OPINION OF ADVOCATE GENERAL TIZZANO

delivered on 11 July 2002 [1]

Introduction

1. In this case the Commission claims that the Republic of Finland has failed to comply with Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems ('the Directive') [2] and in particular Article 6 thereof, which concerns the procedure for the inclusion of a medicine in the positive list of products covered by a national health insurance system.

1 — Original language: Italian.
2 — OJ 1989 L 40, p. 8.

Legal background

Community law

2. As is clear from its preamble, the Directive is intended to render transparent national measures relating to the marketing of medicinal products introduced by the Member States in order to control costs payable by their national health services.

3. Article 1(1) of the Directive illustrates both its objective and scope:

'Member States shall ensure that any national measure, whether laid down by law, regulation or administrative action, to control the price of medicinal products for human use or to restrict the range of medicinal products covered by their national health insurance systems complies with the requirements of this directive.'

4. Article 2 of the Directive provides that:

'The following provisions shall apply if the marketing of a medicinal product is permitted only after the competent authorities of the Member State concerned have approved the price of the product:

...'

1. Member States shall ensure that a decision on the price which may be charged for the medicinal product concerned is adopted and communicated to the applicant within 90 days of the receipt of an application submitted, in accordance with the requirements laid down in the Member State concerned, by the holder of a marketing authorisation. The applicant shall furnish the competent authorities with adequate information. If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of what detailed additional information is required and take their final decision within 90 days of receipt of this additional information. In the absence of such a decision within the above-mentioned period or periods, the applicant shall be entitled to market the product at the price proposed.

2. Should the competent authorities decide not to permit the marketing of the medicinal product concerned at the price proposed by the applicant, the decision shall contain a statement of reasons based on objective and verifiable criteria. In addition, the applicant shall be informed of the remedies available to him under the laws in force and the time-limits allowed for applying for such remedies.

5. Lastly, Article 6 of the Directive provides thus:

'The following provisions shall apply if a medicinal product is covered by the national health insurance system only after the competent authorities have decided to include the medicinal product concerned in a positive list of medicinal products covered by the national health insurance system.

1. Member States shall ensure that a decision on an application submitted, in accordance with the requirements laid down in the Member State concerned, by the holder of a marketing authorisation to include a medicinal product in the list of medicinal products covered by the health insurance systems is adopted and communicated to the applicant within 90 days of its receipt. Where an application under this article may be made before the

competent authorities have agreed the price to be charged for the product pursuant to Article 2, or where a decision on the price of a medicinal product and a decision on its inclusion within the list of products covered by the health insurance system are taken after a single administrative procedure, the time-limit shall be extended for a further 90 days. The applicant shall furnish the competent authorities with adequate information. If the information supporting the application is inadequate, the time-limit shall be suspended and the competent authorities shall forthwith notify the applicant of what detailed additional information is required.

Where a Member State does not permit an application to be made under this article before the competent authorities have agreed the price to be charged for the product pursuant to Article 2, the Member State concerned shall ensure that the overall period of time taken by the two procedures does not exceed 180 days. This time-limit may be extended in accordance with Article 2 or suspended in accordance with the provisions of the preceding subparagraph.

2. Any decision not to include a medicinal product in the list of products covered by the health insurance system shall contain a statement of reasons based upon objective and verifiable criteria, including, if appropriate, any expert opinions or recommendations on which the decision is based. In addition, the applicant shall be informed of the remedies available to him under the laws in force and of the time-limits allowed for applying for such remedies.

3. Before the date referred to in Article 11(1), Member States shall publish in an appropriate publication and communicate to the Commission the criteria which are to be taken into account by the competent authorities in deciding whether or not to include medicinal products on the lists.

...'

National law

6. Pursuant to Articles 5 and 9 of the Finnish law on health insurance (*sairausvakuutuslaki*, hereinafter 'the law on health insurance') in order for a medicinal product to be covered by the health insurance system, the holder of a licence to market the medicine must apply to the reimbursement authority within the Ministry of Social Affairs and Health, which sub-

sequently became the Commission for Medicine Prices (*lääkekorvauslautakunta*, then *lääkkeiden hintalautakunta*, hereinafter 'the ministerial commission'), stating a reasonable wholesale price which it undertakes to charge. If the ministerial commission agrees that the proposed price is reasonable, the product is automatically entered on the list of 'prescribable' products which come under the ordinary scheme of insurance cover, under which 50% of the price, after deduction of a contribution of FIM 50 payable by the patient, is reimbursed.

7. Pursuant to Articles 23 and 24 of Law No 598/82 on administrative procedure (*hallintomenettelylaki*; hereinafter 'the law on administrative procedure'), a refusal to enter a medicine in the abovementioned list must be properly reasoned, with a clear statement of the rights and obligations of the party concerned, the factors taken into consideration, and, in particular, the essential factors and the legal provisions on which the decision is based. A refusal may be challenged before the Finnish administrative courts, in particular before the Supreme Administrative Court (*Korkein hallinto-oikeus*).

8. In addition to the ordinary scheme of insurance cover, the law on health insurance provides for two special schemes of insurance cover which differ either by reason of a reduced insured person's contribution of FIM 25 or a higher level of reimbursement, amounting to either 75% or 100% of the remaining cost depending on whether or not the active ingredient is patented.

9. In order to come within either of those special schemes the medicinal product must be included in a special list drawn up by the national institute of social security (*Kansaneläkelaitos*, hereinafter 'the institute for social security'), pursuant to a decision (later called a 'decree') of the Finnish Council of Ministers. That decision will identify the serious illnesses which entitle chronic sufferers to higher-level cover of the costs of medicines and the active ingredients in respect of which reimbursement at a higher rate is, in principle, guaranteed. The decree is submitted in draft form to the Council of Ministers by the Ministry of Health on the basis of an opinion of the institute for social security and is normally adopted by the Council of Ministers without being put to a vote.

10. Since this is a regulatory act of general application and not a decision handed down at the conclusion of a procedure set in train on the application of a particular interested party no duty to give reasons is provided for. Parties who may have an interest have no right to be heard at any stage of the proceedings; furthermore, neither preparatory documents nor the decree are open to challenge before a court.

11. As mentioned, once the decree has been passed the institute for social security draws up the final list. At this stage, however, the institute has no discretion and must include in the list any product placed on the market in Finland and already covered by the basic insurance scheme that contains an active ingredient mentioned in the decree. Similarly, the institute has no discretion in amending the list and must add to it any new preparation which contains an active ingredient referred to in the Council of Ministers' decree, once that preparation has been entered on the list for reimbursement at the basic level.

12. The decision of the institute for social security adopting the final list is duly published and is not open to challenge.

13. Final decisions on higher-rate reimbursement are taken by the relevant local branch of the institute for social security in response to individual applications submitted by patients with serious and chronic illnesses. Decisions must be reasoned and may be appealed.

14. The procedure thus outlined is not, however, the only one which may lead to higher-rate reimbursement of the costs of medicines. In addition to identifying serious illnesses and the active ingredients used to cure them, the Council of Ministers' decree provides that anyone who incurs costs in excess of FIM 3 319.91 per annum will receive full reimbursement of the excess.

Facts

15. Following the receipt of a complaint in April 1997 and on the basis of certain additional information obtained informally from the Finnish authorities, on 11 August 1997 the Commission addressed a request for clarification to Finland, observing that, from a preliminary examination of the national legislation, the procedure by which medicinal products are made subject to the higher-rate reimbursement scheme did not appear to comply with the conditions laid down by Article 6 of the Directive.

16. The Finnish authorities replied on 10 October 1997, explaining how the Finnish system for reimbursement of the cost of medicines operates. Invoking the principle of subsidiarity, they maintained that defining the extent of special insurance cover was not a matter which fell within the scope of the Directive, since it merely involved the exercise of legislative power and was governed by considerations of administrative law and health policy.

17. Not satisfied with that reply, on 29 May 1998 the Commission sent Finland a letter of formal complaint, asserting, first of all, that the procedure for drawing up the list of medicinal products covered by the special higher-rate reimbursement scheme failed to comply with the conditions laid down by Article 6 of the Directive.

18. Second, the Commission contended that certain decisions of the competent authorities refusing to agree the wholesale price of medicines merely contained a standard phrase, in the following terms: 'The application is refused because the applicant has not provided detailed reasons such as to enable the proposed wholesale price to be adjudged reasonable'. [3] That practice, according to the Commission, clearly failed to satisfy the requirement to give reasons laid down by Article 2(2) of the Directive.

19. In its reply of 20 July 1998, Finland acknowledged that the complaint of lack of reasoning was well-founded as regards certain refusal decisions taken by the ministerial commission concerning the ordinary reimbursement scheme, but submitted that the procedure had since been amended. As for the remainder, Finland claimed that the procedure complied fully with the requirements laid down by Article 6 of the Directive.

3 — Unofficial translation.

20. The Commission took the view that the explanations provided by Finland were inadequate and on 17 December 1998 issued a reasoned opinion reiterating the abovementioned complaints.

21. In its reply, Finland repeated its explanations in the terms just outlined, whereupon, on 6 June 2000, the Commission brought the present action.

Legal analysis

Introduction

22. In the present action the Commission makes two complaints. First, Finland failed to implement Article 6(1) and (2) of the Directive as regards decisions establishing certain special categories of higher-rate reimbursement of the cost of medicines. Second, it failed to comply with its obligation under the Directive to give reasons for decisions refusing to include medicines in the general positive list, omitting to inform applicants of sufficiently objective and verifiable criteria of assessment.

I — *The complaint concerning the decision of the Council of Ministers*

Arguments of the parties

23. By its first complaint, the Commission submits that neither the Council of Ministers' decree nor the subsequent implementing decision of the institute for social security establishing which medicinal products come within the special scheme of higher-rate reimbursement comply with the conditions laid down by the Directive.

24. In particular, the Commission laments the fact that interested parties are given no opportunity to argue their point of view, either in the preparatory phase of the decree, or subsequently. No official and transparent reply is given to applications which interested parties address to the various institutions involved in the decision-making process. No particular obligation to give reasons is provided for, either for the inclusion of an active ingredient in the relevant list or for its exclusion from it. Finally, none of the documents or measures relating to the definition of the extent of the special scheme of higher-rate reimbursement is subject to review by a court.

25. Furthermore, the Commission takes issue with the explanations advanced by the defendant government in the pre-litigation phase, in particular the assertion that the principle of subsidiarity enables a Member State to opt out of the conditions imposed by the Directive and maintain in force a system of health insurance of the type found in Finland. Admittedly, in Case 238/82 *Duphar* [1984] ECR 523, the Court recognised that 'Community law does not detract from the powers of Member States to organise their social security systems and to adopt, in particular, provisions intended to govern the consumption of pharmaceutical preparations in order to promote the financial stability of their health-care insurance schemes'. [4] That ruling was, however, made before the Directive was adopted and therefore no argument can be drawn from it to justify failure to comply with the Directive.

26. Second, again according to the Commission, it is indisputable that defining the extent of the special scheme of higher-rate reimbursement falls squarely within the scope of the Directive, which applies, as has been seen, to 'any national measure, whether laid down by law, regulation or administrative action, to control the price of medicinal products for human use or to restrict the range of medicinal products covered by their national health insurance systems' (Article 1). Therefore, even where national decisions on the prices of medicines must be adopted at Council of Ministers level, as happens in Finland, the relevant procedure should in all cases comply with the conditions laid down by the Directive and in particular by Article 6.

4 — Paragraph 16.

27. Finland, for its part, after raising a plea of inadmissibility in respect of part of the present complaint, objects on the merits, first of all, that Article 6(1) and (2) does not apply to the procedure in question, in that it is intended to apply to individual decisions, whilst the Council of Ministers' decree is a measure of general application, the adoption of which falls within the exercise of a legislative power delegated by the Parliament.

28. Finland continues that Article 6(3) is more likely to apply. That provision establishes the system of transparency applicable to measures fixing 'the criteria which are to be taken into account by the competent authorities in deciding whether or not to include medicinal products on the lists'. The decree in question, in fact, merely established the criteria for setting the scope of the special scheme of higher-rate reimbursement, indicating the relevant types of diseases, and the active ingredients by which they may be cured. In so doing, the Council of Ministers is required, in accordance with the law on sickness insurance, to take into consideration both the nature of the illnesses and the characteristics of the active ingredients, in particular the need for them and their therapeutic efficacy, proven in practice and by research, as well as their cost-effectiveness.

29. But on closer scrutiny, adds the defendant, it is not in fact this or that paragraph of Article 6, but the provision as a whole that does not apply to the present case, because it merely addresses decisions on the inclusion of substances in the list of substances covered by health insurance and not decisions determining the amount of the insurance cover.

30. Lastly, Finland argues in support of its defence that the interpretation proposed by the Commission necessarily implies interference in the establishment of the criteria used in the Finnish health insurance scheme inconsistent with the principle, stated by the Court in *Duphar*, that the Member States are free to adopt provisions intended to govern the consumption of pharmaceutical preparations in order to promote the financial stability of their health-care insurance schemes.

Assessment

31. First of all it is appropriate briefly to examine the plea of inadmissibility raised by the defendant government, to which I referred earlier.

32. According to Finland, at no point in the pre-litigation phase did the Commission claim that the conditions laid down in Article 6(1) and (2) had been breached in the procedure whereby the institute for

social security amends the list of medicines which come under the special scheme of reimbursement. That complaint was raised for the first time in the action before the Court and so, according to the well-known case-law of the Court on the point, [5] the plea is inadmissible.

33. However, it seems to me that the Commission is right to reply that, in reality, this is not a case of a new complaint, but merely of arguing and further defining the principal complaint concerning breach of the procedural safeguards laid down by Article 6(1) and (2) by the higher-rate reimbursement scheme as a whole. It seems to me, therefore, that the plea is unfounded and should be dismissed accordingly.

34. Turning to the substance of the present complaint, I must say that the arguments advanced by Finland on the merits do not persuade me either.

35. I note, first, that Finland does not deny that the Council of Ministers' decree fixing the list of active ingredients which come under the scheme of higher-rate cover was passed at the conclusion of a procedure that fails to comply with the requirements of Article 6(1) and (2) of the Directive. Instead it denies that those provisions are applicable in this particular case because the decree in question is regulatory in nature and therefore falls within the scope of Article 6(3).

36. I am not, therefore, able to share the view that the Council of Ministers' decree is a measure laying down general and abstract criteria 'which are to be taken into account by the competent authorities in deciding whether or not to include medicinal products on the lists' (Article 6(3)). One need only consider the fact that, were that interpretation to be accepted, one would be justified in saying that the general criteria on which the Finnish health insurance scheme is based were changed fully seven times between 1994 and 2000, that being the number of decrees passed in that interval of time!

37. Furthermore, I must record that the general and abstract nature which, according to Finland, the criteria referred to in Article 6(3) have, is certainly not found in the decree by which the Council of Ministers draws up the list of illnesses and active ingredients which come under the special scheme of reimbursement, given that that list specifically names each illness and each active ingredient. It is, if anything, reflected in the law on health insurance, which provides that, in taking its decision, the Council of Ministers must consider the necessity, therapeutic efficacy and cost-ef-

5 — See, *inter alia*, Case C-365/97 *Commission* v *Italy* [1999] ECR I-7773, particularly paragraph 23, and Case C-191/95 *Commission* v *Germany* [1998] ECR I-5449, particularly paragraph 55.

fectiveness of the treatment. It is therefore to that legislative provision rather than to the decree that Article 6(3) of the Directive ought to apply.

38. But there is more: it emerges clearly from the reconstruction of the system provided by the defendant government that, in fact, the Council of Ministers' decree conclusively determines not only whether certain active ingredients are to be included in the higher-rate reimbursement scheme, but also whether individual medicinal products containing them are to be included. The choices made in the decree *necessarily* dictate the list of medical preparations containing the relevant active ingredients and in respect of which the competent authorities have granted marketing authorisation. Every preparation is, in turn, directly attributable to a given producer, which holds the relevant marketing authorisation.

39. Moreover, the defendant government itself does not deny that this is so inasmuch as it acknowledges that the institute for social security has no discretion in adopting the decision implementing the decree and must simply enter on the list all medicines for which there is marketing authorisation and for which the ministerial commission has approved the wholesale price proposed for the purposes of inclusion in the basic insurance scheme (cf. point 6 above).

40. It therefore follows that, notwithstanding the fact that it is a piece of delegated legislation, the decree essentially contains a series of individual decisions on the inclusion of specific medicinal products in one of the national health insurance schemes. It cannot, therefore, be regarded as falling outside the scope of Article 6(1) and (2).

41. In any event, even if one takes the view that the Council of Ministers' decree contributes to establishing the general criteria mentioned in Article 6(3), that has no bearing on the substance of the present complaint. What matters is that Finland has not fulfilled its obligations under Article 6(1) and (2) of the Directive and therefore has not attained the desired result.

42. Indeed, as we have seen, Article 6(1) and (2) requires the Member States to ensure that '*a decision on an application... to include* a medicinal product in the list of medicinal products covered by the health insurance systems is adopted' [6] and that that decision is adopted within precise time-limits and is duly reasoned.

43. In Finland's case, however, it is not disputed that the inclusion of a medicinal

6 — Article 6(1). The italics are mine.

product in the list for higher-rate cover occurs at the conclusion of the procedure illustrated above, and that that procedure is *not* implemented at the request of an interested party and fails to comply with the further conditions laid down by Article 6(1) and (2).

44. On the other hand, Finland argues that, where a scheme comprises different scales of reimbursement, as in Finland, Article 6 applies only to the entry of medicinal products on the basic list relating to the lower scale of reimbursement; and not to entries on other lists relating to the higher rates of reimbursement, with which the present case is concerned.

45. However, that interpretation does not seem to me to be well founded. As the Court has already made clear, in a case similar in many respects to the present one, Article 6 is to be interpreted in the light of 'the purpose of the Directive which, under Article 1 thereof, is to ensure that *any* national measure to control the prices of medicinal products for human use or to restrict the range of medicinal products covered by... national health insurance systems complies with the requirements of the Directive.' [7]

7 — Case C-424/99 *Commission* v *Austria* [2001] ECR I-9285, paragraph 30. The italics are mine.

46. The decisions which, within the Finnish system, establish the extent of higher-rate reimbursement of the cost of medicines are, at the same time, measures for controlling prices — in that they presuppose that the ministerial commission accepts the wholesale price proposed by the producer as the basis for reimbursement — and a means for establishing the extent of the range of medicinal products covered, substantially and predominantly, by the national health insurance scheme. I conclude from that that both of the conditions for application of the Directive laid down in Article 1 thereof are satisfied in this case.

47. It follows, in my opinion, that Article 6 is to be interpreted as including within its scope not only measures relating to the entry of medicines in the basic list of products covered by health insurance, but also subsequent decisions which, within a system structured like Finland's, alter the amount of insurance cover for certain products already covered by the basic scheme by means of the provision of special lists.

48. Moreover, such an interpretation is the only one capable of ensuring the effectiveness of the Directive in that it enables interested parties to check that national health insurance scheme subsidies are not used for protectionist purposes and, in particular, do not constitute measures having equivalent effect to quantitative restrictions on imports or exports of medicines

(see the sixth recital of the preamble). It is clear, in fact, that the higher the insurance cover for a medicine, the greater the inducement to the persons concerned to purchase the product, or have it purchased, preferring it to others of similar therapeutic efficacy.

49. It should be added that the interpretation proposed by the Finnish Government risks encouraging the Member States to employ formal devices to evade the obligations imposed by the Directive. As the Commission has noted, in fact, with structured schemes of assistance comprising several scales of reimbursement, States could achieve the paradoxical result of substantially circumventing the requirements of the Directive while formally complying with it. Member States would merely have to make provision for minimal or even symbolic reimbursement of medicinal products entered on a general list and then set up 'special' lists for the medicinal products properly covered by the health insurance scheme.

50. Finally, on a more general level, the Finnish Government objects that the Commission's complaint amounts to interference in the organisation of national social security schemes, which, by reason of the principle of subsidiarity, is a matter falling within the exclusive competence of the Member States.

51. I wonder, however, what that worrisome interference might consist of, given that neither Finland's political choices with regard to social security, nor the current organisation of its medical insurance scheme are in issue here. In particular, neither the structuring of the scheme over several levels of insurance cover, nor the decision-making power of the Council of Ministers, nor the considerations governing the selection of illnesses for which curative medicines may attract higher-rate reimbursement nor, finally, the criteria for including certain active ingredients in the higher-rate reimbursement scheme is in issue.

52. Finland was merely asked to ensure that interested persons could apply for the inclusion of medicines in the list of products coming within the higher-rate reimbursement scheme, that decisions on such applications be given within the time-limits laid down in Article 6(1) and, lastly, that in the case of negative decisions the requirements to state reasons and to inform applicants of the possibility of appeal laid down by Article 6(2) are complied with.

53. None of that occurred and I, therefore, consider that, in respect of this part, the Commission's application should succeed.

II — *The complaint concerning the statement of reasons on which refusal decisions are based*

54. The Commission's second complaint is focused on an alleged failure to state reasons in the decisions whereby the ministerial commission refuses to approve wholesale prices proposed by the persons who market, or intend to market, medicines in Finland. The Commission contends that that is a breach of the part of the Directive which imposes an obligation to give precise reasons for '[a]ny decision not to include a medicinal product in the list of products covered by the health insurance system', and provides, in particular, that such decisions should contain 'a statement of reasons based upon objective and verifiable criteria' (Article 6(2)).

(a) Admissibility

55. As a preliminary point, I must reiterate that the Finnish Government has asked the Court to declare this complaint inadmissible, in particular on the ground that, by comparison with the reasoned opinion, it was improperly amended in the application, as regards both the provisions invoked and the substance of the complaint.

56. As regards the first aspect, the defendant government objects that the reasoned opinion complained of a breach of Article 2(2), which applies where the authorities' approval of the proposed wholesale price of a medicine is a precondition of marketing it. In the application, by contrast, the Commission makes no express reference to Article 2(2) of the Directive and asserts that the law and administrative practice in Finland do not comply with Article 6 of the Directive.

57. As regards the substance of this complaint, Finland objects that, whilst in the letter of formal complaint and in the reasoned opinion the Commission merely charged it with certain shortcomings, which Finland does not dispute, in its administrative practices in connection with certain specific decisions of the ministerial commission, in the application the Commission makes the more fundamental complaint that the Finnish legislation which governs the obligation to state reasons for the decisions in question is inadequate.

58. For my part, I note first that, as is clear from the settled case-law of the Court, 'the purpose of the pre-litigation procedure is to give the Member State concerned an opportunity, on the one hand, to comply with its obligations under Community law and, on the other, to avail itself of its right to defend itself against the complaints made by the Commission'. [8] It necessarily follows from that that the complaint in the appli-

8 — See, most recently, Case C-287/00 *Commission* v *Germany* [2002] ECR I-5811, paragraph 16.

cation must correspond to the changes made in the pre-litigation phase.[9] However, as the Court has clarified, 'that requirement cannot be carried so far as to mean that in every case the statement of complaints in the letter of formal notice, the operative part of the reasoned opinion and the form of order sought in the application must be exactly the same, where the subject-matter of the proceedings has not been extended or altered'.[10]

59. In my opinion, the course of the pre-litigation procedure in the present case proves that, notwithstanding that the Commission complained of infringement of first one, and then another, different provision of the Directive in relation to the same aspect of the Finnish legal system, Finland nevertheless has had the 'opportunity... to comply with its obligations under Community law and... to avail itself of its right to defend itself against the complaints' made against it.

60. The defendant, in fact, was perfectly well aware from the beginning which national procedure was the subject of the Commission's complaint. It was clear to the defendant government that the Commission's criticisms focused on the procedure by which the ministerial commission assesses the fairness of proposed prices for the purposes of bringing medicines within the health insurance scheme.

61. The fact that the defendant government was not misled by imprecise references to the legislation is confirmed, moreover, by the defences it put forward during the pre-litigation phase inasmuch as it asserted that it had taken certain steps to ensure that the commission observes the proper form when taking decisions on prices. That demonstrates in my opinion that, as regards this aspect, the subject-matter of the dispute was clear from the start and cannot be said to have changed as a result of the commission's legal (re)characterisation of the case in the application.

62. However, it remains to be considered whether the plea of inadmissibility is nevertheless well founded in the other respects mentioned, that is to say inasmuch as the Commission's complaint, initially limited to certain consequences of Finnish administrative practice, was subsequently extended in the application to include the relevant legislative provisions.

63. I must confess to being perplexed by this point. Whilst, in fact, in the terse statement of reasons on which the complaint was based set out in the letter of

9 — See *Commission* v *Italy*, already cited, paragraph 23 and *Commission* v *Germany*, already cited, paragraph 55.

10 — See, *inter alia*, *Commission* v *Italy*, cited above, paragraph 25.

formal notice and in the reasoned opinion reference is made solely to administrative practice, in the operative part of the latter, Finland is instead charged with failing to adopt 'the laws, regulations and administrative provisions necessary to comply with the Directive', and consequently with failing to fulfil its obligations under the Directive and — in the version notified in the Swedish language — that that failure concerned, in particular, negative decisions 'concerning prices'.

64. It may, therefore, be considered that already by that stage the complaint had been extended, albeit with many ambiguities, to include the overall consistency of Finnish law with the Directive. I do not, however, consider it necessary to attempt to resolve that ambiguity because of what I shall now say about the substance of the application.

(b) Substance

65. As I have said, essentially on the basis of certain effects of administrative practice in Finland, the Commission claims that that State has failed to ensure that the competent authorities are required to give reasons for their own negative decisions in such a way as to comply with the relevant provisions of the Directive 'inasmuch as those provisions require a more detailed statement of reasons than the Finnish legislation'. In particular, the Commission mentions two decisions of the ministerial commission, subsequently overturned by the Supreme Administrative Court for failure to state reasons.

66. In challenging the allegation, Finland points out that, pursuant to Articles 23 and 24 of the law on administrative procedure, any administrative decision must be properly reasoned, with a clear statement of the rights and obligations of the party concerned, the factors taken into consideration and the legal provisions on which the decision is based. From the express wording of those provisions it is to be inferred that the extent of the obligation to state reasons is to be determined by reference to the specific rules governing the relevant administrative procedure, and therefore, in the present case, to the law on health insurance and the decree relating to the Commission for Medicine Prices. Those specific provisions, besides expressly stating certain factors which the ministerial commission must take into consideration when agreeing a reasonable wholesale price, also state the factors and parameters that must form the basis of any application. Thus, the statement of reasons for the ministerial commission's decision must be based on those same factors and parameters.

67. In support of those conclusions, the defendant government invokes the explana-

tory statement of the law on health insurance, which stresses the necessity of stating reasons for decisions relating to the prices of medicines in such a way as to satisfy the requirements of the Directive. That explanatory statement represents an important aid to interpretation and is intended to ensure that the legislative intention is safeguarded in practice.

68. Lastly, Finland concludes that the fact that the Supreme Administrative Court set aside certain decisions of the ministerial commission for failure to state reasons, remitting them to the commission for fresh determination, far from proving the inadequacy of the relevant Finnish legislation, as the applicant claims, merely proves that in those particular cases the statement of reasons was inadequate as a matter of both Community law and Finnish law. That is especially so given that, as regards the two specific cases mentioned by the applicant, following the judgment of the Supreme Administrative Court, the ministerial commission did in fact provide a proper statement of reasons for its own refusal decisions.

69. It is not possible, on the other hand, to infer from certain cases of defective practical application a general failure on the part of the administrative authorities to comply with the Directive. Suffice it to point out that, of the decisions given by the ministerial commission, only 84 out of 2 029 in 1998, and 133 out of 3 266 in the following year were flawed, representing only 4.1% of the total in both cases.

70. For my part I note that, according to settled case-law, '[i]n proceedings under Article 226 EC for failure to fulfil an obligation, it is incumbent upon the Commission to prove the allegation that the obligation has not been fulfilled and to place before the Court the information needed to enable it to determine whether the obligation has not been fulfilled'. [11]

71. In the present case, however, it seems to me that the Commission is attempting to base its complaint on certain allegations which fail to meet the requisite standard of proof.

72. It starts off from a hypothetical proposition, asserting that a comparison between the Directive and the applicable national provisions 'seems to indicate' that the latter do not require the ministerial commission to give sufficiently detailed reasons for its decisions on medicine prices. To illustrate that proposition, however, the Commission merely points to a very small number of refusal decisions of the ministerial commission for which the statement of reasons has been shown to be inadequate.

73. As has been seen, however, those decisions were set aside by the Finnish

11 — See, to refer only to some of the most recent authorities, Case C-263/99 *Commission* v *Italy* [2001] ECR I-4195, paragraph 27, Case C-347/98 *Commission* v *Belgium* [2001] ECR I-3327, paragraph 39, and Case C-159/94 *Commission* v *France* [1997] ECR I-5815, paragraph 102.

Supreme Administrative Court for the very reason that the statement of reasons was inadequate and it is also clear that they were subsequently adopted afresh by the competent administrative body, this time with an appropriate statement of reasons. In short, the Commission relies upon an allegedly defective administrative practice which, in addition to being neither substantial nor widespread, reveals, on the contrary, a proper functioning of the system of national judicial remedies ensuring compliance with the very requirements with which the Directive seeks to ensure compliance.

74. In those circumstances, I do not consider that the Commission has proved that the defendant government failed to fulfil its obligations as alleged in the present complaint. I will go further: it seems to me, in fact, that, from the reconstruction of the Finnish system provided in these proceedings, it must be inferred that that system properly implements the provisions of the Directive as regards the giving of reasons for refusal decisions.

75. That conclusion is not undermined by the lack of any express provision implementing Article 6(2) of the Directive. According to the Court's case-law, in fact, 'the implementation of a directive does not necessarily require legislative action in each Member State. In particular, the existence of general principles of constitutional or administrative law may render implementation by specific legislation superfluous provided, however, that those principles guarantee that the national authorities will in fact apply the directive fully and that, where the directive is intended to create rights for individuals, the legal position arising from those principles is sufficiently precise and clear, and the persons concerned are made fully aware of their rights and, where appropriate, afforded the possibility of relying on them before the national courts'. [12] In the light of the facts set out by the Finnish Government, and not contradicted by the Commission, this is precisely what happened in this particular case.

76. Accordingly, it appears to me that the Commission's application insofar as it relates to the present complaint must be rejected.

Costs

77. Under Article 69(3) of the Rules of Procedure, the Court may, where each party succeeds on some and fails on other heads, order that the costs be shared or that each party bear its own costs. Since, as I have said above, I find that Finland and the Commission have both failed in part, it appears to me to be fair to propose also that each party should bear its own costs.

12 — See Case C-365/93 *Commission* v *Greece* [1995] ECR I-499, paragraph 9, and Case 29/84 *Commission* v *Germany* [1985] ECR 1661.

Conclusion

78. In light of the foregoing considerations, I propose that the Court:

(1) declare that, by failing to adopt all the laws, regulations and administrative provisions necessary to comply with Article 6(1) and (2) of Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems, in relation to decisions establishing certain special categories of higher-rate reimbursement of the cost of medicines, the Republic of Finland has failed to fulfil its obligations under that Directive and the EC Treaty;

(2) dismiss the remainder of the action;

(3) order each party to bear its own costs.