# OPINION OF ADVOCATE GENERAL TIZZANO

delivered on 31 May 2001 [1]

## I — Introduction

1. In this case, brought by the European Commission under Article 226 EC, the Court of Justice is called upon to determine whether the Republic of Austria has failed to fulfil its obligations under the EC Treaty by not adopting or by not communicating to the Commission all the measures necessary for complete transposition of Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems (OJ 1989 L 40, p. 8; hereinafter 'the directive'). In particular, the Commission complains of infringements of Article 6 of the directive, both in respect of the maximum period of 90 days allowed to the national authorities for deciding on applications to include a product in the list of medicinal products covered by the national health insurance system, and in regard to the remedies afforded to the applicant under that article against such decisions.

1 — Original language: Italian.

## II — Relevant provisions

### A — *Community legislation*

2. Article 1(1) of the directive provides that:

'Member States shall ensure that any national measure, whether laid down by law, regulation or administrative action, to control the prices 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.'

3. Article 6 of the directive provides that:

'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.

...'.

4. Under Article 11(1) of the directive:

'Member States shall bring into force the laws, regulations and administrative provi-

sions necessary to comply with this Directive by 31 December 1989 at the latest...'.

5. The obligations referred to in the Directive have applied to the Republic of Austria since it joined the European Community, on 1 January 1995.

B — *National law*

6. The Austrian national health insurance system enshrines the right of insured persons to be covered against the costs of all medicinal products which, according to the diagnosis of the doctor in charge of the case, are from time to time considered necessary and appropriate. More specifically, Articles 116 and 122(1) of the Allgemeines Sozialversicherungsgesetz (General Law on Social Security; hereinafter the 'ASVG') provide that each insured person is entitled, in respect of himself and the members of his family, to benefits from the national health insurance system comprising, among other items, adequate and appropriate medical treatment, including the relevant medicinal products, but without that being in excess of what is necessary (Article 133 of the ASVG).

7. Article 350 of the ASVG recognises entitlement to cover in respect of the costs of a medicinal product if prescribed by a doctor contracted to the social insurance body with which the patient is registered and if it is a product which that doctor may prescribe without restriction because it is included in the list of medicinal products published by the Hauptverband der österreichischen Sozialversicherungsträger (Principal Federation of Austrian social insurance organisations; hereinafter the 'Federation').[2] Alternatively, it is possible to obtain cover for a medicinal product that is not on the list where a qualified doctor of the competent social insurance body accepts that it is necessary and appropriate to use it having regard to the patient's state of health; in such case, it must issue an authorisation.

8. Under Articles 31(3)(12) and 133(2) of the ASVG, the Federation has the task of keeping a register (hereinafter the 'register') containing the list of those medicinal products which may be prescribed in general or subject to specified conditions (for example, for certain groups of patients or by age categories, or to be given in specified quantities or forms).

9. The procedure for including a medicinal product in the register is subject to specific rules, although these were adopted only recently (Soziale Sicherheit, No 11/98 of

2 — In fact, by virtue of the particular relationship between them and the social insurance bodies of the patients whom they are treating, 'contracted doctors' operate as a kind of representative for those bodies and they may therefore prescribe medicinal products, subject to the conditions specified in the ASVG and, if these are on the register, they are paid for direct by the competent body (Article 361(1) of the ASVG).

27 November 1998, Communication No 104/1998, page 853; hereinafter the 'rules' or 'rules of procedure') and were notified to the Commission on 3 March 1999 in connection with the response to the reasoned opinion of 30 December 1998.

10. An application for inclusion in the register must be made to the relevant office of the Federation, which conducts the preliminary examination (Paragraph 2(1) of the rules of procedure) of the application. The outcome of the examination is notified at the same time to the small technical advisory board and to the applicant (Paragraph 2(2)). That board makes a recommendation in the case [Paragraph 2(3)(a)] and this is notified to the applicant.

11. If the recommendation is unfavourable, the applicant has six weeks to submit a written complaint to the Federation, appending it together with any additional documents regarding those products to the application for inclusion [Paragraph 2(4)(a)]. The complaint is then re-examined by the small technical advisory board, which may request further information from the applicant [Paragraph 2(4)(b)]. If that board does not make a recommendation in favour of the applicant, it passes the complaint, the additional information, if any, and any observations of its own, to the main technical advisory board. The latter has to verify that the opinion is 'reasonable' ('nachvollziehbar') or, if necessary, must amend it (Paragraph 2(5)), and make its own recommendation not more than six months after the complaint is made.

12. At all events, the Federation must decide within 180 days after the application is lodged whether and on what conditions it is able to accept it [Paragraph 2(7)(a)]. However, the time-limit is suspended if the Federation asks the applicant undertaking for further particulars regarding the technical or administrative information specified in Annex I to the rules of procedure [Paragraph 2(7)(a)] and it may be extended by 60 days if there is an exceptional workload at the Federation offices: this occurs if more than 100 applications to register medicinal products are submitted within a three-month period [Paragraph 2(7)(b)], but the Federation may not invoke such an event more than three times within a period of two years [Paragraph 2(7)(b)].

## III — Legal Analysis

### A — *Introduction*

13. The Commission makes two separate complaints regarding the Republic of Austria: first, that the rules of procedure lay

down a time-limit of 180 days within which the Federation is required to decide on applications to include a medicinal product in the register, whereas Article 6(1) of the directive, as has been seen, sets a limit of 90 days; and secondly that a complaint against an unfavourable opinion by the small technical advisory board cannot be regarded as a remedy within the meaning of the last sentence of Article 6(2) of the directive.

14. The defendant government contends, primarily, that the register referred to in Article 133(2) of the ASVG does not constitute a 'positive list' within the meaning of Article 6 of the directive and that this provision cannot therefore be applied to the Austrian system; it contends in the alternative that the time-limits and remedies laid down in the rules of procedure comply with the provisions of Article 6.

15. In its application in the present case, the Commission no longer included a third complaint which had been raised in the reasoned opinion of 30 December 1998, on the failure to respond regarding the requirement to state reasons for unfavourable decisions on applications for inclusion in the register, although that requirement is imposed in Article 6(2) of the directive. In fact, Article 2(3)(b) of the rules of procedure now provides that the Federation must provide a written statement of reasons for its decisions and the Commission has therefore withdrawn this head of claim.

16. I would make one final point before moving on to the merits of the case. The Commission is asking the Court to declare that, by failing to notify or by failing to adopt fully the measures required for implementation of the directive, the Republic of Austria has failed to fulfil its obligations under the EC Treaty. However, it is clear from the application lodged that, when it responded to the reasoned opinion, the Austrian Government informed the Commission that it had adopted the rules of procedure and it also submitted the text of those rules, showing at least implicitly that it considered it was fulfilling its obligations. However, whether or not it did so consider, I feel that once the rules had been forwarded the Republic of Austria cannot be said to have failed to inform the Commission of the measures intended to transpose Article 6 of the directive. Nor did the applicant press this point at the hearing. I shall therefore examine below only the objections that the implementing provisions which the Austrian Government notified to the Commission fail to comply with the Directive.

B — *Is the register referred to in Article 133(2) of the ASVG structured as a 'positive list' within the meaning of Article 6 of the Directive?*

1. Arguments of the parties

17. As has been seen, the Republic of Austria is raising a preliminary and general

objection to the Commission's application, that is, that the register kept by the Federation is not a 'positive list' within the meaning of Article 6 of the Directive and that in this case, therefore, the conditions for applicability of that provision are not met; nor are, *a fortiori*, the requirements laid down therein whose infringement the Commission is alleging.

18. In support of its objection, the Austrian Government chiefly stresses the actual wording of Article 6 — particularly the introductory passage. The defendant claims that this provision clearly shows that a list of medicinal products constitutes a 'positive list' *only* where inclusion on that list is the *sole means* of accepting a medicinal product for cover by the national health insurance system.

19. However, in the Austrian system, even a medicinal product excluded from the register kept by the Federation may be reimbursed, provided that the patient obtains authorisation from his own health insurance body; just as, on the other hand, the prescribing of a medicine included in the register gives absolutely no guarantee of reimbursement if it were found to be unsuitable for or disproportionate to the actual requirements of necessary and appropriate treatment.[3] Furthermore, according to the Austrian Government, the possibility of obtaining reimbursement in the case of medicinal products not included in the register is not just theoretical, if it is considered that around 15% of the expenditure incurred by the national social insurance system for reimbursement of medical costs is accounted for by this possibility. And that does not take into account the medicinal products dispensed in hospitals, where no condition of inclusion in the register applies.

20. In the end, the defendant government observes, the register kept by the Federation does not constitute an exhaustive list of the range of medicinal products covered by the national health insurance system. Its usefulness lies rather in its function as a working tool, as a kind of manual, for contracted doctors, enabling them more easily to check which of the medicines they propose to prescribe are covered by the social insurance body with which their patient is registered, without having to seek specific authorisation. Furthermore, the Austrian Government continues, it also makes it possible to reduce the costs of the national social insurance system because it compels the pharmaceutical companies, in exchange for inclusion of a medicine in the register, to give discounts

3 — This conclusion is borne out also by the case-law of the Oberster Gerichtshof (the supreme court in social insurance matters), referred to by the Austrian Government (see in particular the judgment of 13 December 1996, 10 Ob S 62/94, and further references), which considers that, under Article 133(1) of the ASVG, those registered under the national health insurance system are entitled to cover of the costs of all medicinal products which they actually need, *regardless of* whether these are included in the register.

on its cost, even to the extent that those firms almost benefit more from non-inclusion of the medicine in the register rather than inclusion (but perhaps this 'sacrifice' is offset by the wider distribution of the product that is presumably guaranteed by registration).

21. In broader terms still, the Austrian Government objects that, in purporting to classify the register as a 'positive list' within the meaning of the directive, thus misinterpreting its nature and function, the Commission is seeking to interfere in the organisation of a national system of social insurance and in determination of the conditions attaching to entitlement to benefit. It quite clearly constitutes unlawful interference by the Community in a matter which is reserved to the exclusive power of the Member States, as has long since been explained in the case-law of the Court,[4] is expressly confirmed in Article 152(5) EC, as amended by the Treaty of Amsterdam,[5] and, finally, is reaffirmed in the directive (sixth recital).

22. For its part, the Commission insists that Article 6 of the directive is applicable and considers that the conditions for its application are fully satisfied. First, the Federation may be regarded as one of the 'competent authorities' referred to in that provision. Secondly, the register of medicines must be treated as a 'positive list' within the meaning of the directive since normally the medicines listed there are reimbursed by the national health insurance system. On the other hand, it notes the fact that a medicinal product not included in the register may also be reimbursed because, as we have seen, that is permitted only on the basis of a specific authorisation from a qualified doctor of the social insurance body. But, according to the Commission, the criteria for giving such authorisation — that is, that the medicinal product is suitable and necessary for the insured person's state of health — are so vague that it is not possible to predict with certainty whether a product not included in the register can be reimbursed or not, with the result that real certainty on that point can be achieved only by inclusion in the register; and that is precisely the condition laid down in Article 6 of the Directive for a 'positive list' and, hence, for application of that provision.

23. The Commission's response to the Austrian objections to the alleged Community interference in a sector reserved to State competence is that the directive has no such purpose and no such outcome. It seeks only to impose certain minimum rules on transparency regarding national measures to restrict the range of medicinal products covered or reimbursed by national health insurance systems (Article 1). In

4 — See judgment in Case C-158/96 *Kohll* [1998] ECR I-1931, paragraphs 17 and 18, and further references.

5 — In the new version, the provision states clearly that: 'Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care ...'.

particular, this is intended to avoid possible measures having equivalent effect to quantitative restrictions on import or export.

titative restrictions on imports or exports or measures having equivalent effect thereto' (sixth recital).

2. Evaluation

24. I begin by observing that on this latter point I find it difficult to disagree with the Commission. The present application does not call in question either the policy decisions or the competence of Austria in social insurance matters, and therefore does not call in question the current organisation of its system of medical assistance, which the Commission has indeed expressly remarked upon favourably; even less does it question the conditions regarding entitlement to reimbursement of medicinal products. The Commission's claims do not in fact relate either to the foundation of the system or to the criteria underlying its operation; similarly, acceptance of these claims would have no effect on the existence or operation of the register, on the inclusion or non-inclusion of any medicine therein, or on its reimbursable status. At issue in the present case are only — *and then, so to speak, only as part of an unchanged system* — certain specific operational rules of the system that are intended to secure compliance with general principles of objectivity and transparency for the purposes explicitly stated in the directive and which, as I have said, are to '... ensure that all concerned can verify that the national measures [governing inclusion of medicinal products in national health insurance systems] do not constitute quan-

25. Here I must stress that, although the directive confirms that pursuit of the aims set out therein must not affect national policies on the determination of social security schemes, it does not rule out that this might occur 'as far as it is necessary to attain transparency within the meaning of this Directive' (sixth recital).

26. Indeed, it is the Community legislature itself which has adopted this viewpoint inasmuch as, while respecting national policies in the matter, it has in fact been concerned to use coordinating rather than harmonising legislation for progressive attainment of conformity with Community law of national measures to control public health expenditure by restricting the range of medicinal products covered by health insurance systems. The directive is part of this process, standing as a 'first step' towards 'further harmonisation' of those measures (sixth and seventh recitals) and the progressive elimination of disparities that exist between them, since these might 'hinder or distort intra-Community trade in medicinal products and thereby directly affect the functioning of the common market in medicinal products' (fourth recital).

27. I would add that these concerns — which, I repeat, are those of the Community legislature even before of the Commission — seem fully in line with the principle, which the Court of Justice has consistently enunciated, that, in exercising the competence to organise their social security systems, the Member States must comply with Community law. [6] Even more specifically, those concerns reflect the position stated in *Duphar* (which in fact prompted the adoption of the Directive [7]), where — with reference to the criteria laid down by a Member State for including reimbursable medicinal products in a limitative list — the Court clearly affirmed that Community law, in that instance Article 30 of the EC Treaty (now, after amendment, Article 28 EC), requires those criteria to be objective and verifiable, [8] in order to prevent any discrimination to the detriment of imported products.

28. To conclude on this point therefore, it seems to me that the objection is not substantiated. Indeed, perhaps the defendant government must have been aware of this if, in the course of the pre-litigation procedure, it adopted those rules of procedure which do in fact seem prompted by the intention of ensuring that the Austrian health insurance system complies with the principles of transparency and objectivity.

29. Having eliminated this objection of principle, let us turn to the principal argument used by the defendant government, which is that the register kept by the Austrian Federation under Article 133(2) of the ASVG cannot be regarded as a 'positive list' under Article 6 of the Directive.

30. As I have pointed out, the Austrian Government is relying here primarily on the actual wording of the introductory passage in Article 6 of which, for convenience, I shall quote again: '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' (my italics). According to the defendant government, this wording means that the provision applies only to national social insurance systems where reimbursement of medicinal products is allowed solely on those products included in a specific list. If this is not so, because — as in the case of Austria — the costs can also be covered (even if on certain conditions) for medicines not included in the list, the circumstances described in Article 6 would not obtain.

31. I readily agree that this provision is not particularly well worded; but I do not believe that this allows the inferences that the Austrian Government draws from it. Indeed, it seems clear to me that the logic of this provision, and the intention of the

6 — For example, see *Kohll*, paragraph 19.

7 — See the Commission report accompanying the proposal for the directive (COM(86) 765 final, of 23 December 1986, point II.1).

8 — Judgment in Case 238/82 *Duphar and Others* [1984] ECR 523, paragraphs 17 to 22.

directive, cannot but mean that Article 6 is referring to all cases where inclusion of a medicinal product in a list entails automatic reimbursement of it. The fact that in one Member State there is a register rather than a 'positive list', or that in that Member State reimbursement is also under certain conditions permitted for medicines not included in the list, cannot detract from the only factor relevant here, which is, that to include a medicinal product in the list normally means that it is automatically reimbursed. That is in fact the supposition on which application of the directive is based; it is also why the directive requires, for the purpose stated in the sixth recital, that inclusion in the list be attended with the maximum objectivity and transparency.

32. I believe that this is the only interpretation of this provision which reconciles its wording, which is open to discussion, with the declared intent of the directive. This interpretation is also supported by the wording of Article 1(1) of the directive, under which: 'Member States shall ensure that *any* national measure, whether laid down by law, regulation or administrative action, to... restrict the range of medicinal products covered by their national health insurance systems complies with the requirements of this Directive' (emphasis added).

33. However, for me the decisive factor is that here we have a provision which is intended to guarantee one of the cornerstones of Community legislation, namely the free movement of goods. According to well-known and settled case-law, this requires a broad interpretation of the relevant requirement and, thus, an interpretation which is not restrictive of its scope or prejudicial to its efficacy. [9] But that is precisely the result that would be achieved if the Austrian Government's argument were accepted, for it would mean removing from the scope of Article 6 national health insurance systems which essentially satisfy the conditions set out therein, with the additional risk of encouraging Member States to evade, by means of formal and nominalistic arrangements, the obligations imposed in the directive, thereby prejudicing its efficacy.

34. In conclusion, I consider that the provisions of Article 6 of the Directive apply to a list, such as the register referred to in Article 133(2) of the ASVG, which guarantees acceptance by the national health insurance system of the medicinal products included therein, even if that system also

9 — Amongst more recent precedents, see Case C-346/97 *Braathens* [1999] ECR I-3419, paragraph 24, and Case C-437/97 *EKW and Wein & Co.* [2000] ECR I-1157, paragraph 41, with further references. Similarly, see also the consultative opinion of 24 November 1998 from the Court of the European Free Trade Association regarding Article 4 of the directive, on measures to freeze prices of medicinal products (Case E-2/98, *FIS*, Reports 172, in particular points 20 to 22).

enables the cost of medicines not included in the list to be reimbursed under specific conditions.

C — *The time-limit within which the Federation must adopt a decision regarding an application to include a medicinal product in the register referred to in Article 133(2) of the ASVG*

35. Turning now to the two specific objections raised by the Commission, I shall begin with that relating to the disparity in the time-limits laid down in Article 6(1) of the directive (90 days) and in Paragraph 2(7)(a) of the rules of procedure (180 days) within which an application for inclusion of a medicinal product in a positive list and in the register, respectively, must be decided.

36. In its defence, the Republic of Austria maintained that the time-limit of 180 days specified in the rules of procedure should be held to comply with the directive since the Federation's decision-making process on whether to include a product in the register entails overall monitoring of the price at which the product is offered to insured persons. Now Article 6(1) of the directive allows the time-limit laid down therein to be extended by 90 days to a total of 180 days 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'.

37. At the hearing, the defendant government's representative confirmed that this was indeed how the Austrian system operated in this regard, given that the Federation examines the price for a medicinal product at the same time as the application to register it. The Commission has cast doubt on the correctness of that assertion. Yet it seems to me that it has been unable to show either that examination of the price for the medicinal product is not contemporaneous with examination for inclusion of the product in the register or that these examinations are only occasionally contemporaneous.

38. But it is well known that, in cases brought under Article 226 EC, 'it is incumbent on the Commission to prove that the obligation has not been fulfilled and to place before the Court the information necessary to enable it to determine whether that is so'. [10] That has not occurred in the present case and I therefore consider that in that respect, the Commission's application cannot be upheld.

10 — For recent judgments, see those in Case C-96/98 *Commission* v *France* [1999] ECR I-8531, paragraph 36, in Case C-337/98 *Commission* v *France* [2000] ECR I-8377, paragraph 45, and in Case C-55/99 *Commission* v *France* [2000] ECR I-11499, paragraph 30.

39. However, I do consider the objection raised by the Commission at the hearing to the provision in the rules of procedure which allows a possible 60-day extension of the 180-day time-limit, where an excessive administrative burden falls on the Federation's offices (see Article 2(7)(b) of the rules of procedure) to be substantiated. First, the directive makes no provision for this possibility and, secondly, the grounds for the extension cannot justify a derogation from the maximum time-limit prescribed by the directive. As is well known, the Court has consistently held that a Member State may not plead provisions, practices or circumstances of its own legal system in order to justify non-compliance with the obligations laid down in a directive. [11]

40. However, as I have indicated, the Commission in fact only raised the objection at the hearing; it clearly did not do so in the reasoned opinion, since the Austrian rules of procedure were not then available to it, but neither did it do so in the application, nor throughout the written part of the procedure. This objection being therefore clearly substantially out of time, it cannot, under the Court's Rules of Procedure (Article 42(2)), be taken into consideration. The objection must therefore be declared inadmissible.

11 — See, for example, Case C-42/89 *Commission* v *Belgium* [1990] ECR I-2821, paragraph 24, and Case C-71/97 *Commission* v *Spain* [1998] ECR I-5991, paragraph 15.

D — *Remedies against decisions on applications to include medicinal products in the register referred to in Article 133(2) of the ASVG*

41. As I have indicated, the Commission alleges finally that the Austrian system does not provide effective remedies for those concerned, although Article 6(5) of the directive provides that any 'decision' to exclude a medicinal product from the positive list of products is to contain 'a statement of reasons based on objective and verifiable criteria... including, if appropriate, any expert opinions or recommendations on which the decisions are based' and that the applicant is to be 'informed of the remedies available to him under the laws in force...'.

42. According to the Commission, the complaint against the initial opinion of the 'small technical advisory board' referred to in Paragraph 2(4)(a) of the rules of procedure is not a remedy capable of affording to those concerned genuine and effective protection. Nor can it be held that the condition is satisfied in that, where the small technical advisory board gives a further negative opinion, the application for inclusion may be submitted to re-examination by the 'main technical advisory board'. Although, as the Austrian Government objects, this body, just as the small technical advisory board, consists of technical and professional persons entirely

independent of the social insurance bodies, some appointed for a specified period and others appointed for an unlimited period, none the less these boards are still merely review bodies within the Federation rather than truly independent judicial bodies and, furthermore, do not have any real decision-making power, inasmuch as they can only make recommendations.

43. The Austrian Government has responded by stressing in particular the technical competence and the independence of the members of the main technical advisory board; reference was also made at the hearing, if I have understood aright, to the Austrian tradition in the social insurance sector, of providing for appeals to be heard by administrative bodies consisting of professional persons rather than for judicial appeals, given the technical nature of the issues.

44. However, in requiring the applicant to be informed of his 'remedies', Article 6 of the Directive is clearly referring to remedies affording full and effective protection of the rights of those concerned, that is to say, remedies of a judicial nature. The requirement in that Article to provide a statement of the reasons for decisions whether to include a medicinal product in the list is based on the supposition that it will be possible for the decision to be submitted to judicial review.

45. But, over and above that, it appears to me to be of decisive importance to recall the Court's case-law under which, where a Community provision, as in the present case, requires the Member States to provide remedies against decisions by national authorities in order to protect rights stemming from Community law, although that provision leaves the State free to choose the appropriate methods for implementing the requirement, it has in contemplation some real 'system of judicial review' before independent courts and not administrative or similar appeals. [12] In turn, this case-law is in fact simply the expression of a more general approach by the Court, guided by the notion that 'the requirement of *judicial control* of *any decision* of a national authority reflects a general principle of Community law stemming from the constitutional traditions common to the Member States [which] has been enshrined in Articles 6 and 13 of the European Convention for the Protection of Human Rights and Fundamental Freedoms'. [13]

46. It is therefore difficult to reconcile with this case-law a system which, like the Austrian one, provides only for appeals to bodies that not only are not judicial in nature but also lack decision-making

12 — See Case C-120/97 *Upjohn* [1999] ECR I-223, paragraph 29, relating to Article 12 of 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 (I), p. 20), which provides that: 'All decisions [refusing, suspending or revoking marketing authorisations for proprietary medicinal products] shall state in detail the reasons on which they are based. A decision shall be notified to the party concerned, who shall at the same time be informed of the remedies available to him under the laws in force and of the time-limit allowed for the exercise of such remedies'.

13 — Case C-97/91 *Borelli* v *Commission* [1992] ECR I-6313, paragraph 14, with further references, Case C-1/99 *Kofisa Italia* [2001] ECR I-207, paragraph 46, and Case C-226/99 *Siples* [2001] ECR I-277, paragraph 17.

power, since they can only give opinions or make recommendations, the final decision being reserved to the Federation.

47. Given the foregoing, I have to conclude that, on this point, the Republic of Austria has failed to fulfil its obligations under Article 6(2) of the Directive and that, therefore, albeit on this more limited ground, the Commission's action must be upheld.

## IV — Costs

48. Under Article 69(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the Commission has asked for costs to be awarded in its favour and in view of my considerations concerning determination of the action, I consider that the application for costs should be granted.

## V — Conclusion

49. In light of the foregoing considerations, I therefore propose that the Court should declare that:

(1) By failing to adopt all the laws, regulations and administrative provisions for complete transposition of Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems, the Republic of Austria has failed to fulfil its obligations under the EC Treaty.

(2) The Republic of Austria is ordered to pay the costs.