Registry's translation, the French text alone being authoritative.

SEVENTIETH SESSION

In re KARRAN (No. 2)

Judgment 1088

THE ADMINISTRATIVE TRIBUNAL,

Considering the second complaint filed by Mr. Günther Karran against the European Organisation for the Safety of Air Navigation (Eurocontrol Agency) on 9 February 1990 and corrected on 16 February, Eurocontrol's reply of 26 April, the complainant's rejoinder of 15 June, Eurocontrol's surrejoinder of 10 September 1990, its brief of 21 September in answer to questions the Tribunal put to it in the Registrar's letter of 30 August, the complainant's observations of 9 October and the Organisation's submissions thereon of 31 October 1990;

Considering Article II, paragraph 5, of the Statute of the Tribunal, Articles 72 and 92(2) of the Staff Regulations governing officials of the Agency and Articles 14, 24(2) and 25b(2) of Rule No. 10 concerning sickness and accident insurance;

Having examined the written evidence and decided not to order oral proceedings, which neither party has applied for;

Considering that the facts of the case and the pleadings may be summed up as follows:

A. The complainant, who is employed at Eurocontrol headquarters in Brussels, is covered by the Sickness Insurance Scheme provided for in Article 72 of the Agency's Staff Regulations. Article 14 of Rule No. 10 concerning sickness and accident insurance reads:

"Pharmaceutical products prescribed by the practitioner or on a `repeat' basis as evidenced by the prescription subject to a maximum of six months shall be reimbursed at the rate of 85%. Mineral waters, tonic wines and beverages, infant foods, hair care products, cosmetics, special diet foods, hygiene product, irrigators, syringes, thermometers and similar products and instruments shall not be considered as pharmaceutical products."

At the end of May 1989 the complainant got a statement from the Scheme which showed as "not refundable" items for which he had paid and claimed 4,550 Belgian francs. The Scheme later explained to him that the items were supplies of a drug known as Serocytol. The complainant took the view that that drug was a pharmaceutical product the costs of which were refundable under Article 14. On 24 August 1989 he lodged a "complaint" under Article 92(2) of the Staff Regulations. In a letter of 30 October, which he got on 14 November 1989 and which is the decision impugned, the Director General said that after consulting the medical officer and the Management Committee of the Scheme he had concluded that Serocytol did not constitute a refundable pharmaceutical product within the meaning of Article 14 and so was rejecting the claim as unfounded.

B. The complainant submits that Eurocontrol is misconstruing Article 14 of Rule No. 10. In his view that article, which constitutes a binding rule, means that all pharmaceutical products a doctor has prescribed are refundable, and the Director General may not allow refund for some and refuse it for others by criteria such as their therapeutic efficacy or the financial burden they lay on the Scheme. Nor may the Management Committee of the Scheme, which, as Article 25b(2) of Rule No. 10 shows, is just an advisory body. Insofar as the impugned decision seeks to lighten the financial burden it is, for reasons the complainant explains, misguided. There is no question of the Scheme's having to pay for all products: to qualify they must have been obtained on medical prescription.

Since Rule No. 10 does not define pharmaceutical products the Scheme has cited a directive of the Council of the European Economic Community (EEC) of 26 January 1965 (65/65), but the definition it draws therefrom is, in the complainant's view, too narrow; properly construed that ruling is wide enough to cover Serocytol. The efficacy of the drug is immaterial and is not in doubt anyway. It is a registered drug in Switzerland, the country where it is made. Refund of the costs of Serocytol cannot reasonably be deemed to be excluded by the phrase "and similar products" in the second sentence of Article 14 since the items that sentence does list are cosmetic, tonic or dietetic

and so not "similar" at all.

The refund of the costs of Serocytol is not barred by office notice 2/89 of 9 February 1989, whereby the Director General purported to refuse to refund the costs of trace-

element therapy and the like and which the complainant challenges in his first complaint: such items are not akin to Serocytol.

The complainant relies on a judgment the Court of Justice of the European Communities delivered on 13 December 1989 (in re Prelle).

He seeks the quashing of the impugned decision, an order that the Scheme refund to him the costs of Serocytol in accordance with the rules, in particular Article 14 of Rule No. 10, and an award of costs.

C. In its reply Eurocontrol submits that the complaint is devoid of merit. It observes that neither Article 72 of the Staff Regulations nor Rule No. 10 confers any right to the refund of all the costs of illness: it is the Scheme that determines, after consulting the medical officer and, in keeping with Article 25b(2) of Rule No. 10, its Management Committee, what the policy on refund and the practical arrangements should be. It is the Director General who in the last resort is responsible for ensuring the financial soundness of the Scheme, and the complainant's comments on that subject are immaterial and in any event unfounded. In exercising his responsibility the Director General may seek to prevent the indulgent handling of claims.

Since the case raises medical issues and matters of management policy the Organisation appends observations by the medical officer and by the Scheme.

In those observations the Scheme explains the criteria which it follows in determining whether an item is a "pharmaceutical product" within the meaning of Article 14 of Rule No. 10 and the reasons why Serocytol fails to qualify as such a product. It observes that the complainant misconstrues the ruling of the Council of the EEC on the subject.

The medical officer cites Article 24(2) of the Rule ("Expenses relating to treatments considered to be non-functional, superfluous or unnecessary, after the Medical Officer has been consulted, shall not be reimbursed") and is against refunding the cost of Serocytol because it is not efficacious. It is not a registered drug in any of the member countries of the European Communities; indeed in some of them the sale of it is forbidden.

The judgment on Prelle is irrelevant to this case.

D. In his rejoinder the complainant develops his pleas on the merits and seeks to refute the defendant's, which he submits betray uncertainty about what Serocytol really is and misunderstanding about Prelle. That judgment showed that it is not the therapeutic efficacy of a drug that determines whether it qualifies as a pharmaceutical product: the whole point is that the Director General does not have discretion to determine, even after consulting the Management Committee and the medical officer, that some products on the market should be disallowed according to criteria relating to their efficacy or cost. Eurocontrol is in bad faith in refusing to follow that ruling since it professes a desire for alignment with the European Communities. Article 24 of the Rule, which Eurocontrol relies on for the first time, is irrelevant anyway: it applies to medical treatment, not to pharmaceutical products.

In an appendix to his brief the complainant, while maintaining that the main issue is not medical but legal, discusses the efficacy and the properties of Serocytol and medical opinion on the subject. He attributes "remarkable efficacy" to the product, though the medical officer has dismissed what he says as an isolated instance. It is immaterial that Serocytol is not a registered drug in any of the countries belonging to the Communities: that is not a criterion that appears in Rule No. 10.

E. In its surrejoinder Eurocontrol develops the case made out in its reply and discusses some of the questions the complainant raises in his rejoinder. It appends further comments by the medical officer and the Scheme in support of its pleas.

F. At the Tribunal's invitation the parties further address several specific issues relating to Serocytol.

CONSIDERATIONS:

1. The complainant, whom Eurocontrol employs at headquarters in Brussels, is impugning its Sickness Insurance Scheme's refusal to refund the cost of a product it regards as of no curative effect and possibly dangerous.

2. He supplies the text of the instructions for use: the product is labelled "Serocytol, neuroglandular F", made in Switzerland, intended for treatment in gynaecology and made up of extracts from the ovarian, antehypophysial, diencephalic, thyroidal and subrenal "immunological anti-tissues" of horses.

The background to the case and the pleadings

3. The complainant lodged a "complaint" under Article 92(2) of the Staff Regulations against the Scheme's decision. The Director of Personnel and Finance sent him a fully substantiated reply on 30 October 1989: Eurocontrol's policy, determined after consulting the medical officer and the Management Committee, a joint body, was to refund the cost of a marketed drug only if it was a genuine pharmaceutical product of acknowledged curative effect; there was no evidence to show that Serocytol, described as an "organotherapeutic" remedy, had any such effect; and the Organisation took the same stand as did the authorities of the European Communities in similar cases.

4. The complainant filed on 9 February 1990 and receivability is not at issue.

5. His argument is that the first sentence of Article 14 of Rule No. 10 concerning sickness and accident insurance requires Eurocontrol to refund the cost of any "pharmaceutical product" not expressly excluded by the second sentence. He submits that, subject to that exception, any product will be a "pharmaceutical product" that is stated to be efficacious in treating a human ailment and Eurocontrol may not exclude such a product by financial criteria, or on health considerations, or on grounds of curative effect.

6. He further argues that Serocytol is refundable because it is stated to be efficacious in curing several human ailments and does not come under any of the exceptions in the second sentence of Article 14. He cites a bibliography taken from a "Vademecum on serocytotherapy" which the manufacturer of Serocytol published in 1987 and alleges that someone whom he does not name used the product to very good effect.

7. He seeks support for his case from a judgment of 13 December 1989 by the First Chamber of the Court of Justice of the European Communities on a case (Prelle v. Commission of the European Communities: C-169/88) about an "organotherapeutic" product. He points out that the Court cited definitions in directive 65/65 of 26 January 1965 of the Council of the European Economic Community on the harmonisation of legislative and other rules on pharmaceutical products. Paragraph 22 of its judgment then defined as a pharmaceutical product any that was stated to have the property of curing a human ailment provided that it was prescribed by a doctor and bought from a pharmacy.

8. The complainant goes on to argue that since Eurocontrol's rules on the matter are word for word the same as those of the European Communities Rule No. 10 too must be construed by reference to directive 65/65 and to the ruling on Prelle. As paragraphs 28 and 29 of the judgment make plain, any product prescribed by a doctor and bought from a pharmacy will therefore be refundable provided that Eurocontrol has not brought it within the express exceptions in the second sentence of Article 14.

9. Citing the views of the Scheme and its medical officer, Eurocontrol retorts that, whether "organotherapeutic" or not, Serocytol is not a registered drug in any of its member countries and indeed in some of them the selling of it is forbidden on the grounds that the ingestion of animal extracts may be harmful to health.

10. Eurocontrol therefore asks the Tribunal not to follow Prelle in treating as refundable anything the manufacturer passes off as a drug and in perhaps so requiring social security schemes to refund the cost of worthless or even dangerous items.

11. Construing Article 14, the Organisation submits that "pharmaceutical products" in the Rule means only those of proven curative effect. So a product will not be refundable, even one stated to be a medical remedy, if it has not been shown to be safe to use and to have such an effect. On the strength of its medical officer's opinions Eurocontrol is just following the same line as national auditing bodies and social security schemes. In particular it is relying on the views of the European Communities' medical board, a co-ordinating body made up of the medical officers of the various institutions of the Communities.

12. Eurocontrol submits that the policy on refund cannot overlook the need for sound financial management. Its Scheme treats staff better than public schemes do and if it is to go on doing so must not become indulgent.

13. Lastly, Eurocontrol addresses the issue of the scope of judicial review in the realm of medicine. Though it does not challenge the Tribunal's competence it believes that it should be left reasonably free to set the social policy it wants to apply to its own staff according to proper financial, therapeutic and health considerations.

14. The parties not being agreed on the properties of Serocytol, the Tribunal asked the Organisation for further medical data on Serocytol and "organotherapy" in general and invited the complainant in turn to comment.

15. Several findings may be made on the strength of the medical data thus supplied and the other items of evidence.

(a) Organotherapeutic remedies and Serocytol are extracts from animal organs. Whereas the former are produced by direct extraction Serocytol is made by extraction from antibodies generated in the animal by the injection of extracts from human organs.

(b) Their curative effect is not proven and both types of product may cause dangerous secondary reactions.

(c) It is illegal in most European countries to sell them.

The merits

16. The provisions the parties are relying on and that are material to this case are the following.

Article 14 of Rule No. 10, which is headed "Pharmaceutical products (under medical prescription)" reads:

"Pharmaceutical products prescribed by the practitioner or on a 'repeat' basis as evidenced by the prescription subject to a maximum of six months shall be reimbursed at the rate of 85%. Mineral waters, tonic wines and beverages, infant foods, hair care products, cosmetics, special diet foods, hygiene product, irrigators, syringes, thermometers and similar products and instruments shall not be considered as pharmaceutical products."

Article 24(2) of Rule No. 10 states:

"Expenses relating to treatments considered to be non-functional, superfluous or unnecessary, after the Medical Officer has been consulted shall not be reimbursed."

17. In answer to Eurocontrol's submissions the Tribunal will first take up the issue of the ambit of its own competence. What it has to do is ensure compliance with the law in staff management. If medical issues arise it may, if it deems fit, take evidence from experts. It may draw on such evidence where the parties have submitted it - provided that there have been adversarial pleadings on the subject - or it may itself bring in experts for the purpose.

18. The Tribunal may rule on this case on the strength of the material rules and the parties' submissions. However the term "pharmaceutical products" in Article 14 of Rule No. 10 is to be construed, Article 24(2) in any event empowers Eurocontrol to refuse to refund the cost of treatment which, after consulting the medical officer, it considers to be "non-functional, superfluous or unnecessary". The article is general in purport in that it covers all sorts of "treatments", and the term includes the medical prescription of pharmaceutical products.

19. It is clear on the evidence that after consulting the medical officer Eurocontrol has come to the view that treatment with Serocytol is "non-functional". The complainant has failed to adduce a shred of evidence to suggest that in coming to that view the Organisation went beyond the bounds of the discretion it has in the matter under Article 24. His complaint therefore fails on the merits.

DECISION:

For the above reasons,

The complaint is dismissed.

In witness of this judgment Mr. Jacques Ducoux, President of the Tribunal, Miss Mella Carroll, Judge, and Mr.

Pierre Pescatore, Deputy Judge, have signed hereunder, as have I, Allan Gardner, Registrar.

Delivered in public sitting in Geneva on 29 January 1991.

(Signed)

Jacques Ducoux
Mella Carroll
P. Pescatore
A.B. Gardner

Updated by PFR. Approved by CC. Last update: 7 July 2000.