OPINION OF ADVOCATE GENERAL FENNELLY

delivered on 6 April 2000 *

I — Introduction

1. The present infringement action essentially raises a question regarding the proportionality of the restriction imposed on the free movement of goods, in the interests of public health, by a national registration system for medical diagnostic reagents. The Court has been invited to assess the issue of proportionality in the light of the provision made for an allegedly less restrictive registration system for *in vitro* medical diagnostic devices in a Community harmonising measure which had not yet entered into force at the material time.

II — Legal and factual context

2. Article L-761-14-1, first indent, of the French Public Health Code, inserted by Law No 94-43 of 18 January 1994, requires that reagents intended for use *in vitro*, either in laboratories, for medical biological analyses, or by the public, for medical diagnosis or pregnancy testing, be registered with the Medicines Agency (Agence du Médicament) in accordance with conditions to be specified by decree before being placed on the market.

3. A year after the adoption of this amendment, on 19 January 1995, the French authorities notified the text of a draft decree concerning medical reagents to the Commission in accordance with Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations,[1] and stated, pursuant to Article 9(3) of that Directive, that, for urgent reasons relating to the protection of public health and safety, it was obliged to introduce the measure immediately without any consultations being possible. It cited recent tests of reagents for diagnosing AIDS and Hepatitis B and C, which had found several to be of only mediocre sensitivity, and the urgent need for a legal means to require the withdrawal from the market of products associated with such serious illnesses which did not satisfy the requisite high standards.

* Original language: English.

1 — OJ 1983 L 109, p. 8.

4. In a telex of 23 January 1995, the Commission accepted France's recourse to the urgent procedure, but stated that this did not prejudge its assessment of the compatibility of the notified text with Community law.

5. In a letter of 6 April 1995 to the Permanent Representative of France to the European Union, the Commission raised concerns regarding the system of prior authorisation for the marketing of all medical reagents envisaged by the proposed decree. It stated that this approach diverged markedly from that in the draft proposal for a European Parliament and Council Directive on *in vitro* diagnostic medical devices,[2] which would simply require, in the case of most such devices, the supply of specified information by manufacturers. A system of prior approval would apply only to devices intended for the diagnosis of certain grave illnesses such as AIDS and certain forms of hepatitis. The Commission also questioned the necessity for some of the information which the draft decree would require interested parties to submit — in particular, that regarding the therapeutic interest of the reagent, the results of stability tests even in the case of inorganic reagents, and the results of clinical and analytical tests in cases where the necessary performance data was already available in scientific literature —, the requirement that the file be updated whenever alterations are made to a reagent, the requirement that a registration number appear on the packaging of reagents, and the absence of a clause providing for mutual recognition of tests and inspections already undertaken, or of registration of reagents, in other Member States. These criticisms form the basis of the subsequent exchanges between the parties.

6. The draft decree was eventually adopted by the French authorities as Decree No 96-351 of 19 April 1996[3] (hereinafter 'the impugned Decree' or, simply, 'the Decree'). Article 1 of the Decree makes the marketing of diagnostic reagents in France conditional on prior registration. Article 2 requires the application for registration to contain a considerable amount of information about the product and how it is to be presented to the public, including the requirements already criticised by the Commission regarding the therapeutic interest of the product, and the results of stability tests as well as those of clinical and analytical tests.

7. Articles 6 and 7 of the impugned Decree provide for the establishment of a consultative committee on the registration of reagents, composed of representatives of the State, of the reagent industry and of scientific experts. Its function is to give its opinion, at the request of either the Minister for Health or the director-general of the Medicines Agency, on, *inter alia*, applications for the registration of reagents and

2 — The proposal was eventually published in July 1995 in OJ 1995 C 172, p. 21.

3 — *Journal Officiel de la République Française* of 26 April 1996, p. 6386.

for the evaluation and re-evaluation of reagents. Article 3 of the Decree provides that, if the application file referred to in Article 2 is complete, the director-general of the Medicines Agency shall register a reagent, after having consulted, in certain cases ('le cas échéant'), the consultative committee. Article 4 of the Decree states that any alteration affecting the contents of the application file must be notified by the beneficiary of registration to the Medicines Agency.

8. Article 5 of the impugned Decree requires a reagent's external packaging or, in the absence of external packaging, the packaging of the reagent itself to bear the registration number of the product. Both forms of packaging must also bear the relevant production batch number. The notice accompanying the product must mention the fact of registration. The accompanying notice must also bear the names and addresses of the manufacturer, the distributor and, where applicable, the importer; the packaging is required to bear the name and address of the distributor.

9. On 15 April 1997, the Commission sent France a letter of formal notice of its view that the Decree constituted a measure equivalent to a quantitative restriction on the free movement of goods contrary to Article 30 of the EC Treaty (now, after amendment, Article 28 EC), repeating the criticisms summarised above.

10. In its reply of 3 July 1997, France observed that the checks performed on 289 different reagents since 1993 had resulted in 108 products being withdrawn from the market and in 25 products being modified. It noted that those aspects of the registration system which the Commission had criticised were substantially replicated in the approval system for diagnostic devices for certain dangerous illnesses such as AIDS and Hepatitis B and C then envisaged by the draft directive, or were the subject of proposed amendments. It added that the extension of some of these requirements to reagents intended to diagnose other illnesses was still under discussion, that any diagnostic device could be the source of errors whose consequences for patients could be dramatic, and that mounting public concerns about public health, fuelled by recent crises, justified a high level of protection.

11. On 10 August 1998, the Commission delivered a reasoned opinion stating that the impugned Decree was not justified either by the objective of protecting public health or by that of consumer protection because the restrictions it imposed on the free movement of goods were disproportionate, and invited France to comply with the opinion within two months. The Commission expanded upon its earlier criticism of the requirement that diagnostic reagents marketed in France bear a registration number. It stated that, as the registration process did not involve a detailed examination of products before their approval, the

inclusion of this number on the packaging did not afford any greater guarantee of safety to consumers. France responded on 19 October 1998, saying that an amendment to the impugned Decree incorporating the principle of mutual recognition had been submitted to the relevant authority for approval.

12. On 27 October 1998, the European Parliament and the Council adopted Directive 98/79/EC on *in vitro* diagnostic medical devices [4] (hereinafter 'the Directive'). The Directive was not in force when the reasoned opinion was issued in this case, but it is necessary, none the less, to consider its terms, as the Commission has used it as a frame of reference in its pleadings. Although the original proposal was subject to numerous amendments, the basic model was preserved, based on different regimes for two different classes of *in vitro* medical diagnostic devices. The 22nd recital in the preamble to the Directive states:

'Whereas it is necessary, essentially for the purpose of the conformity assessment procedures, to group *in vitro* diagnostic medical devices into two main product classes; whereas, since the large majority of such devices do not constitute a direct risk to patients and are used by competently trained professionals, and the results obtained can often be confirmed by other means, the conformity assessment procedures can be carried out, as a general rule, under the sole responsibility of the manufacturer; whereas, taking account of existing national regulations and of notifications received following the procedure laid down in Directive 98/34/EC, the intervention of notified bodies is needed only for defined devices, the correct performance of which is essential to medical practice and the failure of which can cause a serious risk to health.'

The 23rd recital gives as examples of products in the second class 'the groups of products used in blood transfusion and the prevention of AIDS and certain types of hepatitis'.

13. Article 3 of the Directive provides that all devices must meet the essential requirements set out in Annex I, regarding matters such as safety, acceptable levels of risk and performance. Annex II to the Directive contains two lists of products, the marketing of which is considered to require the intervention of notified bodies designated by the Member States. List A in Annex II refers to reagents for determining certain blood groups and for the detection, confirmation and quantification of HIV, HTLV and Hepatitis B, C and D in humans, while List B lists reagents or devices for determining certain other blood groups, for measuring blood sugar, and for determin-

4 — OJ 1998 L 331, p. 1.

ing, detecting, quantifying or diagnosing specified illnesses or conditions, or evaluating risk.[5] Article 9(2) and (3) of the Directive provides, in relation to Lists A and B respectively, for different possible approval procedures, set out in Annexes IV to VII to the Directive. All of the permitted combinations of procedures involve approval of marketing of the device by a notified body designated by one of the Member States, with List A products being subjected to more onerous requirements.

14. For all products other than those listed in Annex II to the Directive, manufacturers are required, in order to affix the CE marking which permits free movement of their products in the Community,[6] to follow a procedure referred to in Annex III to the Directive and to draw up the CE declaration of conformity with the Directive required before placing the devices on the market. This procedure entails preparation of technical documentation and taking measures to ensure quality assurance in the manufacturing process. The technical documentation required includes performance evaluation data, which 'should originate from studies in a clinical or other appropriate environment or result from relevant biographical [*sic*] references',[7] and 'the results of stability studies'. For devices for self-testing, intended for use by lay persons in a home environment, additional provision is made in Article 9(1) and in Annex III for approval of the design by a notified body.

15. Article 12 of the Directive provides for the establishment of a European data bank containing data relating to the registration of manufacturers and devices, data relating to certificates issued, modified, supplemented, suspended, withdrawn or refused according to the procedures laid down in Annexes III to VII and data obtained from the Member States pursuant to Article 11 of the Directive regarding any malfunction or failure, or inadequacy in a product's labelling or instructions, with actual or potential fatal consequences for, or serious effects on the health of, any person.

16. The Directive came into force on the day of its publication, 7 December 1998.[8] Article 22(1) of the Directive provides that Member States must adopt implementing measures by 7 December 1999 at the latest. These measures must be applied with effect from 7 June 2000. By virtue of Article 22(5), Member States are required to accept the placing on the market of devices which conform to the rules in force in their territory on the date when the Directive entered into force.

5 — These relate to anti-erythrotic antibodies, rubella, toxoplasmosis, phenylketonuria, cytomegalovirus, chlamydia, certain HLA tissue groups, the tumoral marker PSA and trisomy 21.

6 — See Articles 4 and 16 of the Directive.

7 — There is clearly a mistake in the English-language version. The other language versions refer to relevant *bibliographical* references.

8 — Article 23 of the Directive.

III — The present proceedings

17. On 16 February 1999, the Commission requested the Court, pursuant to Article 169 of the EC Treaty (now Article 226 EC), to declare that the French Republic was in breach of its obligations under Article 30 of the Treaty as a result of its establishment, by the Decree, of a registration procedure for all medical reagents, and of its requiring, by the same Decree, that the external packaging and the accompanying notice for all reagents bear the relevant registration number. The Commission formally abandoned its complaint regarding the lack of a mutual recognition clause, in the light of the undertaking given by France that it would amend the Decree. France opposes the Commission's application.

18. I would like to make clear at the outset that the case does not involve any alleged breach or abuse of the procedures set out in Directive 83/189/EEC. Furthermore, when the Commission approved France's recourse to the urgent procedure, it reserved its position regarding the compatibility with the Treaty of the measure to be introduced, and outlined its objections at some length before the Decree was actually adopted. I do not see any objection to the Court now being asked to examine whether or not those substantive objections are well founded. As Advocate General Jacobs has recently pointed out, the 'directive contains only procedural rules which are by definition neutral from a substantive point of view'. [9]

19. It is common case that the French rules referred to in the Commission's application constitute measures with effect equivalent to a quantitative restriction on imports. They impose delays and additional costs on the marketing of reagents. The debate has concentrated, therefore, on the issue of justification and, in particular, on the question whether the Decree, which, the Commission concedes, serves a public health objective, constitutes a proportionate restriction on trade in goods. It has not been suggested that the impugned Decree has any discriminatory effect.

20. Although the Directive was not yet applicable when the Decree was adopted, the Commission submits that its terms furnish useful guidance as to what sorts of registration requirements, involving a simple declaration by manufacturers in most cases, may be imposed on trade in medical reagents in the interests of public health without breaching the principle of proportionality. [10] The Commission has not suggested, however, that the impugned Decree was, at the material time — the expiry on 10 October 1998 of the time-limit for compliance with the reasoned opinion in

9 — Case C-443/98 *Unilever Italia* v *Central Food*, [2000] ECR I-7535, I-7537, paragraph 85.

10 — See Case C-350/97 *Monsees* [1999] ECR I-2921, paragraph 30.

the present case —, a measure which was liable seriously to compromise the achievement of the result prescribed by the Directive at the end of the period for its transposition. [11]

21. In contrast with the Directive, the Commission argues that the scope of the Decree is over-broad, by requiring prior registration as a condition of placing any medical reagent on the market, without distinguishing between products by reference to the degree of risk posed, in the event of malfunctioning or unreliability, to the life and health of persons.

22. The Commission initially contended that a registration system would only be justified in respect of reagents related to certain serious conditions such as AIDS and some varieties of Hepatitis, which had been mentioned in France's application to use the urgent procedure and which were also listed in Annex II to the Directive. It later accepted that the detection of other conditions or illnesses cited by France, such as pregnancy and certain inflammatory diseases, could also be of essential importance to public health, but continued to argue that *all* medical reagents should not be subjected to an identical registration process. At the oral hearing, the agent for the Commission stated that some 60% of the 20 000 *in vitro* medical diagnostic products on the market in the Community fell into the non-risk category and mentioned, as examples, tests for cholesterol, allergies, salmonella, menopause and diabetes.

23. It should be noted that under this rubric of the Commission's case, it has not made any reference to the degree of scrutiny to which reagents are subjected during the registration process. As has been seen above, its specific complaints relate to certain elements which the application file is required to contain in the case of all products — matters relating to the therapeutic interest of the product and to the results of stability tests and of clinical and analytical tests — as well as to the need to update the file when products are altered.

24. In relation to the requirement that the reagent's packaging and accompanying notice bear the applicable registration number, the Commission contends — as regards *all* reagents — that the registration process is merely formal, with the result that publicising the fact of registration in the manner required gives no particular guarantee of product safety to consumers. It also reiterates the argument from its earlier exchanges with the French authorities that this requirement does not contribute to the traceability either of defective

11 — See Case C-129/96 *Inter-Environnement Wallonie* v *Région Wallonne* [1997] ECR I-7411, paragraphs 44 and 45.

products or of the origin of such products, given the requirement, whose appropriateness is accepted by the Commission, that the packaging and notice bear the names and addresses of the manufacturers, distributors and importers as well as the production batch number.

25. France states that the Commission bears the burden of proof that the impugned Decree is disproportionate. [12] It objects to use of the Directive as the point of reference for the examination of the question of the proportionality of the impugned Decree. It observes that Member States remain free, by virtue of Article 100a(4) of the EC Treaty (now, after amendment, Article 95(4) to (9) EC), to apply national provisions on public health grounds even after the adoption of harmonising measures. Furthermore, the Court has confirmed that, in the absence of harmonised rules, it is for the Member States to decide on their intended level of protection of human health and life and on whether to require prior authorisation for the marketing of products which contain dangerous substances, even if they have already received approval in another Member State. [13] All of the reagents governed by the Decree permit the detection and treatment of illnesses or conditions which require a medical response and which may, in the absence of detection or a response, have effects just as grave as those of AIDS or hepatitis.

26. France submits that the registration process is not merely formal and administrative in character. Although the impugned Decree does not establish a system of checks equivalent to those applied before a marketing authorisation is given for a proprietary medical product — and is not, therefore, as demanding, rigid or time-consuming —, the information to be presented with the application file for registration permits unreliable or ineffective medical reagents to be detected. This requirement, along with that of presenting any new information about the composition or performance of reagents, also permits the compilation of a regularly updated data base (such as is also provided for in the Directive), which is essential for permanent reacto-vigilance. [14] Although not all reagents are tested before registration, the file also forms the basis for later evaluation or re-evaluation tests by the consultative committee on the registration of reagents, thus permitting long-term surveillance of the market for such products.

27. As regards the obligatory indication of the registration number of reagents, France

12 — Case C-159/94 *Commission v France* [1997] ECR I-5815, paragraph 102.

13 — Case C-400/96 *Harpegnies* [1998] ECR I-5121, paragraphs 33 and 35.

14 — On the importance of pharmaco-vigilance, see Case C-94/98 *Rhône-Poulenc Rorer* [1999] ECR I-8789, paragraphs 33 and 46.

notes the importance of traceability in public health contexts,[15] and adds that this number is necessary to prevent confusion between different versions of a medical reagent which bear the same or similar brand names.

IV — Analysis

(i) *The allegation of over-breadth*

28. I am not persuaded by the main ground invoked by the Commission in the present case, regarding the over-broad application of the registration regime for medical reagents established by the impugned Decree and the requirement that applications for registration be accompanied by certain information which is alleged to be unnecessary. In my view, the Commission's allegations against France regarding the impugned Decree are, in a number of respects, insufficiently clear or convincing for me to recommend that the Court make the declaration sought by the Commission.

29. First, the Commission has not furnished the Court with any criterion, other than the list in Annex II to the Directive, for determining the degree, if any, of the allegedly over-broad application of the French regime. It has not convincingly rebutted, and may, perhaps, be understood as having conceded, France's point that the detection of inflammatory illnesses and of conditions such as pregnancy — neither of which appears in Annex II — may have public health implications as important as those of AIDS and certain forms of hepatitis. The list furnished by the Commission of illnesses and conditions whose diagnosis did not merit similar scrutiny included illnesses such as diabetes and problems regarding cholesterol levels which, in the absence of further explanation, appear to the non-expert to be far from minor. It should be possible to deduce from the Commission's complaint the steps which a Member State should take if the Court were to uphold that complaint. I do not think that this is possible in the present case, since the Commission confines itself exclusively to the distinction adopted in the Directive. The latter was not in force at the relevant time. Even if it constitutes a helpful point of reference, it cannot exhaustively determine the scope of a Member State's exercise of its power to lay down the range of reagents which merit registration.

30. Secondly, the precise nature of the Commission's case regarding over-breadth is unclear. It appears to comprise two partially overlapping elements.

15 — It refers to Case C-180/96 *United Kingdom* v *Commission* [1998] ECR I-2265.

31. One relates to the allegedly superfluous documentation required to obtain registration. The scope of this complaint seems to vary with the alleged superfluity at issue. It applies: to inorganic reagents, as regards the requirement that the results of stability tests be provided; to reagents which have been the subject of extensive published studies, as regards the requirement that the results of clinical and analytical tests be presented; and to all reagents as regards the indication of the therapeutic interest of the product.

32. The Commission's concern about the necessity of providing such documentation or information seems to me to be logically quite distinct from the second element of its case, that a prior registration procedure is not necessary in the case of at least 60% of medical reagents. It is not clear whether, in the Commission's view, prior registration can be dispensed with in these cases, which, as we have seen, are difficult to identify, simply because, by analogy with the Directive, producers or distributors of such devices can be safely required to provide the necessary information to the authorities by simple declaration, or, in the alternative, because the Commission regards the registration process as merely formal and administrative in character, with the result that it is burdensome without making any contribution to the attainment of the objective of better health protection.

33. The former appears to be the case, given that, as I have already pointed out, above, the Commission only qualifies the regime established by the impugned Decree as essentially formal in its discussion of its complaint regarding the indication of reagents' registration numbers on their packaging and the accompanying notice. However, there is some inconsistency in the Commission's position. If the procedure is essentially formal, but none the less burdensome, it would arguably be disproportionate as regards *all* diagnostic products, rather than simply in so far as it affects products whose health implications the Commission regards as minor.

34. In any event, both possible versions of this aspect of the Commission's case have been answered by France in reliance on its power, in the absence of harmonised rules, to decide on the level of health protection in its territory.

35. The Court's ruling in *Harpegnies*, which itself draws on earlier cases such as *Frans-Nederlandse Maatschappij voor Biologische Producten* [16] and *Brandsma*, [17] that it is for the Member States, in the absence of harmonising rules, to decide on

16 — Case 272/80 [1981] ECR 3277, paragraphs 12 and 13.
17 — Case C-293/94 [1996] ECR I-3159, paragraph 11.

their intended level of protection of human health and life and on whether to require prior authorisation for the marketing of products containing dangerous substances, can, in my view, be extended by analogy to cover national rules governing approval of products which, while not normally dangerous in themselves, may, though only indirectly, pose a danger to the life or health of persons if their diagnostic performance is unreliable.

36. France has chosen what may be characterised as both a broad and a high level of protection. It is broad in that *all* medical reagents are covered, and high in that it is intended to prevent, or at least reduce, even possibly slight injurious effects on the life or health of persons arising from such products' diagnostic malfunctioning or unreliability. The danger consists in the foreseeable consequential failure to adopt an appropriate medical response to an illness or condition. France's policy may be distinguished from that adopted in the Directive in that the latter provides for a more rigorous procedure for diagnostic medical devices which are perceived to constitute a *direct* risk to patients. France's decision to seek to combat all risks posed to patients, directly or indirectly, by medical reagents by means of the registration system provided for in the Decree is, to my mind, legitimate, provided that the means adopted to execute it are not overly restrictive.

37. The means adopted by the Member States to achieve the objectives of protection being legitimately pursued should, of course, be confined to what is necessary. [18] The French registration procedure would clearly fail to satisfy this test if it were merely formal in character, without any element of assessment of the qualities of the products for which registration was sought. The restriction imposed upon the free movement of goods would not, in that case, be outweighed by any concomitant gain for the protection of public health. However, in the absence of any further counter-argument on the part of the Commission, I am satisfied by France's assurances that the system established by the impugned Decree is not a mere formality. The fact that it does not involve systematic checking and testing of all reagents by the Medicines Agency before approval need not necessarily be taken as a sign of ineffectiveness. Random testing, or testing in the light of discrepancies in the application file, combined with a system of post-registration evaluation and re-evaluation, whether pursuant to complaints or more generally, may result in an adequate level of reacto-vigilance while avoiding the greater degree of restriction inherent in a system of comprehensive pre-registration testing. The agent for France stated at the oral hearing that the starting-point for such evaluations

18 — *Harpegnies*, op. cit., paragraph 34.

was the data bank of products on the market compiled from applications for registration.

38. The contested French registration regime differs from that envisaged by the Directive in that it provides for a single procedure which assures a level of protection — and of restriction on trade — which is probably higher as regards the great majority of medical diagnostic devices not listed in Annex II to the Directive and, at most, equivalent as regards Annex II products. This choice seems to me to be legitimate, in the light of the line of cases culminating in *Harpegnies*, and not disproportionate, in the light of the claimed effectiveness of the system adopted.

39. For a number of reasons, I do not think that the Court's judgment in *Monsees* requires a different conclusion to be reached. First, that case related to measures to protect the health of animals. The Court does not appear to have viewed the pursuit of that objective as being subject to the same wide Member State discretion as it has recognised in the case of human health. Its invocation of the provisions of a directive whose implementation period had not yet expired as an example of '[conceivable] measures appropriate to the objective of protecting the health of animals and less restrictive of the free movement of goods' [19] seems to indicate a comparatively narrow approach to the margin of discretion of Member States in pursuit of this objective. Secondly, the restriction at issue in that case was much more severe, making all international transit by road of animals for slaughter almost impossible in Austria, [20] with the result that much more compelling arguments were required to establish its efficacy and necessity and, consequently, its proportionality.

40. I also agree with France that the possibility conferred by Article 100a(4) of the Treaty of invoking the public health ground in Article 36 of the EC Treaty (now, after amendment, Article 30 EC) in order to derogate from harmonising measures weakens the Commission's case regarding the use of the Directive as a point of reference for the assessment of the proportionality of the impugned Decree. Although the Commission must verify the compliance of such national measures with the second sentence of Article 36 of the Treaty, [21] the point remains that, in exceptional circumstances, the Treaty envisages the potential lawfulness, and, thus, the proportionality, of national measures which are more restrictive of trade than a harmonising measure. Thus, the mere existence of a harmonising measure does not foreclose a full contextual analysis of the proportionality of such measures. This applies *a fortiori* when the period for transposition of the harmonising measure has not yet expired.

19 — Loc. cit., footnote 10 above, paragraph 30.

20 — Ibid., paragraph 29.

21 — See Article 100a(4), second indent, of the Treaty.

41. I now return to the more specific complaints made by the Commission regarding the application file which must be submitted in order to register reagents in France. The Commission is, of course, correct in stating that requirements that superfluous documentation be submitted with an application are inevitably disproportionate. [22] However, the Commission has not shown to my satisfaction that the French regime does in fact and in law require the production of documents which are unnecessary. It has confined itself to assertions which might very well be regarded as mere asides, rather than explaining its complaints by reference to scientific and medical practice.

42. As regards the results of stability tests, it may be noted that the declaration of conformity by manufacturers of *in vitro* medical diagnostic devices referred to in Annex III to the Directive must also include the results of stability studies. Given the degree of reliance placed by the Commission on the Directive, this is enough to cause me to doubt the point it made, without, it may be said, any further evidence, in respect of inorganic reagents.

43. The Commission further states simply that the requirement that the application file contain a statement of the therapeutic interest of the reagent concerned seems to relate more to the function of the doctor. In the absence of any additional explanation, it is far from evident to me that information about [their] therapeutic qualities is irrelevant to the assessment of medical reagents, or indeed that the provision of a brief statement on the matter is unnecessarily burdensome.

44. By the same token, the Commission has not furnished the Court with any evidence — other than the different position taken in the Directive — as to why a Member State is not entitled to require manufacturers to conduct clinical and analytical tests of the efficacy of their diagnostic products even in cases covered by substantial scientific literature. When considering this issue, it is, I think, important to bear in mind the different level of protection of public health pursued by the Decree relative to that envisaged by the Directive. In the absence of some convincing indication that in all cases bibliographical references would suffice, I am not persuaded that the requirement in the impugned Decree is a disproportionate element of the pursuit of that national public health objective. I would note, in passing, that this issue is quite unrelated to that of recognition of tests conducted in other countries.

45. The requirement that the file be updated when products are altered also appears to me to be legitimate, once one accepts the legitimacy of the French system of reacto-vigilance based on continuous assessment.

22 — In this regard, see, for example, *Harpegnies*, op. cit., paragraphs 34 and 35.

(ii) *The allegation regarding labelling*

46. In contrast to the foregoing analysis, I accept the Commission's argument that the French requirement that the packaging and accompanying notice of reagents bear the relevant registration number constitutes a disproportionate restriction on trade in goods. The Court has long held that the extension of labelling requirements to imported products may make their marketing more difficult or more expensive, especially in the case of parallel imports, through the need to alter the label under which the product is lawfully marketed in the Member State in which it is produced. [23] As well as forcing a change in the presentation of the product according to the place where it is to be marketed, it may also oblige the manufacturer or distributor to set up separate distribution channels. [24] The Court has consequently held that, in the absence of harmonising measures, the application to goods coming from other Member States where they are lawfully manufactured and marketed of rules on the labelling of such goods constitutes a measure of equivalent effect prohibited by Article 30 of the Treaty, unless their application can be justified by a public-interest objective taking precedence over the free movement of goods. [25]

47. I accept the Commission's submission that the fact that both the external packaging of reagents and the packaging of the reagent itself must bear the name and address of the distributor and the relevant manufacturing batch number, while the accompanying notice must bear the names and addresses of the manufacturer, the distributor and the importer, if any, means that no additional contribution is made to the traceability of faulty products or of their manufacturers or suppliers by the requirement that the packaging of reagents also bear the applicable French registration number. [26] The possibility of confusion between different versions of similarly or identically named products can be countered adequately by the use of batch numbers, which should, in fact, be of much greater use than the registration number, which is common to all products of a particular type, in narrowing down the category of products which provoke public health concerns, particularly in cases where such concerns arise from errors, contamination, etc. which are known to have occurred during a limited period of time.

23 — See Case 27/80 *Fietje* [1980] ECR 3839, paragraph 10; Case 94/82 *De Kikvorsch* [1983] ECR 947, paragraph 10.

24 — Case C-238/89 *Pall* [1990] ECR I-4827, paragraph 13; Case C-315/92 *Verband Sozialer Wettbewerb* v *Clinique Laboratories and Estée Lauder* [1994] ECR I-317, paragraph 19.

25 — Joined Cases C-267/91 and C-268/91 *Keck and Mithouard* [1993] ECR I-6097, paragraph 15 and Case C-33/97 *Colim* v *Bigg's Continent Noord* [1999] ECR I-3175, paragraphs 37 and 38.

26 — It is not clear to me from the impugned Decree that the notice accompanying diagnostic products must bear their registration number, rather than simply mentioning the fact of registration: 'la mention de l'enregistrement du réactif'. As a result, I do not discuss this aspect of the Commission's case, although I would remark that such a requirement is probably equally burdensome and ineffective.

V — Costs

48. As I propose that the Court accept one part of the Commission's case and reject the other, I recommend that the Court also order, by virtue of Article 69(3) of the Rules of Procedure of the Court, that each party bear its own costs in these proceedings.

VI — Conclusion

49. In the light of the foregoing analysis, I recommend that the Court:

(1) Declare that the French Republic is in breach of its obligations under Article 30 of the EC Treaty (now, after amendment, Article 28 EC) as a result of its requiring, by Decree No 96-351 of 19 April 1996, that the external packaging of every medical reagent, or, in the absence of such packaging, the packaging of the reagent itself, bear the national registration number awarded upon the registration of the reagent pursuant to the terms of that Decree;

(2) Dismiss the rest of the Commission's case;

(3) Order the Commission and the French Republic to bear their own costs.