risks which required them to be carefully regulated. The State was entitled to deny permission for the use of an unauthorised medicinal product, and that did not breach the right to life but safeguarded it. The positive obligations under Article 2 of the Convention had limits and could not exceed what was reasonable. The applicants had been given conventional medical treatment. There was no further duty to allow them to use a product which was not authorised in any Member State of the European Union or subjected to a clinical trial. A State could not be obliged to make available all possible drugs, let alone products with unclear contents and origin that were not authorised in developed countries with strong health-care capabilities. The product at issue did not comply with the requirements for "compassionate use" under Article 83 of Regulation (EC) no. 726/2004. If its producer met the applicable requirements, the authorities could envisage allowing its use in the future. In that sense, the applicants were not left without any hope.

100. The applicants submitted that the refusal to allow them to use the product had been in breach of their right to life. They highlighted the similarities and differences between their case and previous cases in which the Court had dealt with complaints under Article 2 of the Convention in relation to the health-care sphere. They argued that, properly framed, the issue in their case was whether the State had taken appropriate steps to safeguard the lives of those under its jurisdiction. In their view it had not, because the rules governing "compassionate use" were not adequate, in that they did not allow the authorities to have regard to specific circumstances. All persons in Bulgaria who, like the applicants, were in the terminal phase of cancer and no longer responded to conventional treatment were being denied access to experimental medicinal products. In the applicants' case,

this was not justified by scarce budgetary resources because the company which developed the product was willing to provide it free of charge. There were indications that the condition of some cancer patients had improved as a result of its use. That had given the applicants hope that it might help them as well.

*2. Concerning Article 3 of the Convention*

101. The Government drew attention to the minimum threshold bringing Article 3 of the Convention into play, which had in their view not been reached, and to the limited extent of the State's positive obligations under that Article. They pointed out that there had been no intention of denying the applicants access to safe medicinal products. The experimental product that they wished to use had not been authorised in any country, and had not undergone clinical trials. Its safety and efficacy had not been established. The impossibility to use it could not therefore be regarded as inhuman treatment. On the contrary, its use, which would have amounted to a medical experiment, might have resulted in a breach of Article 3.

102. The applicants submitted that they had been forced to await their death in spite of being aware of the existence of an experimental product which might improve their condition and prolong their life. Those of them who had died had had to endure pain and suffering before their death while knowing that the use of the product in other countries had in some cases led even to complete remission of the disease.

*3. Concerning Article 8 of the Convention*

103. The Government submitted that any interference with the applicants' rights under Article 8 of the Convention had been lawful and necessary. The refusals to allow them to use the experimental product had been reasoned, made by an independent authority, and based on legal provisions which were fully in line with European Union law. It could therefore be presumed that they were compliant with the Convention. Those provisions, which took into account the need to balance the public interest and personal autonomy, sought to protect the health and life of those concerned by preventing abuses and the risks accompanying the use of untested products. For that purpose, they laid down certain conditions, which in the applicants' cases had not been met. That regulatory arrangement could not be described as a blanket prohibition on the "compassionate use" of unauthorised medicinal products.

104. The applicants highlighted the similarities and differences between their case and previous cases in which the Court had dealt with similar issues under Article 8 of the Convention. They pointed out that they were not trying to derive from that provision a right to die, but on the contrary a right to try to prolong their lives and avert death. The refusals to allow them

access to an experimental medicinal product which might help them do so amounted to interference with their rights under that Article. The manner in which a person chose to live, even if that choice could entail harmful consequences, was part of that person's private life. The refusals had been of a blanket nature, not taking into account the specifics of each case. They had been based on inadequate legal provisions which did not permit an individualised assessment, and had not corresponded to a pressing social need. They had not been intended to protect the applicants' lives because each of them was in the terminal phase of a disease and, without the intervention of some new medicinal product, had a short amount of life left. In that connection, it had to be borne in mind that the exception contended for would have simply given the applicants a chance to prolong their lives, not shielded someone else from criminal liability. It might have helped them avert suffering and death, as had happened with some patients in other countries.

### B. The Court's assessment

#### *1. Scope of the case*

105. The Court's task in cases arising from individual applications is not to review domestic law in the abstract, but to examine the manner in which that law has been applied to the applicants (see, among other authorities, *McCann and Others v. the United Kingdom*, 27 September 1995, § 153, Series A no. 324; *Pham Hoang v. France*, 25 September 1992, § 33, Series A no. 243; *Sommerfeld v. Germany* [GC], no. 31871/96, § 86, ECHR 2003-VIII; and *S.H. and Others v. Austria* [GC], no. 57813/00, § 92, ECHR 2011-...). The Court must also confine its attention, as far as possible, to the particular circumstances of the case before it (see, among other authorities, *Wettstein v. Switzerland*, no. 33958/96, § 41, ECHR 2000-XII, and *Sommerfeld*, cited above, § 86). It is therefore not called upon in the present case to pass judgment on the system of rules governing access to unauthorised medicinal products in Bulgaria, or to decide whether denial of access to medicinal products is in principle compatible with the Convention. Moreover, the Court is not equipped to express an opinion as to the suitability of a particular medical treatment. Lastly, the Court does not have to establish whether the product that the applicants wished to use met the requirements of European Union law and in particular the requirement of Article 83 § 2 of Regulation (EC) no. 726/2004 to be undergoing clinical trials (see paragraphs 10, 45 and 50 above); the Court is competent to apply only the Convention, and it is not its task to review compliance with other international instruments (see *Di Giovine v. Portugal* (dec.), no. 39912/98, 31 August 1999; *Hermida Paz v. Spain* (dec.), no. 4160/02, 28 January 2003; *Somogyi v. Italy*, no. 67972/01, § 62, ECHR 2004-IV; *Calheiros*

*Lopes and Others v. Portugal* (dec.), no. 69338/01, 3 June 2004; and *Böheim v. Italy* (dec.), no. 35666/05, 22 May 2007). In the present case, the Court must determine only whether the refusals to allow the applicants access to the product at issue were compatible with their Convention rights.

*2. Alleged violation of Article 2 of the Convention*

106. The first sentence of Article 2 enjoins the State not only to refrain from the intentional and unlawful taking of life, but also to take appropriate steps to safeguard the lives of those within its jurisdiction (see, among other authorities, *Calvelli and Ciglio v. Italy* [GC], no. 32967/96, § 48, ECHR 2002-I; and *Wiater v. Poland* (dec.), no. 42290/08, § 33, 15 May 2012). The Court has previously said that it cannot be excluded that acts and omissions of the authorities in the field of health-care policy may in some circumstances engage the State's responsibility under Article 2 (see *Powell v. the United Kingdom* (dec.), no. 45305/99, ECHR 2000-V; *Nitecki v. Poland* (dec.), no. 65653/01, 21 March 2002; *Trzepałko v. Poland* (dec.), no. 25124/09, § 23, 13 September 2011; and *Wiater*, cited above, § 34). It has also said that, with respect to the scope of the State's positive obligations in the provision of health care, an issue may arise under Article 2 where it is shown that the authorities have put an individual's life at risk through the denial of health care which they have undertaken to make available to the population generally (see *Cyprus v. Turkey* [GC], no. 25781/94, § 219, ECHR 2001-IV; *Nitecki*, cited above; *Pentiacova and Others v. Moldova* (dec.), no. 14462/03, ECHR 2005-I; *Gheorghe v. Romania* (dec.), no. 19215/04, 22 September 2005; and *Wiater*, cited above, § 35).

107. In the present case, it is not being argued that the applicants have been denied health care which is otherwise generally available in Bulgaria. Nor are the applicants suggesting that the State should pay for a particular form of conventional treatment because they are unable to meet its costs (contrast *Nitecki*, *Pentiacova and Others*, *Gheorghe*, and *Wiater*, all cited above). The applicants' claim is rather that, because conventional treatments did not work in their cases, domestic law should be framed in such a way as to entitle them, exceptionally, to have access to an experimental and yet untested product that would be provided free of charge by the company which develops it.

108. 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 *Öneryıldız 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 were recently 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 that access to unauthorised medicinal products for the terminally ill 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 of providing access to unauthorised medicinal products (see paragraphs 54-55 above).

109. There has therefore been no violation of Article 2 of the Convention.

*3. Alleged violation of Article 3 of the Convention*

110. Article 3 of the Convention enshrines one of the most fundamental values of democratic society. It prohibits in absolute terms torture or inhuman or degrading treatment or punishment. However, to fall under that provision, a given form of treatment must attain a minimum level of severity. The assessment of this minimum level is relative. It depends on all the circumstances of the case, such as the duration of the treatment, its physical and mental effects and, in some cases, the sex, age and state of health of the victim (see, as a recent authority, *A, B and C v. Ireland* [GC], no. 25579/05, § 164, ECHR 2010-...). In considering whether a treatment is "degrading", the Court will have regard to whether its object was to humiliate and debase the person concerned and whether, as far as the consequences are concerned, it adversely affected his or her personality in a manner incompatible with Article 3 (see, among other auhtorities, *Wainwright v. the United Kingdom*, no. 12350/04, § 41, ECHR 2006-X).

111. An examination of the Court's case-law shows that Article 3 has been most commonly applied in contexts in which the risk of being subjected to a proscribed form of treatment has emanated from intentionally inflicted acts of State agents or public authorities. It may be described in general terms as imposing a primarily negative obligation on States to refrain from inflicting serious harm on persons within their jurisdiction. However, in light of the fundamental importance of Article 3, the Court has reserved to itself sufficient flexibility to address its application in other situations (see *Pretty v. the United Kingdom*, no. 2346/02, § 50, ECHR 2002-III). For instance, suffering which flows from naturally occurring illness may be covered by Article 3 where it is, or risks being, exacerbated by treatment stemming from measures for which the authorities can be held responsible (see *N. v. the United Kingdom* [GC], no. 26565/05, § 29, ECHR 2008-...). However, the threshold in such situations is high,

because the alleged harm emanates not from acts or omissions of the authorities but from the illness (ibid., § 43).

112. In the present case, there is no complaint that the applicants have not received adequate medical treatment. It appears that all of them have benefited from such treatment, which has sadly proved insufficient to treat their medical conditions. Their situation is therefore not comparable to those of persons in custody who complain of the lack of medical treatment (see, for example, *Keenan v. the United Kingdom*, no. 27229/95, §§ 109-16, ECHR 2001-III; *McGlinchey and Others v. the United Kingdom*, no. 50390/99, §§ 47-58, ECHR 2003-V; and *Sławomir Musiał v. Poland*, no. 28300/06, §§ 85-98, 20 January 2009), seriously ill persons who would be unable to obtain treatment because of their removal to a country which lacks adequate medical facilities (see *N. v. the United Kingdom*, cited above, §§ 32-51, and the cases cited there), or persons in a vulnerable situation who have, as a result of the callous indifference of health-care professionals, been denied access to otherwise available diagnostic services to which they were entitled as a matter of law (see *R.R. v. Poland*, no. 27617/04, §§ 148-62, 26 May 2011).

113. The applicants rather claim that the refusals of the authorities to allow them access to an experimental product which, according to them, was potentially life-saving amounted to inhuman and degrading treatment for which the State is responsible, as it thereby failed to protect them from the suffering resulting from the ultimate stages of their illness. However, as in *Pretty* (cited above, § 54), 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, in as much 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 (see, *mutatis mutandis*, *A, B and C v. Ireland*, cited above, §§ 163-64). It notes in this connection that Article 3 does not place an obligation on the Contracting States to alleviate the disparities between the levels of health care available in various countries (see, *mutatis mutandis*, *N. v. the United Kingdom*, cited above, § 44). Lastly, the Court does not consider that the refusals can be regarded as humiliating or debasing the applicants.

114. Whether the refusals unduly interfered with the applicants' right to respect for their physical integrity is a point which the Court will examine below by reference to Article 8 of the Convention (see, *mutatis mutandis*,

*Tysiąc v. Poland*, no. 5410/03, § 66, ECHR 2007-I, and *L. v. Lithuania*, no. 27527/03, § 47, ECHR 2007-IV).

115. There has therefore been no violation of Article 3 of the Convention.

*4. Alleged violation of Article 8 of the Convention*

**(a) Applicability of Article 8**

116. The gist of the applicants' grievance concerns a regulatory limitation on their capacity to choose, in consultation with their medical doctors, the way in which they should be medically treated with a view to possibly prolonging their lives. This complaint clearly falls to be examined under Article 8, whose interpretation, in so far as the notion of "private life" is concerned, is underpinned by the notions of personal autonomy and quality of life (see *Pretty*, cited above, §§ 61 *in fine* and 65, and *Christine Goodwin v. the United Kingdom* [GC], no. 28957/95, § 90, ECHR 2002-VI). It is by reference to that provision that the Court and the former Commission have most often examined the extent to which States can use compulsory powers to protect people from the consequences of their own conduct, even when that conduct poses a danger to health or is of a life-threatening nature (see, for example, concerning involvement in consensual sado-masochistic activities, *Laskey, Jaggard and Brown v. the United Kingdom*, 19 February 1997, §§ 35-36, *Reports* 1997-I, and *K.A. and A.D. v. Belgium*, no. 42758/98 and 45558/99, §§ 78 and 83, 17 February 2005; concerning imposition of medical treatment without consent, *Acmanne and Others v. Belgium*, no. 10435/83, Commission decision of 10 December 1984, DR 40, p. 251; *Glass v. the United Kingdom*, no. 61827/00, §§ 82-83, ECHR 2004-II; *Storck v. Germany*, no. 61603/00, §§ 143-44, ECHR 2005-V; *Jehovah's Witnesses of Moscow v. Russia*, no. 302/02, § 135, ECHR 2010-...; and *Shopov v. Bulgaria*, no. 11373/04, § 41, 2 September 2010; and, concerning assisted suicide, *Pretty*, cited above, §§ 62-67, and *Haas v. Switzerland*, no. 31322/07, § 51, ECHR 2011-...).

**(b) Positive obligation or interference with a right?**

117. The parties argued the case in terms of interference with the applicants' rights under Article 8. In the Court's view, however, the point is not so clear cut. The central issue in the case may be seen as either a curtailment of the applicants' choice of medical treatment, to be analysed as an interference with their right to respect for their private life (compare, *mutatis mutandis*, with *Pretty*, cited above, § 67; with *A, B and C v. Ireland* [GC], no. 25579/05, § 216, ECHR 2010-...; and with *S.H. and Others v. Austria*, cited above, §§ 85-88), or as an alleged failure on the part of the State to provide an appropriate regulatory framework securing the rights of

persons in the applicants' situation, to be analysed in terms of the State's positive duty to ensure respect for their private life (compare, *mutatis mutandis*, with *Christine Goodwin*, § 71; *Tysiąc*, §§ 107-08; *Haas*, §§ 52-53; *A, B and C v. Ireland*, §§ 244-46; and *R.R. v. Poland*, § 188, all cited above). The Court does not find it necessary to determine this point. Although the boundaries between the State's positive and negative obligations under Article 8 do not lend themselves to precise definition, the applicable principles are similar. In both contexts regard must be had to the fair balance that has to be struck between the competing interests of the individual and of the community as a whole (see, among other authorities, *Powell and Rayner v. the United Kingdom*, 21 February 1990, § 41, Series A no. 172; *Evans v. the United Kingdom* [GC], no. 6339/05, § 75, ECHR 2007-I; and *Dickson v. the United Kingdom* [GC], no. 44362/04, § 70, ECHR 2007-V). The salient issue in this case is precisely whether such a balance has been struck, regard being had to the State's margin of appreciation in this domain.

**(c) The competing interests and the applicable margin of appreciation**

118. In its recent judgment in *S.H. and Others v. Austria* (cited above, § 94), the Court summarised the principles for determining the breadth of the State's margin of appreciation under Article 8 as follows. A number of factors must be taken into account. Where a particularly important facet of an individual's existence or identity is at stake, the margin will normally be restricted. Where, however, there is no consensus within the Contracting States, either as to the relative importance of the interest at stake or as to the best means of protecting it, particularly where the case raises sensitive moral or ethical issues, the margin will be wider. There will usually be a wide margin if the State is required to strike a balance between competing private and public interests or Convention rights.

119. The Court starts with the general point that matters of health-care policy are in principle within the margin of appreciation of the domestic authorities, who are best placed to assess priorities, use of resources and social needs (see *Shelley v. the United Kingdom* (dec.), no. 23800/06, 4 January 2008).

120. Turning to the competing interests, the Court observes that it is undeniable that the applicants' interest to obtain medical treatment capable of mitigating their illness or helping them defeat it is of the highest order. However, the analysis cannot stop there. When it comes to experimental medicinal products, it is in the nature of things that their quality, efficacy and safety are open to doubt. The applicants do not deny this. They rather seek to argue that because of the dire prognosis attaching to their medical condition, they should have been allowed to assume the risks attendant on a potentially life-saving experimental product. Framed in these terms, the applicants' interest is of a different nature. It may be described as the

freedom to opt, as a measure of last resort, for an untested treatment which may carry risks but which the applicants and their medical doctors consider appropriate to their circumstances, in an attempt to save their life.

121. That said, the Court nonetheless accepts that, in view of their medical condition and the prognosis for its development, the applicants had a stronger interest than other patients to obtain access to experimental treatment whose quality, safety and efficacy have not yet been subjected to comprehensive testing.

122. The countervailing public interest in regulating the access of terminally ill patients such as the applicants to experimental products appears based on three premises. First, 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). The Court notes in this connection that it has emphasised, albeit in a different context, the importance of informed consent to medical procedures (see *V.C. v. Slovakia*, no. 18968/07, §§ 107-17 and 152, ECHR 2011-... (extracts), and *N.B. v. Slovakia*, no. 29518/10, §§ 76-78 and 96, 12 June 2012). Secondly, to ensure that the prohibition, laid down in section 7(1) of the Medicinal Products in Human Medicine Act 2007 (see paragraph 22 above) against the production, importation, trade in, advertisement, or use for medical treatment, prophylaxis or diagnostics of products which have not been granted authorisation under the appropriate regulatory channels would not be diluted and circumvented. Thirdly, to ensure that the development of new medicinal products would not be compromised by, for instance, diminished patient participation in clinical trials. All of those interests relate – the first in a more specific and the second and third in a more general way – to rights guaranteed under Articles 2, 3 and 8 the Convention. Moreover, their balancing against the applicants' interest touches upon complex ethical and risk-assessment issues, against a background of fast-moving medical and scientific developments.

123. As for the consensus within the Contracting States, the Court observes that, according to the comparative law information available to it, a number of those States have made provision in their laws for exceptions – in particular in the case of terminally ill patients – to the rule that only authorised medicinal products may be used for medical treatment. They have, however, made this option subject to conditions of varying strictness (see paragraphs 54-55 above). Based on that, and on the manner in which the issue is regulated in the law of the European Union (see paragraphs 44-51 above), the Court concludes that there is now a clear trend in the Contracting States towards allowing, under certain exceptional conditions, the use of unauthorised medicinal products. However, that emerging consensus is not based on settled principles in the law of the Contracting

States. Nor does it appear to extend to the precise manner in which that use should be regulated.

124. Based on the above considerations, the Court concludes that the margin of appreciation to be afforded to the respondent State must be a wide one, especially as regards the detailed rules it lays down with a view to achieving a balance between the competing public and private interests (see, *mutatis mutandis*, *Evans*, § 82, and *S.H. and Others v. Austria*, § 97, both cited above).

**(d) Balancing the interests**

125. The Bulgarian authorities have chosen to balance the competing interests by allowing patients who cannot be satisfactorily treated with authorised medicinal products, including terminally ill patients like the applicants, to obtain, under certain conditions, medicinal products which have not been authorised in Bulgaria, but only if those products have already been authorised in another country (see paragraphs 26 and 31 above). That was apparently the main reason for the refusals by the Executive Medicines Agency in the applicants' cases (see paragraph 14 above). Such a solution tilts the balance between potential therapeutic benefit and medicine risk avoidance decisively in favour of the latter, because medicinal products authorised in another country are likely to have been already subjected to comprehensive safety and efficacy testing. At the same time, it leaves beyond the pale products which are still in the various stages of development. In view of the authorities' broad margin of appreciation in this domain, the Court does not consider that that regulatory solution fell foul of Article 8. It is not for an international court to determine in the place of the competent national authorities what is the acceptable level of risk in such circumstances. The salient question in terms of Article 8 is not whether a different solution might have struck a fairer balance, but whether, in striking the balance at the point at which they did, the Bulgarian authorities exceeded the wide margin of appreciation afforded to them (see, *mutatis mutandis*, *Evans*, § 91, and *S.H. and Others v. Austria*, § 106, both cited above). In view of the considerations set out above, the Court is unable to find that they did.

126. The applicants' other criticism against the regulatory arrangement was that it did not sufficiently allow individual circumstances to be taken into account. However, the Court does not find that this was necessarily inconsistent with Article 8. It is not in itself contrary to the requirements of that provision for a State to regulate important aspects of private life without making provision for the weighing of competing interests in the circumstances of each individual case (see, *mutatis mutandis*, *Pretty*, §§ 74-76; *Evans*, § 89; and *S.H. and Others v. Austria*, § 110, all cited above).

127. The Court therefore concludes that there has been no violation of Article 8 of the Convention.

## IV. ALLEGED VIOLATION OF ARTICLE 13 OF THE CONVENTION

128. The applicants complained that they did not have effective remedies in respect of the alleged breaches of Articles 2, 3 and 8 the Convention. They relied on its Article 13, which provides as follows:

> "Everyone whose rights and freedoms as set forth in [the] Convention are violated shall have an effective remedy before a national authority notwithstanding that the violation has been committed by persons acting in an official capacity."

129. The Government submitted that the applicants could have sought to vindicate their rights under Articles 2, 3 and 8 of the Convention by bringing tort claims, under either the general law of tort or under the special provisions governing the tort liability of the authorities. They could have also appealed against the refusals to the Minister of Health and then sought judicial review.

130. The applicants referred to their submissions in relation to the exhaustion of domestic remedies.

131. The Court observes that in as much as the alleged breaches of Articles 2, 3 and 8 of the Convention appear to stem from the state of Bulgarian law, no issue arises under Article 13 of the Convention (see *Christine Goodwin*, cited above, § 113; *Appleby and Others v. the United Kingdom*, no. 44306/98, § 56, ECHR 2003-VI; *Iordachi and Others v. Moldova*, no. 25198/02, § 56, 10 February 2009; and *V.C. v. Slovakia*, no. 18968/07, § 167, 8 November 2011).

132. 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

1. *Declares* unanimously the complaints concerning the authorities' refusal to allow the applicants to use the experimental product that they wished to have administered admissible and the remainder of the applications inadmissible;

2. *Holds* by five votes to two that there has been no violation of Article 2 of the Convention;

3. *Holds* by five votes to two that there has been no violation of Article 3 of the Convention;

4. *Holds* by four votes to three that there has been no violation of Article 8 of the Convention.

Done in English, and notified in writing on 13 November 2012, pursuant to Rule 77 §§ 2 and 3 of the Rules of Court.

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| Lawrence Early | Lech Garlicki |
| Registrar | President |

In accordance with Article 45 § 2 of the Convention and Rule 74 § 2 of the Rules of Court, the following separate opinions are annexed to this judgment:

(a) Partly dissenting opinion of Judge Kalaydjieva;

(b) Dissenting opinion of Judge De Gaetano joined by Judge Vučinić

L.G.
T.L.E.

# PARTLY DISSENTING OPINION OF JUDGE KALAYDJIEVA

The present case raises important issues concerning the interpretation of the legitimate purposes pursued by State regulation of public health and pharmaceutical services and its limits under the Convention. I regret being unable to join the opposing conclusions of my learned colleagues as to the principles governing this important sphere.

I am not convinced that a comparison between the applicants' situation and those obtaining in the cases of *Pretty v. the United Kingdom* (no. 2346/02, ECHR 2002-III), *Evans v. the United Kingdom* ([GC], no. 6339/05, ECHR 2007-I) and *S.H. and Others v. Austria* ([GC], no. 57813/00, ECHR 2011-...) is appropriate for the purposes of the analysis of the circumstances in the present case. The applicants in the above-mentioned three cases sought to secure increased positive involvement by the authorities – including the enactment of new legislation – to facilitate the pursuit of their private lives. In their cases this involvement inevitably risked conflicts with potentially competing or already protected individual rights or public interests. By contrast, the applicants in the present case cannot be said to have requested the establishment of any further positive obligations for the authorities beyond the ones already laid down in the context of the State's regulatory functions. Furthermore, it is questionable whether the exercise of these functions in the present case risked any conflict with public welfare or with any other rights or interests – as was apparently assumed to be the case by the majority (see below).

It appears appropriate to mention that the situation of the applicants is not necessarily different from that of any other patient affected by a disease which is regrettably not curable with standard products available for market distribution. While for centuries human medicine has been concerned with the treatment of individual patients under the responsibility of medical doctors, State authorities undertook to share this responsibility through stricter regulations only fifty years ago. In this regard, the finding that "there is now a clear trend in the Contracting States towards allowing, under exceptional conditions, the use of unauthorised medicinal products" (see paragraph 123 of the judgment) does not seem accurately to reflect the historical development of medical and pharmaceutical services. Furthermore, the conclusion that "[i]t is not contrary to the requirements of [Article 8] to regulate [these] important aspects of private life without making provision for the weighing of competing interests in the circumstances of each individual case" (see paragraph 126 of the judgment) appears inappropriate for the future development of the recent undertaking to ensure safe progress in that it "tilts the balance between potential

therapeutic benefit and medicine risk avoidance decisively in favour" of the status quo.

Indeed, a proper definition of the principles governing the State's regulatory functions in human medicine may not be achieved by using the safety-valve of the "wide margin of appreciation" before analysing the scope and purposes of the positive obligations undertaken in ensuring safe progress in this field and the extent to which the operation of the established mechanisms met those obligations. These issues concern the compatibility of the impugned refusals with the legitimate aims pursued by State regulation of medical and pharmaceutical services and I regret the Court's failure to deal with the issue of lawfulness before turning to the doctrine of the margin of appreciation – an instrument introduced by this very Court to facilitate the assessment of the necessity and proportionality of interferences with the free exercise of the rights and freedoms guaranteed by the Convention and not as a general waiver of the duty of States to respect them as required by Article 1 of the Convention.

The reasoning of the majority leaves the impression that for the first time the phrase "margin of appreciation" has been interpreted not in the sense of an estimation and evaluation of merit, but as an instrument to justify the national authorities' complete failure to demonstrate any appreciation whatsoever of the applicants' right to personal life, or to strike the requisite balance between this right and the presumed counterbalancing public interests. It is a separate issue whether the interests of individual patients and those of the community in ensuring safe progress in improved medical and pharmaceutical services may indeed be seen as competing (see paragraph 117 of the judgment), or as giving rise to any potential conflict (see paragraph 125 of the judgment). I fail to see any conflict between the public and the individual interest in ensuring the safe progress of medical treatment. In any event, the existence of such a conflict in the present case has neither been demonstrated nor alleged.

This dangerous use by the Court of its own motion of the instrument of "wide margin of appreciation" can easily be interpreted as granting the executive authorities unwarranted power to impose their own decisions as to the appropriate treatment of any patient, or the unjustified restriction of such treatment to the use of a limited pre-defined list of products – disregarding equally the opinion of medical professionals and the personal wishes of patients. I am far from convinced that any individual's medical treatment may be seen to necessarily (not to mention exclusively) fall within the executive authorities' margin of appreciation. In my understanding, such a result renders the exercise of the medical profession and the notion of informed consent (which should be one aspect of the State's regulatory functions) redundant. This goes far beyond the legitimate aims pursued in the establishment of regulatory mechanisms.

It is true that the national regulations governing the applicants' situation "do not appear to run counter to a higher-ranking statutory or constitutional rule, or to a rule of European Union law" (see paragraph 88 of the judgment) in allowing for exceptions to the general rule that only authorised medicinal products may be "produced, imported, traded ... or used for medical treatment" (see paragraphs 22-23 of the judgment). However, in this regard the State authorities have a margin of appreciation in deciding whether or not to undertake regulatory functions in relation to individual patients' treatment (see paragraphs 45, 49, 50, 51 and 54-55). The extent to which the implementation of the national secondary legislation fulfilled the intended purposes of such functions is highly questionable. The fact remains that these regulations did not require any analysis or consultation for the purposes of quality control of the product requested and the risk/benefit test normally involved in the process of authorisation. In this regard, these regulations served to restrict the meeting of individual needs concerning the "exceptional use of unauthorised products" only to "already authorised" ones (see paragraph 125 of the judgment), thus rendering meaningless the "exceptional" nature of such permission. On the other hand, the same regulations relieved the national authority "in charge of supervising the quality, safety and efficacy of medicinal products" (see paragraph 14 of the judgment) of any duty to carry out such supervision, by redirecting this duty to other countries' regulatory bodies, thus rendering its own functions redundant.

The facts of the present case illustrate that a failure to discharge the functions of "supervising the quality, safety and efficacy of medicinal products" leads automatically to unjustified restrictions of medical treatment, seeing that "unlike the situation obtaining in other European countries, in Bulgaria the compassionate use of unauthorised products was not possible" (see paragraph 14 of the judgment). The Court has failed to analyse whether the limited access of Bulgarian patients to allegedly useful products available elsewhere may be justified and, if so, on what grounds.

Far from wishing to see my country become an arena for dangerous or degrading medical experiments with human beings, I am prepared to agree that there is no established positive obligation on the State authorities to ensure the access of individual patients to products for medicinal purposes which have not been tested for their quality, efficacy and safety – as concluded by the majority. If any positive obligations exist with regard to individual patients, they concern the duty to respect their rights and to ensure their properly informed consent to proposed medical treatment.

However, where the authorities have undertaken the obligation to put in place regulatory mechanisms to control the practice of medical and pharmaceutical professions so as to meet the public and individual interests regarding safety, this undertaking requires them to assume relevant and appropriate functions capable of meeting this obligation, rather than

substituting the undertaking with a discretion to refuse treatment in the absence of any justification. I am not prepared to accept that fifty years after the thalidomide tragedy, which triggered the necessity of stricter State regulation, this responsibility may be interpreted as involving some "wide margin of appreciation" as to how to avoid discharging it. Unlike the dissenting minority, I consider that this is a question of the lawfulness of the purpose of the restrictions, which appear to have been imposed instead of the promised proactive functions in the interests of safe medical services, and not a question of the authorities' "margin of appreciation" in striking the requisite balance between the allegedly competing public and individual interests in obtaining such services. I also fail to agree with the opinion of the minority that "the public interest identified by the majority in paragraph 122 of the judgment may be usefully served by more narrowly tailored requirements" (see paragraph 8 of the dissenting opinion of Judge De Gaetano joined by Judge Vučinić) rather than by the effective exercise of the responsibility undertaken, while in fact "there are no major factors of public interest to weigh against the interest of the applicants" (see paragraph 9). No specific considerations in this regard were submitted before the Court.

Turning to the specific substantive issue of the presumed risk involved in "unauthorised", "untested" or "experimental" products, it is impossible not to share the view that no particular dangers calling for the applicants' protection were ever indicated or alleged, nor were they informed of such dangers in the course of the brief examination of their requests. In this regard, it cannot be overlooked that the applicants' condition rendered them eligible for the compassionate use of morphine – a substance whose distribution is not only unauthorised, but also criminalised. It was not argued that the new product to which the applicants sought access was more dangerous or less effective than morphine. I mention this fact as it cannot be overlooked that the State's functions relating to the authorisation of medicinal products involve a distinction of different levels of authorisation for the use of medicinal products for different purposes. I will not make any contribution to pharmaceutical or medical science in noting that some products, including poisons, are never authorised for market distribution, whereas their use is legitimate and authorised for specific medical purposes. Thus, even the thalidomide tragedy, which triggered the introduction of stricter controls on the distribution of medicinal products on the market, did not result in the "prohibition" of that product, but in its limited use, which is currently authorised for specific patients. Regrettably, the distinction of authorised use for different purposes, such as market distribution, prescribed use, off-label individual treatment or compassionate individual use, was neither reflected in the applicable secondary legislation nor taken into consideration by the majority in their analysis of the proportionality or necessity of the automatic refusal with which the applicants were

confronted, despite the already approved use of the experimental product for specific purposes in other countries. Finally, it appears that the impugned refusals served neither to inform the applicants of any risk to life or of any degrading experiments which the treatment requested might entail, nor to prevent such treatment. In fact, some of the applicants availed themselves of the product in question outside the territory over which the national authorities exercised jurisdiction. Is State regulation of patients' and public safety in medical treatment only a question of money?

Regrettably, in adopting the secondary regulations in question and issuing the resulting refusals, the national authorities failed to indicate any convincing reason pertinent to the regulatory functions of State authorities in relation to individual patients' medical treatment.

Looking at the cited case-law of other courts (see paragraphs 59-67 of the judgment), I find it embarrassing that the Court, when called upon to examine the extent to which the authorities complied with their duty to respect the individual right to medical services, as well as their positive obligations to ensure the effective and safe exercise of that right, seems to be the first to fail to examine the complex ethical and moral issues arising in similar cases.

# DISSENTING OPINION OF JUDGE DE GAETANO JOINED BY JUDGE VUČINIĆ

1. I regret that I cannot share the majority's conclusions in this case, other than on the question of the admissibility of the complaints concerning the authorities' refusal to allow the applicants to use the experimental product that they wished to have administered and on the question of the inadmissibility of the complaint in respect of the alleged violation of Article 13. In my view there was in this case a violation of Article 8, and such a finding would have rendered it unnecessary to examine the issue under Articles 2 and 3 (see *Guerra and Others v. Italy*, 19 February 1998, *Reports of Judgments and Decisions* 1998-I).

2. The facts of the case may be summed up as follows: a number of cancer patients in the late stage of their disease want, as a measure of last resort, to be allowed to try an experimental, and possibly controversial, anticancer product which is being developed by a Canadian company. They are fully aware of the risks which go with this treatment. The treatment is not available in Bulgaria, and, although it has been offered for free by the Canadian company, the participation of Bulgarian medical institutions and Bulgarian doctors is nevertheless required for it to be administered in Bulgaria. Hence the need for the applicants to apply to the domestic authorities for the necessary permission (see paragraphs 14 and 26 of the judgment).

3. In my view the possibility to "treat oneself" – whether it be by the use of non-medical products, the use of ordinary medication, or the use of available extraordinary medication, as in this case – and to make an informed and free choice in this connection (and provided such a choice does not negatively impinge upon another's life or health) falls within the ambit of one's private life. Indeed, as correctly pointed out in paragraph 116 of the judgment, the very notion of "private life" implies a degree of personal autonomy coupled with an assessment of the quality of life in a concrete situation. I also agree that matters of health-care policy are, in principle, within the margin of appreciation of the domestic authorities, who are best placed to assess priorities, use of resources and social needs (paragraph 119 of the judgment). However, the issue in the present case is a considerably narrower one, and does not involve the allocation of resources. No financial considerations or imperatives were involved. The applicants were not calling upon the State to pay for this treatment (contrast, among others, *Wiater v. Poland* (dec.), no. 42290/08, § 33, 15 May 2010). They were simply asking for the State to "get out of the way" and allow them access to an experimental product which would be provided to them free of charge. In the instant case, therefore, the Court should have determined the applicable margin of appreciation by reference to factors that are more specific to the situation at hand (see *Hatton and Others v. the United*

*Kingdom* [GC], no. 36022/97, § 103, ECHR 2003-VIII, where the court said that a conflict of views on the margin of appreciation can be resolved only by reference to the context of a particular case), and in particular to the applicants' critical medical condition and the available prognosis.

4. Moreover, a State's margin of appreciation is not unlimited and, broad as it may be, must always be viewed in the light of the values underpinning the Convention, chief among them the value of life. The Court has often stated that the Convention must be read as a whole and interpreted (and I would say also applied) in such a way as to promote internal consistency and harmony between its various provisions and the various values enshrined therein (see, albeit in different contexts, *Stec and Others v. the United Kingdom* (dec.) [GC], nos. 65731/01 and 65900/01, § 48, ECHR 2005-X; *Austin and Others v. the United Kingdom* [GC], nos. 39692/09, 40713/09 and 41008/09, § 54, ECHR 2012-...). The Court, therefore, in assessing this margin of appreciation in the circumstances of the instant case, and the method chosen by the Bulgarian authorities to "balance" the interests mentioned in paragraphs 120 and 122 of the judgment, should have given more weight to the value of life.

5. As is stated in paragraph 125 of the judgment, the Bulgarian authorities chose "to balance the competing interests" – I very much doubt whether those interests were really "in competition" with each other given the facts of the case – by adopting the general formula that if a medicinal product is not authorised in another country, it cannot be exceptionally used to treat patients in Bulgaria. In my view, in the case of the applicants – terminally ill patients – this generalised solution is unnecessarily restrictive and exceeds the State's margin of appreciation in this domain, and this for two reasons. The first reason concerns the manner in which the solution was arrived at (see, *mutatis mutandis*, *Hatton and Others*, cited above, § 99). There is no evidence that when adopting the regulations at issue, or those that succeeded them, the Minister of Health sought to weigh the competing interests or to assess the proportionality of the restriction (see, *mutatis mutandis*, *Dickson v. the United Kingdom* [GC], no. 44362/04, § 83 *in limine*, ECHR 2007-V) by, for instance, carrying out a public consultation process (contrast, *mutatis mutandis*, *Hatton and Others*, cited above, § 128). Moreover, since the bar on access to unauthorised medicinal products which have not been authorised in another country was not embodied in primary legislation, the various competing interests were never weighed, nor were issues of proportionality ever assessed, by the legislature (see, *mutatis mutandis*, *Dickson*, § 83, cited above, and contrast *Evans v. the United Kingdom* [GC], no. 6339/05, § 86, ECHR 2007-I). It is important to observe in this connection that the issue has obvious life-or-death implications, and that its importance cannot be emphasised enough.

6. The second reason has to do with the solution's substantive content. It is an unfortunate fact of life in the modern world that the development of

new medicinal products is a complex endeavour facing scientific, financial and regulatory hurdles, and as a rule taking many years to complete. As a result, terminally ill patients often do not have the time to await the full testing and authorisation of new medicines which may help them mitigate or defeat their disease. A number of Contracting States, as well as other States and the European Union, are apparently alive to this problem and have for this reason made provision for early access to experimental products which have not yet obtained regulatory approval (see paragraphs 45, 49-51 and 54-58 of the judgment). It is true that the specific way in which such access is being provided varies among countries. However, it appears that in many of them it embraces products which have not obtained regulatory approval anywhere and are in this sense truly new and experimental. The development of new medicinal products is a field which is constantly impacted by scientific developments and advances in technology. By denying the applicants – terminally ill patients – any access to those developments, the Bulgarian authorities effectively disregarded completely their very strong interest to be able to try treatment which, although involving acceptance of additional uncertainty as to risk, may prove to be the only remaining possibility to attempt to save their lives.

7. I am, of course, fully aware that that allowing too many exceptions to the system of authorising medicinal products may undermine its function to ensure that only products whose quality, safety and efficacy have been convincingly demonstrated should be allowed for use by patients. However, I cannot overlook – and unfortunately the majority decision overlooks – the fact that such exceptions already exist and do not appear to have imperilled the operation of that system, both at the national and higher level. The fact that a number of other States operate such mechanisms in respect of products which have not been authorised anywhere in the world shows that any difficulties that are likely to arise are manageable.

8. The public interest identified in paragraph 122 of the judgment may be usefully served by more narrowly tailored requirements. For instance, the applicable regulations could require the authorities to assure themselves that the possible benefit of using an unauthorised product justifies the possible risks of using it, and that the risks posed by the product are not unreasonable in the circumstances and do not outweigh the risks posed by the disease which it is purported to treat. They could additionally insist that medical practitioners who propose to treat terminally ill patients with an unauthorised product explain in detail the known and unknown risks, so as to allow those patients to make truly informed decisions. They could also require that the use of unauthorised products does not get in the way of clinical trials of those products, and remains an option of last resort. The majority decision washes its hands of all these considerations by using the safety-valve of the “wide margin of appreciation” (see paragraph 125 of the judgment).

9. In sum, I am of the view that there are no major factors of public interest to weigh against the very significant – indeed vital, in a very literal sense – interest of the applicants in obtaining access to experimental medicinal products which have not been authorised for use in another country. Naturally, the State cannot be required to grant access to such medicines without a regulatory framework. But this framework must allow for a proper balancing exercise of the interests involved. In the present case, however, there is no indication that such an examination was undertaken, and in fact nowhere does the judgment conclude that the State struck a fair balance. The near uniformity of the reasons given by the Director of the Executive Medicines Agency for rejecting each of the applicants' requests indicates that those refusals did not flow from relevant considerations but were entirely based on the blanket prohibition on the compassionate use of products not authorised in other countries. More specifically, no attention was given to the special and vulnerable situation of the applicants and the consequent need for respect for, and protection of, their physical and psychological integrity.

10. For these reasons, as has already been stated in paragraph 1, above, I am of the view that there has been a violation of Article 8 of the Convention in this case, and that as a consequence it was unnecessary to examine the applicants' complaints under Articles 2 and 3.