OPINION OF ADVOCATE GENERAL JACOBS
delivered on 22 May 2003 [1]

1. These four joined cases raise a number of questions concerning the compatibility with the Community competition rules of the arrangement, provided for by statute, whereby the leading associations of sickness funds in Germany collectively determine the maximum amounts (known as 'fixed amounts') paid by sickness funds towards the cost of various types of medicinal product. Insured patients are left to pay the excess cost of any prescribed product which is priced above the amount thus fixed.

2. Cases C-264/01 and C-306/01 are references from the Competition Chamber of the Oberlandesgericht Düsseldorf. Cases C-354/01 and C-355/01 are references from the Bundesgerichtshof. The questions referred by each of the national courts differ somewhat in formulation and scope. When taken together, the issues which they raise include in particular whether sickness funds are undertakings and therefore subject to the Community competition rules; whether the decisions of their leading associations to set fixed amounts are capable of breaching Article 81 EC; and, if so, whether those decisions might be defended by reference to Article 86(2) EC.

3. Article 81(1) EC prohibits decisions by associations of undertakings which may affect trade between MemberStates and which have as their object or effect the prevention, restriction or distortion of competition within the common market, and in particular, under Article 81(1)(a), those which directly or indirectly fix purchase or selling prices or any other trading conditions.

4. Article 86(2) EC provides:

'Undertakings entrusted with the operation of services of general economic interest or having the character of a revenue-producing monopoly shall be subject to the rules contained in this Treaty, in particular to the

1 — Original language: English.

rules on competition, in so far as the application of such rules does not obstruct the performance, in law or in fact, of the particular tasks assigned to them. The development of trade must not be affected to such an extent as would be contrary to the interests of the Community.'

National legal framework

5. The great majority of employees in Germany are required to belong to the statutory health insurance system, which is governed by the fifth book of the Sozialgesetzbuch (the social security code), (hereinafter the 'SGB V'). Employees are subject to statutory health insurance unless their income exceeds a certain level or unless they receive sufficient cover from another statutory source, as in the case of civil servants. Employees' insurance extends also to unemployed family members. Other persons may insure themselves on a voluntary basis provided certain conditions are met.

6. The system is funded by compulsory contributions from insured persons and their employers, the levels of which are fixed according to the insured person's income. Under Paragraph 1(1) SGB V, the system is described as based on the principle of solidarity, [2] and is assigned the task of maintaining, restoring or improving the health of insured persons.

7. Statutory health insurance is provided by the sickness funds, most of which are bodies governed by public law (Paragraph 4 (1) SGB V). The sickness funds are organised together regionally and sectorally into associations. The appellants in the main proceedings operate at the federal level, and are identified by Paragraph 213(1) SGB V as the leading associations of sickness funds. Most of the appellants represent a number of sickness funds. However, the Bundesknappschaft (the miners' sickness fund) and the See-Krankenkasse (the seamen's sickness fund) are themselves direct providers of statutory health insurance.

8. Provision was made for the setting of fixed amounts by the Gesetz zur Strukturreform im Gesundheitswesen (the law on structural reform in the health sector) of 1988. Its object was to reduce the costs of the health insurance system by giving the sickness funds a means of influencing doctors' and patients' choice of medicines and by developing awareness of the cost of medicines on the part of insured persons. To that end, the appellants are,

2 — For the principle of solidarity, see paragraph 32 below.

as explained below, given joint responsibility for determining the fixed amounts which funds may contribute towards the cost of various types of medicinal product.

9. Ordinarily, under Paragraph 2(2) SGB V, funds are required to purchase medical services and products directly and to supply them in kind to the insured persons who need them (the so-called benefit in kind principle). However, Paragraph 12(2) SGB V provides that 'where a fixed amount has been determined in respect of a supply, the sickness fund fulfils its obligation by paying that fixed amount'. By Paragraph 31(2), if the price of a prescribed product exceeds the fixed amount applicable to it, the insured person must himself bear the excess cost. In such a case, the prescribing doctor must inform the insured person, in advance, of the obligation to pay the excess cost (Paragraph 73(5) SGB V).

10. In principle, therefore, pharmaceutical companies remain free to set a price for their products above any applicable fixed amount. In practice, however, it appears that only around 7% of medicinal products on the German market to which a fixed amount applies are sold at a price exceeding that amount.

11. The procedure for determining fixed amounts is laid down by Paragraph 35 SGB V, and has two stages. The first stage serves to select the categories of medicinal products to which fixed amounts are to apply. That task is performed by the Bundesausschuss der Ärzte und Krankenkassen (Federal Committee of Doctors and Sickness Funds hereinafter 'Bundesausschuss'), a body comprising representatives of the appellants and of the Kassenärztlichen Bundesvereinigungen (Federal Associations of Sickness Fund Doctors). By Paragraph 35(1) SGB V, each category is to consist of products which have active substances which are the same or are pharmacologically or therapeutically comparable, or which have a pharmacologically or therapeutically comparable effect. The selections made by the Bundesausschuss must be laid before the Federal Ministry of Health. They come into force only if the Ministry adopts them, or does not object to them within two months.

12. At the second stage of the procedure, the appellants then determine a fixed amount for each category of medicinal products. Under Paragraph 35(3) SGB V the appellants jointly determine uniform fixed amounts on the basis of average daily or single dosages or other suitable comparable quantities determined by the Bundesausschuss. Under Paragraph 35(5) SGB V, amounts must be set:

'so that they ensure generally an adequate, effective and economically efficient treatment of assured quality. They must exploit

all reserves in terms of economy and produce effective price competition and therefore take as a basis the most inexpensive supply possibilities; so far as is possible, a range of medicinal products which is adequate for therapeutic purposes must be ensured.'

13. In 1998, at the time when the main proceedings were commenced, Paragraph 35(5) SGB V also provided that the determination of fixed amounts should 'proceed from the least expensive pharmacy sale prices of the comparator group'. It has since been amended to require only that the fixed amount fall within the bottom third of the range of prices represented by the comparator group.

14. If the appellants are unable to reach agreement on the fixed amount for a given category of medicinal products, the Federal Ministry of Health makes the decision in consultation with the Federal Ministry of the Economy. At the time when the orders for reference were made, it appears that the Ministry of Health had never yet had cause to reach a decision determining fixed amounts.

15. At both stages of the procedure, experts in the theory and practice of medicine and pharmacology must be given an opportunity to state their views, and those views must be taken into account. The fixed amounts, once set, are subject to annual review by the appellants and must at appropriate intervals be adapted to changes in the market. Once determined, they are to be published in the *Bundesanzeiger* (Federal Gazette), and are open to challenge before the courts.

The main proceedings and questions referred

16. The present joined cases involve separate but similar factual situations and raise the same basic legal issues. The respondents are pharmaceutical companies. They seek to challenge decisions of the appellants pursuant to Paragraph 35 SGB V varying the level of fixed amounts applicable to the categories of medicinal product to which their own products belong. In each case, the respondents were successful either at first instance or at the first stage of appeal. The appellants have therefore in turn appealed to the referring courts which have decided to stay the proceedings before them and to refer various questions to the Court of Justice.

17. Since those orders for reference were made, the Bundesverfassungsgericht (the German Constitutional Court) has examined the compatibility of the setting of fixed amounts with the German Constitution and

in particular with pharmaceutical companies' right to pursue a profession. By its judgment of 17 December 2002, [3] the Bundesverfassungsgericht upheld the constitutionality of Paragraph 35 SGB V. It is therefore clear that the questions referred to the Court remain necessary to enable the referring courts to reach judgment in the main proceedings.

18. The two orders for reference made by the Oberlandesgericht in Cases C-264/01 and C-306/01 address the following questions to the Court:

'1. Is Article 81(1) EC to be interpreted as meaning that the leading associations of statutory sickness funds of a Member State are to be regarded as associations of undertakings or, where a leading association is also a direct provider of statutory sickness insurance, as undertakings within the meaning of Article 81(1) EC when they jointly determine the applicable level of uniform fixed amounts for medicinal products in the Member State, where such amounts constitute the highest price at which the statutory sickness funds, who are required to provide benefits in kind to insured persons, will purchase and pay for medicinal products and thereby limit their liability to insured persons?

2. If the answer to the first question is in the affirmative:

(a) are determinations of fixed amounts as described in [question] 1 above to be regarded as agreements (or decisions) of the leading associations of statutory sickness funds which restrict competition, in particular within the meaning of Article 81(1)(a) EC, and are prohibited by Article 81(1) EC?

(b) is question 2(a) to be answered in the affirmative at least where the object of the regulation concerning fixed amounts is, *inter alia*, to exploit all reserves of medicinal product manufacturers in terms of economy as regards sale price, and the application of the regulation concerning fixed amounts in the Member State so far has had the effect that, of the finished medicinal product packages offered on the market that fall within the regulations concerning fixed amounts, approximately 93% do not now exceed the amount fixed for them?

3. If the answer to either or both of the questions in [question] 2 above is in the affirmative:

Can a system of fixed amounts as described in questions 1 and 2 be

3 — Judgment of the Bundesverfassungsgericht of the 17 December 2002, 1 BvL 28/95, 1BvL 29/95 and 1 BvL 30/95.

exempted from Article 81(1) EC under Article 86(2) EC, first sentence, even though when they determine fixed amounts the leading associations of statutory sickness funds represent the biggest purchasers on the medicinal product market, who when taken together dominate the market, and it would be possible, as a solution to the problem of trying to reduce costs in the health sector, to grant power to determine such fixed amounts to an institution other than a participant in the medicinal product market, in particular to the Federal Government or a Federal Minister?

4. If the answer to question 3 is also in the affirmative:

(a) what conditions must be set forth and proved by the leading associations of statutory sickness funds so that they may be exempted under Article 86(2) EC, first sentence, in relation to determinations of fixed amounts? or

(b) is the grant of an exemption under Article 86(2) EC, first sentence, precluded in any case by Article 86(2) EC, second sentence, owing to the effects the system of fixed amounts has on trade?'

19. The two orders for reference made by the Bundesgerichtshof in Cases C-354/01 and C-355/01 address the following questions to the Court:

'1. Are Articles 81 and 82 EC to be interpreted as precluding national rules under which national leading associations of statutory sickness insurance determine binding maximum amounts for all statutory sickness funds and compensatory sickness funds up to which the funds bear the costs of medicines, where the legislature defines the criteria by which the maximum amounts are to be calculated, providing in particular that the fixed amounts must ensure comprehensive and quality-assured treatment of insured persons as well as an adequate range of therapeutic alternatives, and the determination is subject to comprehensive review by the courts, which may be initiated by both insured persons and affected product manufacturers?

2. If question 1 is answered in the affirmative:

Does Article 86(2) EC exempt such a determination from Articles 81 and 82 EC where the purpose of the determination is to safeguard, in the manner provided for in Paragraph 35 SGB V, a sickness insurance scheme whose existence was endangered by a significant increase in costs?

20. The first question referred by the Bundesgerichtshof is very general, and effectively encompasses the first two questions referred by the Oberlandesgericht. Although by referring to Article 82 EC it appears to be wider in its scope, the Bundesgerichthof's order for reference in fact contains no more detailed discussion of whether that article might apply. The second question referred by the Bundesgerichtshof concerns the application of Article 86(2) EC, and therefore covers the same territory as the third and fourth questions referred by the Oberlandesgericht. The third question referred by the Bundesgerichtshof, concerning the remedies which might be obtained against the sickness funds, is raised only by it.

3. If question 1 is answered in the affirmative and question 2 in the negative:

Are leading associations such as the defendants liable to claims under Community law for damages and an injunction even where in determining maximum amounts they follow a statutory direction, notwithstanding that national law does not impose any penalty for refusal to assist in the making of such a determination?'

21. The following five issues can therefore be distilled from the various orders for reference. The first relates to the applicability of the Community competition rules to the sickness funds and their leading associations. The answer to that issue lies in a consideration of the case-law relating to the meaning of an undertaking and an association of undertakings. The second issue concerns whether the setting of fixed amounts would, in the absence of any available defence, put the leading associations of sickness funds in breach of Article 81 EC. Despite the Bundesgerichtshof's mention of Article 82 EC in its first question, given that the parties' submissions do not elaborate upon the applicability of that article to the setting of fixed amounts, I consider it appropriate to confine the second issue to a consideration of Article 81. The third issue is whether, if Article 81 EC were in principle applicable to the setting of fixed amounts, the leading associations of sickness funds might defend

themselves on the basis that Article 81 EC applies only to conduct which is autonomous and that they were compelled by national law to behave as they did. Fourthly, it is necessary to consider whether the setting of fixed amounts might be defended under Article 86(2) EC as necessary to the operation of a service of general economic interest. Finally, there is the issue whether remedial relief might be granted against the appellants even assuming that they were acting under statutory direction, despite the lack of a penalty for non-compliance with that direction.

22. Written observations were submitted by the appellants, the respondents and the Commission, all of whom were represented at the hearing. Oral submissions were also made on behalf of the German Government at the hearing.

Assessment

The classification of the appellants as an association of undertakings when setting fixed amounts

24. It is first necessary to consider whether Community competition law is applicable at all to the determination of fixed amounts. That issue, which turns on whether the appellants act as an 'association of undertakings' when setting fixed amounts, is explicitly raised by the Oberlandesgericht's first question. It must also be addressed in order to give an answer to the Bundesgerichtshof's more general first question.

24. There are three stages involved in such an assessment. First, it must be established whether the sickness funds represented by the appellants are undertakings when they provide health insurance services. If so, it must then be determined whether the setting of fixed amounts in principle falls within the sphere of the sickness funds' economic activity. Thirdly, it must be ascertained whether the appellants act as an association of undertakings when they set the uniform fixed amounts which are then applied by the sickness funds.

Do the sickness funds act as undertakings in providing health insurance services?

25. As to the status of the sickness funds, the Court's general approach to whether a

given entity is an undertaking within the meaning of the Community competition rules can be described as functional, in that it focuses on the type of activity performed rather than on the characteristics of the actors which perform it, the social objectives associated with it, or the regulatory or funding arrangements to which it is subject in a particular Member State. [4] Provided that an activity is of an economic character, those engaged in it will be subject to Community competition law.

26. The status of actors in national law is not therefore relevant when assessing whether they amount to undertakings in Community law. Hence, no weight can be attached to the fact that in German law sickness funds are classified as bodies subject to public law or as part of the administration of the State. Likewise, the regulatory or funding arrangements applied by a Member State to a given field of activity will not determine the applicability of the Community competition rules. Such choices may themselves fall to be assessed under those rules. Nor will the existence of social or general interest objectives associated with a given field of activity deprive it of its economic character. Such objectives may, however, supply a justification under Article 86(2) EC for arrangements which would otherwise infringe Community competition law. [5]

27. In assessing whether an activity is economic in character, the basic test appears to me to be whether it could, at least in principle, be carried on by a private undertaking in order to make profits. [6] If there were no possibility of a private undertaking carrying on a given activity, there would be no purpose in applying the competition rules to it. [7]

28. However, the application of that test in relation to certain fields of activity is by no means straightforward, and the Court has developed a more elaborate set of criteria to assist in the assessment. Of particular relevance for present purposes, there is now a considerable body of case-law concerning the proper classification of pension and social insurance schemes.

4 — See, for example, Case C-41/90 *Höfner and Elser* [1991] ECR I-1979, at paragraph 21 of the judgment; Joined Cases C-159/91 and C-160/91 *Poucet and Pistre* [1993] ECR I-637, at paragraph 17; Case C-218/00 *Cisal* [2002] ECR I-691, at paragraph 22.

5 — See Case C-67/96 *Albany* [1999] ECR I-5751, paragraphs 85 and 86 of the judgment.

6 — See *Höfner and Elser*, cited in note 4, paragraphs 22 and 23 of the judgment. See also my Opinion in *Albany*, cited in note 5, at paragraph 311.

7 — See Case C-244/94 *Fédération française des sociétés d'assurance* [1995] ECR I-4013 ('*FFSA*'), paragraph 21 of the judgment.

29. Some such schemes have been held by the Court not to involve economic activities and therefore to fall outside the scope of the Community competition rules.

30. In *Poucet and Pistre*, [8] the Court considered the status of an old-age pension scheme and a sickness and maternity insurance scheme. It held that neither scheme involved an economic activity in circumstances where affiliation was compulsory, where there was no link between the level of contributions made and benefits received, where the level of contributions and benefits was fixed by law, and where (in the case of the pension scheme) current benefits were paid directly out of current contributions rather than on the basis of income from a capital fund.

31. Similarly, in *Cisal*, [9] the Court found a scheme providing insurance cover against accidents at work not to constitute an economic activity where affiliation was compulsory, where there was only a limited correlation between the level of contributions made and benefits received, and where both contributions and benefits were subject to ministerial control.

32. It seems to me clear that compulsory state social security schemes such as those at issue in *Cisal* and *Poucet and Pistre* are not classified as economic activities because they are incompatible, even in principle, with the possibility of a private undertaking carrying them on. Such schemes entail such an element of redistribution in the interests of social solidarity that little or no scope remains for the various actuarial, investment and intermediary services which private pensions and insurance providers can and do supply on the market. [10]

33. As I stated in my Opinion in *Albany*, [11] I cannot see how a private undertaking could offer on the market a non-funded pension whereby present contributions fund present benefits. In such a scheme, redistribution is not ancillary to some other activity which could exist independently of it. Rather, the scheme consists entirely of the State-compelled redistribution of resources from those currently employed to those who have retired. Similarly, as I indicated in my Opinion in *Cisal*, [12] it would appear to be an essential feature of

8 — Cited in note 4.

9 — Cited in note 4.

10 — For the principle of solidarity in social insurance schemes, see *Poucet and Pistre*, cited in note 4, paragraph 10 et seq. of the judgment.

11 — Cited in note 5, paragraph 338 of the Opinion.

12 — Cited in note 4, paragraph 62 of the Opinion.

private insurance of income against the risk of occupational injury that contributions and benefits are linked not only on an aggregate level (the sum of benefits must be financed by the sum of contributions) but also on an individual level.

34. By contrast, pension schemes which are funded through the administration of a capital fund, into which contributions are paid, and in which benefits are directly related to contributions, have been held in *FFSA* [13] and *Albany* [14] to be subject to the Community competition rules, despite the existence of certain elements of solidarity. In such schemes, the redistributive element is not such as to entail a suppression of the types of activity habitually provided by private insurance and pension companies, such as actuarial assessment and the management of investments.

35. It is of course difficult to arrive at any precise statement of the point at which the redistributive component of a pension or insurance scheme will be so pronounced as to eclipse the economic activities which private pension and insurance providers compete to supply. Schemes come in a wide variety of forms, ranging from State social security schemes at one end of the spectrum to private individual schemes operated by commercial insurers at the other. Classification is thus necessarily a question of degree.

36. The appellants, the German Government and the Commission argue on the basis of *Poucet and Pistre* and *Cisal* [15] that sickness funds are not involved in economic activities and are therefore not undertakings for the purposes of EC competition law. The sickness funds are founded on the principle of social solidarity. All Germans are guaranteed the same basic level of benefits regardless of their income, state of health or the level of risk which they represent. Contributions are unrelated to benefits on an individual level. In order to sustain such solidarity, membership of funds is compulsory for most German employees.

37. Certainly, the German statutory health insurance system does have a number of points in common with the schemes at issue in *Poucet and Pistre* and *Cisal*. However, it appears to me also to possess various features which distinguish it by introducing a degree of competition between the sickness funds, as well as between the sickness

13 — Cited in note 7.

14 — Cited in note 5.

15 — Both cited in note 4.

funds and private insurers, and which thereby demonstrate that the system's redistributive element is not such as to preclude economic activity.

38. First, as the Bundesgerichtshof states in its order for reference, and as the appellants themselves acknowledged at the hearing, sickness funds are engaged in a degree of price competition with one another. Employees have a choice as to which fund they join. The funds determine for themselves the level of contribution which they require from insured persons. In consequence, the levels of contribution do show some variation from fund to fund. Solidarity is apparently guaranteed by means of a mechanism (the Risikostrukturausgleich) designed to correct any difference in the degree of risk borne by the various funds, thereby allowing them to compete without in the process undermining the redistributive aspect of the system. If some funds have a population of insured persons which requires disproportionately expensive medical care, the other funds must make a contribution towards those higher costs.

39. As I stated in my Opinion in *Cisal*,[16] the fact that, as here, the level of benefits provided under a scheme is determined by law cannot in itself rule out the application of the competition rules. In several sectors of the economy, the legislature determines in advance obligatory characteristics of the goods or services to be supplied by undertakings. As long as the undertakings concerned can compete, for example, on the price of those goods or services, they continue to be engaged in an economic activity.

40. Secondly, according to the respondents, there is also some potential for the funds to compete in terms of the services which they offer. Although the basic level of benefits is statutorily defined, the respondents claim that the funds possess some discretion as to how to meet their obligations. For example, they may decide whether to offer certain complementary and preventive treatments. Insofar as the respondents' contention is correct, the funds are therefore able to differentiate themselves in an effort to render themselves more attractive to insured persons.

41. Finally, as the appellants acknowledged at the hearing, sickness funds and private health insurers are clearly in competition with one another for the business of those employees who are not obliged to take out statutory health insurance.

16 — At paragraph 73.

42. It therefore appears that the sickness funds are indeed able to compete, albeit within defined margins, with one another and with private undertakings in the provision of health insurance services. Given the existence of such competition, the EC competition rules should in my view apply.

Does the setting of fixed amounts fall within the sphere of the economic activity performed by the sickness funds?

43. Even if one concludes that the sickness funds act as undertakings in supplying health insurance, it is still necessary to consider whether the setting of fixed amounts, which is the alleged anti-competitive conduct, falls within the sphere of the economic activity which the sickness funds perform.

44. In my view, there is no merit to the argument, advanced by the appellants, that the setting of fixed amounts can somehow be separated from the sickness funds' main activity of providing health insurance, so that while the latter may be economic in nature the former need not be.

45. It is true that the notion of undertaking is a relative concept in the sense that a given entity might be regarded as an undertaking for one part of its activities while the rest fall outside the competition rules. [17] However, it is clear to me that if the supply of a service is an economic activity, so also are the supplier's decisions regarding the parameters of the service to be offered. In determining fixed amounts, the sickness funds specify the maximum price at which they will purchase a key input; they also specify the level of insurance cover which they will provide to insured persons. Such decisions are thus indissociable from the core activity of health insurance.

46. In the light of that conclusion, it is not necessary to consider whether the setting of fixed amounts might constitute an economic activity even if the main activity of the sickness funds did not qualify as such. The Oberlandesgericht suggests that purchasing may amount to an economic activity whether or not the entity which

17 — See, for example, the *Amministrazione Autonoma dei Monopoli di Stato* in Case 118/85 *Commission* v *Italy* [1987] ECR 2599, at paragraph 7 of the judgment and the *Bundesanstalt fur Arbeit* in *Hofner and Elser*, cited in note 4.

purchases is itself active on another market for which the goods or services purchased constitute an input. The Commission, the appellants and the German Government all contend otherwise. The question does not arise, however, given that the sickness funds are active on another market, and contribute towards the purchase of pharmaceuticals as part of their activity on that market. [18]

Do the appellants act as an association of undertakings when setting fixed amounts?

47. The final stage involved in assessing the status of the appellants under Community competition law is to consider whether they act as an association of undertakings when they set the uniform fixed amounts which are then applied by the sickness funds.

48. The parties differ as to whether the appellants' determinations of fixed amounts can be regarded as decisions of an association of undertakings within the meaning of Article 81 EC. The respondents assert that, at the first stage of the procedure, [19] decisions are taken by the appellants in conjunction with the Bundesausschuss, a body which is itself partly composed of the appellants' representatives, whilst at the second stage of the procedure, fixed amounts are set exclusively by the appellants. If sickness funds are undertakings, their leading associations are just as clearly associations of undertakings, and the decisions reached by those associations constitute decisions by an association of undertakings.

49. The appellants submit that, even if their member funds are undertakings, they themselves operate within a statutory framework when setting fixed amounts which ensures that they act independently and in the general interest. As such, their determinations cannot be classed as decisions of an association of undertakings.

50. They point first to the fact that they must act pursuant to statutory criteria, laid down by Paragraph 35(5) SGB V, when setting fixed amounts. Secondly, they emphasise that the procedure to which they are subject ensures that a variety of interests are taken into account both at the stage of

18 — That factor distinguishes the Court of First Instance's judgment in Case T-319/99 *FENIN* delivered on 4 March 2003; see paragraphs 38 and 40 of that judgment.

19 — See paragraphs 11 to 14 above

determining the categories to which fixed amounts are to apply, and at the subsequent stage where the fixed amounts are actually set. Medical experts representing pharmaceutical companies and the pharmacists' profession are given the opportunity to make representations and their views must be taken into account. Thirdly, they emphasise the various supervisory controls applicable to them. Decisions reached at the first stage require the approval of the Federal Ministry of Health. At the latter stage, they are subject to judicial review.

51. I am not convinced by the appellants' submissions.

52. As the Court has consistently held, the fact that a body responsible for fixing prices is appointed by public authority does not automatically exclude the existence of agreements or decisions within the meaning of Article 81 EC. Nor, however, does the fact that a body comprises persons drawn from undertakings or associations of undertakings mean that its determinations are automatically within the scope of that article. In each case, it is necessary to assess whether the members of the body act as representatives of and in the interests of undertakings, or in an independent manner in the public interest. [20]

53. One important factor in performing that assessment will be the criteria for selecting members of the body in question. If members are chosen for their independent expertise, their determinations can ordinarily be presumed not to constitute decisions under Article 81 EC. Another important factor to consider is the substantive and procedural obligations to which the body in question is subject in reaching its determinations. If it is required to take account of general interest considerations, and to consult with various interested parties, it will generally not be held to constitute an association of undertakings. [21]

54. As regards the setting of fixed amounts, it is in my view arguable that the first stage of the procedure [22] does not result in decisions by an association of undertakings. The decision-making body is composed of representatives of doctors as well as of the appellants. The criteria specified in Paragraph 35(1) SGB V require decisions to be made exclusively on the

20 — See, for example, Case C-185/91 *Reiff* [1993] ECR I-5801, at paragraph 16 of the judgment.

21 — See Case C-35/96 *Commission* v *Italy* [1998] ECR I-3851, at paragraph 44 of the judgment.

22 — See paragraph 11 above.

basis of expertise. Moreover, decisions are subject to control by the Federal Ministry of Health before they become effective.

55. As regards the second stage of the procedure, however, I am much less persuaded of the appellants' case that they are acting independently and in the general interest. The decision-making body consists exclusively of the appellants. Their decisions become immediately effective, without any prior approval procedure by the Ministry of Health. The sickness funds which the leading associations represent compete with one another in a variety of ways, and have a clear interest as undertakings in setting fixed amounts at as low as possible a level. The lower the fixed amount, the less their resources will be tied up in assuring the supply of medicinal products, and the more will be available to fund their ability to compete with one another in other regards.

56. It is true that Paragraph 35 SGB V does specify criteria pursuant to which the appellants must act when setting fixed amounts, so that any discretion which they may possess is bounded. However, the applicable criteria are in my view not sufficiently differentiated from the appellants' own interests to prevent the determinations applying those criteria from constituting decisions of an association of undertakings.

57. The reference in Paragraph 35(3) SGB V to the need to set fixed amounts on the basis of the average daily or single dosages or other suitable comparative quantities is a purely practical aspect of the calculation of fixed amounts and will, in any event, have been specified at the first stage of the procedure.

58. As to the criteria specified in Paragraph 35(5) SGB V,[23] the emphasis is upon securing prices for medicinal products which are as low as possible consistent with the appellants' overriding mission of maintaining treatment for all at an adequate, effective and quality-assured level. That goal is to be achieved by exhausting all reserves in terms of economy and securing the most inexpensive supply possibilities. At the time to which the present proceedings relate, Paragraph 35 (5) SGB V further emphasised the need for the fixed amounts to be based on the lowest pharmacy sale prices of the comparator group. In its more recent formulation, the paragraph still requires that the fixed amounts should not exceed the highest sale

23 — See paragraph 12 above.

price of the lowest third of the range between the lowest and highest prices for the medicinal products in the particular comparator group.

59. Nor, in my view, does the need to secure effective price competition serve as a meaningful counterweight to the various criteria emphasising the need to set fixed amounts at a low level. Fixed amounts may serve to overcome the high prices resulting from a lack of price competition in the market for medicinal products, but they cannot in themselves introduce price competition if by that is meant that prices find their own level by means of effective competition amongst suppliers.

60. The obligation upon the appellants when setting fixed amounts to consult medical and pharmacological experts and to take account of their views does not alter my opinion. Medical and pharmacological expertise is only one of the factors on the basis of which the appellants discharge their responsibility to set fixed amounts at the lowest possible level, and a duty to take account of such expertise therefore does not remove the possibility of the appellants acting as representatives of their member funds.

61. Thus, whilst it remains to be seen whether the appellants' determinations setting fixed amounts may be capable of justification, they cannot in my view be convincingly characterised as decisions of a public body distinct from the undertakings of which the appellants are comprised, and must instead be considered as decisions of an association of undertakings within the meaning of Article 81(1) EC.

The application of Article 81 EC to the decisions of the leading associations of sickness funds determining fixed amounts.

62. Once it is accepted that the appellants reach decisions of an association of undertakings when they set fixed amounts, the application of Article 81 to such decisions then depends on whether it can be shown, first, that they have as their object or effect to prevent, restrict, or distort competition; secondly that they may affect trade between Member States; and thirdly that their effects on competition and trade are appreciable. The disagreement between the parties regarding the application of Article 81(1) is focused on the first of those three elements.

63. The respondents assert that, whether directly or indirectly, such decisions amount to a fixing of the purchase price payable for medicinal products, which is specified by Article 81(1)(a) as one of the practices to which that Article is intended to apply. They point to the undisputed fact that at least 93% of the medicinal products to which fixed amounts apply are sold on the German market at a price at or below the applicable fixed amount. In practice, therefore, the fixed amounts can be seen to impose a ceiling on the purchase price for medicinal products in Germany.

64. The respondents note that an agreement among suppliers to fix the price at which goods or services are sold has been held by the Court to have as its object to restrict competition, without there being any need to consider its actual effects.[24] The same approach should be taken, they submit, to an agreement among buyers to fix their purchasing price on a given market.

65. The appellants deny that the decisions at issue amount to the fixing of purchase prices for medicinal products. As a matter of German law, such products are purchased by patients and their doctors, not by the sickness funds. Fixed amounts simply define the maximum contribution which the sickness funds are prepared to make towards the costs incurred by the persons whom they insure. As such, they are merely the natural and necessary corollary of the sickness funds' statutory obligation to secure the supply of necessary medical care to all insured persons in an economical fashion.

66. The appellants also contend that, prior to the introduction of fixed amounts, the market for medicinal products in Germany was prone to structural distortions which prevented the operation of price competition. Because neither patients nor doctors had to pay for medicines prescribed, there was no incentive for either group to purchase the most affordable available products, and pharmaceutical companies were under no pressure to compete on price. Hence, it is claimed, the setting of fixed amounts cannot be said to have had a negative effect on competition.

67. It seems clear to me that, whether or not the funds are, as a matter of national law, the purchasers of medicinal products, they are engaged in a fixing of trading conditions within the meaning of Article 81 (1)(a) when they coordinate, by setting fixed amounts, the maximum level of contribution which they will make towards

24 — Case 123/83 *BNIC* v *Clair* [1985] ECR 391, at paragraph 22 of the judgment.

the cost of those products. The respondents are also correct, in my opinion, to characterise such a practice as fixing the purchase price for medicinal products.

68. Contrary to the Commission's observations, that conclusion does not appear to me to depend on how the contractual relations underlying the purchase of medicinal products are analysed as a matter of national law. To my mind, the status of the sickness funds as purchasers turns instead on whether as a matter of fact it is they who provide the funds with which, and determine the price at which, those products are to be acquired. It seems clear that for most of the products in question, the sickness funds perform both of those functions. A contribution towards the cost of a medicinal product by the insured person is only required where the fixed amount is exceeded. Given the understandable reluctance of insured persons to incur cost on their own account, the demand for medicinal products is heavily determined by the fixed amount set by the leading associations of sickness funds. That economic reality is borne out by the small percentage of medicinal products sold in Germany the price of which exceeds the applicable fixed amount.

69. I am likewise persuaded that an agreement or decision on the part of buyers to fix the purchase price on a given market must be understood to have as its object to restrict competition, without the need, at that stage of the analysis, for any investigation of its competitive effects. Purchasing cartels are expressly identified in Article 81 (1)(a) as falling within the mischief of Article 81. The special attention which they receive can be understood in the light of their potential to suppress the price of purchased products to below the competitive level, with negative consequences for the supply side of the relevant market. In my view, therefore, they should be subject to the same strict control applied by Community competition law to supply cartels.

70. I am in any event of the view that the setting of fixed amounts has the effect of restricting competition on the market for medicinal products within the meaning of Article 81(1) EC. From the information contained in the orders for reference, fixed amounts have had a very clear impact on the prices charged by pharmaceutical companies in Germany. Nor am I convinced by the appellants' argument that no anti-competitive effect can be shown given that prior to the introduction of fixed amounts, structural distortions prevented price competition on the market for medicinal products in Germany. Even assuming the existence of such structural distortions, the setting of fixed amounts does not remove those distortions by introducing price competition. Instead, it introduces another type of anti-competitive effect not previously seen on the German market for medicinal products, by coordinating a large part of demand on that market.

71. As to the remaining elements necessary for a finding that Article 81(1) applies, it seems clear to me — although it is ultimately a matter for the national court — that the decisions at issue may affect trade between Member States to an appreciable extent, and are also liable to have an appreciable effect on competition. None of the parties attempts to assert otherwise.

72. I am therefore of the opinion that decisions setting fixed amounts are in principle caught by Article 81(1). If that is so, the liability of the sickness funds will thus depend on whether they are able either to claim the benefit of the State action defence or to justify their decisions pursuant to Article 86(2).

The application of the State action defence to the decisions of the leading associations of sickness funds determining fixed amounts

73. Article 81 applies only to anti-competitive conduct engaged in by undertakings on their own initiative. If anti-competitive conduct is required of undertakings by national legislation or if the latter creates a legal framework which eliminates any possibility of competitive activity on their part, Article 81 does not apply. In such a situation, the restriction of competition is not attributable, as that provision requires, to the autonomous conduct of the undertakings. [25] In order to avail themselves of what may be termed the State action defence, undertakings must therefore show that the national legislation to which they are subject precludes them from engaging in autonomous conduct which restricts competition. [26] As the case-law of the Court makes clear, that test is to be applied restrictively. [27]

74. Before considering whether the appellants are indeed deprived of any scope for autonomous conduct by the legal framework within which they operate, it is first necessary to consider three threshold objections raised by the respondents to the applicability of the State action defence to the present proceedings.

25 — Joined Cases C-359/95 P and C-379/95 P *Ladbroke* [1997] ECR I-6265, at paragraph 33 of the judgment.

26 — *Ladbroke*, cited in note 25, at paragraph 34 of the judgment.

27 — See paragraph 60 of the Court of First Instance's judgment in Case T-513/93 *Consiglio Nazionale Spedizionieri Doganali* v *Commission* [2000] ECR II-1807, and the case-law cited there.

75. First, the respondents submit that the State action defence is applicable only in the context of a complaint procedure before the Commission. I do not believe that there is any such limitation on the application of the State action defence. The Court's restatement of the defence, in paragraphs 33 and 34 of its judgment in *Ladbroke*,[28] makes no reference to such a limitation. Indeed, contrary to the respondents' assertion that all the authorities relied on by the Court at paragraph 33 in *Ladbroke* concerned complaint procedures before the Commission, the Court cites, by way of authority in support of its restatement, paragraph 20 of its judgment in *GB-Inno-BM*,[29] a case which arose out of a reference for preliminary ruling. In any event, it is clear that the State action defence is a doctrine of general application, since it is based on fundamental principles of the Community legal order, notably the principle of legal certainty and the associated prohibition of retroactive penalisation of conduct (*nulla poena sine lege*).[30]

76. Secondly, the respondents suggest that the State action defence should not apply in situations where a Member State deprives its own rules of the character of legislation by delegating to undertakings the responsibility for taking decisions affecting the economic sphere. I agree that if in a given case there had indeed been such a delegation of decision-making responsibility, the undertakings in question would almost certainly possess a sufficient element of autonomy to prevent them from asserting the State action defence. However, in the present case it is necessary in my view to examine the statutory framework applicable to the appellants before it can be determined whether they have in fact been accorded such a degree of autonomy.

77. Thirdly, the respondents assert that the State action defence is unavailable to the appellants who in effect seek to define themselves as indirectly forming part of the State administration. If the appellants' objectively anti-competitive conduct is indeed to be considered as a form of State implementation of the law, they must according to the respondents accept the duty of loyal cooperation which Community law attaches to the State. That argument is in my view misconceived. Undertakings seeking to rely on the State action defence will always operate within a national legal framework. If for that reason they were held to constitute a part of the State, the State action defence would never apply.

28 — Cited in note 25.

29 — Case C-18/88 [1991] ECR I-5941.

30 — See Case C-198/01 *C.I.F.*, at paragraphs 48 to 50 of my Opinion delivered on 30 January 2003.

78. The referring courts offer differing assessments of the degree to which the leading associations of sickness funds are constrained by the national legal framework when setting fixed amounts. The Oberlandesgericht Düsseldorf is of the view that the appellants possess a significant degree of autonomy. First, the legislation does not lay down mandatory rules as to the precise time at which the fixed amount must be initially determined or subsequently adapted. Secondly, the statute leaves some discretion to the appellants when determining the level of the fixed amounts. This is especially so given that the criteria specified in Paragraph 35(5) SGB V may point in differing directions.

79. The Bundesgerichtshof, by contrast, suggests that the appellants lack any freedom of manoeuvre when determining fixed amounts. They are obligated to set fixed amounts, and should they fail to do so the Federal Minister of Health will perform the duty instead. The determination of fixed amounts is governed by the requirements specified in the statute, and is subject to comprehensive judicial review.

80. It is clearly for the national courts to resolve whether the statutory framework does eliminate any scope for autonomous conduct on the part of the appellants when setting fixed amounts. It may none the less be useful to distinguish two enquiries which are in my view necessarily implicated in such an assessment.

81. First, it is necessary to consider whether the appellants are able to avoid setting fixed amounts under SGB V altogether. If not, they clearly cannot be held liable in a given case for the simple act of determining the fixed amount. In addressing that enquiry, the national courts may be able to confine itself to a consideration of the second stage of the procedure for setting fixed amounts. As I have indicated above,[31] the first stage of the procedure may quite possibly fall outside Article 81(1) altogether, given the composition of the decision-making body and the level of expertise involved. As regards the scope for autonomous conduct at the second stage of the procedure, Paragraph 35(3) of the SGB V would certainly seem to impose on the appellants a clear and categorical obligation to act. It would not in my view detract from the binding nature of that obligation even if no penalty were specified for its breach. As regards timing, although the appellants clearly enjoy some discretion as to when to set fixed amounts, it is clear that they must review the level of fixed amounts at least once every year and must change the level when appropriate in the light of market conditions. It is therefore

31 — At paragraph 54.

not credible to suggest that they could exercise their discretion as regards timing so as to avoid setting fixed amounts altogether.

82. Secondly, it is necessary to consider whether the appellants have any real degree of autonomy in determining the level of the fixed amounts. If not, the State action defence is made out. If, however, they do possess such freedom, it is necessary to investigate whether any *prima facie* breach of Article 81(1) may either be wholly attributable to the manner in which they have exercised their discretion, or may at least have been exacerbated by the choices which they have made. [32]

83. As regards the setting of fixed amounts, the former possibility, whereby the breach of Article 81 would be wholly attributable to the appellants, can in my view be excluded. Given that at the material time the appellants were under an obligation to set fixed amounts on the basis of the lowest pharmacy sale prices of the comparator group, it would not realistically be open to them to choose a fixed price which avoided any appreciable anti-competitive effects upon the market for medicinal products in Germany.

84. When addressing the second enquiry, the national courts may therefore in all probability confine themselves to a consideration of whether on the facts of the case before them any discretion vested in the appellants has been used in that particular instance to generate an appreciably greater restriction on competition than would have resulted from another of the permissible range of determinations open to them.

85. If the State action defence is applicable, the appellants escape liability in the present proceedings. However, it should be remembered that the applicable provisions of German law might themselves be open to challenge on the ground that they violated the obligation imposed upon Member States by virtue of the combined operation of Articles 3(1)(g), 10 and 81 EC, [33] subject to the possibility of defending them pursuant to Article 86(2) EC. According to the Court's consistent case-law, Member States must not require or favour the adoption of agreements, decisions or concerted practices contrary to Article 81 or reinforce their effects, or deprive their own rules of the character of legislation by delegating to private economic operators responsibility for taking decisions affecting the economic sphere. [34]

32 — See paragraph 69 of my Opinion in *C.I.F.*, cited in note 30.

33 — See paragraph 51 of my Opinion in *C.I.F.*, cited in note 30.

34 — See paragraph 54 of the judgment in *Commission* v *Italy*, cited in note 21 and the cases which are cited there.

The application of Article 86(2) EC

86. If the appellants have acted autonomously in setting fixed amounts in breach of Article 81(1) and therefore cannot invoke the State action defence, there remains the possibility of their defending their conduct under Article 86(2). With regard to that possibility, the Oberlandesgericht addresses several questions to the Court. By its third question, it asks whether the application of Article 86(2) is ruled out by the fact that the power to determine fixed amounts could be granted to an institution other than a participant in the medicinal product market, in particular to the Federal Government or a Federal minister, instead of to the appellants. By the first limb of its fourth question, it asks what conditions must be set forth and proved by the appellants in order for them to have a defence under Article 86(2), first sentence. By the second limb of its fourth question, it asks whether the grant of an exemption is precluded by the second sentence of Article 86(2) owing to the effects the system of fixed amounts has on trade. The Bundesgerichtshof (in its second question) asks simply whether Article 86(2) exempts the determination of fixed amounts from Articles 81 and 82 where the purpose of that determination is to safeguard a sickness insurance scheme whose existence is endangered by a significant increase in costs.

87. To avail themselves of Article 86(2), the appellants would need first to show that they have been entrusted with the operation of a service of general economic interest. There is no doubt in my mind that German sickness funds are charged with such a service, namely in the provision of a solidarity-based system of statutory health insurance. Neither the parties nor the referring courts dispute that proposition.

88. The appellants would need also to show that the setting of fixed amounts is necessary in order to allow them to perform correctly their general interest task. [35] As the Court's case-law makes clear, the burden upon them would not extend to demonstrating that their task would be rendered impossible if they were unable to set fixed amounts. [36] It would suffice that their task could not be performed in

35 — Case C-320/91 *Corbeau* [1993] ECR I-2533, paragraph 14 of the judgment.

36 — Case C-157/94 *Commission* v *Netherlands* [1997] ECR I-5699, paragraph 43 of the judgment.

economically acceptable conditions [37] or in conditions of financial stability. [38]

89. There can therefore be no doubt that the appellants could in principle defend the setting of fixed amounts along the lines suggested in the Bundesgerichtshof's second question. It is, of course, the national courts which must determine in the main proceedings whether the setting of fixed amounts is indeed necessary to the financial stability of the German sickness funds.

90. The main disagreement regarding the application of Article 86(2) arises in relation to the proportionality of the current system for setting fixed amounts.

91. The respondents argue that Article 86 (2) is not available to defend a decision or an agreement falling within Article 81(1) which has not been notified to the Commission for exemption under Article 81 (3). They submit that such notification constitutes a more proportionate method of assuring the conformity of such a decision or agreement with the Community competition rules. Given that no notifications have been made in respect of determinations setting fixed amounts, they submit that Article 86(2) cannot be relied upon by the appellants.

92. I do not consider that it is necessary for a notification to have been made to the Commission for exemption pursuant to Article 81(3) in order to be able to have recourse to Article 86(2) in defence of a decision or agreement which is in breach of Article 81(1). In *Almelo*, [39] the Court considered Article 86(2) to be applicable to the agreements at issue [40] even though they were unnotified. [41]

93. The respondents also contend, as does the Oberlandesgericht, that the appellants' determinations of fixed amounts cannot be justified because of the existence of alternative institutional arrangements for controlling the costs of medicinal products. The appellants and the Commission disagree.

37 — *Corbeau*, cited in note 35, paragraph 16 of the judgment.

38 — Ibid., paragraph 17 and the operative part of the judgment.

39 — Case C-393/92 *Almelo* [1994] ECR I-1477.

40 — At paragraphs 49 to 51 of the judgment.

41 — See paragraph 108 of Advocate General Darmon's Opinion

94. In that regard, it should first be noted that, as the Court held in *Commission* v *Netherlands*, in order successfully to invoke Article 86(2), a Member State is not required, 'when setting out in detail the reasons for which, in the event of elimination of the contested measures, the performance, under economically acceptable conditions, of the tasks of general economic interest which it has entrusted to an undertaking would, in its view, be jeopardised, to go even further and prove, positively, that no other conceivable measure, which by definition would be hypothetical, could enable [those tasks] to be performed under the same conditions'.[42] In my view, the appellants, as undertakings which are themselves seeking to defend their actions, are similarly spared any such burden.

95. Secondly, in applying Article 86(2) in the present context, it is in my view important also to have regard to the freedom which Community law accords to the Member States in organising their own social security systems.[43] Given the wide margin of discretion which the national authorities therefore enjoy,[44] I consider that the application of Article 86(2) would be precluded only if the setting of fixed amounts could be shown to be manifestly disproportionate as a method of controlling the cost of medicinal products to the sickness funds.

96. In my view, such is not the case here. As the Commission notes, the German system of setting fixed amounts is significantly less invasive a method for controlling expenditure on pharmaceuticals than certain mechanisms which have been adopted by other States. For example, by contrast with the system of negative lists examined and found in principle to be compatible with Community law in *Duphar*,[45] the setting of fixed amounts does not impose an outright ban on the prescription of specified pharmaceutical products to insured persons.

97. Nor can I agree with the Oberlandesgericht that the possibility of entrusting the setting of fixed amounts to the Federal Government or a Federal Minister is sufficient to show the manifest disproportionality of the existing arrangements for determining fixed amounts.

98. As the Court held in *Albany*, a national measure in the social security field may be capable of justification under Article 86(2) even where it involves granting a power of decision to an undertaking and thereby

42 — Cited in note 36, at paragraph 58 of the judgment.

43 — See Case 238/82 *Duphar* [1984] ECR 523, at paragraph 16 of the judgment.

44 — See *Albany*, cited in note 5, at paragraph 122 of the judgment.

45 — Cited at note 43.

gives rise to a potential conflict of interest.[46] The Court had regard to the following four factors in particular. The first was the specification of criteria according to which the undertaking must act when exercising its decision-making power. In the present case also, the appellants act pursuant to criteria when setting fixed amounts. Indeed, it is by no means clear to me that a Federal Ministry, acting pursuant to the same statutory criteria as the appellants, would be under any less pressure than the appellants to set fixed amounts at as low as possible a level.

99. The second factor which influenced the Court in *Albany* was the complexity of evaluating the effects of particular decisions upon the financial equilibrium of the undertaking. As regards the second factor, there is no doubt that the appellants are well placed to assess both the medical needs of those whom they insure and the impact of pharmaceutical costs on their own financial equilibrium.

100. The third was the Member States' margin of appreciation in relation to social security. That factor is clearly equally applicable to the present proceedings.

101. The fourth was the existence of an adequate level of judicial review to prevent the economic operator exercising its decision-making power in an arbitrary manner. As to the application of that factor to the circumstances of the present case, there is disagreement among the parties as to adequacy of subsequent judicial control over the setting of fixed amounts. What is required, in the light of *Albany*, is that national courts must exercise sufficient control to ensure that fixed amounts are not determined in an arbitrary or discriminatory manner, and are fixed in accordance with the criteria and procedures specified by paragraph 35. It is for the referring courts to determine whether that condition is indeed met.

102. As to the Oberlandesgericht's fourth question, the limb concerning the conditions which the appellants are required to prove so as to obtain an exemption of the setting of fixed amounts under Article 86(2) has already, in my view, been adequately addressed in the foregoing analysis. As regards its second limb, concerning the applicability of the second sentence of Article 86(2), even if it were accepted that that sentence were capable of direct effect, the observations before the Court do not, in my view, supply any grounds for thinking that the setting of fixed amounts has such an effect on the development of trade as would be contrary to the interests of the Community. The Oberlandesgericht refers to the scale of savings which have resulted from the setting of fixed amounts, without pointing to any data showing a significant attendant impact on the flow of medicinal products into or out of Germany or other

46 — Cited at note 5, at paragraphs 116 to 122.

impact on the development of trade. In the absence of any more substantial submissions either for or against the application of the second sentence of Article 86(2) to the present case, I consider that it would be inappropriate to address the issue further.

The possibility under Community law of obtaining damages or an injunction against the sickness funds

103. There only remains to consider the third question posed by the Bundesgerichtshof, as to whether remedial relief might be obtained against the appellants in respect of a determination setting fixed amounts if they acted pursuant to a statutory direction, notwithstanding that national law does not impose any penalty for refusal to assist in the making of such a determination.

104. If the appellants could be shown to have acted autonomously in setting fixed amounts, in such a way as to breach Article 81 EC, and if they did not succeed in defending their conduct under Article 86 (2), I have no doubt that both damages and injunctive relief would as a matter of Community law be available to anyone suffering loss as a consequence of that conduct, subject to such national procedural rules as were compatible with the principles of equivalence and effectiveness. As the Court has held, the full effectiveness of Article 81 EC and, in particular, the practical effect of the prohibition of Article 81(1) would be put at risk if it were not open to any individual in proceedings before a national court to claim damages for loss caused to him by a contract or by conduct liable to restrict or distort competition. [47] The same analysis would in my view apply equally to injunctive relief.

105. However, the question posed by the Bundesgerichtshof would appear to be based on the assumption that the appellants are required by the applicable statutory framework to set fixed amounts in breach of Article 81. If the appellants were so compelled, as I have already made clear in my discussion of the State action defence, they would not themselves be subject to Article 81, and could not be held liable for its breach, even in the absence of any penalty for a refusal to comply with their national legal obligations. In my opinion, therefore, the Bundesgerichtshof's final question is adequately addressed by the second of my proposed answers to the questions referred.

47 — Case C-453/99 *Courage and Crehan* [2001] ECR I-6297, at paragraph 26 of the judgment.

Conclusion

107. It is therefore my opinion that the Court should answer the questions referred to it by the Oberlandesgericht Düsseldorf and the Bundesgerichtshof in the following manner:

(1) The leading associations of statutory sickness funds in a Member State such as those in question in the main proceedings are to be regarded as an association of undertakings within the meaning of Article 81(1) EC when they jointly determine the highest price at which the sickness funds will purchase and pay for medicinal products and thereby limit their liability to insured persons.

(2) Such joint determination constitutes a decision of an association of undertakings which has as its object or effect to prevent, restrict or distort competition within the meaning of Article 81(1) EC.

When reaching such a determination, the leading associations will not, however, infringe Article 81 EC in so far as the restriction of competition which results is not attributable to autonomous conduct on their part but is rather required by national law, regardless of whether any penalty is specified for failure to comply with the national law in question.

(3) Such joint determination is by virtue of Article 86(2) EC not subject to the Community competition rules unless it can be shown to be manifestly disproportionate as a method for ensuring the ability of the sickness funds to perform their task of general economic interest in conditions of financial stability. It is for the national courts to determine whether that condition is fulfilled.