OPINION OF ADVOCATE GENERAL LÉGER

delivered on 9 June 1998 *

1. Does 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 [1] require Member States to adopt specific procedural rules in regard to legal proceedings brought against a decision revoking a marketing licence for a proprietary medicinal product (otherwise known as a 'medicinal product for human use' or a 'medicinal product') delivered by the competent national authority? That, in substance, is the question which the Court of Appeal, London, has submitted to the Court.

2. Although the Court has sought on several occasions [2] to define the meaning and scope of numerous provisions of that directive, it strikes me as a useful exercise to retrace its purpose and general scheme and to specify the content of the provisions relevant to the present case.

The Community law framework

3. Medicinal products, given their specific nature, have been the subject of very close attention by the Community legislature, which has been reflected in the adoption of a complex but coherent body of harmonising directives, of which Directive 65/65 remains the basic text. The objective pursued has been twofold: to safeguard public health [3] while at the same time bringing about progressively the free movement of medicinal products for human use. [4]

4. The Community system governing marketing licences applicable in this case [5] is based on three fundamental texts: Directives 65/65, 75/318 (otherwise known as the '"standards

* Original language: French.

1 — OJ, English Special Edition 1965-1966, p. 20.

2 — See, in particular, Case 301/82 *Clin-Midy and Others* v *Belgium* [1984] ECR 251; Case C-83/92 *Pierrel and Others* v *Ministero della Sanità* [1993] ECR I-6419; Case C-440/93 *R* v *Licensing Authority of the Department of Health and Norgine*, ex parte *Scotia Pharmaceuticals* [1995] ECR I-2851; and Case C-201/94 *Smith & Nephew and Primecrown* [1996] ECR I-5819. See also Case C-127/95 *Norbrook Laboratories* v *Ministry of Agriculture, Fisheries and Food* [1998] ECR I-1531, concerning the interpretation and assessment of the validity of the directives harmonising national procedures governing veterinary medicinal products, the aims and many provisions of which are similar to the Community rules involved in the present case (paragraph 36).

3 — First recital in the preamble to Directive 65/65.

4 — Ibid., second, third and fourth recitals.

5 — In contradistinction to the new Community system relating to marketing licences which entered into force on 1 January 1995; this constitutes a further step in bringing about the single market in medicinal products and implements two new procedures:
— a decentralised procedure brought about on 14 June 1993 by Council Directive 93/39/EEC amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC in respect of medicinal products (OJ 1993 L 214, p. 22), which organises mutual recognition of marketing licences;
— a centralised procedure adopted on 22 July 1993 by Council Regulation (EEC) No 2309/93 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (OJ 1993 L 214, p. 1), which introduces a Community marketing licence issued by the European Agency for the Evaluation of Medicinal Products; this marketing licence is valid throughout the Community.

and protocols" directive') [6] and 75/319, [7] as amended by Council Directive 83/570/EEC of 26 October 1983. [8]

5. Under this system, the competent authority in the matter of marketing licences for medicinal products for human use ('the authority' or 'the national authority') is essentially national.

6. Article 3 of Directive 65/65 provides that no proprietary medicinal product may be placed on the market in a Member State unless an authorisation has been previously issued by the competent authority of that State. The marketing licence thus issued is valid only in the territory of the issuing State. A new marketing licence is necessary and must be obtained in each State within the territory of which the medicinal product is marketed.

7. In order to avoid divergent assessments among national authorities and to attain the twofold objective of free movement of medicinal products and safeguarding of public health, Directives 75/318 and 75/319 supplemented the provisions laid down by Directive 65/65.

8. These directives require the national authorities to process applications for marketing licences in accordance with the protocols described in the annex to the 'standards and protocols' directive. Medicinal products placed on the market are thus subject to controls carried out in accordance with harmonised methods and by experts with specific technical and professional qualifications.

9. Article 4 of Directive 65/65, as amended by Directives 75/318, 75/319 and 83/570, defines precisely the procedure to be followed and what must feature in the documentation to be submitted in support of an application for a marketing licence. This documentation must, *inter alia*, contain the results of specific tests intended to establish the quality, safety and efficacy of the medicinal product.

10. In addition, the national authorities may refuse, revoke or suspend a marketing licence only on the grounds strictly defined by Articles 5, 11 and 21 of Directive 65/65.

11. The first paragraph of Article 5 of Directive 65/65 provides that a marketing licence must be refused if the medicinal product does

6 — Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products (OJ 1975 L 147, p. 1).

7 — Second Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ 1975 L 147, p. 13).

8 — OJ 1983 L 332, p. 1.

not satisfy the three criteria pursuant to which decisions to issue marketing licences must be taken, that is to say, safety, quality and therapeutic efficacy of the product, and if the documentation and particulars submitted in support of the application do not comply with the abovementioned Article 4.

12. Article 21 of Directive 65/65 provides that: 'An authorisation to market a proprietary medicinal product shall not be refused, suspended or revoked except on the grounds set out in this Directive'.

13. Those grounds are set out in Article 11 of Directive 65/65, as amended by Directive 83/570, which states that: 'The competent authorities of the Member States shall suspend or revoke an authorisation to place a proprietary medicinal product on the market where that product proves to be harmful in the normal conditions of use, or where its therapeutic efficacy is lacking, or where its qualitative and quantitative composition is not as declared. Therapeutic efficacy is lacking when it is established that therapeutic results cannot be obtained with the proprietary product.

An authorisation shall also be suspended or revoked where the particulars supporting the application as provided for in Articles 4 and 4a are incorrect ... or when the controls [carried out on the finished product, on the components and intermediary products in the manufacture under harmonised methods by Directives 65/65 and 75/319 and by experts having specific technical or professional qualifications] ... have not been carried out'.

14. Furthermore, the first paragraph of Article 12 of Directive 65/65 provides that: 'All decisions taken pursuant to Articles 5 ... or 11 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'.

15. Finally, these harmonising directives introduce several mutual recognition factors into the Community pharmaceutical legislation. This is the case with regard to Article 8 et seq. of Directive 75/319, as amended by Directive 83/570, which set in place a consultation procedure through the intervention of a Community body, the Committee for Proprietary Medicinal Products.

16. Under Article 8 of Directive 75/319, as amended, the purpose of this Committee is '... to facilitate the adoption of a common position by the Member States with regard to decisions on the issuing of marketing authorisations and to promote thereby the free movement of proprietary medicinal products ...'.

17. In accordance with Article 11, second paragraph, of Directive 75/319, as amended, 'where one or more Member States have suspended or revoked a marketing authorisation while one or more other Member States have not done so', one of the Member States concerned may refer the matter to the Committee.

18. Under the first subparagraph of Article 14(1) and under Article 14(2) of Directive 75/319, as amended, the reasoned opinion which that Committee is required to deliver within 60 days may concern only the grounds on which the marketing licence has been refused, suspended or withdrawn. The Committee is also required immediately to inform the Member States concerned and the person responsible for placing the product on the market of its opinion or of those of its members in the case of divergent opinions (second subparagraph of Article 14(2)).

19. Article 14(3) provides that: 'The Member State(s) concerned shall decide what action to take on the Committee's opinion within 60 days of receipt of ... [the Committee's opinion]. They shall immediately inform the Committee of their decision'.

The national legal framework

20. The Medicines Act 1968 ('the 1968 Act') is the basic text governing marketing licences for proprietary medicinal products in the United Kingdom. It designates the Licensing Authority as the national authority having competence in regard to marketing licences. The Licensing Authority delegates its regulatory functions to an executive agency known as the Medicines Control Agency ('the MCA').

21. The 1968 Act also sets out the procedure to be followed for processing an application for a marketing licence, [9] and for renewal or refusal of such a licence. [10]

22. The Community legislation on proprietary medicinal products has legal force in the United Kingdom pursuant to section 2 of the European Communities Act 1972.

23. The Committee for the Safety of Medicines ('the CSM') is a body which the Licensing Authority must consult in proceed-

9 — Section 19.

10 — Section 20(1) of the 1968 Act, as amended by SI 1977/1050, regulation 4(3).

ings relating to the suspension, revocation or variation of a marketing licence.

24. The Medicines Commission is also a body responsible for advising the Licensing Authority in relation to licences and certificates concerning proprietary medicinal products.

25. Pursuant to the national legislation in force, when the Licensing Authority is considering revoking a marketing licence, an administrative phase is instituted in which the holder of the marketing licence may argue his case and, in particular, submit any relevant documentation and be assisted by experts of his choosing in order to establish that the medicinal product which the authorities are investigating possesses the characteristics required by Directive 65/65 (safety, therapeutic efficacy and quality).

26. Legal proceedings brought against a decision by the Licensing Authority to revoke a marketing licence must follow the procedural rules governing judicial review. In judicial review proceedings, the national court must verify that the proper procedure has been followed but does not re-examine the facts on which the contested revocatory decision was based. [11] In other words, the national court cannot determine whether the scientific judgment of the Licensing Authority was well founded or whether the scientific evidence adduced was relevant; it may state only whether, in deciding to revoke the licence in question, the Authority committed a manifest error in the appraisal of the facts.

27. It is precisely this limitation on the powers of review which the national courts can exercise over the acts of an administrative authority that forms the subject-matter of the reference for a preliminary ruling.

Facts, procedure and questions referred for a preliminary ruling

28. Upjohn Ltd ('Upjohn') is the United Kingdom operating company of The Upjohn Company of Kalamazoo, Michigan, United States of America, a research-based worldwide pharmaceutical undertaking which specialises in the production of antibiotics, anti-inflammatories and drugs used in childbirth. Halcion, which is Upjohn's brand name for Triazolam, is a benzodiazepine-based prescription drug for the treatment of insomnia (in what follows, references to Triazolam include references to Halcion). Triazolam was first licensed in the United Kingdom in Sep-

11 — In this case, as will be seen, the competent national court cannot rule on whether Triazolam is harmful in dosages of 0.125 mg and 0.25 mg.

tember 1978 for tablets in dosages of 0.25 mg and 0.125 mg.

29. In July 1991 the MCA had its attention drawn to a case in the United States in which a woman had killed her mother while under the influence of Triazolam. After obtaining the opinion of the CSM and the Medicines Commission, [12] the MCA informed Upjohn on 2 October 1991 that the Licensing Authority had decided to suspend the Triazolam marketing licences for three months. That provisional suspensory decision was renewed at three-monthly intervals.

30. In parallel to the national procedure and in accordance with the second paragraph of Article 11 of Directive 75/319, as amended by Directive 83/570, the French Republic and the Kingdom of the Netherlands referred the matter to the Committee for Proprietary Medicinal Products ('the Committee') in October 1991. The opinion of the Committee, delivered on 11 December 1991, was itself not in favour of total revocation of the marketing licence, and the Committee invited an *ad hoc* rapporteurs' group to supplement its opinion by assessing the relative risk-benefit ratios of all short-acting hypnotics (including Triazolam). At its meeting on 14 and 15 September 1993 the Committee adopted that group's report, which had concluded that Triazolam administered in authorised dosages did not appear to involve unacceptable risks that were greater than those of other comparable medicinal products. The Licensing Authority was aware that this report was being prepared.

31. However, through the MCA, the Licensing Authority informed Upjohn on 17 July 1992 of its intention to proceed with the definitive revocation of all marketing licences for Triazolam and stated that it had taken account of the Committee's opinion of 11 December 1991. The Licensing Authority also informed Upjohn that, in accordance with the national legislation in force, it was entitled, inasmuch as the Licensing Authority's view differed from that of the Medicines Commission, to appeal to the 'Person Appointed' or 'Persons Appointed'. The report by the Persons Appointed concluded that the benefits of Triazolam in dosages of 0.25 mg and 0.125 mg outweighed the risks.

32. On 9 June 1993, however, the Licensing Authority informed Upjohn of its decision to revoke all marketing licences for Triazolam with immediate effect. It set out the detailed reasons for its decision of revocation and also explained why it had rejected the conclusions of the Persons Appointed, particularly on the issues of dose equivalence and safety margins.

33. Upjohn instituted proceedings before the High Court for the quashing of that decision. In the course of those proceedings, Upjohn argued that it was necessary, prior to examination of the merits, to request the Court of

12 — After hearing Upjohn, the CSM and the Medicines Commission recommended respectively the total and immediate withdrawal of Triazolam on grounds of safety and the institution of the revocation procedure, and the revocation of the marketing licence only for the product in dosages of 0.25 mg and a simple variation of the product in dosages of 0.125 mg.

Justice for clarification as to how the national courts ought to proceed to examination of the case.

34. Upjohn takes the view that the judicial procedure in force in the United Kingdom is contrary to Community law, which, in its opinion, requires Member States to institute a procedure for judicial review of decisions taken by national authorities enabling national courts to verify the reliability of the scientific evidence on which the administration bases its decision to revoke marketing licences, and thus to assess afresh the issues of fact and law and to rule, in particular, on whether the decision taken is 'correct' [13] and complies with the principle of proportionality.

35. By order of 3 February 1995, the High Court rejected that preliminary request. On appeal, however, the Court of Appeal formed the view that it was necessary for the Court of Justice to resolve this preliminary issue before the merits of the case could be examined.

36. In those circumstances, the Court of Appeal, London, stayed the proceedings and requested the Court of Justice to deliver a preliminary ruling on the following questions:

'Question 1

On the true construction of Council Directive 65/65/EEC as amended and in the light of Community law generally, is it the duty of a national court when ruling upon the compatibility with the aforesaid Community law of a decision of a Licensing Authority of a Member State to revoke a licence held by the manufacturer of a medicine product to decide whether or not the said decision was the correct decision as opposed to a decision which the Licensing Authority could reasonably have reached on the material before it?

Question 2

If the answer to Question 1 is that the national court has to decide whether the decision of the competent authority was the correct decision does Community law require it to answer that question solely on the basis of the material before the Competent Authority or is it obliged to look at any relevant material coming to light after the decision?

Question 3

Was it lawful for the Licensing Authority to revoke the licence when the Committee for Proprietary Medicinal Products (CPMP) was

13 — In other words, the national court ought to verify that the decision taken by the Authority is the proper decision and, if necessary, substitute its own decision for that of the Authority.

known to the Licensing Authority to be soon to produce an Opinion as to continuance of the licence?'

The first question

37. By its first question, the Court of Appeal is asking the Court to determine whether Directive 65/65, or Community law more generally, requires Member States to introduce a procedure for judicial review of decisions taken by national authorities that enables the competent national courts to substitute their assessment for that of the national authorities. The Court of Appeal is specifically unsure as to whether Directive 65/65 requires it to verify the relevance of the scientific evidence adduced by the Authority in support of its revocatory decision.

38. I shall thus consider in turn whether Directive 65/65 or certain rules of Community law impose obligations of this kind on Member States.

39. It is clear from the overall system established by Directives 65/65, 75/318 and 75/319, as amended by Directive 83/570, that they do not set out any precise rule on the procedural arrangements governing legal proceedings designed to ensure that the rights which individuals derive directly from Articles 11 and 21 of Directive 65/65 are respected.

40. Article 12 of Directive 65/65, in contrast, provides that it is for the domestic legal order of each Member State to regulate such arrangements. Article 12, it should be recalled, provides that: 'All decisions taken pursuant to Articles 5 ... or 11 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'. [14]

41. Directive 65/65 cannot therefore be construed as imposing on Member States an obligation to establish a procedure for judicial review of decisions taken by national authorities under which the competent national courts would be empowered to substitute their assessment for that of the national authorities or to determine the relevance of the scientific evidence adduced by the authorities in support of their revocatory decision.

42. With regard, more generally, to the other rules of Community law, Upjohn invokes the principle of effectiveness, which, it claims, implies that the powers of review enjoyed by national courts over the action taken by administrative authorities are not limited.

14 — Emphasis added.

43. That principle, which the Court has consistently confirmed, [15] requires Member States, in the absence of measures harmonising the procedural conditions governing actions at law intended to ensure the protection of the rights which individuals derive from the direct effect of Community law, to ensure that the national procedural conditions introduced to ensure respect for those rights are not '... framed so as to render virtually impossible the exercise of rights conferred by Community law'. [16]

44. According to Upjohn, Articles 11 and 21 of Directive 65/65 are directly effective. The first paragraph of Article 11 of Directive 65/65 thus expressly authorises Member States to revoke marketing licences only '... where [the proprietary medicinal product] proves to be harmful in the normal conditions of use, or where its therapeutic efficacy is lacking, or where its qualitative and quantitative composition is not as declared'. The Court has consistently ruled that national courts are required to safeguard the protection that individuals derive from the direct effect of Community law. From this Upjohn concludes that the effectiveness of Article 11 of Directive 65/65 would be frustrated if the national court were to carry out a mere restricted review of the disputed decision revoking the marketing licence. Upjohn therefore contends that, within the context of the judicial review carried out by the competent national courts, the task of the national court should be to assess whether that decision is factually and legally sound, and in particular to determine whether it complies with the principle of proportionality and, should the need arise, to substitute its own assessment of the facts for that made by the Authority.

45. The United Kingdom Government, the French Government and the Commission, on the other hand, argue that it follows from the overall system established by Directives 65/65, 75/318, 75/319 and 83/570 that the national authorities alone are entitled to issue marketing licences for proprietary medicinal products, to renew them, suspend them or revoke them, at the conclusion of a precise and detailed procedure; the fundamental objective pursued by those directives is to ensure that human health is safeguarded, which requires that decisions be taken rapidly; in performing their functions, national authorities are required to carry out complex assessments, and thus to make sensitive choices. It is for those reasons that they take the view that the judicial review of the manner in which an authority exercises its powers, consisting in the exercise of a limited review of decisions concerning marketing licences, complies fully with the requirements of Community law.

46. Indeed, there can scarcely be any doubt that Articles 11 and 21 of Directive 65/65 meet the conditions laid down in the Court's case-law [17] for the recognition of direct effect. It follows from the overall system established by Directives 65/65, 75/318 and 75/319, as amended by Directive 83/570, that they establish precise and detailed rules governing appli-

15 — See, *inter alia*, Case 45/76 *Comet* v *Produktschap voor Siergewassen* [1976] ECR 2043, paragraphs 13 and 16; Case 199/82 *Amministrazione delle Finanze dello Stato* v *San Giorgio* [1983] ECR 3595, paragraph 12; and Case C-208/90 *Emmott* v *Minister for Social Welfare and the Attorney General* [1991] ECR I-4269.

16 — *Emmott*, cited above, paragraph 16.

17 — See, *inter alia*, Case 8/81 *Becker* v *Finanzamt Münster-'nnenstadt* [1982] ECR 53, paragraph 25.

cations for marketing licences, the manner in which such applications are processed and the resulting decisions.

47. Article 21 of Directive 65/65 thus clearly prohibits Member States from revoking a marketing licence on grounds other than those set out in that directive, and Article 11 of Directive 65/65, as amended by Directives 75/318, 75/319 and 83/570, specifically sets out those grounds, as has already been seen.

48. The obligations which those articles impose on Member States reflect perfectly the twofold objective pursued by the above harmonising directives, which, as already seen, consists in seeking to safeguard public health and eliminating barriers to the free movement of medicinal products, as stated in particular in the first and second recitals in the preamble to Directive 65/65.

49. The Court has, moreover, already ruled that Article 21 of Directive 65/65 is directly effective and that it must be interpreted as meaning that the suspension or revocation of a marketing licence may be decided only on the grounds laid down in that directive or in supplementary directives. [18]

50. In my opinion, the limited judicial review of the decisions taken by the national authority in regard to marketing licences implemented by the contested national legislation does not in any way call in question the effectiveness of Articles 11 and 21 of Directive 65/65. The Court has always taken the view that when an authority is required, in the exercise of its functions, to undertake complex assessments, a limited judicial review of the action which that authority alone is entitled to perform must be exercised, since otherwise that authority's freedom of action would be definitively paralysed. [19]

51. It is clear from the wording of numerous provisions of the relevant directives cited above that the national authorities alone are competent in regard to marketing licences for medicinal products [20] and that, in the exercise of that function, they are indeed required to undertake complex assessments [21] on the basis

18 — See *Clin-Midy and Others* and *Pierrel and Others*, cited above.

19 — In a similar situation, see for instance *Norbrook Laboratories*, cited above, paragraph 90. In another area, see for instance Case C-84/94 *United Kingdom* v *Council* [1996] ECR I-5755, paragraph 58.

20 — See, in particular, Articles 3 and 4 of Directive 65/65.

21 — See, in particular, Article 4, second paragraph, point (7) of Directive 65/65, as amended by Directive 75/319, and Article 18 of Directive 75/319, which provide respectively that the national authority must submit the medicinal product for testing by a State laboratory or by a laboratory designated for that purpose in order to ensure that the control methods employed by the manufacturer and described in the particulars accompanying the application for a marketing licence comply with the requirements laid down in Directives 65/65, 75/318 and 75/319 and that it must make sure, following an inquiry carried out by its agents, that the particulars supplied pursuant to the requirements of Directive 75/319 are accurate.

of technical and scientific factors which are capable of rapid evolution. [22]

52. Upjohn also argues that in this case it has been unable fully to defend its rights under the national procedure in force. The Authority, it contends, opposed the production of evidence which would have allowed it to show that the decision revoking the marketing licences for Triazolam was vitiated by a manifest error. In support of these contentions, Upjohn argues in particular that the Authority definitively withdrew the marketing licences in question without taking account of the results of the report compiled by the *ad hoc* group which had been instructed by the Committee to evaluate the risk-benefit ratio for hypnotics. It should be recalled that this report concluded that Triazolam administered in authorised dosages did not appear to involve unacceptable risks any greater than those of other comparable medicinal products. This last argument forms the subject of the third question.

53. Like Upjohn, I take the view that the principle of effectiveness undoubtedly prohibits a national authority from implementing national procedural arrangements that limit the exercise by the holder of a marketing licence of his rights to a fair hearing.

54. In two judgments delivered on 14 December 1995 in *Peterbroeck* [23] and *Van Schijndel and Van Veen*, [24] the Court held that: 'For the purposes of applying ... [the principle of effectiveness], each case which raises the question whether a national procedural provision renders application of Community law impossible or excessively difficult must be analysed by reference to the role of that provision in the procedure, its progress and its special features, viewed as a whole, before the various national instances. In the light of that analysis the basic principles of the domestic judicial system, such as protection of the rights of the defence, the principle of legal certainty and the proper conduct of procedure, must, where appropriate, be taken into consideration'.

55. In this case, however, the assertions of Upjohn are challenged by the respondent in the main proceedings. According to the latter, no less than 15 items of evidence have been adduced before the national court. It also submits that the comments made by the United Kingdom Government and contained in the documents before the Court, and on which, according to Upjohn, the parties were unable to set out their views before the national

22 — See, in particular, Article 9a of Directive 65/65, as amended by Directive 83/570, which requires the national authority to ensure that the person holding a marketing licence, after the licence has been issued, has taken account, in respect of the control methods provided for in Article 4, point (7), of Directive 65/65, of technical and scientific progress and introduced any changes that may be required to enable the medicinal product to be checked by means of generally accepted scientific methods.

23 — Case C-312/93 *Peterbroeck* v *Belgian State* [1995] ECR I-4599, paragraph 14.

24 — Joined Cases C-430/93 and C-431/93 *Van Schijndel and Van Veen* v *Stichting Pensioenfonds voor Fysiotherapeuten* [1995] ECR I-4705, paragraph 19.

court, were made after the contested decision had been adopted.

56. The outcome of this dispute depends on the assessment of purely factual matters of which the Court cannot be expected to have cognisance. It is thus a matter for the competent national court to ascertain whether the national authority did in fact prevent Upjohn from exercising its rights of defence and in particular whether, because of that, Upjohn was unable to put forward the evidence which would have enabled it to establish that the Licensing Authority's decision was vitiated by a manifest error or to enable a finding to be made that the decision taken was unlawful.

57. With regard to Upjohn's final ground of complaint, to the effect that the national court must verify that the decision by a national authority revoking marketing licences complies with the principle of proportionality, it should be noted that, according to settled case-law, review by national courts of compliance with this principle is subject to the absence of measures harmonising penalties for breaches of a Community law obligation. [25]

58. It follows clearly from the overall system of Community legislation cited above [26] that Member States do not have any discretion as to the *penalty* for non-compliance with the three fundamental characteristics which a medicinal product must possess to enable it to be marketed within the territory of the Union, since Article 11 of Directive 65/65, as amended by Directive 83/570, expressly states that a medicinal product which does not possess those three characteristics must be withdrawn from the market by the national authority.

59. It follows that Directive 65/65 and, more generally, Community law do not require Member States to introduce a procedure for judicial review of decisions taken by national authorities which would enable the competent national courts to substitute their assessment for that of the national authority or to verify whether the scientific evidence adduced by that authority in support of its revocatory decision is relevant.

60. In view of this conclusion, a reply to the second question no longer serves any purpose.

The third question

61. By its third question, the Court of Appeal is specifically asking the Court to state whether Directive 65/65 must be construed as authorising a national authority to deliver a decision revoking marketing licences without

25 — See, *a contrario*, in particular, Case C-7/90 *Vandevenne and Others* [1991] ECR I-4371, paragraph 11.

26 — In particular, Articles 4 and 5 of Directive 65/65.

awaiting the definitive opinion of the Committee, irrespective of how long it takes the Committee to deliver that opinion.

62. It seems to me that the wording of the provisions of Directives 75/319 and 65/65 and the purpose which they serve do not preclude an authority from revoking a marketing licence where the Committee has not delivered its opinion within the period laid down by Directive 75/319.

63. It must be borne in mind that Article 14(1) of Directive 75/319, as amended by Directive 83/570, requires the Committee to issue a *reasoned opinion within 60 days*. This period has been shortened (prior to the amendment effected by Directive 83/570 it was 120 days). The unavoidable conclusion here is that the Committee did not comply with that period. Since the issue in this case is one of public health, that provision cannot be construed as requiring Member States to await the Committee's opinion before deciding to withdraw a medicinal product that may prove to be harmful.

64. Moreover, the opinion of the Committee is in no wise binding. Article 8 of Directive 75/319, as amended by Directive 83/570, expressly provides that the function of the Committee, in cases where there is a risk of divergent opinions between the different national authorities with regard to marketing licences, is to *facilitate* the adoption of a common position by the Member States, and not to *impose* a common decision. Article 14(3) of Directive 75/319, as amended by Directive 83/570, also simply provides that the Member States concerned must indicate within 60 days what action they intend to take on the Committee's opinion. The wording of that provision thus makes it clear that the Member States are free to take a position other than that of the Committee.

65. This interpretation is perfectly compatible with the purpose and wording of the provisions of Directive 65/65.

66. So far as the system established by Directive 65/65 is concerned, it has been seen that the national authorities alone are competent in regard to marketing licences for medicinal products intended for human use. [27] The provisions relating to the procedure and scope of the opinion adopted by the Committee cannot therefore be construed as limiting the powers of those authorities.

67. It follows that the relevant Community directives do not require the national authorities to await the opinion of the Committee before delivering their decisions to revoke marketing licences if the Committee has failed to comply with the period laid down by Directive 75/319, as amended.

27 — See, in particular, Article 3 of Directive 65/65 and points 4 and 6 of the present Opinion.

Conclusion

68. For those reasons, I propose that the Court reply as follows to the questions submitted to it by the Court of Appeal, London:

(1) 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, as amended by Council Directive 83/570/EEC of 26 October 1983, must be construed as not requiring Member States to introduce a procedure for judicial review of decisions taken by the competent national authority which would allow the competent national courts to substitute their assessment for that of the national authority or to determine the relevance of the scientific evidence adduced by that authority in support of its decision to revoke a marketing licence for a medicinal product intended for human use.

(2) Directive 65/65 does not require the competent national authority to await the opinion of the Committee for Proprietary Medicinal Products before delivering the above revocatory decision if that Committee has failed to comply with the period laid down by Second Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, as amended by above Directive 83/570.