Reports of Cases

JUDGMENT OF THE COURT (Fifth Chamber)

23 October 2014*

(Reference for a preliminary ruling — Approximation of laws — Industrial policy — Directive 2001/83/EC — Medicinal products for human use — Article 6 — Marketing authorisation — Article 8(3)(i) — Requirement to attach to the application for authorisation the results of pharmaceutical pre-clinical tests and clinical trials — Derogations relating to pre-clinical tests and clinical trials — Article 10 — Generic medicinal products — Concept of 'reference medicinal product' — Whether the holder of a marketing authorisation for a reference medicinal product has an individual right to oppose the marketing authorisation of a generic of the reference product — Article 10a — Medicinal products of which the active substances have been in well-established medicinal use within the European Union for at least 10 years — Whether it is possible to use a medicinal product for which authorisation has been granted on the basis of the derogation provided for in Article 10a as a reference medicinal product for the purpose of obtaining a marketing authorisation for a generic product)

In Case C-104/13,

REQUEST for a preliminary ruling under Article 267 TFEU from the Augstākās Tiesas Senāts (Latvia), made by decision of 26 February 2013, received at the Court on 4 March 2013, in the proceedings

Olainfarm AS

v

Latvijas Republikas Veselības ministrija,

Zāļu valsts aģentūra,

intervening party:

Grindeks AS,

THE COURT (Fifth Chamber),

composed of T. von Danwitz, President of the Chamber, C. Vajda, A. Rosas, E. Juhász and D. Šváby (Rapporteur), Judges,

Advocate General: N. Wahl,

Registrar: V. Tourrès, Administrator,

having regard to the written procedure and further to the hearing on 20 March 2014,

* Language of the case: Latvian.

after considering the observations submitted on behalf of:

— Olainfarm AS, by M. Grudulis, advokāts,

— Grindeks AS, by J. Bundulis, Chairman of the Board of Directors, assisted by D. Lasmanis, advokāts, and L. Jāgere and Z. Sedlova,

— the Latvian Government, by I. Kalniņš and M. Ošleja, acting as Agents,

— the Estonian Government, by M. Linntam, acting as Agent,

— the Italian Government, by G. Palmieri, acting as Agent, and, initially, G. De Socio and, subsequently, G. Fiengo, avvocati dello Stato,

— the European Commission, by A. Sipos, A. Sauka and M. Šimerdová, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 20 May 2014,

gives the following

Judgment

1 This reference for a preliminary ruling concerns the interpretation 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 (OJ 2001 L 311, p. 67), as amended by Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 (OJ 2007 L 324, p. 121, and corrigendum OJ 2009 L 87, p. 174) ('Directive 2001/83').

2 The request has been made in proceedings between Olainfarm AS ('Olainfarm'), the applicant in the main proceedings, and the Latvijas Republikas Veselības ministrija (Ministry of Health of the Latvian Republic) and the Zāļu valsts aģentūra (National Medicinal Products Agency) concerning the latter's decision to grant to Grindeks AS ('Grindeks') a marketing authorisation ('MA') for a generic of a reference medicinal product for which Olainfarm holds a MA.

Legal context

EU law

3 Directive 2001/83 contains the following recitals:

'…

(2) The essential aim of any rules governing the production, distribution and use of medicinal products must be to safeguard public health.

(3) However, this objective must be attained by means which will not hinder the development of the pharmaceutical industry or trade in medicinal products within the Community.

…

(9) Experience has shown that it is advisable to stipulate more precisely the cases in which the results of toxicological and pharmacological tests or clinical trials do not have to be provided with a view to obtaining authorisation for a medicinal product which is essentially similar to an authorised product, while ensuring that innovative firms are not placed at a disadvantage.

(10) However, there are reasons of public policy for not conducting repetitive tests on humans or animals without over-riding cause.

…’

4 Recital 14 in the preamble to Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83 (OJ 2004 L 136, p. 34) is worded as follows:

‘Since generic medicines account for a major part of the market in medicinal products, their access to the Community market should be facilitated in the light of the experience acquired. …’

5 Article 6(1) of Directive 2001/83 provides as follows:

‘No medicinal product may be placed on the market of a Member State unless a [MA] 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 [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 (OJ 2004 L 136, p. 1)] ...

…’

6 Article 8 of Directive 2001/83 states as follows:

‘1. In order to obtain an authorisation to place a medicinal product on the market regardless of the procedure established by [Regulation No 726/2004], an application shall be made to the competent authority of the Member State concerned.

…

3. The application shall be accompanied by the following particulars and documents, submitted in accordance with Annex I:

…

(i) Results of:

— pharmaceutical (physico-chemical, biological or microbiological) tests,

— pre-clinical (toxicological and pharmacological) tests,

— clinical trials.

…’

7 Directive 2001/83 provides for certain derogations from the requirement laid down in Article 8(3)(i), in particular in Articles 10 and 10a, which are worded as follows:

'Article 10

1. By way of derogation from Article 8(3)(i), and without prejudice to the law relating to the protection of industrial and commercial property, the applicant shall not be required to provide the results of pre-clinical tests and of clinical trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product which is or has been authorised under Article 6 for not less than eight years in a Member State or in the Community.

A generic medicinal product authorised pursuant to this provision shall not be placed on the market until ten years have elapsed from the initial authorisation of the reference product.

…

The ten-year period referred to in the second subparagraph shall be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications which, during the scientific evaluation prior to their authorisation, are held to bring a significant clinical benefit in comparison with existing therapies.

2. For the purposes of this Article:

(a) "reference medicinal product" shall mean a medicinal product authorised under Article 6, in accordance with the provisions of Article 8;

(b) "generic medicinal product" shall mean a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. In such cases, additional information providing proof of the safety and/or efficacy of the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. Bioavailability studies need not be required of the applicant if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriate detailed guidelines.

…

5. In addition to the provisions laid down in paragraph 1, where an application is made for a new indication for a well-established substance, a non-cumulative period of one year of data exclusivity shall be granted, provided that significant pre-clinical or clinical studies were carried out in relation to the new indication.

6. Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products.

Article 10a

By way of derogation from Article 8(3)(i), and without prejudice to the law relating to the protection of industrial and commercial property, the applicant shall not be required to provide the results of pre-clinical tests or clinical trials if he can demonstrate that the active substances of the medicinal product have been in well-established medicinal use within the Community for at least ten years, with recognised efficacy and an acceptable level of safety in terms of the conditions set out in Annex I. In that event, the test and trial results shall be replaced by appropriate scientific literature.'

8 Section 1 of Part II of Annex I to Directive 2001/83 concerns the specific requirements for marketing authorisation dossiers submitted pursuant to Article 10a of the directive. Section 1 is worded as follows:

'For medicinal products the active substance(s) of which has/have a "well-established medicinal use" as referred to Article [10a], with recognised efficacy and an acceptable level of safety, the following specific rules shall apply.

The applicant shall submit Modules 1, 2 and 3 [relating, respectively, to administrative information, summaries, and chemical, pharmaceutical and biological information for medicinal products containing chemical and/or biological active substances] as described in part I of this Annex.

For Modules 4 and 5 [relating, respectively, to non-clinical reports and clinical study reports] a detailed scientific biography shall address non-clinical and clinical characteristics.

The following specific rules shall apply in order to demonstrate the well-established medicinal use:

(a) Factors which have to be taken into account in order to establish a well-established medicinal use of constituents of medicinal products are:

— the time over which a substance has been used,

— quantitative aspects of the use of the substance,

— the degree of scientific interest in the use of the substance (reflected in the published scientific literature), and

— the coherence of scientific assessments.

…

(b) The documentation submitted by the applicant should cover all aspects of the safety and/or efficacy assessment and must include or refer to a review of the relevant literature, taking into account pre- and post-marketing studies and published scientific literature concerning experience in the form of epidemiological studies and in particular of comparative epidemiological studies. All documentation, both favourable and unfavourable, must be communicated. With respect to the provisions on "well-established medicinal use" it is in particular necessary to clarify that "bibliographic reference" to other sources of evidence (post marketing studies, epidemiological studies, etc.) and not just data related to tests and trials may serve as a valid proof of safety and efficacy of a product if an application explains and justifies the use of these sources of information satisfactorily.

…'

Latvian law

9 The derogations provided for in Articles 10 and 10a of Directive 2001/83 have been incorporated into Latvian law by Article 28 of Decree No 376 of the Council of Ministers of 9 May 2006 on the procedure for registration of medicinal products (Ministru kabineta 2006. gada 9. maija noteikumi Nr. 376 'Zāļu reģistrēšanas kārtība').

10 The Law on pharmacy (Farmācijas likuma) provides in Article 31 thereof as follows:

'Registration of medicinal products shall be suspended or annulled:

…

(4) if the information provided is false or the information in the documentation submitted for registration is incomplete, or if the testing of medicinal products or of their constituents has not been carried out in accordance with the information contained in the documentation submitted for registration;

…

(6) if there is a decision by a court concerning breach of intellectual property rights;

(7) if the documentation submitted for the registration of the medicinal products does not comply with the requirements of [EU] law;

…'

The dispute in the main proceedings and the questions referred for a preliminary ruling

11 In 2003, Olainfarm registered the medicinal product NEIROMIDIN in Latvia in accordance with the statutory provisions then applicable in that Member State, which corresponded only partially with the Community law applicable at that time.

12 In 2008, Olainfarm obtained a MA for that medicinal product in Latvia in accordance with Article 10a of Directive 2001/83, having demonstrated, inter alia, that the active substances of the medicinal product had been in well established medicinal use within the Community for at least 10 years.

13 In 2011, Grindeks obtained from the Zāļu valsts aģentūra a MA for a generic medicinal product, IPIDAKRINE-GRINDEKS, having indicated in its application for authorisation that NEIROMIDIN was the reference product for the purpose of Article 10 of Directive 2001/83.

14 Olainfarm challenged Grindeks' MA before the Latvijas Republikas Veselības ministrija, arguing that the documents submitted for registration of the reference product did not comply with EU law requirements for generic medicinal products. That complaint was rejected on the ground that the holder of a MA for a reference medicinal product does not enjoy an individual right to challenge a MA granted for a generic of the reference product.

15 Olainfarm subsequently brought proceedings for annulment of the MA granted in respect of IPIDAKRINE-GRINDEKS.

16 Olainfarm maintained in those proceedings that, as manufacturer of the reference product, it enjoys an individual right to challenge the unjustified advantage which, in its view, had been conferred on the manufacturer of the generic product in question.

17 As to the substance, Olainfarm considers that a medicinal product for which a MA has been granted in accordance with Article 10a of Directive 2001/83 does not constitute a 'reference medicinal product' within the meaning of Article 10(2)(a) of the directive. That provision should be interpreted strictly, so that only those medicinal products in respect of which a MA has been granted in conformity with the requirements laid down in Article 8 of the directive, which include the requirement to submit the results of pre-clinical tests and clinical trials in accordance with Annex I to the directive, may be regarded as reference products.

18 The defendants in the main proceedings and Grindeks contend that the issue of a MA for a generic product does not infringe the rights of the manufacturer of the reference product.

19 Moreover, they argue that the MA for IPIDAKRINE-GRINDEKS was issued lawfully because, as a result of the second MA granted in 2008 for NEIROMIDIN in compliance with Directive 2001/83, the requirements for enabling that product to be used as a reference product by any medicinal products manufacturer in accordance with Article 10 of the directive were fulfilled. Grindeks submits in that regard that the period of data protection enjoyed by Olainfarm for the reference product in question has expired. Furthermore, in view of the fact that it is not possible to obtain more than one MA for the same medicinal product, there would be no point in the manufacturer of the reference product carrying out new pre-clinical tests and clinical trials and claiming entitlement to a further protection period, which relates only to genuinely new active substances and may be obtained only once.

20 Lastly, the Zāļu valsts aģentūra refers to Section 5.3.1. of the recommendations of the European Commission published in November 2005 in connection with the document entitled 'Notice to Applicants Volume 2A Procedures for marketing authorisation, Chapter 1 Marketing Authorisation', according to which the reference medicinal product must registered in accordance with Articles 8(3), 10a, 10b or 10c of Directive 2001/83.

21 The referring court is of the view that Directive 2001/83 does not make it clear either whether the manufacturer of a reference medicinal product possible on the basis of the derogation provided for in Article 10a has an individual right to oppose the granting of a MA for a generic product or whether a medicinal product for which a MA has been granted under Article 10a of the directive may be used as reference product for the purpose of obtaining a MA for a generic product.

22 In those circumstances, the Augstākās Tiesas Senāts (Senate of the Supreme Court), decided to stay the proceedings and to refer the following questions to the Court for a preliminary ruling:

'(1) On a proper construction of Article 10 or of any other provision of Directive 2001/83 …, has the manufacturer of a medicinal product [A, registered by that manufacturer] an individual right to bring an action challenging the decision of a competent authority by which a generic medicinal product of another manufacturer was registered using, as the reference product, product [A]? In other words, does that directive confer on the manufacturer of the reference medicinal product the right to a judicial remedy, the object of which is to determine whether the manufacturer of the generic product made lawful, well-founded reference to the product registered by the manufacturer of the reference product, relying on Article 10 of the directive?

(2) If the reply to the first question is in the affirmative, on a proper construction of Articles 10 and 10a of … Directive [2001/83], may a medicinal product registered in accordance with Article 10a of the directive as a medicinal product [whose active substances have been in well-established medicinal use] be employed as a reference product for the purpose of Article 10(2)(a)?'

Consideration of the questions referred

Question 2

23 By its second question, which it is appropriate to examine first, for the reasons given by the Advocate General at point 19 of his Opinion, the referring court asks, in essence, whether the concept of a 'reference medicinal product' within the meaning of Article 10(2)(a) of Directive 2001/83 must be construed as encompassing a medicinal product for which the MA was granted on the basis of Article 10a of the directive.

24 The term 'reference medicinal product' is defined in Article 10(2)(a) of Directive 2001/83 as a medicinal product authorised under Article 6 of the directive, in accordance with the provisions of Article 8 thereof.

25 By way of derogation from Article 8(3)(i) of Directive 2001/83, Article 10a thereof provides that an applicant for a MA for a given medicinal product is not required to provide the results of pre-clinical tests or clinical trials and that these may be replaced by appropriate scientific literature if the applicant can demonstrate, in accordance with the conditions set out in Annex I to the directive, that the active substances of the medicinal product have been in well-established medicinal use within the EU for at least 10 years, with recognised efficacy and an acceptable level of safety.

26 Article 10a of Directive 2001/83 therefore has the effect of exempting the applicant from one of the requirements laid down in Article 8 of the directive for obtaining a MA under Article 6 thereof. Accordingly, a medicinal product for which the MA was granted pursuant to Article 10a of the directive, the applicant for that authorisation having availed himself of the derogation under that provision and also having fulfilled all the other requirements laid down in Article 8 of the directive, must be regarded as a medicinal product authorised under Article 6 of the directive, in accordance with the provision of Article 8 thereof.

27 In that regard, it should be observed, first, that the purpose of the requirement for applicants seeking marketing authorisation to attach to their application the results of preclinical tests and clinical trials, laid down in Article 8(3)(i) of Directive 2001/83, is to provide proof of the safety and efficacy of the medicinal product concerned (see, to that effect, judgment in *Generics (UK)*, C-527/07, EU:C:2009:379, paragraph 22 and the case-law cited).

28 Second, bearing in mind in particular the fact that the essential aim of any rules governing the production and distribution of medicinal products must be to safeguard public health, as stated in recital 2 in the preamble to Directive 2001/83, the concept of a 'reference medicinal product', within the meaning of Article 10(2)(a) of that directive, cannot be interpreted in such a way that the abridged procedure provided for in that article amounts to a relaxation of the requirements of safety and efficacy which must be met by medicinal products (judgment in *Generics (UK)*, EU:C:2009:379, paragraph 24 and the case-law cited). It is therefore essential, in order for it to be possible to grant a marketing authorisation for a generic medicinal product on the basis of the abridged procedure, that all the particulars and documents relating to the reference product and demonstrating its safety and efficacy should remain available to the competent authority concerned by the application for authorisation (see, to that effect, judgment in *Generics (UK)*, EU:C:2009:379, paragraph 25 and the case-law cited).

29 As regards Article 10a of Directive 2001/83, it should be noted in the first place that the procedure governed by that provision does not provide for any relaxation of the requirements of safety and efficacy which must be met by medicinal products, that procedure being simply designed to reduce the preparation period for a MA application by relieving the applicant of the obligation to perform the preclinical tests and clinical trials referred to in Article 8(3)(i) of Directive 2001/83, provided that

it is established by means of appropriate scientific literature, in accordance with the requirements laid down in Section 1 of Part II of Annex I to the directive, that those tests and trials have been carried out previously and have demonstrated that the constituent or constituents of the medicinal product concerned satisfy the criteria set out in Article 10a (see, with regard to the comparable provision in Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ English Special Edition 1965-1966, p. 20), as amended by Council Directive 87/21/EEC of 22 December 1986 (OJ 1987 L 15, p. 36), judgment in *Scotia Pharmaceuticals*, C-440/93, EU:C:1995:307, paragraph 17). Accordingly, as observed by the Advocate General at point 39 of his Opinion, such a medicinal product may be placed on the market only after the competent authority has verified its safety and efficacy.

30 In the second place and as a consequence, the dossier for the MA granted for a medicinal product under Article 10a of Directive 2001/83 will contain all the information and documents needed to demonstrate the safety and efficacy of the product.

31 Accordingly, there is nothing to preclude such a medicinal product from being used as a reference product for the purpose of obtaining a MA for a generic product.

32 The answer to Question 2 is therefore that the concept of 'reference medicinal product' within the meaning of Article 10(2)(a) of Directive 2001/83 must be interpreted as encompassing a medicinal product for which the MA was granted on the basis of Article 10a of the directive.

Question 1

33 By its first question, the referring court asks whether the manufacturer of a medicinal product used by another manufacturer as a reference product with a view to obtaining a MA for a generic product under Article 10 of Directive 2001/83 enjoys, under the directive, the right to a judicial remedy, the object of which is to determine whether the manufacturer of the generic product made lawful, well-founded reference to the reference product, in conformity with the provisions of Article 10.

34 It should be noted, first, that, under Directive 2001/83, the procedure for the granting of a MA is conceived as a bilateral procedure involving only the applicant and the competent authority (see, by analogy, judgment in *Olivieri* v *Commission and EMEA*, T-326/99, EU:T:2003:351, paragraph 94) and that that directive does not contain any express provision to the effect that a judicial remedy is available to the holder of a MA granted for an original medicinal product to challenge the decision of the competent authority which granted, pursuant to Article 10 of the directive, a MA for a generic medicinal product for which the original product served as the reference product.

35 However, Article 47 of the Charter of Fundamental Rights of the European Union ('the Charter') provides that any person whose rights guaranteed by the law of the European Union are violated has the right to an effective remedy before a tribunal.

36 Accordingly, the first question is to be understood as raising, in essence, the issue whether Article 10 of Directive 2001/83, read in conjunction with Article 47 of the Charter, is to be interpreted as conferring on the holder of a MA for a medicinal product used as the reference product in an application under Article 10 for a MA for a generic product of another manufacturer the right to a judicial remedy enabling that holder to challenge the decision of the competent authority which granted a MA for the generic product.

37 It should be observed that Article 10 of Directive 2001/83 lays down the conditions under which the holder of a MA for a medicinal product is required to accept that the manufacturer of another medicinal product is entitled to refer to the results of pre-clinical tests and clinical trials contained in

the dossier relating to the application for the MA for the former product, rather than perform those tests or trials himself, for the purpose of obtaining a MA for the other medicinal product. It is apparent that that provision confers a concomitant right on the holder of the MA for the former medicinal product to demand that the rights attaching to him by virtue of those conditions are observed.

38 Thus, without prejudice to the law relating to the protection of industrial and commercial property, the holder of a MA for a medicinal product has the right to demand, pursuant to the second and fifth subparagraphs of Article 10(1) of Directive 2001/83, that that medicinal product is not to be used as a reference product for the purpose of authorising the placing on the market of a medicinal product of another manufacturer until a period of 8 years has elapsed from the date on which that MA was granted, or to demand that a medicinal product authorised to be placed on the market on the basis of Article 10 is not to be marketed until a period of 10 years — which may be extended, where appropriate, to 11 — has elapsed from the date on which that MA was granted. Similarly, that holder may demand that his medicinal product is not to be used for the purpose of obtaining, under Article 10, a MA for another medicinal product in relation to which his own product cannot be regarded as a reference product within the meaning of Article 10(2)(a), as contended by Olainfarm before the referring court, or for a product which does not fulfil the requirement, laid down in Article 10(2)(b) of the directive, that it should be similar to the reference product in terms of its composition in active substances and pharmaceutical form.

39 It should therefore be recognised that the holder of a MA for a medicinal product used as a reference product in an application for a MA under Article 10 of Directive 2001/83 is, by virtue of that provision, read in conjunction with Article 47 of the Charter, entitled to judicial protection in so far as concerns respect for his rights.

40 In the light of the foregoing considerations, the answer to Question 1 is that, on a proper construction of Article 10 of Directive 2001/83, read in conjunction with Article 47 of the Charter, the holder of a MA for a medicinal product used as a reference product in an application for a MA under Article 10 of the directive for a generic product of another manufacturer has the right to a judicial remedy enabling him to challenge the decision of the competent authority which granted the MA for the generic product, provided that that holder is seeking judicial protection of a right conferred on him by Article 10. Such a judicial remedy exists, inter alia, where the holder demands that his medicinal product is not to be used for the purpose of obtaining, under Article 10, a MA for another medicinal product in relation to which his own product cannot be regarded as a reference product within the meaning of Article 10(2)(a) of the directive.

Costs

41 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Fifth Chamber) hereby rules:

1. **The concept of 'reference medicinal product' within the meaning of Article 10(2)(a) 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 by Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007, must be interpreted as encompassing a medicinal product for which the marketing authorisation was granted on the basis of Article 10a of the directive.**

2. **On a proper construction of Article 10 of Directive 2001/83, as amended by Regulation No 1394/2007, read in conjunction with Article 47 of the Charter of Fundamental Rights of the European Union, the holder of a marketing authorisation for a medicinal product used as a reference product in an application for a marketing authorisation under Article 10 of the directive for a generic product of another manufacturer has the right to a judicial remedy enabling him to challenge the decision of the competent authority which granted the marketing authorisation for the generic product, provided that that holder is seeking judicial protection of a right conferred on him by Article 10. Such a judicial remedy exists, inter alia, where the holder demands that his medicinal product is not to be used for the purpose of obtaining, under Article 10, a marketing authorisation for another medicinal product in relation to which his own product cannot be regarded as a reference product within the meaning of Article 10(2)(a) of the directive.**

[Signatures]