II

(Preparatory Acts)

EUROPEAN ECONOMIC AND SOCIAL COMMITTEE

409th PLENARY SESSION OF 2 AND 3 JUNE 2004

Opinion of the European Economic and Social Committee on the ‘Proposal for a Regulation of the European Parliament and the Council on the law applicable to non-contractual obligations (Rome II)’


(2004/C 241/01)

On 8 September 2003 the Council decided to consult the European Economic and Social Committee, under Article 262 of the Treaty establishing the European Community, on the:

Proposal for a Regulation of the European Parliament and the Council on the law applicable to non-contractual obligations (Rome II).

The Section for the Single Market, Production and Consumption, which was responsible for preparing the Committee’s work on the subject, adopted its opinion on 4 May 2004. The rapporteur was Mr Frank von Fürstenwerth.

At its 409th plenary session of 2 and 3 June 2004 (meeting of 2 June 2004) the European Economic and Social Committee adopted the following opinion with 168 votes in favour and eight abstentions.

1. Summary of the conclusions

1.1 The European Economic and Social Committee welcomes the Commission proposal laying down rules on conflict of laws regarding non-contractual obligations in the form of a European regulation. This closes a gap which has hitherto significantly impeded the development of a single European legal area.

1.2 The Committee offers its encouragement to the Commission and urges it to complete its initiative as rapidly as possible, taking account of the suggested changes and corrections set out in point 9 below, so that the regulation can enter into force.

1.3 The Committee welcomes the Commission’s efforts to remedy, through full harmonisation, the fragmentation of the important area of private international law relating to non-contractual obligations. This will bring inestimable benefits in terms of simpler application of the law. Instead of having to establish in each individual case which system of rules on conflict of laws will apply and familiarise themselves with these rules which, at least in detail, differ from one Member State to another, users of the law will in future be able to use a single set of rules which, as regulations are directly applicable, will be identical in all Member States.

2. Introduction: Explanatory Memorandum

2.1 With this regulation the Commission for the first time sets out to create a single set of rules on conflict of laws regarding non-contractual obligations in the European Union. A single set of rules on conflict of laws regarding contractual obligations has already existed since 1980, when the majority of western European states decided to conclude the Convention on the law applicable to contractual obligations (the Rome Convention). Other states subsequently acceded to the Convention. The vehicle of a multilateral convention was chosen because, at that time, the EEC Treaty did not provide a legal basis for the adoption of an appropriate legal instrument by the Community. Conflict of laws regarding non-contractual obligations is still governed by the rules of the Member States which, although often based on a common understanding of the subject matter, differ significantly, at least in their details, and have been differently shaped by national case law and academic interpretation. This results in many difficulties for users of the law, including problems in obtaining the relevant rules, language problems, and problems of familiarisation with foreign legal culture and academic and case-law interpretation. Because these areas are closely interrelated, the law on obligations covers both the contractual and non-contractual kind, and the provisions of the Rome Convention, while representing a major improvement, have always been considered incomplete. The Convention has always lacked a section dealing with non-contractual obligations. The harmonisation of
the rules on conflict of laws regarding non-contractual obligations promises considerable progress vis-à-vis the current situation in the Community in view of the greater certainty and predictability it will bring to the process of determining the applicable substantive law. It would of course be still more beneficial to users of the law if the Rome I and Rome II instruments were to be combined in a single legal instrument. However, the Committee recognises that the procedures regarding the two projects are at completely different stages and that this is therefore a remote prospect. Rather, the priority must be to establish a functioning system for non-contractual obligations. The Committee regrets that, because of the reservation expressed by Denmark on the basis of Title IV of the EC Treaty, the planned legal instrument will not be directly applicable in that Member State (although there will be an option for voluntary application), and the harmonisation effect will therefore be less than ideal. The Committee is glad that the United Kingdom and Ireland have expressed a willingness to apply the instrument.

2.2 The legislative background

2.2.1 The regulation should be seen against the backdrop of a broad range of Commission legislative activities, whether complete, planned or still in preparation. The Committee has on several occasions had the opportunity to comment on individual Commission proposals.

2.2.2 Attention should first be drawn to activities in the field of procedural civil law, in particular:

— the adoption of the 1968 Brussels Convention in the form of a regulation (1);

— the proposal for a Council Regulation creating a European enforcement order for uncontested claims (2);

— the Regulation on the service in the Member States of judicial and extrajudicial documents in civil or commercial matters (3);

— the Council Regulation on cooperation between the courts of the Member States in the taking of evidence in civil or commercial matters (4);

— the Commission Recommendation on the principles applicable to bodies responsible for out-of-court settlement of consumer disputes (5);

— the Council Decision establishing a European Judicial Network in civil and commercial matters (6).

2.2.3 Attention should also be drawn to activities in the field of substantive civil law, in particular:

— the Commission Communication of 11.7.2001 on European contract law (7),

— the Consumer Credit Directive (8),


2.2.4 The initiative is particularly closely related to the Commission’s work on conflict of substantive laws, which it began with the publication of a Green Paper on the conversion of the Rome Convention into a Community instrument (10). The Rome II Regulation is complementary to, and a natural extension of, the Rome I Regulation proposed in the Green Paper.

2.2.5 All these activities are geared to the objectives of establishing a European area of justice, creating a legal framework which makes it easier for all economic operators to use the European internal market, increasing legal certainty and facilitating application of the law by the courts and European citizens’ access to the law.

3. Legal basis

3.1 The purpose of the regulation is the unification of the rules on conflict of laws regarding non-contractual obligations. The harmonisation of conflict rules falls under Article 65(b) TEC. This means that the Commission is empowered to act where this is necessary for the smooth operation of the internal market. In the Committee’s view, this is the case, as harmonisation will help to ensure equal treatment of economic operators in the Community in cross-border cases, increase legal certainty, simplify application of the law and thus promote

willingness to enter into cross-border business, as well as promote the mutual recognition of legal acts of the Member States by making it easier for nationals of other Member States to check that they are legally correct.

4. Material scope, application of third-country law (Articles 1, 2)

4.1 The regulation is intended to apply to conflict of laws in civil and commercial matters (Article 1(1)). In order to avoid misunderstandings, this should be specifically stated. The Commission could use the terminology of Council Regulation (EC) No 44/2001 (Article 1), as this is clearly defined. The exclusion of tax and customs matters is self-evident. There is no harm in specifically mentioning it, however.

4.2 The regulation does not set out to regulate the entire area of non-contractual obligations. The Commission would therefore be well advised not to aim too high and thereby make the project unwieldy. The exclusion of family, maintenance and succession issues (Article 1(2)) is therefore to be welcomed. In view of their social implications, these matters are traditionally dealt with in conflict rules by means of separate instruments.

4.3 The exclusion of obligations arising under the bills of exchange or cheques, as well as those arising out of nuclear damage (Article 1(2)), is justified by the fact that these matters are adequately dealt with in separate agreements (1), the scope of which extends beyond the Community and the continued existence of which should not be called into question.

4.4 The exclusion of company law matters in Article 1(2)(f) is unavoidable, as the issues in question are so closely bound up with the company statute as to require regulation in this context.

4.5 Trusts are a specific feature of Anglo-American law. They are a legal vehicle situated mid-way between company law and the law on foundations, functionally similar to the German Treuhand and without legal personality. Trusts are unknown in the legal systems of the continental European states. Because of these specific features and because of their proximity to company law they were excluded from the scope of the Rome Convention (Article 1(2)(g)). As the regulation excludes company law, it is logically consistent that trusts should also be excluded (Article 1(e)).

4.6 The regulation requires the specified law to be applied, whether it is the law of a Member State or of a third country (Article 2). In so doing it is following a generally recognised standard in conflict of laws, which in principle prohibits discrimination against other systems of law in conflict rules. The

Committee wholeheartedly welcomes this. If the circumstances of a case require that a specific system of law be applied, it makes no difference whether or not it is that of a Member State.

5. Rules applicable to non-contractual obligations arising out of a tort or delict (Articles 3 to 8)

5.1 Article 3, which deals with obligations arising out of a tort or delict, goes to the heart of the matter. Theoretically, a number of criteria, usually grouped together without distinction under the catch-all heading lex loci delicti (commissi) could be applied here, i.e. the law of the place where the event occurs, that of the place where the damage arises, that of the place in which the indirect consequences of the event arise or that of the place of habitual residence of the injured party. All these criteria have a basis in tradition and strong arguments in their favour. All are in fact used in various current systems of conflict rules. The priority task of the Commission is therefore to introduce a uniform set of rules in all Member States. This is the key task, and the question as to which of the existing solutions is adopted is secondary to this. With regard to subsequent practical application, it must be borne in mind that in most cases all or many of these criteria in practice coincide. The place of habitual residence of the injured party will generally be the same as the place where the event occurred, which will in turn be the same as the place where the damage arose. In practice, therefore, any dispute over the criterion to be applied will perhaps be rather theoretical. The Commission has opted for the law of the country in which the damage arises. It is perhaps questionable whether this is consistent with recent developments in legal consolidation in this area (2), but the Commission's choice is justifiable on the grounds that it gives priority to protection of the injured party, without however completely neglecting the interests of the party causing the damage. This would for example be the case if the law of the habitual place of residence of the injured party alone were to apply. Exclusive reliance on the law of the place where the event occurred would inappropriately favour the party causing the damage (3), as the injured party's legitimate claim to protection would not be met. The Commission's attempt to balance the interests of the various parties seems in every respect acceptable. The restriction placed on the general rule by Article 3(2) in cases where both parties have their habitual residence in the same country is realistic and prevents unnecessary recourse to foreign systems of law. Paragraph 3 is appropriate as a general corrective and corresponds functionally to Article 4(5) of the Rome Convention. In practice, however, care will have to be taken to ensure that this exception clause for individual cases is not used in those Member States which have hitherto applied the system of law of the place where the event occurred to circumvent the new approach intended by the Commission.

(1) The Geneva Convention providing a uniform law for bills of exchange and promissory notes of 7 June 1930, the Geneva Convention providing a uniform law for cheques of 19 March 1931, the Paris Convention of 29 July 1960 and a number of complementary conventions.

(2) In contrast, for example, to the law in force in Germany since 1999 (Article 40(1) of the implementing law for the Code of Civil Law - EGBGB), which takes the place where the event occurred as the decisive criterion.

(3) Who is likely to be familiar with local law, will not need to concern himself with other systems of law and may benefit from a lower level of liability for dangerous practices.
5.2 In cases involving product liability (Article 4), the applicable law is that of the place where the person sustaining damage has his habitual residence. The approach adopted can be seen as a compromise proposal, particularly in the light of the sometimes stormy debates preceding the hearing of 6 January 2003. Other possible criteria discussed seem less appropriate: the place of purchase may be purely fortuitous, and under certain circumstances may even be virtually impossible to establish (Internet purchases). In product liability cases the place in which the damage arises may also be fortuitous (if for example the purchaser suffers the damage when travelling). Finally, the place of manufacture might also not be a satisfactory criterion, as, against the background of globalisation, this may have little relevance to the issue. The criterion actually chosen, on the other hand, focuses on protecting the interests of the injured party. The choice of this criterion is all the more justified, given that, at the hearing held by the Commission on 1 January 2003, the representatives of industry, which is most directly affected by the proposal, and the insurance sector mainly came out in favour of that approach as a concession to the consumer representatives. The restriction to the general rule (marketing without consent) takes sufficient account of the legitimate interests of industry, as its representatives themselves conceded at the hearing.

5.3 The provisions of the regulation on unfair competition (Article 5) are based on the principle traditionally applied in this area, namely that the applicable law shall be that of the country in which competition is directly and substantially affected. This rule entails equal treatment of domestic and foreign competitors in relation to the rules which they are affected. This rule (marketing without consent) takes sufficient account of the legitimate interests of industry, as its representatives themselves conceded at the hearing.

5.4 It might at first sight appear surprising to find rules on violations of privacy and rights relating to the personality (Article 6) in a legal instrument dealing with conflict of laws regarding non-contractual obligations, as in many systems of law these issues fall within the ambit of law relating to the person. Recently, however, a different approach has gained ground in many Member States, with this issue being brought into the ambit of torts and delicts. In this sense, it is reasonable to deal with it here. Moreover, there is an undeniable link with the issues dealt with in Articles 5 and 8. The rule laid down in Article 6(1) is worthy of support. The same is true of the rule on the right to reply in Article 6(2). The Committee wonders whether the exception in favour of the lex fori might not in certain circumstances be rendered superfluous by Article 22.

5.5 With regard to violation of the environment (Article 7), the basic rule is consistent with the reference to the tort and delict provisions of Article 3, although the person sustaining damage has the option to base his claim on the law of the country in which the event giving rise to the damage occurred (which may be more favourable for him). Clearly, by providing an exception to the general rule which, disguised as a conflict of laws provision, allows the injured party the choice of applicable law, the Commission is pursuing objectives which actually have nothing to do with conflict of laws, but which are rather intended to encourage potential environmental polluters to take environmental protection very seriously by threatening them with the application of a more stringent system of substantive law. This is also made clear in the explanatory memorandum to Article 7.

5.6 The principle applicable to protection of intellectual property rights (Article 8), that the applicable law shall be that of the country for which protection is sought, is already generally accepted in this area. The consequent equal treatment of EU and foreign citizens in a given jurisdiction is welcome. A situation where a foreign citizen’s intellectual property received either greater or lesser protection than those of an EU citizen would be difficult to justify. Article 8(2) is therefore merely stating the obvious.

6. Rules applicable to non-contractual obligations arising out of an act other than a tort or delict

6.1 Although the law on torts and delicts, dealt with in Chapter II, Section 1 of the regulation, forms the core of non-contractual obligations, rules dealing with unjust enrichment and actions performed without due authority are nonetheless also needed. Other non-contractual obligations, varying in number and scope, are recognised in the Member States, which could be regulated by a general clause, as the Commission rightly does in Article 9(1).

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6.2 If a non-contractual obligation is based on an existing legal relationship between the parties (which would include contracts), it is self-evident that the law governing the existing legal relationship would apply (secondary connection). The Rome Convention, which lays down rules on application, should, however, be applied to contracts specifically referred to in the regulation. Article 9(1) is, however, worded sufficiently flexibly to permit its application in conjunction with the provisions of the Rome Convention without any conflict arising. The provisions of Article 9(2) correspond to the text of Article 3(2) of the regulation and are therefore justified for the same reasons.

6.3 The provision on unjust enrichment, which applies the law of the country in which the enrichment takes place (Article 9(3)), is consistent with the principles recognised in most Member States. If the enrichment takes place on the basis of an (ineffective) contractual relationship, the logic of Article 9 dictates that Article 9(1) shall apply. This should be stated more explicitly in the operative part of the text so as to leave no doubt in the minds of those less well versed in the law. The rule set out in Article 38(1) and (3) of the German civil law implementing law (EGBG), which follows the same principle, could serve as a model. According to information provided by the Commission representative, this would be the case only if no secondary connection could be established under Article 9(1) or (2). The Committee feels that this should be stated much more clearly in order to prevent misunderstandings on the part of users of the law.

6.4 With regard to actions performed without due authority, the regulation applies the law of the country in which the beneficiary has his habitual residence (with the exception of the special cases referred to in the second sentence of Article 9(4)). This rule confers an advantage on the beneficiary in relation to the conflict rules. If the law of the beneficiary's habitual place of residence were applied, this would place him at an advantage. One way, apparently not considered by the Commission, of achieving neutrality in the conflict rules would be to declare the law of the country in which the beneficiary has his habitual place of residence (with the exception of the special cases referred to in the second sentence of Article 9(4)). This should be stated more explicitly in the operative part of the text so as to leave no doubt in the minds of those less well versed in the law. The Committee feels that this should be stated much more clearly in order to prevent misunderstandings on the part of users of the law.

6.5 The exception clause of Article 9(5), which invokes the law of another country if this is manifestly more closely connected with the obligation, is consistent with Article 3(3) of the regulation and is therefore justified. The question arises as to whether an overarching principle cannot be derived from this which would apply to all the provisions of the regulation, including those set out in Articles 4-8, to which it is not intended to apply. The Commission should consider this and, if appropriate, incorporate a corresponding rule into Section 3. In this case Article 3(3) and Article 9(5) should be deleted.

6.6 The Committee considers Article 9(6) to be superfluous, as the same effect is already achieved by the special rule contained in Article 8. It would do no harm to retain the provision, however.

7. Common rules applicable to non-contractual obligations arising out of a tort or delict and out of an act other than a tort or delict

7.1 The title of Section 3 of Chapter II is unnecessarily complicated and difficult to understand. The Committee recommends that the example of the Rome Convention be followed and that the section be entitled ‘Common Provisions’.

7.2 By granting the parties the freedom to choose the system of law after the dispute has arisen (Article 10), the regulation is rightly following a progressive trend which can, for example, also be seen in Article 42 of the German EGBG or Article 6 of the Dutch private international law. The Committee welcomes this. The reservation regarding non-applicable law in Article 10(2) and (3) is standard practice for preventing parties from circumventing the law and is therefore unexceptionable, although it does make practical application of the law more complicated.

7.3 The provisions regarding the scope of the regulation contained in Articles 3-10 are based in a modified form on the model of Article 10 of the Rome Convention. The considerable detail testifies to the Commission’s commendable efforts to achieve a high level of legal certainty.

7.4 One potential problem area, however, is the provision of Article 11(d), in view of the fact that, in accordance with generally accepted principles, the procedural law will be subject to the lex fori. The Commission should leave this principle intact. Any procedural steps for enforcing and (in a preventive way) safeguarding material claims should be taken in accordance with the law of the competent jurisdiction. The question as to whether such a material claim exists should be dealt with in accordance with the law designated under Articles 3-10. The wording of the explanatory memorandum suggests that this may have been the Commission’s intention. Where court procedures and material claims are inextricably linked, an exception from the lex fori rule would appear justified and the lex causae could be applied.

7.5 Article 12, which deals with the difficult subject of overriding mandatory rules, is based, mutatis mutandis, on Article 7 of the Rome Convention and is therefore in line with standard practice in conflict rules. The title, which differs from that used in the Rome Convention, reflects developments in terminology since 1980.
7.6 Article 13 provides for the automatic applicability of rules of safety and conduct, which is in principle justified. However, the Committee considers that the rules applied should be those in force at the place where the perpetrator acted, as he could be expected to observe them. The provisions of Article 7 of the Hague Convention on the law applicable to traffic accidents can, contrary to the assertions of the explanatory memorandum (p. 25), be interpreted in this way, as the article refers to the rules in force at the place and time of the accident. The Commission representative also interpreted Article 13 in this way. The Committee considers that this is not made sufficiently clear, at least in some language versions. The Committee therefore calls on the Commission to state unequivocally in Article 13 of the regulation that the applicable rules of safety and conduct shall be those in force at the place where the perpetrator acted.

7.7 The rule regarding direct action against the insurer of the person claimed to be liable is appropriate and is the substantive corollary to the procedural rule set out in Article 11(2) of Council Regulation (EC) No 44/2001.

7.8 The rule regarding subrogation (Article 15) is consistent with Article 13 of the Rome Convention and poses no problem. The Commission will need to make sure that this remains true when the Rome Convention is reworked as a European regulation (Rome I Regulation). The same is true of Article 17 (Burden of proof), which is consistent with Article 14 of the Rome Convention. Article 16 is a successful adaptation of the provisions of Article 9(4) of the Rome Convention which, in the light of the different subject matter, can only serve as a starting point.

8. Other provisions/Final provisions

8.1 The matters dealt with in Chapters III and IV are predominantly technical rules consistent with general standards in conflict of laws; they therefore pose no problem and require no detailed comment. This applies in particular to Article 20 (Exclusion of renvoi), which is consistent with Article 15 of the Rome Convention, Article 21 (States with more than one legal system), which is consistent with Article 19 of the Rome Convention, Article 22 (Public policy of the forum), which is consistent with Article 16 of the Rome Convention and Article 25 (Relationship with existing international conventions), which is consistent with Article 21 of the Rome Convention.

8.2 For the purposes of the regulation, Article 18 assimilates to the territory of a state certain areas which do not normally fall within such territory. This has the effect of closing certain undesirable gaps in the law and preventing fortuitous application of systems of law. The Committee welcomes this.

8.3 The habitual place of residence of a person plays a central role in current private international law, and consequently in the regulation, when determining the applicable law. Although determining the habitual place of residence of a natural person is usually unproblematic, doubts may arise in relation to legal persons. The regulation disposes of such doubts in an appropriate way by declaring the main place of business to be the decisive criterion. It would not have been appropriate to model this provision on Article 60 of Council Regulation (EC) No 44/2001, as this regulation generally takes the place of permanent residence rather than that of habitual residence as the criterion, and also as the threefold solution adopted there would have meant less legal certainty.

8.4 Article 24 was incorporated into the text by the Commission only as a result of proposals made at the hearing of January 2003. It is based on Article 40(3) of the German EGBG, the purpose of which is to prevent, by means of substantive law, claims being lodged which are generally regarded in the Community as excessive, thus rendering superfluous any dispute or discussion as to whether such claims are incompatible with public policy. The Committee wholeheartedly endorses the Commission’s intention. But would the interests of a party claiming compensation be served if (for otherwise perfectly sound legal reasons) he were to be denied compensation for damage suffered merely because, under a foreign system of law, provision was made both for damages which would be considered acceptable in the Member States but also for punitive (e.g. triple) damages which would not be considered acceptable? The Committee fears that the current wording of Article 24 might have exactly this effect. It therefore proposes that the provision be reworded as follows:

‘The application of a provision of the law designated by this Regulation shall give rise to no claim for damages only where such damages would clearly serve purposes other than the appropriate compensation of the injured party.’

8.5 Article 25 of the regulation contains a proviso on international conventions to which Member States are parties, giving these priority regarding conflict-of-law rules relating to non-contractual obligations. This provision broadly corresponds to Article 21 of the Rome Convention but, unlike the Rome Convention, does not exempt future treaty commitments which deviate from Community law. This difference arises from the intention that the regulation should be binding on national legislative authorities and from the need to prevent further fragmentation of the law in the Community in the future. The Committee welcomes this proviso, as it enables the Member States to continue to honour existing treaty commitments and to continue to be parties to important conventions, which in some cases are applied worldwide. In this context, the Committee would quote as examples the Berne Convention on the protection of literary and artistic works of 9 September 1896, the Agreement on trade-related aspects of intellectual property rights (TRIPS), the International Convention for the limitation of certain damage claims for saving life and salvage at sea of 23 September 1910 and the International Convention relating to the limitation of the liability of owners of sea-going ships.
9. Conclusion

The Committee calls on the Commission, once corrections have been made, to complete work on the regulation as rapidly as possible so that it can enter into force. The Commission should:

— clarify the relationship between the Article 5 of the regulation and Article 4(1) of the directive on unfair competition and adapt the explanatory memorandum accordingly;
— reconsider whether giving the injured party the choice of applicable law in cases involving violation of the environment (Article 7) is really appropriate;
— clarify the relationship between Article 9(3) and (4), on the one hand, and Article 9(1) and (2), on the other, in the text of the regulation;
— consider whether, in Article 9(4), it would not be more appropriate to declare applicable the system of law of the place where the transaction takes place;
— consider whether Article 9(5) should be made a general principle of the regulation and inserted in Section 3;
— amend the title of Section 3 to read ‘Common Provisions’;
— make it clear in Article 13 that the rules of safety and conduct applied shall be those in force at the place where the event occurred;
— reword Article 24 to read as follows:

‘The application of a provision of the law designated by this Regulation shall give rise to no claim for damages only where such damages would clearly serve purposes other than the appropriate compensation of the injured party.’


Roger BRIESCH
President
of the European Economic and Social Committee

Opinion of the European Economic and Social Committee on the ‘Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions — A Stronger European-based Pharmaceutical Industry for the Benefit of the Patient — A Call for Action’

(COM(2003) 383 final)

(2004/C 241/02)

On 16 October 2003, the European Commission decided to consult the European Economic and Social Committee, under Article 262 of the Treaty establishing the European Community, on the Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions — A Stronger European-based Pharmaceutical Industry for the Benefit of the Patient — A Call for Action.

The Section for the Single Market, Production and Consumption, which was responsible for preparing the Committee’s work on this subject, adopted its opinion on 4 May 2004. The rapporteur was Mrs O’Neill.

At its 409th plenary session of 2 and 3 June 2004 (meeting of 2 June), the European Economic and Social Committee adopted the following opinion by 164 votes to 1 with 10 abstentions.

1. Background

1.1 It has long been recognised that the European-based pharmaceutical industry plays a critical role in both the industrial and health sectors. Within European institutions there has been considerable emphasis on developing the various components which make up the industry and the consequent advantages to patients.

1.2 To this effect the Lisbon Council in 2000 set the EU a strategic goal of ‘building the most competitive and dynamic knowledge-based economy in the world, capable of sustainable economic growth with more and better jobs and greater social cohesion’, in which the pharmaceutical industry would play a vital role.

1.3 The Council of Ministers, in its conclusions on Medical Products and Public Health in June 2000, underlined the importance of innovative medicines, with significant added therapeutic value, to the attainment of both industrial and public health sector goals.